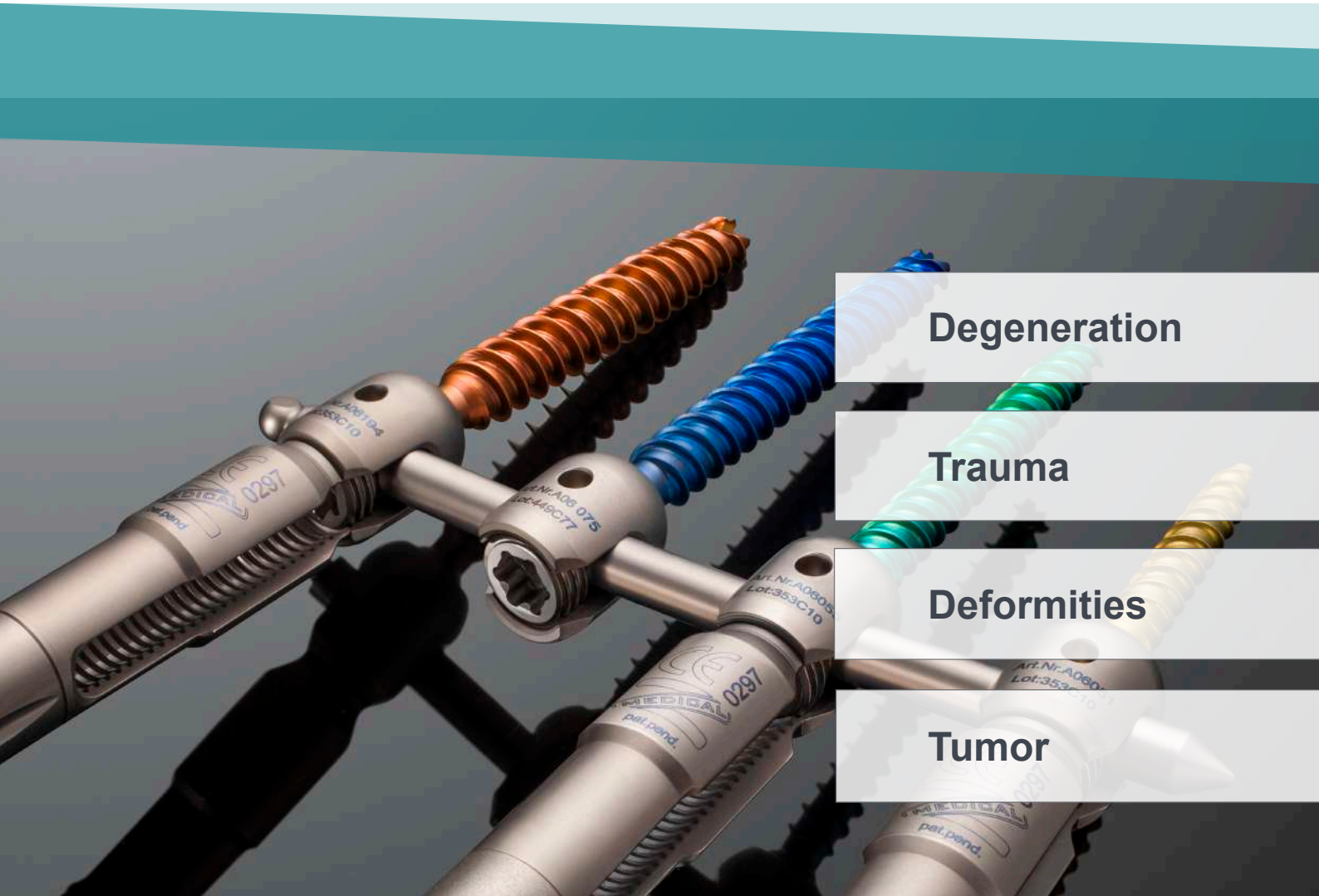
lot 1, lot 15

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

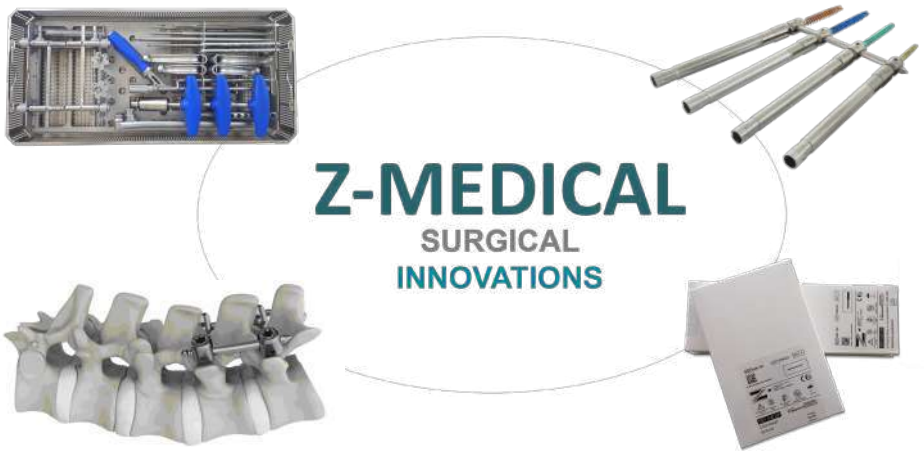
The MIS Z-Pedicle Screw System offers surgeons an ideal solution for their indication specific needs. The Z-Pedicle Screw System comprises sterile implants and only one instrument set.

- 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

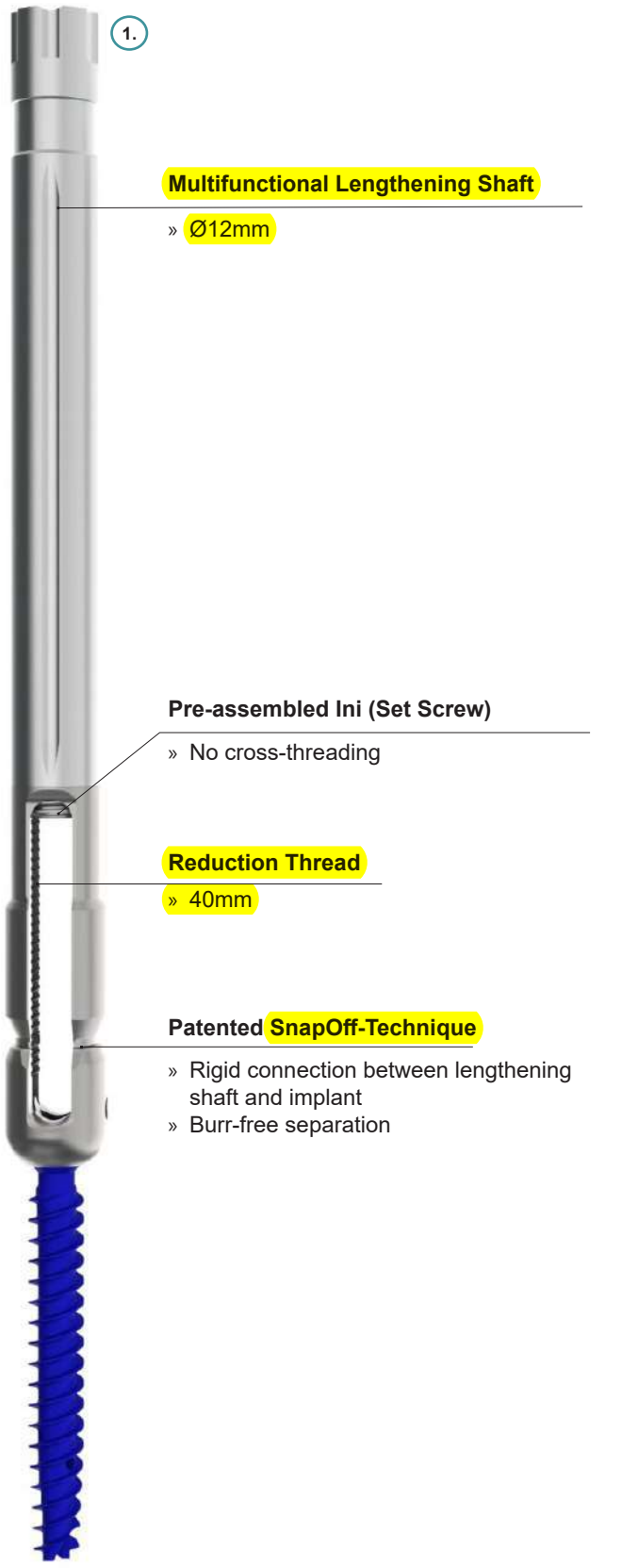
All implants are single sterile packaged and ready for surgery.

- 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

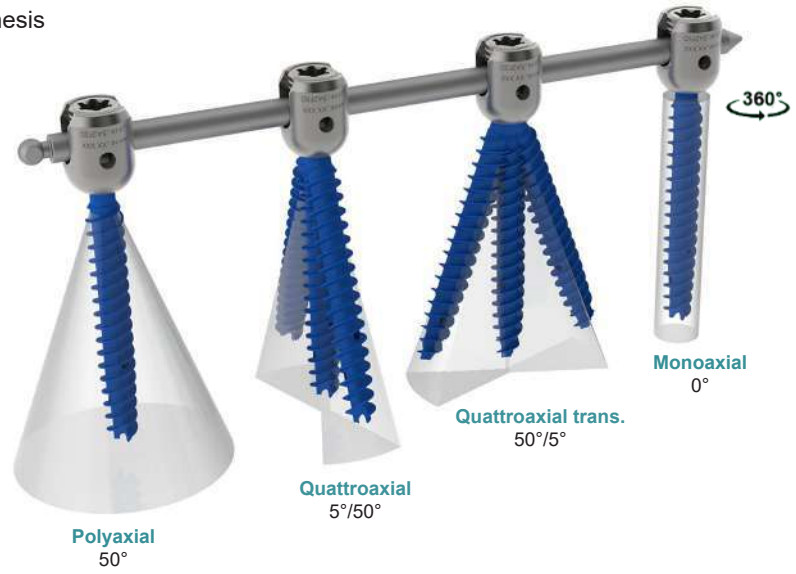
Thread features

» 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

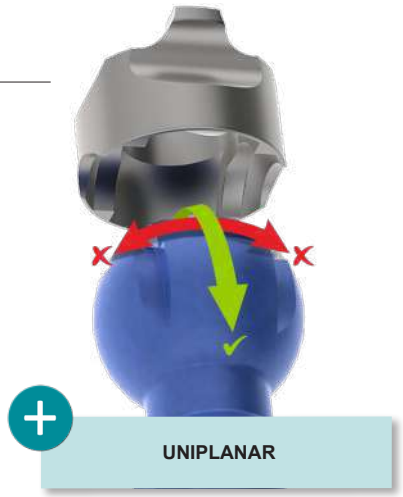
The **Quattroaxial Screw** allows shorter instrumentation and simplifies reposition.

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

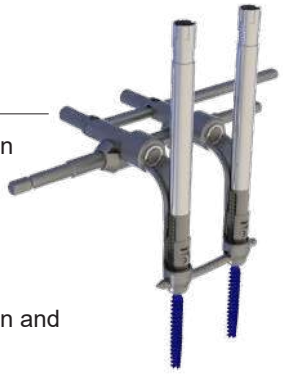
The universal distraction and compression instrument enables:

» A direct and controlled correction of complex fractures

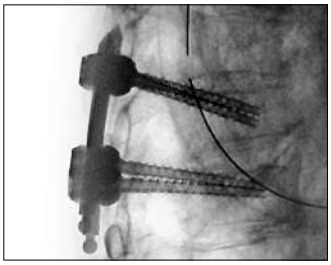
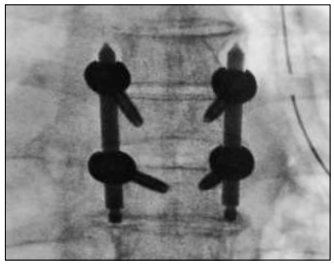
» An open and percutaneous distraction and compression along the rod

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

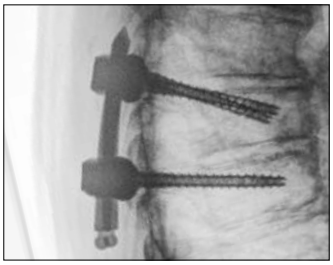
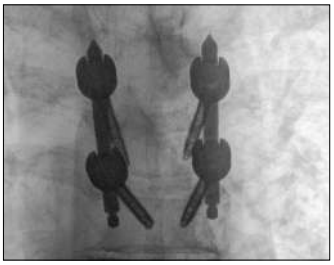
» Same approach as MIS screw, application via the lengthening shaft



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

Intraoperative X-ray

Follow-Up at 9 month

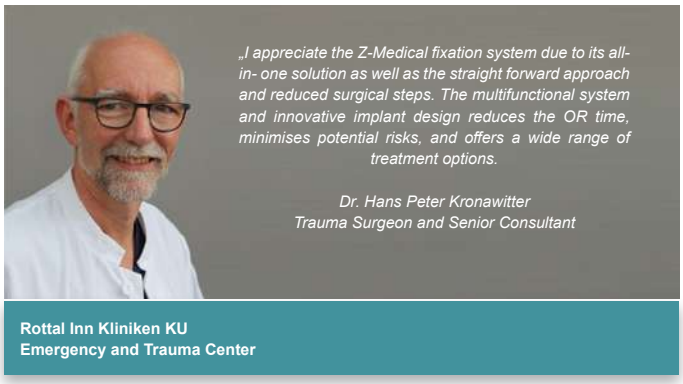
Patient
Male, 75 years, retired farmer

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

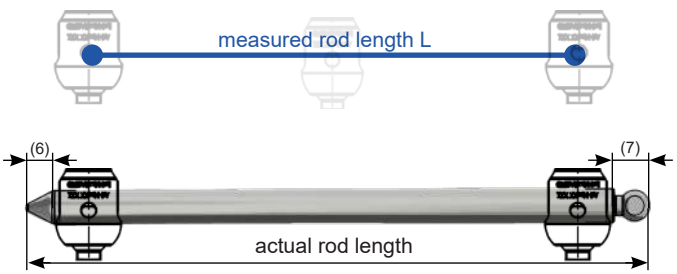
Instrument	Art.No.	Description	Q
	A06 081 S	Z-Guide Wire	2
Distributive products	**Art.No.**	**Description**	**Q**
	900140	First Access Needle	1
	900146	Bone Cement Filler Cannula for Screw Cementation	1
	800039	V-Steady Radiopaque Bone Cement	1

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

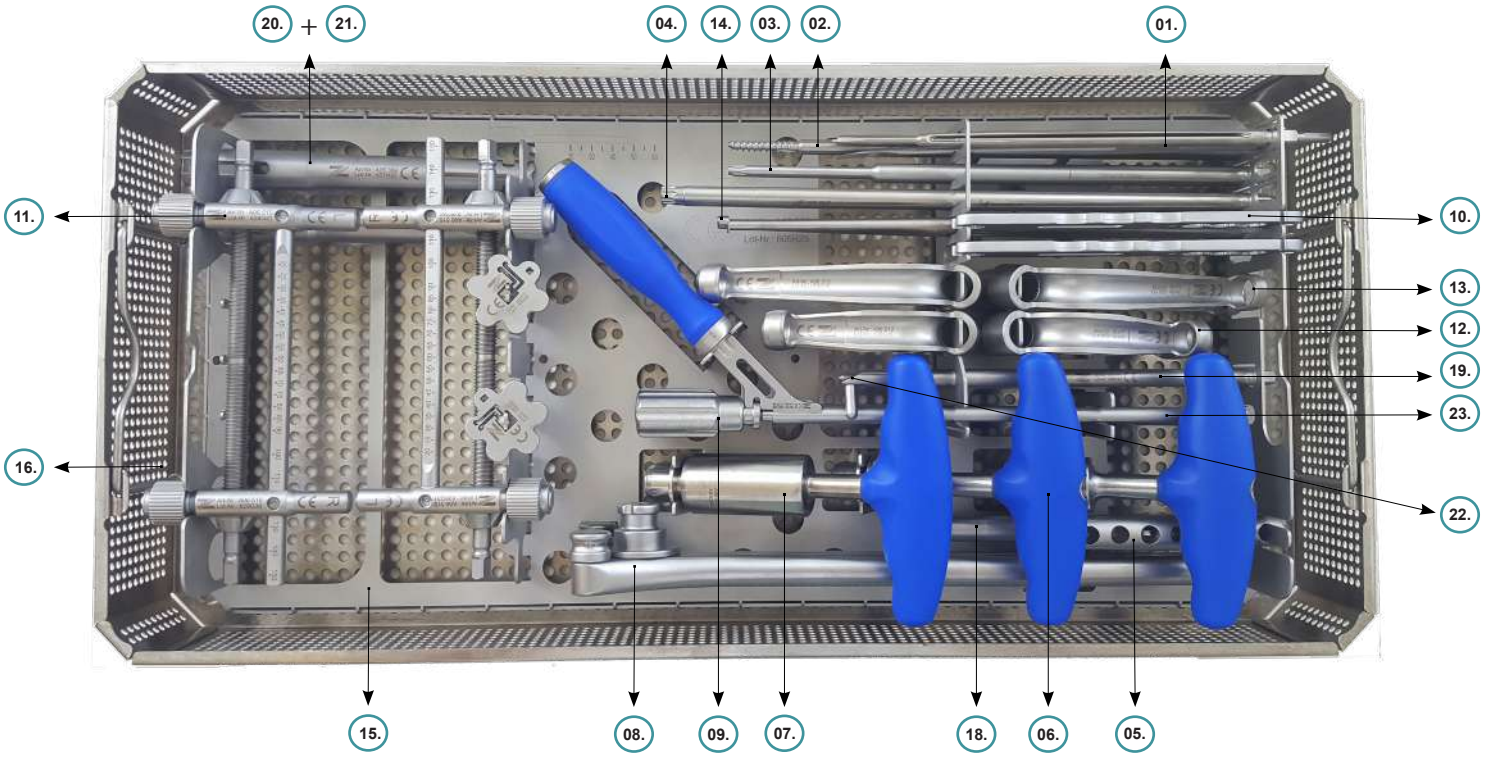
Z-Rods | Sterile, Ø5.5mm

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

01. Awl Set
02. Thread Drill
03. Screwdriver Pedicle Screw
04. Screwdriver Ini
05. Z-Handle
06. T-Handle with Ratchet
07. T-Handle with Torque Limiter
08. Rod Bender
09. Rod Inserter
10. Counter Support
11. Distraction- and Compression Instrument (Dico)
12. Adapter short
13. Adapter long
14. Tulip Breaker

Storage

15. Rack
16. Perforated Container Set
17. Sterilisation Container Set

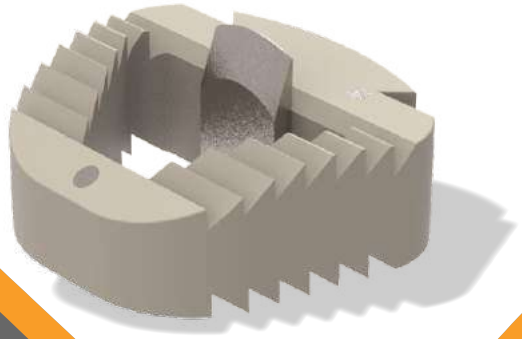
Instruments Optional

18. Reamer

Instruments Extension / Revision

19. Screwdriver Revision
20. Tulip Adapter
21. Clamping Tube
22. Revision Instrument Inner Part
23. Chuck Rod

lot 7

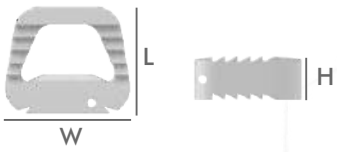


AGENA-X
Cervical Cage With Blade

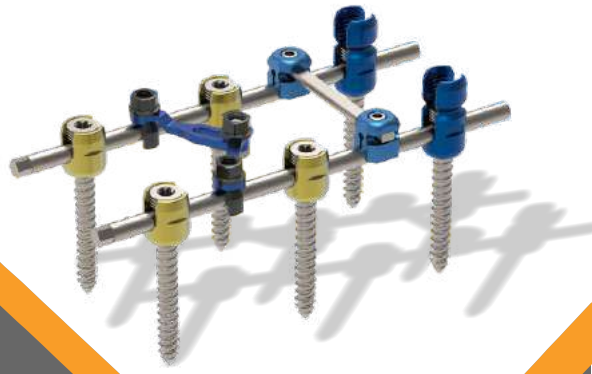
Features

- 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 5



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		Sacral Screw	
Code	Size	Code	Size
MSFX-SR1704	6.0x40 mm	MSFX-SSS6035	6.0x35 mm
MSFX-SR1705	6.0x50 mm	MSFX-SSS6040	6.0x40 mm
MSFX-SR1706	6.0x60 mm	MSFX-SSS6045	6.0x45 mm
MSFX-SR1707	6.0x70 mm	MSFX-SSS6050	6.0x50 mm
MSFX-SR1708	6.0x80 mm	MSFX-SSS6055	6.0x55 mm
MSFX-SR1709	6.0x90 mm	MSFX-SSS7040	7.0x40 mm
MSFX-SR1710	6.0x100 mm	MSFX-SSS7045	7.0x45 mm
MSFX-SR1711	6.0x110 mm	MSFX-SSS7050	7.0x50 mm
MSFX-SR1712	6.0x120 mm	MSFX-SSS7055	7.0x55 mm
MSFX-SR1713	6.0x140 mm	MSFX-SSC15	15mm
MSFX-SR1714	6.0x150 mm	MSFX-SSC20	20mm
MSFX-SR1715	6.0x160 mm	MSFX-SOCNT	
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			

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	30-60 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

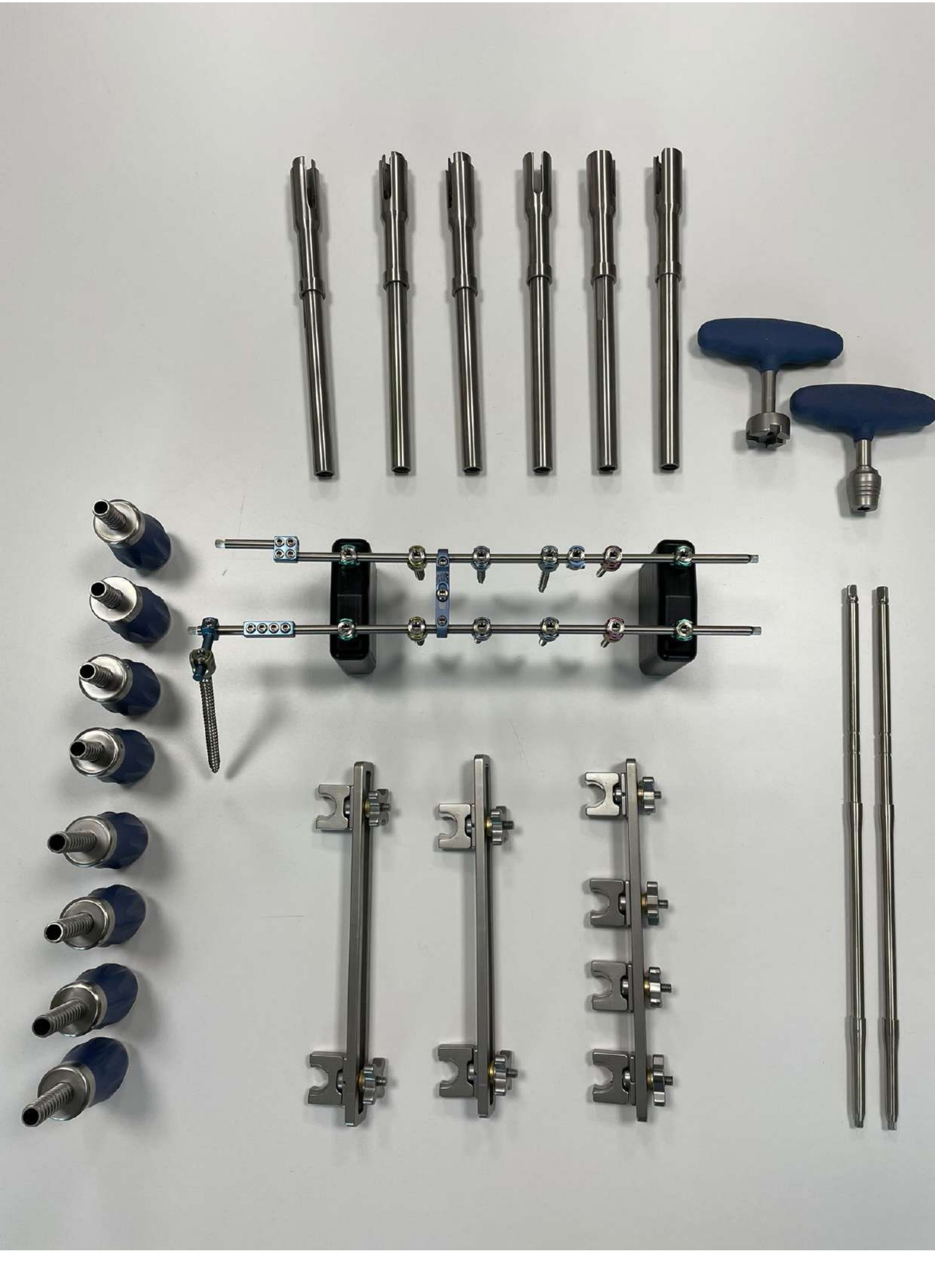
Laminar Hooks

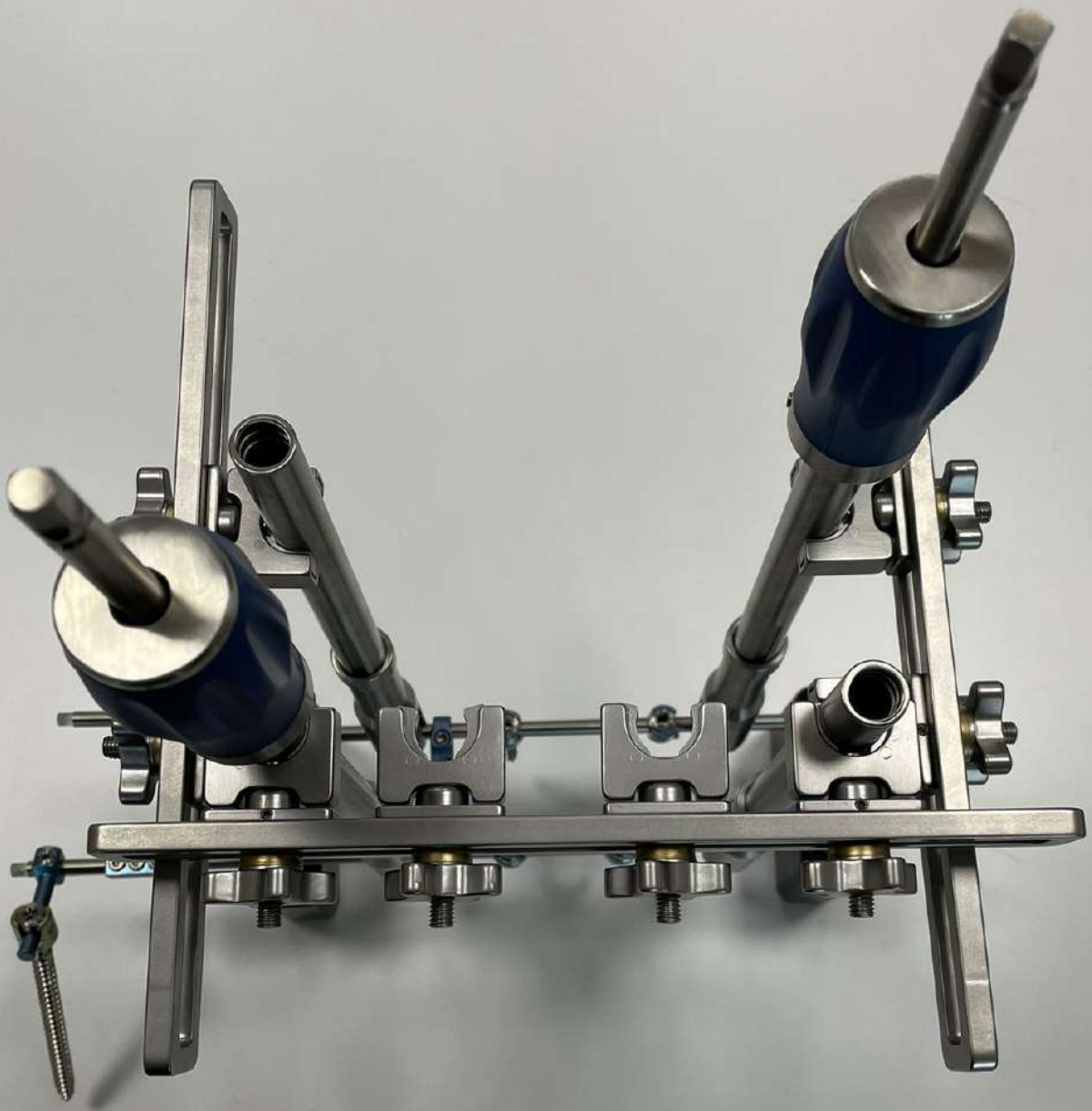
Code	Size
MSFX-LH0505	5x5 mm
MSFX-LH0507	5x7 mm
MSFX-LH0509	5x9 mm
MSFX-LH0706	7x6 mm
MSFX-LH0707	7x7 mm
MSFX-LH0709	7x9 mm
MSFX-LH0711	7x11 mm
MSFX-LHF0505	5x5 mm
MSFX-LHF0507	5x7 mm
MSFX-LHLA709	7x9 mm
MSFX-LHLA711	7x11 mm
MSFX-LHRA709	7x9 mm
MSFX-LHRA711	7x11 mm

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



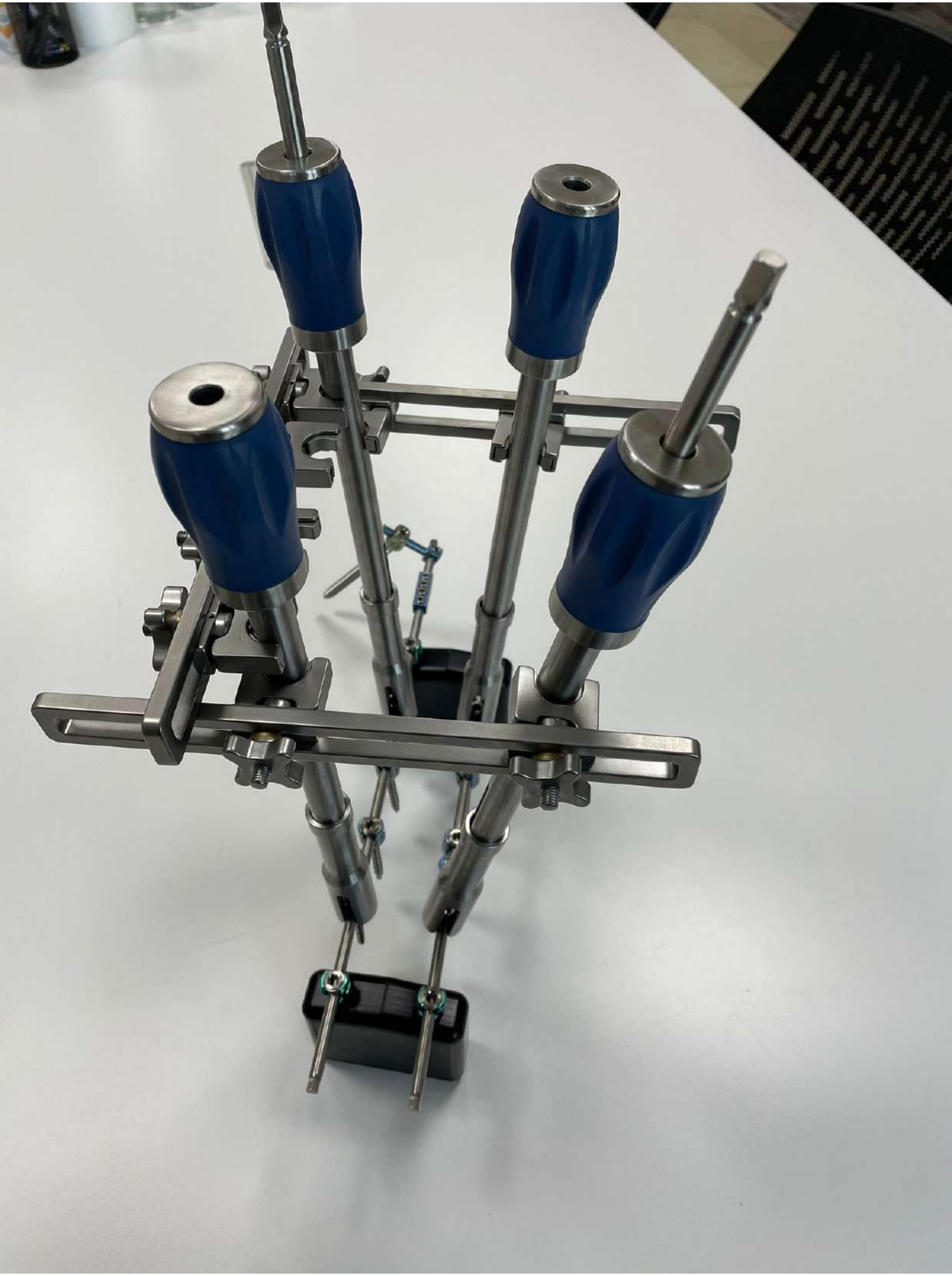


Osteotomy
instrument set

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

Arc-shaped Cervical Interbody Fusion Cage				
Anterior Lumbar Interbody Fusion Cage				
Posterior Lumbar Interbody Fusion Cage (Expansion Type)				
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)		TT457-2601	10 x 40-100mm	Ti6Al4V ELI
		TT457-2602	12 x 40-100mm	Ti6Al4V ELI
		TT457-2603	14 x 40-100mm	Ti6Al4V ELI
		TT457-2604	16 x 40-100mm	Ti6Al4V ELI
		TT457-2605	18 x 40-100mm	Ti6Al4V ELI
		TT457-2606	20 x 40-100mm	Ti6Al4V ELI
		TT457-2607	24 x 40-100mm	Ti6Al4V ELI
		TT457-2608	28 x 40-100mm	Ti6Al4V ELI
Hook System				
Laminar Hook				
Pedicle Hook				



lot 4, lot 9

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

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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.

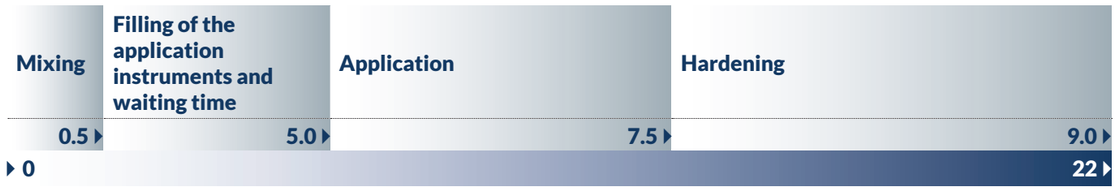
BonOs® Inject fulfills all requirements for bone cements in spinal surgery:

- 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

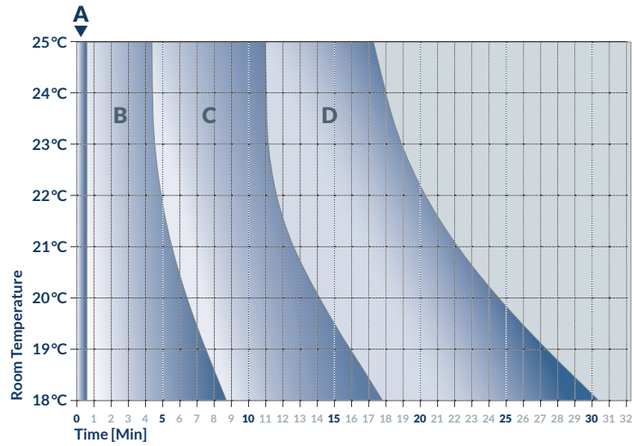
Bone cement volume

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)



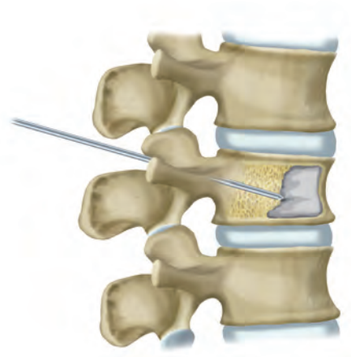
A: Mixing Phase (30 sec) | **B:** Syringe Filling and Waiting Phase
C: Injection Phase | **D:** Hardening Phase

Fast achievement of application viscosity

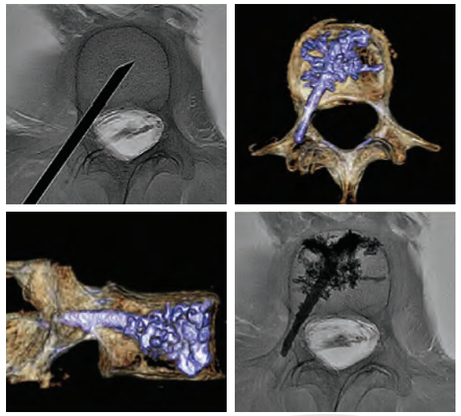
The composition of the polymers ensures a high initial cohesion and therefore reduces the risk of cement leakage.
After a short waiting time the cement attains an ideal viscosity for application. BonOs® Inject can be used for vertebroplasty, kyphoplasty as well as for the augmentation of pedicle screws.

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

LOT 13

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 3 channels 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

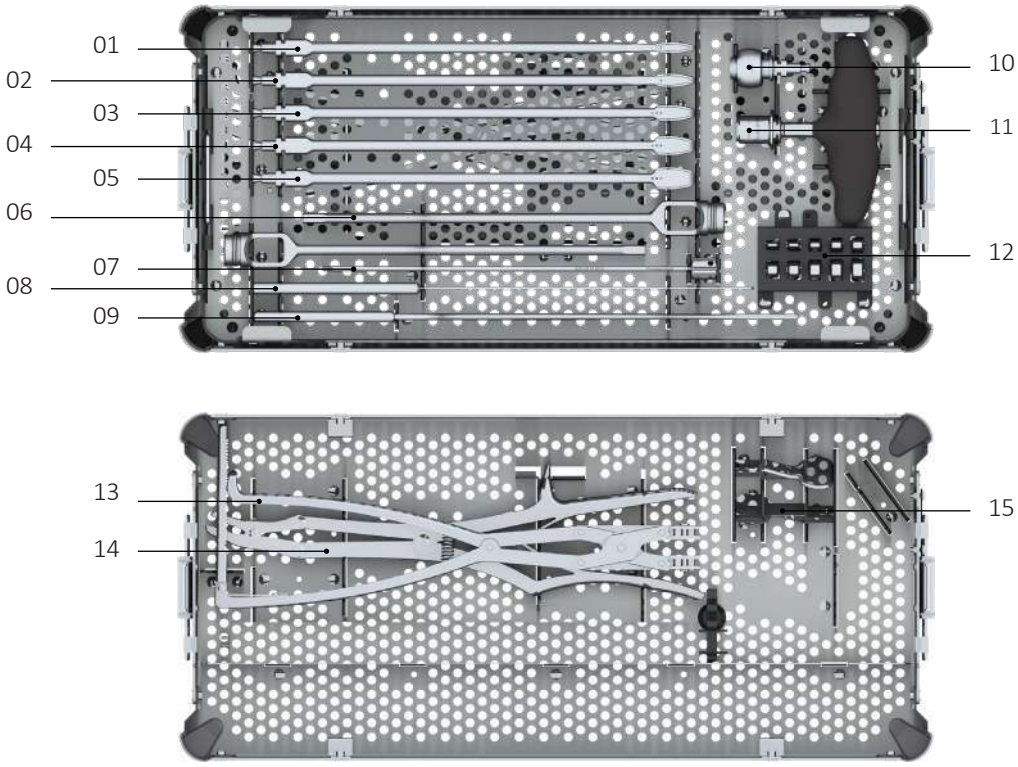
DISC PREPARATION 1

#	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

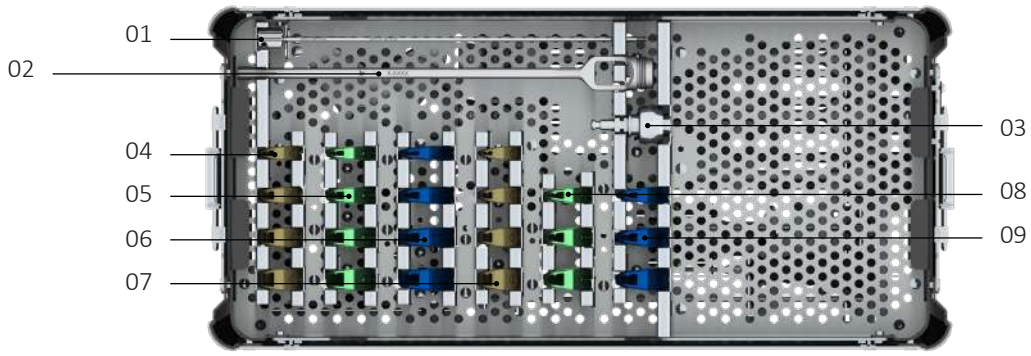


#	DESCRIPTION	REFERENCE
01	DISC SHAVER H08	SCA-IN 14 08-N
02	DISC SHAVER H10	SCA-IN 14 10-N
03	DISC SHAVER H12	SCA-IN 14 12-N
04	DISC SHAVER H14	SCA-IN 14 14-N
05	DISC SHAVER H16	SCA-IN 14 16-N
06	PADDLE DISTRACTOR HOLDER	SCA-IN 15 00-N
07	THREADED SHAFT	SCA-IN 18 00-N
08	BALL TIP PROBE	SCA-IN 20 00-N
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

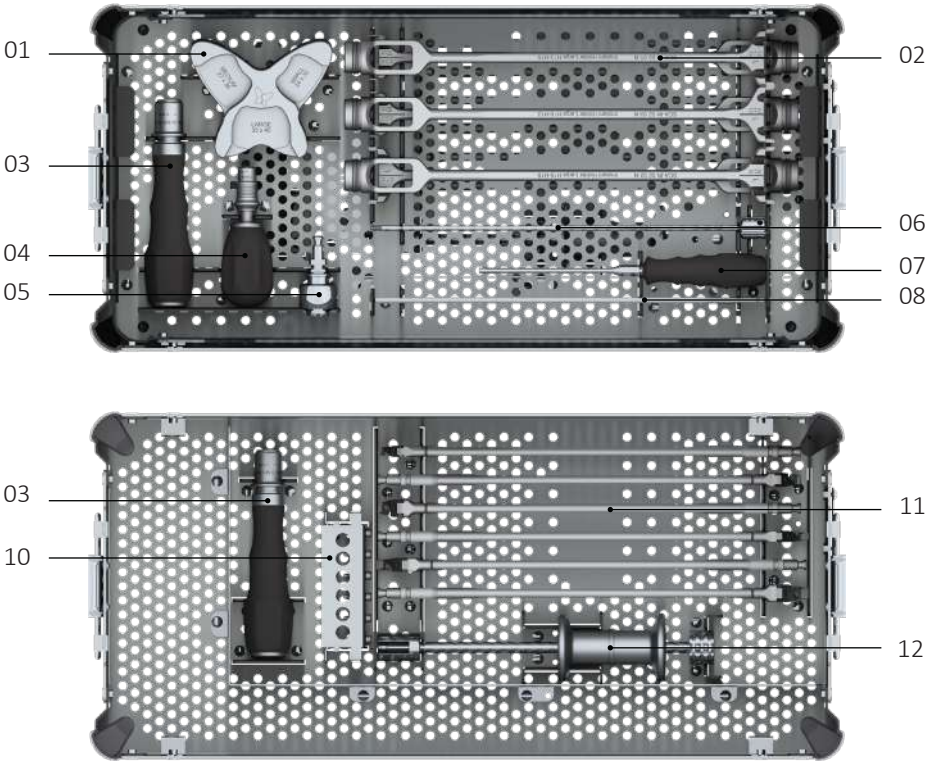
IMPLANT TRIALS AND CAGES INSERTION



#	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

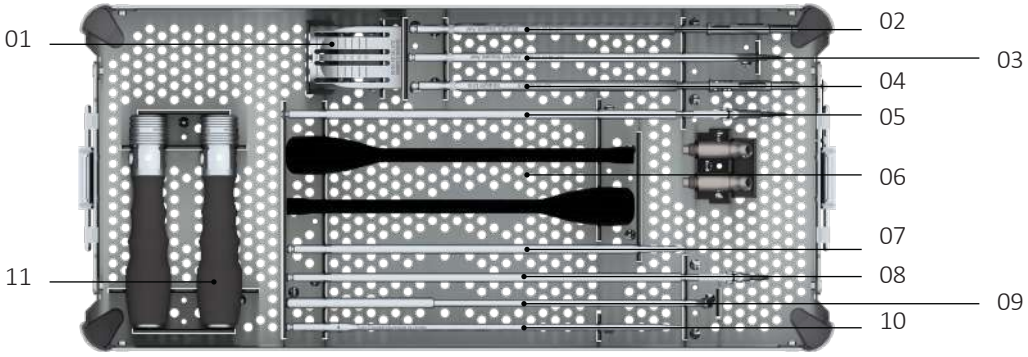


#	DESCRIPTION	REFERENCE
01	COMPACTION BASE	SCA-IN 07 00-N
02	IMPLANT HOLDERS: SMALL/MEDIUM H10-H12 SMALL/MEDIUM H13-H15 SMALL/MEDIUM H16-H18 LARGE H10-H12 LARGE H13-H15 LARGE H16-H18	 SCA-IN 01 01-N SCA-IN 01 02-N SCA-IN 01 03-N SCA-IN 02 00-N SCA-IN 02 01-N SCA-IN 02 02-N
03	STRAIGHT HANDLE (HUDSON 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

LOT 14

AT A GLANCE

Streamlined Tip
Polyaxial Head
Low Profile Implants
Blunt tip

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

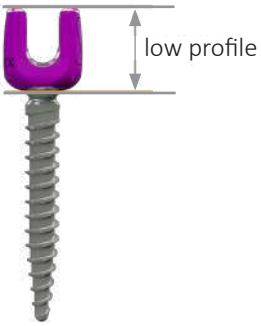
Implants can be delivered Non Sterile (ELL-xx xx xx-**N**) on demand.

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.

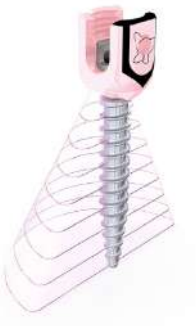
STREAMLINED SCREW TIP & LOW PROFILE IMPLANTS



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

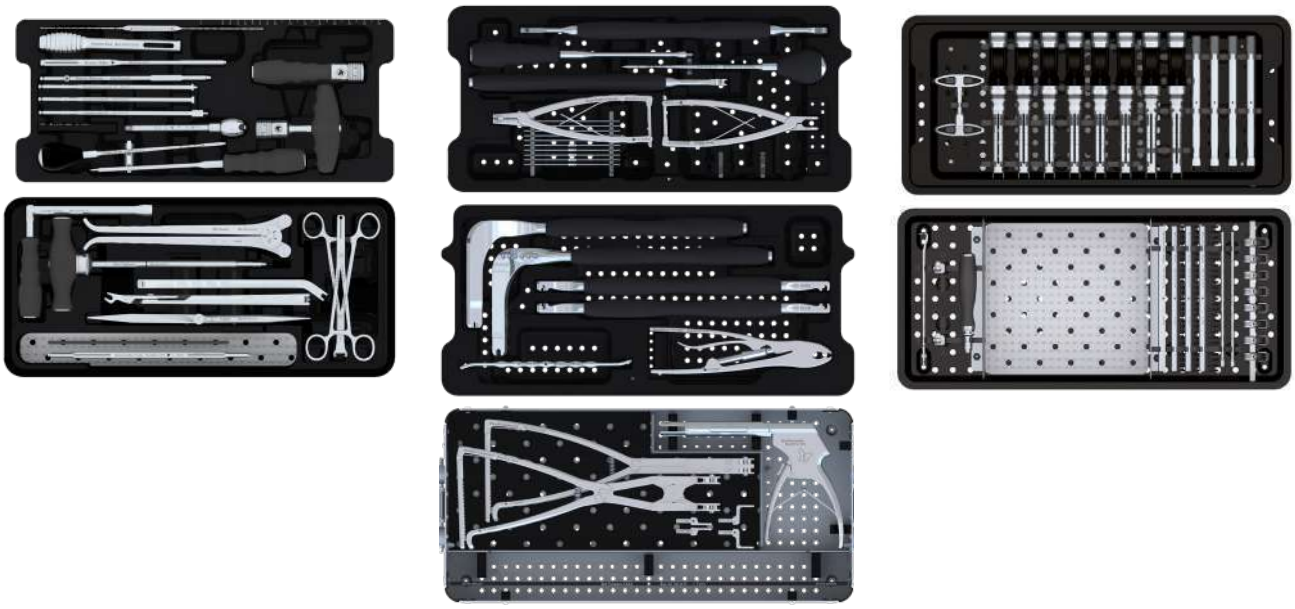
The ROMEO®2 25D semi-polyaxial screw provides the benefits of monoaxial screw for controlled powerful reduction and the versatility of the polyaxial screw for ease of rod connection.

TECHNICAL FEATURES

HOOKS

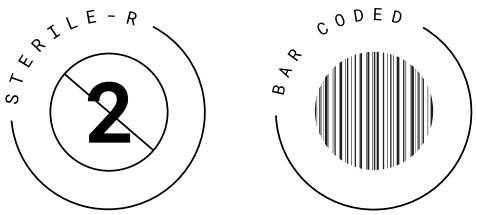
A full range of hooks with various sizes is available with ROMEO®2. Their autostatic teeth enhance their stability once impacted

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

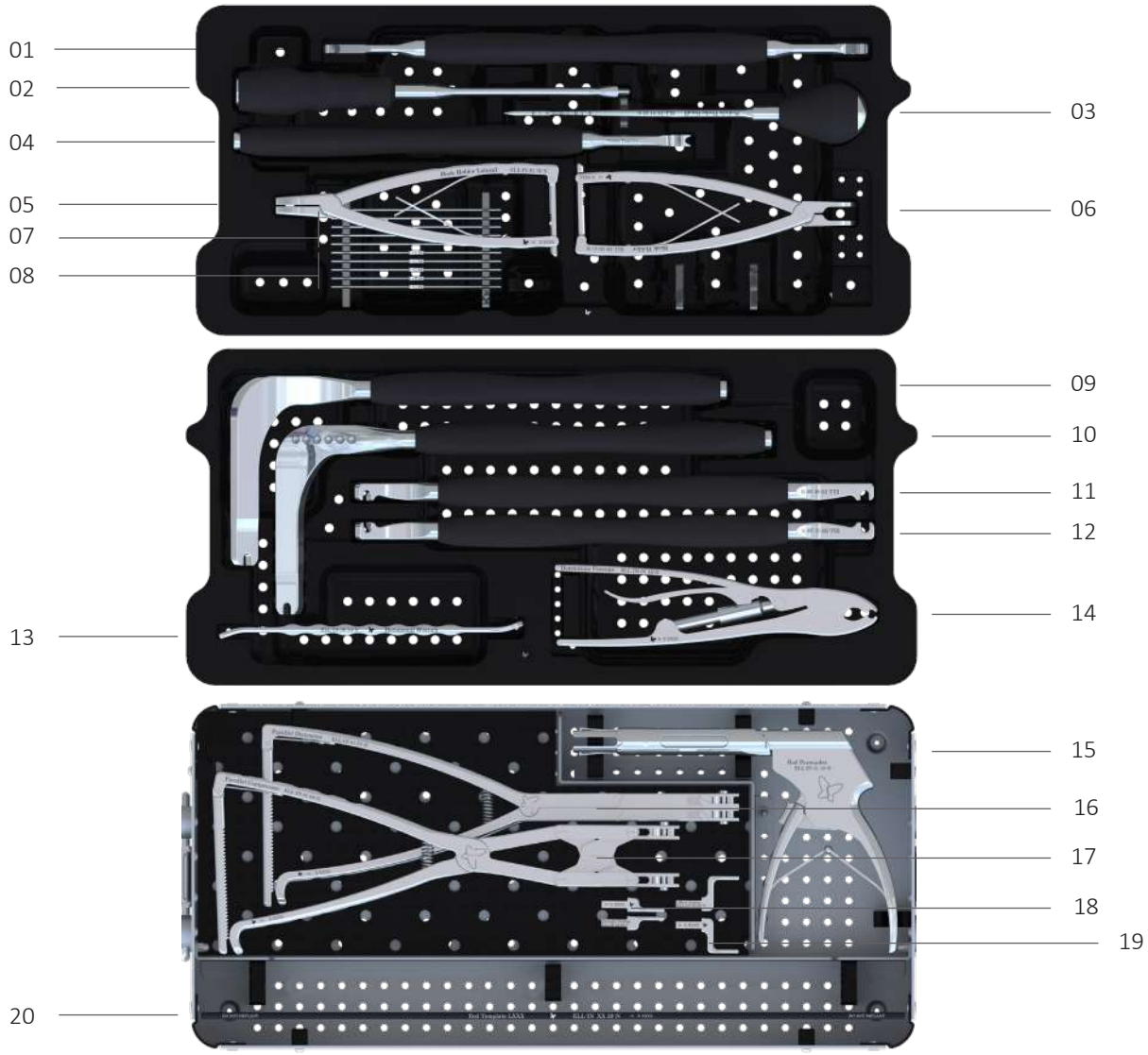
#	DESCRIPTION	REFERENCE
01	PEDICLE SOUNDER	ELL-IN 01 02-N
02	SET SCREW TUBE	ELL-IN 01 15-N
03	SET SCREW HOLDER W	ELL-IN 03 10-N
04	SET SCREW TIGHTENER	ELL-IN 04 06-N
05	SCREWDRIVER SHAFT PS	ELL-IN 05 03-N
06	SCREWDRIVER SHAFT MS	ELL-IN 01 20-N
07	SCREWDRIVER SHAFT SS	ELL-IN 01 16-N
08	SCREWDRIVER SLEEVE	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



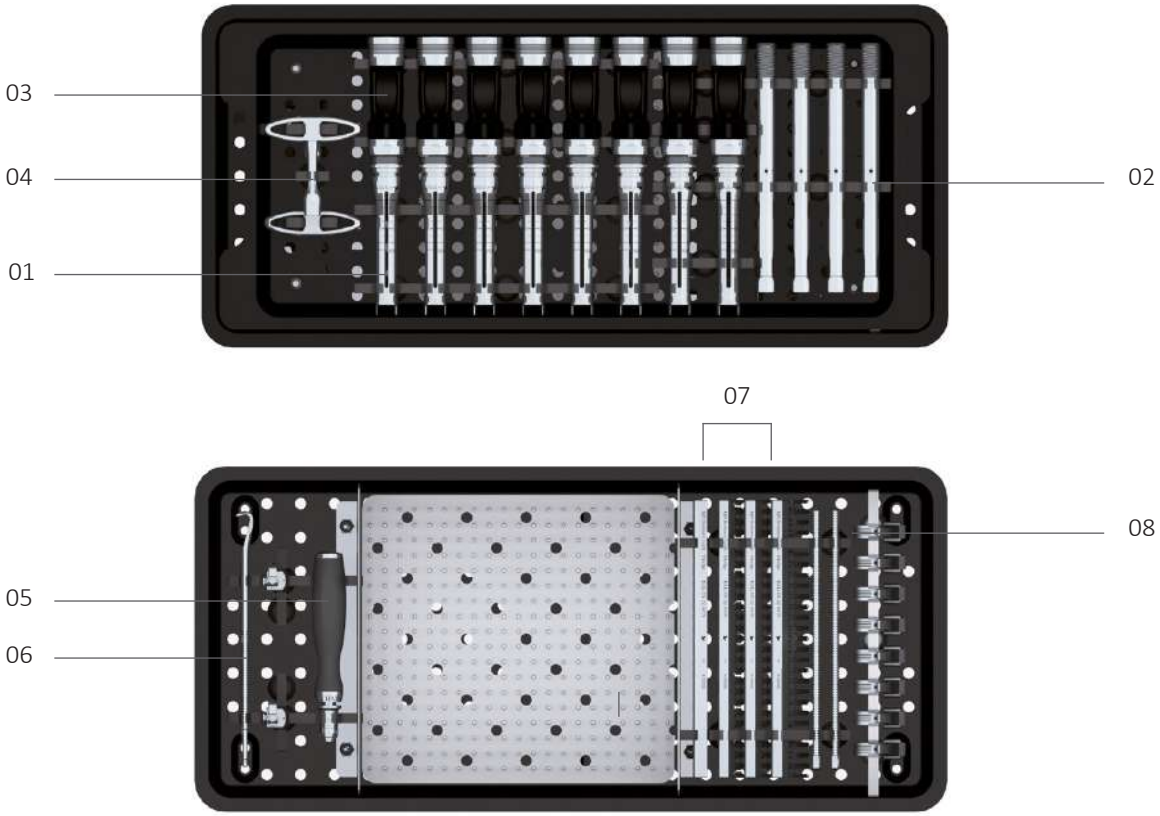
#	DESCRIPTION	REFERENCE
01	LAMINA PREPARER	ELL-IN 00 30-N
02	HOOK PUSHER	ELL-IN 00 32-N
03	PEDICLE PROBE SMALL	ELL-IN 02 23-N
04	PEDICLE PREPARER	ELL-IN 00 29-N
05	HOOK HOLDER LATERAL	ELL-IN 01 31-N
06	HOOK HOLDER	ELL-IN 00 31-N
07	MARKER LEFT	ELL-IN 00 25-N
08	MARKER RIGHT	ELL-IN 00 24-N
09	CORONAL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

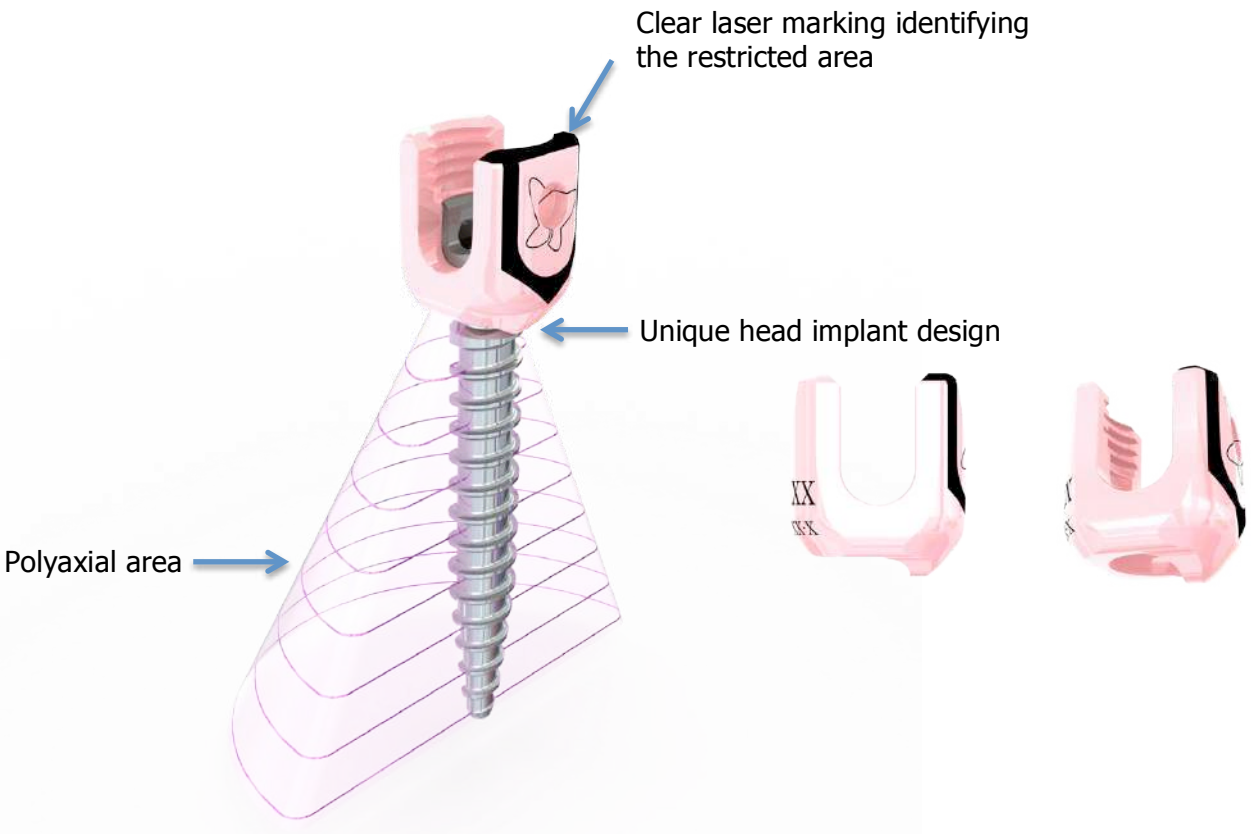
Dear collaboration partner,

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.

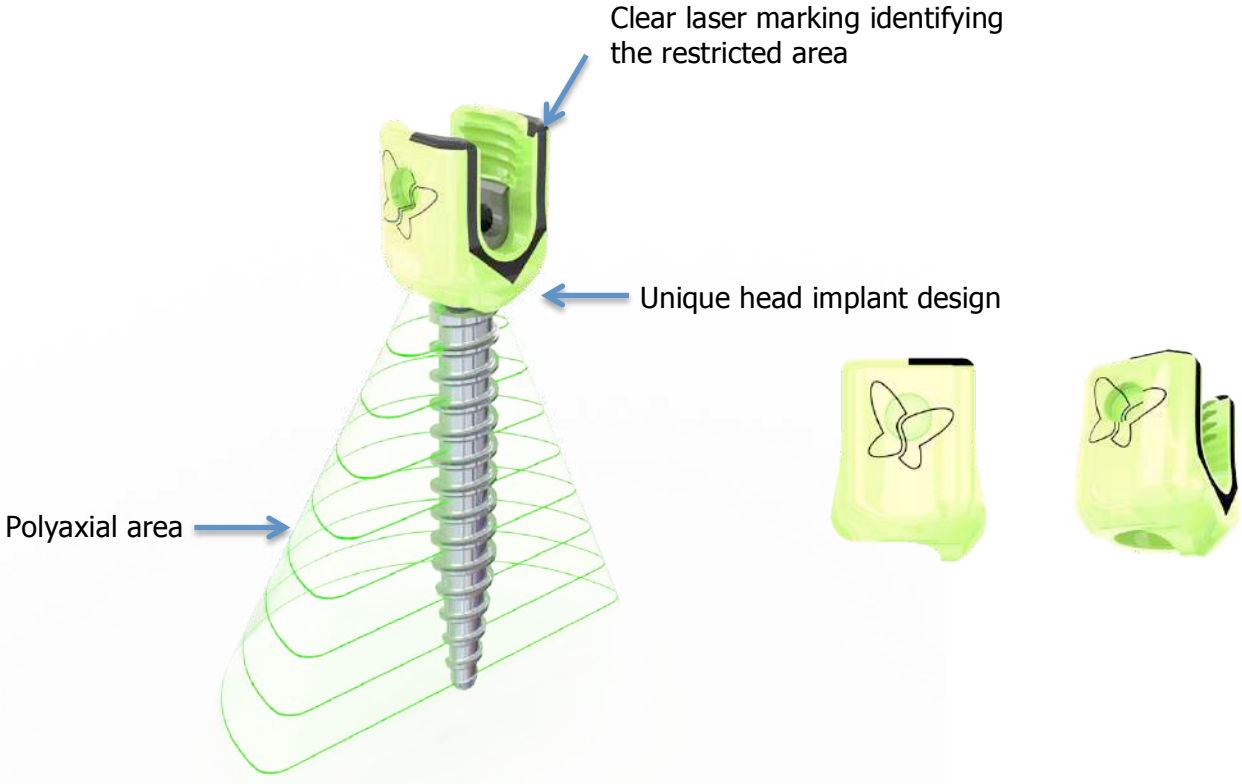
Dear collaboration partner,

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®

CONCEPT AND DESIGN

LOT 15

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

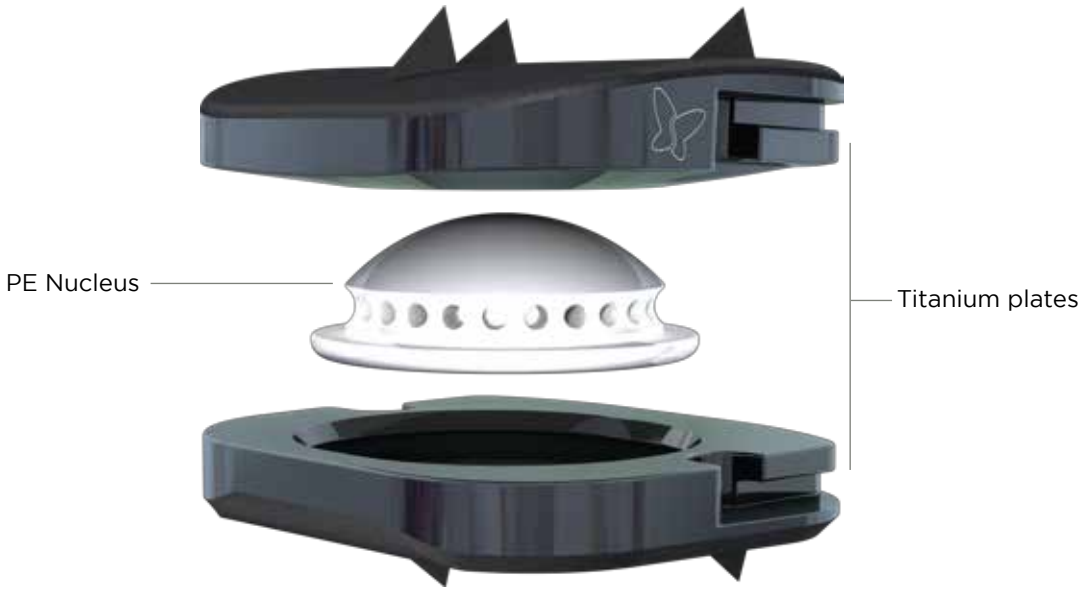
RADIOLUCENT HOLDER

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

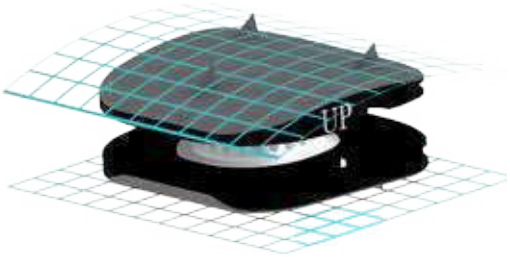
TECHNICAL FEATURES

GUIDED MOBILE NUCLEUS

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

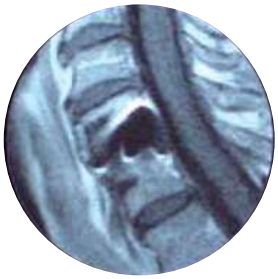
ANATOMICAL DESIGN

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



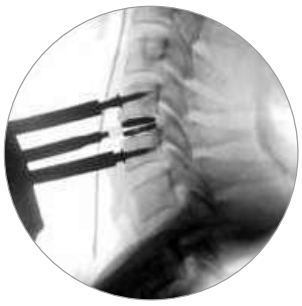
LIMITED MRI ARTIFACT

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



RADIOLUCENT HOLDER

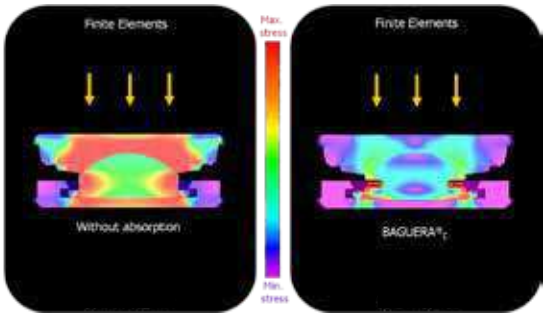
- The radiolucent holder allows for both verification of the anterior position of the device and confirmation of the fitting accuracy. Thanks to this holder, the device is delivered pre-assembled for better handling.



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

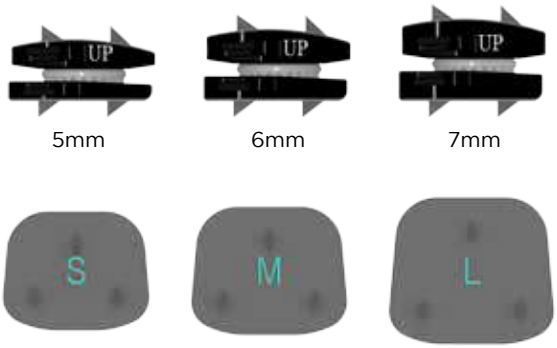
- The 3 upper and 3 lower fins as well as the porous titanium coating are designed for primary and secondary stability.

COMPACT SET

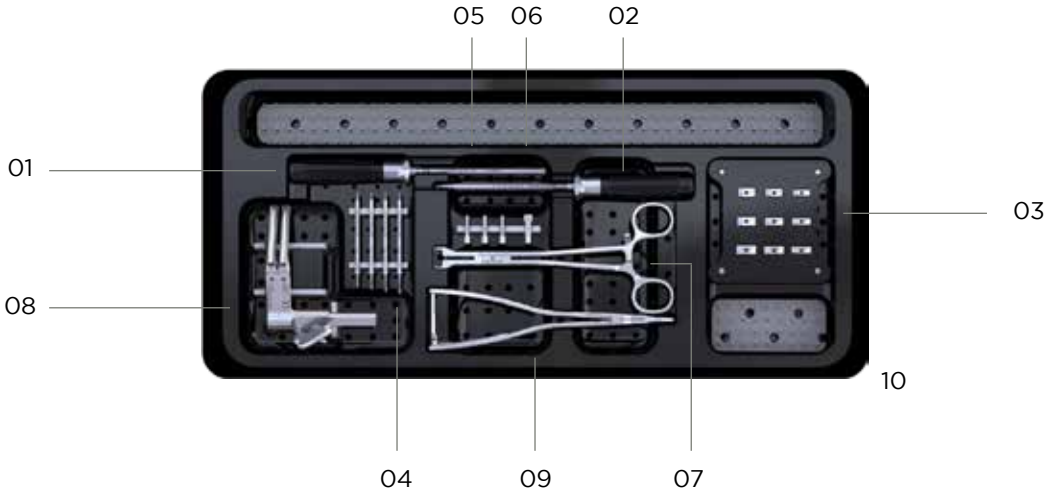
- The set includes 4 instruments, trials, and a lockable cervical system.

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

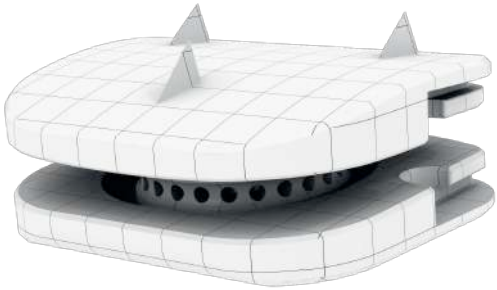
IMPLANT HOLDER	CDP-IN 00 01-N

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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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

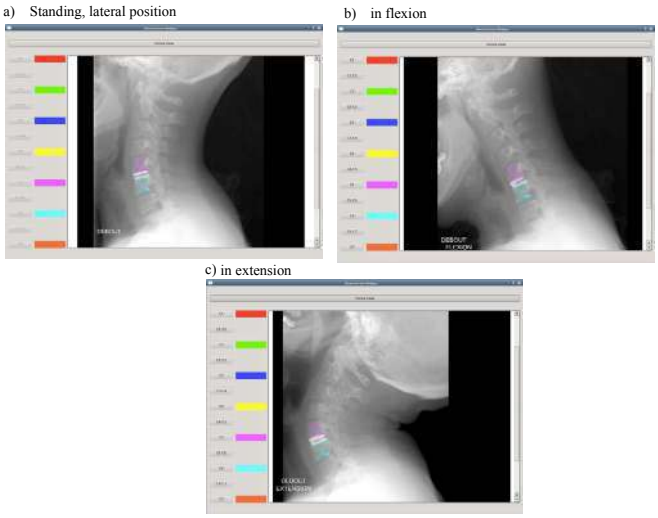

Figure 2: Radiographic images two years after surgery (annotated) Subjects who underwent 1 level (C5-C6) total disc replacement using Baguera®C.

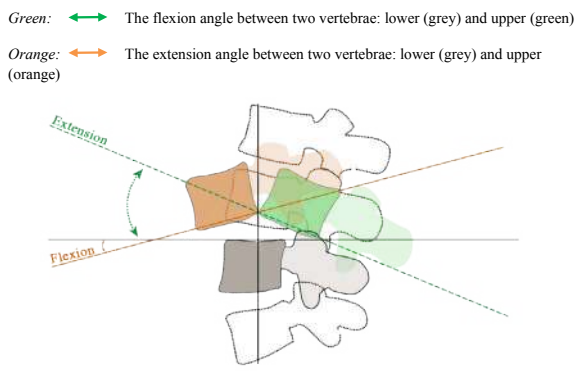

Figure 3: Range of Motion (ROM): The angles used to transform the vertebrae above and below the Baguera®C between flexion and extension provide the range of motion. Grey color is used for lower vertebra. Green and orange are used for upper vertebra in extension and flexion, respectively. The fixed reference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

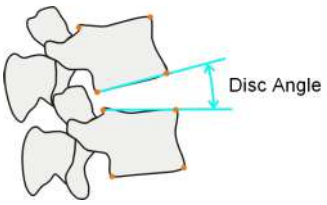

Figure 4: Disc angle.

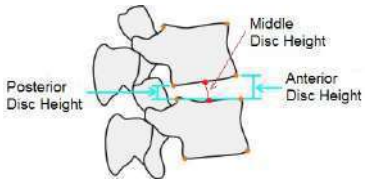

Figure 5: Disc height (middle).

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.

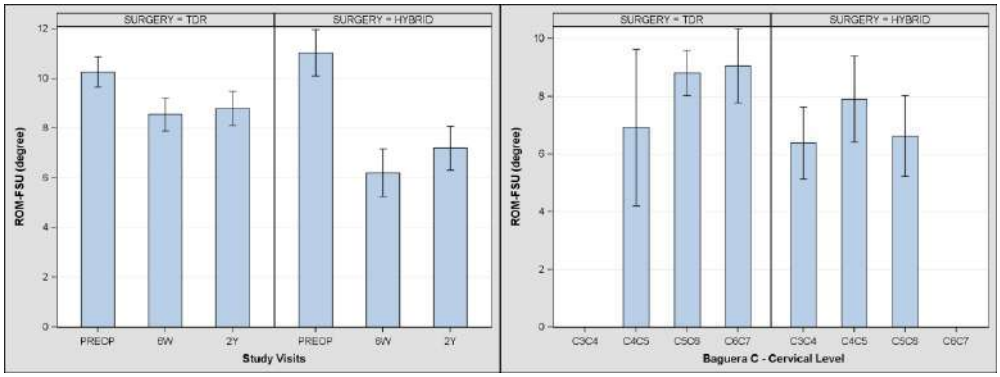

Figure 6: Range of Motion at the treated level (ROM-FSU). **Left:** Pre- and post-operative values for subjects treated by 1 level TDR using Baguera®C. Non-significant changes between pre-operative and post-operative data were observed. **Right:** Two years after surgery values, by treated level for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

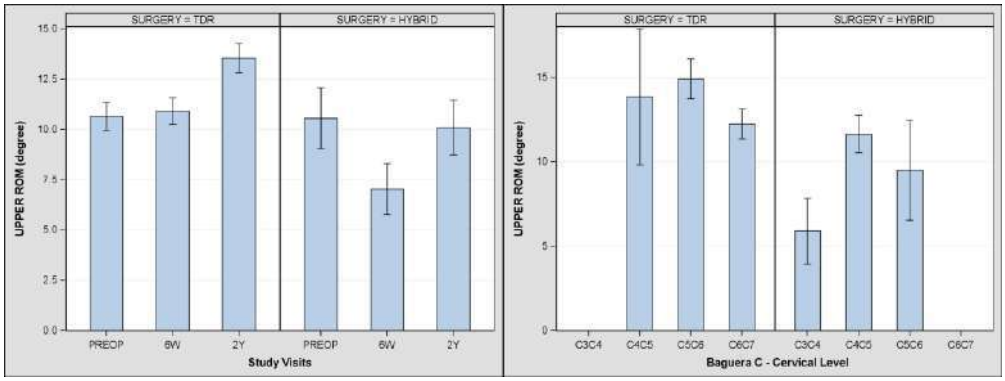

Figure 7: Range of Motion at the upper adjacent level (UPPER ROM). **Left:** Pre- and post-operative values for subjects treated by 1 level TDR using Baguera®C. Significant improvement (p=0.01) between pre-operative and 2 year's post-operative data. **Right:** Two years after surgery values, by treated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

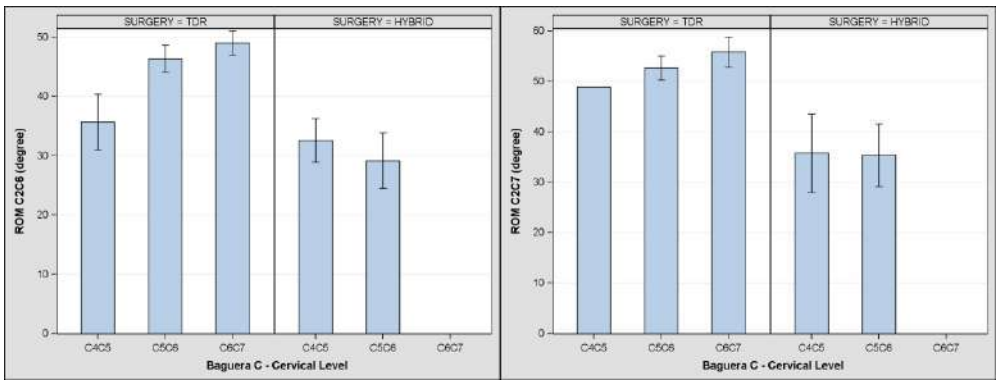

Figure 8: Overall cervical range of motion two years after surgery for subjects who underwent 1 level TDR using Baguera®C by treated level and type of surgery (TDR, HYBRID): ROM-C2C6 (left), ROM-C2C7 (right).

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:

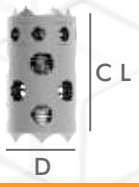
- UPPER ROM: Range of motion of the Upper Functional Spine Unit
- ROM C2-C6: Range of motion of C2-C6 levels
- ROM C2-C7: Range of motion of C2-C7 levels
- ANGLE FSU: Angle of the Functional Spine Unit
- UPPER ANGLE: Angle of the Upper Functional Spine Unit
- ANGLE C2-C6: Angle of C2-C6 levels
- ANGLE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

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	
MCTC101317	10	13	16	
MCTC101625	10	16	25	
MCTC121013	12	10	13	
MCTC121317	12	13	17	
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°



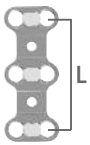
MIRACH
Cervical Plate

Features

- The locking system that secures screws for one-step locking
- The plate has a low profile and smooth surface designed to help minimize irritation.
- MRI and CT compatible titanium alloy material

Cervical Plate

Code	Size
MSFX-CAP17	17
MSFX-CAP20	20
MSFX-CAP23	23
MSFX-CAP25	25
MSFX-CAP27	27
MSFX-CAP30	30
MSFX-CAP33	33
MSFX-CAP36	36
MSFX-CAP40	40
MSFX-CAP45	45
MSFX-CAP50	50
MSFX-CAP55	55
MSFX-CAP60	60
MSFX-CAP65	65
MSFX-CAP70	70
MSFX-CAP75	75
MSFX-CAP80	80
MSFX-CAP90	90
MSFX-CAP100	100



Width 20mm

Cervical Plate Screws

	Code	
	MSFX-CAPS12	4.0x12 mm
	MSFX-CAPS14	4.0x14 mm
	MSFX-CAPS16	4.0x16 mm
	MSFX-CAPS18	4.0x18 mm
	MSFX-CAPS20	4.0x20 mm
	MSFX-CAPSR12	4.5x12 mm
	MSFX-CAPSR14	4.5x14 mm
	MSFX-CAPSR16	4.5x16 mm
	MSFX-CAPSR18	4.5x18 mm
	MSFX-CAPSR20	4.5x20 mm

TL-5555	PS® Reduction Screw Multi Set 5.5x55mm
TL-5560	PS® Reduction Screw Multi Set 5.5x60mm
TL-6530	PS® Reduction Screw Multi Set 6.5x30mm
TL-6535	PS® Reduction Screw Multi Set 6.5x35mm
TL-6540	PS® Reduction Screw Multi Set 6.5x40mm
TL-6545	PS® Reduction Screw Multi Set 6.5x45mm
TL-6550	PS® Reduction Screw Multi Set 6.5x50mm
TL-6555	PS® Reduction Screw Multi Set 6.5x55mm
TL-6560	PS® Reduction Screw Multi Set 6.5x60mm
TL-7530	PS® Reduction Screw Multi Set 7.5x30mm
TL-7535	PS® Reduction Screw Multi Set 7.5x35mm
TL-7540	PS® Reduction Screw Multi Set 7.5x40mm
TL-7545	PS® Reduction Screw Multi Set 7.5x45mm
TL-7550	PS® Reduction Screw Multi Set 7.5x50mm
TL-7555	PS® Reduction Screw Multi Set 7.5x55mm
TL-7560	PS® Reduction Screw Multi Set 7.5x60mm

Code	Product Name
	Multi-Axial Iliac Screw
TI-7560	PS® Multi-Axial Iliac Screw Set 7.5x60mm
TI-7570	PS® Multi-Axial Iliac Screw Set 7.5x70mm
TI-7580	PS® Multi-Axial Iliac Screw Set 7.5x80mm
TI-7590	PS® Multi-Axial Iliac Screw Set 7.5x90mm
TI-7500	PS® Multi-Axial Iliac Screw Set 7.5x100mm
TI-7510	PS® Multi-Axial Iliac Screw Set 7.5x110mm
TI-8060	PS® Multi-Axial Iliac Screw Set 8.0x60mm
TI-8070	PS® Multi-Axial Iliac Screw Set 8.0x70mm
TI-8080	PS® Multi-Axial Iliac Screw Set 8.0x80mm
TI-8090	PS® Multi-Axial Iliac Screw Set 8.0x90mm
TI-8000	PS® Multi-Axial Iliac Screw Set 8.0x100mm
TI-8010	PS® Multi-Axial Iliac Screw Set 8.0x110mm
TI-9060	PS® Multi-Axial Iliac Screw Set 9.0x60mm
TI-9070	PS® Multi-Axial Iliac Screw Set 9.0x70mm
TI-9080	PS® Multi-Axial Iliac Screw Set 9.0x80mm
TI-9090	PS® Multi-Axial Iliac Screw Set 9.0x90mm
TI-9000	PS® Multi-Axial Iliac Screw Set 9.0x100mm
TI-9010	PS® Multi-Axial Iliac Screw Set 9.0x110mm
	Rod
TR-0050	PS® Rod 6.0 x 50mm
TR-0060	PS® Rod 6.0 x 60mm
TR-0070	PS® Rod 6.0 x 70mm
TR-0080	PS® Rod 6.0 x 80mm
TR-0090	PS® Rod 6.0 x 90mm
TR-0100	PS® Rod 6.0 x 100mm
TR-0120	PS® Rod 6.0 x 120mm
TR-0150	PS® Rod 6.0 x 150mm
TR-0160	PS® Rod 6.0 x 160mm
TR-0200	PS® Rod 6.0 x 200mm
TR-0400	PS® Rod 6.0 x 400mm
TR-0500	PS® Rod 6.0 x 500mm
* 5.5mm rods available upon request	
	CoCr Vitallium Rod
TVR-0140	PS® Rod 6.0 x 140mm
TVR-0160	PS® Rod 6.0 x 160mm
TVR-0200	PS® Rod 6.0 x 200mm
TVR-0400	PS® Rod 6.0 x 400mm
TVR-0500	PS® Rod 6.0 x 500mm
* 5.5mm rods available upon request	
	Multi-Axial Transverse Link
TT-0030	PS® Multi-Axial Transverse Link S
TT-0034	PS® Multi-Axial Transverse Link M
TT-0040	PS® Multi-Axial Transverse Link L
TT-0050	PS® Multi-Axial Transverse Link XL
	Set Screw
TS-0010	PS® Set Screw
	Domino
TDS-2205	PS® Domino Single
TDD-2210	PS® Domino Double
	Lateral Connector
TLC-1100	PS® Multi-Axial Offset Lateral Connector
TLC-1110	PS® Lateral Connector

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
OCC-3580	PS® Mini CoCr Rod 3.5x80mm
OCC-3160	PS® Mini CoCr Rod 3.5x160mm
OCC-3240	PS® Mini CoCr Rod 3.5x240mm
	Hybrid Rod
OCR-3480	PS® Mini Titanium Hybrid Rod 3.5mm-6.0mm x 480mm
	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

TUREIS
Tlif Cage

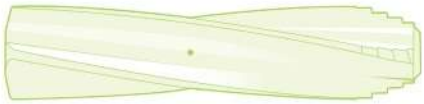
Features

- Bi-convex graft contour, with a 4° angle of lordosis, conforms easily to the concavity of the endplate
- Stracture on the surface, minimizing the risk of expulsion
- Large contact area, minimizing the risk of subsidence
- Large graft area, maximizing the chances of a successful fusion
- Simple, ergonomic and intelligent instrumentation

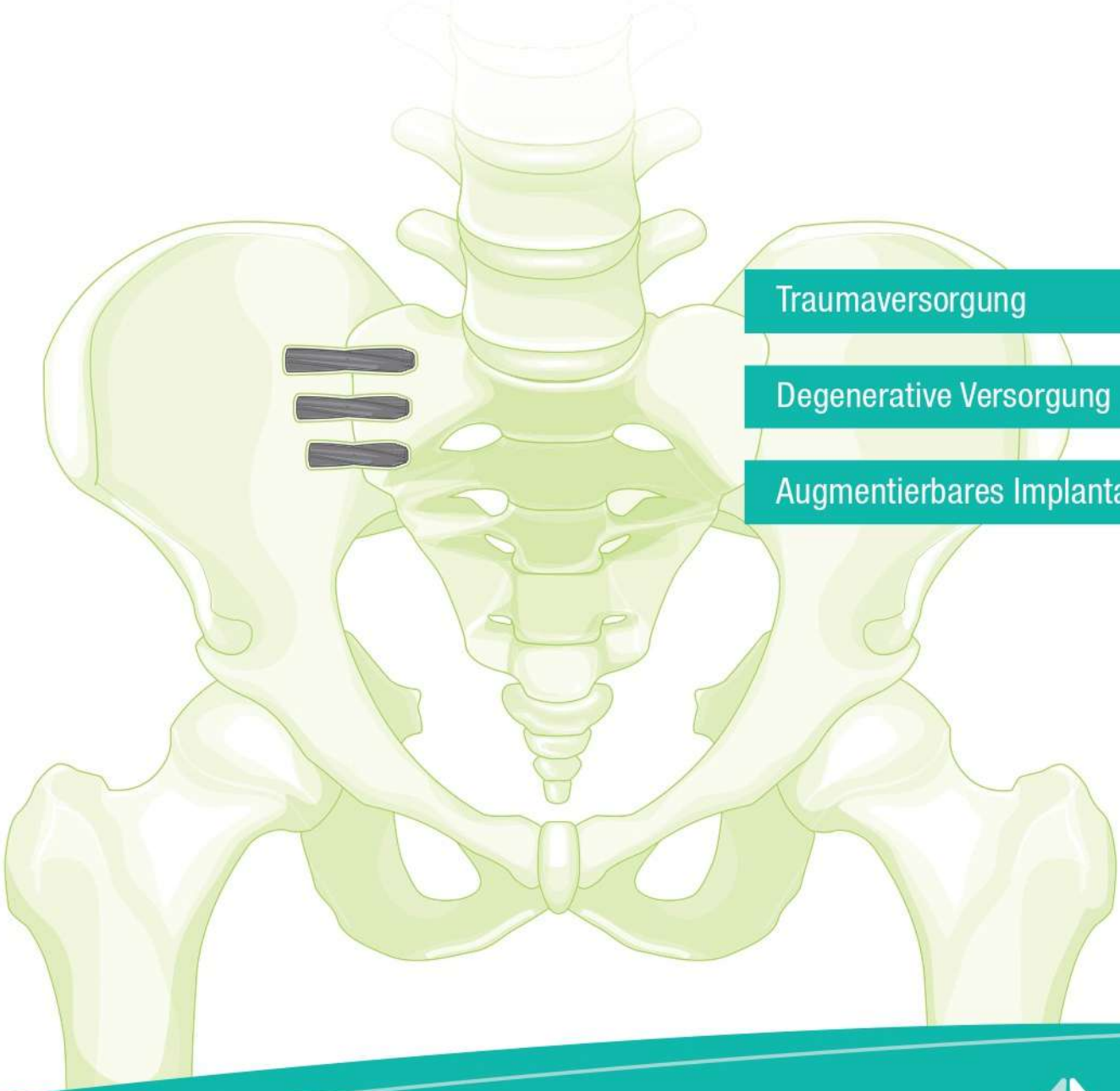
Code	Height	Length	Width
MSFX-BC2407	7	24	10
MSFX-BC2408	8	24	10
MSFX-BC2409	9	24	10
MSFX-BC2410	10	24	10
MSFX-BC2411	11	24	10
MSFX-BC2412	12	24	10
MSFX-BC2413	13	24	10
MSFX-BC2807	7	28	10
MSFX-BC2808	8	28	10
MSFX-BC2809	9	28	10
MSFX-BC2810	10	28	10
MSFX-BC2811	11	28	10
MSFX-BC2812	12	28	10
MSFX-BC2813	13	28	10
MSFX-BC3207	7	32	10
MSFX-BC3208	8	32	10
MSFX-BC3209	9	32	10
MSFX-BC3210	10	32	10
MSFX-BC3211	11	32	10
MSFX-BC3212	12	32	10
MSFX-BC3213	13	32	10

Code	Height	Length	Width	Angled
MSFX-BCA2407	7	24	10	4°
MSFX-BCA2408	8	24	10	4°
MSFX-BCA2409	9	24	10	4°
MSFX-BCA2410	10	24	10	4°
MSFX-BCA2411	11	24	10	4°
MSFX-BCA2412	12	24	10	4°
MSFX-BCA2413	13	24	10	4°
MSFX-BCA2807	7	28	10	4°
MSFX-BCA2808	8	28	10	4°
MSFX-BCA2809	9	28	10	4°
MSFX-BCA2810	10	28	10	4°
MSFX-BCA2811	11	28	10	4°
MSFX-BCA2812	12	28	10	4°
MSFX-BCA2813	13	28	10	4°
MSFX-BCA3207	7	32	10	4°
MSFX-BCA3208	8	32	10	4°
MSFX-BCA3209	9	32	10	4°
MSFX-BCA3210	10	32	10	4°
MSFX-BCA3211	11	32	10	4°
MSFX-BCA3212	12	32	10	4°
MSFX-BCA3213	13	32	10	4°

spineart®



Die Arthrodese des Iliosakralgelenks mit Deltacor TORPEDO



- Traumaversorgung
- Degenerative Versorgung
- Augmentierbares Implantat

Deltacor
TORPEDO
Made in Germany

Chronische Schmerzen, die durch das Iliosakralgelenk bedingt sind, treten nachweislich in der Literatur mit einer Häufigkeit zwischen 14,5% und 44% aller Patienten mit tief lumbalen Rückenschmerzen (Low Back Pain) auf.

Das Deltacor Torpedo System ist eine minimal-invasive Operationsmethode, mit der über einen lateralen Zugang wendelförmige und oberflächenoptimierte Titanimplantate über das Iliosakralgelenks eingebracht werden. Da im Regelfall 3 Implantate eingesetzt werden, wird eine Rotation sowie Translation des Gelenks ausgeschaltet.

Durch diese direkte Stabilisierung des Gelenks wird langfristig eine Arthrodese des schmerzauslösenden ISG angestrebt.

Torpedo und seine Eigenschaften:

Wendelförmige CST-Profil - verhindert neben der rotatorischen auch die translatorische Bewegung im ISG und bietet eine bestmögliche Verankerung des Implantates.

Poröse SLA-Oberflächenbeschichtung - die millionenfach bewerte Oberfläche setzt neue Maßstäbe im Hinblick auf die Osseointegration des Torpedos.

Dreifach Platzierung - durch die Implantation von drei Torpedos wird eine direkt belastbare Stabilisierung erreicht.

Intuitive Instrumentation - ein durchdachtes Instrumentendesign ermöglicht eine schnelle und intuitive Operationsdurchführung.

Deltacor **TORPEDO** Instrumente

Abstandhalter

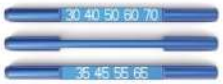
Gewebeschutzhülse

Vorbohrer

Trokar

Einschläger

Schlitzhammer



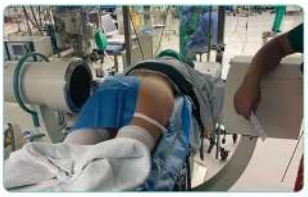
Längenmesser

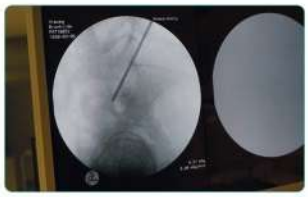
Stabhaltezange

Ein etablierter Weg der richtigen Diagnosestellung beinhaltet unter anderem:

1.) adäquate ISG-bezogene Anamnese
2.) klinische Untersuchung zum Ausschluss anderer Pathologien
3.) Funktionstests: Empfindlichkeit bei Palpation, Straight-Leg-Raise-Test, Ein-Bein-Stand
4.) ISG-Provokationstests: Distraktion, Thigh-Thrust, Kompression, FABER, Gaenslen
5.) CT- oder röntgengeführte intraartikuläre Injektionen

Deltacor **TORPEDO** Implantationsschritte


Schritt 1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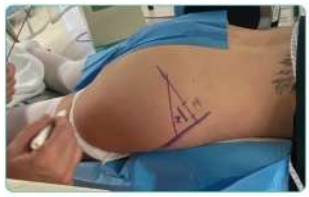
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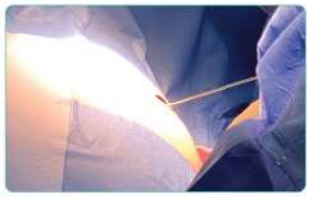
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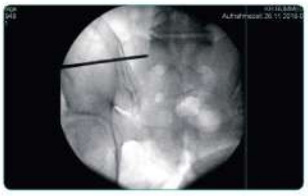
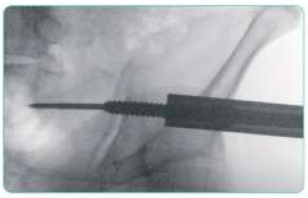

Schritt 5


Schritt 6


Schritt 7


Schritt 8


Schritt 9

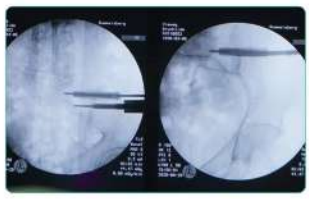

Schritt 10

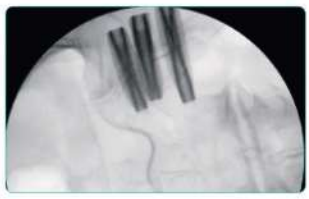

Schritt 11


Schritt 12


Schritt 13


Schritt 14

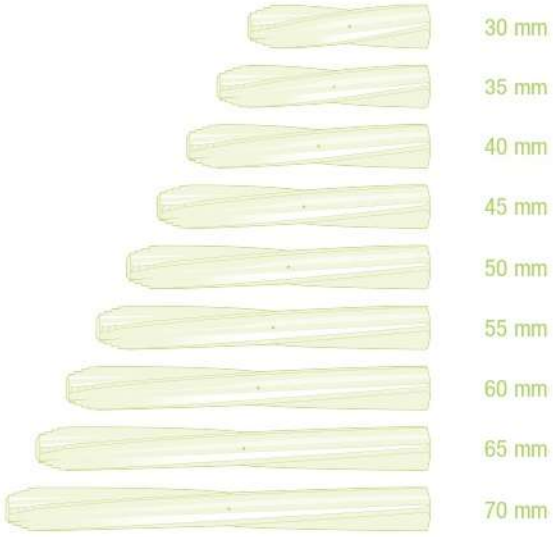

Schritt 15


Schritt 16

One implant for all options

Produktliste Deltacor TORPEDO

Beschreibung	Artikelnummer
Torpedo 30 x 7mm	142-0730-S
Torpedo 35 x 7mm	142-0735-S
Torpedo 40 x 7mm	142-0740-S
Torpedo 45 x 7mm	142-0745-S
Torpedo 50 x 7mm	142-0750-S
Torpedo 55 x 7mm	142-0755-S
Torpedo 60 x 7mm	142-0760-S
Torpedo 65 x 7mm	142-0765-S
Torpedo 70 x 7mm	142-0770-S
Führungsdraht	142-0325



Universitätsmedizin Mannheim, Haus 41
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D-68167 Mannheim

HRB: 733534
USt-ID: DE325241900

OSARTIS®

PerOssal®

Product Guide

Package sizes & bulk volume

PerOssal® is indicated for filling or reconstruction of bone defects and is available in the following package sizes:

1x6 — 6 pellets ≙ 1.5 cm³ bulk volume

03-01031

1.5 cm³ bulk volume total

2x6 — 12 pellets ≙ 3.0 cm³ bulk volume

03-01032

3.0 cm³ bulk volume total

1x50 — 50 pellets ≙ 12.5 cm³ bulk volume

03-0102

12.5 cm³ bulk volume total

Note:
1 pellet ≙ 0.25 cm³

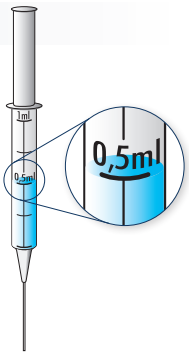
Fluid uptake

PerOssal® are cylindrical pellets measuring 6 mm x 6 mm, with one spherical and one flat end. PerOssal® has a porous structure that allows the safe absorption of aqueous solutions. The fluid uptake is 0.08 ml/pellet.

1x6

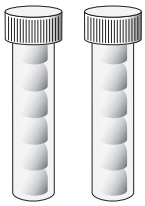
6 pellets can absorb **0.48 ml fluid**

fluid uptake
0.48 ml

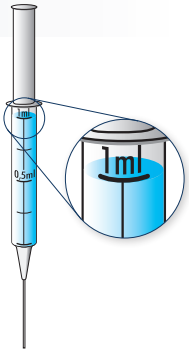


2x6

12 pellets can absorb **0.96 ml fluid**

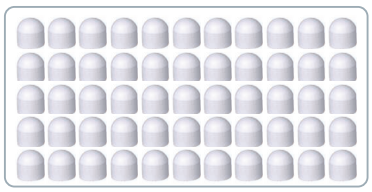


fluid uptake
0.96 ml

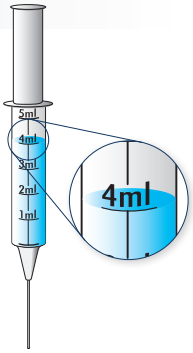


1x50

50 pellets can absorb **4 ml fluid**



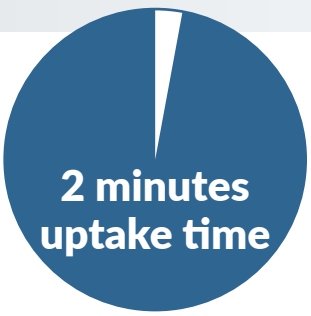
fluid uptake
4 ml



Preparation time

PerOssal® is »Ready to Use« as soon as the fluid is completely absorbed (after approx. 2 minutes).

2 minutes fluid uptake time



Dosage recommendation* for antibiotic load based on antibiotic products available in the market

Antibiotic solution

Various antibiotics are provided as solutions and are therefore ready to use. According to the dosage recommendations from the manufacturer (see IFU) the antibiotic solution can be used immediately for drenching of the pellets.

For instance:

Gentamicin

40 mg/ml

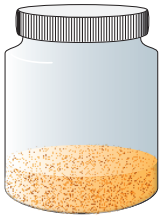
Tobramycin

40 mg/ml

Antibiotic powder

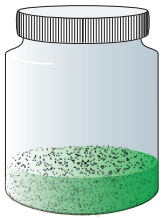
Some antibiotics are provided as powder. As PerOssal® is a carrier for fluid substances, the powder has to be dissolved in a fluid** before drenching of the pellets. Please follow the Instructions for Use enclosed with the antibiotic powder.

For instance:



Vancomycin

100 mg/ml



Rifampicin

60 mg/ml

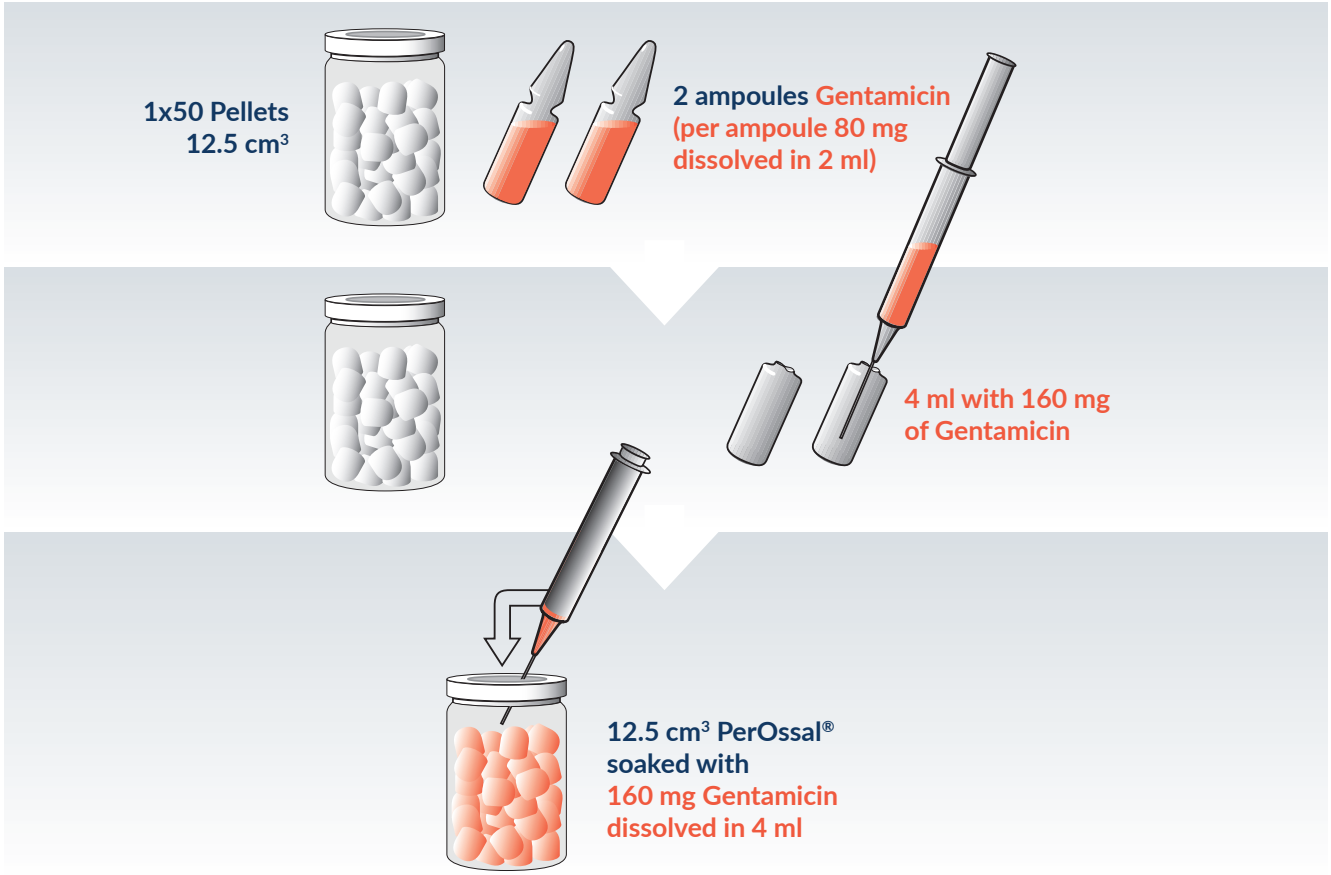
* The dosage recommendation relates to the in vitro results, as well as to the results obtained within the scope of clinical testing. The treating physician is responsible for the final decision regarding the type and quantity of the corresponding antibiotic. The contraindications of the applied antibiotic have to be considered.

**e.g. sterile water for injection purposes (aqua ad iniectabilia)

Antibiotic solution (Single application)

Dosage recommendation*

Example: Gentamicin with PerOssal® 1x50



Gentamicin

	1x50 pellets	2x50 pellets	3x50 pellets
Bulk volume	12.5 cm³	25 cm³	37.5 cm³
Amount of antibiotic	160 mg	320 mg	480 mg
Volume of antibiotic solution	4 ml	8 ml	12 ml

40 mg/ml

Tobramycin

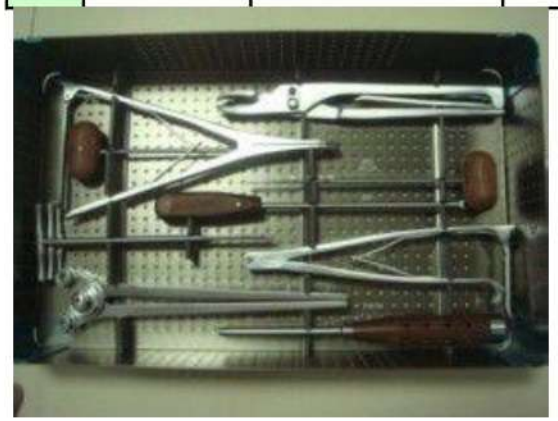
	1x50 pellets	2x50 pellets	3x50 pellets
Bulk volume	12.5 cm³	25 cm³	37.5 cm³
Amount of antibiotic	160 mg	320 mg	480 mg
Volume of antibiotic solution	4 ml	8 ml	12 ml

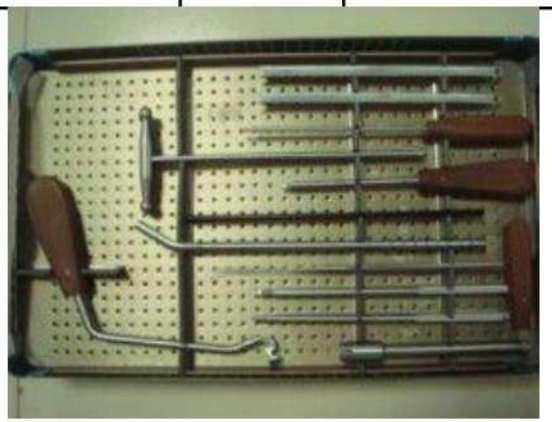
40 mg/ml

JINLU MEDICAL RSS-III spinal system

NO	P/N	Product Name	Picture	Size	Unit	Material
1	T080-T120	Rod		6.0*80-120mm	PC	Ti6Al4V
2	T140-T200			6.0*140-200mm	PC	Ti6Al4V
3	T220-T280			6.0*220-280mm	PC	Ti6Al4V
4	T300-T360			6.0*300-360mm	PC	Ti6Al4V
5	T380-T400			6.0*380-400mm	PC	Ti6Al4V
6	T001-T004	Mono Axis Screws		Φ4.5*25-40mm	PC	Ti6Al4V
7	T005-T010			Φ5.5*30-50mm	PC	Ti6Al4V
8	T010-T015			Φ6.5*40-60mm	PC	Ti6Al4V
9	T015-T020			Φ7.5*40-60mm	PC	Ti6Al4V
10	T021-T025	Break-off Mono Axis Screws		Φ4.5*25-40mm	PC	Ti6Al4V
11	T026-T031			Φ5.5*30-50mm	PC	Ti6Al4V
12	T032-T037			Φ6.5*40-60mm	PC	Ti6Al4V
13	T038-T043			Φ7.5*40-60mm	PC	Ti6Al4V
14	T044-T048	Multi-axial Screws		Φ4.5*25-40mm	PC	Ti6Al4V
15	T049-T054			Φ5.5*30-50mm	PC	Ti6Al4V
16	T055-T060			Φ6.5*40-60mm	PC	Ti6Al4V
17	T061-T066			Φ7.5*40-60mm	PC	Ti6Al4V
18	T067-T071	Break-off Multi-axial Screws		Φ4.5*25-40mm	PC	Ti6Al4V
19	T072-T077			Φ5.5*30-50mm	PC	Ti6Al4V
20	T078-T083			Φ6.5*40-60mm	PC	Ti6Al4V
21	T084-T089			Φ7.5*40-60mm	PC	Ti6Al4V

22	T041	Crosslink connector		30-100mm	PC	Ti6Al4V
23	T042	Crosslink connector		30-75mm	PC	Ti6Al4V
24		RSS III instruments set		3 trays	set	SS





* All Ti implants are Type II anodized for biocompatibility and improved fatique strength.
  Color anodizing Type III available upon request.
  Custom sizes available upon request.