



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 15 11 39040 059

Manufacturer: **Medtronic Sofamor Danek USA, Inc.**
1800 Pyramid Place
Memphis, TN 38132
USA



EC-Representative: **Medtronic B.V.**
Earl Bakkenstraat 10
6422 PJ Heerlen
THE NETHERLANDS

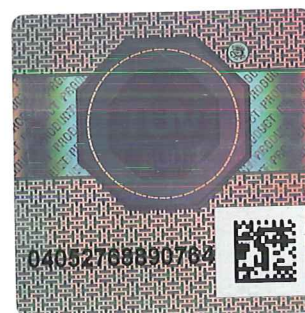
Product Category(ies): **Synthetic Bone Graft (class III), Interspinous Process Implants, Bone Cement (IIb), Kyphoplasty Devices, Bone Tamps, Bone Filler Devices, Osteo Introducer Kits, Bone Biopsy Devices (class IIa), Inflation Syringes, Spinal, Cranial, Dental, and Orthopedic Implants, Sterile Spinal Implants, Sterile Synthetic Bone Substitutes, Sterile Instruments, Cutters, Retractors, Electrical Drive Systems, Electrosurgical Instruments, Endoscopes, Neurological Electrodes, Radio-Frequency Ablation System Generators, Radio-Frequency Ablation Systems Including Sterile Probes, Tubing Kits, Pumps, Connectors and Cannulas/Introducers**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72107860
Valid from: 2016-01-28
Valid until: 2020-04-19

Date, 2016-01-28

Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Product Service

EC Certificate**Full Quality Assurance System****Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)****No. G1 15 11 39040 059****Facility(ies):**

Medtronic Sofamor Danek USA, Inc.
4340 Swinnea Road, Memphis TN 38118, USA

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place, Memphis, TN 38132, USA

Medtronic Sofamor Danek Manufacturing
2500 Silveus Crossing, Warsaw, IN 46582, USA

Medtronic Sofamor Danek Deggendorf GmbH
Wertstr. 17, 94469 Deggendorf, GERMANY

Medtronic Sofamor Danek Deggendorf GmbH
Ulrichsberger Str. 17, 94469 Deggendorf, GERMANY

Medtronic Spine LLC
1860 Barber Lane, Milpitas CA 95035, USA

Kyphon Sàrl
Pierre-à-Bôt 97, 2000 Neuchâtel, SWITZERLAND



Product Service

EC Certificate
Production Quality Assurance System
 Directive 93/42/EEC on Medical Devices, Annex V
 (Devices in class I with measuring function)
No. G2M 18 04 39040 070

Manufacturer: **Medtronic Sofamor Danek USA, Inc.**
 1800 Pyramid Place
 Memphis, TN 38132
 USA



EC-Representative: **Medtronic B.V.**
 Earl Bakkenstraat 10
 6422 PJ Heerlen
 THE NETHERLANDS

Product Category(ies): **Instruments with Measuring Function:
 Trials, Gauges, Probes, Torque Wrenches,
 Templates and Cable Tensioners**

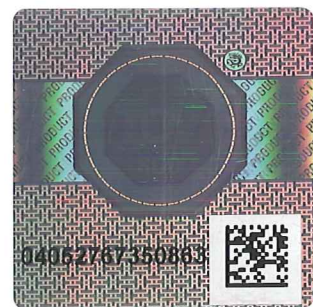
The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for the manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with the metrological requirements of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 72137722

Valid from: 2018-07-01
Valid until: 2023-06-30

Date, 2018-06-27

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Product Service

EC Certificate
Production Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex V
(Devices in class I with measuring function)
No. G2M 18 04 39040 070

Facility(ies):

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place, Memphis, TN 38132, USA

Medtronic Sofamor Danek Manufacturing
2500 Silveus Crossing, Warsaw, IN 46582, USA

Medtronic Sofamor Danek USA, Inc.
4340 Swinnea Road, Memphis TN 38118, USA



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 14 12 39040 054

Manufacturer: **Medtronic Sofamor Danek
USA, Inc.**

1800 Pyramid Place
Memphis, TN 38132
USA

EC-Representative: **Medtronic B.V.**

Earl Bakkenstraat 10
6422 PJ Heerlen
THE NETHERLANDS

**Product
Category(ies):** **Bone Cement Mixer, Cement
Cartridges (class 1 sterile),
and Adapter**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: NM1207722

Valid from: 2015-04-20

Valid until: 2020-04-19

Hans-Heiner Junker

Date, 2015-04-16



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 14 12 39040 054

Facility(ies):

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place, Memphis, TN 38132, USA

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Product Service

CERTIFICATE

No. Q1N 17 01 39040 065

Holder of Certificate: **Medtronic Sofamor Danek
USA, Inc.**

1800 Pyramid Place
Memphis, TN 38132
USA

Certification Mark:



Scope of Certificate:

- Design and Development, Production, Servicing and Distribution of Spinal, Cranial, Dental and, Orthopedic Implants, Instruments and Accessories, Neurological Electrodes, Electrical Drive System, Bone Graft Kits and Materials. Radio-Frequency Ablation System Generators, Radio-Frequency Ablation Systems including sterile probes, tubing kits, pumps, connectors and cannulas/introducers
- Distribution of Electrosurgical Instruments, Endoscopes and Accessories
- Design and Development, Production and Distribution of Kyphoplasty Devices, Bone Tamps, Bone Filler Devices, Introducer Kits, Synthetic Bone Graft, Bone Cement Mixer, Interspinous Process Implants Bone Cements and Inflation Syringes, Sterile and Non-Sterile Medical Devices for Minimally Invasive Spinal Procedures.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

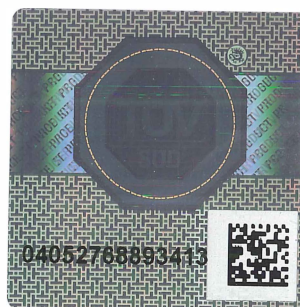
Report No.: 72107493

Valid from: 2017-01-27

Valid until: 2019-09-28

Date, 2017-01-27

Stefan Preiß



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Product Service

CERTIFICATE

No. Q1N 17 01 39040 065

Applied Standard(s): EN ISO 13485:2012 + AC:2012
 Medical devices - Quality management systems -
 Requirements for regulatory purposes
 (ISO 13485:2003 + Cor. 1:2009)
 DIN EN ISO 13485:2012

Facility(ies):

- Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place, Memphis, TN 38132, USA
- Medtronic Sofamor Danek USA, Inc.
4340 Swinnea Road, Memphis TN 38118, USA
- Medtronic Sofamor Danek Manufacturing
2500 Silveus Crossing, Warsaw, IN 46582, USA
- Medtronic Spine LLC
1860 Barber Lane, Milpitas CA 95035, USA
- Kyphon Sàrl
Pierre-à-Bot 97, 2000 Neuchâtel, SWITZERLAND



DECLARATION OF CONFORMITY

TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES



MANUFACTURER: Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
USA

MEDICAL DEVICE: *TL Stabilization Bundle*
Technical File (TF009)
Reference Product List including GMDN and UMDNS codes

CLASSIFICATION IN ACCORDANCE WITH ANNEX IX: *Class I, Rule 6; Class I, Rule 1*
Reference Product List for specific device classifications

CONFORMITY ASSESSMENT ROUTE: *Annex VII*
Reference Product List for specific device routes

WE, THE MANUFACTURER, UNDER OUR SOLE RESPONSIBILITY, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, OF THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC AND IF APPLICABLE, COMMISSION REGULATION NO. 722/2012.

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: REFER TO LIST OF HARMONISED – EN STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED. THIS LIST IS LOCATED WITH THE TECHNICAL FILE.

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MUNICH, GERMANY

IDENTIFICATION NUMBER: *N/A for Class I*

(EC) CERTIFICATE(S): *Q1N 17 01 39040 065* Exp Date: *28-Sep-19*



EUROPEAN REPRESENTATIVE: Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

START OF CE-MARKING: DATE OF FIRST CE MARKING (Reference attached list)

SIGNATURE: *[Signature]* *04 Feb 2019*
NAME *Rahmya H. Simpson, PhD* DATE
REGULATORY AFFAIRS Director or Designee
Director, Regulatory Affairs
TITLE

PLACE: *Memphis, TN, USA*

Product List
Last updated by: Fernand Terradas
Tech File Bundle: TL Stabilization

Date: 2/4/2019

Product: General Instruments						
Class: I						
P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
CD Horizon- Instruments						
2345050	THREADED BLUNT 24" GUIDEWIRE	February 2013	Rule 6	Annex VII	13180	13180
5618000	HK HOLDER FOR STAPLE INTRODUC	April 2005	Rule 6	Annex VII	47807	13180
5618001	STAPLE INTRODUCER	April 2005	Rule 6	Annex VII	47807	12143
803-043	GUIDE WIRE	March 2000	Rule 6	Annex VII	46165	12143
8161020	SMA TWO-PRONG STAPLE HOLDER	November 2002	Rule 6	Annex VII	47807	12143
8161022	SMA FOUR-PRONG STAPLE INSERTER	November 2003	Rule 6	Annex VII	61325	12143
8880034	ROD PUSHER	June 2005	Rule 6	Annex VII	47554	13180
89602	INSERTER	May 2000	Rule 6	Annex VII	61325	12143
89608	CURVED HOLDER	October 2000	Rule 6	Annex VII	47807	13180
89652	HOLDER	October 2000	Rule 6	Annex VII	13180	13180
89653	T-WRENCH	October 2000	Rule 6	Annex VII	32871	12143
89654	PEN SCREWDRIVER	October 2000	Rule 6	Annex VII	61324	12143
89662	CURRETTE	May 2001	Rule 6	Annex VII	31335	12143
89701	INTERPEDICULAR PLATE	November 2000	Rule 6	Annex VII	61324	12143
89702	INTERPEDICULAR PLATE	November 2000	Rule 6	Annex VII	61324	12143
89703	DOUBLE ROD INTRODUCOR	November 2000	Rule 6	Annex VII	61324	12143
89734	CHOPIN	November 2000	Rule 6	Annex VII	61324	12143
89736	SCREWDRIVER	April 2000	Rule 6	Annex VII	61324	12143
803-290	HOLT PROBE FLAT	April 1998	Rule 6	Annex VII	13180	16868
89737	SCREWDRIVER	November 2000	Rule 6	Annex VII	61324	12143
CD Horizon Perc- Instruments						
5484902	Sequential Reducer	February 2013	Rule 6	Annex VII	44804	13180
9010000849	PERCUTANEOUS ROD INSERTER	April 2014	Rule 6	Annex VII	12696	13180
X0300016	PERCUTANEOUS INSERTION PLUG	May 2001	Rule 6	Annex VII	47807	12143
X0300017	PERCUTANEOUS INSERTION TUBE	May 2001	Rule 6	Annex VII	61325	12143
CDH Antares-Instrument						
8691000	Awl, Quick Connect	April 2001	Rule 6	Annex VII	15275	12143
8691001	Awl Guide, 21mm	April 2001	Rule 6	Annex VII	13180	13180
8691002	Awl Guide, 23mm	April 2001	Rule 6	Annex VII	13180	13180
8691003	Awl Guide, 25mm	April 2001	Rule 6	Annex VII	13180	13180
8691004	Guide Shaft	April 2001	Rule 6	Annex VII	13180	13180
8691005	Staple Impactor	April 2001	Rule 6	Annex VII	32856	12143
8691017	ANTERIOR DISTRATOR	November 2001	Rule 6	Annex VII	47870	12143
8691018	COMPRESSOR, PARALLEL ACTION	November 2001	Rule 6	Annex VII	47870	12143
8691118	ANTARES SCREW GAUGE	July 2001	Rule 6	Annex VII	13180	13180
CDH Crosslink- Instruments						
810-510	LOW PROFILE CROSSLINK PLATE HO	December 2002	Rule 6	Annex VII	47807	12143
810-525	LOW PRFL CRSLNK PLT BENDER	October 2002	Rule 6	Annex VII	61325	12143
8114505	4.75 CROSSLINK BENDING IRON	October 2009	Rule 6	Annex VII	44795	15884
8691011	Inline Crosslink Holder	April 2001	Rule 6	Annex VII	61325	12143
8691012	Crosslink Measuring Tool, 11/12mm	April 2001	Rule 6	Annex VII	61325	12143
8691013	Crosslink Measuring Tool, 13/14mm	April 2001	Rule 6	Annex VII	61325	12143
8691014	Crosslink Measuring Tool, 15/16mm	April 2001	Rule 6	Annex VII	61325	12143
8691015	Crosslink Measuring Tool, 17/18mm	April 2001	Rule 6	Annex VII	61325	12143
8691016	Crosslink Measuring Tool, 19mm	April 2001	Rule 6	Annex VII	61325	12143
X0105159	X10 CROSSLINK HOLDER-FORCEP	February 2005	Rule 6	Annex VII	61325	12143

Product List
Last updated by: Fernand Terradas
Tech File Bundle: TL Stabilization

Date: 2/4/2019

Product: General Instruments						
Class: I						
P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
5482302	Caliper	July 2016	Rule 6	Annex VII	32262	13180
5482301	Counter Torque	July 2016	Rule 6	Annex VII	47554	12143
5482300	5/16" Revision Driver	July 2016	Rule 6	Annex VII	44759	12143
5482304	7/32" BREAKOFF DRIVER	July 2016	Rule 6	Annex VII	44759	12143
5482303	Plate Template	July 2016	Rule 6	Annex VII	46479	13180
CDH Eclipse- Instruments						
8481910	6.5MM RM CANNULATED TAP	June 2002	Rule 6	Annex VII	61325	12143
8481912	7.5MM RM CANNULATED TAP	June 2002	Rule 6	Annex VII	61325	12143
8482900	12MM PORTAL	December 2003	Rule 6	Annex VII	32579	10561
8482901	12MM OBTURATOR	December 2003	Rule 6	Annex VII	33968	13517
8482902	13 X 26MM RIGID PORTAL	December 2003	Rule 6	Annex VII	32579	10561
8482903	13 X 26MM OBTURATOR	December 2003	Rule 6	Annex VII	33968	13517
8482908	5.5MM TAP, QUICK CONNECT	December 2003	Rule 6	Annex VII	17507	13517
8482910	6.5MM RED. MINOR DIA. TAP, Q/C	November 2003	Rule 6	Annex VII	17507	13517
8482912	7.5MM RED. MINOR DIA. TAP, Q/C	November 2003	Rule 6	Annex VII	17507	13517
8482924	DUAL-HEADED FIXED SCREWDRIVER	November 2003	Rule 6	Annex VII	33968	13517
8482930	PLUG INTRODUCER DH	December 2003	Rule 6	Annex VII	47807	12143
8482931	PLUG INTRODUCER DH W/WINDOWS	December 2003	Rule 6	Annex VII	47807	12143
8489007	CD HORIZON ECLIPSE SCREW GAUGE	December 2002	Rule 6	Annex VII	13180	13180
848-905	WIRE GUIDE	April 2005	Rule 6	Annex VII	46165	12143
848-907	CANNULATED AWL	April 2005	Rule 6	Annex VII	15275	12143
X0703000	COUNTER TORQUE ECLIPSE 5.5ROD	September 2002	Rule 6	Annex VII	47554	12143
X848-924	QC ECLIPSE SCREWDRIVER W/ WING	November 2003	Rule 6	Annex VII	33968	13517
CDH Engage- Instruments						
9960045	4.5MM CANNULATED TAP	August 2005	Rule 6	Annex VII	17507	13517
9960055	5.5MM CANNULATED TAP	August 2005	Rule 6	Annex VII	17507	13517
9960065	6.5MM CANNULATED TAP	August 2005	Rule 6	Annex VII	17507	13517
9960070	7.0MM CANNULATED TAP	August 2005	Rule 6	Annex VII	17507	13517
9960075	7.5MM CANNULATED TAP	August 2005	Rule 6	Annex VII	17507	13517
9960104	ROUND AWL, INLINE HANDLE	April 2004	Rule 6	Annex VII	15275	12143
9960105	AWL	March 2005	Rule 6	Annex VII	15275	12143
9960107	PRIMARY BOLT DRIVER	March 2005	Rule 6	Annex VII	33968	13517
9960108	AUXILIARY BOLT DRIVER	March 2005	Rule 6	Annex VII	33968	13517
9960109	ANGLED WRENCH	March 2005	Rule 6	Annex VII	32871	15766
9960111	NUT DRIVER	March 2005	Rule 6	Annex VII	33968	13517
9960112	TORQUE LIMITING NUT DRIVER	March 2005	Rule 6	Annex VII	33968	13517
9960113	RBC COUNTER TORQUE	March 2005	Rule 6	Annex VII	47554	13180
9960115	T25 SCREWDRIVER	April 2004	Rule 6	Annex VII	33968	13517
9960116	9MM BOLT DRIVER	April 2004	Rule 6	Annex VII	33968	13517
9960119	T25 BOLT COUNTER TORQUE	April 2004	Rule 6	Annex VII	61325	12143
9960120	9MM NUT DRIVER	April 2004	Rule 6	Annex VII	33968	13517
9960121	9MM HEX TORQUE LIMITING DRIVER	April 2004	Rule 6	Annex VII	33968	13517
9960122	9MM HEX TO T25 INSERT	April 2004	Rule 6	Annex VII	33968	13517
9960130	BOLT COUNTERTORQUE	March 2005	Rule 6	Annex VII	47554	13180
9960131	SPEED WRENCH	March 2005	Rule 6	Annex VII	32871	15766
9960133	DISTRACTOR	March 2005	Rule 6	Annex VII	56637	11291
9960135	CLOSED SETSCREW INSERT	March 2005	Rule 6	Annex VII	13180	13180

Product List
Last updated by: Fernand Terradas
Tech File Bundle: TL Stabilization

Date: 2/4/2019

Product: General Instruments						
Class: I						
P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
9960136	TLIF DISTRACTOR	March 2005	Rule 6	Annex VII	56637	11291
9960142	6.35MM ROCKER	April 2004	Rule 6	Annex VII	13180	13180
9960150	6.35 COUNTER TORQUE	May 2004	Rule 6	Annex VII	47554	13180
9960155	DISTRACTOR, SMALL	May 2004	Rule 6	Annex VII	61325	12143
9960175	POWER GRIPS	April 2004	Rule 6	Annex VII	61325	12143
9960176	WIDE NOSE POWER GRIPS	March 2005	Rule 6	Annex VII	13180	13180
9960201	TUBE, OUTER, BOLT CUTTER	April 2005	Rule 6	Annex VII	13180	13180
9960202	TUBE, INNER, BOLT CUTTER	April 2005	Rule 6	Annex VII	13180	13180
9960203	HANDLE, BOTTOM, BOLT CUTTER	April 2005	Rule 6	Annex VII	44805	12143
9960204	HANDLE, TOP, BOLT CUTTER	April 2005	Rule 6	Annex VII	13180	13180
9960210	LARGE CORKSCREW ASSEMBLY	April 2004	Rule 6	Annex VII	61325	12143
9960211	LATERAL IMPLANT HOLDER	April 2004	Rule 6	Annex VII	47807	12143
9960212	LATERAL IMPLANT HOLDER	March 2005	Rule 6	Annex VII	47807	13180
9960216	STRAIGHT IMPLANT HOLDER	April 2004	Rule 6	Annex VII	47807	12143
9960217	CURVED HOOK HOLDER	April 2004	Rule 6	Annex VII	61325	12143
9960220	WIDE LAMINAR ELEVATOR	April 2004	Rule 6	Annex VII	61325	12143
9960255	INSITU BENDER-LEFT	April 2004	Rule 6	Annex VII	61325	12143
9960260	INSITU BENDER-RIGHT	April 2004	Rule 6	Annex VII	61325	12143
9960265	ROD/PLATE BENDER, LEFT	January 2005	Rule 6	Annex VII	44795	12143
9960266	ROD/PLATE BENDER, RIGHT	January 2005	Rule 6	Annex VII	44795	12143
9960320	ANGLED VISE GRIPS	May 2004	Rule 6	Annex VII	61325	12143
9960400	THREADED NUT DRIVER	May 2006	Rule 6	Annex VII	33968	13517
9960401	TORQUE LIMITING NUT DRIVER	May 2006	Rule 6	Annex VII	47829	12143
9960402	THREADED NUT SPEED WRENCH	May 2006	Rule 6	Annex VII	32871	15766
9960403	BOLT COUNTERTORQUE	May 2006	Rule 6	Annex VII	47554	13180
9960404	OPEN PLATE INSERTER	May 2006	Rule 6	Annex VII	47807	12143
9960414	TORQUE LIMITING REV NUT DRIVER	May 2006	Rule 6	Annex VII	47829	12143
9960415	CAPTIVE HEAD SCREWDRIVER	July 2005	Rule 6	Annex VII	33968	13517
9960418	3.5MM BALL END HEX SCREWDRIVER	June 2006	Rule 6	Annex VII	61325	12143
9960421	PIVOTING PLATE INSERTER	June 2006	Rule 6	Annex VII	61325	12143
9960432	THREADED NUT CAP INSERTER	November 2005	Rule 6	Annex VII	47807	12143
9960450	SCREW EXTENDER, T25	October 2005	Rule 6	Annex VII	13180	13180
9960460	HAND HELD PLATE BENDER	October 2005	Rule 6	Annex VII	44795	12143
9960466	PLATE PUSHER	July 2005	Rule 6	Annex VII	13180	13180
9960468	PLATE COMPRESSOR	October 2005	Rule 6	Annex VII	15800	12143
9960470	PLATE DISTRACTOR	October 2005	Rule 6	Annex VII	56637	11291
9960489	MINIMAL ACCESS COMPRESSOR	May 2006	Rule 6	Annex VII	15800	12143
9960490	MINIMAL ACCESS DISTRACTOR	May 2006	Rule 6	Annex VII	56637	11291
9960595	ENGAGE BOLT GAUGE	July 2005	Rule 6	Annex VII	13180	13180
9960596	ENGAGE SCREW GAUGE	July 2005	Rule 6	Annex VII	13180	13180
9960598	CDH ENGAGE PLATE SCREW GAUGE	July 2006	Rule 6	Annex VII	13180	13180
9966231	6.35MM HOOK PUSHER	November 2004	Rule 6	Annex VII	13180	13180
X2820601	BENDER X2820601 ROD/PLATE RIGHT	September 2007	Rule 6	Annex VII	44795	12143
X2820602	BENDER X2820602 ROD/PLATE LEFT	September 2007	Rule 6	Annex VII	44795	12143
CDH FNS- Instruments						
7480523	FNS Adapter Driver	February 2011	Rule 6	Annex VII	33968	13517
7480702	Fenestrated MAS Removal Driver	February 2011	Rule 6	Annex VII	33968	13517

Product List
Last updated by: Fernand Terradas
Tech File Bundle: TL Stabilization

Date: 2/4/2019

Product: General Instruments						
Class: I						
P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
CDH Legacy- Instruments						
96130H	C-RING FOR 6.35 ROD	October 2002	Rule 6	Annex VII	61325	12143
5485001V	DISTRACTOR, PIVOTING 5.5	February 2008	Rule 6	Annex VII	56637	11291
5485003V	HEAD POSITIONER 5.5	February 2008	Rule 6	Annex VII	13180	13180
5485004V	T27 METAL PLUG STARTER	February 2008	Rule 6	Annex VII	32865	13517
5485005V	T-27 TAPERED 5.5 ST SCREW	February 2008	Rule 6	Annex VII	61325	12143
5485008V	SEQUENTIAL REDUCTION INNER SLEEVE	February 2008	Rule 6	Annex VII	44804	12143
5485009V	SEQUENTIAL REDUCTION OUTER SLEEVE ASM	February 2008	Rule 6	Annex VII	44804	12143
5485010V	SET SCREW CONFIRMATION TOOL	February 2008	Rule 6	Annex VII	61325	12143
5485134V	REDUCER, BEALE ROD 5.5 RCKR HLS	February 2008	Rule 6	Annex VII	61325	12143
5485171V	DISTRACTOR PLIERS 5.5	February 2008	Rule 6	Annex VII	47870	12143
5485201V	T25 MAS SCREWDRIVER	February 2008	Rule 6	Annex VII	33968	13517
5485235V	ROD PUSHER 5.5	February 2008	Rule 6	Annex VII	47554	13180
6480122	INSTRUMENT 6480122 PLUG STARTER	September 2007	Rule 6	Annex VII	32865	13517
6480136	INSTRUMENT 6480136 ROD REDUCER	August 2007	Rule 6	Annex VII	44804	12143
6480144	INSTRUMENT 6480144 BREAK-OFF DRIVER	September 2007	Rule 6	Annex VII	13180	13180
6480150	INSTRUMENT 6480150 COUNTER TORQUE	September 2007	Rule 6	Annex VII	47554	13180
6480172	INSTRUMENT 6480172 DISTRACTOR	September 2007	Rule 6	Annex VII	56637	11291
6480173	INSTRUMENT 6480173 DISTRACTOR	September 2007	Rule 6	Annex VII	56637	11291
6480282	INSTRUMENT 6480282 SCREWDRIVER	September 2007	Rule 6	Annex VII	33968	13517
6481000	INSTRUMENT 6481000 QUICK CONNECT AWL	August 2007	Rule 6	Annex VII	15275	12143
6481005	INSTRUMENT 6481005 STAPLE IMPACTOR	August 2007	Rule 6	Annex VII	32856	12143
6481007	THUMB WHEEL	October 2007	Rule 6	Annex VII	13502	12143
6481010	INSTRUMENT 6481010 SCREW POSITIONER	September 2007	Rule 6	Annex VII	13180	13180
6481011	INSTRUMENT 6481011 CROSSLINK HOLDER	September 2007	Rule 6	Annex VII	47807	12143
6481019	INSTRUMENT 6481019 AWL GUIDE - 19MM	August 2007	Rule 6	Annex VII	47831	12143
6481021	INSTRUMENT 6481021 AWL GUIDE - 21MM	August 2007	Rule 6	Annex VII	47831	12143
6481023	INSTRUMENT 6481023 AWL GUIDE - 23MM	August 2007	Rule 6	Annex VII	47831	12143
6481025	INSTRUMENT 6481025 AWL GUIDE - 25MM	August 2007	Rule 6	Annex VII	47831	12143
6481205	INSTRUMENT 6481205 STAPLE IMPACTOR	August 2007	Rule 6	Annex VII	32856	12143
6956190R	BENDING IRON - RIGHT	November 2004	Rule 6	Annex VII	61325	12143
7030032	SCREW GAUGE	October 2004	Rule 6	Annex VII	13180	13180
7350122	3MM HEX PLUG STARTER	February 2004	Rule 6	Annex VII	32865	13517
7350131	3.0MM PROVISIONAL DRIVER	February 2004	Rule 6	Annex VII	33968	13517
7350132	2.5MM REVISION DRIVER	April 2004	Rule 6	Annex VII	33968	13517
7350142	FORCEP ROCKER	January 2004	Rule 6	Annex VII	61325	12143
7350144	3.0MM DRIVER	February 2004	Rule 6	Annex VII	33968	13517
7350145	T-HANDLE BREAK OFF DRIVER	May 2006	Rule 6	Annex VII	33968	13517
7350150	COUNTERTORQUE	February 2004	Rule 6	Annex VII	47554	13180
7350162	ROD BENDER F/ 3.5MM ROD	January 2004	Rule 6	Annex VII	61325	12143
7350175	3.5MM ROD GRIPPER	February 2004	Rule 6	Annex VII	47807	12143
7350211	CURVED HOOK HOLDER	February 2004	Rule 6	Annex VII	47807	13180
7350216	STRAIGHT HOOK HOLDER	February 2004	Rule 6	Annex VII	47807	13180
7350231	HOOK PUSHER	February 2004	Rule 6	Annex VII	47870	12143
7350232	HOOK PUSHER	May 2006	Rule 6	Annex VII	47870	12143
7350236	3.5MM ROD PUSHER	February 2004	Rule 6	Annex VII	47554	13180
7350255	IN-SITU BENDER-LEFT	February 2004	Rule 6	Annex VII	44795	12143

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7350260	IN-SITU BENDER-RIGHT	February 2004	Rule 6	Annex VII	44795	12143
7350265	CORONAL BENDER-LEFT,3.5MM ROD	January 2004	Rule 6	Annex VII	44795	12143
7350270	CORONAL BENDER-RIGHT,3.5MM ROD	January 2004	Rule 6	Annex VII	61325	12143
7350280	FIXED SCREWDRIVER	February 2004	Rule 6	Annex VII	61325	12143
7350621	ELEVATOR, REDUCED TRANS. PROC.	April 2004	Rule 6	Annex VII	35048	12143
7350626	FINDER, REDUCED PEDICLE	April 2004	Rule 6	Annex VII	47862	12143
7350631	ELEVATOR, REDUCED LAMINAR	April 2004	Rule 6	Annex VII	35048	12143
7352030	3.5MM TAP	February 2004	Rule 6	Annex VII	17507	13517
7352032	4.5MM TAP	February 2004	Rule 6	Annex VII	17507	13517
7352034	5.5MM TAP	February 2004	Rule 6	Annex VII	17507	13517
7480104	ROUND AWL, INLINE HANDLE	August 2003	Rule 6	Annex VII	15275	15275
7480107	SQUARE AWL W/ INLINE HANDLE	August 2003	Rule 6	Annex VII	15275	12143
7480109	LEGACY 5.5 SHORT MAS DRIVER	June 2004	Rule 6	Annex VII	33968	13517
7480111	LEGACY 5.5 IMAGE GUIDED MAS DRIVER	April 2004	Rule 6	Annex VII	32865	13517
7480113	LEGACY 5.5 MAS DRIVER	August 2003	Rule 6	Annex VII	32865	13517
7480118	SCREWDRIVER T20	September 2003	Rule 6	Annex VII	33968	13517
7480119	MAS SCREWDRIVER WITH THUMBWEEL	August 2003	Rule 6	Annex VII	33968	12143
7480131	PROVISIONAL DRIVER, SHORT	August 2003	Rule 6	Annex VII	33968	13517
7480134	ROD REDUCER, 5.5 ROD, SHORT	August 2003	Rule 6	Annex VII	44804	12143
7480136	5.5MM ROD REDUCER, LONG	September 2003	Rule 6	Annex VII	44804	17993
7480141	ROCKER PUSH BUTTON	April 2003	Rule 6	Annex VII	13180	13180
7480142	LEGACY 5.5 ROCKER	August 2003	Rule 6	Annex VII	13180	17993
7480147	DRIVER, QUICK CONNECT, T27	August 2003	Rule 6	Annex VII	33968	13517
7480156	T27 NON BREAKOFF PLUG STARTER	August 2003	Rule 6	Annex VII	33968	13517
7480172	5.5MM TLIF/PLIF DISTRACTOR	September 2005	Rule 6	Annex VII	56637	11291
7480221	NARROW LAMINER ELEVATOR	August 2003	Rule 6	Annex VII	35048	12143
7480222	TRANSVERSE PROCESS ELEVATOR	August 2003	Rule 6	Annex VII	35048	12143
7480236	ROD PUSHER, C-SHAPED	August 2003	Rule 6	Annex VII	47554	13180
7480240	LATERAL TRANSLATOR	April 2003	Rule 6	Annex VII	61325	12143
7480245	LATERAL TRANSLATOR HOLDER	April 2003	Rule 6	Annex VII	47807	12143
7480250	COUNTERTORQUE, CENT. CONNECTOR, 2 IN 1	July 2006	Rule 6	Annex VII	47554	13180
7480251	COUNTERTORQUE, CENT. CONNECTOR, ONE-SIDED	July 2006	Rule 6	Annex VII	47554	13180
7480270	CORONAL PLANE BENDER-RIGHT	April 2003	Rule 6	Annex VII	61325	12143
7480275	ROD & PLUG INTRODUCER	April 2003	Rule 6	Annex VII	47807	12143
7480277	LATERAL REDUCER ARM	August 2003	Rule 6	Annex VII	61325	12143
7480278	LATERAL ROD REDUCER- CDHL5.5	August 2003	Rule 6	Annex VII	44804	12143
7480280	LEGACY 5.5 FIXED SCRWDRVR	March 2003	Rule 6	Annex VII	32865	13517
7480281	LEGACY 5.5 SHORT FIXED SCRWDRVR	January 2004	Rule 6	Annex VII	33968	13517
7480282	LEGACY 5.5 IMAGE GUIDED FIXED DRIVER	April 2004	Rule 6	Annex VII	32865	13517
7480290	LEGACY 5.5 APICAL DEROTATOR	August 2003	Rule 6	Annex VII	61325	12143
7480300	DRIVER, BREAK-OFF, 8MM HEX	October 2003	Rule 6	Annex VII	33968	13517
7480317	SELF RETAINING TAH HOOK PUSHER	August 2004	Rule 6	Annex VII	47870	12143
7484109	LEGACY 4.5 SHORT MAS DRIVER	November 2004	Rule 6	Annex VII	33968	13517
7484111	LEGACY 4.5 FNAV MAS DRIVER	April 2004	Rule 6	Annex VII	32865	13517
7484114	3.5MM HEX DRIVER, TAPERED	March 2006	Rule 6	Annex VII	33968	13517

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7484151	COUNTERTORQUE WITH WINDOWS	September 2007	Rule 6	Annex VII	47554	13180
7484216	IMPLANT HOLDER, STRAIGHT, L4.5	February 2006	Rule 6	Annex VII	61325	12143
7484217	HOOK INSERTER, CAPTIVE, L4.5	March 2006	Rule 6	Annex VII	47870	12143
7484219	IMPLANT HOLDER, OFFSET, L4.5	February 2006	Rule 6	Annex VII	61325	12143
7484220	ELEVATOR, REDUCED LAMINAR	March 2006	Rule 6	Annex VII	35048	12143
7484221	ELEVATOR, REDUCED NARROW LAMINAR	March 2006	Rule 6	Annex VII	35048	12143
7484222	ELEVATOR, REDUCED TRANS. PROCESS	March 2006	Rule 6	Annex VII	35048	12143
7484225	PEDICLE FINDER	March 2006	Rule 6	Annex VII	13180	13180
7484231	HOOK PUSHER FOR IMPLANT HOLDER, L4.5	March 2006	Rule 6	Annex VII	47870	12143
7484235	4.5 ROD PUSHER	March 2006	Rule 6	Annex VII	47554	13180
7484236	4.5 ROD PUSHER, C-SHAPED	March 2006	Rule 6	Annex VII	47554	13180
7484281	SCREWDRIVER, SHORT, L4.5 FAS	March 2006	Rule 6	Annex VII	33968	13517
7484282	LEGACY 4.5 IMAGE GUIDED FIXED DRIVER	April 2004	Rule 6	Annex VII	32865	13517
7484285	ROD ROTATION WRENCH, 4.5MM ROD	March 2006	Rule 6	Annex VII	32871	15766
7484290	4.5 APICAL DEROTATOR	November 2004	Rule 6	Annex VII	35048	12143
7485207	LEGACY 5.5 7MM EXT. SLEEVE	June 2004	Rule 6	Annex VII	45200	12143
7485214	LEGACY 5.5 14MM EXT. SLEEVE	June 2004	Rule 6	Annex VII	45200	12143
7485248	5.5MM RING COUNTERTORQUE	June 2004	Rule 6	Annex VII	61325	12143
7485249	5.5 TAB BREAKER	June 2004	Rule 6	Annex VII	61325	12143
7485250	SHORT DRIVER RMAS L5.5	June 2004	Rule 6	Annex VII	61325	12143
7486109	LEGACY 6.35 SHORT MAS DRIVER	June 2004	Rule 6	Annex VII	33968	13517
7486111	L6.35 IGS MAS DRIVER	June 2004	Rule 6	Annex VII	32865	13517
7486113	LEGACY 6.35 MAS DRIVER	February 2004	Rule 6	Annex VII	32865	13517
7486126	6.35 ROD INSERTER	February 2004	Rule 6	Annex VII	61325	12143
7486134	ROD REDUCER, 6.35 ROD, SHORT	February 2004	Rule 6	Annex VII	44804	12143
7486142	LEGACY 6.35 ROCKER	February 2004	Rule 6	Annex VII	61325	12143
7486150	6.35 CLOSED COUNTER TORQUE	March 2004	Rule 6	Annex VII	47554	13180
7486163	L6.35 PRL CMPSR, SM, MOD TIP	December 2005	Rule 6	Annex VII	47870	13180
7486164	L6.35 PRL CMPSR, SM, MOD TIPS	December 2005	Rule 6	Annex VII	47870	13180
7486167	L6.35 PRL CMPSR, LG, MOD TIPS	December 2005	Rule 6	Annex VII	47870	13180
7486168	L6.35 PRL CMPSR, LG, MOD TIP	December 2005	Rule 6	Annex VII	47870	13180
7486172	6.35MM TLIF/PLIF DISTRACTOR	June 2006	Rule 6	Annex VII	56637	11291
7486175	6.35 ROD GRIPPER	February 2004	Rule 6	Annex VII	47807	12143
7486205	DUAL PURPOSE INST., L6.35	February 2004	Rule 6	Annex VII	61325	12143
7486207	6.35 EXTENSION SLEEVE, 7MM	March 2004	Rule 6	Annex VII	45200	12143
7486211	6.35 LATERAL IMPLANT HOLDER	February 2004	Rule 6	Annex VII	61325	12143
7486214	6.35 EXTENSION SLEEVE, 14MM	March 2004	Rule 6	Annex VII	45200	12143
7486216	6.35 STRAIGHT IMPLANT HOLDER	February 2004	Rule 6	Annex VII	61325	12143
7486217	6.35 SELF RETAINING HOOK PUSHE	March 2004	Rule 6	Annex VII	47870	12143
7486219	OFFSET HOOK HOLDER, L6.35	July 2004	Rule 6	Annex VII	47807	13180
7486231	6.35 HOOK PUSHER	March 2004	Rule 6	Annex VII	47554	13180
7486235	6.35 ROD PUSHER	March 2004	Rule 6	Annex VII	47554	13180
7486236	6.35 C-SHAPED ROD PUSHER	March 2004	Rule 6	Annex VII	47554	13180
7486248	RING COUNTERTORQUE, 6.35MM	March 2004	Rule 6	Annex VII	47554	13180
7486249	6.35 TAB BREAKER	February 2004	Rule 6	Annex VII	61325	12143
7486250	REDUCTION DRIVER, LEGACY 6.35	March 2004	Rule 6	Annex VII	33968	13517
7486255	6.35 INSITU BENDER-LEFT	February 2004	Rule 6	Annex VII	61325	12143

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7486260	6.35 INSITU BENDER-RIGHT	February 2004	Rule 6	Annex VII	61325	12143
7486265	6.35 CORONAL PLANE BENDER-LT	February 2004	Rule 6	Annex VII	44975	12143
7486270	6.35 CORONAL PLANE BENDER-RT	February 2004	Rule 6	Annex VII	44975	12143
7486275	ROD & PLUG INTRODUCER, 6.35	February 2004	Rule 6	Annex VII	47870	12143
7486277	6.35 LATERAL REDUCER ARM	February 2004	Rule 6	Annex VII	61325	12143
7486278	LATERAL ROD REDUCER- CDHL6.35	February 2004	Rule 6	Annex VII	44804	12143
7486280	LEGACY 6.35 FIXED DRIVER	March 2004	Rule 6	Annex VII	32865	12143
7486281	LEGACY 6.35 SHORT FIXED DRIVER	March 2004	Rule 6	Annex VII	33968	13517
7486285	6.35 ROD ROTATION WRENCH	February 2004	Rule 6	Annex VII	32871	15766
7486290	LEGACY 6.35 APICAL DEROTATOR	February 2004	Rule 6	Annex VII	47807	12143
7486391	DEROTATOR IMPLANT HOLDER, 6.35	April 2006	Rule 6	Annex VII	47807	12143
7486481	SSR SCREW EXTENDER 6.35	June 2011	Rule 6	Annex VII	44804	13180
7486482	SSR REDUCTION SLEEVE 6.35	June 2011	Rule 6	Annex VII	47831	13180
7486491	ROD CAPTURE 6.35	February 2011	Rule 6	Annex VII	44804	13180
7486492	PUSHER HEAD 6.35	February 2011	Rule 6	Annex VII	44804	13180
7486494	SETSCREW LOADER 6.35	February 2011	Rule 6	Annex VII	13180	13180
7570020	LEGACY ATTACHMENT DRIVER	June 2004	Rule 6	Annex VII	33968	13517
8150500	EXTENDED ROCKER	July 2001	Rule 6	Annex VII	61325	12143
8570525	L.P. CROSSLINK PLATE BENDER	June 2001	Rule 6	Annex VII	61325	12143
8572001	CURVED SPREADER FOR 4.5mm ROD	May 2001	Rule 6	Annex VII	15800	12143
8572004	COMPRESSION PLIERS FOR 4.5mm ROD	May 2001	Rule 6	Annex VII	47870	12143
8572005	STRAIGHT IMPLANT HOLDER	June 2001	Rule 6	Annex VII	47807	13180
8572006	ROCKER, 4.5mm ROD	May 2001	Rule 6	Annex VII	61325	12143
8572007	OFFSET IMPLANT HOLDER	June 2001	Rule 6	Annex VII	47807	12143
8572008	4.5mm CANNULATED TAP, FENESTRATED	May 2001	Rule 6	Annex VII	17507	13517
8572009	5.0mm CANNULATED TAP, FENESTRATED	May 2001	Rule 6	Annex VII	17507	13517
8572010	6.0mm CANNULATED TAP, FENESTRATED	May 2001	Rule 6	Annex VII	17507	13517
8572011	LATERAL BENDER, RIGHT, 4.5mm ROD	May 2001	Rule 6	Annex VII	61325	12143
8572012	LATERAL BENDER, LEFT, 4.5mm ROD	May 2001	Rule 6	Annex VII	61325	12143
8572014	IN-SITU BENDER, LEFT, 4.5mm ROD	May 2001	Rule 6	Annex VII	61325	12143
8572017	4.5MMROD COUNTER TORQUE WRENCH	June 2001	Rule 6	Annex VII	32871	15766
8572018	FINAL PLUG DRIVER	May 2001	Rule 6	Annex VII	33968	13517
8572019	DORSAL GRIP ROD HOLDER, 4.5mm ROD	May 2001	Rule 6	Annex VII	47807	12143
8572020	FRENCH ROD BENDER, 4.5mm ROD	May 2001	Rule 6	Annex VII	61325	12143
8572021	L. P. CROSSLINK PLATE TEMPLATE, 4.5mm ROD	May 2001	Rule 6	Annex VII	46479	12143
8572022	STRAIGHT IMPLANT HOLDER	September 2002	Rule 6	Annex VII	47807	12143
8572023	OFFSET IMPLANT HOLDER	September 2002	Rule 6	Annex VII	47807	12143
8784000	4.0MM SOLID CORTICAL TAP	September 2010	Rule 6	Annex VII	17507	17507
8784500	4.5MM SOLID CORTICAL TAP	September 2010	Rule 6	Annex VII	17507	17507
8785000	5.0MM SOLID CORTICAL TAP	September 2010	Rule 6	Annex VII	17507	17507
8785500	5.5MM SOLID CORTICAL TAP	September 2010	Rule 6	Annex VII	17507	17507
8786500	6.5 MM SOLID CORTICAL TAP	September 2010	Rule 6	Annex VII	17507	17507
8787500	7.5 MM SOLID CORTICAL TAP	September 2010	Rule 6	Annex VII	17507	17507
96130HT	C-RING FOR 6.35 ROD	December 2003	Rule 6	Annex VII	61325	12143
976-401	DRILL SLEEVE	March 2004	Rule 6	Annex VII	45200	12143
X0404040	CDH LEG 5.5 MAS SCR EXTNDR-SHT	June 2004	Rule 6	Annex VII	13180	13180

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X0404041	CDH LEG 5.5 MAS SCR EXTNDR-LG	June 2004	Rule 6	Annex VII	13180	13180
X0705155	LEG6.35 MAS THUMBWHEEL DRIVER	December 2005	Rule 6	Annex VII	32865	13517
X0806300	SCREWDRIVER X0806300 FIXED ANGLE-5.5	March 2007	Rule 6	Annex VII	33968	13517
X0806301	SCREWDRIVER X0806301 MULTI-AXIAL-5.5	March 2007	Rule 6	Annex VII	33968	13517
X0901034	TAP SLEEVE (FOR 5.5 AND 6.5MM)	January 2002	Rule 6	Annex VII	17507	13517
X0901045	BENT NOSE ROD HOLDER, 5.5MM	October 2001	Rule 6	Annex VII	13180	13180
X1004005	LEG 6.35 HEAD ADJUSTER-PEAR HN	February 2005	Rule 6	Annex VII	13180	13180
X1005277	CAN SHORT SCRWDRIWER L6.35 MAS	November 2005	Rule 6	Annex VII	61325	12143
X1104303	LEG 5.5 T-HANDLE ALIGN GUIDE	February 2005	Rule 6	Annex VII	46165	12143
X1105217	DRIVER X1105217 4.5 FIXED 172MM	April 2007	Rule 6	Annex VII	33968	13517
X1204319	LEG 5.5 LAT IMP HLDR-LFT HAND	April 2005	Rule 6	Annex VII	47807	13180
X2290601	ILIO SACRAL SCREWDRIVER	March 2007	Rule 6	Annex VII	61325	12143
X43506134	REDUCER X43506134 BEALE 4.5MM ROD	June 2008	Rule 6	Annex VII	61324	12143
X43506211	HOLDER X43506211 IMPLANT LATERAL	June 2008	Rule 6	Annex VII	47807	13180
X43506216	HOLDER X43506216 IMPLANT STRAIGHT 4.5	June 2008	Rule 6	Annex VII	47807	13180
X7480169	PARALLEL COMPRESSOR, X-LARGE	October 2005	Rule 6	Annex VII	15800	17993
X7480255	INSITU BENDER-L-W/O TOGL-5.5	July 2004	Rule 6	Annex VII	61325	12143
X7480260	INSITU BENDER-R-W/O TOGL-5.5	July 2004	Rule 6	Annex VII	61325	12143
7480110	LUMBAR PROBE	April 2003	Rule 6	Annex VII	13180	13180
8572002	BALL HANDLED PROBE, 3.5mm	May 2001	Rule 6	Annex VII	13180	13180
8581901	ILIO-SACRAL STRAIGHT PROBE	July 2007	Rule 6	Annex VII	13180	13180
CDH Legacy PEEK- Instruments						
7578015	TROCAR 50MM EXTENDED LENGTH	February 2011	Rule 6	Annex VII	47457	14154
7578019	TROCAR 90MM EXTENDED LENGTH	February 2011	Rule 6	Annex VII	47457	14154
CDH M8- Instruments						
9680959	M10 FIXED SCREWDRIVER	April 2001	Rule 6	Annex VII	33968	13517
X0904015	M9 MULTI AXIAL SCREWDRIVER	November 2004	Rule 6	Annex VII	33968	13517
807-065	COUNTR TORQUE WRENCH /6.35 ROD	November 2003	Rule 6	Annex VII	32871	15766
858-950	5.5MM FIXED SCREW DRIVER M8	June 2004	Rule 6	Annex VII	33968	13517
858-957	M8 ROD REDUCER	September 2001	Rule 6	Annex VII	44804	12143
858-985	LATERAL IMPLANT HOLDER	April 2001	Rule 6	Annex VII	47807	13180
858-988	ROD REDUCER LEVER ARM,MS	September 2002	Rule 6	Annex VII	44804	12143
858-989	ROD REDUCER, M8	October 2001	Rule 6	Annex VII	44804	12143
858-990	COUNTER TORQUE M8	April 2000	Rule 6	Annex VII	47554	13180
8680052	M8 MAS Screwdriver	September 2000	Rule 6	Annex VII	33968	13517
8680926	T25 Split Driver	March 2001	Rule 6	Annex VII	33968	13517
8682048	M8 RING COUNTER TORQUE	July 2001	Rule 6	Annex VII	61325	12143
8682049	M8 TAB BREAKER	July 2001	Rule 6	Annex VII	61325	12143
8682050	M8 REDUCTION SCREWDRIVER	July 2001	Rule 6	Annex VII	33968	13517
8682907	M8 ROD REDUCER SLEEVE 7MM	January 2002	Rule 6	Annex VII	47831	12143
8682914	M8 ROD REDUCER SLEEVE 14MM	January 2002	Rule 6	Annex VII	47831	12143
8683750	3.75MM SOLID TAP	August 2003	Rule 6	Annex VII	17507	13517
8684000	4.0MM SOLID TAP	August 2003	Rule 6	Annex VII	17507	13517
8684500	4.5 TAP	March 2000	Rule 6	Annex VII	17507	13517
8685000	5.0 TAP	October 2001	Rule 6	Annex VII	17507	13517
8691008	M8 F.A.S. SCREWDRIVER	September 2002	Rule 6	Annex VII	33968	13517
89690E	CURVED IMPLANT HOLDER	June 2005	Rule 6	Annex VII	47807	13180

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89691E	STRAIGHT IMPLANT HOLDER	June 2005	Rule 6	Annex VII	47807	13180
9680050	M10 MULTI AXIAL SCREWDRIVER	September 2000	Rule 6	Annex VII	33968	13517
9680927	QUICK CONNECT DRIVE FOR TORX 30 DRIVER	March 2001	Rule 6	Annex VII	33968	13517
C6201	CCD ROD PUSHER	August 2001	Rule 6	Annex VII	47554	12143
C6202	ROD HOLDER	August 2001	Rule 6	Annex VII	47870	12143
C6205	CCD FRENCH BENDER	August 2001	Rule 6	Annex VII	44795	12143
C6207	FLEXIBLE CAM ON CURVED CCD	October 2000	Rule 6	Annex VII	32579	12143
C6301	SCREWDRIVER FOR CLOSED SACRAL	August 2001	Rule 6	Annex VII	13180	12143
C6302	SCREWDRIVER FOR HOPF SCREWS	August 2001	Rule 6	Annex VII	13180	12143
X0301020	M8 MAS LOCKING SCREWDRIVER	August 2001	Rule 6	Annex VII	33968	13517
X0302011	MAS DISTRACOR/SPREADER	May 2002	Rule 6	Annex VII	56637	11291
X0401012	M8 SCREW HEAD ADJUSTER	October 2001	Rule 6	Annex VII	13180	13180
X0402002	3D RETRACTOR	July 2002	Rule 6	Annex VII	45182	13386
X0403008	M8 FIXED SCREWDRIVER-U/V JOINT	May 2003	Rule 6	Annex VII	33968	13517
X0601008	DUAL HNDL M8 COUNTER TORQUE	November 2001	Rule 6	Annex VII	47554	13180
X0801034	M8 PLUG INTRODUCER	September 2001	Rule 6	Annex VII	47807	12143
X0801039	M8 TRANSLATOR	December 2001	Rule 6	Annex VII	47870	12143
X0801040	M8 LATERAL IMPLANT HOLDER	December 2001	Rule 6	Annex VII	47807	13180
X0803022	M8 DISTRACOR PARALLEL MOD ARM	September 2003	Rule 6	Annex VII	56637	11291
X0903959	M10 FA REDUCTION SCREWDRIVER	February 2004	Rule 6	Annex VII	61325	12143
X8691001	AWL GUIDE, 19MM	August 2002	Rule 6	Annex VII	61325	12143
X8691004	19MM STAPLE GUIDE SHAFT	August 2002	Rule 6	Annex VII	61325	12143
X8691005	19MM STAPLE IMPACTOR	August 2002	Rule 6	Annex VII	32856	12143
XA002106	M8 ROD AND PLUG INTRODUCER	October 2001	Rule 6	Annex VII	47870	12143
185.047	M8 SCREW GAUGE	February 2003	Rule 6	Annex VII	13180	13180
X0699014	M8 CAPTIVE HOOK PUSHER	July 2008	Rule 6	Annex VII	13180	13180
CDH Sextant- Instruments						
7575300	ROD INSERTER	June 2005	Rule 6	Annex VII	44869	12143
75753019	MULTI-LEVEL OUTER EXTENDER	February 2006	Rule 6	Annex VII	13180	13180
75753029	MULTI-LEVEL MIDDLE EXTENDER	February 2006	Rule 6	Annex VII	13180	13180
75753039	SINGLE LEVEL EXTENDER A	February 2006	Rule 6	Annex VII	13180	13180
75753049	SINGLE LEVEL EXTENDER B	February 2006	Rule 6	Annex VII	13180	13180
75753059	EXTENDER INNER SLEEVE	February 2006	Rule 6	Annex VII	13180	13180
7576301	SEXTANT II REDUCTION OUTER EXTENDER M/L	October 2006	Rule 6	Annex VII	61325	12143
7576302	SEXTANT II REDUCTION MIDDLE EXTENDER M/L	October 2006	Rule 6	Annex VII	61325	12143
7576303	SEXTANT II REDUCTION EXTENDER A S/L	October 2006	Rule 6	Annex VII	61325	12143
7576304	SEXTANT II REDUCTION EXTENDER B S/L	October 2006	Rule 6	Annex VII	61325	12143
8675309	ROD INSERTER ASSEM, MULT-LVL	June 2003	Rule 6	Annex VII	61325	12143
7570021	BONE SCREW DRIVER	June 2005	Rule 6	Annex VII	33968	13517
7570022	BALL ENDED BONE SCREW DRIVER	June 2005	Rule 6	Annex VII	33968	13517
7570023	RETAINING BONESCREW DRIVER	June 2005	Rule 6	Annex VII	33968	13517
7570031	ROD TROCAR	September 2006	Rule 6	Annex VII	47457	14154
7570088	T-27 REMOVAL DRIVER	June 2005	Rule 6	Annex VII	33968	13517
7576310	Q/C SEXTANT II REDUCTION NUT DRIVER	September 2006	Rule 6	Annex VII	33968	13517
7576312	SEXTANT II REDUCTION ROD TEMP POINTER	October 2006	Rule 6	Annex VII	44788	12143

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P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANC E PATHWAY	GMDN	UMDNS
7578095	MODULAR SET SCREW RETAINING COMPRESSOR	October 2007	Rule 6	Annex VII	15800	12143
7578195	SEXTANT 2 FOR M8 COMPRESSOR	June 2009	Rule 6	Annex VII	32865	13517
8670000	SEXTANT QUICK CONNECT TROCAR	November 2001	Rule 6	Annex VII	47457	14154
8670001	SEXTANT GUIDEWIRE, BLUNT	November 2001	Rule 6	Annex VII	46165	11925
8670002	SEXTANT GUIDEWIRE, SHARP	November 2001	Rule 6	Annex VII	46165	11925
8670003	SEXTANT Q/C PEDICLE PROBE	November 2001	Rule 6	Annex VII	13180	13180
8670004	SEXTANT GUIDE WIRE SLEEVE	October 2001	Rule 6	Annex VII	45200	12143
8670005	350 MM GUIDEWIRE, SHARP	September 2006	Rule 6	Annex VII	46165	12143
8670007	SEXTANT TORCAR / PROBE SLEEVE	December 2001	Rule 6	Annex VII	45200	12143
8670020	SEXTANT M8 MAS SCREWDRIVER	December 2001	Rule 6	Annex VII	33968	13517
8670021	SEXTANT M8 REATTACHMENT DRIVER	December 2001	Rule 6	Annex VII	61325	12143
8670030	SEXTANT ROD TROCAR	December 2001	Rule 6	Annex VII	47457	14154
8670040	SEXTANT COMBINATION PLUGDRIVER	December 2001	Rule 6	Annex VII	33968	13517
8670051	SHORT THREADED GUIDEWIRE BLUNT	December 2004	Rule 6	Annex VII	46165	11925
8670052	SHORT THREADED GUIDEWIRE SHARP	December 2004	Rule 6	Annex VII	46165	11925
8670076	DRILL FOR 1.98MM PIN	August 2004	Rule 6	Annex VII	44759	12143
8670077	1.98MM PIN	August 2004	Rule 6	Annex VII	44759	12143
8670086	SEXTANT CANNULATED DRILL BIT	July 2003	Rule 6	Annex VII	61325	12143
8670090	SEXTANT FINAL PLUG DRIVER	January 2002	Rule 6	Annex VII	33968	13517
8670095	COMPRESSOR HANDLE	December 2001	Rule 6	Annex VII	61325	12143
8675203	DRIVER 8675203 5MM HEX	August 2007	Rule 6	Annex VII	33968	13517
8675204	DRIVER 8675204 SET SCREW BREAKOFF	August 2007	Rule 6	Annex VII	33968	13517
8675206	TEMPLATE 8675206 SPONDY ROD POINTER	August 2007	Rule 6	Annex VII	46479	12143
8675207	DRIVER 8675207 LONG	August 2007	Rule 6	Annex VII	33968	13517
8675306	NEEDLE GUIDE, PLASTIC	July 2003	Rule 6	Annex VII	61325	12143
8675307	DILATOR GUIDE, MULTI LEVEL	June 2003	Rule 6	Annex VII	61325	12143
8675310	RADIOLUCENT CLAMP ASSEMBLY	June 2003	Rule 6	Annex VII	61325	12143
8675312	ROD TEMPLATE POINTER	July 2003	Rule 6	Annex VII	46479	12143
8675422	SEXTANT DILATOR	November 2001	Rule 6	Annex VII	13180	13180
X1104128	SEXT INSULATED SCREW EXTENDER	February 2005	Rule 6	Annex VII	13180	13180
8675300	SEXTANT ROD INSERTER ASSEMBLY	January 2002	Rule 6	Annex VII	61325	12143
7570988	SEXTANT II REDUCTION T27 REMOVAL	September 2006	Rule 6	Annex VII	13180	13180
Shilla Growth Rods-Instruments						
7484126	ROD INSERTER, 4.5MM	March 2006	Rule 6	Annex VII	61325	12143
7484134	ROD REDUCER, L4.5	December 2004	Rule 6	Annex VII	44804	12143
7484142	ROCKER, L4.5	February 2006	Rule 6	Annex VII	61325	12143
7484147	T25 DRIVER, QUICK-CONNECT	March 2006	Rule 6	Annex VII	32865	13517
7484171	DISTRACTOR, L4.5	March 2006	Rule 6	Annex VII	47870	12143
7484175	4.5 ROD GRIPPER	November 2004	Rule 6	Annex VII	47807	12143
7484255	BENDER, LEFT INSITU, 4.5MM RODS	March 2006	Rule 6	Annex VII	61325	12143
7484260	BENDER, RIGHT INSITU, 4.5MM RODS	March 2006	Rule 6	Annex VII	61325	12143
7484265	BENDER, LEFT CORONAL, 4.5MM RODS	March 2006	Rule 6	Annex VII	61325	12143
7484270	BENDER, RIGHT CORONAL, 4.5MM RODS	March 2006	Rule 6	Annex VII	61325	12143
7674444	4.5 MULTI-AXIAL SCREWDRIVER	November 2010	Rule 6	Annex VII	33968	13517
7675555	5.5 MULTI-AXIAL SCREWDRIVER	November 2010	Rule 6	Annex VII	33968	12143
CHD Longitude- Instruments						

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7570011	ROD CONFIRMATION TOOL	March 2007	Rule 6	Annex VII	13180	13180
75700305	Nitinol Blunt Guidewire 305mm	February 2014	Rule 6	Annex VII	13180	13180
75700350	Nitinol Blunt Guidewire 350mm	February 2014	Rule 6	Annex VII	13180	13180
75700450	Nitinol Blunt Guidewire 450mm	February 2014	Rule 6	Annex VII	13180	13180
75700610	Nitinol Blunt Guidewire 610mm	February 2014	Rule 6	Annex VII	13180	13180
75700720	Nitinol Blunt Guidewire 720mm	February 2014	Rule 6	Annex VII	13180	13180
75701305	Nitinol Sharp Guidewire 305mm	February 2014	Rule 6	Annex VII	13180	13180
75701350	Nitinol Sharp Guidewire 350mm	February 2014	Rule 6	Annex VII	13180	13180
75701450	Nitinol Sharp Guidewire 450mm	February 2014	Rule 6	Annex VII	13180	13180
75701610	Nitinol Sharp Guidewire 610mm	February 2014	Rule 6	Annex VII	13180	13180
75701720	Nitinol Sharp Guidewire 720mm	February 2014	Rule 6	Annex VII	13180	13180
7570800	ROD ENTRY POINT ESTIMATOR	March 2007	Rule 6	Annex VII	13180	13180
7570801	COUNTER TORQUE	March 2007	Rule 6	Annex VII	47554	13180
7570802	SUCTION TREPHINE	March 2007	Rule 6	Annex VII	38749	12143
7570900	ROD INSERTER ASSEMBLY	March 2007	Rule 6	Annex VII	61325	12143
7570901	LONGITUDE REDUCTION EXTENDER ASSEMBLY	March 2007	Rule 6	Annex VII	61325	12143
7570907	FAS DRIVER	March 2007	Rule 6	Annex VII	33968	13517
7570909	SEXTANT II REDUCTION BONESCREW DRIVER	September 2006	Rule 6	Annex VII	61324	12143
7570922	SEXTANT II REDUCTION BALL-END DRIVER	September 2006	Rule 6	Annex VII	33968	13517
7570923	SEXTANT II REDUCTION RETAIN DRIVER	September 2006	Rule 6	Annex VII	33968	13517
7570930	LONGITUDE COMPRESSOR/ DISTRATOR RACK	March 2007	Rule 6	Annex VII	13180	13180
7570932	COMPRESSOR/DISTRATOR POSITIONER ARM	March 2007	Rule 6	Annex VII	47554	13180
7570942	FRACTURE REDUCER	January 2011	Rule 6	Annex VII	13180	16031
7570944	EXTENDER COLLAR	January 2011	Rule 6	Annex VII	13180	16031
7570946	SCREW GHOST	January 2011	Rule 6	Annex VII	13180	16031
7570947	Fracture Reducer Clip	February 2014	Rule 6	Annex VII	13180	13180
7570948	Compressor-Distractor Clip	February 2014	Rule 6	Annex VII	13180	13180
7578301	Longitude LX Extender (4.75)	February 2013	Rule 6	Annex VII	44804	13180
7578302	Longitude LX Extender (5.5/6.0)	February 2013	Rule 6	Annex VII	33968	13517
7578309	Longitude 2 Reduction Nut Driver	February 2013	Rule 6	Annex VII	47554	13180
7578801	COUNTER TORQUE	February 2013	Rule 6	Annex VII	47554	13180
7578900	SET SCREW RETAINING DRIVER	February 2013	Rule 6	Annex VII	33968	13517
7578911	Longitude LX Rod Confirmation Tool	February 2013	Rule 6	Annex VII	13180	13180
7578930	5.5 INSITU BENDER (RIGHT) [20/45]	February 2013	Rule 6	Annex VII	44795	15884
7578945	5.5 INSITU BENDER (LEFT) [20/45]	February 2013	Rule 6	Annex VII	44795	15884
X1205112	LONGITUDINAL BLADE, SHORT TIPS, 30MM	February 2006	Rule 6	Annex VII	46774	15558
X1205113	LONGITUDINAL BLADE, SHORT TIPS, 40MM	February 2006	Rule 6	Annex VII	46774	15558
X1205114	LONGITUDINAL BLADE, SHORT TIPS, 50MM	February 2006	Rule 6	Annex VII	46774	15558
X1205115	LONGITUDINAL BLADE, SHORT TIPS, 60MM	February 2006	Rule 6	Annex VII	46774	15558
X1205116	LONGITUDINAL BLADE, SHORT TIPS, 70MM	February 2006	Rule 6	Annex VII	46774	15558
6640002	Percutaneous Inserter	December 2015	Rule 6	Annex VII	12696	12143
6640011	Bayonnetted Bender Left (Ø5.5mm)	December 2015	Rule 6	Annex VII	44795	12143
6640012	Bayonnetted Bender Right (Ø5.5mm)	December 2015	Rule 6	Annex VII	44795	12143
6640013	Bayonnetted Bender Left (Ø6.0)	December 2015	Rule 6	Annex VII	44795	12143

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6640014	Bayoneted Bender Right (Ø6.0)	December 2015	Rule 6	Annex VII	44795	12143
6640016	HEAD POSITIONER	December 2015	Rule 6	Annex VII	47870	12143
6640017	Ø4.75 TLIF DISTRACTOR	December 2015	Rule 6	Annex VII	56637	12143
6640018	Rod Rotator	December 2015	Rule 6	Annex VII	47807	12143
6640019	Ø5.5/6.0 TLIF Distractor	December 2015	Rule 6	Annex VII	56637	12143
6640030	4.75 REATTACHMENT PROBE	December 2015	Rule 6	Annex VII	47829	12143
6640031	4.75 REATTACHMENT SLEEVE	December 2015	Rule 6	Annex VII	47829	12143
6640032	REATTACHMENT HANDLE	December 2015	Rule 6	Annex VII	47829	12143
6640033	5.5-6.0 REATTACHMENT PROBE	December 2015	Rule 6	Annex VII	47829	12143
6640034	5.5-6.0 REATTACHMENT SLEEVE	December 2015	Rule 6	Annex VII	47829	12143
6640052	Speculum Handle	December 2015	Rule 6	Annex VII	47829	12143
6640056	30mm Speculum C-Tube	December 2015	Rule 6	Annex VII	35315	12143
6640057	50mm Speculum C-Tube	December 2015	Rule 6	Annex VII	35315	12143
6640058	70mm Speculum C-Tube	December 2015	Rule 6	Annex VII	35315	12143
6640059	90mm Speculum C-Tube	December 2015	Rule 6	Annex VII	35315	12143
COLORADO™ 2- Instruments						
R50111	PEDICLE SCREW WRENCH	July 2008	Rule 6	Annex VII	32871	12143
R50201	HEXAGONAL SCREWDRIVER	March 2000	Rule 6	Annex VII	61325	12143
5618003	CLAW COMPRESSOR	April 2005	Rule 6	Annex VII	15800	12143
5618005	REDUCTION INSTRUMENT (SAGGI)	April 2005	Rule 6	Annex VII	13180	13180
5618006	HOOK CLAW HOLDER W PLUG GUIDE	April 2005	Rule 6	Annex VII	13180	13180
5618007	HOOK CLAW SCREWDRIVER	April 2005	Rule 6	Annex VII	33968	12143
5618008	COUNTER TORQUE FOR ROD PLATE	April 2005	Rule 6	Annex VII	47554	13180
5618009	FORCEPS HOOK HOLDER	April 2005	Rule 6	Annex VII	47807	13180
5618010	UNIVERSAL PLATE HOLDER	April 2005	Rule 6	Annex VII	47807	13180
5618011	EXTENDED POST SCREWDRIVER	April 2005	Rule 6	Annex VII	61325	12143
7480689	ADAPTOR POST M5	December 2012	Rule 6	Annex VII	13180	13180
8616001	DUAL PURPOSE NUT DRIVER	May 2000	Rule 6	Annex VII	32865	12143
8616002	NUT BREAKING WRENCH	April 2000	Rule 6	Annex VII	32871	12143
8616003	ACTUATOR OF THREAD ROD	June 2003	Rule 6	Annex VII	61325	12143
8616004	PEDICULAR SCREWDRIVER	March 2002	Rule 6	Annex VII	61325	12143
8616005	UNIVERSAL COUNTER TORQUE	May 2003	Rule 6	Annex VII	61325	12143
8616006	SHAFT, ANT SACRAL SCREWDRIVER	March 2002	Rule 6	Annex VII	61325	12143
8616007	UNIVERSAL PLATE HOLDER	March 2002	Rule 6	Annex VII	61325	12143
8616008	WRENCH FOR DISMANTLING	March 2002	Rule 6	Annex VII	32871	12143
8616009	IMPLANT HOLDER	July 2008	Rule 6	Annex VII	61325	12143
8616010	HOOK HOLDER/INSERTER	February 2006	Rule 6	Annex VII	47807	12143
8616011	DRILLING GUIDE/ PEDICLE STAPLE	July 2008	Rule 6	Annex VII	61325	12143
8616012	PERFORATOR	June 2005	Rule 6	Annex VII	61325	12143
8616013	STAPLE IMPACTOR	October 2003	Rule 6	Annex VII	61325	12143
8616014	STRAIGHT RATCHETING HANDLE	January 2006	Rule 6	Annex VII	61325	12143
8616015	DUAL PURPOSE STRAIGHT HANDLE	July 2008	Rule 6	Annex VII	61325	12143
8616017	AWL FOR STAPLE DISMANTLING	December 2000	Rule 6	Annex VII	15275	12143
8616018	STAPLE SUPPORT	March 2002	Rule 6	Annex VII	61325	12143
8616019	SHAFT SHORT, PED SCREWDRIVER	March 2002	Rule 6	Annex VII	61325	12143
8616020	SQUARE AWL	March 2002	Rule 6	Annex VII	15275	12143
8616021	NUT AND SCREWDRIVER SHAFT	April 2000	Rule 6	Annex VII	32865	12143

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8616022	RIGHT ROD BENDER	April 2003	Rule 6	Annex VII	61325	12143
8616023	LEFT ELBOW ROD BENDER	April 2003	Rule 6	Annex VII	61325	12143
8616024	STRAIGHT PROBE	July 2008	Rule 6	Annex VII	13180	13180
8616025	WRENCH FOR 5MM ROD	March 2005	Rule 6	Annex VII	32871	12143
8616030	ANTERIOR STAPLE IMPACTOR	January 2003	Rule 6	Annex VII	32856	12143
8616031	SCREW FOR SELF HOLDING DEVICE	September 2000	Rule 6	Annex VII	61325	12143
8616035	DISMANTLING SOCKET	November 2003	Rule 6	Annex VII	13180	13180
8616036	LATERAL IMPLANT HOLDER	July 2008	Rule 6	Annex VII	13180	13180
8616040	ANTERIOR PLATE IMPACTOR	May 2001	Rule 6	Annex VII	61325	12143
8616041	IMPACTOR GUIDE TYPE 1	May 2001	Rule 6	Annex VII	61325	12143
8616042	IMPACTOR GUIDE TYPE 2	May 2001	Rule 6	Annex VII	61325	12143
8616043	ANTERIOR GUIDING TUBE	May 2001	Rule 6	Annex VII	61325	12143
8616044	ANTERIOR SQUARE AWL	May 2001	Rule 6	Annex VII	15275	12143
8616045	ANTERIOR VERTEBRA GAUGE	August 2001	Rule 6	Annex VII	61325	12143
8616046	ANTERIOR SCREWDRIVER	May 2001	Rule 6	Annex VII	61325	12143
8616049	ANTERIOR SCREW HOLDER	May 2001	Rule 6	Annex VII	61325	12143
8616051	CURVED SQUARE AWL	May 2001	Rule 6	Annex VII	15275	12143
8616060	HEX 3.5 COUNTER TORQUE	March 2012	Rule 6	Annex VII	33968	13517
8616061	SCREW EXTENDER	March 2012	Rule 6	Annex VII	13180	13180
8616062	ROD COUNTER TORQUE	March 2012	Rule 6	Annex VII	33968	13517
8616145	4.5mm Tap	December 2001	Rule 6	Annex VII	61325	12143
8616155	5.5MM TAPS	December 2001	Rule 6	Annex VII	61325	12143
8616165	6.5MM TAP	December 2001	Rule 6	Annex VII	61325	12143
8616170	7MM TAP	December 2001	Rule 6	Annex VII	61325	12143
8616175	7.5MM TAP	December 2001	Rule 6	Annex VII	61325	12143
8617500	ROD COUNTER TORQUE	July 2013	Rule 6	Annex VII	33968	16868
8617520	DUAL PURPOSE BREAK OFF DRIVER	July 2013	Rule 6	Annex VII	33968	16868
8617530	LONG PROVISIONAL DRIVER	July 2013	Rule 6	Annex VII	33968	16868
8617540	HOOK INTRODUCER	July 2013	Rule 6	Annex VII	47807	13180
8617550	HOOK CLAW HOLDER WITH PLUG GUIDE	July 2013	Rule 6	Annex VII	47807	13180
8646003	THREADED END BREAKER	August 2001	Rule 6	Annex VII	13180	13180
8646005	COUNTER TORQUE	September 2001	Rule 6	Annex VII	47554	13180
8646007	ILIO-SACRAL PLATE HOLDER	July 2002	Rule 6	Annex VII	13180	13180
8646008	SHAFT FOR DISMANTLING	September 2001	Rule 6	Annex VII	61325	12143
8646009	IMPLANT HOLDER	September 2001	Rule 6	Annex VII	47807	13180
8646010	HOOK HOLDER	September 2001	Rule 6	Annex VII	47807	13180
8646011	TEMPLATE FOR PEDICULAR STAPLE	September 2001	Rule 6	Annex VII	46479	12143
8646012	AWL FOR PEDICULAR STAPLE	September 2001	Rule 6	Annex VII	15275	12143
8646013	STAPLE IMPACTOR	September 2001	Rule 6	Annex VII	61325	12143
8646017	AWL FOR STAPLE DISMANTLING	September 2001	Rule 6	Annex VII	15275	12143
8646018	SUPPORT FOR PEDICULAR STAPLE	September 2001	Rule 6	Annex VII	61325	12143
8646021	SCREWDRIVER SHAFT	September 2001	Rule 6	Annex VII	61325	12143
8646030	ANTERIOR STAPLE IMPACTOR	September 2001	Rule 6	Annex VII	13180	13180
8646040	ANTERIOR BRIDGE PLATE HOLDER	September 2001	Rule 6	Annex VII	47807	13180
X1103933	CO2 SCREW EXTENDER-CAPTIVE	January 2004	Rule 6	Annex VII	61325	12143
DYNALOK- Instruments						
8239517	RBC COUNTER TRQ WRENCH	March 2003	Rule 6	Annex VII	32871	15766

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X0503032	PERFORATING AWL W/ EGG HANDLE	July 2003	Rule 6	Annex VII	15275	12143
X9339042	HANDLE TORQUE LIMITING DRIVER	August 2003	Rule 6	Annex VII	47554	13180
X9339043	NUT STARTER SOCKET	August 2003	Rule 6	Annex VII	61325	15766
XA600906	COUNTER-TORQUE FOR HOLY PLATE	April 2002	Rule 6	Annex VII	47554	13180
823-326	7/16" OPEN END CROWFOOT	October 2008	Rule 6	Annex VII	61325	12143
823-327	DYNA-LOK NUT STARTER SHAFT	October 2008	Rule 6	Annex VII	61325	12143
823-328	T-HANDLE TORQUE WRENCH 80"/LB	October 2008	Rule 6	Annex VII	32871	15766
823-329	DYNA-LOK NUT STARTER SOCKET	January 2007	Rule 6	Annex VII	61325	12143
823-339	DYNA-LOK TAP BAR	September 2002	Rule 6	Annex VII	17507	13517
823-340	DYNA-LOK BOLT/SCREW DRIVER	October 2008	Rule 6	Annex VII	33968	13517
823-345	DYNA-LOK PLATE HOLDER	June 2005	Rule 6	Annex VII	13180	13180
823-346	DYNA-LOK DISTRACTOR	November 2002	Rule 6	Annex VII	56637	11291
823-352	NUT STARTER WRENCH	October 2002	Rule 6	Annex VII	32871	15766
823-366	CURVED PROBE	October 2000	Rule 6	Annex VII	13180	13180
823-368	DYNA-LOK CONNECTING BOLT HOLDE	October 2008	Rule 6	Annex VII	13180	13180
823-369	COMBINATION PLATE BENDER	October 2008	Rule 6	Annex VII	44795	12143
823-380	1/4" BOLT CUTTER	June 2004	Rule 6	Annex VII	13180	13180
X1102018	40MM T-HANDLE HOLT PROBE	January 2003	Rule 6	Annex VII	13180	13180
X1102019	45MM T-HANDLE HOLT PROBE	January 2003	Rule 6	Annex VII	13180	13180
X1102020	50MM T-HANDLE HOLT PROBE	January 2003	Rule 6	Annex VII	13180	13180
X1102023	35MM T-HANDLE HOLT PROBE	January 2003	Rule 6	Annex VII	13180	13180
8230956R	POST BREAK-OFF WRENCH	October 2008	Rule 6	Annex VII	32871	15766
CDH LONGITUDE II- Instruments						
7570398	MAST Deformity VCM Adapter	February 2014	Rule 6	Annex VII	13180	13180
X0405293	TL BLADE-LONG-35X30	August 2005	Rule 6	Annex VII	46774	15558
X0405294	TL BLADE-LONG-35X40	August 2005	Rule 6	Annex VII	46774	15558
X0405295	LONG BLADE 50MM X 35MM	August 2005	Rule 6	Annex VII	46774	15558
X0405296	LONG BLADE 60MM X 35MM	August 2005	Rule 6	Annex VII	46774	15558
X0405297	LONG BLADE 70MM X 35MM	August 2005	Rule 6	Annex VII	46774	15558
MAST QUADRANT- Instruments						
9568000	QUADRANT RETRACTOR	September 2005	Rule 6	Annex VII	45182	13180
9568008	MEDIAL/LATERAL RACK ASSEMBLY	September 2005	Rule 6	Annex VII	45182	13180
9568010	ROTATING FLEX ARM ATTACHMENT	September 2005	Rule 6	Annex VII	45182	13180
9568011	QUADRANT OPENER	September 2005	Rule 6	Annex VII	45182	13180
9568105	5CM WIDE BLADE	September 2005	Rule 6	Annex VII	46774	15558
9568107	7CM WIDE BLADE	September 2005	Rule 6	Annex VII	46774	15558
9568109	9CM WIDE BLADE	September 2005	Rule 6	Annex VII	46774	15558
9568115	5CM NARROW BLADE	September 2005	Rule 6	Annex VII	46774	15558
9568117	7CM NARROW BLADE	September 2005	Rule 6	Annex VII	46774	15558
9568119	9CM NARROW BLADE	September 2005	Rule 6	Annex VII	46774	15558
9568224	LEFT HALF TUBE, 40MM	September 2005	Rule 6	Annex VII	32579	13180
9568225	LEFT HALF TUBE, 50MM	September 2005	Rule 6	Annex VII	32579	13180
9568226	LEFT HALF TUBE, 60MM	September 2005	Rule 6	Annex VII	32579	13180
9568227	LEFT HALF TUBE, 70MM	September 2005	Rule 6	Annex VII	32579	13180
9568228	LEFT HALF TUBE, 80MM	September 2005	Rule 6	Annex VII	32579	13180
9569214	CNTRLAT TRNSVRS BLD ASSY, 40MM	March 2004	Rule 6	Annex VII	45182	13386
9569215	CNTRLAT TRNSVRS BLD ASSY, 50MM	March 2004	Rule 6	Annex VII	45182	13386

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Product: General Instruments						
Class: I						
P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
9569216	CNTRLAT TRNSVRS BLD ASSY, 60MM	March 2004	Rule 6	Annex VII	45182	13386
9569217	CNTRLAT TRNSVRS BLD ASSY, 70MM	March 2004	Rule 6	Annex VII	45182	13386
9569218	CNTRLAT TRNSVRS BLD ASSY, 80MM	March 2004	Rule 6	Annex VII	45182	13386
9569224	RIGHT HALF TUBE, 40MM	September 2005	Rule 6	Annex VII	32579	13180
9569225	RIGHT HALF TUBE, 50MM	September 2005	Rule 6	Annex VII	32579	13180
9569226	RIGHT HALF TUBE, 60MM	September 2005	Rule 6	Annex VII	32579	13180
9569227	RIGHT HALF TUBE, 70MM	September 2005	Rule 6	Annex VII	32579	13180
9569228	RIGHT HALF TUBE, 80MM	September 2005	Rule 6	Annex VII	32579	13180
9568264	26mm LEFT HALF TUBE, 4cm	July 2009	Rule 6	Annex VII	32579	10561
9568265	26mm LEFT HALF TUBE, 5cm	July 2009	Rule 6	Annex VII	32579	10561
9568266	26mm LEFT HALF TUBE, 6cm	July 2009	Rule 6	Annex VII	32579	10561
9568267	26mm LEFT HALF TUBE, 7cm	July 2009	Rule 6	Annex VII	32579	10561
9568268	26mm LEFT HALF TUBE, 8cm	July 2009	Rule 6	Annex VII	32579	10561
9569264	26mm RIGHT HALF TUBE, 4cm	July 2009	Rule 6	Annex VII	32579	10561
9569265	26mm RIGHT HALF TUBE, 5cm	July 2009	Rule 6	Annex VII	32579	10561
9569266	26mm RIGHT HALF TUBE, 6cm	July 2009	Rule 6	Annex VII	32579	10561
9569267	26mm RIGHT HALF TUBE, 7cm	July 2009	Rule 6	Annex VII	32579	10561
9569268	26mm RIGHT HALF TUBE, 8cm	July 2009	Rule 6	Annex VII	32579	10561
X1105220	70MM RIGHT HALF TUBE	December 2005	Rule 6	Annex VII	32579	14175
X1105221	70MM LEFT HALF TUBE	December 2005	Rule 6	Annex VII	32579	14175
Medtronic Rod Connector- Instruments						
778000004	DIA. 4.5MM ROD OSTEOOTOME - STRAIGHT	January 2008	Rule 6	Annex VII	10455	12845
778000005	DIA. 4.5MM ROD OSTEOOTOME, ANGLED	January 2008	Rule 6	Annex VII	10455	12845
778000009	DIA. 5.5MM ROD OSTEOOTOME - STRAIGHT	January 2008	Rule 6	Annex VII	10455	12845
778000010	DIA. 5.5MM ROD OSTEOOTOME, ANGLED	January 2008	Rule 6	Annex VII	10455	12845
778000012	DIA. 6.35MM COUNTER TORQUE	January 2008	Rule 6	Annex VII	47554	13180
778000013	DIA. 5.5MM COUNTER TORQUE	January 2008	Rule 6	Annex VII	47554	13180
778000014	DIA. 4.5MM COUNTER TORQUE	January 2008	Rule 6	Annex VII	47554	13180
778000016	IMPLANT HOLDER	January 2008	Rule 6	Annex VII	47807	13180
778000017	VA DOMINO FORCEPS	January 2008	Rule 6	Annex VII	47807	13180
778000018	DIA. 6.35MM ROD OSTEOOTOME, STRAIGHT	January 2008	Rule 6	Annex VII	10455	12845
778000019	DIA. 6.35MM ROD OSTEOOTOME, ANGLED	January 2008	Rule 6	Annex VII	10455	12845
778000023	4.0MM / 4.5MM ROD TEMPLATE	January 2008	Rule 6	Annex VII	46479	13180
778000024	4.75MM/5.0MM / 5.5MM ROD TEMPLATE	January 2008	Rule 6	Annex VII	46479	13180
778000025	6.0MM / 6.35MM ROD TEMPLATE	January 2008	Rule 6	Annex VII	46479	13180
778000026	4.0MM / 4.5MM ROD TEMPLATE, TI	January 2008	Rule 6	Annex VII	46479	13180
778000027	4.75MM/5.0MM / 5.5MM ROD TEMPLATE, TI	January 2008	Rule 6	Annex VII	46479	13180
778000028	6.0MM / 6.35MM ROD TEMPLATE, TI	January 2008	Rule 6	Annex VII	46479	13180
9339082	MODIFIED QC RATCHET HANDLE	July 2003	Rule 6	Annex VII	13180	17993
X0704713	12/7 & 13/7 MESH TRIAL	September 2004	Rule 6	Annex VII	44759	12143
METRx- Instruments						
9560008	18MM MED SCOPE ATTACHMENT	April 1998	Rule 6	Annex VII	13180	13180
9560106	C-MOUNT ADAPTER	April 1998	Rule 6	Annex VII	13180	18104
9560107	METRX 3 CHIP ADAPTER	April 1998	Rule 6	Annex VII	36292	18104
9560207	5.0MM METRX LIGHT CABLE	April 1998	Rule 6	Annex VII	13180	13180
9560758	25MM X 50MM EXPANDING RETRACT	August 2002	Rule 6	Annex VII	45182	13386
9560760	25MMX40MM EXPANDING RETRACTOR	June 2002	Rule 6	Annex VII	45182	13386

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9560762	25MMX60MM EXPANDING RETRACTOR	June 2002	Rule 6	Annex VII	45182	13386
9560764	25MMX80MM EXPANDING RETRACTOR	June 2002	Rule 6	Annex VII	45182	13386
9560768	25MM X 70MM EXPANDING RETRACT	August 2002	Rule 6	Annex VII	45182	13386
9565660	14MM X 3CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565661	14MM X 4CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565662	14MM X 5CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565663	14MM X 6CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565664	14MM X 7CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565665	14MM X 8CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565666	14MM X 9CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565670	16MM X 3CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565671	16MM X 4CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565672	16MM X 5CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565673	16MM X 6CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565674	16MM X 7CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565675	16MM X 8CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565676	16MM X 9CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565680	18MM X 3CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565681	18MM X 4CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565682	18MM X 5CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565683	18MM X 6CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565684	18MM X 7CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565685	18MM X 8CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565686	18MM X 9CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565720	20MM X 3CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143

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9565722	20MM X 5CM TUBULAR RETRACTOR-NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565723	20MM X 6CM TUBULAR RETRACTOR-NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565724	20MM X 7CM TUBULAR RETRACTOR-NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565725	20MM X 8CM TUBULAR RETRACTOR-NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9565726	20MM X 9CM TUBULAR RETRACTOR-NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9567013	S-VIDEO CABLE	September 2004	Rule 6	Annex VII	32579	10561
9567014	VIDEO CABLE	September 2004	Rule 6	Annex VII	32579	10561
9567027	REPLACEMENT FUSE, LIGHT SOURCE	September 2004	Rule 6	Annex VII	32579	10561
9567028	REPLACEMENT FUSE, ALL CAMERAS	September 2004	Rule 6	Annex VII	32579	10561
9567029	RGB CABLE, 3-CHIP CAMER SYSTEM	September 2004	Rule 6	Annex VII	32579	10561
9569660	14MM X 3CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569661	14MM X 4CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569662	14MM X 5CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569663	14MM X 6CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569664	14MM X 7CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569665	14MM X 8CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569666	14MM X 9CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569670	16MM X 3CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569671	16MM X 4CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569672	16MM X 5CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569673	16MM X 6CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569674	16MM X 7CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569675	16MM X 8CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	32579	10561
9569676	16MM X 9CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569680	18MM X 3CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569681	18MM X 4CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569682	18MM X 5CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569683	18MM X 6CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569684	18MM X 7CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569685	18MM X 8CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569686	18MM X 9CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569720	20MM X 3CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569721	20MM X 4CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569722	20MM X 5CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569723	20MM X 6CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569724	20MM X 7CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569725	20MM X 8CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569726	20MM X 9CM COATED/ANGLED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569730	22MM X 3CM COATED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569731	22MM X 4CM COATED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569732	22MM X 5CM COATED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569733	22MM X 6CM COATED TUBE	June 2005	Rule 6	Annex VII	45182	13386

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Product: General Instruments						
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P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
9569734	22MM X 7CM COATED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569735	22MM X 8CM COATED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569736	22MM X 9CM COATED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569750	26MM X 3CM COATED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569751	26MM X 4CM COATED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569752	26MM X 5CM COATED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569753	26MM X 6CM COATED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569754	26MM X 7CM COATED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569755	26MM X 8CM COATED TUBE	June 2005	Rule 6	Annex VII	45182	13386
9569756	26MM X 9CM COATED TUBE	June 2005	Rule 6	Annex VII	45182	13386
X1007055	X1007055 METRX TUBE RETRACTOR 26MMX10CM	February 2008	Rule 6	Annex VII	45182	12143
X9566000	26MM SCOPE ATTACHMENT	February 2005	Rule 6	Annex VII	32579	12143
9560421	METRx DILATOR 9.4MM	February 2001	Rule 6	Annex VII	13180	13180
9560523	METRX BED RAIL ATTACHMENT	March 2002	Rule 6	Annex VII	32579	10561
9560524	METRX FLEX ARM	March 2002	Rule 6	Annex VII	32579	10561
9560528	2MM LARGE SHAFT MICROPITUITARY	May 2004	Rule 6	Annex VII	32579	10561
9560529	2MM LARGE SHAFT UPBIT MICROPIT	May 2004	Rule 6	Annex VII	32579	10561
9560534	SUCKER #10	February 2001	Rule 6	Annex VII	38749	12143
9560535	SUCKER #8	February 2001	Rule 6	Annex VII	38749	12143
9560537	METRx KERRISON, 3MM, 40	February 2001	Rule 6	Annex VII	32579	10561
9560538	METRx KERRISON, 5MM, 40	February 2001	Rule 6	Annex VII	32579	10561
9560539	METRx KERRISON, 3MM, 90	February 2001	Rule 6	Annex VII	32579	10561
9560540	METRx KERRISON, 5MM, 90	February 2001	Rule 6	Annex VII	32579	10561
9560553	WOODSON PROBE, 45 DEGREE	February 2001	Rule 6	Annex VII	32579	10561
9560556	METRx 90 DEGREE BALL PROBE, LONG	December 2000	Rule 6	Annex VII	32579	10561
9560557	METRx 90 DEGREE BALL PROBE, SHORT	December 2000	Rule 6	Annex VII	32579	10561
9560561	SUCTION RETRACTOR	February 2001	Rule 6	Annex VII	45182	12143
9560580	KERRISON 2MM 40 DEG UPBITING	November 2002	Rule 6	Annex VII	31335	12143
9560581	KERRISON 2MM 90 DEG UPBITING	November 2002	Rule 6	Annex VII	31335	12143
9560582	KERRISON 1MM 40 DEG UPBITING	January 2003	Rule 6	Annex VII	31335	12143
9560583	KERRISON 1MM 90 DEG UPBITING	January 2003	Rule 6	Annex VII	31335	12143
9560600	BAYONETED KERRINSON, 1MM, 40	February 2002	Rule 6	Annex VII	31335	12143
9560601	BAYONETED KERRINSON, 1MM, 90	February 2002	Rule 6	Annex VII	31335	12143
9560602	BAYONETED KERRINSON, 2MM, 40	February 2002	Rule 6	Annex VII	31335	12143
9560603	BAYONETED KERRINSON, 2MM, 90	February 2002	Rule 6	Annex VII	31335	12143
9560604	BAYONETTED KERRISON 3MM 40 DEG	February 2001	Rule 6	Annex VII	31335	10561
9560605	BAYONETTED KERRISON 3MM 90 DEG	February 2001	Rule 6	Annex VII	31335	10561
9560606	BAYONETTED KERRISON 4MM 40 DEG	February 2001	Rule 6	Annex VII	31335	10561
9560607	BAYONETTED KERRISON 4MM 90 DEG	February 2001	Rule 6	Annex VII	31335	10561
9560608	BAYONETTED KERRISON 5MM 40 DEG	February 2001	Rule 6	Annex VII	31335	10561
9560609	BAYONETTED KERRISON 5MM 90 DEG	February 2001	Rule 6	Annex VII	31335	10561
9560624	BAYNTTD CURTT 5.2MM ANGLED CUP	June 2001	Rule 6	Annex VII	32579	10561
9560628	BAYNTTD CURTT 5.2MM REVERSE	June 2001	Rule 6	Annex VII	32579	10561
9560636	STYLIST	May 2002	Rule 6	Annex VII	32579	10561
9560637	Sucker #6	April 2001	Rule 6	Annex VII	38749	10561
9560638	Micro Bayonet Nerve Hook, Straight	June 2001	Rule 6	Annex VII	32579	10561

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9560639	Bayonet Penfield #7, Pull	April 2001	Rule 6	Annex VII	32579	10561
9560640	WOODSON PROBE, BAYONETED	February 2001	Rule 6	Annex VII	32579	10561
9560641	BAYONETED BALL PROBE SHORT RIGHT	December 2000	Rule 6	Annex VII	32579	10561
9560642	BAYONETED BALL PROBE SHORT STRAIGHT	December 2000	Rule 6	Annex VII	32579	10561
9560643	BAYONETED BALL PROBE SHORT LEFT	December 2000	Rule 6	Annex VII	32579	10561
9560644	BAYONETED BALL PROBE LONG RIGHT	December 2000	Rule 6	Annex VII	32579	10561
9560645	BAYONETED BALL PROBE LONG STRAIGHT	December 2000	Rule 6	Annex VII	32579	10561
9560646	BAYONETED BALL PROBE LONG LEFT	December 2000	Rule 6	Annex VII	32579	10561
9560647	PENFIELD #2 PUSH, BAYONETED	December 2000	Rule 6	Annex VII	32579	10561
9560648	PENFIELD #2 PULL, BAYONETED	December 2000	Rule 6	Annex VII	32579	10561
9560649	PENFIELD #4 PUSH, BAYONETED	December 2000	Rule 6	Annex VII	32579	10561
9560650	PENFIELD #4 PULL, BAYONETED	December 2000	Rule 6	Annex VII	32579	10561
9560651	NERVE HOOK RIGHT, BAYONETED	December 2000	Rule 6	Annex VII	32579	10561
9560652	NERVE HOOK STRAIGHT, BAYONETED	December 2000	Rule 6	Annex VII	32579	10561
9560653	NERVE HOOK LEFT, BAYONETED	December 2000	Rule 6	Annex VII	32579	10561
9560654	DISSECTOR RIGHT, BAYONETED	December 2000	Rule 6	Annex VII	32579	10561
9560655	DISSECTOR STRAIGHT, BAYONETED	December 2000	Rule 6	Annex VII	32579	10561
9560656	DISSECTOR LEFT, BAYONETED	December 2000	Rule 6	Annex VII	32579	10561
9560672	METRx 16MM X 5CM TUBULAR RETRACTOR	February 2001	Rule 6	Annex VII	45182	13386
9560687	BAYONETED PENFIELD #7 PUSH	February 2002	Rule 6	Annex VII	32579	10561
9560688	MICROBAYONETED NERVE HOOK LT	February 2002	Rule 6	Annex VII	32579	10561
9560689	MICROBAYONETED NERVE HOOK RT	February 2002	Rule 6	Annex VII	32579	10561
9560691	MICRO SCISSORS	March 2002	Rule 6	Annex VII	44378	12143
9560710	SUITCASE, METRX I DISPOSABLE TUBES	October 2010	Rule 6	Annex VII	32579	10561
9560720	20MM X 3CM TUBULAR RETRACTOR	February 2002	Rule 6	Annex VII	45182	13386
9560721	20MM X 4CM TUBULAR RETRACTOR	February 2002	Rule 6	Annex VII	45182	13386
9560722	20MM X 5CM TUBULAR RETRACTOR	February 2002	Rule 6	Annex VII	45182	13386
9560723	20MM X 6CM TUBULAR RETRACTOR	February 2002	Rule 6	Annex VII	45182	13386
9560724	20MM X 7CM TUBULAR RETRACTOR	February 2002	Rule 6	Annex VII	45182	13386
9560725	20MM X 8CM TUBULAR RETRACTOR	February 2002	Rule 6	Annex VII	45182	13386
9560726	20MM X 9CM TUBULAR RETRACTOR	February 2002	Rule 6	Annex VII	45182	13386
9560730	22MM X 3CM TUBULAR RETRACTOR	February 2002	Rule 6	Annex VII	45182	13386
9560731	22MM X 4CM TUBULAR RETRACTOR	February 2002	Rule 6	Annex VII	45182	13386
9560732	22MM X 5CM TUBULAR RETRACTOR	February 2002	Rule 6	Annex VII	45182	13386
9560733	22MM X 6CM TUBULAR RETRACTOR	February 2002	Rule 6	Annex VII	45182	13386
9560734	22MM X 7CM TUBULAR RETRACTOR	February 2002	Rule 6	Annex VII	45182	13386
9560735	22MM X 8CM TUBULAR RETRACTOR	February 2002	Rule 6	Annex VII	45182	13386
9560736	22MM X 9CM TUBULAR RETRACTOR	February 2002	Rule 6	Annex VII	45182	13386
9560747	ROD HOLDER, 5.5MM	September 2003	Rule 6	Annex VII	47870	12143
9560750	METRX TUBE RETRACTOR 26MMX3CM	July 2002	Rule 6	Annex VII	45182	13386
9560751	METRX TUBE RETRACTOR 26MMX4CM	July 2002	Rule 6	Annex VII	45182	13386
9560752	METRX TUBE RETRACTOR 26MMX5CM	July 2002	Rule 6	Annex VII	45182	13386
9560753	METRX TUBE RETRACTOR 26MMX6CM	July 2002	Rule 6	Annex VII	45182	13386
9560754	METRX TUBE RETRACTOR 26MMX7CM	July 2002	Rule 6	Annex VII	45182	13386
9560756	METRX TUBE RETRACTOR 26MMX9CM	July 2002	Rule 6	Annex VII	45182	13386
9560761	40MM OPENER/CLOSER F/EXP RETRA	July 2002	Rule 6	Annex VII	45182	13386
9560763	60MM OPENER/CLOSER F/EXP RETRA	July 2002	Rule 6	Annex VII	45182	13386

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9560765	80MM OPENER/CLOSER F/EXP RETRA	July 2002	Rule 6	Annex VII	45182	13386
9560787	MECHANICAL COMPRESSOR	August 2003	Rule 6	Annex VII	15800	12143
9560788	MECHANICAL DISTRACTOR	September 2003	Rule 6	Annex VII	56637	11291
9561523	BED RAIL ATTACHMENT	December 2003	Rule 6	Annex VII	32579	10561
9561524	FLEXIBLE ARM ASSEMBLY	December 2003	Rule 6	Annex VII	61325	10561
9561525	SELF RETAINING NERVE ROOT RETR	December 2003	Rule 6	Annex VII	45182	13386
9561526	ARM POST	December 2003	Rule 6	Annex VII	32579	10561
9561660	METRX14MMX3CMTUBULAR RETRACTOR	March 2002	Rule 6	Annex VII	45182	13386
9561661	METRX14MMX4CMTUBULAR RETRACTOR	March 2002	Rule 6	Annex VII	45182	12143
9561662	METRX14MMX5CMTUBULAT RETRACTOR	March 2002	Rule 6	Annex VII	45182	13386
9561663	METRX14MMX6CMTUBULAR RETRACTOR	March 2002	Rule 6	Annex VII	45182	13386
9561664	METRX14MMX7CMTUBULAR RETRACTOR	March 2002	Rule 6	Annex VII	45182	13386
9561665	METRX14MMX8CMTUBULAR RETRACTOR	March 2002	Rule 6	Annex VII	45182	13386
9561666	METRX14MMX9CMTUBULAR RETRACTOR	March 2002	Rule 6	Annex VII	45182	12143
9561670	METRX16MMX3CMTUBULAR RETRACTOR	March 2002	Rule 6	Annex VII	45182	13386
9561671	METRX16MMX4CMTUBULAR RETRACTOR	March 2002	Rule 6	Annex VII	45182	13386
9561672	METRX16MMX5CMTUBULAR RETRACTOR	March 2002	Rule 6	Annex VII	45182	13386
9561673	METRX16MMX6CMTUBULAR RETRACTOR	March 2002	Rule 6	Annex VII	45182	13386
9561674	METRX16MMX7CMTUBULAR RETRACTOR	March 2002	Rule 6	Annex VII	45182	13386
9561675	METRX16MMX8CMTUBULAR RETRACTOR	March 2002	Rule 6	Annex VII	45182	13386
9561676	METRX16MMX9CMTUBULAR RETRACTOR	March 2002	Rule 6	Annex VII	45182	13386
9561680	METRX18MMX3CMTUBULAR RETRACTOR	March 2002	Rule 6	Annex VII	45182	13386
9561681	METRX18MMX4CMTUBULAR RETRACTOR	March 2002	Rule 6	Annex VII	45182	13386
9561682	METRX18MMX5CMTUBULAR RETRACTOR	March 2002	Rule 6	Annex VII	45182	13386
9561683	METRX18MMX6CMTUBULAR RETRACTOR	March 2002	Rule 6	Annex VII	45182	13386
9561684	METRX18MMX7CMTUBULAR RETRACTOR	March 2002	Rule 6	Annex VII	45182	13386
9561685	METRX18MMX8CMTUBULAR RETRACTOR	March 2002	Rule 6	Annex VII	45182	13386
9561686	METRX18MMX9CMTUBULAR RETRACTOR	March 2002	Rule 6	Annex VII	45182	13386
9565721	20MM X 4CM TUBULAR RETRACTOR- NONBEVELED	January 2008	Rule 6	Annex VII	45182	12143
9569525	4MM PITUITARY RONGEUR	June 2005	Rule 6	Annex VII	13180	13180
9569559	SUCKER #12	June 2005	Rule 6	Annex VII	38749	12143
9569560	WIDE SUCTION RETRACTOR	June 2005	Rule 6	Annex VII	45182	12143
9569565	2MM MICROPITUITARY	June 2005	Rule 6	Annex VII	13180	13180
9569566	2MM PITUITARY WITH TOOTH	June 2005	Rule 6	Annex VII	13180	13180
9569567	2MM UPBITING MICROPITUITARY	June 2005	Rule 6	Annex VII	13180	13180
9569568	CURVED SCISSORS	June 2005	Rule 6	Annex VII	44378	12143
9569600	BAYONETED KERRISON, 1MM, 40	June 2005	Rule 6	Annex VII	31335	12143
9569601	BAYONETED KERRISON, 1MM, 90	June 2005	Rule 6	Annex VII	31335	12143
9569602	BAYONETED KERRISON, 2MM, 40	June 2005	Rule 6	Annex VII	31335	12143
9569603	BAYONETED KERRISON, 2MM, 90	June 2005	Rule 6	Annex VII	31335	12143
9569604	BAYONETED KERRISON, 3MM, 40	June 2005	Rule 6	Annex VII	31335	12143
9569605	BAYONETED KERRISON, 3MM, 90	June 2005	Rule 6	Annex VII	31335	12143
9569606	BAYONETED KERRISON, 4MM, 40	June 2005	Rule 6	Annex VII	31335	12143
9569607	BAYONETED KERRISON, 4MM, 90	June 2005	Rule 6	Annex VII	31335	12143
9569608	BAYONETED KERRISON, 5MM, 40	June 2005	Rule 6	Annex VII	31335	12143
9569609	BAYONETED KERRISON, 5MM, 90	June 2005	Rule 6	Annex VII	31335	12143

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P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
9569638	MICROBAYONETED NERVE HOOK, STR	June 2005	Rule 6	Annex VII	61325	12143
9569639	BAYONET PENFIELD #7, PUSH/PULL	June 2005	Rule 6	Annex VII	61325	12143
9569640	BAYONETED WOODSON PROBE	June 2005	Rule 6	Annex VII	13180	13180
9569641	BAYON BALL PROBE, SHORT RT	June 2005	Rule 6	Annex VII	13180	13180
9569642	BAYON BALL PROBE, SHORT STR	June 2005	Rule 6	Annex VII	13180	13180
9569643	BAYON BALL PROBE, SHORT LT	June 2005	Rule 6	Annex VII	13180	13180
9569644	BAYON BALL PROBE, LONG RT	June 2005	Rule 6	Annex VII	13180	13180
9569645	BAYON BALL PROBE, LONG STR	June 2005	Rule 6	Annex VII	13180	13180
9569646	BAYON BALL PROBE, LONG LT	June 2005	Rule 6	Annex VII	13180	13180
9569647	BAYONET PENFIELD #2, PUSH/PULL	June 2005	Rule 6	Annex VII	61325	12143
9569649	BAYONET PENFIELD #4, PUSH/PULL	June 2005	Rule 6	Annex VII	61325	12143
9569651	BAYON NERVE HOOK, RT	June 2005	Rule 6	Annex VII	61325	12143
9569652	BAYON NERVE HOOK, STR	June 2005	Rule 6	Annex VII	61325	12143
9569653	BAYON NERVE HOOK, LT	June 2005	Rule 6	Annex VII	61325	12143
9569654	BAYON DISSECTOR, RT	June 2005	Rule 6	Annex VII	32579	10561
9569655	BAYON DISSECTOR, STR	June 2005	Rule 6	Annex VII	32579	10561
9569656	BAYON DISSECTOR, LT	June 2005	Rule 6	Annex VII	32579	10561
9569688	MICROBAYONETED NERVE HOOK, LT	June 2005	Rule 6	Annex VII	61325	12143
9569689	MICROBAYONETED NERVE HOOK, RT	June 2005	Rule 6	Annex VII	61325	12143
9569954	NERVE ROOT RETRACTOR	June 2005	Rule 6	Annex VII	45182	12143
X0102014	TL DISTRACT PIN-SD-14MM	March 2002	Rule 6	Annex VII	44759	12143
X0102638	MICRO NERVE HOOK, STRAIGHT	January 2002	Rule 6	Annex VII	32579	10561
X0102639	MX PENFIELD-NOBAY-PULL-#7	January 2002	Rule 6	Annex VII	32579	10561
X0303002	MX ELEVATOR-BAY-COBB-9MM	July 2003	Rule 6	Annex VII	35048	12143
X0303007	MX PITUITARY RONGEUR-BAY-3.6	July 2003	Rule 6	Annex VII	32853	12143
X0303008	MX PITUITARY RONGEUR-BAY-8.6	July 2003	Rule 6	Annex VII	32853	12143
X0303009	6MM BAYONETED RING CURRETTE	March 2003	Rule 6	Annex VII	31335	12143
X0303019	THO STRAIGHT AWL-2"-EXT SHAFT	April 2003	Rule 6	Annex VII	15275	12143
X0303024	MX KERRISON-BAY-EJ-2MM-40D-THF	April 2003	Rule 6	Annex VII	31335	12143
X0303025	MX KERRISON-BAY-EJ-2MM-90D-THF	April 2003	Rule 6	Annex VII	31335	12143
X0303026	MX KERRISON-BAY-EJ-3MM-40D-THF	April 2003	Rule 6	Annex VII	31335	12143
X0303027	MX KERRISON-BAY-EJ-3MM-90D-THF	April 2003	Rule 6	Annex VII	31335	12143
X0303028	MX KERRISON-BAY-EJ-4MM-40D-THF	April 2003	Rule 6	Annex VII	31335	12143
X0303029	MX KERRISON-BAY-EJ-4MM-90D-THF	April 2003	Rule 6	Annex VII	31335	12143
X0303031	MX KERRISON-BAY-EJ-5MM-40D-THF	May 2003	Rule 6	Annex VII	31335	12143
X0303032	MX KERRISON-BAY-EJ-5MM-90D-THF	May 2003	Rule 6	Annex VII	31335	12143
X0303050	SPECIAL 8-9MM BONE GRAFT TRIAL	April 2003	Rule 6	Annex VII	44759	12143
X0404035	MX EXT STR BAY NERVE HOOK	September 2004	Rule 6	Annex VII	45182	12143
X0404110	MX TUBE RETR-14MMX11CM	May 2004	Rule 6	Annex VII	45182	12143
X0404111	MX TUBE RETR-14MMX11CM-ANGLED	May 2004	Rule 6	Annex VII	45182	12143
X0404113	MX TUBE RETR-14MMX13CM	May 2004	Rule 6	Annex VII	45182	12143
X0404131	MX TUBE RETR-14MMX13CM-ANGLED	June 2004	Rule 6	Annex VII	45182	12143
X0404611	MX TUBE RETR-16MMX11CM-ANGLED	May 2004	Rule 6	Annex VII	45182	12143
X0404631	MX TUBE RETR-16MMX13CM-ANGLED	May 2004	Rule 6	Annex VII	45182	12143
X0404638	MX MICRO NERVE HK-BAY-STR-SM	August 2004	Rule 6	Annex VII	61325	12143
X0404652	MX NERVE HK-BAY-STR-DWN	July 2004	Rule 6	Annex VII	61325	12143
X0405128	SHORTENED METRX FLEX ARM	June 2005	Rule 6	Annex VII	13180	13180

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X0405236	MX MICRO SCISSORS STRAIGHT	April 2005	Rule 6	Annex VII	44378	12143
X0503007	MX SUCKER #12	June 2003	Rule 6	Annex VII	38749	10561
X050301514	14MM STD DISTRACTOR	July 2005	Rule 6	Annex VII	56637	11291
X050301614	14MM C DISTRACTOR	July 2005	Rule 6	Annex VII	56637	11291
X050301716	16MM STD DISTRACTOR	July 2005	Rule 6	Annex VII	56637	11291
X050301816	16MM C DISTRACTOR	July 2005	Rule 6	Annex VII	56637	11291
X0503022	MX X-TUBE WAND	August 2003	Rule 6	Annex VII	13180	13180
X0504610	MX TUBE RETR-16MMX11CM	June 2004	Rule 6	Annex VII	32579	10561
X0504630	MX TUBE RETR-16MMX13CM	June 2004	Rule 6	Annex VII	32579	10561
X0504639	MX PENFIELD-BAY-PULL-#7	September 2004	Rule 6	Annex VII	61325	12143
X0504687	MX PENFIELD-BAY-PUSH-#7	September 2004	Rule 6	Annex VII	61325	12143
X0704561	45 DEGREE SUCTION RETRACTOR	September 2004	Rule 6	Annex VII	45182	13386
X0704602	MX KERRISON-BAY-2MM-40D-SHT	September 2004	Rule 6	Annex VII	31335	12143
X0704604	MX KERRISON-BAY-3MM-40D-SHT	September 2004	Rule 6	Annex VII	31335	12143
X0803001	MX PITUITARY-5MM-OPEN-INTL	September 2003	Rule 6	Annex VII	15800	12143
X0803002	MX KERRISON-LPBAY-3MM-40D	September 2003	Rule 6	Annex VII	31335	12143
X0803003	MX SUCTION RETRACTOR-RND TIP	September 2003	Rule 6	Annex VII	45182	12143
X0803004	MX BIPOLAR FORCEP-ANG45	September 2003	Rule 6	Annex VII	15800	12143
X0803005	CURVED TIP KERRISON, 20 DEGREE	September 2003	Rule 6	Annex VII	31335	12143
X0804021	MX TUBE RETR-26MMX11CM	January 2005	Rule 6	Annex VII	44869	12143
X0804022	MX TUBE RETR-26MMX12CM	January 2005	Rule 6	Annex VII	45182	12143
X0804110	MX TUBE RETR-11MMX11CM	September 2004	Rule 6	Annex VII	44869	12143
X1101571	ANGLED BIPOLAR W/ IRRIGATING	November 2001	Rule 6	Annex VII	32579	10561
X1101572	STRAIGHT BIPOLAR W/ IRRIGATING	November 2001	Rule 6	Annex VII	32579	10561
X1103003	MX NERVE ROOT RETR-ANGLED TIP	February 2004	Rule 6	Annex VII	44869	12143
X1103009	MOD SUCTION RETRACTOR	February 2004	Rule 6	Annex VII	45182	12143
X1103016	MX BALL PROBE-BAY-RT-40D	January 2004	Rule 6	Annex VII	13180	13180
X1103017	MX BALL PROBE-BAY-ST-40D	January 2004	Rule 6	Annex VII	13180	13180
X1103018	MX BALL PROBE-BAY-LT-40D	January 2004	Rule 6	Annex VII	13180	13180
X1103019	MX NERVE HOOK-BAY-40D	January 2004	Rule 6	Annex VII	61325	12143
X1103021	MX TEARDROP SUCTION RETRACTOR	January 2004	Rule 6	Annex VII	45182	12143
X1103183	MX TUBE RETR-18MMX3CM-ANGLED	March 2004	Rule 6	Annex VII	45182	12143
X1103184	MX TUBE RETR-18MMX4CM-ANGLED	March 2004	Rule 6	Annex VII	45182	12143
X1103185	MX TUBE RETR-18MMX5CM-ANGLED	March 2004	Rule 6	Annex VII	45182	12143
X1103186	MX TUBE RETR-18MMX6CM-ANGLED	March 2004	Rule 6	Annex VII	45182	12143
X1103187	MX TUBE RETR-18MMX7CM-ANGLED	March 2004	Rule 6	Annex VII	45182	12143
X1103188	MX TUBE RETR-18MMX8CM-ANGLED	March 2004	Rule 6	Annex VII	45182	12143
X1103189	MX TUBE RETR-18MMX9CM-ANGLED	March 2004	Rule 6	Annex VII	45182	12143
X1104255	MX TUBE-22MMX3CM-ANG-R90°	February 2005	Rule 6	Annex VII	45182	12143
X1104256	MX TUBE-22MMX4CM-ANG-R90°	February 2005	Rule 6	Annex VII	45182	12143
X1104257	MX TUBE-22MMX5CM-ANG-R90°	February 2005	Rule 6	Annex VII	45182	12143
X1104258	MX TUBE-22MMX6CM-ANG-R90°	February 2005	Rule 6	Annex VII	45182	12143
X1104259	MX TUBE-22MMX7CM-ANG-R90°	February 2005	Rule 6	Annex VII	45182	12143
X1104260	MX TUBE-22MMX8CM-ANG-R90°	February 2005	Rule 6	Annex VII	45182	12143
X1104261	MX TUBE-22MMX9CM-ANG-R90°	February 2005	Rule 6	Annex VII	45182	12143
X1104262	MX TUBE-22MMX3CM-ANG-L90°	February 2005	Rule 6	Annex VII	45182	12143
X1104263	MX TUBE-22MMX4CM-ANG-L90°	February 2005	Rule 6	Annex VII	45182	12143

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P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANC E PATHWAY	GMDN	UMDNS
X1104264	MX TUBE-22MMX5CM-ANG-L90°	February 2005	Rule 6	Annex VII	45182	12143
X1104265	MX TUBE-22MMX6CM-ANG-L90°	February 2005	Rule 6	Annex VII	45182	12143
X1104266	MX TUBE-22MMX7CM-ANG-L90°	February 2005	Rule 6	Annex VII	45182	12143
X1104267	MX TUBE-22MMX8CM-ANG-L90°	February 2005	Rule 6	Annex VII	45182	12143
X1104268	MX TUBE-22MMX9CM-ANG-L90°	February 2005	Rule 6	Annex VII	45182	12143
X1105078	TUBULAR RETRACTOR 22MM X 4CM W CUT	December 2005	Rule 6	Annex VII	45182	12143
X1105079	TUBULAR RETRACTOR 22MM X 5CM W CUT	December 2005	Rule 6	Annex VII	45182	12143
X1105080	TUBULAR RETRACTOR 22MM X 6CM W CUT	December 2005	Rule 6	Annex VII	45182	12143
X1105081	TUBULAR RETRACTOR 22MM X 7CM W CUT	December 2005	Rule 6	Annex VII	45182	12143
X1105082	TUBULAR RETRACTOR 22MM X 8CM W CUT	December 2005	Rule 6	Annex VII	45182	12143
X1105083	TUBULAR RETRACTOR 22MM X 9CM W CUT	December 2005	Rule 6	Annex VII	45182	12143
X1106094	RETRACTOR X1106094 16MM X 3CM TUBE	February 2007	Rule 6	Annex VII	32579	10561
X1106095	RETRACTOR X1106095 16MM X 4CM TUBE	February 2007	Rule 6	Annex VII	32579	10561
X1106096	RETRACTOR X1106096 16MM X 5CM TUBE	February 2007	Rule 6	Annex VII	32579	10561
X1106097	RETRACTOR X1106097 16MM X 6CM TUBE	February 2007	Rule 6	Annex VII	32579	10561
X1106098	RETRACTOR X1106098 16MM X 7CM TUBE	February 2007	Rule 6	Annex VII	32579	10561
X1106099	RETRACTOR X1106099 16MM X 8CM TUBE	February 2007	Rule 6	Annex VII	32579	10561
X1106100	RETRACTOR X1106100 16MM X 9CM TUBE	February 2007	Rule 6	Annex VII	32579	10561
X1106101	RETRACTOR X1106101 18MM X 3CM TUBE	February 2007	Rule 6	Annex VII	32579	10561
X1106102	RETRACTOR X1106102 18MM X 4CM TUBE	February 2007	Rule 6	Annex VII	32579	10561
X1106103	RETRACTOR X1106103 18MM X 5CM TUBE	February 2007	Rule 6	Annex VII	32579	10561
X1106104	RETRACTOR X1106104 18MM X 6CM TUBE	February 2007	Rule 6	Annex VII	32579	10561
X1106105	RETRACTOR X1106105 18MM X 7CM TUBE	February 2007	Rule 6	Annex VII	32579	10561
X1106106	RETRACTOR X1106106 18MM X 8CM TUBE	February 2007	Rule 6	Annex VII	32579	10561
X1106107	RETRACTOR X1106107 18MM X 9CM TUBE	February 2007	Rule 6	Annex VII	32579	10561
X1201534	EXTENDED SUCKER (#10)	January 2002	Rule 6	Annex VII	32579	10561
X1201535	EXTENDED SUCKER (#8)	January 2002	Rule 6	Annex VII	32579	10561
X1201537	EXT KERRISON 3MM, ANG UPBITING	February 2002	Rule 6	Annex VII	32579	10561
X1201538	EXT KERRISON 5MM, ANG UPBITING	February 2002	Rule 6	Annex VII	32579	10561
X1201539	EXT KERRISON 3MM, STR UPBITING	February 2002	Rule 6	Annex VII	32579	10561
X1201540	EXT KERRISON 5MM, STR UPBITING	February 2002	Rule 6	Annex VII	32579	10561
X1201541	EXT KERRISON 3MM, ANG DOWNBTNG	February 2002	Rule 6	Annex VII	32579	10561
X1201542	EXT KERRISON 5MM, ANG DOWNBTNG	February 2002	Rule 6	Annex VII	32579	10561
X1201543	EXT KERRISON 3MM, STR DOWNBTNG	February 2002	Rule 6	Annex VII	32579	10561
X1201544	EXT KERRISON 5MM, STR DOWNBTNG	February 2002	Rule 6	Annex VII	32579	10561
X1201545	EXT KERRISON 2MM, ANG UPBITING	February 2002	Rule 6	Annex VII	32579	10561
X1201546	EXT KERRISON 2MM, STR UPBITING	February 2002	Rule 6	Annex VII	32579	10561
X1201547	EXT KERRISON 2MM, ANG DOWNBTNG	February 2002	Rule 6	Annex VII	32579	10561
X1202003	SHORT M8 MAS SCREWDRIVER	January 2003	Rule 6	Annex VII	61325	12143
X1202004	EXTENDED HOOK SPREADER	January 2003	Rule 6	Annex VII	61325	12143
X1203042	MX X TUBE MANIPULATOR-10CM	February 2004	Rule 6	Annex VII	15800	12143
X1203054	MX X TUBE MANIPULATOR-12CM	February 2004	Rule 6	Annex VII	15800	12143
X21906106	MX TUBE-10MMX6CM	December 2004	Rule 6	Annex VII	13180	13180
X1201564	EXT 2MM UPBITING PITUITARY	January 2002	Rule 6	Annex VII	32579	10561
X1201565	EXT 2MM MICROPITUITARY	January 2002	Rule 6	Annex VII	32579	10561
X1201566	EXT 2MM PITUITARY W/ TOOTH	January 2002	Rule 6	Annex VII	32579	10561
X1201567	EXT 2MM UPBITING MICROPITUITAR	January 2002	Rule 6	Annex VII	32579	10561

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P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
X1201569	EXT 2MM DOWNBITE PITUITARY	January 2002	Rule 6	Annex VII	32579	10561
X1201570	EXT 4MM UPBITING PITUITARY	January 2002	Rule 6	Annex VII	32579	10561
X0301001	1mm Micropituitary with Teeth	December 2001	Rule 6	Annex VII	32579	10561
X0301002	1mm Upbiting Micropituitary with Teeth	December 2001	Rule 6	Annex VII	32579	10561
MICRO-ENDO System- Instruments						
893-571	18MM THRDE CORT DOWEL ADJ TAP	July 2008	Rule 6	Annex VII	17507	13517
950-911	ANTERIOR CUP CURETTE 30D 2MM	April 2001	Rule 6	Annex VII	31335	12143
950-913	CUP CURETTE, 0 DEGREE, SIZE 0	April 2001	Rule 6	Annex VII	31335	12143
950-919	MICRO-PENFIELD #4	April 2001	Rule 6	Annex VII	61325	12143
950-921	CHISEL, 5MM	April 2001	Rule 6	Annex VII	10825	12143
950-922	CHISEL, 10MM	April 2001	Rule 6	Annex VII	10825	12143
950-924	OSTEOTOME, 10MM	April 2001	Rule 6	Annex VII	12844	12845
950-925	RIB DISSECTOR	April 2001	Rule 6	Annex VII	32579	10561
950-931	ANTERIOR KERRISON RANGEUR,5MM	December 2001	Rule 6	Annex VII	31335	12143
955-519	MED GUIDEWIRE, .062"	April 2005	Rule 6	Annex VII	13180	13180
955-524	MED TUBULAR RETRACTOR 16MM	November 2002	Rule 6	Annex VII	45182	12143
9560118	ME TUBULAR RETRACTOR, 18MM	April 2000	Rule 6	Annex VII	45182	12143
9560216	ME TUBULAR RETRACTOR, 16MM LON	October 2002	Rule 6	Annex VII	45182	12143
9560218	ME TUBULAR RETRACTOR, 18MM LON	November 2002	Rule 6	Annex VII	45182	12143
9560554	ME WIDE NERVE ROOT RETRACTOR	October 2002	Rule 6	Annex VII	45182	12143
9560555	ME NERVE ROOT RETRACTOR	January 2002	Rule 6	Annex VII	45182	12143
9560558	ME PENFIELD #4	December 2002	Rule 6	Annex VII	13180	13180
9560559	ME PENFIELD #2	December 2002	Rule 6	Annex VII	13180	13180
9560560	ME NERVE HOOK	April 2002	Rule 6	Annex VII	13180	13180
9560562	ME 90 DISSECTOR	August 2002	Rule 6	Annex VII	32579	10561
9560565	ME 2MM MICROPITUITARY	November 2002	Rule 6	Annex VII	13180	13180
9560567	ME 2MM UPBITING MICROPITUITARY	March 2000	Rule 6	Annex VII	13180	13180
9560568	ME CURVED SCISSORS	July 2003	Rule 6	Annex VII	13180	13180
X1003218	MX TUBE RETR-18MMX9.5CM	November 2003	Rule 6	Annex VII	13180	13180
X1004816	MED TUBE-SHORT-16MMX5CM	October 2004	Rule 6	Annex VII	13180	13180
X1004818	MED TUBE-SHORT-18MMX5CM	October 2004	Rule 6	Annex VII	13180	13180
Midline Focus- Instruments						
9563000	Retractor Arm, Left	August 2011	Rule 6	Annex VII	45181	12143
9563001	T-HANDLE	August 2011	Rule 6	Annex VII	45181	12143
9563002	BLADE HANDLE MIDLINE	March 2013	Rule 6	Annex VII	45181	45181
9563003	Translation Key	May 2010	Rule 6	Annex VII	45181	12143
9563011	2nd Posterior Dilator	August 2011	Rule 6	Annex VII	13180	13180
9563049	Lateral Blade, Left, 9	August 2011	Rule 6	Annex VII	45181	12143
9563050	Lateral Blade, Left, 10	August 2011	Rule 6	Annex VII	45181	12143
9563051	Lateral Blade, Left, 11	August 2011	Rule 6	Annex VII	45181	12143
9563052	Lateral Blade, Left, 12	August 2011	Rule 6	Annex VII	45181	12143
9563053	Lateral Blade, Left, 13	August 2011	Rule 6	Annex VII	45181	12143
9563054	Lateral Blade, Left, 14	August 2011	Rule 6	Annex VII	45181	12143
9563055	Lateral Blade, Left, 15	August 2011	Rule 6	Annex VII	45181	12143
9563056	Lateral Blade, Left, 16	August 2011	Rule 6	Annex VII	45181	12143
9563057	Lateral Blade, Left, 17	August 2011	Rule 6	Annex VII	45181	12143
9563059	Lateral CP Blade, Left, 9	August 2011	Rule 6	Annex VII	45181	12143

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9563060	MIDLINE BLADE ASSEMBLY, LEFT, 4	November 2012	Rule 6	Annex VII	45181	45181
9563061	MIDLINE BLADE ASSEMBLY, LEFT, 5	November 2012	Rule 6	Annex VII	45181	45181
9563062	MIDLINE BLADE ASSEMBLY, LEFT, 6	November 2012	Rule 6	Annex VII	45181	45181
9563063	MIDLINE BLADE ASSEMBLY, LEFT, 7	November 2012	Rule 6	Annex VII	45181	45181
9563064	MIDLINE BLADE ASSEMBLY, LEFT, 8	November 2012	Rule 6	Annex VII	45181	45181
9563065	MIDLINE BLADE ASSEMBLY, LEFT, 9	November 2012	Rule 6	Annex VII	45181	45181
9563066	MIDLINE BLADE ASSEMBLY, LEFT, 10	November 2012	Rule 6	Annex VII	45181	45181
9563067	MIDLINE BLADE ASSEMBLY, LEFT, 11	November 2012	Rule 6	Annex VII	45181	45181
9563080	MIDLINE BLADE HANDLE ASSEMBLY	April 2012	Rule 6	Annex VII	45181	45181
9563081	D Adapter	August 2011	Rule 6	Annex VII	45181	12143
9563082	Midline Speculum	November 2011	Rule 6	Annex VII	45181	45181
9563083	Midline Weitlaner	November 2011	Rule 6	Annex VII	45181	45181
9563084	Midline Blade, Left, 4	November 2011	Rule 6	Annex VII	45181	45181
9563085	Midline Blade, Left, 5	November 2011	Rule 6	Annex VII	45181	45181
9563086	Midline Blade, Left, 6	November 2011	Rule 6	Annex VII	45181	45181
9563087	Midline Blade, Left, 7	November 2011	Rule 6	Annex VII	45181	45181
9563088	Midline Blade, Left, 8	November 2011	Rule 6	Annex VII	45181	45181
9563089	Midline Blade, Left, 9	November 2011	Rule 6	Annex VII	45181	45181
9563090	Midline Blade, Left, 10	November 2011	Rule 6	Annex VII	45181	45181
9563091	Midline Blade, Left, 11	November 2011	Rule 6	Annex VII	45181	45181
9563094	Posterior CP Blade, Left, 4	August 2011	Rule 6	Annex VII	45181	12143
9563095	Posterior CP Blade, Left, 5	August 2011	Rule 6	Annex VII	45181	12143
9563096	Posterior CP Blade, Left, 6	August 2011	Rule 6	Annex VII	45181	12143
9563097	Posterior CP Blade, Left, 7	August 2011	Rule 6	Annex VII	45181	12143
9563098	Posterior CP Blade, Left, 8	August 2011	Rule 6	Annex VII	45181	12143
9563099	Posterior CP Blade, Left, 9	August 2011	Rule 6	Annex VII	45181	12143
9563100	Retractor Arm, Right	August 2011	Rule 6	Annex VII	45181	12143
9563102	Superior/ Inferior Bar- 100mm	August 2011	Rule 6	Annex VII	45181	12143
9563104	Posterior Blade, Right, 4	August 2011	Rule 6	Annex VII	45181	12143
9563105	Posterior Blade, Right, 5	August 2011	Rule 6	Annex VII	45181	12143
9563106	Posterior Blade, Right, 6	August 2011	Rule 6	Annex VII	45181	12143
9563107	Posterior Blade, Right, 7	August 2011	Rule 6	Annex VII	45181	12143
9563108	Posterior Blade, Right, 8	August 2011	Rule 6	Annex VII	45181	12143
9563109	Posterior Blade, Right, 9	August 2011	Rule 6	Annex VII	45181	12143
9563111	1st Dilator	August 2011	Rule 6	Annex VII	45181	12143
9563112	2nd Posterior CP Dilator	August 2011	Rule 6	Annex VII	45181	12143
9563113	3rd Posterior CP Dilator	August 2011	Rule 6	Annex VII	45181	12143
9563124	1st Lateral Dilator	August 2011	Rule 6	Annex VII	45181	12143
9563125	2nd Lateral Dilator	August 2011	Rule 6	Annex VII	45181	12143
9563126	3rd Lateral Dilator	August 2011	Rule 6	Annex VII	45181	12143
9563127	4th Lateral Dilator	August 2011	Rule 6	Annex VII	45181	12143
9563128	2nd Lateral CP Dilator	August 2011	Rule 6	Annex VII	45181	12143
9563129	3rd Lateral CP Dilator	August 2011	Rule 6	Annex VII	45181	12143
9563130	4th Lateral CP Dilator	August 2011	Rule 6	Annex VII	45181	12143
9563149	Lateral Blade, Right, 9	August 2011	Rule 6	Annex VII	45181	12143
9563150	Lateral Blade, Right, 10	August 2011	Rule 6	Annex VII	45181	12143
9563151	Lateral Blade, Right, 11	August 2011	Rule 6	Annex VII	45181	12143

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9563152	Lateral Blade, Right, 12	August 2011	Rule 6	Annex VII	45181	12143
9563153	Lateral Blade, Right, 13	August 2011	Rule 6	Annex VII	45181	12143
9563154	Lateral Blade, Right, 14	August 2011	Rule 6	Annex VII	45181	12143
9563155	Lateral Blade, Right, 15	August 2011	Rule 6	Annex VII	45181	12143
9563156	Lateral Blade, Right, 16	August 2011	Rule 6	Annex VII	45181	12143
9563157	Lateral Blade, Right, 17	August 2011	Rule 6	Annex VII	45181	12143
9563159	Lateral CP Blade, Right, 9	August 2011	Rule 6	Annex VII	45181	12143
9563160	MIDLINE BLADE ASSEMBLY, RIGHT, 4	November 2012	Rule 6	Annex VII	45181	45181
9563161	MIDLINE BLADE ASSEMBLY, RIGHT, 5	November 2012	Rule 6	Annex VII	45181	45181
9563162	MIDLINE BLADE ASSEMBLY, RIGHT, 6	November 2012	Rule 6	Annex VII	45181	45181
9563163	MIDLINE BLADE ASSEMBLY, RIGHT, 7	November 2012	Rule 6	Annex VII	45181	45181
9563164	MIDLINE BLADE ASSEMBLY, RIGHT, 8	November 2012	Rule 6	Annex VII	45181	45181
9563165	MIDLINE BLADE ASSEMBLY, RIGHT, 9	November 2012	Rule 6	Annex VII	45181	45181
9563166	MIDLINE BLADE ASSEMBLY, RIGHT, 10	November 2012	Rule 6	Annex VII	45181	45181
9563167	MIDLINE BLADE ASSEMBLY, RIGHT, 11	November 2012	Rule 6	Annex VII	45181	45181
9563181	T Adapter	November 2011	Rule 6	Annex VII	45181	13386
9563184	Midline Blade, Right, 4	November 2011	Rule 6	Annex VII	45181	45181
9563185	Midline Blade, Right, 5	November 2011	Rule 6	Annex VII	45181	45181
9563186	Midline Blade, Right, 6	November 2011	Rule 6	Annex VII	45181	45181
9563187	Midline Blade, Right, 7	November 2011	Rule 6	Annex VII	45181	45181
9563188	Midline Blade, Right, 8	November 2011	Rule 6	Annex VII	45181	45181
9563189	Midline Blade, Right, 9	November 2011	Rule 6	Annex VII	45181	45181
9563190	Midline Blade, Right, 10	November 2011	Rule 6	Annex VII	45181	45181
9563191	Midline Blade, Right, 11	November 2011	Rule 6	Annex VII	45181	45181
9563194	Posterior CP Blade, Right, 4	August 2011	Rule 6	Annex VII	45181	12143
9563195	Posterior CP Blade, Right, 5	August 2011	Rule 6	Annex VII	45181	12143
9563196	Posterior CP Blade, Right, 6	August 2011	Rule 6	Annex VII	45181	12143
9563197	Posterior CP Blade, Right, 7	August 2011	Rule 6	Annex VII	45181	12143
9563198	Posterior CP Blade, Right, 8	August 2011	Rule 6	Annex VII	45181	12143
9563199	Posterior CP Blade, Right, 9	August 2011	Rule 6	Annex VII	45181	12143
9563300	Bed Rail Attachment, Bottom	August 2011	Rule 6	Annex VII	45181	12143
9563301	Bed Rail Attachment, Top	August 2011	Rule 6	Annex VII	45181	12143
9563302	WEITLANER MIDLINE HINGED	March 2013	Rule 6	Annex VII	45181	45181
9563303	RETRACTOR ASSEMBLY	November 2012	Rule 6	Annex VII	45181	45181
9563308	Long Stability Pin Driver	August 2011	Rule 6	Annex VII	45181	12143
9563309	Low Profile Stability Pin, 9	August 2011	Rule 6	Annex VII	45181	12143
9563310	Low Profile Stability Pin, 10	August 2011	Rule 6	Annex VII	45181	12143
9563311	Low Profile Stability Pin, 11	August 2011	Rule 6	Annex VII	45181	12143
9563312	Low Profile Stability Pin, 12	August 2011	Rule 6	Annex VII	45181	12143
9563313	Low Profile Stability Pin, 13	August 2011	Rule 6	Annex VII	45181	12143
9563314	Low Profile Stability Pin, 14	August 2011	Rule 6	Annex VII	45181	12143
9563315	Low Profile Stability Pin, 15	August 2011	Rule 6	Annex VII	45181	12143
9563316	Low Profile Stability Pin, 16	August 2011	Rule 6	Annex VII	45181	12143
9563317	Low Profile Stability Pin, 17	August 2011	Rule 6	Annex VII	45181	12143
9563400	Snake Arm	August 2011	Rule 6	Annex VII	45181	12143
9563401	Snake Arm Handle	August 2011	Rule 6	Annex VII	45181	12143
9563402	Snake Arm Extender	August 2011	Rule 6	Annex VII	45181	12143

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MSD WIRE- Instruments						
6523	WIRE CUTTER	April 2002	Rule 6	Annex VII	13180	13180
IPC® POWERASE- Instruments						
2342280L	4.75 FAS SCREWDRIVER, LONG	April 2012	Rule 6	Annex VII	33968	13517
2342280M	4.75 FAS SCREWDRIVER, MEDIUM	April 2012	Rule 6	Annex VII	33968	13517
2342280S	4.75 FAS SCREWDRIVER, SHORT	April 2012	Rule 6	Annex VII	33968	13517
2342281L	5.5 FAS SCREWDRIVER, LONG	April 2012	Rule 6	Annex VII	33968	13517
2342281M	5.5 FAS SCREWDRIVER, MEDIUM	April 2012	Rule 6	Annex VII	33968	13517
2342281S	5.5 FAS SCREWDRIVER, SHORT	April 2012	Rule 6	Annex VII	33968	13517
2342300L	4.75 RMAS SCREWDRIVER, LONG	April 2012	Rule 6	Annex VII	33968	13517
2342300M	4.75 RMAS SCREWDRIVER, MEDIUM	April 2012	Rule 6	Annex VII	33968	13517
2342300S	4.75 RMAS SCREWDRIVER, SHORT	April 2012	Rule 6	Annex VII	33968	13517
2342301L	5.5 RMAS SCREWDRIVER, LONG	April 2012	Rule 6	Annex VII	33968	13517
2342301M	5.5 RMAS SCREWDRIVER, MEDIUM	April 2012	Rule 6	Annex VII	33968	13517
2342301S	5.5 RMAS SCREWDRIVER, SHORT	April 2012	Rule 6	Annex VII	33968	13517
2342305L	4.75 MAS SCREWDRIVER, LONG	April 2012	Rule 6	Annex VII	33968	13517
2342305M	4.75 MAS SCREWDRIVER, MEDIUM	April 2012	Rule 6	Annex VII	33968	13517
2342305S	4.75 MAS SCREWDRIVER, SHORT	April 2012	Rule 6	Annex VII	33968	13517
2342306L	5.5 MAS SCREWDRIVER, LONG	April 2012	Rule 6	Annex VII	33968	13517
2342306M	5.5 MAS SCREWDRIVER, MEDIUM	April 2012	Rule 6	Annex VII	33968	13517
2342306S	5.5 MAS SCREWDRIVER, SHORT	April 2012	Rule 6	Annex VII	33968	13517
2342326L	THREADED POST SCREWDRIVER, LONG	April 2012	Rule 6	Annex VII	33968	13517
2342326M	THREADED POST SCREWDRIVER, MEDIUM	April 2012	Rule 6	Annex VII	33968	13517
2342375L	MPA SCREWDRIVER, LONG	April 2012	Rule 6	Annex VII	33968	13517
2342375M	MPA SCREWDRIVER, MEDIUM	April 2012	Rule 6	Annex VII	33968	13517
2342393L	PRIMARY SCREWDRIVER SHAFT, LONG	April 2012	Rule 6	Annex VII	33968	13517
2342393M	PRIMARY SCREWDRIVER SHAFT, MEDIUM	April 2012	Rule 6	Annex VII	33968	13517
2342393S	PRIMARY SCREWDRIVER SHAFT, SHORT	April 2012	Rule 6	Annex VII	33968	13517
2342401	Locking MPA Driver	April 2012	Rule 6	Annex VII	33968	13517
2342402	Locking MPA Sleeve	April 2012	Rule 6	Annex VII	33968	13517
2343422L	4.5 SLEEVE, LONG	April 2012	Rule 6	Annex VII	45200	13517
2343422M	4.5 SLEEVE, MEDIUM	April 2012	Rule 6	Annex VII	45200	13517
2343422S	4.5 SLEEVE, SHORT	April 2012	Rule 6	Annex VII	45200	13517
2343426L	6.5 SLEEVE, LONG	April 2012	Rule 6	Annex VII	45200	13517
2343426M	6.5 SLEEVE, MEDIUM	April 2012	Rule 6	Annex VII	45200	13517
2343426S	6.5 SLEEVE, SHORT	April 2012	Rule 6	Annex VII	45200	13517
2343429L	8.0 SLEEVE, LONG	April 2012	Rule 6	Annex VII	45200	13517
2343429M	8.0 SLEEVE, MEDIUM	April 2012	Rule 6	Annex VII	45200	13517
2343429S	8.0 SLEEVE, SHORT	April 2012	Rule 6	Annex VII	45200	13517
2343431L	9.0 SLEEVE, LONG	April 2012	Rule 6	Annex VII	45200	13517
2343431M	9.0 SLEEVE, MEDIUM	April 2012	Rule 6	Annex VII	45200	13517
2343431S	9.0 SLEEVE, SHORT	April 2012	Rule 6	Annex VII	45200	13517
2343435	15.0 SLEEVE	April 2012	Rule 6	Annex VII	45200	13517
2346010	Set Screw Breakoff Instrument	April 2012	Rule 6	Annex VII	32390	13180
2346011	4.75 MAS/FAS Counter Torque	April 2012	Rule 6	Annex VII	13180	13180
2346012	5.5/6.0 MAS/FAS Counter Torque	April 2012	Rule 6	Annex VII	13180	13180
2346013	5.5/6.0 MAS/FAS Counter Torque	April 2012	Rule 6	Annex VII	13180	13180

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2346020	POST CUTTER	April 2012	Rule 6	Annex VII	13180	13180
2346030	ROD CUTTER	March 2011	Rule 6	Annex VII	13180	13180
2346050	1/4" Square Adapter	April 2012	Rule 6	Annex VII	13180	13180
2346051	Handle Adapter	April 2012	Rule 6	Annex VII	13180	13180
2300105L	5.5 FAS/MAS COUNTER TORQUE, LONG	January 2009	Rule 6	Annex VII	13180	13180
2300105M	5.5 FAS/MAS COUNTER TORQUE, MEDIUM	January 2009	Rule 6	Annex VII	13180	13180
2300105S	5.5 FAS/MAS COUNTER TORQUE, SHORT	January 2009	Rule 6	Annex VII	13180	13180
2300106L	6.35 FAS/MAS COUNTER TORQUE, LONG	January 2009	Rule 6	Annex VII	13180	13180
2300106M	6.35 FAS/MAS COUNTER TORQUE, MEDIUM	January 2009	Rule 6	Annex VII	13180	13180
2300106S	6.35 FAS/MAS COUNTER TORQUE, SHORT	January 2009	Rule 6	Annex VII	13180	13180
2300205L	5.5 COUNTER TORQUE SHAFT, OFFSET, LONG	January 2009	Rule 6	Annex VII	13180	13180
2300205M	5.5 COUNTER TORQUE SHAFT, OFFSET, MEDIUM	January 2009	Rule 6	Annex VII	13180	13180
2300205S	5.5 COUNTER TORQUE SHAFT, OFFSET, SHORT	January 2009	Rule 6	Annex VII	13180	13180
2300304L	4.75 FAS/MAS COUNTER TORQUE, LONG	January 2009	Rule 6	Annex VII	13180	13180
2300304M	4.75 FAS/MAS COUNTER TORQUE, MEDIUM	January 2009	Rule 6	Annex VII	13180	13180
2300304S	4.75 FAS/MAS COUNTER TORQUE, SHORT	January 2009	Rule 6	Annex VII	13180	13180
2301000L	BREAKER SHAFT LONG SUB-ASSY, SSBO	December 2008	Rule 6	Annex VII	13180	13180
2301000M	BREAKER SHAFT MEDIUM SUB-ASSY, SSBO	December 2008	Rule 6	Annex VII	13180	13180
2301000S	BREAKER SHAFT SHORT SUB-ASSY, SSBO	December 2008	Rule 6	Annex VII	13180	13180
X1013202	SCREWDRIVER CANN WITH CAPTIVE TWIST, T25	March 2014	Rule 6	Annex VII	17507	17507
X1013203	SCREWDRIVER 5.5mm FOR CANCELLOUS CMAS SC	March 2014	Rule 6	Annex VII	17507	17507
X1013204	SCREWDRIVER W/TAPER HEX CANCELLOUS CMAS	March 2014	Rule 6	Annex VII	17507	17507
X1013205	SCREWDRIVER 5.5mm FOR CANCELLOUS MAS SCR	March 2014	Rule 6	Annex VII	17507	17507
X1013206	SCREWDRIVER 6.35mm FOR CANCELLOUS MAS SC	March 2014	Rule 6	Annex VII	17507	17507
X1013207	SCREWDRIVER 5.5mm FOR CANCELLOUS FAS SCR	March 2014	Rule 6	Annex VII	17507	17507
X1013208	SCREWDRIVER 6.35mm FOR CANCELLOUS FAS SC	March 2014	Rule 6	Annex VII	17507	17507
X1013209	SCREWDRIVER 5.5mm CANCELLOUS MAS SCR, SH	March 2014	Rule 6	Annex VII	17507	17507
X1013210	SCREWDRIVER NONCANN W/STEP,4.75 OST MAS	March 2014	Rule 6	Annex VII	17507	17507
X1013211	SCREWDRIVER CANN W/STEP, 4.75 OST MAS SC	March 2014	Rule 6	Annex VII	17507	17507
X1013212	SCREWDRIVER NONCAN W/STP,5.5/6.0 OST MAS	March 2014	Rule 6	Annex VII	17507	17507
X1013213	SCREWDRIVER CAN W/STP,5.5/6.0 OST MAS SC	March 2014	Rule 6	Annex VII	17507	17507
X1013214	SCREWDRIVER NONCAN W/STEP, 4.75 OST RMAS	March 2014	Rule 6	Annex VII	17507	17507

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X1013215	SCREWDRIVER CAN W/STEP, 4.75 OST RMAS SC	March 2014	Rule 6	Annex VII	17507	17507
X1013216	SCREWDRIVER NONCAN W/STP5.5/6.0 OST RMAS	March 2014	Rule 6	Annex VII	17507	17507
X1013217	SCREWDRIVER CAN W/STEP, 5.5/6.0 OST RMAS	March 2014	Rule 6	Annex VII	17507	17507
2300000V	SET SCREW BREAKOFF INSTRUMENT BODY	October 2008	Rule 1	Annex VII	61325	12143
2302000V	SET SCREW BREAKOFF INSTRUMENT NOSE PIECE	October 2008	Rule 1	Annex VII	61325	12143
SOLERA FNS- Instruments						
7480741	ADAPTER DRIVER QC SHAFT	March 2014	Rule 6	Annex VII	32865	16868
7480745	LOCK SLEEVE 4.75	March 2014	Rule 6	Annex VII	32865	16868
7480755	LOCK SLEEVE 5.5/6.0	March 2014	Rule 6	Annex VII	32865	16868
7480741T	ADAPTER DRIVER T25	October 2016	Rule 6	Annex VII	32865	16868
7480745T	LOCK SLEEVE DRIVER 4.75	October 2016	Rule 6	Annex VII	32865	16868
7480755T	LOCK SLEEVE DRIVER 5.5/6.0	October 2016	Rule 6	Annex VII	32865	16868
7480760	STABILIZATION CLIP	March 2014	Rule 6	Annex VII	13180	12143
CDH SOLERA- Instruments						
5480004V	BALL ENDED REMOVAL T-25	February 2008	Rule 6	Annex VII	33968	13517
5480008V	5480008V- DRIVER, RMVL 3.5MM HEX 5.5 MAS	February 2008	Rule 6	Annex VII	33968	13517
5484003	4.75 HEAD POSITIONER	October 2009	Rule 6	Annex VII	47870	13180
5484004	T25 NON BREAKOFF & BREAKOFF PLUG STARTER	October 2009	Rule 6	Annex VII	32865	13517
5484006	4.75 DUAL ACTION ROD GRIPPER	October 2009	Rule 6	Annex VII	47807	13180
5484008	SLEEVE 5485008 SEQNTL REDUCER INNER 4.75	October 2009	Rule 6	Annex VII	44804	13180
5484009	SLEEVE 5484009 SEQNTL REDUCER OUTER 4.75	October 2009	Rule 6	Annex VII	44804	13180
5484010	TOOL 5484010 SET SCRW CONFIRM 4.75	October 2009	Rule 6	Annex VII	13180	13180
5484011	DRIVER 5484011 QC REDUCTION NUT DRVR	October 2009	Rule 6	Annex VII	32865	13180
5484109	T25 SCREWDRIVER	October 2009	Rule 6	Annex VII	32865	13517
5484111	MAS LOCK SLEEVE DRIVER	October 2009	Rule 6	Annex VII	33968	13517
5484113	DRIVER TWISTED T-25	October 2009	Rule 6	Annex VII	32865	13517
5484134	REDUCER ASSEMBLY FOR 4.75MM ROD - G5	October 2009	Rule 6	Annex VII	44804	13180
5484136	REDUCER ASSEMBLY FOR 4.75MM ROD - G5	October 2009	Rule 6	Annex VII	44804	13180
5484150	COUNTER-TORQUE 4.75	October 2009	Rule 6	Annex VII	47554	13180
5484157	MAS SCREWDRIVER WITH THUMBWEEL	February 2011	Rule 6	Annex VII	33968	13517
5484165	COMPRESSOR PLIERS 4.75	October 2009	Rule 6	Annex VII	47870	13180
5484171	DISTRACTION PLIERS 4.75	October 2009	Rule 6	Annex VII	47870	13180
5484172	HINGED TRANSLATOR FOR 4.75	October 2009	Rule 6	Annex VII	47870	13180
5484211	TRADITIONAL LATERAL IMPLANT HOLDER	October 2009	Rule 6	Annex VII	47807	13180
5484216	STRAIGHT IMPLANT HOLDER	October 2009	Rule 6	Annex VII	47807	13180
5484217	4.75 SELF RETAINING IMPLANT HOLDER	October 2009	Rule 6	Annex VII	47807	13180
5484219	IMPLANT HOLDER, OFFSET, L4.75	October 2009	Rule 6	Annex VII	47807	13180
5484231	4.75 HOOK PUSHER	October 2009	Rule 6	Annex VII	47870	13180
5484235	ROD PUSHER 4.75	October 2009	Rule 6	Annex VII	47870	13180

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P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
5484255	IN-SITU BENDER - LEFT	October 2009	Rule 6	Annex VII	44795	15884
5484260	IN-SITU BENDER - RIGHT	October 2009	Rule 6	Annex VII	44795	15884
5484265	4.75 CORONAL PLANE BENDER - LEFT	October 2009	Rule 6	Annex VII	44795	15884
5484270	4.75 CORONAL PLANE BENDER - RIGHT	October 2009	Rule 6	Annex VII	44795	15884
5484280	FIXED SCREWDRIVER 4.75 OR 4.5	October 2009	Rule 6	Annex VII	32865	13517
5484285	ROD ROTATION WRENCH	October 2009	Rule 6	Annex VII	32871	13180
5484300	SCREWDRIVER RMAS T25	October 2009	Rule 6	Annex VII	33968	13517
5484301	4.75 - HEAD POSITIONER	January 2011	Rule 6	Annex VII	47870	13180
5484302	PLUG STARTER WITH PROVISIONAL DRIVER TIP	January 2011	Rule 6	Annex VII	32865	13517
5484303	4.75 ROD GRIPPER	February 2011	Rule 6	Annex VII	47807	13180
5484304	SEQUENTIAL REDUCTION SLEEVE	February 2011	Rule 6	Annex VII	44804	13180
5484305	SCREWDRIVER MAS T25	February 2011	Rule 6	Annex VII	32865	13517
5484306	SCREWDRIVER LOCK SLEEVE 4.75	January 2011	Rule 6	Annex VII	33968	13517
5484307	4.75 MM ROD REDUCER ASSEMBLY - G5	January 2011	Rule 6	Annex VII	44804	13180
5484308	COUNTER-TORQUE 4.75	January 2011	Rule 6	Annex VII	47554	13180
5484309	COMPRESSOR PLIERS 4.75	January 2011	Rule 6	Annex VII	47870	13180
5484310	HINGED TRANSLATOR FOR 4.75 RIGHT	February 2011	Rule 6	Annex VII	47870	13180
5484311	HINGED TRANSLATOR FOR 4.75 LEFT	January 2011	Rule 6	Annex VII	47870	13180
5484313	IN-SITU BENDER - LEFT 4.75	February 2011	Rule 6	Annex VII	44795	15884
5484314	IN-SITU BENDER - RIGHT 4.75	February 2011	Rule 6	Annex VII	44795	15884
5484315	CORONAL PLANE BENDER - LEFT 4.75	February 2011	Rule 6	Annex VII	44795	15884
5484316	CORONAL PLANE BENDER - RIGHT 4.75	February 2011	Rule 6	Annex VII	44795	15884
5484317	4.75 SELF RETAINING HOOK PUSHER	October 2009	Rule 6	Annex VII	47870	13180
5484318	ROD INTRODUCER	January 2011	Rule 6	Annex VII	47807	13180
5484319	PUSH BUTTON ROCKER	February 2011	Rule 6	Annex VII	44804	13180
5484327	4.75 - TLIF DISTRACTOR	January 2011	Rule 6	Annex VII	47870	13180
5484328	SEQUENTIAL REDUCER OUTER ASSEMBLY	January 2011	Rule 6	Annex VII	44804	13180
5484329	MEASURING CALIPER	January 2011	Rule 6	Annex VII	32262	13180
5484330	PLATE TEMPLATE	January 2011	Rule 6	Annex VII	46479	13180
5484331	RMAS LOCK SLEEVE SCREWDRIVER	December 2011	Rule 6	Annex VII	32865	13180
5484332	4.75MM RING COUNTERTORQUE	December 2011	Rule 6	Annex VII	47554	13180
5484333	4.75 RMAS EXTENDED ROCKER	December 2011	Rule 6	Annex VII	44804	13180
5484334	FAS LOCK SLEEVE SCREWDRIVER	February 2011	Rule 6	Annex VII	32865	13517
5484335	4.75 RMAS Tab Breaker	December 2011	Rule 6	Annex VII	13180	13180
5484336	RMAS Breakoff Driver	December 2011	Rule 6	Annex VII	32865	13517
5484337	RMAS Provisional Driver	December 2011	Rule 6	Annex VII	32865	13517
5484338	RMAS SWIZZLE STICK PROVISIONAL DRIVER	December 2011	Rule 6	Annex VII	32865	13517
5484339	4.75 Dual Purpose Screwdriver	December 2011	Rule 6	Annex VII	32865	13517
5484348	4.75 CNRMAS SCREWDRIVER LOCK SLEEVE	October 2011	Rule 6	Annex VII	33968	13517
5484391	4.75mm Derotator Implant Holder	June 2011	Rule 6	Annex VII	47807	13180
5484520	20 cm Rod Template	January 2011	Rule 6	Annex VII	46479	13180
54848136	4.75MM ROD REDUCER, LONG	February 2011	Rule 6	Annex VII	44804	13180
54848140	ROD HOLDER, 4.75mm	February 2011	Rule 6	Annex VII	47870	13180
5484821	MAS SCREW DRIVER	February 2011	Rule 6	Annex VII	33968	13517
5484823	RETAINING BONE SCREWDRIVER	February 2011	Rule 6	Annex VII	32865	13517
5484830	ROD TROCAR	June 2011	Rule 6	Annex VII	47457	14154

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5484898	SUCTION TREPINE	June 2011	Rule 6	Annex VII	47829	14146
5485900	Open Extender - 5.5/6.0	October 2012	Rule 6	Annex VII	47807	47807
5485901	Closed Extender - 5.5/6.0	October 2012	Rule 6	Annex VII	47807	47807
5485902	Reducer, Std Length - 5.5/6.0	October 2012	Rule 6	Annex VII	47807	47807
5485903	Driver - 5.5/6.0	October 2012	Rule 6	Annex VII	32865	47807
5485906	Extender Guide - 5.5/6.0	October 2012	Rule 6	Annex VII	47807	13180
5485908	Reducer, HS - 5.5/6.0	October 2012	Rule 6	Annex VII	47807	13180
5485910	Segmental Link	October 2012	Rule 6	Annex VII	47807	13180
5485911	Interlink	October 2012	Rule 6	Annex VII	47807	13180
5485912	Screw Locker	October 2012	Rule 6	Annex VII	47807	13180
5485913	Global Link	October 2012	Rule 6	Annex VII	47807	13180
5485914	Lateral Handle	October 2012	Rule 6	Annex VII	47807	13180
5584001	RING COUNTER TORQUE 5.5/6.0	January 2012	Rule 6	Annex VII	47554	13180
5584002	NON B/O PROVISIONAL DRIVER INSERT	January 2012	Rule 6	Annex VII	32865	13517
5584003	5.5/6.0mm - HEAD POSITIONER	January 2012	Rule 6	Annex VII	47870	13180
5584005	NON B/O DUAL ENDED PLUG STARTER	January 2012	Rule 6	Annex VII	32865	13517
5584006	5.5/6.0 ROD GRIPPER	January 2012	Rule 6	Annex VII	47807	13180
5584007	SCREW CONFIRMATION TOOL	January 2011	Rule 6	Annex VII	13180	13180
5584009	RMAS BREAK OFF DRIVER 5.5/6.0	January 2012	Rule 6	Annex VII	32865	13517
5584099	MAST DEF 5.5/6.0 RMAS DRIVER	February 2013	Rule 6	Annex VII	33968	13517
5584109	5.5 STANDARD SLEEVE SCREWDRIVER	September 2012	Rule 6	Annex VII	33968	13517
5584111	5.5/6.0 SCREWDRIVER LOCK SLEEVE	January 2012	Rule 6	Annex VII	33968	13517
5584119	Implant Holder Offset, L5.5/6.0	November 2013	Rule 6	Annex VII	47870	13180
5584134	5.5/6.0 MM ROD REDUCER ASSEMBLY - G5	January 2012	Rule 6	Annex VII	44804	13180
5584150	5.5/6.0 CLOSED COUNTER-TORQUE	January 2012	Rule 6	Annex VII	47554	13180
5584157	5.5/6.0 MAS SCREWDRIVER WITH THUMBWHEEL	September 2012	Rule 6	Annex VII	32865	13517
5584165	COMPRESSOR PLIER 5.5/6.0	January 2012	Rule 6	Annex VII	47870	13180
5584171	5.5/6.0 Distractor	January 2012	Rule 6	Annex VII	13180	13180
5584172	HINGED TRANSLATOR FOR 5.5/6.0 RIGHT	January 2012	Rule 6	Annex VII	47870	13180
5584173	HINGED TRANSLATOR FOR 5.5/6.0 LEFT	January 2012	Rule 6	Annex VII	47870	13180
5584235	5.5/6.0 ROD PUSHER	September 2012	Rule 6	Annex VII	47554	13180
5584255	IN-SITU BENDER - LEFT 5.5/6.0	January 2012	Rule 6	Annex VII	44795	15884
5584260	IN-SITU BENDER - RIGHT 5.5/6.0	January 2012	Rule 6	Annex VII	44795	15884
5584265	CORONAL PLANE BENDER - LEFT 5.5/6.0	January 2012	Rule 6	Annex VII	44795	15884
5584266	COUNTER TORQUE BENDER - LEFT 5.5/6.0	September 2012	Rule 6	Annex VII	44795	15884
5584270	CORONAL PLANE BENDER - RIGHT 5.5/6.0	January 2012	Rule 6	Annex VII	44795	15884
5584271	COUNTER TORQUE BENDER - RIGHT 5.5/6.0	September 2012	Rule 6	Annex VII	44795	15884
5584280	FAS SCREWDRIVER 5.5/6.0	September 2012	Rule 6	Annex VII	32865	13517
5584305	5.5 RMAS STANDARD SLEEVE SCREWDRIVER	September 2012	Rule 6	Annex VII	33968	13517
5584312	6.0/5.5 ROD INTRODUCER	January 2012	Rule 6	Annex VII	47870	13180
5584317	5.5/6.0 Self Retaining Hook Pusher	November 2013	Rule 6	Annex VII	47870	13180
5584327	5.5/6.0 - TLIF DISTRACTOR	January 2012	Rule 6	Annex VII	47870	13180
5584331	5.5/6.0 RMAS LOCK SLEEVE SCREWDRIVER	January 2012	Rule 6	Annex VII	33968	13517
5584332	5.5 CNRMAS SCREWDRIVER LOCK SLEEVE	September 2012	Rule 6	Annex VII	32865	13517
5584334	FAS LOCK SLEEVE SCREWDRIVER, 5.5/6.0	January 2012	Rule 6	Annex VII	32865	13517
5584339	5.5/6.0 EAC FAS Driver	September 2012	Rule 6	Annex VII	32865	13517

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5584418	5.5/6.0 Hook Pusher for Implant Holder	November 2013	Rule 6	Annex VII	47870	13180
5584900	6.0 INSITU BENDER (RIGHT) [20/45]	February 2013	Rule 6	Annex VII	44795	15884
5584922	MAST DEF T25 BALL-END REMOVAL	February 2013	Rule 6	Annex VII	33968	13517
5584928	FAS DRIVER	February 2013	Rule 6	Annex VII	33968	13517
5584999	MAST DEF MAS SCREW DRIVER	February 2013	Rule 6	Annex VII	33968	13517
5585335	5.5/6.0 RMAS TAB BREAKER	January 2012	Rule 6	Annex VII	13180	13517
5585336	5.5/6.0 RMAS EXTENDED ROCKER	January 2012	Rule 6	Annex VII	44804	13517
5484800	SOLERA SEXTANT ROD INSERTER	June 2011	Rule 6	Annex VII	12696	17543
5484801	SOLERA SEXTANT REDUCTION OUTER EXTENDER	June 2011	Rule 6	Annex VII	13180	13180
5484802	SOLERA SEXTANT REDUCTION MIDDLE EXTENDER	June 2011	Rule 6	Annex VII	13180	13180
5484803	SOLERA SEXTANT REDUCTION S/L EXTENDER A	June 2011	Rule 6	Annex VII	13180	13180
5484804	SOLERA SEXTANT REDUCTION S/L EXTENDER B	June 2011	Rule 6	Annex VII	13180	13180
5484859	SOLERA SEXTANT INNER SLEEVE	June 2011	Rule 6	Annex VII	47831	13180
CD Horizon Solera (3CO_ DRMAS)						
5330000	Screw Link Assembly	April 2017	Rule 6	Annex VII	47847	13180
5330001	Controller Mount Assembly	April 2017	Rule 6	Annex VII	47847	13180
5330002	Controller	April 2017	Rule 6	Annex VII	47847	13180
5330004	SCREW COUNTER TORQUE	April 2017	Rule 6	Annex VII	47554	13180
5330007	Adjacent Rod Reducer	April 2017	Rule 6	Annex VII	44804	12143
5330014	DRMAS ROCKER	April 2017	Rule 6	Annex VII	44804	12143
5330030	Nerve Elevator 25mm	April 2017	Rule 6	Annex VII	35048	11508
5331010	BOX SCRAPER 9X9	April 2017	Rule 6	Annex VII	31335	12143
5331012	BOX SCRAPER 11x11	April 2017	Rule 6	Annex VII	31335	12143
5331015	DURAL GUARD ASSEMBLY, 15MM	April 2017	Rule 6	Annex VII	34004	13386
5331017	DURAL GUARD ASSEMBLY, 17MM	April 2017	Rule 6	Annex VII	34004	13386
5332015	Cupped Osteotome 15mm	April 2017	Rule 6	Annex VII	12844	12845
5332017	Cupped Osteotome, 17mm	April 2017	Rule 6	Annex VII	12844	12845
5333010	STRAIGHT OSTEOTOME 10MM	April 2017	Rule 6	Annex VII	12844	12845
5333015	STRAIGHT OSTEOTOME 15MM	April 2017	Rule 6	Annex VII	12844	12845
5341010	CURVED BOX SCRAPER 10X10	April 2017	Rule 6	Annex VII	31335	12143
5330006	CONNECTOR COUNTERTORQUE	February 2019	Rule 6	Annex VII	47554	13180
5330030	NERVE ELEVATOR 25MM	February 2019	Rule 6	Annex VII	35048	12143
5330015	DURAL GUARD, 15mm	February 2019	Rule 6	Annex VII	34004	13386
5330017	DURAL GUARD, 17mm	February 2019	Rule 6	Annex VII	34004	13386
5330025	NERVE ELEVATOR 25MM	February 2019	Rule 6	Annex VII	35048	12143
5330032	ROCKER REDUCER	February 2019	Rule 6	Annex VII	44804	12143
5330019	DUAL BEALE REDUCER	February 2019	Rule 6	Annex VII	44804	12143
5330033	SCREW COUNTERTORQUE	February 2019	Rule 6	Annex VII	47554	13180
Tenor- Instruments						
80615501	SQUARE AWL	August 2000	Rule 6	Annex VII	15275	12143
80615503D	LOCATING PIN RIGHT	July 2002	Rule 6	Annex VII	61325	12143
80615503G	LOCATING PIN LEFT	August 2002	Rule 6	Annex VII	61325	12143
80615505	ROD PUSHER	July 2007	Rule 6	Annex VII	47554	13180

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80615506	NUT AND PEDICULAR SCREW-DRIVER	March 2000	Rule 6	Annex VII	61324	12143
80615507	REDUCTION SCREW BREAKER	April 2003	Rule 6	Annex VII	61325	12143
80615508	COUNTER TORQUE	April 2001	Rule 6	Annex VII	47554	13180
80615510	UNIVERSAL HOLDER	August 2002	Rule 6	Annex VII	13180	13180
80615511	EXTENSION ASSEMBLY	March 2000	Rule 6	Annex VII	61325	12143
80615513	COMPRESSOR	October 2000	Rule 6	Annex VII	15800	12143
80615513B	COMPRESSION SYSTEM LARGE	October 2008	Rule 6	Annex VII	61325	12143
80615515	T-WRENCH	January 2005	Rule 6	Annex VII	32871	12143
80615517	SCRWDRIVER/CONICAL HEX END CAP	December 2003	Rule 6	Annex VII	33968	12143
80615518	NUT DRIVER	November 2001	Rule 6	Annex VII	32865	12143
80615521	PEDICLE SCREWDRIVER	January 2005	Rule 6	Annex VII	61325	12143
80615521D	DISMANTLING TIE ROD	July 2002	Rule 6	Annex VII	61325	12143
80615521R	SPONDYLO SCREW TIE ROD	July 2002	Rule 6	Annex VII	61325	12143
80615521S	STD SCREW TIE ROD (GRAY)	July 2002	Rule 6	Annex VII	61325	12143
80615522R	TEMP POSITIONER-OFFSET CLAMP	October 2000	Rule 6	Annex VII	61325	12143
80615522S	TEMP POSITIONER-DUAL CLAMP	October 2000	Rule 6	Annex VII	61325	12143
80615523	COUNTER TORQUE DEVICE	February 2012	Rule 6	Annex VII	47554	13180
80615525	SCREW REMOVER	April 2001	Rule 6	Annex VII	61325	12143
80615527	ROD PUSHER	April 2001	Rule 6	Annex VII	47554	13180
80615528	COUNTER-TORQUE	April 2001	Rule 6	Annex VII	47554	13180
80615529	SCREW REMOVER	December 2000	Rule 6	Annex VII	61325	12143
922501S	SQUARE AWL, SHORT	December 2004	Rule 6	Annex VII	15275	12143
X1001019	MODIFIED SCREWDRIVER HANDLE	November 2001	Rule 6	Annex VII	61325	15766
X1001020	MOD REDUCTION SCREW TIE ROD	November 2001	Rule 6	Annex VII	61325	15766
X1001021	MOD STANDARD SCREW TIE ROD	November 2001	Rule 6	Annex VII	61325	15766
X3840601	SCREWDRIVER	September 2006	Rule 6	Annex VII	61325	12143
X3840610	DISTRACTION FORCEPS 6.35	March 2007	Rule 6	Annex VII	44378	12143
X441060	NUTDRIVER X441060 HEX 7.5 MM	January 2008	Rule 6	Annex VII	33968	13517
X441062	INSTRUMENT X441062 EXTENDER	January 2008	Rule 6	Annex VII	47554	13180
X441063	COUNTER TORQUE HEX 3.5	February 2008	Rule 6	Annex VII	47554	13180
X441064	SLEEVE X441064 QUICK CONNECT	April 2008	Rule 6	Annex VII	45200	12143
X441065	DRIVER X441065 REMOVAL	June 2008	Rule 6	Annex VII	33968	13517
TSRH- Instruments						
803-108	GUIDE WIRE INSERTER	July 2004	Rule 6	Annex VII	13180	13180
8080180	TSRH RP IMPLANT HOLDER	October 2003	Rule 6	Annex VII	61325	12143
808-053	OPEN END WRENCH	November 2001	Rule 6	Annex VII	32871	15766
8080533	TSRH RP DS SCREWDRIVER SHAFT	October 2003	Rule 6	Annex VII	61325	12143
8081532R	3/8" HEX DRIVER - REFURBISHED	June 2007	Rule 6	Annex VII	33968	13517
8081533	DUAL SCREWDRIVER SHAFT	July 2006	Rule 6	Annex VII	61325	12143
808-180	CENTRAL POST HOOK HOLDER	June 2003	Rule 6	Annex VII	47870	12143
8350020	PEDICLE MARKER, CYLINDRICAL	February 2011	Rule 6	Annex VII	13180	13180
8350021	PEDICAL MARKER, SPHERICAL	February 2011	Rule 6	Annex VII	13180	13180
8350045	Ø4.5 DUAL THREAD TAP	February 2011	Rule 6	Annex VII	17507	13517
8350105	THREADED POST SCREWDRIVER	February 2011	Rule 6	Annex VII	17507	13517
8350210	DOUBLE ACTION ROD GRIPPER, 5.5	July 2005	Rule 6	Annex VII	47870	12143
X0803071	VAS TLIF DISTRACTOR	January 2004	Rule 6	Annex VII	56637	11291
8081188	POSITIONING CLIP, 6.35MM ROD	September 2002	Rule 6	Annex VII	45200	12143

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8350313	5.5MM ROD GRIPPER	February 2011	Rule 6	Annex VII	47870	13517
8350314	SCREW TLIF DISTRACTOR	February 2011	Rule 6	Annex VII	56637	11291
8350315	LAMINAR TLIF DISTRACTOR	February 2011	Rule 6	Annex VII	56637	11291
8350316	SETSCREW BREAKOFF DRIVER	February 2011	Rule 6	Annex VII	33968	13517
8350319	PARELLEL COMPRESSOR	February 2011	Rule 6	Annex VII	15800	13517
8350321	PARALLEL DISTRACTOR	February 2011	Rule 6	Annex VII	56637	11291
8350322	SETSCREW OBTURATOR	February 2011	Rule 6	Annex VII	33968	13517
8350325	MPA SCREWDRIVER	February 2011	Rule 6	Annex VII	33968	13517
8350326	SCREWDRIVER FOR THREADED POST	February 2011	Rule 6	Annex VII	33968	13517
8350327	REDUCTION CRIMP	February 2011	Rule 6	Annex VII	33968	13517
8350328	QUICK THREAD CRIMP DRIVER	February 2011	Rule 6	Annex VII	33968	13517
8350331	REDUCTION COUNTER TORQUE	February 2011	Rule 6	Annex VII	33968	13517
8350338	LEFT INSITU BENDER	February 2011	Rule 6	Annex VII	44798	13517
8350339	RIGHT INSITU BENDER	February 2011	Rule 6	Annex VII	44798	13517
8350374	T25 PROVISIONAL DRIVER	February 2011	Rule 6	Annex VII	32865	13517
8350375	SCREWDRIVER	February 2011	Rule 6	Annex VII	33968	13517
8350380	4.5MM DUAL LEAD TAP	March 2009	Rule 6	Annex VII	17507	17507
8350381	5.5MM DUAL LEAD TAP	March 2009	Rule 6	Annex VII	17507	17507
8350382	6.5MM DUAL LEAD TAP	March 2009	Rule 6	Annex VII	17507	17507
8350383	7.5MM DUAL LEAD TAP	March 2009	Rule 6	Annex VII	17507	17507
8350390	FRENCH BENDER WITH SILICONE HANDLES	February 2011	Rule 6	Annex VII	44795	13180
8350392	SCREW ADJUSTMENT DRIVER	February 2011	Rule 6	Annex VII	32865	13517
8350393	Primary Driver Shaft	February 2011	Rule 6	Annex VII	32865	13517
8350394	Primary Driver Sleeve	June 2009	Rule 6	Annex VII	45200	12143
8350399	3.2mm Hex Bit	February 2011	Rule 6	Annex VII	32390	16868
8350505	MAST Distractor	July 2009	Rule 6	Annex VII	56637	11291
8350517	T25 SWIZZLE STICK	February 2011	Rule 6	Annex VII	32865	13517
8350536	Rigid Extender, 50mm	July 2009	Rule 6	Annex VII	13180	13180
8350537	Rigid Extender, 70mm	July 2009	Rule 6	Annex VII	13180	13180
8350538	Rigid Extender, 90mm	July 2009	Rule 6	Annex VII	13180	13180
8350539	Rigid Extender, 110mm	July 2009	Rule 6	Annex VII	13180	13180
8350540	Rigid Extender, 130mm	July 2009	Rule 6	Annex VII	13180	13180
8350542	COMPRESSOR	July 2009	Rule 6	Annex VII	47870	12143
8350747	CONSTRUCT HOLDER, 5.5mm	November 2009	Rule 6	Annex VII	47870	12143
8350748	LOADING BLOCK	July 2009	Rule 6	Annex VII	47815	12143
836-014	4.5MM DIA. SOLID TAP	February 2003	Rule 6	Annex VII	17507	13517
8360201	5.2MM BOLT CUTTER, OUTER TUBE	March 2006	Rule 6	Annex VII	13180	13180
8360202	5.2MM BOLT CUTTER INNER TUBE	March 2006	Rule 6	Annex VII	13180	13180
8360203	5.2MM FLUSH BOLT CUTTER, OUTER TUBE	February 2011	Rule 6	Annex VII	47831	13180
8360204	5.2MM BOLT CUTTER, OUTER TUBE	February 2011	Rule 6	Annex VII	47831	13180
836-061	3D REDUCTION PLIERS--REFURBISH	September 2002	Rule 6	Annex VII	47870	13180
8361011	3.2MM HEX SCREWDRIVER	May 2004	Rule 6	Annex VII	33968	13517
8361012	7/32" FLUSH BREAK DRIVER	September 2004	Rule 6	Annex VII	33968	13517
8361014	7/32" TO 3.5MM HEX BIT	May 2004	Rule 6	Annex VII	44491	12143
8361029	NITINOL SCREW EXTENDER	April 2003	Rule 6	Annex VII	13180	13180
8361030	7/32" TO 3.0MM HEX BIT	October 2004	Rule 6	Annex VII	44491	12143
8361031	POSITIONER 8361031 WITH HEX	February 2007	Rule 6	Annex VII	32865	13517

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8361032	POSITIONER 8361032 WITH T25 SPLIT	February 2007	Rule 6	Annex VII	13180	13180
8361546	Counter Torque Wrench	May 2001	Rule 6	Annex VII	32871	15766
8361941	QUICK THREAD CRIMP DRIVER	January 2005	Rule 6	Annex VII	33968	13517
8361942	CRIMP REMOVAL TOOL	January 2005	Rule 6	Annex VII	44378	12143
8361953	Reduction Nut Driver - 7.5mm Hex	February 2001	Rule 6	Annex VII	33968	13517
8361954	Threaded Post Screwdriver Shaft	February 2001	Rule 6	Annex VII	32865	13517
8361955	Threaded Post Screwdriver Sleeve	February 2001	Rule 6	Annex VII	45200	12143
8361956	Counter Torque - 3.5mm Hex	February 2001	Rule 6	Annex VII	47554	13180
8361960	Reduction Nut - 7.5mm Hex	February 2001	Rule 6	Annex VII	33968	13517
8361962	QUICK THREAD REDUCTION NUT	May 2004	Rule 6	Annex VII	33968	13517
8361963	PROVISIONAL REDUCTION CRIMP	January 2005	Rule 6	Annex VII	33968	13517
8361971	MPA SLEEVELESS SCREWDRIVER	January 2005	Rule 6	Annex VII	61325	12143
8361972	MPA SLEEVE SCREWDRIVER SHAFT	January 2005	Rule 6	Annex VII	47831	12143
8361973	MPA SLEEVE SCREWDRIVER SLEEVE	January 2005	Rule 6	Annex VII	47831	12143
804-104	OPEN EYEBOLT CLOSER	March 2000	Rule 6	Annex VII	61325	12143
804-109	EYEBOLT HOLDER	March 2000	Rule 6	Annex VII	13180	13180
8361018	TLIF DISTRACT-FOOT SET SCREW	March 2003	Rule 6	Annex VII	61325	12143
8361019	TLIF DISTRACTOR ASSEMBLY	March 2003	Rule 6	Annex VII	47554	13180
8361023	7/32 RETAINING HEX DRIVER	June 2001	Rule 6	Annex VII	61325	12143
8361961	EXTENDED REDUCTION NUT	February 2001	Rule 6	Annex VII	61325	12143
1701194	SCREW/CROSSLINK GAUGE	August 2003	Rule 6	Annex VII	13180	13180
8361005	CYLINDRICAL AWL	March 2003	Rule 6	Annex VII	15275	15275
8361015	COMPRESSOR, STANDARD PARALLEL	March 2003	Rule 6	Annex VII	15800	17993
8361017	DISTRACTOR, STANDARD PARALLEL	March 2003	Rule 6	Annex VII	56637	11291
808-037	HOOK HOLDER WITH ROD MOVER	May 2012	Rule 6	Annex VII	13180	13180
808-041	HOOK INSERTER	March 2000	Rule 6	Annex VII	61325	12143
808-660	STRAIGHT AWL	April 2000	Rule 6	Annex VII	15275	12143
8080210	REDUCED PROFILE T-BOLT REDUCER	August 2004	Rule 6	Annex VII	44804	12143
8350005	AWL	February 2011	Rule 6	Annex VII	15275	13517
8350100	SCREW ADJUSTMENT DRIVER	February 2011	Rule 6	Annex VII	33968	13517
8350110	SCREW EXTENDER, 3.2 HEX, LONG	February 2011	Rule 6	Annex VII	33968	13517
8350111	SCREW EXTENDER, 3.2 HEX, MEDIUM	February 2011	Rule 6	Annex VII	33968	13517
8350112	SCREW EXTENDER, 3.2 HEX, SHORT	February 2011	Rule 6	Annex VII	33968	13517
8350120	NUT DRIVER	June 2005	Rule 6	Annex VII	33968	13517
8350160	COUNTER TORQUE, STANDARD	February 2011	Rule 6	Annex VII	33968	13517
8350276	TSRH SCREW GAUGE	May 2006	Rule 6	Annex VII	13180	13180
8350385	COMPRESSOR	February 2011	Rule 6	Annex VII	15800	10971
8350386	Single Spring Wide Compressor	February 2011	Rule 6	Annex VII	56637	11291
8350387	DISTRACTOR	February 2011	Rule 6	Annex VII	56637	11291
8350395	STANDARD COUNTER TORQUE	February 2011	Rule 6	Annex VII	47554	13180
8880005	CORKSCREW REDUCER	September 2004	Rule 6	Annex VII	44804	12143
8880007	QC T-25 DRIVER	September 2004	Rule 6	Annex VII	33968	13517
8880009	TORQUE LIMITING DRIVER-90IN-LB	September 2004	Rule 6	Annex VII	33968	13517
8880011	PROVISIONAL T25 DRIVER	September 2004	Rule 6	Annex VII	33968	13517
8880016	5.5MM SIDE HOOK PUSHER	October 2004	Rule 6	Annex VII	47554	13180
8880018	SET SCREW STARTER	June 2005	Rule 6	Annex VII	32865	13517
8880019	SET SCREW STARTER WITH STOPS	June 2005	Rule 6	Annex VII	32865	13517

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8880021	AWL	October 2004	Rule 6	Annex VII	15275	12143
8880022	Q/C FIXED EGG HANDLE- BLUE	September 2004	Rule 6	Annex VII	61325	12143
8880027	HOOK HOLDER FORCEPS	June 2005	Rule 6	Annex VII	47807	13180
8880029	ROD INSERTER	June 2005	Rule 6	Annex VII	61325	12143
8880030	SHORT ROD REDUCER, 5.5MM RIGHT	July 2005	Rule 6	Annex VII	44804	12143
8880032	PARALLEL DISTRACTOR	June 2005	Rule 6	Annex VII	56637	11291
8880033	CURVED DISTRACTOR	June 2005	Rule 6	Annex VII	56637	11291
8880035	SCREW POSITIONER	June 2005	Rule 6	Annex VII	13180	13180
8880036	DUAL ENDED FEELER	June 2005	Rule 6	Annex VII	13180	13180
8880039	LONG ROD REDUCER, 5.5MM RIGHT	July 2005	Rule 6	Annex VII	44804	12143
8880040	LONG ROD REDUCER, 5.5MM, LEFT	July 2005	Rule 6	Annex VII	44804	12143
8880041	SL FAS SCREWDRIVER	June 2005	Rule 6	Annex VII	33968	13517
8880042	MAS SCREWDRIVER	June 2005	Rule 6	Annex VII	33968	13517
8880043	SILO MAS COUNTER TORQUE, 5.5MM	June 2005	Rule 6	Annex VII	47554	13180
8880044	FAS/SAS COUNTER TORQUE, 5.5MM	June 2005	Rule 6	Annex VII	47554	13180
8880045	ROD GRIPPER, 5.5MM	June 2005	Rule 6	Annex VII	47807	12143
8880046	MAS HEIGHT ADJUSTER	June 2005	Rule 6	Annex VII	13180	13180
8880047	SHORT PROVISIONAL T25 DRIVER	June 2005	Rule 6	Annex VII	33968	13517
8880048	SL SAS SCREWDRIVER	June 2005	Rule 6	Annex VII	33968	13517
8880049	FEELER PROBE	June 2005	Rule 6	Annex VII	13180	13180
8880051	HOOK TRIAL, PEDICLE	June 2005	Rule 6	Annex VII	61325	12143
8880053	HOOK TRIAL, LAMINAR, LARGE	October 2004	Rule 6	Annex VII	61325	12143
8880054	HOOK TRIAL, LAMINAR, LARGE	August 2005	Rule 6	Annex VII	61325	12143
8880064	EXTRA LONG PROV T25 DRIVER	October 2004	Rule 6	Annex VII	33968	13517
8880065	MEDIAL CORKSCREW	September 2005	Rule 6	Annex VII	61325	12143
8880070	CURVED ROD REDUCER,5.5MM RIGHT	July 2005	Rule 6	Annex VII	44804	12143
8880072	FRENCH ROD BENDER	July 2005	Rule 6	Annex VII	44795	12143
8880100	MANIPULATOR STICK	June 2005	Rule 6	Annex VII	32865	13517
8889082	CANNULATED QC RATCHET HANDLE	November 2004	Rule 6	Annex VII	61325	12143
X0300018	T-HANDLE TAP	July 2008	Rule 6	Annex VII	17507	17507
7221000	6.35 DISTRACTOR	May 2005	Rule 6	Annex VII	47554	13180
7221001	6.35 MECHANICAL COMPRESSOR	May 2005	Rule 6	Annex VII	47554	13180
7221002	6.35 COUNTER TORQUE	May 2005	Rule 6	Annex VII	33968	16868
7221005	ATTACHMENT DRIVER - PR	June 2006	Rule 6	Annex VII	33968	16868
7221006	ARTICULATING PEEK ROD HOLDER	August 2005	Rule 6	Annex VII	13180	17993
7221007	SHORT SCREWDRIVER FOR MAS	June 2006	Rule 6	Annex VII	33968	16868
4123CV06	ENLARGED TIP SQUARE AWL	March 2000	Rule 6	Annex VII	61324	12143
X0205087	8HX10WX24L OVOID MESH TRIAL	March 2005	Rule 6	Annex VII	44759	12143
X0205088	10HX10WX24L OVOID MESH TRIAL	March 2005	Rule 6	Annex VII	44759	12143
X0205089	12HX10WX24L OVOID MESH TRIAL	March 2005	Rule 6	Annex VII	44759	12143
X0205090	14HX10WX24L OVOID MESH TRIAL	March 2005	Rule 6	Annex VII	44759	12143
848-961	RASP	April 2010	Rule 6	Annex VII	35559	12143
General Instruments						
X0409031	Coplanar Tube M9	March 2012	Rule 6	Annex VII	13180	13180
X0409032	Coplanar Tube M10	March 2012	Rule 6	Annex VII	13180	13180
X0409033	Coplanar Kyphosing Tube M9	March 2012	Rule 6	Annex VII	13180	13180
X0409034	Coplanar Kyphosing Tube M10	March 2012	Rule 6	Annex VII	13180	13180

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X0409035	Reduction Rod 400mm	March 2012	Rule 6	Annex VII	13180	13180
X0409036	Reduction Rod 300mm	March 2012	Rule 6	Annex VII	13180	13180
X0409043	Rod Pusher	March 2012	Rule 6	Annex VII	47554	13180
X0409182	Coronal Plane Bender 5.5 - 130° - Left	September 2010	Rule 6	Annex VII	13180	13180
X0409183	Coronal Plane Bender 5.5 - 130° - RIGHT	September 2010	Rule 6	Annex VII	13180	13180
0308CN70	14MM LENGTHENED REAMER	March 2000	Rule 6	Annex VII	45111	12143
0308CR54	CLAMP PLIERS	March 2001	Rule 6	Annex VII	47870	12143
0443CH66	12/7 LONG DISTRACTOR	March 2000	Rule 6	Annex VII	56637	11291
0443CH69	DIA 12MM LENGTHENED REAMER	March 2000	Rule 6	Annex VII	45111	12143
0443CH71	LNGTHND OF 60 IMPLANT HOLDER	March 2000	Rule 6	Annex VII	13180	13180
5480114V	DRIVER TWISTED T-25	February 2008	Rule 6	Annex VII	13180	13180
5480131V	PROVISIONAL DRVR 6.35 HEX	February 2008	Rule 6	Annex VII	13180	13180
5480140V	ADJUSTABLE DRIVER	February 2008	Rule 6	Annex VII	13180	13180
7480114	TAPERED HEX SCREWDRIVER	August 2003	Rule 6	Annex VII	33968	16868
7480122	SET SCREW STARTER	August 2003	Rule 6	Annex VII	13180	13117
7480130	DRIVER, PROVISIONAL	April 2003	Rule 6	Annex VII	33968	16868
7480144	DRIVER, BREAK-OFF, 6.35MM HEX	August 2003	Rule 6	Annex VII	33968	16868
7480150	CLOSED COUNTER-TORQUE	April 2003	Rule 6	Annex VII	47554	13180
7480154	T27 WITH OBTURATOR	August 2003	Rule 6	Annex VII	13180	17993
7480156R	T27 NON BRKFF PLG STARTER, LNG	September 2005	Rule 6	Annex VII	33968	13517
7480162	FRENCH BENDER W/ SILICONE HDLS	August 2003	Rule 6	Annex VII	44795	12143
7480163	PARALLEL CMPRSR, SM, MOD TIP	December 2005	Rule 6	Annex VII	15800	12143
7480164	PARALLEL CMPRSR, SM, MOD TIPS	December 2005	Rule 6	Annex VII	15800	12143
7480165	PARALLEL COMPRESSOR, SMALL	September 2003	Rule 6	Annex VII	15800	17993
7480166	PARALLEL COMPRESSOR, LARGE	September 2003	Rule 6	Annex VII	15800	12143
7480167	PARALLEL COMPRSR, LG, MOD TIPS	December 2005	Rule 6	Annex VII	15800	12143
7480168	PARALLEL COMPRSR, LG, MOD TIP	December 2005	Rule 6	Annex VII	15800	12143
7480170	PARALLEL DISTRACTOR	August 2003	Rule 6	Annex VII	44378	11291
7480171	DISTRACTOR	September 2003	Rule 6	Annex VII	56637	11291
7480190	T20 TORQUE LIMITING DRIVER, 7.3NM	April 2009	Rule 6	Annex VII	47554	13180
7480391	DEROTATOR IMPLANT HOLDER, 5.5	April 2006	Rule 6	Annex VII	47807	12143
7480392	DEROTATOR BRIDGE - S	April 2006	Rule 6	Annex VII	61325	12143
7480393	DEROTATOR BRIDGE - M	April 2006	Rule 6	Annex VII	61325	12143
7480394	DEROTATOR BRIDGE - L	April 2006	Rule 6	Annex VII	61325	12143
7480395	DEROTATOR INTERLINK	April 2006	Rule 6	Annex VII	47807	12143
7480396	DEROTATOR BRIDGE HANDLE	April 2006	Rule 6	Annex VII	47829	12143
7480397	DEROTATOR INLINE HANDLE	April 2006	Rule 6	Annex VII	47829	12143
7480398	DEROTATOR BRIDGE NUT	April 2006	Rule 6	Annex VII	61325	12143
7480511	POSTERIOR BODY RESECTOR, 15MM	September 2007	Rule 6	Annex VII	13180	13180
7480512	POSTERIOR BODY RESECTOR, 20MM	September 2007	Rule 6	Annex VII	13180	13180
7480513	POSTERIOR BODY RESECTOR, 20MM WIDE	September 2007	Rule 6	Annex VII	13180	13180
7480514	POSTERIOR BODY RESECTOR, 25MM	September 2007	Rule 6	Annex VII	13180	13180
7480515	POSTERIOR BODY RESECTOR, 34MM	September 2007	Rule 6	Annex VII	13180	13180
7480540	12MM FLAT NERVE ROOT RETRACTOR	September 2007	Rule 6	Annex VII	45182	12143
7480543	15MM ANGLED NERVE ROOT RETRACTOR	September 2007	Rule 6	Annex VII	45182	12143
7480551	15MM PSO ELEVATOR	September 2007	Rule 6	Annex VII	35048	12143
7480552	20MM PSO ELEVATOR	September 2007	Rule 6	Annex VII	35048	12143

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7480553	30MM PSO ELEVATOR	September 2007	Rule 6	Annex VII	35048	12143
7480600	SMALL BODY REAMER	September 2007	Rule 6	Annex VII	45111	12143
7480601	LARGE BODY REAMER	September 2007	Rule 6	Annex VII	45111	12143
7480660	OSTEOTOME CORNER 7X7 mm	December 2012	Rule 6	Annex VII	12844	12845
7480661	OSTEOTOME FOOTED 12.5 mm	December 2012	Rule 6	Annex VII	12844	12845
7480662	OSTEOTOME FOOTED 17.5 mm	December 2012	Rule 6	Annex VII	12844	12845
7480663	OSTEOTOME GUILLOTINE 7.5 mm	December 2012	Rule 6	Annex VII	12844	12845
7480664	OSTEOTOME TILE SHARP 10 mm	December 2012	Rule 6	Annex VII	12844	12845
7480665	DILATOR INITIAL	December 2012	Rule 6	Annex VII	13180	13180
7480666	DILATOR 7X6 mm	December 2012	Rule 6	Annex VII	13180	13180
7480667	DILATOR 9X8 mm	December 2012	Rule 6	Annex VII	13180	13180
7480668	VERTEBRAL BODY PROBE	December 2012	Rule 6	Annex VII	13180	13180
7480669	VERTEBRAL BODY SCRAPER	December 2012	Rule 6	Annex VII	13180	13180
7480670	CURETTE ANGLED INTERNAL	December 2012	Rule 6	Annex VII	31335	11084
7480671	CURETTE ANGLED EXTERNAL	December 2012	Rule 6	Annex VII	31335	11084
7480672	POSTERIOR BODY IMPACTOR 20MM	December 2012	Rule 6	Annex VII	13180	13180
7480680	REDUCTION PLIER	December 2012	Rule 6	Annex VII	13180	13180
7480681	ADAPTOR POST 5.2	December 2012	Rule 6	Annex VII	13180	13180
7480682	ADAPTOR 5.5/6.0	December 2012	Rule 6	Annex VII	13180	13180
7480683	ADAPTOR SACRAL CONNECTOR	December 2012	Rule 6	Annex VII	13180	13180
7480684	BRIDGING LINK	December 2012	Rule 6	Annex VII	13180	13180
7480685	DOVE TAIL NUT	December 2012	Rule 6	Annex VII	13180	13180
7480686	INSERTER	December 2012	Rule 6	Annex VII	13180	13180
7480687	DRIVER HEX 9	December 2012	Rule 6	Annex VII	33968	16868
7480688	DRIVER HEX 3.5	December 2012	Rule 6	Annex VII	33968	16868
7480885	8.5MM TAP	February 2004	Rule 6	Annex VII	17507	12143
7480911	ILIAC COUNTER-TORQUE	March 2004	Rule 6	Annex VII	47554	13180
7480930	CLOSED MAS SCREWDRIVER	June 2005	Rule 6	Annex VII	33968	13517
7480931	CLSD MAS DRIVER SELF-RETAINING	April 2005	Rule 6	Annex VII	33968	13517
7484150	COUNTERTORQUE, L4.5	November 2004	Rule 6	Annex VII	47554	13180
7484154	T25 WITH OBTURATOR	November 2004	Rule 6	Annex VII	61325	12143
7484163	PRLLEL CMPSRSR, SM, SINGLE MOD TIP, L4.5	March 2006	Rule 6	Annex VII	47870	12143
7484164	PARALLEL CMPSRSR, SM, MOD TIPS, L4.5	March 2006	Rule 6	Annex VII	47870	12143
7484165	PARALLEL COMPRESSOR, SMALL, L4.5	March 2006	Rule 6	Annex VII	47870	12143
7484166	PARALLEL COMPRESSOR, LARGE, L4.5	March 2006	Rule 6	Annex VII	47870	12143
7484167	PARALLEL COMPSRSR, LG, MOD TIPS, L4.5	March 2006	Rule 6	Annex VII	47870	12143
7484168	PRLLEL CMPSRSR, LG, SINGLE MOD TIP, L4.5	March 2006	Rule 6	Annex VII	47870	12143
7484170	PARALLEL DISTRACOR, L4.5	March 2006	Rule 6	Annex VII	47870	12143
7570090	REMOVABLE BREAK OFF HANDLE	June 2005	Rule 6	Annex VII	61325	12143
7570095	SET SCREW RETAINING COMPRESSOR	June 2005	Rule 6	Annex VII	15800	12143
7575306	NEEDLE GUIDE	June 2005	Rule 6	Annex VII	58183	12143
7575307	RADIOLUCENT CLAMP	June 2005	Rule 6	Annex VII	47807	12143
7575312	ROD TEMPLATE POINTER	June 2005	Rule 6	Annex VII	46479	12143
7576309	REDUCTION NUT DRIVER	March 2007	Rule 6	Annex VII	33968	13517
7578001	DEPTH GAUGE SLIDER	November 2007	Rule 6	Annex VII	61325	12143
7578010	SLIDE	December 2007	Rule 6	Annex VII	13180	13180
7578011	THREADED HANDLE	December 2007	Rule 6	Annex VII	13180	13180

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7578200	ROD VERIFIER	October 2007	Rule 6	Annex VII	13180	13180
7579000	QC RATCHETING T-HANDLE	June 2005	Rule 6	Annex VII	13180	13180
7650090	SET SCREW RETAINING DRIVER	July 2004	Rule 6	Annex VII	33968	13517
7650091	SET SCREW RETAINING DRIVER	April 2007	Rule 6	Annex VII	33968	13517
803-100	FENESTRATED BONE SCREWDRIVER	August 2002	Rule 6	Annex VII	33968	13517
803-501	TAP BONE SCREW 6.5MM CANN	November 2004	Rule 6	Annex VII	61325	12143
803-808	RATCHETING HANDLE	August 2002	Rule 6	Annex VII	13180	13180
803-809	RATCHET, T-HANDLE DRIVER	March 2003	Rule 6	Annex VII	33968	13517
803-900	HEX HEAD SCREWDRIVER 3900-10	August 2002	Rule 6	Annex VII	33968	13517
804-014	1/2" HEX SOCKET, L=6"	March 2000	Rule 6	Annex VII	33968	13517
804-016	3/8" TAPERED BOX END CROWFOOT	April 2003	Rule 6	Annex VII	61325	12143
804-018	T-HANDLE HEX DRIVER 1/2	March 2000	Rule 6	Annex VII	32865	13517
807-050	MAS HEXDRIVER	August 2002	Rule 6	Annex VII	33968	13517
807-913	STRAIGHT GRAFT IMPACTOR	September 2002	Rule 6	Annex VII	32856	12143
807-923	ANGLED OSTEOTOME	July 2001	Rule 6	Annex VII	12844	12845
807-925	STRAIGHT SERRATED CUP CURETTE	July 2001	Rule 6	Annex VII	31335	12143
807-926	LEFT ANG SERRATED CUP CURETTE	July 2001	Rule 6	Annex VII	31335	12143
807-927	RIGHT ANG SERRATED CUP CURETTE	June 2001	Rule 6	Annex VII	31335	12143
807-932	LARGE ANGLED RING CURETTE	July 2001	Rule 6	Annex VII	31335	12143
808-500	HOOK SPREADER (DISTRATOR)	April 2003	Rule 6	Annex VII	56637	11291
808-501	CURVED HK DISTRATOR RATCHETED	March 2000	Rule 6	Annex VII	56637	11291
808-502	HOOK COMPRESSOR	December 2002	Rule 6	Annex VII	15800	12143
808-503	MULTI LEVEL HOOK COMPRESSOR	September 2002	Rule 6	Annex VII	15800	12143
808-521	TSRH ROD PUSHER	November 2002	Rule 6	Annex VII	47554	13180
808-524	ROD HOLDER	December 2002	Rule 6	Annex VII	13180	13180
808-529	TABLE TOP ROD CUTTER, RMV HNDL	January 2002	Rule 6	Annex VII	13180	13180
808-530	TSRH FRENCH ROD BENDER	February 2001	Rule 6	Annex VII	44795	12143
808-539	3/8" BOX END WRENCH, TAPERED	March 2000	Rule 6	Annex VII	32871	15766
808-541	SOCKET DRIVER 7/32"	March 2003	Rule 6	Annex VII	33968	13517
808-543	OFFSET MINICORK SCREW	January 2001	Rule 6	Annex VII	61325	12143
808-545	T-BOLT POS W/LOCK SCR INS, ASM	June 2002	Rule 6	Annex VII	61325	12143
808-546	COUNTER TORQUE WRENCH	July 2003	Rule 6	Annex VII	32871	15766
808-553	OPEN END WRENCH, ANGLED	March 2000	Rule 6	Annex VII	32871	15766
808-555	DANEK POWER GRIP WITH RELEASE	August 2005	Rule 6	Annex VII	38622	12143
808-561	ANGLED BACKUP WRENCH	March 2000	Rule 6	Annex VII	32871	15766
808-587	3/16" HEX ROD ROTATION WRENCH	October 2002	Rule 6	Annex VII	32871	15766
8110510	HOLDER, FORCEPS STYLE	March 2003	Rule 6	Annex VII	13180	13180
8110511	INLINE X10 CROSSLINK HOLDER	April 2003	Rule 6	Annex VII	13180	13180
8110525	BENDING IRON	March 2003	Rule 6	Annex VII	44795	12143
8110530	3.0MM HEX DRIVER	March 2003	Rule 6	Annex VII	33968	13517
8110540	COUNTERTORQUE	April 2003	Rule 6	Annex VII	47554	13180
8114510	HOLDER, L4.5, FORCEPS STYLE	April 2006	Rule 6	Annex VII	13180	13180
8114511	CROSSLINK PLATE HOLDER, L4.5	April 2006	Rule 6	Annex VII	61325	12143
8114526	BENDING IRON (4.5MM)	April 2006	Rule 6	Annex VII	44975	15884
8114530	2.5MM HEX DRIVER	April 2006	Rule 6	Annex VII	33968	13517
8114539	COUNTERTORQUE	April 2006	Rule 6	Annex VII	47554	13180
8114545	IMPLANT POSITIONER, L4.5	April 2006	Rule 6	Annex VII	13180	13180

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815-500	OFFSET HOOK HOLDER/ROCKER	February 2001	Rule 6	Annex VII	13180	13180
815-502	ROD APPROX	October 2001	Rule 6	Annex VII	13180	13180
815-507	THREADED AWL	August 2002	Rule 6	Annex VII	15275	12143
815-515	MULTI-PURPOSE HANDLE	March 2000	Rule 6	Annex VII	47829	12143
815-516	SQR DRIVE TAPERED HEX DRVR 5MM	April 1998	Rule 6	Annex VII	33968	16868
815-517	SQUARE DRIVE T-20 DRIVER	August 2005	Rule 6	Annex VII	33968	13517
815-518	SQUARE DRIVE T-25 DRIVER	January 2002	Rule 6	Annex VII	33968	13517
815-519	SQUARE DRIVE TORX 30 DRIVER	October 2008	Rule 6	Annex VII	33968	13517
815-520	SQUARE DRIVE 3.5MM DRIVER	October 2008	Rule 6	Annex VII	33968	13517
815-905	DORSAL GRIP ROD HOLDER 5.5MM	August 2002	Rule 6	Annex VII	47807	12143
820-512	3/16" IN SITU BENDER, STRAIGHT	October 2008	Rule 6	Annex VII	44795	12143
820-555	3/16" ROD / PLATE HOLDER	July 2002	Rule 6	Annex VII	13180	13180
8230907	PLATE/ROD BENDER	July 2008	Rule 6	Annex VII	61325	12143
8230909	5 X 10MM PEDICLE MARKER	February 2003	Rule 6	Annex VII	58183	12143
8230914	BONE BOLT HEX DRIVER, SHORT	July 2008	Rule 6	Annex VII	33968	13517
8230920	5.5 TAP SHORT	November 2002	Rule 6	Annex VII	17507	13517
8230924	6.5 TAP SHORT	November 2002	Rule 6	Annex VII	17507	13517
8230928	7.5 TAP SHORT	November 2002	Rule 6	Annex VII	17507	13517
8230932	DISTRACTOR, RACK	July 2008	Rule 6	Annex VII	13180	13180
8230954	WASHER HOLDER	July 2008	Rule 6	Annex VII	13180	13180
8230964	7.5MM NUT DRIVER	July 2008	Rule 6	Annex VII	33968	13517
8230966	POST BREAK OFF WRENCH	May 2000	Rule 6	Annex VII	61325	12143
8230970	POST BREAK-OFF SLEEVE	July 2008	Rule 6	Annex VII	47831	12143
8231330	5.5MM CANNULATED TAP	September 2002	Rule 6	Annex VII	17507	13517
8231331	6.5MM TAP	September 2002	Rule 6	Annex VII	17507	13517
8231333	7.5MM TAP	September 2002	Rule 6	Annex VII	17507	13517
8231926	7.0MM TAP-SHORT	November 2002	Rule 6	Annex VII	17507	13517
823-527	T-HANDLE NUT STARTER SHAFT	October 2002	Rule 6	Annex VII	61325	12143
823-529	T-HANDLE NUT STARTER SOCKET	April 2001	Rule 6	Annex VII	61325	12143
830-150	DRILL GUIDE LEFT	October 2000	Rule 6	Annex VII	47807	12143
830-155	DRILL GUIDE RIGHT	October 2000	Rule 6	Annex VII	47807	12143
830-160	IN SITU BENDER	October 2008	Rule 6	Annex VII	44795	12143
8350291	AWL	February 2011	Rule 6	Annex VII	15275	13517
8350292	STRAIGHT PROBE	February 2011	Rule 6	Annex VII	13180	13180
8350298	4.5MM TAP	February 2011	Rule 6	Annex VII	17507	13517
8350299	5.5MM TAP	February 2011	Rule 6	Annex VII	17507	13517
8350300	6.5MM TAP	February 2011	Rule 6	Annex VII	17507	13517
8350301	7.5MM TAP	February 2011	Rule 6	Annex VII	17507	13517
8350302	DUAL FEELER	February 2011	Rule 6	Annex VII	13180	13180
8350303	STRAIGHT FEELER	February 2011	Rule 6	Annex VII	13180	13180
8350304	PRIMARY SCREWDRIVER	February 2011	Rule 6	Annex VII	33968	13517
8350305	SCREW ADJUSTMENT DRIVER	February 2011	Rule 6	Annex VII	33968	13517
8350311	FRENCH BENDER WITH SILICONE HANDLES	February 2011	Rule 6	Annex VII	44798	13517
8350312	ROD INTRODUCER	February 2011	Rule 6	Annex VII	47870	13517
836-011	Q/C RATCHET SCREWDRIVER HANDLE	December 2001	Rule 6	Annex VII	33968	12143
836-015	5.5MM TAP	April 1998	Rule 6	Annex VII	17507	17507
836-016	6.5MM TAP	April 1998	Rule 6	Annex VII	17507	17507

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836-018	7.5MM TAP	April 1998	Rule 6	Annex VII	17507	17507
836-021	ROD PUSHER	February 2004	Rule 6	Annex VII	47554	13180
836-022	AWL STAPLE DRIVER	February 2004	Rule 6	Annex VII	33968	12143
836-023	7/32" HEX DRIVER	February 2004	Rule 6	Annex VII	33968	12143
836-030	5.2MM POST CUTTER	February 2004	Rule 6	Annex VII	13180	13180
836-061	REDUCTION PLIERS	March 2001	Rule 6	Annex VII	47870	13180
836-062	REDUCTION PLIERS LOCK SCREW	March 2001	Rule 6	Annex VII	61325	12143
836-063	REDUCTION PLIERS MANIPULATOR	March 2001	Rule 6	Annex VII	61325	12143
8360908	PEDICLE MARKER, SPHERE	June 2001	Rule 6	Annex VII	13180	13180
8360909	PEDICLE MARKER, CYLINDER	June 2001	Rule 6	Annex VII	13180	13180
8360911	PEDICLE MARKER, CONICAL W/ HEX, SHORT	January 2007	Rule 6	Annex VII	13180	13180
8360912	PEDICLE MARKER, CONICAL W/ CYL, SHORT	January 2007	Rule 6	Annex VII	13180	13180
8361007	COMPASS ROD HOLDER	June 2003	Rule 6	Annex VII	13180	13180
8361020R	5.5 ROD HOLDER REWORKED	February 2003	Rule 6	Annex VII	13180	13180
8361021	6.35 ROD HOLDER	February 2003	Rule 6	Annex VII	13180	13180
8361021R	6.35 ROD HOLDER REWORKED	February 2003	Rule 6	Annex VII	13180	13180
8361024	COUNTER TORQUE	February 2003	Rule 6	Annex VII	47554	13180
8361025	3.2MM HEX QUICK CONNECT DRIVER	May 2002	Rule 6	Annex VII	33968	13517
8361026	3.2MM QUICK CONNECT SLEEVE	May 2002	Rule 6	Annex VII	33968	13517
8367645	4.5MM BONE SCREW EXTRACTOR	July 2004	Rule 6	Annex VII	32865	13517
8367650	5.0MM BONE SCREW EXTRACTOR	July 2004	Rule 6	Annex VII	32865	13517
8367655	5.5MM BONE SCREW EXTRACTOR	July 2004	Rule 6	Annex VII	32865	13517
8367660	6.0MM BONE SCREW EXTRACTOR	July 2004	Rule 6	Annex VII	32865	13517
8367665	6.5MM BONE SCREW EXTRACTOR	July 2004	Rule 6	Annex VII	32865	13517
8367670	7.0MM BONE SCREW EXTRACTOR	July 2004	Rule 6	Annex VII	32865	13517
8367675	7.5MM BONE SCREW EXTRACTOR	July 2004	Rule 6	Annex VII	32865	13517
8367680	8.0MM BONE SCREW EXTRACTOR	July 2004	Rule 6	Annex VII	32865	13517
8367745	4.5MM BONE SCREW TREPHINE	July 2004	Rule 6	Annex VII	61325	12143
8367750	5.0MM BONE SCREW TREPHINE	July 2004	Rule 6	Annex VII	61325	12143
8367755	5.5MM BONE SCREW TREPHINE	July 2004	Rule 6	Annex VII	61325	12143
8367760	6.0MM BONE SCREW TREPHINE	July 2004	Rule 6	Annex VII	61325	12143
8367765	6.5MM BONE SCREW TREPHINE	July 2004	Rule 6	Annex VII	61325	12143
8367770	7.0MM BONE SCREW TREPHINE	July 2004	Rule 6	Annex VII	61325	12143
8367775	7.5MM BONE SCREW TREPHINE	July 2004	Rule 6	Annex VII	61325	12143
8367780	8.0MM BONE SCREW TREPHINE	July 2004	Rule 6	Annex VII	61325	12143
836-900	3.5MM HEX HEAD SCREWDRIVER	February 2004	Rule 6	Annex VII	33968	12143
8369040K	FLUSH POST CUTTER KIT	February 2004	Rule 6	Annex VII	13180	13180
8369041	MODULAR CUTTER OPEN WRENCH	October 2002	Rule 6	Annex VII	32871	12143
8369042	MODULAR CUTTER CLOSED WRENCH	October 2002	Rule 6	Annex VII	32871	12143
8369043	MODULAR CUTTER OBTURATOR	October 2002	Rule 6	Annex VII	13180	13180
8369045	5.2MM FLUSH BOLT CUTTER	November 2004	Rule 6	Annex VII	13180	13180
8369046	5.2MM CUTTER OUTER TUBE ASSM	November 2004	Rule 6	Annex VII	13180	13180
8369048	5.2MM CUTTER INNER TUBE ASSM	November 2004	Rule 6	Annex VII	13180	13180
836-991	RING DISTRATOR RIGHT	October 2002	Rule 6	Annex VII	61325	12143
8451188	POSITIONING CLIP, 5.5MM ROD	September 2002	Rule 6	Annex VII	45200	12143
845-520	5.5MM IN-SITU BENDER	June 2006	Rule 6	Annex VII	44795	12143
84601	RIGHT HOOK HOLDER	October 2000	Rule 6	Annex VII	47807	13180

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P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
84603	ROD HOLDER	July 2008	Rule 6	Annex VII	13180	13180
84607	ROD INTRODUTOR	October 2000	Rule 6	Annex VII	61324	12143
84614	ROD PUSHER	October 2000	Rule 6	Annex VII	47554	13180
84621	TRANSVERSE HOOK	August 2003	Rule 6	Annex VII	61325	12143
84626	PEDICLE HOOK	June 2005	Rule 6	Annex VII	61325	12143
84630/1	STRAIGHT ROD BENDER	October 2000	Rule 6	Annex VII	61324	12143
84630/2	CURVED ROD BENDER	October 2000	Rule 6	Annex VII	61324	12143
84631	LAMINAR ELEVATOR	May 2003	Rule 6	Annex VII	35048	12143
84636/J	SACRAL SCREWDRIVER	December 2000	Rule 6	Annex VII	61325	12143
84642	ROTATOR	July 2008	Rule 6	Annex VII	61325	12143
84658	DRILL FOR ILIO-SACRAL SCREW	October 2000	Rule 6	Annex VII	61325	12143
84659	CANNULAT SCREWDRIVER	October 2000	Rule 6	Annex VII	61325	12143
84664	4MM SQUARE AWL FOR DIA 6MM SCR	October 2000	Rule 6	Annex VII	15275	12143
84675H	FLAT HANDLE FOR SCREWDRIVER	September 2002	Rule 6	Annex VII	61325	12143
84676H	ILIO SACRAL CONNECTOR GUIDE	September 2008	Rule 6	Annex VII	61325	12143
84677H	5.5MM CAPTIVE HOOK PUSHER	June 2005	Rule 6	Annex VII	13180	13180
84679	CD UNIVERSAL WRENCH	October 2000	Rule 6	Annex VII	32871	12143
84681H	HOOK PUSHER ASSEMBLY	February 2003	Rule 6	Annex VII	13180	13180
84682E	PLUG INTRODUCER RIGHT GUIDE	November 2004	Rule 6	Annex VII	47807	12143
84683E	CORKSCREW (ROD INTRODUCER)	April 2005	Rule 6	Annex VII	61325	12143
84687E	PROVISIONAL PLUG DRIVER	April 2002	Rule 6	Annex VII	61325	12143
84689E	LATERAL IMPLANT HOLDER	June 2005	Rule 6	Annex VII	13180	13180
84692E	PLUG/DTT STARTER	July 2001	Rule 6	Annex VII	32865	12143
84693E	PLUG SET SCREW STARTER	July 2001	Rule 6	Annex VII	32865	12143
84694H	IMPLANT HOLDER / SCREWDRIVER	February 2001	Rule 6	Annex VII	13180	13180
84696H	COUNTER TORQUE	March 2006	Rule 6	Annex VII	47554	13180
84697H	TRANSLATOR PLUG INTRODUCER	August 2002	Rule 6	Annex VII	47870	12143
84699LH	LEFT IN-SITU BENDER	October 2002	Rule 6	Annex VII	61325	12143
84699RH	RIGHT IN-SITU BENDER	October 2002	Rule 6	Annex VII	61325	12143
84777H	CAPTIVE HOOK PUSHER FOR 6.35	September 2008	Rule 6	Annex VII	13180	13180
84782H	PLUG INTRODUCER FOR 6.35 ROD	September 2008	Rule 6	Annex VII	61325	12143
84799LH	LEFT IN-SITU BENDER	July 2000	Rule 6	Annex VII	44795	12143
84799RH	RIGHT IN-SITU BENDER	July 2000	Rule 6	Annex VII	44795	12143
8480908	CANN. AWL W/ STAPLE INTERFACE	July 2003	Rule 6	Annex VII	15275	12143
848-908	5.5MM TAP	March 2001	Rule 6	Annex VII	17507	13517
848-910	6.5MM TAP	March 2001	Rule 6	Annex VII	17507	13517
848-912	7.5MM TAP	March 2001	Rule 6	Annex VII	17507	13517
848-920	IN-SITU ROD BENDER	March 2001	Rule 6	Annex VII	44795	12143
848-922	Bone Graft Tamp, 5x13mm	June 2001	Rule 6	Annex VII	47872	12143
848-923	Bone Graft Funnel, 5x13mm	June 2001	Rule 6	Annex VII	47872	12143
848-925	RIGID SCREWDRIVER	August 2012	Rule 6	Annex VII	33968	13517
848-926	SPLIT T25 DRIVER	March 2001	Rule 6	Annex VII	33968	13517
848-927	SOLID T25 DRIVER	March 2001	Rule 6	Annex VII	33968	13517
848-928	PLUG CAPTURING T25 DRIVER	March 2001	Rule 6	Annex VII	33968	13517
848-930	PLUG INTRODUCTION TUBE	March 2001	Rule 6	Annex VII	32579	10561
848-950	COMPRESSOR	June 2004	Rule 6	Annex VII	15800	12143
853-620	BONE CUTTER	November 2006	Rule 6	Annex VII	44788	17704

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85601	STRAIGHT IMPLANT	October 2000	Rule 6	Annex VII	61325	12143
85603	ROD GRIPPER	October 2000	Rule 6	Annex VII	61325	12143
85621	TRANSVERSE	October 2000	Rule 6	Annex VII	61325	12143
85626	TITAN 6-4ELI .5625 RD +/- .002	October 2000	Rule 6	Annex VII	61325	12143
85630/2	CURVED ROD BENDER	March 2000	Rule 6	Annex VII	61324	12143
85631	REDUCED LAMINAR	October 2000	Rule 6	Annex VII	61325	12143
8570957	REDUCER FOR 4.5MM ROD	January 2003	Rule 6	Annex VII	44804	12143
8572102	SOUDING/FEELER PROBE, 2MM	September 2002	Rule 6	Annex VII	13180	13180
8691009	Angled Awl, Quick Connect	April 2001	Rule 6	Annex VII	15275	12143
890-521	3.5MM 3/32 HEX DRIVER	June 2004	Rule 6	Annex VII	33968	13517
897-400	RETRACTOR BLADE 18MM X 120MM	July 2003	Rule 6	Annex VII	45182	12143
897-401	RET BLADE 28MM X 120MM RIGHT	July 2003	Rule 6	Annex VII	45182	12143
897-402	RET BALDE 28MM X 120MM LEFT	July 2003	Rule 6	Annex VII	45182	12143
897-403	RETRACTOR BLADE PUSHER	July 2003	Rule 6	Annex VII	13180	13180
897-404	STABILITY PIN DRIVER	July 2003	Rule 6	Annex VII	33968	13517
897-405	STABILITY PIN 170MM RET BLADE	July 2003	Rule 6	Annex VII	45182	12143
897-406	STABILITY PIN 120MM RET BLADE	March 2002	Rule 6	Annex VII	45182	12143
897-410	RETRACTOR BLADE 18MM X 170MM	February 2003	Rule 6	Annex VII	45182	12143
897-411	RET BLADE 28MM X 170MM RIGHT	February 2003	Rule 6	Annex VII	45182	12143
897-412	RET BLADE 28MM X 170MM LEFT	February 2003	Rule 6	Annex VII	45182	12143
897-421	ER FRAME/BLADE CONNECTOR	August 2003	Rule 6	Annex VII	61325	12143
897-423	TIGHTENING WRENCH	August 2003	Rule 6	Annex VII	32871	15766
897-424	ENDO RING HANDLE	August 2003	Rule 6	Annex VII	13180	13180
897-432	FRAME S 150MM X 150MM	December 2004	Rule 6	Annex VII	45200	12143
897-441	RATCHET ADAPTER	July 2003	Rule 6	Annex VII	36292	12143
897-442	9.5 ADAPTER	July 2003	Rule 6	Annex VII	36292	12143
897-443	6.35 ADAPTER	July 2003	Rule 6	Annex VII	36292	12143
897-452	FRAME M 150MM X 200MM	December 2004	Rule 6	Annex VII	45200	12143
89761	SCREW HOLDER	November 2000	Rule 6	Annex VII	13180	13180
9010000814	EXTENDED TAB SCREWDRIVER	September 2011	Rule 6	Annex VII	32865	13517
9198270	STRAIGHT REAMER	February 2004	Rule 6	Annex VII	45111	12143
922501L	SQUARE AWL, LONG	December 2004	Rule 6	Annex VII	15275	12143
922502S	STRAIGHT SPATULA	April 2001	Rule 6	Annex VII	39610	12143
9225030	CURETTE	April 2001	Rule 6	Annex VII	31335	12143
9293008	BONE INSERTER	June 2006	Rule 6	Annex VII	61325	12143
9296090	ANTERIOR PUSHER, SINGLE TOOTH	November 2007	Rule 6	Annex VII	47554	13180
9297009	TRIAL HANDLE	May 2008	Rule 6	Annex VII	13180	13180
94632	COMPRESSION PLIERS 2 POSTITION	December 2002	Rule 6	Annex VII	47870	12143
94633	CURVED SPREADER W/30 DEG AXIS	August 2001	Rule 6	Annex VII	15800	12143
9870009	TACK 9870009 TEMPORARY PLATE	April 2007	Rule 6	Annex VII	61325	12143
9960310	6.35MM BOLT CUTTER ASSEMBLY	June 2004	Rule 6	Annex VII	13180	13180
9960311	6.35MM CUTTER OUTER TUBE ASSM	June 2004	Rule 6	Annex VII	13180	13180
9960313	6.35MM CUTTER INNER TUBE ASSM	June 2004	Rule 6	Annex VII	13180	13180
9960335	6.35MM MAS HEAD POSITIONER	March 2005	Rule 6	Annex VII	47807	12143
9960355	5.5MM MAS HEAD POSITIONER	May 2006	Rule 6	Annex VII	47807	12143
A6004	STRAIGHT AWL	March 2000	Rule 6	Annex VII	15275	12143
A6010	STRAIGHT SCREWDRIVER T20	July 2002	Rule 6	Annex VII	61325	12143

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C6841	T20 SCREWDRIVER	March 2000	Rule 6	Annex VII	61325	12143
C6880	FINAL PLUG DRIVER	March 2000	Rule 6	Annex VII	13180	12143
C6901	CURETTE, CCD WITH STOP	March 2000	Rule 6	Annex VII	31335	12143
C6903	PROBE,STRAIGHT W/MM GRADUATION	March 2000	Rule 6	Annex VII	13180	13180
C6904	PROBE,3MM FLEXIBLE FEELER	March 2000	Rule 6	Annex VII	13180	13180
C6905	PROBE,STIFF BALL 2MM	March 2000	Rule 6	Annex VII	13180	13180
C6906	MARKER,ROUND-LEFT W/35MM ROD	March 2000	Rule 6	Annex VII	58183	12143
C6907	MARKER,SQUARE-RIGHT W/35MM ROD	March 2000	Rule 6	Annex VII	58183	12143
C6908	HANDLE,LOCKING MARKER	March 2000	Rule 6	Annex VII	58183	12143
C899	CDD M4 SCREW FOR FLAT HANDLE	March 2000	Rule 6	Annex VII	61325	12143
HD6107	DRAWER REMOVER	October 2000	Rule 6	Annex VII	61325	12143
HD6503	CURVED DRAWER HOLDER	July 2008	Rule 6	Annex VII	13180	13180
X0100041	SHORT M8 COUNTER TORQUE WRENCH	April 2005	Rule 6	Annex VII	32871	15766
X0103005	M8 FAS LOCKING SCR DRVR 4.5 RD	February 2003	Rule 6	Annex VII	13180	13180
X0103012	4MM SCRAPER	March 2003	Rule 6	Annex VII	35559	12143
X0103013	6MM SCRAPER	March 2003	Rule 6	Annex VII	35559	12143
X0103014	8MM SCRAPER	March 2003	Rule 6	Annex VII	35559	12143
X0103015	12MM SCRAPER	March 2003	Rule 6	Annex VII	35559	12143
X0103016	PYX 12.5 - ANG & SERR CURRETTE	March 2003	Rule 6	Annex VII	31335	12143
X0104026	MODULAR STEP DRILL 10MM	March 2004	Rule 6	Annex VII	36545	12143
X0104053	VER 4MM NON-CANN DRILL	February 2004	Rule 6	Annex VII	44759	12143
X0104179	6/8 CERVICAL SHUCKER	June 2004	Rule 6	Annex VII	32579	10561
X0104180	10/12 CERVICAL SHUCKER	June 2004	Rule 6	Annex VII	32579	10561
X0104181	14/16 CERVICAL SHUCKER	June 2004	Rule 6	Annex VII	32579	10561
X0105077	LEG 5.5 SHORT PROV PLUG DRIVR	February 2005	Rule 6	Annex VII	33968	13517
X0105101	MODIFIED POWER GRIP	August 2005	Rule 6	Annex VII	15800	12143
X0105102	10MM 3/8" REMOVAL DRIVER	February 2005	Rule 6	Annex VII	33968	13517
X0105183	TISSUE RETRACTOR W/ BIFID TIP	February 2005	Rule 6	Annex VII	61325	12143
X0105290	DISTRATOR SHAFT 12	March 2005	Rule 6	Annex VII	56637	11291
X0105297	DEPTH STOP WRENCH	March 2005	Rule 6	Annex VII	32871	15766
X0106110	SACRAL GUIDE, RIGHT	September 2006	Rule 6	Annex VII	61325	12143
X0106120	SACRAL GUIDE LEFT	September 2006	Rule 6	Annex VII	61325	12143
X0106150	HANDLE X0106150 TOMITA SAW HANDLE EM	March 2007	Rule 6	Annex VII	13180	13180
X0106210	ILIO-SACRAL GUIDE, RIGHT	September 2006	Rule 6	Annex VII	61325	12143
X0106220	ILIO-SACRAL GUIDE, LEFT	September 2006	Rule 6	Annex VII	61325	12143
X0107241	RETRACTOR X0107241 SUCTION	March 2007	Rule 6	Annex VII	45182	12143
X0201008	14X40 LONG TOOTH DISC BLADE	November 2001	Rule 6	Annex VII	46774	15558
X0202006	M8 FAS UNIV. SCREWDRIVER	March 2002	Rule 6	Annex VII	33968	13517
X0203004	TL KERRISON-7MM-40 DEG-THNFT	March 2003	Rule 6	Annex VII	31335	12143
X0203007	CS CTR-G8-13MM-DPT-6MM-DIA-STP	March 2003	Rule 6	Annex VII	32845	12143
X0203008	CS CTR-G8-16MM-DPT-6MM-DIA-STP	March 2003	Rule 6	Annex VII	32845	12143
X0204052	VER TAP-3.5MM-FLOURONAV	March 2004	Rule 6	Annex VII	17507	13517
X0204555	NERVE ROOT RETR-LG HNDL	June 2004	Rule 6	Annex VII	44869	12143
X0204556	NERVE RETRACTOR	February 2005	Rule 6	Annex VII	45182	12143
X0205001	ATL TAP-3.5 X 13MM	March 2005	Rule 6	Annex VII	17507	13517
X0205033	PLATE HOLDING PIN	March 2005	Rule 6	Annex VII	61325	12143
X0205047	COUNTERSINK ADAPTER, +1MM	March 2005	Rule 6	Annex VII	36292	12143

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X0205048	COUNTERSINK ADAPTER, +2MM	March 2005	Rule 6	Annex VII	36292	12143
X0205126	MX KERRISON-BAY-CURV-2MM-40°	May 2005	Rule 6	Annex VII	31335	12143
X0205144	MODIFIED X10 COUNTERTORQUE	March 2005	Rule 6	Annex VII	47554	13180
X0205146	LEFT FLAT BENDER W/IN-SITU	May 2005	Rule 6	Annex VII	44795	12143
X0205147	RIGHT FLAT BENDER W/IN-SITU	May 2005	Rule 6	Annex VII	44795	12143
X0206021	7MM WIDE SUCTION RETRACTOR	April 2006	Rule 6	Annex VII	45182	12143
X0206205	LONGER GRASPING INSERTER	April 2006	Rule 6	Annex VII	61325	12143
X0207038	GUIDE X0207038 FIXED DRILL ANGLE	June 2007	Rule 6	Annex VII	13180	13180
X0303051	SPECIAL 10MM BONE GRAFT TRIAL	April 2003	Rule 6	Annex VII	44759	12143
X0303251	TL KERRISON-1MM-EXLNG-11"	April 2003	Rule 6	Annex VII	31335	12143
X0303252	TL KERRISON-2MM-EXLNG-11"	April 2003	Rule 6	Annex VII	31335	12143
X0303253	TL KERRISON-3MM-EXLNG-11"	April 2003	Rule 6	Annex VII	31335	12143
X0303254	TL KERRISON-4MM-EXLNG-11"	April 2003	Rule 6	Annex VII	31335	12143
X0303255	TL KERRISON-5MM-EXLNG-11"	April 2003	Rule 6	Annex VII	31335	12143
X0304002	MODIFIED TLIF DISTRATOR	March 2004	Rule 6	Annex VII	56637	11291
X0305017	FEMORAL RING INSERTER/IMPACTOR	July 2005	Rule 6	Annex VII	32856	12143
X0305018	PLATE HOLDING PIN	May 2005	Rule 6	Annex VII	61325	12143
X0305027	ICE PICK AWL	June 2005	Rule 6	Annex VII	15275	12143
X0305033	IMPLANT INSERTER	April 2006	Rule 6	Annex VII	12696	17543
X0305057	HOLDING PIN REMOVAL TOOL	May 2005	Rule 6	Annex VII	47807	12143
X0305183	STABILITY PIN 120MM,8MM THREAD	April 2005	Rule 6	Annex VII	44759	12143
X0305184	STABILITY PIN 170MM,8MM THREAD	April 2005	Rule 6	Annex VII	44759	12143
X0305208	MX KERRISON-BAY-CURV-3MM-40°	May 2005	Rule 6	Annex VII	31335	12143
X0306104	T-BOLT POS W/ 7/32" HEX DRIVER ASSY	July 2006	Rule 6	Annex VII	61325	12143
X0306105	T-BOLT POS W/ T25 SPLIT DRIVER	July 2006	Rule 6	Annex VII	33968	13517
X0306150	8MM DISTRATOR HOUSING	July 2006	Rule 6	Annex VII	56637	11291
X0306151	8MM DISTRATOR	July 2006	Rule 6	Annex VII	56637	11291
X0306152	8+1 CHISEL GUIDE	July 2006	Rule 6	Annex VII	61325	12143
X0306153	8+2 CHISEL GUIDE	July 2006	Rule 6	Annex VII	13180	13180
X0306154	8+3 CHISEL GUIDE	July 2006	Rule 6	Annex VII	61325	12143
X0306443	10MM TRIAL, 8°	July 2006	Rule 6	Annex VII	44759	12143
X0306444	12MM TRIAL, 8°	July 2006	Rule 6	Annex VII	44759	12143
X0400001	BENDING IRON	June 2000	Rule 6	Annex VII	44975	12143
X0401004	T-HANDLE ALIGNMENT GUIDE	January 2002	Rule 6	Annex VII	61325	12143
X0403010	MX TUBE RETR-22X35-TPR-OVAL	May 2003	Rule 6	Annex VII	44869	12143
X0403011	MX MICRO NERVE HOOK-NOBAY-90DG	May 2003	Rule 6	Annex VII	61325	12143
X0403016	REMOVABLE HANDLE-FOR 4MM SHAFT	May 2003	Rule 6	Annex VII	13180	13180
X0404001	SPECIAL PARALLEL SPREADER	July 2004	Rule 6	Annex VII	15800	12143
X0404013	8H X 12W BOX CHISEL	June 2004	Rule 6	Annex VII	61325	12143
X0404014	10H X 12W BOX CHISEL	June 2004	Rule 6	Annex VII	61325	12143
X0404015	12H X 12W BOX CHISEL	June 2004	Rule 6	Annex VII	61325	12143
X0404016	14H X 12W BOX CHISEL	June 2004	Rule 6	Annex VII	61325	12143
X0405052	T27 SCREWDRIVER WITH T-HANDLE	May 2005	Rule 6	Annex VII	61325	12143
X0405291	BONE GRAFT FUNNEL	May 2005	Rule 6	Annex VII	47872	12143
X0405292	BONE GRAFT FUNNEL TAMP	May 2005	Rule 6	Annex VII	47872	12143
X0405325	TRIAL X0405325 LARGE STOP 5X14X11MM	May 2005	Rule 6	Annex VII	44788	12143
X0405326	TRIAL X0405326 LARGE STOP 6X14X11MM	May 2005	Rule 6	Annex VII	44788	12143

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X0405327	TRIAL X0405327 LARGE STOP 7X14X11MM	May 2005	Rule 6	Annex VII	44788	12143
X0405328	TRIAL X0405328 LARGE STOP 8X14X11MM	May 2005	Rule 6	Annex VII	44788	12143
X0405329	TRIAL X0405329 LARGE STOP 9X14X11MM	May 2005	Rule 6	Annex VII	44788	12143
X0405330	TRIAL X0405330 LARGE STOP 10X14X11MM	May 2005	Rule 6	Annex VII	44788	12143
X0405332	CS L RASP 5X14X11 LARGE STOP	May 2005	Rule 6	Annex VII	35559	12143
X0405333	CS L RASP 6X14X11 LARGE STOP	May 2005	Rule 6	Annex VII	35559	12143
X0405334	CS L RASP 7X14X11 LARGE STOP	May 2005	Rule 6	Annex VII	35559	12143
X0405335	CS L RASP 8X14X11 LARGE STOP	May 2005	Rule 6	Annex VII	35559	12143
X0405336	CS L RASP 9X14X11 LARGE STOP	May 2005	Rule 6	Annex VII	35559	12143
X0405337	CS L RASP 10X14X11 LARGE STOP	May 2005	Rule 6	Annex VII	35559	12143
X0405360	FIXED ANGLE AWL TROCAR TIP VEN	July 2005	Rule 6	Annex VII	15275	12143
X0405362	SCREWDRIVER SLEEVE	January 2006	Rule 6	Annex VII	33968	13517
X0406124	HANDLE X0406124 T COUNTER TORQUE	May 2007	Rule 6	Annex VII	13180	13180
X0406220	HANDLE X0406220 T CT OFFSET CONNECTOR	May 2007	Rule 6	Annex VII	61325	12143
X0406221	HANDLE X0406221 OFFSET CT CONNECTOR	May 2007	Rule 6	Annex VII	61325	12143
X0406285	TAP X0406285 4.0MM CORT WSTOP, 6MM DEPTH	February 2007	Rule 6	Annex VII	17507	13517
X0406286	TAP X0406286 4.0MM CORT WSTOP, 8MM DEPTH	February 2007	Rule 6	Annex VII	17507	12143
X0406287	TAP X0406287 4.0MM CORT WSTOP, 10MM DEPT	February 2007	Rule 6	Annex VII	17507	12143
X0406288	TAP X0406288 4.0MM CORT WSTOP 12MM DEPTH	February 2007	Rule 6	Annex VII	17507	12143
X0406289	TAP X0406289 4.5MM CORT WSTOP 6MM DEPTH	February 2007	Rule 6	Annex VII	17507	12143
X0406290	TAP X0406290 4.5MM CORT WSTOP 8MM DEPTH	February 2007	Rule 6	Annex VII	17507	12143
X0406291	TAP X0406291 4.5MM CORT WSTOP 10MM DEPTH	February 2007	Rule 6	Annex VII	17507	12143
X0406292	TAP X0406292 4.5MM CORT WSTOP 12MM DEPTH	February 2007	Rule 6	Annex VII	17507	12143
X0406349	PITUITARY RONGEUR, STRAIGHT, 420MM	July 2006	Rule 6	Annex VII	32853	13146
X0406350	PITUITARY RONGEUR, STRAIGHT, 472MM	July 2006	Rule 6	Annex VII	32853	13146
X0407053	PITUITARY X0407053 2MM UP W/INT TEETH	May 2007	Rule 6	Annex VII	15800	12143
X0407054	PITUITARY X0407054 3MM UP W/INT TEETH	May 2007	Rule 6	Annex VII	15800	12143
X0407055	PITUITARY X0407055 3MM W/INT TEETH	May 2007	Rule 6	Annex VII	15800	12143
X0407056	PITUITARY X0407056 2MM W/INT TEETH	May 2007	Rule 6	Annex VII	15800	12143
X0502005	TAPERED TIP AWL/PROBE	June 2002	Rule 6	Annex VII	15275	13180
X0502014	M8 COUNTER TORQ W/ KNURL SHAFT	June 2002	Rule 6	Annex VII	47554	13180
X0504023	PYR NERVE ROOT RETR-EX HNDL	July 2004	Rule 6	Annex VII	44869	12143
X0505014	DISCECTOMY BLADE, 30X35MM	August 2005	Rule 6	Annex VII	46774	15558
X0505015	DISCECTOMY BLADE, 40X35MM	August 2005	Rule 6	Annex VII	46774	15558
X0505016	DISCECTOMY BLADE, 50X35MM	August 2005	Rule 6	Annex VII	46774	15558
X0505017	DISCECTOMY BLADE, 60X35MM	August 2005	Rule 6	Annex VII	46774	15558
X0505018	DISCECTOMY BLADE, 70X35MM	August 2005	Rule 6	Annex VII	46774	15558
X0505028	HANDLE FOR DIAMOND SAW	August 2005	Rule 6	Annex VII	13180	13180
X0505204	MODIFIED T27 QC DRIVER	June 2005	Rule 6	Annex VII	32865	13517

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P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
X0506138	NON-SWIVEL PLATE HOLDING PIN DRIVER	September 2006	Rule 6	Annex VII	33968	13517
X0506139	NON-SWIVEL DRILL BIT HANDLE	September 2006	Rule 6	Annex VII	13180	13180
X0506140	NON-SWIVEL LOCKSCREW DRIVER	September 2006	Rule 6	Annex VII	33968	13517
X0506208	RETRACTOR BLADE LL RIGHT, 28MM X 220MM	July 2006	Rule 6	Annex VII	45182	13386
X0506324L	DISCECTOMY BLADE, ANGLED TIP, LEFT,50MM	October 2006	Rule 6	Annex VII	46774	15558
X0506325L	DISCECTOMY BLADE, ANGLED TIP, LEFT,60MM	October 2006	Rule 6	Annex VII	46774	15558
X0506326L	DISCECTOMY BLADE, ANGLED TIP, LEFT,70MM	October 2006	Rule 6	Annex VII	46774	15558
X0506327L	DISCECTOMY BLADE, ANGLED TIP, LEFT,80MM	October 2006	Rule 6	Annex VII	46774	15558
X0506328R	DISCECTOMY BLADE, ANGLED TIP, RIGHT,50MM	October 2006	Rule 6	Annex VII	46774	15558
X0506329R	DISCECTOMY BLADE, ANGLED TIP, RIGHT,60MM	October 2006	Rule 6	Annex VII	46774	15558
X0506330R	DISCECTOMY BLADE, ANGLED TIP, RIGHT,70MM	October 2006	Rule 6	Annex VII	46774	15558
X0506331R	DISCECTOMY BLADE, ANGLED TIP, RIGHT,80MM	October 2006	Rule 6	Annex VII	46774	15558
X0508049	TAP X0508049 NAV 3.5	July 2008	Rule 6	Annex VII	17507	13517
X0595-007	DISTRATOR W/EXTD HANDLE	July 2004	Rule 6	Annex VII	44378	11291
X0602001	MINI-REAMER	July 2002	Rule 6	Annex VII	45114	13297
X0602018	NUT STARTER/COUNTER TORQ SLEEVE	July 2002	Rule 6	Annex VII	47554	13180
X0603009	PYX SCRAPER-PULL-ANG-LT-45D	July 2003	Rule 6	Annex VII	35559	12143
X0603011	END RETR BLD-38MMX140MM	July 2003	Rule 6	Annex VII	45182	12143
X0603012	END RETR BLD-38MMX152MM	July 2003	Rule 6	Annex VII	45182	12143
X0603017	PYX SCRAPER-PULL-ANG-RT-45D	July 2003	Rule 6	Annex VII	35559	12143
X0603030	TL BLADE-DISC-35X30-TPR	June 2003	Rule 6	Annex VII	46774	15558
X0603033	MX TUBE-RETR-33MMX14CM	June 2003	Rule 6	Annex VII	45182	12143
X0603035	TL BLADE-DISC-35X35-TPR	June 2003	Rule 6	Annex VII	46774	15558
X0603040	TL BLADE-DISC-35X40-TPR	June 2003	Rule 6	Annex VII	46774	15558
X0603045	TL BLADE-DISC-35X45-TPR	June 2003	Rule 6	Annex VII	46774	15558
X0603050	TL BLADE-DISC-35X50-TPR	June 2003	Rule 6	Annex VII	46774	15558
X0603055	TL BLADE-DISC-35X55-TPR	June 2003	Rule 6	Annex VII	46774	15558
X0603060	TL BLADE-DISC-35X60-TPR	June 2003	Rule 6	Annex VII	46774	15558
X0603065	TL BLADE-DISC-35X65-TPR	June 2003	Rule 6	Annex VII	46774	15558
X0603070	TL BLADE-DISC-35X70-TPR	June 2003	Rule 6	Annex VII	46774	15558
X0603075	TL BLADE-DISC-35X75-TPR	June 2003	Rule 6	Annex VII	46774	15558
X0603401	ROTATION WRENCH-5MM	July 2003	Rule 6	Annex VII	32871	15766
X0604003	MX WOODSON PROBE-STR	September 2004	Rule 6	Annex VII	13180	13180
X0604018	DIA 3.2MM GUIDE WIRE	September 2004	Rule 6	Annex VII	46165	12143
X0604130	TL BLADE-DISC-23X30-6SHP7.5TTH	September 2004	Rule 6	Annex VII	46774	15558
X0604135	TL BLADE-DISC-23X35-6SHP7.5TTH	September 2004	Rule 6	Annex VII	46774	15558
X0604140	TL BLADE-DISC-23X40-6SHP7.5TTH	September 2004	Rule 6	Annex VII	46774	15558
X0604145	TL BLADE-DISC-23X45-6SHP7.5TTH	September 2004	Rule 6	Annex VII	46774	15558
X0604150	TL BLADE-DISC-23X50-6SHP7.5TTH	September 2004	Rule 6	Annex VII	46774	15558

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P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
X0604155	TL BLADE-DISC-23X55-6SHP7.5TTH	September 2004	Rule 6	Annex VII	46774	15558
X0604160	TL BLADE-DISC-23X60-6SHP7.5TTH	September 2004	Rule 6	Annex VII	46774	15558
X0604165	TL BLADE-DISC-23X65-6SHP7.5TTH	September 2004	Rule 6	Annex VII	46774	15558
X0604170	TL BLADE-DISC-23X70-6SHP7.5TTH	September 2004	Rule 6	Annex VII	46774	15558
X0604175	TL BLADE-DISC-23X75-6SHP7.5TTH	September 2004	Rule 6	Annex VII	46774	15558
X0604960	DISC SHAVER 10MM Q/C	July 2004	Rule 6	Annex VII	35720	12143
X0604961	DISC SHAVER 11MM Q/C	July 2004	Rule 6	Annex VII	35720	12143
X0604962	DISC SHAVER 12MM Q/C	July 2004	Rule 6	Annex VII	35720	12143
X0605002	SINGLE BARREL DRIVER CAP	June 2005	Rule 6	Annex VII	61325	12143
X0605193	90° BAYONETED WOODSON PROBE	June 2005	Rule 6	Annex VII	13180	13180
X0605195	14MM/8MM WORKING CHANNEL	October 2005	Rule 6	Annex VII	13180	13180
X0605196	12MM/6MM WORKING CHANNEL	October 2005	Rule 6	Annex VII	13180	13180
X0605199	12MM / 6MM WORKING CHANNEL (NO SPIKES)	January 2006	Rule 6	Annex VII	61325	12143
X0606192	EXT PEDICLE MARKER SPHERE	August 2006	Rule 6	Annex VII	58183	12143
X0606193	EXT PEDICLE MARKER CYLINDER	August 2006	Rule 6	Annex VII	58183	12143
X0606321	STRAIGHT PLATE HOLDER W/ ROTATING HANDLE	August 2006	Rule 6	Annex VII	13180	13180
X0606322	MODIFIED GUIDE, 19MM	August 2006	Rule 6	Annex VII	13180	13180
X0606323	MODIFIED GUIDE, 21MM	August 2006	Rule 6	Annex VII	13180	13180
X0606324	MODIFIED GUIDE, 23MM	August 2006	Rule 6	Annex VII	13180	13180
X0606325	MODIFIED GUIDE, 25MM	August 2006	Rule 6	Annex VII	13180	13180
X0640969	DISC SHAVER 9MM Q/C	July 2004	Rule 6	Annex VII	35720	12143
X065061	BENDER	June 2003	Rule 6	Annex VII	44795	12143
X065062	NUT DRIVER	June 2003	Rule 6	Annex VII	33968	13517
X0697-001	AXIS DRILL BIT HANDLE	October 2005	Rule 6	Annex VII	61325	12143
X0701013	SCREW / CONNECTOR POSITIONER	October 2001	Rule 6	Annex VII	61325	12143
X0701020	PEDICLE REAMER-5.5MM-EXT-HUDDR	March 2002	Rule 6	Annex VII	45111	12143
X0701100	ADJUSTABLE SACRAL AWL	October 2001	Rule 6	Annex VII	15275	12143
X0703008	MX KERRISON-BAY-EJ-1MM-40D-THF	August 2003	Rule 6	Annex VII	31335	12143
X0703009	MX KERRISON-BAY-EJ-1MM-90D-THF	August 2003	Rule 6	Annex VII	31335	12143
X0704000	CANNULATED AWL WITH QUICK CONN	January 2005	Rule 6	Annex VII	15275	15766
X0704200	IMPLANT HOLDER	September 2004	Rule 6	Annex VII	13180	13180
X0704714	LICINA AWL	September 2004	Rule 6	Annex VII	15275	12143
X0705069	MICRO SCISSORS	August 2005	Rule 6	Annex VII	44378	12143
X0706260	AWL X0706260 8MM X 2.4 MM DIA.	April 2007	Rule 6	Annex VII	15275	12143
X0706263	CURETTE BOOT 8MM	March 2007	Rule 6	Annex VII	31335	12143
X0706264	MODIFIED 5MM HEX DRIVER QC	October 2006	Rule 6	Annex VII	33968	13517
X0803680	CD DIA. 7.0 ROD REDUCER	October 2003	Rule 6	Annex VII	44804	12143
X0804032	SHORT 2MM FEELER	November 2004	Rule 6	Annex VII	13180	13180
X0804033	MED BONE CURR, STRAIGHT, 12MM	November 2004	Rule 6	Annex VII	31335	12143
X0804034	EXT. NITINOL SCREW EXTENDER	September 2004	Rule 6	Annex VII	13180	13180
X0805108	PARALLEL COMPRESSOR SM, LEFT	September 2005	Rule 6	Annex VII	47870	12143
X0805109	PARALLEL COMPRESSOR SM, RIGHT	September 2005	Rule 6	Annex VII	47870	13180
X0805148	DRIVER X0805148 5.5 W/CROSSBAR 180MM	April 2007	Rule 6	Annex VII	33968	13517
X0805149	DRIVER X0805149 5.5 W/O CROSSBAR 165MM	April 2007	Rule 6	Annex VII	32865	13517

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X0805213	MICROSUTURE INSTRUMENT	August 2006	Rule 6	Annex VII	15800	12143
X0805214	MICROSUTURE NEEDLE HOLDER	August 2006	Rule 6	Annex VII	13180	13180
X0805215	MICROSUTURE GRASPING FORCEPS	August 2006	Rule 6	Annex VII	15800	12143
X0805314	BAYONETED KERRISON, 1.5MM, 40°	October 2005	Rule 6	Annex VII	31335	12143
X0805315	BAYONETED KERRISON, 1.5MM, 90°	October 2005	Rule 6	Annex VII	31335	12143
X0805316	BAYONETED KERRISON, 2.5MM, 40°	October 2005	Rule 6	Annex VII	31335	12143
X0805317	BAYONETED KERRISON, 2.5MM, 90°	October 2005	Rule 6	Annex VII	31335	12143
X0902010	MOD FIXED RETRACTOR BLADE	November 2002	Rule 6	Annex VII	45182	12143
X0902011	METRX SNAKE-FIXED BLADE CONN.	November 2002	Rule 6	Annex VII	13180	13180
X0902030	20 X 30MM FIXED DISCECTOMY BLD	September 2002	Rule 6	Annex VII	44378	12143
X0902040	20 X 40MM FIXED DISCECTOMY BLD	September 2002	Rule 6	Annex VII	44378	12143
X0902050	20 X 50MM FIXED DISCECTOMY BLD	September 2002	Rule 6	Annex VII	44378	12143
X0902060	20 X 60MM FIXED DISCECTOMY BLD	September 2002	Rule 6	Annex VII	44378	12143
X0902070	20 X 70MM FIXED DISCECTOMY BLD	September 2002	Rule 6	Annex VII	44378	12143
X0902150	23X30, FIXED CONN. DISC. BLADE	November 2002	Rule 6	Annex VII	44378	12143
X0902152	23X40, FIXED CONN. DISC. BLADE	November 2002	Rule 6	Annex VII	44378	12143
X0902154	23X50, FIXED CONN. DISC. BLADE	November 2002	Rule 6	Annex VII	44378	12143
X0902156	23X60, FIXED CONN. DISC. BLADE	November 2002	Rule 6	Annex VII	44378	12143
X0902158	23X70, FIXED CONN. DISC. BLADE	November 2002	Rule 6	Annex VII	44378	12143
X0902160	20X30 FIXED CONN. LONG. BLADE	November 2002	Rule 6	Annex VII	44378	12143
X0902162	20X40 FIXED CONN. LONG. BLADE	November 2002	Rule 6	Annex VII	44378	12143
X0902164	20X50 FIXED CONN. LONG. BLADE	November 2002	Rule 6	Annex VII	44378	12143
X0902166	20X60 FIXED CONN. LONG. BLADE	November 2002	Rule 6	Annex VII	44378	12143
X0902168	20X70 FIXED CONN. LONG. BLADE	November 2002	Rule 6	Annex VII	44378	12143
X0903053	6.0 CANNULATED DRILL	October 2003	Rule 6	Annex VII	61325	12143
X0905007	RET BLADE SS 18MMX120MM-30°	July 2006	Rule 6	Annex VII	45182	16046
X0905008	RET BLADE LEFT 28MMX120MM-30°	July 2006	Rule 6	Annex VII	45182	16046
X0905009	RET BLADE LS 18MMX170MM-30°	July 2006	Rule 6	Annex VII	45182	16046
X0905010	RET BLADE LEFT 28MMX170MM-30°	July 2006	Rule 6	Annex VII	45182	16046
X0905052	2MM NEEDLE DRIVER	September 2005	Rule 6	Annex VII	33968	13517
X0905155	BAYONETED WOODSON PROBE	September 2005	Rule 6	Annex VII	13180	13180
X0905262	16X32MM DISTRACTOR/TRIAL	October 2005	Rule 6	Annex VII	44378	12143
X0905263	16X36MM DISTRACTOR/TRIAL	October 2005	Rule 6	Annex VII	44378	12143
X0905264	60MM RIGHT HALF TUBE	October 2005	Rule 6	Annex VII	32579	14175
X0905265	80MM RIGHT HALF TUBE	October 2005	Rule 6	Annex VII	32579	14175
X0905266	60MM LEFT HALF TUBE	October 2005	Rule 6	Annex VII	32579	14175
X0905267	80MM LEFT HALF TUBE	October 2005	Rule 6	Annex VII	32579	14175
X0905315	26MM STR BLADE, TOP_SS	December 2005	Rule 6	Annex VII	46774	15558
X0905316	26MM STR BLADE, BOTTOM_SS	December 2005	Rule 6	Annex VII	46774	15558
X0906049	QC RATCHETING T-HANDLE	February 2007	Rule 6	Annex VII	13180	13180
X0906050	QC RATCHET SCREWDRIVER HANDLE	February 2007	Rule 6	Annex VII	61325	12143
X0906062	SCREWDRIVER X0906062 SCREWDRIVER	February 2007	Rule 6	Annex VII	33968	13517
X0906064	INSTRUMENT X0906064 PLATE HOLDER FORCEPS	February 2007	Rule 6	Annex VII	13180	13180
X0906171	RATCHETING T-HANDLE	February 2007	Rule 6	Annex VII	13180	13180
X0906187	SLEEVE X0906187 SCREW REMOVAL DRVR OUTER	September 2007	Rule 6	Annex VII	45200	12143

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X0912105	Box Chisel, 6mm	April 2013	Rule 6	Annex VII	10825	12143
X0912106	Box Chisel, 8mm	April 2013	Rule 6	Annex VII	10825	12143
X0912107	Box Chisel, 10mm	April 2013	Rule 6	Annex VII	10825	12143
X0912108	Box Chisel, 12mm	April 2013	Rule 6	Annex VII	10825	12143
X0912109	Box Chisel, 14mm	April 2013	Rule 6	Annex VII	10825	12143
X0912110	DL Cobb Elevator, 14mm - 10DEG	April 2013	Rule 6	Annex VII	35048	12143
X0912111	Rotating Kerrison, 3mm - 40DEG	April 2013	Rule 6	Annex VII	35287	12143
X0912112	Rotating Kerrison 5mm - 40DEG	April 2013	Rule 6	Annex VII	35287	12143
X1002028	SEX DILATOR-LONG-180MM	December 2002	Rule 6	Annex VII	13180	13180
X1002031	M8MAS DRIVER, HUDSON DRIVE	November 2002	Rule 6	Annex VII	33968	13517
X1002033	SCREWDRIVER WITH LARGE HANDLE	December 2002	Rule 6	Annex VII	13180	13180
X1002034	ZEP MONO DRILL GUIDE RIGHT HND	January 2003	Rule 6	Annex VII	47807	12143
X1003014	MX RETRACTOR HANDLE-ANGLD	December 2003	Rule 6	Annex VII	45182	12143
X1003023	TSR3 TLIF DISTRACTOR-90 DEG FT	March 2004	Rule 6	Annex VII	44378	12143
X1003024	MX 90 DEGREE WOODSON PROBE	December 2003	Rule 6	Annex VII	61325	12143
X1003031	KNIFE X1003031 BAYONETED	January 2004	Rule 6	Annex VII	32850	12143
X1003216	MX TUBE RETR-16MMX9.5CM	November 2003	Rule 6	Annex VII	13180	13180
X1003476	5MM PILOT REAMER	January 2004	Rule 6	Annex VII	45111	12143
X1004007	WEITLANER RETRACTOR	November 2004	Rule 6	Annex VII	45182	12143
X1004029	LAP VEIN RETRACTOR	April 2005	Rule 6	Annex VII	45182	12143
X1004031	VEIN RETRACTOR BLADE	April 2005	Rule 6	Annex VII	45182	12143
X1004821	OSTEOTOME, STRAIGHT	March 2005	Rule 6	Annex VII	12844	12845
X1004824	KERRISON CURVED 4.0MM	February 2005	Rule 6	Annex VII	31335	12143
X1004834	KERRISON CURVED 2.0MM	February 2005	Rule 6	Annex VII	31335	12143
X1004835	KERRISON CURVED 3.0MM	February 2005	Rule 6	Annex VII	31335	12143
X1004836	BAYONETED KERRISON, 2MM, EJECT	February 2005	Rule 6	Annex VII	31335	12143
X1004837	BAYONETED KERRISON, 3MM, EJECT	February 2005	Rule 6	Annex VII	31335	12143
X1004887	LEG 5.5 MED PARALLEL COMPRESS	December 2004	Rule 6	Annex VII	15800	12143
X1005095	K-WIRE IMPACTOR	November 2005	Rule 6	Annex VII	61325	12143
X1005317	GRASPER	December 2005	Rule 6	Annex VII	15800	12143
X1012015	Straight Ring Curette	April 2013	Rule 6	Annex VII	31335	12143
X1012016	Straight Osteotome	April 2013	Rule 6	Annex VII	10825	12143
X1012022	DL Cobb Elevator 10mm - 10DEG	April 2013	Rule 6	Annex VII	35048	12143
X1012023	DL Cobb Elevator 15mm - 10DEG	April 2013	Rule 6	Annex VII	35048	12143
X1012031	Angled Ring Curette	April 2013	Rule 6	Annex VII	31335	12143
X1012032	Angled Osteotome	April 2013	Rule 6	Annex VII	10825	12143
X1102012	CANNULATED T-HANDLE AWL	March 2003	Rule 6	Annex VII	15275	12143
X1102014	CANNULATED BALL-HANDLE PROBE	March 2003	Rule 6	Annex VII	61325	12143
X1102015	OFFSET Q.C. RATCHETING HANDLE	March 2003	Rule 6	Annex VII	13180	13180
X1103022	NERVE ROOT RETRACTOR	October 2004	Rule 6	Annex VII	35048	12143
X1103024	MODIFIED MANIPULATOR	December 2003	Rule 6	Annex VII	13180	13180
X1103040	TL-BLADE-DISC-23X40-5TTH	December 2003	Rule 6	Annex VII	61325	12143
X1103050	TL-BLADE-DISC-23X50-5TTH	December 2003	Rule 6	Annex VII	61325	12143
X1103060	TL-BLADE-DISC-23X60-5TTH	December 2003	Rule 6	Annex VII	61325	12143
X1103070	TL-BLADE-DISC-23X70-5TTH	December 2003	Rule 6	Annex VII	61325	12143
X1103481	10MM/5MM FIXED DISTRACTOR	January 2004	Rule 6	Annex VII	56637	11291
X1104132	10" VEIN RETRACTOR	December 2004	Rule 6	Annex VII	45182	12143

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X1104281	PEDICLE MARKER, CONICAL, SHORT	February 2005	Rule 6	Annex VII	58183	12143
X1104282	PEDICLE MARKER, CONICAL SHORT	February 2005	Rule 6	Annex VII	58183	12143
X1105067	NERVE ROOT RETRACTOR 6MM WIDE	January 2006	Rule 6	Annex VII	45182	12143
X1106196	FRENCH BENDER W/ SILICONE HDLS	June 2010	Rule 6	Annex VII	44795	12143
X1109152	Coronal Plane Bender 6.35 - 130° -Left	January 2010	Rule 6	Annex VII	13180	12143
X1109153	Coronal Plane Bender 6.35 - 130° -Right	January 2010	Rule 6	Annex VII	13180	12143
X1204103	LAT ROD REDUCER W/ T-HANDLE	April 2005	Rule 6	Annex VII	44804	12143
X1204129	OSTEOTOME, CURVED 5MM	March 2005	Rule 6	Annex VII	12844	12845
X1204315	STR AWL WITH IMP HANDLE-SQ TIP	February 2005	Rule 6	Annex VII	15275	12143
X1204361	3/32 HEX HEAD SCREWDRIVER	December 2005	Rule 6	Annex VII	61325	12143
X1206052	HEAD DEROTATOR	February 2007	Rule 6	Annex VII	61325	12143
X1208110	IMPACTOR CAP	January 2009	Rule 6	Annex VII	32856	12143
X2820605C	MARKER X2820605C CYLINDRICAL WITH HEAD	September 2007	Rule 6	Annex VII	58183	12143
X2820605S	MARKER X2820605C SPHERICAL WITH HEAD	September 2007	Rule 6	Annex VII	58183	12143
X382060	HEX 3.5 MM DRIVER	August 2006	Rule 6	Annex VII	33968	13517
X382062	BREAK-OFF DRIVER	August 2006	Rule 6	Annex VII	33968	13517
X3986501	ROD GUIDE 8 MM	February 2007	Rule 6	Annex VII	13180	13180
X3986502	ROD GUIDE 10 MM	February 2007	Rule 6	Annex VII	13180	13180
X3986503	PARALLEL HANDLE	February 2007	Rule 6	Annex VII	13180	13180
X3986504	ANGLE CAP HANDLE 3°	February 2007	Rule 6	Annex VII	13180	13180
X3986505	ANGLE CAP HANDLE 6°	February 2007	Rule 6	Annex VII	13180	13180
X3986506	STRAIGHT OSTEOTOME 10 MM	February 2007	Rule 6	Annex VII	12844	12845
X3986507	STRAIGHT OSTEOTOME 15 MM	February 2007	Rule 6	Annex VII	12844	12845
X3986508	TILE ROUNDED OSTEOTOME 10 MM	February 2007	Rule 6	Annex VII	12844	12845
X3986509	SHARP TILE ROUNDED OSTEOTOME 10 MM	February 2007	Rule 6	Annex VII	12844	12845
X3986510	KNIFE OSTEOTOME 7.5 MM	February 2007	Rule 6	Annex VII	12844	12845
X3986511	KNIFE OSTEOTOME 12.5 MM	February 2007	Rule 6	Annex VII	12844	12845
X3986512	GUILLOTINE 7.5 MM	February 2007	Rule 6	Annex VII	12844	12845
X3986513	GUILLOTINE 12.5 MM	February 2007	Rule 6	Annex VII	12844	12845
X3986514	FOOTED OSTEOTOME 12.5 MM	February 2007	Rule 6	Annex VII	12844	12845
X3986515	FOOTED OSTEOTOME 17.5 MM	February 2007	Rule 6	Annex VII	12844	12845
X3986516	BOX OSTEOTOME 15X10 MM	February 2007	Rule 6	Annex VII	12844	12845
X3986517	BOX OSTEOTOME 17.5X11 MM	February 2007	Rule 6	Annex VII	12844	12845
X3986518	BOX OSTEOTOME 20X12 MM	February 2007	Rule 6	Annex VII	12844	12845
X3986519	BOX OSTEOTOME 15X10 MM	February 2007	Rule 6	Annex VII	12844	12845
X3986520	BOX OSTEOTOME 17.5X11 MM	February 2007	Rule 6	Annex VII	12844	12845
X3986521	BOX OSTEOTOME 20X12 MM	February 2007	Rule 6	Annex VII	12844	12845
X3986522	SLAP HAMMER	February 2007	Rule 6	Annex VII	32856	12143
X3986523	ROOT RETRACTOR	February 2007	Rule 6	Annex VII	45182	12143
X3986524	SOFT TISSUE RETRACTOR	February 2007	Rule 6	Annex VII	45182	12143
X3986525	PROBE / DISTRACTOR SMALL	February 2007	Rule 6	Annex VII	44378	12143
X3986526	PROBE / DISTRACTOR SMALL (THORACIC)	February 2007	Rule 6	Annex VII	44378	12143
X3986527	PROBE DISTRACTOR MEDIUM	February 2007	Rule 6	Annex VII	44378	12143
X3986528	PROBE DISTRACTOR MEDIUM	February 2007	Rule 6	Annex VII	44378	12143
X3986529	RASP	February 2007	Rule 6	Annex VII	35559	12143
X3986530	SCRAPER	February 2007	Rule 6	Annex VII	35559	12143

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P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
X3986531	BACK PUSHER 8X20	February 2007	Rule 6	Annex VII	13180	13180
X3986532	BACK PUSHER 10X22.5	February 2007	Rule 6	Annex VII	13180	13180
X3986533	BACK PUSHER 12X25	February 2007	Rule 6	Annex VII	13180	13180
X3986534	SPATULA 6	February 2007	Rule 6	Annex VII	39610	12143
X3986535	SPATULA 10	February 2007	Rule 6	Annex VII	39610	12143
X3986536	ROOT PROBE	February 2007	Rule 6	Annex VII	13180	13180
X3986537	PROBE	February 2007	Rule 6	Annex VII	13180	13180
X3986538	DILATOR 7X6	February 2007	Rule 6	Annex VII	13180	13180
X3986539	DILATOR 9X8	February 2007	Rule 6	Annex VII	13180	13180
X3986540	INITIAL DILATER	February 2007	Rule 6	Annex VII	13180	13180
X3986541	BOX OSTEOTOME 17.5 X 11 MM L	February 2007	Rule 6	Annex VII	12844	12845
X3986542	BOX OSTEOTOME 17.5 X 11 MM L	February 2007	Rule 6	Annex VII	12844	12845
X3986543	CURVED SPATULA 8	February 2007	Rule 6	Annex VII	39610	12143
X3986550	FORK HAMMER	April 2009	Rule 6	Annex VII	32856	12143
X4090601	HOOK HOLDER	February 2007	Rule 6	Annex VII	47807	13180
X4090602	CLOSED COUNTER TORQUE	February 2007	Rule 6	Annex VII	47554	13180
X4090603	DISTRACTION FORCEPS 3.6	July 2007	Rule 6	Annex VII	44378	12143
X4090604	DISTRACTION FORCEPS 4.5	July 2007	Rule 6	Annex VII	44378	12143
X418060	RFAS SCREWDRIVER WITH THUMBWHEEL	April 2007	Rule 6	Annex VII	61325	12143
X435060	PROBE X435060 SOUNDING/FEELER 1MM	June 2008	Rule 6	Annex VII	13180	13180
X441061	INSTRUMENT X441061 COUNTER TORQUE	January 2008	Rule 6	Annex VII	47554	13180
X461060	HEXALOBE DRIVER T8	January 2009	Rule 6	Annex VII	33968	13517
X461061	FLAT 5.6 REMOVAL NUT DRIVER	January 2009	Rule 6	Annex VII	33968	13517
X461062	FLAT 6.3 REMOVAL NUT DRIVER	January 2009	Rule 6	Annex VII	33968	13517
X461063	SCREW REMOVER DRIVER	January 2009	Rule 6	Annex VII	33968	13517
X461064	SCREW REMOVER DRIVER	January 2009	Rule 6	Annex VII	33968	13517
X461065	7.5 MM FEMALE HEX DRIVER	January 2009	Rule 6	Annex VII	33968	13517
X465060	COBB CURETTE	March 2009	Rule 6	Annex VII	31335	12143
X836-025	TSR3 DRIVER SHORT 120MM	January 2004	Rule 6	Annex VII	33968	13517
X836-027	MODIFIED 3D DRIVER SLEEVE	January 2004	Rule 6	Annex VII	33968	13517
X8361005	MODIFIED CYLINDRICAL AWL	January 2004	Rule 6	Annex VII	15275	12143
X8370030	3.0CM X 5.5 BENT ROD TEMPLATE	December 2004	Rule 6	Annex VII	46479	13180
X8370050	5.0CM X 5.5 BENT ROD TEMPLATE	December 2004	Rule 6	Annex VII	46479	13180
X8370060	6.0CM X 5.5 BENT ROD TEMPLATE	December 2004	Rule 6	Annex VII	46479	13180
X8370070	7.0CM X 5.5 BENT ROD TEMPLATE	December 2004	Rule 6	Annex VII	46479	13180
X8370080	8.0CM X 5.5 BENT ROD TEMPLATE	December 2004	Rule 6	Annex VII	46479	13180
X8370090	9.0CM X 5.5 BENT ROD TEMPLATE	December 2004	Rule 6	Annex VII	46479	13180
X8370100	10.0CM X 5.5 BENT ROD TEMPLATE	December 2004	Rule 6	Annex VII	46479	13180
X84693E	PLUG STARTER W/ BALL HANDLE	October 2001	Rule 6	Annex VII	32865	13517
X84701	STAGNARA GOUGE, 16MM	February 2003	Rule 6	Annex VII	35090	12143
X84702	STAGNARA GOUGE, 20MM	February 2003	Rule 6	Annex VII	35090	12143
X848-969	9MM ECLIPSE SHAVER	August 2002	Rule 6	Annex VII	35720	12143
X848-970	10MM ECLIPSE SHAVER	August 2002	Rule 6	Annex VII	35720	12143
X8616010	PEN FORCEPS HOOK HOLDER	October 2001	Rule 6	Annex VII	47807	12143
X8616013	STAPLE IMPACTOR	October 2001	Rule 6	Annex VII	61325	12143
X8680052	CANN M8 MAS SCREWDRIVER	June 2002	Rule 6	Annex VII	61325	12143
X8680060	M8 MULTI AXIAL HEAD POSITIONER	March 2002	Rule 6	Annex VII	61325	12143

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P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANC E PATHWAY	GMDN	UMDNS
X8750251	1MM KERRISON	September 2004	Rule 6	Annex VII	31335	13180
X8750252	2MM KERRISON	September 2004	Rule 6	Annex VII	31335	13180
X8750253	3MM KERRISON	September 2004	Rule 6	Annex VII	31335	13180
X8750254	4MM KERRISON	September 2004	Rule 6	Annex VII	31335	13180
X8750255	5MM KERRISON	September 2004	Rule 6	Annex VII	31335	13180
X8750265	MICRO PITUITARY W/ 1MM TOOTH	April 2005	Rule 6	Annex VII	15800	12143
X8750266	2MM Micropituitary	April 2005	Rule 6	Annex VII	15800	12143
X8750267	3 X 10MM PITUITARY	April 2005	Rule 6	Annex VII	15800	12143
X8750268	3 X 10MM UPBITE PITUITARY	April 2005	Rule 6	Annex VII	15800	12143
X8750415	TL BLADE-LONG-14X15	March 2003	Rule 6	Annex VII	46774	15558
X875-082	EXT MULTILEVEL DISTRACT, RIGHT	November 2002	Rule 6	Annex VII	47870	12143
X875-083	EXT MULTILEVEL DISTRACT, LEFT	November 2002	Rule 6	Annex VII	47870	12143
X896510	10MM DISTRACTOR HEAD	October 2005	Rule 6	Annex VII	44378	11291
X9000431	14/8 WORKING CHANNEL NO SPIKES	May 2003	Rule 6	Annex VII	61325	12143
X9000531	14/8 WORKING CHANNEL ONE TANG	May 2003	Rule 6	Annex VII	61325	12143
X9181920	MOD ANTERIOR DISC SPREADER	April 2005	Rule 6	Annex VII	15800	12143
X9560571	MX BIPOLAR FORCEP-ANG25-NOLCK	June 2003	Rule 6	Annex VII	61325	12143
X9560572	MX BIPOLAR FORCEP-STR-NOLCK	June 2003	Rule 6	Annex VII	61325	12143
X9680060	M10 MLTI AXIAL HEAD POSITIONER	March 2002	Rule 6	Annex VII	61325	12143
X99912110	DRIVER X99912110 PRIMARY	April 2009	Rule 6	Annex VII	33968	13517
X99912112	COUNTER TORQUE X99912112	April 2009	Rule 6	Annex VII	13180	13180
X99912121	PUSHER X99912121 PLATE	April 2009	Rule 6	Annex VII	13180	13180
X99912122	AWL X99912122	April 2009	Rule 6	Annex VII	15275	12143
XC803406	FINAL PLUG DRIVER	January 2003	Rule 6	Annex VII	33968	13517
XIB0403019	DEEP STAKE RETRACTOR	July 2003	Rule 6	Annex VII	45182	12143
XIB0403020	DRIVER SHAFT	July 2003	Rule 6	Annex VII	33968	13517
XIB0403021	TAPERED STAKE	July 2003	Rule 6	Annex VII	13180	13180
XIB0403022	STRAIGHT STAKE	July 2003	Rule 6	Annex VII	13180	13180
XIB0403023	SLAP HAMMER	July 2003	Rule 6	Annex VII	32856	12143
XIB0603038	PYX OSTEOTOME-STR-SHT 101MM	July 2003	Rule 6	Annex VII	12844	12845
XIB0603039	PYX OSTEOTOME-ANG-SHT 101MM	July 2003	Rule 6	Annex VII	12844	12845
XIB0603040	PYX SER CUP CURET-STR-DWN	July 2003	Rule 6	Annex VII	31335	12143
5480132	TWISTED T25 PROVISIONAL DRIVER	October 2009	Rule 6	Annex VII	32865	13517
5480165V	COMPRESSOR PLIERS SMALL 5.5	February 2008	Rule 6	Annex VII	47870	13180
5484900	ROD ENTRY POINT ESTIMATOR	February 2014	Rule 6	Annex VII	13180	13180
5484901	MAST DEF 4.75 RMAS DRIVER	February 2013	Rule 6	Annex VII	33968	13517
5484904	6.0 INSITU BENDER (LEFT) [20/45]	February 2013	Rule 6	Annex VII	44795	15884
5484907	DISTRACTOR	February 2013	Rule 6	Annex VII	47554	13180
5485904	5.5/6.0 Lateral Rod Reducer	July 2012	Rule 6	Annex VII	44804	13180
5485905	Hex Driver	July 2012	Rule 6	Annex VII	32865	13517
5613040	30-40mm Non-Expandable Template 6.0 PEEK	September 2014	Rule 6	Annex VII	46479	13180
5613545	35-45mm Non-Expandable Template 6.0 PEEK	September 2014	Rule 6	Annex VII	46479	13180
5614560	45-60mm Non-Expandable Template 6.0 PEEK	September 2014	Rule 6	Annex VII	46479	13180

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5616090	60-90mm Non-Expandable Template 6.0 PEEK	September 2014	Rule 6	Annex VII	46479	13180
7050031	SCREW GAUGE MAS	January 2011	Rule 1	Annex VII	12143	12143
7050032	SCREW GAUGE FAS	January 2011	Rule 1	Annex VII	12143	12143
7480100	DUAL ENDED FEELER	April 2003	Rule 6	Annex VII	13180	13180
7480105	ROUND AWL	April 2003	Rule 6	Annex VII	15275	12143
7480106	SQUARE AWL	April 2003	Rule 6	Annex VII	15275	12143
7480112	THORACIC PROBE	July 2003	Rule 6	Annex VII	13180	13180
7480116	MAS SCREWDRIVER - T BASIC	April 2003	Rule 6	Annex VII	33968	13517
7480117	MAS SCREWDRIVER - T	April 2003	Rule 6	Annex VII	33968	13517
7480126	ROD INSERTER	April 2003	Rule 6	Annex VII	33968	13517
7480175	ROD GRIPPER	September 2003	Rule 6	Annex VII	61325	12143
7480205	DUAL PURPOSE SCREWDRIVER	April 2003	Rule 6	Annex VII	33968	13517
7480211	TRAD LATERAL IMPLANT HOLDER	May 2003	Rule 6	Annex VII	47807	12143
7480216	TRAD STRAIGHT IMPLANT HOLDER	May 2003	Rule 6	Annex VII	47807	12143
7480217	SELF RETAINING HOOK PUSHER	August 2003	Rule 6	Annex VII	47870	12143
7480220	WIDE LAMINAR ELEVATOR	April 2003	Rule 6	Annex VII	61325	12143
7480225	PEDICLE FINDER	April 2003	Rule 6	Annex VII	61325	12143
7480230	HOOK PUSHER FOR DUAL PURPOSE	April 2003	Rule 6	Annex VII	47870	12143
7480231	HOOK PUSHER FOR IMPLANT HOLDER	April 2003	Rule 6	Annex VII	47807	12143
7480235	ROD PUSHER	April 2003	Rule 6	Annex VII	47554	13180
7480255	INSITU BENDER-LEFT	April 2003	Rule 6	Annex VII	61325	12143
7480260	INSITU BENDER-RIGHT	April 2003	Rule 6	Annex VII	61325	12143
7480265	CORONAL PLANE BENDER-LEFT	April 2003	Rule 6	Annex VII	61325	12143
7480285	ROD ROTATION WRENCH	April 2003	Rule 6	Annex VII	32871	15766
7480305	THREADED, BREAK-OFF	September 2003	Rule 6	Annex VII	61325	12143
7480315	SACRAL PLATE HOLDER	September 2003	Rule 6	Annex VII	47807	12143
7480320	DRIVER - NUT REMOVAL	October 2003	Rule 6	Annex VII	61325	12143
7480325	PROVISIONAL DRIVER, 8MM HEX	September 2003	Rule 6	Annex VII	61325	12143
7480480	SSR THREADED PUSHER	June 2011	Rule 6	Annex VII	44804	13180
7480481	SSR SCREW EXTENDER 5.5	June 2011	Rule 6	Annex VII	44804	13180
7480482	SSR REDUCTION SLEEVE 5.5	June 2011	Rule 6	Annex VII	47831	13180
7480483	SSR ALIGNMENT TOOL	June 2011	Rule 6	Annex VII	13180	13180
7480484	SSR RELEASE FORK	June 2011	Rule 6	Annex VII	13180	13180
7480490	THREADED PUSHER	February 2011	Rule 6	Annex VII	44804	13180
7480491	ROD CAPTURE 5.5	February 2011	Rule 6	Annex VII	44804	13180
7480492	PUSHER HEAD 5.5	February 2011	Rule 6	Annex VII	44804	13180
7480493	MANIPULATOR	February 2011	Rule 6	Annex VII	13180	13180
7480494	SETSCREW LOADER 5.5	February 2011	Rule 6	Annex VII	13180	13180
7480495	DRIVER HEX 5	February 2011	Rule 6	Annex VII	33968	16868
7480496	THIN DRIVER T27	February 2011	Rule 6	Annex VII	33968	16868
7480497	VCM LINK	February 2011	Rule 6	Annex VII	13180	13180
7480900	0 DEG ILIO SACRAL SCREWDRIVER	February 2004	Rule 6	Annex VII	33968	13517
7480910	10 DEG ILIO SACRAL SCREWDRIVER	February 2004	Rule 6	Annex VII	33968	13517
7480920	20 DEG ILIO SACRAL SCREWDRIVER	February 2004	Rule 6	Annex VII	33968	13517
7578003	COMPRESSOR 9CM	February 2013	Rule 6	Annex VII	47554	13180
84674H	REMOVAL SCREWDRIVER T20/T25	June 2001	Rule 6	Annex VII	33968	12143

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848-915	LOEMAN-STYLE ROD HOLDER	April 2005	Rule 6	Annex VII	47807	12143
848-916	4.5MM ROD HOLDER	July 2003	Rule 6	Annex VII	61325	12143
848-931	TUBE INTRODUCER	April 2005	Rule 6	Annex VII	47807	12143
848-940	MEASURING CABLE	April 2005	Rule 6	Annex VII	61325	12143
848-946	T-HANDLE CLEANER	April 2005	Rule 6	Annex VII	61325	12143
848-957	ECLIPSE ROD REDUCER	November 2002	Rule 6	Annex VII	44804	12143
848-958	SCREW COMPRESSION CABLE	September 2000	Rule 6	Annex VII	61325	12143
848-959	CABLE COMPRESSOR	September 2000	Rule 6	Annex VII	61325	12143
9166010	LAMINAR ELEVATOR	November 2001	Rule 6	Annex VII	61325	12143
9166050	STRAIGHT IMPLANT HOLDER	February 2002	Rule 6	Annex VII	61325	12143
9166060	LATERAL IMPLANT HOLDER	February 2002	Rule 6	Annex VII	61325	12143
9166080	DUAL PURPOSE SCREWDRIVER	February 2002	Rule 6	Annex VII	32865	13517
9166130	PLUG DRIVER	February 2002	Rule 6	Annex VII	33968	13517
9166140	COUNTER TORQUE	February 2002	Rule 6	Annex VII	61325	12143
X0502013	THREADED AWL W/ QUICK CONNECT	August 2002	Rule 6	Annex VII	15275	12143
848-924	M8 QC SCRWDVR SHFT 4.5MM HEAD	August 2002	Rule 6	Annex VII	33968	12143
897-425	CONNECTOR SET SCREW	August 2003	Rule 6	Annex VII	61325	12143
8691010	Rod Rotation Wrench, Anterior	April 2001	Rule 6	Annex VII	32871	15766
897-422	FRAME L 150MM X 250MM	August 2003	Rule 6	Annex VII	45200	12143
X0404058	STRAIGHT 16+3 HOUSING	September 2004	Rule 6	Annex VII	61325	12143
X0404059	STRAIGHT 16+3 CHISEL GUIDE	September 2004	Rule 6	Annex VII	61325	12143
X0404060	HOUSING IMPACTOR	September 2004	Rule 6	Annex VII	32856	12143
7005776	LOCK NUT DRIVER SHAFT TRI-FLAT	September 2004	Rule 6	Annex VII	13180	13180
X0704710	VER DRILL BIT-CANC-10MM	September 2004	Rule 6	Annex VII	44491	12143
X0704712	VER DRILL BIT-CANC-12MM	September 2004	Rule 6	Annex VII	44491	12143
X0301019	Zephir Awl	September 2001	Rule 6	Annex VII	15275	12143
X0104027	MODULAR STEP DRILL 15MM	March 2004	Rule 6	Annex VII	36545	12143
X0403014	PRE COMPRESSOR-CRANK FRAME	May 2003	Rule 6	Annex VII	47870	12143
9098010	Guide Tube - Open	April 2001	Rule 6	Annex VII	61325	12143
9098020	Trocar	April 2001	Rule 6	Annex VII	47457	14154
9098030	Awl	April 2001	Rule 6	Annex VII	15275	12143
9098060	Hex Driver, Captive Twist	April 2001	Rule 6	Annex VII	33968	13517
9098100	Guide Handle	April 2001	Rule 6	Annex VII	13180	13180
9098110	Gear Driver	April 2001	Rule 6	Annex VII	33968	13517
9098130	FREE HAND ATTACHMENT	August 2001	Rule 6	Annex VII	33968	13517
X0505002	UNION CC TRIAL 6 X 0° X 30MM	July 2004	Rule 6	Annex VII	44759	12143
X0505003	UNION CC TRIAL 6 X 3° X 30MM	July 2004	Rule 6	Annex VII	44759	12143
X0505004	UNION CC TRIAL 6 X 8° X 30MM	July 2004	Rule 6	Annex VII	44759	12143
X0505005	UNION CC TRIAL 8 X 3° X 30MM	July 2004	Rule 6	Annex VII	44759	12143
X0505006	UNION CC TRIAL 8 X 8° X 30MM	July 2004	Rule 6	Annex VII	44759	12143
9339000	STAPLE IMPCTR/DRILL GDE, ATL	January 2003	Rule 6	Annex VII	61325	12143
9339001	STAPLE IMPCTR/DRILL GDE, THRC	January 2003	Rule 6	Annex VII	61325	12143
9339005	PLATE PERSUADER/COUNTER TORQUE	January 2003	Rule 6	Annex VII	61325	12143
9339010	MODULAR DRILL HANDLE	January 2003	Rule 6	Annex VII	61325	12143
9339012	QUICK CONNECT EGG HANDLE, BLUE	June 2003	Rule 6	Annex VII	13180	13180
9339021	FIXED DRILL	January 2003	Rule 6	Annex VII	61325	12143
9339022	4.8MM FIXED DRILL	August 2003	Rule 6	Annex VII	61325	12143

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9339031	9/64 IN HEX DRIVER, QC	January 2003	Rule 6	Annex VII	33968	16868
9339040	COUNTER TORQUE WRENCH	January 2003	Rule 6	Annex VII	32871	12143
9339041	TORQUE LIMITING NUT DRIVER	January 2003	Rule 6	Annex VII	33968	12143
9339042	TORQUE LIMITING DRIVER	June 2003	Rule 6	Annex VII	33968	13517
9339060	MODULAR DISTRACOR RACK	June 2003	Rule 1	Annex VII	12143	12143
9339061	MODULAR DISTRACOR SHAFT	June 2003	Rule 6	Annex VII	47870	12143
9339085	RACK DISTRACOR	January 2003	Rule 6	Annex VII	56637	11291
9339094	PARALLEL COMPRESSOR, TI	June 2003	Rule 6	Annex VII	15800	12143
9339096	AWL, QUICK CONNECT	January 2003	Rule 6	Annex VII	15275	12143
X0904207	5.0MM CANNULATED BONE DRILL	February 2005	Rule 6	Annex VII	61325	12143
1858711	CDHL ANTERIOR SCREW GAUGE	October 2006	Rule 6	Annex VII	13180	13180
8350293	LUMBAR PROBE	February 2011	Rule 6	Annex VII	13180	13180
8350294	THORACIC PROBE	February 2011	Rule 6	Annex VII	13180	13180
7486282	I/G FIXED SCREWDRIVER, L6.35	December 2004	Rule 6	Annex VII	32865	13517
836-119	3.2 HEX DRIVER, EXTENDED POST	September 2001	Rule 6	Annex VII	32865	13517
8361027	SCREW REMOVAL DRIVER	February 2003	Rule 6	Annex VII	32865	13517
8361028	SCREW REMOVAL SLEEVE	February 2003	Rule 6	Annex VII	32865	13517
8572030	3.75mm IGS SOLID TAP - BLACK BAND	November 2002	Rule 6	Annex VII	17507	17507
8572031	4.0mm IGS SOLID TAP - GRAY BAND	November 2002	Rule 6	Annex VII	17507	17507
8572032	4.5mm IGS SOLID TAP - MAGENTA BAND	November 2002	Rule 6	Annex VII	17507	17507
8572033	5.0mm IGS SOLID TAP - SF GREEN BAND	November 2002	Rule 6	Annex VII	17507	17507
8572034	5.5mm IGS SOLID TAP - GREEN BAND	November 2002	Rule 6	Annex VII	17507	17507
8572035	6.0mm IGS SOLID TAP - GRAY BAND	November 2002	Rule 6	Annex VII	17507	17507
8572036	6.5mm IGS SOLID TAP - BLUE BAND	November 2002	Rule 6	Annex VII	17507	17507
8572037	7.5MM SOLID TAP - GOLD BAND	November 2002	Rule 6	Annex VII	17507	17507
8572041	4.0mm IGS CANN TAP - GRAY BAND	November 2002	Rule 6	Annex VII	17507	17507
8572042	4.5mm IGS CANN TAP - MAGENTA BAND	November 2002	Rule 6	Annex VII	17507	17507
8572043	5.0mm IGS CANN TAP - SF GREEN BAND	November 2002	Rule 6	Annex VII	17507	17507
8572044	5.5mm IGS CANN TAP - GREEN BAND	November 2002	Rule 6	Annex VII	17507	17507
8572045	6.0mm IGS CANN TAP - GRAY BAND	November 2002	Rule 6	Annex VII	17507	17507
8572046	6.5mm IGS CANN TAP - BLUE BAND	November 2002	Rule 6	Annex VII	17507	17507
8572047	7.5MM CANN. TAP - GOLD BAND	November 2002	Rule 6	Annex VII	17507	17507
858-959	M8 FIXED IGS DRIVER	April 2001	Rule 6	Annex VII	32865	13517
8670045	4.5MM DIA SEXTANT TAP	November 2001	Rule 6	Annex VII	17507	17507
8670055	5.5MM DIA SEXTANT TAP	November 2001	Rule 6	Annex VII	17507	17507
8670065	6.5MM DIA SEXTANT TAP	November 2001	Rule 6	Annex VII	17507	17507
8670085	4.5MM-5.5MM SELF DRILLING TAP	January 2002	Rule 6	Annex VII	17507	17507
8670087	5.5-6.5 SELF DRILLING TAP	June 2005	Rule 6	Annex VII	17507	17507
8674000	4.0MM CANNULATED TAP	March 2007	Rule 6	Annex VII	17507	17507
8680059	M8 IGS MAS DRIVER	May 2002	Rule 6	Annex VII	32865	13517
8682059	M8 IGS RMAS DRIVER	December 2002	Rule 6	Annex VII	32865	13517
8684509	4.5mm IGS SOLID TAP	September 2001	Rule 6	Annex VII	17507	17507
8685509	5.5mm IGS SOLID TAP	September 2001	Rule 6	Annex VII	17507	17507
8686509	6.5mm IGS SOLID TAP	September 2001	Rule 6	Annex VII	17507	17507
8687509	7.5mm IGS SOLID TAP	September 2001	Rule 6	Annex VII	17507	17507
5580120	Extender Adapter *	September 2016	Rule 6	Annex VII	56637	13180
5580111	Distractor Rack L *	September 2016	Rule 6	Annex VII	56637	11291

Product List
Last updated by: Fernand Terradas
Tech File Bundle: TL Stabilization

Date: 2/4/2019

Product: General Instruments
Class: I

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANC E PATHWAY	GMDN	UMDNS
5580112	Distractor Pinion L *	September 2016	Rule 6	Annex VII	56637	11291
5580113	Distractor Key L *	September 2016	Rule 6	Annex VII	56637	11291
5580114	Distractor Nut L *	September 2016	Rule 6	Annex VII	13180	13180
5580115	Lordosis Ratchet *	September 2016	Rule 6	Annex VII	56637	13180
5580116	Lordosis Rack *	September 2016	Rule 6	Annex VII	56637	13180
5580135	Setscrew Driver T27 *	September 2016	Rule 6	Annex VII	33968	16868
5580101	Distractor Rack *	September 2016	Rule 6	Annex VII	56637	11291
5580102	Distractor Pinion *	September 2016	Rule 6	Annex VII	56637	11291
5580103	Distractor Key *	September 2016	Rule 6	Annex VII	56637	11291
5580104	Distractor Nut *	September 2016	Rule 6	Annex VII	13180	13180
5580130	Extender Open *	September 2016	Rule 6	Annex VII	56637	13180
5580133	Rod Persuader *	September 2016	Rule 6	Annex VII	44804	13180
5580134	Rod Reducer *	September 2016	Rule 6	Annex VII	44804	13180
5580131	Extender Guide *	September 2016	Rule 6	Annex VII	13180	13180
5580132	Crossing Block *	September 2016	Rule 6	Annex VII	13180	13180
5580121	Adapter Template *	September 2016	Rule 6	Annex VII	35315	13386
5584184	FAS-SAS 5.5 SCREW ADAPTER°	December 2016	Rule 6	Annex VII	33968	13517
5580144	BREAKOFF NUT DRIVER°	December 2016	Rule 6	Annex VII	32865	13180
5580145	RETAINER SHAFT°	December 2016	Rule 6	Annex VII	32865	13180
5584182	4.75-5.5/6.0 MAS SHAFT°	December 2016	Rule 6	Annex VII	33968	13517
5584183	FAS/SAS SHAFT°	December 2016	Rule 6	Annex VII	33968	13517
5584250	QC 5.5/6.0 COUNTERTORQUE°	December 2016	Rule 6	Annex VII	47554	13180
5584780	5.5 MAS HEX SHAFT°	December 2016	Rule 6	Annex VII	33968	13517
5484250	QC 4.75 COUNTERTORQUE°	December 2016	Rule 6	Annex VII	47554	13180
5484184	FAS 4.75 SCREW ADAPTER°	December 2016	Rule 6	Annex VII	33968	13517
5584180	5.5/6.0 LOCK SLEEVE°	December 2016	Rule 6	Annex VII	33968	13517
5484180	4.75 LOCK SLEEVE°	December 2016	Rule 6	Annex VII	33968	13517
9564000	Retractor Forceps - Upward#	February 2019	Rule 6	Annex VII	45181	13180
9564001	Retractor Forceps - Downward#	February 2019	Rule 6	Annex VII	45181	13180
9564002	Retractor Key#	February 2019	Rule 6	Annex VII	45181	13180
9564005	Blade Holder#	February 2019	Rule 6	Annex VII	45181	13180
9564006	Endoscope Holder 16#	February 2019	Rule 6	Annex VII	45181	13180
9564008	Endoscope Holder 18#	February 2019	Rule 6	Annex VII	45181	13180
9564010	One-step Dilator#	February 2019	Rule 6	Annex VII	45181	13180
9564030	Micro Dilator#	February 2019	Rule 6	Annex VII	45181	13180
9564034	Blade Quarter Tube 40 Ti #	February 2019	Rule 6	Annex VII	45181	13180
9564035	Blade Quarter Tube 50 Ti #	February 2019	Rule 6	Annex VII	45181	13180
9564036	Blade Quarter Tube 60 Ti #	February 2019	Rule 6	Annex VII	45181	13180
9564037	Blade Quarter Tube 70 Ti #	February 2019	Rule 6	Annex VII	45181	13180
9564038	Blade Quarter Tube 80 Ti #	February 2019	Rule 6	Annex VII	45181	13180
9564039	Blade Quarter Tube 90 Ti #	February 2019	Rule 6	Annex VII	45181	13180
9564040	Micro Dilator Small #	February 2019	Rule 6	Annex VII	45181	13180
9564044	Blade Quarter Tube S 40 Ti #	February 2019	Rule 6	Annex VII	45181	13180
9564045	Blade Quarter Tube S 50 Ti #	February 2019	Rule 6	Annex VII	45181	13180
9564046	Blade Quarter Tube S 60 Ti #	February 2019	Rule 6	Annex VII	45181	13180
9564047	Blade Quarter Tube S 70 Ti #	February 2019	Rule 6	Annex VII	45181	13180
9564048	Blade Quarter Tube S 80 Ti #	February 2019	Rule 6	Annex VII	45181	13180

Product List

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Product: General Instruments						
Class: I						
P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANC E PATHWAY	GMDN	UMDNS
9564049	Blade Quarter Tube S 90 Ti #	February 2019	Rule 6	Annex VII	45181	13180
5580150	Sleeve 4.75 - type A §	February 2019	Rule 6	Annex VII	56637	11291
5580151	Sleeve 4.75 - type B §	February 2019	Rule 6	Annex VII	56637	11291
5580152	Inner Guide 4.75 §	February 2019	Rule 6	Annex VII	13180	13180
5580153	CounterTorque 4.75 §	February 2019	Rule 6	Annex VII	47554	13180
5580154	Rod curve template 4.75 §	February 2019	Rule 6	Annex VII	46479	13180
5580160	Sleeve 5.5/6.0 - type A §	February 2019	Rule 6	Annex VII	56637	11291
5580161	Sleeve 5.5/6.0 - type B §	February 2019	Rule 6	Annex VII	56637	11291
5580162	Inner Guide 5.5/6.0 §	February 2019	Rule 6	Annex VII	13180	13180
5580163	CounterTorque 5.5/6.0 §	February 2019	Rule 6	Annex VII	47554	13180
5580164	Rod curve template 5.5/6.0 §	February 2019	Rule 6	Annex VII	46479	13180
* Items are part of NFORCE™ Instruments/° items are part of the Procedural Degenerative Kit Instruments/# Items are part of						
Navigated SOLERA® Complete						
NAV2001K	TAP NAV2001K SOLERA AWLTIPTAP 4.0MM	November 2015	Rule 6	Annex VII	17507	17507
NAV2002K	TAP NAV2002K SOLERA AWLTIPTAP 4.5MM	November 2015	Rule 6	Annex VII	17507	17507
NAV2003K	TAP NAV2003K SOLERA AWLTIPTAP 5MM	November 2015	Rule 6	Annex VII	17507	17507
NAV2004K	TAP NAV2004K SOLERA AWLTIPTAP 5.5MM	November 2015	Rule 6	Annex VII	17507	17507
NAV2005K	TAP NAV2005K SOLERA AWLTIPTAP 6MM	November 2015	Rule 6	Annex VII	17507	17507
NAV2006K	TAP NAV2006K SOLERA AWLTIPTAP 6.5MM	November 2015	Rule 6	Annex VII	17507	17507
NAV2007K	TAP NAV2007K SOLERA AWLTIPTAP 7MM	November 2015	Rule 6	Annex VII	17507	17507
NAV2008K	TAP NAV2008K SOLERA AWLTIPTAP 7.5MM	November 2015	Rule 6	Annex VII	17507	17507
NAV2009K	TAP NAV2009K SOLERA AWLTIPTAP 8MM	November 2015	Rule 6	Annex VII	17507	17507
NAV2010K	TAP NAV2010K SOLERA AWLTIPTAP 8.5MM	November 2015	Rule 6	Annex VII	17507	17507
NAV2011K	TAP NAV2011K SOLERA AWLTIPTAP 9MM	November 2015	Rule 6	Annex VII	17507	17507
NAV2012K	TAP NAV2012K SOLERA AWLTIPTAP 9.5MM	November 2015	Rule 6	Annex VII	17507	17507
NAV2013K	TAP NAV2013K SOLERA AWLTIPTAP 10MM	November 2015	Rule 6	Annex VII	17507	17507
NAV2014K	TAP NAV2014K SOLERA AWLTIPTAP 10.5MM	November 2015	Rule 6	Annex VII	17507	17507
NAV2015K	TAP NAV2015K SOLERA AWLTIPTAP 4.5-5.5MM	November 2015	Rule 6	Annex VII	17507	17507
NAV2016K	TAP NAV2016K SOLERA AWLTIPTAP 5.5-6.5MMK	November 2015	Rule 6	Annex VII	17507	17507
NAV2017K	DILATOR NAV2017K SOLERA AWLTIPTAP SMALL	November 2015	Rule 6	Annex VII	13180	11254
NAV2018K	DILATOR NAV2018K SOLERA AWLTIPTAP LARGE	November 2015	Rule 6	Annex VII	13180	11254
NAV2019K	DRIVER NAV2019K SOLERA 5.5/6 MAS LG	November 2015	Rule 6	Annex VII	33968	16868
NAV2020K	DRIVER NAV2020K SOLERA 5.5/6 MAS LG2	November 2015	Rule 6	Annex VII	33968	16868
NAV2021K	DRIVER NAV2021K SOLERA 5.5/6 FAS/SAS LG	November 2015	Rule 6	Annex VII	33968	16868
NAV2022K	DRIVER NAV2022K SOLERA 5.5/6 FAS/SAS LG2	November 2015	Rule 6	Annex VII	33968	16868
NAV2023K	DRIVER NAV2023K SOLERA 4.75 MAS LG2	November 2015	Rule 6	Annex VII	33968	16868
NAV2024K	DRIVER NAV2024K SOLERA 4.75 STANDARD MAS	November 2015	Rule 6	Annex VII	33968	16868
NAV2025K	DRIVER NAV2025K SOLERA 4.75 REDUCT MAS	November 2015	Rule 6	Annex VII	33968	16868
CDH SOLERA® VOYAGER™ Instruments						
6640004	DRIVER 6640004 4.75 BALL-ENDED DRIVER	June 2015	Rule 6	Annex VII	44759	13517

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Product: General Instruments						
Class: I						
P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANC E PATHWAY	GMDN	UMDNS
6640005	DRIVER 6640005 4.75 NON-RETAINING DRIVER	June 2015	Rule 6	Annex VII	44759	13517
6640008	DRIVER 6640008 4.75 SCREWDRIVER	June 2015	Rule 6	Annex VII	44759	13517
6642000	COMPRESSOR 6642000 COMPR/DISTR A	June 2015	Rule 6	Annex VII	47870	13180
6642001	COMPRESSOR 6642001 COMPR/DISTR B	June 2015	Rule 6	Annex VII	47870	13180
6642002	DRIVER 6642002 4.75 SET SCRW RETAINING	June 2015	Rule 6	Annex VII	44759	13517
6642004	COUNTERTORQUE 6642004 COUNTERTORQUE	June 2015	Rule 6	Annex VII	47554	13180
6642006	CAP 6642006 TAB EXTENDER CAP	June 2015	Rule 6	Annex VII	47831	13180
6642007	EXTENDER 6642007 TAB EXTENDER	June 2015	Rule 6	Annex VII	47831	13180
6642008	PUSHER 6642008 ROD PUSHER	June 2015	Rule 6	Annex VII	47554	13180
6642009	GRIPPER 6642009 ROD GRIPPER	June 2015	Rule 6	Annex VII	47807	13180
6642010	TOOL 6642010 ROD CONFIRMATION TOOL	June 2015	Rule 6	Annex VII	13180	13180
6642011	TEMPLATE 6642011 ROD TEMPLATE	June 2015	Rule 6	Annex VII	46479	13180
6642012	TOOL 6642012 TAB REMOVAL TOOL	June 2015	Rule 6	Annex VII	13180	13180
6642013	TOOL 6642013 TAB BREAKOFF TOOL	June 2015	Rule 6	Annex VII	13180	13180
6642014	DILATOR 6642014 ONE-STEP INNER	June 2015	Rule 6	Annex VII	35315	13180
6642016	One-Step Large Outer Dilator	June 2015	Rule 6	Annex VII	35315	13180
6642015	DILATOR 6642015 ONE-STEP SMALL OUTER	June 2015	Rule 6	Annex VII	35315	13180
6642017	COMPRESSOR PLIERS COMPRESSOR	June 2015	Rule 6	Annex VII	47870	13180
NAV6640009	DRIVER NAV6640009 4.75 NAV AND POWER	June 2015	Rule 6	Annex VII	38723	13180
6550000	TAP SLEEVE	Feburary 2018	Rule 6	Annex VII	35315	12143
6550003	T25 NON-RETAINING DRIVER Ø5.5/6.0	Feburary 2018	Rule 6	Annex VII	44759	12143
6550004	T25 BALL-ENDED DRIVER Ø5.5/6.0	Feburary 2018	Rule 6	Annex VII	44759	12143
6550006	Ø5.5/6.0 SV SET SCREW DRIVER	Feburary 2018	Rule 6	Annex VII	44759	12143
6550007	Ø5.5/6.0 COMPRESSOR/DISTRATOR A	Feburary 2018	Rule 6	Annex VII	47870	12143
6550008	Ø5.5/6.0 COMPRESSOR/DISTRATOR B	Feburary 2018	Rule 6	Annex VII	47870	12143

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Date: 2/4/2019

Product: General Instruments						
Class: I						
P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANC E PATHWAY	GMDN	UMDNS
6550009	Ø5.5/6.0 PLIER COMPRESSOR	Feburary 2018	Rule 6	Annex VII	47870	12143
6550011	Ø5.5/6.0 RACK COMPRESSOR/DISTRACTOR	Feburary 2018	Rule 6	Annex VII	47870	12143
6550013	Rod Template 5.5	Feburary 2018	Rule 6	Annex VII	46479	13180
6550014	ROD GRIPPER 5.5 mm	Feburary 2018	Rule 6	Annex VII	47807	13180
6550016	Ø5.5/6.0 CAP	Feburary 2018	Rule 6	Annex VII	47831	12143
6550017	Ø5.5/6.0 TAB EXTENDER	Feburary 2018	Rule 6	Annex VII	47831	12143
6550019	TAB BREAKER 5.5	Feburary 2018	Rule 6	Annex VII	13180	13180
6550020	BREAK-OFF REMOVAL TOOL 5.5/6.0	Feburary 2018	Rule 6	Annex VII	13180	13180
6550021	Ø5.5/6.0 REDUCER COUNTER TORQUE	Feburary 2018	Rule 6	Annex VII	47554	13180
6550022	Ø5.5/6.0 RING COUNTER TORQUE	Feburary 2018	Rule 6	Annex VII	47554	13180
6550027	Ø5.5/6.0 ROD REDUCER	Feburary 2018	Rule 6	Annex VII	44804	13180
6550031	NUT DRIVER Ø5.5/6.0	Feburary 2018	Rule 6	Annex VII	33968	13517
6550034	Ø5.5/6.0 REINFORCEMENT SLEEVE	Feburary 2018	Rule 6	Annex VII	44804	13180
6550035	Ø5.5/6.0 FULCRUM PLIERS	Feburary 2018	Rule 6	Annex VII	47870	12143
6550036	Ø5.5/6.0 SV FULCRUM	Feburary 2018	Rule 6	Annex VII	47870	12143
6550037	Ø5.5/6.0 COUNTER TORQUE	Feburary 2018	Rule 6	Annex VII	47554	13180
CD HORIZON® BALLAST Spinal System						
25010600	BIASED ANGLE POSITIONER	December 2016	Rule 6	Annex VII	44759	44759
25010800	COUNTERTORQUE	December 2016	Rule 6	Annex VII	47554	16046
25000200	PROBE, STRAIGHT	December 2016	Rule 6	Annex VII	13180	16046
25000300	PROBE, CURVED	December 2016	Rule 6	Annex VII	13180	16046
NAV0200	PROBE, NAV	December 2016	Rule 6	Annex VII	13180	16046
CD HORIZON® ESSENCE Spinal System						
4591000	MAS Driver	December 2016	Rule 6	Annex VII	33968	13517
TRANSLACE™ Spinal Tethering System						
8239000	Tensioner	June 2018	Rule 6	Annex VII	44801	16140
8239001	Tensioner T-Handle	June 2018	Rule 6	Annex VII	47829	12143
8239002	Counter Torque Handle	June 2018	Rule 6	Annex VII	47554	13180

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Product: Cases and Trays						
Class: I						
P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
CD Horizon Perc- Case and Trays						
11010907	CD HORIZON® Instrument Tray 1	July 2014	Rule 1	Annex VII	12143	12143
11010908	CD HORIZON® Instrument Tray 2	July 2014	Rule 1	Annex VII	12143	12143
1859100	Verifyi Tag Sorter	October 2009	Rule 1	Annex VII	12143	12143
1859101	Verifyi Tag Sorter Lid	October 2009	Rule 1	Annex VII	12143	12143
7574041	Ø4.75 Percutaneous Rod and Inserter Tray	July 2013	Rule 1	Annex VII	12143	12143
7574043	Ø5.5 Percutaneous Rod and Inserter Tray	July 2013	Rule 1	Annex VII	12143	12143
911B	BASE,CCD TI STANDARD	March 2000	Rule 1	Annex VII	12143	12143
X0209188	TRAY (BOTTOM), CSP DLIF IMPLANT	April 2009	Rule 1	Annex VII	12143	12143
X0209189	TRAY(TOP), CSP DLIF INSTRUMENT	April 2009	Rule 1	Annex VII	12143	12143
X0209190	CADDY, CSP DLIF PLATE AND NUT	April 2009	Rule 1	Annex VII	12143	12143
X0209191	LID, CSP DLIF PLATE AND NUT CADDY	April 2009	Rule 1	Annex VII	12143	12143
X105-150P	TRAY PLATE	April 2003	Rule 1	Annex VII	12143	12143
CD Horizon- Case and Trays						
9010001660	Percutaneous Inserter Tray	April 2014	Rule 1	Annex VII	12143	12143
CDH Antares- Case and Trays						
1858692	ANTARES INST TRAY #2	July 2001	Rule 1	Annex VII	12143	12143
1858693	ANTARES INST TRAY #3	July 2001	Rule 1	Annex VII	12143	12143
1858694	ANTARES IMPLANT TRAY	July 2001	Rule 1	Annex VII	12143	12143
1858694L	ANTARES IMPLANT TRAY LID	July 2001	Rule 1	Annex VII	12143	12143
1858695	ANTARES CROSSLINKS TRAY	July 2001	Rule 1	Annex VII	12143	12143
1858695L	ANTARES CROSSLINKS TRAY LID	July 2001	Rule 1	Annex VII	12143	12143
1858699	ANTARES SET SCREW CADDY	July 2001	Rule 1	Annex VII	12143	12143
1858699L	ANTARES SET SCREW CADDY LID	July 2001	Rule 1	Annex VII	12143	12143
CDH Crosslink- Case and Trays						
105-121	CASE L-BRACKET	March 2000	Rule 1	Annex VII	12143	12143
105-129	MODULE,5.5MM SS LP CROSSLINK	March 2000	Rule 1	Annex VII	12143	12143
105-130	MODULE,5.5MM SS LP CROSSLINK	March 2000	Rule 1	Annex VII	12143	12143
105-157	MODULE,MINI LP SET SCREW	March 2000	Rule 1	Annex VII	12143	12143
110-129	MODULE,1/4" LP CROSSLINK TI	March 2000	Rule 1	Annex VII	12143	12143
110-130	MODULE,1/4"LP CROSSLINK TI	March 2000	Rule 1	Annex VII	12143	12143
115-129	MODULE,5.5MM LP CROSSLINK TI	March 2000	Rule 1	Annex VII	12143	12143
115-130	MODULE,5.5MM LP CROSSLINK TI	March 2000	Rule 1	Annex VII	12143	12143
125-128	LID,LP CROSSLINK MODULE	March 2000	Rule 1	Annex VII	12143	12143
125-166	TRAY,LP CROSSLINK	March 2000	Rule 1	Annex VII	12143	12143
1858710	CDHL ANTERIOR CROSSLINK MODULE	October 2006	Rule 1	Annex VII	12143	12143
8104501	LEGACY 4.5 X10 CROSSLINK MODULE, SS	July 2006	Rule 1	Annex VII	12143	12143
8105501	X-10 CROSSLINK 5.5, SS MODULE	May 2003	Rule 1	Annex VII	12143	12143
8106401	X-10 CROSSLINK 6.35, SS MODULE	May 2003	Rule 1	Annex VII	12143	12143
8110111	LEGACY 4.5 X10 OUTER CASE, SS	July 2006	Rule 1	Annex VII	12143	12143
8110112	LEGACY 4.5 X10 OUTER CASE LID	July 2006	Rule 1	Annex VII	12143	12143
8110113	LEGACY 4.5 X10 INSTRUMENT TRAY	July 2006	Rule 1	Annex VII	12143	12143
8110114	LEGACY 4.5 X10 CROSSLINK MODULE LID, GEN	July 2006	Rule 1	Annex VII	12143	12143
8110115	LEGACY 4.5 X10 CROSSLINK MODULE LID, SS	July 2006	Rule 1	Annex VII	12143	12143
8111111	X-10 CROSSLINK OUTER BASE	May 2003	Rule 1	Annex VII	12143	12143
8111112	X-10 CROSSLINK OUTER BASE LID	May 2003	Rule 1	Annex VII	12143	12143
8111113	X-10 CROSSLINK INSTRUMENT TRAY	May 2003	Rule 1	Annex VII	12143	12143
8111114	IMPLANT MODULE UPPER LID	June 2003	Rule 1	Annex VII	12143	12143
8111115	IMPLANT MODULE LOWER LID	June 2003	Rule 1	Annex VII	12143	12143
8111141	LEGACY 4.5 X10 OUTER CASE, TI	July 2006	Rule 1	Annex VII	12143	12143
8111142	LEGACY 4.5 X10 CROSSLINK MODULE LID, TI	July 2006	Rule 1	Annex VII	12143	12143
8114401	LEGACY 4.5 X10 CROSSLINK MODULE, TI	July 2006	Rule 1	Annex VII	12143	12143
8115501	X-10 CROSSLINK 5.5, TI MODULE	May 2003	Rule 1	Annex VII	12143	12143

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Product: Cases and Trays

Class: I

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
8116401	X-10 CROSSLINK 6.35, TI MODULE	May 2003	Rule 1	Annex VII	12143	12143
7062300	4.75 PROLOCK CROSSLINK SYSTEM CASE LABEL	July 2016	Rule 1	Annex VII	12143	12143
7062303	5.5/6.0 PROLOCK CROSSLINK CASE LABEL	July 2016	Rule 1	Annex VII	12143	12143
7062302	PROLOCK INSTRUMENT TRAY	July 2016	Rule 1	Annex VII	12143	12143
7062301	PROLOCK IMPLANT TRAY	July 2016	Rule 1	Annex VII	12143	12143
7062305	4.75 IMPLANT MODULE	July 2016	Rule 1	Annex VII	12143	12143
7062306	4.75 IMPLANT MODULE LID	July 2016	Rule 1	Annex VII	12143	12143
7062307	5.5/6.0 IMPLANT MODULE	July 2016	Rule 1	Annex VII	12143	12143
7062308	5.5/6.0 IMPLANT MODULE LID	July 2016	Rule 1	Annex VII	12143	12143
7062304	LABEL-4.75 & 5.5/6.0 PROLOCK CROSSLINKS	July 2016	Rule 1	Annex VII	12143	12143
CDH Eclipse-Case and Trays						
8489001	CD HORIZON ECLIPSE SCREW PREP/INSERTION TRAY	March 2015	Rule 1	Annex VII	12143	12143
8489002	CD HORIZON ECLIPSE ROD REDUCTION/PLUG INTRODUCTION TRAY	March 2015	Rule 1	Annex VII	12143	12143
8489004	CD HORIZON ECLIPSE COMPRSSION/AUXILIARY INSTRUMENT TRAY	March 2015	Rule 1	Annex VII	12143	12143
8489012	CD HORIZON ECLIPSE TI SCREW TRAY LID	November 2014	Rule 1	Annex VII	12143	12143
8489014	CD HORIZON ECLIPSE TI SCREW TRAY	June 2011	Rule 1	Annex VII	12143	12143
8489015	SS REDUCED MINOR DIAM TRAY LID	December 2002	Rule 1	Annex VII	12143	12143
8489016	TI REDUCED MINOR DIAM TRAY LID	December 2002	Rule 1	Annex VII	12143	12143
8489017	SS REDUCED MINOR DIAM TRAY	December 2002	Rule 1	Annex VII	12143	12143
8489018	TI REDUCED MINOR DIAM TRAY	December 2002	Rule 1	Annex VII	12143	12143
8489019	M8 NON-BREAKOFF CADDY BASE	December 2002	Rule 1	Annex VII	12143	12143
8489020	M8 NON-BREAKOFF CADDY LID	December 2002	Rule 1	Annex VII	12143	12143
8489021	REDUCTION/COMPRESSION TRAY	December 2002	Rule 1	Annex VII	12143	12143
8489026	ECLIPSE TI IMPLANT TRAY,LID DH	March 2004	Rule 1	Annex VII	12143	12143
8489028	ECLIPSE TI IMPLANT TRAY DH	March 2004	Rule 1	Annex VII	12143	12143
8489034	ECLIPSE DH PORTAL TRAY	March 2004	Rule 1	Annex VII	12143	12143
8489038	ECLIPSE DH INSTRUMENT TRAY #1	March 2004	Rule 1	Annex VII	12143	12143
8489100	ECLIPSE BASE - TRIPLE	March 2004	Rule 1	Annex VII	12143	12143
8489102	ECLIPSE DH INSTR/PORTAL SET	March 2004	Rule 1	Annex VII	12143	12143
8489104	ECLIPSE BASE - DOUBLE OUTER	February 2004	Rule 1	Annex VII	12143	12143
8489106	ECLIPSE BASE - TRIPLE OUTER	February 2004	Rule 1	Annex VII	12143	12143
CDH Engage- Case and Trays						
9960500	ENGAGE GEN INST OUTER CASE 1	June 2005	Rule 1	Annex VII	12143	12143
9960500L	ENGAGE OUTER CASE LID	June 2005	Rule 1	Annex VII	12143	12143
9960501	ENGAGE GEN INST OUTER CASE 2	June 2005	Rule 1	Annex VII	12143	12143
9960505L	ENGAGE IMPLANT TRAY LID	June 2005	Rule 1	Annex VII	12143	12143
9960510L	CDH ENGAGE IMPLANT TRAY LID	November 2005	Rule 1	Annex VII	12143	12143
9960511	ENGAGE GENERAL INST TRAY 1	July 2005	Rule 1	Annex VII	12143	12143
9960512	ENGAGE GENERAL INST TRAY 2	July 2005	Rule 1	Annex VII	12143	12143
9960513	ENGAGE GENERAL INST TRAY 3	July 2005	Rule 1	Annex VII	12143	12143
9960514	ENGAGE GENERAL INST TRAY 4	July 2005	Rule 1	Annex VII	12143	12143
9960517	ENGAGE RBC INST OUTER CASE	June 2005	Rule 1	Annex VII	12143	12143
9960518	ENGAGE RBC INST TRAY 1	July 2005	Rule 1	Annex VII	12143	12143
9960519	ENGAGE RBC INST TRAY 2	July 2005	Rule 1	Annex VII	12143	12143
9960531L	ENGAGE CLOSED HOOK LID, GEN	July 2005	Rule 1	Annex VII	12143	12143
9960532L	ENGAGE OPEN HOOK LID, GEN	July 2005	Rule 1	Annex VII	12143	12143
9960535	ENGAGE HOOK INSTRUMENT TRAY	July 2005	Rule 1	Annex VII	12143	12143
9960580R	ENGAGE CLOSED SET SCREW MOD	July 2005	Rule 1	Annex VII	12143	12143
9960581	ENGAGE NUT SET SCREW MODULE	July 2005	Rule 1	Annex VII	12143	12143
9960582	ENGAGE WASHER SET SCREW MODULE	July 2005	Rule 1	Annex VII	12143	12143

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9960590	ENGAGE SET SCREW CADDY	July 2005	Rule 1	Annex VII	12143	12143
9960610	ENGAGE RBC OUTER CASE, SS	June 2005	Rule 1	Annex VII	12143	12143
9960614	ENGAGE RBC IMPLANT TRAY 1, SS	July 2005	Rule 1	Annex VII	12143	12143
9960615	ENGAGE RBC IMPLANT TRAY 2, SS	July 2005	Rule 1	Annex VII	12143	12143
9960616	ENGAGE RBC IMPLANT TRAY 3, SS	July 2005	Rule 1	Annex VII	12143	12143
9960620	ENGAGE SCREW OUTER CASE, SS	June 2005	Rule 1	Annex VII	12143	12143
9960621	ENGAGE SCREW INST OUTER, SS	July 2005	Rule 1	Annex VII	12143	12143
9960625	ENGAGE FAS IMPLANT TRAY 1, SS	July 2005	Rule 1	Annex VII	12143	12143
9960627	ENGAGE MAS IMPLANT TRAY 1, SS	July 2005	Rule 1	Annex VII	12143	12143
9960628	ENGAGE MAS IMPLANT TRAY 2, SS	July 2005	Rule 1	Annex VII	12143	12143
9960629	ENGAGE SCREW INST TRAY, SS	July 2005	Rule 1	Annex VII	12143	12143
9960630	ENGAGE HOOK OUTER CASE, SS	June 2005	Rule 1	Annex VII	12143	12143
9960631	ENGAGE CLOSED HOOK MODULE, SS	July 2005	Rule 1	Annex VII	12143	12143
9960631L	ENGAGE CLOSED HOOK MODULE, SS	July 2005	Rule 1	Annex VII	12143	12143
9960632	ENGAGE OPEN HOOK MODULE, SS	July 2005	Rule 1	Annex VII	12143	12143
9960632L	ENGAGE OPEN HOOK LID, SS	July 2005	Rule 1	Annex VII	12143	12143
9960633	ENGAGE HOOK IMPLANT, SS	July 2005	Rule 1	Annex VII	12143	12143
9960640	ENGAGE 4.5 & 8.5 BOLT OUTER SS	June 2005	Rule 1	Annex VII	12143	12143
9960641	ENGAGE 4.5&8.5 IMPL TRAY 1, SS	July 2005	Rule 1	Annex VII	12143	12143
9960642	ENGAGE 4.5&8.5 IMPL TRAY 2, SS	July 2005	Rule 1	Annex VII	12143	12143
9960645	ENGAGE LP BOLT OUTER CASE, SS	June 2005	Rule 1	Annex VII	12143	12143
9960646	ENGAGE EX IMPLANT TRAY 1, SS	July 2005	Rule 1	Annex VII	12143	12143
9960647	ENGAGE EX IMPLANT TRAY 2, SS	July 2005	Rule 1	Annex VII	12143	12143
9960648	ENGAGE EX IMPLANT TRAY 3, SS	July 2005	Rule 1	Annex VII	12143	12143
9960680L	ENGAGE CLOSED SET SCREW LID SS	July 2005	Rule 1	Annex VII	12143	12143
9960681L	ENGAGE NUT SET SCREW LID, SS	July 2005	Rule 1	Annex VII	12143	12143
9960682L	ENGAGE WASHER SET SCREW LID SS	July 2005	Rule 1	Annex VII	12143	12143
9960683	ENGAGE ROD CONNECT MODULE, SS	July 2005	Rule 1	Annex VII	12143	12143
9960683L	ENGAGE ROD CONNECT LID, SS	July 2005	Rule 1	Annex VII	12143	12143
9960690L	ENGAGE SET SCREW CADDY LID, SS	July 2005	Rule 1	Annex VII	12143	12143
9960710	ENGAGE RBC OUTER CASE, TI	June 2005	Rule 1	Annex VII	12143	12143
9960714	ENGAGE RBC IMPLANT TRAY 1, TI	July 2005	Rule 1	Annex VII	12143	12143
9960715	ENGAGE RBC IMPLANT TRAY 2, TI	July 2005	Rule 1	Annex VII	12143	12143
9960716	ENGAGE RBC IMPLANT TRAY 3, TI	July 2005	Rule 1	Annex VII	12143	12143
9960717	ENGAGE RBC IMPLANT TRAY 4, TI	July 2005	Rule 1	Annex VII	12143	12143
9960720	ENGAGE SCREW OUTER CASE, TI	June 2005	Rule 1	Annex VII	12143	12143
9960721	ENGAGE SCREW INST OUTER, TI	July 2005	Rule 1	Annex VII	12143	12143
9960725	ENGAGE FAS IMPLANT TRAY 1, TI	July 2005	Rule 1	Annex VII	12143	12143
9960726	ENGAGE FAS IMPLANT TRAY 2, TI	July 2005	Rule 1	Annex VII	12143	12143
9960727	ENGAGE MAS IMPLANT TRAY 1, TI	July 2005	Rule 1	Annex VII	12143	12143
9960728	ENGAGE MAS IMPLANT TRAY 2, TI	July 2005	Rule 1	Annex VII	12143	12143
9960729	ENGAGE SCREW INST TRAY, TI	July 2005	Rule 1	Annex VII	12143	12143
9960730	ENGAGE HOOK OUTER CASE, TI	June 2005	Rule 1	Annex VII	12143	12143
9960731	ENGAGE CLOSED HOOK MODULE, TI	July 2005	Rule 1	Annex VII	12143	12143
9960731L	ENGAGE CLOSED HOOK LID, TI	July 2005	Rule 1	Annex VII	12143	12143
9960732	ENGAGE OPEN HOOK MODULE, TI	July 2005	Rule 1	Annex VII	12143	12143
9960732L	ENGAGE OPEN HOOK LID, TI	July 2005	Rule 1	Annex VII	12143	12143
9960733	ENGAGE HOOK IMPLANT TRAY, TI	July 2005	Rule 1	Annex VII	12143	12143
9960740	ENGAGE 4.5 & 8.5 BOLT OUTER TI	June 2005	Rule 1	Annex VII	12143	12143
9960741	ENGAGE 4.5&8.5 IMPL TRAY 1, TI	July 2005	Rule 1	Annex VII	12143	12143
9960742	ENGAGE 4.5&8.5 IMPL TRAY 2, TI	July 2005	Rule 1	Annex VII	12143	12143
9960745	ENGAGE LP BOLT OUTER CASE, TI	June 2005	Rule 1	Annex VII	12143	12143
9960746	ENGAGE EX IMPLANT TRAY 1, TI	July 2005	Rule 1	Annex VII	12143	12143

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9960747	ENGAGE EX IMPLANT TRAY 2, TI	July 2005	Rule 1	Annex VII	12143	12143
9960748	ENGAGE EX IMPLANT TRAY 3, TI	July 2005	Rule 1	Annex VII	12143	12143
9960780L	ENGAGE CLOSED SET SCREW LID TI	July 2005	Rule 1	Annex VII	12143	12143
9960781L	ENGAGE NUT SET SCREW LID, TI	July 2005	Rule 1	Annex VII	12143	12143
9960782L	ENGAGE WASHER SET SCREW LID TI	July 2005	Rule 1	Annex VII	12143	12143
9960783	ENGAGE ROD CONNECT MODULE, TI	July 2005	Rule 1	Annex VII	12143	12143
9960783L	ENGAGE ROD CONNECT LID, TI	July 2005	Rule 1	Annex VII	12143	12143
9960790L	ENGAGE SET SCREW LID, TI	July 2005	Rule 1	Annex VII	12143	12143
9960815	ENGAGE PLT - WASHER MOD LID	December 2005	Rule 1	Annex VII	12143	12143
9960817	ENGAGE PLT-THREAD NUT MOD LID	December 2005	Rule 1	Annex VII	12143	12143
9960818	ENGAGE PLT-REVIS NUT MODULE	December 2005	Rule 1	Annex VII	12143	12143
9960819	ENGAGE PLT-REVIS NUT MOD LID	December 2005	Rule 1	Annex VII	12143	12143
9960820	ENGAGE PLT MLTI-AX BLT EX CSE	December 2005	Rule 1	Annex VII	12143	12143
9960822	ENGAGE PLT-SLIDER MODULE	December 2005	Rule 1	Annex VII	12143	12143
9960823	ENGAGE PLT-SLIDER MODULE LID	December 2005	Rule 1	Annex VII	12143	12143
9960833	OUTER LID	December 2005	Rule 1	Annex VII	12143	12143
9960835	ENGAGE PLATE - WASHER MODULE	July 2006	Rule 1	Annex VII	12143	12143
9960836	ENGAGE PLATE - THREADED NUT MODULE	July 2006	Rule 1	Annex VII	12143	12143
9960851	ENG PLT - PED PRP-SCRW INSRT OUTER CASE	July 2006	Rule 1	Annex VII	12143	12143
9960852	ENG PLT - PED PREP AND SCRW INSRT TRAY	July 2006	Rule 1	Annex VII	12143	12143
9960853	ENG PLT - NUT INSERTION TRAY	July 2006	Rule 1	Annex VII	12143	12143
9960854	ENG PLT - PLT & ANC IMP-PLT INS OTR CASE	July 2006	Rule 1	Annex VII	12143	12143
9960856	CDH ENG PLT - PLATE INSTRUMENT TRAY	July 2006	Rule 1	Annex VII	12143	12143
9960857	ENG PLT - BOLT CUTTER OUTER CASE	July 2006	Rule 1	Annex VII	12143	12143
9960858	ENG PLT - BOLT CUTTER TRAY	July 2006	Rule 1	Annex VII	12143	12143
9960859	ENG PLT - MAST OUTER CASE	July 2006	Rule 1	Annex VII	12143	12143
9960860	ENG PLT - MAST TRAY	July 2006	Rule 1	Annex VII	12143	12143
9960861	ENG PLT - FIXED SHRT & LNG BLTS OTR CASE	July 2006	Rule 1	Annex VII	12143	12143
9960862	CDH ENG PLT - FIXED POST BOLTS LID	July 2006	Rule 1	Annex VII	12143	12143
9960863	CDH ENG PLT - FIX SHRT PST BLTS TRAY	July 2006	Rule 1	Annex VII	12143	12143
9960864	CDH ENG PLT - FIX LNG PST BLT TRAY	July 2006	Rule 1	Annex VII	12143	12143
9960865	ENG PLT - MUL-AX SHRT&LNG BLTS OTR CASE	July 2006	Rule 1	Annex VII	12143	12143
9960866	ENG PLT - MULTI-AX IAL BOLTS IMPL LID	July 2006	Rule 1	Annex VII	12143	12143
9960867	ENG PLT - MULTI-AX SHRT PST BOLTS TRAY	July 2006	Rule 1	Annex VII	12143	12143
9960868	ENG PLT - MULTI-AX LNG PST BLTS TRAY	July 2006	Rule 1	Annex VII	12143	12143
9960869	CDH ENG PLT - STRAIGHT PLATES TRAY LID	July 2006	Rule 1	Annex VII	12143	12143
9960870	CDH ENG PLT - STRAIGHT PLATES TRAY	July 2006	Rule 1	Annex VII	12143	12143
9960871	ENG PLT - PLATE AND ANCILL IMPL TRAY LID	July 2006	Rule 1	Annex VII	12143	12143
9960873	ENG PLT - STRAIGHT PLATES OUTER CASE	July 2006	Rule 1	Annex VII	12143	12143
9960874	ENG PLT - PLATE AND ANCILL IMPLANT TRAY	March 2007	Rule 1	Annex VII	12143	12143
CDH FNS-Case and Trays						
1850093	Fenestrated Adapter/Driver Tray	February 2011	Rule 1	Annex VII	12143	12143
7480732	Fenestrated Screw Tray	February 2011	Rule 1	Annex VII	12143	12143
CDH Legacy- Case and Trays						
1850069	EXTRAS SET - FULL SIZE LID	February 2003	Rule 1	Annex VII	12143	12143
1858543	CROSSLINK TRAY	September 2002	Rule 1	Annex VII	12143	12143
1858543L	CROSSLINK TRAY LID	September 2002	Rule 1	Annex VII	12143	12143
1858544	CROSSLINK TRAY INSERT	September 2002	Rule 1	Annex VII	12143	12143
1858642	PEDICLE PREPARATION KIT TRAY	November 2003	Rule 1	Annex VII	12143	12143
1858642L	PEDICLE PREPARATION TRAY LID	November 2003	Rule 1	Annex VII	12143	12143
1858700L	CDHL ANTERIOR OUTER CASE LID	October 2006	Rule 1	Annex VII	12143	12143
1858701	CDHL ANTERIOR INSTRUMENT TRAY 1	October 2006	Rule 1	Annex VII	12143	12143
1858702	CDHL ANTERIOR INSTRUMENT TRAY 2	October 2006	Rule 1	Annex VII	12143	12143

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1858703	CDHL ANTERIOR INST OUTER CASE 2	October 2006	Rule 1	Annex VII	12143	12143
1858704	CDHL ANTERIOR INSTRUMENT TRAY 3	October 2006	Rule 1	Annex VII	12143	12143
1858705	CDHL ANTERIOR INSTRUMENT TRAY 4	October 2006	Rule 1	Annex VII	12143	12143
1858706	CDHL ANTERIOR IMPLANT OUTER CASE	October 2006	Rule 1	Annex VII	12143	12143
1858707	CDHL ANTERIOR IMPLANT TRAY 2	October 2006	Rule 1	Annex VII	12143	12143
1858707L	CDHL ANTERIOR IMPLANT TRAY LID	October 2006	Rule 1	Annex VII	12143	12143
1858708	CDHL ANTERIOR IMPLANT TRAY 1	October 2006	Rule 1	Annex VII	12143	12143
1858709	CDHL ANTERIOR SET SCREW MODULE	October 2006	Rule 1	Annex VII	12143	12143
1858709L	CDHL ANTERIOR SET SCREW MODULE LID	October 2006	Rule 1	Annex VII	12143	12143
1858710L	CDHL ANTERIOR CROSSLINK MODULE LID	October 2006	Rule 1	Annex VII	12143	12143
1858712	CDHL ANTERIOR INST TRAY 5	October 2006	Rule 1	Annex VII	12143	12143
1858713	CDHL ANTERIOR INST OUTER CASE 1	October 2006	Rule 1	Annex VII	12143	12143
1858714	CDHL ANTERIOR INST OUTER CASE 3	October 2006	Rule 1	Annex VII	12143	12143
1859002	EXTRAS TRAY w/ DIVIDERS	January 2008	Rule 1	Annex VII	12143	12143
1859010	CDH LEGACY 5.5 EVAL ROD MANIP INSTR CASE	March 2008	Rule 1	Annex VII	12143	12143
1859011	CDH LEGACY 5.5 EVAL SCREW PREP INST CASE	March 2008	Rule 1	Annex VII	12143	12143
1859012	CDH LEGACY 5.5 EVAL INSTRUMENT CASE	March 2008	Rule 1	Annex VII	12143	12143
1859025	Legacy Navigation Driver Tray 5.5	May 2009	Rule 1	Annex VII	12143	12143
1859026	Legacy Navigation Driver Tray 6.35	May 2009	Rule 1	Annex VII	12143	12143
7022200	LEGACY ILIAC OUTER BASE	January 2011	Rule 1	Annex VII	12143	12143
7022201	OUTER LID, FULLY THREADED,SS	May 2004	Rule 1	Annex VII	12143	12143
7022202	IMPLANT TRAY, FULL THRD, SS	May 2004	Rule 1	Annex VII	12143	12143
7022203	IMPLANT LID, FULLY THREADED,SS	May 2004	Rule 1	Annex VII	12143	12143
7022204	LEGACY ILIAC INSTRUMENT TRAY	January 2011	Rule 1	Annex VII	12143	12143
7022205	LEGACY ILIAC SET SCREW MODULE	May 2004	Rule 1	Annex VII	12143	12143
7022206	LEGACY ILIAC SET SCREW LID, SS	May 2004	Rule 1	Annex VII	12143	12143
7023100	LEGACY ILIAC, SS, CMAS OUTER	July 2005	Rule 1	Annex VII	12143	12143
7023110L	LEGACY ILIAC,CMAS OUTER LID	January 2011	Rule 1	Annex VII	12143	12143
7023120	LEGACY ILIAC, SS CMAS IMPL TRY	July 2005	Rule 1	Annex VII	12143	12143
7023125	LEGACY ILIAC INSTRUMENT TRAY	July 2005	Rule 1	Annex VII	12143	12143
7023125L	LEGACY ILIAC CMAS IMPL TRY LID	January 2011	Rule 1	Annex VII	12143	12143
7023130	LEGACY ILIAC SET SCREW MODULE	January 2011	Rule 1	Annex VII	12143	12143
7023135L	LEGACY ILIAC SETSCW MOD LID SS	July 2005	Rule 1	Annex VII	12143	12143
7030010L	LEGACY 3.5 OUTER CASE LID	October 2004	Rule 1	Annex VII	12143	12143
7030235	SET SCREW CADDY	October 2004	Rule 1	Annex VII	12143	12143
7030236	SET SCREW CADDY, SS	October 2004	Rule 1	Annex VII	12143	12143
7030510	OUTER CASE, INSTRUMENTS, TRIPL	October 2004	Rule 1	Annex VII	12143	12143
7030521	INSTRUMENT TRAY #1	October 2004	Rule 1	Annex VII	12143	12143
7030522	INSTRUMENT TRAY #2	October 2004	Rule 1	Annex VII	12143	12143
7030523	INSTRUMENT TRAY #3	October 2004	Rule 1	Annex VII	12143	12143
7034139	LEGACY ILIAC CMAS INSTRUMENT TRAY	January 2011	Rule 1	Annex VII	12143	12143
7038235L	SET SCREW CADDY LID, SS	October 2004	Rule 1	Annex VII	12143	12143
7038510	LEGACY 3.5 OUTER CASE, SS	October 2004	Rule 1	Annex VII	12143	12143
7038510L	IMPLANT TRAY LID, SS	October 2004	Rule 1	Annex VII	12143	12143
7038520	IMPLANT TRAY, SS	October 2004	Rule 1	Annex VII	12143	12143
7038533	HOOK MODULE, SS	October 2004	Rule 1	Annex VII	12143	12143
7038533INT	CDHL MINI HOOK MODULE, SS	April 2007	Rule 1	Annex VII	12143	12143
7038533L	HOOK MODULE LID, SS	October 2004	Rule 1	Annex VII	12143	12143
7038830	X10 CROSSLINKS MODULE, SS	October 2004	Rule 1	Annex VII	12143	12143
7038830L	X10 CROSSLINKS MODULE LID, SS	October 2004	Rule 1	Annex VII	12143	12143
7039235L	SET SCREW CADDY LID, TI	October 2004	Rule 1	Annex VII	12143	12143
7039510	LEGACY 3.5 OUTER CASE, TI	October 2004	Rule 1	Annex VII	12143	12143
7039510L	IMPLANT TRAY LID, TI	October 2004	Rule 1	Annex VII	12143	12143

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7039520	IMPLANT TRAY, TI	October 2004	Rule 1	Annex VII	12143	12143
7039533	HOOK MODULE, TI	October 2004	Rule 1	Annex VII	12143	12143
7039533L	HOOK MODULE LID, TI	October 2004	Rule 1	Annex VII	12143	12143
7039830	X10 CROSSLINKS MODULE, TI	October 2004	Rule 1	Annex VII	12143	12143
7039830L	X10 CROSSLINKS MODULE LID, TI	October 2004	Rule 1	Annex VII	12143	12143
7040110	LEGACY 4.5 APICAL DEROTATOR OUTER CASE	May 2005	Rule 1	Annex VII	12143	12143
7040124	CDHL 4.5 G4 DEROTATOR TRAY	May 2005	Rule 1	Annex VII	12143	12143
7042201	OUTER LID, FULLY THREADED, TI	January 2011	Rule 1	Annex VII	12143	12143
7042202	IMPLANT TRAY, FULL THRD, TI	May 2004	Rule 1	Annex VII	12143	12143
7042203	IMPLANT LID, FULLY THREADED, TI	January 2011	Rule 1	Annex VII	12143	12143
7042206	LEGACY ILIAC SET SCREW LID, TI	May 2004	Rule 1	Annex VII	12143	12143
7043100	LEGACY ILIAC, TI, CMAS OUTR CS	January 2011	Rule 1	Annex VII	12143	12143
7043120	LEGACY ILIAC, TI, CMAS IMP TRY	July 2006	Rule 1	Annex VII	12143	12143
7043135L	LEGACY ILIAC STSCW MOD LID, TI	January 2011	Rule 1	Annex VII	12143	12143
7049400	LEGACY 4.5 MAS OUTER CASE, TI	May 2006	Rule 1	Annex VII	12143	12143
7049400L	LEGACY 4.5 OUTER CASE LID	May 2006	Rule 1	Annex VII	12143	12143
7049420	LEGACY 4.5 MAS IMPLANT TRAY (1 OF 2), TI	May 2006	Rule 1	Annex VII	12143	12143
7049420L	LEGACY 4.5 IMPLANT TRAY LID	May 2006	Rule 1	Annex VII	12143	12143
7049421	LEGACY 4.5 MAS IMPLANT TRAY (2 OF 2), TI	May 2006	Rule 1	Annex VII	12143	12143
7049422	LEGACY 4.5 MAS INSTRUMENT TRAY	May 2006	Rule 1	Annex VII	12143	12143
7049423	MODULE 7049423 LEGACY 4.5 SET SCREW	December 2007	Rule 1	Annex VII	12143	12143
7049425L	LEGACY 4.5 SET SCREW MODULE LID	June 2006	Rule 1	Annex VII	12143	12143
7049430	LEGACY 4.5 SET SCREW MODULE, TI	June 2006	Rule 1	Annex VII	12143	12143
7049438	LEGACY 4.5 HOOK MODULE LID, GENERIC	June 2006	Rule 1	Annex VII	12143	12143
7049440	LEGACY 4.5 MAS OUTER CASE, SS	May 2006	Rule 1	Annex VII	12143	12143
7049441	LEGACY 4.5 MAS IMPLANT TRAY (1 OF 2), SS	May 2006	Rule 1	Annex VII	12143	12143
7049442	LEGACY 4.5 MAS IMPLANT TRAY (2 OF 2), SS	May 2006	Rule 1	Annex VII	12143	12143
7049444	LEGACY 4.5 SET SCREW MODULE, SS	June 2006	Rule 1	Annex VII	12143	12143
7049450	LEGACY 4.5 FAS OUTER CASE, TI	May 2006	Rule 1	Annex VII	12143	12143
7049451	LEGACY 4.5 FAS IMPLANT TRAY (1 OF 2), TI	May 2006	Rule 1	Annex VII	12143	12143
7049452	LEGACY 4.5 FAS IMPLANT TRAY (2 OF 2), TI	May 2006	Rule 1	Annex VII	12143	12143
7049453	LEGACY 4.5 FAS INSTRUMENT TRAY	May 2006	Rule 1	Annex VII	12143	12143
7049460	LEGACY 4.5 FAS OUTER CASE, SS	May 2006	Rule 1	Annex VII	12143	12143
7049461	LEGACY 4.5 FAS IMPLANT TRAY (1 OF 2), SS	May 2006	Rule 1	Annex VII	12143	12143
7049462	LEGACY 4.5 FAS IMPLANT TRAY (2 OF 2), SS	May 2006	Rule 1	Annex VII	12143	12143
7049470	LEGACY 4.5 HOOK OUTER CASE, TI	May 2006	Rule 1	Annex VII	12143	12143
7049471	LEGACY 4.5 HOOK IMPLANT TRAY, TI	June 2006	Rule 1	Annex VII	12143	12143
7049472	LEGACY 4.5 HOOK INSTRUMENT TRAY	June 2006	Rule 1	Annex VII	12143	12143
7049473	LEGACY 4.5 HOOK MODULE, TI	June 2006	Rule 1	Annex VII	12143	12143
7049473T	LEGACY 4.5 HOOK MODULE LID, TI	June 2006	Rule 1	Annex VII	12143	12143
7049480	LEGACY 4.5 HOOK OUTER CASE, SS	May 2006	Rule 1	Annex VII	12143	12143
7049481	LEGACY 4.5 HOOK IMPLANT TRAY, SS	June 2006	Rule 1	Annex VII	12143	12143
7049483	LEGACY 4.5 HOOK MODULE, SS	June 2006	Rule 1	Annex VII	12143	12143
7049483S	LEGACY 4.5 HOOK MODULE LID, SS	June 2006	Rule 1	Annex VII	12143	12143
7049490	LEGACY 4.5 INSTRUMENT OUTER CASE (1 OF 2)	June 2006	Rule 1	Annex VII	12143	12143
7049491	LEGACY 4.5 INSTRUMENT TRAY (1 OF 4)	May 2006	Rule 1	Annex VII	12143	12143
7049492	LEGACY 4.5 INSTRUMENT TRAY (2 OF 4)	May 2006	Rule 1	Annex VII	12143	12143
7049493	LEGACY 4.5 INSTRUMENT OUTER CASE(2 OF 2)	June 2006	Rule 1	Annex VII	12143	12143
7049494	LEGACY 4.5 INSTRUMENT TRAY (3 OF 4)	May 2006	Rule 1	Annex VII	12143	12143
7049495	LEGACY 4.5 INSTRUMENT TRAY (4 OF 4)	May 2006	Rule 1	Annex VII	12143	12143
7049496	CDH LEGACY 4.5 G4 INSTRUMENT TRAY 2	December 2007	Rule 1	Annex VII	12143	12143
7050010	CDHL 5.5 INST SET CASE 1	January 2004	Rule 1	Annex VII	12143	12143
7050010L	OUTER CASE LID	January 2004	Rule 1	Annex VII	12143	12143

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7050011L	CDHL MINIMAL ACC INST CASE LID	January 2004	Rule 1	Annex VII	12143	12143
7050020	CDHL INST CASE 2	January 2004	Rule 1	Annex VII	12143	12143
7050033	CDHL SCREW GAUGE EXTRA	March 2004	Rule 1	Annex VII	12143	12143
7050110	CDHL 5.5 APIC DEROT INST CASE	January 2004	Rule 1	Annex VII	12143	12143
7050120	CDHL INST TRAY 1	December 2003	Rule 1	Annex VII	12143	12143
7050121	CDHL INST TRAY 2	December 2003	Rule 1	Annex VII	12143	12143
7050122	CDHL INST TRAY 3	December 2003	Rule 1	Annex VII	12143	12143
7050123	CDHL INST TRAY 4	December 2003	Rule 1	Annex VII	12143	12143
7050124	CDHL 5.5 APIC DERO INST TRAY	March 2004	Rule 1	Annex VII	12143	12143
7050130	CDHL 5.5 APICAL DEROTATOR EVAL	December 2005	Rule 1	Annex VII	12143	12143
7050135	CDHL 5.5 VERT COLUMN MANIPULATION TRAY	July 2006	Rule 1	Annex VII	12143	12143
7050135L	CDHL 5.5 VERT COLUMN MANIPULATION LID	July 2006	Rule 1	Annex VII	12143	12143
7050233	CDHL SET SCREW MODULE	September 2010	Rule 6	Annex VII	12143	12143
7050234	CDHL NON BREAKOFF SET SCR MOD	March 2004	Rule 1	Annex VII	12143	12143
7050235	CDHL SET SCREW MOD	December 2003	Rule 1	Annex VII	12143	12143
7050238	LEGACY RMAS 5.5 ST SCW MOD	December 2004	Rule 1	Annex VII	12143	12143
7050310L	LEGACY 5.5 TAH OUTER LID	November 2004	Rule 1	Annex VII	12143	12143
7050314	DEGEN OUTER INSTRUMENT CASE	January 2004	Rule 1	Annex VII	12143	12143
7050316	CDHL MINIMAL ACC INST CASE	July 2004	Rule 1	Annex VII	12143	12143
7050324	LEGACY 5.5 TAH IMPLANT TRAY	November 2004	Rule 1	Annex VII	12143	12143
7050324L	LEGACY 5.5 TAH IMPLANT LID	November 2004	Rule 1	Annex VII	12143	12143
7050327	CDHL NON BREAKOFF SCR TRAY	March 2004	Rule 1	Annex VII	12143	12143
7050331	CDHL DEGEN INST TRAY 1	December 2003	Rule 1	Annex VII	12143	12143
7050333	CDHL DEGEN INST TRAY 3	December 2003	Rule 1	Annex VII	12143	12143
7050334	CDHL SCREW PREP INST TRAY	December 2003	Rule 1	Annex VII	12143	12143
7050335	CDHL MINIMAL ACC INST TRAY	December 2003	Rule 1	Annex VII	12143	12143
7050336	CDHL 5.5 DEGEN INSTRUMENT TRAY	February 2004	Rule 1	Annex VII	12143	12143
7050355L	CDHL COLORADO II MOD GEN LID	February 2004	Rule 1	Annex VII	12143	12143
7050420	CDH LGCY 5.5 INSTR TRAY- TLIF DISTR	January 2006	Rule 1	Annex VII	12143	12143
7050420L	CDH LEGACY 5.5 INSTR TRAY LID-TLIF DISTR	January 2006	Rule 1	Annex VII	12143	12143
7050423	CDHL FAS SCREW PREP INST TRAY	December 2003	Rule 1	Annex VII	12143	12143
7050524L	CDHL HOOK IMPL TRAY LID	December 2003	Rule 1	Annex VII	12143	12143
7050525	CDHL HOOK INST TRAY	December 2003	Rule 1	Annex VII	12143	12143
7050532L	CDHL STANDARD HOOK MOD LID	December 2003	Rule 1	Annex VII	12143	12143
7050533L	CDHL SPECIALTY HOOK MOD LID	December 2003	Rule 1	Annex VII	12143	12143
7050534	CDHL HOOK STAGING MOD	December 2003	Rule 1	Annex VII	12143	12143
7050620	LEGACY RMAS 5.5 INSTR TRAY	December 2004	Rule 1	Annex VII	12143	12143
7054300	CDHL EU FLUORONAV CASE	February 2004	Rule 1	Annex VII	12143	12143
7054310	CDHL EU FLUORONAV INST TRAY	February 2004	Rule 1	Annex VII	12143	12143
7055300	CDHL EUROPE IMPL CASE SS	February 2004	Rule 1	Annex VII	12143	12143
7055310L	CDHL EUROPE IMPL TRAY 1 LID SS	February 2004	Rule 1	Annex VII	12143	12143
7055310R	CDHL 5.5 EU MAS IMPLANT TRAY	September 2004	Rule 1	Annex VII	12143	12143
7055311	CDHL EUROPE IMPL TRAY 2 SS	March 2004	Rule 1	Annex VII	12143	12143
7055320	CDHL EUROPE INST TRAY	January 2004	Rule 1	Annex VII	12143	12143
7055330	CDHL EUROPE INST CASE	February 2004	Rule 1	Annex VII	12143	12143
7055331	CDHL EUROPE INST TRAY 1	February 2004	Rule 1	Annex VII	12143	12143
7055332	CDHL EUROPE INST TRAY 2	February 2004	Rule 1	Annex VII	12143	12143
7055333	CDHL EUROPE INST TRAY 3	February 2004	Rule 1	Annex VII	12143	12143
7055335	CDHL INSTRUMENTS OUTER CASE 2	February 2004	Rule 1	Annex VII	12143	12143
7055340	CDHL HOOK OUTER CASE	February 2004	Rule 1	Annex VII	12143	12143
7055341	CDHL EUROPE HOOK INST TRAY 1	December 2003	Rule 1	Annex VII	12143	12143
7055342	CDHL EUROPE HOOK INST INSERT	March 2004	Rule 1	Annex VII	12143	12143
7055350	CDHL EU MAS CASE SS	February 2004	Rule 1	Annex VII	12143	12143

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7055351	CDHL 5.5 ADD-ON IMPLNT TRAY SS	March 2004	Rule 1	Annex VII	12143	12143
7055351L	CDHL EU ADDON IMPL TRAY LID SS	February 2004	Rule 1	Annex VII	12143	12143
7055352	CDHL EU ADDON TRANSVERSE MOD	January 2004	Rule 1	Annex VII	12143	12143
7055352L	CDHL EU ADDON TRNSVRSE MOD LID	January 2004	Rule 1	Annex VII	12143	12143
7055353	CDHL EU ADD ON DOM CONN MOD	May 2004	Rule 1	Annex VII	12143	12143
7055353L	CDHL EU ADD ON DOM CONN LID	February 2004	Rule 1	Annex VII	12143	12143
7055354	CDHL EU ADD ON STEP CONN MOD	January 2004	Rule 1	Annex VII	12143	12143
7055354L	CDHL EU ADD ON STEP CONN LID	January 2004	Rule 1	Annex VII	12143	12143
7055355	CDHL EU ADD ON COL2 PLATE MOD	January 2004	Rule 1	Annex VII	12143	12143
7055355L	CDHL EU ADD ON COL2 PLATE LID	January 2004	Rule 1	Annex VII	12143	12143
7055357	CDHL EU ADD ON INST TRAY	January 2004	Rule 1	Annex VII	12143	12143
7056135	CDHL 6.35 VERT COLUMN MANIPULATION TRAY	July 2006	Rule 1	Annex VII	12143	12143
7056135L	CDHL 6.35 VERT COLUMN MANIPULATION LID	July 2006	Rule 1	Annex VII	12143	12143
7056300	CDHL EUROPE IMPL CASE, TI	February 2004	Rule 1	Annex VII	12143	12143
7056310L	CDHL EUROPE IMPL TRAY 1 LID TI	February 2004	Rule 1	Annex VII	12143	12143
7056310R	CDHL 5.5 EU MAS IMPLANT TRAY	September 2004	Rule 1	Annex VII	12143	12143
7056311	CDHL EUROPE IMPL TRAY 2 TI	January 2004	Rule 1	Annex VII	12143	12143
7056340	CDHL EUROPE HOOK CASE, TI	February 2004	Rule 1	Annex VII	12143	12143
7056350	CDHL EUROPE ADD ON CASE TI	February 2004	Rule 1	Annex VII	12143	12143
7056351	CDHL 5.5 ADD-ON IMPLNT TRAY TI	March 2004	Rule 1	Annex VII	12143	12143
7056351L	CDHL EUROPE ADD ON IMPL LID TI	February 2004	Rule 1	Annex VII	12143	12143
7056352	CDHL EU ADD ON TRANS LINK MOD	January 2004	Rule 1	Annex VII	12143	12143
7056352L	CDHL EU ADD ON TRANS LINK LID	January 2004	Rule 1	Annex VII	12143	12143
7056353	CDHL EU ADD ON DOM CONN MOD TI	May 2004	Rule 1	Annex VII	12143	12143
7056353L	CDHL EU ADD ON DOM CONN LID TI	February 2004	Rule 1	Annex VII	12143	12143
7056354	CDHL EU ADD ON STEP CONN MOD	January 2004	Rule 1	Annex VII	12143	12143
7056354L	CDHL EU ADD ON STEP CONN LID T	January 2004	Rule 1	Annex VII	12143	12143
7056355	CDHL EU ADD ON COL2 PLATE MOD	January 2004	Rule 1	Annex VII	12143	12143
7056355L	CDHL EU ADD ON COL2 PLATE LID	January 2004	Rule 1	Annex VII	12143	12143
7056420	CDH LGCY 6.35 INST TRY - TLIF/PLIF DISTR	July 2006	Rule 1	Annex VII	12143	12143
7056420L	CDH LGCY 6.35 INS TRY LID-TLIF/PLIF DIST	July 2006	Rule 1	Annex VII	12143	12143
7058220	CDHL 5.5 DEGEN IMPL TRAY 1, SS	September 2004	Rule 1	Annex VII	12143	12143
7058221	CDHL 5.5 DEGEN IMPL TRAY 2, SS	September 2004	Rule 1	Annex VII	12143	12143
7058222	CDHL 5.5 DEFORM IMPL TRAY 1 SS	September 2004	Rule 1	Annex VII	12143	12143
7058223	CDHL 5.5 DEFORM IMPL TRAY 3 SS	September 2004	Rule 1	Annex VII	12143	12143
7058224	CDHL 5.5 DEFORM IMPL TRAY 2 SS	September 2004	Rule 1	Annex VII	12143	12143
7058225	CDHL 5.5 4.0-5.5 IMP TRAY 1 SS	September 2004	Rule 1	Annex VII	12143	12143
7058226	CDHL 5.5 4.0-5.5 IMP TRAY 2 SS	September 2004	Rule 1	Annex VII	12143	12143
7058227	CDHL 5.5 5.5-8.5 IMP TRAY 1 SS	September 2004	Rule 1	Annex VII	12143	12143
7058228	CDHL 5.5 5.5-8.5 IMP TRAY 2 SS	September 2004	Rule 1	Annex VII	12143	12143
7058233L	SET SCREW MODULE LID, SS	September 2005	Rule 1	Annex VII	12143	12143
7058233ML	CDHL 5.5 SET SCREW MOD LID, SS	August 2005	Rule 1	Annex VII	12143	12143
7058234L	CDHL NON BREAKOFF MOD LID, SS	September 2005	Rule 1	Annex VII	12143	12143
7058234ML	CDHL 5.5 NONBREAK MOD LID, SS	August 2005	Rule 1	Annex VII	12143	12143
7058235L	SET SCREW MODULE LID, SS	April 2004	Rule 1	Annex VII	12143	12143
7058235ML	CDHL 5.5 SET SCREW MOD LID, SS	August 2005	Rule 1	Annex VII	12143	12143
7058238L	LEGACY RMAS 5.5 ST SCW LID, SS	December 2004	Rule 1	Annex VII	12143	12143
7058238ML	CDHL RMAS 5.5 ST SCW LID, SS	August 2005	Rule 1	Annex VII	12143	12143
7058313	CDHL DEGEN MAS CASE 1, SS IMPL	March 2004	Rule 1	Annex VII	12143	12143
7058314	LEGACY 5.5 UAS OUTER CASE, SS	May 2005	Rule 1	Annex VII	12143	12143
7058315	CDHL NON BREAKOFF SCR CASE, SS	January 2004	Rule 1	Annex VII	12143	12143
7058317	CDHL MAS 4.0-5.5 EX CASE, SS	January 2004	Rule 1	Annex VII	12143	12143
7058318	CDHL MAS 5.5-8.5 EX CASE, SS	January 2004	Rule 1	Annex VII	12143	12143

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7058319	CDHL DEF MAS CASE, SS	January 2004	Rule 1	Annex VII	12143	12143
7058320	CDHL 5.5 ROD ADD-ON OUTER, SS	September 2005	Rule 1	Annex VII	12143	12143
7058325L	CDHL DEGEN MAS IMPL TRAY LID	September 2005	Rule 1	Annex VII	12143	12143
7058327L	CDHL NON BREAKOFF TRAY LID, SS	September 2005	Rule 1	Annex VII	12143	12143
7058328L	CDHL MAS 4.0-5.5 TRAY LID, SS	September 2005	Rule 1	Annex VII	12143	12143
7058329L	CDHL MAS 5.5-8.5 TRAY LID, SS	September 2005	Rule 1	Annex VII	12143	12143
7058341L	CDHL DEF MAS IMPL TRAY LID, SS	September 2005	Rule 1	Annex VII	12143	12143
7058351	LEGACY 5.5 UAS IMPL TRAY 1, SS	May 2005	Rule 1	Annex VII	12143	12143
7058351L	LEGACY 5.5 UAS IMPLANT LID, SS	May 2005	Rule 1	Annex VII	12143	12143
7058352	LEGACY 5.5 UAS IMPL TRAY 2, SS	May 2005	Rule 1	Annex VII	12143	12143
7058353	LEGACY 5.5 UAS IMPL TRAY 3, SS	May 2005	Rule 1	Annex VII	12143	12143
7058410	CDHL 5.5 FAS EXTRA CASE, SS	June 2012	Rule 1	Annex VII	12143	12143
7058411	CDHL FAS CASE, SS	January 2004	Rule 1	Annex VII	12143	12143
7058420	CDHL 5.5 ROD ADD-ON TRAY, SS	September 2005	Rule 1	Annex VII	12143	12143
7058420L	CDHL 5.5 ROD ADD-ON LID, SS	September 2005	Rule 1	Annex VII	12143	12143
7058421	CDHL FAS IMPL TRAY 1, SS	June 2004	Rule 1	Annex VII	12143	12143
7058421L	CDHL FAS IMPL TRAY LID, SS	September 2005	Rule 1	Annex VII	12143	12143
7058422	CDHL FAS IMPL TRAY 3, SS	June 2004	Rule 1	Annex VII	12143	12143
7058423	CDHL FAS IMPL TRAY 2, SS	June 2004	Rule 1	Annex VII	12143	12143
7058428	CDHL 5.5 LRG SCREW CASE, SS	September 2004	Rule 1	Annex VII	12143	12143
7058429L	CDHL 5.5 FAS EX CASE LID, SS	September 2005	Rule 1	Annex VII	12143	12143
7058511	CDHL HOOK CASE, SS	January 2004	Rule 1	Annex VII	12143	12143
7058524	CDHL HOOK IMPLANT TRAY, SS	April 2004	Rule 1	Annex VII	12143	12143
7058532	CDHL STANDARD HOOK MOD, SS	December 2003	Rule 1	Annex VII	12143	12143
7058532L	CDHL STANDARD HOOK MOD LID, SS	December 2003	Rule 1	Annex VII	12143	12143
7058533	CDHL SPECIALTY HOOK MOD, SS	December 2003	Rule 1	Annex VII	12143	12143
7058533L	CDHL SPECIAL HOOK MOD LID, SS	December 2003	Rule 1	Annex VII	12143	12143
7058610	LEGACY RMAS 5.5 OUTER CASE, SS	December 2004	Rule 1	Annex VII	12143	12143
7058620	LEGACY RMAS 5.5 IMPL TRAY, SS	December 2004	Rule 1	Annex VII	12143	12143
7058620L	LEGACY RMAS 5.5 IMPL LID, SS	December 2004	Rule 1	Annex VII	12143	12143
7058630	CDHL DOMINO MOD, SS	September 2005	Rule 1	Annex VII	12143	12143
7058630L	CDHL DOMINO MOD LID, SS	September 2005	Rule 1	Annex VII	12143	12143
7059220	CDHL 5.5 DEGEN IMPL TRAY 1, TI	September 2004	Rule 1	Annex VII	12143	12143
7059220INT	Legacy Degenerative Instrument tray	April 2013	Rule 1	Annex VII	12143	12143
7059221	CDHL 5.5 DEGEN IMPL TRAY 2, TI	September 2004	Rule 1	Annex VII	12143	12143
7059221INT	Legacy Degen Implant and Instrument tray	April 2013	Rule 1	Annex VII	12143	12143
7059222	CDHL 5.5 DEFORM IMPL TRAY 1 TI	September 2004	Rule 1	Annex VII	12143	12143
7059223	CDHL 5.5 DEFORM IMPL TRAY 3 TI	September 2004	Rule 1	Annex VII	12143	12143
7059224	CDHL 5.5 DEFORM IMPL TRAY 2 TI	September 2004	Rule 1	Annex VII	12143	12143
7059225	CDHL 5.5 4.0-5.5 IMP TRAY 1 TI	September 2004	Rule 1	Annex VII	12143	12143
7059226	CDHL 5.5 4.0-5.5 IMP TRAY 2 TI	September 2004	Rule 1	Annex VII	12143	12143
7059227	CDHL 5.5 5.5-8.5 IMP TRAY 1 TI	September 2004	Rule 1	Annex VII	12143	12143
7059228	CDHL 5.5 5.5-8.5 IMP TRAY 2 TI	September 2004	Rule 1	Annex VII	12143	12143
7059233L	CDHL SET SCREW MODULE LID, TI	December 2003	Rule 1	Annex VII	12143	12143
7059233ML	CDHL 5.5 SET SCREW MOD LID, TI	September 2010	Rule 1	Annex VII	12143	12143
7059234L	CDHL NON BREAKOFF SCR MOD LID	March 2004	Rule 1	Annex VII	12143	12143
7059234ML	CDHL 5.5 NONBREAK MOD LID, TI	August 2005	Rule 1	Annex VII	12143	12143
7059235L	CDHL SET SCREW MOD LID, TI	December 2003	Rule 1	Annex VII	12143	12143
7059235ML	CDHL 5.5 SET SCREW MOD LID, TI	August 2005	Rule 1	Annex VII	12143	12143
7059238L	LEGACY RMAS 5.5 ST SCW LID, TI	December 2004	Rule 1	Annex VII	12143	12143
7059238ML	CDHL RMAS 5.5 ST SCW LID, TI	August 2005	Rule 1	Annex VII	12143	12143
7059311	LEGACY 5.5 TAH OUTER CASE	November 2004	Rule 1	Annex VII	12143	12143
7059313	CDHL DEGEN MAS CASE 1, TI IMPL	January 2004	Rule 1	Annex VII	12143	12143

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7059314	LEGACY 5.5 UAS OUTER CASE, TI	May 2005	Rule 1	Annex VII	12143	12143
7059315	CDHL NON BREAKOFF SCR CASE, TI	January 2004	Rule 1	Annex VII	12143	12143
7059317	CDHL MAS 4.0-5.5MM EX CASE, TI	January 2004	Rule 1	Annex VII	12143	12143
7059318	CDHL MAS 5.5-8.5 EX CASE, TI	January 2004	Rule 1	Annex VII	12143	12143
7059319	CDHL DEF MAS CASE, TI	January 2004	Rule 1	Annex VII	12143	12143
7059320	CDHL 5.5 ROD ADD-ON OUTER, TI	September 2005	Rule 1	Annex VII	12143	12143
7059325L	CDHL DEGEN MAS IMPL TRAY LID	December 2003	Rule 1	Annex VII	12143	12143
7059327L	CDHL NON BREAKOFF TRAY LID, TI	March 2004	Rule 1	Annex VII	12143	12143
7059328L	CDHL MAS 4.0-5.5 TRAY LID, TI	November 2003	Rule 1	Annex VII	12143	12143
7059329L	CDHL MAS 5.5-8.5 TRAY LID, TI	March 2004	Rule 1	Annex VII	12143	12143
7059332	LEGACY 5.5 TAH STD HOOK MODULE	November 2004	Rule 1	Annex VII	12143	12143
7059333	LEGACY 5.5 TAH SPC HOOK MODULE	November 2004	Rule 1	Annex VII	12143	12143
7059341L	CDHL DEF MAS IMPL TRAY LID, TI	December 2003	Rule 1	Annex VII	12143	12143
7059351	LEGACY 5.5 UAS IMPL TRAY 1, TI	May 2005	Rule 1	Annex VII	12143	12143
7059351L	LEGACY 5.5 UAS IMPLANT LID, TI	May 2005	Rule 1	Annex VII	12143	12143
7059352	LEGACY 5.5 UAS IMPL TRAY 2, TI	May 2005	Rule 1	Annex VII	12143	12143
7059353	LEGACY 5.5 UAS IMPL TRAY 3, TI	May 2005	Rule 1	Annex VII	12143	12143
7059410	CDHL 5.5 FAS EXTRA CASE, TI	February 2013	Rule 1	Annex VII	12143	12143
7059411	CDHL FAS CASE, TI	January 2004	Rule 1	Annex VII	12143	12143
7059420	CDHL 5.5 ROD ADD-ON TRAY, TI	September 2005	Rule 1	Annex VII	12143	12143
7059420L	CDHL 5.5 ROD ADD-ON LID, TI	September 2005	Rule 1	Annex VII	12143	12143
7059421	CDHL FAS IMPL TRAY 1, TI	December 2003	Rule 1	Annex VII	12143	12143
7059421L	CDHL FAS IMPL TRAY LID, TI	December 2003	Rule 1	Annex VII	12143	12143
7059422	CDHL FAS IMPL TRAY 3, TI	December 2003	Rule 1	Annex VII	12143	12143
7059423	CDHL FAS IMPL TRAY 2, TI	December 2003	Rule 1	Annex VII	12143	12143
7059428	CDHL 5.5 LRG SCREW CASE, TI	September 2004	Rule 1	Annex VII	12143	12143
7059429L	CDHL 5.5 FAS EX CASE LID, TI	March 2004	Rule 1	Annex VII	12143	12143
7059500	CORTICAL BONE SCREW OUTER CASE	September 2010	Rule 1	Annex VII	12143	12143
7059501L	CORTICAL BONE SCREW OUTER CASE LID	September 2010	Rule 1	Annex VII	12143	12143
7059510	CORTICAL BONE SCREW IMPLANT TRAY, TOP	September 2010	Rule 1	Annex VII	12143	12143
7059511	CDHL HOOK CASE, TI	January 2004	Rule 1	Annex VII	12143	12143
7059511L	CORTICAL BONE SCREW IMPLANT TRAY LID	September 2010	Rule 1	Annex VII	12143	12143
7059520	CORTICAL BONE SCREW IMPLANT TRAY, BOTTOM	September 2010	Rule 1	Annex VII	12143	12143
7059524	CDHL HOOK IMPLANT TRAY, TI	December 2003	Rule 1	Annex VII	12143	12143
7059530	MEDIAL ROD OUTER CASE	December 2006	Rule 1	Annex VII	12143	12143
7059531L	MEDIAL ROD OUTER CASE LID	December 2006	Rule 1	Annex VII	12143	12143
7059532	CDHL STANDARD HOOK MOD, TI	December 2003	Rule 1	Annex VII	12143	12143
7059532L	CDHL STANDARD HOOK MOD LID, TI	December 2003	Rule 1	Annex VII	12143	12143
7059533	CDHL SPECIALTY HOOK MOD, TI	December 2003	Rule 1	Annex VII	12143	12143
7059533L	CDHL SPECIALTY HOOK MOD LID	December 2003	Rule 1	Annex VII	12143	12143
7059540	MEDIAL ROD IMPLANT TRAY	December 2006	Rule 1	Annex VII	12143	12143
7059541L	MEDIAL ROD IMPLANT TRAY LID	December 2006	Rule 1	Annex VII	12143	12143
7059550	MEDIAL ROD INSTRUMENT TRAY	December 2006	Rule 1	Annex VII	12143	12143
7059610	LEGACY RMAS 5.5 OUTER CASE, TI	December 2004	Rule 1	Annex VII	12143	12143
7059620	LEGACY RMAS 5.5 IMPL TRAY, TI	December 2004	Rule 1	Annex VII	12143	12143
7059620L	LEGACY RMAS 5.5 IMPL LID, TI	December 2004	Rule 1	Annex VII	12143	12143
7059630	CDHL DOMINO MOD, TI	December 2003	Rule 1	Annex VII	12143	12143
7059630L	CDHL DOMINO MOD LID, TI	December 2003	Rule 1	Annex VII	12143	12143
7060010	CDHL 6.35 INSTRUMENT OUTER 1	August 2004	Rule 1	Annex VII	12143	12143
7060010L	CDHL 6.35 OUTER CASE LID	August 2004	Rule 1	Annex VII	12143	12143
7060020	CDHL 6.35 INSTRUMENT OUTER 2	August 2004	Rule 1	Annex VII	12143	12143
7060030	CDHL6.35 APICAL DEROTATOR EVAL	December 2005	Rule 1	Annex VII	12143	12143
7060110	CDHL 6.35 APICAL OUTER	August 2004	Rule 1	Annex VII	12143	12143

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7060120	CDHL 6.35 INST SET TRAY 1	August 2004	Rule 1	Annex VII	12143	12143
7060121	CDHL 6.35 INST SET TRAY 2	August 2004	Rule 1	Annex VII	12143	12143
7060122	CDHL 6.35 INST SET TRAY 3	August 2004	Rule 1	Annex VII	12143	12143
7060123	CDHL 6.35 INST SET TRAY 4	August 2004	Rule 1	Annex VII	12143	12143
7060124	CDHL 6.35 APICAL INST TRAY	August 2004	Rule 1	Annex VII	12143	12143
7060233	CDHL 6.35 SET SCREW CADDY	August 2004	Rule 1	Annex VII	12143	12143
7060234	CDHL 6.35 SET SCREW MODULE	August 2004	Rule 1	Annex VII	12143	12143
7060238	LEGACY RMAS 6.35 ST SCW MOD	December 2004	Rule 1	Annex VII	12143	12143
7060314	CDHL 6.35 DEGEN OUTER 2, GEN	August 2004	Rule 1	Annex VII	12143	12143
7060327	CDHL 6.35 NON-BREAK IMPL TRAY	August 2004	Rule 1	Annex VII	12143	12143
7060331	CDHL 6.35 DEGEN INST TRAY	September 2004	Rule 1	Annex VII	12143	12143
7060333	CDHL 6.35 DEGEN INST TRAY 2	August 2004	Rule 1	Annex VII	12143	12143
7060334	CDHL 6.35 DEFORM INST TRAY	August 2004	Rule 1	Annex VII	12143	12143
7060336	CDHL 6.35 DEGEN INST TRAY 1	August 2004	Rule 1	Annex VII	12143	12143
7060423	CDHL 6.35 FAS INST TRAY	August 2004	Rule 1	Annex VII	12143	12143
7060524L	CDHL 6.35 HOOK IMPLANT LID	August 2004	Rule 1	Annex VII	12143	12143
7060525	CDHL 6.35 HOOK INST TRAY	August 2004	Rule 1	Annex VII	12143	12143
7060532L	CDHL 6.35 STD HOOK MOD LID GEN	August 2004	Rule 1	Annex VII	12143	12143
7060533L	CDHL 6.35 SPEC HK MOD LID, GEN	August 2004	Rule 1	Annex VII	12143	12143
7060620	LEGACY RMAS 6.35 INSTR TRAY	December 2004	Rule 1	Annex VII	12143	12143
7068220	CDH LEGACY 5.5 EVAL SCREW PREP INST TRAY	March 2008	Rule 1	Annex VII	12143	12143
7068221	CDH LEGACY 5.5 EVAL INSTRUMENT TRAY	March 2008	Rule 1	Annex VII	12143	12143
7068222	CDH LEGACY 5.5 EVAL ROD MANIP INS TRAY 1	March 2008	Rule 1	Annex VII	12143	12143
7068223	CDH LEGACY 5.5 EVAL ROD MANIP INS TRAY 2	March 2008	Rule 1	Annex VII	12143	12143
7068233ML	CDHL 6.35 SCREW CADDY LID, SS	August 2005	Rule 1	Annex VII	12143	12143
7068234L	CDHL 6.35 SET SCREW LID, SS	August 2004	Rule 1	Annex VII	12143	12143
7068234ML	CDHL 6.35 SET SCREW LID, SS	August 2005	Rule 1	Annex VII	12143	12143
7068238L	LEGACY RMAS 6.35 ST SCW LID,SS	December 2004	Rule 1	Annex VII	12143	12143
7068238ML	CDHL RMAS 6.35 ST SCW LID, SS	August 2005	Rule 1	Annex VII	12143	12143
7068313	CDHL 6.35 DEGEN OUTER 1, SS	August 2004	Rule 1	Annex VII	12143	12143
7068314	LEGACY 6.35 UAS OUTER CASE, SS	April 2005	Rule 1	Annex VII	12143	12143
7068315	CDHL 6.35 NON-BREAK OUTER, SS	August 2004	Rule 1	Annex VII	12143	12143
7068317	CDHL 6.35 4.0-5.5 OUTER, SS	August 2004	Rule 1	Annex VII	12143	12143
7068318	CDHL 6.35 5.5-8.5 OUTER, SS	August 2004	Rule 1	Annex VII	12143	12143
7068319	CDHL 6.35 DEFORM OUTER, SS	August 2004	Rule 1	Annex VII	12143	12143
7068320	CDHL 6.35 ROD ADD-ON OUTER, SS	May 2005	Rule 1	Annex VII	12143	12143
7068324	6.5 MAS Screw Module	January 2011	Rule 1	Annex VII	12143	12143
7068325	CDHL 6.35 DEGEN IMP TRAY 1, SS	August 2004	Rule 1	Annex VII	12143	12143
7068325L	CDHL 6.35 DEGEN IMPL LID, SS	August 2004	Rule 1	Annex VII	12143	12143
7068326	CDHL 6.35 DEGEN IMP TRAY 2, SS	August 2004	Rule 1	Annex VII	12143	12143
7068327L	CDHL 6.35 NONBREAK IMPL LID TI	August 2004	Rule 1	Annex VII	12143	12143
7068328	CDHL 6.35 4.0-5.5 IMP TRAY1 SS	August 2004	Rule 1	Annex VII	12143	12143
7068328L	CDHL 6.35 4.0-5.5 IMPL LID, SS	August 2004	Rule 1	Annex VII	12143	12143
7068329	CDHL 6.35 5.5-8.5 IMP TRAY1 SS	August 2004	Rule 1	Annex VII	12143	12143
7068329L	CDHL 6.35 5.5-8.5 IMPL LID, SS	August 2004	Rule 1	Annex VII	12143	12143
7068338	CDHL 6.35 4.0-5.5 IMP TRAY2 SS	August 2004	Rule 1	Annex VII	12143	12143
7068339	CDHL 6.35 5.5-8.5 IMP TRAY2 SS	September 2004	Rule 1	Annex VII	12143	12143
7068341	CDHL 6.35 DEFORM IMPL TRAY LID	August 2004	Rule 1	Annex VII	12143	12143
7068341L	CDHL 6.35 DEFORM IMP TRAY 2 SS	September 2004	Rule 1	Annex VII	12143	12143
7068342	CDHL 6.35 DEFORM IMPL TRAY, SS	September 2004	Rule 1	Annex VII	12143	12143
7068343	CDHL 6.35 DEFORM IMP TRAY 3 SS	September 2004	Rule 1	Annex VII	12143	12143
7068348	CDHS 4.75mm Cannulated MAS Tray	February 2011	Rule 1	Annex VII	12143	12143
7068350	CDHS Cannulated Tap Module	April 2011	Rule 1	Annex VII	12143	12143

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7068351	LEGACY 6.35 UAS IMPL TRAY 1 SS	April 2005	Rule 1	Annex VII	12143	12143
7068351L	LEGACY 6.35 UAS IMPLANT LID SS	April 2005	Rule 1	Annex VII	12143	12143
7068352	LEGACY 6.35 UAS IMPL TRAY 2 SS	April 2005	Rule 1	Annex VII	12143	12143
7068353	LEGACY 6.35 UAS IMPL TRAY 3 SS	April 2005	Rule 1	Annex VII	12143	12143
7068411	CDHL 6.35 FAS OUTER, SS	August 2004	Rule 1	Annex VII	12143	12143
7068421	CDHL 6.35 FAS IMPL TRAY 1, SS	October 2005	Rule 1	Annex VII	12143	12143
7068422	CDHL 6.35 FAS IMPL TRAY 2, SS	October 2005	Rule 1	Annex VII	12143	12143
7068511	CDHL 6.35 HOOK OUTER, SS	August 2004	Rule 1	Annex VII	12143	12143
7069313	CDHL 6.35 DEGEN OUTER 1, TI	August 2004	Rule 1	Annex VII	12143	12143
7069315	CDHL 6.35 NON-BREAK OUTER, TI	August 2004	Rule 1	Annex VII	12143	12143
7069317	CDHL 6.35 4.0-5.5 OUTER, TI	August 2004	Rule 1	Annex VII	12143	12143
7069318	CDHL 6.35 5.5-8.5 OUTER, TI	August 2004	Rule 1	Annex VII	12143	12143
7069319	CDHL 6.35 DEFORM OUTER, TI	August 2004	Rule 1	Annex VII	12143	12143
7069411	CDHL 6.35 FAS OUTER, TI	August 2004	Rule 1	Annex VII	12143	12143
7069421	CDHL 6.35 FAS IMPL TRAY 1, TI	October 2005	Rule 1	Annex VII	12143	12143
7069422	CDHL 6.35 FAS IMPL TRAY 2, TI	October 2005	Rule 1	Annex VII	12143	12143
7449000	LEGACY 4.5 IMPLANTS OUTER CASE 1	July 2008	Rule 1	Annex VII	61325	12143
7449001	LEGACY 4.5 IMPLANTS TRAY CASE 1	July 2008	Rule 1	Annex VII	12143	12143
7449002	LEGACY 4.5 CONNECTOR MODULE LID	July 2008	Rule 1	Annex VII	12143	12143
7449003	LEGACY 4.5 CONNECTOR MODULE	July 2008	Rule 1	Annex VII	12143	12143
7449004	LEGACY 4.5 HOOK MODULE LID	July 2008	Rule 1	Annex VII	12143	12143
7449005	LEGACY 4.5 HOOK MODULE	July 2008	Rule 1	Annex VII	12143	12143
7449006	LEGACY 4.5 INSTRUMENT TRAY CASE 1	July 2008	Rule 1	Annex VII	12143	12143
7449007	LEGACY 4.5 INSTRUMENTS OUTER CASE 2	July 2008	Rule 1	Annex VII	12143	12143
7449008	LEGACY 4.5 INSTRUMENT TRAY 1 CASE 2	July 2008	Rule 1	Annex VII	12143	12143
7449009	LEGACY 4.5 INSTRUMENT TRAY 2 CASE 2	July 2008	Rule 1	Annex VII	12143	12143
7449010	LEGACY 4.5 INSTRUMENTS OUTER CASE 3	July 2008	Rule 1	Annex VII	12143	12143
7449011	LEGACY 4.5 INSTRUMENT TRAY 3 CASE 3	July 2008	Rule 1	Annex VII	12143	12143
7449012	LEGACY 4.5 INSTRUMENT TRAY 4 CASE 3	July 2008	Rule 1	Annex VII	12143	12143
7449013	LEGACY 4.5 SCREW TRAY CASE 1	July 2008	Rule 1	Annex VII	12143	12143
7850324	CD HORIZON EUR MAS INST TRAY 1	May 2003	Rule 1	Annex VII	12143	12143
8390304	CANN LEGACY 5.5MM OUTER CASE	September 2004	Rule 1	Annex VII	12143	12143
8390305	CANN LEGACY 5.5MM OUTER LID	September 2004	Rule 1	Annex VII	12143	12143
8390306	CANN LGCY 5.5MM INSTR TRAY TOP	September 2004	Rule 1	Annex VII	12143	12143
8390307	CANN LGCY 5.5MM INS TRY BOTTOM	September 2004	Rule 1	Annex VII	12143	12143
8390309	CANN LEGACY 5.5MM IMP TRAY LID	September 2004	Rule 1	Annex VII	12143	12143
8390310	MAST QUAD/MAST LGCY OUTR (NEW)	July 2005	Rule 1	Annex VII	12143	12143
8390313	CANN LEGACY INSTR TRAY TOP	December 2004	Rule 1	Annex VII	12143	12143
8390314	CANN LEGACY INSTR TRAY BOTTOM	December 2004	Rule 1	Annex VII	12143	12143
8390315	CANNULATED LEGACY IMPLANT TRAY	December 2004	Rule 1	Annex VII	12143	12143
X0808023	TRAY 6.5MM 7.5MM CORTICAL BONE SCREW	November 2008	Rule 1	Annex VII	12143	12143
CDH Legacy PEEK- Case and Trays						
1002722	CDHL PERC PEEK ROD INST/IMPL TRAY	June 2008	Rule 1	Annex VII	12143	12143
1003722	CDHL PERC PEEK ROD INSTRUMENT TRAY	June 2008	Rule 1	Annex VII	12143	12143
7220001	CDHL PEEK RODS INSTRUMENT TRAY	December 2006	Rule 1	Annex VII	12143	12143
7220010L	CDH PEEK ROD OUTER LID	August 2006	Rule 1	Annex VII	12143	12143
7220011	PEEK PERC ROD HALF TRAY	July 2007	Rule 1	Annex VII	12143	12143
7220011L	PEEK PERC ROD HALF TRAY LID	July 2007	Rule 1	Annex VII	12143	12143
7220031	CDH PEEK ROD SCREW GAUGE	August 2006	Rule 1	Annex VII	12143	12143
7220233	CDH PEEK ROD SET SCREW MODULE	August 2006	Rule 1	Annex VII	12143	12143
7220314	CDH PEEK ROD INSTRUMENT CASE	August 2006	Rule 1	Annex VII	12143	12143
7220331	CDH PEEK ROD SCREW PREP TRAY	August 2006	Rule 1	Annex VII	12143	12143
7220333	CDH PEEK ROD INSTRUMENT TRAY 2	August 2006	Rule 1	Annex VII	12143	12143

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7220336	CDH PEEK ROD INSTRUMENT TRAY 1	August 2006	Rule 1	Annex VII	12143	12143
7229003	PEEK 5.5MM INST TRAY TOP	September 2005	Rule 1	Annex VII	12143	12143
7229004	PEEK 5.5 MM INST TRAY BOTTOM	September 2005	Rule 1	Annex VII	61325	12143
7229006	PEEK 5.5MM IMPLANT TRAY LID	September 2005	Rule 1	Annex VII	12143	12143
7229012	PEEK MAST OUTER CASE	September 2005	Rule 1	Annex VII	12143	12143
7229014	PEEK CANN LEGACY SET SCREW MODULE	March 2006	Rule 1	Annex VII	12143	12143
7229233L	CDH PEEK ROD SET SCREW MODULE LID	August 2006	Rule 1	Annex VII	12143	12143
7229234L	PEEK PERC ROD SET SCREW MODULE LID	July 2007	Rule 1	Annex VII	12143	12143
7229313	CDH PEEK ROD IMPLANT OUTER CASE	August 2006	Rule 1	Annex VII	12143	12143
7229325	CDH PEEK ROD IMPLANT TRAY	August 2006	Rule 1	Annex VII	12143	12143
7229325L	CDH PEEK ROD IMPLANT TRAY LID	August 2006	Rule 1	Annex VII	12143	12143
7229326	CDHL PEEK WORK SHOP RODS TRAY	December 2006	Rule 1	Annex VII	12143	12143
7229326L	CDHL PEEK WORK SHOP RODS LID	December 2006	Rule 1	Annex VII	12143	12143
7229327	PEEK ROD NON-CANNULATED MAS IMPLANT TRAY	April 2007	Rule 1	Annex VII	12143	12143
CDH M8- Case and Trays						
165.326	M8 MAS EXTRA SCREW TRAY - SS	September 2001	Rule 1	Annex VII	12143	12143
170.025	CASE M8 4.5 5.0MM SCREW MOD TI	July 2012	Rule 1	Annex VII	12143	12143
170.125	CASE M8 5.5MM SCREW MOD TI	July 2012	Rule 1	Annex VII	12143	12143
170.129	HOOK AND SCREW IMPLANT TRAY	February 2003	Rule 1	Annex VII	12143	12143
170.133	HOOK AND SCREW IMPLANT TRAY	February 2003	Rule 1	Annex VII	12143	12143
170.143	Rods Module, Ti	September 2011	Rule 1	Annex VII	12143	12143
170.225	6.5/7.5mm Screw Module, Ti	September 2011	Rule 1	Annex VII	12143	12143
1700026	M8 MAS 4.5/5.0 IMPLNT MOD TI	September 2004	Rule 1	Annex VII	12143	12143
1700126	M8 MAS 5.5 IMPLNT MOD TI	September 2004	Rule 1	Annex VII	12143	12143
1700226	M8 MAS 6.5/7.5 IMPLNT MOD TI	September 2004	Rule 1	Annex VII	12143	12143
185.049	M8 MAS SCREW IMPLANT TRAY SET	July 2012	Rule 1	Annex VII	12143	12143
185-004	MODULE, PLUG CLOSURE INSTR BR	March 2000	Rule 1	Annex VII	12143	12143
185-008	MODULE, IMPLANT-HOLDER REDUCT	March 2000	Rule 1	Annex VII	12143	12143
185-012	MODULE, ROD REDUCER	March 2000	Rule 1	Annex VII	12143	12143
185-016	MODULE HOOK PRED-PEDI	March 2000	Rule 1	Annex VII	12143	12143
185-020	MODULE, COMP/DISTR/ROD HOLD	March 2000	Rule 1	Annex VII	12143	12143
185-028	MODULE, SCREW PREP	March 2000	Rule 1	Annex VII	12143	12143
185-052	BASE, SINGLE	March 2000	Rule 1	Annex VII	12143	12143
185-054	BASE, OUTER 2.5 INCH DEEP	March 2000	Rule 1	Annex VII	12143	12143
185-060	BASE, TRIPLE	May 2013	Rule 1	Annex VII	12143	12143
2800001L	M8 DEGEN MAS IMPL TRAY LID	August 2005	Rule 1	Annex VII	12143	12143
2880002	M8 DEGEN OUTER INST CASE	August 2005	Rule 1	Annex VII	12143	12143
8692001	M8 RMAS OUTER BASE - TI	September 2001	Rule 1	Annex VII	12143	12143
8692002	M8 RMAS INSTRUMENT TRAY - TI	September 2001	Rule 1	Annex VII	12143	12143
8692003	5.5 RMAS MODULE - TI	September 2001	Rule 1	Annex VII	12143	12143
8692004	6.5 & 7.5 RMAS MODULE - TI	September 2001	Rule 1	Annex VII	12143	12143
8692005	M8 REDUCTION PLUG MODULE- TI	September 2001	Rule 1	Annex VII	12143	12143
8692006	M8 RMAS MODULE TRAY - TI	September 2001	Rule 1	Annex VII	12143	12143
8692008	M8 RMAS TRAY RADEL LID - TI	September 2001	Rule 1	Annex VII	12143	12143
8692011	M8 PREBENT ROD MODULE	January 2002	Rule 1	Annex VII	12143	12143
8692012	M8 PREBENT ROD MODULE LID	January 2002	Rule 1	Annex VII	12143	12143
CDH Mini- Case and Trays						
7030010LINT	CDHL MINI OUTER CASE LID	April 2007	Rule 1	Annex VII	12143	12143
7030235INT	CDHL MINI SET SCREW MODULE, TI	April 2007	Rule 1	Annex VII	12143	12143
7030236INT	CDHL MINI SET SCREW MODULE, SS	April 2007	Rule 1	Annex VII	12143	12143
7030510INT	CDHL MINI INSTRUMENT OUTER CASE	April 2007	Rule 1	Annex VII	12143	12143
7030521INT	CDHL MINI INSTRUMENT TRAY 1	April 2007	Rule 1	Annex VII	12143	12143
7030522INT	CDHL MINI INSTRUMENT TRAY 2	April 2007	Rule 1	Annex VII	12143	12143

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7030523INT	CDHL MINI INSTRUMENT TRAY 3	April 2007	Rule 1	Annex VII	12143	12143
7038235LINT	CDHL MINI SET SCREW MODULE LID, SS	April 2007	Rule 1	Annex VII	12143	12143
7038510INT	CDHL MINI OUTER CASE, SS	April 2007	Rule 1	Annex VII	12143	12143
7038510LINT	CDHL MINI IMPLANT TRAY LID, SS	April 2007	Rule 1	Annex VII	12143	12143
7038520INT	CDHL MINI IMPLANT TRAY, SS	April 2007	Rule 1	Annex VII	12143	12143
7038533LINT	CDHL MINI HOOK MODULE LID, SS	April 2007	Rule 1	Annex VII	12143	12143
7038830INT	CDHL MINI X10 CROSSLINK MODULE, SS	April 2007	Rule 1	Annex VII	12143	12143
7038830LINT	CDHL MINI X10 CROSSLINK MODULE LID, SS	April 2007	Rule 1	Annex VII	12143	12143
7039235LINT	CDHL MINI SET SCREW MODULE LID, TI	April 2007	Rule 1	Annex VII	12143	12143
7039510INT	CDHL MINI OUTER CASE, TI	April 2007	Rule 1	Annex VII	12143	12143
7039510LINT	CDHL MINI IMPLANT TRAY LID, TI	April 2007	Rule 1	Annex VII	12143	12143
7039520INT	CDHL MINI IMPLANT TRAY, TI	April 2007	Rule 1	Annex VII	12143	12143
7039533INT	CDHL MINI HOOK MODULE, TI	April 2007	Rule 1	Annex VII	12143	12143
7039533LINT	CDHL MINI HOOK MODULE LID, TI	April 2007	Rule 1	Annex VII	12143	12143
7039830INT	CDHL MINI X10 CROSSLINK MODULE, TI	April 2007	Rule 1	Annex VII	12143	12143
7039830LINT	CDHL MINI X10 CROSSLINK MODULE LID, TI	April 2007	Rule 1	Annex VII	12143	12143
CDH Sextant- Case and Trays						
7572012	SEXTANT II TRAY 1 FOR EUROPE	February 2008	Rule 1	Annex VII	12143	12143
7573005	SEXTANT II REDUCTION INNER TRAY A	December 2007	Rule 1	Annex VII	12143	12143
7573006	SEXTANT II REDUCTION INNER TRAY B	December 2007	Rule 1	Annex VII	12143	12143
7573007	SEXTANT II REDUCTION INNER TRAY C	December 2007	Rule 1	Annex VII	12143	12143
8671001	SEXTANT TRIPLE OUTER CASE	January 2002	Rule 1	Annex VII	12143	12143
8671002	SEXTANT LOWER INSTRUMENT TRAY	January 2002	Rule 1	Annex VII	12143	12143
8671003	SEXTANT UPPER INSTRUMENT TRAY	January 2002	Rule 1	Annex VII	12143	12143
8671005	SEXTANT IMPLANT TRAY LID	January 2002	Rule 1	Annex VII	12143	12143
8671014	SEXTANT IMPLANT TRAY	September 2004	Rule 1	Annex VII	12143	12143
8675208	CDH SEXTANT REDUCTION OUTER LID	September 2007	Rule 1	Annex VII	12143	12143
8675209	CDH SEXTANT REDUCTION OUTER CASE	September 2007	Rule 1	Annex VII	12143	12143
8675210	CDH SEXTANT REDUCTION INSTRUMENT TRAY 1	September 2007	Rule 1	Annex VII	12143	12143
8675211	CDH SEXTANT REDUCTION INSTRUMENT TRAY 2	September 2007	Rule 1	Annex VII	12143	12143
8675301	SEXTANT MULTILEVEL OUTER CASE	August 2003	Rule 1	Annex VII	12143	12143
8675302	SEXTANT MULTILEVEL INST TRAY	August 2003	Rule 1	Annex VII	12143	12143
8675303	SEXTANT MULTILEVEL INST MODULE	August 2003	Rule 1	Annex VII	12143	12143
7679001	SHILLA Instrument Tray 1 - Case 3	April 2012	Rule 1	Annex VII	12143	12143
7679002	SHILLA Instrument Tray 2 - Case 3	April 2012	Rule 1	Annex VII	12143	12143
7679004	SHILLA Instrument Tray 1 - Case 4	April 2012	Rule 1	Annex VII	12143	12143
7679005	SHILLA Instrument Tray 2 - Case 4	April 2012	Rule 1	Annex VII	12143	12143
7679007	SHILLA Instrument Tray 1 - Case 5	April 2012	Rule 1	Annex VII	12143	12143
7679008	SHILLA Instrument Tray 2 - Case 5	April 2012	Rule 1	Annex VII	12143	12143
7679009	SHILLA Instrument Tray 3 - Case 5	April 2012	Rule 1	Annex VII	12143	12143
7679011	SHILLA Instrument Tray 1 - Case 6	April 2012	Rule 1	Annex VII	12143	12143
7679014	SHILLA 4.5 FAS IMPLANT TRAY 1	April 2012	Rule 1	Annex VII	12143	12143
7679016	SHILLA 4.5 IMPLANT TRAY	April 2012	Rule 1	Annex VII	12143	12143
7679017	Shilla 4.5 Imp/Inst Tray	April 2012	Rule 1	Annex VII	12143	12143
7679018	SHILLA 4.5 CROSSLINK CADDY	April 2012	Rule 1	Annex VII	12143	12143
7679019	SHILLA 4.5 CROSSLINK CADDY LID	April 2012	Rule 1	Annex VII	12143	12143
7679020	SHILLA 4.5 SET SCREW CADDY	April 2012	Rule 1	Annex VII	12143	12143
7679021	SHILLA 4.5 SET SCREW CADDY LID	April 2012	Rule 1	Annex VII	12143	12143
7679026	SHILLA 4.5 Implant/Instrument OCL	April 2012	Rule 1	Annex VII	12143	12143
7679027	SHILLA 4.5 FAS Implant Tray 2	April 2012	Rule 1	Annex VII	12143	12143
7679029	SHILLA 4.5 MAS Implant Tray 2	April 2012	Rule 1	Annex VII	12143	12143
7679051	SHILLA 5.5 FAS Implant Case 1	April 2012	Rule 1	Annex VII	12143	12143
7679053	SHILLA 5.5 MAS Implant Case 1	April 2012	Rule 1	Annex VII	12143	12143

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7679054	SHILLA 5.5 Implant and Instrument Tray	April 2012	Rule 1	Annex VII	12143	12143
7679055	SHILLA 5.5 Crosslink Caddy	April 2012	Rule 1	Annex VII	12143	12143
7679056	SHILLA 5.5 Crosslink Caddy Lid	April 2012	Rule 1	Annex VII	12143	12143
7679057	SHILLA 5.5 Set Screw Caddy	April 2012	Rule 1	Annex VII	12143	12143
7679058	SHILLA 5.5 Set Screw Caddy Lid	April 2012	Rule 1	Annex VII	12143	12143
7679060	SHILLA 5.5 Instrument Tray 1 - Case 3	April 2012	Rule 1	Annex VII	12143	12143
7679061	SHILLA 5.5 Instrument Tray 2 - Case 3	April 2012	Rule 1	Annex VII	12143	12143
7679063	SHILLA 5.5 Instrument Tray 1 - Case 4	April 2012	Rule 1	Annex VII	12143	12143
7679064	SHILLA 5.5 Instrument Tray 2 - Case 4	April 2012	Rule 1	Annex VII	12143	12143
7679066	SHILLA 5.5 Instrument Tray 1 - Case 5	April 2012	Rule 1	Annex VII	12143	12143
7679067	SHILLA 5.5 Instruments Tray 2 - Case 5	April 2012	Rule 1	Annex VII	12143	12143
7679068	SHILLA 5.5 Instrument Tray 3 - Case 5	April 2012	Rule 1	Annex VII	12143	12143
7679070	SHILLA 5.5 Instrument Tray 1 - Case 6	April 2012	Rule 1	Annex VII	12143	12143
7679073	SHILLA 5.5 MAS Implant Case 2	April 2012	Rule 1	Annex VII	12143	12143
7679076	SHILLA 5.5 FAS Implant Case 2	April 2012	Rule 1	Annex VII	12143	12143
CHD Longitude-Case and Trays						
7064800	Longitude II 4.75 Extenders tray Japan	December 2012	Rule 1	Annex VII	12143	12143
7064801	Longitude II 4.75 Reducers Tray Japan	December 2012	Rule 1	Annex VII	12143	12143
7064802	Longitude II 5.5-6.0 Extenders Tray JPN	December 2012	Rule 1	Annex VII	12143	12143
7064803	Longitude II 5.5-6.0 Reducers Tray JPN	December 2012	Rule 1	Annex VII	12143	12143
7064804	Longitude II JPN Universal Inst tray 1	December 2012	Rule 1	Annex VII	12143	12143
7064805	Longitude II JPN Universal INST Tray 2	December 2012	Rule 1	Annex VII	12143	12143
7064806	Longitude II JPN Universal INST Tray	December 2012	Rule 1	Annex VII	12143	12143
7064900	CDHL II 5.5 CN MAS 8.5-10.5 TRAY 1	February 2013	Rule 1	Annex VII	12143	12143
7064903	5.5 SET SCREW CADDY	February 2013	Rule 1	Annex VII	12143	12143
7064904	5.5 SET SCREW CADDY LID	February 2013	Rule 1	Annex VII	12143	12143
7064905	CDHL II 5.5 CN MAS 4.5-7.5 TRAY	March 2013	Rule 1	Annex VII	12143	12143
7064906	CDHL 4.75 CCM+ ROD LOWER TRAY	March 2013	Rule 1	Annex VII	12143	12143
7064907	CDHL 4.75 CCM+ ROD UPPER TRAY	March 2013	Rule 1	Annex VII	12143	12143
7064908	Sequential Reducer Tray for 5.5/6.0	February 2013	Rule 1	Annex VII	12143	12143
7064909	Extender Tray for 5.5/6.0	February 2013	Rule 1	Annex VII	12143	12143
7064910	Sequential Reducer tray for 4.75	February 2013	Rule 1	Annex VII	12143	12143
7064911	Extenders tray for 4.75	February 2013	Rule 1	Annex VII	12143	12143
7064912	CDHL II GEN INSTR 1 UPPER TRAY	February 2013	Rule 1	Annex VII	12143	12143
7064913	CDHL II GEN INSTR 1 LOWER TRAY	February 2013	Rule 1	Annex VII	12143	12143
7064914	CDHL II GEN INSTR 2 TRAY	February 2013	Rule 1	Annex VII	12143	12143
7064915	CDHL 5.5 CCM ROD LOWER TRAY	February 2013	Rule 1	Annex VII	12143	12143
7064916	CDHL 5.5 CCM ROD UPPER TRAY	February 2013	Rule 1	Annex VII	12143	12143
7064917	4.75 CANN MAS 4.5-7.5 TRAY	March 2013	Rule 1	Annex VII	12143	12143
7572000	SEXTANT II OUTER CASE	August 2005	Rule 1	Annex VII	12143	12143
7572001	SEXTANT II OUTER CASE LID	August 2005	Rule 1	Annex VII	12143	12143
7572002R	SEXTANT II, INSTRUMENT TRAY #1	October 2005	Rule 1	Annex VII	12143	12143
7572003	SEXTANT II, INSTRUMENT TRAY #2	August 2005	Rule 1	Annex VII	12143	12143
7572004	SEXTANT II INSTRUMENT TRAY #3	August 2005	Rule 1	Annex VII	12143	12143
7572006	SEXTANT II, IMPLANT TRAY LID	August 2005	Rule 1	Annex VII	12143	12143
7572008	SEXTANT II, IMPLANT TRAY	October 2005	Rule 1	Annex VII	12143	12143
7573001	SEXTANT II REDUCTION OUTER CASE	December 2006	Rule 1	Annex VII	12143	12143
7573004	SEXTANT II REDUCTION OUTER LID	December 2006	Rule 1	Annex VII	12143	12143
7574000	CDH LNGITUDE INSTR SET 1 (OUTR CASE)	August 2007	Rule 1	Annex VII	12143	12143
7574001	CDH LNGITUDE INSTR TRAY 1	August 2007	Rule 1	Annex VII	12143	12143
7574002	CDH LNGITUDE INSTR TRAY 2	August 2007	Rule 1	Annex VII	12143	12143
7574003	CDH LNGITUDE INSTR SET 2 (OUTR CASE)	August 2007	Rule 1	Annex VII	12143	12143
7574004	CDH LNGITUDE INSTRUMENT TRAY 3	August 2007	Rule 1	Annex VII	12143	12143

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7574005	CDH LNGITUDE IMPL SET (OUTR CASE)	August 2007	Rule 1	Annex VII	12143	12143
7574006	CDH LNGITUDE IMPL TRAY	August 2007	Rule 1	Annex VII	12143	12143
7574006L	CDH LNGITUDE IMPL TRAY LID	August 2007	Rule 1	Annex VII	12143	12143
7574007	CDH LNGITUDE STRGHT RODS TRAY	August 2007	Rule 1	Annex VII	12143	12143
7574008	CDH LNGITUDE SET SCREW MODULE	August 2007	Rule 1	Annex VII	12143	12143
7574008L	CDH LNGITUDE SETSCREW MOD LID	August 2007	Rule 1	Annex VII	12143	12143
7574009	CDH LNGITUDE MAS SCREW CADDY	August 2007	Rule 1	Annex VII	12143	12143
7574010	CDH LNGITUDE FAS IMPL TRAY	June 2012	Rule 1	Annex VII	12143	12143
7574010L	CDH LNGITUDE FAS IMPL TRAY LID	August 2007	Rule 1	Annex VII	12143	12143
7574040	LONGITUDE TRAUMA CASE	January 2011	Rule 1	Annex VII	12143	12143
7574040L	LONGITUDE TRAUMA LID	January 2011	Rule 1	Annex VII	12143	12143
1665000	Hybrid Universal Instrument Tray Upper	December 2015	Rule 1	Annex VII	12143	12143
1665001	Hybrid Universal Instrument Tray Lower	December 2015	Rule 1	Annex VII	12143	12143
1665002	LGII 4.75 Instrument Tray	December 2015	Rule 1	Annex VII	12143	12143
1665003	Hybrid General Instrument Tray	December 2015	Rule 1	Annex VII	12143	12143
1665004	CDHS 4.75mm Hybrid Perc Implant Tray	December 2015	Rule 1	Annex VII	12143	12143
1665005	MIS TLIF Distractor Instrument Tray	December 2015	Rule 1	Annex VII	12143	12143
1665006	LGII Refresh MAST SCR Tray	December 2015	Rule 1	Annex VII	12143	12143
1665007	Extender Reattachment Tool Tray	December 2015	Rule 1	Annex VII	12143	12143
1665008	CDHS VOYAGER™ Tab Extender Module	December 2015	Rule 1	Annex VII	12143	12143
1665009	CDHS VOYAGER™ Tab Extender Cap Module	December 2015	Rule 1	Annex VII	12143	12143
1665010	CDHS VOYAGER™ Tab Extender Module Lid	December 2015	Rule 1	Annex VII	12143	12143
1665011	CDHS VOYAGER™ Tab Extender Cap Module Ld	December 2015	Rule 1	Annex VII	12143	12143
1850049	Generic 3/4 Metal Lid	December 2015	Rule 1	Annex VII	12143	12143
1850176	CASE 1850176 SINGLE GENERIC OUTER CASE	December 2015	Rule 1	Annex VII	12143	12143
1850460	Generic 1/2 Lid	December 2015	Rule 1	Annex VII	12143	12143
7574141	CDH MAST Trauma Instrument Tray 1	December 2015	Rule 1	Annex VII	12143	12143
7574142	CDH MAST Trauma Instrument Tray 2	December 2015	Rule 1	Annex VII	12143	12143
7574144	CDH Set Screw Module	December 2015	Rule 1	Annex VII	12143	12143
7574145	CDH Set Screw Module Lid	December 2015	Rule 1	Annex VII	12143	12143
7574147	CDH MAST Trauma Rods and Set Screws Tray	December 2015	Rule 1	Annex VII	12143	12143
7574148	CDH MAST Trauma Instrments & Screws Tray	December 2015	Rule 1	Annex VII	12143	12143
COLORADO™ 2- Case and Trays						
5639011	PRAXIS PF LID	July 2005	Rule 1	Annex VII	12143	12143
5639012	PRAXIS PF UPPER INSERT LID	July 2005	Rule 1	Annex VII	12143	12143
5639013	PRAXIS PF UPPER INSERT	July 2005	Rule 1	Annex VII	12143	12143
5639014	PRAXIS PF LOWER INSERT LID	July 2005	Rule 1	Annex VII	12143	12143
5639015	PRAXIS PF LOWER INSERT	July 2005	Rule 1	Annex VII	12143	12143
5639016	PRAXIS PF SCREW RACK	July 2005	Rule 1	Annex VII	12143	12143
5639017	PRAXIS PF BASE	July 2005	Rule 1	Annex VII	12143	12143
5639021	PRAXIS CO LID	July 2005	Rule 1	Annex VII	12143	12143
5639022	PRAXIS CO UPPER INSERT LID	July 2005	Rule 1	Annex VII	12143	12143
5639023	PRAXIS CO UPPER INSERT	July 2005	Rule 1	Annex VII	12143	12143
5639024	PRAXIS CO INTER INSERT LID	July 2005	Rule 1	Annex VII	12143	12143
5639025	PRAXIS CO INTER INSERT	July 2005	Rule 1	Annex VII	12143	12143
5639026	PRAXIS CO LOWER INSERT	July 2005	Rule 1	Annex VII	12143	12143
5639027	PRAXIS CO SCREW RACK	July 2005	Rule 1	Annex VII	12143	12143
5639028	PRAXIS CO BASE	July 2005	Rule 1	Annex VII	12143	12143
5639031	PRAXIS HC LID	July 2005	Rule 1	Annex VII	12143	12143
5639032	PRAXIS HC UPPER INSERT LID	July 2005	Rule 1	Annex VII	12143	12143
5639033	PRAXIS HC UPPER INSERT	July 2005	Rule 1	Annex VII	12143	12143
5639034	PRAXIS HC INTER INSERT LID	July 2005	Rule 1	Annex VII	12143	12143
5639035	PRAXIS HC INTER INSERT	July 2005	Rule 1	Annex VII	12143	12143

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5639036	PRAXIS HC LOWER INSERT	July 2005	Rule 1	Annex VII	12143	12143
5639037	PRAXIS HC SCREW RACK	July 2005	Rule 1	Annex VII	12143	12143
5639038	PRAXIS HC BASE	July 2005	Rule 1	Annex VII	12143	12143
8617110	BASE,COLORADO 2 IMPLANT	March 2000	Rule 1	Annex VII	12143	12143
8617115	LID,BASE COLORADO 2 IMPLANT	March 2000	Rule 1	Annex VII	12143	12143
8617120	TRAY,COLO.2 LOWER-SCOLIOSIS	March 2000	Rule 1	Annex VII	12143	12143
8617125	TRAY,COLO.2 UPPER-SCOLIOSIS	March 2000	Rule 1	Annex VII	12143	12143
8617130	TRAY,COLO.2 LOWER DEGENER.	March 2000	Rule 1	Annex VII	12143	12143
8617140	MODULE,COLO.2 SCREW RACK	March 2000	Rule 1	Annex VII	12143	12143
8617150	BASE,COLO.2 INSTRUMENT U.S.	April 2013	Rule 1	Annex VII	12143	12143
8617160	TRAY,COLO.2 INSTRUMENT U.S.	March 2000	Rule 1	Annex VII	12143	12143
8617170	LID,BASE COLO.2 INSTRUMENT	March 2000	Rule 1	Annex VII	12143	12143
8617210	INSTRUMENT TRAY	March 2012	Rule 1	Annex VII	12143	12143
8617211	INSTRUMENT SCREW TRAY	March 2012	Rule 1	Annex VII	12143	12143
8617212	SCREW CADDY	March 2012	Rule 1	Annex VII	12143	12143
8617213	IMPLANT TRAY	March 2012	Rule 1	Annex VII	12143	12143
8617214	IMPLANT MODULE	March 2012	Rule 1	Annex VII	12143	12143
8617215	MODULE LID	March 2012	Rule 1	Annex VII	12143	12143
8617216	LID	March 2012	Rule 1	Annex VII	12143	12143
8617400	GENERIC LID	July 2013	Rule 1	Annex VII	12143	12143
8617410	IMPLANT CASE	July 2013	Rule 1	Annex VII	12143	12143
8617412	BREAK-OFF NUT MODULE	July 2013	Rule 1	Annex VII	12143	12143
8617413	CONNECTOR MODULE	July 2013	Rule 1	Annex VII	12143	12143
8617414	PEDICLE SCREW MODULE	July 2013	Rule 1	Annex VII	12143	12143
8617415	ROD MODULE	July 2013	Rule 1	Annex VII	12143	12143
8617416	SACRAL SCREW MODULE	July 2013	Rule 1	Annex VII	12143	12143
8617417	ADD-ON MODULE	July 2013	Rule 1	Annex VII	12143	12143
8617420	INSTRUMENT CASE #1	July 2013	Rule 1	Annex VII	12143	12143
8617422	INSTRUMENT CASE #2	July 2013	Rule 1	Annex VII	12143	12143
8617424	INSTRUMENT CASE #3	July 2013	Rule 1	Annex VII	12143	12143
8617430	IMPLANT CASE	July 2013	Rule 1	Annex VII	12143	12143
8617432	PEDICLE SCREW MODULE	July 2013	Rule 1	Annex VII	12143	12143
8617433	CONNECTOR MODULE	July 2013	Rule 1	Annex VII	12143	12143
8617434	PELVIC FIXATION MODULE	July 2013	Rule 1	Annex VII	12143	12143
8617435	HOOK MODULE	July 2013	Rule 1	Annex VII	12143	12143
8617436	HOOK CLAW MODULE	July 2013	Rule 1	Annex VII	12143	12143
8617437	SACRAL SCREW MODULE	July 2013	Rule 1	Annex VII	12143	12143
8617440	INSTRUMENT CASE #1	July 2013	Rule 1	Annex VII	12143	12143
8617450	CASE	July 2013	Rule 1	Annex VII	12143	12143
8617451	LID	July 2013	Rule 1	Annex VII	12143	12143
8617452	TRAY	July 2013	Rule 1	Annex VII	12143	12143
8617453	PELVIC FIXATION MODULE	July 2013	Rule 1	Annex VII	12143	12143
8617454	PELVIC FIXATION LID	July 2013	Rule 1	Annex VII	12143	12143
8617455	CONNECTOR MODULE	July 2013	Rule 1	Annex VII	12143	12143
8617456	CONNECTOR LID	July 2013	Rule 1	Annex VII	12143	12143
8617457	SACRAL SCREW RACK	July 2013	Rule 1	Annex VII	12143	12143
8617458	SACRAL SCREW LID	July 2013	Rule 1	Annex VII	12143	12143
8617459	ILIO-SACRAL AND REVISION SCREW RACK	July 2013	Rule 1	Annex VII	12143	12143
8617460	ILIO-SACRAL AND REVISION SCREW LID	July 2013	Rule 1	Annex VII	12143	12143
8617462	BREAK-OFF NUT MODULE LID	July 2013	Rule 1	Annex VII	12143	12143
8617463	CONNECTOR MODULE LID	July 2013	Rule 1	Annex VII	12143	12143
8617464	PEDICLE SCREW MODULE LID	July 2013	Rule 1	Annex VII	12143	12143
8617465	ROD MODULE LID	July 2013	Rule 1	Annex VII	12143	12143

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8617466	SACRAL SCREW MODULE LID	July 2013	Rule 1	Annex VII	12143	12143
8617467	ADD-ON MODULE LID	July 2013	Rule 1	Annex VII	12143	12143
8617472	PEDICLE SCREW MODULE LID	July 2013	Rule 1	Annex VII	12143	12143
8617473	CONNECTOR MODULE LID	July 2013	Rule 1	Annex VII	12143	12143
8617474	PELVIC FIXATION MODULE LID	July 2013	Rule 1	Annex VII	12143	12143
8617475	HOOK MODULE LID	July 2013	Rule 1	Annex VII	12143	12143
8617476	HOOK CLAW MODULE LID	July 2013	Rule 1	Annex VII	12143	12143
8617477	SACRAL SCREW MODULE LID	July 2013	Rule 1	Annex VII	12143	12143
8627180	CASE,COLO.2 FIXATION	February 2003	Rule 1	Annex VII	12143	12143
8627190	LID,COLO.2 SS CASE	February 2003	Rule 1	Annex VII	12143	12143
8627200	COLORADO II SS SCREW TRAY	February 2003	Rule 1	Annex VII	12143	12143
8627205	COLORADO II SS SCREW LID	February 2003	Rule 1	Annex VII	12143	12143
8627210	COLORADO II SS CONNECTOR TRAY	February 2003	Rule 1	Annex VII	12143	12143
8627215	COLORADO II SS CONNECTOR LID	February 2003	Rule 1	Annex VII	12143	12143
8627220	COLORADO II SS INSTRUMENT TRAY	February 2003	Rule 1	Annex VII	12143	12143
8637110	BASE,COLO.2 IMPLANT - TI	March 2000	Rule 1	Annex VII	12143	12143
8637115	LID,COLO.2 IMPLANT BASE - TI	March 2000	Rule 1	Annex VII	12143	12143
8637120	TRAY,COLO.2 SCOLIOSIS TI-LOWER	March 2000	Rule 1	Annex VII	12143	12143
8637125	TRAY,COLO.2 SCOLIOSIS TI-UPPER	March 2000	Rule 1	Annex VII	12143	12143
8637130	TRAY,COLO.2 LOWER DEGENER. TI	March 2000	Rule 1	Annex VII	12143	12143
8637145	MODULE,COLO.2 ROD SUPPORT TI	March 2000	Rule 1	Annex VII	12143	12143
8637190	LID,CASE COLO.2 TI	March 2000	Rule 1	Annex VII	12143	12143
8647100	PEDIATRIC INSTRUMENT CASE	February 2002	Rule 1	Annex VII	12143	12143
8647180	CO II, TI OUTER BASE	August 2002	Rule 1	Annex VII	12143	12143
8647190	CO II, TI OUTER LID	August 2002	Rule 1	Annex VII	12143	12143
8647200	CO II, TI SACRAL SCREW TRAY	August 2002	Rule 1	Annex VII	12143	12143
8647205	CO II, TI SACRAL SCREW LID	August 2002	Rule 1	Annex VII	12143	12143
8647210	CO II, TI SACRAL CONNECT TRAY	August 2002	Rule 1	Annex VII	12143	12143
8647215	CO II, TI SACRAL CONNECTOR LID	August 2002	Rule 1	Annex VII	12143	12143
8647220	CO II, TI INSTRUMENT TRAY	August 2002	Rule 1	Annex VII	12143	12143
8667210	COLORADO II SS 6.35MM MODULE	January 2003	Rule 1	Annex VII	12143	12143
Coplanar- Case and Trays						
X0709071	Upper Tray	March 2012	Rule 1	Annex VII	12143	12143
X0709072	Lower Tray	March 2012	Rule 1	Annex VII	12143	12143
DYNALOK Classic- Case and Trays						
1850331	INSTRUMENT TRAY # 1	October 2000	Rule 1	Annex VII	12143	12143
1850333	INSTRUMENT TRAY # 2	October 2000	Rule 1	Annex VII	12143	12143
General Instruments- Case and Trays						
105-101	CASE,GENERIC OUTER-BASE	April 1998	Rule 1	Annex VII	12143	12143
105-102	CASE LID - GENERIC	April 1998	Rule 1	Annex VII	12143	12143
105-109	LID,FULL MODULAR-GENERIC	March 2000	Rule 1	Annex VII	12143	12143
165-322	GENERIC FULL IMPLANT TRAY LID	May 2013	Rule 1	Annex VII	12143	12143
1850065	EXTRAS SET - HALF SIZE LID	March 2011	Rule 1	Annex VII	12143	12143
1850066	EXTRAS SET - HALF SIZE	March 2011	Rule 1	Annex VII	12143	12143
1850094	Generic 3/4 Tray Lid (Greatbatch)	January 2011	Rule 1	Annex VII	12143	12143
1850094K*	GENERIC 3/4 TRAY LID (GREATBACH)	March 2016	Rule 1	Annex VII	12143	12143
1850095	Generic Metal Implant Lid	January 2011	Rule 1	Annex VII	12143	12143
1850096	Generic Metal Implant Lid	July 2014	Rule 1	Annex VII	12143	12143
1850098	IMPLANT TRAY LID	April 2012	Rule 1	Annex VII	12143	12143
1850099	GENERIC RADEL IMPLANT TRAY LID	January 2011	Rule 1	Annex VII	12143	12143
185-460L	GENERIC 1/2 TRAY LID	December 2011	Rule 1	Annex VII	12143	12143
3280048	GENERAL KIT BASE	February 2004	Rule 1	Annex VII	12143	12143
3280050	GENERAL KIT LOWER TRAY	February 2004	Rule 1	Annex VII	12143	12143

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3280051	GENERAL KIT MIDDLE TRAY	February 2004	Rule 1	Annex VII	12143	12143
3280052	GENERAL KIT UPPER TRAY	February 2004	Rule 1	Annex VII	12143	12143
4390000G	GENERIC TISSUE CASE LID	May 2005	Rule 1	Annex VII	12143	12143
7480400	LID GENERIC	July 2012	Rule 1	Annex VII	12143	12143
7480401	CASE SSR ONLY	July 2012	Rule 1	Annex VII	12143	12143
7480402	CASE WRT ONLY	July 2012	Rule 1	Annex VII	12143	12143
7480403	CASE WRT ADD-ON	July 2012	Rule 1	Annex VII	12143	12143
7480404	TRAY SSR ONLY	July 2012	Rule 1	Annex VII	12143	12143
7480405	TRAY WRT ONLY	July 2012	Rule 1	Annex VII	12143	12143
7480406	TRAY WRT ADD-ON	July 2012	Rule 1	Annex VII	12143	12143
7480504	CASE 7480504 DOUBLE OUTER	October 2007	Rule 1	Annex VII	12143	12143
7480505	TRAY 7480505 INNER TRAY 1	October 2007	Rule 1	Annex VII	12143	12143
7480506	TRAY 7480506 PSO INSTRUMENT SET 2 OF 2	October 2007	Rule 1	Annex VII	12143	12143
7480651	CASE OSTEOTOMES	December 2012	Rule 1	Annex VII	12143	12143
7480652	TRAY OSTEOTOMES LEVEL 1	December 2012	Rule 1	Annex VII	12143	12143
7480653	TRAY OSTEOTOMES LEVEL 2	December 2012	Rule 1	Annex VII	12143	12143
7480654	CASE REDUCTION PLIER	December 2012	Rule 1	Annex VII	12143	12143
7480655	TRAY REDUCTION PLIER	December 2012	Rule 1	Annex VII	12143	12143
7480656	MODULE ADAPTORS	December 2012	Rule 1	Annex VII	12143	12143
8361234	SCREW REMOVAL	December 2005	Rule 1	Annex VII	12143	12143
8489601	CD HORIZON ECLIPSE DISCECTOMY SHAVER TRAY	NO RELEASE DATE	Rule 1	Annex VII	12143	12143
8670016	PAK KIT LOANER TRAY	July 2004	Rule 1	Annex VII	12143	12143
8670017	PAK KIT LOANER TRAY LID	July 2004	Rule 1	Annex VII	12143	12143
8690001	COBALT CHROME ROD MODULE	May 2006	Rule 1	Annex VII	12143	12143
8690002	COBALT CHROME ROD MODULE LID	May 2006	Rule 1	Annex VII	12143	12143
897-900	BASE, ENDORING	January 2007	Rule 1	Annex VII	12143	12143
897-901	TRAY, ENDORING-UPPER	March 2003	Rule 1	Annex VII	12143	12143
897-902	TRAY, ENDORING-LOWER	March 2003	Rule 1	Annex VII	12143	12143
X0204990	TRANS SACRAL SCREW OUTER CASE	July 2004	Rule 1	Annex VII	12143	12143
X0204991	TRANS SACRAL SCREW OUTER LID	July 2004	Rule 1	Annex VII	12143	12143
X0204992	TRANS SACRAL SCREW INNER TRAY	July 2004	Rule 1	Annex VII	12143	12143
X0206017	SPECIALS SCREW TRAY	November 2006	Rule 1	Annex VII	12143	12143
X0304998S	VAS SPACER TRAY (SS)	June 2004	Rule 1	Annex VII	12143	12143
X0304998T	VAS SPACER TRAY (TI)	June 2004	Rule 1	Annex VII	12143	12143
X0304999S	VAS SPACER TRAY LID (SS)	June 2004	Rule 1	Annex VII	12143	12143
X0304999T	VAS SPACER LID (TI)	June 2004	Rule 1	Annex VII	12143	12143
X0406070	SPECIALS CROSSLINK INSTRUMENT TRAY	September 2006	Rule 1	Annex VII	12143	12143
X0406072	SPECIALS CROSSLINK MODULE SMALL LID 1	September 2006	Rule 1	Annex VII	12143	12143
X0406073	SPECIALS CROSSLINK MODULE SMALL LID 2	September 2006	Rule 1	Annex VII	12143	12143
X0406075	SPECIALS CROSSLINK MODULE LARGE LID 1	September 2006	Rule 1	Annex VII	12143	12143
X0406076	SPECIALS CROSSLINK MODULE LARGE LID 2	September 2006	Rule 1	Annex VII	12143	12143
X0804400	OUTER CASE-CUSTOM THREADED MODULAR RODS	January 2007	Rule 1	Annex VII	12143	12143
X0903050	OUTER CASE	November 2003	Rule 1	Annex VII	12143	12143
X0903051	DISC SHAVERS TRAY	November 2003	Rule 1	Annex VII	12143	12143
X0903052	REAMERS AND BROACHES TRAY	November 2003	Rule 1	Annex VII	12143	12143
X0905180	CUSTOM TUBE TRAY	November 2005	Rule 1	Annex VII	12143	12143
X1009009	CSP DLIF Plate and Nut Caddy	November 2009	Rule 1	Annex VII	12143	12143
X1009010	CSP DLIF Plate and Nut Caddy Lid	November 2009	Rule 1	Annex VII	12143	12143
X1009522	Cannulated DLIF Implant Tray	March 2010	Rule 1	Annex VII	12143	12143
X1009523	Cannulated DLIF Instrument Tray	March 2010	Rule 1	Annex VII	12143	12143
X105-129	UPPER IMPLANT MODULE	April 2003	Rule 1	Annex VII	12143	12143
X105-130	LOWER IMPLANT MODULE	April 2003	Rule 1	Annex VII	12143	12143
X1205140	ABT IMPLANTS LID	March 2006	Rule 1	Annex VII	12143	12143

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X1205141	ABT IMPLANTS OUTER	March 2006	Rule 1	Annex VII	12143	12143
X1205142	ABT IMPLANTS TRAY 1	March 2006	Rule 1	Annex VII	12143	12143
X1205143	ABT IMPLANTS TRAY 2	March 2006	Rule 1	Annex VII	12143	12143
X8689999	CUSTOM M8 SCREW CASE SS	April 2003	Rule 1	Annex VII	12143	12143
X8699999	CUSTOM M8 SCREW CASE TI	April 2003	Rule 1	Annex VII	12143	12143
X9198994	REDUCED PROFILE SCISSOR JACK TRAY	June 2006	Rule 1	Annex VII	12143	12143
X9198995	REDUCED PROFILE SCISSOR JACK LID	June 2006	Rule 1	Annex VII	12143	12143
43000000	SUITCASE LARGE (GENERIC)	April 1998	Rule 1	Annex VII	12143	12143
9167100	INSTRUMENTS CASE	October 2002	Rule 1	Annex VII	12143	12143
9099081	FACET SCREW GUIDE TRAY	September 2001	Rule 1	Annex VII	12143	12143
9099082	FACET SCREW GUIDE TRAY	September 2001	Rule 1	Annex VII	12143	12143
9099083	FACET SCREW GUIDE CADDY	September 2001	Rule 1	Annex VII	12143	12143
9099084	FACET SCREW GUIDE CADDY LID	September 2001	Rule 1	Annex VII	12143	12143
7068010	INSTRUMENT OUTER TRAY *	September 2016	Rule 1	Annex VII	12143	12143
7068011	INSTRUMENT INNER TRAY *	September 2016	Rule 1	Annex VII	12143	12143
7068012	GENERIC LID *	September 2016	Rule 1	Annex VII	12143	12143
7068013	GENERIC LID HALF *	September 2016	Rule 1	Annex VII	12143	12143
7068016	SOL 5.5/6.0 SAS CANNULATED TRAY *	September 2016	Rule 1	Annex VII	12143	12143
1850022	IMPLANT TRAY 5.5/6.0°	December 2016	Rule 1	Annex VII	12143	12143
1850021	INSTRUMENT TRAY°	December 2016	Rule 1	Annex VII	12143	12143
1850020	GENERIC LID°	December 2016	Rule 1	Annex VII	12143	12143
7068014	LEG 5.5 FAS CANNULATED OUTER TRAY°	December 2016	Rule 1	Annex VII	12143	12143
7068015	LEG 5.5 FAS CANNULATED INNER TRAY°	December 2016	Rule 1	Annex VII	12143	12143
7068017	ROD TRAY°	December 2016	Rule 1	Annex VII	12143	12143
7068018	SETSCREW MODULE°	December 2016	Rule 1	Annex VII	12143	12143
7068019	SETSCREW MODULE LID°	December 2016	Rule 1	Annex VII	12143	12143
1850023	IMPLANT TRAY 4.75°	December 2016	Rule 1	Annex VII	12143	12143
1850024	SETSCREW MODULE°	December 2016	Rule 1	Annex VII	12143	12143
1850025	SETSCREW MODULE LID°	December 2016	Rule 1	Annex VII	12143	12143
7068021	5.5/6.0 Core Kit Tray A §	February 2019	Rule 1	Annex VII	12143	12143
7068022	5.5/6.0 Core Kit Tray B §	February 2019	Rule 1	Annex VII	12143	12143
7068023	Extender tab module §	February 2019	Rule 1	Annex VII	12143	12143
7068031	4.75 Distractor Degen Tray §	February 2019	Rule 1	Annex VII	12143	12143
7068032	5.5/6.0 Distractor Degen Tray §	February 2019	Rule 1	Annex VII	12143	12143
7068033	Retractor Tray §	February 2019	Rule 1	Annex VII	12143	12143
7068027	5.5/6.0 Capped Rod Tray §	February 2019	Rule 1	Annex VII	12143	12143
7068025	Extension Kit Tray §	February 2019	Rule 1	Annex VII	12143	12143
7068026	Open Kit Tray §	February 2019	Rule 1	Annex VII	12143	12143
7068030	Half DIN lid §	February 2019	Rule 1	Annex VII	12143	12143

* Items are part of NFORCE™ Instruments/° items are part of the Procedural Degenerative Kit Instruments/§ Items are part of Space-D™ or SpaceView™ Instrument Systems

MAST QUADRANT- Case and Trays

9568006	QUADRANT BLADE MODULE TRAY	September 2005	Rule 1	Annex VII	12143	12143
9568012	MAST QUADRANT OUTER CASE (NEW)	July 2005	Rule 1	Annex VII	12143	12143
9568013	MAST QUADRANT TRAY	July 2005	Rule 1	Annex VII	12143	12143

Medtronic Rod Connector- Case and Trays

778001101	CASE, MRC IMPLANT, TI	January 2008	Rule 1	Annex VII	12143	12143
778001103	TRAY, MRC INSTRUMENT #1	January 2008	Rule 1	Annex VII	12143	12143
778001104	TRAY, MRC INSTRUMENT #2	January 2008	Rule 1	Annex VII	12143	12143
778001105	MOD LID, MRC 6.35	January 2008	Rule 1	Annex VII	12143	12143
778001106	MOD LID, MRC 5.5	January 2008	Rule 1	Annex VII	12143	12143
778001107	IMPLANT MOD, MRC 6.35 TI	January 2008	Rule 1	Annex VII	12143	12143
778001108	IMPLANT MOD, MRC 5.5 TI	January 2008	Rule 1	Annex VII	12143	12143

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778001109	IMPLANT MOD, MRC 4.5 TI	January 2008	Rule 1	Annex VII	12143	12143
778001110	MOD LID, MRC 4.5	January 2008	Rule 1	Annex VII	12143	12143
778001111	CASE, MRC IMPLANT, SS	July 2008	Rule 1	Annex VII	12143	12143
778001114	IMPLANT MOD, MRC 6.35 SS	July 2008	Rule 1	Annex VII	12143	12143
778001115	IMPLANT MOD, MRC 5.5 SS	July 2008	Rule 1	Annex VII	12143	12143
778001116	IMPLANT MOD, MRC 4.5 SS	July 2008	Rule 1	Annex VII	12143	12143
778001118	IMPLANT MOD MRC SAGITTAL, SS	July 2008	Rule 1	Annex VII	12143	12143
778001119	IMPLANT MOD MRC SAGITTAL, TI	January 2008	Rule 1	Annex VII	12143	12143
778001120	MODULE LID MRC SAGITTAL	January 2008	Rule 1	Annex VII	12143	12143
778001136	TRAY MRC IMPLANT	January 2008	Rule 1	Annex VII	12143	12143
778001139	CASE MRC INSTRUMENT	July 2008	Rule 1	Annex VII	12143	12143
778001141	MRC Implant Tray, Ti	February 2010	Rule 1	Annex VII	12143	12143
778001142	MRC 6.35 Module, Ti	February 2010	Rule 1	Annex VII	12143	12143
778001143	MRC 6.35 Module Lid	February 2010	Rule 1	Annex VII	12143	12143
778001144	MRC 5.5 Module, Ti	February 2010	Rule 1	Annex VII	12143	12143
778001145	MRC 5.5 Module Lid	February 2010	Rule 1	Annex VII	12143	12143
778001148	MRC 4.5 Module, Ti	February 2010	Rule 1	Annex VII	12143	12143
778001149	MRC 4.5 Module Lid	February 2010	Rule 1	Annex VII	12143	12143
778001152	MRC Setscrew Module, Ti	February 2010	Rule 1	Annex VII	12143	12143
778001153	MRC Setscrew Module Lid	February 2010	Rule 1	Annex VII	12143	12143
778001155	MRC Implant Tray, SS	February 2010	Rule 1	Annex VII	12143	12143
778001156	MRC 6.35 Module, SS	February 2010	Rule 1	Annex VII	12143	12143
778001157	MRC 6.35 Module Lid, SS	February 2010	Rule 1	Annex VII	12143	12143
778001158	MRC 5.5 Module, SS	February 2010	Rule 1	Annex VII	12143	12143
778001159	MRC 5.5 Module Lid, SS	February 2010	Rule 1	Annex VII	12143	12143
778001160	MRC 4.5 Module, SS	February 2010	Rule 1	Annex VII	12143	12143
778001161	MRC 4.5 Module Lid, SS	February 2010	Rule 1	Annex VII	12143	12143
778001164	MRC Setscrew Module, SS	February 2010	Rule 1	Annex VII	12143	12143
778001165	MRC Setscrew Module Lid, SS	February 2010	Rule 1	Annex VII	12143	12143
778001170	MRC OUS Instrument Tray 1	April 2010	Rule 1	Annex VII	12143	12143
METRx- Case and Trays						
9560007	KERRISON / PITUITARY TRAY	July 2003	Rule 1	Annex VII	12143	12143
9560009	GENERAL INSTRUMENT TRAY	July 2003	Rule 1	Annex VII	12143	12143
9560011	METRX INSTRUMENTS OUTER CASE	July 2003	Rule 1	Annex VII	12143	12143
9560517	METRX MED INSTRUMENT CASE LID	April 2004	Rule 1	Annex VII	12143	12143
9560518	METRX MED INST. MID TRAY	April 2004	Rule 1	Annex VII	12143	12143
9560519	METRX MED INST. BASE ASM	April 2004	Rule 1	Annex VII	12143	12143
9560520	METRX MED INST. UPPER TRAY	April 2004	Rule 1	Annex VII	12143	12143
9560521	METRX MED CABLE CASSETTE ASM	April 2004	Rule 1	Annex VII	12143	12143
9560522	METRX MED INST. LOWER TRAY	April 2004	Rule 1	Annex VII	12143	12143
9560530	BASE, MET RX	October 2004	Rule 1	Annex VII	12143	12143
9560531	METRX MED SET	December 2003	Rule 1	Annex VII	12143	12143
9560692	BI POLAR CABLE CASSETTE	September 2004	Rule 1	Annex VII	12143	12143
9560693	METRX STRAIGHT BI POLAR SPOOL	October 2002	Rule 1	Annex VII	12143	12143
9560694	METRX (GENERIC) OUTER BASE LID	May2001	Rule 1	Annex VII	12143	12143
9560695	METRX MICRO INSTRUMENT BASE	October 2002	Rule 1	Annex VII	12143	12143
9560696	METRX MICRO INSTR. TOP TRAY	October 2002	Rule 1	Annex VII	12143	12143
9560697	METRX MICRO INSTR. BOTTOM TRAY	October 2002	Rule 1	Annex VII	12143	12143
9560698	CASE, METRX MD BASE	September 2004	Rule 1	Annex VII	12143	12143
9560699	TRAY, METRX MD INST	September 2004	Rule 1	Annex VII	12143	12143
9560700	METRX LARGE TUBES OUTER BASE	October 2002	Rule 1	Annex VII	12143	12143
9560701	METRX LARGE TUBES TRAY	October 2002	Rule 1	Annex VII	12143	12143
9560711	METRX DOUBLE OUTER BASE	February 2003	Rule 1	Annex VII	12143	12143

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9560799	QUADRANT STERILE SUITCASE	October 2010	Rule 1	Annex VII	12143	12143
9562012	METRX SCOPE OUTER BASE	October 2002	Rule 1	Annex VII	12143	12143
9562013	METRX SCOPE SET TRAY	October 2002	Rule 1	Annex VII	12143	12143
9562014	METRX 5MM LIGHT CABLE SPOOL	October 2002	Rule 1	Annex VII	12143	12143
9562015	METRX V-MOUNT CAMERA HEAD SPOOL	October 2002	Rule 1	Annex VII	12143	12143
9562016	X-TUBE OUTER BASE	November 2002	Rule 1	Annex VII	12143	12143
9562017	X-TUBE UPPER INSTRUMENT TRAY	November 2002	Rule 1	Annex VII	12143	12143
9562018	X-TUBE LOWER INSTRUMENT TRAY	October 2002	Rule 1	Annex VII	12143	12143
9562019	DYNALOK MAST OUTER BASE	October 2002	Rule 1	Annex VII	12143	12143
9562020	DYNALOK MAST INSTRUMENT TRAY	October 2002	Rule 1	Annex VII	12143	12143
9562021	DYNALOK MAST IMPLANT TRAY	October 2002	Rule 1	Annex VII	12143	12143
9562022	DYNALOK MAST OUTER BASE LID	October 2002	Rule 1	Annex VII	12143	12143
9562023	DYNALOK MAST IMPLANT TRAY LID	October 2002	Rule 1	Annex VII	12143	12143
9562118	TRAY METRX X-TUBE LOWER INSTRUMENT TRAY	May 2008	Rule 1	Annex VII	12143	12143
9569529	DILATORS TRAY, RIGID	September 2005	Rule 1	Annex VII	12143	12143
9569530	OUTER CASE, FLEX ARM	September 2005	Rule 1	Annex VII	12143	12143
9569532	METRX FLEX ARM TRAY RIGID	January 2006	Rule 1	Annex VII	12143	12143
9569667	TUBE CADDY, 14MM	June 2005	Rule 1	Annex VII	12143	12143
9569677	TUBE CADDY, 16MM	June 2005	Rule 1	Annex VII	12143	12143
9569687	TUBE CADDY, 18MM	June 2005	Rule 1	Annex VII	12143	12143
9569694	OUTER CASE, LID	May 2006	Rule 1	Annex VII	12143	12143
9569712	FLEX ARM/DILATORS TRAY, ARTIC	May 2006	Rule 1	Annex VII	12143	12143
9569727	TUBE CADDY, 20MM	September 2005	Rule 1	Annex VII	12143	12143
9569737	TUBE CADDY, 22MM	September 2005	Rule 1	Annex VII	12143	12143
9569757	TUBE CADDY, 26MM	September 2005	Rule 1	Annex VII	12143	12143
9569790	OUTER CASE, METRX II INSTRMNTS	September 2005	Rule 1	Annex VII	12143	12143
9569791	INSTRUMENT TRAY 1	September 2005	Rule 1	Annex VII	12143	12143
9569792	INSTRUMENT TRAY 2	September 2005	Rule 1	Annex VII	12143	12143
9569793	INSTRUMENT TRAY 3	September 2005	Rule 1	Annex VII	12143	12143
9569794	INSTRUMENT TRAY 4	September 2005	Rule 1	Annex VII	12143	12143
9569795	INSTRUMENT TRAY 2 (NESTED)	September 2005	Rule 1	Annex VII	12143	12143
9569796	OUTER CASE, NON DISP TUBES	September 2005	Rule 1	Annex VII	12143	12143
9569797	TUBE TRAY 1	September 2005	Rule 1	Annex VII	12143	12143
9569798	TUBE TRAY 2	September 2005	Rule 1	Annex VII	12143	12143
MICRO-ENDO System- Case and Trays						
9562004	METRX MICRODISECTOMY TRAY 4	February 2003	Rule 1	Annex VII	12143	12143
9562005	METRX MICRODISECTOMY TRAY 3	February 2003	Rule 1	Annex VII	12143	12143
MILDLINE Focus- Case and Trays						
9563200	FOCUS Access Instr Rigid Arm Tray	September 2011	Rule 1	Annex VII	12143	12143
9563201	FOCUS Access Instr Snake Arm Tray	September 2011	Rule 1	Annex VII	12143	12143
9563202	FOCUS Access Instr Posterior CP Tray	September 2011	Rule 1	Annex VII	12143	12143
9563203	FOCUS Access Instr Lateral CP Tray	September 2011	Rule 1	Annex VII	12143	12143
9563204	FOCUS Access Instr Posterior Tray	September 2011	Rule 1	Annex VII	12143	12143
9563205	FOCUS Access Instr Lateral Tray	September 2011	Rule 1	Annex VII	12143	12143
9563214	FOCUS Access Instruments Retractor Tray	September 2011	Rule 1	Annex VII	12143	12143
9563215	MidLine Access Instr Tray (Core)	November 2011	Rule 1	Annex VII	12143	45181
9563217	FOCUS Access Instr Stability Pin Tray	September 2011	Rule 1	Annex VII	12143	12143
9563218	MidLine disc prep tray 1	November 2011	Rule 1	Annex VII	12143	45181
9563219	MidLine disc prep tray 2	November 2011	Rule 1	Annex VII	12143	45181
9563250	MidLine Instrument Tray (Gen2)	November 2011	Rule 1	Annex VII	12143	45181
MSD WIRE SYSTEM- Case and Trays						
3490020	MSD WIRE SYSTEM CASE	September 2002	Rule 1	Annex VII	12143	12143
3490040	MSD WIRE INSTRUMENT TRAY	September 2002	Rule 1	Annex VII	12143	12143

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3490062	MSD WIRE CADDY	September 2002	Rule 1	Annex VII	12143	12143
3490072	MSD WIRE CADDY LID (WIRE 3508)	September 2002	Rule 1	Annex VII	12143	12143
3490074	MSD WIRE CADDY LID (WIRE 3510)	September 2002	Rule 1	Annex VII	12143	12143
3490075	MSD Wire 1.0mm Caddy	January 2010	Rule 1	Annex VII	12143	12143
3490076	MSD WIRE CADDY LID (WIRE 3512)	September 2002	Rule 1	Annex VII	12143	12143
3490077	MSD Wire 1.2mm Caddy	January 2010	Rule 1	Annex VII	12143	12143
3490078	MSD 3516 WIRE CADDY LID	April 2003	Rule 1	Annex VII	12143	12143
3490079	MSD Wire 1.6mm Caddy	January 2010	Rule 1	Annex VII	12143	12143
IPC® POWERASE Instruments- Case and Trays						
2393002	Tapping/Driving Set w/ NIM Sleeves Tray	April 2012	Rule 1	Annex VII	12143	12143
2395002	Set Screw Break Off and Rod Cutter Tray	April 2012	Rule 1	Annex VII	12143	12143
2397002	PowerEase Driver Tray	April 2012	Rule 1	Annex VII	12143	12143
CDH Solera Instruments- Case and Trays						
11010938	CD HORIZON® SOLERA? ATS Imp Tray	March 2014	Rule 1	Annex VII	12143	12143
1850070	EXTRAS SET - FULL SIZE	February 2003	Rule 1	Annex VII	12143	12143
1850078	CASE 1850078 TRIPLE GENERIC OUTER CASE	February 2013	Rule 1	Annex VII	12143	12143
1850103	Set Screw Module Lid	January 2011	Rule 1	Annex VII	12143	12143
1850104	4.0 MAS Screw Module Lid	January 2011	Rule 1	Annex VII	12143	12143
1850105	4.5 MAS Screw Module Lid	January 2011	Rule 1	Annex VII	12143	12143
1850106	5.0 MAS Screw Module Lid	January 2011	Rule 1	Annex VII	12143	12143
1850107	5.5 MAS Screw Module Lid	January 2011	Rule 1	Annex VII	12143	12143
1850108	6.0 MAS Screw Module Lid	January 2011	Rule 1	Annex VII	12143	12143
1850109	6.5 MAS Screw Module Lid	January 2011	Rule 1	Annex VII	12143	12143
1850110	7.5 MAS Screw Module Lid	January 2011	Rule 1	Annex VII	12143	12143
1850111	8.5 MAS Screw Module Lid	January 2011	Rule 1	Annex VII	12143	12143
1850112	9.5 MAS Screw Module Lid	January 2011	Rule 1	Annex VII	12143	12143
1854010	Hook Module Lid 1	January 2011	Rule 1	Annex VII	12143	12143
1854011	Hook Module Lid 2	January 2011	Rule 1	Annex VII	12143	12143
1854101	CDHS4.75 Degenerative Implant Lower Tray	January 2011	Rule 1	Annex VII	12143	12143
1854102	CDHS4.75 Degenerative Implant Upper Tray	January 2011	Rule 1	Annex VII	12143	12143
1854104	CDHS 4.75 Degen Inst. Tray 2	January 2011	Rule 1	Annex VII	12143	12143
1854105	CDHS 4.75 Degen Inst. Tray 1	January 2011	Rule 1	Annex VII	12143	12143
1854106	Triple Lift Basket	January 2011	Rule 1	Annex VII	12143	12143
1854200	CDHS 4.75 S471 Upper Tray	January 2011	Rule 1	Annex VII	12143	12143
1854201	CDHS 4.75 S471 Lower Tray	January 2011	Rule 1	Annex VII	12143	12143
1854202	CHDS 4.75 G147 Upper Tray	January 2011	Rule 1	Annex VII	12143	12143
1854203	CDHS 4.75 Reduction Instrument Tray	January 2011	Rule 1	Annex VII	12143	12143
1854204	CDHS 4.75 4SHI Hook Instrument Tray	January 2011	Rule 1	Annex VII	12143	12143
1854205	CDHS 4.75 4SHI Hook Module Lid	January 2011	Rule 1	Annex VII	12143	12143
1854206	CDHS 4.75 4SHI Hook Module	January 2011	Rule 1	Annex VII	12143	12143
1854207	CDHS 4.75 Crosslink Instruments Tray	January 2011	Rule 1	Annex VII	12143	12143
1854208	CDHS 4.75 G147 Lower Tray	January 2011	Rule 1	Annex VII	12143	12143
1854209	Deformity Tag Sorter	January 2011	Rule 1	Annex VII	12143	12143
1854210	Deformity Tag Sorter Lid	January 2011	Rule 1	Annex VII	12143	12143
1854211	CDHS Degenerative Tag Sorter	January 2011	Rule 1	Annex VII	12143	12143
1854212	CDHS Degenerative Tag Sorter Lid	January 2011	Rule 1	Annex VII	12143	12143
1854213	Ø4.75mm Solera Crosslink Implant Tray	January 2011	Rule 1	Annex VII	12143	12143
1854214	Ø4.75mm Solera Crosslink Instrument Tray	January 2011	Rule 1	Annex VII	12143	12143
1854221	CDHS Degenerative Setscrew Module Lid	January 2011	Rule 1	Annex VII	12143	12143
1854222	CDHS Degenerative Setscrew Module	January 2011	Rule 1	Annex VII	12143	12143
1855117	CDHS ECA 4.75 Crosslink Instrument Tray	February 2011	Rule 1	Annex VII	12143	12143
1855118	CDHS ECA 4.75 Crosslink Implant Module	February 2011	Rule 1	Annex VII	12143	12143
1855119	CDHS ECA Crosslink Implant Module Lid	February 2011	Rule 1	Annex VII	12143	12143

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1855120	CDHS ECA Long Screw Module	February 2011	Rule 1	Annex VII	12143	12143
1855121	CDHS ECA Long Screw Module Lid	February 2011	Rule 1	Annex VII	12143	12143
1855123	CDH 5.5/6.35 Combined x-link inst tray	September 2012	Rule 1	Annex VII	12143	12143
1855125	CD Horizon Solera 5.5/6.0 MAS EU tray	September 2012	Rule 1	Annex VII	12143	12143
1855127	CD Horizon Solera 5.5/6.0 FAS EU tray	September 2012	Rule 1	Annex VII	12143	12143
1855129	CD Horizon Solera 5.5/6.0 SAS EU tray	November 2012	Rule 1	Annex VII	12143	12143
1855131	CD Horizon Solera 5.5/6.0 Ex MAS EU try	September 2012	Rule 1	Annex VII	12143	12143
1855133	CDHS EU Additional short imp/inst tray	September 2012	Rule 1	Annex VII	12143	12143
1855134	CDHS EU 5.5 Prebent rod tray	September 2012	Rule 1	Annex VII	12143	12143
1855135	CDH EU 5.5 x-link module	September 2012	Rule 1	Annex VII	12143	12143
1855136	CDH EU 5.5 x-link mod lid	September 2012	Rule 1	Annex VII	12143	12143
1855137	CDHS EU 5.5/6.0 set screw mod lid	September 2012	Rule 1	Annex VII	12143	12143
1855139	CDHS EU 5/6 Std Instrument Upper Tray	September 2012	Rule 1	Annex VII	12143	12143
1855140	CDHS EU 5/6 Std Instrument Lower Tray	September 2012	Rule 1	Annex VII	12143	12143
1855142	CD Horizon Solera 5.5/6.0 lg rod tray 1	September 2012	Rule 1	Annex VII	12143	12143
1855143	CD Horizon Solera 5.5/6.0 lg rod tray 2	September 2012	Rule 1	Annex VII	12143	12143
1855144	CD Horizon Legacy 6.35mm Hook mod lid	September 2012	Rule 1	Annex VII	12143	12143
1855145	CD Horizon Legacy 5.5mm Hook Module	September 2012	Rule 1	Annex VII	12143	12143
1855146	CD Horizon Legacy 5.5mm Hook mod lid	September 2012	Rule 1	Annex VII	12143	12143
1855147	CD Horizon Legacy 5.5/6.35 Hook Tray	September 2012	Rule 1	Annex VII	12143	12143
1855149	CDHS 5.5 EU Deformity Inst upper tray	September 2012	Rule 1	Annex VII	12143	12143
1855150	CDHS 5.5 EU Deformity Inst lower tray	September 2012	Rule 1	Annex VII	12143	12143
1855152	CDHS EU 5.5/6.0 set screw module	September 2012	Rule 1	Annex VII	12143	12143
1855153	CD Horizon Legacy 6.35 Hook Module	September 2012	Rule 1	Annex VII	12143	12143
7068047	IMPLANT INSTRUMENT 4.75 TRAY	March 2014	Rule 1	Annex VII	12143	12143
7068060	IMPLANT INSTRUMENT 5.5/6.0 TRAY	March 2014	Rule 1	Annex VII	12143	13180
7068300	Instrument Tray 1	January 2011	Rule 1	Annex VII	12143	12143
7068301	Instrument Tray 2	January 2011	Rule 1	Annex VII	12143	12143
7068302	Hook Implant Tray	January 2011	Rule 1	Annex VII	12143	12143
7068303	Hook Instrument Tray	January 2011	Rule 1	Annex VII	12143	12143
7068304	Instrument Set 2 Tray 1	January 2011	Rule 1	Annex VII	12143	12143
7068305	Instrument Set 2 Tray 2	January 2011	Rule 1	Annex VII	12143	12143
7068306	Instrument Set 1 Tray 1	January 2011	Rule 1	Annex VII	12143	12143
7068307	Instrument Set 1 Tray 2	January 2011	Rule 1	Annex VII	12143	12143
7068308	Crosslink Implant Tray	January 2011	Rule 1	Annex VII	12143	12143
7068309	Crosslink Instrument Tray	January 2011	Rule 1	Annex VII	12143	12143
7068310	4.75 MAS Screw Tray 4.0 - 5.0	January 2011	Rule 1	Annex VII	12143	12143
7068311	4.0 MAS Screw Module	January 2011	Rule 1	Annex VII	12143	12143
7068312	4.75 MAS Screw Tray 5.5 - 6.5	January 2011	Rule 1	Annex VII	12143	12143
7068321	4.75 Sextant Instrument Set Tray 2	June 2011	Rule 1	Annex VII	12143	12143
7068323	4.75 Sextant Instrument Set Tray 1	June 2011	Rule 1	Annex VII	12143	12143
7068334	4.75 Sextant Reduction Inst Set Tray 2	June 2011	Rule 1	Annex VII	12143	12143
7068335	4.75 Sextant Reduction Inst Set Tray 1	June 2011	Rule 1	Annex VII	12143	12143
7068337	4.75 Sextant Bilateral Inst Set Tray 2	June 2011	Rule 1	Annex VII	12143	12143
7068349	Solera 4.75 Mini Open Instrument Tray 1	April 2011	Rule 1	Annex VII	12143	12143
7068360	FAS Implant Tray	January 2011	Rule 1	Annex VII	12143	12143
7068363	Set Screw Module	January 2011	Rule 1	Annex VII	12143	12143
7068364	Instrument Set 3 Tray 1	January 2011	Rule 1	Annex VII	12143	12143
7068365	4.5 MAS Screw Module	January 2011	Rule 1	Annex VII	12143	12143
7068366	Hook Module 1	April 2011	Rule 1	Annex VII	12143	12143
7068367	Hook Module 2	April 2011	Rule 1	Annex VII	12143	12143
7068368	7.5 MAS Screw Module	January 2011	Rule 1	Annex VII	12143	12143
7068369	8.5 MAS Screw Module	January 2011	Rule 1	Annex VII	12143	12143

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7068370	9.5 MAS Screw Module	January 2011	Rule 1	Annex VII	12143	12143
7068371	Instrument Set 3 Tray 2	January 2011	Rule 1	Annex VII	12143	12143
7068372	4.75 Rod Tray	January 2011	Rule 1	Annex VII	12143	12143
7068373	Iliac Fully Threaded Implant Tray	January 2011	Rule 1	Annex VII	12143	12143
7068374	Iliac CMAS Implant Tray	January 2011	Rule 1	Annex VII	12143	12143
7068378	4.75 Sextant Set Screw Caddy Lid	June 2011	Rule 1	Annex VII	12143	12143
7068379	4.75 Sextant Implant and Inst. Set	June 2011	Rule 1	Annex VII	12143	12143
7068380	Solera 4.75 Mini Open Instrument Tray 2	April 2011	Rule 1	Annex VII	12143	12143
7068384	4.75 Sextant Set Screw Caddy	June 2011	Rule 1	Annex VII	12143	12143
7068386	4.75 Sextant Bilateral Inst Set Tray 1	June 2011	Rule 1	Annex VII	12143	12143
7068387	4.75 MAS Screw Tray 7.5 - 9.5	January 2011	Rule 1	Annex VII	12143	12143
7068388	5.0 MAS Screw Module	January 2011	Rule 1	Annex VII	12143	12143
7068389	5.5 MAS Screw Module	January 2011	Rule 1	Annex VII	12143	12143
7068390	6.0 MAS Screw Module	January 2011	Rule 1	Annex VII	12143	12143
7068391	Set Screw Module Lid	January 2011	Rule 1	Annex VII	12143	12143
7068392	Set Screw Module	January 2011	Rule 1	Annex VII	12143	12143
7068393	Hook Module Lid 3	January 2011	Rule 1	Annex VII	12143	12143
7068394	Hook Module Lid 4	January 2011	Rule 1	Annex VII	12143	12143
7068395	Lift Basket (DOUBLE)	January 2011	Rule 1	Annex VII	12143	12143
7068400	CDH Solera Hook Module 1 (Revised)	January 2011	Rule 1	Annex VII	12143	12143
7068401	CDH Solera Hook Module 2 (Revised)	January 2011	Rule 1	Annex VII	12143	12143
7068402	CDHS Cannulated Tap Module Lid	April 2011	Rule 1	Annex VII	12143	12143
7068403	4.75 Standalone/Extra Setscrew Module	April 2011	Rule 1	Annex VII	12143	12143
7068404	4.75 Extra Non BOff Setscrew ModuleLid	January 2011	Rule 1	Annex VII	12143	12143
7068405	4.75 Extra Breakoff Setscrew ModuleLid	January 2011	Rule 1	Annex VII	12143	12143
7068406	CDHS Ø4.75mm Degenerative Rod Tray	February 2011	Rule 1	Annex VII	12143	16046
7068408	CDHS 4.75 Sequential Reducer InstTray	April 2011	Rule 1	Annex VII	12143	12143
7068410	CDHL 6.35 FAS EXTRA CASE, SS	September 2005	Rule 1	Annex VII	12143	12143
7068420	CDHL 6.35 ROD ADD-ON TRAY, SS	September 2005	Rule 1	Annex VII	12143	12143
7068420L	CDHL 6.35 ROD ADD-ON LID, SS	September 2005	Rule 1	Annex VII	12143	12143
7068421L	CDHL 6.35 FAS IMPLANT LID, SS	August 2004	Rule 1	Annex VII	12143	12143
7068429	CDHL 6.35 LRG CAP SCREWS, SS	August 2004	Rule 1	Annex VII	12143	12143
7068429L	CDHL 6.35 LRG CAP SCREW LID SS	August 2004	Rule 1	Annex VII	12143	12143
7068500	CDHS 4.75 Small MAS Screw Tray	January 2011	Rule 1	Annex VII	12143	12143
7068501	CDHS 4.75 Small MAS Lower Tray	January 2011	Rule 1	Annex VII	12143	12143
7068502	CDHS 4.75 Medium MAS Screw Tray	January 2011	Rule 1	Annex VII	12143	12143
7068503	CDHS 4.75 Medium MAS Lower Tray	January 2011	Rule 1	Annex VII	12143	12143
7068504	CDHS 4.75 Large MAS Screw Tray	January 2011	Rule 1	Annex VII	12143	12143
7068505	CDHS 4.75 RMAS Screw Tray	December 2011	Rule 1	Annex VII	12143	12143
7068506	CDH Solera 4.75 Reduct Screw Inst Tray	December 2011	Rule 1	Annex VII	12143	12143
7068507	CDHS 4.75 RMAS Setscrew Module	December 2011	Rule 1	Annex VII	12143	12143
7068508	CDHS 4.75 RMAS Setscrew Module Lid	December 2011	Rule 1	Annex VII	12143	12143
7068509	CDHS 4.75 FAS Screw Tray	February 2011	Rule 1	Annex VII	12143	12143
7068510	CDHS 4.75 FAS Lower Screw Tray	February 2011	Rule 1	Annex VII	12143	12143
7068512	CDHS Extra 4.0 MAS Module Lid	January 2011	Rule 1	Annex VII	12143	12143
7068513	CDHS Extra 6.0 Module	February 2011	Rule 1	Annex VII	12143	12143
7068514	CDHS Extra 6.0 MAS Module Lid	February 2011	Rule 1	Annex VII	12143	12143
7068515	CDHS Extra 6.5-7.5 MAS Module	February 2011	Rule 1	Annex VII	12143	12143
7068516	CDHS Extra 6.5-7.5 MAS Module Lid	February 2011	Rule 1	Annex VII	12143	12143
7068517	CDHS Ø4.75mm Expanded Rod Tray	February 2011	Rule 1	Annex VII	12143	12143
7068518	CDHS Ø4.75mm Setscrew Module	February 2011	Rule 1	Annex VII	12143	12143
7068519	CDHS Ø4.75mm Setscrew Module Lid	February 2011	Rule 1	Annex VII	12143	12143
7068520	CDHS 4.75 Deformity Instr Tray 1 Upper	January 2011	Rule 1	Annex VII	12143	12143

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7068521	CDHS 4.75 Deformity Instr Tray 2 Lower	January 2011	Rule 1	Annex VII	12143	12143
7068522	CDHS 4.75 Deformity Instr Tray 3 Upper	January 2011	Rule 1	Annex VII	12143	12143
7068523	CDHS 4.75 Deformity Inst Tray 4 Lower	January 2011	Rule 1	Annex VII	12143	12143
7068524	CDHL 6.35 HOOK IMPLANT TRAY SS	August 2004	Rule 1	Annex VII	12143	12143
7068525	Non-Breakoff Set Screw Module	January 2011	Rule 1	Annex VII	12143	12143
7068526	Instrument Set 3 Module	April 2011	Rule 1	Annex VII	12143	12143
7068527	Instrument Set 3 Module Lid	January 2011	Rule 1	Annex VII	12143	12143
7068528	Pedicle Marker Module	February 2011	Rule 1	Annex VII	12143	12143
7068529	Pedicle Marker Module Lid	February 2011	Rule 1	Annex VII	12143	12143
7068530	CDHS 4.75 4.0mm Extra Screw Module	January 2011	Rule 1	Annex VII	12143	12143
7068531	Non-Breakoff 3/4 Tray	January 2011	Rule 1	Annex VII	12143	12143
7068532	CDHL 6.35 STD HOOK MOD, SS	September 2004	Rule 1	Annex VII	12143	12143
7068532L	CDHL 6.35 STD HOOK MOD LID, SS	August 2004	Rule 1	Annex VII	12143	12143
7068533	CDHL 6.35 SPEC HOOK MOD, SS	September 2004	Rule 1	Annex VII	12143	12143
7068533L	CDHL 6.35 SPEC HOOK MOD LID SS	August 2004	Rule 1	Annex VII	12143	12143
7068534	CDHS 4.75 Small MAS Lower Module 1	January 2011	Rule 1	Annex VII	12143	12143
7068535	CDHS 4.75 Small MAS Lower Module 2	January 2011	Rule 1	Annex VII	12143	12143
7068536	CDHS 4.75 Medium MAS Lower Module 1	January 2011	Rule 1	Annex VII	12143	12143
7068537	CDHS 4.75 Medium MAS Lower Module 2	January 2011	Rule 1	Annex VII	12143	12143
7068538	CDHS 4.75 Medium MAS Lower Module 3	January 2011	Rule 1	Annex VII	12143	12143
7068539	CDHS 4.75 FAS Lower Module (7.5)	February 2011	Rule 1	Annex VII	12143	12143
7068540	CDHS Extra 4.5-5.0 MAS Module	February 2011	Rule 1	Annex VII	12143	12143
7068541	CDHS Extra 4.5-5.0 MAS Module Lid	February 2011	Rule 1	Annex VII	12143	12143
7068542	CDHS Extra 5.5-7.5 FAS Module	February 2011	Rule 1	Annex VII	12143	12143
7068543	CDHS Extra 5.5-7.5 FAS Module Lid	February 2011	Rule 1	Annex VII	12143	12143
7068544	CDHS Extra 5.5-7.5 MAS Module	February 2011	Rule 1	Annex VII	12143	12143
7068545	ECA Standard Instrument Tray 1	February 2011	Rule 1	Annex VII	12143	12143
7068546	ECA Standard Instrument Tray 2	February 2011	Rule 1	Annex VII	12143	12143
7068547	ECA Addtl Deformity Instr Tray 1	February 2011	Rule 1	Annex VII	12143	12143
7068548	ECA Addtl Deformity Instr Tray 2	February 2011	Rule 1	Annex VII	12143	12143
7068549	CDHS ECA Hook, Hook Trial, and Setscrew Module	February 2011	Rule 1	Annex VII	12143	12143
7068550	CDHS ECA Hook, Hook Trial, and Setscrew Module Lid	February 2011	Rule 1	Annex VII	12143	12143
7068555	CDHS ECA Hook Instrument Tray	February 2011	Rule 1	Annex VII	12143	12143
7068556	CDHS ECA Long Construct Upper Tray	February 2011	Rule 1	Annex VII	12143	12143
7068557	CDHS ECA Long Construct Lower Tray	February 2011	Rule 1	Annex VII	12143	12143
7068558	4.75 OUS ROD MODULE 80-120MM	February 2011	Rule 1	Annex VII	12143	12143
7068559	4.75 OUS ROD MODULE 30-70MM	February 2011	Rule 1	Annex VII	12143	12143
7068560	CDHS ECA Short Construct Upper Tray	February 2011	Rule 1	Annex VII	12143	12143
7068561	CDHS ECA Short Construct Lower Tray	February 2011	Rule 1	Annex VII	12143	12143
7068562	CDH Solera 4.75 VCM Instrument Tray	June 2011	Rule 1	Annex VII	12143	12143
7068563	CDH Solera Comp/Distractor Tray	February 2011	Rule 1	Annex VII	12143	12143
7068564	CDHS Extra 7.5 CNMAS Module	December 2011	Rule 1	Annex VII	12143	12143
7068565	CDHS Extra 7.5 CNMAS Module Lid	December 2011	Rule 1	Annex VII	12143	12143
7068566	CDHS Extra 5.5-8.5 CNMAS Module	December 2011	Rule 1	Annex VII	12143	12143
7068567	CDHS Extra 5.5-8.5 CNMAS Module Lid	December 2011	Rule 1	Annex VII	12143	12143
7068568	CDHS - 4.75 Degen Rod Insert Tray 90-120	December 2011	Rule 1	Annex VII	12143	12143
7068569	CDHS - 4.75mm Long (500mm) Rod Module	December 2011	Rule 1	Annex VII	12143	12143
7068570	CDHS 4.75 JPN SEXTANT SSMO INST TRAY	December 2011	Rule 1	Annex VII	12143	12143
7068571	Small Tag Sorter Lid with RFID	December 2011	Rule 1	Annex VII	12143	12143
7068573	CDHS ECA Sextant Instrument Set 1	December 2011	Rule 1	Annex VII	12143	12143
7068575	CDHS ECA Sextant Instrument Set 2	December 2011	Rule 1	Annex VII	12143	12143
7068576	CDHS 4.75 Sextant Bi-Lat Instr Tray Up	December 2011	Rule 1	Annex VII	12143	12143
7068577	CDHS 4.75 Sexant Bi-Lat Instr Tray Lwr	December 2011	Rule 1	Annex VII	12143	12143

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7068578	CDHS 4.75 Jpn Sextant Std Instr Tray 1	December 2011	Rule 1	Annex VII	12143	12143
7068579	CDHS 4.75 Jpn Sextant Std Instr Tray 2	December 2011	Rule 1	Annex VII	12143	12143
7068581	CDHS 4.75 CNRMAS INSTRUMENT TRAY	September 2011	Rule 1	Annex VII	12143	12143
7068582	SMARTLINK Extender Instr Tray 1	January 2012	Rule 1	Annex VII	12143	12143
7068583	SMARTLINK Extender Instr Tray 2	January 2012	Rule 1	Annex VII	12143	12143
7068585	Cortical Screw Implant Tray	March 2013	Rule 1	Annex VII	12143	12143
7068586	Cortical Screw Implant Module	March 2013	Rule 1	Annex VII	12143	12143
7068587	Cortical Screw Implant Module Lid	March 2013	Rule 1	Annex VII	12143	12143
7068588	Cannulated SAS Screw Implant Tray	June 2013	Rule 1	Annex VII	12143	12143
7068589	Cannulated SAS Screw Lower Instr Tray	June 2013	Rule 1	Annex VII	12143	12143
7068610	LEGACY RMAS 6.35 OUTER CASE,SS	December 2004	Rule 1	Annex VII	12143	12143
7068620	LEGACY RMAS 6.35 IMPL TRAY, SS	December 2004	Rule 1	Annex VII	12143	12143
7068620L	LEGACY RMAS 6.35 IMPL LID, SS	December 2004	Rule 1	Annex VII	12143	12143
7069000	CDHS 4.75 Mini Open Implant Upper Tray	December 2011	Rule 1	Annex VII	12143	12143
7069001	CDHS 4.75 Sextant Implant Upper Tray	December 2011	Rule 1	Annex VII	12143	12143
7069002	CDHS 4.75 Cannulated Screw Lower Tray	December 2011	Rule 1	Annex VII	12143	12143
7069003	CDHS Sextant Setscrew Module Lid	December 2011	Rule 1	Annex VII	12143	12143
7069004	CDHS 5.5/6.0mm Setscrew Module Lid	January 2012	Rule 1	Annex VII	12143	12143
7069005	Dual Lead Tap Tray	December 2011	Rule 1	Annex VII	12143	12143
7069006	CDHS 5.5/6.0 Instrument Set 1 Upr Tray	January 2012	Rule 1	Annex VII	12143	12143
7069007	CDHS 5.5/6.0 Instrument Set 1 Lwr Tray	January 2012	Rule 1	Annex VII	12143	12143
7069008	CDHS 5.5 INSTRUMENT SET 2 UPPER TRAY	January 2012	Rule 1	Annex VII	12143	12143
7069009	CDHS 5.5 INSTRUMENT SET 2 LOWER TRAY	January 2012	Rule 1	Annex VII	12143	12143
7069011	CDHS 5.5/6.0 Ø4.0-5.0 (Small) Screw Tray	January 2012	Rule 1	Annex VII	12143	12143
7069012	CDHS 5.5/6.0 Ø4.0-5.0 MAS Upper Imp Tray	January 2012	Rule 1	Annex VII	12143	12143
7069013	CDHS 5.5/6.0 Ø4.0-5.0 MAS Lower Imp Tray	January 2012	Rule 1	Annex VII	12143	12143
7069014	CDHS 5.5/6.0 Ø4.0-5.0 MAS Lower Mod 1	January 2012	Rule 1	Annex VII	12143	12143
7069015	CDHS 5.5/6.0 Ø5.0 MAS Lower Mod 2	January 2012	Rule 1	Annex VII	12143	12143
7069016	CDHS 5.5/6.0 Ø5.5-7.5 MAS Upper Imp Tray	January 2012	Rule 1	Annex VII	12143	12143
7069017	CDHS 5.5/6.0 Ø5.5-7.5 MAS Lower Imp Tray	January 2012	Rule 1	Annex VII	12143	12143
7069018	CDHS 5.5/6.0 Ø5.5-6.5 MAS Lower Mod 1	January 2012	Rule 1	Annex VII	12143	12143
7069019	CDHS 5.5/6.0 Ø6.5 MAS Lower Mod 2	January 2012	Rule 1	Annex VII	12143	12143
7069020	CDHS 5.5/6.0 Ø6.5-7.5 MAS Lower Mod 3	January 2012	Rule 1	Annex VII	12143	12143
7069021	CDHS 5.5/6.0 Ø8.5-9.5 MAS Imp & Tap Tray	January 2012	Rule 1	Annex VII	12143	12143
7069022	CDHS 5.5/6.0 Ø4.5-6.5 SAS Upper Tray	January 2012	Rule 1	Annex VII	12143	12143
7069023	CDHS 5.5/6.0 Ø4.0-7.5 SAS Lower Tray	January 2012	Rule 1	Annex VII	12143	12143
7069024	CDHS 5.5/6.0 Ø5.5-7.5 (Med) Screw Tray	January 2012	Rule 1	Annex VII	12143	12143
7069025	CDHS 5.5/6.0 Ø4.5-7.5 FAS Upper Imp Tray	January 2012	Rule 1	Annex VII	12143	12143
7069026	CDHS 5.5/6.0 Ø4.5-7.5 FAS Lower Imp Tray	January 2012	Rule 1	Annex VII	12143	12143
7069027	CDHS 5.5/6.0 Ø4.5-5.0 FAS Lower Mod 1	January 2012	Rule 1	Annex VII	12143	12143
7069028	CDHS 5.5/6.0 Ø5.0-7.5 FAS Lower Mod 2	January 2012	Rule 1	Annex VII	12143	12143
7069029	Large Tag Sorter Lid with RFID.	December 2011	Rule 1	Annex VII	12143	12143
7069030	CDHS 5.5 INSTRUMENT SET 3 UPPER TRAY	January 2012	Rule 1	Annex VII	12143	12143
7069031	CDHS 5.5mm Prebent Rod Tray	January 2012	Rule 1	Annex VII	12143	12143
7069032	CDHS 5.5mm Setscrew Module	January 2012	Rule 1	Annex VII	12143	12143
7069033	CDHS 5.5/6.0 Setscrew Module Lid	January 2012	Rule 1	Annex VII	12143	12143
7069034	CDHS 5.5 INSTRUMENT SET 3 LOWER TRAY	January 2012	Rule 1	Annex VII	12143	12143
7069035	CDHS 5.5/6.0mm Non-Breakoff Instr Tray	January 2012	Rule 1	Annex VII	12143	12143
7069036	CDHS 5.5/6.0 500mm Rod Tray Lower Tray	January 2012	Rule 1	Annex VII	12143	12143
7069037	CDHS 5.5/6.0 500mm Rod Tray Upper Tray	January 2012	Rule 1	Annex VII	12143	12143
7069038	CDHS 5.5/6.0 Set Screw Caddy	January 2012	Rule 1	Annex VII	12143	12143
7069039	CDHS 5.5/6.0 Set Screw Caddy Lid	January 2012	Rule 1	Annex VII	12143	12143
7069040	CDHS 5.5/6.0 Ø4.0 SAS Lower Mod 1	November 2012	Rule 1	Annex VII	12143	12143

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7069041	CDHS 5.5/6.0 Reduction Instrument Tray	January 2012	Rule 1	Annex VII	12143	12143
7069044	CDHS 5.5/6.0 RMAS Implant Tray	January 2012	Rule 1	Annex VII	12143	12143
7069045	CDHS 5.5/6.0 RMAS Setscrew Module	January 2012	Rule 1	Annex VII	12143	12143
7069046	CDHS 5.5/6.0 RMAS Setscrew Module Lid	January 2012	Rule 1	Annex VII	12143	12143
7069047	CDHS 5.5/6.0 MAS Extras Lower Mod 3	January 2012	Rule 1	Annex VII	12143	12143
7069048	CDHS 5.5/6.0 Ø7.5 FAS Lower Mod 3	January 2012	Rule 1	Annex VII	12143	12143
7069049	CDHS 5.5/6.0 Ø4.0-7.5 SAS Lower Mod 2	November 2012	Rule 1	Annex VII	12143	12143
7069050	CDHS 5.5/6.0 Ø7.5 SAS Lower Mod 3	November 2012	Rule 1	Annex VII	12143	12143
7069051	CDH Solera 5.5/6.0 MAS 6.0 Screw Caddy	September 2012	Rule 1	Annex VII	12143	12143
7069052	CDH Solera 5.5/6.0 MAS 6.0 Scrw Cdy Lid	September 2012	Rule 1	Annex VII	12143	12143
7069053	CDH Solera 5.5/6.0 MAS 6.5-9.5 Screw Cdy	September 2012	Rule 1	Annex VII	12143	12143
7069054	CDH 5.5/6.0 MAS 6.5-9.5 Srew Caddy Lid	September 2012	Rule 1	Annex VII	12143	12143
7069055	CDH 5.5/6.0 MAS Large 8.5-9.5 Screw Cdy	September 2012	Rule 1	Annex VII	12143	12143
7069056	CDH 5.5/6.0 MAS 8.5-9.5 Lrge Scrw Cdy Ld	September 2012	Rule 1	Annex VII	12143	12143
7069057	CDHS 5.5/6.0 FL Small Lower Mod 1	September 2012	Rule 1	Annex VII	12143	12143
7069058	CDHS 5.5/6.0 FL Small Lower Mod 2	September 2012	Rule 1	Annex VII	12143	12143
7069059	CDHS 5.5/6.0 FL Med Lower Mod 1	September 2012	Rule 1	Annex VII	12143	12143
7069060	CDHS 5.5/6.0 FL Med Lower Mod 2	September 2012	Rule 1	Annex VII	12143	12143
7069061	CDHS 5.5/6.0 FL Med Lower Mod 3	September 2012	Rule 1	Annex VII	12143	12143
7069062	CDHS 5.5/6.0 FL FAS Lower Mod 1	September 2012	Rule 1	Annex VII	12143	12143
7069063	CDHS 5.5/6.0 FL FAS Lower Mod 2	September 2012	Rule 1	Annex VII	12143	12143
7069064	CDHS 5.5/6.0 FL FAS Lower Mod 3	September 2012	Rule 1	Annex VII	12143	12143
7069065	Lumbar Focused Impl & Inst Set Tray 1	October 2012	Rule 1	Annex VII	12143	12143
7069066	Lumbar Focused Impl & Inst Set Tray 2	October 2012	Rule 1	Annex VII	12143	12143
7069067	Lumbar Focused Instrument Set Tray 1	October 2012	Rule 1	Annex VII	12143	12143
7069068	Lumbar Focused Instrument Set Tray 2	October 2012	Rule 1	Annex VII	12143	12143
7069070	CDH 5.5/6.0 FAS Extra Screw Cdy 5.5-7.5	September 2012	Rule 1	Annex VII	12143	12143
7069071	CDH 5.5/6.0 FAS 5.5-7.5 Xtra Scw Cdy Ld	September 2012	Rule 1	Annex VII	12143	12143
7069072	5.5/6.0 MAS Extra (4.5-5.0) Screw Caddy	September 2012	Rule 1	Annex VII	12143	12143
7069073	5.5/6.0 MAS Xtra (4.5-5.0) Screw Cdy Lid	September 2012	Rule 1	Annex VII	12143	12143
7069074	5.5/6.0 MAS Extras (5.5-7.5) Tray	September 2012	Rule 1	Annex VII	12143	12143
7069075	CDHS 5.5/6.0 SA Extra Set Screw Module	September 2012	Rule 1	Annex VII	12143	12143
7069076	CDHS 5.5/6.0 SA Extra Set Screw Mod Lid	September 2012	Rule 1	Annex VII	12143	12143
7069078	SEGMENTAL TRAY	June 2013	Rule 1	Annex VII	12143	12143
7069079	Custom Generic Lid	September 2012	Rule 1	Annex VII	12143	12143
7069080	INSTRMT TRAY, SOLERA HOOKS 5.5/6.0 US/EU	November 2013	Rule 1	Annex VII	12143	12143
7069082	MODULE, SOLERA HOOKS IMPLANT 5.5/6.0 US	November 2013	Rule 1	Annex VII	12143	12143
7069084	MODULE LID,SOLERA HOOKS 5.6/6.0 US	November 2013	Rule 1	Annex VII	12143	12143
7069090	SMARTLINK EXTENDER TRAY 1	June 2013	Rule 1	Annex VII	12143	12143
7069091	SMARTLINK EXTENDER TRAY 2	June 2013	Rule 1	Annex VII	12143	12143
7069092	CD HORIZON SOLERA Lateral Connector Tray	November 2013	Rule 1	Annex VII	12143	12143
7069093	Set Screw Caddy	November 2013	Rule 1	Annex VII	12143	12143
7069094	Set Screw Lid	November 2013	Rule 1	Annex VII	12143	12143
7069097	MODULE,SOLERA HOOKS 5.5/6.0 EU	August 2004	Rule 1	Annex VII	12143	12143
7069098	CD HORIZON SOLERA Lateral Connector Tray	November 2013	Rule 1	Annex VII	12143	12143
7069233L	CDHL 6.35 SCREW CADDY LID, TI	September 2004	Rule 1	Annex VII	12143	12143
7069233ML	CDHL 6.35 SCREW CADDY LID, TI	August 2005	Rule 1	Annex VII	12143	12143
7069234L	CDHL 6.35 SET SCREW MOD LID SS	August 2004	Rule 1	Annex VII	12143	12143
7069234ML	CDHL 6.35 SET SCW MOD LID, TI	August 2005	Rule 1	Annex VII	12143	12143
7069238L	LEGACY RMAS 6.35 ST SCW LID, TI	December 2004	Rule 1	Annex VII	12143	12143
7069238ML	CDHL RMAS 6.35 ST SCW LID, TI	August 2005	Rule 1	Annex VII	12143	12143
7069314	LEGACY 6.35 UAS OUTER CASE, TI	April 2005	Rule 1	Annex VII	12143	12143
7069320	CDHL 6.35 ROD ADD-ON OUTER, TI	May 2005	Rule 1	Annex VII	12143	12143

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P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
7069325	CDHL 6.35 DEGEN IMP TRAY 1, TI	September 2004	Rule 1	Annex VII	12143	12143
7069325L	CDHL 6.35 DEGEN IMPL LID, TI	August 2004	Rule 1	Annex VII	12143	12143
7069326	CDHL 6.35 DEGEN IMP TRAY 2, TI	August 2004	Rule 1	Annex VII	12143	12143
7069327L	CDHL 6.35 NONBREAK IMPL LID TI	August 2004	Rule 1	Annex VII	12143	12143
7069328	CDHL 6.35 4.0-5.5 IMP TRAY1 TI	September 2004	Rule 1	Annex VII	12143	12143
7069328L	CDHL 6.35 4.0-5.5 IMPL LID, TI	August 2004	Rule 1	Annex VII	12143	12143
7069329	CDHL 6.35 5.5-8.5 IMP TRAY1 TI	August 2004	Rule 1	Annex VII	12143	12143
7069329L	CDHL 6.35 5.5-8.5 IMPL LID, TI	August 2004	Rule 1	Annex VII	12143	12143
7069338	CDHL 6.35 4.0-5.5 IMP TRAY2 TI	September 2004	Rule 1	Annex VII	12143	12143
7069339	CDHL 6.35 5.5-8.5 IMP TRAY2 TI	August 2004	Rule 1	Annex VII	12143	12143
7069341	CDHL 6.35 DEFORM IMP TRAY 1 TI	August 2004	Rule 1	Annex VII	12143	12143
7069341L	CDHL 6.35 DEFORM IMP LID, TI	August 2004	Rule 1	Annex VII	12143	12143
7069342	CDHL 6.35 DEFORM IMP TRAY 2 TI	August 2004	Rule 1	Annex VII	12143	12143
7069343	CDHL 6.35 DEFORM IMP TRAY 3 TI	August 2004	Rule 1	Annex VII	12143	12143
7069351	LEGACY 6.35 UAS IMPL TRAY 1 TI	April 2005	Rule 1	Annex VII	12143	12143
7069351L	LEGACY 6.35 UAS IMPLANT LID TI	April 2005	Rule 1	Annex VII	12143	12143
7069352	LEGACY 6.35 UAS IMPL TRAY 2 TI	April 2005	Rule 1	Annex VII	12143	12143
7069353	LEGACY 6.35 UAS IMPL TRAY 3 TI	April 2005	Rule 1	Annex VII	12143	12143
7069410	CDHL 6.35 FAS EXTRA CASE, TI	September 2005	Rule 1	Annex VII	12143	12143
7069420	CDHL 6.35 ROD ADD ON TRAY, TI	September 2005	Rule 1	Annex VII	12143	12143
7069420L	CDHL 6.35 ROD ADD-ON LID, TI	September 2005	Rule 1	Annex VII	12143	12143
7069421L	CDHL 6.35 FAS IMPLANT LID, TI	August 2004	Rule 1	Annex VII	12143	12143
7069429	CDHL 6.35 LRG CAP SCREWS, TI	August 2004	Rule 1	Annex VII	12143	12143
7069429L	CDHL 6.35 LRG CAP SCREW LID TI	August 2004	Rule 1	Annex VII	12143	12143
7069511	CDHL 6.35 HOOK OUTER, TI	August 2004	Rule 1	Annex VII	12143	12143
7069524	CDHL 6.35 HOOK IMPLANT TRAY TI	August 2004	Rule 1	Annex VII	12143	12143
7069532	CDHL 6.35 STD HOOK MOD, TI	September 2004	Rule 1	Annex VII	12143	12143
7069532L	CDHL 6.35 STD HOOK MOD LID, TI	August 2004	Rule 1	Annex VII	12143	12143
7069533	CDHL 6.35 SPEC HOOK MOD, TI	August 2004	Rule 1	Annex VII	12143	12143
7069533L	CDHL 6.35 SPEC HOOK MOD LID TI	August 2004	Rule 1	Annex VII	12143	12143
7069610	LEGACY RMAS 6.35 OUTER CASE, TI	December 2004	Rule 1	Annex VII	12143	12143
7069620	LEGACY RMAS 6.35 IMPL TRAY, TI	December 2004	Rule 1	Annex VII	12143	12143
7069620L	LEGACY RMAS 6.35 IMP LID, TI	December 2004	Rule 1	Annex VII	12143	12143
7078300	CDHS 4.75 Sextant Standard Instr Tray	August 2011	Rule 1	Annex VII	12143	12143
7078301	CDHS 4.75 Sextant Reduction Instr Tray	August 2011	Rule 1	Annex VII	12143	12143
8081527	4.75 Hand Held Rod Cutter Tray	January 2011	Rule 1	Annex VII	12143	12143
8081528	CASE - HAND HELD ROD CUTTER	November 2008	Rule 1	Annex VII	12143	12143
8081529	CASE - TABLE TOP ROD CUTTER	November 2008	Rule 1	Annex VII	12143	12143
8081530	LID - ROD CUTTER	January 2011	Rule 1	Annex VII	12143	12143
7069077	SMARTLINK Global Derotator Set	October 2013	Rule 1	Annex VII	12143	12143
7068061	CD HORIZON® SOLERA® IMPLANT TRAY	October 2017	Rule 1	Annex VII	12143	12143
7068062	CD HORIZON SOLERA Fenestrated Screw INSTRUMENT TRAY	October 2017	Rule 1	Annex VII	12143	12143
7068060T	5.5/6.0mm FENESTRATED SCREW & INSTRUMENT TRAY	October 2017	Rule 1	Annex VII	12143	12143
5332040	TRAY 5332040 GENERAL INSTRUMENTS UPPER	February 2019	Rule 1	Annex VII	12143	12143
5332041	TRAY 5332041 GENERAL INSTRUMENTS LOWER	February 2019	Rule 1	Annex VII	12143	12143
5332024	LABEL 5332024 3CO GENERAL INSTRUMENT SET	February 2019	Rule 1	Annex VII	12143	12143
5332028	TRAY 5332028 DRMAS INSTRUMENT SET TRAY	February 2019	Rule 1	Annex VII	12143	12143
5332048	LABEL 5332048 DRMAS AND VAD INSTRUMENTS	February 2019	Rule 1	Annex VII	12143	12143
METRx- Case and Trays						
9241091	CD HORIZON SPIRE - INNER TRAY	September 2005	Rule 1	Annex VII	12143	12143
9241094	CD HORIZON SPIRE - OUTER LID	September 2005	Rule 1	Annex VII	12143	12143

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P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
General Instruments- Case and Trays						
9110497	TAPERED LAP 18MM INST TRAY	November 2001	Rule 1	Annex VII	12143	12143
9116897	GENERAL INST, TAPERED TRAY	November 2001	Rule 1	Annex VII	12143	12143
Tenor Instruments- Case and Trays						
8069000	TENOR SPINAL SYSTEM (EU) OUTER CASE	August 2008	Rule 1	Annex VII	12143	12143
8069001	TENOR INSTRUMENT TRAY	August 2008	Rule 1	Annex VII	12143	12143
8069002	TENOR IMPLANT TRAY	August 2008	Rule 1	Annex VII	12143	12143
8069003	TENOR SCREW CADDY	August 2008	Rule 1	Annex VII	12143	12143
8069004	TENOR CONNECTOR CADDY	August 2008	Rule 1	Annex VII	12143	12143
8069005	TENOR CONNECTOR CADDY LID	August 2008	Rule 1	Annex VII	12143	12143
TSRH Instruments- Case and Trays						
1200110	TRAY, TSRH V A SCREW TI	March 2000	Rule 1	Annex VII	12143	12143
8359103	TSRH TC DEG, TI IMPL TRAY LID	January 2006	Rule 1	Annex VII	12143	12143
8359113	TSRH TC SCREW SET IMPLANT TRAY	June 2006	Rule 1	Annex VII	12143	12143
8350373	TSRH 3DX CONNECTOR/SETSCREW MODULE	March 2008	Rule 1	Annex VII	12143	12143
8350403	TSRH® 3Dx? Degen Screw Module	October 2009	Rule 1	Annex VII	12143	12143
8359003	SCREW MODULE	March 2009	Rule 1	Annex VII	12143	12143
8359004	CONNECTOR MODULE	March 2009	Rule 1	Annex VII	12143	12143
8359005	CONNECTOR MODULE LID	March 2009	Rule 1	Annex VII	12143	12143
8359006	PRE-BENT ROD MODULE LID	March 2009	Rule 1	Annex VII	12143	12143
8361000	TSRH-3D TSRH-3D IMPLANT TRAY	January 2005	Rule 1	Annex VII	12143	12143
8361004	TSRH-3D MPA SCREW TRAY	October 2004	Rule 1	Annex VII	12143	12143
8361055	TSRH-3D 5.5MM MPA SCREW CADDY	January 2005	Rule 1	Annex VII	12143	12143
8361090	TSRH-3D PLUS OUTER CASE	March 2005	Rule 1	Annex VII	12143	12143
8361091	TSRH-3D PLUS VBR IMPLANT TRAY	March 2005	Rule 1	Annex VII	12143	12143
8361092	TSRH-3D PLUS MPA IMPLANT TRAY	March 2005	Rule 1	Annex VII	12143	12143
8361093	TSRH-3D PLUS INSTRUMENT TRAY	March 2005	Rule 1	Annex VII	12143	12143
8372001	TSRH-3D OUTER CASE LID	August 2003	Rule 1	Annex VII	12143	12143
8372002	TSRH-3D IMPLANT TRAY LID	August 2003	Rule 1	Annex VII	12143	12143
8350366	TRAY - TSRH 3DX DEFOMRITY IMPLT TRAY	March 2008	Rule 1	Annex VII	12143	12143
8350366L	LID - TSRH 3DX DEFOMRITY IMPLT TRAY LID	March 2008	Rule 1	Annex VII	12143	12143
8350368	TRAY - TSRH 3DX DEFOMRITY INST TRAY #1	March 2008	Rule 1	Annex VII	12143	12143
8350369	TRAY - TSRH 3DX DEFOMRITY INST TRAY #2	March 2008	Rule 1	Annex VII	12143	12143
8350409	TSRH® 3Dx? Deformity BC Bottom Tray	October 2009	Rule 1	Annex VII	12143	12143
8359000	INSTRUMENT TRAY 1	March 2009	Rule 1	Annex VII	12143	12143
8359001	INSTRUMENT TRAY 2	March 2009	Rule 1	Annex VII	12143	12143
8359002	IMPLANT TRAY	March 2009	Rule 1	Annex VII	12143	12143
8361065	TSRH-3D 6.5 MPA SCREW MODULE	January 2005	Rule 1	Annex VII	12143	12143
8361075	TSRH-3D 7.5MM MPA SCREW CADDY	January 2005	Rule 1	Annex VII	12143	12143
8372500	TSRH-3D 5.5MM SCREW MODULE	May 2003	Rule 1	Annex VII	12143	12143
8372600	TSRH-3D 6.5MM SCREW MODULE	May 2003	Rule 1	Annex VII	12143	12143
1701188	TSRH-3D 6.35MM IMPLANT TRAY	June 2003	Rule 1	Annex VII	12143	12143
1701188R	TSRH-3D IMPLANT TRAY	February 2005	Rule 1	Annex VII	12143	12143
1701189	TSRH-3D IMPLANT TRAY	May 2003	Rule 1	Annex VII	12143	12143
1701190	TSRH-3D SET SCREW MODULE	May 2003	Rule 1	Annex VII	12143	12143
1701191	TSRH-3D SET SCREW CADDY LID	May 2003	Rule 1	Annex VII	12143	12143
1701192	NON BREAKOFF SET SCREW MODULE	August 2003	Rule 1	Annex VII	12143	12143
1701193	TSRH-3D SET SCREW CADDY LID	May 2003	Rule 1	Annex VII	12143	12143
1701195	TSRH-3D FLUSH BREAK MODULE	September 2004	Rule 1	Annex VII	12143	12143
1701196	TSRH-3D FLUSH BREAK MODULE LID	September 2004	Rule 1	Annex VII	12143	12143
1701197	TSRH-3D FLUSH BREAK MOD LID	September 2004	Rule 1	Annex VII	12143	12143
170-189	TSRH 3D IMPLANT TRAY-TOP	June 2001	Rule 1	Annex VII	12143	12143
170-190	5.5MM INMPLANT MODULE	June 2001	Rule 1	Annex VII	12143	12143

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1851121	TSRH-3D MIDDLE INSTRUMENT TRAY	May 2003	Rule 1	Annex VII	12143	12143
1851125	TSRH-3D BOTTOM INSTRUMENT TRAY	May 2003	Rule 1	Annex VII	12143	12143
185-121	TSRH 3D INSTRUMENT TRAY MIDDLE	June 2001	Rule 1	Annex VII	12143	12143
185-125	TSRH 3D INSTRUMENT TRAY BOTTOM	June 2001	Rule 1	Annex VII	12143	12143
2396002	TSRH 3Dx Deformity Bolt/Post Cutter Tray	April 2012	Rule 1	Annex VII	12143	12143
8350400	TSRH® 3Dx? Degen Instr. Top Tray	October 2009	Rule 1	Annex VII	12143	12143
8350401	TSRH® 3Dx? Degen Instr. Middle Tray	October 2009	Rule 1	Annex VII	12143	12143
8350402	TSRH® 3Dx? Degen Instr. Bottom Tray	October 2009	Rule 1	Annex VII	12143	12143
8350404	TSRH® 3Dx? Degen Screw Module Lid	October 2009	Rule 1	Annex VII	12143	12143
8350405	TSRH® 3Dx? Degen Conn/Set Srew Module	October 2009	Rule 1	Annex VII	12143	12143
8350406	TSRH® 3Dx? Deformity Instr. Top Tray	October 2009	Rule 1	Annex VII	12143	12143
8350407	TSRH® 3Dx? Deformity Instr Bottom Tray	October 2009	Rule 1	Annex VII	12143	12143
8350408	TSRH® 3Dx? Deformity Imp. Top Tray	October 2009	Rule 1	Annex VII	12143	12143
8350410	TSRH® 3Dx? Degen Imp and Instr Set	October 2009	Rule 1	Annex VII	12143	12143
8350413	TSRH 3Dx Degenerative Screw Module	September 2010	Rule 1	Annex VII	12143	12143
8350500	TRAY 8350500 TSRH 3Dx MAST INSTRUMENT	September 2009	Rule 1	Annex VII	12143	12143
8359010	TSRH® 3Dx? Pre-Bent Rod Double Sided Mod	July 2010	Rule 1	Annex VII	12143	12143
8359011	TSRH® 3Dx? Pre-Bent Rod Module Lid Chrom	July 2010	Rule 1	Annex VII	12143	12143
8359012	TSRH® 3Dx? Pre-Bent Rod Module Lid Titan	July 2010	Rule 1	Annex VII	12143	12143
8359013	TSRH® 3Dx? Connector/Set Screw Module (s	July 2010	Rule 1	Annex VII	12143	12143
8359014	TSRH® 3Dx? OSTEOGRIP® Screw Supplement M	July 2010	Rule 1	Annex VII	12143	12143
8361001	VERT. BODY REDUC. INST. TRAY	May 2001	Rule 1	Annex VII	12143	12143
8361002	VERT. BODY REDUC. IMPLANT TRAY	May 2001	Rule 1	Annex VII	12143	12143
8372000	TSRH-3D OUTER CASE	May 2003	Rule 1	Annex VII	12143	12143
8372400	TSRH-3D 4.5MM SCREW MODULE	May 2003	Rule 1	Annex VII	12143	12143
8372700	TSRH-3D 7.5MM SCREW MODULE	May 2003	Rule 1	Annex VII	12143	12143
8372800	TSRH-3D 8.5MM SCREW MODULE	May 2003	Rule 1	Annex VII	12143	12143
8350340	TSRH TC INSTRUMENT OUTER CASE	September 2007	Rule 1	Annex VII	12143	12143
8350341	TSRH TC INSTR SET TRAY 1	September 2007	Rule 1	Annex VII	12143	12143
8350342	TSRH TC INSTR SET TRAY 2	September 2007	Rule 1	Annex VII	12143	12143
8350343	TSRH TC INSTR SET TRAY 3	September 2007	Rule 1	Annex VII	12143	12143
8350345	TSRH TC SPINAL SYSTEM	September 2007	Rule 1	Annex VII	12143	12143
8350346	TSRH TC IMPL TRAY	September 2007	Rule 1	Annex VII	12143	12143
8350347	TSRH TC MPA SCREW SET TRAY	September 2007	Rule 1	Annex VII	12143	12143
8350348	TSRH TC MPA SCRW SET CADDY SPRT TRAY	September 2007	Rule 1	Annex VII	12143	12143
8350349	TSRH TC SCRWDVRVS & OSTEOGRIP SCREWS MOD	September 2007	Rule 1	Annex VII	12143	12143
8350350	TSRH TC PRE-BENT ROD MOD	September 2007	Rule 1	Annex VII	12143	12143
8350351	TSRH TC PRE-BENT ROD MOD LID	September 2007	Rule 1	Annex VII	12143	12143
8350353	TSRH TC CONN-SETSCRW MOD LID	September 2007	Rule 1	Annex VII	12143	12143
8350354	TSRH TC IMPL TRAY LID	September 2007	Rule 1	Annex VII	12143	12143
8350364	CASE TSRH 3DX INST & IMPLT	March 2008	Rule 1	Annex VII	12143	12143
8350367	TSRH TC OSTEOGRIP TRAY	January 2008	Rule 1	Annex VII	12143	12143
8350370	TSRH Implant Tray	February 2009	Rule 1	Annex VII	12143	12143
8350372	CASE TSRH 3DX INST	March 2008	Rule 1	Annex VII	12143	12143
8359100	TSRH TC DEG IMPLANT OUTER	January 2006	Rule 1	Annex VII	12143	12143
8359102	TSRH TC DEG, TI IMPL TRAY	January 2006	Rule 1	Annex VII	12143	12143
8359104	TSRH TC DEG SCREW MODULE	January 2006	Rule 1	Annex VII	12143	12143
8359105	TSRH TC DEG INSTR TRAY 1	January 2006	Rule 1	Annex VII	12143	12143
8359106	TSRH TC DEG INSTR TRAY2	January 2006	Rule 1	Annex VII	12143	12143
8359107	TSRH TC DEG INSTR OUTER	January 2006	Rule 1	Annex VII	12143	12143
8359108	TSRH TC SCREW MODULE	June 2006	Rule 1	Annex VII	12143	12143
8359109	TSRH TC SCREW SET OUTER CASE	June 2006	Rule 1	Annex VII	12143	12143
8359114	TSRH TC SCREW SET IMPLANT TRAY LID	July 2006	Rule 1	Annex VII	12143	12143

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8889200	TSRH SILO OUTER CASE LID	September 2005	Rule 1	Annex VII	12143	12143
8889201	TSRH SILO INST OUTER CASE 1	September 2005	Rule 1	Annex VII	12143	12143
8889202	TSRH SILO INST OUTER CASE 2	September 2005	Rule 1	Annex VII	12143	12143
8889203	TSRH SILO INST OUTER CASE 3	September 2005	Rule 1	Annex VII	12143	12143
8889204	SILO INSTRUMENT TRAY 1	September 2005	Rule 1	Annex VII	12143	12143
8889205	TSRH SILO INSTRUMENT TRAY 2	September 2005	Rule 1	Annex VII	12143	12143
8889206	TSRH SILO INSTRUMENT TRAY 3	September 2005	Rule 1	Annex VII	12143	12143
8889207	TSRH SILO INSTRUMENT TRAY 4	September 2005	Rule 1	Annex VII	12143	12143
8889208	TSRH SILO INSTRUMENT TRAY 5	September 2005	Rule 1	Annex VII	12143	12143
8889209	TSRH SILO INSTRUMENT TRAY 6	September 2005	Rule 1	Annex VII	12143	12143
8889220	TSRH SILO HOOK OUTER CASE, TI	September 2005	Rule 1	Annex VII	12143	12143
8889221	TSRH SILO HOOK IMPL TRAY, TI	September 2005	Rule 1	Annex VII	12143	12143
8889222	TSRH SILO RT HOOK MODULE, TI	September 2005	Rule 1	Annex VII	12143	12143
8889223	TSRH SILO RT HOOK MOD LID, TI	September 2005	Rule 1	Annex VII	12143	12143
8889224	TSRH SILO GENERIC HOOK MOD LID	September 2005	Rule 1	Annex VII	12143	12143
8889225	TSRH SILO LFT HOOK MODULE, TI	September 2005	Rule 1	Annex VII	12143	12143
8889226	TSRH SILO LFT HOOK MOD LID, TI	September 2005	Rule 1	Annex VII	12143	12143
8889227	TSRH SILO HOOK STAGING MODULE	September 2005	Rule 1	Annex VII	12143	12143
8889229	TSRH SILO HOOK INST TRAY	September 2005	Rule 1	Annex VII	12143	12143
8889230	TSRH SILO FAS OUTER CASE, TI	September 2005	Rule 1	Annex VII	12143	12143
8889231	TSRH SILO FAS IMPL TRAY 3, TI	September 2005	Rule 1	Annex VII	12143	12143
8889232	TSRH SILO FAS IMPL TRAY 2, TI	September 2005	Rule 1	Annex VII	12143	12143
8889233	TSRH SILO FAS IMPL TRAY 1, TI	September 2005	Rule 1	Annex VII	12143	12143
8889240	TSRH SILO SAS OUTER CASE, TI	September 2005	Rule 1	Annex VII	12143	12143
8889241	TSRH SILO SAS IMPL TRAY 3, TI	September 2005	Rule 1	Annex VII	12143	12143
8889242R	TSRH SILO SAS IMPLANT TRAY 2, TI	January 2006	Rule 1	Annex VII	12143	12143
8889243	TSRH SILO SAS IMPL TRAY 1, TI	September 2005	Rule 1	Annex VII	12143	12143

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8889250	TSRH SILO IMPLANT TRAY LID	September 2005	Rule 1	Annex VII	12143	12143
8889251	TSRH SILO SET SCREW MODULE	September 2005	Rule 1	Annex VII	12143	12143
8889252	TSRH SILO SET SCREW LID, TI	September 2005	Rule 1	Annex VII	12143	12143
8889253	TSRH SILO LAT CONNECT MOD, TI	September 2005	Rule 1	Annex VII	12143	12143
8889254	TSRH SILO LAT CONNECT LID, TI	September 2005	Rule 1	Annex VII	12143	12143
8889255	TSRH SILO SCREW GAUGE	September 2005	Rule 1	Annex VII	12143	12143
8889260	TSRH SILO MAS OUTER CASE, TI	September 2005	Rule 1	Annex VII	12143	12143
8889261	TSRH SILO MAS IMPL TRAY 3, TI	September 2005	Rule 1	Annex VII	12143	12143
8889262	TSRH SILO MAS IMPL TRAY 2, TI	September 2005	Rule 1	Annex VII	12143	12143
8889263	TSRH SILO MAS IMPL TRAY 1, TI	September 2005	Rule 1	Annex VII	12143	12143
8889282	TSRH SILO LAT CONNECT TRAY, TI	September 2005	Rule 1	Annex VII	12143	12143
X0205071	TSRH L-PLATE INSTRUMENT TRAY	April 2008	Rule 1	Annex VII	12143	12143
General Instruments- Case and Trays						
9337007	VANTAGE INSTRUMENT TRAY #2	August 2003	Rule 1	Annex VII	12143	12143
9337008	VANTAGE IMPLANT TRAY	August 2003	Rule 1	Annex VII	12143	12143
9339996	VANTAGE SINGLE BOLT OUTER CASE LID	July 2006	Rule 1	Annex VII	12143	12143
Navigated SOLERA® Complete						
NAV2027	TAP MODULE	March 2016	Rule 1	Annex VII	12143	12143
NAV2027K*	TAP MODULE	March 2016	Rule 1	Annex VII	12143	12143
NAV2028	TAP MODULE LID	March 2016	Rule 1	Annex VII	12143	12143
NAV2028K*	TAP MODULE LID	March 2016	Rule 1	Annex VII	12143	12143
*NAV2027K is identical to part number NAV2027, NAV2028K is identical to part number NAV2028 and NAV1850094K is identical to the part number 1850094. Navigated SOLERA Complete Instruments are sold in the OUS market as K parts by the MNAV business unit. MNAV receives the non-K parts from Medtronic Spine and distributes them as K parts.						
CDH SOLERA® Voyager™ Spinal System-Case and Trays						
1664000	CDHS Voyager™ Perc Rod Tray	June 2015	Rule 1	Annex VII	12143	12143
1664001	CDHS VOYAGER™ Set screw Caddy	June 2015	Rule 1	Annex VII	12143	12143
1664002	CDHS VOYAGER™ Set screw Caddy Lid	June 2015	Rule 1	Annex VII	12143	12143
1664004	CDHS VOYAGER™ 4.75mm Screw & Instrument Tray	June 2015	Rule 1	Annex VII	12143	12143
1664005	CDHS VOYAGER™ Tab Extender Cap Caddy	June 2015	Rule 1	Annex VII	12143	12143
1664006	CDHS VOYAGER™ Tab Extender Cap Caddy Lid	June 2015	Rule 1	Annex VII	12143	12143
1664007	CDHS VOYAGER™ Tab Extender Caddy	June 2015	Rule 1	Annex VII	12143	12143
1664008	CDHS VOYAGER™ Tab Extender Caddy Lid	June 2015	Rule 1	Annex VII	12143	12143
1664009	CDHS VOYAGER™ Universal Instrument Tray Upper	June 2015	Rule 1	Annex VII	12143	12143
1664010	CDHS VOYAGER™ Universal Instrument Tray Lower	June 2015	Rule 1	Annex VII	12143	12143
1664012	CDHS VOYAGER™ Capped Rod Tray	June 2015	Rule 1	Annex VII	12143	12143
1664016	CDHS VOYAGER™ Perc Inserter Tray	June 2015	Rule 1	Annex VII	12143	12143
Nav2030	Nav Taps and Driver Tray	June 2015	Rule 1	Annex VII	12143	12143
Nav2030K*	Tray NAV2030 NAV Drivers and Taps	March 2016	Rule 1	Annex VII	12143	12143
1664021	CD HORIZON® SOLERA® VOYAGER™ Ø4.75 General Instrument Tray	February 2018	Rule 1	Annex VII	12143	12143
1664022	CD HORIZON® SOLERA® VOYAGER™ Tab Extender Caddy Lid	February 2018	Rule 1	Annex VII	12143	12143
1664019	CD HORIZON® SOLERA® VOYAGER™ Ø4.75 ATS Implant and Instrument Set Tray	February 2018	Rule 1	Annex VII	12143	12143
6552013	CD HORIZON® SOLERA® VOYAGER™ Ø5.5/6.0 Capped Rod and Instrument Tray	February 2018	Rule 1	Annex VII	12143	12143
6552010	CD HORIZON® SOLERA® VOYAGER™ Ø5.5/6.0 Instrument Set 1 Tray 1	February 2018	Rule 1	Annex VII	12143	12143
6552011	CD HORIZON® SOLERA® VOYAGER™ Ø5.5/6.0 Instrument Set 1 Tray 2	February 2018	Rule 1	Annex VII	12143	12143
6552006	CD HORIZON® SOLERA® VOYAGER™ Ø5.5/6.0 Tab Extender Cap Caddy	February 2018	Rule 1	Annex VII	12143	12143
6552007	CD HORIZON® SOLERA® VOYAGER™ Ø5.5/6.0 Tab Extender Cap Caddy Lid	February 2018	Rule 1	Annex VII	12143	12143

Product List

Last updated by: Fernand Terradas **Date:** 2/4/2019
Tech File Bundle: TL Stabilization, TF009

Product: Cases and Trays

Class: I

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
6552008	CD HORIZON® SOLERA® VOYAGER™ Ø5.5/6.0 Tab Extender Caddy	February 2018	Rule 1	Annex VII	12143	12143
6552009	CD HORIZON® SOLERA® VOYAGER™ Ø5.5/6.0 Tab Extender Caddy Lid	February 2018	Rule 1	Annex VII	12143	12143
6552004	CD HORIZON® SOLERA® VOYAGER™ Ø5.5/6.0 Set Screw Caddy	February 2018	Rule 1	Annex VII	12143	12143
6552005	CD HORIZON® SOLERA® VOYAGER™ Ø5.5/6.0 Set Screw Caddy Lid	February 2018	Rule 1	Annex VII	12143	12143
6552012	CD HORIZON® SOLERA® VOYAGER™ Universal Instruments Tray	February 2018	Rule 1	Annex VII	12143	12143
6552002	CD HORIZON® SOLERA® VOYAGER™ Ø5.5 Large MAS Implant and Instrument Tray	February 2018	Rule 1	Annex VII	12143	12143
6552003	CD HORIZON® SOLERA® VOYAGER™ Ø5.5/6.0 MAS Implant and Instrument Tray	February 2018	Rule 1	Annex VII	12143	12143
6552015	CD HORIZON® SOLERA® VOYAGER™ Ø5.5/6.0 Percutaneous Rod Tray 100-180mm	February 2018	Rule 1	Annex VII	12143	12143
6552016	CD HORIZON® SOLERA® VOYAGER™ Ø5.5/6.0 Percutaneous 190-200mm Rod and Instrument Tray	February 2018	Rule 1	Annex VII	12143	12143
6552014	CD HORIZON® SOLERA® VOYAGER™ Ø5.5/6.0 Percutaneous Rod Tray 30-90mm	February 2018	Rule 1	Annex VII	12143	12143

NAV2030K* is identical to part number NAV2030. Tray NAV2030K is sold in the OUS market as a K part by the MNAV business unit. MNAV receives the non-K part from Medtronic Spine and distributes it as a K part.

CDH BALLAST Spinal System-Case and Trays

2950001	CD HORIZON® BALLAST™ MAS Implant Tray	December 2016	Rule 1	Annex VII	12143	12143
2950002	CD HORIZON® BALLAST™ CMAS Implant Tray	December 2016	Rule 1	Annex VII	12143	12143
2950005	CD HORIZON® BALLAST™ Manual Instrument Tray	December 2016	Rule 1	Annex VII	12143	12143
2950006	CD HORIZON® BALLAST™ NAV Instrument Tray	December 2016	Rule 1	Annex VII	12143	12143
2950007	CD HORIZON® BALLAST™ Cannulated Tap Tray	December 2016	Rule 1	Annex VII	12143	12143
2950009	CD HORIZON® BALLAST™ NAV Cannulated Tap Tray	December 2016	Rule 1	Annex VII	12143	12143
2950010	CD HORIZON® BALLAST™ Torque Multiplier Tray	December 2016	Rule 1	Annex VII	12143	12143

CDH ESSENCE Spinal System-Case and Trays

185-064	Generic Lid Base	December 2016	Rule 1	Annex VII	12143	12143
185-056	Generic Base, Double Case	December 2016	Rule 1	Annex VII	12143	12143
11010915	Generic Implant Tray and Instruments	December 2016	Rule 1	Annex VII	12143	12143

CDH ESSENTIALS™ Spinal System-Case and Trays

7377001	TL INSTRUMENT SCREW TRAY 1	December 2016	Rule 1	Annex VII	12143	12143
7377002	TL INSTRUMENT SCREW TRAY 2	December 2016	Rule 1	Annex VII	12143	12143
7377003	TL DISC PREP TRAY 1	December 2016	Rule 1	Annex VII	12143	12143
7377004	TL DISC PREP TRAY 2	December 2016	Rule 1	Annex VII	12143	12143

CD HORIZON SPIRE™ Spinal Implant

9241090	CD HORIZON SPIRE - OUTER CASE	September 2005	Rule 1	Annex VII	12143	12143
9241092	CD HORIZON SPIRE - PLATE CADDY	September 2005	Rule 1	Annex VII	12143	12143
9241093	CD HORIZON SPIRE - CADDY LID	September 2005	Rule 1	Annex VII	12143	12143

CD Horizon Solera (3CO_ DRMAS)

5332018	3CO General Instrument Upper Tray	April 2017	Rule 1	Annex VII	12143	12143
5332019	3CO General Instrument Lower Tray	April 2017	Rule 1	Annex VII	12143	12143
5332020	3CO General Instrument Tray	April 2017	Rule 1	Annex VII	12143	12143
5332021	3CO CONTROLLER TRAY	April 2017	Rule 1	Annex VII	12143	12143
5332022	CONTROLLER ACCESSORY CADDY	April 2017	Rule 1	Annex VII	12143	12143
5332023	CONTROLLER ACCESSORY CADDY LID	April 2017	Rule 1	Annex VII	12143	12143

CD Horizon Solera Spinal System (Dual Bend Rods) - Cases and Trays

X1015077	Solera Dual Bend Rod Tray (Australia)	May 2017	Rule 1	Annex VII	12143	12143
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TRANSLACE™ Spinal Tethering System - Cases and Trays

8239100	TRANSLACE Instrument Tray	June 2018	Rule 1	Annex VII	12143	12143
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DECLARATION OF CONFORMITY

TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES



MANUFACTURER:

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
USA

MEDICAL DEVICE:

TL Fusion Bundle
Technical File or Design Dossier Number (TF010)
Reference Product List including GMDN and UMDNS codes

CLASSIFICATION IN ACCORDANCE WITH ANNEX IX:

Class Im, Class IIa, Rule 6; Class IIb, Rule 8
Reference Product List for specific device classifications

CONFORMITY ASSESSMENT ROUTE:

Annex II (-Section 4), Annex V
Reference Product List for specific device routes

WE, THE MANUFACTURER, UNDER OUR SOLE RESPONSIBILITY, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, OF THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC AND IF APPLICABLE, COMMISSION REGULATION NO. 722/2012.

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: REFER TO LIST OF HARMONISED – EN STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED. THIS LIST IS LOCATED WITH THE TECHNICAL FILE.

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MUNICH, GERMANY

IDENTIFICATION NUMBER:

0123 for Class Im, Class Is, and above

(EC) CERTIFICATE(S):

G1 15 11 39040 059, G2M 18 04 39040 070



EUROPEAN REPRESENTATIVE:

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

START OF CE-MARKING:

DATE OF FIRST CE MARKING (Reference attached list)

SIGNATURE:

Raphael McInnis
Raphael McInnis

10-July-2014
DATE

Senior Manager
TITLE

PLACE:

Memph., TN USA

Product List

Last updated by: Lila Joe
 Tech File Bundle: TF010, TL Fusion

Date: 8/31/2016

Product: Multiple Product Families
 Class: Im

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
Capstone Instruments, Non-Sterile, Measuring						
907338	8MM OSTEOTOME	Aug-2005	Rule 6	Annex V	12844	12845
907340	SMALL ROTATE CUTTER	Aug-2005	Rule 6	Annex V	44805	15573
907341	MEDIUM ROTATE CUTTER	Aug-2005	Rule 6	Annex V	44805	15573
907342	LARGE ROTATE CUTTER	Aug-2005	Rule 6	Annex V	44805	15573
907347	SMALL FOWARD ANGLE CURETTE	Aug-2005	Rule 6	Annex V	47022	11084
907348	LARGE FOWARD ANGLE CURETTE	Aug-2005	Rule 6	Annex V	47022	11084
907349	SMALL REVERSE ANGLE CURETTE	Aug-2005	Rule 6	Annex V	47022	11084
907350	LARGE REVERSE ANGLE CURETTE	Aug-2005	Rule 6	Annex V	47022	11084
907351	LEFT ANGLED CUP CURETTE	Aug-2005	Rule 6	Annex V	47022	11084
907352	RIGHT ANGLED CUP CURETTE	Aug-2005	Rule 6	Annex V	47022	11084
907353	RIGHT STRAIGHT CUP CURETTE	Aug-2005	Rule 6	Annex V	47022	11084
907354	LEFT STRAIGHT CUP CURETTE	Aug-2005	Rule 6	Annex V	47022	11084
907355	RING CURETTE	Aug-2005	Rule 6	Annex V	47022	11084
Capstone Control Instruments, Non-Sterile, Measuring						
3990001	LONG INSERTER OUTER SLEEVE	Oct-2012	Rule 6	Annex V	12696	16146
3990002	LONG INSERTER THREADED SHAFT	Oct-2012	Rule 6	Annex V	12696	17543
3990003	SHORT INSERTER OUTER SLEEVE	Oct-2012	Rule 6	Annex V	47831	16146
3990004	SHORT INSERTER THREADED SHAFT	Oct-2012	Rule 6	Annex V	12696	17543
3990057	Adjuster	Oct-2012	Rule 6	Annex V	13180	13180
3990070	Short Tapping Extractor	Oct-2012	Rule 6	Annex V	12696	11345
3990071	Long Tapping Extractor	Oct-2012	Rule 6	Annex V	12696	11345
CAPSTONE L Instruments, Non-Sterile, Measuring						
2941308	8MM LATERAL PADDLE SHAVER	Oct-2005	Rule 6	Annex V	31335	13180
2941310	10MM LATERAL PADDLE SHAVER	Oct-2005	Rule 6	Annex V	31335	13180
2941312	12MM LATERAL PADDLE SHAVER	Oct-2005	Rule 6	Annex V	31335	13180
2941314	14MM LATERAL PADDLE SHAVER	Oct-2005	Rule 6	Annex V	31335	13180
Clydesdale Instruments, Non-Sterile, Measuring						
2940053	STRAIGHT SERRATED CUP CURETTE	Sep-2006	Rule 6	Annex V	47022	11084
2940056	RING CURETTE	Sep-2006	Rule 6	Annex V	47022	11084
2940075	4MM PITUITARY	Jan-2006	Rule 6	Annex V	32853	13180
2940076	4MM UPBITING PITUITARY	Jan-2006	Rule 6	Annex V	32853	13180
2941308	8MM LATERAL PADDLE SHAVER	Oct-2005	Rule 6	Annex V	31335	13180
2941310	10MM LATERAL PADDLE SHAVER	Oct-2005	Rule 6	Annex V	31335	13180
2941312	12MM LATERAL PADDLE SHAVER	Oct-2005	Rule 6	Annex V	31335	13180
2941314	14MM LATERAL PADDLE SHAVER	Oct-2005	Rule 6	Annex V	31335	13180
2941608	8 X 45 MM PADDLE SHAVER	Sep-2006	Rule 6	Annex V	31335	13180
2941610	10 X 45 MM PADDLE SHAVER	Sep-2006	Rule 6	Annex V	31335	13180
2941612	12 X 45 MM PADDLE SHAVER	Sep-2006	Rule 6	Annex V	31335	13180
2941614	14 X 45 MM PADDLE SHAVER	Sep-2006	Rule 6	Annex V	31335	13180
2941616	16 X 45 MM PADDLE SHAVER	Sep-2006	Rule 6	Annex V	31335	13180
9561421	DILATOR 10.6MM	Oct-2005	Rule 6	Annex V	13180	13180
9561422	DILATOR 16MM	Oct-2005	Rule 6	Annex V	13180	13180
9561424	DL DILATOR 20.8MM	Sep-2006	Rule 6	Annex V	13180	13180
I-FLY Instruments, Non Sterile, Measuring						
8926000	FLY IMPLANT HOLDER	Feb-2006	Rule 6	Annex V	13180	13180
8926017	FLY DISC DISTRACTOR 7 MM	Feb-2006	Rule 6	Annex V	56637	11291

Tech File Bundle: TF010, TL Fusion

Product: Multiple Product Families

Class: Im

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
8926018	FLY DISC DISTRACTOR 8 MM	Feb-2006	Rule 6	Annex V	56637	11291
8926019	FLY DISC DISTRACTOR 9 MM	Feb-2006	Rule 6	Annex V	56637	11291
8926020	FLY DISC DISTRACTOR 10 MM	Feb-2006	Rule 6	Annex V	56637	11291
8926105	FLY 5 MM ROUND SCRAPER	Feb-2006	Rule 6	Annex V	13180	13180
8926150	FLY STRAIGHT REAMER SMALL	Feb-2006	Rule 6	Annex V	45114	13297
INTERFIX Instruments, Non Sterile, Measuring						
901-514	14MM MD-IV INSERTER	Apr-2000	Rule 6	Annex V	12696	17543
901-516	16MM MD-IV INSERTER	Oct-2000	Rule 6	Annex V	12696	17543
901-518	18MM MD-IV INSERTER	Aug-2003	Rule 6	Annex V	12696	17543
901-520	20MM MD-IV INSERTER	Mar-2000	Rule 6	Annex V	12696	17543
901-522	22MM MD-IV INSERTER	Feb-2007	Rule 6	Annex V	12696	17543
901-524	24MM MD-IV INSERTER	Jul-2008	Rule 6	Annex V	12696	17543
901-582	22MM TCD ADJUSTABLE REAMER	Sep-2006	Rule 6	Annex V	45114	13297
901-583	22MM TCD ADJUSTABLE TAP	Jul-2008	Rule 6	Annex V	17507	17507
901-588	SOLID TCD ADJ REAMER	Jul-2008	Rule 6	Annex V	45114	13297
901-607	24MM TCD ADJUSTABLE REAMER	Sep-2006	Rule 6	Annex V	45114	13297
901-608	24MM TCD ADJUSTABLE TAP	Jul-2008	Rule 6	Annex V	17507	17507
901-613	SOLID TCD ADJ REAMER	Jul-2008	Rule 6	Annex V	45114	13297
902-216	16MM, OPEN ANT, BD INSERTER	Jul-2008	Rule 6	Annex V	12696	17543
902-240	16MM TCD ADJUSTABLE REAMER	Sep-2006	Rule 6	Annex V	45114	13297
902-241	16MM TCD ADJUSTABLE TAP	Jul-2008	Rule 6	Annex V	17507	17507
902-242	SOLID TCD ADJ REAMER	Jul-2008	Rule 6	Annex V	45114	13297
902-318	18MM, OPEN ANT, BD INSERTER	Mar-2000	Rule 6	Annex V	12696	17543
902-340	18MM TCD ADJUSTABLE REAMER	Sep-2006	Rule 6	Annex V	45114	13297
902-341	18MM TCD ADJUSTABLE TAP	Jul-2008	Rule 6	Annex V	17507	17507
902-420	20MM OPEN ANT, BD INSERTER	Jul-2008	Rule 6	Annex V	12696	17543
902-440	20MM TCD ADJUSTABLE REAMER	Sep-2006	Rule 6	Annex V	45114	13297
902-441	20MM TCD ADJUSTABLE TAP	Jun-2005	Rule 6	Annex V	17507	17507
902-442	SOLID TCD ADJ REAMER	Jul-2008	Rule 6	Annex V	45114	13297
LT-CAGE® Instruments, Non Sterile, Measuring						
8951405	14mm IMPLANT HOLLOW REAMER	Sep-2000	Rule 6	Annex V	45114	13297
8951408	14mm IMPLANT DRIVER SLEEVE	Sep-2000	Rule 6	Annex V	47831	16146
8951605	16mm IMPLANT HOLLOW REAMER	Sep-2000	Rule 6	Annex V	45114	13297
8951608	16mm IMPLANT DRIVER SLEEVE	Sep-2000	Rule 6	Annex V	47831	16146
8951805	18mm IMPLANT HOLLOW REAMER	Sep-2000	Rule 6	Annex V	45114	13297
8951808	18mm IMPLANT DRIVER SLEEVE	Sep-2000	Rule 6	Annex V	47831	16146
R90 Spacer Instruments, Non Sterile, Measuring						
2900250	SPREADER 6MM	Apr-2002	Rule 6	Annex V	13180	13180
2900251	SPREADER 8MM	Apr-2002	Rule 6	Annex V	13180	13180
2900252	SPREADER 10MM X 6°	Apr-2002	Rule 6	Annex V	13180	13180
2900253	SPREADER 12MM X 6°	Apr-2002	Rule 6	Annex V	13180	13180
2900254	SPREADER 14MM X 6°	Apr-2002	Rule 6	Annex V	13180	13180
2900255	SPREADER 16MM X 6°	Apr-2002	Rule 6	Annex V	13180	13180
2900256	SPREADER 12MM X 12°	Apr-2002	Rule 6	Annex V	13180	13180
2900257	SPREADER 14MM X 12°	Apr-2002	Rule 6	Annex V	13180	13180
2900258	SPREADER 16MM X 12°	Apr-2002	Rule 6	Annex V	13180	13180
2900350	9MM SHAVER	Apr-2002	Rule 6	Annex V	31335	13180
2900351	10MM SHAVER	Apr-2002	Rule 6	Annex V	31335	13180
2900352	11MM SHAVER	Apr-2002	Rule 6	Annex V	31335	13180

Tech File Bundle: TF010, TL Fusion

Product: Multiple Product Families

Class: Im

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2900353	12MM SHAVER	Apr-2002	Rule 6	Annex V	31335	13180
2900354	13MM SHAVER	Apr-2002	Rule 6	Annex V	31335	13180
2900355	14MM SHAVER	Apr-2002	Rule 6	Annex V	31335	13180
2900356	15MM SHAVER	Apr-2002	Rule 6	Annex V	31335	13180
2900357	16MM SHAVER	Apr-2002	Rule 6	Annex V	31335	13180
2900601	INSERTER HANDLE	Feb-2003	Rule 6	Annex V	47829	13180
2901250	6MM CAM SPREADER	May-2004	Rule 6	Annex V	13180	13180
2901251	8MM CAM SPREADER	May-2004	Rule 6	Annex V	13180	13180
2901252	10MM X 6° CAM SPREADER	May-2004	Rule 6	Annex V	13180	13180
2901253	12MM X 6° CAM SPREADER	May-2004	Rule 6	Annex V	13180	13180
2901254	14MM X 6° CAM SPREADER	May-2004	Rule 6	Annex V	13180	13180
2901255	16MM X 6° CAM SPREADER	May-2004	Rule 6	Annex V	13180	13180
2901256	12MM X 12° CAM SPREADER	May-2004	Rule 6	Annex V	13180	13180
2901257	14MM X 12° CAM SPREADER	May-2004	Rule 6	Annex V	13180	13180
2901258	16MM X 12° CAM SPREADER	May-2004	Rule 6	Annex V	13180	13180
2901259	13MM X 18° CAM SPREADER	May-2004	Rule 6	Annex V	13180	13180
2901260	15MM X 18° CAM SPREADER	May-2004	Rule 6	Annex V	13180	13180
2940255	CAM SPREADER 16MM X 6°	May-2004	Rule 6	Annex V	13180	13180
TELAMON™ Instruments, Non Sterile, Measuring						
9074008	8MM CHISEL - MAST	Jun-2002	Rule 6	Annex V	13180	13180
9074010	10MM CHISEL - MAST	Jun-2002	Rule 6	Annex V	13180	13180
9074012	12MM CHISEL - MAST	Jun-2002	Rule 6	Annex V	13180	13180
9074014	14MM CHISEL - MAST	Jun-2002	Rule 6	Annex V	13180	13180
9074107	SMALL SCRAPER	Jun-2002	Rule 6	Annex V	13180	13180
9074108	MEDIUM SCRAPER	Jun-2002	Rule 6	Annex V	13180	13180
9074109	LARGE SCRAPER	Jun-2002	Rule 6	Annex V	13180	13180
907-530	SMALL ROTATE CUTTER	Sep-2000	Rule 6	Annex V	44805	15573
907-531	LARGE ROTATE CUTTER	Sep-2000	Rule 6	Annex V	44805	15573
907-539	MEDIUM ROTATE CUTTER	Sep-2000	Rule 6	Annex V	44805	15573
907-540	DISTRACTOR 10	Feb-2002	Rule 6	Annex V	56637	11291
907-541	DISTRACTOR 11	Feb-2002	Rule 6	Annex V	56637	11291
907-542	DISTRACTOR 12	Feb-2002	Rule 6	Annex V	56637	11291
907-543	DISTRACTOR 13	Feb-2002	Rule 6	Annex V	56637	11291
907-544	DISTRACTOR 14	Feb-2002	Rule 6	Annex V	56637	11291
907-545	DISTRACTOR 15	Feb-2002	Rule 6	Annex V	56637	11291
907-547	DISTRACTOR 7	Feb-2002	Rule 6	Annex V	56637	11291
907-548	DISTRACTOR 8	Feb-2002	Rule 6	Annex V	56637	11291
907-549	DISTRACTOR 9	Feb-2002	Rule 6	Annex V	56637	11291
907-607	IMPLANT INSERTER	Sep-2001	Rule 6	Annex V	12696	17543
907-609	C-STYLE INSERTER	Jun-2000	Rule 6	Annex V	12696	17543
R90 Spacer Instruments, Non Sterile, Measuring						
2900250	SPREADER 6MM	Apr-2002	Rule 6	Annex V	13180	13180
2900251	SPREADER 8MM	Apr-2002	Rule 6	Annex V	13180	13180
2900252	SPREADER 10MM X 6°	Apr-2002	Rule 6	Annex V	13180	13180
2900253	SPREADER 12MM X 6°	Apr-2002	Rule 6	Annex V	13180	13180
2900254	SPREADER 14MM X 6°	Apr-2002	Rule 6	Annex V	13180	13180
2900255	SPREADER 16MM X 6°	Apr-2002	Rule 6	Annex V	13180	13180
2900256	SPREADER 12MM X 12°	Apr-2002	Rule 6	Annex V	13180	13180
2900257	SPREADER 14MM X 12°	Apr-2002	Rule 6	Annex V	13180	13180

Tech File Bundle: TF010, TL Fusion

Product: Multiple Product Families

Class: Im

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2900258	SPREADER 16MM X 12°	Apr-2002	Rule 6	Annex V	13180	13180
2900350	9MM SHAVER	Apr-2002	Rule 6	Annex V	31335	13180
2900351	10MM SHAVER	Apr-2002	Rule 6	Annex V	31335	13180
2900352	11MM SHAVER	Apr-2002	Rule 6	Annex V	31335	13180
2900353	12MM SHAVER	Apr-2002	Rule 6	Annex V	31335	13180
2900354	13MM SHAVER	Apr-2002	Rule 6	Annex V	31335	13180
2900355	14MM SHAVER	Apr-2002	Rule 6	Annex V	31335	13180
2900356	15MM SHAVER	Apr-2002	Rule 6	Annex V	31335	13180
2900357	16MM SHAVER	Apr-2002	Rule 6	Annex V	31335	13180
2900601	INSERTER HANDLE	Feb-2003	Rule 6	Annex V	47829	13180
2901250	6MM CAM SPREADER	May-2004	Rule 6	Annex V	13180	13180
2901251	8MM CAM SPREADER	May-2004	Rule 6	Annex V	13180	13180
2901252	10MM X 6° CAM SPREADER	May-2004	Rule 6	Annex V	13180	13180
2901253	12MM X 6° CAM SPREADER	May-2004	Rule 6	Annex V	13180	13180
2901254	14MM X 6° CAM SPREADER	May-2004	Rule 6	Annex V	13180	13180
2901255	16MM X 6° CAM SPREADER	May-2004	Rule 6	Annex V	13180	13180
2901256	12MM X 12° CAM SPREADER	May-2004	Rule 6	Annex V	13180	13180
2901257	14MM X 12° CAM SPREADER	May-2004	Rule 6	Annex V	13180	13180
2901258	16MM X 12° CAM SPREADER	May-2004	Rule 6	Annex V	13180	13180
2901259	13MM X 18° CAM SPREADER	May-2004	Rule 6	Annex V	13180	13180
2901260	15MM X 18° CAM SPREADER	May-2004	Rule 6	Annex V	13180	13180
2940255	CAM SPREADER 16MM X 6°	May-2004	Rule 6	Annex V	13180	13180
TELAMON™ Instruments, Non Sterile, Measuring						
9074008	8MM CHISEL - MAST	Jun-2002	Rule 6	Annex V	13180	13180
9074010	10MM CHISEL - MAST	Jun-2002	Rule 6	Annex V	13180	13180
9074012	12MM CHISEL - MAST	Jun-2002	Rule 6	Annex V	13180	13180
9074014	14MM CHISEL - MAST	Jun-2002	Rule 6	Annex V	13180	13180
9074107	SMALL SCRAPER	Jun-2002	Rule 6	Annex V	13180	13180
9074108	MEDIUM SCRAPER	Jun-2002	Rule 6	Annex V	13180	13180
9074109	LARGE SCRAPER	Jun-2002	Rule 6	Annex V	13180	13180
907-530	SMALL ROTATE CUTTER	Sep-2000	Rule 6	Annex V	44805	15573
907-531	LARGE ROTATE CUTTER	Sep-2000	Rule 6	Annex V	44805	15573
907-539	MEDIUM ROTATE CUTTER	Sep-2000	Rule 6	Annex V	44805	15573
907-540	DISTRACTOR 10	Feb-2002	Rule 6	Annex V	56637	11291
907-541	DISTRACTOR 11	Feb-2002	Rule 6	Annex V	56637	11291
907-542	DISTRACTOR 12	Feb-2002	Rule 6	Annex V	56637	11291
907-543	DISTRACTOR 13	Feb-2002	Rule 6	Annex V	56637	11291
907-544	DISTRACTOR 14	Feb-2002	Rule 6	Annex V	56637	11291
907-545	DISTRACTOR 15	Feb-2002	Rule 6	Annex V	56637	11291
907-547	DISTRACTOR 7	Feb-2002	Rule 6	Annex V	56637	11291
907-548	DISTRACTOR 8	Feb-2002	Rule 6	Annex V	56637	11291
907-549	DISTRACTOR 9	Feb-2002	Rule 6	Annex V	56637	11291
907-607	IMPLANT INSERTER	Sep-2001	Rule 6	Annex V	12696	17543
907-609	C-STYLE INSERTER	Jun-2000	Rule 6	Annex V	12696	17543
VANTAGE Instrument, Non Sterile, Measuring						
9339075	SCREW GAGE	Feb-2003	Rule 6	Annex V	32845	13180
Instruments, Non Sterile, Measuring						
3280001	PIT RONGEUR, 6 X 14, STR	Dec-2003	Rule 6	Annex V	32853	13180
3280002	PIT RONGEUR, 4 X 10, STR	Dec-2003	Rule 6	Annex V	32853	13180

Tech File Bundle: TF010, TL Fusion

Product: Multiple Product Families

Class: Im

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
3280003	PIT RONGEUR, 6 X 14, UPBITE	Dec-2003	Rule 6	Annex V	32853	13180
3280004	PIT RONGEUR, 4 X 10, UPBITE	Dec-2003	Rule 6	Annex V	32853	13180
3280005	UTERINE CURETTE, SIZE 0	Jan-2004	Rule 6	Annex V	47022	11084
3280006	UTERINE CURETTE, SIZE 4	Jan-2004	Rule 6	Annex V	47022	11084
3280009	RAKE CURETTE, STRAIGHT	Jan-2004	Rule 6	Annex V	47022	11084
3280010	RAKE CURETTE, ANGLED	Jan-2004	Rule 6	Annex V	47022	11084
3280012	COBB ELEVATOR, 20MM	Jan-2004	Rule 6	Annex V	13180	13180
3280013	COBB ELEVATOR, 32MM	Jan-2004	Rule 6	Annex V	13180	13180
3280015	CUP CURETTE, SZ 5, STR	Jan-2004	Rule 6	Annex V	47022	11084
3280016	CUP CURETTE, SZ 1, STR	Jan-2004	Rule 6	Annex V	47022	11084
3280017	CUP CURETTE, SZ 5, ANG	Jan-2004	Rule 6	Annex V	47022	11084
3280019	REV CURETTE, SZ 5, 90 DEG	Jan-2004	Rule 6	Annex V	47022	11084
3280040	RASP, 12 X 20, FLAT	Jan-2004	Rule 6	Annex V	35559	13288
3280041	RASP, 12 X 20, 20 DEG	Jan-2004	Rule 6	Annex V	35559	13288
3280044	BONE GRAFT TAMP, 6MM	Jan-2004	Rule 6	Annex V	32873	13180
3280046	OSTEOTOME, 15MM	Jan-2004	Rule 6	Annex V	12844	12845
3280047	OSTEOTOME, 25MM	Jan-2004	Rule 6	Annex V	12844	12845
6400840	SMALL INSERTER, 6MM AND 7MM	Oct-2001	Rule 6	Annex V	12696	17543
6400841	MEDIUM INSERTER, 8MM AND 9MM	Oct-2001	Rule 6	Annex V	12696	17543
6400842	LARGE INSERTER, 10MM, 11MM, AND 12MM	Oct-2001	Rule 6	Annex V	12696	17543
6401806	TAP, 6MM	Oct-2001	Rule 6	Annex V	17507	17507
6401807	TAP, 7MM	Sep-2001	Rule 6	Annex V	17507	17507
6401808	TAP, 8MM	Sep-2001	Rule 6	Annex V	17507	17507
6401809	TAP, 9MM	Sep-2001	Rule 6	Annex V	17507	17507
6401810	TAP, 10MM	Sep-2001	Rule 6	Annex V	17507	17507
6401811	TAP, 11MM	Sep-2001	Rule 6	Annex V	17507	17507
6401812	TAP, 12MM	Sep-2001	Rule 6	Annex V	17507	17507
893-576	16MM INSERTER	Jul-2008	Rule 6	Annex V	12696	17543
893-576R	16MM INSERTER	Jul-2008	Rule 6	Annex V	12696	17543
893-578	18MM INSERTER	Jul-2008	Rule 6	Annex V	12696	17543
893-578R	18MM INSERTER	Jul-2008	Rule 6	Annex V	12696	17543
893-580	20MM INSERTER	Jul-2008	Rule 6	Annex V	12696	17543
893-580R	20MM INSERTER	Jul-2008	Rule 6	Annex V	12696	17543
900-030	6MM TREPHINE	Jul-2008	Rule 6	Annex V	14147	14146
900-031	8MM TREPHINE	Jul-2008	Rule 6	Annex V	14147	14146
900-040	DEPTH GAGE	Jul-2008	Rule 6	Annex V	32845	13180
900-241	12MM HOLLOW REAMER	May-2005	Rule 6	Annex V	45114	13297
900-244	12MM INSERTER	Sep-2004	Rule 6	Annex V	12696	17543
900-433	14/8MM ADJ WORKING CHANNEL	Mar-2007	Rule 6	Annex V	13180	13180
900-440	14MM SOLID REAMER	Jul-2004	Rule 6	Annex V	45114	13297
900-441	14MM HOLLOW REAMER	Jul-2000	Rule 6	Annex V	45114	13297
900-442	14MM TAP	Jun-2005	Rule 6	Annex V	17507	17507
900-444	14MM INSERTER	Mar-2006	Rule 6	Annex V	12696	17543
900-445	14MM DOWEL INSERTER	Jan-2001	Rule 6	Annex V	12696	17543
900-633	16/10MM ADJ WORKING CHANNEL	Mar-2007	Rule 6	Annex V	13180	13180
900-640	16MM SOLID REAMER	Jul-2008	Rule 6	Annex V	45114	13297
900-641	16MM HOLLOW REAMER	May-2005	Rule 6	Annex V	45114	13297
900-642	16MM TAP	May-2005	Rule 6	Annex V	17507	17507
900-644	16MM INSERTER	Jan-2005	Rule 6	Annex V	12696	17543

Tech File Bundle: TF010, TL Fusion

Product: Multiple Product Families

Class: Im

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
900-840	18MM SOLID REAMER	Jul-2008	Rule 6	Annex V	45114	13297
900-841	18MM HOLLOW REAMER	May-2005	Rule 6	Annex V	45114	13297
900-842	18MM TAP	May-2005	Rule 6	Annex V	17507	17507
900-844	18MM INSERTER	Mar-2006	Rule 6	Annex V	12696	17543
9030341	16mm LATERAL THREADED CONSTRUCT TAP	Mar-2001	Rule 6	Annex V	17507	17507
9030342	REAMER	Mar-2001	Rule 6	Annex V	45114	13297
9030441	18mm LATERAL THREADED CONSTRUCT TAP	Mar-2001	Rule 6	Annex V	17507	17507
9030442	REAMER	Mar-2001	Rule 6	Annex V	45114	13297
9030541	20mm LATERAL THREADED CONSTRUCT TAP	Mar-2001	Rule 6	Annex V	17507	17507
9030542	REAMER	Mar-2001	Rule 6	Annex V	45114	13297
906-108	INTER BONE GRAFT TRIAL 8-9MM	Feb-2002	Rule 6	Annex V	44788	17704
906-110	INTER BONE GRAFT TRIAL 10-11MM	Feb-2002	Rule 6	Annex V	44788	17704
906-112	INTER BONE GRAFT TRIAL 12-13MM	Feb-2002	Rule 6	Annex V	44788	17704
906-114	INTER BONE GRAFT TRIAL 14-15MM	Feb-2002	Rule 6	Annex V	44788	17704
906-119	INTER BONE GRAFT TRIAL 19-25MM	Feb-2002	Rule 6	Annex V	44788	17704
906-415	BONE GRAFT TAMP, CURVED	Dec-2004	Rule 6	Annex V	32873	13180
907338	8MM OSTEOTOME	Aug-2005	Rule 6	Annex V	12844	12845
907340	SMALL ROTATE CUTTER	Aug-2005	Rule 6	Annex V	44805	15573
907341	MEDIUM ROTATE CUTTER	Aug-2005	Rule 6	Annex V	44805	15573
907342	LARGE ROTATE CUTTER	Aug-2005	Rule 6	Annex V	44805	15573
907347	SMALL FOWARD ANGLE CURETTE	Aug-2005	Rule 6	Annex V	47022	11084
907348	LARGE FOWARD ANGLE CURETTE	Aug-2005	Rule 6	Annex V	47022	11084
907349	SMALL REVERSE ANGLE CURETTE	Aug-2005	Rule 6	Annex V	47022	11084
907350	LARGE REVERSE ANGLE CURETTE	Aug-2005	Rule 6	Annex V	47022	11084
907351	LEFT ANGLED CUP CURETTE	Aug-2005	Rule 6	Annex V	47022	11084
907352	RIGHT ANGLED CUP CURETTE	Aug-2005	Rule 6	Annex V	47022	11084
907353	RIGHT STRAIGHT CUP CURETTE	Aug-2005	Rule 6	Annex V	47022	11084
907354	LEFT STRAIGHT CUP CURETTE	Aug-2005	Rule 6	Annex V	47022	11084
907355	RING CURETTE	Aug-2005	Rule 6	Annex V	47022	11084
907406	DISTRACING OSTEOTOME	Aug-2005	Rule 6	Annex V	12844	12845
907408	8MM DISTRACTOR	Aug-2005	Rule 6	Annex V	56637	11291
907409	9MM DISTRACTOR	Aug-2005	Rule 6	Annex V	56637	11291
907410	10MM DISTRACTOR	Aug-2005	Rule 6	Annex V	56637	11291
907411	11MM DISTRACTOR	Aug-2005	Rule 6	Annex V	56637	11291
907412	12MM DISTRACTOR	Aug-2005	Rule 6	Annex V	56637	11291
907413	13MM DISTRACTOR	Aug-2005	Rule 6	Annex V	56637	11291
907414	14MM DISTRACTOR	Aug-2005	Rule 6	Annex V	56637	11291
907415	15MM DISTRACTOR	Aug-2005	Rule 6	Annex V	56637	11291
907416	16MM DISTRACTOR	Aug-2005	Rule 6	Annex V	56637	11291
907-482	CHISEL 12	Feb-2002	Rule 6	Annex V	13180	13180
907-510	LARGE ROUND SCRAPER	Sep-2000	Rule 6	Annex V	13180	13180
907-518	SMALL ROUND SCRAPER	Sep-2000	Rule 6	Annex V	13180	13180
907-519	MEDIUM ROUND SCRAPER	Sep-2000	Rule 6	Annex V	13180	13180
907-581	FREE HAND CHISEL 12	Jul-2000	Rule 6	Annex V	13180	13180
907-582	FREE HAND CHISEL 14	Jul-2000	Rule 6	Annex V	13180	13180
907-588	FREE HAND CHISEL 8	Jul-2000	Rule 6	Annex V	13180	13180
907-589	FREE HAND CHISEL 10	Jul-2000	Rule 6	Annex V	13180	13180
9110252	TAPERED IMPLANT HOLLOW REAMER, 14mm	Jun-2001	Rule 6	Annex V	45114	13297
9110260	TAPERED IMPLANT DRIVER SLEEVE, 14mm	Jun-2001	Rule 6	Annex V	47831	16146

Tech File Bundle: TF010, TL Fusion

Product: Multiple Product Families

Class: Im

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
9110352	TAPERED IMPLANT HOLLOW REAMER, 16mm	Jun-2001	Rule 6	Annex V	45114	13297
9110365	TAPERED IMPLANT DRIVER SLEEVE, 16mm	Jun-2001	Rule 6	Annex V	47831	16146
9110450	TAPERED IMPLANT HOLLOW REAMER, 18mm	Jun-2001	Rule 6	Annex V	45114	13297
9110460	TAPERED IMPLANT DRIVER SLEEVE, 18mm	Jun-2001	Rule 6	Annex V	47831	16146
9112350	CYLINDRICAL IMPLANT HOLLOW REAMER, 16mm	Jun-2001	Rule 6	Annex V	45114	13297
9112351	BONE DOWEL TAP, 16mm IMPLANT	Jun-2001	Rule 6	Annex V	17507	17507
9112360	CYLINDRICAL IMPLANT INSERTER, 16mm	Jun-2001	Rule 6	Annex V	12696	17543
9112452	CYLINDRICAL IMPLANT HOLLOW REAMER, 18mm	Jun-2001	Rule 6	Annex V	45114	13297
9112453	BONE DOWEL TAP, 18mm IMPLANT	Jun-2001	Rule 6	Annex V	17507	17507
9112465	CYLINDRICAL IMPLANT INSERTER, 18mm	Jun-2001	Rule 6	Annex V	12696	17543
9112550	CYLINDRICAL IMPLANT HOLLOW REAMER, 20mm	Jun-2001	Rule 6	Annex V	45114	13297
9112551	BONE DOWEL TAP, 20mm IMPLANT	Jun-2001	Rule 6	Annex V	17507	17507
9112560	CYLINDRICAL IMPLANT INSERTER, 20mm	Jun-2001	Rule 6	Annex V	12696	17543
9115780	PITUITARY RONGEUR, 4mm X 12mm	Jun-2001	Rule 6	Annex V	32853	13416
9116880	8mm TREPHINE	Jun-2001	Rule 6	Annex V	14147	14146
9116882	PITUITARY RONGEUR, 7mm X 12mm	Dec-2000	Rule 6	Annex V	32853	13416
9116883	6mm TREPHINE	Jun-2001	Rule 6	Annex V	14147	14146
9150031	CIRCULAR TREPHINE, 12MM	Sep-2000	Rule 6	Annex V	14147	14146
9150032	CIRCULAR TREPHINE, 14MM	Sep-2000	Rule 6	Annex V	14147	14146
9150033	CIRCULAR TREPHINE, 16MM	Sep-2000	Rule 6	Annex V	14147	14146
9150034	CIRCULAR TREPHINE, 18MM	Sep-2000	Rule 6	Annex V	14147	14146
9150035	CIRCULAR TREPHINE, 20MM	Sep-2000	Rule 6	Annex V	14147	14146
9150036	CIRCULAR TREPHINE, 22MM	Sep-2000	Rule 6	Annex V	14147	14146
9150037	CIRCULAR TREPHINE, 24MM	Sep-2000	Rule 6	Annex V	14147	14146
9150038	SCALLOPED TREPHINE, 12MM	Sep-2000	Rule 6	Annex V	14147	14146
9150039	SCALLOPED TREPHINE, 14MM	Sep-2000	Rule 6	Annex V	14147	14146
9150040	SCALLOPED TREPHINE, 16MM	Sep-2000	Rule 6	Annex V	14147	14146
9150041	SCALLOPED TREPHINE, 18MM	Sep-2000	Rule 6	Annex V	14147	14146
9150042	SCALLOPED TREPHINE, 20MM	Sep-2000	Rule 6	Annex V	14147	14146
9150043	SCALLOPED TREPHINE, 22MM	Sep-2000	Rule 6	Annex V	14147	14146
9150044	SCALLOPED TREPHINE, 24MM	Sep-2000	Rule 6	Annex V	14147	14146
9181201	KEEL CHISEL BLADE	Aug-2002	Rule 6	Annex V	10825	10824
9181524	9 DEG. X 12 MM SHIM DISTRACTOR	Aug-2002	Rule 6	Annex V	56637	11291
9181525	9 DEG. X 14 MM SHIM DISTRACTOR	Aug-2002	Rule 6	Annex V	56637	11291
9181526	12DEG. X 10 MM SHIM DISTRACTOR	Aug-2002	Rule 6	Annex V	56637	11291
9181527	12DEG. X 12 MM SHIM DISTRACTOR	Aug-2002	Rule 6	Annex V	56637	11291
9181528	12DEG. X 14 MM SHIM DISTRACTOR	Aug-2002	Rule 6	Annex V	56637	11291
9181624	6 DEG. X 12 MM TRIAL SPACER	Aug-2002	Rule 6	Annex V	44788	13180
9181625	9 DEG. X 12 MM TRIAL SPACER	Aug-2002	Rule 6	Annex V	44788	13180
9181626	12 DEG. X 12 MM TRIAL SPACER	Aug-2002	Rule 6	Annex V	44788	13180
9181627	6 DEG. X 14 MM TRIAL SPACER	Aug-2002	Rule 6	Annex V	44788	13180
9181628	9 DEG. X 14 MM TRIAL SPACER	Aug-2002	Rule 6	Annex V	44788	13180
9181629	12 DEG. X 14 MM TRIAL SPACER	Jun-2005	Rule 6	Annex V	44788	13180
9198120	STRAIGHT OSTEOTOME - 1/4"	Jan-2004	Rule 6	Annex V	12844	12845
9198125	STRAIGHT OSTEOTOME - 1/2"	Jan-2004	Rule 6	Annex V	12844	12845
9198130	ANGLED OSTETOME - 1/4"	Jan-2004	Rule 6	Annex V	12844	12844
9198135	ANGLED OSTEOTOME - 1/2"	Jan-2004	Rule 6	Annex V	12844	12845
9198260	STRAIGHT BONE GRAFT TAMP	Feb-2004	Rule 6	Annex V	32873	13180
9198312	DISTRACTOR, 12MM	Feb-2004	Rule 6	Annex V	56637	11291

Tech File Bundle: TF010, TL Fusion

Product: Multiple Product Families

Class: Im

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
9198990	MODULAR OPENER	Dec-2005	Rule 6	Annex V	13180	13180
2942026	8 mm Rotate Distractor	Mar-2012	Rule 6	Annex V	56637	11291
2942028	10 mm Rotate Distractor	Mar-2012	Rule 6	Annex V	56637	11291
2942030	12 mm Rotate Distractor	Mar-2012	Rule 6	Annex V	56637	11291
2942032	14 mm Rotate Distractor	Mar-2012	Rule 6	Annex V	56637	11291
7509001	Small Delivery Tube 0 Deg	May-2012	Rule 6	Annex V	13180	13180
7509002	Small Delivery Tube 15 Deg	May-2012	Rule 6	Annex V	13180	13180
7509003	Small Delivery Tube 30 Deg	May-2012	Rule 6	Annex V	13180	13180
7509005	Medium Delivery Tube 0 Deg	May-2012	Rule 6	Annex V	13180	13180
7509006	Medium Delivery Tube 15 Deg	May-2012	Rule 6	Annex V	13180	13180
7509008	Medium Delivery Tube 30 Deg	May-2012	Rule 6	Annex V	13180	13180
9339075	SCREW GAGE	Feb-2003	Rule 6	Annex V	32845	13180
9561421	DILATOR 10.6MM	Oct-2005	Rule 6	Annex V	13180	13180
9561422	DILATOR 16MM	Oct-2005	Rule 6	Annex V	13180	13180
9561424	DL DILATOR 20.8MM	Sep-2006	Rule 6	Annex V	13180	13180
907382	GRAFT IMPACTOR	Aug-2005	Rule 6	Annex V	32856	13180
X0105195	7MM DISC SHAVER	May-2005	Rule 6	Annex V	31335	13180
X0105196	8MM DISC SHAVER	May-2005	Rule 6	Annex V	31335	13180
X0105197	9MM DISC SHAVER	May-2005	Rule 6	Annex V	31335	13180
X0105198	10MM DISC SHAVER	May-2005	Rule 6	Annex V	31335	13180
X0105199	11MM DISC SHAVER	May-2005	Rule 6	Annex V	31335	13180
X0105200	12MM DISC SHAVER	May-2005	Rule 6	Annex V	31335	13180
X0105201	13MM DISC SHAVER	May-2005	Rule 6	Annex V	31335	13180
X0105202	14MM DISC SHAVER	May-2005	Rule 6	Annex V	31335	13180
X0105203	15MM DISC SHAVER	May-2005	Rule 6	Annex V	31335	13180
X010610007	7MM SHAVER	Apr-2006	Rule 6	Annex V	31335	13180
X010610008	8MM SHAVER	Apr-2006	Rule 6	Annex V	31335	13180
X010610009	9MM SHAVER	Apr-2006	Rule 6	Annex V	31335	13180
X010610010	10MM SHAVER	Apr-2006	Rule 6	Annex V	31335	13180
X010610011	11MM SHAVER	Apr-2006	Rule 6	Annex V	31335	13180
X010610012	12MM SHAVER	Apr-2006	Rule 6	Annex V	31335	13180
X010610014	14MM SHAVER	Apr-2006	Rule 6	Annex V	31335	13180
X0903413	IFX TAP-14MM-HUDSON	Dec-2003	Rule 6	Annex V	17507	17507
X1004015	M3 IMPLANT INSERTER	Jan-2005	Rule 6	Annex V	12696	17543
9198250	STRAIGHT GRAFT IMPACTOR	Jan-2004	Rule 6	Annex V	32856	13180
9198251	ANGLED GRAFT IMPACTOR	Jan-2004	Rule 6	Annex V	32856	13180
9198988	OPENER 9198988 MODULAR	May-2007	Rule 6	Annex V	13180	13180
9219002	ANGLED PENFIELD, BAYONETED	Sep-2006	Rule 6	Annex V	13180	13180
9219003	BAYONETED PENFIELD	Sep-2006	Rule 6	Annex V	13180	13180
9870060	TAP 9870060 6.0MM	Mar-2009	Rule 6	Annex V	17507	17507
9870065	TAP 9870065 6.5MM	Mar-2009	Rule 6	Annex V	17507	17507
X010610013	13MM SHAVER	Apr-2006	Rule 6	Annex V	31335	13180



Product List

Last updated by: Lila Joe
 Tech File Bundle: TL Fusion, TF010

Date: 1/25/2016

Product: GENERAL Interbody Trial Instruments, Non-Sterile
 Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
6400856	DUAL TRIAL 6MM	Oct-2001	Rule 6	Annex II (-Section4)	44788	17704
6400857	TRIAL 7MM	Oct-2001	Rule 6	Annex II (-Section4)	44788	17704
6400858	TRIAL 8MM	Oct-2001	Rule 6	Annex II (-Section4)	44788	17704
6400859	TRIAL 9MM	Oct-2001	Rule 6	Annex II (-Section4)	44788	17704
6400860	TRIAL 10MM	Oct-2001	Rule 6	Annex II (-Section4)	44788	17704
6400861	TRIAL 11MM	Oct-2001	Rule 6	Annex II (-Section4)	44788	17704
6400862	TRIAL 12MM	Oct-2001	Rule 6	Annex II (-Section4)	44788	17704
6400863	DUAL TRIAL 7MM	Oct-2001	Rule 6	Annex II (-Section4)	44788	17704
6400864	DUAL TRIAL 8MM	Oct-2001	Rule 6	Annex II (-Section4)	44788	17704
8910508	ALIF TRIAL, 8MM	Dec-2003	Rule 6	Annex II (-Section4)	44788	17704
8910510	ALIF TRIAL, 10MM	Dec-2003	Rule 6	Annex II (-Section4)	44788	17704
8910512	ALIF TRIAL, 12MM	Dec-2003	Rule 6	Annex II (-Section4)	44788	17704
8910514	ALIF TRIAL, 14MM	Dec-2003	Rule 6	Annex II (-Section4)	44788	17704
8910516	ALIF TRIAL, 16MM	Dec-2003	Rule 6	Annex II (-Section4)	44788	17704
8910518	ALIF TRIAL, 18MM	Dec-2003	Rule 6	Annex II (-Section4)	44788	17704
8910520	ALIF TRIAL, 20MM	Dec-2003	Rule 6	Annex II (-Section4)	44788	17704
9097012	IMPLANT TRIAL, 12MM	Jan-2004	Rule 6	Annex II (-Section4)	44788	17704
9097014	IMPLANT TRIAL, 14MM	Sep-2000	Rule 6	Annex II (-Section4)	44788	17704
9097016	IMPLANT TRIAL, 16MM	Sep-2000	Rule 6	Annex II (-Section4)	44788	17704
9097018	IMPLANT TRIAL, 18MM	Sep-2000	Rule 6	Annex II (-Section4)	44788	17704
9097020	IMPLANT TRIAL, 20MM	Sep-2000	Rule 6	Annex II (-Section4)	44788	17704
9119870	LAP SEAL KIT PKG ASSEMBLY	Aug-2001	Rule 6	Annex II (-Section4)	13180	13180



Product List

Last updated by: Fernand Terradas
 Tech File Bundle: TL Fusion, TF010

Date: 10/5/2015

Product: AVILA Interbody Fusion Device, Instruments non sterile

Class: Ila

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
3695310806	SMALL ALIF TRIAL 8° 6MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695310808	SMALL ALIF TRIAL 8° 8MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695310810	SMALL ALIF TRIAL 8° 10MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695310812	SMALL ALIF TRIAL 8° 12MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695310814	SMALL ALIF TRIAL 8° 14MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695311206	SMALL ALIF TRIAL 12° 6MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695311208	SMALL ALIF TRIAL 12° 8MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695311210	SMALL ALIF TRIAL 12° 10MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695311212	SMALL ALIF TRIAL 12° 12MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695311214	SMALL ALIF TRIAL 12° 14MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695311606	SMALL ALIF TRIAL 16° 6MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695311608	SMALL ALIF TRIAL 16° 8MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695311610	SMALL ALIF TRIAL 16° 10MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695311612	SMALL ALIF TRIAL 16° 12MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695311614	SMALL ALIF TRIAL 16° 14MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695312006	SMALL ALIF TRIAL 20° 6MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695312008	SMALL ALIF TRIAL 20° 8MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695312010	SMALL ALIF TRIAL 20° 10MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695312012	SMALL ALIF TRIAL 20° 12MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695312014	SMALL ALIF TRIAL 20° 14MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695312406	SMALL ALIF TRIAL 24° 6MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695312408	SMALL ALIF TRIAL 24° 8MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695312410	SMALL ALIF TRIAL 24° 10MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695312412	SMALL ALIF TRIAL 24° 12MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695312414	SMALL ALIF TRIAL 24° 14MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695320806	MEDIUM ALIF TRIAL 8° 6MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695320808	MEDIUM ALIF TRIAL 8° 8MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695320810	MEDIUM ALIF TRIAL 8° 10MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695320812	MEDIUM ALIF TRIAL 8° 12MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695320814	MEDIUM ALIF TRIAL 8° 14MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695321206	MEDIUM ALIF TRIAL 12° 6MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695321208	MEDIUM ALIF TRIAL 12° 8MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695321210	MEDIUM ALIF TRIAL 12° 10MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695321212	MEDIUM ALIF TRIAL 12° 12MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695321214	MEDIUM ALIF TRIAL 12° 14MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695321606	MEDIUM ALIF TRIAL 16° 6MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695321608	MEDIUM ALIF TRIAL 16° 8MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695321610	MEDIUM ALIF TRIAL 16° 10MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695321612	MEDIUM ALIF TRIAL 16° 12MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695321614	MEDIUM ALIF TRIAL 16° 14MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695322006	MEDIUM ALIF TRIAL 20° 6MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695322008	MEDIUM ALIF TRIAL 20° 8MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695322010	MEDIUM ALIF TRIAL 20° 10MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695322012	MEDIUM ALIF TRIAL 20° 12MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695322014	MEDIUM ALIF TRIAL 20° 14MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695322406	MEDIUM ALIF TRIAL 24° 6MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695322408	MEDIUM ALIF TRIAL 24° 8MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695322410	MEDIUM ALIF TRIAL 24° 10MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291

Tech File Bundle: TL Fusion, TF010

Product: AVILA Interbody Fusion Device, Instruments non sterile

Class: Ila

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
3695322412	MEDIUM ALIF TRIAL 24° 12MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695322414	MEDIUM ALIF TRIAL 24° 14MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695330806	LARGE ALIF TRIAL 8° 6MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695330808	LARGE ALIF TRIAL 8° 8MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695330810	LARGE ALIF TRIAL 8° 10MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695330812	LARGE ALIF TRIAL 8° 12MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695330814	LARGE ALIF TRIAL 8° 14MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695331206	LARGE ALIF TRIAL 12° 6MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695331208	LARGE ALIF TRIAL 12° 8MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695331210	LARGE ALIF TRIAL 12° 10MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695331212	LARGE ALIF TRIAL 12° 12MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695331214	LARGE ALIF TRIAL 12° 14MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695331606	LARGE ALIF TRIAL 16° 6MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695331608	LARGE ALIF TRIAL 16° 8MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695331610	LARGE ALIF TRIAL 16° 10MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695331612	LARGE ALIF TRIAL 16° 12MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695331614	LARGE ALIF TRIAL 16° 14MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695332006	LARGE ALIF TRIAL 20° 6MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695332008	LARGE ALIF TRIAL 20° 8MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695332010	LARGE ALIF TRIAL 20° 10MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695332012	LARGE ALIF TRIAL 20° 12MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695332014	LARGE ALIF TRIAL 20° 14MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695332406	LARGE ALIF TRIAL 24° 6MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695332408	LARGE ALIF TRIAL 24° 8MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695332410	LARGE ALIF TRIAL 24° 10MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695332412	LARGE ALIF TRIAL 24° 12MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695332414	LARGE ALIF TRIAL 24° 14MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695410806	SMALL OLIF TRIAL 8° 6MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695410808	SMALL OLIF TRIAL 8° 8MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695410810	SMALL OLIF TRIAL 8° 10MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695410812	SMALL OLIF TRIAL 8° 12MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695410814	SMALL OLIF TRIAL 8° 14MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695411206	SMALL OLIF TRIAL 12° 6MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695411208	SMALL OLIF TRIAL 12° 8MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695411210	SMALL OLIF TRIAL 12° 10MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695411212	SMALL OLIF TRIAL 12° 12MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695411214	SMALL OLIF TRIAL 12° 14MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695420806	MEDIUM OLIF TRIAL 8° 6MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695420808	MEDIUM OLIF TRIAL 8° 8MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695420810	MEDIUM OLIF TRIAL 8° 10MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695420812	MEDIUM OLIF TRIAL 8° 12MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695420814	MEDIUM OLIF TRIAL 8° 14MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695421206	MEDIUM OLIF TRIAL 12° 6MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695421208	MEDIUM OLIF TRIAL 12° 8MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695421210	MEDIUM OLIF TRIAL 12° 10MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695421212	MEDIUM OLIF TRIAL 12° 12MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695421214	MEDIUM OLIF TRIAL 12° 14MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695430806	LARGE OLIF TRIAL 8° 6MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695430808	LARGE OLIF TRIAL 8° 8MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695430810	LARGE OLIF TRIAL 8° 10MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291



Tech File Bundle: TL Fusion, TF010

Product: AVILA Interbody Fusion Device, Instruments non sterile

Class: Ila

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
3695430812	LARGE OLIF TRIAL 8° 12MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695430814	LARGE OLIF TRIAL 8° 14MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695431206	LARGE OLIF TRIAL 12° 6MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695431208	LARGE OLIF TRIAL 12° 8MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695431210	LARGE OLIF TRIAL 12° 10MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695431212	LARGE OLIF TRIAL 12° 12MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291
3695431214	LARGE OLIF TRIAL 12° 14MM	Nov-2015	Rule 6	Annex II (-Section4)	44788	11291

Product List

Last updated by:

Tech File Bundle:

Product:

Class:

Elizabeth Hamilton
TL Fusion, TF010

Date:

4/27/2018

ARTiC-L™3D Ti Spinal System						
IIa						
P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
5250800	Interbody fixed trial H_8, Deg_0, L_25	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5250900	Interbody fixed trial H_9, Deg_0, L_25	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5251000	Interbody fixed trial H_10, Deg_0, L_25	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5251100	Interbody fixed trial H_11, Deg_0, L_25	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5251200	Interbody fixed trial H_12, Deg_0, L_25	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5251300	Interbody fixed trial H_13, Deg_0, L_25	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5251400	Interbody fixed trial H_14, Deg_0, L_25	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5251500	Interbody fixed trial H_15, Deg_0, L_25	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5300800	Interbody fixed trial H_08, Deg_0, L_30	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5350800	Interbody fixed trial H_08, Deg_0, L_35	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5250805	Interbody articulating trial H_8, Deg_5, L_25	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5250905	Interbody articulating trial H_9, Deg_5, L_25	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5251005	Interbody articulating trial H_10, Deg_5, L_25	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5251105	Interbody articulating trial H_11, Deg_5, L_25	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5251205	Interbody articulating trial H_12, Deg_5, L_25	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5251305	Interbody articulating trial H_13, Deg_5, L_25	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5251405	Interbody articulating trial H_14, Deg_5, L_25	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5251505	Interbody articulating trial H_15, Deg_5, L_25	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5251020	Interbody articulating trial H_10, Deg_20, L_25	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5251120	Interbody articulating trial H_11, Deg_20, L_25	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5251220	Interbody articulating trial H_12, Deg_20, L_25	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5251320	Interbody articulating trial H_13, Deg_20, L_25	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5251420	Interbody articulating trial H_14, Deg_20, L_25	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5251520	Interbody articulating trial H_15, Deg_20, L_25	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5300805	Interbody articulating trial H_08, Deg_05, L_30	May-2018	Rule 6	Annex II (-Section4)	44788	17704
5350805	Interbody articulating trial H_08, Deg_05, L_35	May-2018	Rule 6	Annex II (-Section4)	44788	17704



Product List

Last updated by: Greg Maschek
 Tech File Bundle: TL Fusion, TF010

Date: 2/27/2015

Product: CAPSTONE Trial Instruments, Non-Sterile
 Class: Ila

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2980622	6x22 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2980626	6x26 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2980722	7x22 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2980726	7x26 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2980732	7x32 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2980736	7X36 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2980922	9x22 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2980926	9X26 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2980932	9x32 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2980936	9X36 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981122	11x22 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981126	11x26 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981132	11x32 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981136	11X36 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981322	13x22 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981326	13x26 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981332	13x32 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981336	13X36 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981522	15x22 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981526	15x26 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981532	15X32 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981536	15X36 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981622	16x22 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981626	16X26 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981632	16X32 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981636	16x36 DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2980822	8 X 22MM DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2980826	8 X 26MM DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2980832	8 X 32MM DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2980836	8 X 36MM DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981022	10 X 22MM DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981026	10 X 26MM DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981032	10 X 32MM DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981036	10 X 36MM DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981222	12 X 22MM DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981226	12 X 26MM DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981232	12 X 32MM DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981236	12 X 36MM DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981422	14 X 22MM DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981426	14 X 26MM DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981432	14 X 32MM DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
2981436	14 X 36MM DISTRACTOR/TRIAL	Oct-2009	Rule 6	Annex II (-Section4)	44788	11291
29900822	TRIAL 8mm x 22mm	Dec-2016	Rule 6	Annex II (-Section4)	44788	11291
29900826	TRIAL 8mm x 26mm	Dec-2016	Rule 6	Annex II (-Section4)	44788	11291
29900832	TRIAL 8mm x 32mm	Dec-2016	Rule 6	Annex II (-Section4)	44788	11291
29900836	TRIAL 8mm x 36mm	Dec-2016	Rule 6	Annex II (-Section4)	44788	11291
29901022	TRIAL 10mm x 22mm	Dec-2016	Rule 6	Annex II (-Section4)	44788	11291
29901026	TRIAL 10mm x 26mm	Dec-2016	Rule 6	Annex II (-Section4)	44788	11291
29901032	TRIAL 10mm x 32mm	Dec-2016	Rule 6	Annex II (-Section4)	44788	11291
29901036	TRIAL 10mm x 36mm	Dec-2016	Rule 6	Annex II (-Section4)	44788	11291
29901222	TRIAL 12mm x 22mm	Dec-2016	Rule 6	Annex II (-Section4)	44788	11291
29901226	TRIAL 12mm x 26mm	Dec-2016	Rule 6	Annex II (-Section4)	44788	11291
29901232	TRIAL 12mm x 32mm	Dec-2016	Rule 6	Annex II (-Section4)	44788	11291
29901236	TRIAL 12mm x 36mm	Dec-2016	Rule 6	Annex II (-Section4)	44788	11291



Product List

Last updated by: Greg Maschek
 Tech File Bundle: TL Fusion, TF010

Date: 2/27/2015

Product: CRESCENT Trial Instruments, Non-Sterile

Class: Ila

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
6680725	TRIAL CRESCENT TI 07MMX25MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6680730	TRIAL CRESCENT TI 07MMX30MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6680736	TRIAL CRESCENT TI 07MMX36MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6680825	TRIAL CRESCENT TI 08MMX25MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6680830	TRIAL CRESCENT TI 08MMX30MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6680836	TRIAL CRESCENT TI 08MMX36MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6680925	TRIAL CRESCENT TI 09MMX25MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6680930	TRIAL CRESCENT TI 09MMX30MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6680936	TRIAL CRESCENT TI 09MMX36MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6681025	TRIAL CRESCENT TI 10MMX25MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6681030	TRIAL CRESCENT TI 10MMX30MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6681036	TRIAL CRESCENT TI 10MMX36MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6681125	TRIAL CRESCENT TI 11MMX25MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6681130	TRIAL CRESCENT TI 11MMX30MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6681136	TRIAL CRESCENT TI 11MMX36MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6681225	TRIAL CRESCENT TI 12MMX25MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6681230	TRIAL CRESCENT TI 12MMX30MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6681236	TRIAL CRESCENT TI 12MMX36MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6681325	TRIAL CRESCENT TI 13MMX25MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6681330	TRIAL CRESCENT TI 13MMX30MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6681336	TRIAL CRESCENT TI 13MMX36MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6681425	TRIAL CRESCENT TI 14MMX25MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6681430	TRIAL CRESCENT TI 14MMX30MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6681436	TRIAL CRESCENT TI 14MMX36MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6681525	TRIAL CRESCENT TI 15MMX25MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6681530	TRIAL CRESCENT TI 15MMX30MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6681536	TRIAL CRESCENT TI 15MMX36MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6681625	TRIAL CRESCENT TI 16MMX25MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6681630	TRIAL CRESCENT TI 16MMX30MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6681636	TRIAL CRESCENT TI 16MMX36MM WIDE STR	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6682507	TRIAL CRESCENT TI 07MMX25MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6682508	TRIAL CRESCENT TI 08MMX25MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6682509	TRIAL CRESCENT TI 09MMX25MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6682510	TRIAL CRESCENT TI 10MMX25MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6682511	TRIAL CRESCENT TI 11MMX25MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6682512	TRIAL CRESCENT TI 12MMX25MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6682513	TRIAL CRESCENT TI 13MMX25MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6682514	TRIAL CRESCENT TI 14MMX25MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6682515	TRIAL CRESCENT TI 15MMX25MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6682516	TRIAL CRESCENT TI 16MMX25MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6683007	TRIAL CRESCENT TI 07MMX30MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6683008	TRIAL CRESCENT TI 08MMX30MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6683009	TRIAL CRESCENT TI 09MMX30MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6683010	TRIAL CRESCENT TI 10MMX30MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6683011	TRIAL CRESCENT TI 11MMX30MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6683012	TRIAL CRESCENT TI 12MMX30MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6683013	TRIAL CRESCENT TI 13MMX30MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6683014	TRIAL CRESCENT TI 14MMX30MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704

Tech File Bundle: TL Fusion, TF010

Product: CRESCENT Trial Instruments, Non-Sterile

Class: Ila

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
6683015	TRIAL CRESCENT TI 15MMX30MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6683016	TRIAL CRESCENT TI 16MMX30MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6683607	TRIAL CRESCENT TI 07MMX36MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6683608	TRIAL CRESCENT TI 08MMX36MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6683609	TRIAL CRESCENT TI 09MMX36MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6683610	TRIAL CRESCENT TI 10MMX36MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6683611	TRIAL CRESCENT TI 11MMX36MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6683612	TRIAL CRESCENT TI 12MMX36MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6683613	TRIAL CRESCENT TI 13MMX36MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6683614	TRIAL CRESCENT TI 14MMX36MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6683615	TRIAL CRESCENT TI 15MMX36MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
6683616	TRIAL CRESCENT TI 16MMX36MM WIDE ANGLED	Nov-2011	Rule 6	Annex II (-Section4)	44788	17704
9500730	TRIAL CRESCENT TI 07MMX30MM STR	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9500830	TRIAL CRESCENT TI 08MMX30MM STR	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9500930	TRIAL CRESCENT TI 09MMX30MM STR	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9501030	TRIAL CRESCENT TI 10MMX30MM STR	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9501130	TRIAL CRESCENT TI 11MMX30MM STR	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9501230	TRIAL CRESCENT TI 12MMX30MM STR	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9501330	TRIAL CRESCENT TI 13MMX30MM STR	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9501430	TRIAL CRESCENT TI 14MMX30MM STR	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9501530	TRIAL CRESCENT TI 15MMX30MM STR	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9501630	TRIAL CRESCENT TI 16MMX30MM STR	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9503007	TRIAL CRESCENT TI 07MMX30MM ANGLED	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9503008	TRIAL CRESCENT TI 08MMX30MM ANGLED	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9503009	TRIAL CRESCENT TI 09MMX30MM ANGLED	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9503010	TRIAL CRESCENT TI 10MMX30MM ANGLED	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9503011	TRIAL CRESCENT TI 11MMX30MM ANGLED	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9503012	TRIAL CRESCENT TI 12MMX30MM ANGLED	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9503013	TRIAL CRESCENT TI 13MMX30MM ANGLED	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9503014	TRIAL CRESCENT TI 14MMX30MM ANGLED	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9503015	TRIAL CRESCENT TI 15MMX30MM ANGLED	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9503016	TRIAL CRESCENT TI 16MMX30MM ANGLED	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9590725	TRIAL CRESCENT TI 07MMX25MM STR	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9590736	TRIAL CRESCENT TI 07MMX36MM STR	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9592507	TRIAL CRESCENT TI 07MMX25MM ANGLED	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9593607	TRIAL CRESCENT TI 07MMX36MM ANGLED	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9197006	TRIAL HANDLE	Apr-1998	Rule 6	Annex II (-Section4)	47829	17704
9290725	STRAIGHT TRIAL, 7MM X 30MM	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9290730	15 DEGREE TRIAL, 7MM X 30MM	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9290825	STRAIGHT TRIAL, 8MM X 30MM	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9290830	15 DEGREE TRIAL, 8MM X 30MM	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9290925	STRAIGHT TRIAL, 9MM X 30MM	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9290930	15 DEGREE TRIAL, 9MM X 30MM	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9291025	STRAIGHT TRIAL, 10MM X 30MM	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9291030	15 DEGREE TRIAL, 10MM X 30MM	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9291125	STRAIGHT TRIAL, 11MM X 30MM	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9291130	15 DEGREE TRIAL, 11MM X 30MM	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9291225	STRAIGHT TRIAL, 12MM X 30MM	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9291230	15 DEGREE TRIAL, 12MM X 30MM	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9291325	STRAIGHT TRIAL, 13MM X 30MM	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704

Tech File Bundle: TL Fusion, TF010

Product: CRESCENT Trial Instruments, Non-Sterile

Class: Ila

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
9291330	15 DEGREE TRIAL, 13MM X 30MM	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9291425	STRAIGHT TRIAL, 14MM X 30MM	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9291430	15 DEGREE TRIAL, 14MM X 30MM	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9291525	STRAIGHT TRIAL, 15MM X 30MM	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9291530	15 DEGREE TRIAL, 15MM X 30MM	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9296010	LENGTH TRIAL, 7MM X 25MM	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9296011	LENGTH TRIAL, 7MM X 30MM	Apr-1998	Rule 6	Annex II (-Section4)	44788	17704
9593015	15X30 ANGLED FULL LENGTH TRIAL	Dec-2006	Rule 6	Annex II (-Section4)	44788	17704
9590730	7X30 STRAIGHT FULL LENGTH TRIAL	Apr-2007	Rule 6	Annex II (-Section4)	44788	17704
9590830	8X30 STRAIGHT FULL LENGTH TRIAL	Apr-2007	Rule 6	Annex II (-Section4)	44788	17704
9590930	9X30 STRAIGHT FULL LENGTH TRIAL	Apr-2007	Rule 6	Annex II (-Section4)	44788	17704
9591030	10X30 STRAIGHT FULL LENGTH TRIAL	Apr-2007	Rule 6	Annex II (-Section4)	44788	17704
9591130	11X30 STRAIGHT FULL LENGTH TRIAL	Apr-2007	Rule 6	Annex II (-Section4)	44788	17704
9591230	12X30 STRAIGHT FULL LENGTH TRIAL	Apr-2007	Rule 6	Annex II (-Section4)	44788	17704
9591330	13X30 STRAIGHT FULL LENGTH TRIAL	Apr-2007	Rule 6	Annex II (-Section4)	44788	17704
9591430	14X30 STRAIGHT FULL LENGTH TRIAL	Apr-2007	Rule 6	Annex II (-Section4)	44788	17704
9591530	15X30 STRAIGHT FULL LENGTH TRIAL	Apr-2007	Rule 6	Annex II (-Section4)	44788	17704
9593007	7X30 ANGLED FULL LENGTH TRIAL	Apr-2007	Rule 6	Annex II (-Section4)	44788	17704
9593008	8X30 ANGLED FULL LENGTH TRIAL	Apr-2007	Rule 6	Annex II (-Section4)	44788	17704
9593009	9X30 ANGLED FULL LENGTH TRIAL	Apr-2007	Rule 6	Annex II (-Section4)	44788	17704
9593010	10X30 ANGLED FULL LENGTH TRIAL	Apr-2007	Rule 6	Annex II (-Section4)	44788	17704
9593011	11X30 ANGLED FULL LENGTH TRIAL	Apr-2007	Rule 6	Annex II (-Section4)	44788	17704
9593012	12X30 ANGLED FULL LENGTH TRIAL	Apr-2007	Rule 6	Annex II (-Section4)	44788	17704
9593013	13X30 ANGLED FULL LENGTH TRIAL	Apr-2007	Rule 6	Annex II (-Section4)	44788	17704
9593014	14X30 ANGLED FULL LENGTH TRIAL	Apr-2007	Rule 6	Annex II (-Section4)	44788	17704



Product List

Last updated by: Greg Maschek
 Tech File Bundle: TL Fusion, TF010

Date: 2/27/2015

Product: CAPSTONE L Distractor/Trial Instruments, Non-Sterile

Class: Ila

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2982036	10 X 36MM L DISTRACTOR/TRIAL	Oct-2005	Rule 6	Annex II (-Section4)	44788	11291
2982040	10 X 40MM L DISTRACTOR/TRIAL	Oct-2005	Rule 6	Annex II (-Section4)	44788	11291
2982044	10 X 44MM L DISTRACTOR/TRIAL	Oct-2005	Rule 6	Annex II (-Section4)	44788	11291
2982236	12 X 36MM L DISTRACTOR/TRIAL	Oct-2005	Rule 6	Annex II (-Section4)	44788	11291
2982240	12 X 40MM L DISTRACTOR/TRIAL	Oct-2005	Rule 6	Annex II (-Section4)	44788	11291
2982244	12 X 44MM L DISTRACTOR/TRIAL	Oct-2005	Rule 6	Annex II (-Section4)	44788	11291
2982436	14 X 36MM L DISTRACTOR/TRIAL	Oct-2005	Rule 6	Annex II (-Section4)	44788	11291
2982440	14 X 40MM L DISTRACTOR/TRIAL	Oct-2005	Rule 6	Annex II (-Section4)	44788	11291
2982444	14 X 44MM L DISTRACTOR/TRIAL	Oct-2005	Rule 6	Annex II (-Section4)	44788	11291
2982836	8 X 36MM L DISTRACTOR/TRIAL	Oct-2005	Rule 6	Annex II (-Section4)	44788	11291
2982840	8 X 40MM L DISTRACTOR/TRIAL	Oct-2005	Rule 6	Annex II (-Section4)	44788	11291
2982844	8 X 44MM L DISTRACTOR/TRIAL	Oct-2005	Rule 6	Annex II (-Section4)	44788	11291



Product List

Last updated by: Ankit Shah

Date: 9/30/2015

Tech File Bundle: TL Fusion, TF010

Product: CAPSTONE CONTROL Cam Spreader Trial Instruments, Non-Sterile

Class: Ila

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
3990008	Cam Spreader Trial 0 DEG 8MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
3990009	Cam Spreader Trial 0 DEG 9MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
3990010	Cam Spreader Trial 0 DEG 10MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
3990011	Cam Spreader Trial 0 DEG 11MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
3990012	Cam Spreader Trial 0 DEG 12MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
3990013	Cam Spreader Trial 0 DEG 13MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
3990014	Cam Spreader Trial 0 DEG 14MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
3990015	Cam Spreader Trial 0 DEG 15MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
3990016	Cam Spreader Trial 0 DEG 16MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
3990017	Cam Spreader Trial 0 DEG 17MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
3990018	CAM SPREADER TRIAL 0DEG 18MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4000010	Cam Spreader Trial 6 DEG 10MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4000011	Cam Spreader Trial 6 DEG 11MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4000012	Cam Spreader Trial 6 DEG 12MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4000013	Cam Spreader Trial 6 DEG 13MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4000014	Cam Spreader Trial 6 DEG 14MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4000015	Cam Spreader Trial 6 DEG 15MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4000016	Cam Spreader Trial 6 DEG 16MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4000017	Cam Spreader Trial 6 DEG 17MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4000018	Cam Spreader Trial 6 DEG 18MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4010010	Cam Spreader Trial 12 DEG 10MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4010011	Cam Spreader Trial 12 DEG 11MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4010012	Cam Spreader Trial 12 DEG 12MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4010013	Cam Spreader Trial 12 DEG 13MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4010014	Cam Spreader Trial 12 DEG 14MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4010015	Cam Spreader Trial 12 DEG 15MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4010016	Cam Spreader Trial 12 DEG 16MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4010017	Cam Spreader Trial 12 DEG 17MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4010018	Cam Spreader Trial 12 DEG 18MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4020013	Cam Spreader Trial 18 DEG 13MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4020014	Cam Spreader Trial 18 DEG 14MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4020015	Cam Spreader Trial 18 DEG 15MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4020016	Cam Spreader Trial 18 DEG 16MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4020017	Cam Spreader Trial 18 DEG 17MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
4020018	Cam Spreader Trial 18 DEG 18MM	Oct-2012	Rule 6	Annex II (-Section4)	44788	17704
X1013390	CAPSTONE CONTROL TRIAL 8x24.5x0DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013391	CAPSTONE CONTROL TRIAL 9x24.5x0DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013392	CAPSTONE CONTROL TRIAL 10x24.5x0DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013393	CAPSTONE CONTROL TRIAL 11x24.5x0DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013394	CAPSTONE CONTROL TRIAL 12x24.5x0DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013395	CAPSTONE CONTROL TRIAL 13x24.5x0DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013396	CAPSTONE CONTROL TRIAL 14x24.5x0DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013397	CAPSTONE CONTROL TRIAL 15x24.5x0DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013398	CAPSTONE CONTROL TRIAL 16x24.5x0DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013399	CAPSTONE CONTROL TRIAL 17x24.5x0DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013400	CAPSTONE CONTROL TRIAL 10x29.5x0DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013401	CAPSTONE CONTROL TRIAL 11x29.5x0DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013402	CAPSTONE CONTROL TRIAL 12x29.5x0DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704



Tech File Bundle: TL Fusion, TF010

Product: CAPSTONE CONTROL Cam Spreader Trial Instruments, Non-Sterile

Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
X1013403	CAPSTONE CONTROL TRIAL 13x29.5x0DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013404	CAPSTONE CONTROL TRIAL 14x29.5x0DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013405	CAPSTONE CONTROL TRIAL 15x29.5x0DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013406	CAPSTONE CONTROL TRIAL 16x29.5x0DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013407	CAPSTONE CONTROL TRIAL 17x29.5x0DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013408	CAPSTONE CONTROL TRIAL 10x22x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013409	CAPSTONE CONTROL TRIAL 11x22x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013410	CAPSTONE CONTROL TRIAL 12x22x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013411	CAPSTONE CONTROL TRIAL 13x22x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013412	CAPSTONE CONTROL TRIAL 14x22x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013413	CAPSTONE CONTROL TRIAL 15x22x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013414	CAPSTONE CONTROL TRIAL 16x22x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013415	CAPSTONE CONTROL TRIAL 17x22x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013416	CAPSTONE CONTROL TRIAL 10x24.5x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013417	CAPSTONE CONTROL TRIAL 11x24.5x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013418	CAPSTONE CONTROL TRIAL 12x24.5x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013419	CAPSTONE CONTROL TRIAL 13x24.5x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013420	CAPSTONE CONTROL TRIAL 14x24.5x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013421	CAPSTONE CONTROL TRIAL 15x24.5x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013422	CAPSTONE CONTROL TRIAL 16x24.5x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013423	CAPSTONE CONTROL TRIAL 17x24.5x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013424	CAPSTONE CONTROL TRIAL 10x27x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013425	CAPSTONE CONTROL TRIAL 11x27x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013426	CAPSTONE CONTROL TRIAL 12x27x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013427	CAPSTONE CONTROL TRIAL 13x27x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013428	CAPSTONE CONTROL TRIAL 14x27x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013429	CAPSTONE CONTROL TRIAL 15x27x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013430	CAPSTONE CONTROL TRIAL 16x27x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013431	CAPSTONE CONTROL TRIAL 17x27x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013432	CAPSTONE CONTROL TRIAL 10x29.5x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013433	CAPSTONE CONTROL TRIAL 11x29.5x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013434	CAPSTONE CONTROL TRIAL 12x29.5x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013435	CAPSTONE CONTROL TRIAL 13x29.5x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013436	CAPSTONE CONTROL TRIAL 14x29.5x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013437	CAPSTONE CONTROL TRIAL 15x29.5x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013438	CAPSTONE CONTROL TRIAL 16x29.5x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013439	CAPSTONE CONTROL TRIAL 17x29.5x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013440	CAPSTONE CONTROL TRIAL 11x32x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013441	CAPSTONE CONTROL TRIAL 12x32x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013442	CAPSTONE CONTROL TRIAL 13x32x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013443	CAPSTONE CONTROL TRIAL 14x32.3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013444	CAPSTONE CONTROL TRIAL 15x32x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013445	CAPSTONE CONTROL TRIAL 16x32x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013446	CAPSTONE CONTROL TRIAL 17x32x3DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013447	CAPSTONE CONTROL TRIAL 10x24.5x6DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013448	CAPSTONE CONTROL TRIAL 11x24.5x6DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013449	CAPSTONE CONTROL TRIAL 12x24.5x6DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013450	CAPSTONE CONTROL TRIAL 13x24.5x6DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013451	CAPSTONE CONTROL TRIAL 14x24.5x6DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013452	CAPSTONE CONTROL TRIAL 15x24.5x6DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704



Tech File Bundle: TL Fusion, TF010

Product: CAPSTONE CONTROL Cam Spreader Trial Instruments, Non-Sterile

Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
X1013453	CAPSTONE CONTROL TRIAL 16x24.5x6DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013454	CAPSTONE CONTROL TRIAL 17x24.5x6DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013455	CAPSTONE CONTROL TRIAL 10x29.5x6DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013456	CAPSTONE CONTROL TRIAL 11x29.5x6DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013457	CAPSTONE CONTROL TRIAL 12x29.5x6DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013458	CAPSTONE CONTROL TRIAL 13x29.5x6DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013459	CAPSTONE CONTROL TRIAL 14x29.5x6DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013460	CAPSTONE CONTROL TRIAL 15x29.5x6DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013461	CAPSTONE CONTROL TRIAL 16x29.5x6DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013462	CAPSTONE CONTROL TRIAL 17x29.5x6DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013463	CAPSTONE CONTROL TRIAL 10x22x9DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013464	CAPSTONE CONTROL TRIAL 11x22x9DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013465	CAPSTONE CONTROL TRIAL 12x22x9DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013466	CAPSTONE CONTROL TRIAL 13x22x9DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013467	CAPSTONE CONTROL TRIAL 14x22x9DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013468	CAPSTONE CONTROL TRIAL 15x22x9DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013469	CAPSTONE CONTROL TRIAL 16x22x9DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013470	CAPSTONE CONTROL TRIAL 17x22x9DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013471	CAPSTONE CONTROL TRIAL 12x24.5x9DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013472	CAPSTONE CONTROL TRIAL 13x24.5x9DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013473	CAPSTONE CONTROL TRIAL 14x24.5x9DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013474	CAPSTONE CONTROL TRIAL 15x24.5x9DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013475	CAPSTONE CONTROL TRIAL 16x24.5x9DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013476	CAPSTONE CONTROL TRIAL 17x24.5x9DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013477	CAPSTONE CONTROL TRIAL 12x27x9DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013478	CAPSTONE CONTROL TRIAL 13x27x9DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013479	CAPSTONE CONTROL TRIAL 14x27x9DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013480	CAPSTONE CONTROL TRIAL 15x27x9DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013481	CAPSTONE CONTROL TRIAL 16x27x9DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013482	CAPSTONE CONTROL TRIAL 17x27x9DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013483	CAPSTONE CONTROL TRIAL 12x24.5x12DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013484	CAPSTONE CONTROL TRIAL 13x24.5x12DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013485	CAPSTONE CONTROL TRIAL 14x24.5x12DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013486	CAPSTONE CONTROL TRIAL 15x24.5x12DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013487	CAPSTONE CONTROL TRIAL 16x24.5x12DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013488	CAPSTONE CONTROL TRIAL 17x24.5x12DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013489	CAPSTONE CONTROL TRIAL 13x22x15DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013490	CAPSTONE CONTROL TRIAL 14x22x15DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013491	CAPSTONE CONTROL TRIAL 15x22x15DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013492	CAPSTONE CONTROL TRIAL 16x22x15DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013493	CAPSTONE CONTROL TRIAL 17x22x15DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013494	CAPSTONE CONTROL TRIAL 14x24.5x15DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013495	CAPSTONE CONTROL TRIAL 15x24.5x15DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013496	CAPSTONE CONTROL TRIAL 16x24.5x15DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013497	CAPSTONE CONTROL TRIAL 17x24.5x15DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013498	CAPSTONE CONTROL TRIAL 14x27x15DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013499	CAPSTONE CONTROL TRIAL 15x27x15DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013500	CAPSTONE CONTROL TRIAL 16x27x15DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013501	CAPSTONE CONTROL TRIAL 17x27x15DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013502	CAPSTONE CONTROL TRIAL 14x24.5x18DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704



Tech File Bundle: TL Fusion, TF010

Product: CAPSTONE CONTROL Cam Spreader Trial Instruments, Non-Sterile

Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
X1013503	CAPSTONE CONTROL TRIAL 15x24.5x18DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013504	CAPSTONE CONTROL TRIAL 16x24.5x18DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1013505	CAPSTONE CONTROL TRIAL 17x24.5x18DEG	Nov-2015	Rule 6	Annex II (-Section4)	44788	17704
X1113101	LONG GRASPING PISTOL GRIP INSERTER	Nov-2015	Rule 6	Annex II (-Section4)	12696	17543
X1113102	SHORT GRASPING PISTOL GRIP INSERTER	Nov-2015	Rule 6	Annex II (-Section4)	12696	17543



Product List

Last updated by: Greg Maschek

Date: 2/27/2015

Tech File Bundle: TL Fusion, TF010

Product: CLYDESDALE Distractor/Trial Instruments, Non-Sterile

Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2984040	18mm, 6 degree, 10x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2984060	18mm, 6 degree, 10x60 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2984240	18mm, 6 degree, 12x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2984260	18mm, 6 degree, 12x60 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2984440	18mm, 6 degree, 14x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2984460	18mm, 6 degree, 14x60 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2984640	18mm, 6 degree, 16x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2984660	18mm, 6 degree, 16x60 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2984840	18mm, 6 degree, 8x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2984860	18mm, 6 degree, 8x60 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2985040	18mm, 0 degree, 10x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2985045	18mm, 0 degree, 10x45 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2985050	18mm, 0 degree, 10x50 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2985055	18mm, 0 degree, 10x55 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2985240	18mm, 0 degree, 12x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2985245	18mm, 0 degree, 12x45 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2985250	18mm, 0 degree, 12x50 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2985255	18mm, 0 degree, 12x55 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2985440	18mm, 0 degree, 14x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2985445	18mm, 0 degree, 14x45 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2985450	18mm, 0 degree, 14x50 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2985455	18mm, 0 degree, 14x55 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2985640	18mm, 0 degree, 16x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2985645	18mm, 0 degree, 16x45 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2985650	18mm, 0 degree, 16x50 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2985655	18mm, 0 degree, 16x55 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2985840	18mm, 0 degree, 8x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2985845	18mm, 0 degree, 8x45 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2985850	18mm, 0 degree, 8x50 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2985855	18mm, 0 degree, 8x55 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2986045	10 X 45 MM DISTRACTOR/TRIAL	Sep-2010	Rule 6	Annex II (-Section4)	44788	17704
2986050	10 X 50 MM DISTRACTOR/TRIAL	Sep-2010	Rule 6	Annex II (-Section4)	44788	17704
2986055	10 X 55 MM DISTRACTOR/TRIAL	Sep-2010	Rule 6	Annex II (-Section4)	44788	17704
2986245	12 X 45 MM DISTRACTOR/TRIAL	Sep-2010	Rule 6	Annex II (-Section4)	44788	17704
2986250	12 X 50 MM DISTRACTOR/TRIAL	Sep-2010	Rule 6	Annex II (-Section4)	44788	17704
2986255	12 X 55 MM DISTRACTOR/TRIAL	Sep-2010	Rule 6	Annex II (-Section4)	44788	17704
2986445	14 X 45 MM DISTRACTOR/TRIAL	Sep-2010	Rule 6	Annex II (-Section4)	44788	17704
2986450	14 X 50 MM DISTRACTOR/TRIAL	Sep-2010	Rule 6	Annex II (-Section4)	44788	17704
2986455	14 X 55 MM DISTRACTOR/TRIAL	Sep-2010	Rule 6	Annex II (-Section4)	44788	17704
2986645	16 X 45 MM DISTRACTOR/TRIAL	Sep-2010	Rule 6	Annex II (-Section4)	44788	17704
2986650	16 X 50 MM DISTRACTOR/TRIAL	Sep-2010	Rule 6	Annex II (-Section4)	44788	17704
2986655	16 X 55 MM DISTRACTOR/TRIAL	Sep-2010	Rule 6	Annex II (-Section4)	44788	17704
2986845	8 X 45 MM DISTRACTOR/TRIAL	Sep-2010	Rule 6	Annex II (-Section4)	44788	17704
2986850	8 X 50 MM DISTRACTOR/TRIAL	Sep-2010	Rule 6	Annex II (-Section4)	44788	17704
2986855	8 X 55 MM DISTRACTOR/TRIAL	Sep-2010	Rule 6	Annex II (-Section4)	44788	17704
2987040	22mm, 0 degree, 10x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987045	22mm, 0 degree, 10x45 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987050	22mm, 0 degree, 10x50 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704

Tech File Bundle: TL Fusion, TF010

Product: CLYDESDALE Distractor/Trial Instruments, Non-Sterile

Class: Ila

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2987055	22mm, 0 degree, 10x55 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987060	22mm, 0 degree, 10x60 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987240	22mm, 0 degree, 12x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987245	22mm, 0 degree, 12x45 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987250	22mm, 0 degree, 12x50 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987255	22mm, 0 degree, 12x55 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987260	22mm, 0 degree, 12x60 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987440	22mm, 0 degree, 14x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987445	22mm, 0 degree, 14x45 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987450	22mm, 0 degree, 14x50 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987455	22mm, 0 degree, 14x55 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987460	22mm, 0 degree, 14x60 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987640	22mm, 0 degree, 16x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987645	22mm, 0 degree, 16x45 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987650	22mm, 0 degree, 16x50 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987655	22mm, 0 degree, 16x55 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987660	22mm, 0 degree, 16x60 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987840	22mm, 0 degree, 8x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987845	22mm, 0 degree, 8x45 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987850	22mm, 0 degree, 8x50 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987855	22mm, 0 degree, 8x55 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2987860	22mm, 0 degree, 8x60 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988040	22mm, 6 degree, 10x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988045	22mm, 6 degree, 10x45 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988050	22mm, 6 degree, 10x50 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988055	22mm, 6 degree, 10x55 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988060	22mm, 6 degree, 10x60 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988240	22mm, 6 degree, 12x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988245	22mm, 6 degree, 12x45 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988250	22mm, 6 degree, 12x50 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988255	22mm, 6 degree, 12x55 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988260	22mm, 6 degree, 12x60 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988440	22mm, 6 degree, 14x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988445	22mm, 6 degree, 14x45 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988450	22mm, 6 degree, 14x50 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988455	22mm, 6 degree, 14x55 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988460	22mm, 6 degree, 14x60 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988640	22mm, 6 degree, 16x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988645	22mm, 6 degree, 16x45 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988650	22mm, 6 degree, 16x50 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988655	22mm, 6 degree, 16x55 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988660	22mm, 6 degree, 16x60 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988840	22mm, 6 degree, 8x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988845	22mm, 6 degree, 8x45 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988850	22mm, 6 degree, 8x50 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988855	22mm, 6 degree, 8x55 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2988860	22mm, 6 degree, 8x60 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2989040	22mm, 12 degree, 10x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2989045	22mm, 12 degree, 10x45 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2989050	22mm, 12 degree, 10x50 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704



Tech File Bundle: TL Fusion, TF010

Product: CLYDESDALE Distractor/Trial Instruments, Non-Sterile

Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2989055	22mm, 12 degree, 10x55 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2989060	22mm, 12 degree, 10x60 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2989240	22mm, 12 degree, 12x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2989245	22mm, 12 degree, 12x45 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2989250	22mm, 12 degree, 12x50 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2989255	22mm, 12 degree, 12x55 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2989260	22mm, 12 degree, 12x60 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2989440	22mm, 12 degree, 14x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2989445	22mm, 12 degree, 14x45 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2989450	22mm, 12 degree, 14x50 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2989455	22mm, 12 degree, 14x55 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2989460	22mm, 12 degree, 14x60 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2989640	22mm, 12 degree, 16x40 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2989645	22mm, 12 degree, 16x45 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2989650	22mm, 12 degree, 16x50 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2989655	22mm, 12 degree, 16x55 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704
2989660	22mm, 12 degree, 16x60 Distractor/Trial	Mar-2012	Rule 6	Annex II (-Section4)	44788	17704



Product List

Last updated by: Justin O'Connor
 Tech File Bundle: TL Fusion, TF010

Date: 6/18/2015

Product: DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System

Class: Ila

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2156410	Interbody Trial, Small, 6 degrees, 10mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2156412	Interbody Trial, Small, 6 degrees, 12mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2156414	Interbody Trial, Small, 6 degrees, 14mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2156416	Interbody Trial, Small, 6 degrees, 16mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2156418	Interbody Trial, Small, 6 degrees, 18mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2156420	Interbody Trial, Small, 6 degrees, 20mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2156510	Interbody Trial, Medium, 6 degrees, 10mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2156512	Interbody Trial, Medium, 6 degrees, 12mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2156514	Interbody Trial, Medium, 6 degrees, 14mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2156516	Interbody Trial, Medium, 6 degrees, 16mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2156518	Interbody Trial, Medium, 6 degrees, 18mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2156520	Interbody Trial, Medium, 6 degrees, 20mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2156610	Interbody Trial, Large, 6 degrees, 10mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2156612	Interbody Trial, Large, 6 degrees, 12mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2156614	Interbody Trial, Large, 6 degrees, 14mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2156616	Interbody Trial, Large, 6 degrees, 16mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2156618	Interbody Trial, Large, 6 degrees, 18mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2156620	Interbody Trial, Large, 6 degrees, 20mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2152410	Interbody Trial, Small, 12 degrees, 10mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2152412	Interbody Trial, Small, 12 degrees, 12mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2152414	Interbody Trial, Small, 12 degrees, 14mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2152416	Interbody Trial, Small, 12 degrees, 16mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2152418	Interbody Trial, Small, 12 degrees, 18mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2152420	Interbody Trial, Small, 12 degrees, 20mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2152510	Interbody Trial, Medium, 12 degrees, 10mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2152512	Interbody Trial, Medium, 12 degrees, 12mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2152514	Interbody Trial, Medium, 12 degrees, 14mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2152516	Interbody Trial, Medium, 12 degrees, 16mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2152518	Interbody Trial, Medium, 12 degrees, 18mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2152520	Interbody Trial, Medium, 12 degrees, 20mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2152612	Interbody Trial, Large, 12 degrees, 12mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2152614	Interbody Trial, Large, 12 degrees, 14mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2152616	Interbody Trial, Large, 12 degrees, 16mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2152618	Interbody Trial, Large, 12 degrees, 18mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2152620	Interbody Trial, Large, 12 degrees, 20mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2158412	Interbody Trial, Small, 18 degrees, 12mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2158414	Interbody Trial, Small, 18 degrees, 14mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2158416	Interbody Trial, Small, 18 degrees, 16mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2158418	Interbody Trial, Small, 18 degrees, 18mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2158420	Interbody Trial, Small, 18 degrees, 20mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2158514	Interbody Trial, Medium, 18 degrees, 14mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2158516	Interbody Trial, Medium, 18 degrees, 16mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2158518	Interbody Trial, Medium, 18 degrees, 18mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2158520	Interbody Trial, Medium, 18 degrees, 20mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2158616	Interbody Trial, Large, 18 degrees, 16mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2158618	Interbody Trial, Large, 18 degrees, 18mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2158620	Interbody Trial, Large, 18 degrees, 20mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2154416	Interbody Trial, Small, 24 degrees, 16mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704



Tech File Bundle: TL Fusion, TF010

Product: DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System

Class: IIa

2154418	Interbody Trial, Small, 24 degrees, 18mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2154420	Interbody Trial, Small, 24 degrees, 20mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2154516	Interbody Trial, Medium, 24 degrees, 16mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2154518	Interbody Trial, Medium, 24 degrees, 18mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2154520	Interbody Trial, Medium, 24 degrees, 20mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2154618	Interbody Trial, Large, 24 degrees, 18mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2154620	Interbody Trial, Large, 24 degrees, 20mm	Nov-2015	Rule 6	Annex II (-Section 4)	44788	17704
2150310	Plate Trial, 10mm	Nov-2015	Rule 6	Annex II (-Section 4)	13180	17993
2150312	Plate Trial, 12mm	Nov-2015	Rule 6	Annex II (-Section 4)	13180	17993
2150314	Plate Trial, 14mm	Nov-2015	Rule 6	Annex II (-Section 4)	13180	17993
2150316	Plate Trial, 16mm	Nov-2015	Rule 6	Annex II (-Section 4)	13180	17993
2150318	Plate Trial, 18mm	Nov-2015	Rule 6	Annex II (-Section 4)	13180	17993
2150320	Plate Trial, 20mm	Nov-2015	Rule 6	Annex II (-Section 4)	13180	17993
2150330	Trial Handle	Nov-2015	Rule 6	Annex II (-Section 4)	13180	17993
2150340	Plate Trial Handle	Nov-2015	Rule 6	Annex II (-Section 4)	13180	17993
2160210	ALIF51 Screw Guide 10mm	Nov-2015	Rule 6	Annex II (-Section 4)	47831	16146
2160212	ALIF51 Screw Guide 12mm	Nov-2015	Rule 6	Annex II (-Section 4)	47831	16146
2160214	ALIF51 Screw Guide 14mm	Nov-2015	Rule 6	Annex II (-Section 4)	47831	16146
2160216	ALIF51 Screw Guide 16mm	Nov-2015	Rule 6	Annex II (-Section 4)	47831	16146
2160218	ALIF51 Screw Guide 18mm	Nov-2015	Rule 6	Annex II (-Section 4)	47831	16146
2160220	ALIF51 Screw Guide 20mm	Nov-2015	Rule 6	Annex II (-Section 4)	47831	16146
2150210	OLIF51 Screw Guide 10mm	Nov-2015	Rule 6	Annex II (-Section 4)	47831	16146
2150212	OLIF51 Screw Guide 12mm	Nov-2015	Rule 6	Annex II (-Section 4)	47831	16146
2150214	OLIF51 Screw Guide 14mm	Nov-2015	Rule 6	Annex II (-Section 4)	47831	16146
2150216	OLIF51 Screw Guide 16mm	Nov-2015	Rule 6	Annex II (-Section 4)	47831	16146
2150218	OLIF51 Screw Guide 18mm	Nov-2015	Rule 6	Annex II (-Section 4)	47831	16146
2150220	OLIF51 Screw Guide 20mm	Nov-2015	Rule 6	Annex II (-Section 4)	47831	16146
2151100	Handle Inserter	Nov-2015	Rule 6	Annex II (-Section 4)	12696	17543
2151150	Interbody Remover	Nov-2015	Rule 6	Annex II (-Section 4)	12696	15580
2150200	OLIF 51 Simple IB Inserter	Nov-2015	Rule 6	Annex II (-Section 4)	12696	17543
2150300	OLIF 51 Simple Plate Inserter	Nov-2015	Rule 6	Annex II (-Section 4)	12696	17543
2150400	OLIF 51 Freehand Inserter	Nov-2015	Rule 6	Annex II (-Section 4)	12696	17543
2160200	ALIF 51 Simple IB Inserter	Nov-2015	Rule 6	Annex II (-Section 4)	12696	17543
2160300	ALIF 51 Simple Plate Inserter	Nov-2015	Rule 6	Annex II (-Section 4)	12696	17543
2160400	ALIF 51 Freehand Inserter	Nov-2015	Rule 6	Annex II (-Section 4)	12696	17543



Product List

dated by: Elizabeth Hamilton
e Bundle: TL Fusion, TF010

Date: 10/1/2015

Product: ELEVATE™ SPINAL SYSTEM INSTRUMENTS , Non Sterile, Measuring

Class: Ila

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
8657005	SMALL STANDARD DISTRACTOR	Nov-2015	Rule 6	Annex II (-Section4)	56637	11291
8657006	LARGE STANDARD DISTRACTOR	Nov-2015	Rule 6	Annex II (-Section4)	56637	11291
8657007	SMALL LORDOTIC DISTRACTOR	Nov-2015	Rule 6	Annex II (-Section4)	56637	11291
8657008	LARGE LORDOTIC DISTRACTOR	Nov-2015	Rule 6	Annex II (-Section4)	56637	11291

Product List

Last updated by: Buanita Benson

Date: 5/9/2018

Tech File Bundle: TL Fusion, TF010

Product: FUSE™ Spinal System

Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2870007	FUSE DISTRACTOR, 7mm, 0deg.	July 2013	Rule 6	Annex VII	44788	17704
2870008	FUSE DISTRACTOR, 8mm, 0deg.	July 2013	Rule 6	Annex VII	44788	17704
2870009	FUSE DISTRACTOR, 9mm, 4deg.	July 2013	Rule 6	Annex VII	44788	17704
2870010	FUSE DISTRACTOR, 10mm, 4deg.	July 2013	Rule 6	Annex VII	44788	17704
2870011	FUSE DISTRACTOR, 11mm, 4deg.	July 2013	Rule 6	Annex VII	44788	17704
2870012	FUSE DISTRACTOR, 12mm, 4deg.	July 2013	Rule 6	Annex VII	44788	17704
2870013	FUSE DISTRACTOR, 13mm, 4deg.	July 2013	Rule 6	Annex VII	44788	17704
2870014	FUSE DISTRACTOR, 14mm, 4deg.	July 2013	Rule 6	Annex VII	44788	17704

Product List

Last updated by: Nick Tabrizi

Date: 7/10/2018

Tech File Bundle: TL Fusion, TF010

Product: LOOP™ Spinal System

Class: Ila

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2570006	LOOP IMPACTOR TRIAL	July 2013	Rule 6	Annex II - Section 4	44759	17704
2570007	LOOP VARIABLE TRIAL 7mm	July 2013	Rule 6	Annex II - Section 4	44759	17704
2570008	LOOP VARIABLE TRIAL 8mm	July 2013	Rule 6	Annex II - Section 4	44759	17704
2570009	LOOP VARIABLE TRIAL 9mm	July 2013	Rule 6	Annex II - Section 4	44759	17704
2570010	LOOP VARIABLE TRIAL 10mm	July 2013	Rule 6	Annex II - Section 4	44759	17704
2570011	LOOP VARIABLE TRIAL 11mm	July 2013	Rule 6	Annex II - Section 4	44759	17704
2570012	LOOP VARIABLE TRIAL 12mm	July 2013	Rule 6	Annex II - Section 4	44759	17704
2570013	LOOP VARIABLE TRIAL 13mm	July 2013	Rule 6	Annex II - Section 4	44759	17704
2570014	LOOP VARIABLE TRIAL 14mm	July 2013	Rule 6	Annex II - Section 4	44759	17704
2570015	LOOP VARIABLE TRIAL 15mm	July 2013	Rule 6	Annex II - Section 4	44759	17704
2570016	LOOP VARIABLE TRIAL 16mm	July 2013	Rule 6	Annex II - Section 4	44759	17704
25700061	LOOP IMPACTOR TRIAL	April 2014	Rule 6	Annex II - Section 4	44759	17704

Product List

Last updated by: Nick Tabrizi
Tech File Bundle: TL Fusion, TF010

Date: 7/10/2018

Product: Navigated Disc Prep Instrument Set
Class: Ila

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
NAV2054	NAV Posterior Rotating Shaver 8mm	July 2018	Rule 6	Annex II (minus section 4)	11290	17704
NAV2055	Rotating Shaver,10mm	July 2018	Rule 6	Annex II (minus section 4)	11290	17704
NAV2056	Rotating Shaver ,12mm	July 2018	Rule 6	Annex II (minus section 4)	11290	17704
NAV2057	Rotating Shaver, 14mm	July 2018	Rule 6	Annex II (minus section 4)	11290	17704
NAV2071	Rotating Shaver 8mm	July 2018	Rule 6	Annex II (minus section 4)	11290	17704
NAV2072	Rotating Shaver 10mm	July 2018	Rule 6	Annex II (minus section 4)	11290	17704
NAV2073	Rotating Shaver 12mm	July 2018	Rule 6	Annex II (minus section 4)	11290	17704
NAV2074	Rotating Shaver 14mm	July 2018	Rule 6	Annex II (minus section 4)	11290	17704
NAV2137	NAV Posterior Rotating Shaver 7mm	July 2018	Rule 6	Annex II (minus section 4)	11290	17704
NAV2139	NAV Posterior Rotating Shaver, 9mm	July 2018	Rule 6	Annex II (minus section 4)	11290	17704
NAV2141	NAV Posterior Rotating Shaver, 11mm	July 2018	Rule 6	Annex II (minus section 4)	11290	17704
NAV2142	NAV Posterior Rotating Shaver, 13mm	July 2018	Rule 6	Annex II (minus section 4)	11290	17704



Product List

Last updated by: Greg Maschek
Tech File Bundle: TL Fusion, TF010

Date: 2/27/2015

Product: Pyramid +4 Trial Instruments, Non-Sterile
Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
9877708	Lordotic 3-Hole Plate Trial Asm, L=33/35	Jun-2010	Rule 6	Annex II (-Section4)	13180	17993
9877709	Lordotic 3-Hole Plate Trial Asm, L=35/37	Jun-2010	Rule 6	Annex II (-Section4)	13180	17993
9877710	Lordotic 3-Hole Plate Trial Asm, L=39/41	Jun-2010	Rule 6	Annex II (-Section4)	13180	17993
9874135	TRIAL 9874135 DOUBLE-ENDED 35MM 37MM	Feb-2008	Rule 6	Annex II (-Section4)	44788	17704
9874139	TRIAL 9874139 DOUBLE-ENDED 39MM 41MM	Feb-2008	Rule 6	Annex II (-Section4)	44788	17704
9874143	TRIAL 9874143 DOUBLE-ENDED 43MM 45MM	Feb-2008	Rule 6	Annex II (-Section4)	44788	17704



Product List

Last updated by: Greg Maschek
 Tech File Bundle: TL Fusion, TF010

Date: 2/27/2015

Product: PERIMETER Trial Instruments, Non-Sterile
 Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
3290110	TRIAL, EXTRA-LARGE, 10MM, 8DEG	Mar-2005	Rule 6	Annex II (-Section4)	44788	17704
3290112	TRIAL, EXTRA-LARGE, 12MM, 8DEG	Mar-2005	Rule 6	Annex II (-Section4)	44788	17704
3290114	TRIAL, EXTRA-LARGE, 14MM, 8DEG	Mar-2005	Rule 6	Annex II (-Section4)	44788	17704
3297108	TRIAL, SMALL, 8MM, 4DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704
3297110	TRIAL, SMALL, 10MM, 4DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704
3297112	TRIAL, SMALL, 12MM, 4DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704
3297114	TRIAL, SMALL, 14MM, 4DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704
3298108	TRIAL, MEDIUM, 8MM, 8DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704
3298110	TRIAL, MEDIUM, 10MM, 8DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704
3298112	TRIAL, MEDIUM, 12MM, 8DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704
3298114	TRIAL, MEDIUM, 14MM, 8DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704
3298116	TRIAL, MEDIUM, 16MM, 8DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704
3298118	TRIAL, MEDIUM, 18MM, 8DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704
3298120	TRIAL, MEDIUM, 20MM, 8DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704
3299108	TRIAL, LARGE, 8MM, 8DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704
3299110	TRIAL, LARGE, 10MM, 8DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704
3299112	TRIAL, LARGE, 12MM, 8DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704
3299114	TRIAL, LARGE, 14MM, 8DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704
3299116	TRIAL, LARGE, 16MM, 8DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704
3299118	TRIAL, LARGE, 18MM, 8DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704
3299120	TRIAL, LARGE, 20MM, 8DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704
3299212	TRIAL, LARGE, 12MM, 12DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704
3299214	TRIAL, LARGE, 14MM, 12DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704
3299216	TRIAL, LARGE, 16MM, 12DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704
3299218	TRIAL, LARGE, 18MM, 12DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704
3299220	TRIAL, LARGE, 20MM, 12DEG	Oct-2004	Rule 6	Annex II (-Section4)	44788	17704



Product List

Last updated by:

Lila Joe

Date:

12/1/2016

Tech File Bundle:

TL Fusion, TF010

Product:

PIVOX™ Oblique Lateral Spine System

Class:

Ila

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2191245	OLIF25 IB TrialL 27mm 6 degree, 10x45	Dec-16	Rule 6	Annex II (-Section4)	47807	13180
2193445	OLIF25 IB Trial 27mm 18 degree, 14X45	Dec-16	Rule 6	Annex II (-Section4)	47807	13180
2193455	OLIF25 IB Trial 27mm 18 degree, 14X55	Dec-16	Rule 6	Annex II (-Section4)	47807	13180
2193545	OLIF25 IB Trial 18 degree, 16 x 45	Dec-16	Rule 6	Annex II (-Section4)	47807	13180
2193555	OLIF25 IB Trial 18 degree, 16 x 55	Dec-16	Rule 6	Annex II (-Section4)	47807	13180
2193645	OLIF25 IB Trial18 degree, 18 x 45	Dec-16	Rule 6	Annex II (-Section4)	47807	13180
2193655	OLIF25 IB Trial 18 degree, 18 x 55.	Dec-16	Rule 6	Annex II (-Section4)	47807	13180
2143001	OLIF25 Plate Trial, Small	Jan-2016	Rule 6	Annex II (-Section4)	44788	13180
2143002	OLIF25 Plate Trial, Large	Jan-2016	Rule 6	Annex II (-Section4)	44708	13180
2171145	OLIF25 IB Trial 20mm wide, 6 degree, 8x45	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2171155	OLIF25 IB Trial 20mm wide, 6 degree, 8x55	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2171245	OLIF25 IB Trial 20mm wide, 6 degree, 10x45	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2171255	OLIF25 IB Trial 20mm wide, 6 degree, 10x55	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2171345	OLIF25 IB Trial 20mm wide, 6 degree, 12x45	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2171355	OLIF25 IB Trial 20mm wide, 6 degree, 12x55	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2171445	OLIF25 IB Trial 20mm wide, 6 degree, 14x45	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2171455	OLIF25 IB Trial 20mm wide, 6 degree, 14x55	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2171545	OLIF25 IB Trial 20mm wide, 6 degree, 16x45	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2171555	OLIF25 IB Trial 20mm wide, 6 degree, 16x55	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2172245	OLIF25 IB Trial 20mm wide, 12 degree, 10x45	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2172255	OLIF25 IB Trial 20mm wide, 12 degree, 10x55	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2172345	OLIF25 IB Trial 20mm wide, 12 degree, 12x45	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2172355	OLIF25 IB Trial 20mm wide, 12 degree, 12x55	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2172445	OLIF25 IB Trial 20mm wide, 12 degree, 14x45	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2172455	OLIF25 IB Trial 20mm wide, 12 degree, 14x55	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2172545	OLIF25 IB Trial 20mm wide, 12 degree, 16x45	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2172555	OLIF25 IB Trial 20mm wide, 12 degree, 16x55	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2172645	OLIF25 IB Trial 20mm wide, 12 degree, 18x45	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2172655	OLIF25 IB Trial 20mm wide, 12 degree, 18x55	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2173345	OLIF25 IB Trial 20mm wide, 18 degree, 12x45	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2173355	OLIF25 IB Trial 20mm wide, 18 degree, 12x55	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2173445	OLIF25 IB Trial 20mm wide, 18 degree, 14x45	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2173455	OLIF25 IB Trial 20mm wide, 18 degree, 14x55	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2173545	OLIF25 IB Trial 20mm wide, 18 degree, 16x45	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2173555	OLIF25 IB Trial 20mm wide, 18 degree, 16x55	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2173645	OLIF25 IB Trial 20mm wide, 18 degree, 18x45	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2173655	OLIF25 IB Trial 20mm wide, 18 degree, 18x55	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2191255	OLIF25 IB Trial 27mm wide, 6 degree, 10x55	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2191345	OLIF25 IB Trial 27mm wide, 6 degree, 12x45	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2191355	OLIF25 IB Trial 27mm wide, 6 degree, 12x55	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2191445	OLIF25 IB Trial 27mm wide, 6 degree, 14x45	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2191455	OLIF25 IB Trial 27mm wide, 6 degree, 14x55	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2191545	OLIF25 IB Trial 27mm wide, 6 degree, 16x45	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2191555	OLIF25 IB Trial 27mm wide, 6 degree, 16x55	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2192345	OLIF25 IB Trial 27mm wide, 12 degree, 12x45	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2192355	OLIF25 IB Trial 27mm wide, 12 degree, 12x55	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2192445	OLIF25 IB Trial 27mm wide, 12 degree, 14x45	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2192455	OLIF25 IB Trial 27mm wide, 12 degree, 14x55	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2192545	OLIF25 IB Trial 27mm wide, 12 degree, 16x45	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2192555	OLIF25 IB Trial 27mm wide, 12 degree, 16x55	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2192645	OLIF25 IB Trial 27mm wide, 12 degree, 18x45	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180
2192655	OLIF25 IB Trial 27mm wide, 12 degree, 18x55	Jan-2016	Rule 6	Annex II (-Section4)	47807	13180



Product List

Last updated by: Greg Maschek
 Tech File Bundle: TL Fusion, TF010

Date: 2/27/2015

Product: SOVEREIGN Trial Instruments, Non-Sterile

Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
7964210	32X23 10MM 12 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7964212	32X23 12MM 12 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7964214	32X23 14MM 12 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7964216	32X23 16MM 12 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7964218	32X23 18MM 12 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7964220	32X23 20MM 12 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7964810	32X23 10MM 8 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7964812	32X23 12MM 8 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7964814	32X23 14MM 8 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7964816	32X23 16MM 8 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7964818	32X23 18MM 8 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7964820	32X23 20MM 8 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7965210	37X27 10MM 12 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7965212	37X27 12MM 12 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7965214	37X27 14MM 12 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7965216	37X27 16MM 12 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7965218	37X27 18MM 12 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7965220	37X27 20MM 12 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7965810	37X27 10MM 8 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7965812	37X27 12MM 8 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7965814	37X27 14MM 8DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7965816	37X27 16MM 8 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7965818	37X27 18MM 8 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7965820	37X27 20MM 8 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7966210	42X30 10MM 12 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7966212	42X30 12MM 12 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7966214	42X30 14MM 12 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7966216	42X30 16MM 12 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7966218	42X30 18MM 12 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7966220	42X30 20MM 12 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7966810	42X30 10MM 8 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7966812	42X30 12MM 8 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7966814	42X3014MM 8 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7966816	42X30 16MM 8 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7966818	42X30 18MM 8 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704
7966820	42X30 20MM 8 DEGREE TRIAL	Oct-2007	Rule 6	Annex II (-Section4)	44788	17704

Product List

Last updated by:

Buanita Benson

Date:

5/9/2018

Tech File Bundle:

TL Fusion, TF010

Product: WAVE D Spinal System

Class: Ila

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2670609	Distractor 9mm, 6°	Aug 2013	Rule 6	Annex II - Section 4	44788	17704
2670610	Distractor 10mm, 6°	Aug 2013	Rule 6	Annex II - Section 4	44788	17704
2670611	Distractor 11mm, 6°	Aug 2013	Rule 6	Annex II - Section 4	44788	17704
2670612	Distractor 12mm, 6°	Aug 2013	Rule 6	Annex II - Section 4	44788	17704
2670613	Distractor 13mm, 6°	Aug 2013	Rule 6	Annex II - Section 4	44788	17704
2670614	Distractor 14mm, 6°	Aug 2013	Rule 6	Annex II - Section 4	44788	17704
2671209	Distractor 9mm, 12°	Aug 2013	Rule 6	Annex II - Section 4	44788	17704
2671210	Distractor 10mm, 12°	Aug 2013	Rule 6	Annex II - Section 4	44788	17704
2671211	Distractor 11mm, 12°	Aug 2013	Rule 6	Annex II - Section 4	44788	17704
2671212	Distractor 12mm, 12°	Aug 2013	Rule 6	Annex II - Section 4	44788	17704
2671213	Distractor 13mm, 12°	Aug 2013	Rule 6	Annex II - Section 4	44788	17704
2671214	Distractor 14mm, 12°	Aug 2013	Rule 6	Annex II - Section 4	44788	17704
X0113134	WAVE Distractor, 28mm x 10mm, 6DEG	May 2014	Rule 6	Annex II - Section 4	44788	17704
X0113135	WAVE Distractor, 28mm x 11mm, 6DEG	May 2014	Rule 6	Annex II - Section 4	44788	17704
X0113136	WAVE Distractor, 28mm x 12mm, 6DEG	May 2014	Rule 6	Annex II - Section 4	44788	17704
X0113137	WAVE Distractor, 28mm x 13mm, 6DEG	May 2014	Rule 6	Annex II - Section 4	44788	17704



Product List

Last updated by: Fernand Terradas
Tech File Bundle: TL Fusion, TF010

Date: 10/5/2015

Product: AVILA Interbody Fusion Device
Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
369110806	SMALL Ti ALIF CAGE 8° 6MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369110808	SMALL Ti ALIF CAGE 8° 8MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369110810	SMALL Ti ALIF CAGE 8° 10MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369110812	SMALL Ti ALIF CAGE 8° 12MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369110814	SMALL Ti ALIF CAGE 8° 14MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369111206	SMALL Ti ALIF CAGE 12° 6MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369111208	SMALL Ti ALIF CAGE 12° 8MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369111210	SMALL Ti ALIF CAGE 12° 10MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369111212	SMALL Ti ALIF CAGE 12° 12MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369111214	SMALL Ti ALIF CAGE 12° 14MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369111606	SMALL Ti ALIF CAGE 16° 6MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369111608	SMALL Ti ALIF CAGE 16° 8MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369111610	SMALL Ti ALIF CAGE 16° 10MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369111612	SMALL Ti ALIF CAGE 16° 12MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369111614	SMALL Ti ALIF CAGE 16° 14MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369112006	SMALL Ti ALIF CAGE 20° 6MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369112008	SMALL Ti ALIF CAGE 20° 8MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369112010	SMALL Ti ALIF CAGE 20° 10MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369112012	SMALL Ti ALIF CAGE 20° 12MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369112014	SMALL Ti ALIF CAGE 20° 14MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369112406	SMALL Ti ALIF CAGE 24° 6MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369112408	SMALL Ti ALIF CAGE 24° 8MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369112410	SMALL Ti ALIF CAGE 24° 10MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369112412	SMALL Ti ALIF CAGE 24° 12MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369112414	SMALL Ti ALIF CAGE 24° 14MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369120806	MEDIUM Ti ALIF CAGE 8° 6MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369120808	MEDIUM Ti ALIF CAGE 8° 8MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369120810	MEDIUM Ti ALIF CAGE 8° 10MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369120812	MEDIUM Ti ALIF CAGE 8° 12MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369120814	MEDIUM Ti ALIF CAGE 8° 14MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369121206	MEDIUM Ti ALIF CAGE 12° 6MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369121208	MEDIUM Ti ALIF CAGE 12° 8MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369121210	MEDIUM Ti ALIF CAGE 12° 10MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369121212	MEDIUM Ti ALIF CAGE 12° 12MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369121214	MEDIUM Ti ALIF CAGE 12° 14MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369121606	MEDIUM Ti ALIF CAGE 16° 6MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369121608	MEDIUM Ti ALIF CAGE 16° 8MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369121610	MEDIUM Ti ALIF CAGE 16° 10MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369121612	MEDIUM Ti ALIF CAGE 16° 12MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369121614	MEDIUM Ti ALIF CAGE 16° 14MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369122006	MEDIUM Ti ALIF CAGE 20° 6MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369122008	MEDIUM Ti ALIF CAGE 20° 8MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369122010	MEDIUM Ti ALIF CAGE 20° 10MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369122012	MEDIUM Ti ALIF CAGE 20° 12MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369122014	MEDIUM Ti ALIF CAGE 20° 14MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766



Tech File Bundle: TL Fusion, TF010

Product: AVILA Interbody Fusion Device

Class: IIb

369122406	MEDIUM Ti ALIF CAGE 24° 6MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369122408	MEDIUM Ti ALIF CAGE 24° 8MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369122410	MEDIUM Ti ALIF CAGE 24° 10MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369122412	MEDIUM Ti ALIF CAGE 24° 12MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369122414	MEDIUM Ti ALIF CAGE 24° 14MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369130806	LARGE Ti ALIF CAGE 8° 6MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369130808	LARGE Ti ALIF CAGE 8° 8MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369130810	LARGE Ti ALIF CAGE 8° 10MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369130812	LARGE Ti ALIF CAGE 8° 12MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369130814	LARGE Ti ALIF CAGE 8° 14MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369131206	LARGE Ti ALIF CAGE 12° 6MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369131208	LARGE Ti ALIF CAGE 12° 8MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369131210	LARGE Ti ALIF CAGE 12° 10MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369131212	LARGE Ti ALIF CAGE 12° 12MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369131214	LARGE Ti ALIF CAGE 12° 14MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369131606	LARGE Ti ALIF CAGE 16° 6MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369131608	LARGE Ti ALIF CAGE 16° 8MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369131610	LARGE Ti ALIF CAGE 16° 10MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369131612	LARGE Ti ALIF CAGE 16° 12MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369131614	LARGE Ti ALIF CAGE 16° 14MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369132006	LARGE Ti ALIF CAGE 20° 6MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369132008	LARGE Ti ALIF CAGE 20° 8MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369132010	LARGE Ti ALIF CAGE 20° 10MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369132012	LARGE Ti ALIF CAGE 20° 12MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369132014	LARGE Ti ALIF CAGE 20° 14MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369132406	LARGE Ti ALIF CAGE 24° 6MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369132408	LARGE Ti ALIF CAGE 24° 8MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369132410	LARGE Ti ALIF CAGE 24° 10MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369132412	LARGE Ti ALIF CAGE 24° 12MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369132414	LARGE Ti ALIF CAGE 24° 14MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369210806	SMALL Ti OLIF CAGE 8° 6MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369210808	SMALL Ti OLIF CAGE 8° 8MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369210810	SMALL Ti OLIF CAGE 8° 10MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369210812	SMALL Ti OLIF CAGE 8° 12MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369210814	SMALL Ti OLIF CAGE 8° 14MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369211206	SMALL Ti OLIF CAGE 12° 6MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369211208	SMALL Ti OLIF CAGE 12° 8MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369211210	SMALL Ti OLIF CAGE 12° 10MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369211212	SMALL Ti OLIF CAGE 12° 12MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369211214	SMALL Ti OLIF CAGE 12° 14MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369220806	MEDIUM Ti OLIF CAGE 8° 6MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369220808	MEDIUM Ti OLIF CAGE 8° 8MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369220810	MEDIUM Ti OLIF CAGE 8° 10MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369220812	MEDIUM Ti OLIF CAGE 8° 12MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369220814	MEDIUM Ti OLIF CAGE 8° 14MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369221206	MEDIUM Ti OLIF CAGE 12° 6MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369221208	MEDIUM Ti OLIF CAGE 12° 8MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369221210	MEDIUM Ti OLIF CAGE 12° 10MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369221212	MEDIUM Ti OLIF CAGE 12° 12MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369221214	MEDIUM Ti OLIF CAGE 12° 14MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369230806	LARGE Ti OLIF CAGE 8° 6MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369230808	LARGE Ti OLIF CAGE 8° 8MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766



Tech File Bundle: TL Fusion, TF010

Product: AVILA Interbody Fusion Device

Class: IIb

369230810	LARGE Ti OLIF CAGE 8° 10MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369230812	LARGE Ti OLIF CAGE 8° 12MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369230814	LARGE Ti OLIF CAGE 8° 14MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369231206	LARGE Ti OLIF CAGE 12° 6MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369231208	LARGE Ti OLIF CAGE 12° 8MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369231210	LARGE Ti OLIF CAGE 12° 10MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369231212	LARGE Ti OLIF CAGE 12° 12MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
369231214	LARGE Ti OLIF CAGE 12° 14MM	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766



Product List

Last updated by: Lila Joe
Tech File Bundle: TL Fusion, TF010

Date: 12/21/2016

Product: CAPSTONE® Spinal System Implants
Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2966040INT	CAPSTONE® PEEK 10X40 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966045INT	CAPSTONE® PEEK 10X45 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966050INT	CAPSTONE® PEEK 10X50 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966055INT	CAPSTONE® PEEK 10X55 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966060INT	CAPSTONE® PEEK 10X60 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966240INT	CAPSTONE® PEEK 12X40 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966245INT	CAPSTONE® PEEK 12X45 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966250INT	CAPSTONE® PEEK 12X50 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966255INT	CAPSTONE® PEEK 12X55 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966260INT	CAPSTONE® PEEK 12X60 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966440INT	CAPSTONE® PEEK 14X40 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966445INT	CAPSTONE® PEEK 14X45 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966450INT	CAPSTONE® PEEK 14X50 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966455INT	CAPSTONE® PEEK 14X55 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966460INT	CAPSTONE® PEEK 14X60 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966640INT	CAPSTONE® PEEK 16X40 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966645INT	CAPSTONE® PEEK 16X45 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966650INT	CAPSTONE® PEEK 16X50 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966655INT	CAPSTONE® PEEK 16X55 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966660INT	CAPSTONE® PEEK 16X60 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966840INT	CAPSTONE® PEEK 08X40 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966845INT	CAPSTONE® PEEK 08X45 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966850INT	CAPSTONE® PEEK 08X50 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966855INT	CAPSTONE® PEEK 08X55 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2966860INT	CAPSTONE® PEEK 08X60 - 6°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967040INT	CAPSTONE® PEEK 10X40 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967045INT	CAPSTONE® PEEK 10X45 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967050INT	CAPSTONE® PEEK 10X50 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967055INT	CAPSTONE® PEEK 10X55 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967060INT	CAPSTONE® PEEK 10X60 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967240INT	CAPSTONE® PEEK 12X40 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967245INT	CAPSTONE® PEEK 12X45 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967250INT	CAPSTONE® PEEK 12X50 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967255INT	CAPSTONE® PEEK 12X55 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967260INT	CAPSTONE® PEEK 12X60 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967440INT	CAPSTONE® PEEK 14X40 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967445INT	CAPSTONE® PEEK 14X45 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967450INT	CAPSTONE® PEEK 14X50 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967455INT	CAPSTONE® PEEK 14X55 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967460INT	CAPSTONE® PEEK 14X60 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967640INT	CAPSTONE® PEEK 16X40 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967645INT	CAPSTONE® PEEK 16X45 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967650INT	CAPSTONE® PEEK 16X50 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967655INT	CAPSTONE® PEEK 16X55 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967660INT	CAPSTONE® PEEK 16X60 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967840INT	CAPSTONE® PEEK 08X40 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967845INT	CAPSTONE® PEEK 08X45 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967850INT	CAPSTONE® PEEK 08X50 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967855INT	CAPSTONE® PEEK 08X55 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2967860INT	CAPSTONE® PEEK 08X60 - 0°	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2990622	CAPSTONE® PEEK 06X22	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2990626	CAPSTONE® PEEK 06X26	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2990722	CAPSTONE® PEEK 07X22	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766



Tech File Bundle: TL Fusion, TF010

Product: CAPSTONE® Spinal System Implants						
Class: IIb						
2990726	CAPSTONE® PEEK 07X26	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2990732	CAPSTONE® PEEK 07X32	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2990736	CAPSTONE® PEEK 07X36	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2990822	CAPSTONE® PEEK 08X22	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2990822INT	CAPSTONE® PEEK 08X22	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2990826	CAPSTONE® PEEK 08X26	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2990826INT	CAPSTONE® PEEK 08X26	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2990832	CAPSTONE® PEEK 08X32	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2990832INT	CAPSTONE® PEEK 08X32	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2990836	CAPSTONE® PEEK 08X36	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2990836INT	CAPSTONE® PEEK 08X36	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2990922	CAPSTONE® PEEK 09X22	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2990926	CAPSTONE® PEEK 09X26	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2990932	CAPSTONE® PEEK 09X32	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2990936	CAPSTONE® PEEK 09X36	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991022	CAPSTONE® PEEK 10X22	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991022INT	CAPSTONE® PEEK 10X22	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2991026	CAPSTONE® PEEK 10X26	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991026INT	CAPSTONE® PEEK 10X26	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2991032	CAPSTONE® PEEK 10X32	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991032INT	CAPSTONE® PEEK 10X32	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2991036	CAPSTONE® PEEK 10X36	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991036INT	CAPSTONE® PEEK 10X36	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2991122	CAPSTONE® PEEK 11X22	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991126	CAPSTONE® PEEK 11X26	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991132	CAPSTONE® PEEK 11X32	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991136	CAPSTONE® PEEK 11X36	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991222	CAPSTONE® PEEK 12X22	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991222INT	CAPSTONE® PEEK 12X22	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2991226	CAPSTONE® PEEK 12X26	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991226INT	CAPSTONE® PEEK 12X26	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2991232	CAPSTONE® PEEK 12X32	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991232INT	CAPSTONE® PEEK 12X32	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2991236	CAPSTONE® PEEK 12X36	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991236INT	CAPSTONE® PEEK 12X36	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2991322	CAPSTONE® PEEK 13X22	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991326	CAPSTONE® PEEK 13X26	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991332	CAPSTONE® PEEK 13X32	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991336	CAPSTONE® PEEK 13X36	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991422	CAPSTONE® PEEK 14X22	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991422INT	CAPSTONE® PEEK 14X22	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2991426	CAPSTONE® PEEK 14X26	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991426INT	CAPSTONE® PEEK 14X26	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2991432	CAPSTONE® PEEK 14X32	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991432INT	CAPSTONE® PEEK 14X32	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2991436	CAPSTONE® PEEK 14X36	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991436INT	CAPSTONE® PEEK 14X36	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2991522	CAPSTONE® PEEK 15X22	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991526	CAPSTONE® PEEK 15X26	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991532	CAPSTONE® PEEK 15X32	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991536	CAPSTONE® PEEK 15X36	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991622	CAPSTONE® PEEK 16X22	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991622INT	CAPSTONE® PEEK 16X22	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2991626	CAPSTONE® PEEK 16X26	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991626INT	CAPSTONE® PEEK 16X26	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2991632	CAPSTONE® PEEK 16X32	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766
2991632INT	CAPSTONE® PEEK 16X32	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
2991636	CAPSTONE® PEEK 16X36	Oct-2009	Rule 8	Annex II (-Section 4)	60847	15766



Tech File Bundle: TL Fusion, TF010

Product: CAPSTONE® Spinal System Implants

Class: IIb

2991636INT	CAPSTONE® PEEK 16X36	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
G2910822	8 X 22 CAPSTONE TI	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
G2910826	8 X 26 CAPSTONE TI	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
G2910832	8 X 32 CAPSTONE TI	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
G2910836	8 X 36 CAPSTONE TI	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
G2911022	10 X 22 CAPSTONE TI	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
G2911026	10 X 26 CAPSTONE TI	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
G2911032	10 X 32 CAPSTONE TI	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
G2911036	10 X 36 CAPSTONE TI	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
G2911222	12 X 22 CAPSTONE TI	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
G2911226	12 X 26 CAPSTONE TI	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
G2911232	12 X 32 CAPSTONE TI	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
G2911236	12 X 36 CAPSTONE TI	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
G2911422	14 X 22 CAPSTONE TI	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
G2911426	14 X 26 CAPSTONE TI	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
G2911432	14 X 32 CAPSTONE TI	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
G2911436	14 X 36 CAPSTONE TI	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766



Product List

Last updated by: Greg Maschek

Date: 2/27/2015

Tech File Bundle: TL Fusion, TF010

Product: CAPSTONE CONTROL® Spinal System Implants

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
3990822	8x22x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3990827	8x27x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3990922	9x22x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3990927	9x27x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991022	10x22x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991027	10x27x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991032	10x32x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991122	11x22x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991127	11x27x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991132	11x32x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991222	12x22x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991227	12x27x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991232	12x32x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991322	13x22x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991327	13x27x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991332	13x32x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991422	14x22x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991427	14x27x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991432	14x32x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991522	15x22x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991527	15x27x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991532	15x32x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991622	16x22x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991627	16x27x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991632	16x32x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991722	17x22x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991727	17x27x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991732	17x32x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991822	18x22x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991827	18x27x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
3991832	18x32x0DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
4001022	10x22x6DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
4001027	10x27x6DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
4001122	11x22x6DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
4001127	11x27x6DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
4001132	11x32x6DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
4001222	12x22x6DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
4001227	12x27x6DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
4001232	12x32x6DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
4001322	13x22x6DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
4001327	13x27x6DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
4001332	13x32x6DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
4001422	14x22x6DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
4001427	14x27x6DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
4001432	14x32x6DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
4001522	15x22x6DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
4001527	15x27x6DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
4001532	15x32x6DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
4001622	16x22x6DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
4001627	16x27x6DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766
4001632	16x32x6DEG CAPSTONE CONTROL PEEK	Oct-2012	Rule 8	Annex II (-Section 4)	60847	15766



Tech File Bundle: TL Fusion, TF010

Product: CAPSTONE CONTROL® Spinal System Implants

Class: IIb

X1013353	16x22x9DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013354	17x22x9DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013355	12x24.5x9DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013356	13x24.5x9DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013357	14x24.5x9DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013358	15x24.5x9DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013359	16x24.5x9DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013360	17x24.5x9DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013361	12x27x9DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013362	13x27x9DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013363	14x27x9DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013364	15x27x9DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013365	16x27x9DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013366	17x27x9DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013367	12x24.5x12DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013368	13x24.5x12DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013369	14x24.5x12DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013370	15x24.5x12DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013371	16x24.5x12DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013372	17x24.5x12DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013373	13x22x15DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013374	14x22x15DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013375	15x22x15DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013376	16x22x15DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013377	17x22x15DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013378	14x24.5x15DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013379	15x24.5x15DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013380	16x24.5x15DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013381	17x24.5x15DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013382	14x27x15DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013383	15x27x15DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013384	16x27x15DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013385	17x27x15DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013386	14x24.5x18DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013387	15x24.5x18DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013388	16x24.5x18DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766
X1013389	17x24.5x18DEG CAPSTONE CONTROL PEEK	Sep-15	Rule 8	Annex II (-Section 4)	60847	15766



Product List

Last updated by: Greg Maschek
Tech File Bundle: TL Fusion, TF010

Date: 2/27/2015

Product: CAPSTONE® L Spinal System Implants

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2964036	6 DEG, 10 MM X 36 MM CAGE	Dec-2013	Rule 8	Annex II (-Section 4	60847	15766
2964040	6 DEG, 10 MM X 40 MM CAGE	Dec-2013	Rule 8	Annex II (-Section 4	60847	15766
2964044	6 DEG, 10 MM X 44 MM CAGE	Dec-2013	Rule 8	Annex II (-Section 4	60847	15766
2964236	6 DEG, 12 MM X 36 MM CAGE	Dec-2013	Rule 8	Annex II (-Section 4	60847	15766
2964240	6 DEG, 12 MM X 40 MM CAGE	Dec-2013	Rule 8	Annex II (-Section 4	60847	15766
2964244	6 DEG, 12 MM X 44 MM CAGE	Dec-2013	Rule 8	Annex II (-Section 4	60847	15766
2964436	6 DEG, 14 MM X 36 MM CAGE	Dec-2013	Rule 8	Annex II (-Section 4	60847	15766
2964440	6 DEG, 14 MM X 40 MM CAGE	Dec-2013	Rule 8	Annex II (-Section 4	60847	15766
2964444	6 DEG, 14 MM X 44 MM CAGE	Dec-2013	Rule 8	Annex II (-Section 4	60847	15766
2964836	6 DEG, 8 MM X 36 MM CAGE	Dec-2013	Rule 8	Annex II (-Section 4	60847	15766
2964840	6 DEG, 8 MM X 40 MM CAGE	Dec-2013	Rule 8	Annex II (-Section 4	60847	15766
2964844	6 DEG, 8 MM X 44 MM CAGE	Dec-2013	Rule 8	Annex II (-Section 4	60847	15766



Product List

Last updated by: Becky Ronner
 Tech File Bundle: TL Fusion, TF010

Date: 7/13/2016

Product: CAPSTONE PTC Spinal System						
Class: IIb						
P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
3992206INT	SPACER 3992206INT 22MM X 6MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3992207INT	SPACER 3992207INT 22MM X 7MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3992208INT	SPACER 3992208INT 22MM X 8MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3992209INT	SPACER 3992209INT 22MM X 9MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3992210INT	SPACER 3992210INT 22MM X 10MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3992211INT	SPACER 3992211INT 22MM X 11MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3992212INT	SPACER 3992212INT 22MM X 12MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3992213INT	SPACER 3992213INT 22MM X 13MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3992214INT	SPACER 3992214INT 22MM X 14MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3992215INT	SPACER 3992215INT 22MM X 15MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3992216INT	SPACER 3992216INT 22MM X 16MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3992606INT	SPACER 3992606INT 26MM X 6MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3992607INT	SPACER 3992607INT 26MM X 7MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3992608INT	SPACER 3992608INT 26MM X 8MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3992609INT	SPACER 3992609INT 26MM X 9MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3992610INT	SPACER 3992610INT 26MM X 10MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3992611INT	SPACER 3992611INT 26MM X 11MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3992612INT	SPACER 3992612INT 26MM X 12MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3992613INT	SPACER 3992613INT 26MM X 13MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3992614INT	SPACER 3992614INT 26MM X 14MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3992615INT	SPACER 3992615INT 26MM X 15MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3992616INT	SPACER 3992616INT 26MM X 16MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3993207INT	SPACER 3993207INT 32MM X 7MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3993208INT	SPACER 3993208INT 32MM X 8MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3993209INT	SPACER 3993209INT 32MM X 9MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3993210INT	SPACER 3993210INT 32MM X 10MM	Jul-14	8	Annex II Minus Section 4	60847	15766



Tech File Bundle: TL Fusion, TF010

Product:	CAPSTONE PTC Spinal System					
Class:	IIb					
3993211INT	SPACER 3993211INT 32MM X 11MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3993212INT	SPACER 3993212INT 32MM X 12MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3993213INT	SPACER 3993213INT 32MM X 13MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3993214INT	SPACER 3993214INT 32MM X 14MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3993215INT	SPACER 3993215INT 32MM X 15MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3993216INT	SPACER 3993216INT 32MM X 16MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3993607INT	SPACER 3993607INT 36MM X 7MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3993608INT	SPACER 3993608INT 36MM X 8MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3993609INT	SPACER 3993609INT 36MM X 9MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3993610INT	SPACER 3993610INT 36MM X 10MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3993611INT	SPACER 3993611INT 36MM X 11MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3993612INT	SPACER 3993612INT 36MM X 12MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3993613INT	SPACER 3993613INT 36MM X 13MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3993614INT	SPACER 3993614INT 36MM X 14MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3993615INT	SPACER 3993615INT 36MM X 15MM	Jul-14	8	Annex II Minus Section 4	60847	15766
3993616INT	SPACER 3993616INT 36MM X 16MM	Jul-14	8	Annex II Minus Section 4	60847	15766

Product List

Last updated by: Lila Joe
 Tech File Bundle: TL Fusion, TF010

Date: 7/10/2018

Product: CLYDESDALE® Spinal System Implants						
Class: IIB						
P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2920040	Cage, Clydesdale 22mm, 0 degree, 10x40	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920045	Cage, Clydesdale 22mm, 0 degree, 10x45	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920050	Cage, Clydesdale 22mm, 0 degree, 10x50	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920055	Cage, Clydesdale 22mm, 0 degree, 10x55	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920060	Cage, Clydesdale 22mm, 0 degree, 10x60	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920240	Cage, Clydesdale 22mm, 0 degree, 12x40	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920245	Cage, Clydesdale 22mm, 0 degree, 12x45	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920250	Cage, Clydesdale 22mm, 0 degree, 12x50	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920255	Cage, Clydesdale 22mm, 0 degree, 12x55	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920260	Cage, Clydesdale 22mm, 0 degree, 12x60	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920440	Cage, Clydesdale 22mm, 0 degree, 14x40	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920445	Cage, Clydesdale 22mm, 0 degree, 14x45	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920450	Cage, Clydesdale 22mm, 0 degree, 14x50	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920455	Cage, Clydesdale 22mm, 0 degree, 14x55	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920460	Cage, Clydesdale 22mm, 0 degree, 14x60	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920640	Cage, Clydesdale 22mm, 0 degree, 16x40	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920645	Cage, Clydesdale 22mm, 0 degree, 16x45	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920650	Cage, Clydesdale 22mm, 0 degree, 16x50	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920655	Cage, Clydesdale 22mm, 0 degree, 16x55	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920660	Cage, Clydesdale 22mm, 0 degree, 16x60	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920840	Cage, Clydesdale 22mm, 0 degree, 8x40	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920845	Cage, Clydesdale 22mm, 0 degree, 8x45	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920850	Cage, Clydesdale 22mm, 0 degree, 8x50	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920855	Cage, Clydesdale 22mm, 0 degree, 8x55	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2920860	Cage, Clydesdale 22mm, 0 degree, 8x60	Mar-2012	Rule 8	Annex II (-Section 4)	60847	15766
2922040INT	Cage, Clydesdale 22mm, 12 degree, 10x40	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2922045INT	Cage, Clydesdale 22mm, 12 degree, 10x45	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2922050INT	Cage, Clydesdale 22mm, 12 degree, 10x50	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2922055INT	Cage, Clydesdale 22mm, 12 degree, 10x55	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2922060INT	Cage, Clydesdale 22mm, 12 degree, 10x60	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2922240INT	Cage, Clydesdale 22mm, 12 degree, 12x40	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2922245INT	Cage, Clydesdale 22mm, 12 degree, 12x45	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2922250INT	Cage, Clydesdale 22mm, 12 degree, 12x50	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2922255INT	Cage, Clydesdale 22mm, 12 degree, 12x55	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2922260INT	Cage, Clydesdale 22mm, 12 degree, 12x60	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2922440INT	Cage, Clydesdale 22mm, 12 degree, 14x40	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2922445INT	Cage, Clydesdale 22mm, 12 degree, 14x45	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2922450INT	Cage, Clydesdale 22mm, 12 degree, 14x50	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2922455INT	Cage, Clydesdale 22mm, 12 degree, 14x55	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2922460INT	Cage, Clydesdale 22mm, 12 degree, 14x60	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2922640INT	Cage, Clydesdale 22mm, 12 degree, 16x40	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2922645INT	Cage, Clydesdale 22mm, 12 degree, 16x45	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2922650INT	Cage, Clydesdale 22mm, 12 degree, 16x50	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2922655INT	Cage, Clydesdale 22mm, 12 degree, 16x55	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2922660INT	Cage, Clydesdale 22mm, 12 degree, 16x60	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926040INT	Cage, Clydesdale 22mm, 6 degree, 10x40	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926045INT	Cage, Clydesdale 22mm, 6 degree, 10x45	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926050INT	Cage, Clydesdale 22mm, 6 degree, 10x50	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926055INT	Cage, Clydesdale 22mm, 6 degree, 10x55	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926060INT	Cage, Clydesdale 22mm, 6 degree, 10x60	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926240INT	Cage, Clydesdale 22mm, 6 degree, 12x40	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766

Tech File Bundle: TL Fusion, TF010

Product: CLYDESDALE® Spinal System Implants
 Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2926245INT	Cage, Clydesdale 22mm, 6 degree, 12x45	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926250INT	Cage, Clydesdale 22mm, 6 degree, 12x50	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926255INT	Cage, Clydesdale 22mm, 6 degree, 12x55	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926260INT	Cage, Clydesdale 22mm, 6 degree, 12x60	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926440INT	Cage, Clydesdale 22mm, 6 degree, 14x40	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926445INT	Cage, Clydesdale 22mm, 6 degree, 14x45	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926450INT	Cage, Clydesdale 22mm, 6 degree, 14x50	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926455INT	Cage, Clydesdale 22mm, 6 degree, 14x55	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926460INT	Cage, Clydesdale 22mm, 6 degree, 14x60	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926640INT	Cage, Clydesdale 22mm, 6 degree, 16x40	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926645INT	Cage, Clydesdale 22mm, 6 degree, 16x45	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926650INT	Cage, Clydesdale 22mm, 6 degree, 16x50	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926655INT	Cage, Clydesdale 22mm, 6 degree, 16x55	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926660INT	Cage, Clydesdale 22mm, 6 degree, 16x60	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926840INT	Cage, Clydesdale 22mm, 6 degree, 8x40	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926845INT	Cage, Clydesdale 22mm, 6 degree, 8x45	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926850INT	Cage, Clydesdale 22mm, 6 degree, 8x50	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926855INT	Cage, Clydesdale 22mm, 6 degree, 8x55	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2926860INT	Cage, Clydesdale 22mm, 6 degree, 8x60	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2969040INT	CAGE, CLYDESDALE, 0 DEG, 10 X 40	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2969045INT	CAGE, CLYDESDALE, 0 DEG, 10 X 45	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2969050INT	CAGE, CLYDESDALE, 0 DEG, 10 X 50	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2969055INT	CAGE, CLYDESDALE, 0 DEG, 10 X 55	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2969240INT	CAGE, CLYDESDALE, 0 DEG, 12 X 40	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2969245INT	CAGE, CLYDESDALE, 0 DEG, 12 X 45	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2969250INT	CAGE, CLYDESDALE, 0 DEG, 12 X 50	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2969255INT	CAGE, CLYDESDALE, 0 DEG, 12 X 55	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2969440INT	CAGE, CLYDESDALE, 0 DEG, 14 X 40	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2969445INT	CAGE, CLYDESDALE, 0 DEG, 14 X 45	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2969450INT	CAGE, CLYDESDALE, 0 DEG, 14 X 50	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2969455INT	CAGE, CLYDESDALE, 0 DEG, 14 X 55	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2969640INT	CAGE, CLYDESDALE, 0 DEG, 16 X 40	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2969645INT	CAGE, CLYDESDALE, 0 DEG, 16 X 45	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2969650INT	CAGE, CLYDESDALE, 0 DEG, 16 X 50	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2969655INT	CAGE, CLYDESDALE, 0 DEG, 16 X 55	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2969840INT	CAGE, CLYDESDALE, 0 DEG, 8 X 40	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2969845INT	CAGE, CLYDESDALE, 0 DEG, 8 X 45	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2969850INT	CAGE, CLYDESDALE, 0 DEG, 8 X 50	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2969855INT	CAGE, CLYDESDALE, 0 DEG, 8 X 55	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968040INT	CAGE, CLYDESDALE, 6 DEG, 10 X 40	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968045INT	CAGE, CLYDESDALE, 6 DEG, 10 X 45	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968050INT	CAGE, CLYDESDALE, 6 DEG, 10 X 50	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968055INT	CAGE, CLYDESDALE, 6 DEG, 10 X 55	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968060INT	CAGE, CLYDESDALE, 6 DEG, 10 X 60	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968240INT	CAGE, CLYDESDALE, 6 DEG, 12 X 40	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968245INT	CAGE, CLYDESDALE, 6 DEG, 12 X 45	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968250INT	CAGE, CLYDESDALE, 6 DEG, 12 X 50	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968255INT	CAGE, CLYDESDALE, 6 DEG, 12 X 55	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968260INT	CAGE, CLYDESDALE, 6 DEG, 12 X 60	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968440INT	CAGE, CLYDESDALE, 6 DEG, 14 X 40	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968445INT	CAGE, CLYDESDALE, 6 DEG, 14 X 45	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968450INT	CAGE, CLYDESDALE, 6 DEG, 14 X 50	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968455INT	CAGE, CLYDESDALE, 6 DEG, 14 X 55	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766

Tech File Bundle: TL Fusion, TF010

Product: CLYDESDALE® Spinal System Implants
Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2968460INT	CAGE, CLYDESDALE, 6 DEG, 14 X 60	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968640INT	CAGE, CLYDESDALE, 6 DEG, 16 X 40	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968645INT	CAGE, CLYDESDALE, 6 DEG, 16 X 45	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968650INT	CAGE, CLYDESDALE, 6 DEG, 16 X 50	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968655INT	CAGE, CLYDESDALE, 6 DEG, 16 X 55	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968660INT	CAGE, CLYDESDALE, 6 DEG, 16 X 60	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968840INT	CAGE, CLYDESDALE, 6 DEG, 8 X 40	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968845INT	CAGE, CLYDESDALE, 6 DEG, 8 X 45	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968850INT	CAGE, CLYDESDALE, 6 DEG, 8 X 50	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968855INT	CAGE, CLYDESDALE, 6 DEG, 8 X 55	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766
2968860INT	CAGE, CLYDESDALE, 6 DEG, 8 X 60	Jul-2018	Rule 8	Annex II (-Section 4)	60847	15766



Product List

Last updated by: Becky Ronner
 Tech File Bundle: TL Fusion, TF010

Date: 7/13/2016

Product: CLYDESDALE PTC Spinal System
 Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
4920040	CAGE,CLYDESDALE PTC,0 DEG, 10MMX40MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920045	CAGE,CLYDESDALE PTC,0 DEG, 10MMX45MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920050	CAGE,CLYDESDALE PTC,0 DEG, 10MMX50MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920055	CAGE,CLYDESDALE PTC,0 DEG, 10MMX55MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920060	CAGE,CLYDESDALE PTC,0 DEG, 10MMX60MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920240	CAGE,CLYDESDALE PTC,0 DEG, 12MMX40MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920245	CAGE,CLYDESDALE PTC,0 DEG, 12MMX45MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920250	CAGE,CLYDESDALE PTC,0 DEG, 12MMX50MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920255	CAGE,CLYDESDALE PTC,0 DEG, 12MMX55MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920260	CAGE,CLYDESDALE PTC,0 DEG, 12MMX60MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920440	CAGE,CLYDESDALE PTC,0 DEG, 14MMX40MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920445	CAGE,CLYDESDALE PTC,0 DEG, 14MMX45MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920450	CAGE,CLYDESDALE PTC,0 DEG, 14MMX50MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920455	CAGE,CLYDESDALE PTC,0 DEG, 14MMX55MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920460	CAGE,CLYDESDALE PTC,0 DEG, 14MMX60MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920640	CAGE,CLYDESDALE PTC,0 DEG, 16MMX40MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920645	CAGE,CLYDESDALE PTC,0 DEG, 16MMX45MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766



Tech File Bundle: TL Fusion, TF010

Product: CLYDESDALE PTC Spinal System

Class: IIb

4920650	CAGE,CLYDESDALE PTC,0 DEG, 16MMX50MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920655	CAGE,CLYDESDALE PTC,0 DEG, 16MMX55MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920660	CAGE,CLYDESDALE PTC,0 DEG, 16MMX60MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920840	CAGE,CLYDESDALE PTC,0 DEG, 8MMX40MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920845	CAGE,CLYDESDALE PTC,0 DEG, 8MMX45MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920850	CAGE,CLYDESDALE PTC,0 DEG, 8MMX50MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920855	CAGE,CLYDESDALE PTC,0 DEG, 8MMX55MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4920860	CAGE,CLYDESDALE PTC, 0 DEG, 8MMX60MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4922040	CAGE,CLYDESDALE PTC,12DEG, 10MMX40MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4922045	CAGE,CLYDESDALE PTC,12DEG, 10MMX45MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4922050	CAGE,CLYDESDALE PTC,12DEG, 10MMX50MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4922055	CAGE,CLYDESDALE PTC,12DEG, 10MMX55MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4922060	CAGE,CLYDESDALE PTC,12DEG, 10MMX60MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4922240	CAGE,CLYDESDALE PTC,12DEG, 12MMX40MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4922245	CAGE,CLYDESDALE PTC,12DEG, 12MMX45MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4922250	CAGE,CLYDESDALE PTC,12DEG, 12MMX50MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4922255	CAGE,CLYDESDALE PTC,12DEG, 12MMX55MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4922260	CAGE,CLYDESDALE PTC,12DEG, 12MMX60MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4922440	CAGE,CLYDESDALE PTC,12DEG, 14MMX40MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766



Tech File Bundle: TL Fusion, TF010

Product: CLYDESDALE PTC Spinal System

Class: IIb

4922445	CAGE,CLYDESDALE PTC,12DEG, 14MMX45MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4922450	CAGE,CLYDESDALE PTC,12DEG, 14MMX50MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4922455	CAGE,CLYDESDALE PTC,12DEG, 14MMX55MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4922460	CAGE,CLYDESDALE PTC,12DEG, 14MMX60MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4922640	CAGE,CLYDESDALE PTC,12DEG, 16MMX40MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4922645	CAGE,CLYDESDALE PTC,12DEG, 16MMX45MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4922650	CAGE,CLYDESDALE PTC,12DEG, 16MMX50MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4922655	CAGE,CLYDESDALE PTC,12DEG, 16MMX55MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4922660	CAGE,CLYDESDALE PTC,12DEG, 16MMX60MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926040	CAGE,CLYDESDALE PTC,6 DEG, 10MMX40MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926045	CAGE,CLYDESDALE PTC,6 DEG, 10MMX45MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926050	CAGE,CLYDESDALE PTC,6 DEG, 10MMX50MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926055	CAGE,CLYDESDALE PTC,6 DEG, 10MMX55MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926060	CAGE,CLYDESDALE PTC,6 DEG, 10MMX60MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926240	CAGE,CLYDESDALE PTC,6 DEG, 12MMX40MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926245	CAGE,CLYDESDALE PTC,6 DEG, 12MMX45MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926250	CAGE,CLYDESDALE PTC,6 DEG, 12MMX50MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926255	CAGE,CLYDESDALE PTC,6 DEG, 12MMX55MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926260	CAGE,CLYDESDALE PTC,6 DEG, 12MMX60MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766



Tech File Bundle: TL Fusion, TF010

Product: CLYDESDALE PTC Spinal System

Class: IIb

4926440	CAGE,CLYDESDALE PTC,6 DEG, 14MMX40MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926445	CAGE,CLYDESDALE PTC,6 DEG, 14MMX45MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926450	CAGE,CLYDESDALE PTC,6 DEG, 14MMX50MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926455	CAGE,CLYDESDALE PTC,6 DEG, 14MMX55MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926460	CAGE,CLYDESDALE PTC,6 DEG, 14MMX60MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926640	CAGE,CLYDESDALE PTC,6 DEG, 16MMX40MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926645	CAGE,CLYDESDALE PTC,6 DEG, 16MMX45MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926650	CAGE,CLYDESDALE PTC,6 DEG, 16MMX50MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926655	CAGE,CLYDESDALE PTC,6 DEG, 16MMX55MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926660	CAGE,CLYDESDALE PTC,6 DEG, 16MMX60MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926840	CAGE,CLYDESDALE PTC,6 DEG, 8MMX40MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926845	CAGE,CLYDESDALE PTC,6 DEG, 8MMX45MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926850	CAGE,CLYDESDALE PTC,6 DEG, 8MMX50MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926855	CAGE,CLYDESDALE PTC,6 DEG, 8MMX55MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4926860	CAGE,CLYDESDALE PTC,6 DEG, 8MMX60MM,22MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4980040	CAGE,CLYDESDALE PTC,0 DEG, 10MMX40MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4980045	CAGE,CLYDESDALE PTC,0 DEG, 10MMX45MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4980050	CAGE,CLYDESDALE PTC,0 DEG, 10MMX50MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4980055	CAGE,CLYDESDALE PTC,0 DEG, 10MMX55MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766



Tech File Bundle: TL Fusion, TF010

Product: CLYDESDALE PTC Spinal System

Class: IIb

4980240	CAGE,CLYDESDALE PTC,0 DEG, 12MMX40MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4980245	CAGE,CLYDESDALE PTC,0 DEG, 12MMX45MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4980250	CAGE,CLYDESDALE PTC,0 DEG, 12MMX50MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4980255	CAGE,CLYDESDALE PTC,0 DEG, 12MMX55MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4980440	CAGE,CLYDESDALE PTC,0 DEG, 14MMX40MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4980445	CAGE,CLYDESDALE PTC,0 DEG, 14MMX45MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4980450	CAGE,CLYDESDALE PTC,0 DEG, 14MMX50MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4980455	CAGE,CLYDESDALE PTC,0 DEG, 14MMX55MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4980640	CAGE,CLYDESDALE PTC,0 DEG, 16MMX40MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4980645	CAGE,CLYDESDALE PTC,0 DEG, 16MMX45MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4980650	CAGE,CLYDESDALE PTC,0 DEG, 16MMX50MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4980655	CAGE,CLYDESDALE PTC,0 DEG, 16MMX55MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4980840	CAGE,CLYDESDALE PTC,0 DEG, 8MMX40MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4980845	CAGE,CLYDESDALE PTC,0 DEG, 8MMX45MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4980850	CAGE,CLYDESDALE PTC,0 DEG, 8MMX50MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4980855	CAGE,CLYDESDALE PTC,0 DEG, 8MMX55MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986040	CAGE,CLYDESDALE PTC,6 DEG, 10MMX40MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986045	CAGE,CLYDESDALE PTC,6 DEG, 10MMX45MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986050	CAGE,CLYDESDALE PTC,6 DEG, 10MMX50MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766



Tech File Bundle: TL Fusion, TF010

Product: CLYDESDALE PTC Spinal System

Class: IIb

4986055	CAGE,CLYDESDALE PTC,6 DEG, 10MMX55MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986060	CAGE,CLYDESDALE PTC,6 DEG, 10MMX60MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986240	CAGE,CLYDESDALE PTC,6 DEG, 12MMX40MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986245	CAGE,CLYDESDALE PTC,6 DEG, 12MMX45MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986250	CAGE,CLYDESDALE PTC,6 DEG, 12MMX50MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986255	CAGE,CLYDESDALE PTC,6 DEG, 12MMX55MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986260	CAGE,CLYDESDALE PTC,6 DEG, 12MMX60MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986440	CAGE,CLYDESDALE PTC,6 DEG, 14MMX40MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986445	CAGE,CLYDESDALE PTC,6 DEG, 14MMX45MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986450	CAGE,CLYDESDALE PTC,6 DEG, 14MMX50MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986455	CAGE,CLYDESDALE PTC,6 DEG, 14MMX55MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986460	CAGE,CLYDESDALE PTC,6 DEG, 14MMX60MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986640	CAGE,CLYDESDALE PTC,6 DEG, 16MMX40MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986645	CAGE,CLYDESDALE PTC,6 DEG, 16MMX45MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986650	CAGE,CLYDESDALE PTC,6 DEG, 16MMX50MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986655	CAGE,CLYDESDALE PTC,6 DEG, 16MMX55MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986660	CAGE,CLYDESDALE PTC,6 DEG, 16MMX60MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986840	CAGE,CLYDESDALE PTC,6 DEG, 8MMX40MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986845	CAGE,CLYDESDALE PTC,6 DEG, 8MMX45MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766



Tech File Bundle: TL Fusion, TF010

Product: CLYDESDALE PTC Spinal System

Class: IIb

4986850	CAGE,CLYDESDALE PTC,6 DEG, 8MMX50MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986855	CAGE,CLYDESDALE PTC,6 DEG, 8MMX55MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766
4986860	CAGE,CLYDESDALE PTC,6 DEG, 8MMX60MM,18MM	Jul-14	8	Annex II Minus Section 4	60847	15766



Product List

Last updated by: Justin O'Connor
 Tech File Bundle: TL Fusion, TF010

Date: 6/18/2015

Product: DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2151110	Interbody, Small, 6 degrees, 10mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2151112	Interbody, Small, 6 degrees, 12mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2151114	Interbody, Small, 6 degrees, 14mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2151116	Interbody, Small, 6 degrees, 16mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2151118	Interbody, Small, 6 degrees, 18mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2151120	Interbody, Small, 6 degrees, 20mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2151210	Interbody, Medium, 6 degrees, 10mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2151212	Interbody, Medium, 6 degrees, 12mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2151214	Interbody, Medium, 6 degrees, 14mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2151216	Interbody, Medium, 6 degrees, 16mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2151218	Interbody, Medium, 6 degrees, 18mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2151220	Interbody, Medium, 6 degrees, 20mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2151310	Interbody, Large, 6 degrees, 10mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2151312	Interbody, Large, 6 degrees, 12mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2151314	Interbody, Large, 6 degrees, 14mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2151316	Interbody, Large, 6 degrees, 16mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2151318	Interbody, Large, 6 degrees, 18mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2151320	Interbody, Large, 6 degrees, 20mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2152110	Interbody, Small, 12 degrees, 10mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2152112	Interbody, Small, 12 degrees, 12mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2152114	Interbody, Small, 12 degrees, 14mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2152116	Interbody, Small, 12 degrees, 16mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2152118	Interbody, Small, 12 degrees, 18mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2152120	Interbody, Small, 12 degrees, 20mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2152210	Interbody, Medium, 12 degrees, 10mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2152212	Interbody, Medium, 12 degrees, 12mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2152214	Interbody, Medium, 12 degrees, 14mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2152216	Interbody, Medium, 12 degrees, 16mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2152218	Interbody, Medium, 12 degrees, 18mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2152220	Interbody, Medium, 12 degrees, 20mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2152312	Interbody, Large, 12 degrees, 12mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2152314	Interbody, Large, 12 degrees, 14mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2152316	Interbody, Large, 12 degrees, 16mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2152318	Interbody, Large, 12 degrees, 18mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2152320	Interbody, Large, 12 degrees, 20mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2153112	Interbody, Small, 18 degrees, 12mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2153114	Interbody, Small, 18 degrees, 14mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2153116	Interbody, Small, 18 degrees, 16mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2153118	Interbody, Small, 18 degrees, 18mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2153120	Interbody, Small, 18 degrees, 20mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2153214	Interbody, Medium, 18 degrees, 14mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2153216	Interbody, Medium, 18 degrees, 16mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2153218	Interbody, Medium, 18 degrees, 18mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2153220	Interbody, Medium, 18 degrees, 20mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2153316	Interbody, Large, 18 degrees, 16mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2153318	Interbody, Large, 18 degrees, 18mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2153320	Interbody, Large, 18 degrees, 20mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2154116	Interbody, Small, 24 degrees, 16mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766



Tech File Bundle: TL Fusion, TF010

Product: DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2154118	Interbody, Small, 24 degrees, 18mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2154120	Interbody, Small, 24 degrees, 20mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2154216	Interbody, Medium, 24 degrees, 16mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2154218	Interbody, Medium, 24 degrees, 18mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2154220	Interbody, Medium, 24 degrees, 20mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2154318	Interbody, Large, 24 degrees, 18mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2154320	Interbody, Large, 24 degrees, 20mm	Nov-2015	Rule 8	Annex II (-Section 4)	38161	15766
2150120	Screws, 20mm	Nov-2015	Rule 8	Annex II (-Section 4)	61324	15766
2150125	Screws, 25mm	Nov-2015	Rule 8	Annex II (-Section 4)	61324	15766
2150130	Screws, 30mm	Nov-2015	Rule 8	Annex II (-Section 4)	61324	15766
2150135	Screws, 35mm	Nov-2015	Rule 8	Annex II (-Section 4)	61324	15766
2150140	Screws, 40mm	Nov-2015	Rule 8	Annex II (-Section 4)	61324	15766
2160010	ALIF51 Plate, 10mm	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
2160012	ALIF51 Plate, 12mm	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
2160014	ALIF51 Plate, 14mm	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
2160016	ALIF51 Plate, 16mm	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
2160018	ALIF51 Plate, 18mm	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
2160020	ALIF51 Plate, 20mm	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
2150010	OLIF51 Plate. 10mm	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
2150012	OLIF51 Plate. 12mm	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
2150014	OLIF51 Plate. 14mm	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
2150016	OLIF51 Plate. 16mm	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
2150018	OLIF51 Plate. 18mm	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766
2150020	OLIF51 Plate. 20mm	Nov-2015	Rule 8	Annex II (-Section 4)	57805	15766



Product List

Last updated by: Lila Joe
 Tech File Bundle: TL Fusion, TF010

Date: 6/1/2016

Product: CRESCENT® Spinal System Implants
 Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
6660725	CRESCENT TI IFD 25X7	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6660730	CRESCENT TI IFD 30X7	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6660736	CRESCENT TI IFD 36X07	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6660825	CRESCENT TI IFD 25X8	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6660830	CRESCENT TI IFD 30X8	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6660836	CRESCENT TI IFD 36X8	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6660925	CRESCENT TI IFD 25X9	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6660930	CRESCENT TI IFD 30X9	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6660936	CRESCENT TI IFD 36X9	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6661025	CRESCENT TI IFD 25X10	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6661030	CRESCENT TI IFD 30X10	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6661036	CRESCENT TI IFD 36X10	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6661125	CRESCENT TI IFD 25x11	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6661130	CRESCENT TI IFD 30X11	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6661136	CRESCENT TI IFD 36X11	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6661225	CRESCENT TI IFD 25X12	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6661230	CRESCENT TI IFD 30X12	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6661236	CRESCENT TI IFD 36X12	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6661325	CRESCENT TI IFD 25X13	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6661330	CRESCENT TI IFD 30X13	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6661336	CRESCENT TI IFD 36X13	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6661425	CRESCENT TI IFD 25X14	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6661430	CRESCENT TI IFD 30X14	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6661436	CRESCENT TI IFD 36X14	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6661525	CRESCENT TI IFD 25X15	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766

Tech File Bundle: TL Fusion, TF010

Product: CRESCENT® Spinal System Implants

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
6661530	CRESCENT TI IFD 30X15	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6661536	CRESCENT TI IFD 36X15	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6661625	CRESCENT TI IFD 25X16	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6661630	CRESCENT TI IFD 30X16	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6661636	CRESCENT TI IFD 36X16	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6670725	CRESCENT TI 12mm IFD 25X7	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6670730	CRESCENT TI 12mm IFD 30X7	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6670736	CRESCENT TI 12mm IFD 36X7	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6670825	CRESCENT TI 12mm IFD 25X8	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6670830	CRESCENT TI 12mm IFD 30X8	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6670836	CRESCENT TI 12mm IFD 36X8	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6670925	CRESCENT TI 12mm IFD 25X9	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6670930	CRESCENT TI 12mm IFD 30X9	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6670936	CRESCENT TI 12mm IFD 36X9	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6671025	CRESCENT TI 12mm IFD 25X10	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6671030	CRESCENT TI 12mm IFD 30X10	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6671036	CRESCENT TI 12mm IFD 36X10	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6671125	CRESCENT TI 12mm IFD 25X11	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6671130	CRESCENT TI 12mm IFD 30X11	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6671136	CRESCENT TI 12mm IFD 36X11	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6671225	CRESCENT TI 12mm IFD 25X12	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6671230	CRESCENT TI 12mm IFD 30X12	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6671236	CRESCENT TI 12mm IFD 36X12	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6671325	CRESCENT TI 12mm IFD 25X13	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6671330	CRESCENT TI 12mm IFD 30X13	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6671336	CRESCENT TI 12mm IFD 36X13	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766



Tech File Bundle: TL Fusion, TF010

Product: CRESCENT® Spinal System Implants

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
6671425	CRESCENT TI 12mm IFD 25X14	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6671430	CRESCENT TI 12mm IFD 30X14	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6671436	CRESCENT TI 12mm IFD 36X14	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6671525	CRESCENT TI 12mm IFD 25X15	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6671530	CRESCENT TI 12mm IFD 30X15	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6671536	CRESCENT TI 12mm IFD 36X15	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6671625	CRESCENT TI 12mm IFD 25X16	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6671630	CRESCENT TI 12mm IFD 30X16	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
6671636	CRESCENT TI 12mm IFD 36X16	Apr-1998	Rule 8	Annex II (-Section 4)	60847	15766
9392507INT	CRESCENT PEEK 25X7	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9392508INT	CRESCENT PEEK 25X8	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9392509INT	CRESCENT PEEK 25X9	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9392510INT	CRESCENT PEEK 25X10	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9392511INT	CRESCENT PEEK 25X11	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9392512INT	CRESCENT PEEK 25X12	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9392513INT	CRESCENT PEEK 25X13	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9392514INT	CRESCENT PEEK 25X14	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9392515INT	CRESCENT PEEK 25X15	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9393007INT	CRESCENT PEEK 30X7	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9393008INT	CRESCENT PEEK 30X8	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9393009INT	CRESCENT PEEK 30X9	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9393010INT	CRESCENT PEEK 30X10	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9393011INT	CRESCENT PEEK 30X11	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9393012INT	CRESCENT PEEK 30X12	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9393013INT	CRESCENT PEEK 30X13	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9393014INT	CRESCENT PEEK 30X14	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766



Tech File Bundle: TL Fusion, TF010

Product: CRESCENT® Spinal System Implants
 Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
9393015INT	CRESCENT PEEK 30X15	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9393607INT	CRESCENT PEEK 36X7	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9393608INT	CRESCENT PEEK 36X8	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9393609INT	CRESCENT PEEK 36X9	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9393610INT	CRESCENT PEEK 36X10	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9393611INT	CRESCENT PEEK 36X11	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9393612INT	CRESCENT PEEK 36X12	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9393613INT	CRESCENT PEEK 36X13	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9393614INT	CRESCENT PEEK 36X14	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
9393615INT	CRESCENT PEEK 36X15	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766



Product List

Last updated by: Becky Ronner
 Tech File Bundle: TL Fusion, TF010

Date: 1/12/2016

Product: ELEVATE™ SPINAL SYSTEM
 Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
7770723	HYBRID STANDARD-23 X 7 MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
7770823	HYBRID STANDARD-23 X 8MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
7770923	HYBRID STANDARD-23 X 9MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
7771023	HYBRID STANDARD-23 X 10MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
7771123	HYBRID STANDARD-23 X 11MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
8880823	HYBRID EXTRA-LORDOTIC STANDARD-23 X 8MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
8880923	HYBRID EXTRA-LORDOTIC STANDARD-23 X 9MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
8881023	HYBRID EXTRA-LORDOTIC STANDARD-23 X 10MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
8881123	HYBRID EXTRA-LORDOTIC STANDARD-23 X 11MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
7770728	HYBRID STANDARD-28 X 7MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
7770828	HYBRID STANDARD-28 X 8MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
7770928	HYBRID STANDARD-28 X 9MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
7771028	HYBRID STANDARD-28 X 10MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
7771128	HYBRID STANDARD-28 X 11MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
8880828	HYBRID EXTRA-LORDOTIC STANDARD-28 X 8MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
8880928	HYBRID EXTRA-LORDOTIC STANDARD-28 X 9MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
8881028	HYBRID EXTRA-LORDOTIC STANDARD-28 X 10MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
8881128	HYBRID EXTRA-LORDOTIC STANDARD-28 X 11MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
7770732	HYBRID STANDARD-32 X 7MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
7770832	HYBRID STANDARD-32 X 8MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
7770932	HYBRID STANDARD-32 X 9MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
7771032	HYBRID STANDARD-32 X 10MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
7771132	HYBRID STANDARD-32 X 11MM IMPLANT	Dec-2015	Rule 8	Annex II (-Section 4)	60847	15766
8880832	HYBRID EXTRA-LORDOTIC STANDARD-32 X 8MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
8880932	HYBRID EXTRA-LORDOTIC STANDARD-32 X 9MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
8881032	HYBRID EXTRA-LORDOTIC STANDARD-32 X 10MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766
8881132	HYBRID EXTRA-LORDOTIC STANDARD-32 X 11MM IMPLANT	Nov-2015	Rule 8	Annex II (-Section 4)	60847	15766

Last updated by: Buanita Benson
 Tech File Bundle: TL Fusion, TF010

Date: 5/9/2018

Product: FUSE® Spinal System
 Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2800724	FUSE PLIF Titanium cage, 7 x 24mm	July 2013	Rule 8	Annex II (excluding section 4)	38161	15766
2800824	FUSE PLIF Titanium cage, 8 x 24mm	July 2013	Rule 8	Annex II (excluding section 4)	38161	15766
2840924	FUSE PLIF Titanium cage, 9 x 24mm, 4°	July 2013	Rule 8	Annex II (excluding section 4)	38161	15766
2880924	FUSE PLIF Titanium cage, 9 x 24mm, 8°	July 2013	Rule 8	Annex II (excluding section 4)	38161	15766
2841024	FUSE PLIF Titanium cage, 10 x 24mm, 4°	July 2013	Rule 8	Annex II (excluding section 4)	38161	15766
2881024	FUSE PLIF Titanium cage, 10 x 24mm, 8°	July 2013	Rule 8	Annex II (excluding section 4)	38161	15766
2841124	FUSE PLIF Titanium cage, 11 x 24mm, 4°	July 2013	Rule 8	Annex II (excluding section 4)	38161	15766
2881124	FUSE PLIF Titanium cage, 11 x 24mm, 8°	July 2013	Rule 8	Annex II (excluding section 4)	38161	15766
2841224	FUSE PLIF Titanium cage, 12 x 24mm, 4°	July 2013	Rule 8	Annex II (excluding section 4)	38161	15766
2881224	FUSE PLIF Titanium cage, 12 x 24mm, 8°	July 2013	Rule 8	Annex II (excluding section 4)	38161	15766
2841324	FUSE PLIF Titanium cage, 13 x 24mm, 4°	July 2013	Rule 8	Annex II (excluding section 4)	38161	15766
2881324	FUSE PLIF Titanium cage, 13 x 24mm, 8°	July 2013	Rule 8	Annex II (excluding section 4)	38161	15766
2841424	FUSE PLIF Titanium cage, 14 x 24mm, 4°	July 2013	Rule 8	Annex II (excluding section 4)	38161	15766
2881424	FUSE PLIF Titanium cage, 14 x 24mm, 8°	July 2013	Rule 8	Annex II (excluding section 4)	38161	15766



Product List

Last updated by: Greg Maschek
 Tech File Bundle: TL Fusion, TF010

Date: 2/27/2015

Product: I-FLY™ Threaded Fusion Device Implants
 Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
8928007	FLY DIAMETER 7 MM CAGE	Feb-2006	Rule 8	Annex II (-Section 4)	57805	15766
8928008	FLY DIAMETER 8 MM CAGE	Feb-2006	Rule 8	Annex II (-Section 4)	57805	15766
8928009	FLY DIAMETER 9 MM CAGE	Feb-2006	Rule 8	Annex II (-Section 4)	57805	15766
8928010	FLY DIAMETER 10 MM CAGE	Feb-2006	Rule 8	Annex II (-Section 4)	57805	15766



Product List

Last updated by: Greg Maschek
 Tech File Bundle: TL Fusion, TF010

Date: 2/27/2015

Product: INTER FIX™ Threaded Fusion Device Implants

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
890-120	12MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-125	12MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-140	14MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-143	14MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-146	14MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-149	14MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-160	16MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-163	16MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-166	16MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-169	16MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-180	18MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-183	18MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-186	18MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-189	18MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-200	20MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-203	20MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-206	20MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-209	20MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-220	22 X 20MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-223	22 X 23MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-226	22 X 26MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-229	22 X 29MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-240	24 X 20MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-243	24 X 23MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-246	24 X 26MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-249	24 X 29MM INTER FIX	Mar-2001	Rule 8	Annex II (-Section 4)	38161	15766
892-100	IMPLANT 10 X 20MM	Jul-2001	Rule 8	Annex II (-Section 4)	38161	15766
892-105	IMPLANT 10 X 25MM	Jul-2001	Rule 8	Annex II (-Section 4)	38161	15766
892-120	IMPLANT 12 X 20MM	Jan-2003	Rule 8	Annex II (-Section 4)	38161	15766
892-125	IMPLANT 12 X 25MM	Jan-2003	Rule 8	Annex II (-Section 4)	38161	15766
892-140	IMPLANT 14 X 20MM	Jan-2003	Rule 8	Annex II (-Section 4)	38161	15766
892-145	IMPLANT 14 X 25MM	Jan-2003	Rule 8	Annex II (-Section 4)	38161	15766
892-166	IMPLANT 16 X 26MM	Jan-2003	Rule 8	Annex II (-Section 4)	38161	15766
890-110	10MM X 20MM INTER FI	Jul-2001	Rule 8	Annex II (-Section 4)	38161	15766
890-115	10MM X 25MM INTER FI	Jul-2001	Rule 8	Annex II (-Section 4)	38161	15766
X0905094	12 X 21MM INTER FIX SP	Oct-2005	Rule 8	Annex II (-Section 4)	38161	15766
X0905096	12 X 26MM INTER FIX SP	Oct-2005	Rule 8	Annex II (-Section 4)	38161	15766
XE206608	DIAMETER 8 MM CAGE	Mar-2003	Rule 8	Annex II (-Section 4)	38161	15766
XE206608	DIAMETER 9 MM CAGE	Mar-2003	Rule 8	Annex II (-Section 4)	38161	15766
XE206608	DIAMETER 10 MM CAGE	Mar-2003	Rule 8	Annex II (-Section 4)	38161	15766



Product List

Last updated by: Greg Maschek
 Tech File Bundle: TL Fusion, TF010

Date: 2/27/2015

Product: INTER FIX™ RP Threaded Fusion Device Implants

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
9011221	12 X 20MM INTER FIX RP	Mar-2000	Rule 8	Annex II (-Section 4)	38161	15766
9011225	12 X 25MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9011420	14 X 20MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9011423	14 X 23MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9011426	14 X 26MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9011429	14 X 29MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9011620	16 X 20MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9011623	16 X 23MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9011626	16 X 26MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9011629	16 X 29MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9011820	18 X 20MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9011823	18 X 23MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9011826	18 X 26MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9011829	18 X 29MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9012020	20 X 20MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9012023	20 X 23MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9012026	20 X 26MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9012029	20 X 29MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9012220	22 X 20MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9012223	22 X 23MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9012226	22 X 26MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9012229	22 X 29MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9012420	24 X 20MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9012423	24 X 23MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9012426	24 X 26MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
9012429	24 X 29MM INTER FIX RP	May-2000	Rule 8	Annex II (-Section 4)	38161	15766
X0903414	14X21MM INTERFIX	Dec-2003	Rule 8	Annex II (-Section 4)	57805	15766
X0903416	14X26MM INTERFIX	Sep-2003	Rule 8	Annex II (-Section 4)	57805	15766
GX060511	12 X 21MM INTER FIX RP SPECIAL	Jul-2005	Rule 8	Annex II (-Section 4)	38161	15766
GX060511	12 X 26MM INTER FIX SPECIAL	Jul-2005	Rule 8	Annex II (-Section 4)	38161	15766
GX060511	12 X 26MM INTER FIX RP SPECIAL	Jul-2005	Rule 8	Annex II (-Section 4)	38161	15766



Product List

Last updated by: Greg Maschek

Date: 2/27/2015

Tech File Bundle: TL Fusion, TF010

Product: LT-CAGE® Lumbar Tapered Fusion Device Implants

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
8941420	LT-CAGE(TM) Lumbar Tapered Fusion Device (14X17X20)	Jul-2008	Rule 8	Annex II (-Section 4)	38161	15766
8941423	LT-CAGE(TM) Lumbar Tapered Fusion Device (14X17.5X23)	Jul-2008	Rule 8	Annex II (-Section 4)	38161	15766
8941620	LT-CAGE(TM) Lumbar Tapered Fusion Device (16X19X20)	Jul-2008	Rule 8	Annex II (-Section 4)	38161	15766
8941623	LT-CAGE(TM) Lumbar Tapered Fusion Device (16X19.5X23)	Jul-2008	Rule 8	Annex II (-Section 4)	38161	15766
8941626	LT-CAGE(TM) Lumbar Tapered Fusion Device (16X20X26)	Jul-2008	Rule 8	Annex II (-Section 4)	38161	15766
8941823	LT-CAGE(TM) Lumbar Tapered Fusion Device (18X21.5X23)	Jul-2008	Rule 8	Annex II (-Section 4)	38161	15766
8941826	LT-CAGE(TM) Lumbar Tapered Fusion Device (18X22X26)	Jul-2008	Rule 8	Annex II (-Section 4)	38161	15766



Product List

Last updated by: Greg Maschek
 Tech File Bundle: TL Fusion, TF010

Date: 2/27/2015

Product: LT-CAGE® (PEEK) Lumbar Tapered Fusion Device Implants
 Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
8941420P	14 X 20MM PEEK LT	Jul-2008	Rule 8	Annex II (-Section 4)	38161	15766
8941423P	14 X 23MM PEEK LT	Jul-2008	Rule 8	Annex II (-Section 4)	38161	15766
8941620P	16 X 20MM PEEK LT	Jul-2008	Rule 8	Annex II (-Section 4)	38161	15766
8941623P	16 X 23MM PEEK LT	Jul-2008	Rule 8	Annex II (-Section 4)	38161	15766
8941626P	16 X 26MM PEEK LT	Jul-2008	Rule 8	Annex II (-Section 4)	38161	15766
8941823P	18 X 23MM PEEK LT	Jul-2008	Rule 8	Annex II (-Section 4)	38161	15766
8941826P	18 X 26MM PEEK LT	Jul-2008	Rule 8	Annex II (-Section 4)	38161	15766

Product List

Last updated by: Buanita Benson
Tech File Bundle: TL Fusion, TF010

Date: 5/9/2018

Product: LOOP® Spinal System

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2560732	LOOP TLIF-Cage 7 mm, 6° small	July 2013	Rule 8	Annex II (-Section 4)	38161	15766
2560832	LOOP TLIF-Cage 8 mm, 6° small	July 2013	Rule 8	Annex II (-Section 4)	38161	15766
2560932	LOOP TLIF-Cage 9 mm, 6° small	July 2013	Rule 8	Annex II (-Section 4)	38161	15766
2561032	LOOP TLIF-Cage 10 mm, 6° small	July 2013	Rule 8	Annex II (-Section 4)	38161	15766
2561132	LOOP TLIF-Cage 11 mm, 6° small	July 2013	Rule 8	Annex II (-Section 4)	38161	15766
2561232	LOOP TLIF-Cage 12 mm, 6° small	July 2013	Rule 8	Annex II (-Section 4)	38161	15766
2561332	LOOP TLIF-Cage 13 mm, 6° small	July 2013	Rule 8	Annex II (-Section 4)	38161	15766
2561432	LOOP TLIF-Cage 14 mm, 6° small	July 2013	Rule 8	Annex II (-Section 4)	38161	15766
2561532	LOOP TLIF-Cage 15 mm, 6° small	July 2013	Rule 8	Annex II (-Section 4)	38161	15766
2561632	LOOP TLIF-Cage 16 mm, 6° small	July 2013	Rule 8	Annex II (-Section 4)	38161	15766



Product List

Last updated by: Lila Joe
 Tech File Bundle: TL Fusion, TF010

Date: 7/10/2018

Product: PERIMETER™ Interbody Fusion Device
 Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
3491208	PERIMETER I/F, SMALL, 4DEG, 8MM	Feb-2012	Rule 8	Annex II (-Section 4)	60847	15766
3491208INT	PERIMETER PEEK, SMALL 4°-8MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3491210	PERIMETER I/F, SMALL, 4DEG, 10MM	Feb-2012	Rule 8	Annex II (-Section 4)	60847	15766
3491210INT	PERIMETER PEEK, SMALL 4°-10MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3491212	PERIMETER I/F, SMALL, 4DEG, 12MM	Feb-2012	Rule 8	Annex II (-Section 4)	60847	15766
3491212INT	PERIMETER PEEK, SMALL 4°-12MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3491214	PERIMETER I/F, SMALL, 4DEG, 14MM	Feb-2012	Rule 8	Annex II (-Section 4)	60847	15766
3491214INT	PERIMETER PEEK, SMALL 4°-14MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3491216	PERIMETER I/F, SMALL, 4DEG, 16MM	Feb-2012	Rule 8	Annex II (-Section 4)	60847	15766
3491216INT	PERIMETER PEEK, SMALL 4°-16MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3491218	PERIMETER I/F, SMALL, 4DEG, 18MM	Feb-2012	Rule 8	Annex II (-Section 4)	60847	15766
3491218INT	PERIMETER PEEK, SMALL 4°-18MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3491220	PERIMETER I/F, SMALL, 4DEG, 20MM	Feb-2012	Rule 8	Annex II (-Section 4)	60847	15766
3491220INT	PERIMETER PEEK, SMALL 4°-20MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3492308INT	PERIMETER PEEK MEDIUM 8°-8 MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3492310INT	PERIMETER PEEK MEDIUM 8°-10MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3492312INT	PERIMETER PEEK MEDIUM 8°-12MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3492314INT	PERIMETER PEEK MEDIUM 8°-14MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3492316INT	PERIMETER PEEK MEDIUM 8°-16MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3492318INT	PERIMETER PEEK MEDIUM 8°-18MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3492320INT	PERIMETER PEEK MEDIUM 8°-20MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3493308INT	PERIMETER PEEK, LARGE 8°-8MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3493310INT	PERIMETER PEEK, LARGE 8°-10MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3493312INT	PERIMETER PEEK, LARGE 8°-12MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3493314INT	PERIMETER PEEK, LARGE 8°-14MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3493316INT	PERIMETER PEEK, LARGE 8°-16MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3493318INT	PERIMETER PEEK, LARGE 8°-18MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3493320INT	PERIMETER PEEK, LARGE 8°-20MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3493412INT	PERIMETER PEEK, LARGE 12°-12MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3493414INT	PERIMETER PEEK, LARGE 12°-14MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3493416INT	PERIMETER PEEK, LARGE 12°-16MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3493418INT	PERIMETER PEEK, LARGE 12°-18MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3493420INT	PERIMETER PEEK, LARGE 12°-20MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3493512	PERIMETER I/F, LARGE, 15DEG, 12MM	Feb-2012	Rule 8	Annex II (-Section 4)	60847	15766
3493512INT	PERIMETER PEEK LARGE 15°-12MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3493514	PERIMETER I/F, LARGE, 15DEG, 14MM	Feb-2012	Rule 8	Annex II (-Section 4)	60847	15766
3493514INT	PERIMETER PEEK LARGE 15°-14MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3493516	PERIMETER I/F, LARGE, 15DEG, 16MM	Feb-2012	Rule 8	Annex II (-Section 4)	60847	15766
3493516INT	PERIMETER PEEK LARGE 15°-16MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3493518	PERIMETER I/F, LARGE, 15DEG, 18MM	Feb-2012	Rule 8	Annex II (-Section 4)	60847	15766
3493518INT	PERIMETER PEEK LARGE 15°-18MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3493520	PERIMETER I/F, LARGE, 15DEG, 20MM	Feb-2012	Rule 8	Annex II (-Section 4)	60847	15766
3493520INT	PERIMETER PEEK LARGE 15°-20MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3494308INT	PERIMETER PEEK EXTRA LARGE 8°-8MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3494310INT	PERIMETER PEEK EXTRA LARGE 8°-10MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3494312INT	PERIMETER PEEK EXTRA LARGE 8°-12MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3494314INT	PERIMETER PEEK EXTRA LARGE 8°-14MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3494316INT	PERIMETER PEEK EXTRA LARGE 8°-16MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3494318INT	PERIMETER PEEK EXTRA LARGE 8°-18MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
3494320INT	PERIMETER PEEK EXTRA LARGE 8°-20MM	Sep-2007	Rule 8	Annex II (-Section 4)	60847	15766
X0305152	XL ADD-ON_8DEG_8MM	May-2005	Rule 8	Annex II (-Section 4)	60847	15766
X0305153	XL ADD-ON_8DEG_10MM	May-2005	Rule 8	Annex II (-Section 4)	60847	15766
X0305154	XL ADD-ON_8DEG_12MM	May-2005	Rule 8	Annex II (-Section 4)	60847	15766
X0305155	XL ADD-ON_8DEG_14MM	May-2005	Rule 8	Annex II (-Section 4)	60847	15766
X0305156	XL ADD-ON_8DEG_16MM	May-2005	Rule 8	Annex II (-Section 4)	60847	15766
X0305157	XL ADD-ON_8DEG_18MM	May-2005	Rule 8	Annex II (-Section 4)	60847	15766
X0305193	SPACER X0305193 PER XL ADDON 12 12MM PEK	2016-April	Rule 8	Annex II (-Section 4)	38161	15766
X0305194	SPACER X0305194 PER XL ADDON 12 14MM PEK	2016-April	Rule 8	Annex II (-Section 4)	38161	15766
X0305195	SPACER X0305195 PER XL ADDON 12 16MM PEK	2016-April	Rule 8	Annex II (-Section 4)	38161	15766
X0305196	SPACER X0305196 PER XL ADDON 12 18MM PEK	2016-April	Rule 8	Annex II (-Section 4)	38161	15766



Product List

Last updated by: Lila Joe
 Tech File Bundle: TL Fusion, TF010

Date: 12/1/2016

Product: PIVOX™ Oblique Lateral Spine System
 Class: llb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2140145	Lumbar Bone Screw, 5.5 x 45	Dec-2016	Rule 8	Annex II (-Section 4)	61324	15766
2140150	Lumbar Bone Screw, 5.5 x 50	Dec-2016	Rule 8	Annex II (-Section 4)	61324	15766
2110140	OLIF25 Interbody 20mm wide, 0 degree, 8x40	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110145	OLIF25 Interbody 20mm wide, 0 degree, 8x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110150	OLIF25 Interbody 20mm wide, 0 degree, 8x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110155	OLIF25 Interbody 20mm wide, 0 degree, 8x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110160	OLIF25 Interbody 20mm wide, 0 degree, 8x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110240	OLIF25 Interbody 20mm wide, 0 degree, 10x40	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110245	OLIF25 Interbody 20mm wide, 0 degree, 10x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110250	OLIF25 Interbody 20mm wide, 0 degree, 10x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110255	OLIF25 Interbody 20mm wide, 0 degree, 10x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110260	OLIF25 Interbody 20mm wide, 0 degree, 10x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110340	OLIF25 Interbody 20mm wide, 0 degree, 12x40	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110345	OLIF25 Interbody 20mm wide, 0 degree, 12x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110350	OLIF25 Interbody 20mm wide, 0 degree, 12x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110355	OLIF25 Interbody 20mm wide, 0 degree, 12x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110360	OLIF25 Interbody 20mm wide, 0 degree, 12x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110440	OLIF25 Interbody 20mm wide, 0 degree, 14x40	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110445	OLIF25 Interbody 20mm wide, 0 degree, 14x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110450	OLIF25 Interbody 20mm wide, 0 degree, 14x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110455	OLIF25 Interbody 20mm wide, 0 degree, 14x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110460	OLIF25 Interbody 20mm wide, 0 degree, 14x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110540	OLIF25 Interbody 20mm wide, 0 degree, 16x40	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110545	OLIF25 Interbody 20mm wide, 0 degree, 16x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110550	OLIF25 Interbody 20mm wide, 0 degree, 16x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110555	OLIF25 Interbody 20mm wide, 0 degree, 16x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2110560	OLIF25 Interbody 20mm wide, 0 degree, 16x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766

Tech File Bundle: TL Fusion, TF010

Product: PIVOX™ Oblique Lateral Spine System

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2111140	OLIF25 Interbody 20mm wide, 6 degree, 8x40	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111145	OLIF25 Interbody 20mm wide, 6 degree, 8x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111150	OLIF25 Interbody 20mm wide, 6 degree, 8x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111155	OLIF25 Interbody 20mm wide, 6 degree, 8x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111160	OLIF25 Interbody 20mm wide, 6 degree, 8x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111240	OLIF25 Interbody 20mm wide, 6 degree, 10x40	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111245	OLIF25 Interbody 20mm wide, 6 degree, 10x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111250	OLIF25 Interbody 20mm wide, 6 degree, 10x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111255	OLIF25 Interbody 20mm wide, 6 degree, 10x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111260	OLIF25 Interbody 20mm wide, 6 degree, 10x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111340	OLIF25 Interbody 20mm wide, 6 degree, 12x40	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111345	OLIF25 Interbody 20mm wide, 6 degree, 12x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111350	OLIF25 Interbody 20mm wide, 6 degree, 12x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111355	OLIF25 Interbody 20mm wide, 6 degree, 12x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111360	OLIF25 Interbody 20mm wide, 6 degree, 12x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111440	OLIF25 Interbody 20mm wide, 6 degree, 14x40	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111445	OLIF25 Interbody 20mm wide, 6 degree, 14x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111450	OLIF25 Interbody 20mm wide, 6 degree, 14x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111455	OLIF25 Interbody 20mm wide, 6 degree, 14x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111460	OLIF25 Interbody 20mm wide, 6 degree, 14x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111540	OLIF25 Interbody 20mm wide, 6 degree, 16x40	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111545	OLIF25 Interbody 20mm wide, 6 degree, 16x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111550	OLIF25 Interbody 20mm wide, 6 degree, 16x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111555	OLIF25 Interbody 20mm wide, 6 degree, 16x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2111560	OLIF25 Interbody 20mm wide, 6 degree, 16x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112240	OLIF25 Interbody 20mm wide, 12 degree, 10x40	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112245	OLIF25 Interbody 20mm wide, 12 degree, 10x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766

Tech File Bundle: TL Fusion, TF010

Product: PIVOX™ Oblique Lateral Spine System

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2112250	OLIF25 Interbody 20mm wide, 12 degree, 10x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112255	OLIF25 Interbody 20mm wide, 12 degree, 10x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112260	OLIF25 Interbody 20mm wide, 12 degree, 10x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112340	OLIF25 Interbody 20mm wide, 12 degree, 12x40	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112345	OLIF25 Interbody 20mm wide, 12 degree, 12x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112350	OLIF25 Interbody 20mm wide, 12 degree, 12x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112355	OLIF25 Interbody 20mm wide, 12 degree, 12x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112360	OLIF25 Interbody 20mm wide, 12 degree, 12x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112440	OLIF25 Interbody 20mm wide, 12 degree, 14x40	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112445	OLIF25 Interbody 20mm wide, 12 degree, 14x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112450	OLIF25 Interbody 20mm wide, 12 degree, 14x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112455	OLIF25 Interbody 20mm wide, 12 degree, 14x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112460	OLIF25 Interbody 20mm wide, 12 degree, 14x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112540	OLIF25 Interbody 20mm wide, 12 degree, 16x40	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112545	OLIF25 Interbody 20mm wide, 12 degree, 16x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112550	OLIF25 Interbody 20mm wide, 12 degree, 16x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112555	OLIF25 Interbody 20mm wide, 12 degree, 16x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112560	OLIF25 Interbody 20mm wide, 12 degree, 16x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112640	OLIF25 Interbody 20mm wide, 12 degree, 18x40	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112645	OLIF25 Interbody 20mm wide, 12 degree, 18x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112650	OLIF25 Interbody 20mm wide, 12 degree, 18x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112655	OLIF25 Interbody 20mm wide, 12 degree, 18x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2112660	OLIF25 Interbody 20mm wide, 12 degree, 18x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2113340	OLIF25 Interbody 20mm wide, 18 degree, 12x40	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2113345	OLIF25 Interbody 20mm wide, 18 degree, 12x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2113350	OLIF25 Interbody 20mm wide, 18 degree, 12x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2113355	OLIF25 Interbody 20mm wide, 18 degree, 12x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766

Tech File Bundle: TL Fusion, TF010

Product: PIVOX™ Oblique Lateral Spine System

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2113360	OLIF25 Interbody 20mm wide, 18 degree, 12x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2113440	OLIF25 Interbody 20mm wide, 18 degree, 14x40	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2113445	OLIF25 Interbody 20mm wide, 18 degree, 14x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2113450	OLIF25 Interbody 20mm wide, 18 degree, 14x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2113455	OLIF25 Interbody 20mm wide, 18 degree, 14x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2113460	OLIF25 Interbody 20mm wide, 18 degree, 14x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2113540	OLIF25 Interbody 20mm wide, 18 degree, 16x40	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2113545	OLIF25 Interbody 20mm wide, 18 degree, 16x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2113550	OLIF25 Interbody 20mm wide, 18 degree, 16x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2113555	OLIF25 Interbody 20mm wide, 18 degree, 16x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2113560	OLIF25 Interbody 20mm wide, 18 degree, 16x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2113640	OLIF25 Interbody 20mm wide, 18 degree, 18x40	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2113645	OLIF25 Interbody 20mm wide, 18 degree, 18x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2113650	OLIF25 Interbody 20mm wide, 18 degree, 18x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2113655	OLIF25 Interbody 20mm wide, 18 degree, 18x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2113660	OLIF25 Interbody 20mm wide, 18 degree, 18x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2131245	OLIF25 Interbody 27mm wide, 6 degree, 10x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2131250	OLIF25 Interbody 27mm wide, 6 degree, 10x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2131255	OLIF25 Interbody 27mm wide, 6 degree, 10x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2131260	OLIF25 Interbody 27mm wide, 6 degree, 10x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2131345	OLIF25 Interbody 27mm wide, 6 degree, 12x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2131350	OLIF25 Interbody 27mm wide, 6 degree, 12x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2131355	OLIF25 Interbody 27mm wide, 6 degree, 12x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2131360	OLIF25 Interbody 27mm wide, 6 degree, 12x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2131445	OLIF25 Interbody 27mm wide, 6 degree, 14x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2131450	OLIF25 Interbody 27mm wide, 6 degree, 14x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2131455	OLIF25 Interbody 27mm wide, 6 degree, 14x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766

Tech File Bundle: TL Fusion, TF010

Product: PIVOX™ Oblique Lateral Spine System

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2131460	OLIF25 Interbody 27mm wide, 6 degree, 14x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2131545	OLIF25 Interbody 27mm wide, 6 degree, 16x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2131550	OLIF25 Interbody 27mm wide, 6 degree, 16x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2131555	OLIF25 Interbody 27mm wide, 6 degree, 16x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2131560	OLIF25 Interbody 27mm wide, 6 degree, 16x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2132345	OLIF25 Interbody 27mm wide, 12 degree, 12x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2132350	OLIF25 Interbody 27mm wide, 12 degree, 12x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2132355	OLIF25 Interbody 27mm wide, 12 degree, 12x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2132360	OLIF25 Interbody 27mm wide, 12 degree, 12x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2132445	OLIF25 Interbody 27mm wide, 12 degree, 14x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2132450	OLIF25 Interbody 27mm wide, 12 degree, 14x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2132455	OLIF25 Interbody 27mm wide, 12 degree, 14x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2132460	OLIF25 Interbody 27mm wide, 12 degree, 14x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2132545	OLIF25 Interbody 27mm wide, 12 degree, 16x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2132550	OLIF25 Interbody 27mm wide, 12 degree, 16x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2132555	OLIF25 Interbody 27mm wide, 12 degree, 16x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2132560	OLIF25 Interbody 27mm wide, 12 degree, 16x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2132640	OLIF25 Interbody 27mm wide, 12 degree, 18x40	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2132645	OLIF25 Interbody 27mm wide, 12 degree, 18x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2132650	OLIF25 Interbody 27mm wide, 12 degree, 18x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2132655	OLIF25 Interbody 27mm wide, 12 degree, 18x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2132660	OLIF25 Interbody 27mm wide, 12 degree, 18x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2133445	OLIF25 Interbody 27mm wide, 18 degree, 14x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2133450	OLIF25 Interbody 27mm wide, 18 degree, 14x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2133455	OLIF25 Interbody 27mm wide, 18 degree, 14x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2133460	OLIF25 Interbody 27mm wide, 18 degree, 14x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2133545	OLIF25 Interbody 27mm wide, 18 degree, 16x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766

Tech File Bundle: TL Fusion, TF010

Product: PIVOX™ Oblique Lateral Spine System

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2133550	OLIF25 Interbody 27mm wide, 18 degree, 16x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2133555	OLIF25 Interbody 27mm wide, 18 degree, 16x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2133560	OLIF25 Interbody 27mm wide, 18 degree, 16x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2133645	OLIF25 Interbody 27mm wide, 18 degree, 18x45	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2133650	OLIF25 Interbody 27mm wide, 18 degree, 18x50	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2133655	OLIF25 Interbody 27mm wide, 18 degree, 18x55	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2133660	OLIF25 Interbody 27mm wide, 18 degree, 18x60	Jan-2016	Rule 8	Annex II (-Section 4)	38161	15766
2140001	OLIF25 2-hole Plate, Small	Jan-2016	Rule 8	Annex II (-Section 4)	46653	15766
2140002	OLIF25 2-hole Plate, Large	Jan-2016	Rule 8	Annex II (-Section 4)	46653	15766
2140120	Lumbar Bone Screw, 5.5 x 20	Jan-2016	Rule 8	Annex II (-Section 4)	61324	15766
2140125	Lumbar Bone Screw, 5.5 x 25	Jan-2016	Rule 8	Annex II (-Section 4)	61324	15766
2140130	Lumbar Bone Screw, 5.5 x 30	Jan-2016	Rule 8	Annex II (-Section 4)	61324	15766
2140135	Lumbar Bone Screw, 5.5 x 35	Jan-2016	Rule 8	Annex II (-Section 4)	61324	15766
2140140	Lumbar Bone Screw, 5.5 x 40	Jan-2016	Rule 8	Annex II (-Section 4)	61324	15766



Product List

Last updated by: Greg Maschek
 Tech File Bundle: TL Fusion, TF010

Date: 2/27/2015

Product: R90™Spacer Implants
 Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2900511S	9/7 X 6° X 21MM PEEK SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	60847	15766
2900512S	10/7 X 12° X 21MM PEEK SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	60847	15766
2900513S	11/9 X 6° X 21MM PEEK SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	60847	15766
2900514S	12/9 X 12° X 21MM PEEK SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	60847	15766
2900515S	13/11 X 6° X 21MM PEEK SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	60847	15766
2900516S	12/7 X 18° X 21MM PEEK SPACER	Sep-2003	Rule 8	Annex II (-Section 4)	60847	15766
2900517S	14/9 X 18° X 21MM PEEK SPACER	Sep-2003	Rule 8	Annex II (-Section 4)	60847	15766
2900521M	10/7 X 6° X 24MM PEEK SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	60847	15766
2900522M	11/7 X 12° X 24MM PEEK SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	60847	15766
2900523M	12/9 X 6° X 24MM PEEK SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	60847	15766
2900524M	13/9 X 12° X 24MM PEEK SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	60847	15766
2900525M	14/11 X 6° X 24MM PEEK SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	60847	15766
2900526M	15/11 X 12° X 24MM PEEK SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	60847	15766
2900527M	13/7 X 18° X 24MM PEEK SPACER	Sep-2003	Rule 8	Annex II (-Section 4)	60847	15766
2900528M	14/9 X 18° X 24MM PEEK SPACER	Sep-2003	Rule 8	Annex II (-Section 4)	60847	15766
2900531L	10/7 X 6° X 27MM PEEK SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	60847	15766
2900532L	12/7 X 12° X 27MM PEEK SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	60847	15766
2900533L	12/9 X 6° X 27MM PEEK SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	60847	15766
2900534L	14/9 X 12° X 27MM PEEK SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	60847	15766
2900535L	14/11 X 6° X 27MM PEEK SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	60847	15766
2900536L	16/11 X 12° X 27MM PEEK SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	60847	15766
2900537L	13/7 X 18° X 27MM PEEK SPACER	Sep-2003	Rule 8	Annex II (-Section 4)	60847	15766
2900538L	15/9 X 18° X 27MM PEEK SPACER	Sep-2003	Rule 8	Annex II (-Section 4)	60847	15766
2920511S	9/7 X 6° X 21MM TI SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	38161	15766
2920512S	10/7 X 12° X 21MM TI SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	38161	15766
2920513S	11/9 X 6° X 21MM TI SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	38161	15766
2920514S	12/9 X 12° X 21MM TI SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	38161	15766
2920515S	13/11 X 6° X 21MM TI SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	38161	15766
2920531L	10/7 X 6° X 27MM TI SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	38161	15766
2920532L	12/7 X 12° X 27MM TI SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	38161	15766
2920533L	12/9 X 6° X 27MM TI SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	38161	15766
2920534L	14/9 X 12° X 27MM TI SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	38161	15766
2920535L	14/11 X 6° X 27MM TI SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	38161	15766
2920536L	16/11 X 12° X 27MM TI SPACER	Feb-2003	Rule 8	Annex II (-Section 4)	38161	15766
XIB0801-036	11-12 DEGREE SPACER	Apr-2002	Rule 8	Annex II (-Section 4)	57805	15766



Product List

Last updated by: Greg Maschek

Date: 2/27/2015

Tech File Bundle: TL Fusion, TF010

Product: PYRAMID® Anterior Plate Fixation System Implants

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
8966525	6.5X25MM TAPER TIP BONE SCREW	Jun-2006	Rule 8	Annex II (-Section 4)	57805	15766
8966530	6.5X30MM TAPER TIP BONE SCREW	Jun-2006	Rule 8	Annex II (-Section 4)	57805	15766
8966535	6.5X35MM TAPER TIP BONE SCREW	Jun-2006	Rule 8	Annex II (-Section 4)	57805	15766
8968625	6.5X25 TAPERED BONE SCREW	Jun-2005	Rule 8	Annex II (-Section 4)	57805	15766
8968630	6.5X30 TAPERED BONE SCREW	Jun-2005	Rule 8	Annex II (-Section 4)	57805	15766
8968635	6.5X35 TAPERED BONE SCREW	Jun-2005	Rule 8	Annex II (-Section 4)	57805	15766
8968640	6.5X40 TAPERED BONE SCREW	Jun-2005	Rule 8	Annex II (-Section 4)	57805	15766
8968645	6.5X45 TAPERED BONE SCREW	Jun-2005	Rule 8	Annex II (-Section 4)	57805	15766
8968650	6.5X50 TAPERED BONE SCREW	Jun-2005	Rule 8	Annex II (-Section 4)	57805	15766
8968655	6.5X55 TAPERED BONE SCREW	Jun-2005	Rule 8	Annex II (-Section 4)	57805	15766
8969117	PLATE 17MM	May-2002	Rule 8	Annex II (-Section 4)	57805	15766
8969119	PLATE 19MM	May-2002	Rule 8	Annex II (-Section 4)	57805	15766
8969121	PLATE 21MM	May-2002	Rule 8	Annex II (-Section 4)	57805	15766
8969123	PLATE 23MM	May-2002	Rule 8	Annex II (-Section 4)	57805	15766
8969125	PLATE 25MM	May-2002	Rule 8	Annex II (-Section 4)	57805	15766
8969127	PLATE 27MM	May-2002	Rule 8	Annex II (-Section 4)	57805	15766
8969201	LOCKING PLATE SET SCREW	May-2002	Rule 8	Annex II (-Section 4)	57805	15766
8969217	17MM PYRAMID COVER PLATE	May-2002	Rule 8	Annex II (-Section 4)	57805	15766
8969219	19MM PYRAMID COVER PLATE	May-2002	Rule 8	Annex II (-Section 4)	57805	15766
8969221	21MM PYRAMID COVER PLATE	May-2002	Rule 8	Annex II (-Section 4)	57805	15766
8969223	23MM PYRAMID COVER PLATE	May-2002	Rule 8	Annex II (-Section 4)	57805	15766
8969225	25MM PYRAMID COVER PLATE	May-2002	Rule 8	Annex II (-Section 4)	57805	15766
8969227	27MM PYRAMID COVER PLATE	May-2002	Rule 8	Annex II (-Section 4)	57805	15766
8969417	17MM PYRAMID LOCKING PLATE	Jun-2010	Rule 8	Annex II (-Section 4)	57805	15766
8969419	19MM PYRAMID LOCKING PLATE	Jun-2010	Rule 8	Annex II (-Section 4)	57805	15766
8969421	21MM PYRAMID LOCKING PLATE	Jun-2010	Rule 8	Annex II (-Section 4)	57805	15766
8969423	23MM PYRAMID LOCKING PLATE	Jun-2010	Rule 8	Annex II (-Section 4)	57805	15766
8969425	25MM PYRAMID LOCKING PLATE	Jun-2010	Rule 8	Annex II (-Section 4)	57805	15766
8969427	27MM PYRAMID LOCKING PLATE	Jun-2010	Rule 8	Annex II (-Section 4)	57805	15766



Product List

Last updated by: Greg Maschek
Tech File Bundle: TL Fusion, TF010

Date: 2/27/2015

Product: PYRAMID® +4 Anterior Plate Fixation System Implants

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
98716200	SCREW 98716200 BONE VAR ANGLE 6.5 X 20	Apr-2009	Rule 8	Annex II (-Section 4)	57805	15766
98716225	SCREW 98716225 BONE VAR ANGLE 6.5 X 22.5	Jun-2010	Rule 8	Annex II (-Section 4)	57805	15766
98716250	SCREW 98716250 BONE VAR ANGLE 6.5 X 25	Mar-2008	Rule 8	Annex II (-Section 4)	57805	15766
98716275	SCREW 98716275 BONE VAR ANGLE 6.5 X 27.5	Jun-2010	Rule 8	Annex II (-Section 4)	57805	15766
98716300	SCREW 98716300 BONE VAR ANGLE 6.5 X 30	Mar-2008	Rule 8	Annex II (-Section 4)	57805	15766
98716325	SCREW 98716325 BONE VAR ANGLE 6.5 X 32.5	Jun-2010	Rule 8	Annex II (-Section 4)	57805	15766
98716350	SCREW 98716350 BONE VAR ANGLE 6.5 X 35	Mar-2008	Rule 8	Annex II (-Section 4)	57805	15766
9873033	PLATE 9873033 3HOLE 33MM	Sep-2009	Rule 8	Annex II (-Section 4)	57805	15766
9873035	PLATE 9873035 3HOLE 35MM	Sep-2009	Rule 8	Annex II (-Section 4)	57805	15766
9873037	PLATE 9873037 3HOLE 37MM	Sep-2009	Rule 8	Annex II (-Section 4)	57805	15766
9873039	PLATE 9873039 3HOLE 39MM	Sep-2009	Rule 8	Annex II (-Section 4)	57805	15766
9873041	PLATE 9873041 3HOLE 41MM	Sep-2009	Rule 8	Annex II (-Section 4)	57805	15766
9873133	Lordotic 3-Hole Plate Assembly, L=33mm	Aug-2009	Rule 8	Annex II (-Section 4)	57805	15766
9873135	Lordotic 3-Hole Plate Assembly, L=35mm	Aug-2009	Rule 8	Annex II (-Section 4)	57805	15766
9873137	Lordotic 3-Hole Plate Assembly, L=37mm	Aug-2009	Rule 8	Annex II (-Section 4)	57805	15766
9873139	Lordotic 3-Hole Plate Assembly, L=39mm	Aug-2009	Rule 8	Annex II (-Section 4)	57805	15766
9873141	Lordotic 3-Hole Plate Assembly, L=41mm	Aug-2009	Rule 8	Annex II (-Section 4)	57805	15766
9874035	PLATE 9874035 4HOLE 35MM	Mar-2008	Rule 8	Annex II (-Section 4)	57805	15766
9874037	PLATE 9874037 4HOLE 37MM	Mar-2008	Rule 8	Annex II (-Section 4)	57805	15766
9874039	PLATE 9874039 4HOLE 39MM	Mar-2008	Rule 8	Annex II (-Section 4)	57805	15766
9874041	PLATE 9874041 4HOLE 41MM	Mar-2008	Rule 8	Annex II (-Section 4)	57805	15766
9874043	PLATE 9874043 4HOLE 43MM	Mar-2008	Rule 8	Annex II (-Section 4)	57805	15766
9874045	PLATE 9874045 4HOLE 45MM	Mar-2008	Rule 8	Annex II (-Section 4)	57805	15766



Product List

Last updated by: **Kanesha Hines**
 Tech File Bundle: **TL Fusion, TF010**

Date: **12/20/2016**

Product: **SOVEREIGN™ Spinal System Implants**
 Class: **IIB**

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
7967211INT	ASSEMBLY 7967211INT S 32X23 11MM 12DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7967213INT	ASSEMBLY 7967213INT S 32X23 13MM 12DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7967215INT	ASSEMBLY 7967215INT S 32X23 15MM 12DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7967217INT	ASSEMBLY 7967217INT S 32X23 17MM 12DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7967219INT	ASSEMBLY 7967219INT S 32X23 19MM 12DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7967221INT	ASSEMBLY 7967221INT S 32X23 21MM 12DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7967223INT	ASSEMBLY 7967223INT S 32X23 23MM 12DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7967811INT	ASSEMBLY 7967811INT S 32X23 11MM 8DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7967813INT	ASSEMBLY 7967813INT S 32X23 13MM 8DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7967815INT	ASSEMBLY 7967815INTS 32X23 15MM 8DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7967817INT	ASSEMBLY 7967817INT S 32X23 17MM 8DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7967819INT	ASSEMBLY 7967819INT S 32X23 19MM 8DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7967821INT	ASSEMBLY 7967821INT S 32X23 21MM 8DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7967823INT	ASSEMBLY 7967823INT S 32X23 23MM 8DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7968211INT	ASSEMBLY 7968211INT M 37X27 11MM 12 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7968213INT	ASSEMBLY 7968213INT M 37X27 13MM 12 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7968215INT	ASSEMBLY 7968215INT M 37X27 15MM 12 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7968217INT	ASSEMBLY 7968217INT M 37X27 17MM 12 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7968219INT	ASSEMBLY 7968219INT M 37X27 19MM 12 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7968221INT	ASSEMBLY 7968221INT M 37X27 21MM 12 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7968223INT	ASSEMBLY 7968223INT M 37X27 23MM 12 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7968811INT	ASSEMBLY 7968811INT M 37X27 11MM 8 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7968813INT	ASSEMBLY 7968813INT M 37X27 13MM 8 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7968815INT	ASSEMBLY 7968815INT M 37X27 15MM 8 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7968817INT	ASSEMBLY 7968817INT M 37X27 17MM 8 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7968819INT	ASSEMBLY 7968819INT M 37X27 19MM 8 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7968821INT	ASSEMBLY 7968821INT M 37X27 21MM 8 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7968823INT	ASSEMBLY 7968823INT M 37X27 23MM 8 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766



Tech File Bundle: TL Fusion, TF010

Product: SOVEREIGN™ Spinal System Implants

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
7969211INT	ASSEMBLY 7969211INT L 42X30 11MM 12 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7969213INT	ASSEMBLY 7969213INT L 42X30 13MM 12 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7969215INT	ASSEMBLY 7969215INT L 42X30 15MM 12 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7969217INT	ASSEMBLY 7969217INT L 42X30 17MM 12 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7969219INT	ASSEMBLY 7969219INT L 42X30 19MM 12 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7969221INT	ASSEMBLY 7969221INT L 42X30 21MM 12 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7969223INT	ASSEMBLY 7969223INT L 42X30 23MM 12 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7969811INT	ASSEMBLY 7969811INT L 42X30 11MM 8 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7969813INT	ASSEMBLY 7969813INT L 42X30 13MM 8 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7969815INT	ASSEMBLY 7969815INT L 42X30 15MM 8 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7969817INT	ASSEMBLY 7969817INT L 42X30 17MM 8 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7969819INT	ASSEMBLY 7969819INT L 42X30 19MM 8 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7969821INT	ASSEMBLY 7969821INT L 42X30 21MM 8 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7969823INT	ASSEMBLY 7969823INT L 42X30 23MM 8 DEG	Sep-2009	Rule 8	Annex II (-Section 4)	60847	15766
7965520INT	SOVEREIGN SCREW, 5.5 X 20MM (INT)	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7965525INT	SOVEREIGN SCREW, 5.5 X 25MM (INT)	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7965530INT	SOVEREIGN SCREW, 5.5 X 30MM (INT)	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7965535INT	SOVEREIGN SCREW, 5.5 X 35MM (INT)	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7966020INT	SOVEREIGN SCREW, 6.0 X 20MM (INT)	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7966025INT	SOVEREIGN SCREW, 6.0 X 25MM (INT)	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7966030INT	SOVEREIGN SCREW, 6.0 X 30MM (INT)	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7966035INT	SOVEREIGN SCREW, 6.0 X 35MM (INT)	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7967210INT	ASSEMBLY 7967210INT S 32X23 10MM 12DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7967212INT	ASSEMBLY 7967212INT S 32X23 12MM 12DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7967214INT	ASSEMBLY 7967214INT S 32X23 14MM 12DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7967216INT	ASSEMBLY 7967216INT S 32X23 16MM 12DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7967218INT	ASSEMBLY 7967218INT S 32X23 18MM 12DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7967220INT	ASSEMBLY 7967220INT S 32X23 20MM 12DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7967222INT	ASSEMBLY 7967222INT S 32X23 22MM 12DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7967224INT	ASSEMBLY 7967224INT S 32X23 24MM 12DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766



Tech File Bundle: TL Fusion, TF010

Product: SOVEREIGN™ Spinal System Implants

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
7967810INT	ASSEMBLY 7967810INT S 32X23 10MM 8DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7967812INT	ASSEMBLY 7967812INT S 32X23 12MM 8DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7967814INT	ASSEMBLY 7967814INT S 32X23 14MM 8DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7967816INT	ASSEMBLY 7967816INT S 32X23 16MM 8DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7967818INT	ASSEMBLY 7967818INT S 32X23 18MM 8DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7967820INT	ASSEMBLY 7967820INT S 32X23 20MM 8DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7967822INT	ASSEMBLY 7967822INT S 32X23 22MM 8DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7967824INT	ASSEMBLY 7967824INT S 32X23 24MM 8DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7968210INT	ASSEMBLY 7968210INT M 37X27 10MM 12 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7968212INT	ASSEMBLY 7968212INT M 37X27 12MM 12 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7968214INT	ASSEMBLY 7968214INT M 37X27 14MM 12 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7968216INT	ASSEMBLY 7968216INT M 37X27 16MM 12 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7968218INT	ASSEMBLY 7968818INT M 37X27 18MM 12 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7968220INT	ASSEMBLY 7968220INT M 37X27 20MM 12 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7968222INT	ASSEMBLY 7968222INT M 37X27 22MM 12 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7968224INT	ASSEMBLY 7968224INT M 37X27 24MM 12 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7968810INT	ASSEMBLY 7968810INT M 37X27 10MM 8 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7968812INT	ASSEMBLY 7968812INT M 37X27 12MM 8 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7968814INT	ASSEMBLY 7968814INT M 37X27 14MM 8 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7968816INT	ASSEMBLY 7968816INT M 37X27 16MM 8 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7968818INT	ASSEMBLY 7968818INT M 37X27 18MM 8 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7968820INT	ASSEMBLY 7968820INT M 37X27 20MM 8 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7968822INT	ASSEMBLY 7968822INT M 37X27 22MM 8 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7968824INT	ASSEMBLY 7968824INT M 37X27 24MM 8 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7969210INT	ASSEMBLY 7969210INT L 42X30 10MM 12DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7969212INT	ASSEMBLY 7969212INT L 42X30 12MM 12 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7969214INT	ASSEMBLY 7969214INT L 42X30 14MM 12 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7969216INT	ASSEMBLY 7969216INT L 42X30 16MM 12 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7969218INT	ASSEMBLY 7969218INT L 42X30 18MM 12 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7969220INT	ASSEMBLY 7969220INT L 42X30 20MM 12 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766



Tech File Bundle: TL Fusion, TF010

Product: SOVEREIGN™ Spinal System Implants

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
7969222INT	ASSEMBLY 7969222INT L 42X30 22MM 12 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7969224INT	ASSEMBLY 7969224INT L 42X30 24MM 12 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7969810INT	ASSEMBLY 7969810INT L 42X30 10MM 8 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7969812INT	ASSEMBLY 7969812INT L 42X30 12MM 8 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7969814INT	ASSEMBLY 7969814INT L 42X30 14MM 8 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7969816INT	ASSEMBLY 7969816INT L 42X30 16MM 8 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7969818INT	ASSEMBLY 7969818INT L 42X30 18MM 8 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7969820INT	ASSEMBLY 7969820INT L 42X30 20MM 8 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7969822INT	ASSEMBLY 7969822INT L 42X30 22MM 8 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7969824INT	ASSEMBLY 7969824INT L 42X30 24MM 8 DEG	Nov 2009	Rule 8	Annex II (-Section 4)	60847	15766
7975520INT	SCREW SOVEREIGN FA, 5.5 X 20MM	Dec 2011	Rule 8	Annex II (-Section 4)	60847	15766
7975525INT	SCREW SOVEREIGN™ FA, 5.5 X 25MM	Dec 2011	Rule 8	Annex II (-Section 4)	60847	15766
7975530INT	SCREW SOVEREIGN™ FA, 5.5 X 30MM	Dec 2011	Rule 8	Annex II (-Section 4)	60847	15766
7975535INT	SCREW SOVEREIGN™ FA, 5.5 X 35MM	Dec 2011	Rule 8	Annex II (-Section 4)	60847	15766
7976020INT	SCREW SOVEREIGN™ FA, 6.0 X 20MM	Dec 2011	Rule 8	Annex II (-Section 4)	60847	15766
7976025INT	SCREW SOVEREIGN™ FA, 6.0 X 25MM	Dec 2011	Rule 8	Annex II (-Section 4)	60847	15766
7976030INT	SCREW SOVEREIGN™ FA, 6.0 X 30MM	Dec 2011	Rule 8	Annex II (-Section 4)	60847	15766
7976035INT	SCREW SOVEREIGN™ FA, 6.0 X 35MM	Dec 2011	Rule 8	Annex II (-Section 4)	60847	15766



Product List

Last updated by: Greg Maschek
 Tech File Bundle: TL Fusion, TF010

Date: 2/27/2015

Product: TELAMON™ Ti Fusion Device Implants
 Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
907-116	IMPCTD TI IMPLNT 12/26MM 3 DEG	Apr-2001	Rule 8	Annex II (-Section 4)	57805	15766
907-117	IMPCTD TI IMPLNT 12/22MM-3 DEG	Apr-2001	Rule 8	Annex II (-Section 4)	57805	15766
907-126	IMPCTD TI IMPLNT 12/26MM-8 DEG	Jul-2008	Rule 8	Annex II (-Section 4)	57805	15766
907-127	IMPCTD TI IMPLNT 12/22MM-8 DEG	Jul-2008	Rule 8	Annex II (-Section 4)	57805	15766
907-173	IMPACTD TI IMPLNT 8/26MM-8 DEG	Jul-2008	Rule 8	Annex II (-Section 4)	57805	15766
907-174	IMPACTD TI IMPLNT 8/22MM-8 DEG	Jul-2008	Rule 8	Annex II (-Section 4)	57805	15766
907-176	IMPACTD TI IMPLNT 8/26MM-3 DEG	Apr-2001	Rule 8	Annex II (-Section 4)	57805	15766
907-177	IMPACTD TI IMPLNT 8/22MM-3 DEG	Apr-2001	Rule 8	Annex II (-Section 4)	57805	15766
907-193	IMPCTD TI IMPLNT 10/26MM-8 DEG	Jul-2008	Rule 8	Annex II (-Section 4)	57805	15766
907-194	IMPCTD TI IMPLNT 10/22MM-8 DEG	Jul-2008	Rule 8	Annex II (-Section 4)	57805	15766
907-196	IMPCTD TI IMPLNT 10/26MM-3 DEG	Apr-2001	Rule 8	Annex II (-Section 4)	57805	15766
907-197	IMPCTD TI IMPLNT 10/22MM-3 DEG	Apr-2001	Rule 8	Annex II (-Section 4)	57805	15766
GX0712724	IMPCTD TI IMPLNT 7/24MM 3DEG	Jul-2005	Rule 8	Annex II (-Section 4)	38161	15766
GX0712824	IMPCTD TI IMPLNT 8/24MM 3DEG	Jul-2005	Rule 8	Annex II (-Section 4)	38161	15766
GX0712924	IMPCTD TI IMPLNT 9/24MM 3DEG	Jul-2005	Rule 8	Annex II (-Section 4)	38161	15766
GX0804218	IMPCTD TI IMPLNT 10/22MM 3DEG	Jul-2005	Rule 8	Annex II (-Section 4)	38161	15766
GXIB0201H027	IMPACTED IMP-TI-10/22MM 5-STER	Jan-2005	Rule 8	Annex II (-Section 4)	38161	15766
GXIB0602H014	IMPCTD TI IMPLNT10/18-8°, STER	Jan-2005	Rule 8	Annex II (-Section 4)	38161	15766
GXIB0602H015	IMPCTD TI IMPLNT10/20-3°, STER	Jan-2005	Rule 8	Annex II (-Section 4)	38161	15766
GXIB0801H035	IMPACTED 10/22MM-12DEG, STER	Jan-2005	Rule 8	Annex II (-Section 4)	38161	15766
GXIB0900H001	IMPACTED TI IMPLANT, STERILE	Jan-2005	Rule 8	Annex II (-Section 4)	38161	15766
GXIB0900H002	IMPACTED TI IMPLANT, STERILE	Jan-2005	Rule 8	Annex II (-Section 4)	38161	15766
GXIB0900H004	IMPACTED TI IMPLANT, STERILE	Jan-2005	Rule 8	Annex II (-Section 4)	38161	15766
X0105091	IMPACTED TI IMPLANT 3-9/22	Mar-2005	Rule 8	Annex II (-Section 4)	38161	15766
X0105093	IMPACTED TI IMPLANT 8-9/22	Mar-2005	Rule 8	Annex II (-Section 4)	38161	15766
X0105094	IMPACTED TI IMPLANT 8-9/26	Mar-2005	Rule 8	Annex II (-Section 4)	38161	15766
X0105096	IMPACTED TI IMPLANT 3-11/26	Mar-2005	Rule 8	Annex II (-Section 4)	38161	15766
X0105097	IMPACTED TI IMPLANT 8-11/22	Mar-2005	Rule 8	Annex II (-Section 4)	38161	15766
X0105098	IMPACTED TI IMPLANT 8-11/26	Mar-2005	Rule 8	Annex II (-Section 4)	38161	15766
X0105099	IMPACTED TI IMPLANT 8-13/22	Mar-2005	Rule 8	Annex II (-Section 4)	38161	15766
X0105100	IMPACTED TI IMPLANT 3-13/26	Mar-2005	Rule 8	Annex II (-Section 4)	38161	15766
X0712824	IMPCTD TI IMPLNT 8/24MM 3DEG	Sep-2004	Rule 8	Annex II (-Section 4)	57805	15766
X0804219	IMPCTD TI IMPLNT 8/22MM 3DEG	Aug-2005	Rule 8	Annex II (-Section 4)	57805	15766
X1004820	IMPCTD TI IMPLNT 13/26MM 3DEG	Nov-2004	Rule 8	Annex II (-Section 4)	57805	15766
X1004822	IMPCTD TI IMPLNT 15/26MM 3DEG	Nov-2004	Rule 8	Annex II (-Section 4)	57805	15766
XIB0801-039	11/9 X 6° X 22 TI SPACER	Jun-2002	Rule 8	Annex II (-Section 4)	57805	15766
XIB0801-040	13/9 X 12° X 22 TI SPACER	Jun-2002	Rule 8	Annex II (-Section 4)	57805	15766
XIB0801-041	13/11 X 6° X 22 TI SPACER	Jun-2002	Rule 8	Annex II (-Section 4)	57805	15766



Product List

Last updated by: Greg Maschek
 Tech File Bundle: TL Fusion, TF010

Date: 2/27/2015

Product: TELAMON™ – PEEK Fusion Device Implants
 Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
4200228INT	TELAMON-P 8° 10 X 22MM IMPLANT	Apr-2002	Rule 8	Annex II (-Section 4)	60847	15766
4200268INT	TELAMON-P 8° 10 X 26MM IMPLANT	Apr-2002	Rule 8	Annex II (-Section 4)	60847	15766
4200822INT	TELAMON-P 3° 8 X 22MM IMPLANT	Apr-2002	Rule 8	Annex II (-Section 4)	60847	15766
4200826INT	TELAMON-P 3° 8 X 26MM IMPLANT	Apr-2002	Rule 8	Annex II (-Section 4)	60847	15766
4201022INT	TELAMON-P 3° 10 X 22MM IMPLANT	Apr-2002	Rule 8	Annex II (-Section 4)	60847	15766
4201026INT	TELAMON-P 3° 10 X 26MM IMPLANT	Apr-2002	Rule 8	Annex II (-Section 4)	60847	15766
4201222INT	TELAMON-P 3° 12 X 22MM IMPLANT	Apr-2002	Rule 8	Annex II (-Section 4)	60847	15766
4201226INT	TELAMON-P 3° 12 X 26MM IMPLANT	Apr-2002	Rule 8	Annex II (-Section 4)	60847	15766
4201422INT	TELAMON-P 3° 14 X 22MM IMPLANT	Apr-2002	Rule 8	Annex II (-Section 4)	60847	15766
4201426INT	TELAMON-P 3° 14 X 26MM IMPLANT	Apr-2002	Rule 8	Annex II (-Section 4)	60847	15766
4202228INT	TELAMON-P 8° 12 X 22MM IMPLANT	Apr-2002	Rule 8	Annex II (-Section 4)	60847	15766
4202268INT	TELAMON-P 8° 12 X 26MM IMPLANT	Apr-2002	Rule 8	Annex II (-Section 4)	60847	15766
4204228INT	TELAMON-P 8° 14 X 22MM IMPLANT	Apr-2002	Rule 8	Annex II (-Section 4)	60847	15766
4204268INT	TELAMON-P 8° 14 X 26MM IMPLANT	Apr-2002	Rule 8	Annex II (-Section 4)	60847	15766
4208228INT	TELAMON-P 8° 8 X 22MM IMPLANT	Apr-2002	Rule 8	Annex II (-Section 4)	60847	15766
4208268INT	TELAMON-P 8° 8 X 26MM IMPLANT	Apr-2002	Rule 8	Annex II (-Section 4)	60847	15766



Product List

Last updated by: Greg Maschek
 Tech File Bundle: TL Fusion, TF010

Date: 2/27/2015

Product: VANTAGE™ Anterior Fixation System Implants

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
9330000	LOCK NUT, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9330001	THORACIC STAPLE, ROSTRAL, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9330002	THORACIC STAPLE, CAUDAL, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9330003	ATL STAPLE, ROSTRAL, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9330004	ATL STAPLE, CAUDAL, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9330040	4CM ATL PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9330045	4.5CM ATL PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9330050	5CM ATL PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9330055	5.5CM ATL PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9330060	6CM ATL PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9330065	6.5CM ATL PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9330070	7CM ATL PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9330075	7.5CM ATL PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9330080	8CM ATL PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9330085	8.5CM ATL PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9330090	9CM ATL PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9330095	9.5CM ATL PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9330100	10CM ATL PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9331025	2.5CM THORACIC PLATE, TI	Oct-2003	Rule 8	Annex II (-Section 4)	57805	15766
9331030	3CM THORACIC PLATE, TI	Oct-2003	Rule 8	Annex II (-Section 4)	57805	15766
9331035	3.5CM THORACIC PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9331040	4CM THORACIC PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9331045	4.5CM THORACIC PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9331050	5CM THORACIC PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9331055	5.5CM THORACIC PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9331060	6CM THORACIC PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9331065	6.5CM THORACIC PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9331070	7CM THORACIC PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9331075	7.5CM THORACIC PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9331080	8CM THORACIC PLATE, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9335515	5.5X15MM SCREW, THORACIC, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9335520	5.5X20MM SCREW, THORACIC, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9335525	5.5X25MM SCREW, THORACIC, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9335530	5.5X30MM SCREW, THORACIC, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9335535	5.5X35MM SCREW, THORACIC, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9335540	5.5X40MM SCREW, THORACIC, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9335545	5.5X45MM SCREW, THORACIC, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9335550	5.5X50MM SCREW, THORACIC, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9336525	6.5X25MM SCREW, ATL, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9336530	6.5X30MM SCREW, ATL, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9336535	6.5X35MM SCREW, ATL, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9336540	6.5X40MM SCREW, ATL, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9336545	6.5X45MM SCREW, ATL, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9336550	6.5X50MM SCREW, ATL, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9336555	6.5X55MM SCREW, ATL, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9336560	6.5X60MM SCREW, ATL, TI	Feb-2003	Rule 8	Annex II (-Section 4)	57805	15766
9338020	8.0X20MM BOLT, TI	Jul-2003	Rule 8	Annex II (-Section 4)	57805	15766
9338025	8.0X25MM BOLT, TI	Jul-2003	Rule 8	Annex II (-Section 4)	57805	15766
9338030	8.0X30MM BOLT, TI	Jul-2003	Rule 8	Annex II (-Section 4)	57805	15766



Tech File Bundle: TL Fusion, TF010

Product: VANTAGE™ Anterior Fixation System Implants

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
9338035	8.0X35MM BOLT, TI	Jul-2003	Rule 8	Annex II (-Section 4)	57805	15766
9338040	8.0X40MM BOLT, TI	Jul-2003	Rule 8	Annex II (-Section 4)	57805	15766
9338045	8.0X45MM BOLT, TI	Jan-2005	Rule 8	Annex II (-Section 4)	57805	15766
9338050	8.0X50MM BOLT, TI	Jan-2005	Rule 8	Annex II (-Section 4)	57805	15766
9338055	8.0X55MM BOLT, TI	Jan-2005	Rule 8	Annex II (-Section 4)	57805	15766
9338920	9.0X20MM BOLT, TI	Jul-2003	Rule 8	Annex II (-Section 4)	57805	15766
9338925	9.0X25MM BOLT, TI	Jul-2003	Rule 8	Annex II (-Section 4)	57805	15766
9338930	9.0X30MM BOLT, TI	Jul-2003	Rule 8	Annex II (-Section 4)	57805	15766
9338935	9.0X35MM BOLT, TI	Jul-2003	Rule 8	Annex II (-Section 4)	57805	15766
9338940	9.0X40MM BOLT, TI	Jul-2003	Rule 8	Annex II (-Section 4)	57805	15766
9338945	9.0X45MM BOLT, TI	Jan-2005	Rule 8	Annex II (-Section 4)	57805	15766
9338950	9.0X50MM BOLT, TI	Jan-2005	Rule 8	Annex II (-Section 4)	57805	15766
9338955	9.0X55MM BOLT, TI	Jan-2005	Rule 8	Annex II (-Section 4)	57805	15766

Product List

Last updated by: Buanita Benson

Date: 5/9/2018

Tech File Bundle: TL Fusion, TF010

Product: WAVE D Spinal System

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2660924	WAVE D CAGE 9mmx24mm 6deg	Aug 2013	Rule 8	Annex II - Section 4	38161	15766
2661024	WAVE D CAGE 10mmx24mm 6deg	Aug 2013	Rule 8	Annex II - Section 4	38161	15766
2661124	WAVE D CAGE 11mmx24mm 6deg	Aug 2013	Rule 8	Annex II - Section 4	38161	15766
2661224	WAVE D CAGE 12mmx24mm 6deg	Aug 2013	Rule 8	Annex II - Section 4	38161	15766
2661324	WAVE D CAGE 13mmx24mm 6deg	Aug 2013	Rule 8	Annex II - Section 4	38161	15766
2661424	WAVE D CAGE 14mmx24mm 6deg	Aug 2013	Rule 8	Annex II - Section 4	38161	15766
2620924	WAVE D CAGE 9mmx24mm 12deg	Aug 2013	Rule 8	Annex II - Section 4	38161	15766
2621024	WAVE D CAGE 10mmx24mm 12deg	Aug 2013	Rule 8	Annex II - Section 4	38161	15766
2621124	WAVE D CAGE 11mmx24mm 12deg	Aug 2013	Rule 8	Annex II - Section 4	38161	15766
2621224	WAVE D CAGE 12mmx24mm 12deg	Aug 2013	Rule 8	Annex II - Section 4	38161	15766
2621324	WAVE D CAGE 13mmx24mm 12deg	Aug 2013	Rule 8	Annex II - Section 4	38161	15766
2621424	WAVE D CAGE 14mmx24mm 12deg	Aug 2013	Rule 8	Annex II - Section 4	38161	15766
X0113130	CAGE WAVE D 10mm x 28mm 6Deg	May 2014	Rule 8	Annex II - Section 4	38161	15766
X0113131	CAGE WAVE D 11mm x 28mm 6Deg	May 2014	Rule 8	Annex II - Section 4	38161	15766
X0113132	CAGE WAVE D 12mm x 28mm 6Deg	May 2014	Rule 8	Annex II - Section 4	38161	15766
X0113133	CAGE WAVE D 13mm x 28mm 6Deg	May 2014	Rule 8	Annex II - Section 4	38161	15766

Product List

Last updated by: Buanita Benson

Date: 5/9/2018

Tech File Bundle: TL Fusion, TF010

Product: WAVE O Spinal System

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
2760922	WAVE O Cage 9mm x 22mm x 6deg	July 2013	Rule 8	Annex II - Section 4	38161	15766
2760926	WAVE O Cage 9mm x 26mm x 6deg	July 2013	Rule 8	Annex II - Section 4	38161	15766
2761022	WAVE O Cage 10mm x 22mm x 6deg	July 2013	Rule 8	Annex II - Section 4	38161	15766
2761026	WAVE O Cage 10mm x 26mm x 6deg	July 2013	Rule 8	Annex II - Section 4	38161	15766
2761122	WAVE O Cage 11mm x 22mm x 6deg	July 2013	Rule 8	Annex II - Section 4	38161	15766
2761126	WAVE O Cage 11mm x 26mm x 6deg	July 2013	Rule 8	Annex II - Section 4	38161	15766
2761222	WAVE O Cage 12mm x 22mm x 6deg	July 2013	Rule 8	Annex II - Section 4	38161	15766
2761226	WAVE O Cage 12mm x 26mm x 6deg	July 2013	Rule 8	Annex II - Section 4	38161	15766
2761322	WAVE O Cage 13mm x 22mm x 6deg	July 2013	Rule 8	Annex II - Section 4	38161	15766
2761326	WAVE O Cage 13mm x 26mm x 6deg	July 2013	Rule 8	Annex II - Section 4	38161	15766
2761422	WAVE O Cage 14mm x 22mm x 6deg	July 2013	Rule 8	Annex II - Section 4	38161	15766
2761426	WAVE O Cage 14mm x 26mm x 6deg	July 2013	Rule 8	Annex II - Section 4	38161	15766
2720922	WAVE O Cage 9mm x 22mm x 12deg	July 2013	Rule 8	Annex II - Section 4	38161	15766
2720926	WAVE O Cage 9mm x 26mm x 12deg	July 2013	Rule 8	Annex II - Section 4	38161	15766
2721022	WAVE O Cage 10mm x 22mm x 12deg	July 2013	Rule 8	Annex II - Section 4	38161	15766
2721026	WAVE O Cage 10mm x 26mm x 12deg	July 2013	Rule 8	Annex II - Section 4	38161	15766
2721122	WAVE O Cage 11mm x 22mm x 12deg	July 2013	Rule 8	Annex II - Section 4	38161	15766
2721126	WAVE O Cage 11mm x 26mm x 12deg	July 2013	Rule 8	Annex II - Section 4	38161	15766
2721222	WAVE O Cage 12mm x 22mm x 12deg	July 2013	Rule 8	Annex II - Section 4	38161	15766
2721226	WAVE O Cage 12mm x 26mm x 12deg	July 2013	Rule 8	Annex II - Section 4	38161	15766
2721322	WAVE O Cage 13mm x 22mm x 12deg	July 2013	Rule 8	Annex II - Section 4	38161	15766
2721326	WAVE O Cage 13mm x 26mm x 12deg	July 2013	Rule 8	Annex II - Section 4	38161	15766

2721422	WAVE O Cage 14mm x 22mm x 12deg	July 2013	Rule 8	Annex II - Section 4	38161	15766
2721426	WAVE O Cage 14mm x 26mm x 12deg	July 2013	Rule 8	Annex II - Section 4	38161	15766



Product List

Last updated by: Greg Maschek

Date: 2/27/2015

Tech File Bundle: TL Fusion, TF010

Product: ZPLATE II™ Anterior Fixation System Implants

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
822-230	TI 6.5MM ATL BONE SCREW 30MM	Aug-2002	Rule 8	Annex II (-Section 4)	57805	15766
822-235	TI 6.5MM ATL BONE SCREW 35MM	Aug-2002	Rule 8	Annex II (-Section 4)	57805	15766



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Procedure Pack Declaration

In accordance with MDD 93/42/EEC, article 12, Medtronic has verified the mutual compatibility of the devices per the manufacturers' instructions and has carried out operations in accordance with these instructions. In addition, Medtronic has packaged this/these procedure packs and supplied relevant information to users incorporating relevant instructions from the manufacturers. Sterilization has been carried out in accordance with the manufacturer's instructions. These activities are subjected to appropriate methods of internal control and inspection.

The products listed below depict the kit configurations by catalog number followed by the internal component part numbers and descriptions for each procedure pack.

Catalog #	Product Name	Inner Tray/Device Part #	Component Description
C05B	ActivOs Bone Cement with Hydroxyapatite and Mixer	C05A	ActivOs Bone Cement with Hydroxyapatite and Mixer
		A07A	Kyphon Mixer
CX01B-C	Xpede Bone Cement and Kyphon Mixer	CX01A-C	Xpede Bone Cement
		A07A	Kyphon Mixer
KPT 1002	KyphoPak Tray, First Fracture with Kyphon Osteo Introducer System, 10/3	M708349B005* (Swinnea) M061113T001 (Tijuana)	Tray subassembly, Xpander 10/3 OIS, KPT 1002
		A08A	Kyphon Xpander Inflation Syringe
KPT 1003	KyphoPak Tray, First Fracture with Kyphon Advanced Osteo Introducer System, 10/3	11006571* (Kyphon Sarl) M061105T001 (Tijuana)	Tray subassembly, 10/3 AOIS FF, KPT1003
		A08A	Kyphon Xpander Inflation Syringe
KPT 1005	KyphoPak One-Step Tray, First Fracture with Kyphon One-Step Osteo Introducer System, 10/3	M708349B006* (Kyphon Sarl) M061105T001 (Tijuana)	Tray subassembly, KPT1005 10/3 One-Step FF
		A08A	Kyphon Xpander Inflation Syringe
KPT 1502	KyphoPak Tray, First Fracture with Kyphon Osteo Introducer System, 15/3	11006574* (Kyphon Sarl) M061106T001 (Tijuana)	Tray subassembly, Xpander 15/3 OIS, KPT 1502
		A08A	Kyphon Xpander Inflation Syringe
KPT 1503	KyphoPak Tray, First Fracture with Kyphon Advanced Osteo Introducer System, 15/3	11006575* (Kyphon Sarl) M061107T001 (Tijuana)	Tray subassembly, 15/3 AOIS, FF
		A08A	Kyphon Xpander Inflation Syringe
KPT 1505	KyphoPak One Step Tray, First Fracture with Kyphon One-Step Osteo Introducer System, 15/3	11006576* (Kyphon Sarl) M061108T001 (Tijuana)	Tray subassembly, KPT1505, 15/3, One-Step FF
		A08A	Kyphon Xpander Inflation Syringe
KPT 2002	KyphoPak Tray, First Fracture with Kyphon Osteo Introducer System, 20/3	11006578* (Kyphon Sarl) M061109T001 (Tijuana)	Tray subassembly, Xpander 20/3 OIS, KPT2002
		A08A	Kyphon Xpander Inflation Syringe
KPT 2003	KyphoPak Tray, First Fracture with Kyphon Advanced Osteo Introducer System, 20/3	11006579* (Kyphon Sarl) M061110T001 (Tijuana)	Tray subassembly, 20/3 AOIS FF, KPT2003
		A08A	Kyphon Xpander Inflation Syringe
KPT 2005	KyphoPak One-Step Tray, First Fracture with Kyphon One-Step Osteo Introducer System, 20/3	11006580* (Kyphon Sarl) M061111T001 (Tijuana)	Tray subassembly, KPT2005 20/3 One-Step FF
		A08A	Kyphon Xpander Inflation Syringe
KPE 1001	KyphoPak Express Tray, First Fracture with Kyphon Express Osteo Introducer System, 10/2	11006568* (Kyphon Sarl) M061104T001 (Tijuana)	Tray subassembly, Express 10/2, KPE1001
		A08A	Kyphon Xpander Inflation Syringe
KPE 1003	KyphoPak Express Tray, First Fracture, with Kyphon Express Osteo Introducer System, 15/2	11006582* (Kyphon Sarl) M061112T001 (Tijuana)	Tray subassembly, FF, KPE1003, 15/2
		A08A	Kyphon Xpander Inflation Syringe



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Catalog #	Product Name	Inner Tray/Device Part #	Component Description
KPT1005-CDS	Cement Delivery System KyphoPak First Fracture Tray with One-Step OIS, 10/3	KSUB0012	KPT1005-CDS FF Tray Assembly 10/3, One-Step OIS
		KSUB0005 / 11010891	Tray Cement Cartridges / CDS Gen 1B Cartridge
		A08A	KYPHON Xpander Inflation Syringe
KPT1505-CDS	Cement Delivery System KyphoPak First Fracture Tray with One-Step OIS, 15/3	KSUB0015	KPT1505-CDS FF Tray Assembly 15/3, One-Step OIS
		KSUB0005	CDS Cement Cartridge
		A08A	KYPHON Xpander Inflation Syringe
KPT2005-CDS	Cement Delivery System KyphoPak First Fracture Tray with One-Step OIS, 20/3	KSUB0018	KPT2005-CDS FF Tray Assembly 20/3, One-Step OIS
		KSUB0005	CDS Cement Cartridge
		A08A	KYPHON Xpander Inflation Syringe
KPE1001-CDS	Cement Delivery System KyphoPak First Fracture Tray with Express OIS, 10/2	KSUB0008	KPE1001-CDS FF Tray Assembly 10/2, Express OIS
		KSUB0005	CDS Cement Cartridge
		A08A	KYPHON Xpander Inflation Syringe
KPE1003-CDS	Cement Delivery System KyphoPak First Fracture Tray with Express OIS, 15/2	KSUB0009	KPE1003-CDS FF Tray Assembly 15/2, Express OIS
		KSUB0005	CDS Cement Cartridge
		A08A	KYPHON Xpander Inflation Syringe
KPT1003-CDS	Cement Delivery System KyphoPak First Fracture Tray with Advanced Osteo Introducer System, 10/3	KSUB0011	KPT1003-CDS FF Tray Assembly 10/3, with AOIS
		KSUB0005	CDS Cement Cartridge
		A08A	KYPHON Xpander Inflation Syringe
KPT1503-CDS	Cement Delivery System KyphoPak First Fracture Tray with Advanced Osteo Introducer System, 15/3	KSUB0014	KPT1503-CDS FF Tray Assembly 15/3, with AOIS
		KSUB0005	CDS Cement Cartridge
		A08A	KYPHON Xpander Inflation Syringe
KPT2003-CDS	Cement Delivery System KyphoPak First Fracture Tray with Advanced Osteo Introducer System, 20/3	KSUB0017	KPT2003-CDS FF Tray Assembly 20/3, with AOIS
		KSUB0005	CDS Cement Cartridge
		A08A	KYPHON Xpander Inflation Syringe
KPT1002-CDS	Cement Delivery System KyphoPak First Fracture Tray with Osteo Introducer System, 10/3	KSUB0010	KPT1002- Cement Delivery System FF OIS Xpander 10/3
		KSUB0005	CDS Cement Cartridge
		A08A	KYPHON Xpander Inflation Syringe
KPT1502-CDS	Cement Delivery System KyphoPak First Fracture Tray with Osteo Introducer System, 15/3	KSUB0013	KPT1502-CDS FF Tray Assembly 15/3, with OIS
		KSUB0005	CDS Cement Cartridge
		A08A	KYPHON Xpander Inflation Syringe
KPT2002-CDS	Cement Delivery System KyphoPak First Fracture Tray with Osteo Introducer System, 20/3	KSUB0016	KPT2002-CDS FF Tray Assembly 20/3, with OIS
		KSUB0005	CDS Cement Cartridge
		A08A	KYPHON Xpander Inflation Syringe



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Catalog #	Product Name	Inner Tray/Device Part #	Component Description
KPX153RB-C	KyphoPak Xpander II First Fracture Tray 15/3 with Osteo Introducer System	11010315*(Kyphon Sarl) M061091T001 (Tijuana)	KPX153RB-C FF Tray Assembly 15/3 with OIS
		11010564	KIS, Double Pack Assembly / Kyphon Inflation Syringe
KPX203RB-C	KyphoPak Xpander II First Fracture Tray 20/3 with Osteo Introducer System	11010316*(Kyphon Sarl) M061092T001 (Tijuana)	KPX203RB-C FF Tray Assembly 20/3 with OIS
		11010564	Kyphon Inflation Syringe
KPX153PB-C	KyphoPak Xpander II First Fracture Tray 15/3 with One-Step System	11010317*(Kyphon Sarl) M061093T001 (Tijuana)	KPX153PB-C FF Tray Assembly 15/3 with One-Step OIS
		11010564	Kyphon Inflation Syringe
KPX203PB-C	KyphoPak Xpander II First Fracture Tray 20/3 with One-Step System	11010318*(Kyphon Sarl) M061094T001 (Tijuana)	KPX203PB-C FF Tray Assembly 20/3 with One-Step OIS
		11010564	Kyphon Inflation Syringe
KPX153AB-C	KyphoPak Xpander II First Fracture Tray 15/3 with Advanced Osteo Introducer System	11010319*(Kyphon Sarl) M061097T001 (Tijuana)	KPX153AB-C FF Tray Assembly 15/3 with Advanced Osteo Introducer System
		11010564	Kyphon Inflation Syringe
ETS103A	InflateFX™ Fracture Management System Small Tool Kit	11010488*	InflateFX Procedure Tray Assembly, 10/3
ETL153A	InflateFX™ Fracture Management System Large Tool Kit	A08A	KYPHON Xpander Inflation Syringe
		11010486*	InflateFX Procedure Tray Assembly, 15/3
IFXG2B	InflateFX™ Fracture Management with Scoop Cannula Gen 2	A08A	KYPHON Xpander Inflation Syringe
		KSUB0001	Scoop Cannula Kit Tray
		A08E	Kyphon Inflation Syringe
KEX102EB-INT	KyphoPak Express II First Fracture Tray -10/2 IBT with Express Osteo Introducer System	11010314	BD Sterile 10mL Luer-lok syringe
		M731499B001*(Kyphon Sarl) M061099T001 (Tijuana)	Tray Assy, 10/2 Express II KyphoPak Kit, EU
KEX152EB-INT	KyphoPak Express II First Fracture Tray -15/2 IBT with Express Osteo Introducer System	11010564	Kyphon Inflation Syringe
		M731504B001*(Kyphon Sarl) M061101T001 (Tijuana)	Tray Assy, 15/2 Express II KyphoPak Kit, EU
KEX202EB-INT	KyphoPak Express II First Fracture Tray -20/2 IBT with Express Osteo Introducer System	11010564	Kyphon Inflation Syringe
		M731507B001*(Kyphon Sarl) M0611103T001 (Tijuana)	Tray Assy, 20/2 Express II KyphoPak Kit, EU
VPK1001	KYPHON® V™ Premium Vertebroplasty Kit, 13GA	11010564	Kyphon Inflation Syringe
		KSUB0002	Tray CDS Gun and 13G Straight VP Needle Tool Kit, Sub. Assy
A25R	KYPHON ELEMENT™ Syringe Kit	KSUB0005	Tray, Cement Cartridges
		96473	QL®1430 14mL Disposable Inflation Syringe
VPK1002	KYPHON® V™ Premium Vertebroplasty Kit, 10GA	K01-07841	VacLok® 30mL Syringe
		KSUB0003	Kyphon V 10G Trocar Kit
VPK1003	KYPHON Kurve™ Curved Bone Filler Device System	KSUB0005	Tray, Cement Cartridges
		KSUB0004	Kyphon V 10G Trocar, 13G Kyphon Kurve Kit
VPK011B	KYPHON® V™ Premium Vertebroplasty Kit, Matched Bevel 11GA	KSUB0005	Tray, Cement Cartridges
		KSUB0019	Kyphon V 11G Match Bevel Kit
VPK013B	KYPHON® V™ Premium Vertebroplasty Kit, Matched Bevel 13GA	KSUB0005	Tray, Cement Cartridges
		KSUB0020	Kyphon V 13G Match Bevel Kit
VPK011D	KYPHON® V™ Premium Vertebroplasty Kit, Bevel/Trocar 11GA	KSUB0005	Tray, Cement Cartridges
		KSUB0021	Kyphon V 11G Trocar/Bevel Kit



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Catalog #	Product Name	Inner Tray/Device Part #	Component Description
VPK013D	KYPHON® V™ Premium Vertebroplasty Kit, Bevel/Trocar 13GA	KSUB0022	Kyphon V 13G Trocar/Bevel Kit
		KSUB0005	Tray, Cement Cartridges
KPX153RB-CDS-C	KyphoPak Xpander II First Fracture Tray 15/3 with Osteo Introducer System and Kyphon Cement Delivery System	KSUB0041	KPX153RB-C FF Tray Assembly 15/3 with OIS
		11010564	Kyphon Inflation Syringe
		CC02A	CDS Cement Cartridges
KPX203RB-CDS-C	KyphoPak Xpander II First Fracture Tray 20/3 with Osteo Introducer System and Kyphon Cement Delivery System	KSUB0040	KPX203RB-C FF Tray Assembly 20/3 with OIS
		11010564	Kyphon Inflation Syringe
		CC02A	CDS Cement Cartridges
KPX153PB-CDS-C	KyphoPak Xpander II First Fracture Tray 15/3 with One-Step System and Kyphon Cement Delivery System	KSUB0039	KPX153PB-C FF Tray Assembly 15/3 with One-Step OIS
		11010564	Kyphon Inflation Syringe
		CC02A	CDS Cement Cartridges
KPX203PB-CDS-C	KyphoPak Xpander II First Fracture Tray 20/3 with One-Step System and Kyphon Cement Delivery System	KSUB0038	KPX203PB-C FF Tray Assembly with One-Step OIS
		11010564	Kyphon Inflation Syringe
		CC02A	CDS Cement Cartridges
KEX102EB-CDS-INT	KyphoPak Express II First Fracture Tray -10/2 IBT with Express Osteo Introducer System and Kyphon Cement Delivery System	KSUB0035	Tray Assy, 10/2 Express II KyphoPak Kit, EU
		11010564	Kyphon Inflation Syringe
		CC02A	CDS Cement Cartridges
KEX152EB-CDS-INT	KyphoPak Express II First Fracture Tray -15/2 IBT with Express Osteo Introducer System and Kyphon Cement Delivery System	KSUB0036	Tray Assy, 15/2 Express II KyphoPak Kit, EU
		11010564	Kyphon Inflation Syringe
		CC02A	CDS Cement Cartridges

*Denotes Agile Change Control System Number for Tray Subassembly

Jeff Sprague

 JEFF SPRAGUE

SR. REGULATORY AFFAIRS PROGRAM MANAGER

PLACE: Memphis, TN

22 JAN 2019

 Date

DECLARATION OF CONFORMITY

TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES



MANUFACTURER:

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
USA

MEDICAL DEVICE:

Vertebral and Extremity Fracture Devices
Technical File Number (TF012)
Reference Product List including GMDN and UMDNS codes

CLASSIFICATION IN ACCORDANCE WITH ANNEX IX:

Class 1 (sterile), Rule 1; Class IIa, Rule 6; Class IIa, Rule 9; Class IIb, Rule 8
Reference Product List for specific device classifications

CONFORMITY ASSESSMENT ROUTE:

Annex II excluding Section 4, Annex V, Annex VII
Reference Product List for specific device routes

WE, THE MANUFACTURER, UNDER OUR SOLE RESPONSIBILITY, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, OF THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC AND IF APPLICABLE, COMMISSION REGULATION NO. 722/2012.

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: REFER TO LIST OF HARMONISED – EN STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED. THIS LIST IS LOCATED WITH THE TECHNICAL FILE.

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MUNICH, GERMANY.

IDENTIFICATION NUMBER:

0123 for Class Im, Class Is, and above

(EC) CERTIFICATE(S):

G1 15 11 39040 059 Exp Date: 19-Apr-20
G25 14 12 39040 054 Exp Date: 19-Apr-20



EUROPEAN REPRESENTATIVE:

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

START OF CE-MARKING:

DATE OF FIRST CE MARKING (Reference attached list)

SIGNATURE:

12 JAN 2019

JEFFREY SPRAGUE
SR. REGULATORY AFFAIRS PROGRAM MANAGER

DATE

PLACE:

Memphis, TN

Product List
Last updated by: Pamela Edwards

Date: 5/29/2015

Tech File Bundle: Vertebral and Extremity Fracture Devices, TF012

Product: Kyphon® Mixer, Multi-Tap™ Adapters and Cement Cartridges

Class: I (sterile)

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
A07A	Kyphon® Mixer	May 2005*	Rule 1	Annex V, Annex VII	61468	16472
A22	Kyphon® Multi-Tap™ Adpater - Size 2	March 2014	Rule 1	Annex V, Annex VII	35809	16634
A23	Kyphon® Multi-Tap™ Adpater - Size 3	March 2014	Rule 1	Annex V, Annex VII	35809	16634
CC02A	KYPHON® CDS Cement Cartridges	Nov 2010	Rule 1	Annex V, Annex VII	35809	16634
KSUB0005	Tray, Cement Cartridges	May 2015	Rule 1	Annex V, Annex VII	35809	16634

*Note: This is the earliest date documented for CE Marking.

Product List
Last updated by: Laveeda Leflore **Date:** 10/26/2017

Tech File Bundle: Vertebral and Extremity Fracture Devices, TF012

Product: Kyphon® 11 Gauge Bone Access Needle
Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
11000460	Kyphon® 11 Gauge Bone Access Needle	Sep 2005	Rule 6	Annex II (-section 4)	60478	12753

Product List
Last updated by: Laveeda Leflore

Date: 10/26/2017

Tech File Bundle: Vertebral and Extremity Fracture Devices, TF012

Product: Kyphon® Bone Biopsy Devices

Class: Ila

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
F05A	Kyphon® Bone Biopsy Devices, Size 3	Sept 2003	Rule 6	Annex II (-section 4)	60478	12734
F05A-10	Kyphon® Bone Biopsy Devices, Size 3 (10 pack)	Sept 2003	Rule 6	Annex II (-section 4)	60478	12734
F07A	Kyphon® Express™ Bone Biopsy Devices, Size 2	Sept 2003	Rule 6	Annex II (-section 4)	60478	12734
F18A	Kyphon® Bone Biopsy Kit, Size 3	Sept 2003	Rule 6	Annex II (-section 4)	46750	12734
VPB11	Kyphon V™ Bone Biopsy Device, 13G	Jan 2016	Rule 6	Annex II (-section 4)	60478	12734
VPB13	Kyphon V™ Bone Biopsy Device, 15G	Jan 2016	Rule 6	Annex II (-section 4)	60478	12734

Product List

Last updated by: Laveeda Leflore **Date:** 10/26/2017
Tech File Bundle: Vertebral and Extremity Fracture Devices, TF012

Product: Kyphon® Osteo Introducer® Devices						
Class: Ila						
P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
T05J	Kyphon® One-Step™ Osteo Introducer™ System	April 2004	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
T15D	Kyphon® Osteo Introducer™ System	Jan 2011	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
T15E	Kyphon® Advanced Osteo Introducer™ System	Jan 2011	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
T15J	Kyphon® One-Step™ Osteo Introducer™ System	Jan 2011	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
T15K	Kyphon® One-Step™ Osteo Introducer™ Device	June 2011	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
T24A	Kyphon® Express™ Osteo Introducer™ System	Dec 2001	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
T24B	Kyphon® Express™ Osteo Introducer™ System	Dec 2001	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
T24C	Kyphon® Express™ Advanced Osteo Introducer™ Device	Dec 2001	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
A20A	Kyphon® Advanced Osteo Introducer™ Device	July 2011	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
T34A	Kyphon® Express™ Osteo Introducer™ Device	Feb 2014	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
T34B	Kyphon® Express™ Osteo Introducer™ Device	Dec 2013	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
T34C	Kyphon® Express™ Osteo Introducer™ Device	Dec 2013	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
T34D	Kyphon® Express™ Osteo Introducer™ Device, Diamond	Dec 2013	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
T34E	Kyphon® Express™ Osteo Introducer™ Device, Bevel	Dec 2013	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
T34F	Kyphon® Precision Drill, Size 2	Dec 2013	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753

Product: Kyphon® Osteo Introducer® Devices

Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
VPT01A	Kyphon® V™ Osteo Introducer® System, 13GA	May 2015	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
T25R	KYPHON ELEMENT™ Osteo Introducer System, Size 3	Nov 2015	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
OCN002	OsteoCool™ Bone Access Kit, 10G	Dec 2015	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
OCN003	OsteoCool™ Bone Access Kit, 8G	Dec 2015	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
OCN005	OsteoCool™ Bone Access Kit, 13G	Dec 2015	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
VPT11B	KYPHON V™ Matched Bevel Tip, 11G	Jan 2016	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
VPT13B	KYPHON V™ Matched Bevel Tip, 13G	Jan 2016	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
VPT11D	KYPHON V™ Trocar Bevel Tip, 11G	Jan 2016	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
VPT13D	KYPHON V™ Trocar Bevel Tip, 13G	Jan 2016	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
VPT01B	KYPHON V™ Straight Cannula, 10G	Jan 2016	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753
OCN004	OsteoCool™ Bone Access Kit, 10G	Mar 2017	Rule 6	Annex II (-section 4)	58031	10561, 17954, 12753

Product List

Last updated by: Pamela Edwards

Date: 11/5/2016

Tech File Bundle: Vertebral and Extremity Fracture Devices, TF012

Product: Kyphon® Inflatable Bone Tamps

Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
K08A	Kyphon® XPANDER™ Inflatable Bone Tamps, 20/3	Jan 2003	Rule 6	Annex II (-section 4)	47021	15766
K09A	Kyphon® XPANDER™ Inflatable Bone Tamps, 15/3	Jan 2003	Rule 6	Annex II (-section 4)	47021	15766
K13A	Kyphon® XPANDER™ Inflatable Bone Tamps, 10/3	Jan 2003	Rule 6	Annex II (-section 4)	47021	15766
K15A	Kyphon® EXPRESS™ Inflatable Bone Tamps, 10/2	Jan 2003	Rule 6	Annex II (-section 4)	47021	15766
K15B	Kyphon® EXPRESS™ Inflatable Bone Tamps, 15/2	Jan 2003	Rule 6	Annex II (-section 4)	47021	15766
K17A	Kyphon® EXACT™ Inflatable Bone Tamps, 10/3	Jan 2003	Rule 6	Annex II (-section 4)	47021	15766
K17B	Kyphon® EXACT™ Inflatable Bone Tamps, 15/3	Jan 2003	Rule 6	Annex II (-section 4)	47021	15766
KE102-INT	Kyphon® Express™ Inflatable Bone Tamps, 10/2	Sep 2013	Rule 6	Annex II (-section 4)	47021	15766
KE152-INT	Kyphon® Express™ Inflatable Bone Tamps, 15/2	Sep 2013	Rule 6	Annex II (-section 4)	47021	15766
KE202-INT	Kyphon® Express™ Inflatable Bone Tamps, 20/2	Sep 2013	Rule 6	Annex II (-section 4)	47021	15766
KX103-C	Kyphon® Xpander™ Inflatable Bone Tamps, 10/3	Mar 2011	Rule 6	Annex II (-section 4)	47021	15766
KX153-C	Kyphon® Xpander™ Inflatable Bone Tamps, 15/3	Mar 2011	Rule 6	Annex II (-section 4)	47021	15766
KX203-C	Kyphon® Xpander™ Inflatable Bone Tamps, 20/3	Mar 2011	Rule 6	Annex II (-section 4)	47021	15766
E103A	InflateFX™ Fracture Management Inflatable Bone Tamp, 10/3	Oct 2012	Rule 6	Annex II (-section 4)	47021	15766
E153A	InflateFX™ Fracture Management Inflatable Bone Tamp, 15/3	Oct 2012	Rule 6	Annex II (-section 4)	47021	15766
KR153	KYPHON ELEMENT™ Inflatable Bone Tamp, 15/3	Sep 2015	Rule 6	Annex II (-section 4)	47021	15766

Product List
Last updated by: Pamela Edwards

Date: 2/9/2015

Tech File Bundle: Vertebral and Extremity Fracture Devices, TF012

Product: Kyphon® Curettes

Class: Ila

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
A11B	KYPHON® Latitude II Curette Device, 8.0 mm T-tip	Jan 2004	Rule 6	Annex II (-section 4)	47022	12845
A11B-05	KYPHON® Latitude II Curette Device, 8.0 mm T-tip (5-pack)	Jan 2004	Rule 6	Annex II (-section 4)	47022	12845
A11D	KYPHON® Latitude II Curette Device, 6.5 mm Wedge tip	Jan 2004	Rule 6	Annex II (-section 4)	47022	12845
A11D-05	KYPHON® Latitude II Curette Device, 6.5 mm Wedge tip (5-pack)	Jan 2004	Rule 6	Annex II (-section 4)	47022	12845
A11E	KYPHON® Latitude II Curette Device, 8.5 mm Wedge tip	Jan 2004	Rule 6	Annex II (-section 4)	47022	12845
A11E-05	KYPHON® Latitude II Curette Device, 8.5 mm Wedge tip (5-pack)	Jan 2004	Rule 6	Annex II (-section 4)	47022	12845
A13A	KYPHON® Express™ Curette Device, T-tip (Size 2)	Jan 2004	Rule 6	Annex II (-section 4)	47022	12845
A13A-05	KYPHON® Express™ Curette Device, T-tip (Size 2) (5-pack)	Jan 2004	Rule 6	Annex II (-section 4)	47022	12845

Product List
Last updated by: Pamela Edwards **Date:** 2/9/2015
Tech File Bundle: Vertebral and Extremity Fracture Devices, TF012

Product: Kyphon® Inflation Syringe

Class: Ila

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
A08E	Kyphon® Inflation Syringe	March 2011	Rule 9	Annex II (-section 4)	17541	15256
11010564	Kyphon® Inflation Syringe	March 2011	Rule 9	Annex II (-section 4)	17541	15256

Product List
Last updated by: Pamela Edwards

Date: 2/9/2015

Tech File Bundle: Vertebral and Extremity Fracture Devices, TF012

Product: Kyphon®Cement Delivery System

Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
CDS2A	KYPHON® Cement Delivery Gun with KYPHON® Bone Filler Device	June 2010	Rule 6	Annex II (-section 4)	35809	16472
CDS3A	KYPHON® Cement Delivery Gun with KYPHON® Express Bone Filler Device	June 2010	Rule 6	Annex II (-section 4)	35809	16472

Product List

Last updated by: Pamela Edwards **Date:** 1/22/2016
Tech File Bundle: Vertebral and Extremity Fracture Devices, TF012

Product: Kyphon® Bone Filler Devices

Class: Ila

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
F04B	KYPHON® Bone Filler Device	Jan 2002	Rule 6	Annex II (-section 4)	35809	16472
F04C	KYPHON® Directional Bone Filler Device	Jan 2002	Rule 6	Annex II (-section 4)	35809	16472
F06A	KYPHON® Express Bone Filler Device	Jan 2002	Rule 6	Annex II (-section 4)	35809	16472
F06B	KYPHON® Express Directional Bone Filler Device	Jan 2002	Rule 6	Annex II (-section 4)	35809	16472
F25R	KYPHON ELEMENT™ Bone Filler Device	Sep 2015	Rule 6	Annex II (-section 4)	35809	16472
VPT02A	KYPHON Kurve™ Curved Bone Filler Device	Jan 2016	Rule 6	Annex II (-section 4)	35809	16472

Product List
Last updated by: Laveeda Leflore

Date: 10/26/2017

Tech File Bundle: Vertebral and Extremity Fracture Devices, TF012

Product: KyphoPak® Trays

Class: Ila

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
M708349B005	KYPHON® KyphoPak Tray for Xpander 10/3 IBT with OIS (KPT1002)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
11006571	KYPHON® KyphoPak Trays for Xpander 10/3 IBT with AOIS (KPT1003)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
11006574	KYPHON® KyphoPak Tray for Xpander 15/3 IBT with OIS (KPT1502)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
11006575	KYPHON® KyphoPak Tray for Xpander 15/3 IBT with AOIS (KPT1503)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
11006579	KYPHON® KyphoPak Tray for Xpander 20/3 IBT with AOIS (KPT2003)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
11006578	KYPHON® KyphoPak Tray for Xpander 20/3 IBT with OIS (KPT2002)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
11006568	KYPHON® KyphoPak Tray for Express 10/2 IBT with EOIS (KPE1001)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KPE1002	KYPHON® KyphoPak Tray for Express 10/2 IBT , Additional Fracture	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
11006582	KYPHON® KyphoPak Tray for Express 15/2 IBT with OIS, First Fracture (KPE1003)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KPE1004	KYPHON® KyphoPak Tray for Express 15/2 IBT, Additional Fracture	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KPT1004	KYPHON® KyphoPak Trays for Xpander 10/3 IBT, Additional Fracture	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KPT1504	KYPHON® KyphoPak Trays for Xpander 15/3 IBT, Additional Fracture	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KPT2004	KYPHON® KyphoPak Trays for Xpander 20/3 IBT, Additional Fracture	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
M708349B006	KYPHON® KyphoPak Tray for Xpander 10/3 IBT with One-Step OIS, First Fracture (KPT1005)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
11006576	KYPHON® KyphoPak Tray for Xpander 15/3 IBT with One-Step OIS (KPT1505)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
11006580	KYPHON® KyphoPak Trays for Xpander 20/3 IBT with One-Step OIS (KPT2005)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KSUB0010	KYPHON® Cement Delivery System KyphoPak Tray 10/3 IBT with OIS (KPT1002-CDS)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KSUB0013	KYPHON® Cement Delivery System KyphoPak Tray 15/3 IBT with OIS (KPT1502-CDS)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KSUB0016	KYPHON® Cement Delivery System KyphoPak Tray 20/3 IBT with OIS (KPT2002-CDS)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KSUB0011	KYPHON® Cement Delivery System KyphoPak Tray 10/3 IBT with AOIS (KPT1003-CDS)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168

Product: KyphoPak® Trays

Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
KSUB0014	KYPHON® Cement Delivery System KyphoPak Tray 15/3 IBT with AOIS (KPT1503-CDS)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KSUB0017	KYPHON® Cement Delivery System KyphoPak Tray 20/3 IBT with AOIS (KPT2003-CDS)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KSUB0012	KYPHON® Cement Delivery System KyphoPak Tray 10/3 IBT with One Step OIS (KPT1005-CDS)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KSUB0015	KYPHON® Cement Delivery System KyphoPak Tray 15/3 IBT with One Step OIS (KPT1505-CDS)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KSUB0018	KYPHON® Cement Delivery System KyphoPak Tray 20/3 IBT with One Step OIS (KPT2005-CDS)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KSUB0008	KYPHON® Cement Delivery System KyphoPak Tray Express 10/2 IBT (KPE1001-CDS)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KSUB0009	KYPHON® Cement Delivery System KyphoPak Tray Express 15/2 IBT (KPE1003-CDS)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KPX153RB-C	KYPHON® KyphoPak Xpander II First Fracture Tray 15/3 IBT with Osteo Introducer System (KPX153RB-C)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KPX203RB-C	KYPHON® KyphoPak Xpander II First Fracture Tray 20/3 IBT with Osteo Introducer System (KPX203RB-C)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KPX153PB-C	KYPHON® KyphoPak Xpander II First Fracture Tray 15/3 IBT with One-Step Osteo Introducer System (KPX153PB-C)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KPX203PB-C	KYPHON® KyphoPak Xpander II First Fracture Tray 20/3 IBT with One-Step Osteo Introducer System (KPX203PB-C)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KPX153AB-C	KYPHON® KyphoPak Xpander II First Fracture Tray 15/3 IBT with Advanced Osteo Introducer System (KPX153AB-C)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
11010488	InflateFX™ Small Kit Tray Assy, 10/3 EU (ETS103A)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
11010486	InflateFX™ Large Kit Tray Assy, 15/3 EU (ETL153A)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KSUB0001	InflateFX™ Gen 2 Fracture Management (IFXG2B)	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KEX102EB-CDS-INT	KyphoPak® First Fracture Tray with KYPHON Express™ Inflatable Bone Tamp 10/2, Osteo Introducer System, Kyphon® Inflation Syringe and Kyphon® Cement Delivery System	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KEX152EB-CDS-INT	KyphoPak® First Fracture Tray with KYPHON Express™ Inflatable Bone Tamp 15/2, Osteo Introducer System, Kyphon® Inflation Syringe and Kyphon® Cement Delivery System	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KPX153PB-CDS-C	KyphoPak® First Fracture Tray with KYPHON Xpander™ II Inflatable Bone Tamp 15/3, One-Step Osteo Introducer System, Kyphon® Inflation Syringe and Kyphon® Cement Delivery System	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KPX153RB-CDS-C	KyphoPak® First Fracture Tray with KYPHON Xpander™ II Inflatable Bone Tamp 15/3, Osteo Introducer System, Kyphon® Inflation Syringe and Kyphon® Cement Delivery System	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KPX203PB-CDS-C	KyphoPak® First Fracture Tray with KYPHON Xpander™ II Inflatable Bone Tamp 20/3, One-Step Osteo Introducer System, Kyphon® Inflation Syringe and Kyphon® Cement Delivery System	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KPX203RB-CDS-C	KyphoPak® First Fracture Tray with KYPHON Xpander™ II Inflatable Bone Tamp 20/3, Osteo Introducer System, Kyphon® Inflation Syringe and Kyphon® Cement Delivery System	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KEX102EB-INT	KyphoPak® EXPRESS™ II First Fracture Tray with KYPHON Express™ Inflatable Bone Tamp 10/2, Osteo Introducer System, and Kyphon® Inflation Syringe	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168

Product: KyphoPak® Trays

Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
KEX152EB-INT	KyphoPak®EXPRESS™ II First Fracture Tray with KYPHON Express™ Inflatable Bone Tamp 15/2, Osteo Introducer System, and Kyphon® Inflation Syringe	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168
KEX202EB-INT	KyphoPak®EXPRESS™ II First Fracture Tray with KYPHON Express™ Inflatable Bone Tamp 20/2, Osteo Introducer System, and Kyphon® Inflation Syringe	Refer to DoC of components	Rule 6	Annex II (-section 4)	47129	17168

Product List
Last updated by: Pamela Edwards

Date: 1/22/2016

Tech File Bundle: Vertebral and Extremity Fracture Devices, TF012

Product: Kyphon V Vertebroplasty Kit

Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
VPK1001	Tray CDS Gun and 13G Straight VP Needle Tool Kit, Sub. Assy	Refer to DoC of components	Rule 6	Annex II (-section 4)	58031	17168
VPK1002	Tray CDS Gun and 10G Straight VP Needle Tool Kit, Sub. Assy	Refer to DoC of components	Rule 6	Annex II (-section 4)	58031	17168
VPK1003	Tray CDS Gun, 10G Straight VP Needle and 13G Curved BFD Tool Kit, Sub. Assy	Refer to DoC of components	Rule 6	Annex II (-section 4)	58031	17168
VPK011B	Tray CDS Gun and 11G Matched Bevel VP Needle Tool Kit, Sub. Assy	Refer to DoC of components	Rule 6	Annex II (-section 4)	58031	17168
VPK013B	Tray CDS Gun and 13G Matched Bevel VP Needle Tool Kit, Sub. Assy	Refer to DoC of components	Rule 6	Annex II (-section 4)	58031	17168
VPK011D	Tray CDS Gun and 11G Trocar/Bevel VP Needle Tool Kit, Sub. Assy	Refer to DoC of components	Rule 6	Annex II (-section 4)	58031	17168
VPK013D	Tray CDS Gun and 13G Trocar/Bevel VP Needle Tool Kit, Sub. Assy	Refer to DoC of components	Rule 6	Annex II (-section 4)	58031	17168
VPB11D	11G Trocar Bevel VP Needle and 13G Biopsy Needle	Refer to DoC of components	Rule 6	Annex II (-section 4)	46750	17168
VPB13D	13G Trocar VP Needle and 15G Biopsy Needle	Refer to DoC of components	Rule 6	Annex II (-section 4)	46750	17168

*Date of CE Mark for each kit is dependent on the last component to receive CE Marking within the kit.

Product List
Last updated by: Pamela Edwards

Date: 2/9/2015

Tech File Bundle: Vertebral and Extremity Fracture Devices, TF012

Product: Kyphon® ActivOs® Bone Cement with Hydroxyapatite

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
C05A	Kyphon® ActivOs® Bone Cement with Hydroxyapatite	Jun-08	Rule 8	Annex II (-section 4)	35217	12830