ORDIN DE PLATĂ

Nr. 56 | DATA EMITERII 3 septembrie 2025 | TIP.DOC.1

PLĂTIȚI: 200-00 LEI Doua sute lei 00 bani

PLĂTITOR: (R) S.C. "OXIVIT-MED" S.R.L.

CODUL IBAN MD44ML000000002251729503

CODUL FISCAL 1007600044280

PRESTATORUL PLĂTITOR: BC'Moldindconbank'S.A.

BENEFICIAR: (R) IMSP Spitalul Clinic Republican Timofei Mosneaga

CODUL IBAN MD57MO2251ASV96476607100

CODUL FISCAL 1003600150783

PRESTATORUL BENEFICIAR: OTP Bank S.A.

DESTINAȚIA PLĂȚII: Pentru garantia pentru oferta la procedura de achizitie publica nr.ocds-b3wdp1-MD-1755511235744 din 05.09.2025

TIPUL TRANSFERULUI
NORMAL/URGENT

N

L.Ș.

CODUL TRANZACȚIEI	DATA PRIMIRII	DATA EXECUTĂRII
001		

KOJEVNIKOV DMITRII ANDREI

KOJEVNIKOV DMITRII ANDREI

SEMNĂTURILE EMITENTULUI

Document transmis prin instrument de plată electronic cu acces la la distanţă de tip internet-banking

/

SEMNĂTURA PRESTATORULUI

Digitally signed by Kojevnikov Dmitrii
Date: 2025.09.03 16:54:25 EEST
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ

L.Ș.

MOTIVUL REFUZULUI

Nota: Responsabilitatea privind veridicitatea şi corectitudinea informaţiei indicate în ordinul de plată îi revine emitentului*

**Regulamentul cu privire la transferul de credit, debitarea directă şi atribuirea codurilor IBAN, aprobat prin HCE al BNM nr. 108 din 08.06.2023*

MOBIAS BANCA

Nr. 12101-304

18.03.2016

CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE

Prin prezentul, **BC „Mobiasbancă – Groupe Societe Generale" S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **OXIVIT-MED SRL**, cod fiscal (IDNO) **1007600044280,** deține următoarele conturi curente la BC "Mobiasbancă-Groupe Societe Generale" S.A., Filiala. 1 Stejaur :

1. **MDL - 2224710SV23488147100; IBAN- MD09MO2224ASV23488147100**
2. **EUR - 2224710SV22227957100; IBAN- MD17MO2224ASV22227957100**
3. **USD - 2224710SV22214937100; IBAN- MD86MO2224ASV22214937100**

Certificatul este emis în baza cererii întreprinderii: Oxivit-Med SRL.

L.Ș.

Dumitru Popa
Director filială „Stejaur"

Executor : Mariana Guzun
Tel: 022 812 614

Filiala Nr. 1 „Stejaur"
Bd. Ştefan cel Mare şi Sfânt 196
MD-2004, Chişinău, Moldova
Cod MOBBMD22
Cont de corespondenţă 35213892
la Centrul de Decontări al BNM

Tel. +373 22 81 26 15
Fax. +373 22 81 26 15
www.mobiasbanca.md

BC „Mobiasbancă – Groupe Société Générale" SA
Capital Social: 100 000 000 MDL
Număr de înregistrare de stat - 1002600006089
Sediul Central:
bd. Ştefan cel Mare şi Sfânt 81a
MD-2012, Chişinău, Moldova

GROUPE SOCIETE GENERALE

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea Comercială "OXIVIT-MED" S.R.L.

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal

1007600044280

Data înregistrării **30.07.2007**

Data eliberării **30.07.2007**

Bordeianu Tatiana, registrator de stat

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

CAMERA ÎNREGISTRĂRII DE STAT A REPUBLICII MOLDOVA L.Ș.

MD 0067985

AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. **531861** data **19.09.2023**

Denumirea completă: **Societatea Comercială "OXIVIT-MED" S.R.L.**
Denumirea prescurtată: **S.C. "OXIVIT-MED" S.R.L.**
Forma juridică de organizare: **Societate cu răspundere limitată,**
Numărul de identificare de stat şi codul fiscal (IDNO): **1007600044280**
Data înregistrării de stat: **30.07.2007**
Sediul: **MD-2032, bd . Decebal, 82, ap.(of.) 90, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1. Fabricarea, comercializarea, asistenţa tehnică, repararea şi verificarea articolelor de tehnică şi optică medicală
2. Comerţul cu ridicata al parfumurilor şi produselor cosmetice
3. Comerţul cu amănuntul al produselor cosmetice şi de parfumerie, articolelor de toaletă
4. Intermedieri pentru vînzarea unui asortiment larg de mărfuri
5. Alte tipuri de comerţ cu amănuntul în magazine nespecializate
6. Alte tipuri de comerţ cu ridicata
7. Închirierea altor maşini şi echipamente

Capitalul social: **5400** lei,

Administrator: **KOJEVNIKOV DMITRII, IDNP 0972305012362,**

Asociaţii:
1. KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 5400 lei, ce constituie 100%
Beneficiar efectiv:
1.1. KOJEVNIKOV DMITRII, IDNP 0972305012362

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: **19.09.2023**.

Registrator în domeniul înregistrării de stat **Rusu Diana**

Digitally signed by Rusu Diana
Date: 2023.09.19 11:22:47 EEST
Reason: MoldSign Signature
Location: Moldova

EB 0461498

Date cu caracter personal

c/f: 1007600044280; adresa: str. Decebal 82-90, or. Chișinău, Republica Moldova
telefon: + 373 22 808002; fax: + 373 22 808003
web: www.oxivit-med.com; e-mail:info@oxivit-med.com

Lista fondatorilor companiei SRL „Oxivit-Med”

Nr.	Numele, Prenumele	Codul Personal
1	Kojevnikov Dmitrii	0972305012362

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:	*Cervical Stabilization Bundle* *Technical File TF001* Reference Product List including GMDN and UMDNS codes
CLASSIFICATION IN ACCORDANCE WITH ANNEX IX:	*Class Im, Rule 6; Class IIa, Rule 6 and Rule 9; Class IIb, Rule 8* Reference Product List for specific device classifications
CONFORMITY ASSESSMENT ROUTE:	*Annex II (-Section 4) and 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):	G1151139040059 G2M130639040047	Expiration Date:	4/19/2020 6/30/2018
EC REP 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:		24 Jan 2018	
	NAME Kathryn H. Simpson, PhD REGULATORY AFFAIRS Director or Designee	DATE	
	Director, Reg Affairs TITLE		
PLACE:	Memphis, TN, USA		

Medtronic

Product List

Last updated by: Tejas Patel

Date: 24-Jan-18

Tech File Bundle: TF001

Product: Instruments (Measuring)

Class: Im

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
UCSS® Screw Set						
873-005	CANNULATED DEPTH GAGE	March 2000	Rule 6	Annex V	32845	13180
873-008	4.0 CANNULATED CORTICAL TAP	March 2000	Rule 6	Annex V	17507	13117
VERTEX® Reconstruction System						
6900241	3.2 X 240MM ROD TEMPLATE	January 2002	Rule 6	Annex V	44788	13180
6905716	PROBE	June 2003	Rule 6	Annex V	44759	13117
6905721	Adjustable Cancellous Drill Bit (Non-Sterile)	June 2001	Rule 6	Annex V	43390	11331
6905722	Adjustable Cortical Drill Bit (Non-Sterile)	September 2002	Rule 6	Annex V	32865	11331
6905744	Depth Gage	June 2001	Rule 6	Annex V	32845	13180
6905765	3.5mm Adjustable Cancellous Tap	June 2001	Rule 6	Annex V	17507	17507
6905770	4.0mm Adjustable Cancellous Tap	June 2001	Rule 6	Annex V	17507	17507
6905771	4.0mm Adjustable Cortical Tap	June 2001	Rule 6	Annex V	17507	17507
6956003	PROBE	October 2004	Rule 6	Annex V	44759	13117
6956004	PROBE, CURVED	March 2007	Rule 6	Annex V	44759	13117
6956005	ADJUSTABLE DEPTH DRILL GUIDE	November 2004	Rule 6	Annex V	35095	11930
6956020	DEPTH GAUGE	November 2004	Rule 6	Annex V	32845	13180
6956030	TAP SLEEVE - REMOVABLE	October 2004	Rule 6	Annex V	17507	17507
6956035	3.5MM TAP SHAFT, 10-24MM	October 2004	Rule 6	Annex V	17507	17507
6956040	4.0MM TAP SHAFT, 10-24MM	October 2004	Rule 6	Annex V	17507	17507
6956041	4.0MM TAP SHAFT, 26-52MM	October 2004	Rule 6	Annex V	17507	17507
6956045	4.5MM TAP SHAFT, 10-42MM	October 2004	Rule 6	Annex V	17507	17507
6956140	4.0MM CORTICAL TAP SHAFT 6-18	October 2004	Rule 6	Annex V	17507	17507
6956145	4.5MM CORTICAL TAP SHAFT 6-24	October 2004	Rule 6	Annex V	17507	17507
6957304	DEPTH GAGE	December 2005	Rule 6	Annex V	32845	13180
6957308	4.0MM CANNULATED TAP (MAS)	December 2006	Rule 6	Annex V	17507	17507
6957309	4.5MM CANNULATED TAP (MAS)	December 2005	Rule 6	Annex V	17507	17507
7756005	ADJUSTABLE DEPTH DRILL GUIDE	August 2006	Rule 6	Annex V	35095	11930
7756035	3.5MM TAP (NON STERILE)	August 2006	Rule 6	Annex V	17507	17507
7756040	4.0MM TAP (NON STERILE)	August 2006	Rule 6	Annex V	17507	17507
7756045	4.5MM TAP (NON STERILE)	August 2006	Rule 6	Annex V	17507	17507
7756300	3.0MM TAP (NON STERILE)	August 2012	Rule 6	Annex V	17507	17507
7757270	250MM NITINOL ROD TEMPLATE	November 2010	Rule 6	Annex V	44788	13180
7759978	FIXED THIN OC GUIDE 6/8MM	August 2008	Rule 6	Annex V	44759	11927
7759979	FIXED THIN OC GUIDE 10/12MM	August 2008	Rule 6	Annex V	44759	11927
7759980	FIXED THIN OC GUIDE 14/16MM	August 2008	Rule 6	Annex V	44759	11927
7759982	FIXED OC GUIDE RS 18MM/DRIVER GUIDE	November 2008	Rule 6	Annex V	44759	11927
X0911001	3.0MM TAP (NON-STERILE)	October 2011	Rule 6	Annex V	17507	17507
X1204291	VER ADJ CORTICAL DRILL BIT	March 2005	Rule 6	Annex V	43390	11331
X1204292	VER ADJ CANCELLOUS DRILL BIT	March 2005	Rule 6	Annex V	43390	11331
XD10430603	ADJUSTABLE CORTICAL DRILL BIT	May 2002	Rule 6	Annex V	43390	11331
XD10430604	ADJUSTABLE CORTICAL TAP Q.C	May 2002	Rule 6	Annex V	17507	13117

Medtronic

Product List

Last updated by: Tejas Patel **Date:** 24-Jan-18

Tech File Bundle: TF001

Product: Instruments

Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
ATLAS® Cable System						
CENTERPIECE® Plate Fixation System						
8530605	TRI FLAT DRILL BIT, STERILE	April 2005	Rule 6	Annex II (-section 4)	43390	11333
8530810	8-10MM BONE TRIAL	October 2005	Rule 6	Annex II (-section 4)	44759	17993
8530812	12-14MM BONE TRIAL	October 2005	Rule 6	Annex II (-section 4)	44759	17993
8530814	16-18MM BONE TRIAL	October 2005	Rule 6	Annex II (-section 4)	44759	17993
ELECTRIC DRIVE SYSTEM						
6471341	FOOT PEDAL, ELECTRIC DRIVE SYS	February 2003	Rule 9	Annex II (-section 4)	44491	17993
6471342	ATTACH, ELECT MOTOR AND CONN	February 2003	Rule 9	Annex II (-section 4)	44491	17993
6471346	PWR CORD, EU ELECT DRIVE SYS	October 2001	Rule 9	Annex II (-section 4)	47857	17993
6471347	UK POWER CORD, EL DR SYS	February 2003	Rule 9	Annex II (-section 4)	47857	17993
6471349	ELECT DR SYSTEM, 230V CONFIG	February 2003	Rule 9	Annex II (-section 4)	44491	17993
6471704	POWER CORD, US, 115V EL DR SYS	February 2003	Rule 9	Annex II (-section 4)	47857	17993
6471707	FUSE, 115V, EL DR SY, 5MMX20MM	May 2003	Rule 9	Annex II (-section 4)	44491	17993
6472340	CONSOLE, ELE DR SYSTEM 230V	May 2003	Rule 9	Annex II (-section 4)	44491	17993
6472701	CONSOLE, ELE DR SYSTEM 115V	May 2003	Rule 9	Annex II (-section 4)	44491	17993
6479000	ELE DR SYS,230/115V CONFIG	July 2003	Rule 9	Annex II (-section 4)	44491	17993
6479001	CONSOLE, 230/115V CONFIG	July 2003	Rule 9	Annex II (-section 4)	44491	17993
UCSS® Screw Set						
8730006	UCSS CANN. DRILL BIT, STERILE	April 2005	Rule 6	Annex II (-section 4)	43390	11331
VERTEX® Reconstruction System						
6905709	14mm Cancellous Drill Bit (Sterile)	June 2001	Rule 6	Annex II (-section 4)	43390	11331
6905710	Adjustable Cancellous Drill Bit (Sterile)	June 2001	Rule 6	Annex II (-section 4)	43390	11331
6905711	Adjustable Cortical Drill Bit (Sterile)	September 2002	Rule 6	Annex II (-section 4)	43390	11331
6956010	2.4MM DRILL BIT (STERILE)	November 2004	Rule 6	Annex II (-section 4)	43390	11331
6956011	2.9MM DRILL BIT (STERILE)	November 2004	Rule 6	Annex II (-section 4)	43390	11331
6956012	3.0MM DRILL BIT (STERILE)	November 2004	Rule 6	Annex II (-section 4)	43390	11331
6956013	3.5MM DRILL BIT (STERILE)	November 2004	Rule 6	Annex II (-section 4)	43390	11331
6956208	TRIAL 6956208 LATERAL CONNECTOR	March 2007	Rule 6	Annex II (-section 4)	44759	17993
7756010	2.4MM DRILL BIT (STERILE)	August 2006	Rule 6	Annex II (-section 4)	43390	11331
7756126	4.0MM TAP (STERILE)	September 2006	Rule 6	Annex II (-section 4)	17507	17507
7756128	2.4MM DRILL BIT (STERILE)	September 2006	Rule 6	Annex II (-section 4)	43390	11331
7756131	3.2MM DRILL BIT (STERILE)	September 2006	Rule 6	Annex II (-section 4)	43390	11331
7756136	4.5MM TAP (STERILE)	September 2006	Rule 6	Annex II (-section 4)	17507	17507
7756137	5.0MM TAP (STERILE)	September 2006	Rule 6	Annex II (-section 4)	17507	17507
7756281S	3.2MM OC FLEXIBLE DRILL (STERILE)	December 2008	Rule 6	Annex II (-section 4)	43390	11333
6957317	GUIDEWIRE - NON THREADED - 720MM-STE	September 2006	Rule 6	Annex II (-section 4)	44759	11925
6957306	3.0MM CANN. DRILL (STERILE)	February 2017	Rule 6	Annex II (-section 4)	43390	11331
INFINITY™ OCT System						
G3606010	2.4mm Drill Bit - Sterile	February 2017	Rule 6	Annex II (-section 4)	43390	11331
G3600320	OC Drill Bit 3.2mm - Sterile	February 2017	Rule 6	Annex II (-section 4)	43390	11331

Medtronic

Product: Instruments

Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
G3600321	OC Drill Bit 3.2mm Flexible - Sterile	February 2017	Rule 6	Annex II (-section 4)	43390	11331
3605791	Medium MAS - Rod Crosslink Trial	February 2017	Rule 6	Annex VII	44788	17704
3605792	Small/Large MAS - Rod Crosslink Trial	February 2017	Rule 6	Annex VII	44788	17704
3600257	OC Plate Template	February 2017	Rule 6	Annex VII	44788	17704
Navigated VERTEX® Reconstruction System						
NAV2075	2.4MM DRILL BIT (STERILE)	October 2015	Rule 6	Annex II (-section 4)	43390	11331
NAV2076	2.9MM DRILL BIT (STERILE)	October 2015	Rule 6	Annex II (-section 4)	43390	11331
NAV2077	3.0MM TAP (NON-STERILE)	October 2015	Rule 6	Annex II (-section 4)	17507	17507
NAV2078	3.5MM TAP (NON-STERILE)	October 2015	Rule 6	Annex II (-section 4)	17507	17507
NAV2079	4.0MM TAP (NON-STERILE)	October 2015	Rule 6	Annex II (-section 4)	17507	17507
NAV2080	4.5MM TAP (NON-STERILE)	October 2015	Rule 6	Annex II (-section 4)	17507	17507
NAV2081	THREADED DRIVER (NON-STERILE)	October 2015	Rule 6	Annex II (-section 4)	33968	33968
NAV2075K*	2.4MM DRILL BIT (STERILE)	February 2016	Rule 6	Annex II (-section 4)	43390	11331
NAV2076K*	2.9MM DRILL BIT (STERILE)	February 2016	Rule 6	Annex II (-section 4)	43390	11331
NAV2077K*	3.0MM TAP (NON-STERILE)	February 2016	Rule 6	Annex II (-section 4)	17507	17507
NAV2078K*	3.5MM TAP (NON-STERILE)	February 2016	Rule 6	Annex II (-section 4)	17507	17507
NAV2079K*	4.0MM TAP (NON-STERILE)	February 2016	Rule 6	Annex II (-section 4)	17507	17507
NAV2080K*	4.5MM TAP (NON-STERILE)	February 2016	Rule 6	Annex II (-section 4)	17507	17507
NAV2081K*	THREADED DRIVER (NON-STERILE)	February 2016	Rule 6	Annex II (-section 4)	33968	33968
Navigated INFINITY™ OCT System						
NAV3606006	NAV DT GUIDE	February 2017	Rule 6	Annex II (-section 4)	32390	32390
NAV3606030	NAV TAP, 3.0MM	February 2017	Rule 6	Annex II (-section 4)	17507	17507
NAV3606035	NAV TAP, 3.5MM	February 2017	Rule 6	Annex II (-section 4)	17507	17507
NAV3606040	NAV TAP, 4.0MM	February 2017	Rule 6	Annex II (-section 4)	17507	17507
NAV3606045	NAV TAP, 4.5MM	February 2017	Rule 6	Annex II (-section 4)	17507	17507
NAV3606195	THREADED DRIVER, NAV	February 2017	Rule 6	Annex II (-section 4)	33968	33968
NAVNS3606010	NAV DRILL BIT, NON-STERILE	February 2017	Rule 6	Annex II (-section 4)	32390	32390

*Part numbers NAV2075K - NAV2081K are identical to part numbers NAV2075-NAV2081. Navigated VERTEX 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.

Medtronic

Product List

Last updated by: Tejas Patel **Date:** 24-Jan-18

Tech File Bundle: TF001

Product: ATLAS® Cable System

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
826-011	DOUBLE CABLE W/IC, STERILE	March 2000	Rule 8	Annex II (-section 4)	44797	15766
826-012	12 PACK DBL CABLE W/IC STERILE	March 2000	Rule 8	Annex II (-section 4)	44797	15766
826-013	SINGLE CABLE W/IC, STERILE	March 2000	Rule 8	Annex II (-section 4)	44797	15766
826-016	INTEGRAL BAR CRIMP, STERILE	March 2000	Rule 8	Annex II (-section 4)	44798	15766
826-211	TI DOUBLE CABLE W/IC STERILE	March 2000	Rule 8	Annex II (-section 4)	44797	15766
826-212	12 PACK DBL CABLE W/IC STERILE	March 2000	Rule 8	Annex II (-section 4)	44797	15766
826-213	TI SINGLE CABLE W/IC, STERILE	March 2000	Rule 8	Annex II (-section 4)	44797	15766
826-216	TI INTEGRAL BAR CRIMP, STERILE	March 2000	Rule 8	Annex II (-section 4)	44798	15766
826-217	TITANIUM FLAT BARS, STERILE	March 2000	Rule 8	Annex II (-section 4)	44797	15766
826-219	TI DBL. LEADER CABLE, STERILE	March 2000	Rule 8	Annex II (-section 4)	44797	15766
826-320	TI DBL. CABLE W/INTEG CRIMP	March 2000	Rule 8	Annex II (-section 4)	61465	15766
826-360	TI SINGLE CABLE W/INTEG.CRIMP	March 2000	Rule 8	Annex II (-section 4)	61465	15766

Medtronic

Product List

Last updated by: Tejas Patel **Date:** 24-Jan-18

Tech File Bundle: TF001

Product: CENTERPIECE® Plate Fixation System

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
8530000	TROUGH PLATE	May 2006	Rule 8	Annex II (-section 4)	61325	15766
8530008	8MM OD PLATE	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853008LH	OD LATERAL HOLE PLATE, 8MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853008LW	OD LAT WIDE MOUTH PLATE, 8MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853008WM	OD WIDE MOUTH PLATE, 8MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853-010	10MM OD PLATE	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853010LH	OD LATERAL HOLE PLATE, 10MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853010LW	OD LAT WIDE MOUTH PLATE, 10MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853010WM	OD WIDE MOUTH PLATE, 10MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853-012	12MM OD PLATE	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853012LH	OD LATERAL HOLE PLATE, 12MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853012LW	OD LAT WIDE MOUTH PLATE, 12MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853012WM	OD WIDE MOUTH PLATE, 12MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853-014	14MM OD PLATE	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853014LH	OD LATERAL HOLE PLATE, 14MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853014LW	OD LAT WIDE MOUTH PLATE, 14MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853014WM	OD WIDE MOUTH PLATE, 14MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853-016	16MM OD PLATE	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853016LH	OD LATERAL HOLE PLATE, 16MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853016LW	OD LAT WIDE MOUTH PLATE, 16MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853016WM	OD WIDE MOUTH PLATE, 16MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853-018	18MM OD PLATE	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853018LH	OD LATERAL HOLE PLATE, 18MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853018LW	OD LAT WIDE MOUTH PLATE, 18MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853018WM	OD WIDE MOUTH PLATE, 18MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
8530408	8MM GRAFT PLATE	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853408LH	GP LATERAL HOLE PLATE, 8MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853-410	10MM GRAFT PLATE	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853410LH	GP LATERAL HOLE PLATE, 10MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853-412	12MM GRAFT PLATE	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853412LH	GP LATERAL HOLE PLATE, 12MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853-414	14MM GRAFT PLATE	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853414LH	GP LATERAL HOLE PLATE, 14MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853-416	16MM GRAFT PLATE	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853416LH	GP LATERAL HOLE PLATE, 16MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853-418	18MM GRAFT PLATE	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853-465	BONE SCREW 2.6 X 5MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853-467	BONE SCREW 2.6 X 7MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853-469	BONE SCREW 2.6 X 9MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853-471	BONE SCREW 2.6 X 11MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853-505	BONE SCREW 3.0 X 5MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853-507	BONE SCREW 3.0 X 7MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853-509	BONE SCREW 3.0 X 9MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766
853-511	BONE SCREW 3.0 X 11MM	May 2006	Rule 8	Annex II (-section 4)	61325	15766

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Product List

Last updated by: Tejas Patel

Date: 24-Jan-18

Tech File Bundle: TF001

Product: UCSS® Screw Set

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
873-030	4.0 MM CANN. CORT SCREW 30MM	March 2000	Rule 8	Annex II (-section 4)	61325	15766
873-032	4.0 MM CANN. CORT SCREW 32MM	March 2000	Rule 8	Annex II (-section 4)	61325	15766
873-034	4.0 MM CANN. CORT SCREW 34MM	March 2000	Rule 8	Annex II (-section 4)	61325	15766
873-036	4.0 MM CANN. CORT SCREW 36MM	March 2000	Rule 8	Annex II (-section 4)	61325	15766
873-038	4.0 MM CANN. CORT SCREW 38MM	March 2000	Rule 8	Annex II (-section 4)	61325	15766
873-040	4.0 MM CANN. CORT SCREW 40MM	March 2000	Rule 8	Annex II (-section 4)	61325	15766
873-042	4.0 MM CANN. CORT SCREW 42MM	March 2000	Rule 8	Annex II (-section 4)	61325	15766
873-044	4.0 MM CANN. CORT SCREW 44MM	March 2000	Rule 8	Annex II (-section 4)	61325	15766
873-046	4.0 MM CANN. CORT SCREW 46MM	March 2000	Rule 8	Annex II (-section 4)	61325	15766
873-048	4.0 MM CANN. CORT SCREW 48MM	March 2000	Rule 8	Annex II (-section 4)	61325	15766
873-050	4.0 MM CANN. CORT SCREW 50MM	March 2000	Rule 8	Annex II (-section 4)	61325	15766
873-136	4.0 MM CANN.CORT.LAG SCREW36MM	March 2000	Rule 8	Annex II (-section 4)	61325	15766
873-138	4.0MM CANN.CORT.LAG SCREW38MM	March 2000	Rule 8	Annex II (-section 4)	61325	15766
873-140	4.0 MM CANN.CORT.LAG SCREW40MM	March 2000	Rule 8	Annex II (-section 4)	61325	15766
873-142	4.0 MM CANN.CORT.LAG SCREW42MM	March 2000	Rule 8	Annex II (-section 4)	61325	15766
873-144	4.0 MM CANN.CORT.LAG SCREW44MM	March 2000	Rule 8	Annex II (-section 4)	61325	15766
873-146	4.0 MM CANN.CORT.LAG SCREW46MM	March 2000	Rule 8	Annex II (-section 4)	61325	15766
873-148	4.0 MM CANN.CORT.LAG SCREW48MM	March 2000	Rule 8	Annex II (-section 4)	61325	15766
873-150	4.0MM CANN.CORT LAG SCREW50MM	March 2000	Rule 8	Annex II (-section 4)	61325	15766
9098526	4.0 CORTICAL BONE SCREW 26MM	March 2002	Rule 8	Annex II (-section 4)	61325	15766
9098530	4.0 CORTICAL BONE SCREW 30MM	March 2002	Rule 8	Annex II (-section 4)	61325	15766
9098534	4.0 CORTICAL BONE SCREW 34MM	March 2002	Rule 8	Annex II (-section 4)	61325	15766
9098538	4.0 CORTICAL BONE SCREW 38MM	March 2002	Rule 8	Annex II (-section 4)	61325	15766
9098540	4.0 CORTICAL BONE SCREW 40MM	March 2002	Rule 8	Annex II (-section 4)	61325	15766
9098542	4.0 CORTICAL BONE SCREW 42MM	March 2002	Rule 8	Annex II (-section 4)	61325	15766
9098544	4.0 CORTICAL BONE SCREW 44MM	March 2002	Rule 8	Annex II (-section 4)	61325	15766
9098546	4.0 CORTICAL BONE SCREW 46MM	March 2002	Rule 8	Annex II (-section 4)	61325	15766
9098548	4.0 CORTICAL BONE SCREW 48MM	March 2002	Rule 8	Annex II (-section 4)	61325	15766
9098550	4.0 CORTICAL BONE SCREW 50MM	March 2002	Rule 8	Annex II (-section 4)	61325	15766
9098552	4.0 CORTICAL BONE SCREW 52MM	March 2002	Rule 8	Annex II (-section 4)	61325	15766
9098554	4.0 CORTICAL BONE SCREW 54MM	March 2002	Rule 8	Annex II (-section 4)	61325	15766
9098556	4.0 CORTICAL BONE SCREW 56MM	March 2002	Rule 8	Annex II (-section 4)	61325	15766
9098558	4.0 CORTICAL BONE SCREW 58MM	March 2002	Rule 8	Annex II (-section 4)	61325	15766
9098560	4.0 CORTICAL BONE SCREW 60MM	March 2002	Rule 8	Annex II (-section 4)	61325	15766
G873H030	4.0 MM CAN. CORT SCREW 30 STER	December 2004	Rule 8	Annex II (-section 4)	61324	15766
G873H032	4.0 CANN CORT BONE SCREW STER	December 2004	Rule 8	Annex II (-section 4)	61324	15766
G873H034	4.0 CANN CORT BONE SCREW STER	December 2004	Rule 8	Annex II (-section 4)	61324	15766
G873H036	4.0 CANN CORT BONE SCREW STER	December 2004	Rule 8	Annex II (-section 4)	61324	15766
G873H038	4.0 CANN CORT BONE SCREW STER	December 2004	Rule 8	Annex II (-section 4)	61324	15766
G873H040	4.0 CANN CORT BONE SCREW STER	December 2004	Rule 8	Annex II (-section 4)	61324	15766

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Product: UCSS® Screw Set

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
G873H042	4.0 CANN CORT BONE SCREW STER	December 2004	Rule 8	Annex II (-section 4)	61324	15766
G873H044	4.0 CANN CORT BONE SCREW STER	December 2004	Rule 8	Annex II (-section 4)	61324	15766
G873H136	4.0 CANN. CORT. LAG SCREW STER	December 2004	Rule 8	Annex II (-section 4)	61324	15766
G873H138	4.0 CANN. CORT. LAG SCREW STER	December 2004	Rule 8	Annex II (-section 4)	61324	15766
G873H140	4.0 CANN. CORT. LAG SCREW STER	December 2004	Rule 8	Annex II (-section 4)	61324	15766
G873H142	4.0 CANN. CORT. LAG SCREW STER	December 2004	Rule 8	Annex II (-section 4)	61324	15766
G873H144	4.0 CANN. CORT. LAG SCREW STER	December 2004	Rule 8	Annex II (-section 4)	61324	15766
GX873H118	UCS 4.0X18 CANN LAG SCR TI-STERILE	December 2005	Rule 8	Annex II (-section 4)	61324	15766
GX873H120	UCS 4.0X20 CANN LAG SCR TI-STERILE	December 2005	Rule 8	Annex II (-section 4)	61324	15766
GX873H122	UCS 4.0X22 CANN LAG SCR TI-STERILE	December 2005	Rule 8	Annex II (-section 4)	61324	15766
GX873H124	UCS 4.0X24 CANN LAG SCR TI-STERILE	Decmeber 2005	Rule 8	Annex II (-section 4)	61324	15766
GX873H126	UCS 4.0X26 CANN LAG SCR TI-STERILE	December 2005	Rule 8	Annex II (-section 4)	61324	15766
GX873H128	UCS 4.0X28 CANN LAG SCR TI-STERILE	December 2005	Rule 8	Annex II (-section 4)	61324	15766
GX873H130	UCS 4.0X30 CANN LAG SCR TI-STERILE	December 2005	Rule 8	Annex II (-section 4)	61324	15766
GX873H132	UCS 4.0X32 CANN LAG SCR TI-STERILE	December 2005	Rule 8	Annex II (-section 4)	61324	15766
GX873H134	UCS 4.0X34 CANN LAG SCR TI-STE	January 2005	Rule 8	Annex II (-section 4)	61324	15766
X873-158	4.0X58MM CANN CORT LAG SCREW	November 2001	Rule 8	Annex II (-section 4)	61325	15766

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Product List

Last updated by: Tejas Patel

Date: 24-Jan-18

Tech File Bundle: TF001

Product: VERTEX® Reconstruction System

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
VERTEX Original						
6900282	PRECURVED OCCIPITAL ROD	September 2003	Rule 8	Annex II (-section 4)	61325	15766
6900285	24MM MIDLINE OCCIPITAL PLATE	September 2003	Rule 8	Annex II (-section 4)	61325	15766
6900286	32MM MIDLINE OCCIPITAL PLATE	September 2003	Rule 8	Annex II (-section 4)	61325	15766
6900287	40MM MIDLINE OCCIPITAL PLATE	September 2003	Rule 8	Annex II (-section 4)	61325	15766
6900506	3.5 X 6MM CANC SCREW, TI	April 2001	Rule 8	Annex II (-section 4)	61325	15766
6900508	3.5 X 8MM CANC SCREW, TI	April 2001	Rule 8	Annex II (-section 4)	61325	15766
6900510	3.5 X 10MM CANC SCREW, TI	April 2001	Rule 8	Annex II (-section 4)	61325	15766
6900512	3.5 X 12MM CANCE SCREW, TI	April 2001	Rule 8	Annex II (-section 4)	61325	15766
6900514	3.5 X 14MM CANC SCREW, TI	April 2001	Rule 8	Annex II (-section 4)	61325	15766
6900516	3.5 X 16MM CANC SCREW, TI	April 2001	Rule 8	Annex II (-section 4)	61325	15766
6900518	3.5 X 18MM CANC SCREW, TI	October 2001	Rule 8	Annex II (-section 4)	61325	15766
6900520	3.5 X 20MM CANC SCREW, TI	October 2001	Rule 8	Annex II (-section 4)	61325	15766
6900522	3.5 X 22MM CANC SCREW, TI	October 2001	Rule 8	Annex II (-section 4)	61325	15766
6900524	3.5 X 24MM CANC SCREW, TI	October 2001	Rule 8	Annex II (-section 4)	61325	15766
6900606	4.0 X 6MM CANC SCREW, TI	April 2001	Rule 8	Annex II (-section 4)	61325	15766
6900608	4.0 X 8MM CANC SCREW, TI	April 2001	Rule 8	Annex II (-section 4)	61325	15766
6900610	4.0 X 10MM CANC SCREW, TI	April 2001	Rule 8	Annex II (-section 4)	61325	15766
6900612	4.0 X 12MM CANC SCREW, TI	April 2001	Rule 8	Annex II (-section 4)	61325	15766
6900614	4.0 X 14MM CANC SCREW, TI	April 2001	Rule 8	Annex II (-section 4)	61325	15766
6900616	4.0 X 16MM CANC SCREW, TI	April 2001	Rule 8	Annex II (-section 4)	61325	15766
6900618	4.0 X 18MM CANC SCREW, TI	October 2001	Rule 8	Annex II (-section 4)	61325	15766
6900620	4.0 X 20MM CANC SCREW, TI	November 2001	Rule 8	Annex II (-section 4)	61325	15766
6900622	4.0 X 22MM CANC SCREW, TI	November 2001	Rule 8	Annex II (-section 4)	61325	15766
6900624	4.0 X 24MM CANC SCREW, TI	November 2001	Rule 8	Annex II (-section 4)	61325	15766
6900626	4.0 X 26MM CORTICAL SCREW, TI	November 2001	Rule 8	Annex II (-section 4)	61325	15766
6900628	4.0 X 28MM CORTICAL SCREW, TI	November 2001	Rule 8	Annex II (-section 4)	61325	15766
6902130	Lateral Connector - Closed, 10mm	June 2001	Rule 8	Annex II (-section 4)	61325	15766
6902131	Lateral Connector - Closed, 13mm	June 2001	Rule 8	Annex II (-section 4)	61325	15766
6902135	10MM OPEN CONNECTOR	July 2002	Rule 8	Annex II (-section 4)	61325	15766
6903070	TITANIUM NUT OF OCCIPITAL HOOK	October 2001	Rule 8	Annex II (-section 4)	61325	15766
6903135	3.5MM OCCIPITAL HOOK, SMALL	March 2003	Rule 8	Annex II (-section 4)	61325	15766
6903150	5.0MM OCCIPITAL HOOK, MEDIUM	March 2003	Rule 8	Annex II (-section 4)	61325	15766
6903165	6.5MM OCCIPITAL HOOK, LARGE	March 2003	Rule 8	Annex II (-section 4)	61325	15766
6904000L	FORAMINAL HOOK, LEFT	October 2001	Rule 8	Annex II (-section 4)	61325	15766
6904000R	FORAMINAL HOOK, RIGHT	October 2001	Rule 8	Annex II (-section 4)	61325	15766
6904003	LAT. CONNECTOR FOR CANCELLOUS	December 2001	Rule 8	Annex II (-section 4)	61325	15766
6904045	4.5MM LAMINAR HOOK	October 2001	Rule 8	Annex II (-section 4)	61325	15766
6904060	6.0MM LAMINAR HOOK	October 2001	Rule 8	Annex II (-section 4)	61325	15766
6904075	7.5MM LAMINAR HOOK	October 2001	Rule 8	Annex II (-section 4)	61325	15766
6904090	9.0MM LAMINAR HOOK	October 2001	Rule 8	Annex II (-section 4)	61325	15766
X0202008	VER EX OCC CUR PLT 5.5 TI	May 2002	Rule 8	Annex II (-section 4)	61325	15766
X0209552	ROD TI 3.2 x 20MM	April 2009	Rule 8	Annex II (-section 4)	61325	15766
X0209553	ROD TI 3.2 x 25MM	April 2009	Rule 8	Annex II (-section 4)	61325	15766
X0209554	ROD TI 3.2 x 30MM	April 2009	Rule 8	Annex II (-section 4)	61325	15766

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Product: VERTEX® Reconstruction System

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
X0209555	ROD TI 3.2 x 35MM	April 2009	Rule 8	Annex II (-section 4)	61325	15766
X0209556	ROD TI 3.2 x 40MM	April 2009	Rule 8	Annex II (-section 4)	61325	15766
X0209557	ROD TI 3.2 x 45MM	April 2009	Rule 8	Annex II (-section 4)	61325	15766
X0209558	ROD TI 3.2 x 50MM	April 2009	Rule 8	Annex II (-section 4)	61325	15766
X0209559	ROD TI 3.2 x 55MM	April 2009	Rule 8	Annex II (-section 4)	61325	15766
X0209560	ROD TI 3.2 x 60MM	April 2009	Rule 8	Annex II (-section 4)	61325	15766
X0209561	ROD TI 3.2 x 65MM	April 2009	Rule 8	Annex II (-section 4)	61325	15766
X0209562	ROD TI 3.2 x 70MM	April 2009	Rule 8	Annex II (-section 4)	61325	15766
X0209563	ROD TI 3.2 x 75MM	April 2009	Rule 8	Annex II (-section 4)	61325	15766
X0407057	CONNECTOR OPEN CABLE TI	June 2007	Rule 8	Annex II (-section 4)	61325	15766
X0507122	CONNECTOR LATERAL SCREW 3.2 TI	June 2007	Rule 8	Annex II (-section 4)	61325	15766
X0507123	CONNECTOR MEDIAL SCREW 3.2 TI	June 2007	Rule 8	Annex II (-section 4)	61325	15766
X0706142	CROSSLINK ADJSTBL CLIP-5.5-TI	September 2006	Rule 8	Annex II (-section 4)	61325	15766
X0706143	CROSSLINK BAR-TI-PRECRV-17X90	September 2006	Rule 8	Annex II (-section 4)	61325	15766
X2390145	VER HK-TI-LAM-4.5MM-3.2	September 2005	Rule 8	Annex II (-section 4)	61325	15766
X4973255	Domino 3.2 open / 5.5 closed	January 2010	Rule 8	Annex II (-section 4)	61325	15766
X49832635	Domino 3.2 / 6.35	January 2010	Rule 8	Annex II (-section 4)	61325	15766
X6959416	4.0 X 16MM CANNULATED MAS	August 2009	Rule 8	Annex II (-section 4)	61325	15766
XD706704	VER CONN DOM-TI-3.2/4.5	Ocotber 2002	Rule 8	Annex II (-section 4)	61325	15766
VERTEX MAX						
6900120	3.2mm Titanium Rod, 120mm	July 2001	Rule 8	Annex II (-section 4)	61325	15766
6900270	3.2 X 100MM PRE-CURVED OCCIPIT	October 2001	Rule 8	Annex II (-section 4)	61325	15766
6900271	3.2 X 100MM OCCIPITO-CERV ROD	November 2002	Rule 8	Annex II (-section 4)	61325	15766
6900280	3.2 X 200MM PRE-CURVED OCCIPIT	October 2001	Rule 8	Annex II (-section 4)	61325	15766
6900281	3.2 X 200MM OCCIPITO-CERV ROD	November 2002	Rule 8	Annex II (-section 4)	61325	15766
6901000	SCREW CONNECTOR	June 2001	Rule 8	Annex II (-section 4)	61325	15766
6902220	ROD CONN 3.2 TO 4.5, TI	April 2003	Rule 8	Annex II (-section 4)	61325	15766
6902525	CROSSLINK CLIP	October 2001	Rule 8	Annex II (-section 4)	61325	15766
6902530	CROSSLINK BAR	October 2001	Rule 8	Annex II (-section 4)	61325	15766
6950300	3.2MM TITANIUM ROD, 300MM	July 2006	Rule 8	Annex II (-section 4)	61325	15766
6950305	SET SCREW	July 2004	Rule 8	Annex II (-section 4)	61325	15766
6950315	M6 SET SCREW	June 2005	Rule 8	Annex II (-section 4)	61325	15766
6952500	SET SCREW	February 2006	Rule 8	Annex II (-section 4)	61325	15766
6952525	ADJ ARCHED CROSSLINK, SM	February 2006	Rule 8	Annex II (-section 4)	61325	15766
6952526	ADJ ARCHED CROSSLINK, MED	February 2006	Rule 8	Annex II (-section 4)	61325	15766
6952527	ADJ ARCHED CROSSLINK, LG	February 2006	Rule 8	Annex II (-section 4)	61325	15766
6955240	3.2 X 240MM THREADED ROD	October 2004	Rule 8	Annex II (-section 4)	61325	15766
6955241	#10-48 SET SCREW	June 2007	Rule 8	Annex II (-section 4)	61325	15766
6955245	4.5 X 360MM THREADED ROD	October 2004	Rule 8	Annex II (-section 4)	61325	15766
6955255	5.5 X 360MM THREADED ROD	October 2004	Rule 8	Annex II (-section 4)	61325	15766
6955255CP	5.5 X 360MM CP THREADED ROD	July 2006	Rule 8	Annex II (-section 4)	61325	15766
6955260	3.2 X 100 PRECURVED OC ROD, TI	September 2005	Rule 8	Annex II (-section 4)	61325	15766
6955270	3.2 X 200 PRECURVED OC ROD, TI	September 2005	Rule 8	Annex II (-section 4)	61325	15766
6955273	OCCIPITAL KEEL PLATE - SMALL	September 2005	Rule 8	Annex II (-section 4)	61325	15766
6955274	OCCIPITAL KEEL PLATE - MEDIUM	September 2005	Rule 8	Annex II (-section 4)	61325	15766
6955275	OCCIPITAL KEEL PLATE - LARGE	September 2005	Rule 8	Annex II (-section 4)	61325	15766
6955406	4.0 X 6MM CORTICAL SCREW	October 2004	Rule 8	Annex II (-section 4)	61325	15766
6955408	4.0 X 8MM CORTICAL SCREW	October 2004	Rule 8	Annex II (-section 4)	61325	15766
6955410	4.0 X 10MM CORTICAL SCREW	October 2004	Rule 8	Annex II (-section 4)	61325	15766
6955412	4.0 X 12MM CORTICAL SCREW	October 2004	Rule 8	Annex II (-section 4)	61325	15766

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Product: VERTEX® Reconstruction System

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
6955414	4.0 X 14MM CORTICAL SCREW	October 2004	Rule 8	Annex II (-section 4)	61325	15766
6955416	4.0 X 16MM CORTICAL SCREW	October 2004	Rule 8	Annex II (-section 4)	61325	15766
6955418	4.0 X 18MM CORTICAL SCREW	October 2004	Rule 8	Annex II (-section 4)	61325	15766
6955506	4.5 X 6MM CORTICAL SCREW	October 2004	Rule 8	Annex II (-section 4)	61325	15766
6955508	4.5 X 8MM CORTICAL SCREW	October 2004	Rule 8	Annex II (-section 4)	61325	15766
6955510	4.5 X 10MM CORTICAL SCREW	October 2004	Rule 8	Annex II (-section 4)	61325	15766
6955512	4.5 X 12MM CORTICAL SCREW	October 2004	Rule 8	Annex II (-section 4)	61325	15766
6955514	4.5 X 14MM CORTICAL SCREW	October 2004	Rule 8	Annex II (-section 4)	61325	15766
6955516	4.5 X 16MM CORTICAL SCREW	October 2004	Rule 8	Annex II (-section 4)	61325	15766
6955518	4.5 X 18MM CORTICAL SCREW	October 2004	Rule 8	Annex II (-section 4)	61325	15766
6955520	4.5 X 20MM CORTICAL SCREW	October 2004	Rule 8	Annex II (-section 4)	61325	15766
6955524	4.5 X 24MM CORTICAL SCREW	October 2004	Rule 8	Annex II (-section 4)	61325	15766
6955960	10MM LATERAL OFFSET CONN- OPEN	October 2004	Rule 8	Annex II (-section 4)	61325	15766
6955965	13MM LATERAL OFFSET CONN- OPEN	October 2004	Rule 8	Annex II (-section 4)	61325	15766
6955973	4.5MM LAMINAR HOOK	December 2004	Rule 8	Annex II (-section 4)	61325	15766
6955974	6.0MM LAMINAR HOOK	December 2004	Rule 8	Annex II (-section 4)	61325	15766
6955975L	4.5 MM OFFSET LAMINAR HOOK, L	February 2005	Rule 8	Annex II (-section 4)	61325	15766
6955975R	4.5 MM OFFSET LAMINAR HOOK, R	February 2005	Rule 8	Annex II (-section 4)	61325	15766
6955976	7.5MM LAMINAR HOOK	December 2004	Rule 8	Annex II (-section 4)	61325	15766
6955977L	6.0 MM OFFSET LAMINAR HOOK, L	February 2005	Rule 8	Annex II (-section 4)	61325	15766
6955977R	6.0 MM OFFSET LAMINAR HOOK, R	February 2005	Rule 8	Annex II (-section 4)	61325	15766
6955978	9.0MM LAMINAR HOOK	December 2004	Rule 8	Annex II (-section 4)	61325	15766
7002500	CROSSLINK SET SCREW	July 2004	Rule 8	Annex II (-section 4)	61325	15766
7002525	ADJ. CROSSLINK, SMALL	July 2004	Rule 8	Annex II (-section 4)	61325	15766
7002526	ADJ. CROSSLINK, MED	July 2004	Rule 8	Annex II (-section 4)	61325	15766
7002527	ADJ. CROSSLINK, LARGE	July 20004	Rule 8	Annex II (-section 4)	61325	15766
G6900080	3.2MM TITANIUM ROD, 80MM	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6900120	3.2MM TITANIUM ROD, 120MM	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6900240	3.2MM TITANIUM ROD, 240MM	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6900281	3.2 X 200MM OCCIPITO-CERV ROD	August 2005	Rule 8	Annex II (-section 4)	61324	15766
G6900285	24MM MIDLINE OC PLATE, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6900286	32MM MIDLINE OC PLATE, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6900287	40MM MIDLINE OC PLATE, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6900512	3.5 X 12MM CANC SCREW, TI	August 2005	Rule 8	Annex II (-section 4)	61324	15766
G6900514	3.5 X 14MM CANC SCREW, TI	August 2005	Rule 8	Annex II (-section 4)	61324	15766
G6900516	3.5 X 16MM CANC SCREW, TI	August 2005	Rule 8	Annex II (-section 4)	61324	15766
G6900518	3.5 X 18MM CANC SCREW, TI	August 2005	Rule 8	Annex II (-section 4)	61324	15766
G6901000	SCREW CONNECTOR, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6902220	ROD CONN 3.2 TO 4.5, TI	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6903070	TITANIUM NUT OF OCCIPITAL HOOK	August 2005	Rule 8	Annex II (-section 4)	61324	15766
G6903135	3.5MM OCCIPITAL HOOK, SMALL	August 2005	Rule 8	Annex II (-section 4)	61324	15766
G6903150	5.0MM OCCIPITAL HOOK, MEDIUM	August 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945712	3.5 X 12MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945714	3.5 X 14MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945716	3.5 X 16MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945718	3.5 X 18MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945810	4.0 X 10MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945812	4.0 X 12MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945814	4.0 X 14MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945816	4.0 X 16MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766

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P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
G6945818	4.0 X 18MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945820	4.0 X 20MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945822	4.0 X 22MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945824	4.0 X 24MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945826	4.0 X 26MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945826PT	4.0 X 26MM-13MM PAR-THRD STER	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945828PT	4.0 X 28MM-14MM PAR-THRD STER	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945830	4.0 X 30MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945830PT	4.0 X 30MM-15MM PAR-THRD STER	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945832	4.0 X 32MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945832PT	4.0 X 32MM-16MM PAR-THRD STER	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945834	4.0 X 34MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945834PT	4.0 X 34MM-17MM PAR-THRD STER	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945836	4.0 X 36MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945836PT	4.0 X 36MM-18MM PAR-THRD STER	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945838	4.0 X 38MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945838PT	4.0 X 38MM-19MM PAR-THRD STER	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945840	4.0 X 40MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945840PT	4.0 X 40MM-20MM PAR-THRD STER	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945920	4.5 X 20MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945922	4.5 X 22MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945924	4.5 X 24MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945926	4.5 X 26MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945928	4.5 X 28MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945930	4.5 X 30MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945932	4.5 X 32MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6945934	4.5 X 34MM MAS, STERILE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6950305	SET SCREW	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6950315	SET SCREW M6	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6955240	3.2 X 240MM THREADED ROD	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6955245	4.5 X 360MM THREADED ROD	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6955255	5.5 X 360MM THREADED ROD	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6955406	4.0 X 6MM CORTICAL SCREW	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6955408	4.0 X 8MM CORTICAL SCREW	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6955410	4.0 X 10MM CORTICAL SCREW	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6955412	4.0 X 12MM CORTICAL SCREW	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6955414	4.0 X 14MM CORTICAL SCREW	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6955416	4.0 X 16MM CORTICAL SCREW	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6955418	4.0 X 18MM CORTICAL SCREW	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6955506	4.5 X 6MM CORTICAL SCREW	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6955508	4.5 X 8MM CORTICAL SCREW	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6955510	4.5 X 10MM CORTICAL SCREW	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6955512	4.5 X 12MM CORTICAL SCREW	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6955514	4.5 X 14MM CORTICAL SCREW	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6955516	4.5 X 16MM CORTICAL SCREW	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6955960	10MM LATERAL OFFSET CONN- OPEN	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6955965	13MM LATERAL OFFSET CONN- OPEN	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6955973	4.5MM LAMINAR HOOK	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G6955974	6.0MM LAMINAR HOOK	July 2005	Rule 8	Annex II (-section 4)	61324	15766
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P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
6900240	3.2mm Titanium Rod, 240mm	July 2001	Rule 8	Annex II (-section 4)	61325	15766
6958710	3.5 X 10MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958712	3.5 X 12MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958714	3.5 X 14MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958716	3.5 X 16MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958718	3.5 X 18MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958718PT	3.5 X 18MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958720	3.5 X 20MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958720PT	3.5 X 20MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958722	3.5 X 22MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958722PT	3.5 X 22MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958724	3.5 X 24MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958724PT	3.5 X 24MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958726	3.5 X 26MM MULTI AXIAL SCREW	January 2008	Rule 8	Annex II (-section 4)	61325	15766
6958726PT	3.5 X 26MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958728	3.5 X 28MM MULTI AXIAL SCREW	January 2008	Rule 8	Annex II (-section 4)	61325	15766
6958728PT	3.5 X 28MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958730	3.5 X 30MM MULTI AXIAL SCREW	January 2008	Rule 8	Annex II (-section 4)	61325	15766
6958730PT	3.5 X 30MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958732	3.5 X 32MM MULTI AXIAL SCREW	January 2008	Rule 8	Annex II (-section 4)	61325	15766
6958732PT	3.5 X 32MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958734	3.5 X 34MM MULTI AXIAL SCREW	January 2008	Rule 8	Annex II (-section 4)	61325	15766
6958734PT	3.5 X 34MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958736	3.5 X 36MM MULTI AXIAL SCREW	January 2008	Rule 8	Annex II (-section 4)	61325	15766
6958736PT	3.5 X 36MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958738	3.5 X 38MM MULTI AXIAL SCREW	January 2008	Rule 8	Annex II (-section 4)	61325	15766
6958738PT	3.5 X 38MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958740	3.5 X 40MM MULTI AXIAL SCREW	January 2008	Rule 8	Annex II (-section 4)	61325	15766
6958740PT	3.5 X 40MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958742	3.5 X 42MM MULTI AXIAL SCREW	January 2008	Rule 8	Annex II (-section 4)	61325	15766
6958742PT	3.5 X 42MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958744	3.5 X 44MM MULTI AXIAL SCREW	January 2008	Rule 8	Annex II (-section 4)	61325	15766
6958744PT	3.5 X 44MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958746	3.5 X 46MM MULTI AXIAL SCREW	January 2008	Rule 8	Annex II (-section 4)	61325	15766
6958746PT	3.5 X 46MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958748	3.5 X 48MM MULTI AXIAL SCREW	January 2008	Rule 8	Annex II (-section 4)	61325	15766
6958748PT	3.5 X 48MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958750	3.5 X 50MM MULTI AXIAL SCREW	January 2008	Rule 8	Annex II (-section 4)	61325	15766
6958750PT	3.5 X 50MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958752	3.5 X 52MM MULTI AXIAL SCREW	January 2008	Rule 8	Annex II (-section 4)	61325	15766
6958752PT	3.5 X 52MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958810	4.0 X 10MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958812	4.0 X 12MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958814	4.0 X 14MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958816	4.0 X 16MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958818	4.0 X 18MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958818PT	4.0 X 18MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958820	4.0 X 20MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958820PT	4.0 X 20MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958822	4.0 X 22MM MULTI AXIAL SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766

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6958822PT	4.0 X 22MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958824	4.0 X 24MM MULTI AXIAL SCREW	September 2007	Rule 8	Annex II (-section 4)	61325	15766
6958824PT	4.0 X 24MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958826	4.0 X 26MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958826PT	4.0 X 26MM-13MM PAR-THRD MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958828	4.0 X 28MM MULTI AXIAL SCREW	October 2007	Rule 8	Annex II (-section 4)	61325	15766
6958828PT	4.0 X 28MM-14MM PAR-THRD MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958830	4.0 X 30MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958830PT	4.0 X 30MM-15MM PAR-THRD MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958832	4.0 X 32MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958832PT	4.0 X 32MM-16MM PAR-THRD MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958834	4.0 X 34MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958834PT	4.0 X 34MM-17MM PAR-THRD MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958836	4.0 X 36MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958836PT	4.0 X 36MM-18MM PAR-THRD MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958838	4.0 X 38MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958838PT	4.0 X 38MM-19MM PAR-THRD MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958840	4.0 X 40MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958840PT	4.0 X 40MM-20MM PAR-THRD MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958842	4.0 X 42MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958842PT	4.0 X 42MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958844	4.0 X 44MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958844PT	4.0 X 44MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958846	4.0 X 46MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958846PT	4.0 X 46MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958848	4.0 X 48MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958848PT	4.0 X 48MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958850	4.0 X 50MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958850PT	4.0 X 50MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958852	4.0 X 52MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958852PT	4.0 X 52MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958910	4.5 X 10MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958912	4.5 X 12MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958914	4.5 X 14MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958916	4.5 X 16MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958918	4.5 X 18MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958918PT	4.5 X 18MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958920	4.5 X 20MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958920PT	4.5 X 20MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958922	4.5 X 22MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958922PT	4.5 X 22MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958924	4.5 X 24MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958924PT	4.5 X 24MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958926	4.5 X 26MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958926PT	4.5 X 26MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958928	4.5 X 28MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958928PT	4.5 X 28MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958930	4.5 X 30MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958930PT	4.5 X 30MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958932	4.5 X 32MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766

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P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
6958932PT	4.5 X 32MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958934	4.5 X 34MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958934PT	4.5 X 34MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958936	4.5 X 36MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958936PT	4.5 X 36MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958938	4.5 X 38MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958938PT	4.5 X 38MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958940	4.5 X 40MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958940PT	4.5 X 40MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958942	4.5 X 42MM MULTI AXIAL SCREW	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6958942PT	4.5 X 42MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958944	4.5 X 44MM MULTI AXIAL SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958944PT	4.5 X 44MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958946	4.5 X 46MM MULTI AXIAL SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958946PT	4.5 X 46MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958948	4.5 X 48MM MULTI AXIAL SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958948PT	4.5 X 48MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958950	4.5 X 50MM MULTI AXIAL SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958950PT	4.5 X 50MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958952	4.5 X 52MM MULTI AXIAL SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6958952PT	4.5 X 52MM PT MAS	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6959418	4.0 X 18MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959418PT	4.0 X 18MM CANNULATED MAS, PT	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6959420	4.0 X 20MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959420PT	4.0 X 20MM CANNULATED MAS, PT	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959422	4.0 X 22MM CANNULATED MAS	October 2007	Rule 8	Annex II (-section 4)	61325	15766
6959422PT	4.0 X 22MM CANNULATED MAS, PT	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959424	4.0 X 24MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959424PT	4.0 X 24MM CANNULATED MAS, PT	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959426	4.0 X 26MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959426PT	4.0 X 26MM CANNULATED MAS, PT	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959428PT	4.0 X 28MM CANNULATED MAS, PT	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959430	4.0 X 30MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959430PT	4.0 X 30MM CANNULATED MAS, PT	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959432	4.0 X 32MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959432PT	4.0 X 32MM CANNULATED MAS, PT	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959434	4.0 X 34MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959434PT	4.0 X 34MM CANNULATED MAS, PT	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959436	4.0 X 36MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959436PT	4.0 X 36MM CANNULATED MAS, PT	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959438	4.0 X 38MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959438PT	4.0 X 38MM CANNULATED MAS, PT	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959440	4.0 X 40MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959440PT	4.0 X 40MM CANNULATED MAS, PT	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959442	4.0 X 42MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959442PT	4.0 X 42MM CANNULATED MAS, PT	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6959444	4.0 X 44MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959444PT	4.0 X 44MM CANNULATED MAS, PT	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6959446	4.0 X 46MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959446PT	4.0 X 46MM CANNULATED MAS, PT	July 2008	Rule 8	Annex II (-section 4)	61325	15766

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6959448	4.0 X 48MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959448PT	4.0 X 48MM CANNULATED MAS, PT	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6959450	4.0 X 50MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959450PT	4.0 X 50MM CANNULATED MAS, PT	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6959452	4.0 X 52MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959452PT	4.0 X 52MM CANNULATED MAS, PT	July 2008	Rule 8	Annex II (-section 4)	61325	15766
6959510	4.5 X 10MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959512	4.5 X 12MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959514	4.5 X 14MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959516	4.5 X 16MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959518	4.5 X 18MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959520	4.5 X 20MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959522	4.5 X 22MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959524	4.5 X 24MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959526	4.5 X 26MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959528	4.5 X 28MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959530	4.5 X 30MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959532	4.5 X 32MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959534	4.5 X 34MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959536	4.5 X 36MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959538	4.5 X 38MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959540	4.5 X 40MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959542	4.5 X 42MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959544	4.5 X 44MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959546	4.5 X 46MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959548	4.5 X 48MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959550	4.5 X 50MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959552	4.5 X 52MM CANNULATED MAS	August 2007	Rule 8	Annex II (-section 4)	61325	15766
6959970	LP OC KEEL PLATE - SMALL	April 2008	Rule 8	Annex II (-section 4)	61325	15766
6959971	LP OC KEEL PLATE - MEDIUM	April 2008	Rule 8	Annex II (-section 4)	61325	15766
6959972	LP OC KEEL PLATE - LARGE	April 2008	Rule 8	Annex II (-section 4)	61325	15766
7750005	3.5MM TI ROD, 80MM	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750010	3.5MM TI ROD, 120MM	august 2006	Rule 8	Annex II (-section 4)	61325	15766
7750015	3.5MM TI ROD, 240MM	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750020	3.5MM TI ROD, 300MM	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750086	3.5MM COCR ROD, 120MM	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750087	3.5MM COCR ROD, 240MM	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750088	3.5MM COCR ROD, 300MM	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750315	M6 REVERSE ANGLE SETSCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750346	AXIAL DOMINO, 3.2/3.5/4.0 TO 3.2/3.5/4.0	October 2006	Rule 8	Annex II (-section 4)	61325	15766
7750347	AXIAL DOMINO, 3.2/3.5/4.0 TO 4.5	October 2006	Rule 8	Annex II (-section 4)	61325	15766
7750348	AXIAL DOMINO, 3.2/3.5/4.0 TO 5.5	October 2006	Rule 8	Annex II (-section 4)	61325	15766
7750406	4.0 X 6MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750408	4.0 X 8MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750410	4.0 X 10MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750412	4.0 X 12MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750414	4.0 X 14MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750416	4.0 X 16MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750418	4.0 X 18MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750420	4.0 X 20MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766

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7750422	4.0 X 22MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750424	4.0 X 24MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750443	OFFSET DOMINO, 3.2-4.0 TO 3.2-4.0	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7750444	OFFSET DOMINO, 3.2/3.5/4.0 TO 4.5/4.75	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7750445	OFFSET DOMINO, 3.2/3.5/4.0 TO 5.5	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7750475	Axial Domino 3.2/3.5/4.0 to 4.5/4.75MM	January 2012	Rule 8	Annex II (-section 4)	61325	15766
7750506	4.5 X 6MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750508	4.5 X 8MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750510	4.5 X 10MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750512	4.5 X 12MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750514	4.5 X 14MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750516	4.5 X 16MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750518	4.5 X 18MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750606	5.0 X 6MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750608	5.0 X 8MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750610	5.0 X 10MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750612	5.0 X 12MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750614	5.0 X 14MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750616	5.0 X 16MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750618	5.0 X 18MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750620	5.0 X 20MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750622	5.0 X 22MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7750624	5.0 X 24MM BONE SCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7751000	SET SCREW POSTED CONNECTOR	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7751101	CONNECTOR, SMALL	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751103	CONNECTOR, MEDIUM	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751105	CONNECTOR, LARGE	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751110	OPEN CABLE CONNECTOR	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7751110EP	5.0 X 10MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751112EP	5.0 X 12MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751114EP	5.0 X 14MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751114PT	5.0 X 14MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751116EP	5.0 X 16MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751116PT	5.0 X 16MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751118EP	5.0 X 18MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751118PT	5.0 X 18MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751120EP	5.0 X 20MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751120PT	5.0 X 20MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751122EP	5.0 X 22MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751122PT	5.0 X 22MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751124EP	5.0 X 24MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751124PT	5.0 X 24MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751126EP	5.0 X 26MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751126PT	5.0 X 26MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751128EP	5.0 X 28MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751128PT	5.0 X 28MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751130EP	5.0 X 30MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751130PT	5.0 X 30MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751132EP	5.0 X 32MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751132PT	5.0 X 32MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766

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7751134EP	5.0 X 34MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751134PT	5.0 X 34MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751136EP	5.0 X 36MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751136PT	5.0 X 36MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751138EP	5.0 X 38MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751138PT	5.0 X 38MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751140EP	5.0 X 40MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751140PT	5.0 X 40MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751142EP	5.0 X 42MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751142PT	5.0 X 42MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751144EP	5.0 X 44MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751144PT	5.0 X 44MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751146EP	5.0 X 46MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751146PT	5.0 X 46MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751148EP	5.0 X 48MM EXT POST BONE SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751148PT	5.0 X 48MM POST PARTIALLY THREADED SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751150EP	5.0 X 50MM EXT POST BONE SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751150PT	5.0 X 50MM POST PARTIALLY THREADED SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751152EP	5.0 X 52MM EXT POST BONE SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751152PT	5.0 X 52MM POST PARTIALLY THREADED SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751710	3.5 X 10MM POSTED BONE SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751710EP	3.5 X 10MM EXT POST BONE SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751712	3.5 X 12MM POSTED BONE SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751712EP	3.5 X 12MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751714	3.5 X 14MM POSTED BONE SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751714EP	3.5 X 14MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751714PT	3.5 X 14MM POST PARTIALLY THREADED SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751716	3.5 X 16MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751716EP	3.5 X 16MM EXT POST BONE SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751716PT	3.5 X 16MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751718	3.5 X 18MM POSTED BONE SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751718EP	3.5 X 18MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751718PT	3.5 X 18MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751720	3.5 X 20MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751720EP	3.5 X 20MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751720PT	3.5 X 20MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751722	3.5 X 22MM POSTED BONE SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751722EP	3.5 X 22MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751722PT	3.5 X 22MM POST PARTIALLY THREADED SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751724	3.5 X 24MM POSTED BONE SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751724EP	3.5 X 24MM EXT POST BONE SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751724PT	3.5 X 24MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751726	3.5 X 26MM POSTED BONE SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751726EP	3.5 X 26MM EXT POST BONE SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751726PT	3.5 X 26MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751728	3.5 X 28MM POSTED BONE SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751728EP	3.5 X 28MM EXT POST BONE SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751728PT	3.5 X 28MM POST PARTIALLY THREADED SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751730	3.5 X 30MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751730EP	3.5 X 30MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766

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7751730PT	3.5 X 30MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751732	3.5 X 32MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751732EP	3.5 X 32MM EXT POST BONE SCREW	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7751732PT	3.5 X 32MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751734	3.5 X 34MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751734EP	3.5 X 34MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751734PT	3.5 X 34MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751736	3.5 X 36MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751736EP	3.5 X 36MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751736PT	3.5 X 36MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751738	3.5 X 38MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751738EP	3.5 X 38MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751738PT	3.5 X 38MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751740	3.5 X 40MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751740EP	3.5 X 40MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751740PT	3.5 X 40MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751742	3.5 X 42MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751742EP	3.5 X 42MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751742PT	3.5 X 42MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751744	3.5 X 44MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751744EP	3.5 X 44MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751744PT	3.5 X 44MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751746	3.5 X 46MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751746EP	3.5 X 46MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751746PT	3.5 X 46MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751748	3.5 X 48MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751748EP	3.5 X 48MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751748PT	3.5 X 48MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751750	3.5 X 50MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751750EP	3.5 X 50MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751750PT	3.5 X 50MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751752	3.5 X 52MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751752EP	3.5 X 52MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751752PT	3.5 X 52MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751810	4.0 X 10MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751810EP	4.0 X 10MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751812	4.0 X 12MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751812EP	4.0 X 12MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751814	4.0 X 14MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751814EP	4.0 X 14MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751814PT	4.0 X 14MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751816	4.0 X 16MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751816EP	4.0 X 16MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751816PT	4.0 X 16MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751818	4.0 X 18MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751818EP	4.0 X 18MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751818PT	4.0 X 18MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751820	4.0 X 20MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751820EP	4.0 X 20MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751820PT	4.0 X 20MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766

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P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
7751822	4.0 X 22MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751822EP	4.0 X 22MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751822PT	4.0 X 22MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751824	4.0 X 24MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751824EP	4.0 X 24MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751824PT	4.0 X 24MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751826	4.0 X 26MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751826EP	4.0 X 26MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751826PT	4.0 X 26MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751828	4.0 X 28MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751828EP	4.0 X 28MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751828PT	4.0 X 28MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751830	4.0 X 30MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751830EP	4.0 X 30MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751830PT	4.0 X 30MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751832	4.0 X 32MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751832EP	4.0 X 32MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751832PT	4.0 X 32MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751834	4.0 X 34MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751834EP	4.0 X 34MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751834PT	4.0 X 34MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751836	4.0 X 36MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751836EP	4.0 X 36MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751836PT	4.0 X 36MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751838	4.0 X 38MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751838EP	4.0 X 38MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751838PT	4.0 X 38MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751840	4.0 X 40MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751840EP	4.0 X 40MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751840PT	4.0 X 40MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751842	4.0 X 42MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751842EP	4.0 X 42MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751842PT	4.0 X 42MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751844	4.0 X 44MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751844EP	4.0 X 44MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751844PT	4.0 X 44MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751846	4.0 X 46MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751846EP	4.0 X 46MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751846PT	4.0 X 46MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751848	4.0 X 48MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751848EP	4.0 X 48MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751848PT	4.0 X 48MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751850	4.0 X 50MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751850EP	4.0 X 50MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751850PT	4.0 X 50MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751852	4.0 X 52MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751852EP	4.0 X 52MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751852PT	4.0 X 52MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751910	4.5 X 10MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751910EP	4.5 X 10MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766

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7751912	4.5 X 12MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751912EP	4.5 X 12MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751914	4.5 X 14MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751914EP	4.5 X 14MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751914PT	4.5 X 14MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751916	4.5 X 16MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751916EP	4.5 X 16MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751916PT	4.5 X 16MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751918	4.5 X 18MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751918EP	4.5 X 18MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751918PT	4.5 X 18MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751920	4.5 X 20MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751920EP	4.5 X 20MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751920PT	4.5 X 20MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751922	4.5 X 22MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751922EP	4.5 X 22MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751922PT	4.5 X 22MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751924	4.5 X 24MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751924EP	4.5 X 24MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751924PT	4.5 X 24MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751926	4.5 X 26MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751926EP	4.5 X 26MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751926PT	4.5 X 26MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751928	4.5 X 28MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751928EP	4.5 X 28MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751928PT	4.5 X 28MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751930	4.5 X 30MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751930EP	4.5 X 30MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751930PT	4.5 X 30MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751932	4.5 X 32MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751932EP	4.5 X 32MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751932PT	4.5 X 32MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751934	4.5 X 34MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751934EP	4.5 X 34MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751934PT	4.5 X 34MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751936	4.5 X 36MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751936EP	4.5 X 36MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751936PT	4.5 X 36MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751938	4.5 X 38MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751938EP	4.5 X 38MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751938PT	4.5 X 38MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751940	4.5 X 40MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751940EP	4.5 X 40MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751940PT	4.5 X 40MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751942	4.5 X 42MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751942EP	4.5 X 42MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751942PT	4.5 X 42MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751944	4.5 X 44MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751944EP	4.5 X 44MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751944PT	4.5 X 44MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766

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7751946	4.5 X 46MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751946EP	4.5 X 46MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751946PT	4.5 X 46MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751948	4.5 X 48MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751948EP	4.5 X 48MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751948PT	4.5 X 48MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751950	4.5 X 50MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751950EP	4.5 X 50MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751950PT	4.5 X 50MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751952	4.5 X 52MM POSTED BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751952EP	4.5 X 52MM EXT POST BONE SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7751952PT	4.5 X 52MM POST PARTIALLY THREADED SCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7752500	M6 CONNECTOR SETSCREW	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7752510	CROSSLINK SETSCREW	Septemeber 2006	Rule 8	Annex II (-section 4)	61325	15766
7752515	FLAT CONNECTOR SETSCREW	October 2006	Rule 8	Annex II (-section 4)	61325	15766
7752517	CCM FLAT CONNECTOR SETSCREW	October 2006	Rule 8	Annex II (-section 4)	61325	15766
7752524	MAS CROSSLINK - EXTRA SMALL (XS)	August 2012	Rule 8	Annex II (-section 4)	61325	15766
7752525	SMALL MAS CROSSLINK	October 2006	Rule 8	Annex II (-section 4)	61325	15766
7752526	MEDIUM MAS CROSSLINK	October 2006	Rule 8	Annex II (-section 4)	61325	15766
7752527	LARGE MAS CROSSLINK	October 2006	Rule 8	Annex II (-section 4)	61325	15766
7752528	MAS CROSSLINK-ROD CONNECTOR	October 2006	Rule 8	Annex II (-section 4)	61325	15766
7752529	CONNECTOR LOCKING SCREW	May 2008	Rule 8	Annex II (-section 4)	61325	15766
7752535	SMALL ROD CROSSLINK	Septemeber 2006	Rule 8	Annex II (-section 4)	61325	15766
7752536	MEDIUM ROD CROSSLINK	September 2006	Rule 8	Annex II (-section 4)	61325	15766
7752537	LARGE ROD CROSSLINK	September 2006	Rule 8	Annex II (-section 4)	61325	15766
7753500	M6 CONNECTOR SETSCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7753505	SET SCREW ADJ. CONN. CROSSLINK	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7753520	10-48 CONE SETSCREW	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7753616	16 MM OPEN LATERAL OFFSET CONNECTOR	August 2012	Rule 8	Annex II (-section 4)	61325	15766
7753616A	16 MM ANGLED OPEN LAT OFFSET CONNECTOR	August 2012	Rule 8	Annex II (-section 4)	61325	15766
7753619	19 MM OPEN LATERAL OFFSET CONNECTOR	august 2012	Rule 8	Annex II (-section 4)	61325	15766
7753619A	19MM ANGLED OPEN LAT OFFSET CONNECTOR	August 2012	Rule 8	Annex II (-section 4)	61325	15766
7753625	25 MM OPEN LATERAL OFFSET CONNECTOR	August 2012	Rule 8	Annex II (-section 4)	61325	15766
7753625A	25 MM ANGLED OPEN LAT OFFSET CONNECTOR	August 2012	Rule 8	Annex II (-section 4)	61325	15766
7753704	3.5/4.75 X 600 MM TAPERED ROD - TITANIUM	August 2012	Rule 8	Annex II (-section 4)	61325	15766
7753705	3.5/5.5 X 600 MM TAPERED ROD - TITANIUM	August 2012	Rule 8	Annex II (-section 4)	61325	15766
7753706	3.5/4.75 X 420 MM TAPERED ROD - TITANIUM	August 2012	Rule 8	Annex II (-section 4)	61325	15766
7753707	3.5/5.5 X 420 MM TAPERED ROD - TITANIUM	August 2012	Rule 8	Annex II (-section 4)	61325	15766
7753714	4.75 X 360MM NON-STERILE THREADED ROD	August 2012	Rule 8	Annex II (-section 4)	61325	15766
7753720	3.5 MM PRE-CUT/BENT TITANIUM ROD - 20 MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753725	3.5 MM PRE-CUT/BENT TITANIUM ROD - 25 MM	August 2012	Rule 8	Annex II (-section 4)	61325	15766
7753730	3.5 MM PRE-CUT/BENT TITANIUM ROD - 30 MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753735	3.5 MM PRE-CUT/BENT TITANIUM ROD - 35 MM	August 2012	Rule 8	Annex II (-section 4)	61325	15766
7753740	3.5 MM PRE-CUT/BENT TITANIUM ROD - 40 MM	August 2012	Rule 8	Annex II (-section 4)	61325	15766
7753745	3.5 MM PRE-CUT/BENT TITANIUM ROD - 45 MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753750	3.5 MM PRE-CUT/BENT TITANIUM ROD - 50 MM	August 2012	Rule 8	Annex II (-section 4)	61325	15766
7753755	3.5 MM PRE-CUT/BENT TITANIUM ROD - 55 MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753760	3.5 MM PRE-CUT/BENT TITANIUM ROD - 60 MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753765	3.5 MM PRE-CUT/BENT TITANIUM ROD - 65 MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753770	3.5 MM PRE-CUT/BENT TITANIUM ROD - 70 MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766

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7753775	3.5 MM PRE-CUT/BENT TITANIUM ROD - 75 MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753780	3.5 MM PRE-CUT/BENT TITANIUM ROD - 80 MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753785	3.5 MM PRE-CUT/BENT TITANIUM ROD - 85 MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753790	3.5 MM PRE-CUT/BENT TITANIUM ROD - 90 MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753795	3.5 MM PRE-CUT/BENT TITANIUM ROD - 95 MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753800	3.5 MM PRE-CUT/BENT TITANIUM ROD - 100MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753804	3.5/4.75 X 600 MM TAPERED ROD - CCM+	August 2012	Rule 8	Annex II (-section 4)	61325	15766
7753805	3.5/5.5 X 600 MM TAPERED ROD - CCM+	August 2012	Rule 8	Annex II (-section 4)	61325	15766
7753806	3.5/4.75 X 420 MM TAPERED ROD - CCM+	August 2012	Rule 8	Annex II (-section 4)	61325	15766
7753807	3.5/5.5 X 420 MM TAPERED ROD - CCM+	August 2012	Rule 8	Annex II (-section 4)	61325	15766
7753820	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 20MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753825	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 25MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753830	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 30MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753835	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 35MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753840	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 40MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753845	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 45MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753850	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 50MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753855	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 55MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753860	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 60MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753865	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 65MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753870	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 70MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753875	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 75MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753880	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 80MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753885	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 85MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753890	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 90MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753895	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 95MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753900	3.5MM PRE-CUT/BENT CHROMALOY+ ROD -100MM	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753916	16MM CLOSED LATERAL CONNECTOR	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753919	19MM CLOSED LATERAL CONNECTOR	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7753925	25MM CLOSED LATERAL CONNECTOR	September 2012	Rule 8	Annex II (-section 4)	61325	15766
7755120	3.5MMX120MM ADJUSTABLE ROD	October 2006	Rule 8	Annex II (-section 4)	61325	15766
7755121	4.0MMX100MM ADJUSTABLE ROD	October 2006	Rule 8	Annex II (-section 4)	61325	15766
7755122	3.2 / 3.5MM X 120MM ADJUSTABLE ROD	March 2007	Rule 8	Annex II (-section 4)	61325	15766
7755123	3.2/3.5MM ADJUSTABLE ROD	December 2008	Rule 8	Annex II (-section 4)	61325	15766
7755124	3.5MM X 220MM ADJUSTABLE ROD	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7755131	3.5MM X 100MM ADJUSTABLE ROD	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7755132	4.0MM X 100MM ADJUSTABLE ROD	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7755134	3.5MM X 200MM ADJUSTABLE ROD	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7755135	4.0MM X 200MM ADJUSTABLE ROD	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7755231	ROD 7755231 3.5 X 100 OC PLATE/ROD	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7755232	ROD 7755232 3.5 X 200 OC PLATE/ROD	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7755240	3.5 X 240MM THREADED ROD	October 2006	Rule 8	Annex II (-section 4)	61325	15766
7755245	4.5 X 360MM THREADED ROD	October 2006	Rule 8	Annex II (-section 4)	61325	15766
7755247	5.5 X 360MM THREADED ROD	October 2006	Rule 8	Annex II (-section 4)	61325	15766
7755250	3.5 X 240MM CCM THREADED ROD	October 2006	Rule 8	Annex II (-section 4)	61325	15766
7755255	4.5 X 360MM CCM THREADED ROD	October 2006	Rule 8	Annex II (-section 4)	61325	15766
7755257	5.5 X 360MM CCM THREADED ROD	October 2006	Rule 8	Annex II (-section 4)	61325	15766
7755270	3.5 X 100MM PRE-CURVED ROD	September 2006	Rule 8	Annex II (-section 4)	61325	15766
7755271	3.5 X 200MM PRE-CURVED ROD	September 2006	Rule 8	Annex II (-section 4)	61325	15766
7755272	4.0 X 100MM PRE-CURVED ROD	September 2006	Rule 8	Annex II (-section 4)	61325	15766

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7755273	4.0 X 200MM PRE-CURVED ROD	September 2006	Rule 8	Annex II (-section 4)	61325	15766
7755274	3.5 X 100MM PRE-CURVED ROD	February 2008	Rule 8	Annex II (-section 4)	61325	15766
7755275	3.5 X 200MM PRE-CURVED ROD	February 2008	Rule 8	Annex II (-section 4)	61325	15766
7755278	ADJUSTABLE OC PLATE	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7755279	ADJUSTABLE OC PLATE - SMALL	August 2012	Rule 8	Annex II (-section 4)	61325	15766
7755325	LP SMALL SCREW CONNECTOR	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7755327	LP LARGE SCREW CONNECTOR	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7755976	7.5MM LAMINAR HOOK	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7755976L	7.5MM OFFSET LAMINAR HOOK, LEFT	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7755976R	7.5MM OFFSET LAMINAR HOOK, RIGHT	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7755978	9.0MM LAMINAR HOOK	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7755978L	9.0MM OFFSET LAMINAR HOOK, LEFT	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7755978R	9.0MM OFFSET LAMINAR HOOK, RIGHT	August 2006	Rule 8	Annex II (-section 4)	61325	15766
7756064	10MM OPEN LATERAL OFFSET CONNECTOR	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7756066	13MM OPEN LATERAL OFFSET CONNECTOR	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7756067	10MM CLOSED LATERAL OFFSET CONNECTOR	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7756068	13MM CLOSED LATERAL OFFSET CONNECTOR	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7756069	CONNECTOR 7756069 3.2/3.5/4.0MM MAS EXT.	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7756071	4.5/4.75 MAS EXT CONNECTOR	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7756072	CONNECTOR 7755972 5.5MM MAS EXT	July 2008	Rule 8	Annex II (-section 4)	61325	15766
7756073	4.5MM LAMINAR HOOK	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7756073L	4.5 MM OFFSET LAMINAR HOOK, L	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7756073R	4.5 MM OFFSET LAMINAR HOOK, R	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7756074	6.0MM LAMINAR HOOK	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7756074L	6.0 MM OFFSET LAMINAR HOOK, L	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7756074R	6.0 MM OFFSET LAMINAR HOOK, R	June 2008	Rule 8	Annex II (-section 4)	61325	15766
7759970	LP OC M PLATE - SMALL	May 2008	Rule 8	Annex II (-section 4)	61325	15766
7759971	LP OC M PLATE - MEDIUM	May 2008	Rule 8	Annex II (-section 4)	61325	15766
7759972	LP OC M PLATE - LARGE	May 2008	Rule 8	Annex II (-section 4)	61325	15766
G6956410	SCREW G6956410 3.5 X 10MM NO FLUTE MAS	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6956412	SCREW G6956412 3.5 X 12MM NO FLUTE MAS	October 2008	Rule 8	Annex II (-section 4)	61324	15766
G6956414	SCREW G6956414 3.5 X 14MM NO FLUTE MAS	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6956416	SCREW G6956416 3.5 X 16MM NO FLUTE MAS	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6956418	SCREW G6956418 3.5 X 18MM NO FLUTE MAS	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6956420	SCREW G6956420 3.5 X 20MM NO FLUTE MAS	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6956422	SCREW G6956422 3.5 X 22MM NO FLUTE MAS	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6956424	SCREW G6956424 3.5 X 24MM NO FLUTE MAS	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6956426	SCREW G6956426 3.5 X 26MM NO FLUTE MAS	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6956428	SCREW G6956428 3.5 X 28MM NO FLUTE MAS	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6956430	SCREW G6956430 3.5 X 30MM NO FLUTE MAS	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6956432	SCREW G6956432 3.5 X 32MM NO FLUTE MAS	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6957610	SCREW G6957610 4.0 X 10MM NO FLUTE MAS	July 2010	Rule 8	Annex II (-section 4)	61324	15766
G6957612	SCREW G6957612 4.0 X 12MM NO FLUTE MAS	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6957614	SCREW G6957614 4.0 X 14MM NO FLUTE MAS	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6957616	SCREW G6957616 4.0 X 16MM NO FLUTE MAS	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6957618	SCREW G6957618 4.0 X 18MM NO FLUTE MAS	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6957620	SCREW G6957620 4.0 X 20MM NO FLUTE MAS	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6957622	SCREW G6957622 4.0 X 22MM NO FLUTE MAS	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6957624	SCREW G6957624 4.0 X 24MM NO FLUTE MAS	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6957626	SCREW G6957626 4.0 X 26MM NO FLUTE MAS	July 2008	Rule 8	Annex II (-section 4)	61324	15766

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G6957628	SCREW G6957628 4.0 X 28MM NO FLUTE MAS	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6957630	SCREW G6957630 4.0 X 30MM NO FLUTE MAS	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6957632	SCREW G6957632 4.0 X 32MM NO FLUTE MAS	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958626PT	SCREW G6958626PT 3.5 X 26MM PT MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958628PT	SCREW G6958628PT 3.5 X 28MM PT MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958630PT	SCREW G6958630PT 3.5 X 30MM PT MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958632PT	SCREW G6958632PT 3.5 X 32MM PT MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958634PT	SCREW G6958634PT 3.5 X 34MM PT MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958636PT	SCREW G6958636PT 3.5 X 36MM PT MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958638PT	SCREW G6958638PT 3.5 X 38MM PT MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958640PT	SCREW G6958640PT 3.5 X 40MM PT MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958710	SCREW G6958710 3.5 X 10MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958712	SCREW G6958712 3.5 X 12MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958714	SCREW G6958714 3.5 X 14MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958716	SCREW G6958716 3.5 X 16MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958718	SCREW G6958718 3.5 X 18MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958718PT	3.5 X 18MM MAS, PARTIALLY THREADED	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958720	SCREW G6958720 3.5 X 20MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958720PT	3.5 X 20MM MAS, PARTIALLY THREADED	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958722	SCREW G6958722 3.5 X 22MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958722PT	3.5 X 22MM MAS, PARTIALLY THREADED	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958724	SCREW G6958724 3.5 X 24MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958724PT	3.5 X 24MM MAS, PARTIALLY THREADED	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958726	SCREW G6958726 3.5 X 26MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958726PT	3.5 X 26MM MAS, PARTIALLY THREADED	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958728	SCREW G6958728 3.5 X 28MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958728PT	3.5 X 28MM MAS, PARTIALLY THREADED	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958730	SCREW G6958730 3.5 X 30MM MAS STR	july 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958730PT	3.5 X 30MM MAS, PARTIALLY THREADED	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958732	SCREW G6958732 3.5 X 32MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958732PT	3.5 X 32MM MAS, PARTIALLY THREADED	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958734	3.5 X 34MM MULTI AXIAL SCREW	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958734PT	3.5 X 34MM MAS, PARTIALLY THREADED	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958736	3.5 X 36MM MULTI AXIAL SCREW	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958736PT	3.5 X 36MM MAS, PARTIALLY THREADED	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958738	3.5 X 38MM MULTI AXIAL SCREW	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958738PT	3.5 X 38MM MAS, PARTIALLY THREADED	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958740	3.5 X 40MM MULTI AXIAL SCREW	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958740PT	3.5 X 40MM MAS, PARTIALLY THREADED	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958742	3.5 X 42MM MULTI AXIAL SCREW	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958744	3.5 X 44MM MULTI AXIAL SCREW	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958746	3.5 X 46MM MULTI AXIAL SCREW	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958748	3.5 X 48MM MULTI AXIAL SCREW	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958750	3.5 X 50MM MULTI AXIAL SCREW	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958752	3.5 X 52MM MULTI AXIAL SCREW	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958810	SCREW G6958810 4.0 X 10MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958812	SCREW G6958812 4.0 X 12MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958814	SCREW G6958814 4.0 X 14MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958816	SCREW G6958816 4.0 X 16MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958818	SCREW G6958818 4.0 X 18MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766

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G6958818PT	4.0 X 18MM MAS, PARTIALLY THREADED	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958820	SCREW G6958820 4.0 X 20MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958820PT	4.0 X 20MM MAS, PARTIALLY THREADED	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958822	SCREW G6958822 4.0 X 22MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958822PT	4.0 X 22MM MAS, PARTIALLY THREADED	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958824	SCREW G6958824 4.0 X 24MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958824PT	4.0 X 24MM MAS, PARTIALLY THREADED	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6958826	SCREW G6958826 4.0 X 26MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958826PT	SCREW G6958826PT 4.0 X 26MM PT MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958828	SCREW G6958828 4.0 X 28MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958828PT	SCREW G6958828PT 4.0 X 28MM PT MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958830	SCREW G6958830 4.0 X 30MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958830PT	SCREW G6958830PT 4.0 X 30MM PT MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958832	SCREW G6958832 4.0 X 32MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958832PT	SCREW G6958832PT 4.0 X 32MM PT MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958834	SCREW G6958834 4.0 X 34MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958834PT	SCREW G6958834PT 4.0 X 34MM PT MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958836	SCREW G6958836 4.0 X 36MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958836PT	SCREW G6958836PT 4.0 X 36MM PT MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958838	SCREW G6958838 4.0 X 38MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958838PT	SCREW G6958838PT 4.0 X 38MM PT MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958840	SCREW G6958840 4.0 X 40MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958840PT	SCREW G6958840PT 4.0 X 40MM PT MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958842	SCREW G6958842 4.0 X 42MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958844	SCREW G6958844 4.0 X 44MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958846	SCREW G6958846 4.0 X 46MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958914	SCREW G6958914 4.5 X 14MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958916	SCREW G6958916 4.5 X 16MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958918	SCREW G6958918 4.5 X 18MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958920	SCREW G6958920 4.5 X 20MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958922	SCREW G6958922 4.5 X 22MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958924	SCREW G6958924 4.5 X 24MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958926	SCREW G6958926 4.5 X 26MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958928	SCREW G6958928 4.5 X 28MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958930	SCREW G6958930 4.5 X 30MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958932	SCREW G6958932 4.5 X 32MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958934	SCREW G6958934 4.5 X 34MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958936	SCREW G6958936 4.5 X 36MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958938	SCREW G6958938 4.5 X 38MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6958940	SCREW G6958940 4.5 X 40MM MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6959410	SCREW G6959410 4.0 X 10MM CANN MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6959412	SCREW G6959412 4.0 X 12MM CANN MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6959414	SCREW G6959414 4.0 X 14MM CANN MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6959416	SCREW G6959416 4.0 X 16MM CANN MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6959418	SCREW G6959418 4.0 X 18MM CANN MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6959420	SCREW G6959420 4.0 X 20MM CANN MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6959420PT	4.0 X 20MM CANNULATED MAS, PT	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959422	SCREW G6959422 4.0 X 22MM CANN MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6959422PT	4.0 X 22MM CANNULATED MAS, PT	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959424	SCREW G6959424 4.0 X 24MM CANN MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766

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G6959424PT	4.0 X 24MM CANNULATED MAS, PT	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959426	SCREW G6959426 4.0 X 26MM CANN MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6959426PT	4.0 X 26MM CANNULATED MAS, PT	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959428	SCREW G6959428 4.0 X 28MM CANN MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6959428PT	4.0 X 28MM CANNULATED MAS, PT	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959430	SCREW G6959430 4.0 X 30MM CANN MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6959430PT	4.0 X 30MM CANNULATED MAS, PT	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959432	SCREW G6959432 4.0 X 32MM CANN MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6959432PT	4.0 X 32MM CANNULATED MAS, PT	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959434	SCREW G6959434 4.0 X 34MM CANN MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6959434PT	4.0 X 34MM CANNULATED MAS, PT	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959436	SCREW G6959436 4.0 X 36MM CANN MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6959436PT	4.0 X 36MM CANNULATED MAS, PT	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959438	SCREW G6959438 4.0 X 38MM CANN MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6959438PT	4.0 X 38MM CANNULATED MAS, PT	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959440	SCREW G6959440 4.0 X 40MM CANN MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6959440PT	4.0 X 40MM CANNULATED MAS, PT	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959442	SCREW G6959442 4.0 X 42MM CANN MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6959444	SCREW G6959444 4.0 X 44MM CANN MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6959446	SCREW G6959446 4.0 X 46MM CANN MAS STR	July 2008	Rule 8	Annex II (-section 4)	61324	15766
G6959448	4.0 X 48MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959450	4.0 X 50MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959452	4.0 X 52MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959510	4.5 X 10MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959512	4.5 X 12MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959514	4.5 X 14MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959516	4.5 X 16MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959518	4.5 X 18MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959520	4.5 X 20MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959522	4.5 X 22MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959524	4.5 X 24MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959526	4.5 X 26MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959528	4.5 X 28MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959530	4.5 X 30MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959532	4.5 X 32MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959534	4.5 X 34MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959536	4.5 X 36MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959538	4.5 X 38MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959540	4.5 X 40MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959542	4.5 X 42MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959544	4.5 X 44MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959546	4.5 X 46MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959548	4.5 X 48MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959550	4.5 X 50MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G6959552	4.5 X 52MM CANNULATED MAS	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G7002525	ADJ. CROSSLINK, SMALL	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G7002526	ADJ. CROSSLINK, MED	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G7002527	ADJ. CROSSLINK, LARGE	July 2005	Rule 8	Annex II (-section 4)	61324	15766
G7750010	3.5 x 120mm Ti Rod	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750015	3.5 x 240mm Ti Rod	April 2010	Rule 8	Annex II (-section 4)	61324	15766

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G7750020	3.5 x 300mm Ti Rod	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750086	3.5 x 120mm Cobalt Chrome Rod	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750087	3.5 x 240mm Cobalt Chrome Rod	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750088	3.5 x 300mm Cobalt Chrome Rod	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750346	Axial Domino, 3.5/4.0 to 3.5/4.0mm	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750347	Axial Domino, 3.5/4.0 to 4.5mm	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750348	Axial Domino, 3.5/4.0 to 5.5mm	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750443	Offset Dom, 3.2/3.5/4.0 to 3.2/3.5/4.0mm	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750444	Offset Domino, 3.2/3.5/4.0 to 4.5mm	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750445	Offset Domino, 3.2/3.5/4.0 to 5.5mm	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750475	Axial Domino 3.5mm to 4.5/4.75mm	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7750506	4.5 x 6mm OC Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750508	4.5 x 8mm OC Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750510	4.5 x 10mm OC Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750512	4.5 x 12mm OC Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750514	4.5 x 14mm OC Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750516	4.5 x 16mm OC Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750518	4.5 x 18mm OC Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750606	5.0 x 6mm OC Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750608	5.0 x 8mm OC Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750610	5.0 x 10mm OC Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750612	5.0 x 12mm OC Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750614	5.0 x 14mm OC Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750616	5.0 x 16mm OC Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7750618	5.0 x 18mm OC Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751000	Connector Set Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751101	SMALL CONNECTOR	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751103	MEDIUM CONNECTOR	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751105	LARGE CONNECTOR	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751110	Cable Connector	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751710	3.5 x 10mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751710EP	3.5x10mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751712	3.5 x 12mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751712EP	3.5x12mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751714	3.5 x 14mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751714EP	3.5x14mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751716	3.5 x 16mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751716EP	3.5x16mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751718	3.5 x 18mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751718EP	3.5x18mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751718PT	3.5x18mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751720	3.5 x 20mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751720EP	3.5x20mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751720PT	3.5x20mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751722	3.5 x 22mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751722EP	3.5x22mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751722PT	3.5x22mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751724	3.5 x 24mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751724EP	3.5x24mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751724PT	3.5x24mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766

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G7751726	3.5 x 26mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751726EP	3.5x26mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751726PT	3.5x26mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751728	3.5 x 28mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751728EP	3.5x28mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751728PT	3.5x28mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751730	3.5 x 30mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751730EP	3.5x30mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751730PT	3.5x30mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751732	3.5 x 32mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751732EP	3.5x32mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751732PT	3.5x32mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751734	3.5 x 34mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751734EP	3.5x34mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751734PT	3.5x34mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751736	3.5 x 36mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751736EP	3.5x36mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751736PT	3.5x36mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751738	3.5 x 38mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751738EP	3.5x38mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751738PT	3.5x38mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751740	3.5 x 40mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751740EP	3.5x40mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751740PT	3.5x40mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751810	4.0 x 10mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751810EP	4.0x10mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751812	4.0 x 12mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751812EP	4.0x12mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751814	4.0 x 14mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751814EP	4.0x14mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751816	4.0 x 16mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751816EP	4.0x16mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751818	4.0 x 18mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751818EP	4.0x18mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751818PT	4.0x18mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751820	4.0 x 20mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751820EP	4.0x20mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751820PT	4.0x20mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751822	4.0 x 22mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751822EP	4.0x22mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751822PT	4.0x22mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751824	4.0 x 24mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751824EP	4.0x24mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751824PT	4.0x24mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751826	4.0 x 26mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751826EP	4.0x26mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751826PT	4.0x26mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751828	4.0 x 28mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751828EP	4.0x28mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751828PT	4.0x28mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766

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P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
G7751830	4.0 x 30mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751830EP	4.0x30mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751830PT	4.0x30mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751832	4.0 x 32mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751832EP	4.0x32mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751832PT	4.0x32mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751834	4.0 x 34mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751834EP	4.0x34mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751834PT	4.0x34mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751836	4.0 x 36mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751836EP	4.0x36mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751836PT	4.0x36mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751838	4.0 x 38mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751838EP	4.0x38mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751838PT	4.0x38mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751840	4.0 x 40mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751840EP	4.0x40mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751840PT	4.0x40mm Posted Partially Threaded Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751842	4.0 x 42mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751842EP	4.0x42mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751844	4.0 x 44mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751844EP	4.0x44mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751846	4.0 x 46mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751846EP	4.0x46mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751848	4.0 x 48mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751848EP	4.0x48mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751850	4.0 x 50mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751850EP	4.0x50mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751852	4.0 x 52mm Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751852EP	4.0x52mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751910	SCREW G7751910 POSTED 4.5 X 10MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751910EP	4.5x10mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751912	SCREW G7751912 POSTED 4.5 X 12MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751912EP	4.5x12mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751914	SCREW G7751914 POSTED 4.5 X 14MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751914EP	4.5x14mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751916	SCREW G7751916 POSTED 4.5 X 16MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751916EP	4.5x16mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751918	SCREW G7751918 POSTED 4.5 X 18MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751918EP	4.5x18mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751920	SCREW G7751920 POSTED 4.5 X 20MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751920EP	4.5x20mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751922	SCREW G7751922 POSTED 4.5 X 22MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751922EP	4.5x22mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751924	SCREW G7751924 POSTED 4.5 X 24MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751924EP	4.5x24mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751926	SCREW G7751926 POSTED 4.5 X 26MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751926EP	4.5x26mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751928	SCREW G7751928 POSTED 4.5 X 28MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751928EP	4.5x28mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766

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P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
G7751930	SCREW G7751930 POSTED 4.5 X 30MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751930EP	4.5x30mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751932	SCREW G7751932 POSTED 4.5 X 32MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751932EP	4.5x32mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751934	SCREW G7751934 POSTED 4.5 X 34MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751934EP	4.5x34mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751936	SCREW G7751936 POSTED 4.5 X 36MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751936EP	4.5x36mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751938	SCREW G7751938 POSTED 4.5 X 38MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751938EP	4.5x38mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751940	SCREW G7751940 POSTED 4.5 X 40MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751940EP	4.5x40mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751942	SCREW G7751942 POSTED 4.5 X 42MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751942EP	4.5x42mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751944	SCREW G7751944 POSTED 4.5 X 44MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751944EP	4.5x44mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751946	SCREW G7751946 POSTED 4.5 X 46MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751946EP	4.5x46mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751948	SCREW G7751948 POSTED 4.5 X 48MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751948EP	4.5x48mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751950	SCREW POSTED 4.5 X 50MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751950EP	4.5x50mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751952	SCREW POSTED 4.5 X 52MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7751952EP	4.5x52mm Extended Posted Screw	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7752510	CROSSLINK SET SCREW	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7752515	FLAT SET SCREW 10-48	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7752524	MAS CROSSLINK - EXTRA SMALL (XS)	August 2012	Rule 8	Annex II (-section 4)	61324	15766
G7752525	SMALL MAS CROSSLINK	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7752526	MEDIUM MAS CROSSLINK	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7752527	LARGE MAS CROSSLINK	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7752528	CLIP MAS/ROD XLINK CONN	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7752529	SCREW CONNECTOR LOCKING	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7752535	CONNECTOR ROD CROSSLINK, S	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7752536	CONNECTOR ROD CROSSLINK, M	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7752537	CONNECTOR ROD CROSSLINK, L	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7753500	MAS CONN SET SCREW	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7753505	CONN SET SCREW	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7753520	CONN SET SCREW 10-48	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7753616	16 MM OPEN LATERAL OFFSET CONNECTOR	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753616A	16MM ANGLED OPEN LAT OFFSET CONNECTOR	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753619	19 MM OPEN LATERAL OFFSET CONNECTOR	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753619A	19MM ANGLED OPEN LAT OFFSET CONNECTOR	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753625	25 MM OPEN LATERAL OFFSET CONNECTOR	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753625A	25MM ANGLED OPEN LAT OFFSET CONNECTOR	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753706	3.5/4.75 X 420 MM TAPERED ROD - TITANIUM	August 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753707	3.5/5.5 X 420 MM TAPERED ROD - TITANIUM	August 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753714	4.75 X 360MM STERILE THREADED ROD	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753720	3.5 MM PRE-CUT/BENT STERILE TI ROD- 20MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753725	3.5 MM PRE-CUT/BENT STERILE TI ROD- 25MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753730	3.5 MM PRE-CUT/BENT STERILE TI ROD- 30MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766

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G7753735	3.5 MM PRE-CUT/BENT STERILE TI ROD- 35MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753740	3.5 MM PRE-CUT/BENT STERILE TI ROD- 40MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753745	3.5 MM PRE-CUT/BENT STERILE TI ROD- 45MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753750	3.5 MM PRE-CUT/BENT STERILE TI ROD- 50MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753755	3.5 MM PRE-CUT/BENT STERILE TI ROD- 55MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753760	3.5 MM PRE-CUT/BENT STERILE TI ROD- 60MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753765	3.5 MM PRE-CUT/BENT STERILE TI ROD- 65MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753770	3.5 MM PRE-CUT/BENT STERILE TI ROD- 70MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753775	3.5 MM PRE-CUT/BENT STERILE TI ROD- 75MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753780	3.5 MM PRE-CUT/BENT STERILE TI ROD- 80MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753785	3.5 MM PRE-CUT/BENT STERILE TI ROD- 85MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753790	3.5 MM PRE-CUT/BENT STERILE TI ROD- 90MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753795	3.5 MM PRE-CUT/BENT STERILE TI ROD- 95MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753800	3.5 MM PRE-CUT/BENT STERILE TI ROD-100MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753806	3.5/4.75 X 420 MM TAPERED ROD - CCM+	August 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753807	3.5/5.5 X 420 MM TAPERED ROD - CCM+	August 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753820	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 20MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753825	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 25MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753830	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 30MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753835	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 35MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753840	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 40MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753845	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 45MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753850	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 50MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753855	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 55MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753860	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 60MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753865	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 65MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753870	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 70MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753875	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 75MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753880	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 80MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753885	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 85MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753890	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 90MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753895	3.5MM PRE-CUT/BENT CHROMALOY+ ROD - 95MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753900	3.5MM PRE-CUT/BENT CHROMALOY+ ROD -100MM	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753916	16MM CLOSED LATERAL CONNECTOR	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753919	19MM CLOSED LATERAL CONNECTOR	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7753925	25MM CLOSED LATERAL CONNECTOR	September 2012	Rule 8	Annex II (-section 4)	61324	15766
G7755120	3.5mm x 120mm Adjustable Rod	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7755122	3.2/3.5mm x 120mm Adjustable Rod	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7755123	3.2/3.5mm x 220mm Adjustable Rod	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7755124	3.5mm x 220mm Adjustable Rod	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7755134	3.5mm x 200mm CoCr Adjustable Rod	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7755231	3.5 X 100 OC PLATE/ROD - STERILE	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G7755232	3.5 X 200 OC PLATE/ROD - STERILE	June 2010	Rule 8	Annex II (-section 4)	61324	15766
G7755240	ROD THREADED 3.5X240MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7755245	ROD THREADED 4.5X360MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7755247	ROD THREADED 5.5X360MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7755250	ROD CCM THREADED 3.5X240MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7755255	ROD CCM THREADED 4.5X360MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7755257	ROD CCM THREADED 5.5X360MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7755270	3.5 x 100mm Pre-Bent Rod	April 2010	Rule 8	Annex II (-section 4)	61324	15766

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G7755271	3.5 x 200mm Pre-Bent Rod	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7755274	3.5 x 100mm Pre-Bent CoCr Rod	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7755275	3.5 x 200mm Pre-Bent CoCr Rod	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7755278	Occipital Midline Plate, Translational	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7755279	ADJUSTABLE OC PLATE - SMALL	August 2012	Rule 8	Annex II (-section 4)	61324	15766
G7755325	LP OC Screw Connector	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7755327	LP OC Screw Connector, Offset	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7756064	10MM OPEN LATERAL OFFSET CONNECTOR	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7756066	13MM OPEN LATERAL OFFSET CONNECTOR	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7756067	CONNECTOR CLOSED-END LAT 10MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7756068	CONNECTOR G7756068 CLOSED-END LAT 13MM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7756069	MAS Extension Connector, 3.2/3.5/4.0mm	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7756071	MAS Extension Connector, 4.5mm	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7756072	MAS Extension Connector, 5.5mm	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7756073	4.5mm Laminar Hook	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7756073L	4.5mm Offset Laminar Hook, Left	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7756073R	4.5mm Offset Laminar Hook, Right	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7756074	6.0mm Laminar Hook	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7756074L	6.0mm Offset Laminar Hook, Left	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7756074R	6.0mm Offset Laminar Hook, Right	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7759970	LP OC M PLATE - SMALL	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7759971	LP OC M PLATE - MEDIUM	April 2010	Rule 8	Annex II (-section 4)	61324	15766
G7759972	LP OC M PLATE - LARGE	April 2010	Rule 8	Annex II (-section 4)	61324	15766
X0603132	VER MAS-TI-3.5X32-DIST-24MMTHR	July 2003	Rule 8	Annex II (-section 4)	61325	15766

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Product List

Last updated by: Tejas Patel **Date:** 24-Jan-18

Tech File Bundle: TF001

Product: INFINITY™ OCT System

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P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
3603512	Multi Axial Screw 3.5mm x 12mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603514	Multi Axial Screw 3.5mm x 14mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603516	Multi Axial Screw 3.5mm x 16mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603518	Multi Axial Screw 3.5mm x 18mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603520	Multi Axial Screw 3.5mm x 20mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603522	Multi Axial Screw 3.5mm x 22mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603524	Multi Axial Screw 3.5mm x 24mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603526	Multi Axial Screw 3.5mm x 26mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603528	Multi Axial Screw 3.5mm x 28mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603530	Multi Axial Screw 3.5mm x 30mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603532	Multi Axial Screw 3.5mm x 32mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603534	Multi Axial Screw 3.5mm x 34mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3604012	Multi Axial Screw 4.0mm x 12mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3604014	Multi Axial Screw 4.0mm x 14mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3604016	Multi Axial Screw 4.0mm x 16mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3604018	Multi Axial Screw 4.0mm x 18mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3604020	Multi Axial Screw 4.0mm x 20mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3604022	Multi Axial Screw 4.0mm x 22mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3604024	Multi Axial Screw 4.0mm x 24mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3604026	Multi Axial Screw 4.0mm x 26mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3604028	Multi Axial Screw 4.0mm x 28mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3604030	Multi Axial Screw 4.0mm x 30mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3604032	Multi Axial Screw 4.0mm x 32mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3604034	Multi Axial Screw 4.0mm x 34mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3604522	Multi Axial Screw 4.5mm x 22mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3604524	Multi Axial Screw 4.5mm x 24mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3604526	Multi Axial Screw 4.5mm x 26mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3604528	Multi Axial Screw 4.5mm x 28mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3604530	Multi Axial Screw 4.5mm x 30mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3604532	Multi Axial Screw 4.5mm x 32mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3604534	Multi Axial Screw 4.5mm x 34mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
360PT3522	Partially Threaded MAS 3.5mm x 22mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
360PT3524	Partially Threaded MAS 3.5mm x 24mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
360PT3526	Partially Threaded MAS 3.5mm x 26mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
360PT3528	Partially Threaded MAS 3.5mm x 28mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
360PT3530	Partially Threaded MAS 3.5mm x 30mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
360PT4022	Partially Threaded MAS 4.0mm x 22mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
360PT4024	Partially Threaded MAS 4.0mm x 24mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
360PT4026	Partially Threaded MAS 4.0mm x 26mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
360PT4028	Partially Threaded MAS 4.0mm x 28mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
360PT4030	Partially Threaded MAS 4.0mm x 30mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3600406	OC Bone Screw 4.5mm x 6mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3600408	OC Bone Screw 4.5mm x 8mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3600410	OC Bone Screw 4.5mm x 10mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3600412	OC Bone Screw 4.5mm x 12mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3600414	OC Bone Screw 4.5mm x 14mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766

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3600506	OC Bone Screw 5.0mm x 6mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3600508	OC Bone Screw 5.0mm x 8mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3600510	OC Bone Screw 5.0mm x 10mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3600512	OC Bone Screw 5.0mm x 12mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3600514	OC Bone Screw 5.0mm x 14mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3600120	OC Ti Set Screw Adj Rod	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3600315	Multi Axial Screw Set Screw M6	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3602615	Closed Connector Flat Set Screw	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3600300	OC Screw Connector	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3600301	OC Screw Connector Offset	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3602535	Rod to Rod Crosslink - Small	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3602536	Rod to Rod Crosslink - Medium	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3602537	Rod to Rod Crosslink - Large	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3602525	MAS to MAS Crosslink - Small	May 2017	Rule 8	Annex II (-section 4)	61325	15766
3602526	MAS to MAS Crosslink - Medium	May 2017	Rule 8	Annex II (-section 4)	61325	15766
3602527	MAS to MAS Crosslink - Large	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3601350	Offset Domino 3.2/3.5mm to 3.2/3.5mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3601475	Offset Domino 3.2/3.5mm to 4.5/4.75mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3601550	Offset Domino 3.2/3.5mm to 5.5/6.0mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603350	Offset O/O Domino 3.2/3.5mm to 3.2/3.5mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603475	Offset O/O Domino 3.2/3.5mm to 4.5/4.75mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603635	Offset O/O Domino 3.2/3.5mm to 5.5/6.0/6.35mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3602120	3.2mm Titanium Rod, 120mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3602240	3.2mm Titanium Rod, 240mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3605120	3.5mm Titanium Rod, 120mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3605240	3.5mm Titanium Rod, 240mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3600201	3.5mm Pre-Curved Titanium Rod, 200mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3600211	3.5mm Pre-Curved Cobalt Chrome Rod, 200mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603706	3.5mm/4.75mm Tapered Titanium Rod, 420mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603707	3.5mm/5.5mm Tapered Titanium Rod, 420mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603806	3.5mm/4.75mm Tapered Cobalt Chrome, 420mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603807	3.5mm/5.5mm Tapered Cobalt Chrome, 420mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603709	3.5mm/6.0mm Tapered Titanium Rod, 420mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603809	3.5mm/6.0mm Tapered Cobalt Chrome, 420mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603708	3.5mm/6.0mm Tapered Titanium Rod, 600mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603808	3.5mm/6.0mm Tapered Cobalt Chrome, 600mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603725	3.5mm Pre-Cut / Bent Titanium Rod, 25mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603730	3.5mm Pre-Cut / Bent Titanium Rod, 30mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766

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3603740	3.5mm Pre-Cut / Bent Titanium Rod, 40mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603750	3.5mm Pre-Cut / Bent Titanium Rod, 50mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603760	3.5mm Pre-Cut / Bent Titanium Rod, 60mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603770	3.5mm Pre-Cut / Bent Titanium Rod, 70mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3603780	3.5mm Pre-Cut / Bent Titanium Rod, 80mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3600600	OC Adjustable Plate – Small	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3600601	OC Adjustable Plate	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3600100	OC Adjustable Rod TI 3.5mm x 100mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3600200	OC Adjustable Rod TI 3.5mm x 200mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3600110	OC Adjustable Rod CCM 3.5mm x 100mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
3600210	OC Adjustable Rod CCM 3.5mm x 200mm	April 2017	Rule 8	Annex II (-section 4)	61325	15766
G3600120	OC Ti Set Screw Adj Rod - Sterile	April 2017	Rule 8	Annex II (-section 4)	61325	15766
G3602615	Closed Connector Flat Set Screw - Sterile	April 2017	Rule 8	Annex II (-section 4)	61325	15766
G3602616	Open Connector Coned Set Screw - Sterile	April 2017	Rule 8	Annex II (-section 4)	61325	15766
G3600300	OC Screw Connector-Sterile	April 2017	Rule 8	Annex II (-section 4)	61325	15766
G3600301	OC Screw Connector Offset-Sterile	April 2017	Rule 8	Annex II (-section 4)	61325	15766
G3602535	Rod to Rod Crosslink Small - Sterile	April 2017	Rule 8	Annex II (-section 4)	61325	15766
G3602536	Rod to Rod Crosslink Medium - Sterile	April 2017	Rule 8	Annex II (-section 4)	61325	15766
G3602537	Rod to Rod Crosslink Large - Sterile	April 2017	Rule 8	Annex II (-section 4)	61325	15766
G3602525	MAS to MAS Crosslink Small - Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766
G3602526	MAS to MAS Crosslink Medium - Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766
G3602527	MAS to MAS Crosslink Large - Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766
G3601350	Offset Domino 3.2/3.5mm to 3.2/3.5mm - Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766
G3601475	Offset Domino 3.2/3.5mm to 4.5/4.75mm - Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766
G3601550	Offset Domino 3.2/3.5mm to 5.5mm/6.0mm - Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766
G3602350	Axial Domino 3.2/3.5mm to 3.2/3.5mm - Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766
G3602475	Axial Domino 3.2/3.5mm to 4.5/4.75mm - Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766
G3602550	Axial Domino 3.2/3.5mm to 5.5/6.0mm - Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766
G3603350	Offset O/O Domino 3.2/3.5mm to 3.2/3.5mm - Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766
G3603475	Offset O/O Domino 3.2/3.5mm to 4.5/4.75mm - Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766
G3603635	Offset O/O Domino 3.2/3.5mm to 5.5/6.0/6.35mm - Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766
G3606072	MAS Ext 5.5mm /6.0mm /6.35mm - Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766
G3603709	3.5mm/6.0mm Tapered Titanium Rod, 420mm-Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766
G3603809	3.5mm/6.0mm Tapered Cobalt Chrome, 420mm-Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766
G3603708	3.5mm/6.0mm Tapered Titanium Rod, 600mm-Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766
G3603808	3.5mm/6.0mm Tapered Cobalt Chrome, 600mm-Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766
G3600600	OC Adjustable Plate Small-Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766

Medtronic

Product:	INFINITY™ OCT System						
Class:	IIb						
	P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
	G3600601	OC Adjustable Plate-Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766
	G3600100	OC Adjustable Rod TI 3.5mm x 100mm-Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766
	G3600200	OC Adjustable Rod TI 3.5mm x 200mm-Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766
	G3600110	OC Adjustable Rod CCM 3.5mm x 100mm-Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766
	G3600210	OC Adjustable Rod CCM 3.5mm x 200mm-Sterile	April 2017	Rule 8	Annex II (-section 4)	61324	15766

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

A1 / 04.11

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD
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):

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Medtronic Sofamor Danek Deggendorf GmbH
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SOCIETATEA COMERCIALA S.R.L. "DENOLEX MEDICAL"

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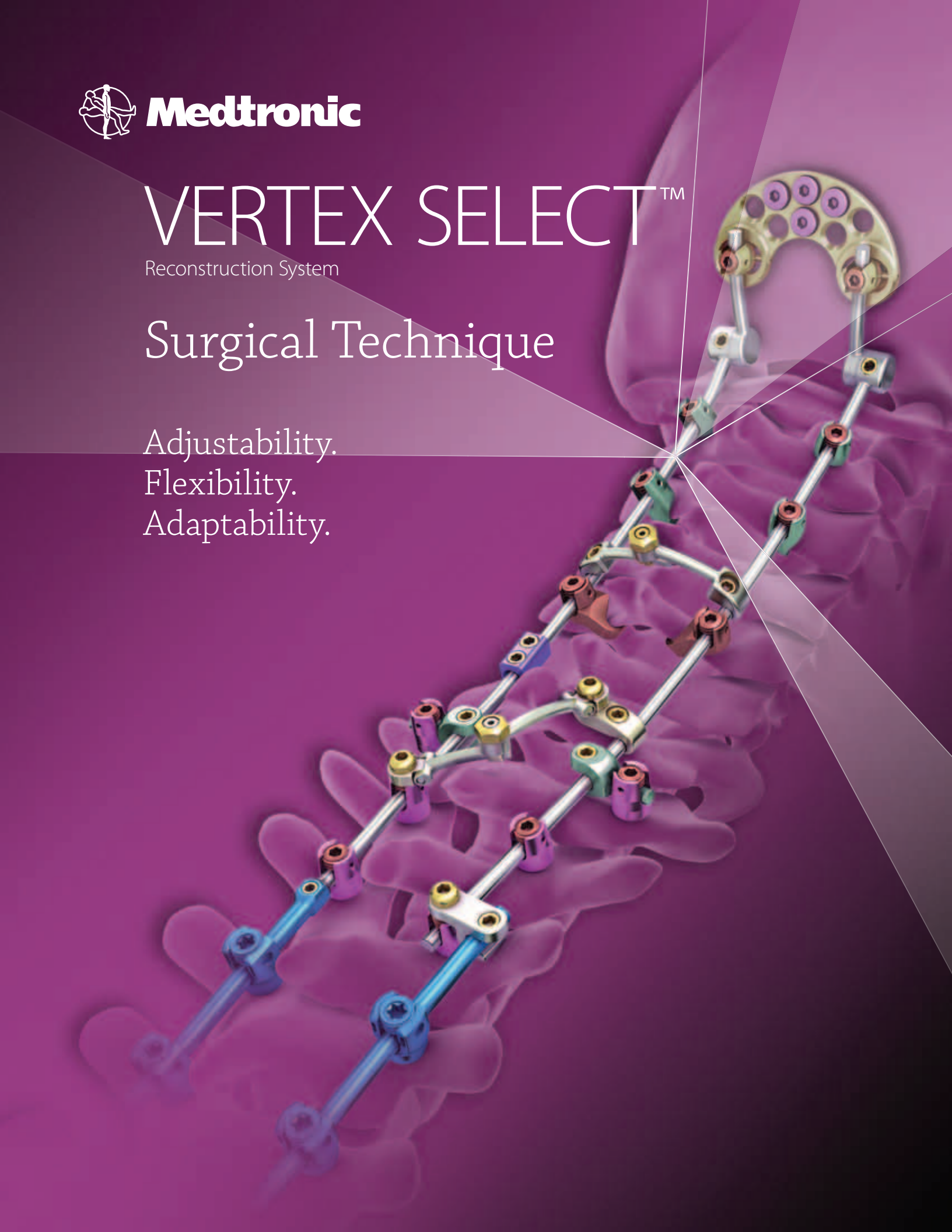
VERTEX SELECT™

Reconstruction System

Surgical Technique

Adjustability.
Flexibility.
Adaptability.



Adjustability. Flexibility. Adaptability.

The VERTEX SELECT™ Reconstruction System is a comprehensive set of options that provides adjustability, flexibility, and adaptability to meet the anatomical challenges of the occipitocervical and upper thoracic spine.

Building upon a strong clinical history... now with even more options.


Adjustability.
Flexibility.
Adaptability.

Medtronic

VERTEX SELECT™

Reconstruction System

Surgical Technique

VERTEX SELECT™

Reconstruction System

VERTEX SELECT™

Reconstruction System Occipitocervical (OC) Module

Implant Features

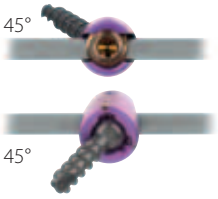
Multi-Axial Screw

- Accepts 3.2mm and 3.5mm rods
- 60° conical angulation
- 30° in any direction
- Up to 45° of angulation in relief notches
- Available in 3.5mm, 4.0mm, and 4.5mm diameters
- Partially threaded options available in 3.5mm and 4.0mm diameters
- Cannulated options available in 4.0mm and 4.5mm diameters

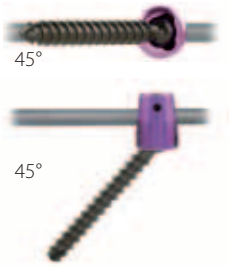
Fully Threaded Multi-Axial Screws (MAS)

Partially Threaded Multi-Axial Screws (MAS)

Top and bottom view of 10mm to 24mm screw relief notches



Bottom and side view of 26mm to 52mm screw relief notches



Laminar Hooks

- Accept 3.2mm and 3.5mm diameter rods
- Left and right laminar offset hooks

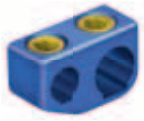
Rods

- Surgeon choice of 3.2mm and 3.5mm rod diameters in various lengths
- Cervical-thoracic threaded rods available in various diameters

Rod Transition Options

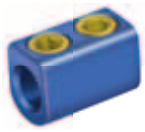
Offset Dominos

- Enable connection from 3.2mm and 3.5mm rod diameters to 3.2mm, 3.5mm, 4.5mm, or 5.5mm rod diameters
- Allow for medial/lateral offset of rods at the transition point



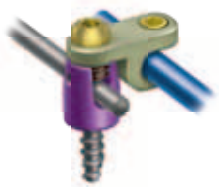
Axial Dominos

- Enable connection from 3.2mm and 3.5mm rod diameters to 4.5mm and 5.5mm rod diameters
- Allow for axial alignment of rods at the transition point



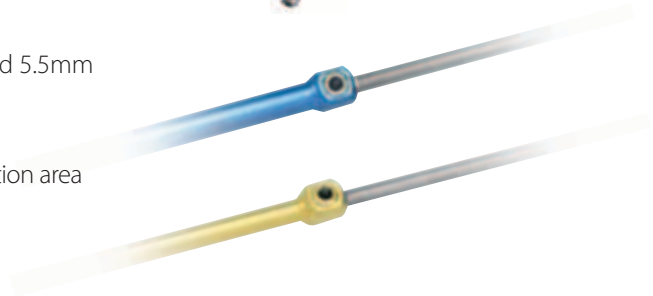
Multi-Axial Screw (MAS) Extension Connectors

- Connect directly to multi-axial screw to allow for extension of adjacent constructs
- Enable connection directly from multi-axial screw to 4.5mm and 5.5mm rod diameters
- "Zero Run on the Rod" transition option to allow for maximum fixation area



Threaded Rods

- Enable connection from 3.2mm and 3.5mm rod diameters to 4.5mm and 5.5mm rod diameters
- Allow for axial alignment of rods at the cervical-thoracic transition point
- Low-profile transition option of the threaded rods allows for maximum fixation area



Implant Features *continued*

Rod Connector Options

Lateral Offset Connectors

- Allow for medial/lateral offset to accommodate nonlinear screws
- Provide additional options for screw placement
- Dorsal height adjustment capabilities to accommodate screw height differences
- Open and closed connector options

Cable Connector

- Allows for connection of ATLAS® Cable to the rod construct

CROSSLINK® Connector Options

CROSSLINK® Connector, MAS to MAS Design

- Connects directly to the top of a multi-axial screw head in cases where adjacent screw heads are in close proximity to one another
- Ability to attach to a different level above or below on each side of construct
- Ability to also connect directly to the rod using the VERTEX SELECT™ System CROSSLINK® Connector Clip
- Arched design allows room for patient anatomy
- Adjustable design and various sizes to accommodate varying distances between rods
- Single-component design for easy placement

CROSSLINK® Connector Clip

- Enables the MAS to MAS CROSSLINK® Connector to attach directly to rod if necessary

CROSSLINK® Connector, Rod to Rod Design

- Adjustable design and various sizes to accommodate varying distances between rods
- Arched design allows room for patient anatomy
- Single-component design for easy placement

Set Screws

- Multi-axial screw and hook standard set screw
- MAS Connector Set Screw enables attachment of a MAS CROSSLINK® Connector or a MAS Extension Connector to a multi-axial screw
- MAS Locking Set Screw locks the MAS CROSSLINK® Connector or the MAS Extension Connector to a multi-axial screw

Instrument Set

Screw Preparation/Placement

Adjustable Drill Guide

Fixed
Drill Guide
(14mm)

Universal Handle

Circular Drill Bit
Adapter

Universal Ratcheting Handle

Pedicle Feeler

Pedicle Probe

Awl

Bone Reamer

Depth Gauge

Quick Release Self-Holding Screwdriver

Tap Sleeve

Threaded Screwdriver

4.0mm External Hex

Instrument Set *continued*

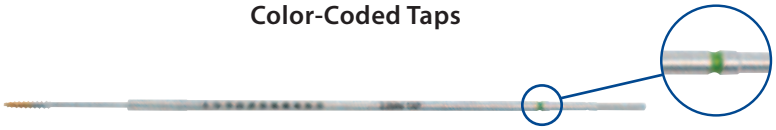
Screw Preparation/Placement *continued*

Color-Coded Drill Bits

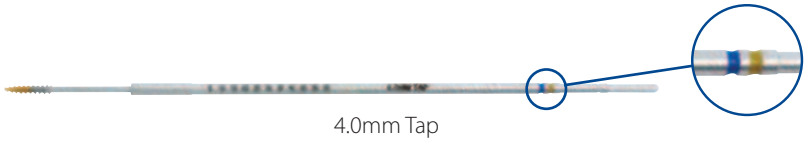
2.4mm Drill Bit

2.9mm Drill Bit

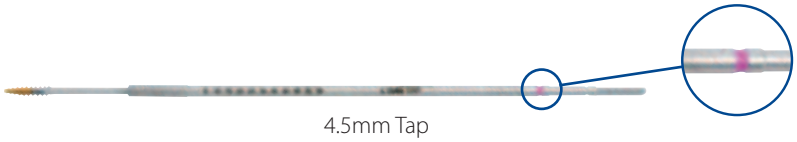
Color-Coded Taps



3.5mm Tap



4.0mm Tap



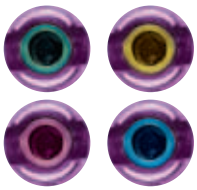
4.5mm Tap

Note

The gold anodized tip of the tap represents the first 10mm of thread.

Color-Coding Reference

	Screw Size	Color	Drill Bit	Tap
VERTEX SELECT™ Multi-Axial Screws (MAS)	3.5mm × 10mm to 40mm	Green	2.4mm	3.5mm Tap
	4.0mm × 10mm to 24mm	Blue	2.4mm	4.0mm Tap
	4.0mm × 26mm to 52mm	Gold	2.9mm	4.0mm Tap
	4.5mm × 10mm to 52mm	Magenta	2.9mm	4.5mm Tap
VERTEX SELECT™ Partially Threaded Multi-Axial Screws (MAS)	3.5mm × 18mm to 40mm	Green	2.4mm	3.5mm Tap
	4.0mm × 18mm to 40mm	Gold	2.9mm	4.0mm Tap



Instrument Set *continued*

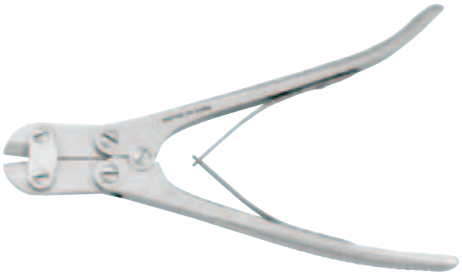
Hook Placement

Laminar Elevator

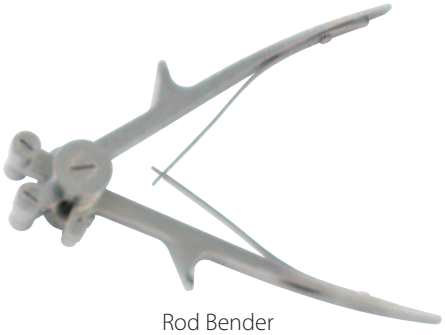
Hook Holder

Rod Preparation

Ratcheting Rod Cutter



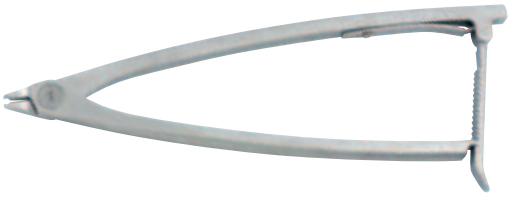
Rod Cutter



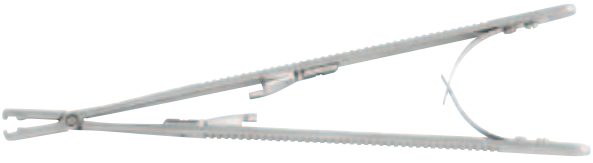
Rod Bender

Rod Template

Rod Insertion/Adjustment



Rod Gripper

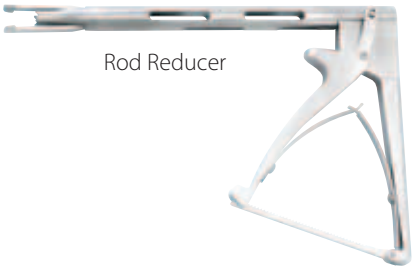


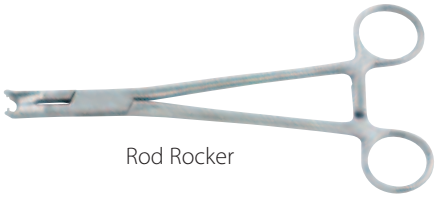
Rod Holder

Alignment Tool

Instrument Set *continued*

Rod Reduction/Correction


Rod Reducer


Rod Rocker

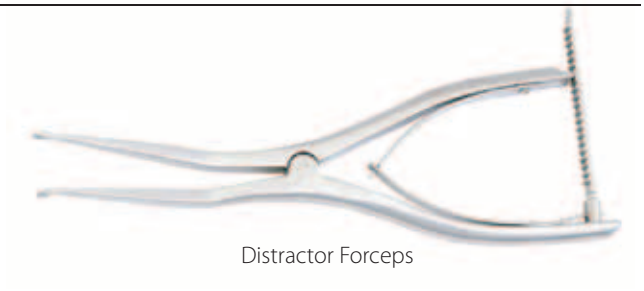

Bending Iron Left

Bending Iron Right


Coronal Benders

Compression/Distraction


Compressor Forceps


Distractor Forceps

Final Tightening


2.5mm Straight Hex Screwdriver

Straight Hex Torque Driver


4.0mm External Hex


4.0mm External Hex Torque Screwdriver


Rod Pusher/Counter Torque


Universal Handle


Torque Limiting Handle


T-Handle

CROSSLINK® Plate Placement


Lock Nut Driver


Universal Handle


Swizzle Stick

Patient Positioning/Posterior Approach

The patient is placed prone in an appropriate manner to avoid specific pressure points.

A midline incision is made, and dissection is carried down to the spinous processes of the appropriate vertebrae.

Dissection is carried laterally to expose the facets and the transverse processes **(Figure 1)**.

Figure 1

Pedicle Preparation

Anatomical landmarks are identified and carefully reviewed to determine the entry point to the pedicle **(Figure 2)**. An entry hole is made over the pedicle with a burr, drill, or awl **(Figure 3)**.

Figure 2

Figure 3

Drilling

The Adjustable Drill Guide, with the lock and unlock adjustment feature, can be used for drilling depths from 6mm to 52mm in 1mm increments.

The drilling depth can be adjusted by pressing the Slide forward while adjusting the Measuring Tube to the desired drill depth **(Figure 4)**.

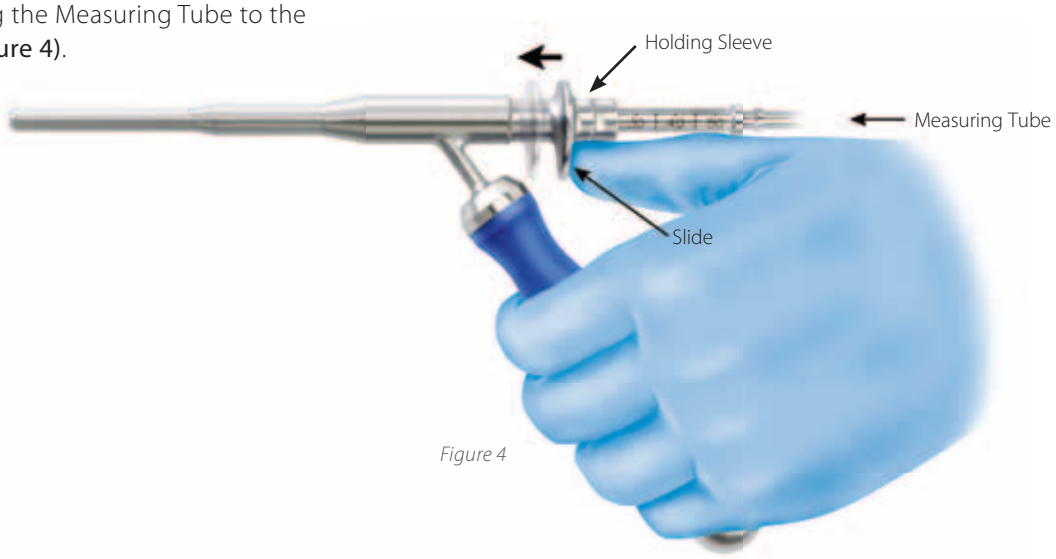


Figure 4

Once the slide reaches the desired depth, rotate the slide into the locked position and prepare the pilot hole in the desired trajectory **(Figures 5 and 6)**.

Figure 5

Figure 6

Screw Measurement

The Pedicle Feeler **(Figure 7)** is used to gently palpate the cancellous bone to the pedicle, and the Depth Gauge is used to determine the screw length **(Figure 8)**.

Figure 7

Figure 8

Optional Tapping

The VERTEX SELECT™ Multi-Axial Screws are self-tapping to eliminate the tapping step.

If the surgeon prefers tapping, place the Tap Sleeve over the tri-flat end of the tap and use the gauge on the tap shaft to visualize the depth of the tap in the pedicle **(Figure 9)**.

Note

The tap may be attached to either the Universal Handle or the Universal Ratcheting Handle.

Note

The gold anodized tip of the tap represents the first 10mm of thread **(Figure 10)**.

Figure 9

Figure 10

Bone Reaming

The Bone Reamer may be used to remove uneven bone, if needed, to maximize the multi-axial capabilities of the bone screw **(Figures 11 and 12).**

Figure 11

Figure 12

Screw Placement

Once the desired screw length is selected, the screw is attached to either the Quick Release Self-Holding Screwdriver or Threaded Screwdriver, along with the Universal Ratcheting Handle, and inserted into the bone **(Figures 13 and 14)**.

Confirmation of screw position can be made using radiographs or intraoperative fluoroscopy.

The remaining screws are placed using a similar technique.

Note

It is recommended, though not required, that for longer length multi-axial screws (>26mm), you use the threaded screwdriver, as it may help give better handling and control of the screw if needed.

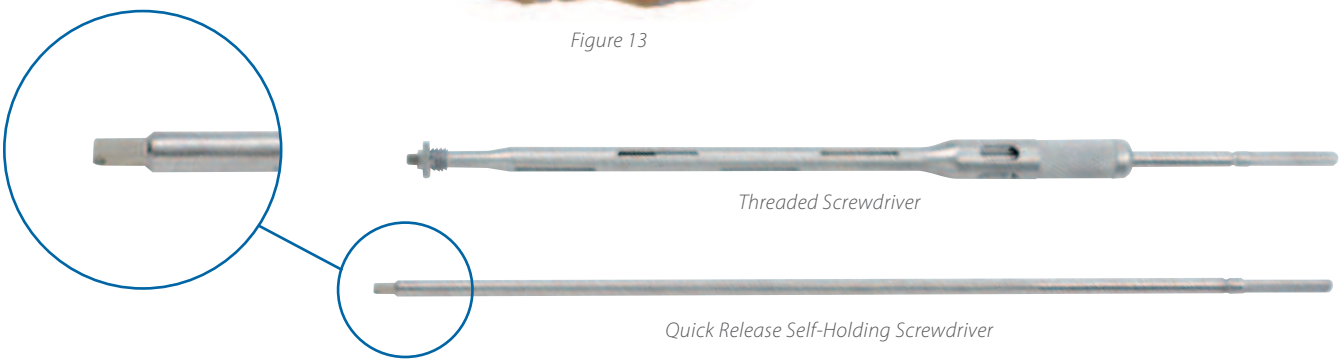
Note

Cannulated multi-axial screws are available.

Figure 13

Figure 14

Universal Ratcheting Handle



Threaded Screwdriver

Quick Release Self-Holding Screwdriver

Screw Placement *continued*

Prior to rod placement, the Alignment Tool may be used to align the saddles of the VERTEX SELECT™ Multi-Axial Screws **(Figures 15 and 16)**.

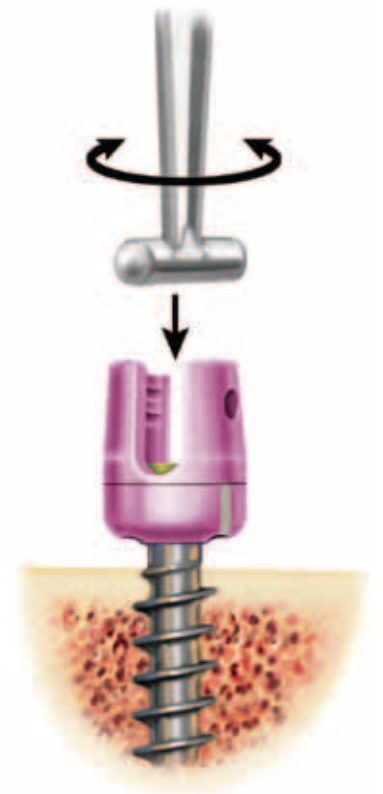


Figure 15

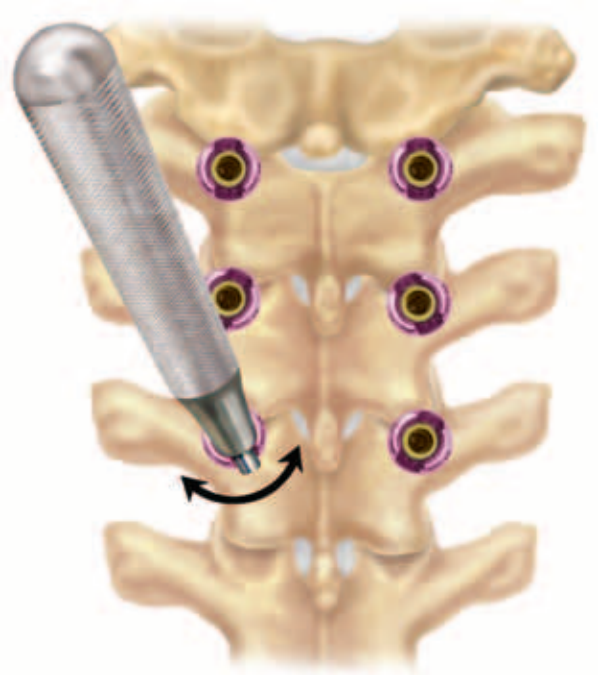


Figure 16

Hook Placement

When using Laminar Hooks in the cervical and upper thoracic spine, lamina preparation and ligamentum flavum dissection are performed using the Laminar Elevator **(Figure 17)**.

If desired, dissection may also be achieved using a hook in the Hook Holder **(Figure 18)**.

The appropriate hook is selected based on the thickness of the lamina and placed at the appropriate position **(Figures 19 and 20)**.

Figure 17

Figure 18

Figure 19

Figure 20

Rod Selection

Straight Rods are available in either 3.2mm or 3.5mm diameters **(Figure 21)**.

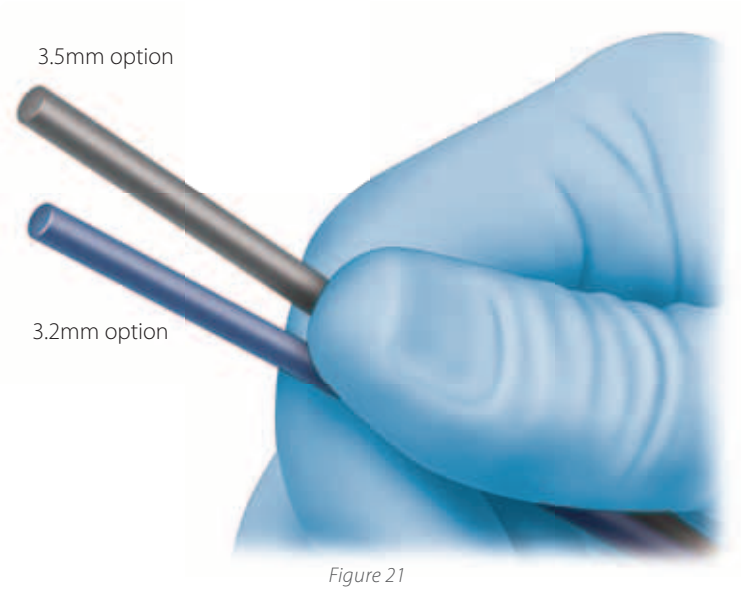


Figure 21

Rod Templating

The Rod Template is used to determine the curvature and length of the rod needed based on the screw or hook positions **(Figure 22)**.

Fit the Template into the desired area and mold into proper shape. Remove the Template and use to shape either your straight or threaded rod to match.

Note

The Rod Template has markings that can help determine the appropriate length of the entire construct **(Figure 23)**.

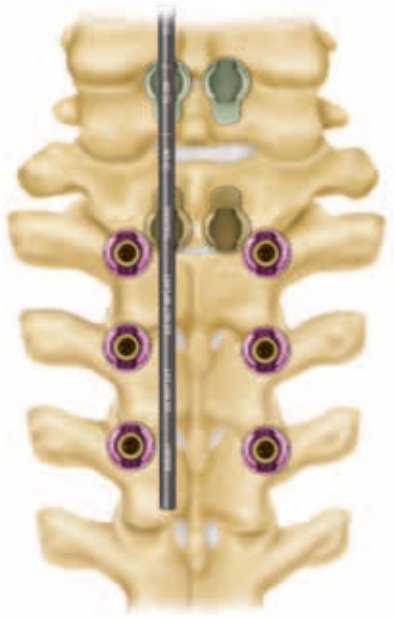


Figure 22

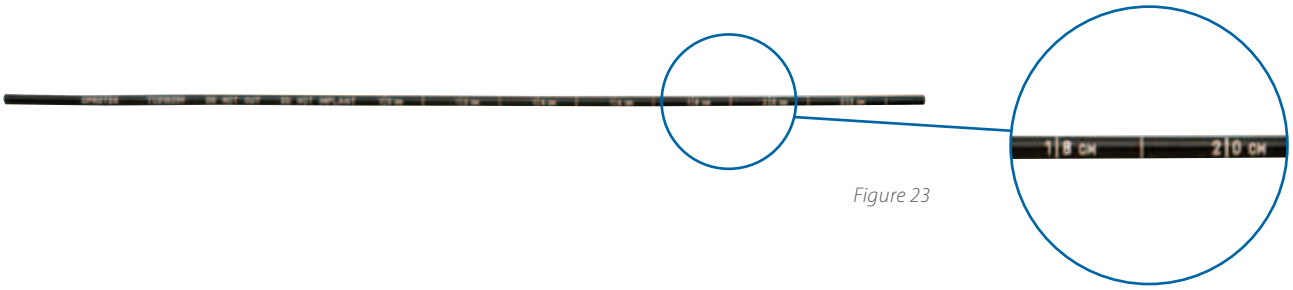


Figure 23

Rod Cutting

Use a marker to mark the rod at the appropriate length as determined by the Rod Template, and then cut the rod using the Rod Cutter **(Figure 24)**.

The Rod Cutter can also be used as an alternate for rod cutting **(Figure 25)**.

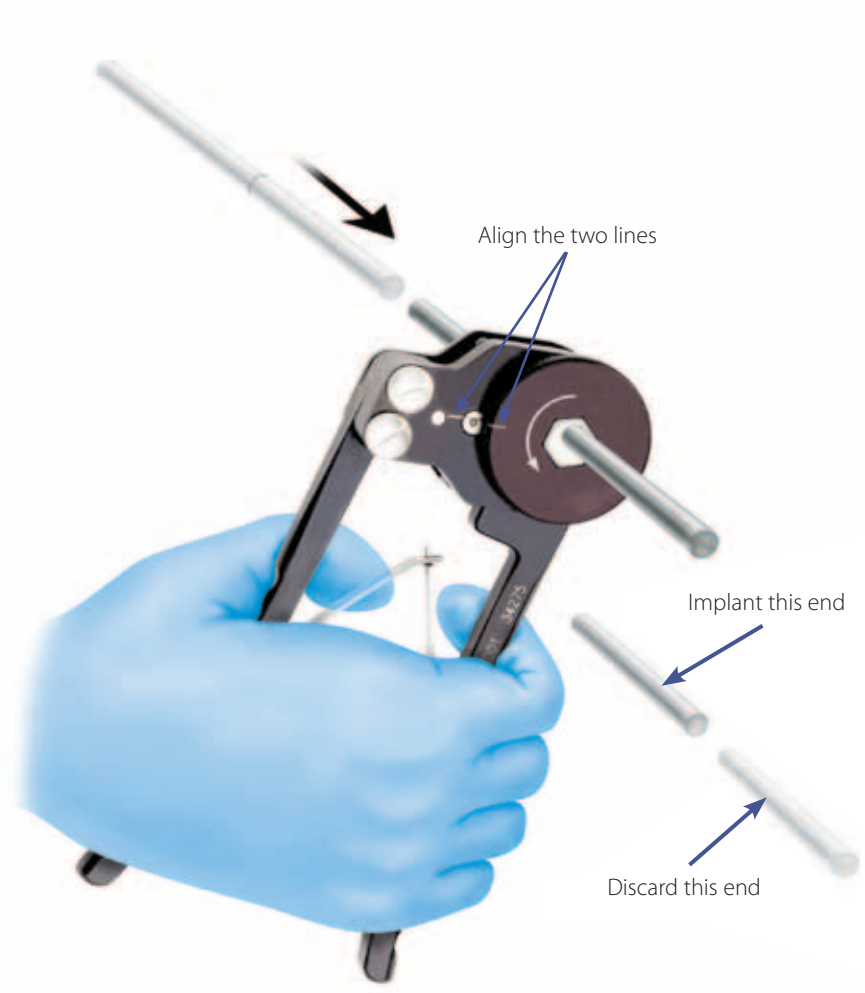


Figure 24

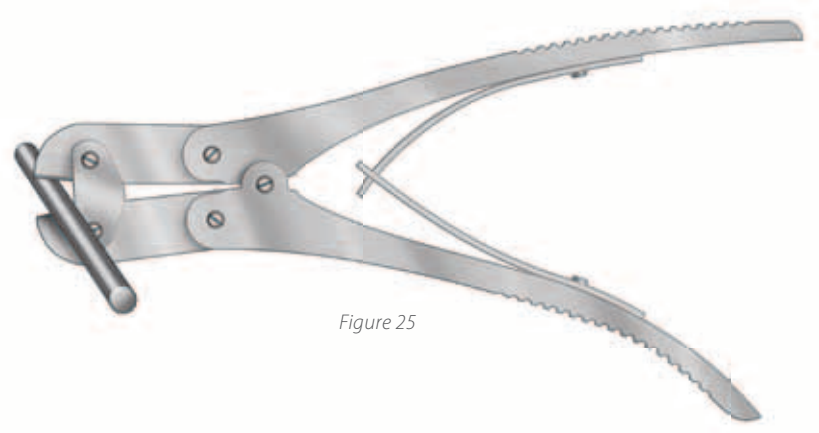


Figure 25

Rod Bending

Contour the rod to the sagittal contour of the spine and the medial/lateral orientation of the implants using the Rod Bender **(Figure 26)**.

If *in situ* bending is needed, the rod can be contoured in the sagittal plane with the Bending Irons **(Figure 27)** and in the medial/lateral plane with the Coronal Benders **(Figure 28)**.

Figure 26

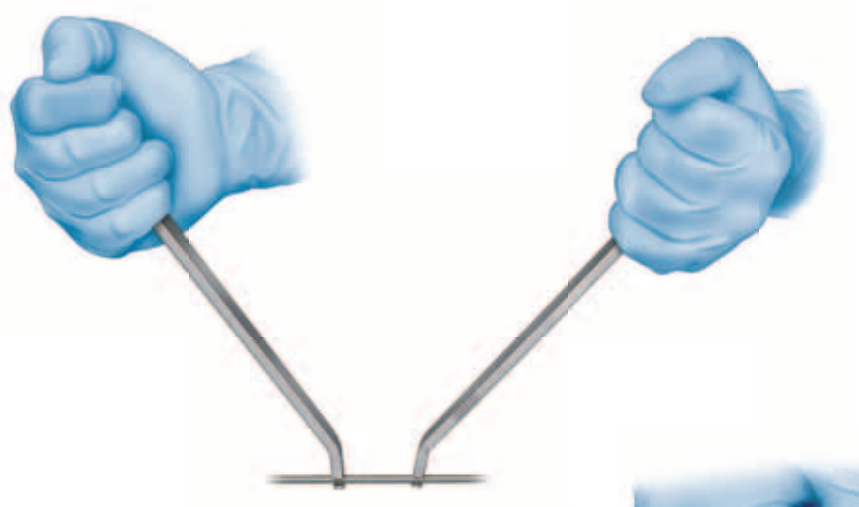


Figure 27

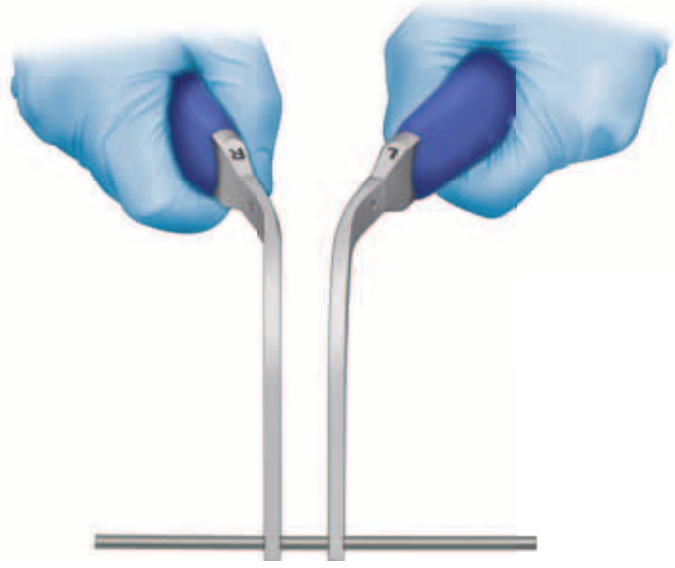


Figure 28

Using Lateral Offset Connectors

The relief notches on the VERTEX SELECT™ Multi-Axial Screw (MAS) allow up to 7.5mm of medial/lateral variability **(Figure 29)**. If additional medial/lateral offset is required, Lateral Connectors can facilitate rod attachment of the non-linear screws and can adjust for screw height difference and excessive angulations.

Closed-Ended Lateral Connectors are provided for placement before rod insertion **(Figure 30)**, and Open-Ended Lateral Connectors are side loading to accommodate placement before or after rod insertion **(Figure 31)**.

Provisionally tighten the set screw on the lateral connector to prevent migration on the rod by using the Quick Release Self-Holding Screwdriver with the Universal Handle.

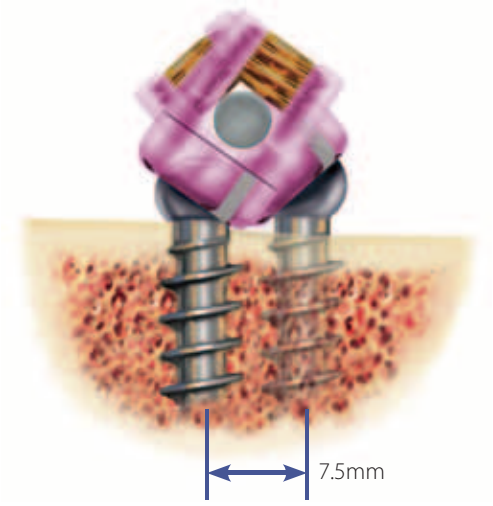


Figure 29

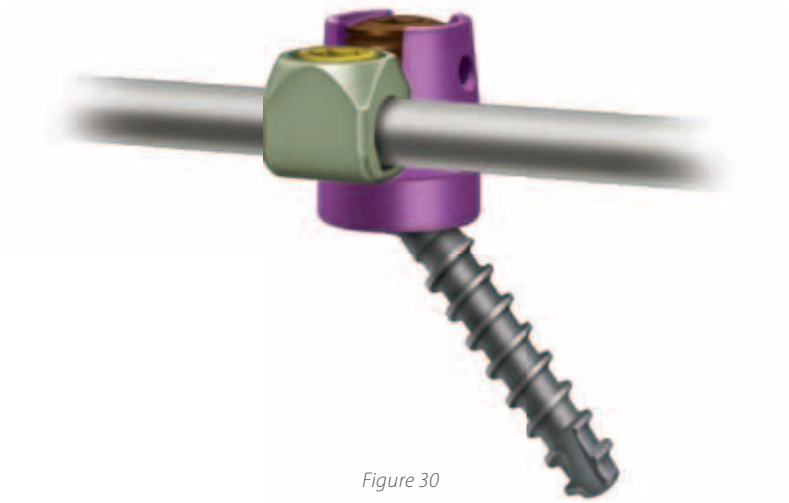


Figure 30

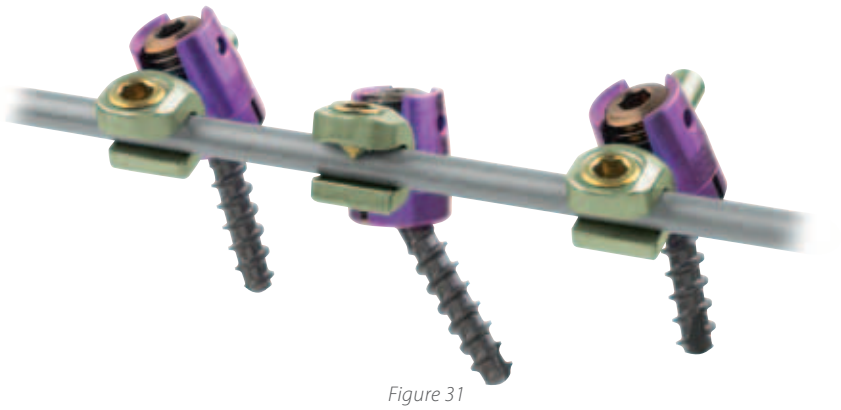


Figure 31

Rod Placement

Place the rod into the implant heads using the Rod Holder **(Figure 32)**.

With the rod fully seated in the screw heads, a set screw can be loaded onto the Quick Release Self-Holding Screwdriver, placed through the Rod Pusher/Counter Torque, and seated into each screw head **(Figure 33)**.

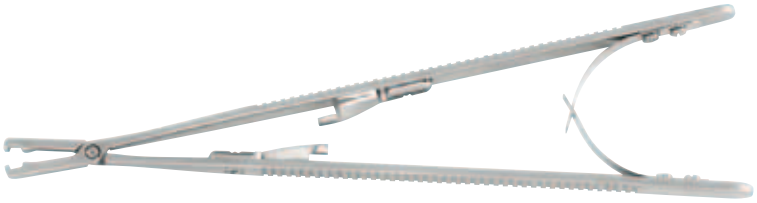


Figure 32

Note

If a MAS CROSSLINK® Connector will be used, a separate set screw is required. Refer to the MAS CROSSLINK® Connector section for more information.

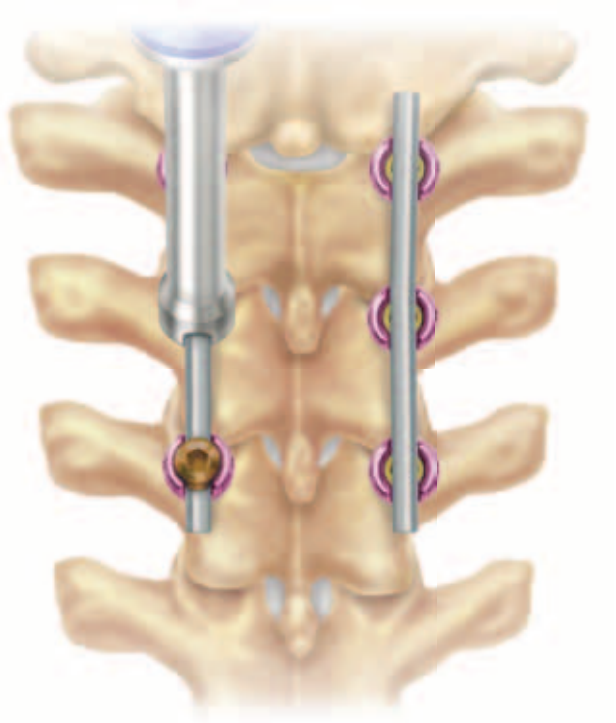


Figure 33

Rod Reduction

If the rod is not easily captured in the screw head, the Rod Reducer or Rod Rocker can be used to fully seat the rod and simplify set screw introduction.

To use the Rod Rocker, place over the rod and grasp the screw head notches **(Figure 34a)**. Gently squeeze and tilt the Rod Rocker to reduce the rod into the screw saddle **(Figure 34b)**.

To use the Rod Reducer, place it over the rod and grasp the screw head notches from above. As the Reducer handle is squeezed, the Rod Reducer sleeve will slide down and seat the rod **(Figure 34c)**.

To secure the rod, load a set screw into the multi-axial screw saddle with the Quick Release Self-Holding Screwdriver, as the Rod Reducer or Rod Rocker continues to hold the rod in place **(Figure 34d)**.

Figure 34a

Figure 34b

Figure 34c

Figure 34d

Compression and Distraction

Once the rod is secured into the implants, *in situ* bending, distraction, and/or compression may be performed to place the implants in the final position.

Compression maneuvers are most often carried out directly on two implants **(Figure 35)**.

A Rod Gripper is also included for additional rod manipulation **(Figure 36)**.

Figure 35

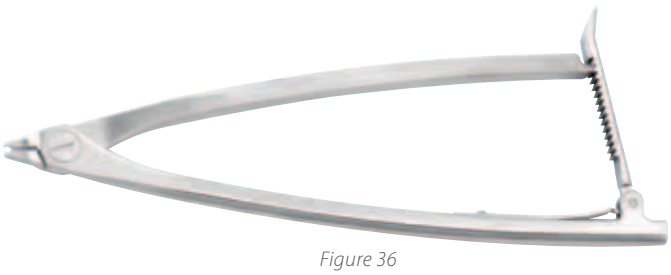


Figure 36

Final Tightening

After the compression and distraction maneuvers are complete, the set screws should be final tightened using the Straight Hex Torque Driver and Torque Limiting T-Handle in conjunction with the Rod Pusher/Counter Torque (Figure 37).

Figure 37

Torque Limiting T-Handle

Rod Transition Options

Rod transition options allow for a transition from the cervical to the thoracic spine or at any location where it is necessary to move from a smaller rod diameter to a large rod diameter.

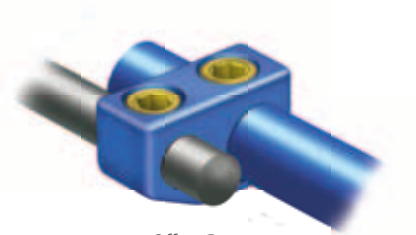
All VERTEX SELECT™ Rod Connectors can be used to connect 3.2mm or 3.5mm rods to 3.2mm, 3.5mm, 4.5mm, or 5.5mm rods.

Various designs are available depending on the alignment and anatomical requirements.

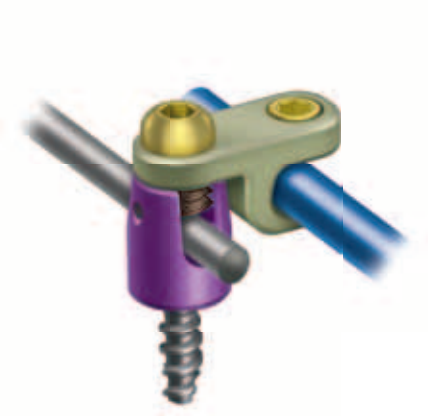
If choosing the threaded rods, insert the threaded portion of the 3.2mm or 3.5mm rod into the receiving end of a 4.5mm or 5.5mm rod and rotate clockwise until fully tightened.

All set screws of the rod transition options utilize a Torque Limiting Driver for final tightening.

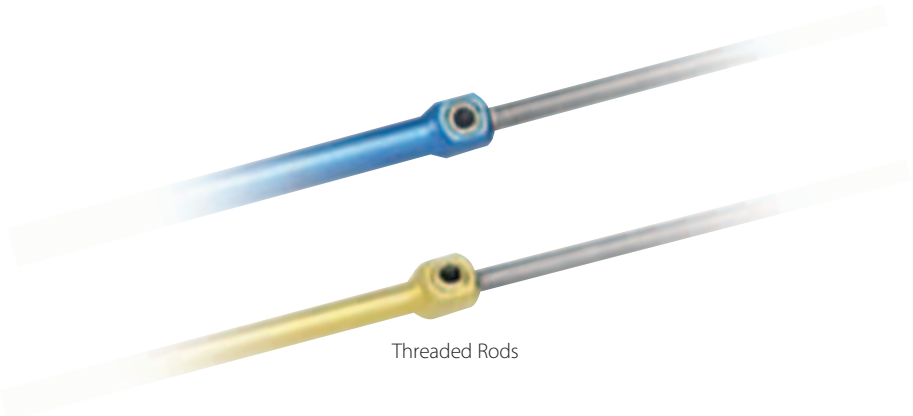
Axial Domino



Offset Domino



Multi-Axial Screw (MAS)
Extension Connector



Threaded Rods

Using Multi-Axial Screw (MAS) Extension Connector Option

The MAS Extension Connector will allow for a "zero run on the rod" connection between dual rods by connecting directly to the head of a multi-axial screw. It also will allow extension of a previous construct directly from a multi-axial screw head.

Place a MAS Connector Set Screw in the head of the multi-axial screw using the Self Holding External 4.0mm Hex Screwdriver **(Figure 38)**.

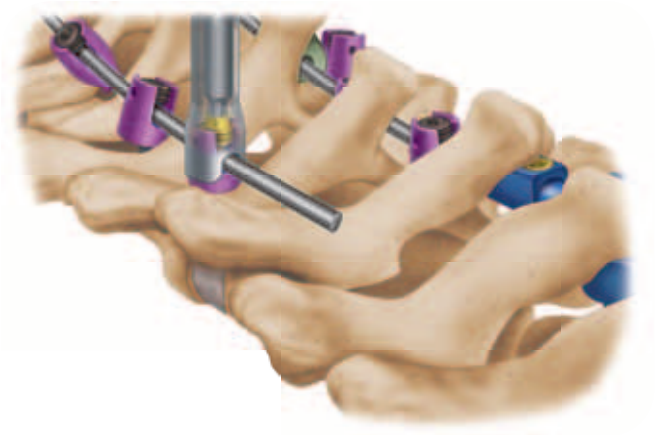


Figure 38

Insert preferred size MAS Extension Connector over the MAS Connector Set Screw, with open end facing lateral.

Place a MAS CROSSLINK® Locking Screw over the MAS Extension Connector **(Figure 39)** and tighten using the Straight Hex Torque Driver and the Torque Limiting T-Handle.

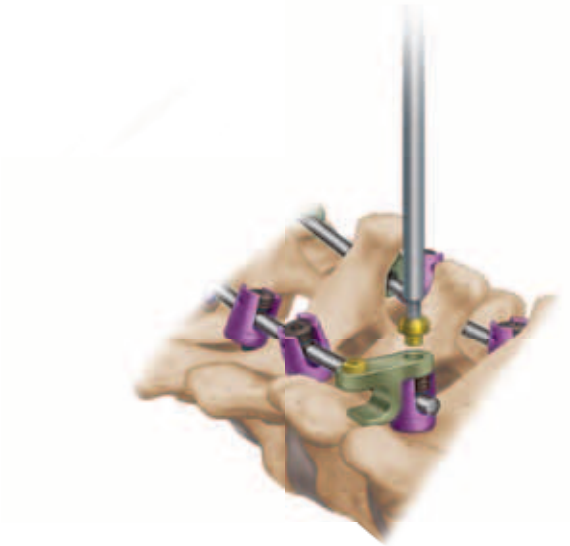


Figure 39

Place the adjoining rod in the open-end portion of the connector and tighten set screw into position using the Straight Hex Torque Driver and the Torque Limiting T-Handle **(Figure 40)**.

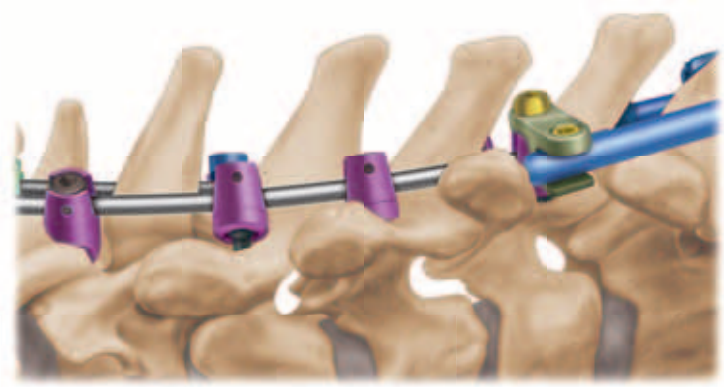
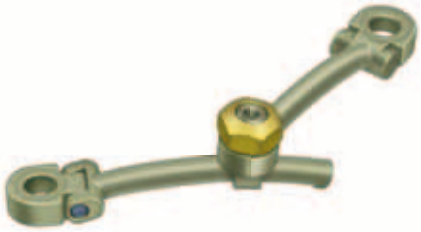


Figure 40

CROSSLINK® Connector Placement

Once decortication is thoroughly performed and bone graft material is placed, CROSSLINK® Connectors are recommended for the top and bottom thirds of the construct to increase rigidity. Two CROSSLINK® Connector designs are available, the MAS CROSSLINK® Connector and the Rod CROSSLINK® Connector.

Optional MAS Connector Clip is available to attach a MAS CROSSLINK® Connector to a rod, if needed.



MAS CROSSLINK® Connector

Rod CROSSLINK® Connector

MAS/Rod Connector Clip

Note

The CROSSLINK® Swizzle Stick can be used for positioning the CROSSLINK® Connectors by threading the Swizzle Stick into the center nut, then removed after final tightening (Figure 41). It may also help to align the center nut driver.

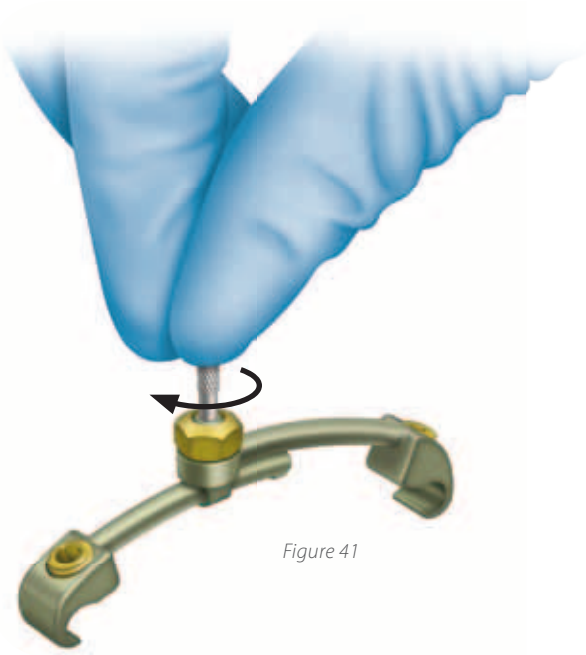


Figure 41

Multi-Axial Screw (MAS) CROSSLINK® Connector Placement

The MAS CROSSLINK® Connector has the ability to connect directly to the head of two multi-axial screws in cases where adjacent screw heads are in close proximity to one another, as well as the ability to span various levels.

To use the MAS CROSSLINK® Connector, first place the MAS Connector set screw in the head of the multi-axial screw (MAS) using the Self-Holding 4.0mm Hex Screwdriver **(Figure 42)**. Attach the MAS CROSSLINK® Connector, then place a MAS CROSSLINK® Locking Screw over the MAS CROSSLINK® Connector and provisionally tighten using the Quick Release Self-Holding Screwdriver **(Figure 43)**.

Also, the MAS CROSSLINK® Connector has the ability to connect directly to the rod if necessary by using the MAS/Rod CROSSLINK® Connector Clip. Place the CROSSLINK® Connector over the clip, attach a MAS CROSSLINK® Locking Screw over the CROSSLINK® Connector, and provisionally tighten using the Quick Release Self-Holding Screwdriver. The MAS CROSSLINK® Locking Screws should be tightened using the Straight Hex Torque Driver and Torque Limiting Handle.

Once the CROSSLINK® Connector is in position, hand tighten the center nut using the Lock Nut Driver **(Figure 44)**.

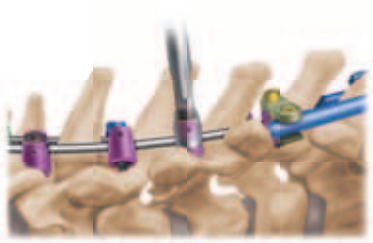


Figure 42

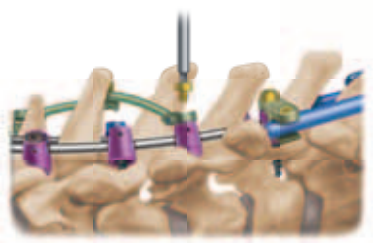


Figure 43

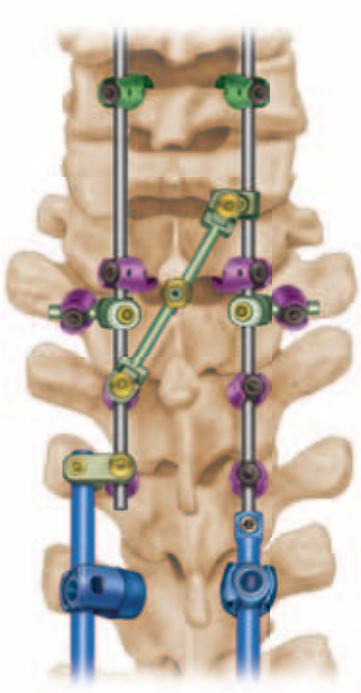


Figure 44

Note

The center nut is not intended for break-off and should be hand tightened only.

Final Construct

An intraoperative image of the final construct should be made to verify proper connection is achieved prior to wound closure **(Figure 45)**.

Note

Cable Connectors are included in the set to allow for additional fixation using the ATLAS® Cable System. Cable Connectors are open-ended connectors and can be placed either medially or laterally on the rod. Once placed, the cable can simply be threaded through the hole and fixated according to the ATLAS® Cable technique **(Figure 46)**.

Figure 46

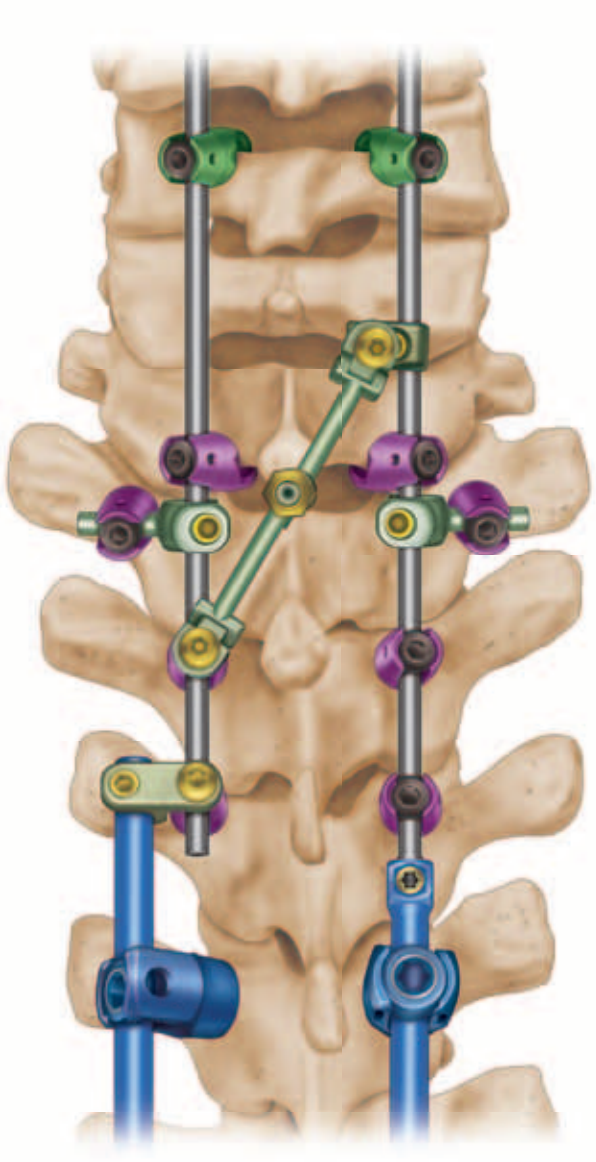


Figure 45

Explantation

To remove any of the VERTEX SELECT™ Reconstruction System implants described throughout this technique, engage the set screw and multi-axial screw with a 2.5mm Hex Screwdriver and turn counterclockwise until the set screw is disengaged from the implant and the bone screw is disengaged from the bone.

VERTEX SELECT™

Reconstruction System Occipitocervical (OC) Module

USING THE OCCIPITAL SCREW CONNECTORS AND OCCIPITAL ADJUSTABLE RODS

and

USING THE OCCIPITAL MIDLINE PLATES AND OCCIPITAL ADJUSTABLE RODS

The VERTEX SELECT™ Reconstruction System Occipitocervical Module must be ordered separately from the standard VERTEX SELECT™ Implants and Instrument Set.

Occipital Fixation Implant Features

Occipitocervical Bone Screws

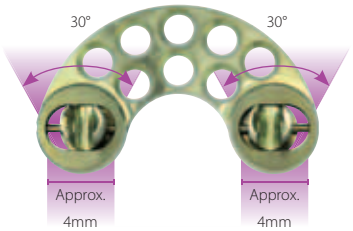
- Increased diameters—4.5mm and 5.0mm*
- Slightly tapered tip for easier insertion*
- Increased thread pitch*

Occipitocervical Screw Connectors

- Allow for six points of occipital midline fixation
- Flexibility in placement on the occiput in the cephalad/caudal directions
- Longer offset connectors for flexibility in the medial/lateral plane
- Dorsal height adjustment capabilities accommodate uneven bone surfaces
- Accept 4.5mm and 5.0mm diameter occipital bone screws
- Accept Pre-Contoured Occipital Rod and Occipital Adjustable Rod
- Low-profile occipital fixation option

Adjustable Occipital (OC) Plate

- Rotating and translating saddles allow for flexibility in rod placement
- Multiple screw holes for flexible screw placement (must place at least four screws)
- Arched design for increased bone graft volume on the occiput
- Low-profile design
- Lateral screw placement for torsional stability
- Contoured with the Occipital Plate Bender



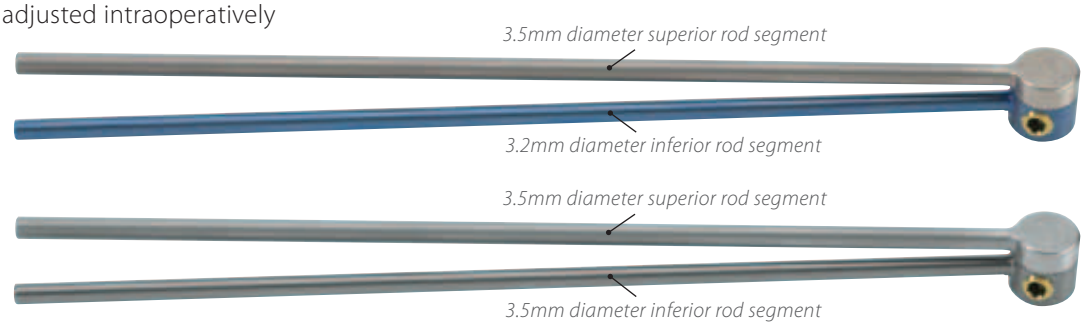
Occipitocervical Midline Fixed Plates

- Allows for occipital midline fixation
- Low-profile design
- Lateral screw placement allows for torsional stability
- Multiple sizes available to match patient anatomy
- Accept 4.5mm and 5.0mm diameter occipital bone screws
- Accept Occipital Pre-Contoured Rods and Occipital Adjustable Rods
- Contoured with the Occipital Plate Bender

"M"-shaped design to allow for increased volume of bone graft in the midline of the occiput

Occipitocervical Adjustable Rods

- Hinge portion of rod adjusts to accommodate various anatomical angles in the occipitocervical junction
- Requires less rod bending to fit difficult anatomy
- 360° of rotation
- Angulation can be adjusted intraoperatively
- Available in 3.2mm/3.5mm diameter or 3.5mm/3.5mm diameter
- Available in 120mm and 220mm lengths



**Versus the VERTEX MAX® Reconstruction System occipitocervical screws.*

Occipital Fixation Implant Features *continued*

Occipitocervical Pre-curved Rods

- Pre-contoured to match anatomy of the occipitocervical junction
- Available in 3.2mm/3.6mm or 3.5mm diameters
- Available in 100mm and 200mm lengths

Occipitocervical Plate/Rods

- Pre-contoured to match anatomy of the occipitocervical junction
- Available in 3.5mm diameters
- Available in 100mm and 200mm lengths

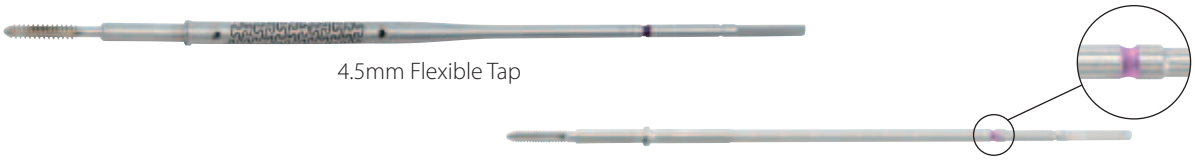
Instrument Set

Drill Bits

3.2mm Flexible Drill Bit

3.2mm Straight Drill Bit

Taps



4.5mm Flexible Tap

4.5mm Straight Tap

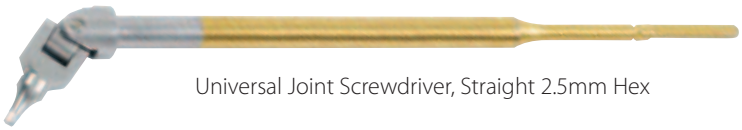
5.0mm Flexible Tap

5.0mm Straight Tap

Screwdrivers

Flexible Screwdriver, Self Holding, 2.5mm Hex

Right Angle Screwdriver, Straight 2.5mm Hex



Universal Joint Screwdriver, Straight 2.5mm Hex

Instrument Set *continued*

Drill-Tap (DT) Screw Guides

Fixed Occipital DT Guide, 6mm/8mm

Fixed Occipital DT Guide, 10mm/12mm

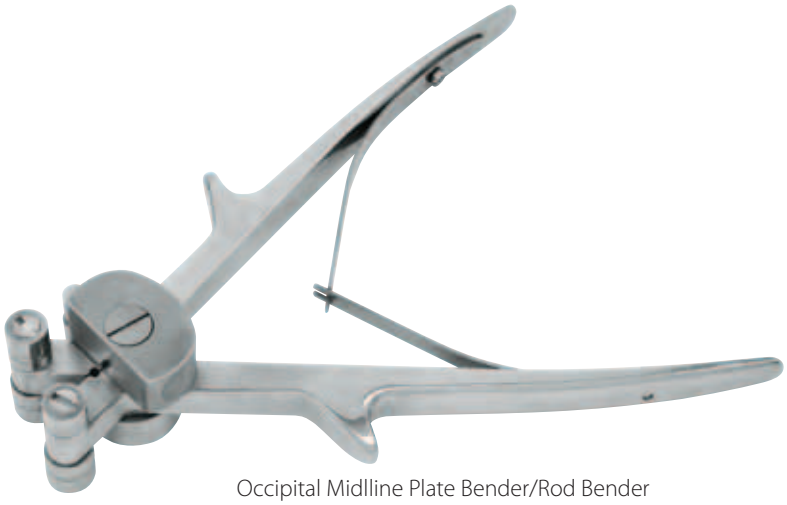
Fixed Occipital DT Guide, 14mm/16mm

18mm Fixed Occipital DT Guide/Screwdriver Guide

Occipital Midline Plate and Rod Benders

Bending Iron, Right

Bending Iron, Left



Occipital Midlline Plate Bender/Rod Bender

Note

The surgical techniques described in this document also include the use of instruments from the VERTEX SELECT™ Reconstruction instrument set. If an instrument does not appear on page 31 or 32 of this document, it can be found in that instrument set.

VERTEX SELECT™

Reconstruction System Occipitocervical Module

USING THE OCCIPITAL SCREW CONNECTORS AND OCCIPITAL ADJUSTABLE RODS

Rod Placement

For occipitocervical stabilization using the Occipital Screw Connectors, first select and insert the cervical laminar hooks at the desired levels of fixation. Once the laminar hooks are in place, use the Rod Holder to position the Occipital Adjustable Rods to determine the necessary adjustments required to align the rods with the laminar hooks and the most preferable occipital screw position **(Figure 47)**. The appropriate location for placement of occipital screws must be determined preoperatively using CT scans or lateral radiographs. Occipital bone thickness varies tremendously, and a clear understanding of the anatomy is required for safe screw placement. Anatomical landmarks should be identified and carefully reviewed to determine the entry points in the thickest bone.

The Occipital Adjustable Rod allows the surgeon to preset the angle of the rod to best accommodate the anatomy and minimize the need for bending. To adjust the angle of the rod, use the Straight Hex Screwdriver to loosen the internal set screw located on the hinge. Adjust the angle as necessary and tighten the internal set screw to secure the rod in a locked position **(Figure 48)**.

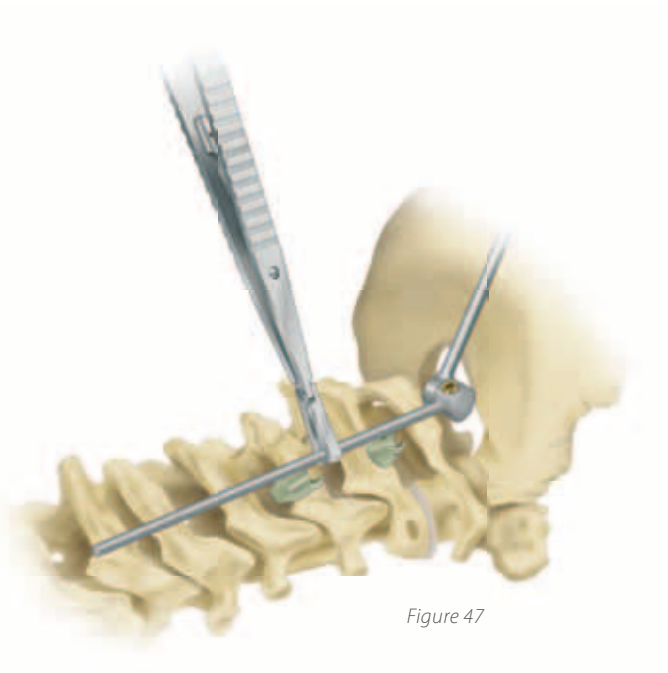


Figure 47

Figure 48

The VERTEX SELECT™ Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter; therefore, the occipital components between the two systems are not compatible and must not be used interchangeably.

Rod Contouring

Use the Rod Bender to contour the Occipital Adjustable Rod to best fit the individual patient anatomy **(Figure 49)**. If additional contouring is needed to increase or decrease the bend in the rod, the Left and Right Bending Irons may be used.

Once the angle and position of the Occipital Adjustable Rod have been determined, cut both ends of the rod to the required lengths using the Ratcheting Rod Cutter **(Figure 50)**.

Figure 49

Figure 50

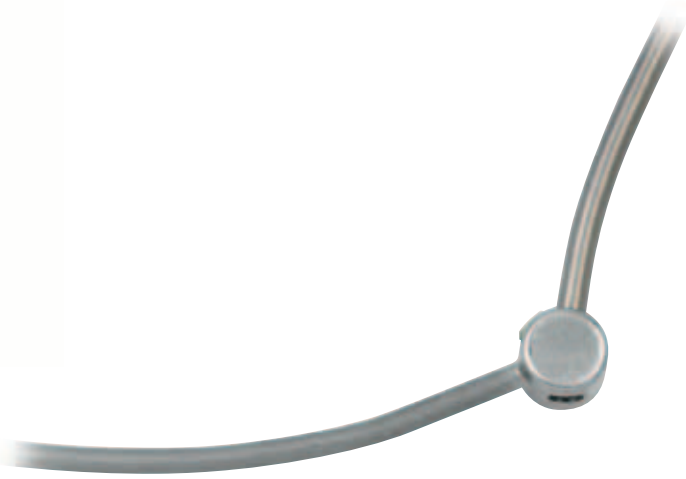


Figure 51

Note

Avoid repeated bending motions to the implants, as excessive bending will decrease the integrity of the implant (Figure 51).

The VERTEX SELECT™ Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter; therefore, the occipital components between the two systems are not compatible and must not be used interchangeably.

Screw Connector Placement

Once all of the laminar hooks have been placed and the Occipital Adjustable Rods have been adjusted and contoured to match the patient's anatomy, place three Occipital Screw Connectors on each rod, for a total of six screw fixation points, and provisionally tighten on the rod by tightening the internal gold set screw with the Straight Hex Screwdriver **(Figure 52)**. Generally, the thickest bone in the suboccipital region is the occipital keel (internal occipital protuberance), near the midline. This should be taken into consideration when determining the position of the Occipital Screw Connectors on the rods. The open portion of the connectors should be positioned medially on the rods (i.e., between the rods) so that midline fixation is achieved with the Occipital Bone Screws. Occipital Screw Connectors with longer offsets are available if additional length is needed to maximize screw purchase in the midline.

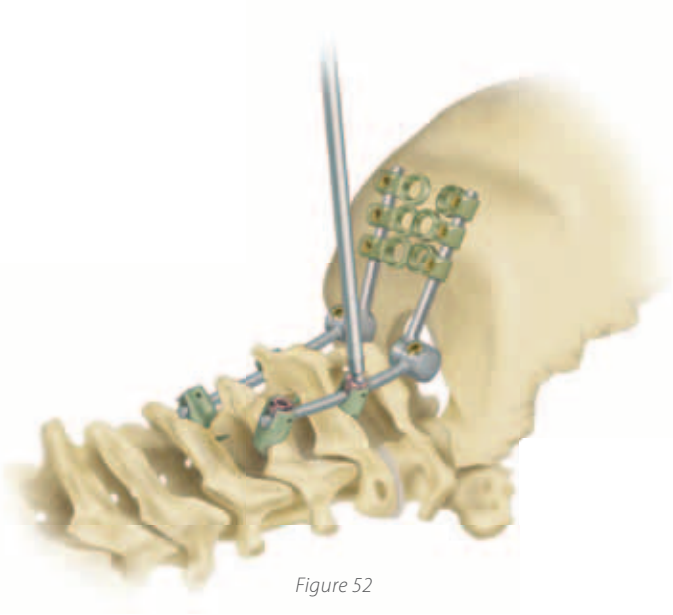


Figure 52

Once the screw connectors have been provisionally placed on the Occipital Adjustable Rods in the desired position, place the rods in the laminar hooks and provisionally tighten the set screws in each hook to stabilize the rods **(Figure 53)**.

The Occipital Screw Connectors can be adjusted on the rod in the cephalad/caudal directions, as well as in the AP plane. This dorsal height adjustment capability will help accommodate uneven bone surfaces and facilitate positioning of the connectors so they lie flush with the bone.

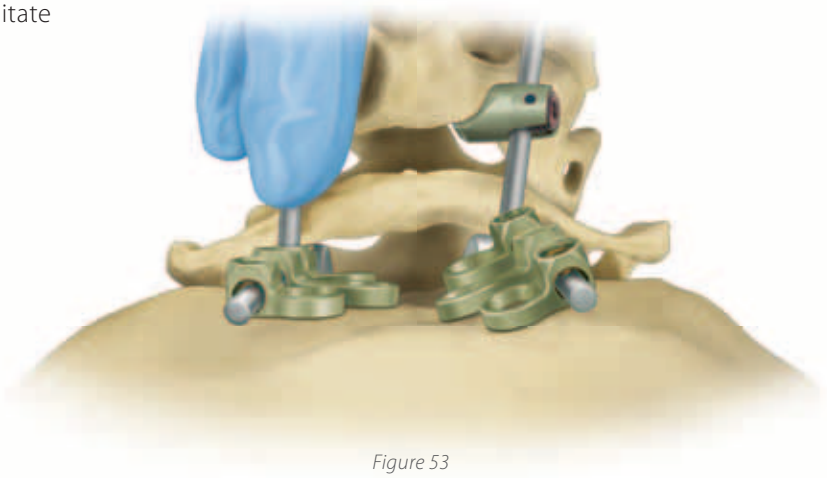


Figure 53

The VERTEX SELECT™ Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter; therefore, the occipital components between the two systems are not compatible and must not be used interchangeably.

Occipital Screw Hole Preparation

For occipital fixation, 4.5mm (6mm to 18mm lengths) and 5.0mm (6mm to 18mm lengths) diameter Occipital Bone Screws are available. Select the appropriate drill bit and tap that match the desired screw diameter for occipital fixation (see the Color-Coding Reference Chart below).

Occipital Bone Screws—Color-Coding Reference

Screw Size	Color	Drill Bit	Tap
4.5mm × 6mm to 18mm	Magenta	3.2mm (Straight Shaft or Flexible Shaft)	4.5mm (Straight Shaft or Flexible Shaft)
5.0mm × 6mm to 18mm	Bronze	3.2mm (Straight Shaft or Flexible Shaft)	5.0mm (Straight Shaft or Flexible Shaft)

The occipital drill bits and taps are available in both straight and flexible shaft designs, based on surgeon preference and anatomical requirements. The straight shaft instruments transfer the energy more efficiently than the flexible shaft instruments, and should be considered the primary instrument choice. The flexible shaft instruments are reserved for use in cases where screw trajectories are difficult to achieve with the straight shaft instruments. For demonstration purposes, the following illustrations depict use of the flexible shaft instruments.

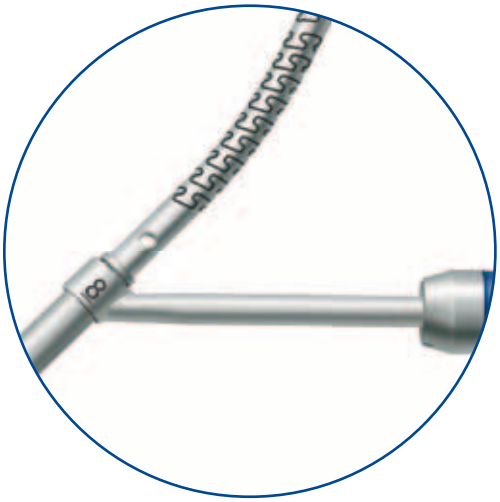


Figure 54

Drilling

Select the appropriate Drill-Tap (DT) Guide based on the desired drilling depth. The DT Guides are available with fixed drilling depths from 6mm to 18mm in 2mm increments. Both the straight and flexible drill bits must be used in conjunction with the DT Guide to achieve a fixed drilling depth **(Figure 54)**. When the flexible drill bit is used, the DT Guide will help stabilize the flexible shaft and direct the drill bit in the proper position. Using the DT Guide to align the drill hole in the Occipital Screw Connector, insert the flexible drill bit through the DT Guide, and drill to the desired depth **(Figure 55)**. Drilling must be done through the Occipital Screw Connectors to ensure proper drilling depth.

Figure 55

The VERTEX SELECT™ Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter; therefore, the occipital components between the two systems are not compatible and must not be used interchangeably.

Occipital Screw Hole Preparation *continued*

Screw Measurement

The Depth Gauge should be used to verify the hole depth as well as the occipital bone thickness **(Figure 56)**.

Figure 56

Tapping

Once a satisfactory depth has been achieved, the appropriate straight or flexible tap can be used to prepare the screw hole. Select the appropriate DT Guide based on the desired tapping depth. Both the straight and flexible taps must be used in conjunction with the DT Guide to achieve a fixed tapping depth. When the Flexible Tap is used, the DT Guide will also prevent excessive motion of the flexible shaft and help direct the tap in the proper position. Insert the Flexible Tap attached to the Universal Handle through the DT Guide and tap to the desired depth **(Figure 57)**. The occipital bone is very dense, and each hole should be completely tapped.

Figure 57

The VERTEX SELECT™ Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter; therefore, the occipital components between the two systems are not compatible and must not be used interchangeably.

Occipital Bone Screw Insertion

Choose the appropriate diameter and length screw for each screw location, and verify the diameter and length before placement.

Use the 2.5mm Self-Holding Screwdriver to engage the bone screw, insert it into the occipital bone, and provisionally tighten. If the patient's anatomical position requires use of the flexible instruments, the 2.5mm Self-Holding Flexible Screwdriver may be used for screw insertion **(Figure 58)**.

Note

To prevent excessive motion of the flexible shaft and to direct the screwdriver in the proper position, the Flexible Screwdriver must be used in conjunction with the DT Guide, located on the opposite end of the 18mm guide.

The remaining screws can be placed using the same technique. Once all of the screws have been placed, use the 2.5mm Straight Hex Screwdriver to hand tighten the screws in their final position. If the patient's anatomical position requires use of the flexible instruments, the Universal Joint Screwdriver or the Right Angled Screwdriver may be used for final tightening **(Figure 59)**.

Figure 58

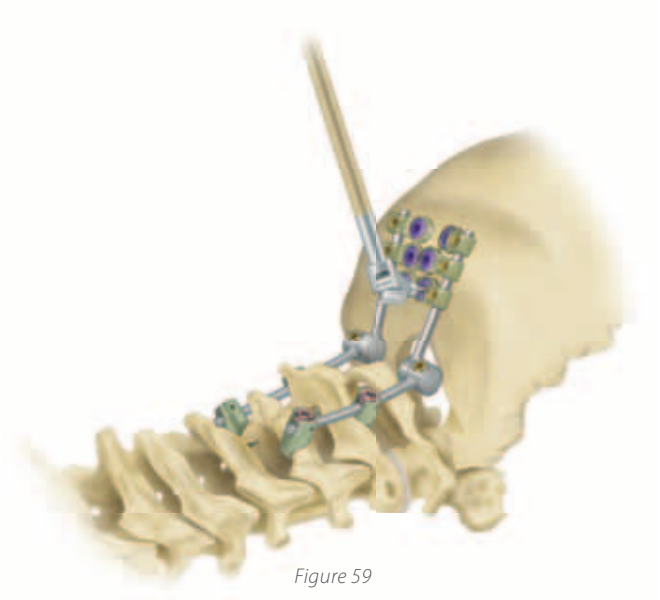


Figure 59

The VERTEX SELECT™ Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter; therefore, the occipital components between the two systems are not compatible and must not be used interchangeably.

Final Tightening of Construct

Once all of the Occipital Bone Screws have been final tightened, all set screws in the laminar hooks should be final tightened using the Straight Hex Torque Driver and Torque Limiting Handle in conjunction with the Rod Pusher/Counter Torque **(Figure 60)**.

Securely tighten the Occipital Screw Connectors on the rod using the Straight Hex Screwdriver **(Figure 61)**.

Figure 60

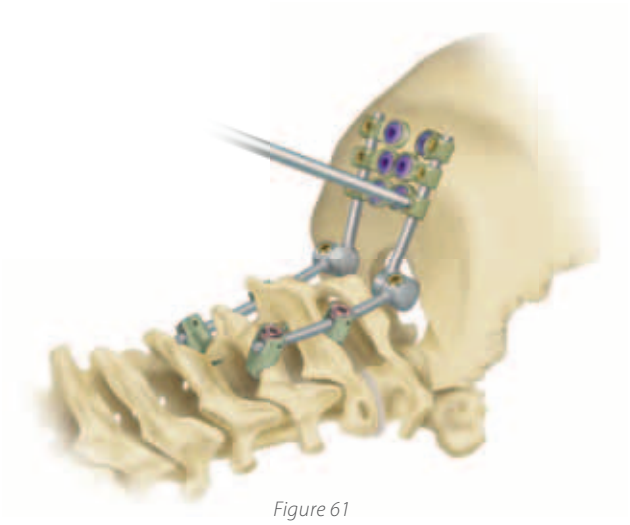


Figure 61

The VERTEX SELECT™ Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter; therefore, the occipital components between the two systems are not compatible and must not be used interchangeably.

Final Construct

Recheck all connections of the final construct prior to wound closure **(Figure 62)**.

Figure 62

The VERTEX SELECT™ Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter; therefore, the occipital components between the two systems are not compatible and must not be used interchangeably.

Explantation

To remove any of the VERTEX SELECT™ Reconstruction System implants described throughout this technique, engage the set screw and the occipital bone screw with a 2.5mm Hex Straight Screwdriver and turn counterclockwise until the set screw is disengaged from the implant, and the bone screw until it is disengaged from the bone. The implants can then be freely removed from the bone.

The VERTEX SELECT™ Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter; therefore, the occipital components between the two systems are not compatible and must not be used interchangeably.

VERTEX SELECT™

Reconstruction System Occipitocervical (OC) Module

USING THE OCCIPITAL MIDLINE
PLATES AND OCCIPITAL
ADJUSTABLE RODS

Occipital Midline Plate Placement

In general, the thickest bone in the suboccipital region is the occipital keel (internal occipital protuberance), near the midline. When positioning the Occipital Midline Plate, it should be centered in the midline between the External Occipital Protuberance (EOP) and the posterior border of the foramen magnum **(Figure 63)**.

There are three midline plate designs available in the Occipitocervical (OC) Module set. Any geometry of plate may be used. The following illustrations depict the use of the Adjustable Occipitocervical (OC) Plate.

The goal is to maximize bone purchase (closer to External Occipital Protuberance [EOP]) while achieving a low profile. The geometry of the Adjustable Occipitocervical (OC) Plate and the "M"-shaped plate are designed to maximize bone graft placement in the midline.

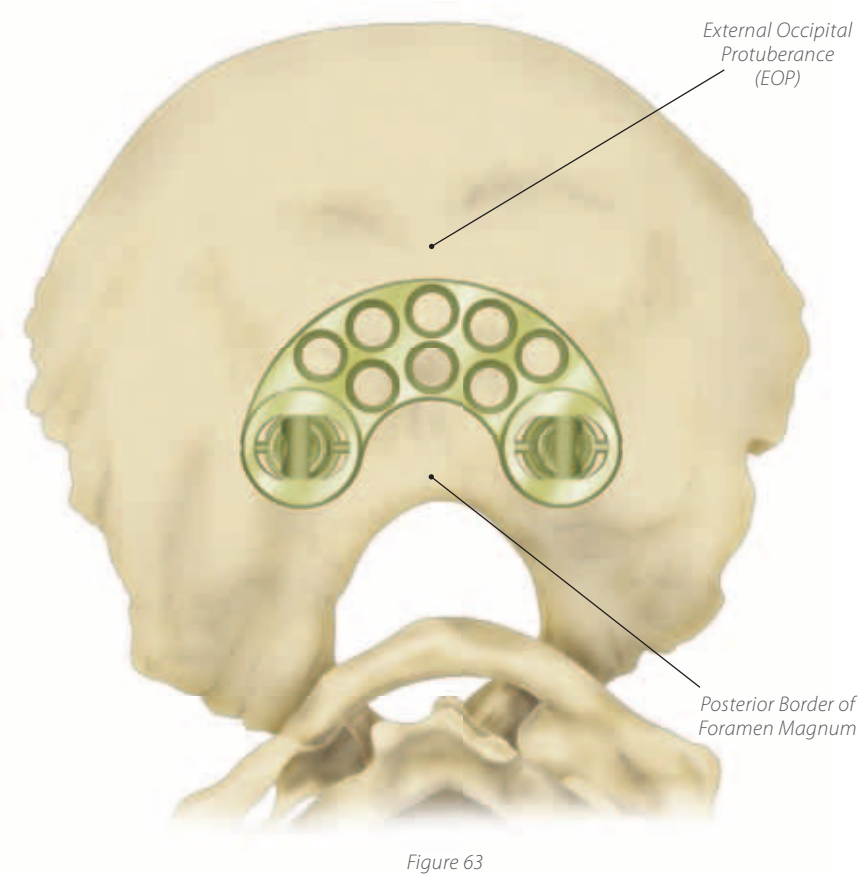


Figure 63

The VERTEX SELECT™ Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter; therefore, the occipital components between the two systems are not compatible and must not be used interchangeably.

Occipital Midline Plate Placement *continued*

Once all of the laminar hooks have been placed, position the Occipital Adjustable Rod in the laminar hooks to determine the proper plate size, as well as any adjustments to align the rod properly **(Figure 64)**. Instructions for use of the Occipital Adjustable Rod are described on page 34.

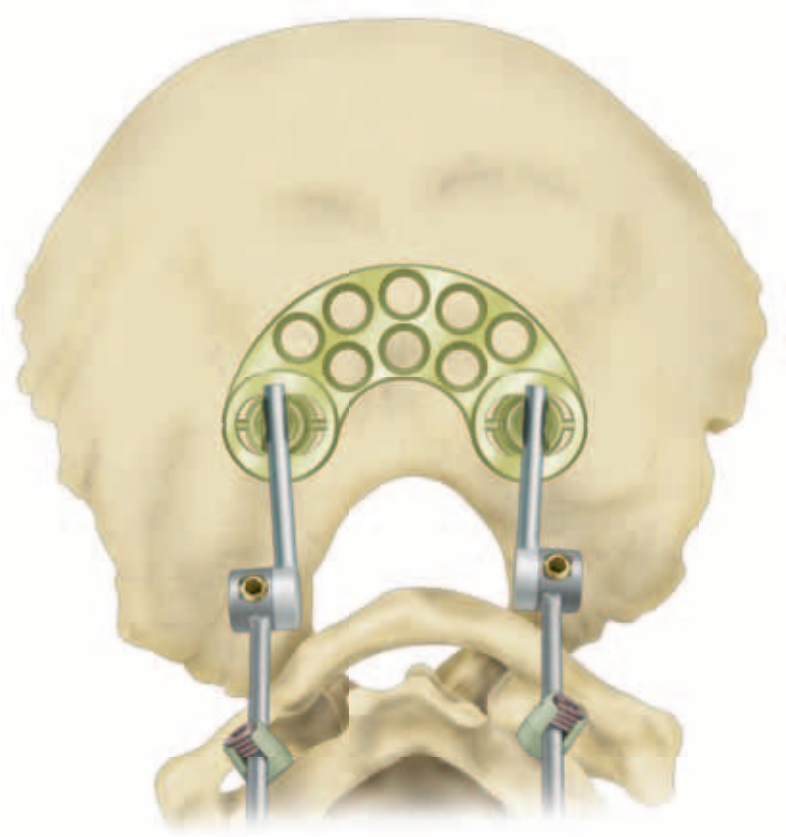


Figure 64

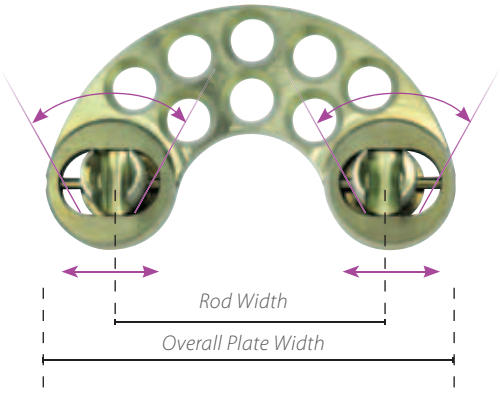


Plate Sizes

Min Rod Width	Max Rod Width	Overall Plate Width
30.3mm	37.7mm	50mm

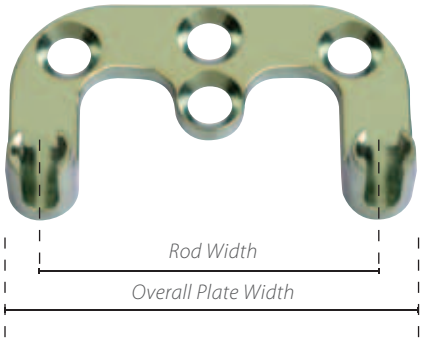


Plate Sizes

Sizes	Rod Width	Overall Width
Small	25.5mm	34mm
Medium	31.5mm	40mm
Large	39.5mm	48mm

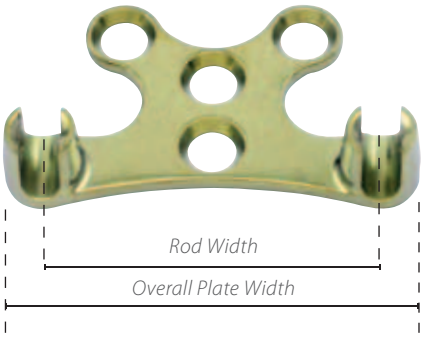


Plate Sizes

Sizes	Rod Width	Overall Width
Small	24mm	32.6mm
Medium	36mm	44.6mm
Large	40mm	48.6mm

The VERTEX SELECT™ Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter; therefore, the occipital components between the two systems are not compatible and must not be used interchangeably.

Occipital Midline Plate Contouring

If necessary, the plate can be contoured using the Occipital Plate Bender for a more anatomic fit against the occiput **(Figure 65)**. The Left and Right Bending Irons may also be used as additional tools to contour the plate **(Figure 66)**. Repeated bending should be avoided, as it may compromise the integrity of the implant. It may be necessary to contour a small portion of uneven occipital bone with a high-speed drill to allow the plate to lie flush.

Note

Avoid repeated bending motions to the implants, as excessive bending will decrease the integrity of the implant.

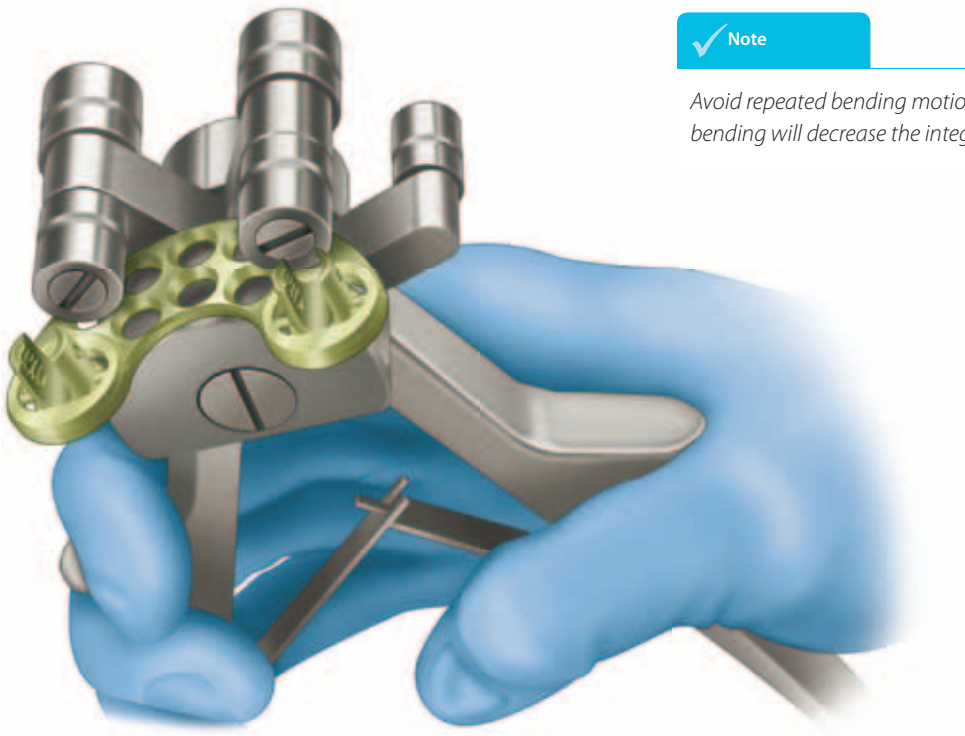


Figure 65

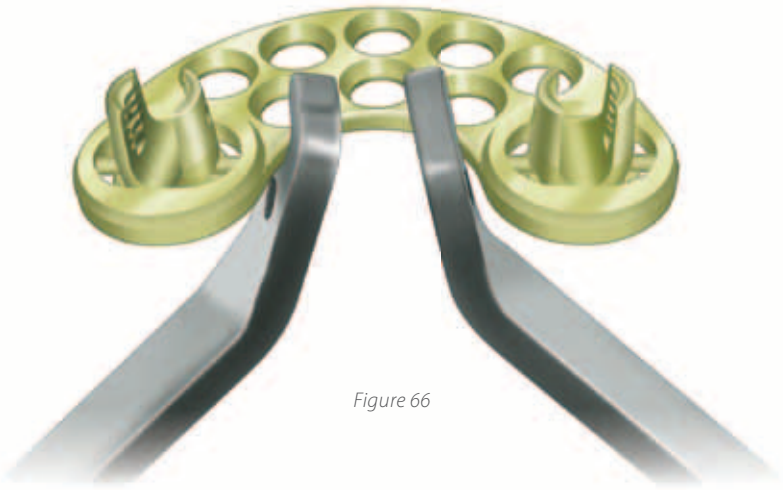


Figure 66

The VERTEX SELECT™ Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter; therefore, the occipital components between the two systems are not compatible and must not be used interchangeably.

Occipital Screw Hole Preparation

For occipital fixation, 4.5mm (6mm to 18mm lengths) and 5.0mm (6mm to 18mm lengths) diameter Occipital Bone Screws are available. Select the appropriate drill bit and tap that match the desired screw diameter for occipital fixation (see the Color-Coding Reference Chart below).

Occipital Bone Screws—Color-Coding Reference

Screw Size	Color	Drill Bit	Tap
4.5mm × 6mm to 18mm	Magenta	3.2mm (Straight Shaft or Flexible Shaft)	4.5mm (Straight Shaft or Flexible Shaft)
5.0mm × 6mm to 18mm	Bronze	3.2mm (Straight Shaft or Flexible Shaft)	5.0mm (Straight Shaft or Flexible Shaft)

The occipital drill bits and taps are available in both straight and flexible shaft designs, based on surgeon preference and anatomical requirements. The straight shaft instruments transfer the energy more efficiently than the flexible shaft instruments, and should be considered the primary instrument choice. The flexible shaft instruments are reserved for use in cases where screw trajectories are difficult to achieve with the straight shaft instruments. For demonstration purposes, the following illustrations depict use of the flexible shaft instruments.

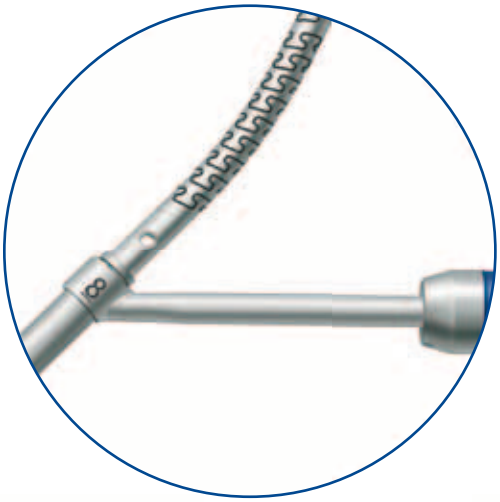


Figure 67

Drilling

Select the appropriate Drill-Tap (DT) Guide based on the desired drilling depth. The DT Guides are available with fixed drilling depths from 6mm to 18mm in 2mm increments. Both the straight and flexible drill bits must be used in conjunction with the DT Guide to achieve a fixed drilling depth **(Figure 67)**. When the flexible drill bit is used, the DT Guide will help stabilize the flexible shaft and direct the drill bit in the proper position. Using the DT Guide to align the drill hole in the Occipital Midline Plate, insert the flexible drill bit through the DT Guide, and drill to the desired depth **(Figure 68)**. Drilling must be done through the Occipital Midline Plate to ensure proper drilling depth.

Figure 68

The VERTEX SELECT™ Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter; therefore, the occipital components between the two systems are not compatible and must not be used interchangeably.

Occcipital Screw Hole Preparation *continued*

Screw Measurement

The Depth Gauge should be used to verify the hole depth as well as the occipital bone thickness **(Figure 69)**.

Figure 69

Tapping

Once a satisfactory depth has been achieved, the appropriate Flexible Tap can be used to prepare the screw hole. Select the appropriate DT Guide based on the desired tapping depth. Both the straight and flexible taps must be used in conjunction with the DT Guide to achieve a fixed tapping depth. When the Flexible Tap is used, the DT Guide will also prevent excessive motion of the flexible shaft and help direct the tap in the proper position. Insert the Flexible Tap attached to the Universal Handle through the DT Guide and tap to the desired depth **(Figure 70)**. The occipital bone is very dense, and each hole should be completely tapped.

Figure 70

The VERTEX SELECT™ Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter; therefore, the occipital components between the two systems are not compatible and must not be used interchangeably.

Occipital Bone Screw Insertion

Choose the appropriate diameter and length screw for each screw location, and verify the diameter and length before placement.

Note

For the Adjustable Occipitocervical (OC) Plate, place at least four screws.

Use the 2.5mm Self-Holding Screwdriver to engage the bone screw, insert it into the occipital bone, and provisionally tighten. If the patient's anatomical position requires use of the flexible instruments, the 2.5mm Self-Holding Flexible Screwdriver may be used for screw insertion **(Figure 71)**.

Note

When the flexible screwdriver is used the DT Guide will help stabilize the flexible shaft and direct the screwdriver.

The remaining screws can be placed using the same technique. Once all of the screws have been placed, use the 2.5mm Straight Hex Screwdriver to hand tighten the screws in their final position. If the patient's anatomical position requires use of the flexible instruments, the Universal Joint Screwdriver or the Right Angled Screwdriver may be used for final tightening **(Figure 72)**.

Figure 71

Figure 72

The VERTEX SELECT™ Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter; therefore, the occipital components between the two systems are not compatible and must not be used interchangeably.

Final Tightening of Construct

Once all of the Occipital Bone Screws have been final tightened and the rods have been adjusted to match the patient's anatomy and placed into the laminar hooks and saddles of the Occipital Midline Plate, use the 2.5mm Self-Holding Screwdriver to provisionally tighten the set screws in the saddles of the Occipital Midline Plate to stabilize the rod. If the patient's anatomical position requires use of the flexible instruments, the 2.5mm Self-Holding Flexible Screwdriver may be used to insert the set screw. Use the 2.5mm Self-Holding Screwdriver to provisionally tighten the set screws in the laminar hooks.

Once all of the set screws have been placed and the rods are secured in the implants, use the Straight Hex Screwdriver and the Torque-Limiting Handle in conjunction with the Rod Pusher/Counter Torque **(Figure 73)** to final tighten the set screws in the saddles of the plate. If the patient's anatomical position requires use of the flexible instruments, the Universal Joint Screwdriver or the Right Angled Screwdriver may be used for final tightening of the set screws **(Figure 74)**. Set screws in the laminar hooks should also be final tightened using the Straight Hex Torque Driver and Torque-Limiting Handle in conjunction with the Rod Pusher/Counter Torque.

Recheck all connections of the final construct prior to wound closure.

Figure 73

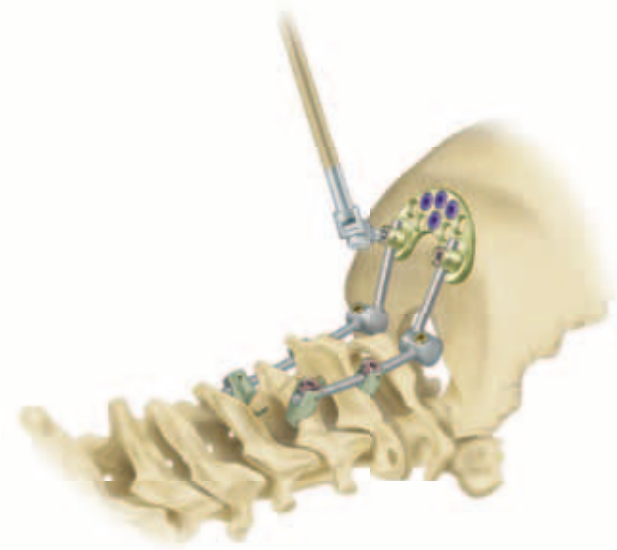
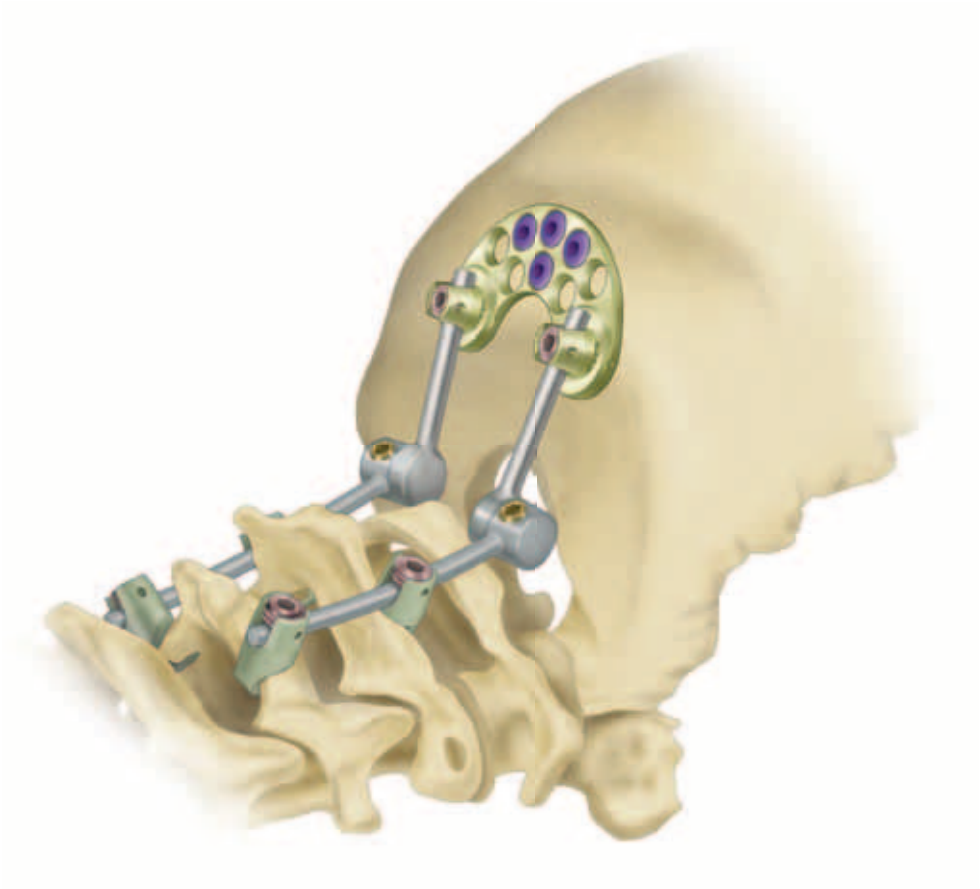


Figure 74

The VERTEX SELECT™ Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter; therefore, the occipital components between the two systems are not compatible and must not be used interchangeably.

Explantation

To remove any of the VERTEX SELECT™ Reconstruction System implants described throughout this technique, engage the set screw and the occipital bone screw with a 2.5mm Straight Hex Screwdriver and turn counterclockwise until the set screw is disengaged from the implant, and the bone screw until it is disengaged from the bone. The implants can then be freely removed from the bone.



The VERTEX SELECT™ Reconstruction System and the VERTEX MAX® Reconstruction System occipital implants and instruments are different in profile and diameter; therefore, the occipital components between the two systems are not compatible and must not be used interchangeably.

Set Configuration

Multi-Axial Screw

Multi-Axial Screws

Part Number	Description	Qty In Standard Set	Loose Goods
6958710	3.5mm × 10mm MAS	6	
6958712	3.5mm × 12mm MAS	10	
6958714	3.5mm × 14mm MAS	14	
6958716	3.5mm × 16mm MAS	8	
6958718	3.5mm × 18mm MAS	6	
6958720	3.5mm × 20mm MAS	4	
6958722	3.5mm × 22mm MAS	2	
6958724	3.5mm × 24mm MAS	2	
6958726	3.5mm × 26mm MAS	2	
6958728	3.5mm × 28mm MAS	2	
6958730	3.5mm × 30mm MAS	2	
6958732	3.5mm × 32mm MAS	2	
6958734	3.5mm × 34mm MAS	2	
6958736	3.5mm × 36mm MAS	0	×
6958738	3.5mm × 38mm MAS	0	×
6958740	3.5mm × 40mm MAS	0	×
6958810	4.0mm × 10mm MAS	2	
6958812	4.0mm × 12mm MAS	4	
6958814	4.0mm × 14mm MAS	6	
6958816	4.0mm × 16mm MAS	4	
6958818	4.0mm × 18mm MAS	2	
6958820	4.0mm × 20mm MAS	2	
6958822	4.0mm × 22mm MAS	2	
6958824	4.0mm × 24mm MAS	2	
6958826	4.0mm × 26mm MAS	2	
6958828	4.0mm × 28mm MAS	2	
6958830	4.0mm × 30mm MAS	2	
6958832	4.0mm × 32mm MAS	2	
6958834	4.0mm × 34mm MAS	2	
6958836	4.0mm × 36mm MAS	0	×
6958838	4.0mm × 38mm MAS	0	×
6958840	4.0mm × 40mm MAS	0	×
6958842	4.0mm × 42mm MAS	0	×
6958844	4.0mm × 44mm MAS	0	×
6958846	4.0mm × 46mm MAS	0	×
6958848	4.0mm × 48mm MAS	0	×
6958850	4.0mm × 50mm MAS	0	×
6958852	4.0mm × 52mm MAS	0	×
6958910	4.5mm × 10mm MAS	0	×
6958912	4.5mm × 12mm MAS	0	×
6958914	4.5mm × 14mm MAS	0	×
6958916	4.5mm × 16mm MAS	0	×
6958918	4.5mm × 18mm MAS	0	×
6958920	4.5mm × 20mm MAS	0	×
6958922	4.5mm × 22mm MAS	0	×
6958924	4.5mm × 24mm MAS	2	
6958926	4.5mm × 26mm MAS	2	
6958928	4.5mm × 28mm MAS	2	

Set Configuration *continued*

Partially Threaded
Multi-Axial Screw

Multi-Axial Screws *continued*

Part Number	Description	Qty In Standard Set	Loose Goods
6958930	4.5mm × 30mm MAS	2	
6958932	4.5mm × 32mm MAS	2	
6958934	4.5mm × 34mm MAS	2	
6958936	4.5mm X 36mm MAS	0	×
6958938	4.5mm × 38mm MAS	0	×
6958940	4.5mm × 40mm MAS	0	×
6958942	4.5mm × 42mm MAS	0	×
6958944	4.5mm × 44mm MAS	0	×
6958946	4.5mm × 46mm MAS	0	×
6958948	4.5mm × 48mm MAS	0	×
6958950	4.5mm × 50mm MAS	0	×
6958952	4.5mm × 52mm MAS	0	×
6958718PT	3.5mm × 18mm PT MAS	0	×
6958720PT	3.5mm × 20mm PT MAS	0	×
6958722PT	3.5mm × 22mm PT MAS	0	×
6958724PT	3.5mm × 24mm PT MAS	2	
6958726PT	3.5mm × 26mm PT MAS	2	
6958728PT	3.5mm × 28mm PT MAS	2	
6958730PT	3.5mm × 30mm PT MAS	2	
6958732PT	3.5mm × 32mm PT MAS	2	
6958734PT	3.5mm × 34mm PT MAS	2	
6958736PT	3.5mm × 36mm PT MAS	0	×
6958738PT	3.5mm × 38mm PT MAS	0	×
6958740PT	3.5mm × 40mm PT MAS	0	×
6958818PT	4.0mm × 18mm PT MAS	0	×
6958820PT	4.0mm × 20mm PT MAS	0	×
6958822PT	4.0mm × 22mm PT MAS	0	×
6958824PT	4.0mm × 24mm PT MAS	2	
6958826PT	4.0mm × 26mm PT MAS	2	
6958828PT	4.0mm × 28mm PT MAS	2	
6958830PT	4.0mm × 30mm PT MAS	2	
6958832PT	4.0mm × 32mm PT MAS	2	
6958834PT	4.0mm × 34mm PT MAS	2	
6958836PT	4.0mm × 36mm PT MAS	0	×
6958838PT	4.0mm × 38mm PT MAS	0	×
6958840PT	4.0mm × 40mm PT MAS	0	×

Laminar Hook

Offset
Laminar Hook

Hooks

Part Number	Description	Qty In Standard Set	Loose Goods
7756073	4.5mm Laminar Hook	2	
7756074	6.0mm Laminar Hook	2	
7756073R	4.5mm Offset Laminar Hook, Right	2	
7756073L	4.5mm Offset Laminar Hook, Left	2	
7756074R	6.0mm Offset Laminar Hook, Right	2	
7756074L	6.0mm Offset Laminar Hook, Left	2	

Set Configuration *continued*

Set Screws

Rods

MAS CROSSLINK® Connector

MAS/Rod CROSSLINK® Connector Clip

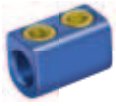
Open-End Lateral Connector

Rod CROSSLINK® Connector

Cable Connector

MAS Extension Connector

Offset Domino



Axial Domino

Set Screws

Part Number	Description	Qty In Standard Set	Loose Goods
6950315	Set Screw	26	
7753500	MAS Connector Set Screw	8	
7752529	MAS CROSSLINK®/MAS Extension Connector Locking Screw	8	

Rods

Part Number	Description	Qty In Standard Set	Loose Goods
7750010	3.5mm × 120mm Titanium Rod	0	×
6900240	3.2mm × 240mm Titanium Rod	3	
7750015	3.5mm × 240mm Titanium Rod	3	
7750020	3.5mm × 300mm Titanium Rod	0	×
6955240	3.2mm × 240mm Threaded Rod	3	
7755240	3.5mm × 240mm Threaded Rod	3	
7755245	4.5mm × 360mm Threaded Rod	3	
7755247	5.5mm × 360mm Threaded Rod	3	

Rod Connectors

Part Number	Description	Qty In Standard Set	Loose Goods
7756064	Open-End Lateral Connector, 10mm	4	
7756066	Open-End Lateral Connector, 13mm	4	
7756067	Closed-End Lateral Connector, 10mm	4	
7756068	Closed-End Lateral Connector, 13mm	4	
7751110	Cable Connector	4	
7752525	MAS CROSSLINK® Connector, S	1	
7752526	MAS CROSSLINK® Connector, M	1	
7752527	MAS CROSSLINK® Connector, L	1	
7752528	MAS/Rod CROSSLINK® Connector Clip	2	
7752535	Rod CROSSLINK® Connector, S	1	
7752536	Rod CROSSLINK® Connector, M	1	
7752537	Rod CROSSLINK® Connector, L	1	

Transition Connectors

Part Number	Description	Qty In Standard Set	Loose Goods
7756069	MAS Extension Connector, 3.2mm/3.5mm	3	
7756071	MAS Extension Connector, 4.5mm	3	
7756072	MAS Extension Connector, 5.5mm	3	
7750443	Offset Domino, 3.2mm/3.5mm to 3.2mm/3.5mm	3	
7750444	Offset Domino, 3.2mm/3.5mm to 4.5mm	3	
7750445	Offset Domino, 3.2mm/3.5mm to 5.5mm	3	
7750346	Axial Domino, 3.2mm/3.5mm to 3.2mm/3.5mm	3	
7750347	Axial Domino, 3.2mm/3.5mm to 4.5mm	3	
7750348	Axial Domino, 3.2mm/3.5mm to 5.5mm	3	

Set Configuration *continued*

Sterile Drill Bits

Part Number	Description	Qty In Standard Set	Loose Goods
6956011	2.9mm Sterile Drill Bit	1	
7756010	2.4mm Sterile Drill Bit	1	

Instruments

Part Number	Description	Qty In Standard Set	Loose Goods
6956016	Universal Handle	3	
7756005	Adjustable Drill Guide	1	
6956006	14mm Drill Guide	1	
7756035	3.5mm Tap	1	
7756040	4.0mm Tap	1	
7756045	4.5mm Tap	1	
6956030	Tap Sleeve	1	
6956193	Screwdriver Shaft, Straight Hex	1	
7756203	CROSSLINK® Lock Nut Driver	1	
7756195	Threaded Screwdriver, 2.5mm Hex	1	
6956001	Awl Shaft	1	
6956003	Pedicle Probe	1	
8572102	Pedicle Feeler	1	
6956020	Depth Gauge	1	
6956148	Bone Reamer	1	
6956158	Laminar Elevator	1	
7756160	Hook Holder/Inserter	1	
7756170	Rod Pusher Counter Torque, Straight, MAS	1	
7756200	Torque Limiting Handle, T-Handle	1	
6956200R	Torque Limiting Handle, Straight Handle	1	
6956201	Straight Hex Torque Shaft, 2.5mm	2	
7756205	CROSSLINK® Swizzle Stick	1	
7756165	Screwdriver Shaft, Self Holding External Hex, 4.0mm	1	
7756202	Straight Hex Torque Shaft, External, 4.0mm	1	
7756154	Universal Rachet Handle	2	
6959993	Quick Release Self Holding Screwdriver	2	
6956163	Rod Gripper	1	
6956164	Rod Holder	1	
6905784	Insitu Rod Cutter	1	
7756167	Rod Rocker	1	
6956175	Rod Reducer	1	
7756290	Bending Iron, Left	1	
7756291	Bending Iron, Right	1	
7756197	Coronal Bender, Left	1	
7756198	Coronal Bender, Right	1	
6905787	Compression Forceps	1	
6905788	Distractor Forceps	1	
6900241	Rod Template	1	
6905785	Alignment Tool	1	
6956165	Rachet Rod Cutter	1	
6905782	Rod Bender	1	

Set Configuration *continued*

Adjustable OC Plate

Occipital Midline Plates

Occipital Screw Connectors

Occipitocervical Adjustable Rods

Occipitocervical Pre-Curved Rod

Occipital Plate/Rod

Occipitocervical Module

Occipital Midline Plates

Part Number	Description	Qty In Standard Set	Loose Goods
7755278	Adjustable OC Plate	2	
7759970	Occipitocervical Midline Plate, S	1	
7759971	Occipitocervical Midline Plate, M	1	
7759972	Occipitocervical Midline Plate, L	1	
6959970	Occipital Midline Keel Plate, S	1	
6959971	Occipital Midline Keel Plate, M	1	
6959972	Occipital Midline Keel Plate, L	1	

Occipital Screw Connectors

Part Number	Description	Qty In Standard Set	Loose Goods
7755325	Occipital Screw Connector	8	
7755327	Occipital Screw Connector, Offset	4	

Occipitocervical Rods

Part Number	Description	Qty In Standard Set	Loose Goods
7755122	3.2mm/3.5mm × 120mm Occipitocervical Adjustable Rod		×
7755123	3.2mm/3.5mm × 220mm Occipitocervical Adjustable Rod	3	
7755120	3.5mm × 120mm Occipitocervical Adjustable Rod		×
7755124	3.5mm × 220mm Occipitocervical Adjustable Rod		×
6955270	3.2mm × 200mm Pre-Curved Occipitocervical Rod	3	
7755271	3.5mm × 200mm Pre-Curved Occipitocervical Rod		×
7755231	3.5mm × 100mm Occipitocervical Pre-Contoured Plate/Rod		×
7755232	3.5mm × 200mm Occipitocervical Plate/Rod		×

Set Configuration *continued*

Occipital Bone Screws

Occipital Bone Screws

Part Number	Description	Qty In Standard Set	Loose Goods
7750506	4.5mm × 6mm Occipital Bone Screw	6	
7750508	4.5mm × 8mm Occipital Bone Screw	6	
7750510	4.5mm × 10mm Occipital Bone Screw	6	
7750512	4.5mm × 12mm Occipital Bone Screw	6	
7750514	4.5mm × 14mm Occipital Bone Screw	4	
7750516	4.5mm × 16mm Occipital Bone Screw		×
7750518	4.5mm × 18mm Occipital Bone Screw		×
7750606	5.0mm × 6mm Occipital Bone Screw	4	
7750608	5.0mm × 8mm Occipital Bone Screw	4	
7750610	5.0mm × 10mm Occipital Bone Screw	4	
7750612	5.0mm × 12mm Occipital Bone Screw	4	
7750614	5.0mm × 14mm Occipital Bone Screw	2	
7750616	5.0mm × 16mm Occipital Bone Screw		×
7750618	5.0mm × 18mm Occipital Bone Screw		×

Occipitocervical Instruments

Part Number	Description	Qty In Standard Set	Loose Goods
7756334	4.5mm Occipital Tap	1	
7756383	4.5mm Occipital Flexible Tap	1	
7756337	5.0mm Occipital Tap	1	
7756384	5.0mm Occipital Flexible Tap	1	
7759978	Fixed Occipital DT Guide, 6mm/8mm	1	
7759979	Fixed Occipital DT Guide, 10mm/12mm	1	
7759980	Fixed Occipital DT Guide, 14mm/16mm	1	
7759982	Fixed Occipital DT Guide, 18mm Screwdriver Guide	1	
7756286	Flexible Screwdriver, Self Holding, 2.5mm Hex	1	
7756187	Universal Joint, Screwdriver, Straight 2.5mm Hex	1	
7756188	Screwdriver, Right Angle 2.5mm Hex	1	
7756290	Bending Iron, Left	1	
7756291	Bending Iron, Right	1	
7756230	Occipital Midline Plate Bender/ Rod Bender	1	

Sterile Drill Bits

Part Number	Description	Qty In Standard Set	Loose Goods
7756131	3.2mm Occipital Drill Bit, Sterile	1	
7756281S	3.2mm Occipitocervical Flexible Drill Bit, Sterile	1	

Important Information on the VERTEX® Reconstruction System

PURPOSE

The VERTEX® Reconstruction System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the occipital, cervical and/or upper thoracic spine.

DESCRIPTION

The VERTEX® Reconstruction System is a posterior system, which consists of a variety of shapes and sizes of plates, rods, hooks, screws, multi-axial screws, and connecting components, which can be rigidly locked to the rod in a variety of configurations, with each construct being tailor-made for the individual case. Titanium ATLAS® cable may be used with this system at the surgeon's discretion. See the package inserts of both of those systems for labeling limitations.

The VERTEX® Reconstruction System is fabricated from medical grade titanium, medical grade titanium alloy, and medical grade cobalt chromium. Medical grade titanium, medical grade titanium alloy, and/or medical grade cobalt chromium may be used together. Never use titanium, titanium alloy, and or/cobalt chromium with stainless steel in the same construct. The VERTEX® Reconstruction System includes a retaining ring for the multi-axial screw made of Shape Memory Alloy (Nitinol – NiTi). Shape Memory Alloy is compatible with titanium, titanium alloy, and cobalt chromium implants only. The posted screw connectors and some multi-axial screws contain elastomeric stakes made of silicone adhesive commonly used in implantable medical devices. Do not use with stainless steel. No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MDT Catalog or price list for further information about warranties and limitations of liability.

To achieve best results, do not use any of the VERTEX® Reconstruction System implant components with components from any other system or manufacturer unless specifically labeled to do so in this or another MEDTRONIC document. As with all orthopedic and neurosurgical implants, none of the VERTEX® Reconstruction System components should ever be reused under any circumstances.

INDICATIONS

When intended as an adjunct to fusion of the occipitocervical spine, cervical spine, and the thoracic spine, (Occiput-T3), the VERTEX® Reconstruction System is indicated for skeletally mature patients using allograft and/or autograft for the following:

DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.

Occipitocervical Components: Plate Rod/Plates/Rods/Occipital Screws/Hooks

The occipitocervical plate rods, plates, rods, occipital screws, and hooks are intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the occipitocervical junction and the cervical spine. When used to treat these occipitocervical and cervical conditions, these screws are limited to occipital fixation only. The screws are not intended to be placed in the cervical spine.

Occipitocervical constructs require bilateral fixation to C2 and below.

Note: Segmental fixation is recommended for these constructs.

Hooks and Rods

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Multi-axial Screws/Connectors

The use of multi-axial screws are limited to placement in T1-T3. The screws are not intended to be placed in the cervical spine.

Titanium ATLAS® Cable System to be used with the VERTEX® Reconstruction System allows for cable attachment to the posterior cervical or thoracic spine.

In order to achieve additional levels of fixation, the VERTEX® Reconstruction System may be connected to the CD HORIZON® Spinal System rods with the VERTEX® rod connectors. Refer to the CD HORIZON® Spinal System package insert for a list of the CD HORIZON® Spinal System indications of use.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Active infectious process or significant risk of infection (immunocompromise).
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Grossly distorted anatomy caused by congenital abnormalities.
8. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
9. Suspected or documented metal allergy or intolerance.
10. Any case not needing a bone graft and fusion.
11. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
12. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
13. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
14. Any patient unwilling to follow postoperative instructions.
15. Any case not described in the indications.

NOTA BENE: Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

1. **Severe bone resorption.**
2. **Osteomalacia.**
3. **Severe osteoporosis.**

POTENTIAL ADVERSE EVENTS

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but is not limited to:

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, and/or pain. Bursitis. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
8. Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
9. Neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
10. Urinary retention or loss of bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
12. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsed graft.
13. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
14. Non-union (or pseudarthrosis). Delayed union. Mal-union.
15. Loss of or increase in spinal mobility or function.
16. Inability to perform the activities of daily living.
17. Bone loss or decrease in bone density, possibly caused by stresses shielding.
18. Graft donor site complications including pain, fracture, or wound healing problems.
19. Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
20. Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
21. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
22. Development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
23. Change in mental status.
24. Death.

Note: Additional surgery may be necessary to correct some of these potential adverse events.

WARNINGS AND PRECAUTION

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. This device system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

Warning: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

Precaution: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

!USA **FOR US AUDIENCES ONLY**

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Important Information on the VERTEX® Reconstruction System *continued*

Other preoperative, intraoperative, and postoperative warnings and precautions are as follows:

IMPLANT SELECTION

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

PREOPERATIVE

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or pre-dispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
4. An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The VERTEX® RECONSTRUCTION SYSTEM components (described in the DESCRIPTION section) are not to be combined with the components from another manufacturer. Different metal types should never be used together.
6. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. The rods should not be repeatedly or excessively bent. The rods should not be reverse bent in the same location. Use great care to insure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field. Whenever possible, use pre-cut rods of the length needed.
4. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
5. To insert a screw properly, drill a pilot hole corresponding to selected screw size and prepare screw site with a sharp tap.
6. **Caution:** Do not overtap or use a screw that is either too long or too large. Overtapping or using an incorrectly sized screw may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert.
7. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.
8. Before closing the soft tissues, all of the screws or set screws should be tightened firmly. Recheck the tightness of all screws or set screws after finishing to make sure that none loosened during the tightening of the other screws or set screws. Failure to do so may cause loosening of the other components.

POSTOPERATIVE

The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke tobacco or utilize nicotine products, or to consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin during the bone graft healing process.
3. The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
5. As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.
6. The VERTEX® Reconstruction System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and should be removed. While the final decision on implant removal is, of course, up to the surgeon and patient, in most patients, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position, possibly resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening and breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; (7) Bone loss due to stress shielding; and (8) Potential unknown and/or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.
7. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the VERTEX® Reconstruction System components should never be reused under any circumstances.

PACKAGING

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to MEDTRONIC.

CLEANING AND DECONTAMINATION

Unless just removed from an unopened MEDTRONIC package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to MEDTRONIC. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning.

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

STERILIZATION

Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using one of the sets of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes
Steam	Gravity	250°F (121°C)	60 Minutes
Steam*	Pre-Vacuum*	273°F (134°C)*	20 Minutes*
Steam*	Gravity*	273°F (134°C)*	20 Minutes*

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g., temperatures, times) used for their equipment.

*For outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

PRODUCT COMPLAINTS

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or MEDTRONIC. Further, if any of the implanted spinal system component(s) ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any MEDTRONIC product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

FURTHER INFORMATION

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact MEDTRONIC.

Contact Customer Service or your Sales Representative for the most up-to-date version of the package insert.

EC REP

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0381090 Rev B

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www.myspinetools.com

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

Medtronic