

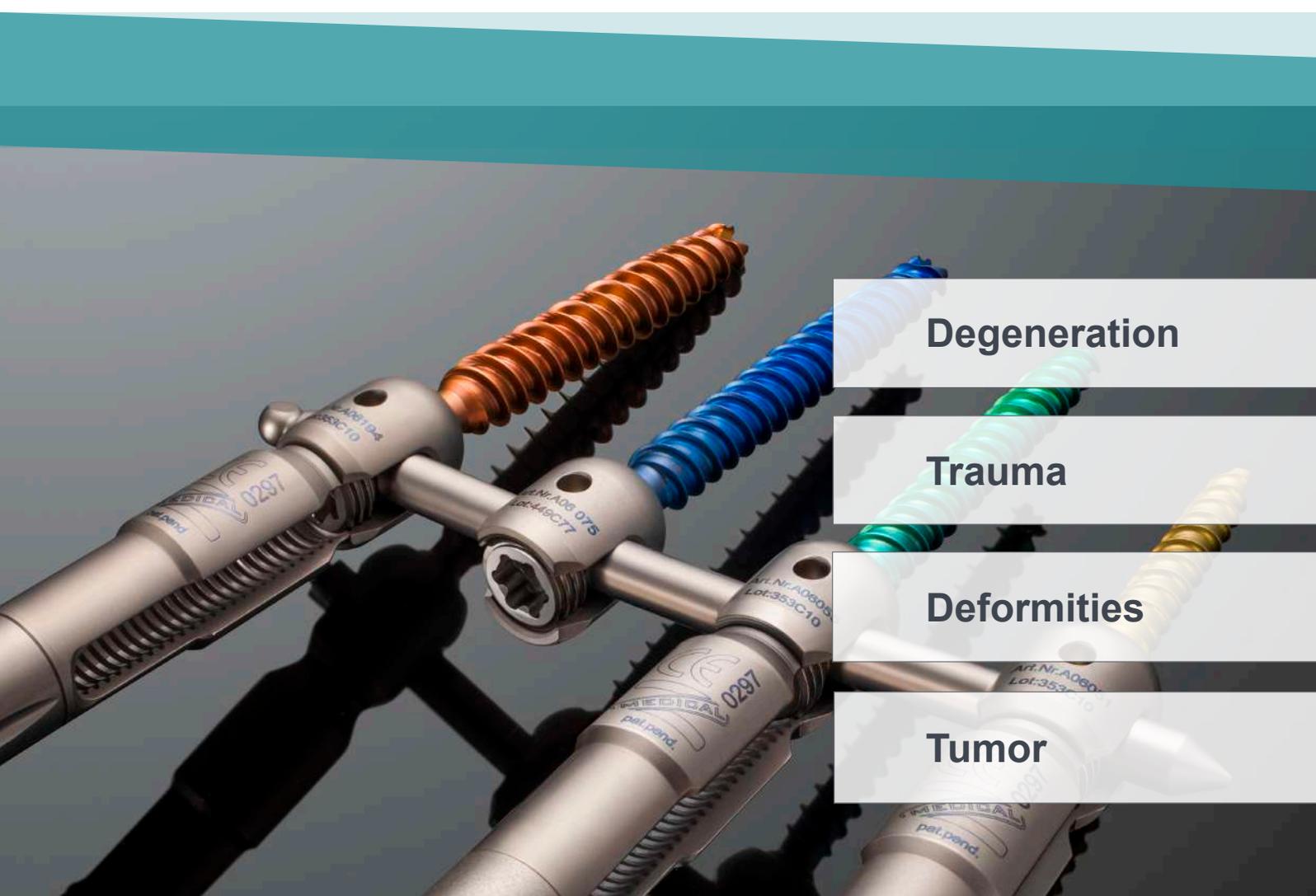


LOT 1, LOT 16



CATALOGUE

MIS Z-PEDICLE SCREW SYSTEM



Degeneration

Trauma

Deformities

Tumor

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.

Patented Pedicle Screws

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

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

- » 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.

Sterile Packaging

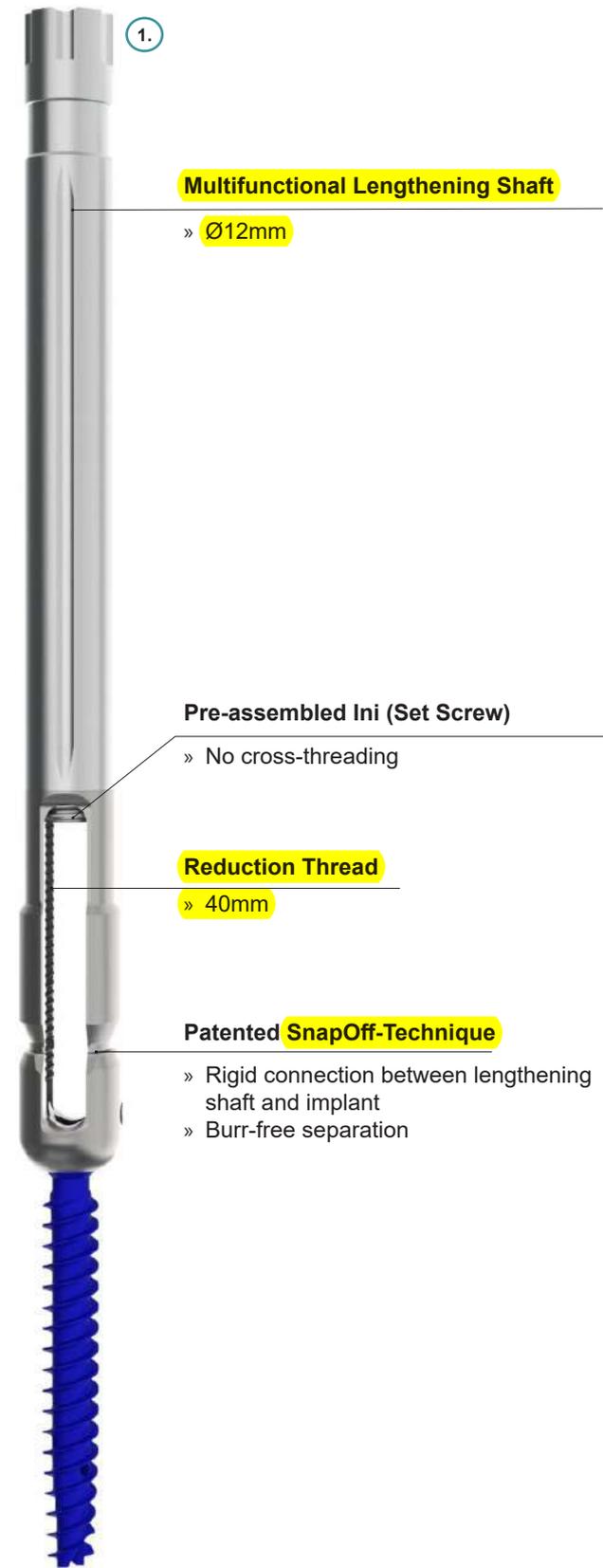
All implants are single sterile packaged and ready for surgery.

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

- » 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 Manipulation | Via reduction thread, 40mm |
| Fractures reduction | Via lengthening shaft |
| Derotation of deformities | Via reduction thread |
| Connection implant / shaft | Via reduction thread |
| Break off implant / shaft | Connected by SnapOff-Technique |
| Cement-Augmentation | With patented Tulip Breaker |
| Approval | With Bone Cement Filler Cannula through Screwdriver Pedicle Screw EEC 93/42 // 510(k) |



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

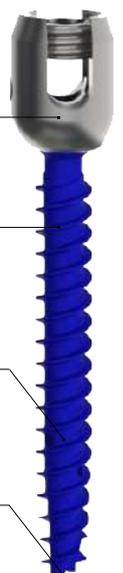
- » High stability
- » Fast insertion, 6mm per rotation

Cannulated and fenestrated

- » Safe insertion over guide wire
- » Controlled cement-augmentation

Thread features

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



3.

4.

Axialities

The Z-Pedicle Screws are available in different axialities:

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



Quattroaxial
Fractures / Spondylolisthesis

Special Screws for Fractures / Spondylolisthesis

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

Degree of freedom:

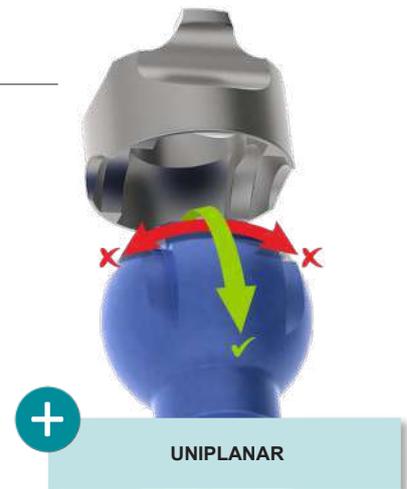
- » Medial-Lateral: moving freely
- » Cranio-Caudal: blocked

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



Reduction / Reposition

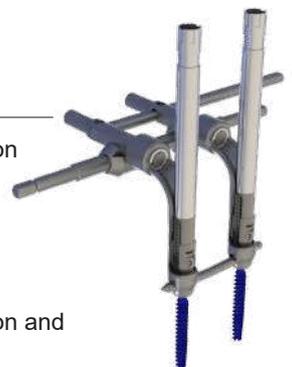
- » Easy alignment after surgical reduction of spondylolisthesis
- » Without additional instruments
- » Directly achieved with the pre-assembled Ini via the reduction thread



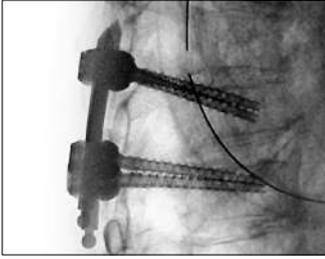
Distraction / Compression

The universal distraction and compression instrument enables:

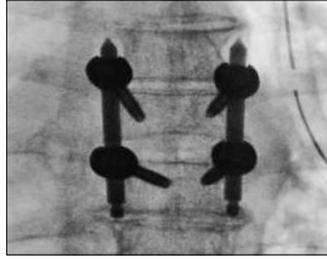
- » A direct and controlled correction of complex fractures
- » An open and percutaneous distraction and compression along the rod
- » Segmental distraction for discectomy and / or insertion of an interbody device
- » Same approach as MIS screw, application via the lengthening shaft



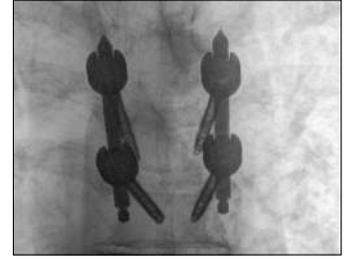
Treatment of Discoligamentous Laceration using the MIS Z-Pedicle Screw System!



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 unproblematic 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.

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



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

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

| 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 |



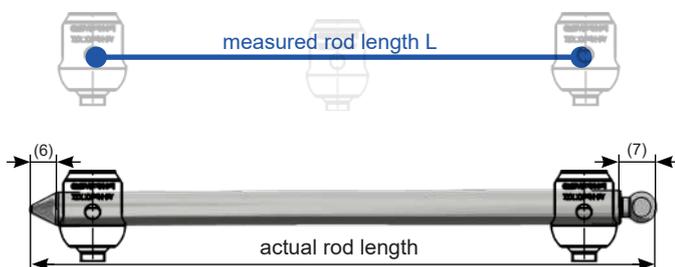
| Instrument | Art.No. | Description | Q |
|-----------------------|-----------|--|---|
| | A06 081 S | Z-Guide Wire | 2 |
| Distributive products | Art.No. | Description | Q |
| | 900140 | First Access Needle | 1 |
| | 900146 | Bone Cement Filler Cannula for Screw Cementation | 1 |
| | 800039 | V-Steady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

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

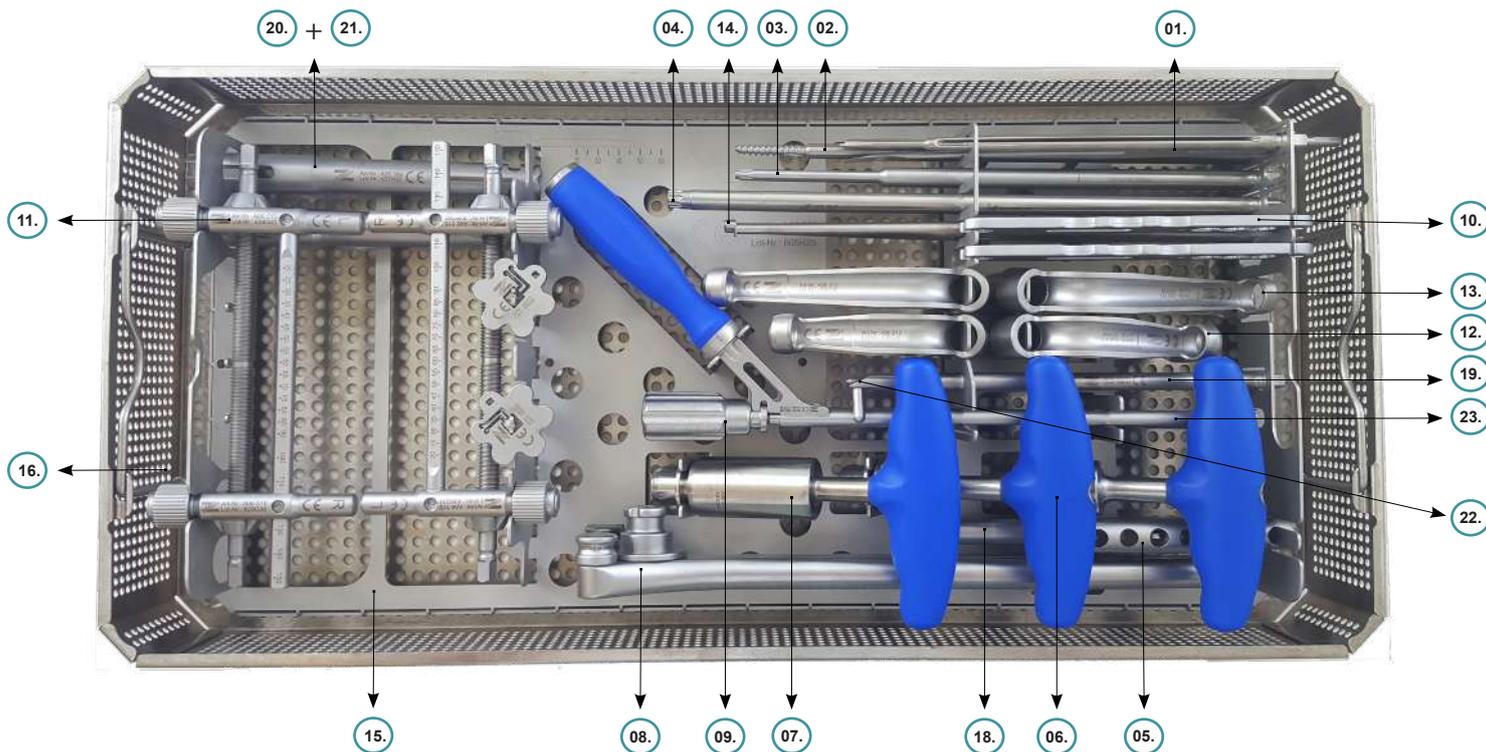
Z-Rods | Sterile, Ø5.5mm

| 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

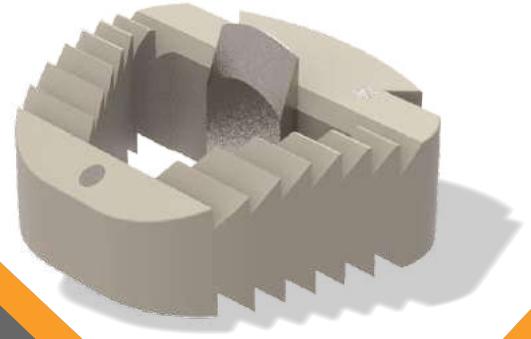
Instruments Optional

- 18. Reamer

Instruments Extension / Revision

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

LOT 8



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 supplemental fixation

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



LOT 3



POLAR Spinal System 6.0

Features

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



Polyaxial Screw



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

Additional sizes available upon request

Monoaxial Screw

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

Monoaxial Spondylolisthesis Screw

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

Additional sizes available upon request

Cemented screws

Polyaxial Spondylolisthesis Screw



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

Polyaxial Cannulated And Fenestrated Screw



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

Additional sizes available upon request

Cemented screw

Monoaxial Cannulated And Fenestrated Screw



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

Rod Titanium alloy



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

Additional sizes available upon request

Polar Polyaxial Screw

Polar Polyaxial Spondylolisthesis 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 | | |



| 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 |

Additional sizes available upon request

Polar Monoaxial Screw

Polar Monoaxial Spondylolisthesis 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 | | |



| 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 | | |

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

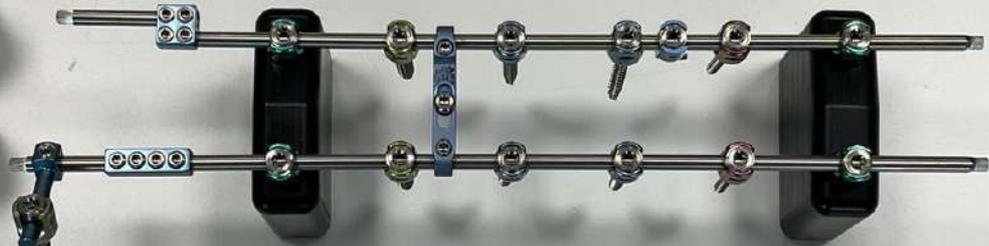
| Code | Size | |
|---------------------|---------|---|
| MSFX-LH0505 | 5x5 mm |  |
| MSFX-LH0507 | 5x7 mm | |
| MSFX-LH0509 | 5x9 mm | |
| MSFX-LH0706 | 7x6 mm | |
| MSFX-LH0707 | 7x7 mm | |
| MSFX-LH0709 | 7x9 mm | |
| MSFX-LH0711 | 7x11 mm | |
| MSFX-LHF0505 | 5x5 mm | |
| MSFX-LHF0507 | 5x7 mm |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







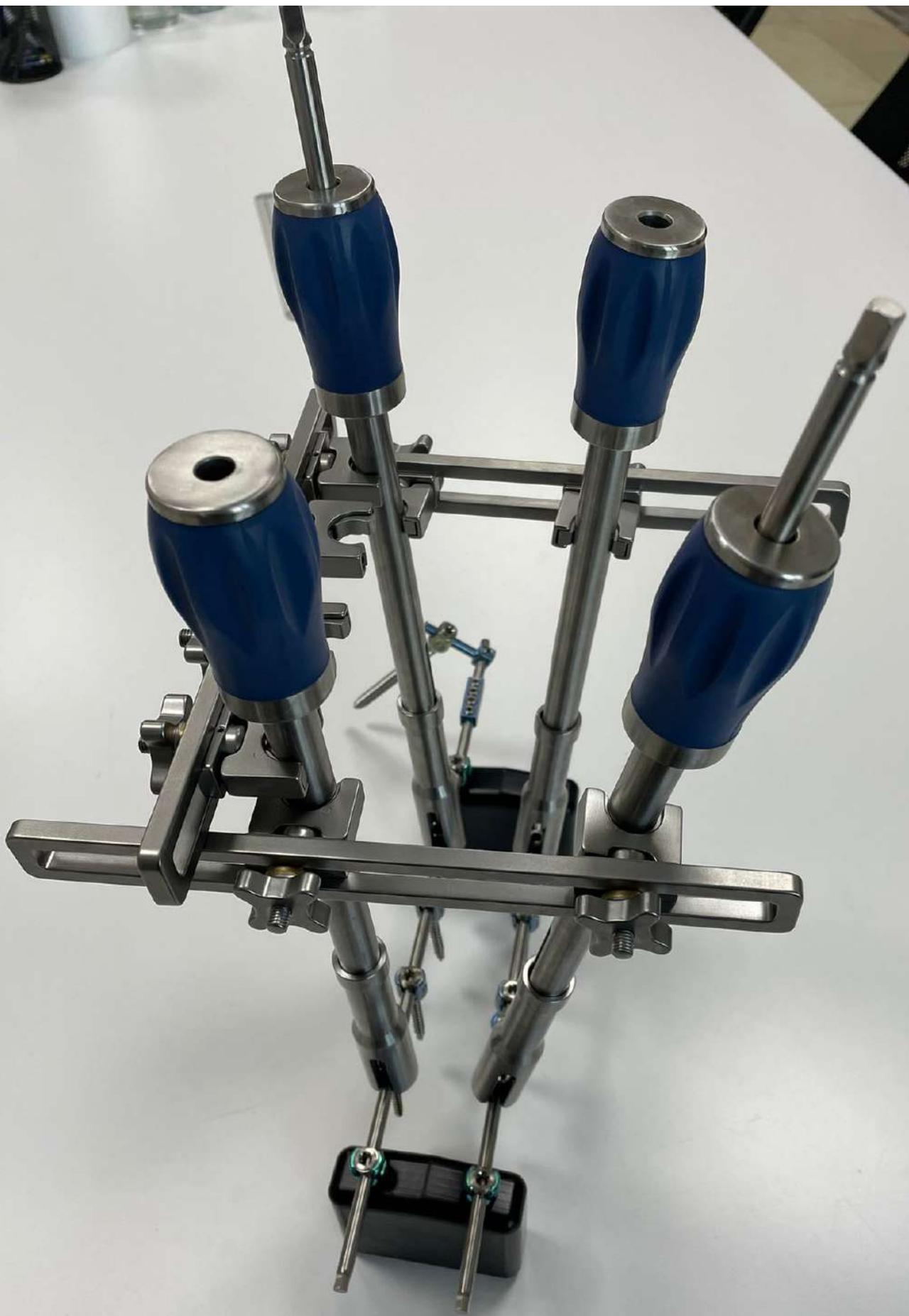
Osteotomy instrument set

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 |  | | | |
| | | | | |
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| | | | | |
| 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 5,10

OSARTIS®

| 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



141-1010-03EN / 082020



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BonOs® Inject

www.osartis.de



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 radiopacity with 45% ZrO₂
- 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*

| Mixing | Filling of the application instruments and waiting time | Application | Hardening |
|--------|---|-------------|-----------|
| 0.5 ▶ | 5.0 ▶ | 7.5 ▶ | 9.0 ▶ |
| ▶ 0 | | | |
| ▶ 22 ▶ | | | |

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

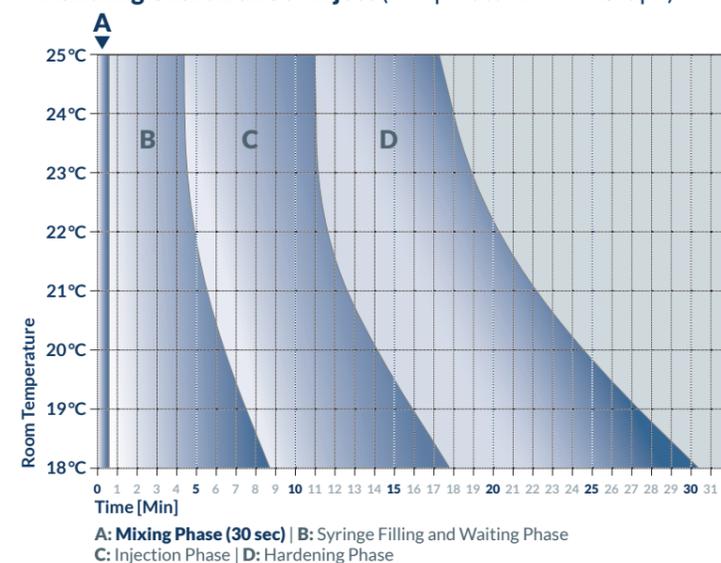
When both components of BonOs® Inject – powder and monomer – are mixed, the PMMA bone cement volume of 25 ml is generated. Depending on parameters such as temperature, mixing system, type of syringes and filling time the cement volume available for injection will differ.

| 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)



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

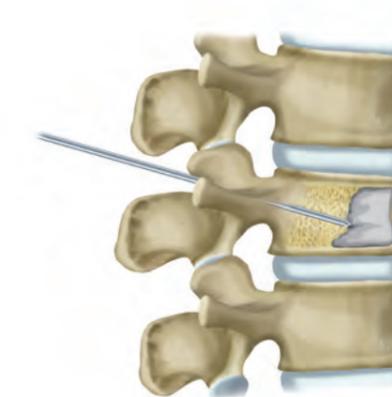
The addition of zirconium dioxide (ZrO₂) allows an optimal X-ray visualization of BonOs® Inject for a safe use.

Good mechanical properties

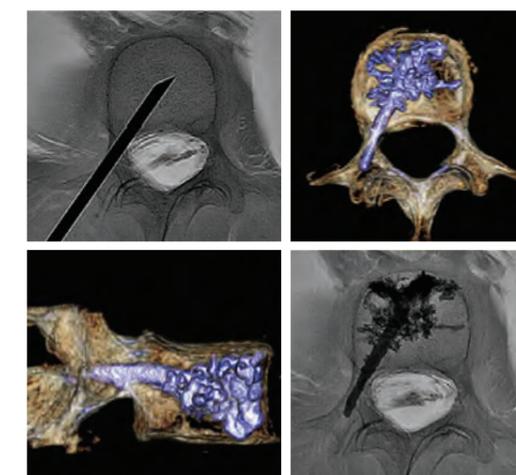
The composition of BonOs® Inject guarantees optimized mechanical properties which exceed the respective requirements of the ISO 5833 standard. Thanks to its medium viscosity, BonOs® Inject can be used with all currently approved PMMA cements application tools.

Chemical composition

| Powder (24 g) | | Liquid (10 ml) | |
|--|---------|----------------------|---------|
| Poly(methyl methacrylate) | 10.95 g | Methyl methacrylate | 9.93 ml |
| Poly(methyl acrylate/ methyl methacrylate) | 1.75 g | Dimethyl-p-toluidine | 0.07 ml |
| Zirconium dioxide | 10.80 g | Hydroquinone | 60 ppm |
| Benzoyl peroxide | 0.50 g | | |



Example of a cemented vertebra



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



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 |

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 |

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 |



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: 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: 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

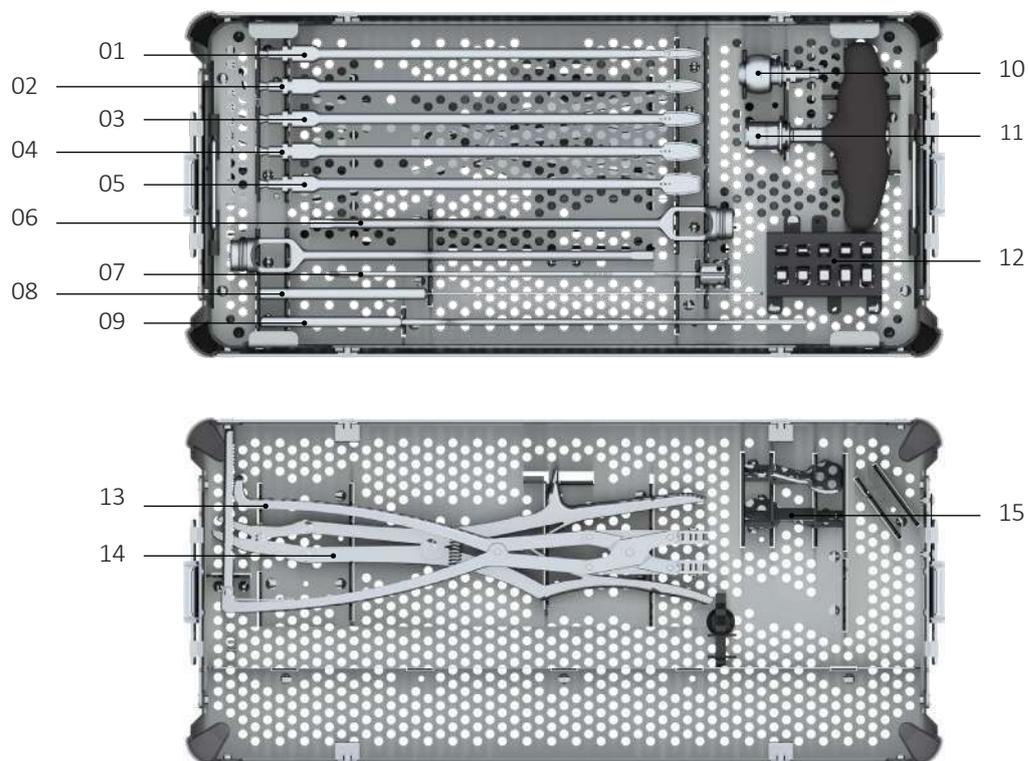


| # | DESCRIPTION | REFERENCE |
|----|----------------------------------|----------------|
| 01 | PITUITARY RONGEUR, STRAIGHT, 5MM | SCA-IN 21 00-N |
| 02 | PITUITARY RONGEUR, STRAIGHT, 3MM | SCA-IN 22 00-N |
| 03 | PITUITARY RONGEUR, 3MM, UP | SCA-IN 21 01-N |
| 04 | PITUITARY RONGEUR, 5MM, UP | SCA-IN 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

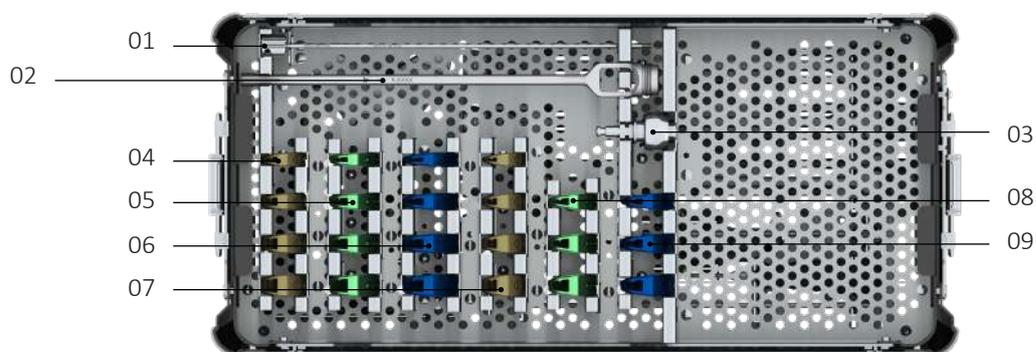


| # | DESCRIPTION | REFERENCE |
|----|---------------------------------|----------------|
| 01 | DISC SHAVER H08 | SCA-IN 14 08-N |
| 02 | DISC SHAVER H10 | SCA-IN 14 10-N |
| 03 | DISC SHAVER H12 | SCA-IN 14 12-N |
| 04 | DISC SHAVER H14 | SCA-IN 14 14-N |
| 05 | DISC SHAVER H16 | SCA-IN 14 16-N |
| 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

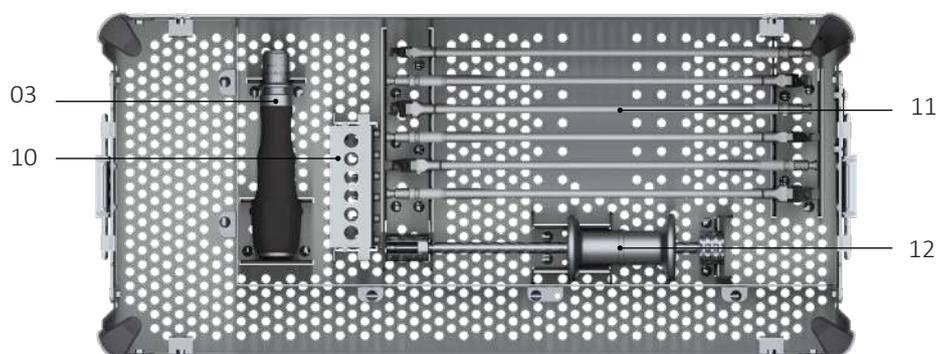
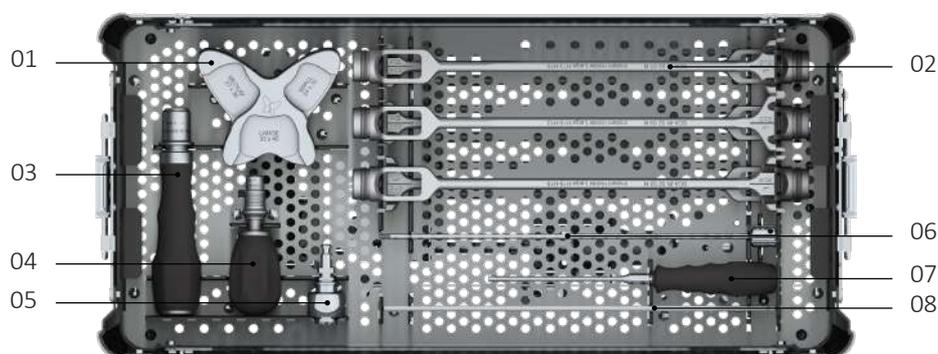
IMPLANT TRIALS AND CAGES INSERTION



| # | 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

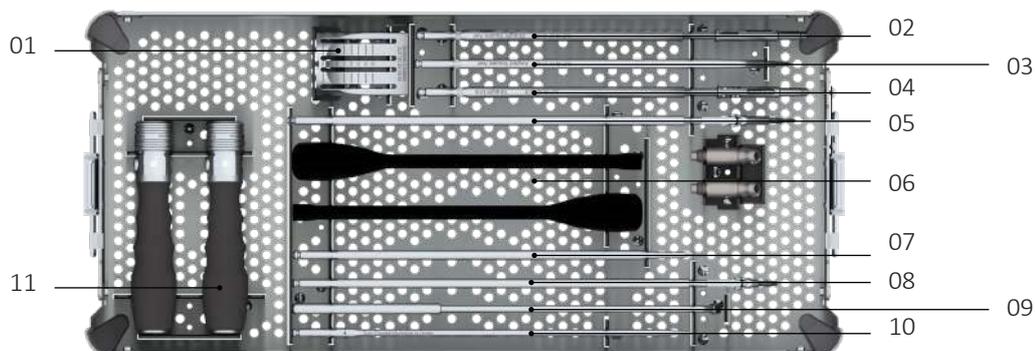


| # | DESCRIPTION | REFERENCE |
|----|---|----------------|
| 01 | COMPACTION BASE | SCA-IN 07 00-N |
| 02 | IMPLANT HOLDERS: | |
| | SMALL/MEDIUM H10-H12 | SCA-IN 01 01-N |
| | SMALL/MEDIUM H13-H15 | SCA-IN 01 02-N |
| | SMALL/MEDIUM H16-H18 | SCA-IN 01 03-N |
| | LARGE H10-H12 | SCA-IN 02 00-N |
| | LARGE H13-H15 | SCA-IN 02 01-N |
| | LARGE H16-H18 | 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 | SCA-IN 03 00-N |
| | SMALL/MEDIUM H13-H15 | SCA-IN 03 01-N |
| | SMALL/MEDIUM H16-H18 | SCA-IN 03 02-N |
| | LARGE H10-H12 | SCA-IN 04 00-N |
| | LARGE H13-H15 | SCA-IN 04 01-N |
| | LARGE H16-H18 | 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 |



AT A GLANCE

Streamlined Tip
Polyaxial Head
Low Profile Implants
Blunt tip

INDICATIONS

ROMEО®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 |



I M P L A N T S

| 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 | OFFSET LEFT | ELL-HO OF 0L-S |
| ANGLED RIGHT | ELL-HO AN 0R-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



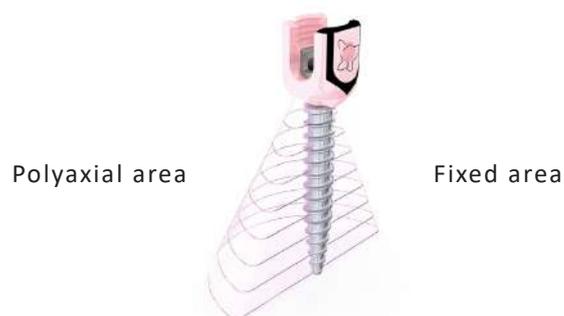
Complete range of polyaxial, semi-polyaxial, monoaxial, reduction screws, transverse connectors and rod connectors provide versatile options to treat numerous pathologies from T1 to the ilium.

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



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.

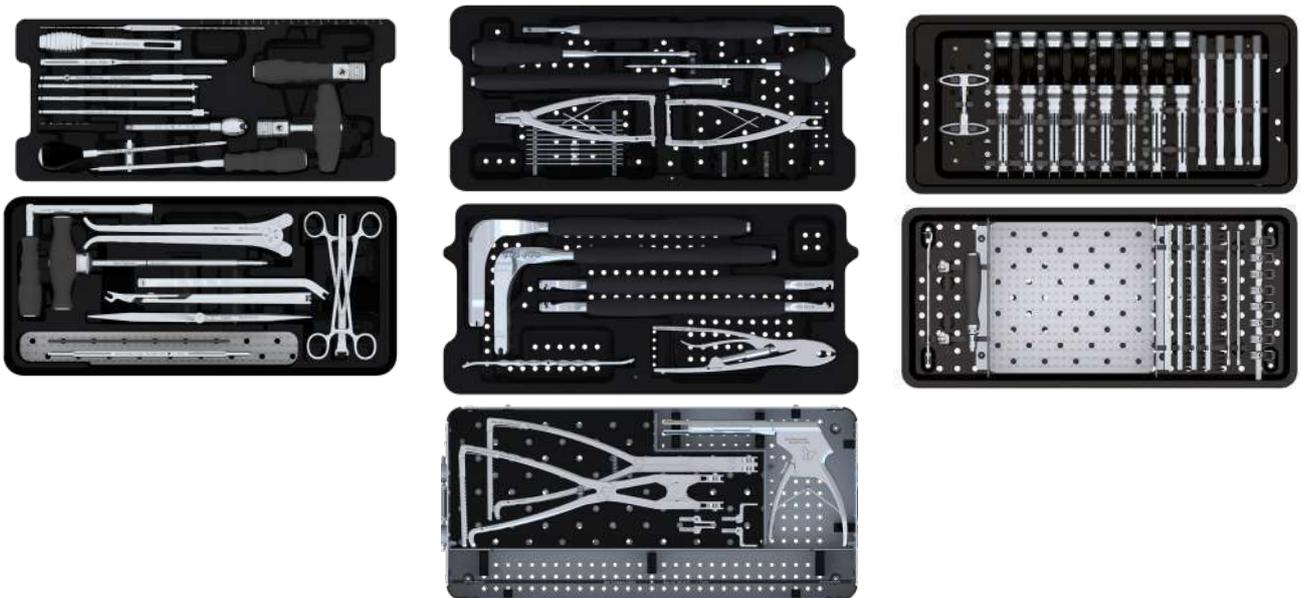
TECHNICAL FEATURES

HOOKS



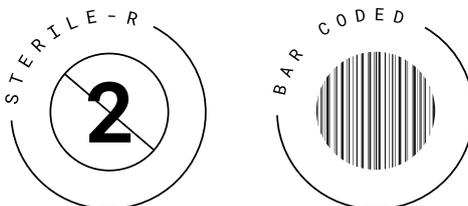
A full range of hooks with various sizes is available with ROMEO®2. Their autostatic teeth enhance their stability once impacted

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

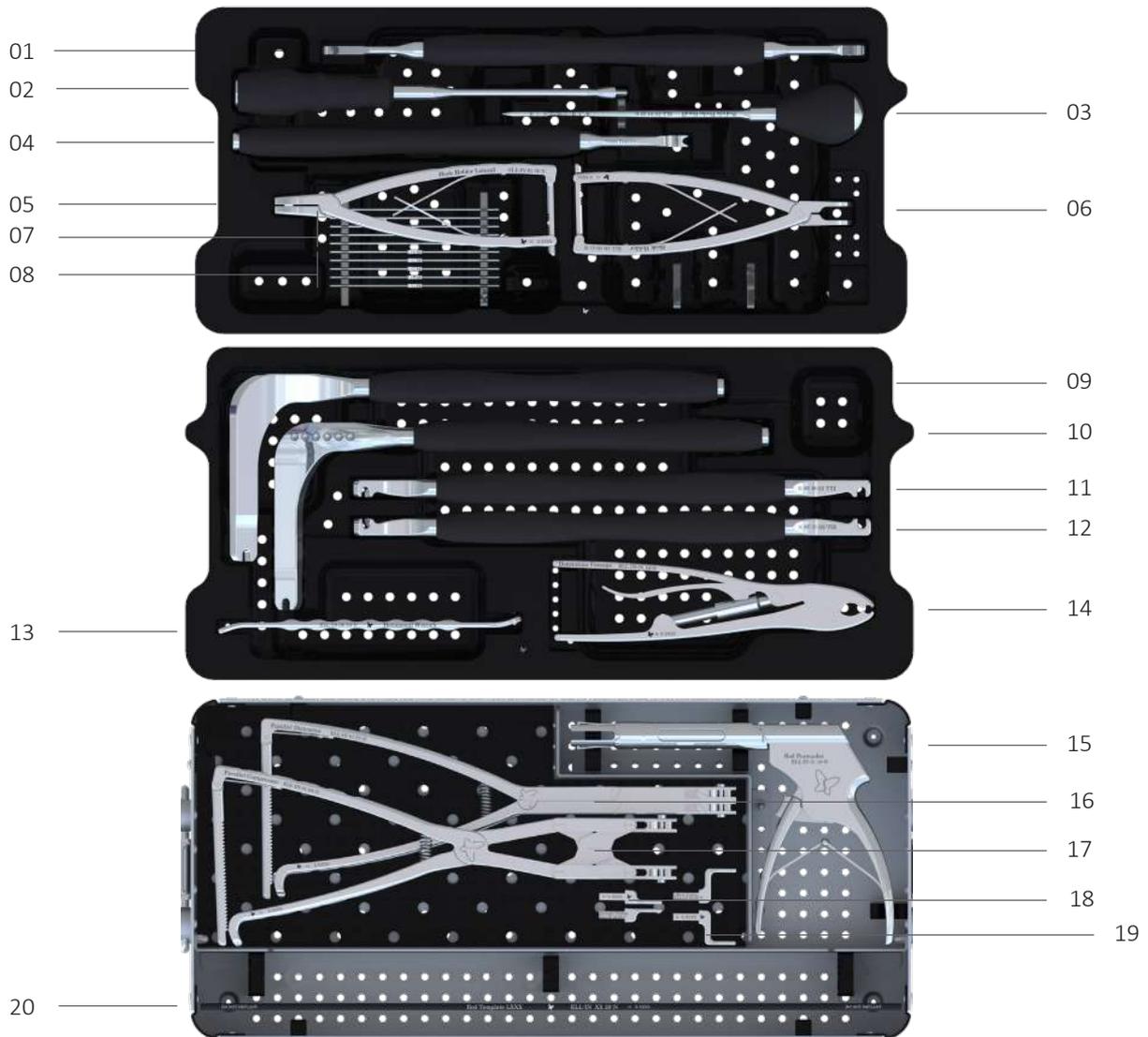


| # | DESCRIPTION | REFERENCE |
|----|-------------------------|----------------|
| 01 | PEDICLE SOUNDER | ELL-IN 01 02-N |
| 02 | SET SCREW TUBE | ELL-IN 01 15-N |
| 03 | SET SCREW HOLDER W | ELL-IN 03 10-N |
| 04 | SET SCREW TIGHTENER | ELL-IN 04 06-N |
| 05 | SCREWDRIVER SHAFT PS | ELL-IN 05 03-N |
| 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 |

INSTRUMENT SET

LONG CONSTRUCT KIT



ROMEO®2 - THORACOLUMBAR FIXATION

| # | 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 |

SURGICAL TECHNIQUE

_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 |



ROMEО®2 deformity screws 25D

Innovative implants.



Dear collaboration partner,

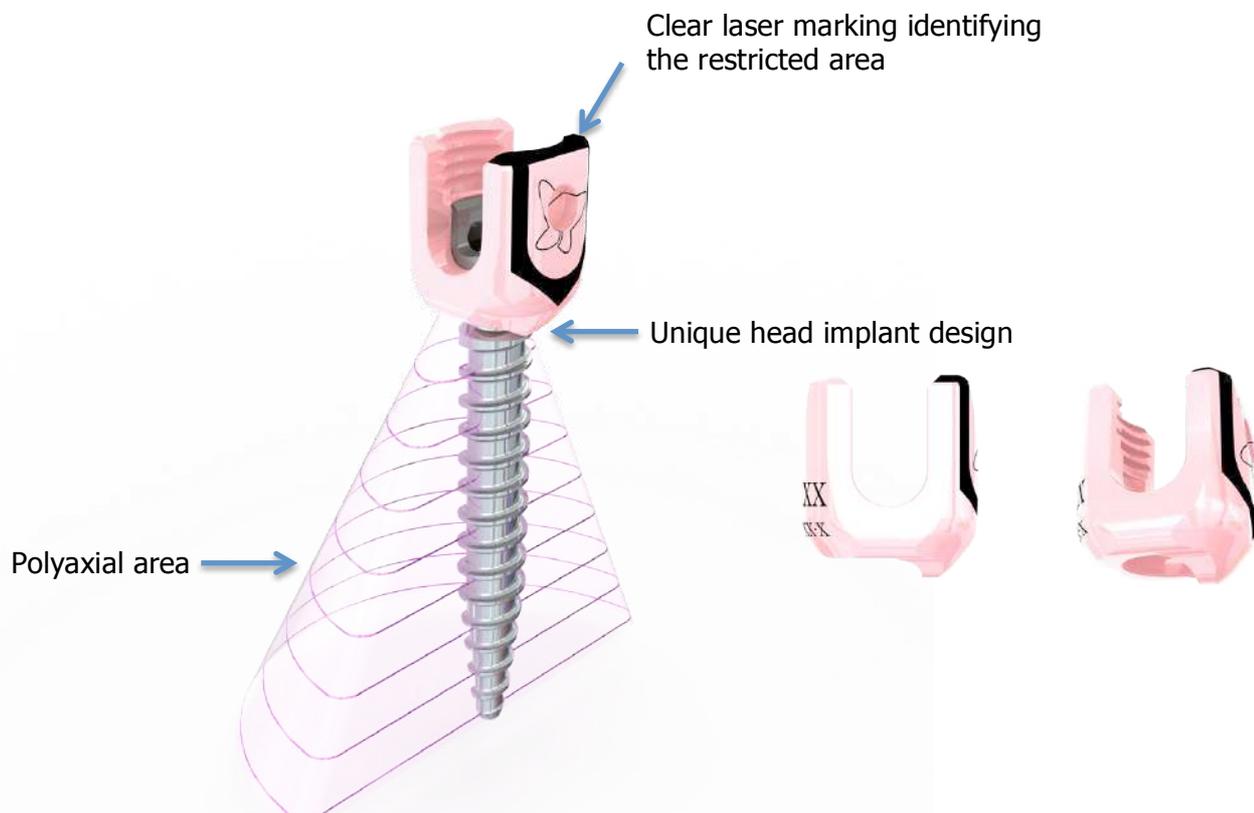
Spineart® is pleased to inform you of the development of the 25D screws, extending the range of ROMEО®2 screws and opening on surgical solutions for the treatment of spinal deformities.

The 25D screws are deformity-oriented screws sharing the same “streamlined tip” and “low profile” features as the currently available ROMEО®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.





PRODUCT MANAGEMENT INFORMATION

ROMEO[®] 2 | No. 01/2013-E

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[®]



ROMEО[®] 2_{MIS} trauma screws 25T

Innovative implants.



Dear collaboration partner,

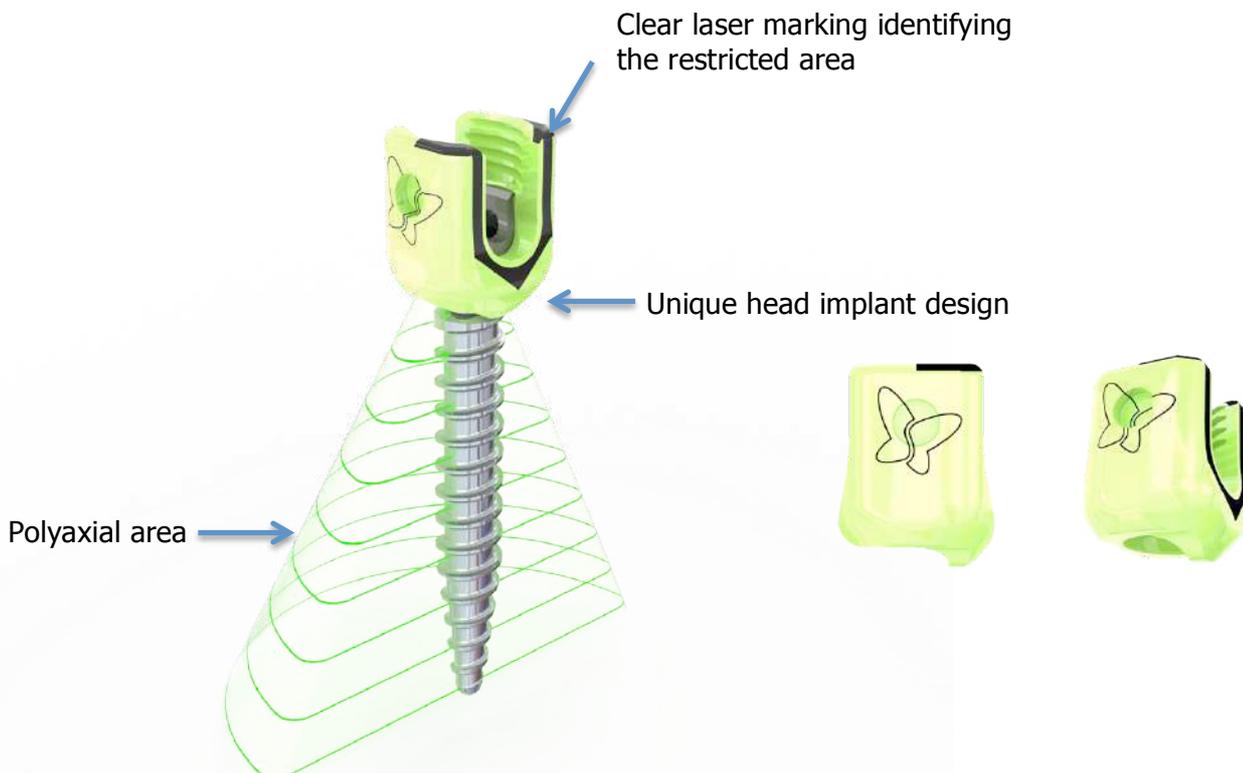
Spineart[®] is pleased to inform you of the development of the 25T screws, extending the range of ROMEО[®] 2_{MIS} screws and providing an innovative alternative for the treatment of spinal trauma cases during minimally invasive surgeries.

The 25T screws are trauma-oriented cannulated screws and present "streamlined tip" and "low profile" features as the currently available ROMEО[®] 2_{MIS} 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.





PRODUCT MANAGEMENT INFORMATION

ROMEO[®] 2_{MIS} | No. 01/2013 ---E

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 discreet, 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



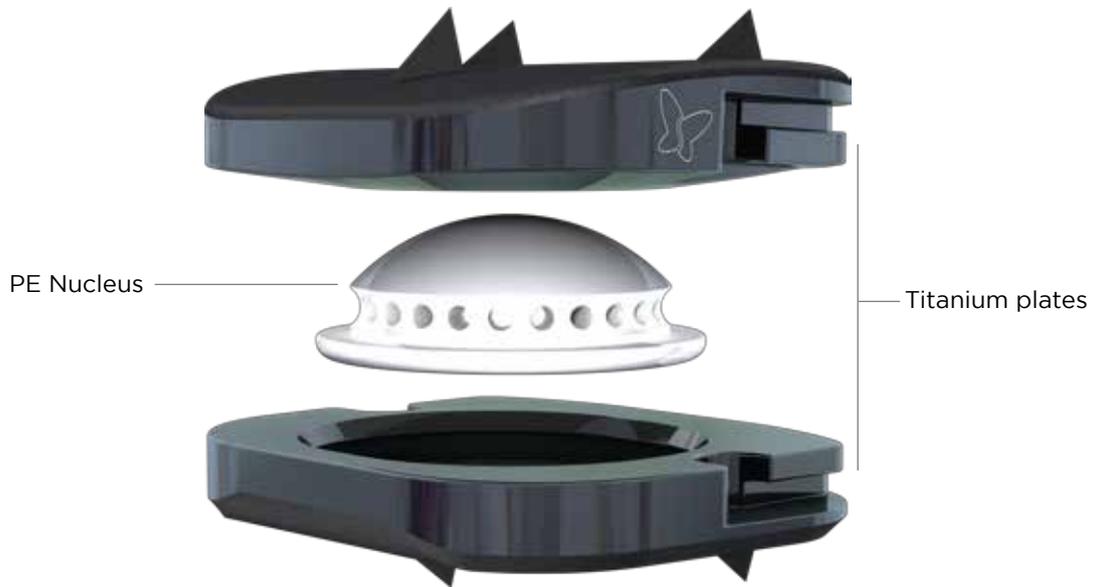
INDICATIONS

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 |

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

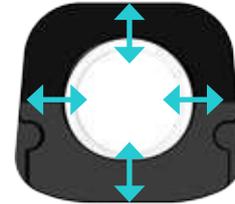
| REFERENCES | |
|------------|-----------------|
| Heights | Large : 16x18mm |
| 5mm | CDP-TI 16 05-S |
| 6mm | CDP-TI 16 06-S |
| 7mm | CDP-TI 16 07-S |



TECHNICAL FEATURES

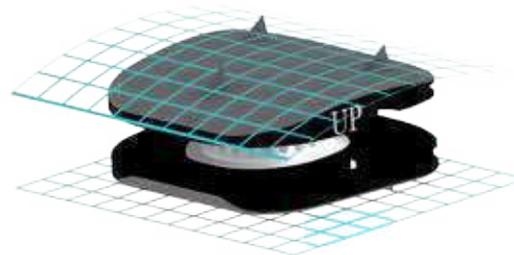
GUIDED MOBILE NUCLEUS

- 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

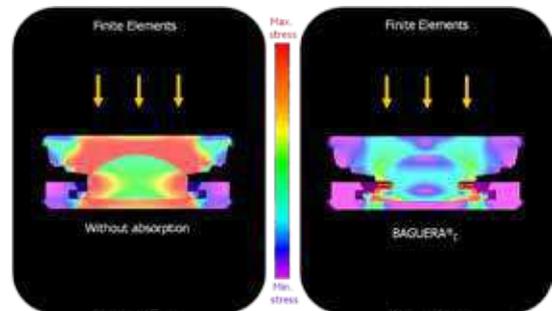
- The radiolucent holder allows for both verification of the anterior position of the device and confirmation of the fitting accuracy. Thanks to this holder, the device is delivered pre-assembled for better handling.



TECHNICAL FEATURES

SHOCK ABSORPTION

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



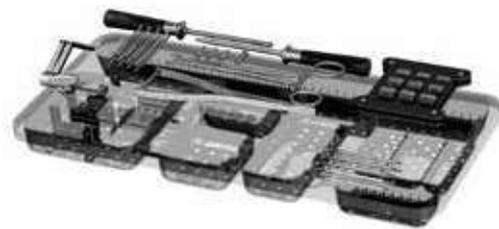
PRIMARY STABILITY

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



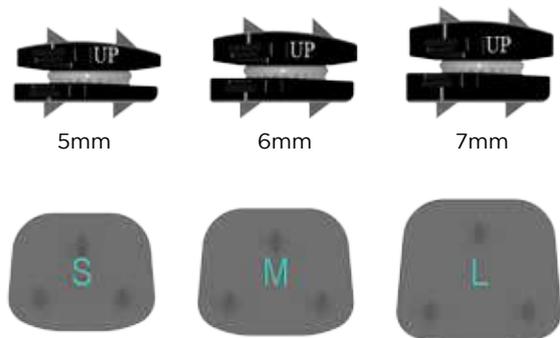
COMPACT SET

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

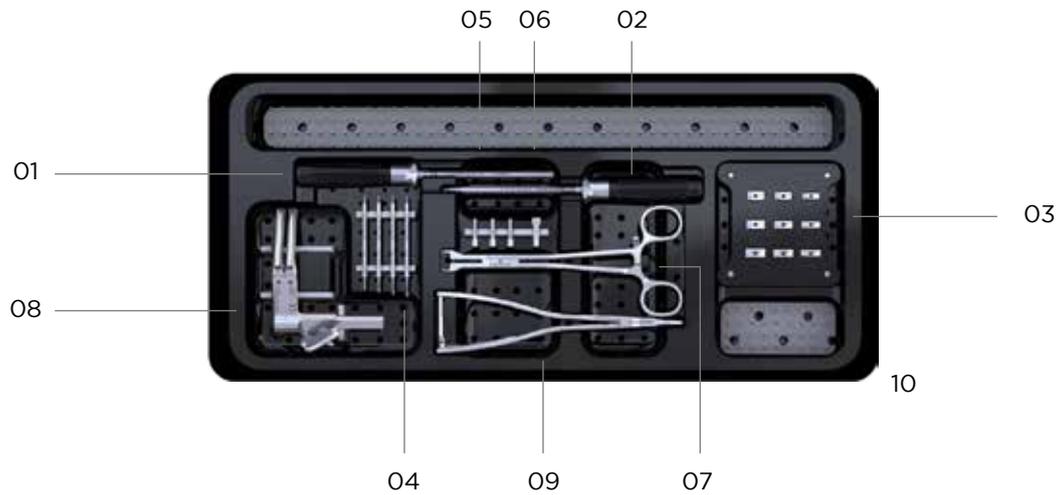


COMPLETE RANGE

- 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



INTERSOMATIC DISTRACTOR CDP-IN 00 04-N



ARTICULATED CERVICAL DISTRACTOR CDP-IN 50 00-N



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



IMPLANT HOLDER CDP-IN 00 01-N



NUT FOR PINS CDP-IN 30 02-N



EXTRACTOR CDP-IN 00 02-N



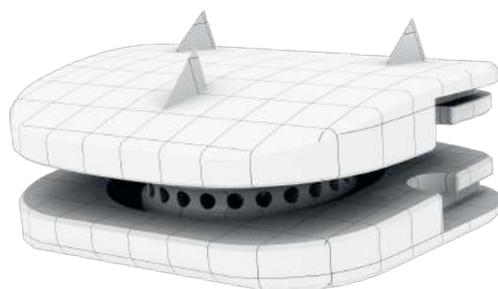
SCREWDRIVER FOR PINS CDP-IN 30 01-N



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.

Radiographic Outcome and Adjacent Segment Evaluation Two Years after Cervical Disc Replacement with the Bagera®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 Bagera®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 Bagera®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 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 Bagera®C cervical disc prostheses.

Material and Methods

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

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Received March 21, 2016; Accepted April 13, 2016; Published April 15, 2016

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

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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 prostheses 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 immediately 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 ($\pm 2^\circ$) 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

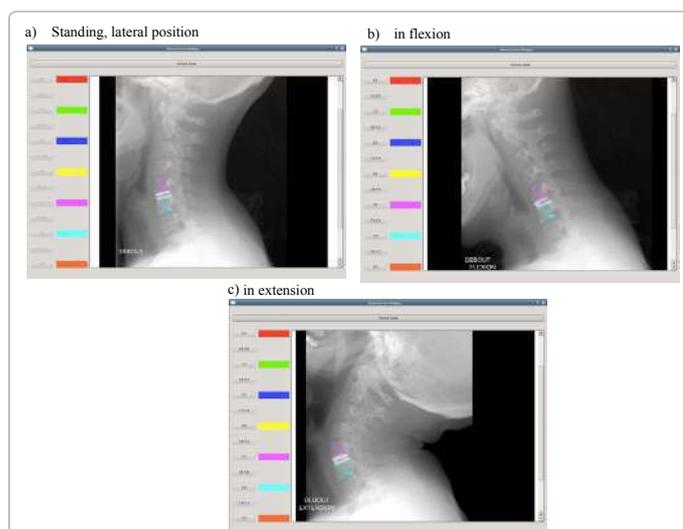


Figure 2: Radiographic images two years after surgery (annotated) Subjects who underwent 1 level (C5-C6) total disc replacement using Baguera®C.

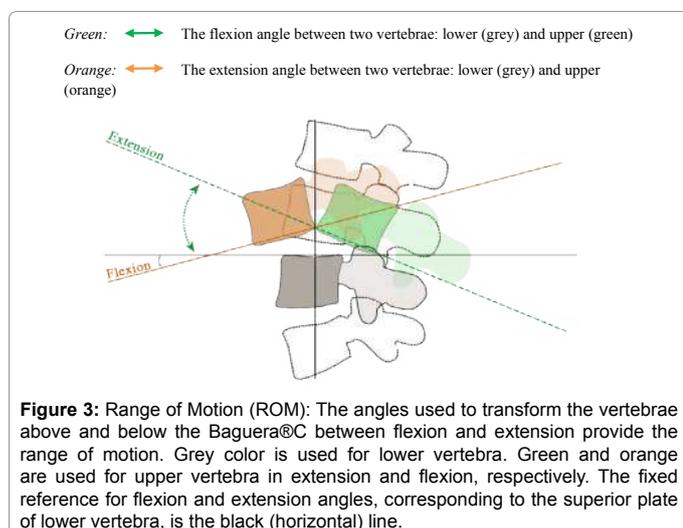


Figure 3: Range of Motion (ROM): The angles used to transform the vertebrae above and below the Baguera®C between flexion and extension provide the range of motion. Grey color is used for lower vertebra. Green and orange are used for upper vertebra in extension and flexion, respectively. The fixed reference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

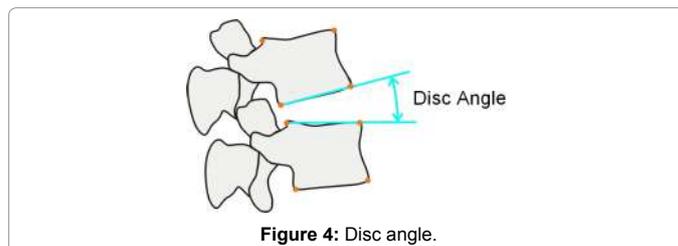


Figure 4: Disc angle.

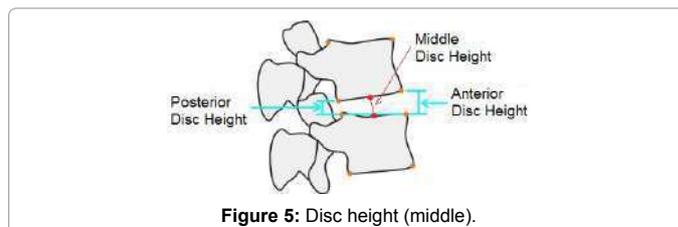


Figure 5: Disc height (middle).

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 summary 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° 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.

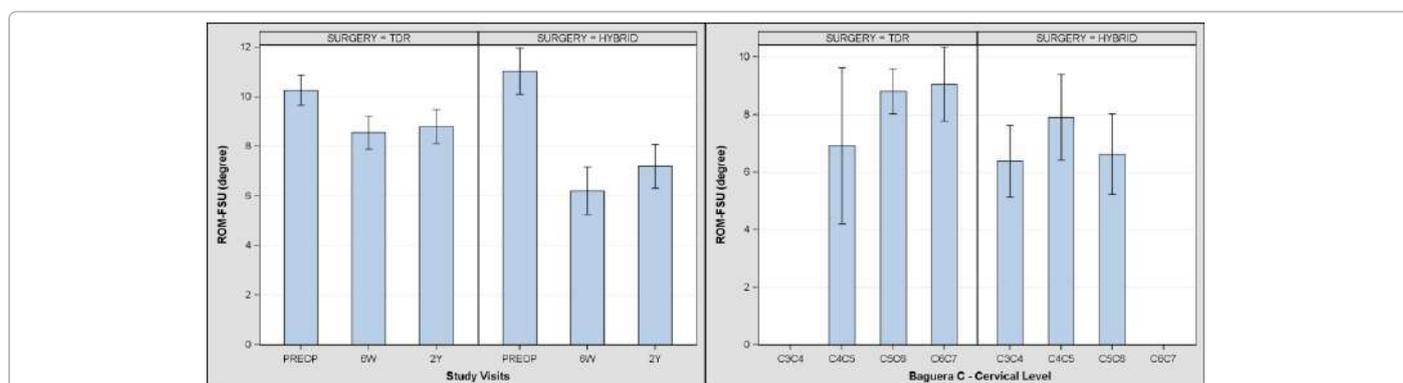


Figure 6: Range of Motion at the treated level (ROM-FSU). **Left:** Pre- and post-operative values for subjects treated by 1 level TDR using Baguera®C. Non-significant changes between pre-operative and post-operative data were observed. **Right:** Two years after surgery values, by treated level for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

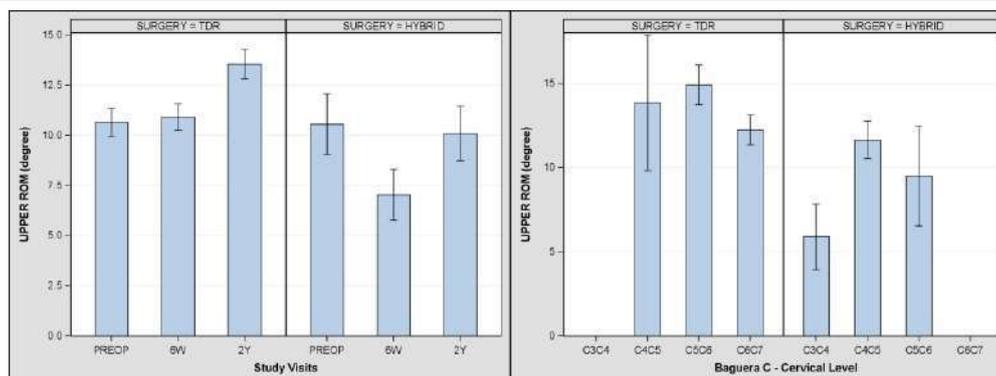


Figure 7: Range of Motion at the upper adjacent level (UPPER ROM). **Left:** Pre- and post-operative values for subjects treated by 1 level TDR using Baguera®C. Significant improvement ($p=0.01$) between pre-operative and 2 year's post-operative data. **Right:** Two years after surgery values, by treated 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 | 3 | 75.20 | . | 18.41 | 9.0 | 28.58 | 7.5 | - | - |
| | | 3 | 3 | 42.07 | 12.4 | 38.98 | 11.2 | 47.10 | 11.0 | 4.43 | ns |
| C2-C6 | TDR | 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 |
| | | 1 | 2 | 40.91 | 15.5 | 26.33 | 14.9 | 31.94 | 10.3 | -6.47 | ns |
| | HYBRID | 3 | 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.

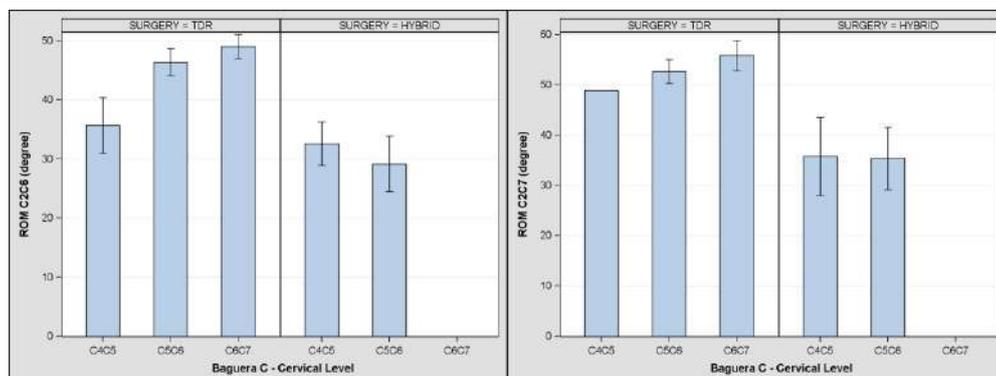


Figure 8: Overall cervical range of motion two years after surgery for subjects who underwent 1 level TDR using Baguera®C by treated level and type of surgery (TDR, HYBRID): ROM-C2C6 (left), ROM-C2C7 (right).

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.

References

1. Smith GW, Robinson RA (1958) The treatment of certain cervical-spine disorders by anterior removal of the intervertebral disc and interbody fusion. *J Bone Joint Surg Am* 40A: 607-624.

2. Cloward RB (1963) Lesions of the intervertebral disks and their treatment by interbody fusion methods. The painful disk. *Clin Orthop Relat Res* 27: 51-77.
3. Hillbrand AS, Carlson GD, Palumbo MA, Jones PK, Bohlman HH (1999) Radiculopathy and myelopathy at segments adjacent to the site of a previous anterior cervical arthrodesis. *J Bone Joint Surg Am* 81: 519-528.
4. Phillips FM, Lee JYB, Geisler FH, Cappuccino A, Chaput CD, et al. (2013) A prospective, randomized, controlled clinical investigation comparing PCM cervical disc arthroplasty with anterior cervical discectomy and fusion. *Spine* 38: E907–E918.
5. Sasso RC, Anderson PA, Riew KD, Heller JG (2011) Results of cervical arthroplasty compared with anterior discectomy and fusion: four-year clinical outcomes in a prospective, randomized controlled trial. *J Bone Joint Surg* 93: 1684–1692.
6. Mehren C, Suchomel P, Grochulla F, Barsa P, Sourkova P, et al. (2006) Heterotopic ossification in total cervical artificial disc replacement. *Spine (Phila Pa 1976)* 31: 2802-2806.
7. Wigfield C, Gill S, Nelson R, Langdon I, Metcalf N, et al. (2002) Influence of an artificial cervical joint compared with fusion on adjacent-level motion in the treatment of degenerative cervical disc disease. *J Neurosurg* 96: 17–21.
8. Bertagnoli R, Yue JJ, Pfeiffer F, Fenk-Mayer A, Lawrence JP, et al. (2005) Early results after ProDisc-C cervical disc replacement. *J Neurosurg Spine* 2: 403-410.
9. Sasso RC, Best NM (2007) Cervical kinematics after fusion and bryan disc arthroplasty. *J Spinal Disord* 21: 19-22.
10. Nabhan A, Ishak B, Steudel WI, Ramadhan S, Steimer O (2011). Assessment of adjacent-segment mobility after cervical disc replacement versus fusion: RCT with 1 year's results. *Eur Spine J* 20: 934-941.
11. Mummaneni PV, Burkus JK, Haid RW, Trainelis VC, Zdeblick TA (2007). Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled clinical trial. *J Neurosurg Spine* 6: 198-209.
12. Zechmeister I, Winkler R, Mad P (2011). Artificial total disc replacement versus fusion for the cervical spine: a systematic review. *Eur Spine J* 20: 177-184.
13. Vital JM, Guérin P, Gille O, Pointillart V (2011) Prothèses discales cervicales. *EMC*: 44-162.
14. Tu TH, Wu JC, Huang WC, Guo WY, Wu CL, et al. (2011) Heterotopic ossification after cervical total disc replacement: determination by CT and effects on clinical outcomes. *J Neurosurg Spine* 14: 457-465.
15. Ryu KS, Park CK, Jun SC, Huh HY (2010) Radiological changes of the operated and adjacent segments following cervical arthroplasty after a minimum 24-month follow-up: comparison between the Bryan and Prodisc-C devices. *J Neurosurg Spine* 13: 299-307.
16. Lee SE, Chung CK, Jahng TA (2012) Early development and progression of heterotopic ossification in cervical total disc replacement. *J Neurosurg Spine* 16: 31-36.
17. Suchomel P, Jurák L, Benes V, Brabec R, Bradác O, et al. (2010) Clinical results and development of heterotopic ossification in total cervical disc replacement during a 4-year follow-up. *Eur Spine J* 19: 307-315.

Citation: Fransen P, Hansen-Algenstaedt N, Chatzisitiriou 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](https://doi.org/10.4172/2165-7939.1000298)

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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

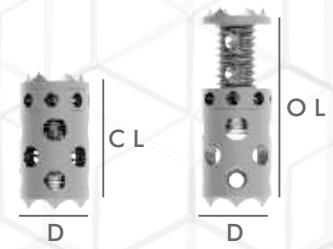
Corpectomy Cage



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

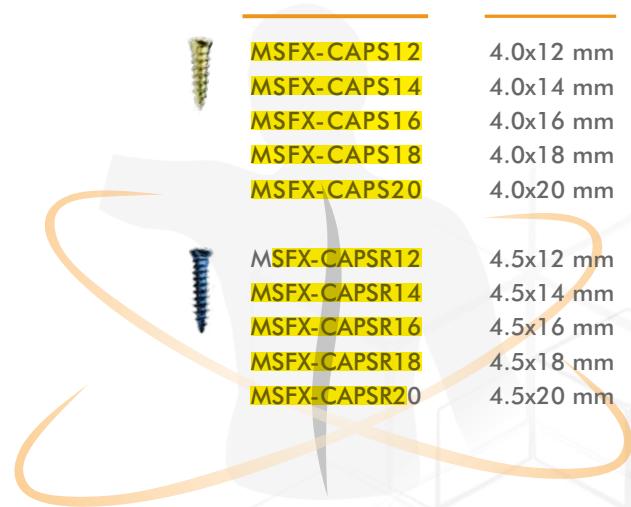


| Code | Size |
|-------------|------|
| MSFX-CAP17 | 17 |
| MSFX-CAP20 | 20 |
| MSFX-CAP23 | 23 |
| MSFX-CAP25 | 25 |
| MSFX-CAP27 | 27 |
| MSFX-CAP30 | 30 |
| MSFX-CAP33 | 33 |
| MSFX-CAP36 | 36 |
| MSFX-CAP40 | 40 |
| MSFX-CAP45 | 45 |
| MSFX-CAP50 | 50 |
| MSFX-CAP55 | 55 |
| MSFX-CAP60 | 60 |
| 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 |

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