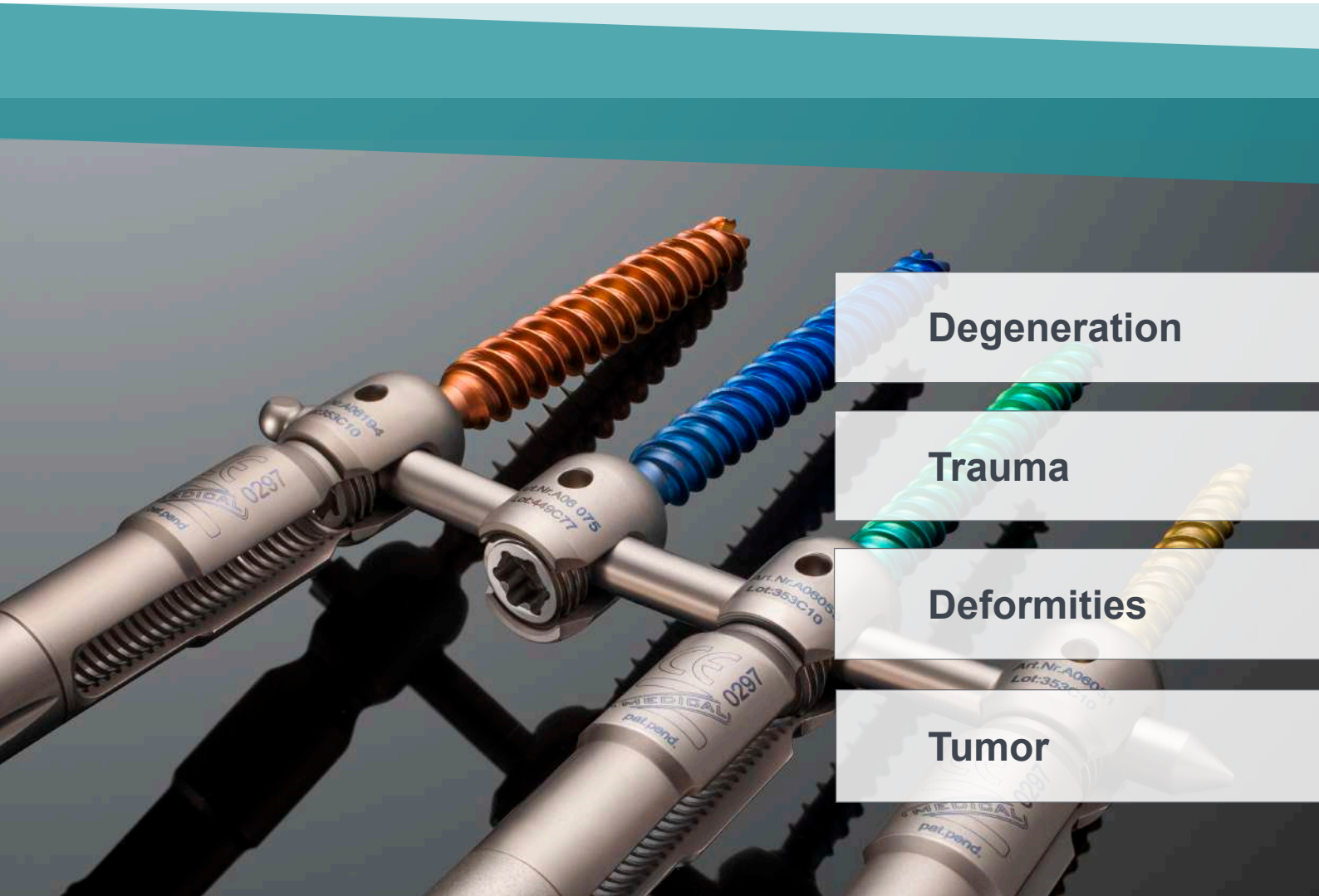
LOT 1, LOT 15

SURGICAL INNOVATIONS

CATALOGUE

MIS Z-PEDICLE SCREW SYSTEM



MIS Z-Pedicle Screw System

The MIS Z-Pedicle Screw System offers surgeons an ideal solution for their indication specific needs. It includes pre-sterilized implants, only one instrument set and an innovative screw design enabling surgeons to efficiently and cost effectively address the most common pathologies. The pedicle screws with lengthening shaft in combination with the patented SnapOff-technique provide a rigid connection between the shaft and the implant and offer the possibility of a direct manipulation without an assembly of additional instruments. Z-Medical implants stand for precision, are single sterile packaged and ready for surgery.

Instrument Set

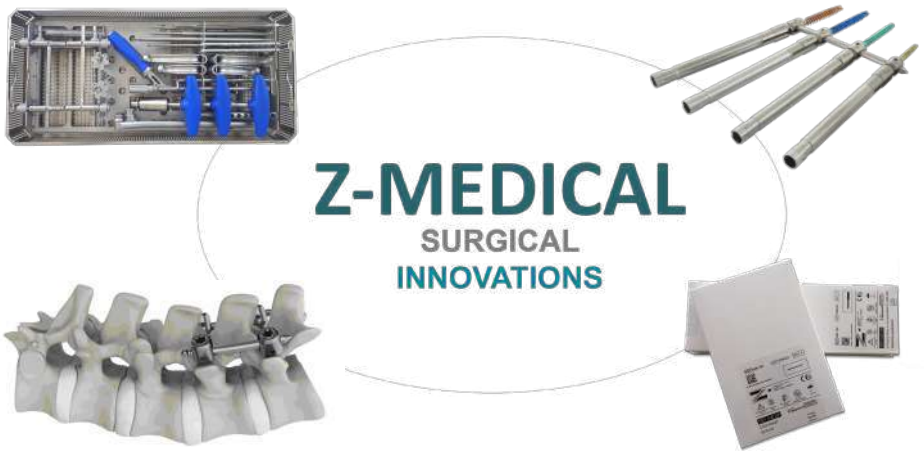
The MIS Z-Pedicle Screw System offers surgeons an ideal solution for their indication specific needs. The Z-Pedicle Screw System comprises sterile implants and only one instrument set.

- Only one instrument set
- High versatility
- Intraoperative control features
- Significant timesaver on logistics & reprocessing

Patented Pedicle Screws

The innovative screw design allows direct manipulation without an assembly of additional instruments.

- Easy handling
- Reduced OR-steps
- Controlled cement-augmentation
- Uniplanar screws for fracture- / deformity treatments



Indications

The multifunctional system enables surgeons to efficiently and cost effectively address the most common pathologies.

- Field of application in degenerative, deformity, trauma and tumors
- Ideal treatment option for spondylolisthesis

Sterile Packaging

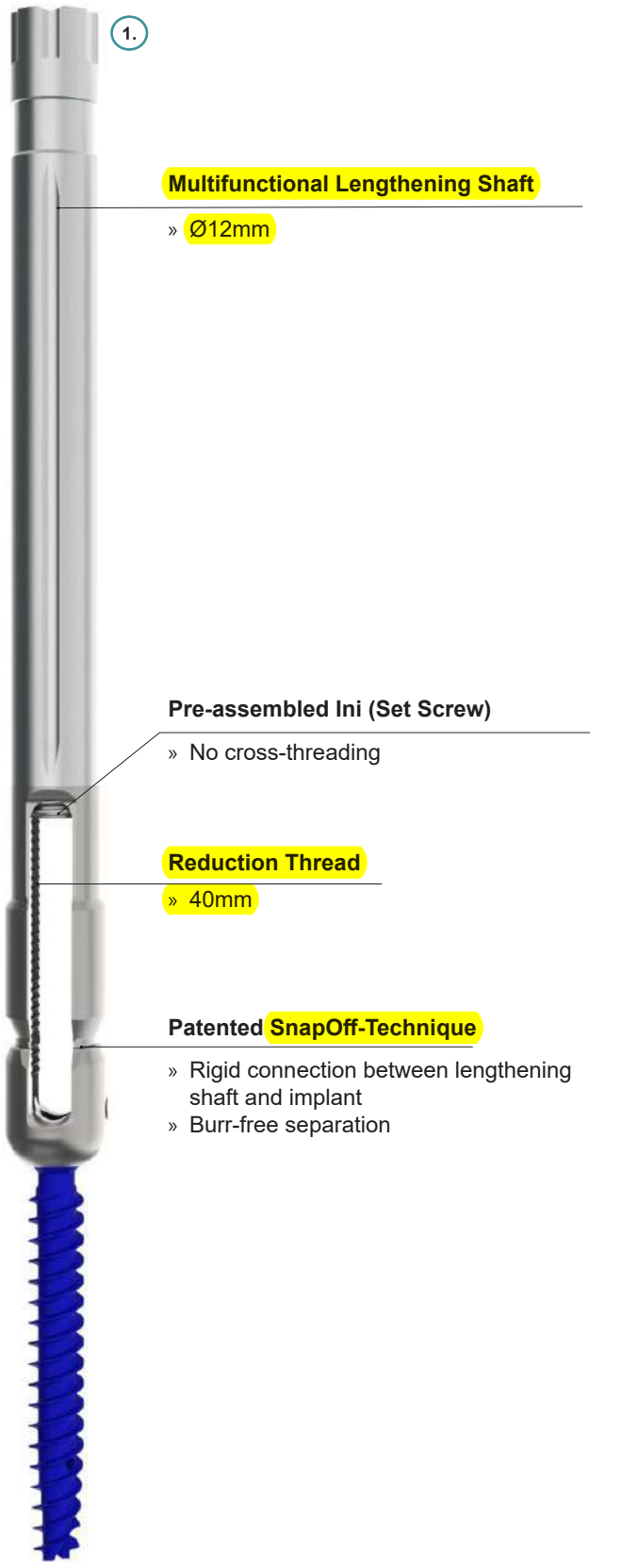
All implants are single sterile packaged and ready for surgery.

- Maximizing safety for surgeons and patients
- Traceability of implants using UDI

Technical Features

Screw diameter	5* / 6 / 7 / 8mm
Screw length	35 / 40 / 45 / 50 / 55mm
Ini (Set Screw)	Pre-assembled
Screw design	Multi-conical double thread, self-drilling and self-tapping
Axialities	Polyaxial, Quattroaxial, Quattroaxial trans., Monoaxial
Reduction of rod	Via reduction thread, 40mm
Manipulation	Via lengthening shaft
Fractures reduction	Via reduction thread
Derotation of deformities	Via reduction thread
Connection implant / shaft	Connected by SnapOff-Technique
Break off implant / shaft	With patented Tulip Breaker
Cement-Augmentation	With Bone Cement Filler Cannula through Screwdriver Pedicle Screw
Approval	EEC 93/42 // 510(k)

Innovative Implant Design



3.

4.

Product Features

The Z-Pedicle Screws are cannulated, fenestrated and available in different diameters and lengths:

1. Slim multifunctional lengthening shaft

with only 12mm diameter and a rigid connection to the implant. With and through this, all surgical steps are performed. The rod can be inserted along the long guiding notch or through a separate incision.

2. Pre-assembled Ini (Set Screw)

With the pre-assembled Ini, all manipulations are performed. A reduction of the rod, reduction of fractures, or derotation of deformities is achieved directly with the Ini and the long reduction thread with the pre-assembled Set Screw.

3. Screw Design

The Z-Pedicle Screws are self-drilling and self-tapping due to its unique tip and thread design. A multi conical double thread design increases stability in the pedicle and offers ease of insertion.

4. Patented SnapOff-Technique

A secure and burr-free separation from the lengthening shaft is possible by a simple rotation of the Tulip Breaker.

Screw Design

Patented Screw(head) Design

» Four axialities

Double thread with high pitch

» High stability
» Fast insertion, 6mm per rotation

Cannulated and fenestrated

» Safe insertion over guide wire
» Controlled cement-augmentation

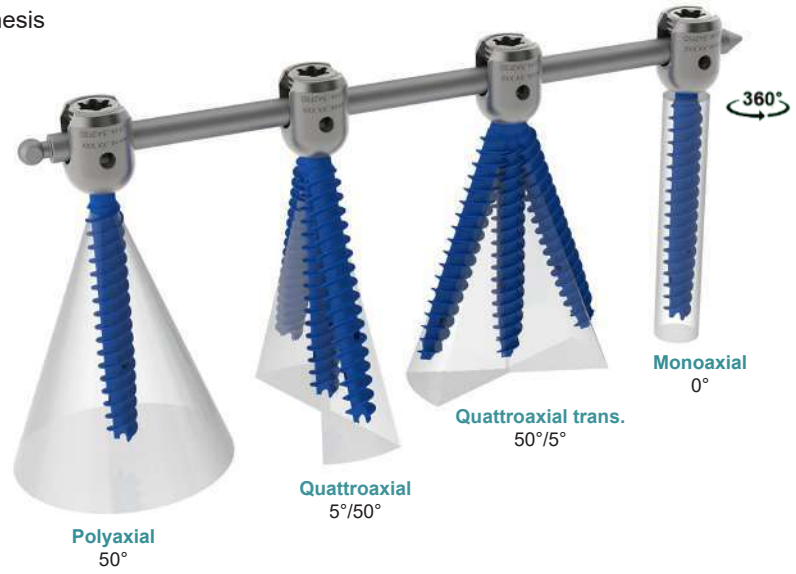
Thread features

» Self-drilling
» Self-tapping
» Optimal initial bone grip

Axialities

The Z-Pedicle Screws are available in different axialities:

» Polyaxial
» Quattroaxial for fractures / spondylolisthesis
» Quattroaxial trans. for deformities
» Monoaxial



Special Screws for Fractures / Spondylolisthesis

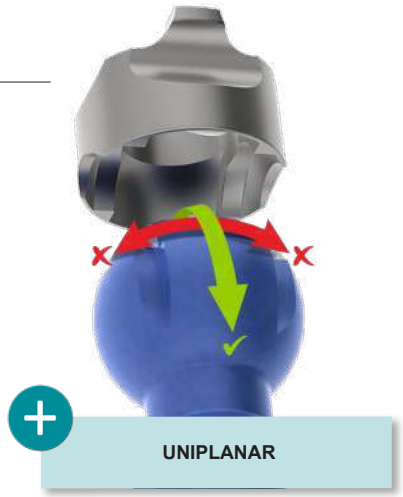
The **Quattroaxial Screw** allows shorter instrumentation and simplifies reposition.

Degree of freedom:
» Medial-Lateral: moving freely
» Cranio-Caudal: blocked

Advantages vs. Polyaxial Screw:
» No sliding of screw head due to the tongue and groove feature
» No anterior height loss due to 2-3 times higher angular stability

Advantages vs. Monoaxial Screw:
» Facilitates the rod insertion and minimizes undesired tension

Quattroaxial
Fractures / Spondylolisthesis



Reduction / Reposition

» Easy alignment after surgical reduction of spondylolisthesis

» Without additional instruments

» Directly achieved with the pre-assembled Ini via the reduction thread

Distraction / Compression

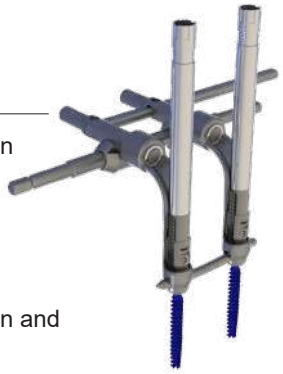
The universal distraction and compression instrument enables:

» A direct and controlled correction of complex fractures

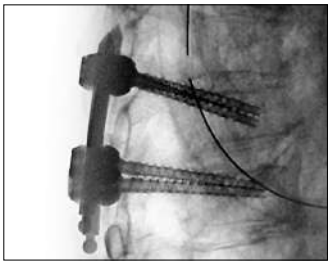
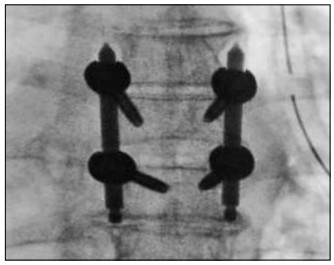
» An open and percutaneous distraction and compression along the rod

» Segmental distraction for discectomy and / or insertion of an interbody device

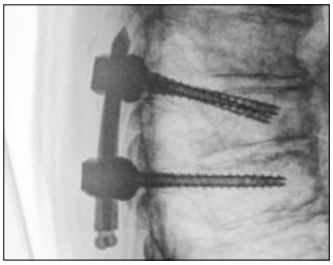
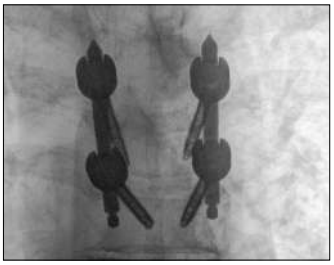
» Same approach as MIS screw, application via the lengthening shaft



Treatment of Discoligamentous Laceration using the MIS Z-Pedicle Screw System!

Intraoperative X-ray

Follow-Up at 9 month

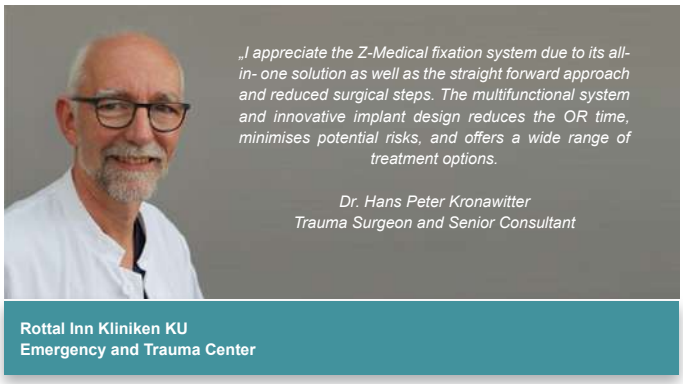
Patient
Male, 75 years, retired farmer

Symptoms
Patient oriented and responsive, circulation stable, RR syst 100 mm Hg, GCS 15, cervical spine free of pressure, pressure pain in middle part of the thoracic spine, lumbar spine NAD, pressure pain right, hemothorax with reduced breathing, abdomen soft, pelvis stable.

Diagnosis
Discoligamentous laceration of T7/8, compression fractures T2 and 3, several rib fractures 4-8 r. with hemothorax r. and discreet pneumothorax bilateral, lung contusions bi-lateral.

Therapy
Primary thoracic drainage right side and therapy in the intensive care unit. Initially problematic pulmonary situation, whereby the patient was incubated. After stabilization of the pulmonary situation on the 7th post-traumatic day, surgery was performed with percutaneous posterior stabilization of T7/8 with 5mm diameter quattroaxial screws. Surgery was free of complications and lasted 60min. The patient remained respirated postoperatively. The post-operative CT shows correct positioning of the pedicle screws with a good correction of the fracture. Two days post-OP the patient was extubation with subsequently unproble- matic mobilization and an uneventful recovery. Inpatient care lasted 3 weeks and then 3 weeks of outpatient treatment.

Follow-Up
Outpatient follow-up after 3, 6, 9 and 12 month with X-ray evaluation Intra-OP, 3 and 9 months. Patient increasingly mobile, with little pain, and helps out again with agricultural duties. However, there is still a load-dependent dyspnoea, as a result of the lung contusions. Radiological results show segment T7/8 ventrally fused.



Advantages of the MIS Z-Pedicle Screw System
* Only one instrument set
* Atraumatic approach and easy handling
* Reduction of OR time
* Excellent reposition result using quattroaxial screws
* No anterior height loss

Indication

The MIS Z-Pedicle Screw System is intended for posterior, non-cervical pedicle fixation for the following indications:

- Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e. fracture or dislocation)
- Spinal stenosis
- Curvatures (i.e. scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

Contraindications

- Infection
- Known allergic reaction to materials the instrument is manufactured of
- Physiologically or psychologically inadequate patient
- Insufficient skin, bone or neurovascular condition
- Possibility of a conservative treatment
- Blood supply limitations and previous infections, which may retard healing
- All non-listed indications

Z-Pedicle Screw | Sterile

Ø x L	Polyaxial 50°	Quattroaxial 5°/50°	Quattroaxial trans. 50°/5°	Monoaxial 0°
5 x 35	A06 051	A06 151	A06 451	A06 251
5 x 40	A06 052	A06 152	A06 452	A06 252
5 x 45	A06 053	A06 153	A06 453	A06 253
5 x 50	A06 054	A06 154	A06 454	A06 254
6 x 35	A06 061	A06 161	A06 461	A06 261
6 x 40	A06 062	A06 162	A06 462	A06 262
6 x 45	A06 063	A06 163	A06 463	A06 263
6 x 50	A06 064	A06 164	A06 464	A06 264
6 x 55	A06 065	A06 165	A06 465	A06 265
7 x 35	A06 071	A06 171	A06 471	A06 271
7 x 40	A06 072	A06 172	A06 472	A06 272
7 x 45	A06 073	A06 173	A06 473	A06 273
7 x 50	A06 074	A06 174	A06 474	A06 274
7 x 55	A06 075	A06 175	A06 475	A06 275
8 x 35	A06 091	A06 191	A06 491	A06 291
8 x 40	A06 092	A06 192	A06 492	A06 292
8 x 45	A06 093	A06 193	A06 493	A06 293
8 x 50	A06 094	A06 194	A06 494	A06 294
8 x 55	A06 095	A06 195	A06 495	A06 295

Instruments | Sterile

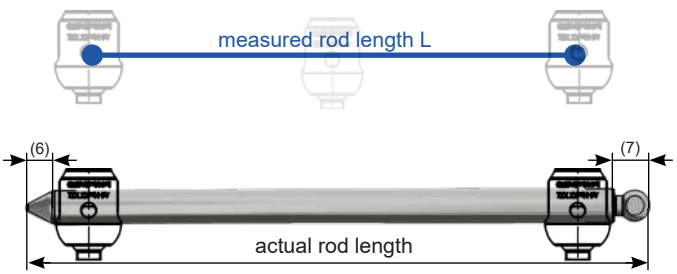
Instrument	Art.No.	Description	Q
	A06 081 S	Z-Guide Wire	2
Distributive products	**Art.No.**	**Description**	**Q**
	900140	First Access Needle	1
	900146	Bone Cement Filler Cannula for Screw Cementation	1
	800039	V-Steady Radiopaque Bone Cement	1

Ø = diameter in mm
L = length in mm
Q = quantity per packaging unit

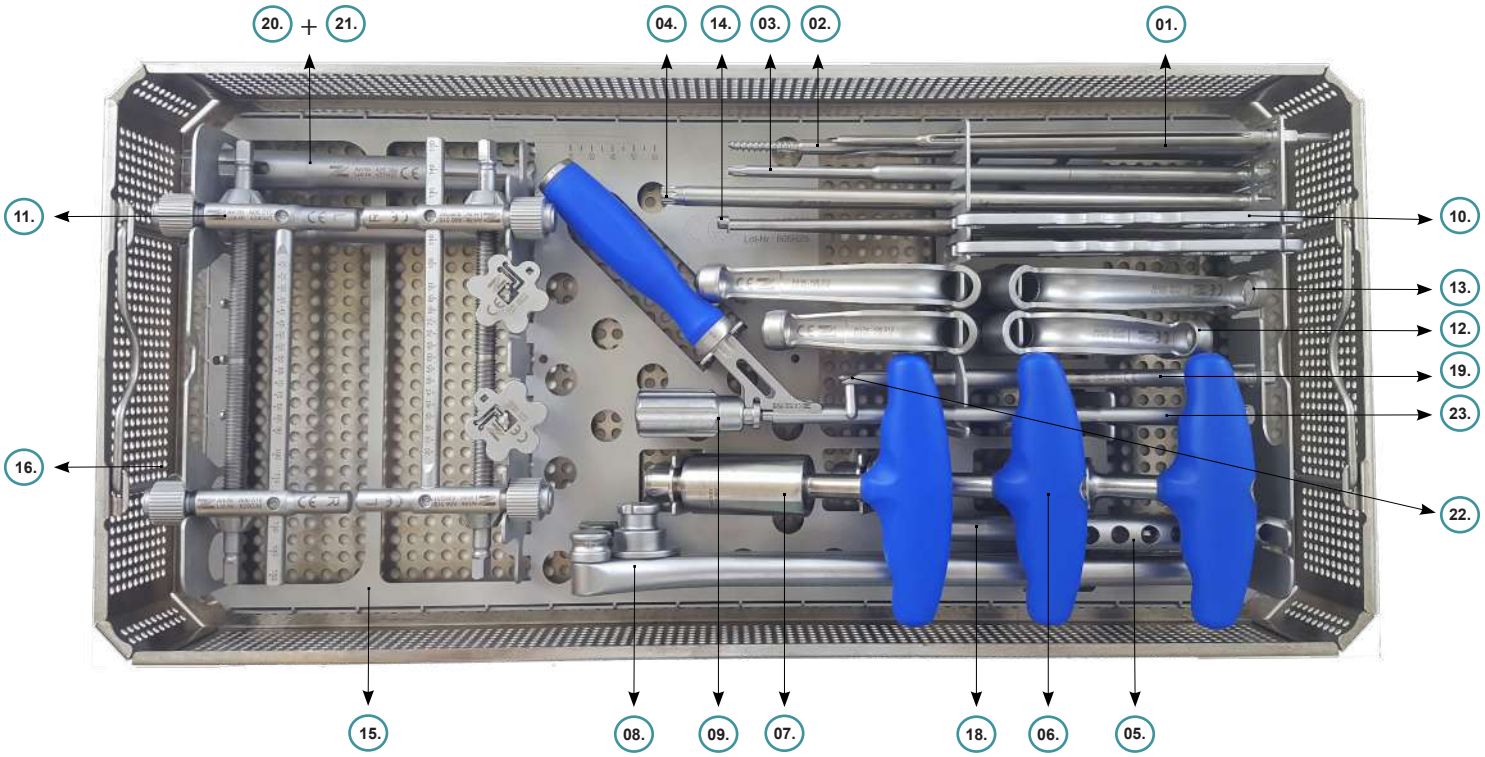
Z-Rods | Sterile, Ø5.5mm

L	bent	L	bent
20	A06 348	75	A06 359
25	A06 349	80	A06 360
30	A06 350	85	A06 361
35	A06 351	90	A06 362
40	A06 352	95	A06 363
45	A06 353	100	A06 364
50	A06 354	110	A06 366
55	A06 355	120	A06 368
60	A06 356		
65	A06 357		
70	A06 358		

L	straight
120	A06 390
130	A06 391
150	A06 392
160	A06 393
180	A06 394
200	A06 395
220	A06 396
240	A06 397
260	A06 398
280	A06 399
300	A06 400

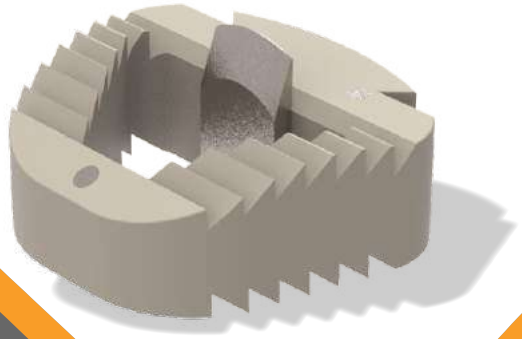


Note:
actual rod length = measured rod length L + 25mm



Instruments		Art. No.	Quantity
01.	Awl Set	A06 530	1
02.	Thread Drill	A06 380	1
03.	Screwdriver Pedicle Screw	A06 006	2
04.	Screwdriver Ini	A06 005	2
05.	Z-Handle	C07 909	1
06.	T-Handle with Ratchet	A06 374	2
07.	T-Handle with Torque Limiter	A06 007	1
08.	Rod Bender	A06 381	1
09.	Rod Inserter	A06 300	2
10.	Counter Support	A06 373	2
11.	Distraction- and Compression Instrument (Dico)	A06 600	2
12.	Adapter short	A06 512	4
13.	Adapter long	A06 513	4
14.	Tulip Breaker	A06 370	2
Storage			
15.	Rack	A06 508	1
16.	Perforated Container Set	A06 488	1
17.	Sterilisation Container Set	A06 490	1
Instruments Optional			
18.	Reamer	A06 524	1
Instruments Extension / Revision			
19.	Screwdriver Revision	A06 310	1
20.	Tulip Adapter	A06 306	2
21.	Clamping Tube	A06 389	2
22.	Revision Instrument Inner Part	A06 384	1
23.	Chuck Rod	A06 385	1

LOT 5

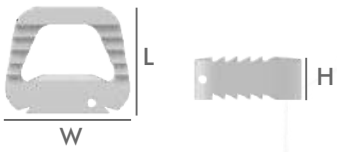


AGENA-X
Cervical Cage With Blade

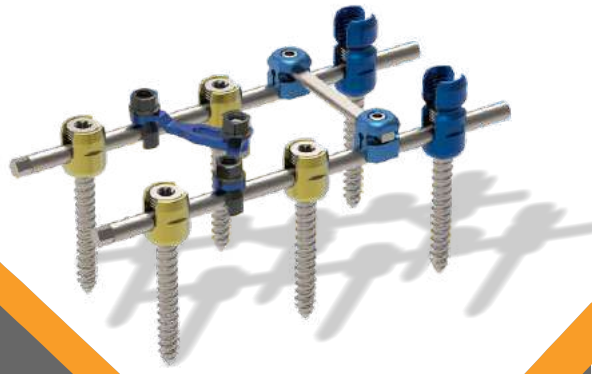
Features

- Agena-X is manufactured by using PEEK and Titanium, which is compatible with MRI and CT and which does not result in permanent lesions.
- Blades for a more reliable holding between the endplates.
- Anterior cervical plate may not required for supplimental fixation

Code	Height	Length	Width
MCPCB41214	4	12	14
MCPCB41216	4	12	16
MCPCB41414	4	14	14
MCPCB51214	5	12	14
MCPCB51216	5	12	16
MCPCB51414	5	14	14
MCPCB61214	6	12	14
MCPCB61216	6	12	16
MCPCB61414	6	14	14
MCPCB71214	7	12	14
MCPCB71216	7	12	16
MCPCB71414	7	14	14
MCPCB81214	8	12	14
MCPCB81216	8	12	16
MCPCB81414	8	14	14



LOT 3



POLAR
Spinal System 6.0

Features

- Easy Lock System
- Pedicle screw feature a double threaded, dual-lead design.
- Implants manufactured from Ti-6Al-4V ELI Titanium alloy, Vitallium CoCr alloy and PEEK according to ASTM International standards.
- Implantable pedicle screws as a Monoaxial,Polyaxial,Cannulated screws pre-bent rods, rod types, hooks in different sizes, easy to use hand tools compatible with implants
- More reliable tightening with the torx design of setscrew. Reverse angled setscrew thread design.

Polyaxial Screw

Code	Size	Code	Size	Code	Size
MSFX-PAS3525	3.5x25 mm	MSFX-PAS5535	5.5x35 mm	MSFX-PAS7540	7.5x40 mm
MSFX-PAS3530	3.5x30 mm	MSFX-PAS5540	5.5x40 mm	MSFX-PAS7545	7.5x45 mm
MSFX-PAS3535	3.5x35 mm	MSFX-PAS5545	5.5x45 mm	MSFX-PAS7550	7.5x50 mm
MSFX-PAS3540	3.5x40 mm	MSFX-PAS5550	5.5x50 mm	MSFX-PAS7555	7.5x55 mm
MSFX-PAS3545	3.5x45 mm	MSFX-PAS5555	5.5x55 mm	MSFX-PAS7560	7.5x60 mm
MSFX-PAS4020	4.0x20 mm	MSFX-PAS5560	5.5x60 mm	MSFX-PAS8030	8.0x30 mm
MSFX-PAS4025	4.0x25 mm	MSFX-PAS6035	6.0x35 mm	MSFX-PAS8035	8.0x35 mm
MSFX-PAS4030	4.0x30 mm	MSFX-PAS6040	6.0x40 mm	MSFX-PAS8040	8.0x40 mm
MSFX-PAS4035	4.0x35 mm	MSFX-PAS6045	6.0x45 mm	MSFX-PAS8045	8.0x45 mm
MSFX-PAS4040	4.0x40 mm	MSFX-PAS6050	6.0x50 mm	MSFX-PAS8050	8.0x50 mm
MSFX-PAS4045	4.0x45 mm	MSFX-PAS6055	6.0x55 mm	MSFX-PAS8055	8.0x55 mm
MSFX-PAS4520	4.5x20 mm	MSFX-PAS6060	6.0x60 mm	MSFX-PAS8060	8.0x60 mm
MSFX-PAS4525	4.5x25 mm	MSFX-PAS6530	6.5x30 mm	MSFX-PAS8070	8.0x70 mm
MSFX-PAS4530	4.5x30 mm	MSFX-PAS6535	6.5x35 mm	MSFX-PAS8080	8.0x80 mm
MSFX-PAS4535	4.5x35 mm	MSFX-PAS6540	6.5x40 mm	MSFX-PAS8090	8.0x90 mm
MSFX-PAS4540	4.5x40 mm	MSFX-PAS6545	6.5x45 mm	MSFX-PAS80100	8.0x100 mm
MSFX-PAS4545	4.5x45 mm	MSFX-PAS6550	6.5x50 mm	MSFX-PAS8530	8.5x30 mm
MSFX-PAS5030	5.0x30 mm	MSFX-PAS6555	6.5x55 mm	MSFX-PAS8535	8.5x35 mm
MSFX-PAS5035	5.0x35 mm	MSFX-PAS6560	6.5x60 mm	MSFX-PAS8540	8.5x40 mm
MSFX-PAS5040	5.0x40 mm	MSFX-PAS7035	7.0x35 mm	MSFX-PAS8545	8.5x45 mm
MSFX-PAS5045	5.0x45 mm	MSFX-PAS7040	7.0x40 mm	MSFX-PAS8550	8.5x50 mm
MSFX-PAS5050	5.0x50 mm	MSFX-PAS7045	7.0x45 mm	MSFX-PAS8555	8.5x55 mm
MSFX-PAS5055	5.0x55 mm	MSFX-PAS7050	7.0x50 mm	MSFX-PAS8560	8.5x60 mm
MSFX-PAS5060	5.0x60 mm	MSFX-PAS7055	7.0x55 mm	MSFX-PAS8570	8.5x70 mm
MSFX-PAS5520	5.5x20 mm	MSFX-PAS7060	7.0x60 mm	MSFX-PAS8580	8.5x80 mm
MSFX-PAS5525	5.5x25 mm	MSFX-PAS7530	7.5x30 mm	MSFX-PAS8590	8.5x90 mm
MSFX-PAS5530	5.5x30 mm	MSFX-PAS7535	7.5x35 mm	MSFX-PAS85100	8.5x100 mm

Additional sizes available upon request

Monoaxial Screw

Code	Size	Code	Size
MSFX-MAS3525	3.5x25 mm	MSFX-MAS6035	6.0x35 mm
MSFX-MAS3530	3.5x30 mm	MSFX-MAS6040	6.0x40 mm
MSFX-MAS3535	3.5x35 mm	MSFX-MAS6045	6.0x45 mm
MSFX-MAS3540	3.5x40 mm	MSFX-MAS6050	6.0x50 mm
MSFX-MAS3545	3.5x45 mm	MSFX-MAS6055	6.0x55 mm
MSFX-MAS4025	4.0x25 mm	MSFX-MAS6530	6.5x30 mm
MSFX-MAS4030	4.0x30 mm	MSFX-MAS6535	6.5x35 mm
MSFX-MAS4035	4.0x35 mm	MSFX-MAS6540	6.5x40 mm
MSFX-MAS4040	4.0x40 mm	MSFX-MAS6545	6.5x45 mm
MSFX-MAS4045	4.0x45 mm	MSFX-MAS6550	6.5x50 mm
MSFX-MAS4525	4.5x25 mm	MSFX-MAS6555	6.5x55 mm
MSFX-MAS4530	4.5x30 mm	MSFX-MAS7035	7.0x35 mm
MSFX-MAS4535	4.5x35 mm	MSFX-MAS7040	7.0x40 mm
MSFX-MAS4540	4.5x40 mm	MSFX-MAS7045	7.0x45 mm
MSFX-MAS4545	4.5x45 mm	MSFX-MAS7050	7.0x50 mm
MSFX-MAS5030	5.0x30 mm	MSFX-MAS7055	7.0x55 mm
MSFX-MAS5035	5.0x35 mm	MSFX-MAS7535	7.5x35 mm
MSFX-MAS5040	5.0x40 mm	MSFX-MAS7540	7.5x40 mm
MSFX-MAS5045	5.0x45 mm	MSFX-MAS7545	7.5x45 mm
MSFX-MAS5050	5.0x50 mm	MSFX-MAS7550	7.5x50 mm
MSFX-MAS5530	5.5x30 mm	MSFX-MAS7555	7.5x55 mm
MSFX-MAS5535	5.5x35 mm	MSFX-MAS8035	8.0x35 mm
MSFX-MAS5540	5.5x40 mm	MSFX-MAS8040	8.0x40 mm
MSFX-MAS5545	5.5x45 mm	MSFX-MAS8045	8.0x45 mm
MSFX-MAS5550	5.5x50 mm	MSFX-MAS8050	8.0x50 mm
MSFX-MAS5555	5.5x55 mm	MSFX-MAS8055	8.0x55 mm

Monoaxial Spondylolisthesis Screw

Code	Size
MSFX-MRS5535	5.5x35 mm
MSFX-MRS5540	5.5x40 mm
MSFX-MRS5545	5.5x45 mm
MSFX-MRS5550	5.5x50 mm
MSFX-MRS6035	6.0x35 mm
MSFX-MRS6040	6.0x40 mm
MSFX-MRS6045	6.0x45 mm
MSFX-MRS6050	6.0x50 mm
MSFX-MRS6535	6.5x35 mm
MSFX-MRS6540	6.5x40 mm
MSFX-MRS6545	6.5x45 mm
MSFX-MRS6550	6.5x50 mm
MSFX-MRS7035	7.0x30 mm
MSFX-MRS7040	7.0x40 mm
MSFX-MRS7045	7.0x45 mm
MSFX-MRS7050	7.0x50 mm
MSFX-MRS7055	7.0x55 mm
MSFX-MRS7540	7.5x40 mm
MSFX-MRS7545	7.5x45 mm
MSFX-MRS7550	7.5x50 mm
MSFX-MRS7555	7.5x55 mm

Additional sizes available upon request

Cemented screws

Polyaxial Spondylolisthesis Screw

Code	Size
MSFX-PRS5530	5.5x30 mm
MSFX-PRS5535	5.5x35 mm
MSFX-PRS5540	5.5x45 mm
MSFX-PRS5545	5.5x45 mm
MSFX-PRS5550	5.5x50 mm
MSFX-PRS5555	5.5x55 mm
MSFX-PRS6035	6.0x35 mm
MSFX-PRS6040	6.0x40 mm
MSFX-PRS6045	6.0x45 mm
MSFX-PRS6050	6.0x50 mm
MSFX-PRS6530	6.5x30 mm
MSFX-PRS6535	6.5x35 mm
MSFX-PRS6540	6.5x40 mm
MSFX-PRS6545	6.5x45 mm
MSFX-PRS6550	6.5x50 mm
MSFX-PRS6555	6.5x55 mm
MSFX-PRS7035	7.0x35 mm
MSFX-PRS7040	7.0x40 mm
MSFX-PRS7045	7.0x45 mm
MSFX-PRS7050	7.0x50 mm
MSFX-PRS7055	7.0x55 mm
MSFX-PRS7535	7.5x35 mm
MSFX-PRS7540	7.5x40 mm
MSFX-PRS7545	7.5x45 mm
MSFX-PRS7550	7.5x50 mm
MSFX-PRS7555	7.5x55 mm

Polyaxial Cannulated And Fenestrated Screw

Code	Size	Code	Size
MSFX-CPS5530	4.5x30 mm	MSFX-CPS6550	6.5x50 mm
MSFX-CPS4535	4.5x35 mm	MSFX-CPS6555	6.5x55 mm
MSFX-CPS4540	4.5x40 mm	MSFX-CPS7030	7.0x30 mm
MSFX-CPS4545	4.5x45 mm	MSFX-CPS7035	7.0x35 mm
MSFX-CPS4550	4.5x50 mm	MSFX-CPS7040	7.0x40 mm
MSFX-CPS4555	4.5x55 mm	MSFX-CPS7045	7.0x45 mm
MSFX-CPS5035	5.0x35 mm	MSFX-CPS7050	7.0x50 mm
MSFX-CPS5040	5.0x40 mm	MSFX-CPS7055	7.0x55 mm
MSFX-CPS5045	5.0x45 mm	MSFX-CPS7530	7.5x30 mm
MSFX-CPS5050	5.0x50 mm	MSFX-CPS7535	7.5x35 mm
MSFX-CPS5055	5.0x55 mm	MSFX-CPS7540	7.5x40 mm
MSFX-CPS5530	5.5x30 mm	MSFX-CPS7545	7.5x45 mm
MSFX-CPS5535	5.5x35 mm	MSFX-CPS7550	7.5x50 mm
MSFX-CPS5540	5.5x40 mm	MSFX-CPS7555	7.5x55 mm
MSFX-CPS5545	5.5x45 mm	MSFX-CPS8035	8.0x35 mm
MSFX-CPS5550	5.5x50 mm	MSFX-CPS8040	8.0x40 mm
MSFX-CPS5555	5.5x55 mm	MSFX-CPS8045	8.0x45 mm
MSFX-CPS6035	6.0x35 mm	MSFX-CPS8050	8.0x50 mm
MSFX-CPS6040	6.0x40 mm	MSFX-CPS8055	8.0x55 mm
MSFX-CPS6045	6.0x45 mm		
MSFX-CPS6050	6.0x50 mm		
MSFX-CPS6055	6.0x55 mm		
MSFX-CPS6530	6.5x30 mm		
MSFX-CPS6535	6.5x35 mm		
MSFX-CPS6540	6.5x40 mm		
MSFX-CPS6545	6.5x45 mm		

Additional sizes available upon request

Cemented screw

Monoaxial Cannulated And Fenestrated Screw

Code	Size
MSFX-CMS5530	5.5x30 mm
MSFX-CMS5535	5.5x35 mm
MSFX-CMS5540	5.5x40 mm
MSFX-CMS5545	5.5x45 mm
MSFX-CMS5550	5.5x50 mm
MSFX-CMS5555	5.5x55 mm
MSFX-CMS6530	6.5x30 mm
MSFX-CMS6535	6.5x35 mm
MSFX-CMS6540	6.5x40 mm
MSFX-CMS6545	6.5x45 mm
MSFX-CMS6550	6.5x50 mm
MSFX-CMS6555	6.5x55 mm
MSFX-CMS7530	7.5x30 mm
MSFX-CMS7535	7.5x35 mm
MSFX-CMS7540	7.5x40 mm
MSFX-CMS7545	7.5x45 mm
MSFX-CMS7550	7.5x50 mm
MSFX-CMS7555	7.5x55 mm

Rod Titanium alloy

Code	Size	Code	Size
MSFX-SR1604	6.0x40 mm	MSFX-SR1622	6.0x220 mm
MSFX-SR1605	6.0x50 mm	MSFX-SR1623	6.0x230 mm
MSFX-SR1606	6.0x60 mm	MSFX-SR1624	6.0x240 mm
MSFX-SR1607	6.0x70 mm	MSFX-SR1625	6.0x250 mm
MSFX-SR1608	6.0x80 mm	MSFX-SR1626	6.0x260 mm
MSFX-SR1609	6.0x90 mm	MSFX-SR1627	6.0x270 mm
MSFX-SR1610	6.0x100 mm	MSFX-SR1628	6.0x280 mm
MSFX-SR1611	6.0x110 mm	MSFX-SR1629	6.0x290 mm
MSFX-SR1612	6.0x120 mm	MSFX-SR1630	6.0x300 mm
MSFX-SR1613	6.0x130 mm	MSFX-SR1631	6.0x310 mm
MSFX-SR1614	6.0x140 mm	MSFX-SR1632	6.0x320 mm
MSFX-SR1615	6.0x150 mm	MSFX-SR1640	6.0x400 mm
MSFX-SR1616	6.0x160 mm	MSFX-SR1648	6.0x480 mm
MSFX-SR1617	6.0x170 mm	MSFX-SR1650	6.0x500 mm
MSFX-SR1618	6.0x180 mm	MSFX-SR1660	6.0x600 mm
MSFX-SR1619	6.0x190 mm		
MSFX-SR1620	6.0x200 mm		
MSFX-SR1621	6.0x210 mm		

Additional sizes available upon request

Polar Polyaxial Screw

Code	Size	Code	Size
MSFX-PPPS3525	3.5x25 mm	MSFX-PPPS6530	6.5x30 mm
MSFX-PPPS3530	3.5x30 mm	MSFX-PPPS6535	6.5x35 mm
MSFX-PPPS3535	3.5x35 mm	MSFX-PPPS6540	6.5x40 mm
MSFX-PPPS3540	3.5x40 mm	MSFX-PPPS6545	6.5x45 mm
MSFX-PPPS3545	3.5x45 mm	MSFX-PPPS6550	6.5x50 mm
MSFX-PPPS4520	4.5x20 mm	MSFX-PPPS6555	6.5x55 mm
MSFX-PPPS4525	4.5x25 mm	MSFX-PPPS7035	7.0x35 mm
MSFX-PPPS4530	4.5x30 mm	MSFX-PPPS7040	7.0x40 mm
MSFX-PPPS4535	4.5x35 mm	MSFX-PPPS7045	7.0x45 mm
MSFX-PPPS4540	4.5x40 mm	MSFX-PPPS7050	7.0x50 mm
MSFX-PPPS4545	4.5x45 mm	MSFX-PPPS7055	7.0x55 mm
MSFX-PPPS5030	5.0x30 mm	MSFX-PPPS7530	7.5x30 mm
MSFX-PPPS5035	5.0x35 mm	MSFX-PPPS7535	7.5x35 mm
MSFX-PPPS5040	5.0x40 mm	MSFX-PPPS7540	7.5x40 mm
MSFX-PPPS5045	5.0x45 mm	MSFX-PPPS7545	7.5x45 mm
MSFX-PPPS5050	5.0x50 mm	MSFX-PPPS7550	7.5x50 mm
MSFX-PPPS5520	5.5x20 mm	MSFX-PPPS7555	7.5x55 mm
MSFX-PPPS5525	5.5x25 mm	MSFX-PPPS8030	8.0x30 mm
MSFX-PPPS5530	5.5x30 mm	MSFX-PPPS8035	8.0x35 mm
MSFX-PPPS5535	5.5x35 mm	MSFX-PPPS8040	8.0x40 mm
MSFX-PPPS5540	5.5x40 mm	MSFX-PPPS8045	8.0x45 mm
MSFX-PPPS5545	5.5x45 mm	MSFX-PPPS8050	8.0x50 mm
MSFX-PPPS5550	5.5x50 mm	MSFX-PPPS8055	8.0x55 mm
MSFX-PPPS5555	5.5x55 mm	MSFX-PPPS8055	8.0x60 mm
MSFX-PPPS6035	6.0x35 mm	MSFX-PPPS8070	8.0x70 mm
MSFX-PPPS6040	6.0x40 mm	MSFX-PPPS8080	8.0x80 mm
MSFX-PPPS6045	6.0x45 mm	MSFX-PPPS8090	8.0x90 mm
MSFX-PPPS6050	6.0x50 mm	MSFX-PPPS80100	8.0x100 mm
MSFX-PPPS6055	6.0x55 mm		

Additional sizes available upon request

Polar Polyaxial Spondylolisthesis Screw

Code	Size
MSFX- PPRPS5530	5.5x30 mm
MSFX- PPRPS5535	5.5x35 mm
MSFX- PPRPS5540	5.5x40 mm
MSFX- PPRPS5545	5.5x45 mm
MSFX- PPRPS5550	5.5x50 mm
MSFX- PPRPS5555	5.5x55 mm
MSFX- PPRPS6035	6.0x35 mm
MSFX- PPRPS6040	6.0x40 mm
MSFX- PPRPS6045	6.0x45 mm
MSFX- PPRPS6050	6.0x50 mm
MSFX- PPRPS6535	6.5x35 mm
MSFX- PPRPS6540	6.5x40 mm
MSFX- PPRPS6545	6.5x45 mm
MSFX- PPRPS6550	6.5x50 mm
MSFX- PPRPS6555	6.5x55 mm
MSFX- PPRPS7035	7.0x35 mm
MSFX- PPRPS7040	7.0x40 mm
MSFX- PPRPS7045	7.0x45 mm
MSFX- PPRPS7050	7.0x50 mm
MSFX- PPRPS7055	7.0x55 mm
MSFX- PPRPS7535	7.5x35 mm
MSFX- PPRPS7540	7.5x40 mm
MSFX- PPRPS7545	7.5x45 mm
MSFX- PPRPS7550	7.5x50 mm
MSFX- PPRPS7555	7.5x55 mm

Polar Monoaxial Screw

Code	Size	Code	Size
MSFX-PPMAS3525	3.5x25 mm	MSFX-PPMAS6040	6.0x40 mm
MSFX-PPMAS3530	3.5x30 mm	MSFX-PPMAS6045	6.0x45 mm
MSFX-PPMAS3535	3.5x35 mm	MSFX-PPMAS6050	6.0x50 mm
MSFX-PPMAS3540	3.5x40 mm	MSFX-PPMAS6055	6.0x55 mm
MSFX-PPMAS3545	3.5x45 mm	MSFX-PPMAS6530	6.5x30 mm
MSFX-PPMAS4025	4.0x25 mm	MSFX-PPMAS6535	6.5x35 mm
MSFX-PPMAS4030	4.0x30 mm	MSFX-PPMAS6540	6.5x40 mm
MSFX-PPMAS4035	4.0x35 mm	MSFX-PPMAS6545	6.5x45 mm
MSFX-PPMAS4040	4.0x40 mm	MSFX-PPMAS6550	6.5x50 mm
MSFX-PPMAS4525	4.5x25 mm	MSFX-PPMAS6555	6.5x55 mm
MSFX-PPMAS4530	4.5x30 mm	MSFX-PPMAS7035	7.0x35 mm
MSFX-PPMAS4535	4.5x35 mm	MSFX-PPMAS7040	7.0x40 mm
MSFX-PPMAS4540	4.5x40 mm	MSFX-PPMAS7045	7.0x45 mm
MSFX-PPMAS4545	4.5x45 mm	MSFX-PPMAS7050	7.0x50 mm
MSFX-PPMAS5030	5.0x30 mm	MSFX-PPMAS7055	7.0x55 mm
MSFX-PPMAS5035	5.0x35 mm	MSFX-PPMAS7535	7.5x35 mm
MSFX-PPMAS5040	5.0x40 mm	MSFX-PPMAS7540	7.5x40 mm
MSFX-PPMAS5045	5.0x45 mm	MSFX-PPMAS7545	7.5x45 mm
MSFX-PPMAS5050	5.0x50 mm	MSFX-PPMAS7550	7.5x50 mm
MSFX-PPMAS5530	5.5x30 mm	MSFX-PPMAS7555	7.5x55 mm
MSFX-PPMAS5535	5.5x35 mm	MSFX-PPMAS8035	8.0x35 mm
MSFX-PPMAS5540	5.5x40 mm	MSFX-PPMAS8040	8.0x40 mm
MSFX-PPMAS5545	5.5x45 mm	MSFX-PPMAS8045	8.0x45 mm
MSFX-PPMAS5550	5.5x50 mm	MSFX-PPMAS8050	8.0x50 mm
MSFX-PPMAS5555	5.5x55 mm	MSFX-PPMAS8055	8.0x55 mm
MSFX-PPMAS6035	6.0x35 mm		

Polar Monoaxial Spondylolisthesis Screw

Code	Size
MSFX-PPMRS5535	5.5x35 mm
MSFX-PPMRS5540	5.5x40 mm
MSFX-PPMRS5550	5.5x50 mm
MSFX-PPMRS6035	6.0x35 mm
MSFX-PPMRS6050	6.0x50 mm
MSFX-PPMRS6535	6.5x35 mm
MSFX-PPMRS6545	6.5x45 mm
MSFX-PPMRS6550	6.5x50 mm
MSFX-PPMRS7040	7.0x40 mm
MSFX-PPMRS7045	7.0x45 mm
MSFX-PPMRS7050	7.0x50 mm
MSFX-PPMRS7055	7.0x55 mm
MSFX-PPMRS7540	7.5x40 mm
MSFX-PPMRS7550	7.5x50 mm
MSFX-PPMRS7555	7.5x55 mm

Additional sizes available upon request

Polar Polyaxial Cannulated And Fenestrated Screw

Code	Size
MSFX-PPCPS5530	5.5x30 mm
MSFX-PPCPS5535	5.5x35 mm
MSFX-PPCPS5540	5.5x40 mm
MSFX-PPCPS5545	5.5x45 mm
MSFX-PPCPS5550	5.5x50 mm
MSFX-PPCPS5555	5.5x55 mm
MSFX-PPCPS6530	6.5x30 mm
MSFX-PPCPS6535	6.5x35 mm
MSFX-PPCPS6540	6.5x40 mm
MSFX-PPCPS6545	6.5x45 mm
MSFX-PPCPS6550	6.5x50 mm
MSFX-PPCPS6555	6.5x55 mm
MSFX-PPCPS7530	7.5x30 mm
MSFX-PPCPS7535	7.5x35 mm
MSFX-PPCPS7540	7.5x40 mm
MSFX-PPCPS7545	7.5x45 mm
MSFX-PPCPS7550	7.5x50 mm
MSFX-PPCPS7555	7.5x55 mm
MSFX-PPCPS8035	8.0x35 mm
MSFX-PPCPS8040	8.0x40 mm
MSFX-PPCPS8045	8.0x45 mm
MSFX-PPCPS8050	8.0x50 mm
MSFX-PPCPS8055	8.0x55 mm
MSFX-PPCPS8060	8.0x60 mm
MSFX-PPCPS8070	8.0x70 mm
MSFX-PPCPS8080	8.0x80 mm
MSFX-PPCPS8090	8.0x90 mm
MSFX-PPCPS80100	8.0x100 mm

Polar Monoaxial Cannulated And Fenestrated Screw

Code	Size
MSFX-PPCMS5530	5.5x30 mm
MSFX-PPCMS5535	5.5x35 mm
MSFX-PPCMS5540	5.5x40 mm
MSFX-PPCMS5545	5.5x45 mm
MSFX-PPCMS5550	5.5x50 mm
MSFX-PPCMS5555	5.5x55 mm
MSFX-PPCMS6530	6.5x30 mm
MSFX-PPCMS6535	6.5x35 mm
MSFX-PPCMS6540	6.5x40 mm
MSFX-PPCMS6545	6.5x45 mm
MSFX-PPCMS6550	6.5x50 mm
MSFX-PPCMS6555	6.5x55 mm
MSFX-PPCMS7530	7.5x30 mm
MSFX-PPCMS7535	7.5x35 mm
MSFX-PPCMS7540	7.5x40 mm
MSFX-PPCMS7545	7.5x45 mm
MSFX-PPCMS7550	7.5x50 mm
MSFX-PPCMS7555	7.5x55 mm

Additional sizes available upon request

Polar Polyaxial Quad Lead Screw

Code	Size	Code	Size
MSFX-PPMFS3525	3.5x25 mm	MSFX-PPMFS6055	6.0x55 mm
MSFX-PPMFS3530	3.5x30 mm	MSFX-PPMFS6530	6.5x30 mm
MSFX-PPMFS3535	3.5x35 mm	MSFX-PPMFS6535	6.5x35 mm
MSFX-PPMFS3540	3.5x40 mm	MSFX-PPMFS6540	6.5x40 mm
MSFX-PPMFS3545	3.5x45 mm	MSFX-PPMFS6545	6.5x45 mm
MSFX-PPMFS4520	4.5x20 mm	MSFX-PPMFS6550	6.5x50 mm
MSFX-PPMFS4525	4.5x25 mm	MSFX-PPMFS6555	6.5x55 mm
MSFX-PPMFS4530	4.5x30 mm	MSFX-PPMFS7035	7.0x35 mm
MSFX-PPMFS4535	4.5x35 mm	MSFX-PPMFS7040	7.0x40 mm
MSFX-PPMFS4540	4.5x40 mm	MSFX-PPMFS7045	7.0x45 mm
MSFX-PPMFS4545	4.5x45 mm	MSFX-PPMFS7050	7.0x50 mm
MSFX-PPMFS5030	5.0x30 mm	MSFX-PPMFS7055	7.0x55 mm
MSFX-PPMFS5035	5.0x35 mm	MSFX-PPMFS7530	7.5x30 mm
MSFX-PPMFS5040	5.0x40 mm	MSFX-PPMFS7535	7.5x35 mm
MSFX-PPMFS5045	5.0x45 mm	MSFX-PPMFS7540	7.5x40 mm
MSFX-PPMFS5050	5.0x50 mm	MSFX-PPMFS7545	7.5x45 mm
MSFX-PPMFS5520	5.5x20 mm	MSFX-PPMFS7550	7.5x50 mm
MSFX-PPMFS5525	5.5x25 mm	MSFX-PPMFS7555	7.5x55 mm
MSFX-PPMFS5530	5.5x30 mm	MSFX-PPMFS8030	8.0x30 mm
MSFX-PPMFS5535	5.5x35 mm	MSFX-PPMFS8035	8.0x35 mm
MSFX-PPMFS5540	5.5x40 mm	MSFX-PPMFS8040	8.0x40 mm
MSFX-PPMFS5545	5.5x45 mm	MSFX-PPMFS8045	8.0x45 mm
MSFX-PPMFS5550	5.5x50 mm	MSFX-PPMFS8050	8.0x50 mm
MSFX-PPMFS5555	5.5x55 mm	MSFX-PPMFS8055	8.0x55 mm
MSFX-PPMFS6035	6.0x35 mm	MSFX-PPMFS8070	8.0x70 mm
MSFX-PPMFS6040	6.0x40 mm	MSFX-PPMFS8080	8.0x80 mm
MSFX-PPMFS6045	6.0x45 mm	MSFX-PPMFS8090	8.0x90 mm
MSFX-PPMFS6050	6.0x50 mm	MSFX-PPMFS80100	8.0x100 mm

Polar Polyaxial Spondylolisthesis Quad Lead Screw

Code	Size
MSFX-PPMFRS5530	5.5x30 mm
MSFX-PPMFRS5540	5.5x40 mm
MSFX-PPMFRS5545	5.5x45 mm
MSFX-PPMFRS5550	5.5x50 mm
MSFX-PPMFRS5555	5.5x55 mm
MSFX-PPMFRS6035	6.0x35 mm
MSFX-PPMFRS6040	6.0x40 mm
MSFX-PPMFRS6045	6.0x45 mm
MSFX-PPMFRS6050	6.0x50 mm
MSFX-PPMFRS6540	6.5x40 mm
MSFX-PPMFRS6545	6.5x45 mm
MSFX-PPMFRS6550	6.5x50 mm
MSFX-PPMFRS6555	6.5x55 mm
MSFX-PPMFRS7035	7.0x35 mm
MSFX-PPMFRS7040	7.0x40 mm
MSFX-PPMFRS7045	7.0x45 mm
MSFX-PPMFRS7050	7.0x50 mm
MSFX-PPMFRS7055	7.0x55 mm
MSFX-PPMFRS7535	7.5x35 mm
MSFX-PPMFRS7540	7.5x40 mm
MSFX-PPMFRS7545	7.5x45 mm
MSFX-PPMFRS7550	7.5x50 mm
MSFX-PPMFRS7555	7.5x55 mm

Additional sizes available upon request

Rod CoCr

Code	Size
MSFX-SR1704	6.0x40 mm
MSFX-SR1705	6.0x50 mm
MSFX-SR1706	6.0x60 mm
MSFX-SR1707	6.0x70 mm
MSFX-SR1708	6.0x80 mm
MSFX-SR1709	6.0x90 mm
MSFX-SR1710	6.0x100 mm
MSFX-SR1711	6.0x110 mm
MSFX-SR1712	6.0x120 mm
MSFX-SR1713	6.0x140 mm
MSFX-SR1714	6.0x150 mm
MSFX-SR1715	6.0x160 mm
MSFX-SR1716	6.0x170 mm
MSFX-SR1717	6.0x180 mm
MSFX-SR1718	6.0x190 mm
MSFX-SR1719	6.0x200 mm
MSFX-SR1720	6.0x210 mm
MSFX-SR1721	6.0x220 mm
MSFX-SR1722	6.0x230 mm
MSFX-SR1723	6.0x240 mm
MSFX-SR1724	6.0x250 mm
MSFX-SR1725	6.0x260 mm
MSFX-SR1726	6.0x270 mm
MSFX-SR1727	6.0x280 mm
MSFX-SR1728	6.0x290 mm
MSFX-SR1729	6.0x300 mm
MSFX-SR1730	6.0x310 mm
MSFX-SR1731	6.0x320 mm
MSFX-SR1732	6.0x400 mm
MSFX-SR1740	6.0x480 mm
MSFX-SR1748	6.0x500 mm
MSFX-SR1750	6.0x600 mm
MSFX-SR1760	

Sacral Screw

Code	Size
MSFX-SSS6035	6.0x35 mm
MSFX-SSS6040	6.0x40 mm
MSFX-SSS6045	6.0x45 mm
MSFX-SSS6050	6.0x50 mm
MSFX-SSS6055	6.0x55 mm
MSFX-SSS7040	7.0x40 mm
MSFX-SSS7045	7.0x45 mm
MSFX-SSS7050	7.0x50 mm
MSFX-SSS7055	7.0x55 mm
MSFX-SSC15	15mm
MSFX-SSC20	20mm
MSFX-SOCNT	

Additional sizes available upon request

Transverse Connector

Code	Size
MSFX-TLH	
MSFX-TLR140	40 mm
MSFX-TLR150	50mm
MSFX-TLR160	60 mm
MSFX-TLR170	70 mm
MSFX-TLR180	80 mm
MSFX-MHTR	

Multiaxial Transverse Connector

Code	Size
MSFX-MTL4060	40-60 mm
MSFX-MTL6080	60-80 mm

Lateral Iliac connector

Code	Size
MSFX-LCNT15	15 mm
MSFX-LCNT20	20 mm
MSFX-LCNT25	25 mm
MSFX-LCNT30	30 mm

Domino Connector

Code
MSFX-ECNT01
MSFX-ECNT02
MSFX-OCNT

Laminar Hooks

Code	Size
MSFX-LH0505	5x5 mm
MSFX-LH0507	5x7 mm
MSFX-LH0509	5x9 mm
MSFX-LH0706	7x6 mm
MSFX-LH0707	7x7 mm
MSFX-LH0709	7x9 mm
MSFX-LH0711	7x11 mm
MSFX-LHF0505	5x5 mm
MSFX-LHF0507	5x7 mm
MSFX-LHLA709	7x9 mm
MSFX-LHLA711	7x11 mm
MSFX-LHRA709	7x9 mm
MSFX-LHRA711	7x11 mm

Pedicular Hooks

Code	Size
MSFX-HT3L0507	5x7 mm
MSFX-HT3L0509	5x9 mm
MSFX-HT3L0511	5x11 mm
MSFX-HT3R0507	5x7 mm
MSFX-HT3R0509	5x9 mm
MSFX-HT3R0511	5x11 mm
MSFX-PH0805	8x5 mm
MSFX-PH0807	8x7 mm
MSFX-PH0809	8x9 mm
MSFX-PHF0505	5x5 mm
MSFX-PHF0507	5x7 mm

Additional sizes available upon request

		2100-0151	Φ7.5x45mm	Ti6Al4V ELI
		2100-0152	Φ7.5x50mm	Ti6Al4V ELI
		2100-0153	Φ7.5x55mm	Ti6Al4V ELI
		2100-0154	Φ7.5x60mm	Ti6Al4V ELI
		2100-0155	Φ7.5x65mm	Ti6Al4V ELI
		2100-0156	Φ7.5x70mm	Ti6Al4V ELI
Polyaxial Pedical Screw	 lot 18	2100-0157	Φ5.0×30mm	Ti6Al4V ELI
		2100-0158	Φ5.0×35mm	Ti6Al4V ELI
		2100-0159	Φ5.0×40mm	Ti6Al4V ELI
		2100-0160	Φ5.5×30mm	Ti6Al4V ELI
		2100-0161	Φ5.5×35mm	Ti6Al4V ELI
		2100-0162	Φ5.5×40mm	Ti6Al4V ELI
		2100-0163	Φ5.5×45mm	Ti6Al4V ELI
		2100-0164	Φ5.5×50mm	Ti6Al4V ELI
		2100-0165	Φ5.5×55mm	Ti6Al4V ELI
		2100-0166	Φ5.5×60mm	Ti6Al4V ELI
		2100-0167	Φ5.5×65mm	Ti6Al4V ELI
		2100-0168	Φ5.5×70mm	Ti6Al4V ELI
		2100-0169	Φ6.5×35mm	Ti6Al4V ELI
		2100-0170	Φ6.5×40mm	Ti6Al4V ELI
		2100-0171	Φ6.5×45mm	Ti6Al4V ELI
		2100-0172	Φ6.5×50mm	Ti6Al4V ELI
		2100-0173	Φ6.5×55mm	Ti6Al4V ELI
		2100-0174	Φ6.5×60mm	Ti6Al4V ELI
		2100-0175	Φ6.5×65mm	Ti6Al4V ELI
		2100-0176	Φ6.5×70mm	Ti6Al4V ELI
		2100-0177	Φ7.5x35mm	Ti6Al4V ELI
		2100-0178	Φ7.5x40mm	Ti6Al4V ELI
		2100-0179	Φ7.5x45mm	Ti6Al4V ELI
		2100-0180	Φ7.5x50mm	Ti6Al4V ELI
		2100-0181	Φ7.5x55mm	Ti6Al4V ELI
		2100-0182	Φ7.5x60mm	Ti6Al4V ELI
		2100-0183	Φ7.5x65mm	Ti6Al4V ELI
		2100-0184	Φ7.5x70mm	Ti6Al4V ELI
Polyaxial Reduction Screw		2100-0185	Φ5.0×30mm	Ti6Al4V ELI
		2100-0186	Φ5.0×35mm	Ti6Al4V ELI
		2100-0187	Φ5.0×40mm	Ti6Al4V ELI
		2100-0188	Φ5.5×30mm	Ti6Al4V ELI
		2100-0189	Φ5.5×35mm	Ti6Al4V ELI
		2100-0190	Φ5.5×40mm	Ti6Al4V ELI
		2100-0191	Φ5.5×45mm	Ti6Al4V ELI
		2100-0192	Φ5.5×50mm	Ti6Al4V ELI
		2100-0193	Φ5.5×55mm	Ti6Al4V ELI
		2100-0194	Φ5.5×60mm	Ti6Al4V ELI
		2100-0195	Φ5.5×65mm	Ti6Al4V ELI
		2100-0196	Φ5.5×70mm	Ti6Al4V ELI
		2100-0197	Φ6.5×35mm	Ti6Al4V ELI
		2100-0198	Φ6.5×40mm	Ti6Al4V ELI
		2100-0199	Φ6.5×45mm	Ti6Al4V ELI
		2100-0200	Φ6.5×50mm	Ti6Al4V ELI
		2100-0201	Φ6.5×55mm	Ti6Al4V ELI
		2100-0202	Φ6.5×60mm	Ti6Al4V ELI
		2100-0203	Φ6.5×65mm	Ti6Al4V ELI
		2100-0204	Φ6.5×70mm	Ti6Al4V ELI
		2100-0205	Φ7.5x35mm	Ti6Al4V ELI
		2100-0206	Φ7.5x40mm	Ti6Al4V ELI
		2100-0207	Φ7.5x45mm	Ti6Al4V ELI
		2100-0208	Φ7.5x50mm	Ti6Al4V ELI
		2100-0209	Φ7.5x55mm	Ti6Al4V ELI
		2100-0210	Φ7.5x60mm	Ti6Al4V ELI
		2100-0211	Φ7.5x65mm	Ti6Al4V ELI
		2100-0212	Φ7.5x70mm	Ti6Al4V ELI

Transverse Connector 6.0mm		2100-0501	50mm	Ti6Al4V ELI
		2100-0502	60mm	Ti6Al4V ELI
		2100-0503	70mm	Ti6Al4V ELI
		2100-0504	80mm	Ti6Al4V ELI
Rod 6.0mm		2100-0601	Φ6.0×60mm	Ti6Al4V ELI
		2100-0602	Φ6.0×80mm	Ti6Al4V ELI
		2100-0603	Φ6.0×100mm	Ti6Al4V ELI
		2100-0604	Φ6.0×120mm	Ti6Al4V ELI
		2100-0605	Φ6.0×150mm	Ti6Al4V ELI
		2100-0606	Φ6.0×170mm	Ti6Al4V ELI
		2100-0607	Φ6.0×200mm	Ti6Al4V ELI
		2100-0608	Φ6.0×220mm	Ti6Al4V ELI
		2100-0609	Φ6.0×250mm	Ti6Al4V ELI
		2100-0610	Φ6.0×300mm	Ti6Al4V ELI
		2100-0611	Φ6.0×350mm	Ti6Al4V ELI
		2100-0612	Φ6.0×400mm	Ti6Al4V ELI
Anterior Cervical Plate System				
Anterior Cervical Plate		2100-0701	4 holes*25mm	Ti6Al4V ELI
		2100-0702	4 holes*27mm	Ti6Al4V ELI
		2100-0703	4 holes*30mm	Ti6Al4V ELI
		2100-0704	4 holes*32mm	Ti6Al4V ELI
		2100-0705	6 holes*35mm	Ti6Al4V ELI
		2100-0706	6 holes*38mm	Ti6Al4V ELI
		2100-0707	6 holes*41mm	Ti6Al4V ELI
		2100-0708	6 holes*44mm	Ti6Al4V ELI
		2100-0709	6 holes*47mm	Ti6Al4V ELI
		2100-0710	8 holes*50mm	Ti6Al4V ELI
		2100-0711	8 holes*53mm	Ti6Al4V ELI
		2100-0712	8 holes*57mm	Ti6Al4V ELI
		2100-0713	8 holes*60mm	Ti6Al4V ELI
		2100-0714	8 holes*63mm	Ti6Al4V ELI
		2100-0715	8 holes*68mm	Ti6Al4V ELI
		2100-0716	10 holes*72mm	Ti6Al4V ELI
		2100-0717	10 holes*75mm	Ti6Al4V ELI
		2100-0718	10 holes*78mm	Ti6Al4V ELI
		2100-0719	10 holes*81mm	Ti6Al4V ELI
Anterior Cervical Screw		2100-0801	Φ4*13mm	Ti6Al4V ELI
		2100-0802	Φ4*14mm	Ti6Al4V ELI
		2100-0803	Φ4*15mm	Ti6Al4V ELI
		2100-0804	Φ4*16mm	Ti6Al4V ELI

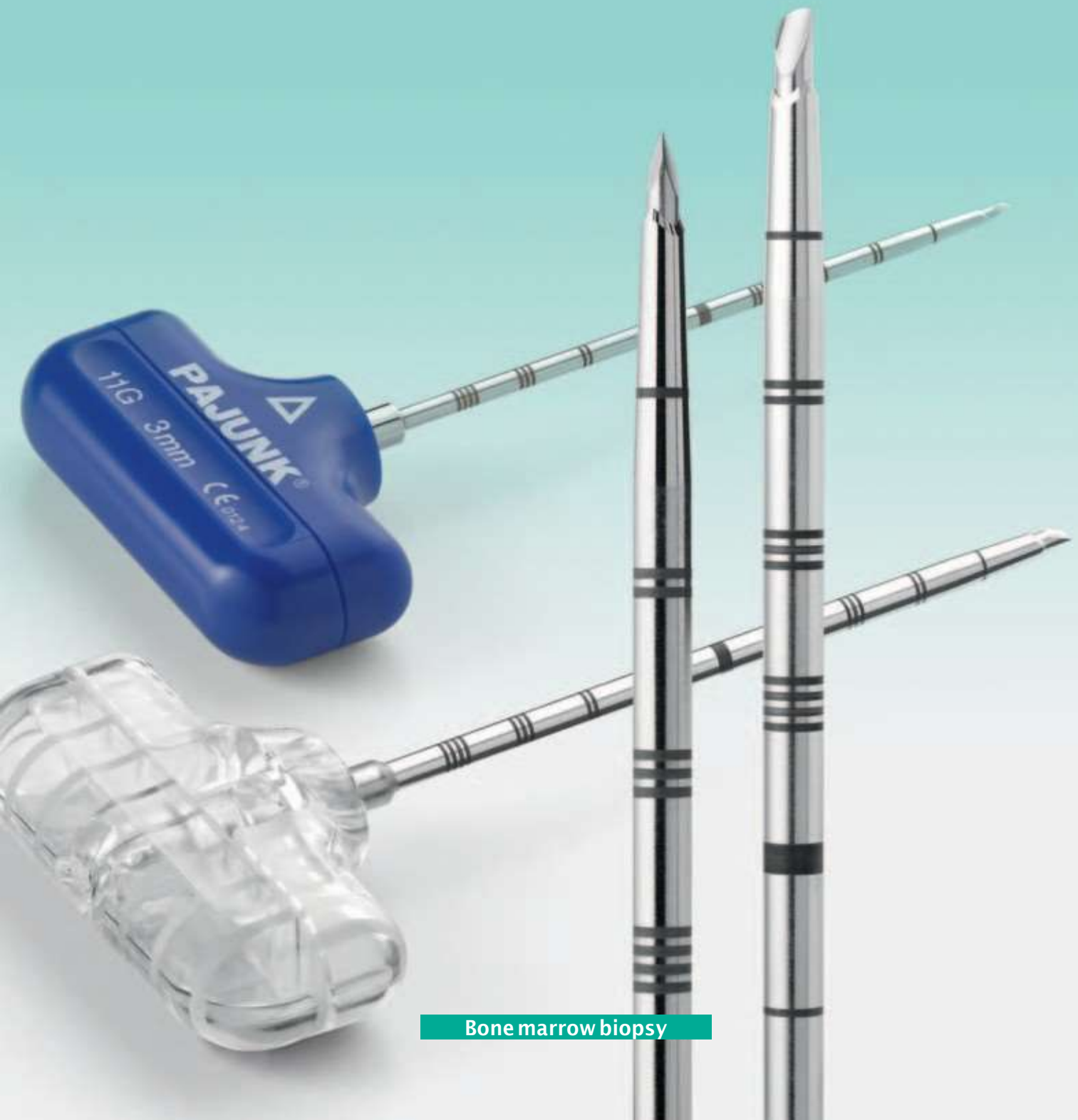
LOT 18

Arc-shaped Cervical Interbody Fusion Cage		2100-2201	12.7*15*4mm	Ti6Al4V ELI	
		2100-2202	12.7*15*4.5mm	Ti6Al4V ELI	
		2100-2203	12.7*15*5mm	Ti6Al4V ELI	
		2100-2204	12.7*15*5.5mm	Ti6Al4V ELI	
		2100-2205	12.7*15*6mm	Ti6Al4V ELI	
		2100-2206	12.7*15*6.5mm	Ti6Al4V ELI	
		2100-2207	12.7*15*7mm	Ti6Al4V ELI	
		2100-2208	12.7*15*8.5mm	Ti6Al4V ELI	
		2100-2209	12.7*15*10mm	Ti6Al4V ELI	
Anterior Lumbar Interbody Fusion Cage		2100-2301	25*30*13.5mm	Ti6Al4V ELI	
		2100-2302	25*30*15mm	Ti6Al4V ELI	
		2100-2303	25*30*17mm	Ti6Al4V ELI	
		2100-2304	25*30*19mm	Ti6Al4V ELI	
Posterior Lumbar Interbody Fusion Cage (Expansion Type)		2100-2401	23.5*11*9mm	Ti6Al4V ELI	
		2100-2402	23.5*11*11mm	Ti6Al4V ELI	
		2100-2403	23.5*11*13mm	Ti6Al4V ELI	
Posterior Lumbar Interbody Fusion Cage		2100-2501	8x10x20mm	Ti6Al4V ELI	
		2100-2502	8x10x22mm	Ti6Al4V ELI	
		2100-2503	8x10x26mm	Ti6Al4V ELI	
		2100-2504	10x10x20mm	Ti6Al4V ELI	
		2100-2505	10x10x22mm	Ti6Al4V ELI	
		2100-2506	10x10x26mm	Ti6Al4V ELI	
		2100-2507	12x10x20mm	Ti6Al4V ELI	
		2100-2508	12x10x22mm	Ti6Al4V ELI	
		2100-2509	12x10x26mm	Ti6Al4V ELI	
Titanium Mesh Cage (Prismatic Hole)		2100-2601	10 x 40-100mm	Ti6Al4V ELI	LOT 1
		2100-2602	12 x 40-100mm	Ti6Al4V ELI	LOT 1
		2100-2603	14 x 40-100mm	Ti6Al4V ELI	LOT 1
		2100-2604	16 x 40-100mm	Ti6Al4V ELI	LOT 1
		2100-2605	18 x 40-100mm	Ti6Al4V ELI	LOT 1
		2100-2606	20 x 40-100mm	Ti6Al4V ELI	LOT 1
		2100-2607	24 x 40-100mm	Ti6Al4V ELI	LOT 1
		2100-2608	28 x 40-100mm	Ti6Al4V ELI	LOT 1
Hook System					
Laminar Hook		2100-2701	Small	Ti6Al4V ELI	
		2100-2702	Medium	Ti6Al4V ELI	
		2100-2703	Large	Ti6Al4V ELI	
Pedicle Hook		2100-2801	Small	Ti6Al4V ELI	
		2100-2802	Medium	Ti6Al4V ELI	
		2100-2803	Large	Ti6Al4V ELI	

PAJUNK®

TrokaBone / TrokaCut

Aspiration and puncture cannulas for bone marrow biopsy



Bone marrow biopsy

LOT 9, LOT 19

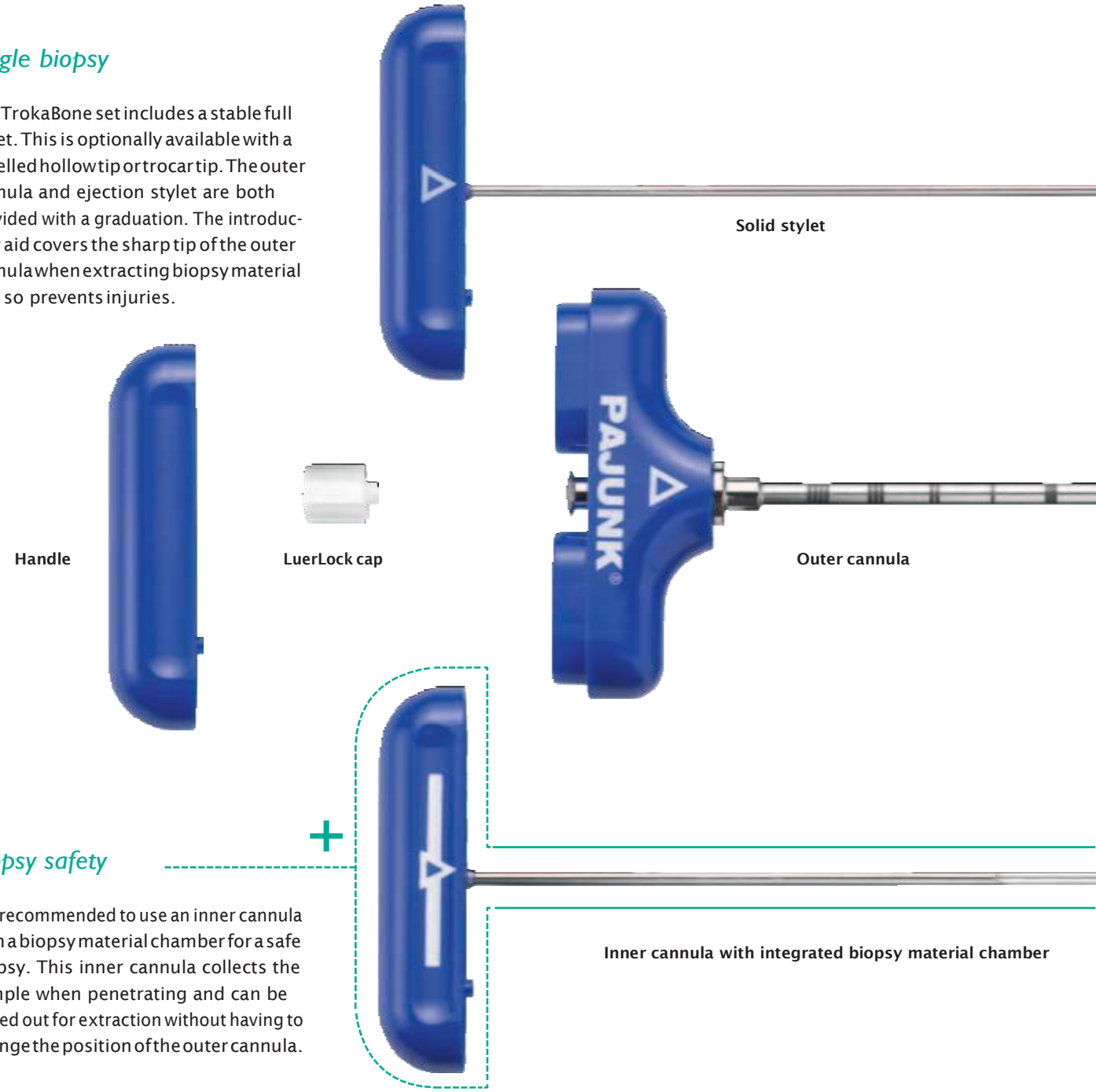
TrokaBone

The robust complete system with stainless steel connection

The TrokaBone puncture set of equipment from PAJUNK® consists of a modular system for the extraction of bone marrow samples. This set is very easy to use for puncture and aspiration. Fitted with an ergonomic handle and manufacturer in robust stainless steel, TrokaBone is characterised by its high level of stability.

Single biopsy

The TrokaBone set includes a stable full stylet. This is optionally available with a bevelled hollow tip or trocar tip. The outer cannula and ejection stylet are both provided with a graduation. The introductory aid covers the sharp tip of the outer cannula when extracting biopsy material and so prevents injuries.



Biopsy safety

It is recommended to use an inner cannula with a biopsy material chamber for a safe biopsy. This inner cannula collects the sample when penetrating and can be pulled out for extraction without having to change the position of the outer cannula.

TrokaBone

Biopsy cannula with alternative tip geometries

A bevelled tip or trocar tip is used to puncture at the pelvic crest. The puncture cannula is advanced forward into the bone wall under clockwise / counter clockwise rotation while applying firm and constant pressure. When it has penetrated and the resistance is reduced, the stylet is pulled out. The outer cannula has a very sharp, serrated tip. The cannula continues to penetrate into the inside of the bone under rotary movements without problem. The cannula tip is cylindrical and tapers towards the front. This eases collection and subsequent extraction of the sample. At the same time, its conical shape contributes to the tissue cylinder maintaining its structure during tissue extraction.

The essential features at a glance:

- *anatomically shaped handle*
- *extremely sharp serrated tip of the outer cannula*
- *full stylet made of stainless steel with high stability*
- *cannula versions with bevelled tip, trocar tip and inner cannula*
- *tapered outer cannula for simplified sample extraction*
- *specially shaped internal lumen*
- *aspiration connection with LuerLock connector*

Tapered cannula tip, serrated tip

Cutting tip with bevelled hollow grind

Sharp tip with trocar grind

TrokaCut

Product	Size	Art. No.	PU
Set for bone marrow biopsy with bevelled hollow tip	13 G x 100 mm (2.4 mm)	1147-1C010	5
	11 G x 100 mm (3.0 mm)	1147-1E010	5
	11 G x 150 mm (3.0 mm)	1147-1E015	5
	8 G x 100 mm (4.0 mm)	1147-1I010	5
	8 G x 150 mm (4.0 mm)	1147-1I015	5
Set for bone marrow biopsy with bevelled hollow tip and inner cannula	11 G x 100 mm (3.0 mm)	1147-6E010	5
	8 G x 100 mm (4.0 mm)	1147-6I010	5

TrokaBone

		Bevelled hollow tip	Trocar tip	
Product	Size	Art. No.	Art. No.	PU
Set for bone marrow biopsy with inner cannula	13 G x 150 mm (2.4 mm)	1145-1C015	1145-2C015	5
	11 G x 100 mm (3.0 mm)	1145-1E010	1145-2E010	5
	11 G x 150 mm (3.0 mm)	1145-1E015	1145-2E015	5
	8 G x 100 mm (4.0 mm)	1145-1I010	1145-2I010	5
	8 G x 150 mm (4.0 mm)	1145-1I015	1145-2I015	5
Set for bone marrow biopsy	11 G x 100 mm (3.0 mm)	1145-6E010		5
	8 G x 100 mm (4.0 mm)	1145-6I010		5

TrokaBone Sternal

Working length 5–25 mm

Product	Size	Art. No.	PU
Set for bone marrow biopsy in sternum region	18 G x 50 mm (1.2 mm)	1146-1D025	5
	17 G x 50 mm (1.5 mm)	1146-1G025	5
	15 G x 50 mm (1.8 mm)	1146-1K025	5
	14 G x 50 mm (2.0 mm)	1146-1M025	5

PAJUNK GmbH
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www.pajunk.com

XS200162A09/11

LOT 7, LOT 8, LOT 19

Article	Packaging Size	Art.-No.
BonOs® Inject 1 x 24 CE-Version	1 x 24 g	01-0310

BonOs® Inject

Bone Cement for Spinal Applications

OSARTIS GmbH
Auf der Beune 101, 64839 Münster, Germany
Subsidiary: Lagerstraße 11-15, 64807 Dieburg, Germany
phone +49 (0) 6071 - 929 0 **e-mail** info@osartis.de
fax +49 (0) 6071 - 929 100 **web** www.osartis.de

141-1010-03EN / 082020

BonOs® Inject

PMMA is been used in orthopedics for almost 50 years.
Within that time the indication fields have been extended step by step until in the 80's PMMA cements were applied in spinal surgery, too. There, they serve to stabilize, to fill cavities of erected vertebral bodies and to eliminate pain. For these specific indications BonOs® Inject was developed.

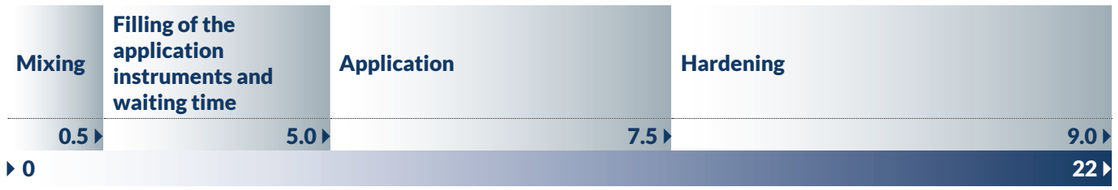
BonOs® Inject fulfills all requirements for bone cements in spinal surgery:

- Suitable viscosity for vertebroplasty and kyphoplasty
- Approved for the augmentation of pedicle screws where bone quality is poor, e.g. in patients with osteoporosis or degenerative or neoplastic changes.
- Short mixing time, long application time
- Fast achievement of application viscosity
- High radiodensity with 45 % ZrO_2
- Good fatigue strength

Long application time

Both components bind quickly to a homogenous paste with the suitable viscosity for percutaneous injection. After a short mixing time, the surgeon has sufficient time for the transfer of BonOs® Inject in the application instruments followed by a long application time.

Max. Time [Min.] at 21°C*



Temperature-Time-chart (Example for 21°C)
Test conditions: Application needle: ø 3 mm, length 210 mm, Syringe capacity: 1 ml
* For further information see the Instructions for Use

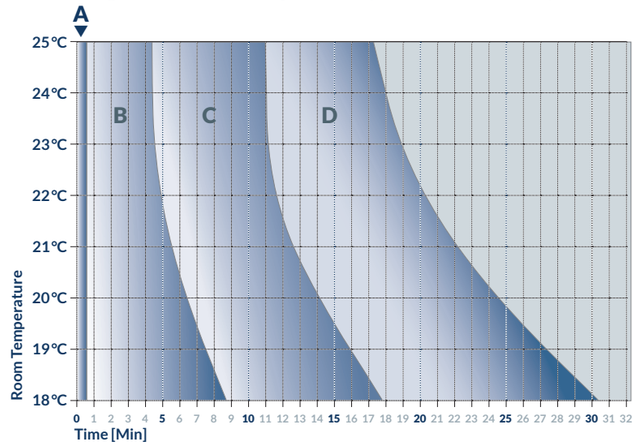
Bone cement volume

When both components of BonOs® Inject – powder and monomer – are mixed, the PMMA bone cement volume of 25 ml is generated. Depending on parameters such as temperature, mixing system, type of syringes and filling time the cement volume available for injection will differ.

Syringe type	Available cement volume** for augmentation, if BonOs® Inject is mixed with EASYMIX® shaker	Available cement volume** for augmentation, if BonOs® Inject is mixed with ManuMix®
1 ml	15 ml	20 ml
3 ml	20 ml	22 ml
6 ml	21 ml	23 ml

Overview of the mean value of available cement volume for augmentation of BonOs® Inject used with different mixing systems and syringe types
** OSARTIS internal reports; Tests were conducted under standardized conditions (23°C)

Handling Chart BonOs® Inject (Temperature-Time-Graph)



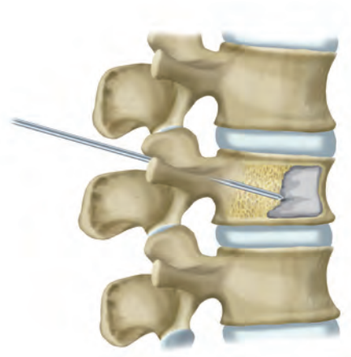
A: Mixing Phase (30 sec) | **B:** Syringe Filling and Waiting Phase
C: Injection Phase | **D:** Hardening Phase

Fast achievement of application viscosity

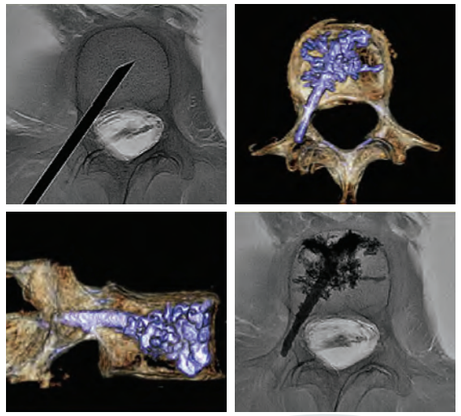
The composition of the polymers ensures a high initial cohesion and therefore reduces the risk of cement leakage.
After a short waiting time the cement attains an ideal viscosity for application. BonOs® Inject can be used for vertebroplasty, kyphoplasty as well as for the augmentation of pedicle screws.

High radiopacity

The addition of zirconium dioxide (ZrO_2) allows an optimal X-ray visualization of BonOs® Inject for a safe use.



Example of a cemented vertebra



X-ray Images
Cadaver Tests © PD Dr. K. Wilhelm, Bonn

Good mechanical properties

The composition of BonOs® Inject guarantees optimized mechanical properties which exceed the respective requirements of the ISO 5833 standard. Thanks to its medium viscosity, BonOs® Inject can be used with all currently approved PMMA cements application tools.

Chemical composition

Powder (24 g)	
Poly(methyl methacrylate)	10.95 g
Poly(methyl acrylate / methyl methacrylate)	1.75 g
Zirconium dioxide	10.80 g
Benzoyl peroxide	0.50 g

Liquid (10 ml)	
Methyl methacrylate	9.93 ml
Dimethyl-p-toluidine	0.07 ml
Hydroquinone	60 ppm

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ 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, Mb or III)

No. G1 18 06 05033 001

Manufacturer:

OSARTIS GmbH
LagerstralJe 11-15
64807 Dieburg
GERMANY

Facility(ies):

OSARTIS GmbH
LagerstralJe 11-15, 64807 Dieburg, GERMANY

OSARTIS GmbH
Nordring 29, 64807 Dieburg, GERMANY

OSARTIS GmbH
BenzstralJe 4, 64807 Dieburg, GERMANY

Product Category(ies):

Mixing and delivery devices for bone cements and sterile accessories (class IIa), bone substitute materials (class III), bone cements (class Mb + class III), and collagen products (class III)

The Certification Body of TOV 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.: 713128814

Valid from: 2020-10-02
Valid until: 2024-10-01

Date, 2020-10-02

Stefan PreilJ

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

TOV®

1

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 107266 0011 Rev. 00

Holder of Certificate: **OSARTIS GmbH**
Auf der Beune 101
64839 Münster
GERMANY

Facility(ies):

OSARTIS GmbH
Auf der Beune 101, 64839 Münster, GERMANY

OSARTIS GmbH
Lagerstraße 11-15, 64807 Dieburg, GERMANY

OSARTIS GmbH
Nordring 29, 64807 Dieburg, GERMANY

OSARTIS GmbH
Benzstraße 4, 64807 Dieburg, GERMANY

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Bone Cements, Mixing and Delivery Devices for Bone Cements (including Accessories), Cementing Technique, Bone Substitute Materials including Application Devices, Collagen Products**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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

Report No.: 713182104
Valid from: 2020-05-28
Valid until: 2023-04-30

Date, 2020-05-28

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

A4 / 07.17

EC CERTIFICATE

for the Quality Assurance System

according the directive 93/42/EEC, Annex II excluding section (4)

As a notified body of the European Union, DEKRA Certification GmbH certifies, that the company

PAJUNK GmbH Medizintechnologie

Karl-Hall-Strafie 1, 78187 Geisingen, Germany

applies a quality assurance system for the medical devices listed in the annex according to the directive 93/42/EEC annex II. The approval is based on the result of the re-certification audit report no. 51365-2-00, the decision dated 2020-09-20 is only valid in connection with the successful performance of the annual surveillance audits.

Date of the first certification:	2010-03-22	Date of the last recertification:	2020-09-22
This certificate is valid until:	2024-09-21	Certificate registration No.:	51365-16-01

DEKRA Certification GmbH
Stuttgart, 2015-03-20
Notified Body ID-number: 0124

Benannt durcWDesignated by
Zentfalstelle det Lander for Gesundheitsschutz bei Arzneimmeln und Medizinprodukten
ZLG-BS-295.10.02

Lack of fulfilment on conditions as set out in the Certification Agreement may render this certificate invalid.

EC Certificate

Directive 93/42/EEC Annex ii, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60126784 0001

Report No.: 15099781 001

Manufacturer:

Jiangsu Jinlu Group Medical Device
Co., Ltd.
Jinfeng Town
Zhangjiagang City
215625 Jiangsu
China

Products:

- Metal Bone Plates & Screw Systems
- Metallic Cannulated Bone Screws
- Metallic Interlocking Intramedullary Nails
- Spinal Fixation Devices
- External Fixation Devices with Needles
- Suture Wires

Expiry Date: 2024-12-11

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-12-11

Date: 2020-12-11

X. Ren

TÜV Rheinland LGA Products GmbH - TillystraTse 2 - 90431 Nurnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Jiangsu Jinlu Group Medical Device Co., Ltd.
Jinfeng Town
Zhangjiagang City
215625 Jiangsu
China

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of Medical Devices
(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-06-30
Certificate Registration No.:	SX 60125147 0001
An audit was performed Report No.:	15097822 001
This Certificate is valid until:	2024-06-30

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2020-06-30

X Ren

TÜV Rheinland LGA Products GmbH - Tillystralie 2 - 90431 Niirnberg
Tel : +49 221 806-1371 Fax: +49 221 806-3935 e-mail·cert-validity@de tuv com http.//www tuv com/safety

LOT 11

AT A GLANCE

Ti-LIFE Technology
Integrated Screw Channel
High Performance Screw
One Step Cam Lock

INDICATIONS

The SCARLET® AL-T system is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one isolated level from L5-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level. These spinal implants are to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Used with the integrated fixation by the mean of the bone screws provided, the SCARLET® AL-T is a stand-alone system and requires no additional supplemental fixation system.

IMPLANTS

SMALL FOOTPRINT D24 MM X W32 MM
LORDOSIS: 10°

HEIGHT	REFERENCE
H10	SCA-LS 10 10-S
H12	SCA-LS 10 12-S
H14	SCA-LS 10 14-S
H16	SCA-LS 10 16-S

SMALL FOOTPRINT D24 MM X W32 MM
LORDOSIS: 15°

HEIGHT	REFERENCE
H10	SCA-LS 15 10-S
H12	SCA-LS 15 12-S
H14	SCA-LS 15 14-S
H16	SCA-LS 15 16-S

MEDIUM FOOTPRINT D27 MM X W36 MM
LORDOSIS: 10°

HEIGHT	REFERENCE
H10	SCA-LM 10 10-S
H12	SCA-LM 10 12-S
H14	SCA-LM 10 14-S
H16	SCA-LM 10 16-S

MEDIUM FOOTPRINT D27 MM X W36 MM
LORDOSIS: 15°

HEIGHT	REFERENCE
H12	SCA-LM 15 12-S
H14	SCA-LM 15 14-S
H16	SCA-LM 15 16-S

LARGE FOOTPRINT D30 MM X W40 MM
LORDOSIS: 10°

HEIGHT	REFERENCE
H10	SCA-LL 10 10-S
H12	SCA-LL 10 12-S
H14	SCA-LL 10 14-S
H16	SCA-LL 10 16-S

LARGE FOOTPRINT D30 MM X W40 MM
LORDOSIS: 15°

HEIGHT	REFERENCE
H12	SCA-LL 15 12-S
H14	SCA-LL 15 14-S
H16	SCA-LL 15 16-S

IMPLANTS

DIA 5.0 MM

LENGTH	REFERENCE
L25	SJT-LS 50 25-S
L30	SJT-LS 50 30-S
L35	SJT-LS 50 35-S
L40	SJT-LS 50 40-S

DIA 5.5 MM

LENGTH	REFERENCE
L25	SJT-LS 55 25-S
L30	SJT-LS 55 30-S
L35	SJT-LS 55 35-S
L40	SJT-LS 55 40-S

TECHNICAL FEATURES

Ti-LIFE TECHNOLOGY

The structure mimics the bone trabecular geometry and is designed to allow bone in-growth. This technology is based on a propriety algorithm associated with a unique additive manufacturing process, commonly referred to as 3D printing.

ZERO PROFILE

The screw heads are completely integrated within the cage. Zero-profile implants may limit the risk of damage to vessels and adjacent soft tissues.

SCREW ANTI-BACKOUT SYTEM

The cages feature a channel to ease screw insertion.
The zero-profile one-step locking mechanism with pre-assembled cam locks prevent screw migration.

COMPREHENSIVE RANGE

10° and 15° lordosis
3 footprints

INSTRUMENT SETS

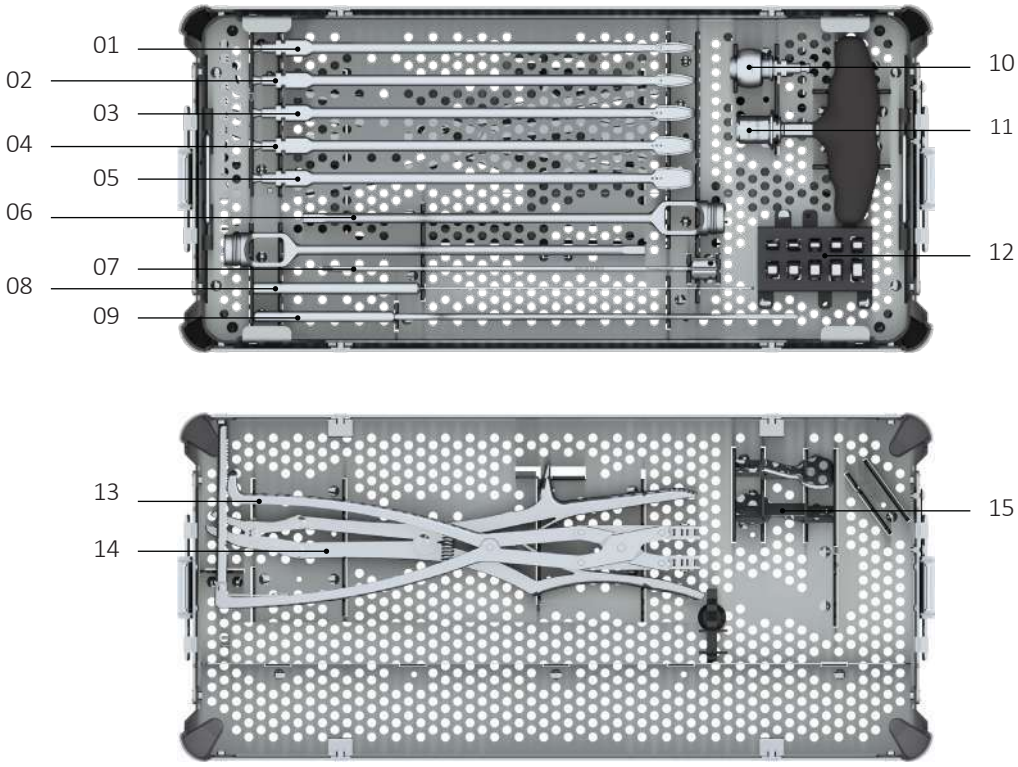
DISC PREPARATION 1

#	DESCRIPTION	REFERENCE
01	PITUITARY RONGEUR, STRAIGHT, 5MM	SCA-IN 21 00-N
02	PITUITARY RONGEUR, STRAIGHT, 3MM	SCA-IN 22 00-N
03	PITUITARY RONGEUR, 3MM, UP	SCA-IN 21 01-N
04	PITUITARY RONGEUR, 5MM, UP	SCA-IN 22 01-N
05	KERRISON RONGEUR, 5MM, 40DEG UP	JLL-IN 14 05-N
06	KERRISON RONGEUR, 3MM, 40DEG UP	SCA-IN 23 00-N

#	DESCRIPTION	REFERENCE
07	STRAIGHT RING CURETTE, 15MM	SCA-IN 09 02-N
08	ANGLED RING CURETTE, 15MM	SCA-IN 09 03-N
09	CUP CURETTE, STRAIGHT, SIZE «2»	SCA-IN 12 00-N
10	CUP CURETTE, ANGLED, DOWN, SIZE «2»	SCA-IN 12 01-N
11	CUP CURETTE, STRAIGHT, SIZE «4»	SCA-IN 24 00-N
12	CUP CURETTE, ANGLED, DOWN, SIZE «4»	SCA-IN 24 01-N
13	FLAT COBB, 30 MM	SCA-IN 10 02-N
14	COBB, 25MM, 10° UP	SCA-IN 10 01-N
15	RASP, STRAIGHT, 14MM	SCA-IN 08 00-N

INSTRUMENT SETS

DISC PREPARATION 2

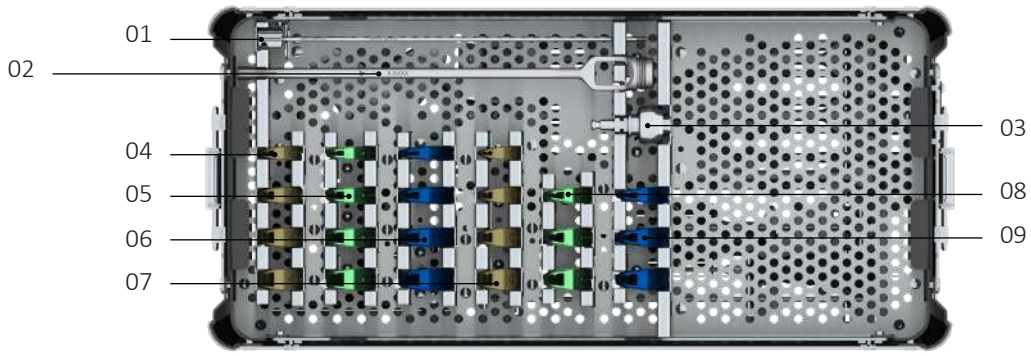


#	DESCRIPTION	REFERENCE
01	DISC SHAVER H08	SCA-IN 14 08-N
02	DISC SHAVER H10	SCA-IN 14 10-N
03	DISC SHAVER H12	SCA-IN 14 12-N
04	DISC SHAVER H14	SCA-IN 14 14-N
05	DISC SHAVER H16	SCA-IN 14 16-N
06	PADDLE DISTRACTOR HOLDER	SCA-IN 15 00-N
07	THREADED SHAFT	SCA-IN 18 00-N
08	BALL TIP PROBE	SCA-IN 20 00-N
09	BLUNT DISSECTOR	JLL-IN 00 01-N
10	HUDSON CONNECTOR	SCA-IN 17 00-N
11	T-HANDLE (HUDSON CONNECTION)	HAN-SI MH TE-N

#	DESCRIPTION	REFERENCE
12	PADDLE DISTRACTOR H07	SCA-IN 15 07-N
	PADDLE DISTRACTOR H08	SCA-IN 15 08-N
	PADDLE DISTRACTOR H09	SCA-IN 15 09-N
	PADDLE DISTRACTOR H10	SCA-IN 15 10-N
	PADDLE DISTRACTOR H11	SCA-IN 15 11-N
	PADDLE DISTRACTOR H12	SCA-IN 15 12-N
	PADDLE DISTRACTOR H13	SCA-IN 15 13-N
	PADDLE DISTRACTOR H14	SCA-IN 15 14-N
	PADDLE DISTRACTOR H15	SCA-IN 15 15-N
	PADDLE DISTRACTOR H16	SCA-IN 15 16-N
13	PARALLEL DISTRACTOR	ELL-IN 01 07-N
14	LEKSELL DOUBLE-ACTION RONGEUR, 8MM	SCA-IN 13 00-N
15	PARALLEL DISTRACTOR / ENDTIP	SCA-IN 01 00-N

INSTRUMENT SETS

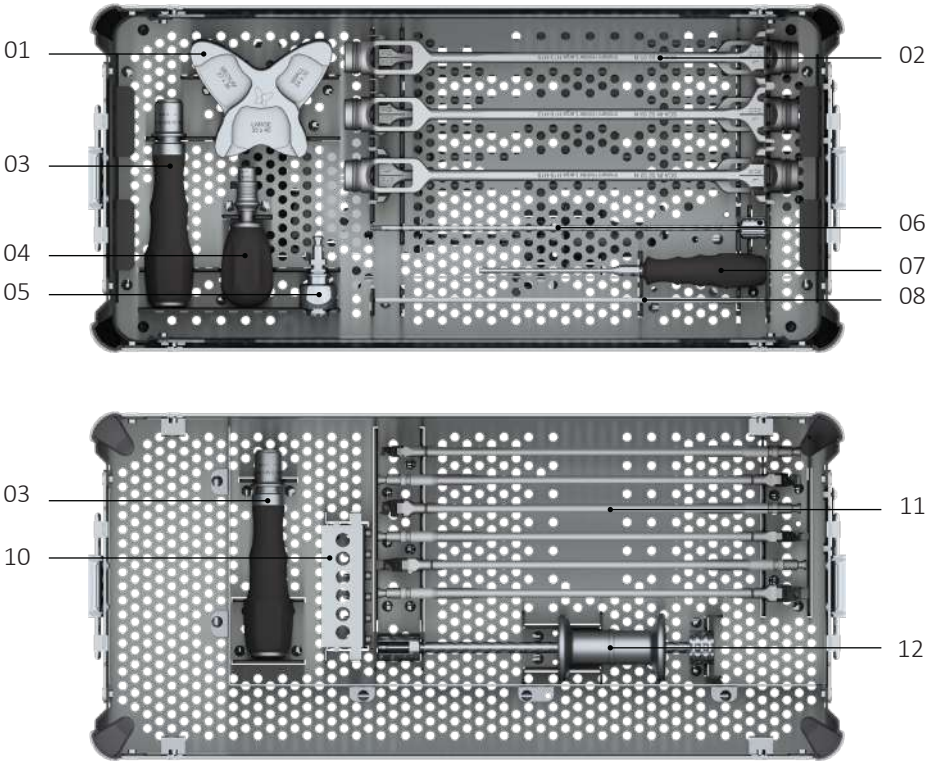
IMPLANT TRIALS AND CAGES INSERTION



#	DESCRIPTION	REFERENCE
01	THREADED SHAFT	SCA-IN 18 00-N
02	TRIAL INSERTER	SCA-IN 05 00-N
03	HUDSON CONNECTOR	SCA-IN 17 00-N
04	TRIAL SMALL H10 LORDOSIS 10°	SCA-TS 10 10-N
	TRIAL SMALL H12 LORDOSIS 10°	SCA-TS 10 12-N
	TRIAL SMALL H14 LORDOSIS 10°	SCA-TS 10 14-N
	TRIAL SMALL H16 LORDOSIS 10°	SCA-TS 10 16-N
05	TRIAL MEDIUM H10 LORDOSIS 10°	SCA-TM 10 10-N
	TRIAL MEDIUM H12 LORDOSIS 10°	SCA-TM 10 12-N
	TRIAL MEDIUM H14 LORDOSIS 10°	SCA-TM 10 14-N
	TRIAL MEDIUM H16 LORDOSIS 10°	SCA-TM 10 16-N
06	TRIAL LARGE H10 LORDOSIS 10°	SCA-TL 10 10-N
	TRIAL LARGE H12 LORDOSIS 10°	SCA-TL 10 12-N
	TRIAL LARGE H14 LORDOSIS 10°	SCA-TL 10 14-N
	TRIAL LARGE H16 LORDOSIS 10°	SCA-TL 10 16-N
07	TRIAL SMALL H10 LORDOSIS 15°	SCA-TS 15 10-N
	TRIAL SMALL H12 LORDOSIS 15°	SCA-TS 15 12-N
	TRIAL SMALL H14 LORDOSIS 15°	SCA-TS 15 14-N
	TRIAL SMALL H16 LORDOSIS 15°	SCA-TS 15 16-N
08	TRIAL MEDIUM H12 LORDOSIS 15°	SCA-TM 15 12-N
	TRIAL MEDIUM H14 LORDOSIS 15°	SCA-TM 15 14-N
	TRIAL MEDIUM H16 LORDOSIS 15°	SCA-TM 15 16-N
09	TRIAL LARGE H12 LORDOSIS 15°	SCA-TL 15 12-N
	TRIAL LARGE H14 LORDOSIS 15°	SCA-TL 15 14-N
	TRIAL LARGE H16 LORDOSIS 15°	SCA-TL 15 16-N

INSTRUMENT SETS

IMPLANT TRIALS AND CAGES INSERTION

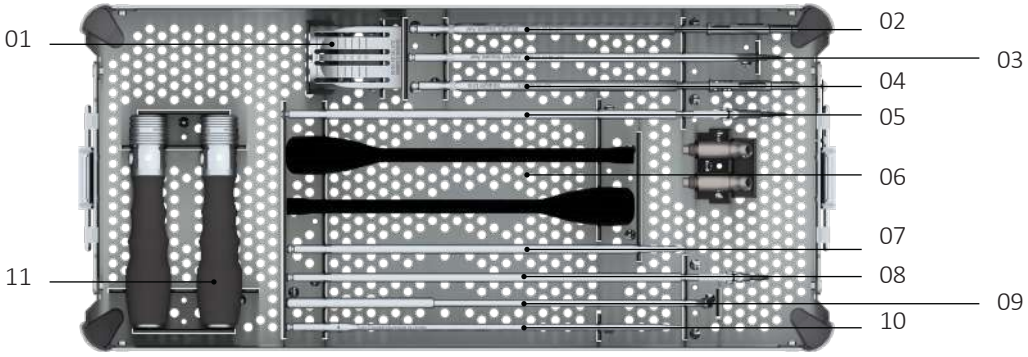


#	DESCRIPTION	REFERENCE
01	COMPACTION BASE	SCA-IN 07 00-N
02	IMPLANT HOLDERS: SMALL/MEDIUM H10-H12 SMALL/MEDIUM H13-H15 SMALL/MEDIUM H16-H18 LARGE H10-H12 LARGE H13-H15 LARGE H16-H18	 SCA-IN 01 01-N SCA-IN 01 02-N SCA-IN 01 03-N SCA-IN 02 00-N SCA-IN 02 01-N SCA-IN 02 02-N
03	STRAIGHT HANDLE (HUDSON CONNECTION)	HAN-SI MH SM-N
04	TORQUE LIMITING HANDLE (1NM) (PALM HANDLE)	HAN-SI AO PA-N
05	HUDSON CONNECTOR	SCA-IN 17 00-N
06	THREADED SHAFT	SCA-IN 18 00-N
07	COMPACTOR	SCA-IN 19 00-N
08	CAMLOCKER DRIVER	SCA-IN 06 00-N

#	DESCRIPTION	REFERENCE
10	LATERAL IMPLANT HOLDER SCREW M4X0.7	SCA-IN 16 00-N
11	LATERAL IMPLANT HOLDERS: SMALL/MEDIUM H10-H12 SMALL/MEDIUM H13-H15 SMALL/MEDIUM H16-H18 LARGE H10-H12 LARGE H13-H15 LARGE H16-H18	 SCA-IN 03 00-N SCA-IN 03 01-N SCA-IN 03 02-N SCA-IN 04 00-N SCA-IN 04 01-N SCA-IN 04 02-N
12	SLAP HAMMER	JLL-IN 12 00-N

INSTRUMENT SETS

SCREW INSERTION



#	DESCRIPTION	REFERENCE
01	SCREW LOADER	SJT-IN 04 00-N
02	STRAIGHT SQUARE AWL	SJT-IN 01 00-N
03	ANGLED SQUARE AWL	SJT-IN 01 01-N
04	STRAIGHT DRILL	SJT-IN 02 00-N
05	U-JOINT DRILL	SJT-IN 02 01-N
06	UNIVERSAL-JOINT TUBE AND UNIVERSAL JOINT ANGLED PART	SJT-IN 06 00-N
07	STRAIGHT SCREWDRIVER	SJT-IN 03 00-N
08	U-JOINT SCREWDRIVER	SJT-IN 03 01-N
09	U-JOINT GUIDE	SJT-IN 05 00-N
10	REVISION SCREWDRIVER	SJT-IN 03 02-N
11	STRAIGHT HANDLE RATCHET	HAN-SI RA ST-N

EC-Certificate

SQS as a conformity assessment body identification number 1250 herewith certifies the organisation

Spineart SA
Chemin du Pré-Fleuri 3
1228 Plan-les-Ouates
Switzerland

the use of a quality assurance system in its design, development, manufacturing and distribution which fulfills the requirements set out in:

ANNEX II — Directive 93/42/EEC (without section 4)

This approval is based on the report dated January 6, 2020.

The scope of validity covers the products

Sterile and non sterile spine instruments

The following CE label can be applied to the products mentioned in the Appendix of this certificate

CE 1250

A condition for the validity of this certificate is a regular examination in accordance with Annex II.5 of the Directive 93/42/EEC.

Reg. no. 45886

Validity 24.01.2020–25.05.2024
Issue 24.01.2020

Approved Medical Responsible
24.01.2020

F. Müller, CEO SQS

D. Taddeo, Medical Responsible

Swiss Association for Quality
and Management Systems (SQS)
Bernstrasse 103, 3052 Zollikofen, Switzerland

Swiss Made

Partner of IQNet

sqs.ch

4174_2/June 2019/Version 2.0

SZUTEST

EC CERTIFICATE
AT SERTİFİKA

According to Annex II of the Directive 93/42/EEC on Medical Devices
93/42/AT Tıbbi Cihaz Yönetmeliği Ek II'ye göre

Full Quality Assurance System
Tam Kalite Güvencesi

Certificate Number: 2195-MED-1404201
Sertifika Numarası

Manufacturer: **TRİA SPİNE MEDİKAL LTD. ŞTİ.**
Üretici
Head Office/Merkez: 1551. Sok. No:35/33 İvedik OSB Yenimahalle Ankara TÜRKİYE
Factory/Fabrika: 1551. Sok. No:35/21 İvedik OSB Yenimahalle Ankara TÜRKİYE

Product(s): **Sterile and Non-Sterile Spinal System Implants**
Ürün(ler) *Steril ve Steril Olmayan Spinal Sistem İmplantları*

Model(s): **Product specifications are given on the second page.**
Model(ler) *Ürün detayları ikinci sayfada verilmiştir.*

Reference Report No: MM0572-P005-R01, MM0572-P005-R02, MM0572-P005-R03
Referans Rapor No

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements

2195 kimlik numaralı Onaylanmış Kuruluş Szutest, yukanda belirtilen üreticinin 93/42/AT Tıbbi Cihaz Yönetmeliği EK II(madde 4 hariç) madde 3'üne göre bir kalite yönetim sistemi uyguladığını, bu yönetim sisteminin yönetmeliğin sadece bahsi geçen ürünün üretiminin güvenlik koşullarını sağlama ve devam ettirme ile ilgili gerekliliklerin karşıladığını beyan eder. Onaylanan bu kalite yönetim sistemi, 93/42/AT Tıbbi Cihaz Yönetmeliği EK II, Madde 5'e göre periyodik olarak gözetime ve habersiz saha denetimlerine tabidir.

Üretici, ürünlerinin tasarımında ve yapısında gerçekleştirdiği önemli değişiklikleri Szutest'e bildirmek zorundadır. Steril kondisyondaki sınıf I ürünler için kalite yönetim sistemi değerlendirmesi üretimin steril kondisyonun sağlanması ve korunmasıyla limitlidir. Ölçüm fonksiyonlu sınıf I ürünler için Kalite yönetim sistemi değerlendirmesi üretimin cihazlann metrolojik şartlara uyumunu sağlamasıyla limitlidir.

This EC certificate is valid till 2024-05-26.
Bu AT Sertifikası 2024-05-26 tarihine kadar geçerlidir.

Issue Date/*Yayın Tarihi:* 2014-02-11
Revision No./ *Revizyon No.:* 05 Recertification/*Yeniden Belgelendirme*
Revision Date/ *Revizyon Tarihi:* 2020-03-27

Rukiye BALKAN
Deputy General Manager
Genel Müdür Yardımcısı

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr

Certificate

SQS herewith certifies that the company named below has a management system which meets the requirements of the standard specified below.

Spineart SA
Chemin du Pré-Fleuri 3
1228 Plan-les-Ouates
Switzerland

Scope of certification

According to appendix

Field of activity

Design, manufacturing and sales of sterile and non-sterile spine medical devices

Normative base

EN ISO 13485:2016 Medical devices – Quality Management System

Validity 03. 10. 2017 – 02. 2022
Issue 27. 06. 2018

Reg. no. H31786

X. Edelmann, President SQS

R. Glauser, CEO SQS

sqs.ch

Swiss Association for Quality and Management Systems SQS
Bernstrasse 103, 3052 Zollikofen, Switzerland

Swiss Made

Partner of IQNet

SZUTEST

CERTIFICATE

Medical Devices Quality Management System

CERTIFICATE NO: 31910501

Tria Spine Medical Ltd. Şti.

Head Office : 1551. Sok. No:35 / 33 İvedik OSB Yenimahalle, Ankara TÜRKİYE

Factory : 1551. Sok. No:35 / 21 İvedik OSB Yenimahalle, Ankara TÜRKİYE

EN ISO 13485:2016

Design, Production and Sales of Sterile and Non-Sterile Neurosurgery and Non-Sterile Trauma Implants and Spinal Surgical Instruments

Approves that the Medical Devices Quality Management System implemented for above scope.

Issue Date	15.04.2019
Expiry Date	14.04.2023

TÜRKAK BDS NO YS-79CB-B206

TÜRKAK Tıbbi Cihazlar K. Y. S. TS EN ISO/IEC 17021 AB-0044-YS

Deputy General Manager

The certificate inquiry is made by reading the QR codes by mobile devices, providing necessary information on http://public.szutest.com.tr or by using BDS No on https://tdbs.turkak.org.tr.

LOT 16

PROCYON
Spinal System

Features

- The Polar 5.5/6.0 Spinal System is low profile system.
- The screws feature a dual - lead, dual thread conical design with blunt tip
- Screws available in 4.5mm. 5.5mm. 6.5mm. 7.5mm and 8.5mm diameters and multiple lengths
- Dual - lead thread pattern for faster insertation and increased pull out strength.
- Polyaxial Range of the motion for ease of use intraoperatively Ability to
- accept diameter 5.5 and 6.0 mm rod.

MIKRON Medikal Implants List		
Product Code	**Product Name**	**EAN Code**
TRANSPEDICULAR POSTERIOR FIXATION SYSTEM		
MSFX-PPMAS4025	POLAR Mono-Axial Screw 4.0x25mm	8680834327935
MSFX-PPMAS4030	POLAR Mono-Axial Screw 4.0x30mm	8680834327942
MSFX-PPMAS4035	POLAR Mono-Axial Screw 4.0x35mm	8680834327959
MSFX-PPMAS4040	POLAR Mono-Axial Screw 4.0x40mm	8680834327966
MSFX-PPMAS4525	POLAR Mono-Axial Screw 4.5x25mm	8680834327973
MSFX-PPMAS4530	POLAR Mono-Axial Screw 4.5x30mm	8680834327980
MSFX-PPMAS4535	POLAR Mono-Axial Screw 4.5x35mm	8680834301652
MSFX-PPMAS4540	POLAR Mono-Axial Screw 4.5x40mm	8680834301669
MSFX-PPMAS4545	POLAR Mono-Axial Screw 4.5x45mm	8680834301676
MSFX-PPMAS5030	POLAR Mono-Axial Screw 5.0x30mm	8680834327997
MSFX-PPMAS5035	POLAR Mono-Axial Screw 5.0x35mm	8680834328000
MSFX-PPMAS5040	POLAR Mono-Axial Screw 5.0x40mm	8680834328017
MSFX-PPMAS5045	POLAR Mono-Axial Screw 5.0x45mm	8680834328024
MSFX-PPMAS5050	POLAR Mono-Axial Screw 5.0x50mm	8680834328031
MSFX-PPMAS5530	POLAR Mono-Axial Screw 5.5x30mm	8680834328048
MSFX-PPMAS5535	POLAR Mono-Axial Screw 5.5x35mm	8680834301744
MSFX-PPMAS5540	POLAR Mono-Axial Screw 5.5x40mm	8680834301751
MSFX-PPMAS5545	POLAR Mono-Axial Screw 5.5x45mm	8680834301768
MSFX-PPMAS5550	POLAR Mono-Axial Screw 5.5x50mm	8680834301775
MSFX-PPMAS5555	POLAR Mono-Axial Screw 5.5x55mm	8680834301782
MSFX-PPMAS6035	POLAR Mono-Axial Screw 6.0x35mm	8680834328055
MSFX-PPMAS6040	POLAR Mono-Axial Screw 6.0x40mm	8680834328062
MSFX-PPMAS6045	POLAR Mono-Axial Screw 6.0x45mm	8680834328079
MSFX-PPMAS6050	POLAR Mono-Axial Screw 6.0x50mm	8680834301829
MSFX-PPMAS6050	POLAR Mono-Axial Screw 6.0x50mm	8680834328086
MSFX-PPMAS6055	POLAR Mono-Axial Screw 6.0x55mm	8680834328093
MSFX-PPMAS6535	POLAR Mono-Axial Screw 6.5x35mm	8680834301843
MSFX-PPMAS6540	POLAR Mono-Axial Screw 6.5x40mm	8680834301850
MSFX-PPMAS6545	POLAR Mono-Axial Screw 6.5x45mm	8680834301867
MSFX-PPMAS6550	POLAR Mono-Axial Screw 6.5x50mm	8680834301874
MSFX-PPMAS6555	POLAR Mono-Axial Screw 6.5x55mm	8680834328109
MSFX-PPMAS7035	POLAR Mono-Axial Screw 7.0x35mm	8680834328116
MSFX-PPMAS7040	POLAR Mono-Axial Screw 7.0x40mm	8680834328123
MSFX-PPMAS7045	POLAR Mono-Axial Screw 7.0x45mm	8680834328130
MSFX-PPMAS7050	POLAR Mono-Axial Screw 7.0x50mm	8680834328147
MSFX-PPMAS7055	POLAR Mono-Axial Screw 7.0x55mm	8680834328154
MSFX-PPMAS7535	POLAR Mono-Axial Screw 7.5x35mm	8680834301942
MSFX-PPMAS7540	POLAR Mono-Axial Screw 7.5x40mm	8680834301959
MSFX-PPMAS7545	POLAR Mono-Axial Screw 7.5x45mm	8680834301966
MSFX-PPMAS7550	POLAR Mono-Axial Screw 7.5x50mm	8680834301973
MSFX-PPMAS7555	POLAR Mono-Axial Screw 7.5x55mm	8680834328161
MSFX-PPMAS8035	POLAR Mono-Axial Screw 8.0x35mm	8680834328178
MSFX-PPMAS8040	POLAR Mono-Axial Screw 8.0x40mm	8680834328185
MSFX-PPMAS8045	POLAR Mono-Axial Screw 8.0x45mm	8680834328192
MSFX-PPMAS8050	POLAR Mono-Axial Screw 8.0x50mm	8680834328208
MSFX-PPMAS8055	POLAR Mono-Axial Screw 8.0x55mm	8680834328215
MSFX-PPMRS5535	POLAR Pedicular Reduction Mono-Axial Screw 4,5x35mm	8680834329281
MSFX-PPMRS5540	POLAR Pedicular Reduction Mono-Axial Screw 4,5x40mm	8680834329298
MSFX-PPMRS5545	POLAR Pedicular Reduction Mono-Axial Screw 4,5x45mm	8680834329304
MSFX-PPMRS5550	POLAR Pedicular Reduction Mono-Axial Screw 4,5x50mm	8680834329311
MSFX-PPMRS5535	POLAR Pedicular Reduction Mono-Axial Screw 5,5x35mm	8680834329281
MSFX-PPMRS5540	POLAR Pedicular Reduction Mono-Axial Screw 5,5x40mm	8680834329298
MSFX-PPMRS5545	POLAR Pedicular Reduction Mono-Axial Screw 5,5x45mm	8680834329304
MSFX-PPMRS5550	POLAR Pedicular Reduction Mono-Axial Screw 5,5x50mm	8680834329311
MSFX-PPMRS6035	POLAR Pedicular Reduction Mono-Axial Screw 6,0x35mm	8680834329328
MSFX-PPMRS6040	POLAR Pedicular Reduction Mono-Axial Screw 6,0x40mm	8680834329335
MSFX-PPMRS6045	POLAR Pedicular Reduction Mono-Axial Screw 6,0x45mm	8680834329342
MSFX-PPMRS6050	POLAR Pedicular Reduction Mono-Axial Screw 6,0x50mm	8680834329359
MSFX-PPMRS6535	POLAR Pedicular Reduction Mono-Axial Screw 6,5x35mm	8680834329366
MSFX-PPMRS6540	POLAR Pedicular Reduction Mono-Axial Screw 6,5x40mm	8680834329373
MSFX-PPMRS6545	POLAR Pedicular Reduction Mono-Axial Screw 6,5x45mm	8680834329380
MSFX-PPMRS6550	POLAR Pedicular Reduction Mono-Axial Screw 6,5x50mm	8680834329397
MSFX-PPMRS7035	POLAR Pedicular Reduction Mono-Axial Screw 7,0x30mm	8680834329403
MSFX-PPMRS7040	POLAR Pedicular Reduction Mono-Axial Screw 7,0x40mm	8680834329410
MSFX-PPMRS7045	POLAR Pedicular Reduction Mono-Axial Screw 7,0x45mm	8680834329427
MSFX-PPMRS7050	POLAR Pedicular Reduction Mono-Axial Screw 7,0x50mm	8680834329434
MSFX-PPMRS7055	POLAR Pedicular Reduction Mono-Axial Screw 7,0x55mm	8680834329441
MSFX-PPMRS7540	POLAR Pedicular Reduction Mono-Axial Screw 7,5x40mm	8680834329458
MSFX-PPMRS7545	POLAR Pedicular Reduction Mono-Axial Screw 7,5x45mm	8680834329465
MSFX-PPMRS7550	POLAR Pedicular Reduction Mono-Axial Screw 7,5x50mm	8680834329472
MSFX-PPMRS7555	POLAR Pedicular Reduction Mono-Axial Screw 7,5x55mm	8680834329489
MSFX-PPPS3525	POLAR Multifunctional Screw 3.5x25mm	8680834300624
MSFX-PPPS3530	POLAR Multifunctional Screw 3.5x30mm	8680834300631
MSFX-PPPS3535	POLAR Multifunctional Screw 3.5x35mm	8680834300648
MSFX-PPPS3540	POLAR Multifunctional Screw 3.5x40mm	8680834300655
MSFX-PPPS3545	POLAR Multifunctional Screw 3.5x45mm	8680834300662
MSFX-PPPS4520	POLAR Multifunctional Screw 4.5x20mm	8680834300679
MSFX-PPPS4525	POLAR Multifunctional Screw 4.5x25mm	8680834300686
MSFX-PPPS4530	POLAR Multifunctional Screw 4.5x30mm	8680834300693
MSFX-PPPS4535	POLAR Multifunctional Screw 4.5x35mm	8680834300709
MSFX-PPPS4540	POLAR Multifunctional Screw 4.5x40mm	8680834300716
MSFX-PPPS4545	POLAR Multifunctional Screw 4.5x45mm	8680834300723
MSFX-PPPS5030	POLAR Multifunctional Screw 5.0x30mm	8680834300730
MSFX-PPPS5035	POLAR Multifunctional Screw 5.0x35mm	8680834300747
MSFX-PPPS5040	POLAR Multifunctional Screw 5.0x40mm	8680834300754
MSFX-PPPS5045	POLAR Multifunctional Screw 5.0x45mm	8680834300761
MSFX-PPPS5050	POLAR Multifunctional Screw 5.0x50mm	8680834300778
MSFX-PPPS5520	POLAR Multifunctional Screw 5.5x20mm	8680834300785
MSFX-PPPS5525	POLAR Multifunctional Screw 5.5x25mm	8680834300792
MSFX-PPPS5530	POLAR Multifunctional Screw 5.5x30mm	8680834300808
MSFX-PPPS5535	POLAR Multifunctional Screw 5.5x35mm	8680834300815
MSFX-PPPS5540	POLAR Multifunctional Screw 5.5x40mm	8680834300822
MSFX-PPPS5545	POLAR Multifunctional Screw 5.5x45mm	8680834300839
MSFX-PPPS5550	POLAR Multifunctional Screw 5.5x50mm	8680834300846
MSFX-PPPS5555	POLAR Multifunctional Screw 5.5x55mm	8680834300853
MSFX-PPPS6035	POLAR Multifunctional Screw 6.0x35mm	8680834300860

MSFX-PPPS6040	POLAR Multifunctional Screw 6.0x40mm	8680834300877
MSFX-PPPS6045	POLAR Multifunctional Screw 6.0x45mm	8680834300884
MSFX-PPPS6050	POLAR Multifunctional Screw 6.0x50mm	8680834300891
MSFX-PPPS6055	POLAR Multifunctional Screw 6.0x55mm	8680834300907
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MSFX-PPPS6540	POLAR Multifunctional Screw 6.5x40mm	8680834300938
MSFX-PPPS6545	POLAR Multifunctional Screw 6.5x45mm	8680834300945
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MSFX-PPPS7040	POLAR Multifunctional Screw 7.0x40mm	8680834300983
MSFX-PPPS7045	POLAR Multifunctional Screw 7.0x45mm	8680834300990
MSFX-PPPS7050	POLAR Multifunctional Screw 7.0x50mm	8680834301003
MSFX-PPPS7055	POLAR Multifunctional Screw 7.0x55mm	8680834301010
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MSFX-PPPS8030	POLAR Multifunctional Screw 8.0x30mm	8680834301089
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MSFX-PPPS8040	POLAR Multifunctional Screw 8.0x40mm	8680834301102
MSFX-PPPS8045	POLAR Multifunctional Screw 8.0x45mm	8680834301119
MSFX-PPPS8050	POLAR Multifunctional Screw 8.0x50mm	8680834301126
MSFX-PPPS8055	POLAR Multifunctional Screw 8.0x55mm	8680834301133
MSFX-CPS5530	POLAR Cannulated Poly-Axial Screw 5.5x30mm	8680834327744
MSFX-CPS5535	POLAR Cannulated Poly-Axial Screw 5.5x35mm	8680834327751
MSFX-CPS5540	POLAR Cannulated Poly-Axial Screw 5.5x40mm	8680834301201
MSFX-CPS5545	POLAR Cannulated Poly-Axial Screw 5.5x45mm	8680834301218
MSFX-CPS5550	POLAR Cannulated Poly-Axial Screw 5.5x50mm	8680834301225
MSFX-CPS5555	POLAR Cannulated Poly-Axial Screw 5.5x55mm	8680834301232
MSFX-CPS6530	POLAR Cannulated Poly-Axial Screw 6.5x30mm	8680834327768
MSFX-CPS6535	POLAR Cannulated Poly-Axial Screw 6.5x35mm	8680834327775
MSFX-CPS6540	POLAR Cannulated Poly-Axial Screw 6.5x40mm	8680834301263
MSFX-CPS6545	POLAR Cannulated Poly-Axial Screw 6.5x45mm	8680834301270
MSFX-CPS6550	POLAR Cannulated Poly-Axial Screw 6.5x50mm	8680834301287
MSFX-CPS6555	POLAR Cannulated Poly-Axial Screw 6.5x55mm	8680834301294
MSFX-CPS7530	POLAR Cannulated Poly-Axial Screw 7.5x30mm	8680834327782
MSFX-CPS7535	POLAR Cannulated Poly-Axial Screw 7.5x35mm	8680834327799
MSFX-CPS7540	POLAR Cannulated Poly-Axial Screw 7.5x40mm	8680834301324
MSFX-CPS7545	POLAR Cannulated Poly-Axial Screw 7.5x45mm	8680834301331
MSFX-CPS7550	POLAR Cannulated Poly-Axial Screw 7.5x50mm	8680834301348
MSFX-CPS7555	POLAR Cannulated Poly-Axial Screw 7.5x55mm	8680834301355
MSFX-SSS6035	POLAR Sacro-Iliac Screw 6.0x35mm	8680834306770
MSFX-SSS6040	POLAR Sacro-Iliac Screw 6.0x40mm	8680834306787
MSFX-SSS6045	POLAR Sacro-Iliac Screw 6.0x45mm	8680834306794
MSFX-SSS6050	POLAR Sacro-Iliac Screw 6.0x50mm	8680834306800
MSFX-SSS6055	POLAR Sacro-Iliac Screw 6.0x55mm	8680834306817
MSFX-SSS7040	POLAR Sacro-Iliac Screw 7.0x40mm	8680834306824
MSFX-SSS7045	POLAR Sacro-Iliac Screw 7.0x45mm	8680834306831
MSFX-SSS7050	POLAR Sacro-Iliac Screw 7.0x50mm	8680834306848
MSFX-SSS7055	POLAR Sacro-Iliac Screw 7.0x55mm	8680834306855
MSFX-SSS7060	POLAR Sacro-Iliac Screw 7.0x60mm	8680834332465
MSFX-SSS7070	POLAR Sacro-Iliac Screw 7.0x70mm	8680834332472
MSFX-SSS7080	POLAR Sacro-Iliac Screw 7.0x80mm	8680834332489
MSFX-SSS7090	POLAR Sacro-Iliac Screw 7.0x90mm	8680834332496
MSFX-SSS70100	POLAR Sacro-Iliac Screw 7.0x100mm	8680834332502
MSFX-SSS8035	POLAR Sacro-Iliac Screw 8.0x35mm	8680834332519
MSFX-SSS8040	POLAR Sacro-Iliac Screw 8.0x40mm	8680834332526
MSFX-SSS8045	POLAR Sacro-Iliac Screw 8.0x45mm	8680834332533
MSFX-SSS8050	POLAR Sacro-Iliac Screw 8.0x50mm	8680834332540
MSFX-SSS8055	POLAR Sacro-Iliac Screw 8.0x55mm	8680834332557
MSFX-SSS8060	POLAR Sacro-Iliac Screw 8.0x60mm	8680834332564
MSFX-SSS8070	POLAR Sacro-Iliac Screw 8.0x70mm	8680834332571
MSFX-SSS8080	POLAR Sacro-Iliac Screw 8.0x80mm	8680834332588
MSFX-SSS8090	POLAR Sacro-Iliac Screw 8.0x90mm	8680834332595
MSFX-SSS80100	POLAR Sacro-Iliac Screw 8.0x100mm	8680834332601
MSFX-PPRPS4525	POLAR Poly-Axial Reduction Screw 4,5x30mm	8680834329280
MSFX-PPRPS4530	POLAR Poly-Axial Reduction Screw 4,5x35mm	8680834329281
MSFX-PPRPS4535	POLAR Poly-Axial Reduction Screw 4,5x40mm	8680834329298
MSFX-PPRPS4540	POLAR Poly-Axial Reduction Screw 4,5x45mm	8680834329304
MSFX-PPRPS4545	POLAR Poly-Axial Reduction Screw 4,5x50mm	8680834329311
MSFX-PPRPS5030	POLAR Poly-Axial Reduction Screw 5.0x30mm	8680834330447
MSFX-PPRPS5035	POLAR Poly-Axial Reduction Screw 5.0x35mm	8680834330454
MSFX-PPRPS5040	POLAR Poly-Axial Reduction Screw 5.0x40mm	8680834330461
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MSFX-PPRPS5530	POLAR Poly-Axial Reduction Screw 5.5x30mm	8680834302307
MSFX-PPRPS5535	POLAR Poly-Axial Reduction Screw 5.5x35mm	8680834302314
MSFX-PPRPS5540	POLAR Poly-Axial Reduction Screw 5.5x40mm	8680834302321
MSFX-PPRPS5545	POLAR Poly-Axial Reduction Screw 5.5x45mm	8680834302338
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MSFX-PPRPS5555	POLAR Poly-Axial Reduction Screw 5.5x55mm	8680834302352
MSFX-PPRPS6035	POLAR Poly-Axial Reduction Screw 6.0x35mm	8680834302369
MSFX-PPRPS6040	POLAR Poly-Axial Reduction Screw 6.0x40mm	8680834302376
MSFX-PPRPS6045	POLAR Poly-Axial Reduction Screw 6.0x45mm	8680834302383
MSFX-PPRPS6050	POLAR Poly-Axial Reduction Screw 6.0x50mm	8680834302390
MSFX-PPRPS6535	POLAR Poly-Axial Reduction Screw 6.5x35mm	8680834302406
MSFX-PPRPS6540	POLAR Poly-Axial Reduction Screw 6.5x40mm	8680834302413
MSFX-PPRPS6545	POLAR Poly-Axial Reduction Screw 6.5x45mm	8680834302420
MSFX-PPRPS6550	POLAR Poly-Axial Reduction Screw 6.5x50mm	8680834302437
MSFX-PPRPS6555	POLAR Poly-Axial Reduction Screw 6.5x55mm	8680834302444
MSFX-PPRPS7035	POLAR Poly-Axial Reduction Screw 7.0x35mm	8680834302451
MSFX-PPRPS7040	POLAR Poly-Axial Reduction Screw 7.0x40mm	8680834302468
MSFX-PPRPS7045	POLAR Poly-Axial Reduction Screw 7.0x45mm	8680834302475
MSFX-PPRPS7050	POLAR Poly-Axial Reduction Screw 7.0x50mm	8680834302482
MSFX-PPRPS7055	POLAR Poly-Axial Reduction Screw 7.0x55mm	8680834302499

MSFX-PPRPS7535	POLAR Poly-Axial Reduction Screw 7.5x35mm	8680834302505
MSFX-PPRPS7540	POLAR Poly-Axial Reduction Screw 7.5x40mm	8680834302512
MSFX-PPRPS7545	POLAR Poly-Axial Reduction Screw 7.5x45mm	8680834302529
MSFX-PPRPS7550	POLAR Poly-Axial Reduction Screw 7.5x50mm	8680834302536
MSFX-PPRPS7560	POLAR Poly-Axial Reduction Screw 7.5x60mm	8680834302543
LH0505	POLAR Laminar Hook 5x5mm	8680834306558
LH0507	POLAR Laminar Hook 5x7mm	8680834306565
LH0509	POLAR Laminar Hook 5x9mm	8680834306572
LH0706	POLAR Laminar Hook 7x6mm	8680834306589
LH0707	POLAR Laminar Hook 7x7mm	8680834306596
LH0709	POLAR Laminar Hook 7x9mm	8680834306602
LH0711	POLAR Laminar Hook 7x11mm	8680834306619
PH0805	POLAR Pedicular Hook, Small 8x5mm	8680834306503
PH0807	POLAR Pedicular Hook, Small 8x7mm	8680834306510
PH0809	POLAR Pedicular Hook, Small 8x9mm	8680834306527
Ti SR1604	POLAR Rod 6,0x40mm	8680834305469
Ti SR1605	POLAR Rod 6,0x50mm	8680834305476
Ti SR1606	POLAR Rod 6,0x60mm	8680834305483
Ti SR1607	POLAR Rod 6,0x70mm	8680834305490
Ti SR1608	POLAR Rod 6,0x80mm	8680834305506
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Ti SR1610	POLAR Rod 6,0x100mm	8680834305520
Ti SR1611	POLAR Rod 6,0x110mm	8680834305537
Ti SR1612	POLAR Rod 6,0x120mm	8680834305544
Ti SR1613	POLAR Rod 6,0x130mm	8680834305551
Ti SR1614	POLAR Rod 6,0x140mm	8680834305568
Ti SR1615	POLAR Rod 6,0x150mm	8680834305575
Ti SR1616	POLAR Rod 6,0x160mm	8680834305582
Ti SR1617	POLAR Rod 6,0x170mm	8680834305599
Ti SR1618	POLAR Rod 6,0x180mm	8680834305605
Ti SR1619	POLAR Rod 6,0x190mm	8680834305612
Ti SR1620	POLAR Rod 6,0x200mm	8680834305629
Ti SR1621	POLAR Rod 6,0x210mm	8680834305636
Ti SR1622	POLAR Rod 6,0x220mm	8680834305643
Ti SR1623	POLAR Rod 6,0x230mm	8680834305650
Ti SR1624	POLAR Rod 6,0x240mm	8680834305667
Ti SR1625	POLAR Rod 6,0x250mm	8680834305674
Ti SR1626	POLAR Rod 6,0x260mm	8680834305681
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Ti SR1628	POLAR Rod 6,0x280mm	8680834305704
Ti SR1629	POLAR Rod 6,0x290mm	8680834305711
Ti SR1630	POLAR Rod 6,0x300mm	8680834305728
Ti SR1631	POLAR Rod 6,0x310mm	8680834305735
Ti SR1632	POLAR Rod 6,0x320mm	8680834305742
Ti SR1640	POLAR Rod 6,0x400mm	8680834305759
Ti SR1648	POLAR Rod 6,0x480mm	8680834305766
Ti SR1650	POLAR Rod 6,0x500mm	8680834305773
Ti SR1660	POLAR Rod 6,0x600mm	8680834305780
Cocr SR1604	POLAR Rod 6,0x40mm	8680834312658
Cocr SR1605	POLAR Rod 6,0x50mm	8680834312665
Cocr SR1606	POLAR Rod 6,0x60mm	8680834312672
Cocr SR1607	POLAR Rod 6,0x70mm	8680834312689
Cocr SR1608	POLAR Rod 6,0x80mm	8680834312696
Cocr SR1609	POLAR Rod 6,0x90mm	8680834312702
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Cocr SR1611	POLAR Rod 6,0x110mm	8680834312726
Cocr SR1612	POLAR Rod 6,0x120mm	8680834312733
Cocr SR1613	POLAR Rod 6,0x130mm	8680834312740
Cocr SR1614	POLAR Rod 6,0x140mm	8680834312757
Cocr SR1615	POLAR Rod 6,0x150mm	8680834312764
Cocr SR1616	POLAR Rod 6,0x160mm	8680834329885
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Cocr SR1623	POLAR Rod 6,0x230mm	8680834329953
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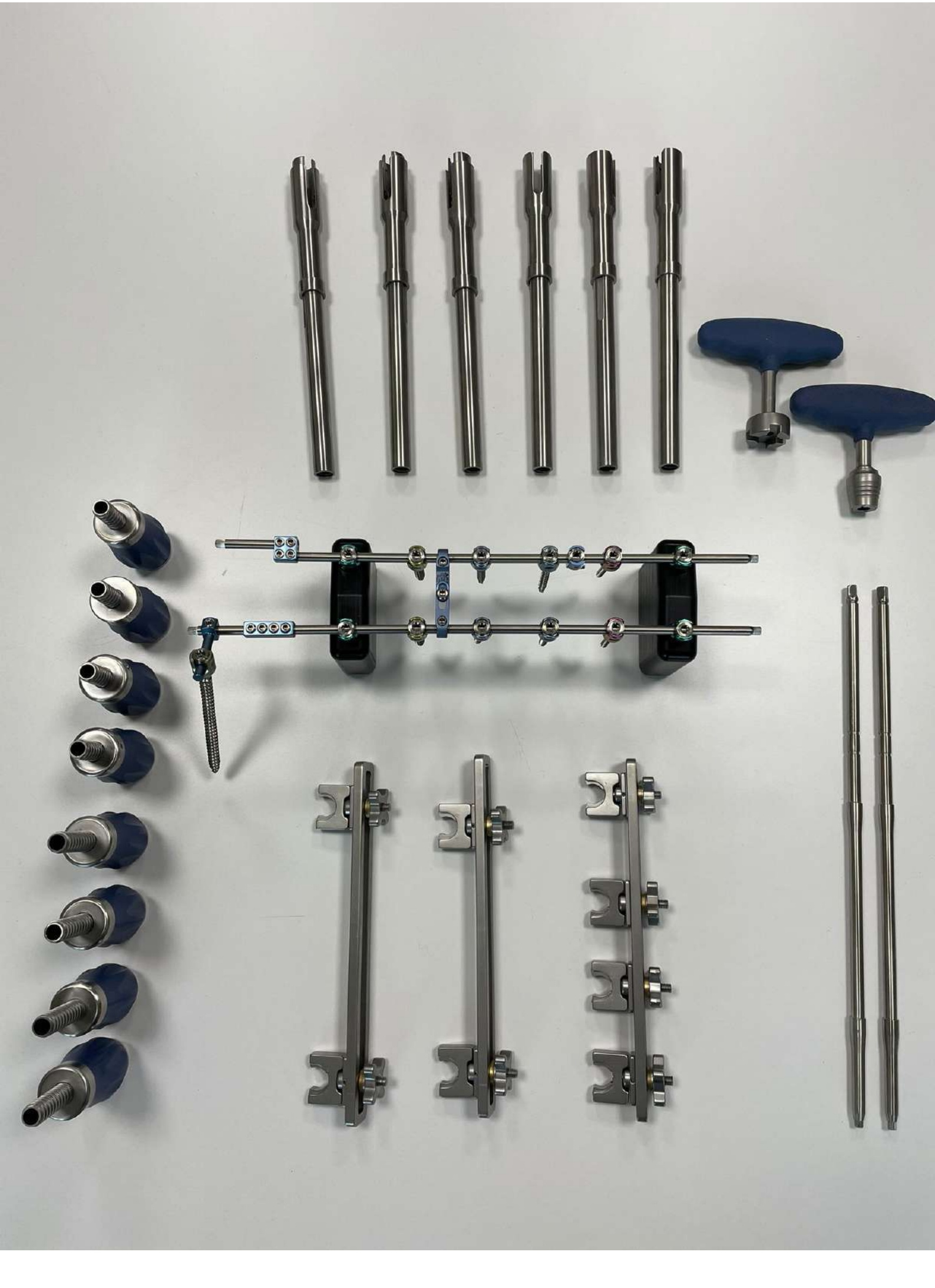
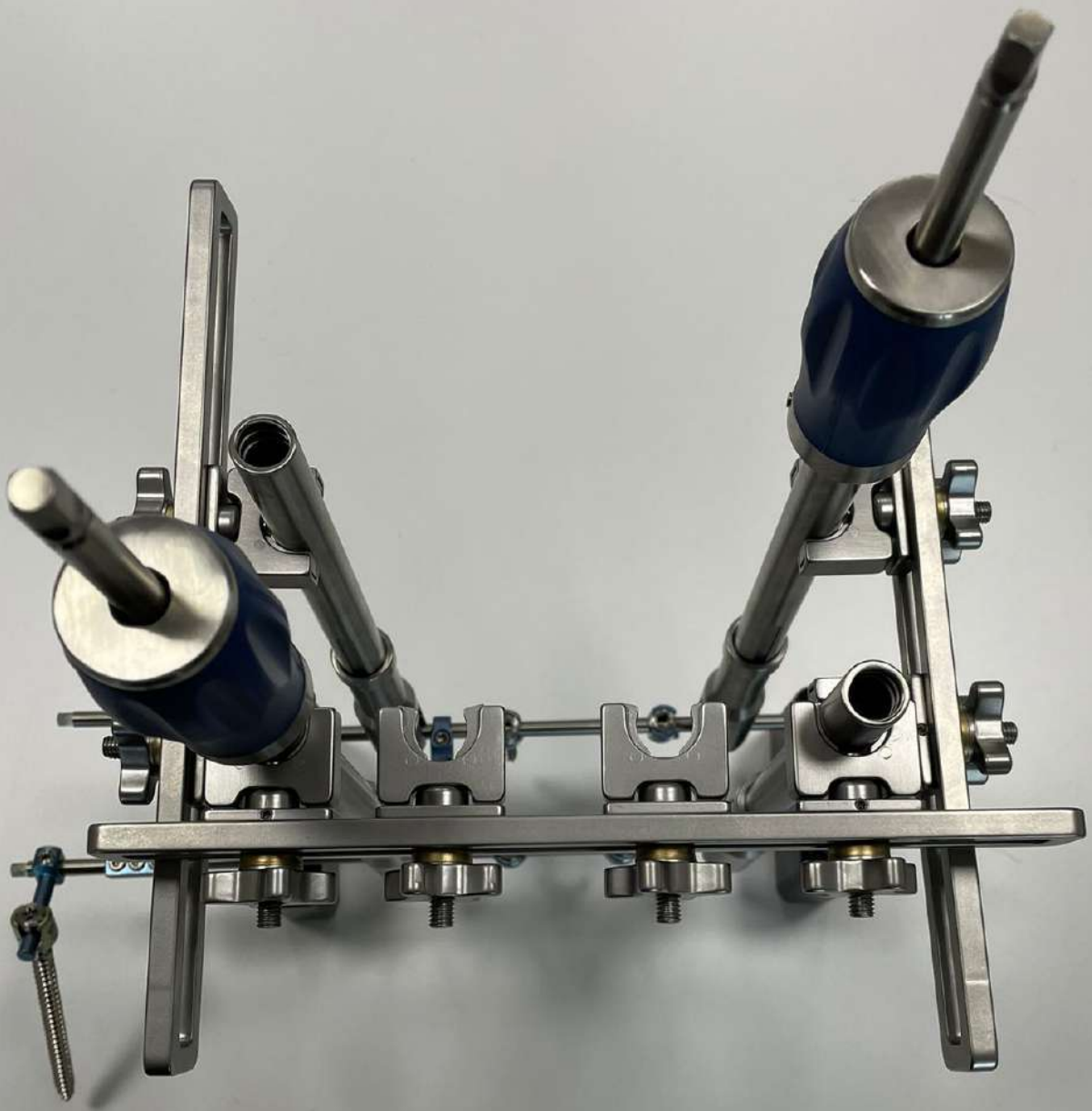
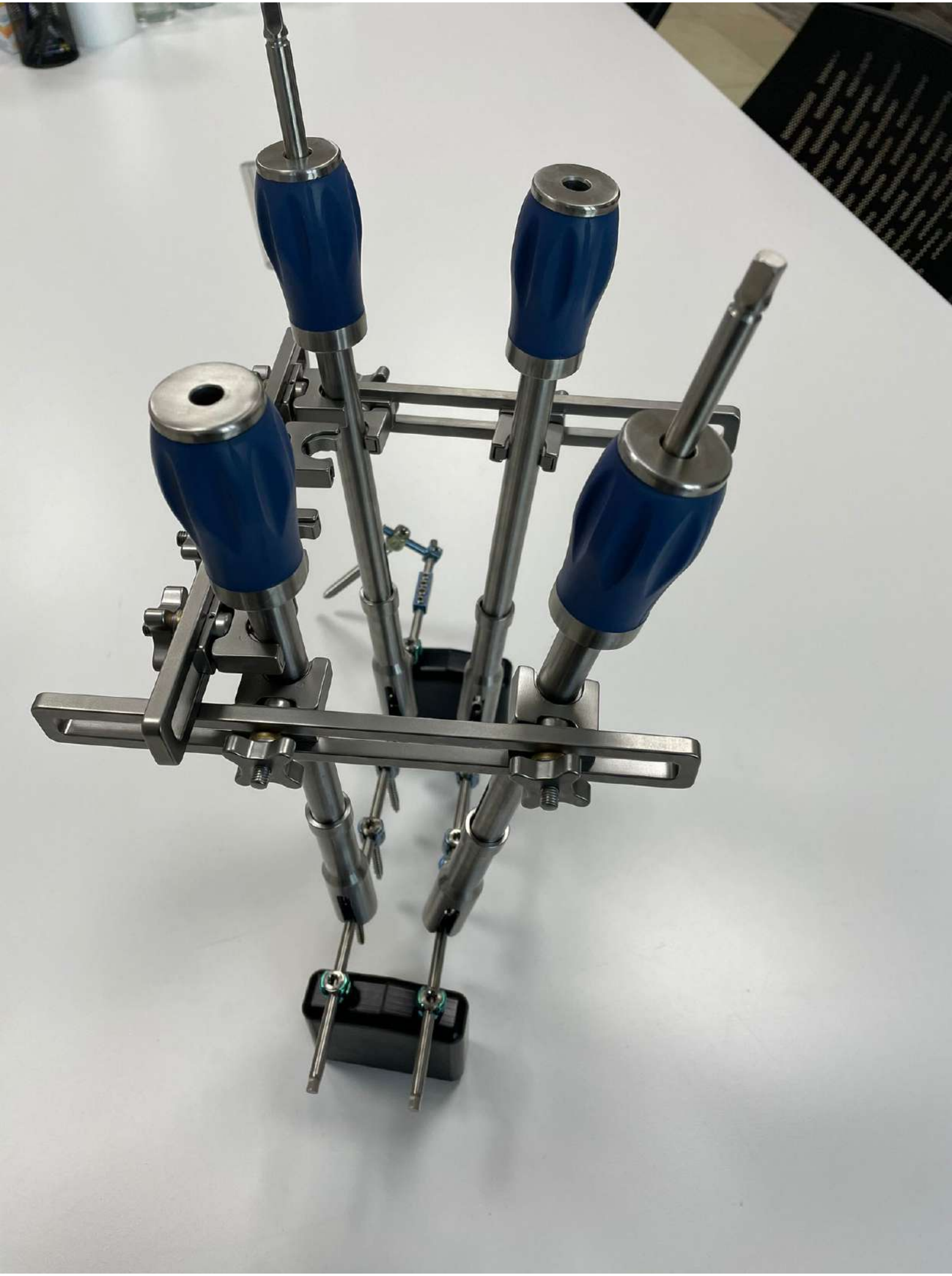
Cocr SR1627	POLAR Rod 6,0x270mm	8680834329991
Cocr SR1628	POLAR Rod 6,0x280mm	8680834330003
Cocr SR1629	POLAR Rod 6,0x290mm	8680834330010
Cocr SR1630	POLAR Rod 6,0x300mm	8680834330027
Cocr SR1631	POLAR Rod 6,0x310mm	8680834330034
Cocr SR1632	POLAR Rod 6,0x320mm	8680834330041
Cocr SR1640	POLAR Rod 6,0x400mm	8680834330058
Cocr SR1648	POLAR Rod 6,0x480mm	8680834330065
Cocr SR1650	POLAR Rod 6,0x500mm	8680834330072
Cocr SR1660	POLAR Rod 6,0x600mm	8680834330089
TLR140	POLAR Transverse Link 40mm	8680834306374
TLR150	POLAR Transverse Link 50mm	8680834306381
TLR160	POLAR Transverse Link 60mm	8680834306398
TLR170	POLAR Transverse Link 70mm	8680834306404
TLR180	POLAR Transverse Link 80mm	8680834306411
TLR190	POLAR Transverse Link 90mm	8680834323548
TLR200	POLAR Transverse Link 100mm	8680834323555
CLC50TB	POLAR Cross Connector 30-40mm	8680834307166
CLC60TB	POLAR Cross Connector 40-50mm	8680834307173
CLC70TB	POLAR Cross Connector 50-60mm	8680834307180
CLC80TB	POLAR Cross Connector 60-70mm	8680834307197
TL140	POLAR Transverse Connector 40-50mm	8680834306329
TL150	POLAR Transverse Connector 50-60mm	8680834306336
TL160	POLAR Transverse Connector 60-70mm	8680834306343
TL170	POLAR Transverse Connector 70-80mm	8680834306350

TL180	POLAR Transverse Connector 80-90mm	8680834306367
TL190	POLAR Transverse Connector 90mm	8680834323524
TL200	POLAR Transverse Connector 100mm	8680834323531
SSTKTD	POLAR Thoracolumbar Domino Connector	8680834323746
ECNT01	POLAR Lateral Connector	8680834306473
LCNT20	POLAR Lateral Extension 20mm	8680834306466







MANAGEMENT SYSTEM
ISO/IEC 17021-1:2015
NAC-002-MS

Certificate of Registration

This is to certify that

Quality Management System
for Medical Devices

of

MİKRON MAKİNA
SANAYİ VE TİCARET LİMİTED ŞİRKETİ

İVEDİK ORGANİZE SANAYİ BÖLGESİ MAH. AĞAÇ İŞLERİ SANAYİ SİTESİ. 1372. SOK. NO:31
YENİMAHALLE - ANKARA / TÜRKİYE

MANUFACTURING SITE: **DAĞYAKA MAH. DAĞYAKA CAD. NO:38 KAHRAMANKAZAN ANKARA / TÜRKİYE**

complies with requirements of

ISO 13485:2016

This certificate is valid concerning all activities related to;

SPİNAL VE TRAVMA İMPLANTLARI, AMELİYAT EL ALETLERİ VE
GENEL EL ALETLERİ TASARIMI ÜRETİMİ VE DAĞITIMI

DESIGN, MANUFACTURE AND DISTRIBUTION OF SPINAL & TRAUMA IMPLANTS,
SURGICAL INSTRUMENTS AND GENERAL INSTRUMENTS

ISO 02 848 1089	Feb. 11, 2021	Mar. 3, 2022
Certificate No.	*Date of this Certificate*	**Next Audit Due Date*
Mar. 4, 2020	Mar. 3, 2023	*Managing Director / Director*
Date of Initial Registration	*Certification Expiry Date*	

MDC MEDICERT CERTIFICATE

Medicert Uluslararası Ürün Ve Sistem Belgelendirme Ltd. Şti.
Tersane Mah. Cemal Gürsel Cad. No:11/3 Halide Hnm. Apt. Karşıyaka / İzmir
Tel: 0232 327 33 44 www.medicert.com.tr info@medicert.com.tr

CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name	: Mikron Makina Sanayi ve Ticaret Ltd. Şti.
Company Address	: İvedik OSB Mah. Ağaç İşleri Sanayi Sitesi 1372. Sk. No:31 Yenimahalle ANKARA / TURKEY
Manufacturing Site (Branch Office)	: Dağyaka Mah. Dağyaka Cad. No:38 Kahramankazan ANKARA / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Non-Sterile Spinal Screw Rod System - Class IIb Sterile Cervical & Lomber Peek Cages - Class IIb Non-Sterile Corpectomy Cages - Class IIb Sterile Cervical Mobile Disc Prosthesis - Class IIb Non-Sterile Plates - Class IIb Non-Sterile Bone Plates & Bone Screw - Class IIb
GMDN	: 37272, 43084, 38161, 34170, 46647, 56642, 35685, 58446, 48011, 61325, 32854

Product Types are attached.

Certificate Number	: M.2017.106.8497
Report Number	: MD.3468.YB
Initial Assessment Date	: 22.05.2017
Registration Date	: 07.06.2017
Recertification Assessment Date	: 20.12.2019
Reissue Date / No	: 15.04.2020/01
Revision Date /No	: -
Expiry Date	: 27.05.2024

APPROVED 2292

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the dev,ce is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returnedupon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com. tr.

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This document containing 3 (three) pages is the Annex of the Certificate with the number M.2017.106.8497 and with the registration date of 07.06.2017 and with the re-issue date 15.04.2020 issued for "Mikron Makina Sanayi ve Ticaret Ltd. Şti." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

LIST OF PRODUCTS	GMDN
Non-Sterile Spinal Screw Rod System	
MSFX -MIKRON SPINAL STABILISATION POLYAXIAL SCREW	37272
MSFX -MIKRON SPINAL STABILISATION MULTIFUNCTIONAL SCREW	37272
MSFX -MIKRON SPINAL STABILISATION POLYAXIAL CANNULATED-CEMENTED SCREW	37272
MSFX -MIKRON SPINAL STABILISATION MONOAXIAL CANNULATED-CEMENTED SCREW	37272
MSFX -MIKRON SPINAL STABILISATION MONOAXIAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLYAXIAL SPONDYLOLISTHESIS SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION MULTIFUNCTIONAL SPONDYLOLISTHESIS SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION MONOAXIAL SPONDYLOLISTHESIS SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR PEDICULAR POLYAXIAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR PEDICULAR MULTIFUNCTIONAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR CANNULATED-CEMENTED MULTIFUNCTIONAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR PEDICULAR CANNULATED-CEMENTED MONOAXIAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR PEDICULAR MONOAXIAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR PEDICULAR SPONDYLOLISTHESIS POLYAXIAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR PEDICULAR SPONDYLOLISTHESIS MULTIFUNCTIONAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR PEDICULAR SPONDYLOLISTHESIS MONOAXIAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION ROD	58446
MSFX-MIKRON SPINAL STABILIZATION ANTERIOR ROD	58446
MSFX -MIKRON SPINAL STABILIZATION TRANSVERSE CONNECTOR	58446
MSFX -MIKRON SPINAL STABILIZATION TRANSVERSE CERVICAL CONNECTOR ROD	58446
MSFX -MIKRON SPINAL STABILIZATION TRANSVERSE CONNECTOR HOOK	48011
MSFX -MIKRON SPINAL STABILIZATION MULTIAXIAL TRANSVERSE CONNECTOR	58446
MSFX -MIKRON SPINAL STABILIZATION LATERAL CONNECTOR	58446
MSFX -MIKRON SPINAL STABILIZATION EXTENSION CONNECTOR FOR 1 ROD	58446
MSFX -MIKRON SPINAL STABILIZATION EXTENSION CONNECTOR FOR 2 ROD	58446
MSFX -MIKRON SPINAL STABILIZATION MULTIAXIAL CONNECTOR	58446
MSFX -MIKRON SPINAL STABILIZATION PEDICULAR HOOK SMALL	61325
MSFX -MIKRON SPINAL STABILIZATION PEDICULAR HOOK OFSET	61325
MSFX -MIKRON SPINAL STABILIZATION LAMINAR HOOK	61325
MSFX -MIKRON SPINAL STABILIZATION LAMINAR HOOK LEFT ANGLED	61325
MSFX -MIKRON SPINAL STABILIZATION LAMINAR HOOK RIGHT ANGLED	61325
MSFX -MIKRON SPINAL STABILIZATION LAMINAR HOOK OFSET LEFT/RIGHT	61325
MSFX -MIKRON SPINAL STABILIZATION 3 TYPE HOOK LEFT	61325
MSFX -MIKRON SPINAL STABILIZATION 3 TYPE HOOK RIGHT	61325
MSFX-MIKRON SPINAL FIKSATION INTERSPINOUS U DEVICE	37272
MSFX-MIKRON SPINAL STABILIZATION CERVICAL POSTERIOR POLIAXIAL SCREW	37272
MSFX-MIKRON SPINAL STABILIZATION CERVICAL ROD	58446
THORACOLUMBAR POSTERIOR POLIAXIAL SCREW TITANIUM SELF TAPPING	37272
THORACOLUMBAR POSTERIOR LINK CONNECTOR TITANIUM DOMINOTO FOR 1 ROD	58446
THORACOLUMBAR POSTERIOR LINK CONNECTOR TITANIUM DOMINOTOR FOR 2 ROD	58446
THORACOLUMBAR POSTERIORLINK CONNECTOR TITANIUM AXIAL	58446
THORACOLUMBAR POSTERIORLINK CONNECTOR TITANIUM AXIAL 2	58446
MSFX-MIKRON SPINAL STABILIZATION POLYAXIAL HEMISPHERICAL SCREW	37272
MSFX-MODULER RIGID PLATE SMALL	46647
MSFX-MODULER RIGID PLATE LARGE	46647
MSFX-MODULER RIGID PLATE SACRUM	46647
MSFX-MODULAR DOUBLE SIDED DYNAMIC PLATE SMALL	46647
MSFX-MODULAR DOUBLE SIDED DYNAMIC PLATE LARGE	46647
MSFX- MODULAR SEMI RIGID PLATE SMALL	46647
MSFX- MODULAR SEMI RIGID PLATE LARGE	46647
MSFX-MIKRON SPINAL STABILIZATION SPHERICAL CONNECTOR	61325
MSFX-MIKRON SPINAL STABILIZATION SPHERICAL CROSS CONNECTOR	61325
POLYAXIAL CONNECTOR CLAMP	58446
MIDDLE CONNECTOR CLAMP	58446
CONNECTOR CLAMP	58446
MSFX-MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC POLYAXIAL SCREW + Setscrew	37272
MSFX-MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC POLYAXIAL SPONDYLOLISTHESIS SCREW + Setscrew	37272
MSFX-MIKRON SPINAL STABILIZATION PEDIATRIC ROD	58446
MSFX-MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC ROD CONNECTOR	58446
MSFX- MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC LAMINAR CONNECTOR	48011
MSFX- MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC PEDICUL HOOK	48011
MSFX- MODULAR DYNAMIC PLATE SMALL	58446
MSFX-MODULAR DYNAMIC PLATE LARGE	58446
MSFX-MODULAR DYNAMIC PLATE SMALL	58446
MSFX-MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC POLYAXIAL SPONDYLOLISTHESIS SCREW + Setscrew	37272
MSFX-MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC TRANSVERSE CONNECTOR	58446
MSFX-MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC ROD CONNECTOR	58446
MSFX-MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC LATERAL CONNECTOR	58446
MSFX-MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC AXIAL CONNECTOR	58446
MSFX- MIKRON SPINAL STABILIZATION MONOAXIAL HOOK TRANSVERSE CONNECTOR	58446
MSFX -MIKRON SPINAL STABILIZATION HIGH FLEX LUMBAR EXPANDABLE PEEK CAGE	38161
MSFX- MIKRON SPINAL STABILIZATION ANTERIOR TITANIUM PLATE CORPUS RIGHT	46647
MSFX- MIKRON SPINAL STABILIZATION ANTERIOR TITANIUM PLATE CORPUS LEFT	46647
MSFX-MIKRON SPINAL STABILIZATION ANTERIOR TRANSVERSE CONNECTOR	58446
MSFX- SPHERICAL TRANSVERSE CONNECTOR SCREW TO SCREW	37272
MSFX-MIKRON SPINAL STABILIZATION SPHERICAL CONNECTOR PEDIATRIC SCREW TO SCREW	37272
MSFX-MIKRON SPINAL STABILIZATION TRANSVERSE LINK AXIAL	58446
MSFX- MIKRON SPINAL STABILIZATION PEDIS TRANSVERSE LINK PEDIATRIC	58446
MSFX- MIKRON SPINAL STABILIZATION SACRAL CONNECTOR	58446
MSFX-MIKRON SPINAL STABILIZATION SACRAL MULTIAXIAL CONNECTOR	58446

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MSFX-MIKRON SPINAL STABILIZATION SACRAL-ILIAC SCREW	37272
MSFX-MIKRON SPINAL STABILIZATION ANTERIOR AGRAF PLATE	61325
MSFX-MIKRON SPINAL STABILIZATION ANTERIOR TRANSVERSE CONNECTOR	58446
Sterile Cervical & Lumbar Peek Cages	
MSFX-MIKRON SPINAL LUMBAR FUSION PEEK CAGE	38161
MSFX-MIKRON SPINAL LUMBAR FUSION PEEK CAGE ANGLED	38161
MSFX-MIKRON SPINAL STABILIZATION MINIMAL INVASIVE TLIF CAGE	38161
MSFX -MIKRON SPINAL STABILIZATION HIGH FLEX LUMBAR EXPANDABLE PEEK CAGE	38161
MSFX MIKRON SPINAL STABILIZATION HIGH FLEX EXPANDABLE CERVICAL PEEK CAGE	38161
MSFX-MIKRON SPINAL STABILIZATION TLIF CAGE	38161
MSFX- MIKRON SPINAL FIXATION BANANA CAGE	38161
MSFX-MIKRON SPINAL STABILIZATION TLIF CAGE ANGLED	38161
MSFX- MIKRON SPINAL FIXATION BANANA CAGE ANGLED	38161
MSFX MIKRON SPINAL STABILIZATION HIGH FLEX EXPANDABLE TLIF PEEK CAGE	38161
MSFX-MIKRON SPINAL STABILIZATION CERVICAL BLADED PEEK CAGE & ANATOMICAL SURFACE	38161
MSFX-MIKRON SPINAL STABILIZATION CERVICAL PEEK CAGE & ANATOMICAL SURFACE	38161
Non-Sterile Corpectomy Cages	
MSFX- MIKRON SPINAL STABILIZATION LUMBAR CORPECTOMY CAGE	38161
MSFX- MIKRON SPINAL STABILIZATION LUMBAR CORPECTOMY CAGE ANGLED	38161
MSFX- MIKRON SPINAL STABILIZATION CERVICAL CORPECTOMY TITANIUM CAGE	38161
MSFX- MIKRON SPINAL STABILIZATION CERVICAL CORPECTOMY TITANIUM CAGE ANGLED	38161
MSFX- MIKRON SPINAL STABILIZATION CORPECTOMY CAGE SCREW	38161
Sterile Cervical Mobile Disc Prosthesis	
MOBILE CERVICAL DISC PROSTHESIS	43084
Non-Sterile Plates	
MSFX-MIKRON SPINAL STABILIZATION CERVICAL ANTERIOR PLATE	61325
MSFX-MIKRON SPINAL STABILIZATION CERVICAL ANTERIOR PLATE SCREW	37272
MSFX-MIKRON SPINAL STABILIZATION CERVICAL ANTERIOR PLATE SCREW- REVISION	37272
Non-Sterile Bone Plates & Bone Screw	
CLAVICLE DISTAL LOCKING PLATE	46647
CLAVICLE SHAFT LOCKING PLATE	46647
CLAVICLE HOOK LOCKING PLATE	46647
HUMERUS PROXIMAL LOCKING PLATE	46647
HUMERUS DISTAL MEDIAL LOCKING PLATE	46647
HUMERUS DISTAL LATERAL LOCKING PLATE	46647
HUMERUS DISTAL POSTEROLATERAL LOCKING PLATE	46647
ULNA PROXIMAL LOCKING PLATE	46647
SMALL BROAD LOCKING PLATE	46647
SMALL NARROW LOCKING PLATE	46647
RADIUS PROXIMAL LOCKING PLATE	46647
RADIUS DISTAL VOLLARE LOCKING PLATE	46647
RADIUS DISTAL DORSAL LOCKING PLATE	46647
PELVIS RECONSTRUCTION STRAIGHT LOCKING PLATE	46647
PELVIS RECONSTRUCTION CURVED LOCKING PLATE	46647
TIBIA DISTAL MEDIAL LOCKING PLATE	46647
TIBIA DISTAL ANTEROLATERAL LOCKING PLATE	46647
FIBULA DISTAL LOCKING PLATE	46647
SMALL METAPHYSEAL LOCKING PLATE	46647
SEMITUBULAR LOCKING PLATE	46647
KALKANEUS LOCKING PLATE	46647
ULNA DISTAL LOCKING PLATE	46647
RECONSTRUCTION SHAFT LOCKING PLATE	46647
ULNA PROXIMAL HOOK LOCKING PLATE	46647
SMALL(MINI) FOOT LOCKING PLATE	46647
SMALL (MINI) FOOT STRAIGHT LOCKING PLATE	46647
SMALL HAND LOCKING PLATE	46647
SMALL HAND STRAIGHT LOCKING PLATE	46647
LARGE NARROW LOCKING PLATE	46647
LARGE BROAD LOCKING PLATE	46647
FEMUR PROXIMAL LOCKING PLATE	46647
FEMUR PROXIMAL NECK LOCKING PLATE	46647
FEMUR PROXIMAL TROCHANTER LOCKING PLATE	46647
FEMUR DISTAL LOCKING PLATE	46647
TIBIA PROXIMAL LATERAL LOCKING PLATE	46647
TIBIA PROXIMAL MEDIAL T LOCKING PLATE	46647
TIBIA PROXIMAL MEDIAL L LOCKING PLATE	46647
TIBIA DISTAL LATERAL LOCKING PLATE	46647
LARGE METAPHYSEAL LOCKING NARROW PLATE	46647
LOCKING SELF TAPPING CORTICAL SCREW	37272
LOCKING SELF DRILLING SCREW	37272
LOCKING SELF TAPPING CANCELLOUS SCREW	37272
HEXAGONAL UNLOCKED SELF TAPPING CORTICAL SCREW	37272
HEXAGONAL UNLOCKED SELF TAPPING CANCELLOUS SCREW	37272
CANNULATED FULL GROVED SCREW	37272
CANNULATED CANCELLOUS SCREW	37272
ANKLE SCREW	37272
HEXAGONAL LOCKING SELF DRILLING CANNULATED SCREW	37272
LOCKING SELF TAPPING CORTICAL SCREW	37272
UNLOCKED SELF TAPPING CORTICAL SCREW	37272
TROCAR KIRSHNER WIRE	35685
WASHER SMALL	56642
WASHER MEDIUM	56642

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WASHER LARGE	56642
WASHER EKSTRA EKSTRA LARGE	56642
WASHER EKSTRA LARGE	56642
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL ELASTIC NAIL RADIUS/ULNA/FEMUR/TIBIA/HUMERUS NOT CANNULATED TEN ELASTIC NAIL SCREW	37272
TEN ELASTIC NAIL AND CAP SMALL	37272
TEN ELASTIC NAIL AND CAP ORTA	37272
TEN ELASTIC NAIL AND CAP LARGE	37272
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL TIBIA CANNULATED ANATOMIC NONCOATED TITANIUM	32854
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL HUMERUS CANNULATED PROXIMAL NAIL LOCKED TITANIUM	32854
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL FEMORAL CANNULATED ANATOMIC NONCOATED FIXED COMBINE CURVED TITANIUM	32854
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL FEMORAL CANNULATED LONG PROXIMAL TITANIUM	32854
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL NECK/CONDILLAR LOCKING IMPLANTS ALL INSTRUMANTATION, ROUGHSHOD BLADE SCREW	37272
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL FEMORAL CANNULATED LONG PROXIMAL TITANIUM	32854
NAIL LOCKING SCREW PROXIMAL-DISTAL-SHAFT	37272
END CAP EXTRA SMALL	37272
END CAP SMALL	37272
END CAPI ORTA	37272
END CAP LARGE	37272
END CAP EXTRA LARGE	37272
END CAP EXTRA LARGE	37272
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL FEMORAL CANNULATED ANATOMIC NONCOATED FIXED CURVED TITANIUM	32854
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL HUMERUS CANNULATED PROXIMAL NAIL UNLOCKED TITANIUM	32854
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL FEMORAL CANNULATED ANATOMIC UNCOATED FIXED CURVED TITANIUM	32854

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

Osteotomy
instrument set

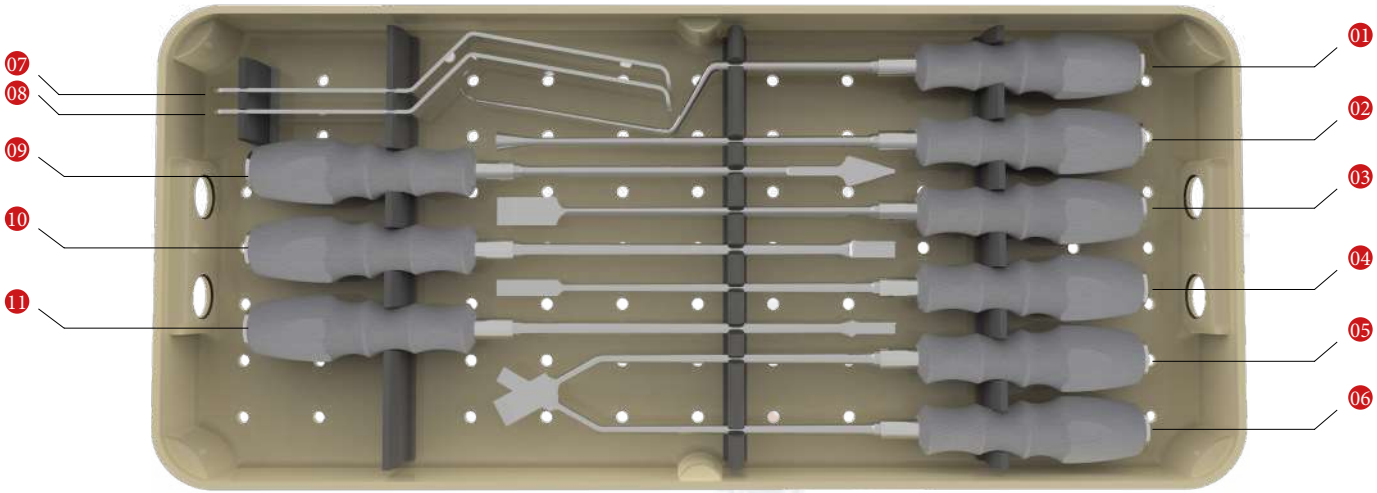
thoracolumbar

- Provide effective and simple use
- Include a wide selection of specialized instrumentation
- A truly complete set with dedicated instruments for corrective osteotomies
- Accommodate surgical preferences and anatomical variations
- Soft Tissue Retraction and Protection

OSTEOTOMY INSTRUMENT SET

Catalogue No.	Instrument Name	Quantity
NOS001	SMALL RING CURETTE	1
NOS002	LARGE RING CURETTE	1
NOS003	CURETTE, STRAIGHT	1
NOS004	CURETTE, LEFT	1
NOS005	CURETTE, RIGHT	1
NOS006	CUP CURETTE, STRAIGHT	1
NOS007	CUP CURETTE, STRAIGHT THREADED	1
NOS008	CUP CURETTE 45 ANGLED	1
NOS009	CUP CURETTE, OFFSET	1
NOS010	CUP CURETTE, RIGHT	1
NOS011	CUP CURETTE, LEFT	1
NOS012	SMALL OSTEOTOMY, ANGLED	1
NOS013	LARGE OSTEOTOMY, ANGLED	1
NOS014	SMALL OSTEOTOMY, STRAIGHT	1
NOS015	LARGE OSTEOTOMY, STRAIGHT	1
NOS016	BELL CURETTE	1
NOS017	NERVE ROOT RETRACTOR	1
NOS018	VERTEBRAL BODY OSTEOTOMY 6mm x 8mm	1
NOS019	VERTEBRAL BODY OSTEOTOMY 8mm x 6mm	1
NOS020	TRIANGLE SHAVER, 30	1
NOS021	BAYONET NERVE ROOT RETRACTOR, 12 mm	1
NOS022	BAYONET NERVE ROOT RETRACTOR, 14 mm	1
NOS023	VERTEBRAL BODY PUNCH, 15 mm	1
NOS024	VERTEBRAL BODY PUNCH, 20 mm	1
NOS025	VERTEBRAL BODY PUNCH, 25 mm	1
NOS026	VERTEBRAL BODY PUNCH, 30 mm	1
NOS027	STRAIGHT BONE IMPACTOR	1
NOS028	OFFSET BONE IMPACTOR	1
NOS029	ADJUSTABLE VERTEBRAL BODY RETRACTOR, 15 mm	2
NOS030	ADJUSTABLE VERTEBRAL BODY RETRACTOR, 30 mm	2

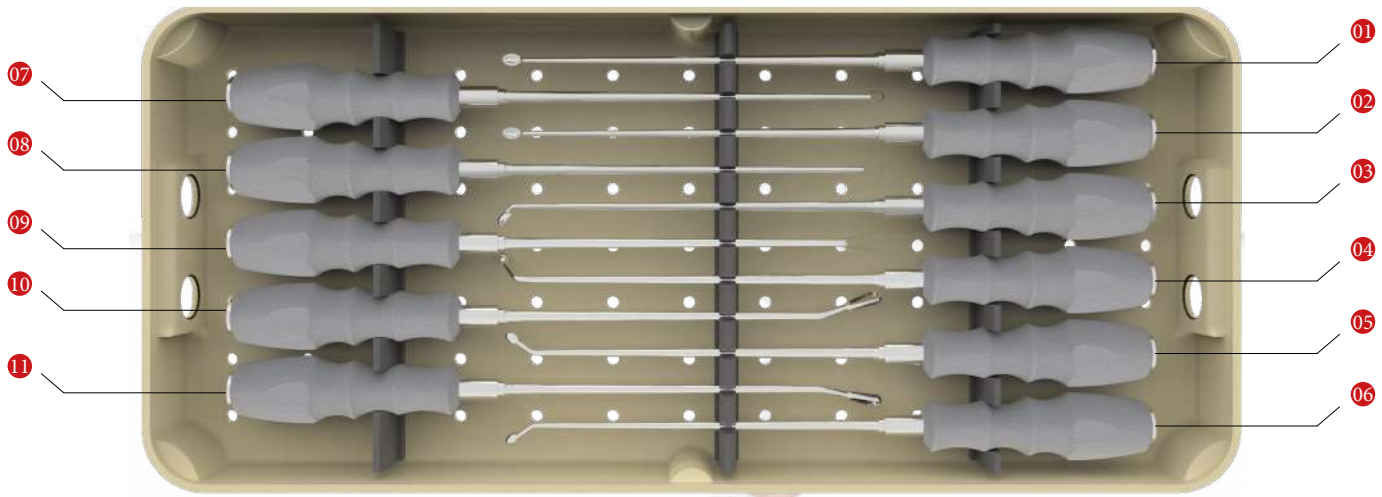
Osteotomy Instrument Set - Tray 1



Instruments	Set No	Catalogue No.	Descprition
	01	NOS017	Nerve Root Retractor
	02	NOS016	Bell Curette
	03	NOS015	Large Osteotomy, Straight

Instruments	Set No	Catalogue No.	Descprition
	04	NOS014	Small Osteotomy, Straight
	05	NOS013	Large Osteotomy, Angled
	06	NOS012	Small Osteotomy, Angled
	07 08	NOS021 NOS022	Bayonet Nerve Root Retractor, 12 mm Bayonet Nerve Root Retractor, 14 mm
	09	NOS020	Triangle Shaver, 30
	10	NOS018	Vertebral Body Osteotomy 6mm X 8mm
	11	NOS019	Vertebral Body Osteotomy 8mm X 6mm

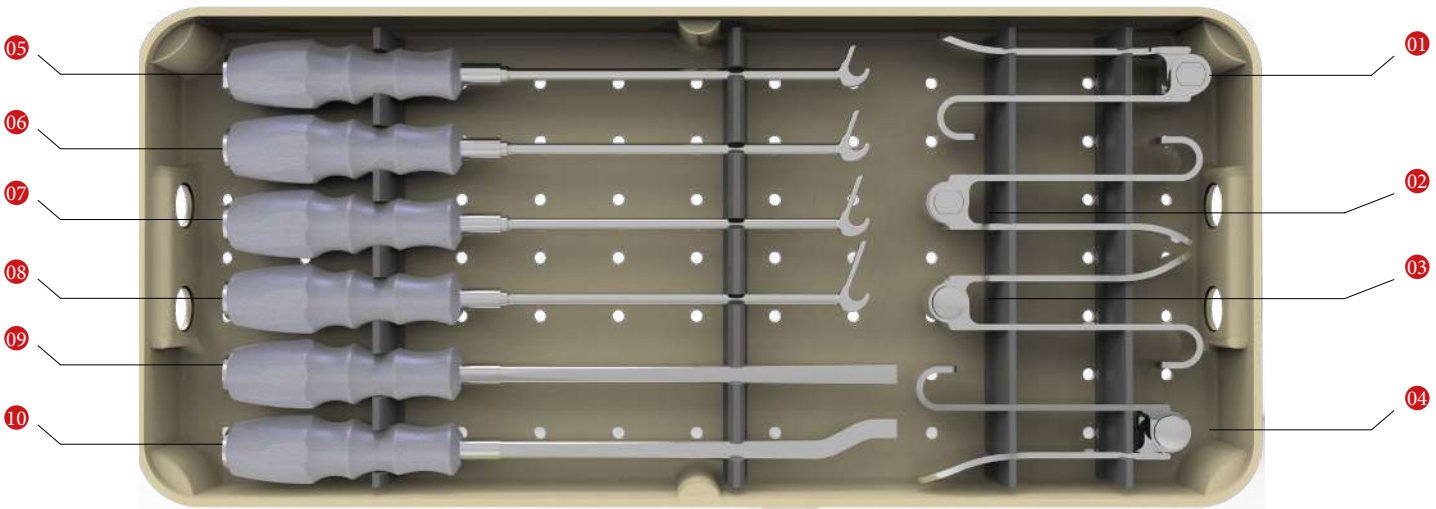
Osteotomy Instrument Set - Tray 2



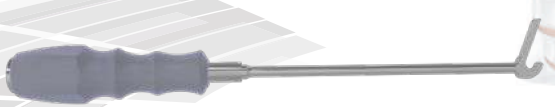
Instruments	Set No	Catalogue No.	Descprition
	01	NOS006	Cup Curette, Straight
	02	NOS007	Cup Curette, Straight Threaded
	03	NOS008	Cup Curette 45 Angled
	04	NOS009	Cup Curette, Offset

Instruments	Set No	Catalogue No.	Descprition
	05	NOS010	Cup Curette, Right
	06	NOS011	Cup Curette, Left
	07	NOS001	Small Ring Curette
	08	NOS002	Large Ring Curette
	09	NOS003	Curette, Straight
	10	NOS004	Curette, Left
	11	NOS005	Curette, Right

Osteotomy Instrument Set - Tray 3



Instruments	Set No	Catalogue No.	Descprition
	01	NOS029	Adjustable Vertebral Body Retractor, 15 mm
	02	NOS029	Adjustable Vertebral Body Retractor, 15 mm
	03	NOS030	Adjustable Vertebral Body Retractor, 30 mm

Instruments	Set No	Catalogue No.	Descprition
	04	NOS030	Adjustable Vertebral Body Retractor, 30 mm
	05	NOS023	Vertebral Body Punch 15 mm
	06	NOS024	Vertebral Body Punch 20 mm
	07	NOS025	Vertebral Body Punch 25 mm
	08	NOS026	Vertebral Body Punch 30 mm
	09	NOS027	Straight Bone Impactor
	10	NOS028	Offset Bone Impactor

LOT 12

AT A GLANCE

Streamlined Tip
Polyaxial Head
Low Profile Implants
Compact Set

INDICATIONS

ROMEO®2 system implants are designed to treat those dorsal and thoracic pathologies:

- Spondylolisthesis
- Degenerative disc disease
- Thoracic and lumbar fractures
- Thoracic and lumbar vertebra tumors
- Pseudarthrosis
- Stenosis
- Spine deformities: scoliosis, kyphosis

IMPLANTS

POLYAXIAL SCREWS

LENGTH / DIAMETER	Ø4	Ø5	Ø6	Ø7	Ø8
L25	ELL-PS 04 25-S	ELL-PS 05 25-S	ELL-PS 06 25-S		
L30	ELL-PS 04 30-S	ELL-PS 05 30-S	ELL-PS 06 30-S	ELL-PS 07 30-S	ELL-PS 08 30-S
L35	ELL-PS 04 35-S	ELL-PS 05 35-S	ELL-PS 06 35-S	ELL-PS 07 35-S	ELL-PS 08 35-S
L40	ELL-PS 04 40-S	ELL-PS 05 40-S	ELL-PS 06 40-S	ELL-PS 07 40-S	ELL-PS 08 40-S
L45	ELL-PS 04 45-S	ELL-PS 05 45-S	ELL-PS 06 45-S	ELL-PS 07 45-S	ELL-PS 08 45-S
L50		ELL-PS 05 50-S	ELL-PS 06 50-S	ELL-PS 07 50-S	ELL-PS 08 50-S
L55		ELL-PS 05 55-S	ELL-PS 06 55-S	ELL-PS 07 55-S	ELL-PS 08 55-S
L60			ELL-PS 06 60-S	ELL-PS 07 60-S	ELL-PS 08 60-S
L70			ELL-PS 06 70-S	ELL-PS 07 70-S	ELL-PS 08 70-S
L80			ELL-PS 06 80-S	ELL-PS 07 80-S	ELL-PS 08 80-S
L90			ELL-PS 06 90-S	ELL-PS 07 90-S	ELL-PS 08 90-S
L100				ELL-PS 07 10-S	ELL-PS 08 10-S
L110				ELL-PS 07 11-S	ELL-PS 08 11-S
L120				ELL-PS 07 12-S	ELL-PS 08 12-S

REDUCTION SCREWS

LENGTH / DIAMETER	Ø4	Ø5	Ø6	Ø7	Ø8
L25	ELL-SS 04 25-S	ELL-SS 05 25-S	ELL-SS 06 25-S		
L30	ELL-SS 04 30-S	ELL-SS 05 30-S	ELL-SS 06 30-S	ELL-SS 07 30-S	ELL-SS 08 30-S
L35	ELL-SS 04 35-S	ELL-SS 05 35-S	ELL-SS 06 35-S	ELL-SS 07 35-S	ELL-SS 08 35-S
L40	ELL-SS 04 40-S	ELL-SS 05 40-S	ELL-SS 06 40-S	ELL-SS 07 40-S	ELL-SS 08 40-S
L45	ELL-SS 04 45-S	ELL-SS 05 45-S	ELL-SS 06 45-S	ELL-SS 07 45-S	ELL-SS 08 45-S
L50		ELL-SS 05 50-S	ELL-SS 06 50-S	ELL-SS 07 50-S	ELL-SS 08 50-S
L55		ELL-SS 05 55-S	ELL-SS 06 55-S	ELL-SS 07 55-S	ELL-SS 08 55-S
L60			ELL-SS 06 60-S	ELL-SS 07 60-S	ELL-SS 08 60-S
L70				ELL-SS 07 70-S	ELL-SS 08 70-S
L80				ELL-SS 07 80-S	ELL-SS 08 80-S
L90				ELL-SS 07 90-S	ELL-SS 08 90-S

IMPLANTS

25D SCREWS

LENGTH /DIAMETER	Ø4	Ø5	Ø6	Ø7
L25	ELL-DS 04 25-S			
L30	ELL-DS 04 30-S	ELL-DS 05 30-S	ELL-DS 06 30-S	ELL-DS 07 30-S
L35	ELL-DS 04 35-S	ELL-DS 05 35-S	ELL-DS 06 35-S	ELL-DS 07 35-S
L40	ELL-DS 04 40-S	ELL-DS 05 40-S	ELL-DS 06 40-S	ELL-DS 07 40-S
L45	ELL-DS 04 45-S	ELL-DS 05 45-S	ELL-DS 06 45-S	ELL-DS 07 45-S
L50		ELL-DS 05 50-S	ELL-DS 06 50-S	ELL-DS 07 50-S
L55			ELL-DS 06 55-S	ELL-DS 07 55-S
L60			ELL-DS 06 60-S	ELL-DS 07 60-S

MONOAXIAL SCREWS

LENGTH / DIAMETER	Ø4	Ø5	Ø6	Ø7	Ø8
L25	ELL-MS 04 25-S				
L30	ELL-MS 04 30-S	ELL-MS 05 30-S	ELL-MS 06 30-S	ELL-MS 07 30-S	ELL-MS 08 30-S
L35	ELL-MS 04 35-S	ELL-MS 05 35-S	ELL-MS 06 35-S	ELL-MS 07 35-S	ELL-MS 08 35-S
L40	ELL-MS 04 40-S	ELL-MS 05 40-S	ELL-MS 06 40-S	ELL-MS 07 40-S	ELL-MS 08 40-S
L45	ELL-MS 04 45-S	ELL-MS 05 45-S	ELL-MS 06 45-S	ELL-MS 07 45-S	ELL-MS 08 45-S
L50		ELL-MS 05 50-S	ELL-MS 06 50-S	ELL-MS 07 50-S	ELL-MS 08 50-S
L55			ELL-MS 06 55-S	ELL-MS 07 55-S	ELL-MS 08 55-S
L60			ELL-MS 06 60-S	ELL-MS 07 60-S	ELL-MS 08 60-S
L70			ELL-MS 06 70-S	ELL-MS 07 70-S	ELL-MS 08 70-S
L80			ELL-MS 06 80-S	ELL-MS 07 80-S	ELL-MS 08 80-S

IMPLANTS

ROD CONNECTOR PARALLEL	ELL-RC PA 00-S

ROD CONNECTOR AXIAL	ELL-RC AX 00-S

ILIAC CONNECTORS	
L15	ELL-IC 00 15-S
L20	ELL-IC 00 20-S
L30	ELL-IC 00 30-S
L40	ELL-IC 00 40-S
L50	ELL-IC 00 50-S
L60	ELL-IC 00 60-S

ROD CONNECTOR PARALLEL OPEN	ELL-RC PA 01-S

ILIAC T CONNECTOR	ELL-RC TE 00-S

OPEN ILIAC CONNECTORS	
L15	ELL-IC 01 15-S
L20	ELL-IC 01 20-S
L30	ELL-IC 01 30-S
L40	ELL-IC 01 40-S
L50	ELL-IC 01 50-S
L60	ELL-IC 01 60-S

SET SCREW	ELL-SC 00 00-S

SET SCREW HEXALOBE *	ELL-SC 01 00-S

* The hexalobe set screw **must be used** with the following instruments:
ELL-IN 07 06-N / SET SCREW TIGHTENER
ELL-IN 08 06-N / FINAL TIGHTENER (11Nm HEXALOBE)

IMPLANTS

CROSS CONNECTORS /MULTIAXIAL	
L30 TO L31	ELL-CC-MU 30-S
L31 TO L33	ELL-CC-MU 31-S
L33 TO L36	ELL-CC MU 33-S
L36 TO L43	ELL-CC MU 36-S
L43 TO L55	ELL-CC MU 43-S
L55 TO L80	ELL-CC MU 55-S

TRANSVERSE ROD CONNECTORS	
L20	ELL-TR 00 20-S
L30	ELL-TR 00 30-S
L40	ELL-TR 00 40-S
L50	ELL-TR 00 50-S
L60	ELL-TR 00 60-S
L70	ELL-TR 00 70-S
L80	ELL-TR 00 80-S

CROSS CONNECTORS / MULTIAXIAL PREBENT	
L33 to L36	ELL-CC MP 33-S
L36 to L43	ELL-CC MP 36-S
L43 to L55	ELL-CC MP 43-S
L55 to L80	ELL-CC MP 55-S

CROSS CONNECTORS TRANSVERSE HOOKS	ELL-TC 00 00-S

CROSS CONNECTORS / STRAIGHT	
L18	ELL-CC ST 18-S
L21	ELL-CC ST 21-S
L24	ELL-CC ST 24-S
L27	ELL-CC ST 27-S
L30	ELL-CC ST 30-S

IMPLANTS

RODS STRAIGHT HEX TIP Ø5.4MM		
LENGTH	TITANIUM ALLOY	COBALT CHROMIUM
L100	ELL-RD 21 00-S	ELL-RD 11 00-S
L120	ELL-RD 21 20-S	ELL-RD 11 20-S
L140	ELL-RD 21 40-S	ELL-RD 11 40-S
L160	ELL-RD 21 60-S	ELL-RD 11 60-S
L180	ELL-RD 21 80-S	ELL-RD 11 80-S
L200	ELL-RD 22 00-S	ELL-RD 12 00-S
L220	ELL-RD 22 20-S	ELL-RD 12 20-S
L240	ELL-RD 22 40-S	ELL-RD 12 40-S
L350	ELL-RD 23 50-S	ELL-RD 13 50-S
L500	ELL-RD 25 00-S	ELL-RD 15 00-S
L550	ELL-RD 25 50-S	ELL-RD 15 50-S

RODS PRE-BENT Ø5.4MM TITANIUM ALLOY	
L30	ELL-RD 00 30-S
L35	ELL-RD 00 35-S
L40	ELL-RD 00 40-S
L45	ELL-RD 00 45-S
L50	ELL-RD 00 50-S
L55	ELL-RD 00 55-S
L60	ELL-RD 00 60-S
L70	ELL-RD 00 70-S
L80	ELL-RD 00 80-S
L90	ELL-RD 00 90-S
L100	ELL-RD 01 00-S
L110	ELL-RD 01 10-S
L120	ELL-RD 01 20-S
L130	ELL-RD 01 30-S

J-RODS Ø5.4MM COBALT CHROME		
L500	40°	ELL-R4 15 00-S
	60°	ELL-R6 15 00-S
L550	40°	ELL-R4 15 50-S
	60°	ELL-R6 15 50-S
	80°	ELL-R8 15 50-S

IMPLANTS

LAMINAR LUMBAR SMALL	ELL-HO LL 0S-S

LAMINAR LUMBAR LARGE	ELL-HO LL 0L-S

LAMINAR LUMBAR EXTENDED	ELL-HO LL-EX-S

PEDICULAR	ELL-HO P0 00-S

LAMINAR THORACIC SUPRA	ELL-HO LT SU-S

LAMINAR INFRA	ELL-HO LT IN-S

ANGLED LEFT	ELL-HO AN 0L-S
ANGLED RIGHT	ELL-HO AN 0R-S

OFFSET LEFT	ELL-HO OF 0L-S
OFFSET RIGHT	ELL-HO OF 0R-S

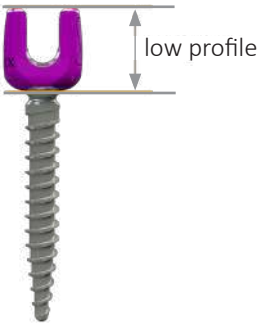
Implants can be delivered Non Sterile (ELL-xx xx xx-**N**) on demand.

TECHNICAL FEATURES

COMPLETE TL FIXATION PLATFORM

Complete range of polyaxial, semi-polyaxial, monoaxial, reduction screws, transverse connectors and rod connectors provide versatile options to treat numerous pathologies from T1 to the ilium.

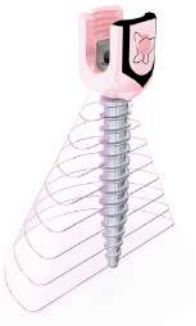
STREAMLINED SCREW TIP & LOW PROFILE IMPLANTS



The screw tip is designed to allow an effortless and self-centering insertion of the screw. The low profile ROMEO®2 implants are designed to enable an atraumatic implantation and minimize anatomical interference.

DEFORMITY SCREW

Polyaxial area



Fixed area

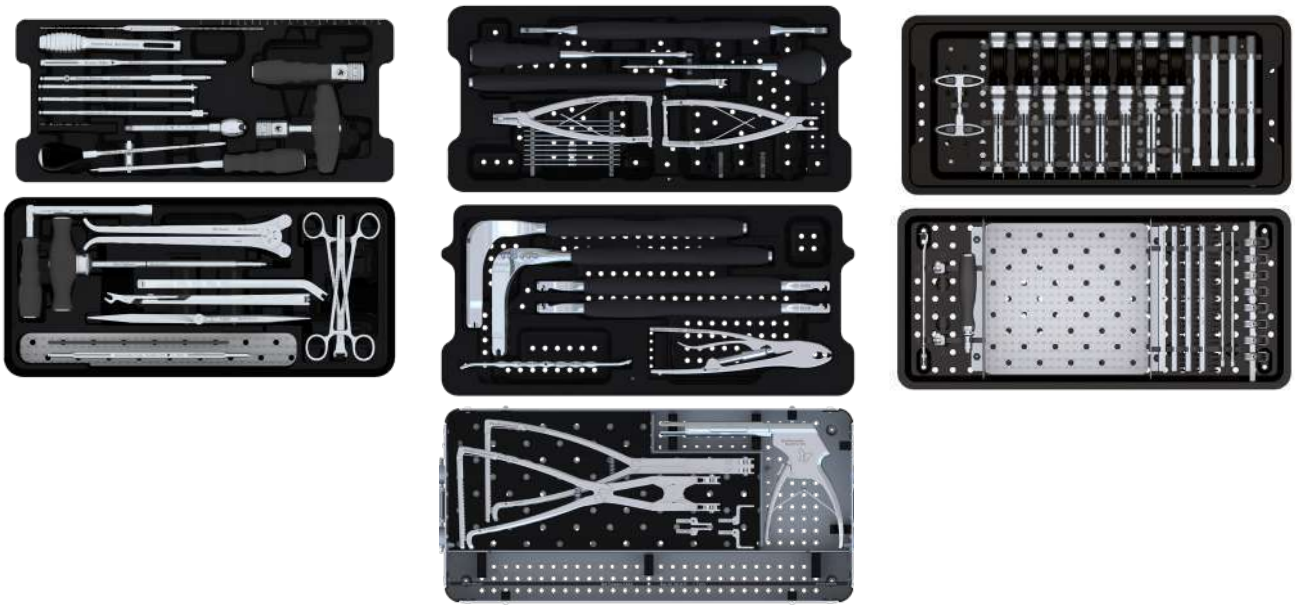
The ROMEO®2 25D semi-polyaxial screw provides the benefits of monoaxial screw for controlled powerful reduction and the versatility of the polyaxial screw for ease of rod connection.

TECHNICAL FEATURES

HOOKS

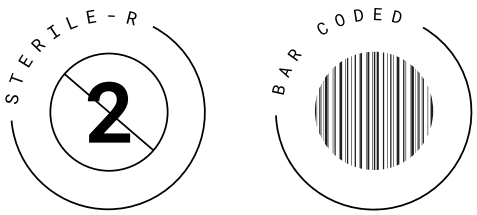
A full range of hooks with various sizes is available with ROMEO®2. Their autostatic teeth enhance their stability once impacted

COMPLETE SETS



One box of specific and intuitive instruments is needed for degenerative cases. A second box of instruments is available for more complex surgeries requesting longer construct. A third one is dedicated to derotation manoeuvre for deformity cases.

SAFETY



ROMEO®2 implants are sterile packaged and barcoded ensuring sterility and traceability.

INSTRUMENT SET

DEGENERATIVE KIT

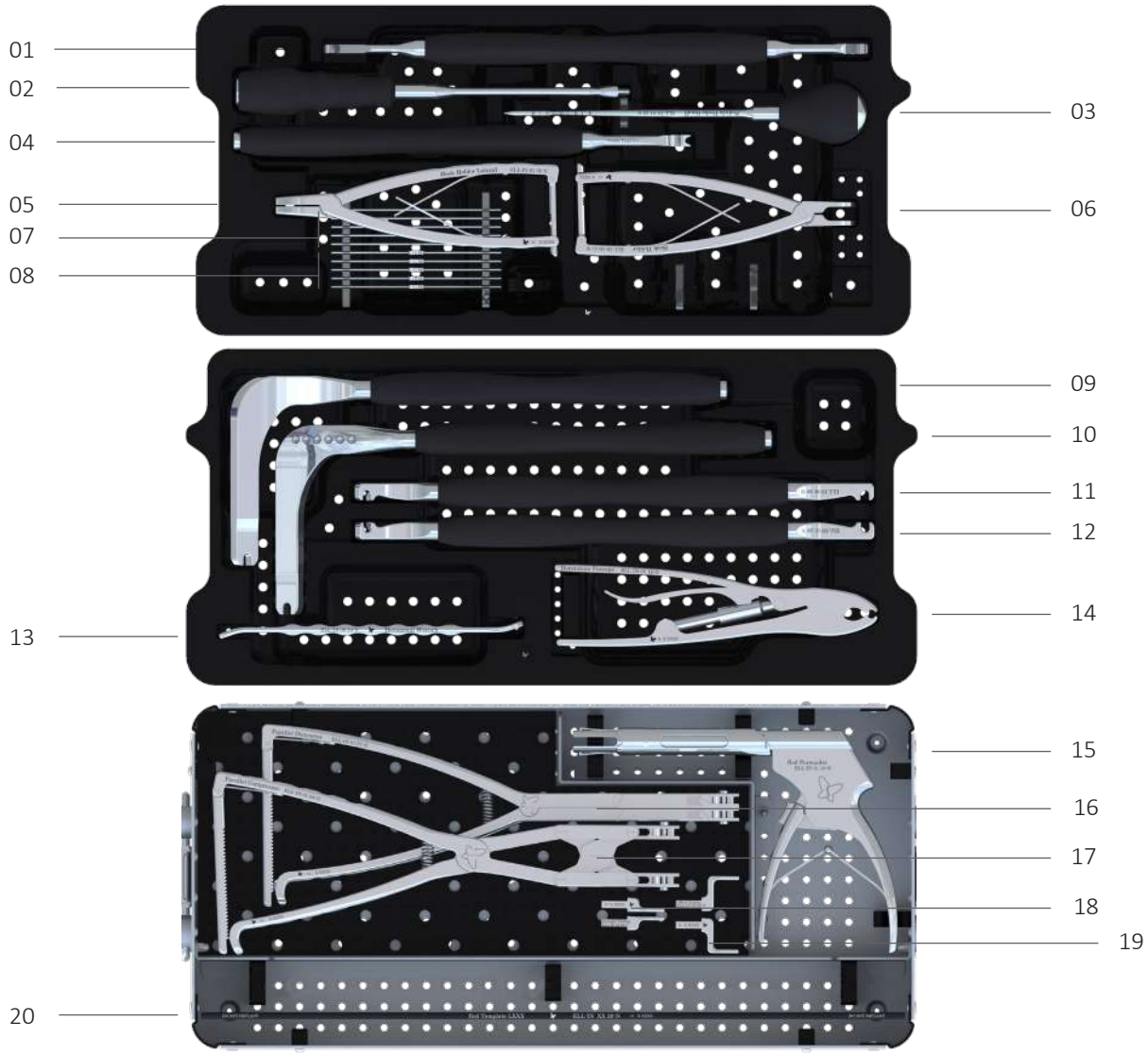
#	DESCRIPTION	REFERENCE
01	PEDICLE SOUNDER	ELL-IN 01 02-N
02	SET SCREW TUBE	ELL-IN 01 15-N
03	SET SCREW HOLDER W	ELL-IN 03 10-N
04	SET SCREW TIGHTENER	ELL-IN 04 06-N
05	SCREWDRIVER SHAFT PS	ELL-IN 05 03-N
06	SCREWDRIVER SHAFT MS	ELL-IN 01 20-N
07	SCREWDRIVER SHAFT SS	ELL-IN 01 16-N
08	SCREWDRIVER SLEEVE	ELL-IN 20 03-N
09	SCREWDRIVER TUBE	ELL-IN 21 03-N
10	PEDICLE PROBE	ELL-IN 02 22-N
11	BONE AWL	ELL-IN 02 01-N
12	STRAIGHT HANDLE RATCHET	HAN-SI RA ST-N
13	T-HANDLE RATCHET	HAN-SI RA TE-N

#	DESCRIPTION	REFERENCE
14	COUNTER TORQUE	ELL-IN 03 11-N
15	ROD BENDER	ELL-IN 00 09-N
16	FINAL TIGHTENER (11Nm - HEXAGONAL)	ELL-IN 05 06-N
17	DISTRACTION FORCEPS	ELL-IN 00 07-N
18	COMPRESSION FORCEPS	ELL-IN 00 08-N
19	CALIPER	ELL-IN 00 12-N
20	IMPLANT HOLDER	ELL-IN 01 04-N
21	ROCKER	ELL-IN 00 05-N
22	ROD TEMPLATE L250	ELL-IN 00 28-N
● 23	SET SCREW HOLDER DOUBLE	ELL-IN 02 10-N
	INSTRUMENTS CONTAINER	ROM-BX 10 01-N

● : OPTIONAL

INSTRUMENT SET

LONG CONSTRUCT KIT



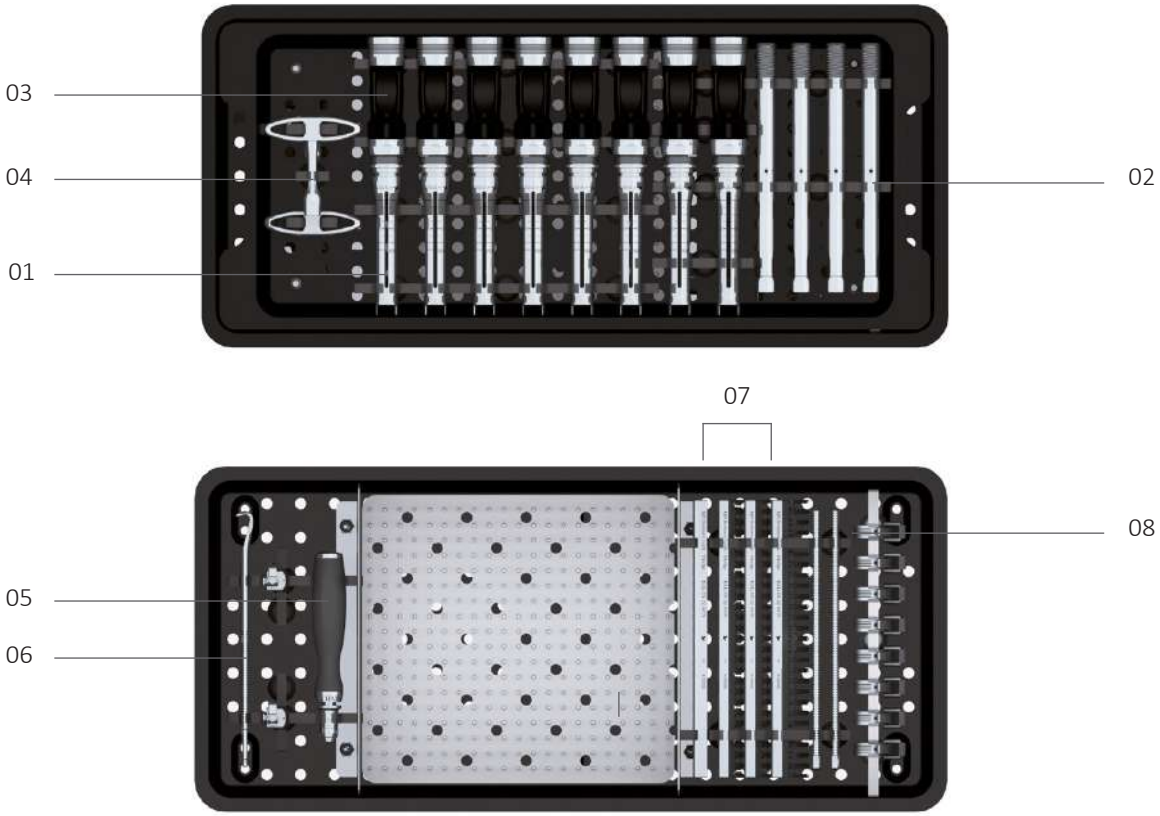
#	DESCRIPTION	REFERENCE
01	LAMINA PREPARER	ELL-IN 00 30-N
02	HOOK PUSHER	ELL-IN 00 32-N
03	PEDICLE PROBE SMALL	ELL-IN 02 23-N
04	PEDICLE PREPARER	ELL-IN 00 29-N
05	HOOK HOLDER LATERAL	ELL-IN 01 31-N
06	HOOK HOLDER	ELL-IN 00 31-N
07	MARKER LEFT	ELL-IN 00 25-N
08	MARKER RIGHT	ELL-IN 00 24-N
09	CORONAL BENDER LEFT	ELL-IN 00 27-N
10	CORONAL BENDER RIGHT	ELL-IN 01 27-N

#	DESCRIPTION	REFERENCE
11	SAGITTAL BENDER LEFT	ELL-IN 00 26-N
12	SAGITTAL BENDER RIGHT	ELL-IN 01 26-N
13	HEXAGONAL WRENCH	ELL-IN 00 33-N
14	DEROTATION FORCEPS	ELL-IN 01 18-N
15	ROD PERSUADER	ELL-IN 01 19-N
● 16	PARALLEL DISTRACTOR	ELL-IN 01 07-N
● 17	PARALLEL COMPRESSOR	ELL-IN 01 08-N
● 18	STRAIGHT ENDTIP	ELL-IN 02 08-N
● 19	OFFSET ENDTIP	ELL-IN 03 08-N
20	ROD TEMPLATE L500	ELL-IN 01 28-N
	INSTRUMENTS CONTAINER LC	ROM-BX 40 01-N

● : OPTIONAL

INSTRUMENT SET

QR LINK KIT



#	DESCRIPTION	REFERENCE
01	QR REDUCER - OUTER TUBE	ELL-IN 31 34-N
02	QR REDUCER - INNER TUBE	ELL-IN 32 34-N
03	QR REDUCER - HANDLE	ELL-IN 33 34-N
04	QR REDUCER T-HANDLE	HAN-SS TY 14-N
05	AO HANDLE	HAN-SI AO 08-N
06	RIBAC	ELL-IN 23 34-N
07	QR REDUCER LINK BRIDGE	ELL-IN 22 34-N
08	QR REDUCER LINK	ELL-IN 21 34-N
	QR LINK INSTRUMENT BOX	ROM-BX 41 01-N

_STEP 19

ROD DEROTATION

The rod is axially rotated at 90° to restore the sagittal plane balance.

Attach two **Derotation Forceps** to the rod and/or one **Hexagonal Wrench** on the hexagonal endtip of the rod.

Derotate the rod to have its curvature moving from the frontal plane to the sagittal plane.

NOTE: Make sure to have all the set screws slightly loose before performing any rod derotation maneuvers.

INSTRUMENT	REFERENCE
DEROTATION FORCEPS	ELL-IN 01 18-N
HEXAGONAL WRENCH	ELL-IN 00 33-N

ROMEO®2 deformity screws 25D

Innovative implants.

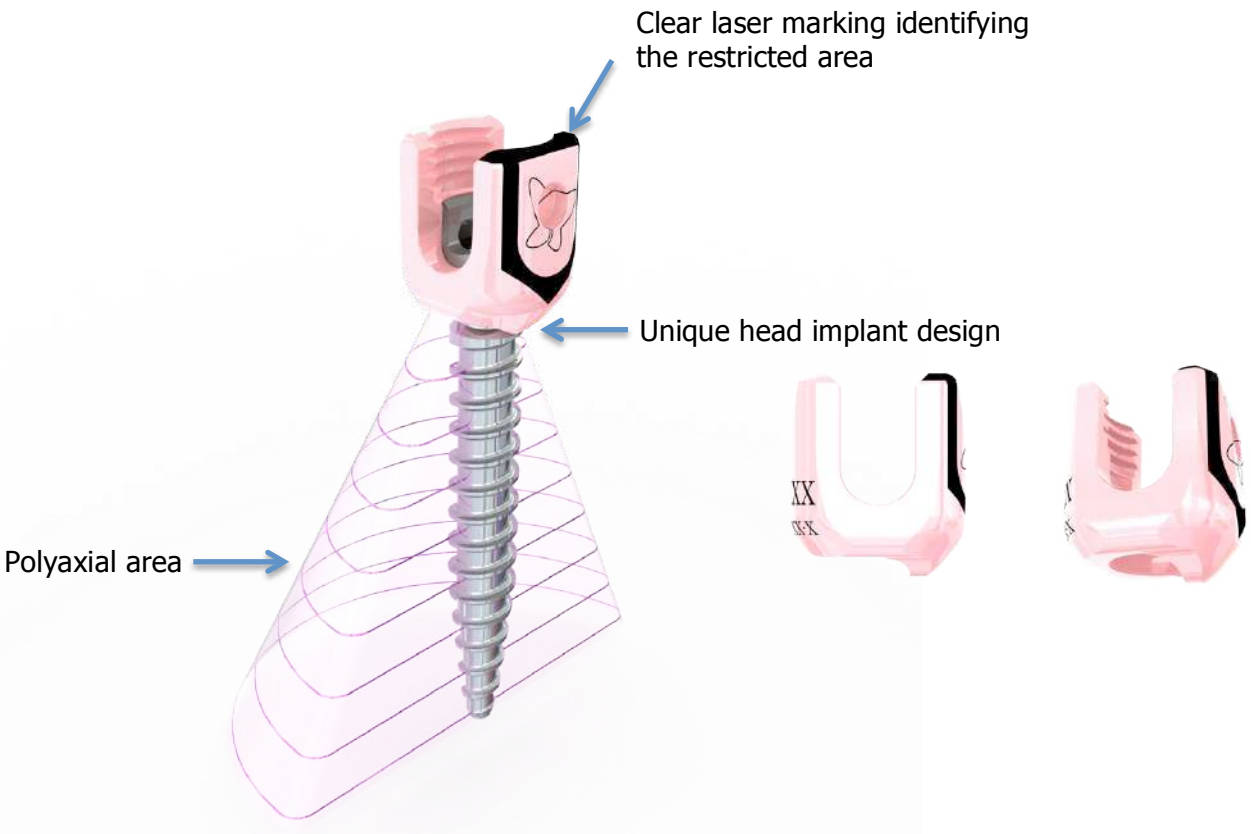
Dear collaboration partner,

Spineart® is pleased to inform you of the development of the 25D screws, extending the range of ROMEO®2 screws and opening on surgical solutions for the treatment of spinal deformities.

The 25D screws are deformity-oriented screws sharing the same "streamlined tip" and "low profile" features as the currently available ROMEO®2 screws.

New feature: SEMI POLYAXIALITY.
The 25D Deformity screws have a specific design offering a semi polyaxial movement. While the polyaxial area eases rod insertion, the locked direction helps manage derotation maneuvers.

A unique design that combines the comfort of polyaxiality and the precision of monoaxiality.



Implants available

Reference	Ø in mm	Length in mm
ELL-DS 04 25-S	4	25
ELL-DS 04 30-S	4	30
ELL-DS 04 35-S	4	35
ELL-DS 04 40-S	4	40
ELL-DS 04 45-S	4	45
ELL-DS 05 30-S	5	30
ELL-DS 05 35-S	5	35
ELL-DS 05 40-S	5	40
ELL-DS 05 45-S	5	45
ELL-DS 05 50-S	5	50
ELL-DS 06 30-S	6	30
ELL-DS 06 35-S	6	35
ELL-DS 06 40-S	6	40
ELL-DS 06 45-S	6	45
ELL-DS 06 50-S	6	50
ELL-DS 06 55-S	6	55
ELL-DS 06 60-S	6	60
ELL-DS 06 70-S	6	70
ELL-DS 06 80-S	6	80
ELL-DS 06 90-S	6	90
ELL-DS 07 30-S	7	30
ELL-DS 07 35-S	7	35
ELL-DS 07 40-S	7	40
ELL-DS 07 45-S	7	45
ELL-DS 07 50-S	7	50
ELL-DS 07 55-S	7	55
ELL-DS 07 60-S	7	60
ELL-DS 07 70-S	7	70
ELL-DS 07 80-S	7	80
ELL-DS 07 90-S	7	90

The 25D screws are delivered **sterile** and **single packed** (including setscrew).

For any further request please do not hesitate to contact me,

Best regards,

OLIVIER PAPUGA
Product Manager
SPINEART®

ROMEO®2MIS trauma screws 25T

Innovative implants.

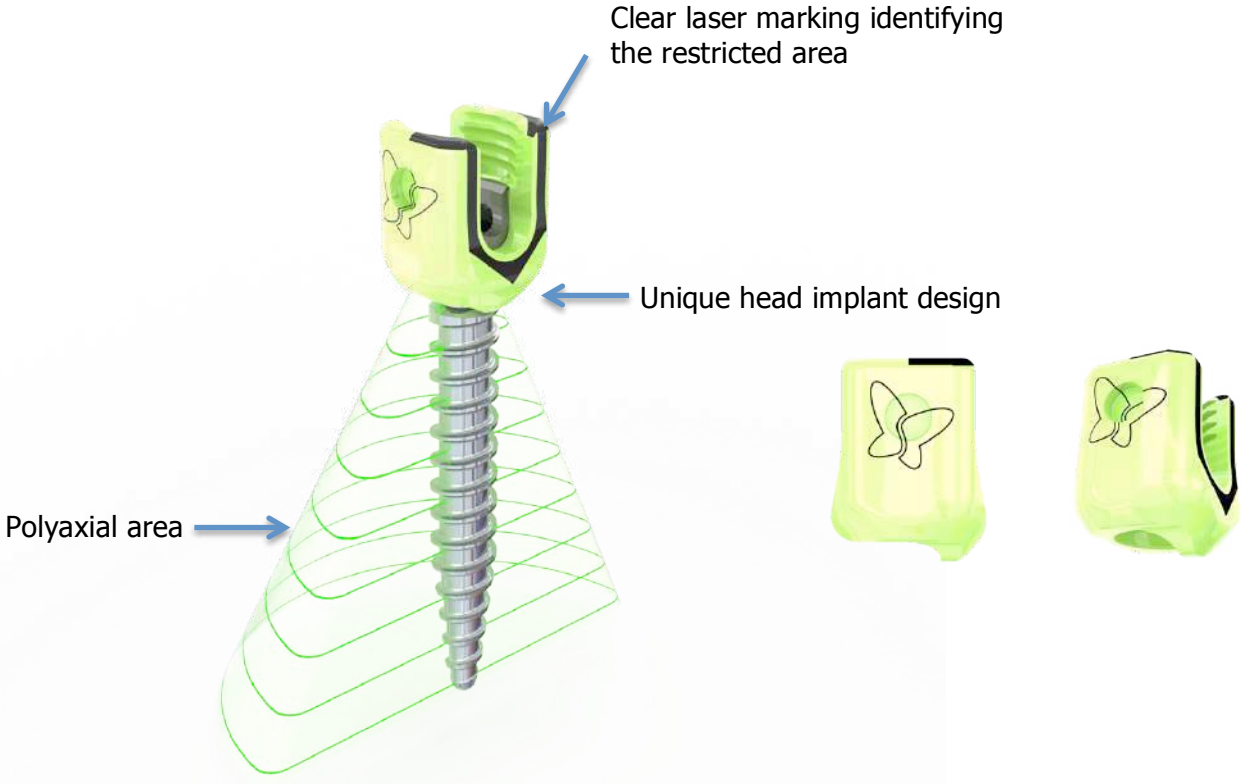
Dear collaboration partner,

Spineart® is pleased to inform you of the development of the 25T screws, extending the range of ROMEO®2MIS screws and providing an innovative alternative for the treatment of spinal trauma cases during minimally invasive surgeries.

The 25T screws are trauma-oriented cannulated screws and present "streamlined tip" and "low profile" features as the currently available ROMEO®2MIS screws.

New feature: SEMI POLYAXIALITY.
The 25T Trauma screws have a specific design offering a semi polyaxial movement. While the polyaxial area eases rod insertion, the locked direction helps manage fracture reduction.

A unique design that combines the comfort of polyaxiality and the precision of monoaxiality.



Implants available

Reference	Ø in mm	Length in mm
MIS-TS 04 25-S	4	25
MIS-TS 04 30-S	4	30
MIS-TS 04 35-S	4	35
MIS-TS 04 40-S	4	40
MIS-TS 04 45-S	4	45
MIS-TS 05 30-S	5	30
MIS-TS 05 35-S	5	35
MIS-TS 05 40-S	5	40
MIS-TS 05 45-S	5	45
MIS-TS 05 50-S	5	50
MIS-TS 06 30-S	6	30
MIS-TS 06 35-S	6	35
MIS-TS 06 40-S	6	40
MIS-TS 06 45-S	6	45
MIS-TS 06 50-S	6	50
MIS-TS 06 55-S	6	55
MIS-TS 06 60-S	6	60
MIS-TS 07 30-S	7	30
MIS-TS 07 35-S	7	35
MIS-TS 07 40-S	7	40
MIS-TS 07 45-S	7	45
MIS-TS 07 50-S	7	50
MIS-TS 07 55-S	7	55
MIS-TS 07 60-S	7	60
MIS-TS 08 40-S	8	40
MIS-TS 08 45-S	8	45
MIS-TS 08 50-S	8	50
MIS-TS 08 55-S	8	55
MIS-TS 08 60-S	8	60

The 25T screws are delivered **sterile** and **packed by two** (including setscrews).

For any further request please do not hesitate to contact me,

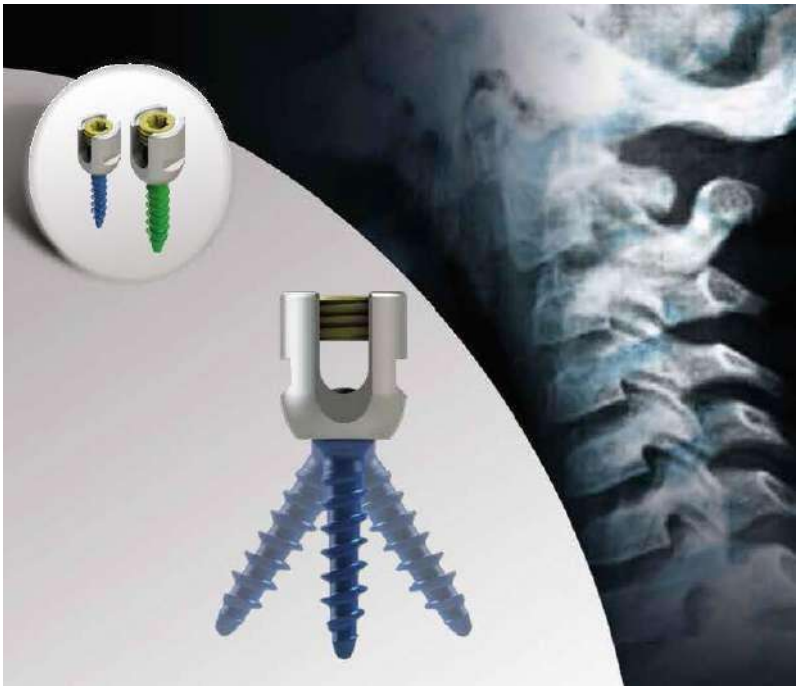
Best regards,

OLIVIER PAPUGA
Product Manager
SPINEART®

PS® MINI OCCIPITO-CERVICO-THORACIC SYSTEM

TECHNICAL GUIDE

LOT 4



Tria Spine®

SPINE | ORTHOPEDICS

www.triaspine.com

Description:

PS® Mini Occipito-Cervico-Thoracic System is a posterior spinal fixation system for stabilization of the upper spine (occiput-T3) in the aim of the treatment of occipito-cervico-thoracic spine diseases.

WARNING: System is not intended for thoracic (T4-T12) and lumbar spine. System can also be linked to thoraco-lumbar systems via hybrid rods, domino connector and inline rod connector.

PS® Mini Occipito-Cervico-Thoracic System is suitable for adults who have enough spinal stability and meet the main indications.

Material:

System elements are made of titanium alloy (Ti6Al4V) or CoCr as per ISO 5832-3 (ASTM F136 and BS 7252-3). All system elements are MRI compatible.

Indications:

PS® Mini Occipito-Cervico-Thoracic System is indicated for degenerated disc disease, spinal stenosis, occipitocervical dislocation, atlantoaxial fracture with instability, trauma, fracture/dislocation, tumors, failed previous fusion (pseudoarthrosis) and spondylolisthesis.

Contraindications:

Contraindications include but are not limited to:

- Pathological obesity, pregnancy, significant osteoporosis, open wounds, severe local inflammation, dependency on pharmaceutical drugs, drug abuse or alcoholism, mental illnesses, significant osteopenia, known or suspected allergy or intolerance to implant material (foreign body sensitivity to the implant material), acute or chronic infections, lack of patient cooperation.

Product Features:

Multi-Axial System

- Provides 65° in angle
- Well known technique
- Easy to use

Wide Application Area

- Suitable for upper spine (occiput-T3)
- Perfect implantation in stenosis, spondylolisthesis, trauma, fractures, tumor and occipito cervical dislocation cases
- Compatible implants and instruments for human anatomy

Better Design

- Special screw body
- Improved screw tip
- Titanium alloy (Ti6Al4V - ISO 5832-3) and CoCr Vitallium
- Biomechanically tested implants according to ASTM standards

Implant Features

- Color coded screw bodies
- Enhanced locking mechanism
- Adjustable transverse connector
- 3.5mm rod system
-

Implants:

Multi-Axial Screws

Diameter : 3.5mm and and 4.0mm

Length : 10mm to 42mm

Nut

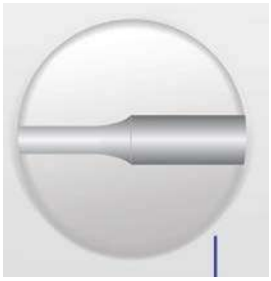
PS MINI Nut

Rods Ti and Vitallium

Diameter : 3.5mm

Length : 80mm to 240mm

Hybrid Rod : Diameter from 3.5mm to 6.0mm in 480mm length



Adjustable Transverse Connector

Size : Small , Medium and Large

Implants:

Occipital Plate

Size : Small , Medium, and Multi-Level

Connectors

PS MINI Lateral Connector

PS MINI Domino Connector 3.5mm to 6.0mm

PS MINI Inline Rod Connector 3.5mm to 6.0mm

Bone Screw

Diameter : 4.0mm

Length : 6mm to 14mm

Packaging & Sterilization:

System elements are supplied clean but not sterile. Re-usable instruments should be cleaned before use and all system elements should be sterilized following the below mentioned methods.

As per ISO 17665-1:2006, AAMI TIR 12:2004 and other respective standards

Implants:

Code	Product Name
	Multi-Axial Screw
OCM-3510	PS® Mini Cervical Multi-Axial Screw+Nut 3.5x10mm
OCM-3512	PS® Mini Cervical Multi-Axial Screw+Nut 3.5x12mm
OCM-3514	PS® Mini Cervical Multi-Axial Screw+Nut 3.5x14mm
OCM-3516	PS® Mini Cervical Multi-Axial Screw+Nut 3.5x16mm
OCM-3518	PS® Mini Cervical Multi-Axial Screw+Nut 3.5x18mm
OCM-3520	PS® Mini Cervical Multi-Axial Screw+Nut 3.5x20mm
OCM-3522	PS® Mini Cervical Multi-Axial Screw+Nut 3.5x22mm
OCM-3524	PS® Mini Cervical Multi-Axial Screw+Nut 3.5x24mm
OCM-3526	PS® Mini Cervical Multi-Axial Screw+Nut 3.5x26mm
OCM-3528	PS® Mini Cervical Multi-Axial Screw+Nut 3.5x28mm
OCM-3530	PS® Mini Cervical Multi-Axial Screw+Nut 3.5x30mm
OCM-3532	PS® Mini Cervical Multi-Axial Screw+Nut 3.5x32mm
OCM-3536	PS® Mini Cervical Multi-Axial Screw+Nut 3.5x36mm
OCM-3540	PS® Mini Cervical Multi-Axial Screw+Nut 3.5x40mm
OCM-4010	PS® Mini Cervical Multi-Axial Screw+Nut 4.0x10mm
OCM-4012	PS® Mini Cervical Multi-Axial Screw+Nut 4.0x12mm
OCM-4014	PS® Mini Cervical Multi-Axial Screw+Nut 4.0x14mm
OCM-4016	PS® Mini Cervical Multi-Axial Screw+Nut 4.0x16mm
OCM-4018	PS® Mini Cervical Multi-Axial Screw+Nut 4.0x18mm
OCM-4020	PS® Mini Cervical Multi-Axial Screw+Nut 4.0x20mm
OCM-4022	PS® Mini Cervical Multi-Axial Screw+Nut 4.0x22mm
OCM-4024	PS® Mini Cervical Multi-Axial Screw+Nut 4.0x24mm
OCM-4026	PS® Mini Cervical Multi-Axial Screw+Nut 4.0x26mm
OCM-4028	PS® Mini Cervical Multi-Axial Screw+Nut 4.0x28mm
OCM-4030	PS® Mini Cervical Multi-Axial Screw+Nut 4.0x30mm
OCM-4032	PS® Mini Cervical Multi-Axial Screw+Nut 4.0x32mm
OCM-4034	PS® Mini Cervical Multi-Axial Screw+Nut 4.0x34mm
OCM-4036	PS® Mini Cervical Multi-Axial Screw+Nut 4.0x36mm
OCM-4038	PS® Mini Cervical Multi-Axial Screw+Nut 4.0x38mm
OCM-4040	PS® Mini Cervical Multi-Axial Screw+Nut 4.0x40mm
OCM-4042	PS® Mini Cervical Multi-Axial Screw+Nut 4.0x42mm

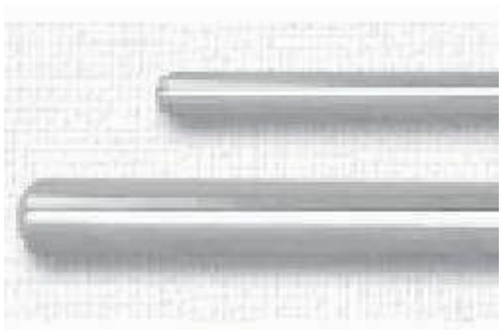
Implants:

Code	Product Name
	Nut
OCN-0010	PS® Mini Nut
	Rod
OCR-3580	PS® Mini Titanium Rod 3.5x80mm
OCR-3160	PS® Mini Titanium Rod 3.5x160mm
OCR-3240	PS® Mini Titanium Rod 3.5x240mm
OCVR-3580	PS® Mini CoCr Rod 3.5x80mm
OCVR-3160	PS® Mini CoCr Rod 3.5x160mm
OCVR-3240	PS® Mini CoCr Rod 3.5x240mm
	Hybrid Rod
OCR-3480	PS® Mini Titanium Hybrid Rod 3.5mm-6.0mm x 240mm
	Adjustable Transverse Connector
OCT-0010	PS® Mini Adjustable Transverse Connector S
OCT-0020	PS® Mini Adjustable Transverse Connector M
OCT-0030	PS® Mini Adjustable Transverse Connector L
	Lateral Connector
OCL-0010	PS® Mini Lateral Connector
	Domino
OCD-0010	PS® Mini Domino Connector 3.5mm-6.0mm
OCD-0020	PS® Mini Inline Rod Connector 3.5mm-6.0mm
	Occipital Plate
OCP-0010	PS® Mini Occipital Plate Small
OCP-0020	PS® Mini Occipital Plate Medium
OCP-0030	PS® Mini Multi-Level Plate
	Bone Screw
OCS-4006	PS® Mini Bone Screw 4.0x6mm
OCS-4008	PS® Mini Bone Screw 4.0x8mm
OCS-4010	PS® Mini Bone Screw 4.0x10mm
OCS-4012	PS® Mini Bone Screw 4.0x12mm
OCS-4014	PS® Mini Bone Screw 4.0x14mm
OCS-4016	PS® Mini Bone Screw 4.0x16mm
OCS-4018	PS® Mini Bone Screw 4.0x18mm
OCS-4020	PS® Mini Bone Screw 4.0x20mm
OCS-4022	PS® Mini Bone Screw 4.0x22mm
OCS-4024	PS® Mini Bone Screw 4.0x24mm

LOT 10

Connecting Road
(Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 427 & Titanium TT 427



Length	20 mm Dia. Code No.	30 mm Dia. Code No.	40 mm Dia. Code No.	50 mm Dia. Code No.
50 mm	SS 427-201	SS 427-301	SS 427-401	SS 427-501
75 mm	SS 427-202	SS 427-302	SS 427-402	SS 427-502
80 mm	SS 427-203	SS 427-303	SS 427-403	SS 427-503
100 mm	SS 427-204	SS 427-304	SS 427-404	SS 427-504
120 mm	SS 427-205	SS 427-305	SS 427-405	SS 427-505
125 mm	SS 427-206	SS 427-306	SS 427-406	SS 427-527
150 mm	SS 427-207	SS 427-307	SS 427-407	SS 427-507
200 mm	SS 427-208	SS 427-308	SS 427-408	SS 427-508
250 mm	SS 427-209	SS 427-309	SS 427-409	SS 427-509
300 mm	SS 427-210	SS 427-310	SS 427-410	SS 427-510
480 mm	SS 427-211	SS 427-311	SS 427-411	SS 427-511

Anterior Cervical Plate
(Titanium)

Code No.	Length
SS 429-020	20 mm
SS 429-025	25 mm
SS 429-030	30 mm
SS 429-035	35 mm
SS 429-040	40 mm
SS 429-045	45 mm
SS 429-050	50 mm
SS 429-055	55 mm
SS 429-060	60 mm
SS 429-065	65 mm
SS 429-070	70 mm
SS 429-075	75 mm
SS 429-080	80 mm
SS 429-085	85 mm
SS 429-090	90 mm
SS 429-095	95 mm
SS 429-100	100 mm
SS 429-105	105 mm
SS 429-110	110 mm

Cage
(Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 428 & Titanium TT 428

Length	10 mm Dia. Code No.	12 mm Dia. Code No.	14 mm Dia. Code No.	16 mm Dia. Code No.	18 mm Dia. Code No.	20 mm Dia. Code No.	22 mm Dia. Code No.	24 mm Dia. Code No.
20 mm	SS 428-120	SS 428-220	SS 428-320	SS 428-420	SS 428-520	SS 428-620	SS 428-720	SS 428-820
25 mm	SS 428-125	SS 428-225	SS 428-325	SS 428-425	SS 428-525	SS 428-625	SS 428-725	SS 428-825
30 mm	SS 428-130	SS 428-230	SS 428-330	SS 428-430	SS 428-530	SS 428-630	SS 428-730	SS 428-830
35 mm	SS 428-135	SS 428-235	SS 428-335	SS 428-435	SS 428-535	SS 428-635	SS 428-735	SS 428-835
40 mm	SS 428-140	SS 428-240	SS 428-340	SS 428-440	SS 428-540	SS 428-640	SS 428-740	SS 428-840
45 mm	SS 428-145	SS 428-245	SS 428-345	SS 428-445	SS 428-545	SS 428-645	SS 428-745	SS 428-845
50 mm	SS 428-150	SS 428-250	SS 428-350	SS 428-450	SS 428-550	SS 428-650	SS 428-750	SS 428-850

4.0 mm Bone Screw for Anterior Cervical Plate
(Titanium)

LOT 10

Code No.	Length
SS 430-010	10 mm
SS 430-012	12 mm
SS 430-014	14 mm
SS 430-016	16 mm
SS 430-018	18 mm
SS 430-020	20 mm
SS 430-022	22 mm
SS 430-024	24 mm

4.5 mm Mono Screw Single Lock
(Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 432 & Titanium TT 432

Code No.	Length
SS 432-015	15 mm
SS 432-020	20 mm
SS 432-025	25 mm
SS 432-030	30 mm
SS 432-035	35 mm

6.5 mm Mono Screw Single Lock
(Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 434 & Titanium TT 434

Code No.	Length
SS 434-030	30 mm
SS 434-035	35 mm
SS 434-040	40 mm
SS 434-045	45 mm
SS 434-050	50 mm
SS 434-055	55 mm

Lock Screw for Anterior Cervical Plate
(Titanium) Code No. TT 431-001

5.5 mm Mono Screw Single Lock
(Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 433 & Titanium TT 433

Code No.	Length
SS 433-030	30 mm
SS 433-035	35 mm
SS 433-040	40 mm
SS 433-045	45 mm
SS 433-050	50 mm
SS 433-055	55 mm

4.5 mm Poly Screw Single Lock
(Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 435 & Titanium TT 435

Code No.	Length
SS 435-015	15 mm
SS 435-020	20 mm
SS 435-025	25 mm
SS 435-030	30 mm
SS 435-035	35 mm

CONCEPT AND DESIGN

LOT 13, LOT 32

Powered in 2006 by a creative and pioneer team, BAGUERA®C was inspired by the black panther of the "Jungle book": black and elegant, agile but discret, mature while irresistible.

The goal at this time was to replace the disc function and to drastically simplify the existing technologies in motion preservation. After several years of usage and clinical follow up, BAGUERA®C is still innovative while clinically validated, and is now a reference in the cervical arthroplasty segment.

BAGUERA®C is a cutting-edge device that respects Spineart's philosophy, Quality, Innovation and Simplicity.

AT A GLANCE

GUIDED MOBILE NUCLEUS

ANATOMICAL DESIGN

LIMITED MRI ARTIFACT

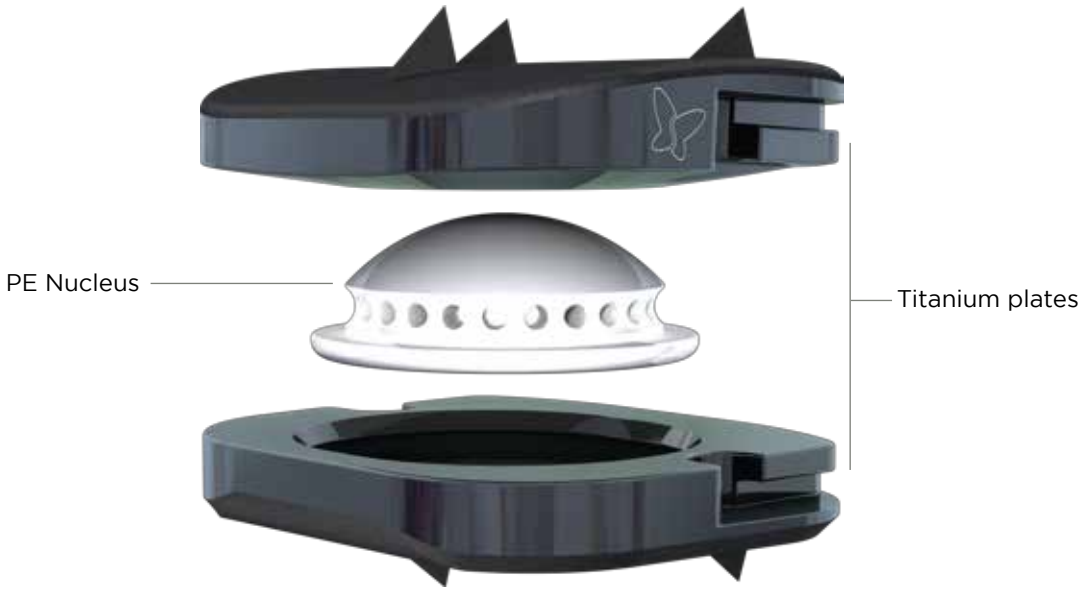
RADIOLUCENT HOLDER

INDICATIONS

The disc prosthesis BAGUERA®C is intended as a replacement for a degenerated cervical disc.

The BAGUERA®C range is indicated for patients presenting with the following pathologies from C3 to C7 : Cervical hernia / Cervicarthrose / Degenerative disc disease.

IMPLANTS



REFERENCES	
Heights	**Small : 13x16mm**
5mm	CDP-TI 13 05-S
6mm	CDP-TI 13 06-S
7mm	CDP-TI 13 07-S

Heights	**Medium : 14x17mm**
5mm	CDP-TI 14 05-S
6mm	CDP-TI 14 06-S
7mm	CDP-TI 14 07-S

REFERENCES	
Heights	**Large : 16x18mm**
5mm	CDP-TI 16 05-S
6mm	CDP-TI 16 06-S
7mm	CDP-TI 16 07-S

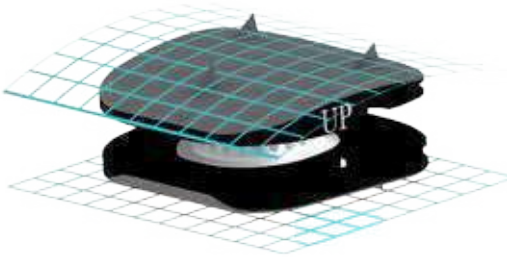
TECHNICAL FEATURES

GUIDED MOBILE NUCLEUS

- The guided mobile PE nucleus is designed to prevent excessive constraints on the facet joints. It allows 6 degrees of freedom.

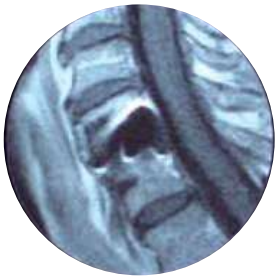
ANATOMICAL DESIGN

- The sloping anatomical design of the plates optimizes the fit between the device and the disc space, and maximizes the endplate coverage.



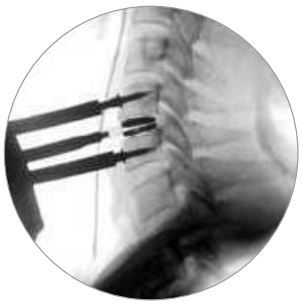
LIMITED MRI ARTIFACT

- The titanium plates, coated with DIAMOLITH® reduce artifacts under MRI for a better postoperative control.



RADIOLUCENT HOLDER

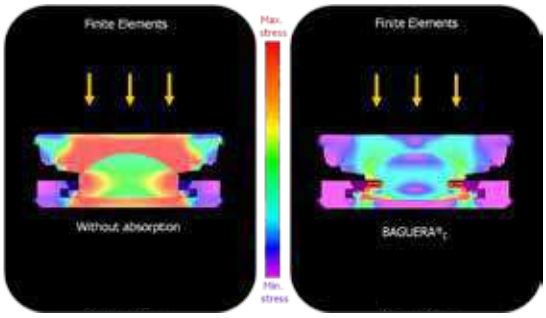
- The radiolucent holder allows for both verification of the anterior position of the device and confirmation of the fitting accuracy. Thanks to this holder, the device is delivered pre-assembled for better handling.



TECHNICAL FEATURES

SHOCK ABSORPTION

- The shape of the inferior plate and the PE nucleus are designed to enable absorption of shocks and vibrations.



PRIMARY STABILITY

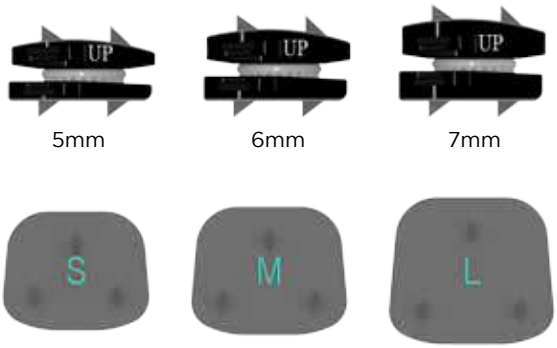
- The 3 upper and 3 lower fins as well as the porous titanium coating are designed for primary and secondary stability.

COMPACT SET

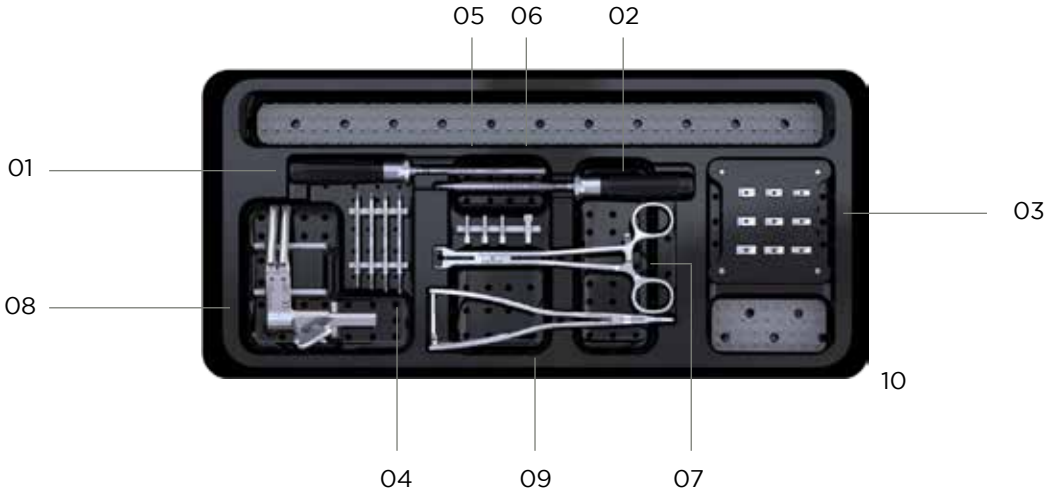
- The set includes 4 instruments, trials, and a lockable cervical system.

COMPLETE RANGE

- The prosthesis is available in 3 footprints, small (13x16), Medium (14x17) and large (16x18) and 3 heights from 5 to 7 mm.



INSTRUMENT SET



#	DESCRIPTION	REFERENCE
01	SCREWDRIVER FOR PINS	CDP-IN 30 01-N
02	IMPLANT HOLDER	CDP-IN 00 01-N
03	TRIAL IMPLANTS	CDP-IN 13 05-N CDP-IN 13 06-N CDP-IN 13 07-N CDP-IN 14 05-N CDP-IN 14 06-N CDP-IN 14 07-N CDP-IN 16 05-N CDP-IN 16 06-N CDP-IN 16 07-N
04	PINS	CDP-IN 30 12-N CDP-IN 30 14-N CDP-IN 30 16-N CDP-IN 30 18-N

#	DESCRIPTION	REFERENCE
05	NUT FOR PINS	CDP-IN 30 02-N
06	PUSHER	CDP-IN 00 03-N
07	EXTRACTOR	CDP-IN 00 02-N
08	ARTICULATED CERVICAL DISTRACTOR	CDP-IN 50 00-N
09	INTERSOMATIC DISTRACTOR	CDP-IN 00 04-N
10	INSTRUMENTS CONTAINER	CDP-BX 10 01-N
	OPTION	
	REVISION PINS	CDP-IN 40-12-N CDP-IN 40-14-N CDP-IN 40-16-N CDP-IN 40-18-N

INSTRUMENTS

PINS	CDP-IN 30 12-N to CDP-IN 30 18-N

ARTICULATED CERVICAL DISTRACTOR	CDP-IN 50 00-N

NUT FOR PINS	CDP-IN 30 02-N

SCREWDRIVER FOR PINS	CDP-IN 30 01-N

INTERSOMATIC DISTRACTOR	CDP-IN 00 04-N

TRIAL IMPLANTS	CDP-IN 13 05-N to CDP-IN 16 07-N

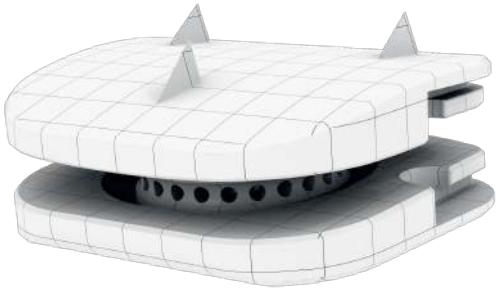
IMPLANT HOLDER	CDP-IN 00 01-N

EXTRACTOR	CDP-IN 00 02-N

PUSHER	CDP-IN 00 03-N

BAGUERA® C

CERVICAL DISC PROSTHESIS



TWO-YEARS PROSPECTIVE CLINICAL FOLLOW-UP

BY SPINEART

CERVICAL ARTHROPLASTY USING BAGUERA® C:
OVERVIEW OF TWO-YEAR, PROSPECTIVE, CLINICAL FOLLOW-UP DATA REGISTRY

POPULATION

118 patients were included in BAGUERA®C Registry, from 5 different hospitals in Europe, with two years prospective follow-up, through five follow-up visits, from 6 weeks to 2 years. The population studied includes 54 males (45.8%) and 64 females (54.2%), aged at the surgery time between 30 and 74 years. A total of 98 subjects were treated exclusively by TDR using BAGUERA®C, 70 subjects at 1 level, 25 subjects at 2 levels and 3 subjects at 3 levels. The rest of studied population, 20 subjects, underwent HYBRID surgery with 1 level TDR using BAGUERA®C for 14 subjects, 2 levels for 6 subjects. A total number of 149 BAGUERA®C cervical disc prostheses were implanted in 118 subjects at 4 cervical levels: C3-C4, C4-C5, C5-C6 and C6-C7.

OVERALL SUCCESS EVALUATION

- No implant-related adverse events were recorded. No patient needed subsequent surgery. Three surgery-related adverse events were recorded.
- A clinical improvement of more than 20% of the NDI score after two years was observed in 81.8% of the TDR patients. In the HYBRID group, this improvement was observed in 50.0% of the patients.
- The neurological examination concerning reflexes, motor function and sensitivity revealed a stable or improved status in all patients in both groups.
- An improvement of more than 20% of the VAS score for neck pain was observed in 75.5% of the patients in the TDR-only group, and 55.0% of the patients in the hybrid group after two years. The minimum 20% improvement of the VAS score for arm pain was observed in 77.6% of the patients in the TDR-only group, and 70.0% of the patients in the hybrid group. All VAS Patient Satisfaction scores show more than 70% satisfaction, with a net positive trend after 3 months post-operative until the end of the observation period for TDR surgeries, with the best results for TDR 2 levels surgeries (91.11% satisfaction).
- A 15% or more improvement in quality of life as evaluated by the Short Form 36 questionnaire was recorded, respectively in 76.5% (TDR group) and 60.0% (HYBRID group) for the physical component of the questionnaire, and in respectively 77.6% (TDR group) and 50.0% (HYBRID group) for the mental health component of the questionnaire.

CONCLUSION

Total disc replacement using BAGUERA®C device for the treatment of symptomatic cervical degenerative disc disease is a safe procedure with a low complication rate and in this study, no device-related adverse event. The best results were observed in patients of maximum 50 years of age, with no previous cervical or other spinal surgeries and with preoperative functional disabilities greater than 30% as evaluated by NDI.
TDR is an effective surgical treatment of one or two levels symptomatic cervical degenerative disc disease, whether used alone or in combination with other techniques. Functional improvement is slightly less frequent (30%) when HYBRID surgery is applied.

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Research Article Open Access

Radiographic Outcome and Adjacent Segment Evaluation Two Years after Cervical Disc Replacement with the Baguera®C Prosthesis as Treatment of Degenerative Cervical Disc Disease

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Abstract

Introduction: In many cases, cervical arthroplasty can avoid adjacent segment degeneration, by preserving the mobility of the operated level. In this paper, we present and analyze the radiological results of a cohort of patients who underwent cervical disc arthroplasty, with the Baguera®C cervical disc prosthesis.

Material and methods: 99 patients and a total of 123 prostheses were included in a retrospective analysis of radiographic images, based on a registry type data collection, with a two-year follow-up (FU). The radiological data was independently assessed for the range of motion, disc angle, disc height at the operated level and at the adjacent level, and for heterotopic ossifications (HO).

Results: At the operated level, the range of motion (ROM) decreased from 10.2° preoperatively to 8.7° (non-significant) after two years in the one level total disc replacement (TDR) group, from 9.8° to 9.1° (non-significant) in the two levels TDR group. The motion of the upper FSU changed from 10.6° preoperatively to 13.5° after two years in the one level TDR group, from 11.6° to 10.9° in the two levels group.

The disc height at the level of the operated FSU changed from 4 mm preoperatively to 7.1 mm after six weeks and 6.5 mm after two years for the one level TDR. The disc height at the level above the highest operated FSU changed from 4.24 mm preoperatively to 4 mm after six weeks and 4.2 mm after two years for the one level TDR, from 4.5 mm to 5.4 mm (6W) and 5.3 mm (2Y) for the two levels TDR.

No heterotopic ossification was observed in 46% of the patients. HO was observed, respectively 20.1% grade I, 14.5% grade II, 13.7% grade III and 5.6% grade IV. HO restricting mobility (grades III and IV) were seen in 19.3%. The prostheses were mobile in 80.6% after two years.

Conclusion: Cervical arthroplasty using the Baguera®C prosthesis, demonstrated cervical mobility preservation in 80.6% of the patients, an HO rate of 54%, mostly grade I and II, no signs of subsidence and no signs of degeneration or kyphosis of the adjacent disc. This motion preserving surgical treatment, either used alone or in combination with segmental fusion, shows encouraging results in term of adjacent level disease protection and appears, therefore, as safe and effective.

Keywords: Cervical disc; Ossification; Spondylarthrosis; Vertebrae

Abbreviations: TDR - Total Disc Replacement; ROM - Range Of Motion; FSU- Functional Spinal Unit; Ns: Non-Significant (Statistically); HO - Heterotopic Ossifications; FU - Follow-Up; COV - Coefficient Of Variation; SD - Standard Deviation; ICC - Intraclass Correlation Coefficient; PO - Post-Operative; SCDD - Symptomatic Cervical Disc Disease; PE - Polyethylene; DLC - Diamond-Like Carbon; AP - Antero-Posterior; ANOVA - Analysis of Variance

Introduction

Anterior cervical discectomy and fusion has been first introduced by Cloward and by Smith and Robinson [1,2] in 1958 and 1963 respectively. Although the clinical results were and still are excellent, the conversion of a functionally mobile spinal unit into an intersomatic fusion has disadvantages. The rigidity of a single fused segment is often well tolerated, but may cause increased strain at the levels i immediately adjacent to the fused segment [3].

Radiological changes have been described mainly above fused cervical discs. Cervical arthroplasty with artificial discs has been used for more than 10 years now, with clinical results equivalent or slightly superior to fusion in selected cases [4,5]. Theoretically, cervical arthroplasty could, by preserving the mobility of the operated level, avoid adjacent segment degeneration.

We describe the radiological results of a cohort of patients who underwent cervical disc arthroplasty, with single or double levels Baguera®C cervical disc prostheses.

Material and Methods

Based on a registry type data collection, we present a retrospective

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analysis of radiographic images. This allows for a quantitative assessment of the treatment's results, two years after implantation of the Baguera®C Prosthesis.

The registry contains data referring to subjects who underwent one- or multilevel arthroplasty using the Baguera®C prosthesis alone or in combination with other surgical treatments (i.e. arthrodesis, referred to as hybrid constructs), and were followed postoperatively for two years. All preoperative, intraoperative and postoperative follow-up visits were documented clinically and radiographically.

Primary and secondary objectives

Two primary objectives were defined: (i) motion at the treated level two years after total disc replacement (TDR), evaluated by its range of motion (ROM) between flexion and extension (motion being defined by a ROM of at least 2°), and (ii) disc height restoration two years after TDR.

The four secondary objectives were defined as: (i) motion at the adjacent level two years after TDR, evaluated by its ROM between flexion and extension (motion being defined by a ROM of at least 2°), (ii) overall cervical alignment, evaluated as overall lordosis by measuring C2-C7 angle, (iii) balance of the spine, evaluated by the angle of functional spine unit (FSU) at the treated level and (iv) impact on adjacent levels, evaluated by the upper adjacent angle and the upper disc height.

Demographics

99 patients from five European investigation centers were included in the analysis. X-Ray images used for the radiographic assessment were collected during three visits: Pre-operative visit, 6 weeks follow-up and 2 years follow-up.

60 patients had one-level surgery, 30 patients had two-level surgery and 9 patients had three-level surgery. 18 patients were treated with hybrid constructs (12 operated at two-levels – one prosthesis, one fusion - and 6 operated at three-levels –one prosthesis, two fusions). 81 patients were treated by prosthesis implantation only (60 operated at one-level, 18 operated at two-levels and 3 operated at three levels).

A total of 123 prostheses were utilized: 4 prosthesis were implanted in C3-C4, 19 in C4-C5, 53 in C5-C6 and 47 in C6-C7.

Inclusion and exclusion criteria

To be included in the registry, the patients had to suffer from symptomatic cervical disc disease (SCDD) between C3 and C7, as defined by the following signs and symptoms: neck or arm pain and/or functional and/or neurological deficit caused by herniated nucleus pulposus and/or spondylarthrosis defined by the presence of osteophytes and/or disc height reduction as confirmed by MRI or X-ray. We included patients aged between 18 and 75 years, not responding to non-surgical treatment for a period of at least six weeks, or presenting signs of progressive nerve root compression despite conservative treatment. Finally, included patients had to be psychologically, physically and mentally able to comply with the treatment protocol.

Exclusion criteria were: severe injury or degeneration of the facet joints confirmed by X-ray, known allergy to any of the constituent materials, prior cervical fractures, severe spondylarthrosis at the treatment site (syndesmophytes and/or absence of mobility (ROM < 2°)), pain unrelated to the cervical disc disease, metabolic bone disease (osteoporosis), Paget disease, severe diabetes requiring daily insulin treatment, pregnancy, active infection (systemic or local), rheumatoid arthritis or other auto-immune disease, systemic disease, including AIDS/HIV and hepatitis or active malignancy.

Figure 1: Baguera®C prosthesis.

All included patients accepted to sign an informed consent form. The registry protocol was reviewed by the local ethics committee on each site. The radiological assessment was performed in a semi-automatic way by an independent evaluator (icoMetrix NV, Leuven, Belgium).

Implant characteristics

The Baguera®C cervical prosthesis (Spineart SA, Geneva, Switzerland) is a biomechanical device designed to be used for TDR. It consists of a high-density polyethylene (PE) nucleus that articulates between two titanium endplate components, with a porous-titanium-coated exterior and a bioceramic (DLC)-coated-interior, in contact with the PE nucleus (Figure 1). The primary stability is obtained by the convex shape of the superior endplate and by three fins on each endplates that allow safe anchoring of the prosthesis i mmediately after the release of the Caspar retractor used during the discectomy. The secondary stability is obtained by bone growth inside the porous titanium coating. The implant allows a physiological rotation as well as translation in both the antero-posterior (AP) (± 0.3 mm) and rotational (± 2°) directions. The controlled mobility of the PE nucleus is designed to prevent excessive constraints on the facet joints, and its rolling feature respects axial rotation movements. The concave superior aspect of the inferior plate and PE nucleus shape allow 0.15 mm elastic deformation to absorb shocks and vibrations

Radiological evaluation protocol

Radiographic images preoperatively, at 6 weeks follow-up and at 2 years follow-up were evaluated for 10 parameters in neutral, flexion and extension position, related to the following three measurements: range of motion (ROM), angles and height.

A semi-automatic process was setup and performed by icoMetrix NV. The manual part, the Annotations phase, used a graphical user interface specially developed for marking and capturing coordinates related to implant and cervical vertebrae. Four landmarks corresponding to the corners were used for vertebrae identification, and they were marked by an expert radiologist using mouse clicks (Figures 2a-2c). Coordinates were automatically recorded in a structured .xml format and used by the automatic component developed using Python (http://www.python.org) as input for all calculations.

Errors of measurement (coming from both manual and algorithmic components) were estimated for each parameter by an extensive reproducibility study: The absolute error, the relative error and the reproducibility coefficients were taken as the standard deviation (SD), the coefficient of variation (CoV) and the intra-class correlation (ICC) respectively. An ANOVA, two-way effect model, was used to quantify the absolute agreement.

The ROM (in degrees) describes the mobility of the observed spine unit. The angles that are used to transform the vertebrae above and below the Baguera®C between flexion and extension provide the range of motion (Figure 3). It was assessed using the flexion and extension images by using a registration (image alignment) algorithm,

which aims at matching two vertebrae in the flexion image with the corresponding vertebrae in the extension image. As a result, two transformations are obtained that describe the matching of the first vertebrae between flexion and extension and the second vertebrae between flexion and extension. Based on the difference between these two geometrical transformations, the range of motion was calculated. The same automatic procedure was used to evaluate the range of motion at the treated level, upper adjacent level, overall between C2 and C7 and overall between C2 and C6.

The disc angle (in degrees) is the angle between the plates of adjacent levels and represents the balance of the spine. It was assessed using neutral images after determination of four landmark points. These landmarks were positioned on the inferior corners of the vertebral body below the artificial disc and on the superior corners of the vertebra above the artificial disc. Once these points were in place, lines connecting the landmarks were automatically drawn (Figure 4). As a result, the angle between both endplates was calculated. The same semi-automated procedure was used to measure the angle of the FSU at the treated level, upper adjacent FSU, and the angle of the overall spine between C2-C7 and C2-C6. The FSU (functional spinal unit) is

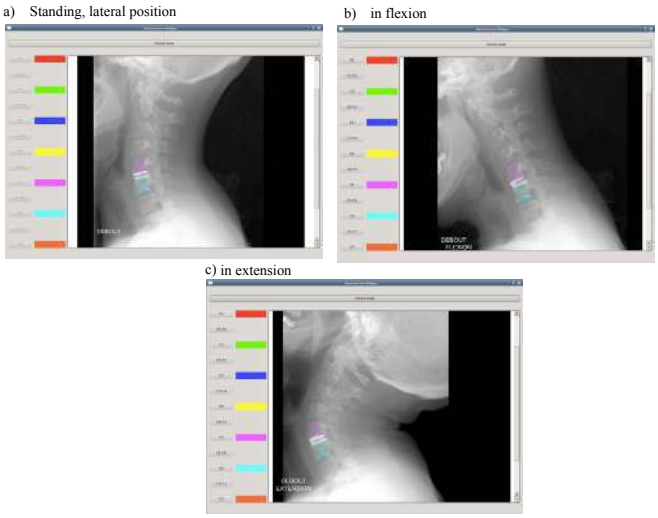

Figure 2: Radiographic images two years after surgery (annotated) Subjects who underwent 1 level (C5-C6) total disc replacement using Baguera®C.

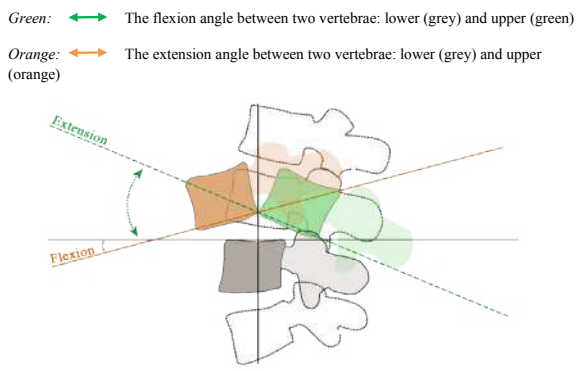

Figure 3: Range of Motion (ROM): The angles used to transform the vertebrae above and below the Baguera®C between flexion and extension provide the range of motion. Grey color is used for lower vertebra. Green and orange are used for upper vertebra in extension and flexion, respectively. The fixed reference for flexion and extension angles, corresponding to the superior plate of lower vertebra, is the black (horizontal) line.

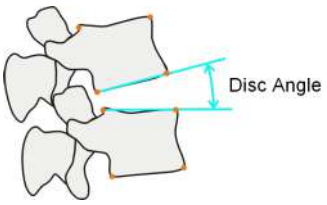

Figure 4: Disc angle.

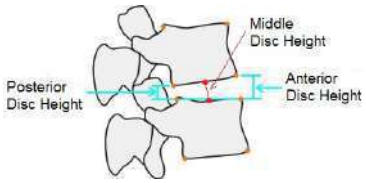

Figure 5: Disc height (middle).

the entity regrouping a disc, the two corresponding facet joints and the two adjacent vertebrae.

Disc height is the distance (in millimeters) between the upper plate of the lower vertebra and the lower plate of the upper vertebra: We used, as its measure, the middle disc height, i.e. the distance measured perpendicular to the plane of the top plate at mean distance (Figure 5). This distance is used to assess the disc height restoration. The disc height was assessed using neutral images, after calibration to cancel any magnification factor.

Heterotopic ossifications (HO) were addressed and classified according to the McAfee classification modified by Mehren et al. [6] The classification has a 5-points grading system: grade 0 = no HO; grade I = presence of HO but not in the interdiscal space; grade II = presence of HO in the interdiscal space; grade III = bridging of ossification with segment movement; grade IV = complete fusion without movement in flexion/extension.

Statistical analysis

The statistical analysis was performed using SAS®9.3 and results are presented as su mmary statistics, overall and by type of surgery, study visit, treated level, illustrated by tables and figures.

Comparisons between preoperative and postoperative values were performed and statistical significance of observed change in values was noted. The results with $p<0.05$ were considered significant. Only subjects with available data at all 3 visits (preoperative and postoperative at 6 weeks, 2 years respectively) were included in these comparisons.

Parametric (paired t-test) or non-parametric Wilcoxon (signed-rank) test was used depending on normality. The normality of distributions was evaluated by Shapiro-Wilcoxon (sign-rank) test.

Comparisons between preoperative and postoperative values were made using paired t-test for normal distributed data and Wilcoxon test when normality was not confirmed.

Results

Range of motion of the functional spine unit

At the operated level, the ROM decreased from 10.2 ° (preoperatively) to 8.7° (ns) after two years in the one level TDR, from 9.8° to 9.1° (ns) in two levels TDR. The decrease was more pronounced in the three levels TDR, dropping from 13.2° preoperatively to 5.9° (ns) after two years, but on a smaller cohort of patients (Table 1). Figure 6

illustrates all results for subjects who underwent one-level TDR, at pre-operative and postoperative visits (left) and by treated level at 2-year FU (right).

For the hybrid constructs, the ROM of the prostheses decreased from 10.7° to 6.9° after two years when implanted in association with one level fusion, and from 11.66° to 7.7° when implanted in association with two fused levels.

Range of motion of the upper functional spine unit

The motion of the upper FSU changed from 10.6° preoperatively to 13.5° after two years in the one level TDR group, from 11.6° to 10.9° in the two levels group and from 11.1° to 7.1° in the three levels group (Table 2). Figure 7 illustrates all results for subjects who underwent one-level TDR, at pre-operative and postoperative visits (left) and by treated level at 2-year FU (right).

Range of motion of the C2C7 levels and C2C6 levels

The overall range of motion of the C2C7 levels changed from 51.1° to 54° after two years in the one level TDR group, from 50.2° to 46.8° in the two levels group and from 60.7° to 32.3° in the three levels group (Table 3). Figure 8 illustrates all results for subjects who underwent one-level TDR, at pre-operative and postoperative visits (left) and by treated level at 2-year FU (right).

Not surprisingly, in the hybrid group the overall C2C7 ROM decreased according to the number of fused levels, changing from 48.2° preoperatively to 40.8° when the prosthesis was implanted in association with one level fusion, and from 75.2° to 28.5° when the prosthesis was implanted in association with two fused levels.

Similar tendencies were observed when measuring the C2C6 ROM.

Angle of the functional spine unit

At the operated level, the angle changed from 5.6° preoperatively to 6.3° after two years for the one level TDR, from 4.6° to 6.8° for the two-level TDR and from 8.21° to 3.93° for the three-levels TDR.

Angle of the upper functional spine unit

The angle of the level above the operated level changed from 7.4° preoperatively to 6.4° after two years for the one level TDR, from 6.8° to 7.6° for the two-level TDR and from 10.8° to 5.2° for the three-levels TDR.

Overall angle of the C2C7 levels and of the C2C6 levels

The overall C2C7 angle changed from 19.9° preoperatively to 12.8° after two years for the one level TDR, from 27.5° to 16.8° for the two-level TDR and from 20.7° to 13.2° for the three-levels TDR.

The overall C2C6 angle changed from 19.17° preoperatively to

Type of Surgery	BAGUERA®C implanted	Treated Levels	Pre-op		6W (PO)		2Y (PO)		Pre-op vs 2Y (absolute change)	
			Mean	SD	Mean	SD	Mean	SD	Mean	p-value
TDR	1	1	10.25	4.1	8.55	4.4	8.79	4.6	-1.3	ns
	2	2	9.80	4.7	6.90	3.4	9.15	5.3	-0.04	ns
	3	3	13.26	3.3	7.21	3.3	5.99	3.5	-6.43	ns
HYBRID	1	2	10.70	3.9	5.65	3.8	6.99	4.0	-4.72	0.05(*)
		3	11.66	3.2	7.59	3.0	7.75	0.4	-	-
(*) - p-value from Wilcoxon teste.										

Table 1: Range of Motion at the treated level (ROM-FSU) (degrees): Pre-operative vs. post-operative values. Summary statistics: Overall and by number of treated levels.

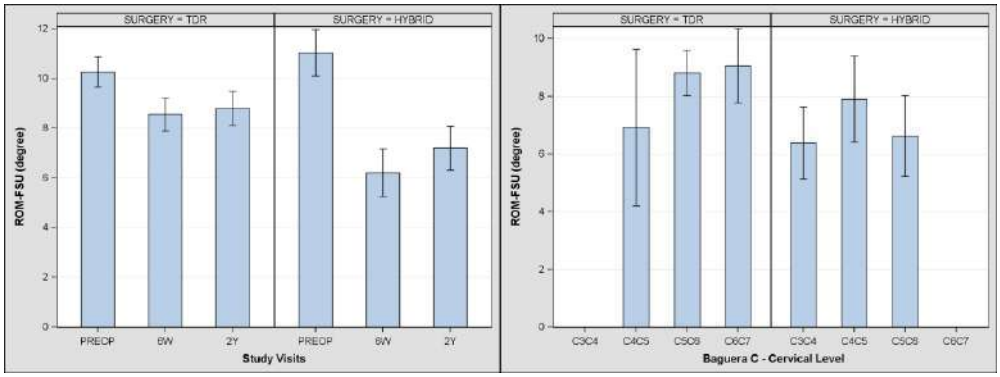

Figure 6: Range of Motion at the treated level (ROM-FSU). **Left:** Pre- and post-operative values for subjects treated by 1 level TDR using Baguera®C. Non-significant changes between pre-operative and post-operative data were observed. **Right:** Two years after surgery values, by treated level for subjects who underwent 1 level TDR using Baguera®C, by type of surgery (TDR, HYBRID).

Type of Surgery	BAGUERA®C implanted	Treated Levels	Pre-op		6W (PO)		2Y (PO)		Pre-op vs 2Y (absolute change)	
			Mean	SD	Mean	Mean	Mean	SD	Mean	p-value
TDR	1	1	10.64	5.2	10.91	5.0	13.54	5.4	2.79	ns
	2	2	11.66	4.7	7.86	3.6	10.94	5.1	-0.64	ns
	3	3	11.15	4.3	6.50	4.0	7.19	3.7	-3.78	ns
HYBRID	1	2	10.36	6.1	6.57	5.3	9.99	6.5	0.08	ns
		3	11.04	4.9	8.15	5.4	10.30	2.9	-2.86	ns

Table 2: Range of Motion at the upper adjacent level (UPPER ROM): Preoperative vs. postoperative values. Summary statistics: Overall and by number of treated levels.

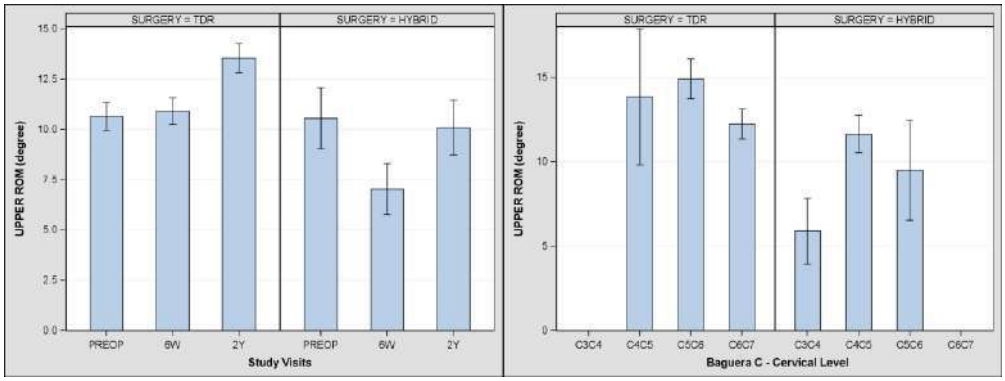

Figure 7: Range of Motion at the upper adjacent level (UPPER ROM). **Left:** Pre- and post-operative values for subjects treated by 1 level TDR using Baguera®C. Significant improvement (p=0.01) between pre-operative and 2 year's post-operative data. **Right:** Two years after surgery values, by treated level for subjects who underwent 1 level TDR using Baguera®C, by type of surgery (TDR, HYBRID).

Overall cervical ROM	Type of Surgery	BAGUERA®C implanted	Treated Levels	Pre-op		6W (PO)		2Y (PO)		Comparison: Pre-op vs 2Y	
				Mean	SD	Mean	SD	Mean	SD	Mean	p-value
C2-C7	TDR	1	1	51.50	15.0	43.93	15.4	54.03	11.6	5.32	ns
		2	2	50.20	13.7	37.82	15.4	46.88	8.9	-0.02	ns
		3	3	60.74	6.8	33.84	8.5	32.38	13.1	-	-
	HYBRID	1	2	48.20	21.1	42.34	5.4	40.86	14.1	-	-
			3	75.20	.	18.41	9.0	28.58	7.5	-	-
C2-C6	TDR	1	1	42.07	12.4	38.98	11.2	47.10	11.0	4.43	ns
		2	2	43.02	11.9	31.11	10.9	41.72	10.6	-1.13	ns
		3	3	44.53	0.8	28.40	7.2	28.62	7.0	-15.91	ns
	HYBRID	1	2	40.91	15.5	26.33	14.9	31.94	10.3	-6.47	ns
			3	38.46	9.3	18.39	12.5	29.53	9.7	-12.29	ns

Table 3: Overall cervical range of motion (ROM-C2C7 and ROM-C2C6) (degrees): Preoperative vs. postoperative values. Summary statistics: Overall and by number of treated levels.

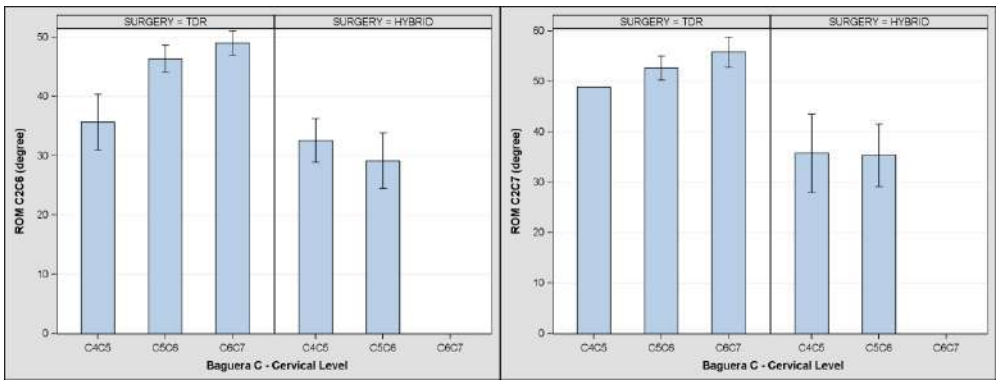

Figure 8: Overall cervical range of motion two years after surgery for subjects who underwent 1 level TDR using Baguera®C by treated level and type of surgery (TDR, HYBRID): ROM-C2C6 (left), ROM-C2C7 (right).

10.4° after two years for the one level TDR, from 24.7° to 15.8° for the two-level TDR and from 14.7° to 13.7° for the three-levels TDR

Disc height of the functional spine unit

The disc height at the level of the operated FSU changed from 4 mm preoperatively to 7.1 mm after six weeks and 6.5 mm after two years for the one level TDR, from 4. mm to 7.5 mm (6W) and 6.5 mm (2Y) for the two levels TDR and 5.1 mm to 7.6 mm (6W) and 7.3 mm (2Y) for the three-levels TDR.

Disc height of the upper functional spine unit

The disc height at the level above the highest operated FSU changed from 4.2 mm preoperatively to 4 mm after six weeks and 4.2 mm after two years for the one level TDR, from 4.5 mm to 5.4 mm (6W) and 5.3 mm (2Y) for the two levels TDR and 5.5 mm to 6.4 mm (6W) and 6.2 mm (2Y) in the three levels TDR.

Heterotopic ossifications

Heterotopic ossifications were measured at the operated level in all 99 patients, accounting for a total of 123 operated levels.

No HO was observed in 46% of the patients (grade 0).

The HO grade for the remaining 54% was: grade I (for 20.1%), grade II (for 14.5%), grade III (for 13.7%) and grade IV (for 5.6%).

HO restricting mobility (grades III and IV) were observed in 19.3% of the patients.

The prostheses were thus mobile in 80.6% of the patients after two years.

Discussion

Although this series covers a limited number of patients, and presents with limitations inherent to its retrospective nature, we found out that most published studies present the same structure and that therefore, a comparison with the literature data was reasonable.

Relevance of the measure

In order to ensure the clinical usability of these results, the relatively scarce, existing, literature was thoroughly reviewed. This provided the necessary insight on which measurements to perform, to evaluate spine mobility and balance [7-12], and on the values to expect: e.g. the ROMs as reported in Sasso et al. [9] or Bertagnoli et al. [8]. Based on these studies, we expected average ROMs to vary between 5° and 15°. Therefore, we aimed at achieving a standard error on the ROM measurement of around 1°, in order to be able to capture the differences between pre-op, 6 weeks and 2 years images. Thanks to the automated measure method, we achieved a sufficient precision in both angular and distance measurements.

Mobility at the operated level

Mobility at the treated level after two years of total disc replacement (TDR) using Baguera®C was evaluated by the range of motion (ROM) between flexion and extension; mobility is present when ROM value is at least 2°, or better 4° as suggested by J.Vital et al. [13,14].

The fact that motion slightly decreased after two years is not an issue because this diminish the constraint on facet joint that can be painful.

Two years after surgery, mobility at the operated level for patients treated by only TDR using Baguera®C was noted for 93%, 93.6% and 87.5% of treated levels, when one-level, two-levels and three-level TDR respectively was performed. In case of Hybrid treatment, mobility at the treated levels was observed for 81.8% and 100% of treated levels when one-level TDR was associated with one or respectively two-level arthrodesis. We observed better results for 1-level TDR (8.79°,) compared to results reported by Sasso et al. [5] and [9] reporting 8.79° and 6.7°, respectively), and Ryu et al. [15] reporting 7.9° for Bryan group and 4.1° for Prodisc group), the average values after 2 years post-surgery.

One explanation for these good results is that semi-constrained prostheses featuring a semi mobile nucleus could enable a more physiological movement than constrained prosthesis with a fixed center of rotation that could limit movement of the operated segment and cause painful friction of the facet joints.

Disc height at the operated level

The disc height was increased after TDR, changing from an average 4.44 mm (1level), 4.35 mm (2 levels) and 4.92 mm (3 levels) preoperatively to respectively 7.27 mm, 6.87 mm and 7.72 mm after two years. The increased disc height was constant between the 6W observation and the 2Y observation, showing no signs of subsidence.

Our data show better results in terms of disc height restoration after 2 years, (6.5 mm in average for 1 level TDR, 6.54 mm for 2 levels TDR), compared to published data by Ryu et al. [15], reporting at the last FU in average 3.3 mm for Bryan group and 3.5 mm for Prodisc group.

Adjacent level degeneration

Although the assessment of adjacent level degeneration over a two years period is debatable, we tried to monitor the changes of the FSU cranial to the highest TDR level, assuming that potential changes would reflect increased stress and more chances of further degeneration.

In the one-level patients, we observed a slightly increased ROM from 10.46° to 13.57°. This increase was not observed in the two- and three levels patients who showed a decreased ROM from 11.66° to 10.94° and from 11.15° to 7.19°, respectively in the two and three levels group.

Also, the measure of the adjacent FSU angle showed no significant sagittal balance changes and the adjacent FSU disc height was preserved. Our interpretation of this data is that TDR had little or no influence on the evolution of the adjacent level over the two years observation period.

Heterotopic ossifications

Several authors have studied heterotopic ossifications with various disc prosthesis [6,14-17]. In some studies, a high rate of HO occurrence and a limitation of mobility were observed: Suchomel et al. [17] studied 65 Prodisc C prostheses. HO was present in 86% of the patients after two years. During a 48-month period on the same cohort, they also found that significant HO (grade III) was present in 45% of the implants and that segmental ankylosis (grade IV) was present in another 18%, adding up to a total of 63% of non-mobile prosthesis. Also, Lee reported 77% HO in a group of patients treated with the Mobi C prosthesis, with two years FU [16], and Mehren reported 66.2% of HO only one year after cervical disc replacement with the Prodisc C prosthesis [6].

Other studies, however, report less concerning results: Tu et al. [14] reported a 50% general rate of HO with the Bryan prosthesis, with less than two years FU. Similarly Ryu et al. [15] reported 57% HO for the Bryan prosthesis and 47% HO for the Prodisc C on a small group of patients and with two years FU.

Our study scores show better results, with an overall HO grade of 54%, mostly grade I and II, explaining the rather high 80.64% rate of mobile implants after two years. We attribute these good results to the semi constrained and more physiological design of the prosthesis and to the careful selection criteria.

Finally, the fact that data from different cervical levels have been combined, may potentially influence the final results of this analysis and should therefore is considered as a limitation of this study.

Conclusion

Radiographic data coming from subjects enrolled in the Baguera®C Registry who met inclusion criteria for current analysis, demonstrate cervical mobility preservation in 80.64% of the patients, and an HO rate of 54%, mostly grade I and II.

There were no signs of subsidence of the prostheses. Measures at the level adjacent to the TDR showed no signs of degeneration, no signs of kyphosis and the adjacent disc height was preserved.

Cervical arthroplasty using the Baguera®C prosthesis is thus a safe, effective and motion preserving surgical treatment, either used alone or in combination with segmental fusion, showing encouraging results in term of adjacent level disease protection.

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Citation: Fransen P, Hansen-Algenstaedt N, Chatzisotiriou A, Noriega DCG, Verheyden J, et al. (2016) Radiographic Outcome and Adjacent Segment Evaluation Two Years after Cervical Disc Replacement with the Baguera®C Prosthesis as Treatment of Degenerative Cervical Disc Disease. J Spine 5: 298. doi:10.4172/2165-7939.1000298

BAGUERA®C Study #16001

Cervical Arthroplasty using BAGUERA® C: A two-year, prospective, clinical follow-up data registry. Retrospective clinical analysis results

Not FDA approved. Non-US study
Region: Europe
Status: Completed

Pilot study for registration in various countries

Primary Objectives:

- **Safety Evaluation:**
  Evaluation at the end of 2 years post-operative follow-up of the safety of the BAGUERA®C cervical disc prosthesis by analyzing all adverse events reported during the observation period, whether anticipated or unanticipated, related or not to the use of the device.

- **Effectiveness Evaluation:**
  An **overall success rate** was defined as a composite primary endpoint, based on individual overall success evaluated for each subject at 24 months post-operative, based on five parameters taken from clinical and safety evaluation:
  1. *Functional improvement* of 20% at 24 months post-operative, compared to the pre-operative status, evaluated by the Neck Disability Index (NDI).
  2. *Neurological improvement*: conservation of or improvement in three main components of the neurological status: *motor functions, reflexes, sensibility*.
  3. *Neck and Arm Pain*: pain relief of 20% at 24 months post-operative, compared to the pre-operative status, evaluated by VAS scores.
  4. *Improvement in Health-related Quality of Life* of 15% at 24 months post-operative, compared to the pre-operative status, assessed using the Short-Form-36 questionnaire (SF-36 scores)
  5. *No subsequent surgery*.

Indication - condition: Symptomatic cervical degenerative disc disease one or two levels from C3 to C7

Study type: Observational, prospective data collection (registry), retrospective analysis, multicenter cohort study

Patients enrolled: 118

Primary outcomes:

- NDI scores
- Adverse events:
  - Duration (starts and end dates),
  - Seriousness, Intensity, Severity, Anticipated/Unanticipated
  - Relationship to the implant (suspected/not suspected),
  - Re-interventions, Revisions,
  - Relationship to the surgery (suspected/not suspected),
  - Removals or supplemental fixation.
- Neck and Arm Pain by Visual Analogic Scale (VAS)
- Neurological status: motor functions, reflexes, sensibility
- SF-36 scores

BAGUERA®C Study #16002

Cervical Arthroplasty using BAGUERA® C: A two-year, prospective, clinical follow-up data registry. Retrospective radiographic evaluation

Not FDA approved. Non-US study
Region: Europe
Status: Completed

Pilot study for registration in various countries

Primary Objectives:

1. *Motion* at the treated level after two years of total disc replacement (TDR) using Baguera C prosthesis, evaluated by its range of motion (ROM) between flexion and extension; motion occurs when ROM value is at least 2°;
2. *Disc height restoration* after two years of total disc replacement (TDR) using Baguera C prosthesis.

Secondary Objectives:

1. *Motion* at the adjacent level after two years of total disc replacement (TDR) using Baguera C prosthesis, evaluated by its range of motion (ROM) between flexion and extension; motion occurs when ROM value is at least 2°;
2. *Overall cervical alignment,* evaluated as overall lordosis by measuring C2-C7 ROM;
3. *Balance of the spine*, evaluated by the angle of functional spine unit (FSU) at the treated level;
4. *Impact on adjacent levels,* evaluated by the upper adjacent angle and the upper disc height.

Indication - condition: Symptomatic cervical degenerative disc disease one or two levels from C3 to C7

Study type: Observational, prospective data collection (registry), retrospective analysis, multicenter cohort study

Patients enrolled: 96

Primary outcomes:

- ROM FSU : Range of motion (ROM) of the Functional Spine Unit (FSU)
- HEIGHT: Disc Height

Secondary outcomes:

- UPPER ROM: Range of motion of the Upper Functional Spine Unit
- ROM C2-C6: Range of motion of C2-C6 levels
- ROM C2-C7: Range of motion of C2-C7 levels
- ANGLE FSU: Angle of the Functional Spine Unit
- UPPER ANGLE: Angle of the Upper Functional Spine Unit
- ANGLE C2-C6: Angle of C2-C6 levels
- ANGLE C2-C7: Angle of C2-C7 levels
- UPPER HEIGHT: Disc Height of the Upper Functional Spine Unit

LOT 6

CE

Tria Spine

Spine | Orthopedics

LorX® TLIF Titanium Cage

- BETTER STABILITY
- TITANIUM
- ANATOMICAL SHAPE
- BIOCOMPATIBILITY
- ENHANCED BONE FUSION
- SPECIAL TEETH DESIGN

LorX® TLIF Titanium Cage is a posterior interbody fusion device for the stabilization and the correction of the lumbo-sacral region in the aim of the treatment of lumbar and/or lumbo-sacral spine (L1-L5) diseases.

LorX® TLIF Titanium Cage is intended for use of one implant per level.

System elements are made of Titanium ASTM F2026, and titanium alloy (Ti6Al4V) as per ISO 5832-3 (ASTM F136 and BS 7252-3).

- Enhanced instrumentation for secure insertion
- Original and anatomical design for a secure and better placement
- Radiolucent and biocompatible Titanium material , ASTM F2026) which provides modulus of elasticity similar to the bone
- Two adequate graft space for bone fusion
- Three titanium markers for the verification of anterior and posterior implant placement
- Specially designed teeth structure for easy insertion and secure placement

WE SERVE LIFE

www.triaspine.com

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CE

Tria Spine

Spine | Orthopedics

LorX® TLIF Titanium Cage

- BETTER STABILITY
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- BIOCOMPATIBILITY
- ENHANCED BONE FUSION
- SPECIAL TEETH DESIGN

LorX® TLIF Titanium Cage Rotating 4° / 8°

LorX® TLIF Titanium Cage Rotating 7x30x12mm
LorX® TLIF Titanium Cage Rotating 8x30x12mm
LorX® TLIF Titanium Cage Rotating 9x30x12mm
LorX® TLIF Titanium Cage Rotating 10x30x12mm
LorX® TLIF Titanium Cage Rotating 11x30x12mm
LorX® TLIF Titanium Cage Rotating 12x30x12mm
LorX® TLIF Titanium Cage Rotating 13x30x12mm
LorX® TLIF Titanium Cage Rotating 14x30x12mm
LorX® TLIF Titanium Cage Rotating 15x30x12mm
LorX® TLIF Titanium Cage Rotating 16x30x12mm
LorX® TLIF Titanium Cage Rotating 17x30x12mm
LorX® TLIF Titanium Cage Rotating 18x30x12mm

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Tria Spine Medikal A.Ş.

DECLARATION OF CONFORMITY

We **Tria Spine Medikal A.Ş.**
Ostim OSB Mah. 1208. Cad. No:5/1 Yenimahalle ANKARA TURKEY

our entire liability, "STERILE" LorX® Titanium Cage System products specified in the attachedlist;

have met the requirements of Council Directive 93/42 / EEC Annex II for medical devices.
All supporting documents are kept at the manufacturer's premises.

Classification	:	MDD 93/42/EEC, Ek IX, Rule 8 - Class IIb
Conformity Assessment Road	:	MDD 93/42/EEC, Annex II (except section 4)
CE Certificate No	:	2195-MED-1404201
Notified Body	:	SZUTEST Uygunluk Değerlendirme A.Ş. Tatlısu Mahallesi, Akif İnan Sk. No:1, 34774 Ümraniye/İstanbul
Authorized Institution Number		2195
Place and Date Arranged	:	Istanbul, 11.02.2014 - Rev06, 25.05.2021
Date of Validity	:	2024-05-26
GMDN Codes	:	60847
Harmonized Standards	:	EN 1041, EN ISO 10993-7, EN ISO 11137, TS EN ISO 11138-2, EN ISO 13485, EN ISO 15223-1, EN ISO 13485, EN ISO 14971,TS EN ISO 10993-1, TS EN ISO 10993-2, TS EN ISO 10993-11, TS EN ISO 10993-10, TS EN ISO 10993-4, TS EN ISO 10993-3 , EN ISO 14630, EN ISO 14602, EN ISO 21534, ASTM 2077-14, EN ISO 11607-1, EN ISO 11607-2, EN 556-1, EN ISO 11737-1 EN ISO 11737-2

05.01.2021/ ANKARA

Kamil BAL
General Manager

Date / Location

LOT 6

Tria Spine
Spine | Orthopedics

Date : 05.01.2021
REV.0

LorX® Cervical Titanium Cage System		
Code	**Product Name**	**EAN code**
LX-65-524	LorX® Cervical Titanium Cage 15x12x4mm	866082535881
LX-65-525	LorX® Cervical Titanium Cage 15x12x5mm	866082535886
LX-65-526	LorX® Cervical Titanium Cage 15x12x6mm	866082535891
LX-65-527	LorX® Cervical Titanium Cage 15x12x7mm	866082535896
LX-65-528	LorX® Cervical Titanium Cage 15x12x8mm	866082535901
LX-65-529	LorX® Cervical Titanium Cage Anchor Screw 3.5 x 8mm	866082535906
LX-65-530	LorX® Cervical Titanium Cage Anchor Screw 3.5 x 10mm	866082535911
LX-65-531	LorX® Cervical Titanium Cage Anchor Screw 3.5 x 12mm	866082535916
LX-69-287	LorX® PLIF Titanium Expandable Cage 7x28x9mm	866082535786
LX-69-288	LorX® PLIF Titanium Expandable Cage 8x28x9mm	866082535785
LX-69-289	LorX® PLIF Titanium Expandable Cage 9x28x9mm	866082535784
LX-69-2810	LorX® PLIF Titanium Expandable Cage 10x28x10mm	866082535783
LX-69-2811	LorX® PLIF Titanium Expandable Cage 11x28x10mm	866082535782
LX-69-2812	LorX® PLIF Titanium Expandable Cage 12x28x10mm	866082535781
LX-69-2813	LorX® PLIF Titanium Expandable Cage 13x28x10mm	866082535780
LX-77-307	LorX® TLIF Titanium Cage Rotating 7x30x12mm 4 degree	866082535987
LX-77-308	LorX® TLIF Titanium Cage Rotating 8x30x12mm 4 degree	866082535997
LX-77-309	LorX® TLIF Titanium Cage Rotating 9x30x12mm 4 degree	866082536007
LX-77-310	LorX® TLIF Titanium Cage Rotating 10x30x12mm 4 degree	866082536017
LX-77-311	LorX® TLIF Titanium Cage Rotating 11x30x12mm 4 degree	866082536027
LX-77-312	LorX® TLIF Titanium Cage Rotating 12x30x12mm 4 degree	866082536037
LX-77-313	LorX® TLIF Titanium Cage Rotating 13x30x12mm 4 degree	866082536047
LX-77-314	LorX® TLIF Titanium Cage Rotating 14x30x12mm 4 degree	866082536057
LX-77-315	LorX® TLIF Titanium Cage Rotating 15x30x12mm 4 degree	866082536067
LX-77-316	LorX® TLIF Titanium Cage Rotating 16x30x12mm 4 degree	866082536077
LX-77-317	LorX® TLIF Titanium Cage Rotating 17x30x12mm 4 degree	866082536087
LX-77-318	LorX® TLIF Titanium Cage Rotating 18x30x12mm 4 degree	866082536097
LX-77-407	LorX® TLIF Titanium Cage Rotating 7x30x12mm 8 degree	866082536123
LX-77-408	LorX® TLIF Titanium Cage Rotating 8x30x12mm 8 degree	866082536129
LX-77-409	LorX® TLIF Titanium Cage Rotating 9x30x12mm 8 degree	866082536135
LX-77-410	LorX® TLIF Titanium Cage Rotating 10x30x12mm 8 degree	866082536141
LX-77-411	LorX® TLIF Titanium Cage Rotating 11x30x12mm 8 degree	866082536147
LX-77-412	LorX® TLIF Titanium Cage Rotating 12x30x12mm 8 degree	866082536153
LX-77-413	LorX® TLIF Titanium Cage Rotating 13x30x12mm 8 degree	866082536159
LX-77-414	LorX® TLIF Titanium Cage Rotating 14x30x12mm 8 degree	866082536165
LX-77-415	LorX® TLIF Titanium Cage Rotating 15x30x12mm 8 degree	866082536171
LX-77-416	LorX® TLIF Titanium Cage Rotating 16x30x12mm 8 degree	866082536177
LX-77-417	LorX® TLIF Titanium Cage Rotating 17x30x12mm 8 degree	866082536183
LX-77-418	LorX® TLIF Titanium Cage Rotating 18x30x12mm 8 degree	866082536189
LX-29-524	LorX® Cervical Titanium Disc Prosthesis 15x12x4,5mm	866082536765
LX-29-525	LorX® Cervical Titanium Disc Prosthesis 15x12x5,5mm	866082536769
LX-29-526	LorX® Cervical Titanium Disc Prosthesis 15x12x6,5mm	866082536773
LX-29-527	LorX® Cervical Titanium Disc Prosthesis 15x12x7,5mm	866082536777
LX-29-528	LorX® Cervical Titanium Disc Prosthesis 15x12x8mm	866082536781
LX-29-529	LorX® Cervical Titanium Disc Prosthesis 15x12x8,5mm	866082536785
LX-30-744	LorX® Cervical Titanium Disc Prosthesis 17x14x4,5mm	866082536789
LX-30-745	LorX® Cervical Titanium Disc Prosthesis 17x14x5,5mm	866082536793
LX-30-746	LorX® Cervical Titanium Disc Prosthesis 17x14x6,5mm	866082536797
LX-30-747	LorX® Cervical Titanium Disc Prosthesis 17x14x7,5mm	866082536801
LX-30-748	LorX® Cervical Titanium Disc Prosthesis 17x14x8mm	866082536805
LX-30-749	LorX® Cervical Titanium Disc Prosthesis 17x14x8,5mm	866082536809

LOT 14

PerOssal®			
Packaging size		**Bulk volume** [3]	**Art.-No.**
1 x 6	pellets (6 mm x 6 mm)	1.5 cm^3	03-01031
2 x 6	pellets (6 mm x 6 mm)	3.0 cm^3	03-01032
1 x 50	pellets (6 mm x 6 mm)	12.5 cm^3	03-0102

PerOssal®

- The osteoconductive synthetic bone substitute
- Prolonged protection against microbial colonization if preloaded with suitable antibiotics [6, 7]
- Completely biodegradable during osteoneogenesis [5]
- No subsequent explantation necessary

References

[1] Rauschmann et al. (2005), **Nanocrystalline hydroxyapatite and calcium sulphate as biodegradable composite carrier material for local delivery of antibiotics in bone infections**, Biomaterials. 26(15):2677-2684.

[2] Englert et al. (2007), **Konduktives Knochenersatzmaterial mit variabler Antibiotikaversetzung [Conductive bone substitute material with variable antibiotic delivery]**, Unfallchirurg. 110(5):408-413.

[3] Standardized bulk volume, data on file at OSARTIS GmbH.

[4] von Stechow and Rauschmann (2009), **Effectiveness of combination use of antibiotic-loaded PerOssal® with spinal surgery in patients with spondylodiscitis**, Eur Surg Res. 43(3):298-305.

[5] Kraus und Schnettler (2008), **Gutachten bei Osteitis [Expert opinion in osteitis]**, in: Bericht über die Unfallmedizinische Tagung in Mainz am 8./9.11.2008, Deutsche Gesetzliche Unfallversicherung (Hrsg.), Heft 108, ISBN 3-88383-082-8.

[6] Fleege et al. (2012), **Systemische und lokale Antibiotikatherapie bei konservativ und operativ behandelten Spondylodiszitiden [Systemic and local antibiotic therapy of conservative and operative treatment of spondylodiscitis]**, Orthopäde. 41(9):727-735.

[7] Fleege et al. (2020), **Development and current use of local antibiotic carriers in spondylodiscitis: Pilot study on reduction of duration of systemic treatment**, Orthopäde. 49(8):714-723.

[8] Fleege et al. (2017), **Antibiotikatherapie der pyogenen Spondylodiszitis bei Erwachsenen [Antibiotic therapy of pyogenic spondylodiscitis in adults]**, Die Wirbelsäule. 01(4):265.

[9] Release kinetic data on file at OSARTIS GmbH.

[10] Visani et al. (2018), **Treatment of chronic osteomyelitis with antibiotic-loaded bone void filler systems: an experience with hydroxyapatites calcium-sulfate biomaterials**, Acta Orthop Belg. 84(1):25-29.

[11] Sakellariou et al. (2015), **Combination of Calcium Hydroxyapatite Antibiotic Carrier with Cement Spacers in Peri-Prosthetic Knee Infections**, Surg Infect. 16(6):748-54.

[12] Jiménez-Martín et al. (2008), **Use of calcium sulfate and hydroxyapatite with antibiotics in osteomyelitis of the hand: Two clinical cases. Utilidad del sulfato cálcico e hidroxiapatita con antibióticos en las osteomielitis de la mano, a propósito de 2 casos clínicos**, Trauma Fund MAPFRE 20(1):45-48.

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141-3010-05EN / 042021

OSARTIS®

PerOssal®

Resorbable Bone Substitute

PerOssal®

PerOssal® is intended for the restoration of bone defects. After thorough surgical debridement and under systemic or local antibiosis, it may be also implanted in infected or contaminated areas.

PerOssal® is a synthetic, biodegradable and osteoconductive bone substitute material for restoration and filling of bone defects. Its unique microporous structure ensures uniform uptake of liquid substances (such as antibiotics) and their controlled sustained release [1].

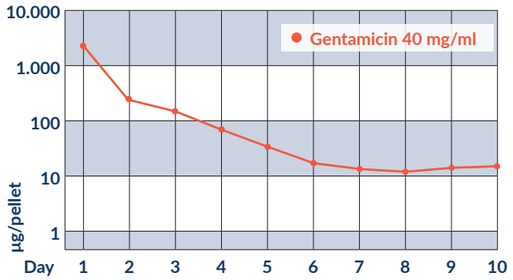
PerOssal® has a porous structure that allows the safe uptake of aqueous solutions: 0.5 ml per 6 pellets and 4 ml per 50 pellets.
These characteristics make PerOssal® the ideal carrier material.

Features

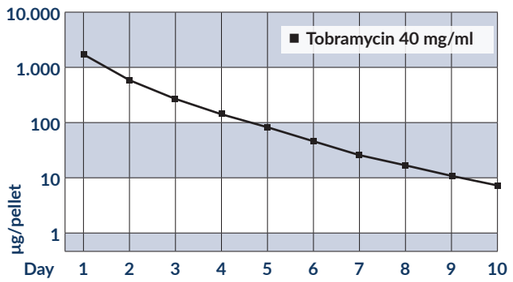
- **Nanocrystalline / porous**
  Suitable as carrier material for aqueous solutions (such as antibiotics)
- **Custom loadable**
  Targeted highly effective antibiotic protection of the bone substitute material and the surrounding tissue according to the individual antibiogram with minimum systemic side effects
- **Prolonged action**
  After drenching with antibiotics controlled long-term (10 days) protection of the bone replacement material against colonization with sensitive bacterial pathogens
- **Biodegradable**
  - Fully absorbed in dependence of the defect size, the implantation site and the quality of the surrounding bone typically within 6 months [8, 10]
  - No second procedure required for explantation

In vitro release of the tested antibiotics from PerOssal® over a period of 10 days

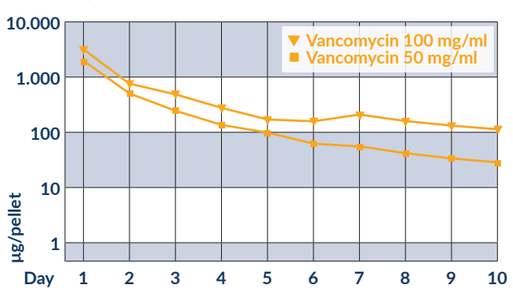
Gentamicin [2]



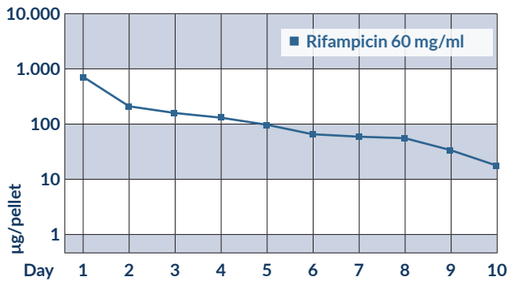
Tobramycin [9]



Vancomycin [9]



Rifampicin [9]



Dosage Recommendation* for Antibiotic Load

Antibiotics	Concentration
Gentamicin	40 mg/ml
Tobramycin	40 mg/ml
Vancomycin	100 mg/ml
Rifampicin	60 mg/ml

* recommended dosage based on in vitro results. The treating physician is responsible for the decision regarding the type and quantity of the corresponding antibiotic. The contraindications of the applied antibiotic have to be considered.

The Biological Basis

Composition:
51.5 % nanocrystalline hydroxyapatite
48.5 % calcium sulfate

Dosage Form and Packaging Sizes

PerOssal® are cylindrical pellets measuring 6 mm x 6 mm, with one spherical and one flat end. Packaging sizes of 1x6, 2x6 and 1x50 pellets are available. The pellets are primarily packed into vials, which are protected by a double peel-off packaging (inner and outer sterile packaging).

Indications

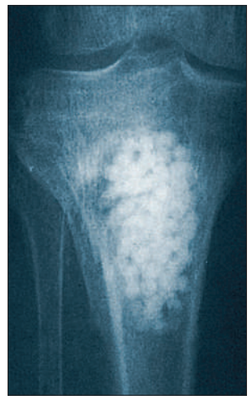
- PerOssal® is indicated for filling or reconstruction of bone defects.
- In case of infected or contaminated bone, PerOssal® is indicated after prior surgical debridement and with simultaneous systemic and/or local administration of antibiotics.
- PerOssal® can be used for augmentation of autogenous bone [4].

Possible Areas of Application

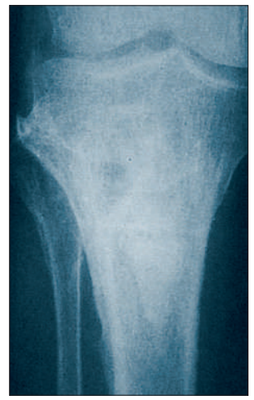
- Traumatology
- Orthopaedic surgery
- Spinal surgery
- Maxillofacial surgery

Clinical Applications

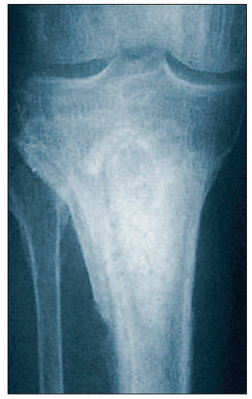
42 years old patient with fistulous osteomyelitis of the proximal tibia 28 months after plate osteosynthesis [5]



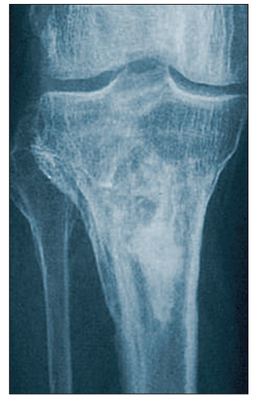
Implantation of 2 x 50 PerOssal® (25 cm³) pellets loaded with 1,000 mg vancomycin after repeated debridement (*Staphylococcus aureus*)



40% resorption of the PerOssal® pellets after the first 4 weeks

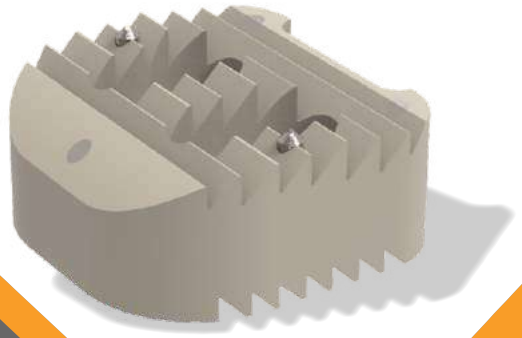


90% resorption of the PerOssal® pellets after 1 year



100% resorption of the PerOssal® pellets and completely new bone formation after 3 years; patient remained free of infection during the entire time

AGENA
Cervical Cage



Features

- Agena is manufactured by using PEEK material, which is compatible with MRI and CT and which does not result in permanent lesions.
- Easy insert and fit anatomic structure.
- Tantalum marker.
- Strong fixation with threaded surface and two titanium pins.

Code	Height	Length	Width	
MSFX-CPC041214	4	12	14	lot 27
MSFX-CPC041216	4	12	16	
MSFX-CPC041414	4	14	14	
MSFX-CPC051214	5	12	14	lot 28
MSFX-CPC051216	5	12	16	
MSFX-CPC051414	5	14	14	
MSFX-CPC061214	6	12	14	lot 29
MSFX-CPC061216	6	12	16	
MSFX-CPC061414	6	14	14	
MSFX-CPC071214	7	12	14	lot 30
MSFX-CPC071216	7	12	16	
MSFX-CPC071414	7	14	14	
MSFX-CPC081214	8	12	14	
MSFX-CPC081216	8	12	16	
MSFX-CPC081414	8	14	14	

REGULUS-C
Corpectomy Cage

Features

- Full contact with angled surface
- Teeth on the surface, minimizing the risk of expulsion
- Angled inferior and superior area allow a complete contact with vertebral surface and composed by one piece.
- With an efficient grafting space, the system allows applying graft before distraction and provides a one stage locking mechanism.

Code	Diameter	Closed Length	Open Length	Angled
MCTC101013	10	10	13	lot 23
MCTC101317	10	13	16	lot 24
MCTC101625	10	16	25	
MCTC121013	12	10	13	lot 25
MCTC121317	12	13	17	lot 26
MCTC121625	12	16	25	
MCTC122440	12	24	40	
MCTC123965	12	39	65	
MCTC141013	14	10	13	
MCTC141317	14	13	17	
MCTC141625	14	16	25	
MCTC142440	14	24	40	
MCTC143965	14	39	65	
MCTC161013	16	10	13	
MCTC161317	16	13	17	
MCTC161625	16	16	25	
MCTC162440	16	24	40	
MCTC163965	16	39	65	
MCTC201013	20	10	13	
MCTC201317	20	13	17	
MCTC201625	20	16	25	
MCTC1216256	12	16	25	6°
MCTC1224406	12	24	40	6°
MCTC1239656	12	39	65	6°
MCTC1416256	14	16	25	6°
MCTC1424406	14	24	40	6°
MCTC1439656	14	39	65	6°