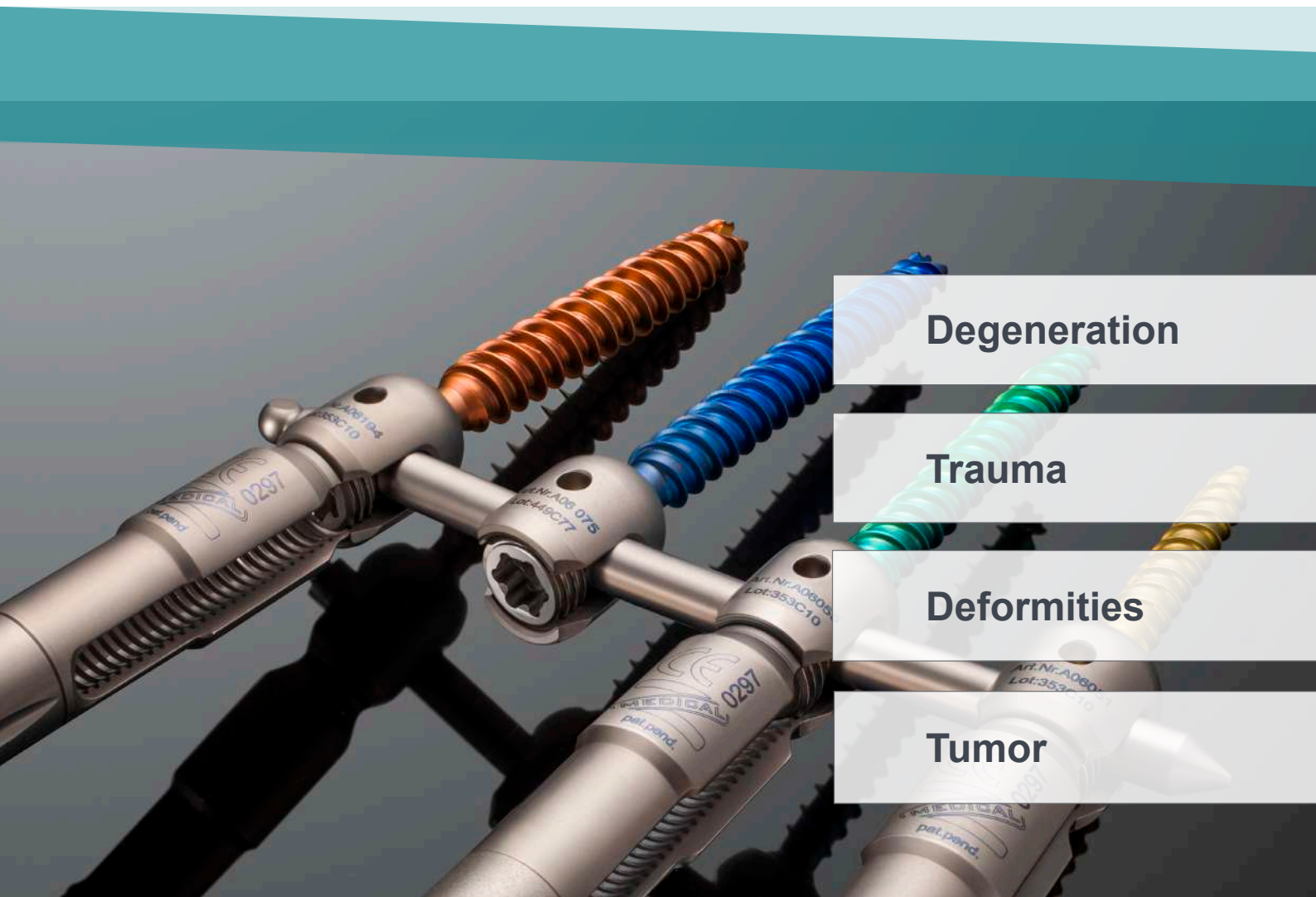


CATALOGUE

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

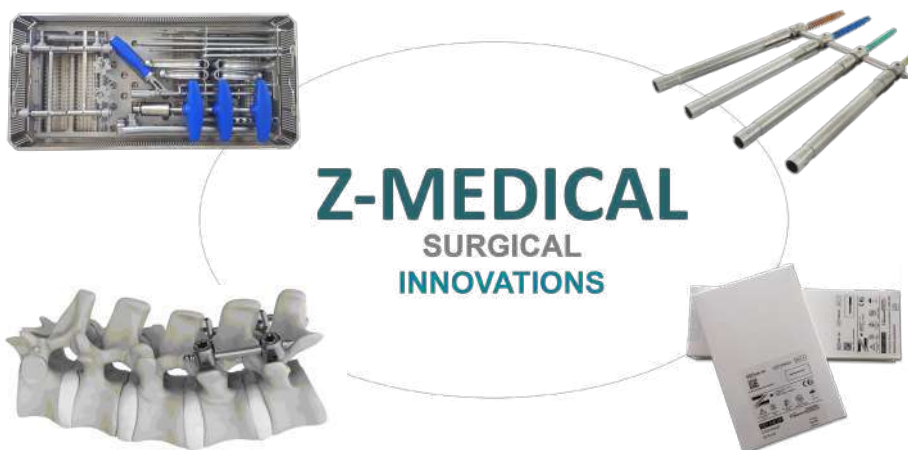
The MIS Z-Pedicle Screw System offers surgeons an ideal solution for their indication specific needs. The Z-Pedicle Screw System comprises sterile implants and only one instrument set.

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

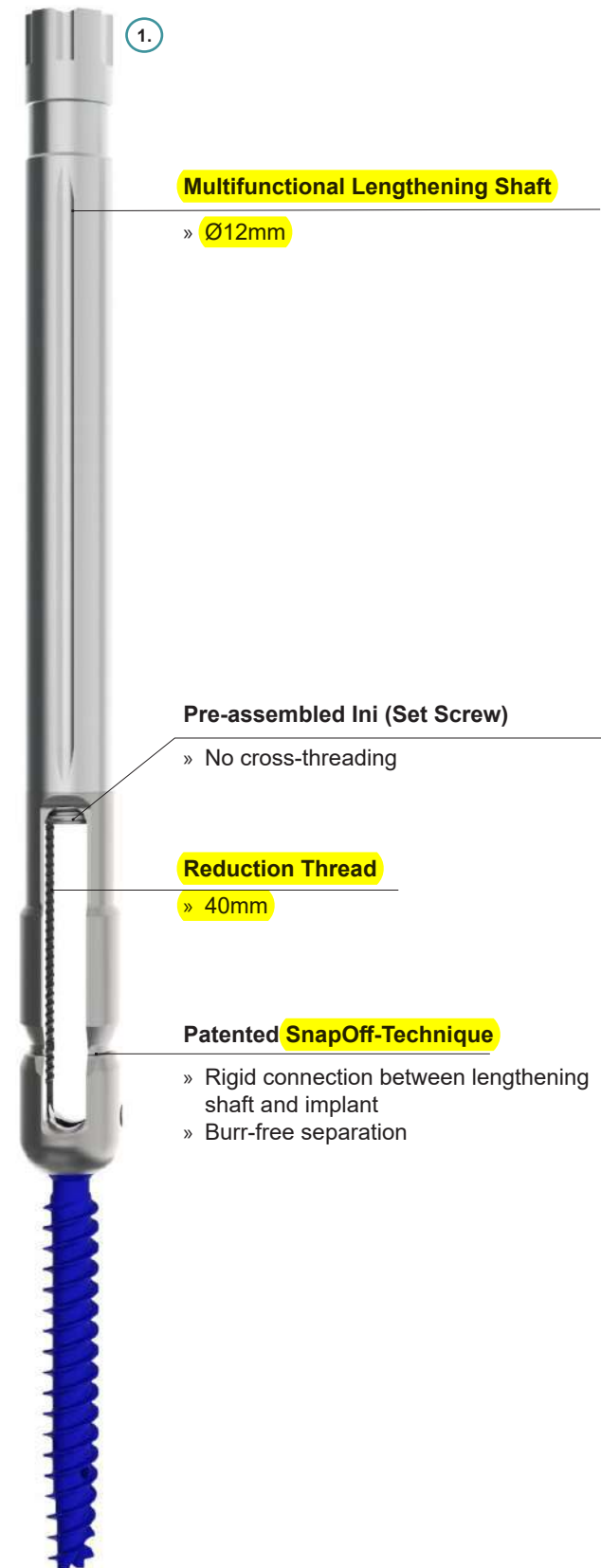
All implants are single sterile packaged and ready for surgery.

- » 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

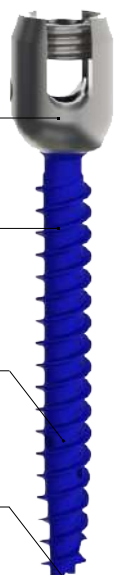
- » High stability
- » Fast insertion, 6mm per rotation

Cannulated and fenestrated

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

Thread features

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



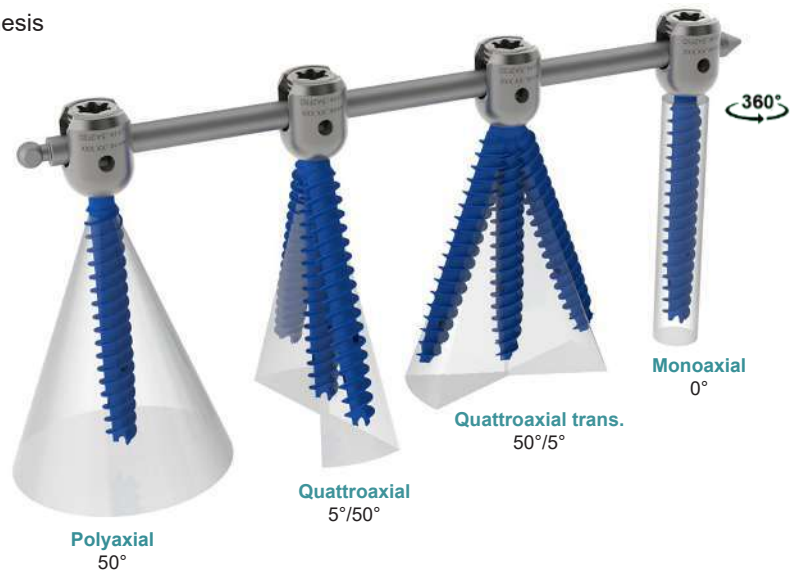
3.

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:

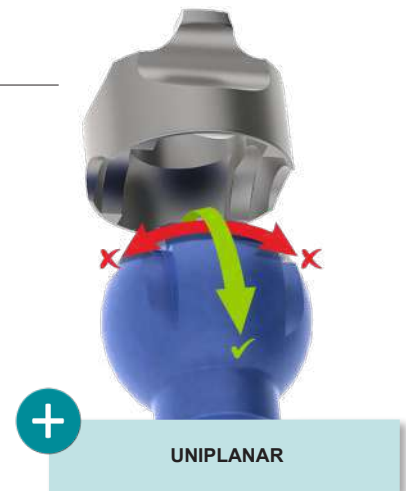
- » Medial-Lateral: moving freely
- » Cranio-Caudal: blocked

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

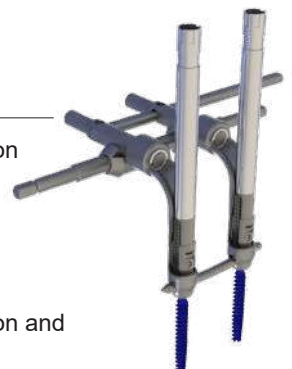
- » Easy alignment after surgical reduction of spondylolisthesis
- » Without additional instruments
- » Directly achieved with the pre-assembled Ini via the reduction thread



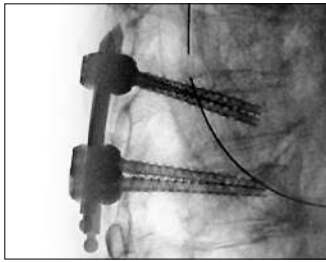
Distraction / Compression

The universal distraction and compression instrument enables:

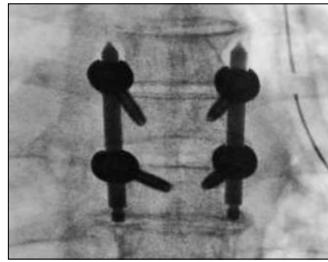
- » A direct and controlled correction of complex fractures
- » An open and percutaneous distraction and compression along the rod
- » Segmental distraction for discectomy and / or insertion of an interbody device
- » Same approach as MIS screw, application via the lengthening shaft



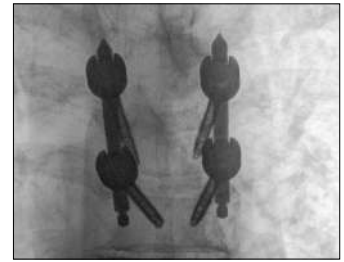
Treatment of Discoligamentous Laceration using the MIS Z-Pedicle Screw System!



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



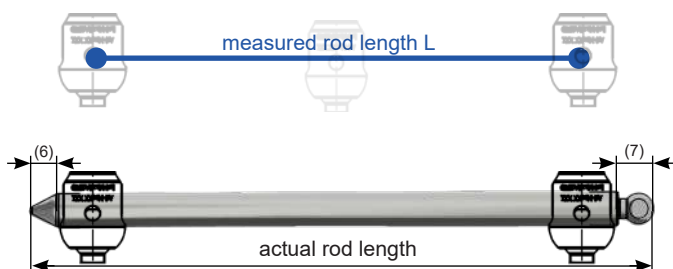
Instrument	Art.No.	Description	Q
	A06 081 S	Z-Guide Wire	2
Distributive products	Art.No.	Description	Q
	900140	First Access Needle	1
	900146	Bone Cement Filler Cannula for Screw Cementation	1
	800039	V-Steady Radiopaque Bone Cement	1

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

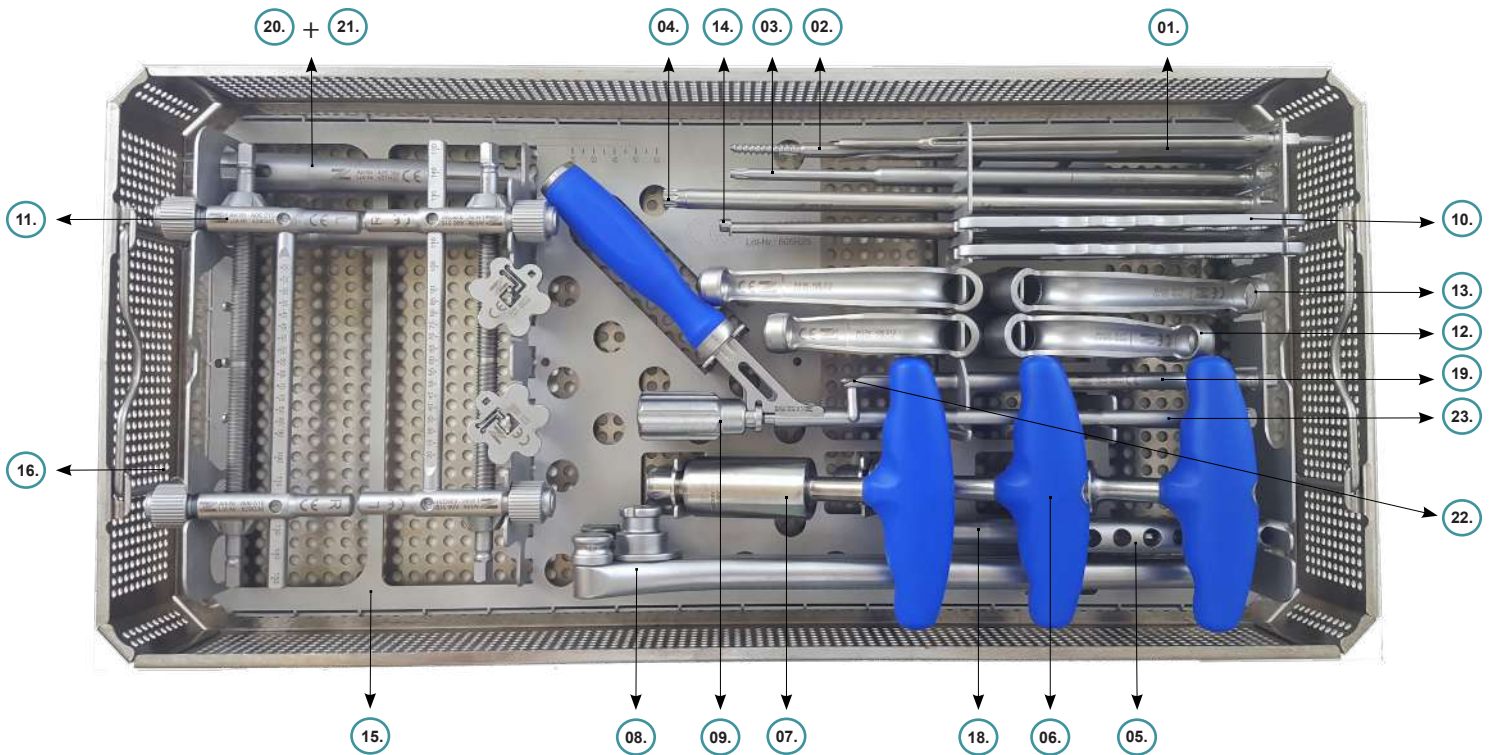
Z-Rods | Sterile, Ø5.5mm

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

Arc-shaped Cervical Interbody Fusion Cage				
Anterior Lumbar Interbody Fusion Cage				
Posterior Lumbar Interbody Fusion Cage (Expansion Type)				
Posterior Lumbar Interbody Fusion Cage		2100-2501	8x10x20mm	Ti6Al4V ELI
		2100-2502	8x10x22mm	Ti6Al4V ELI
		2100-2503	8x10x26mm	Ti6Al4V ELI
		2100-2504	10x10x20mm	Ti6Al4V ELI
		2100-2505	10x10x22mm	Ti6Al4V ELI
		2100-2506	10x10x26mm	Ti6Al4V ELI
		2100-2507	12x10x20mm	Ti6Al4V ELI
		2100-2508	12x10x22mm	Ti6Al4V ELI
		2100-2509	12x10x26mm	Ti6Al4V ELI
Titanium Mesh Cage (Prismatic Hole)		TT457-2601	10 x 40-100mm	Ti6Al4V ELI
		TT457-2602	12 x 40-100mm	Ti6Al4V ELI
		TT457-2603	14 x 40-100mm	Ti6Al4V ELI
		TT457-2604	16 x 40-100mm	Ti6Al4V ELI
		TT457-2605	18 x 40-100mm	Ti6Al4V ELI
		TT457-2606	20 x 40-100mm	Ti6Al4V ELI
		TT457-2607	24 x 40-100mm	Ti6Al4V ELI
		TT457-2608	28 x 40-100mm	Ti6Al4V ELI
		Hook System		
Laminar Hook				
Pedicle Hook				

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

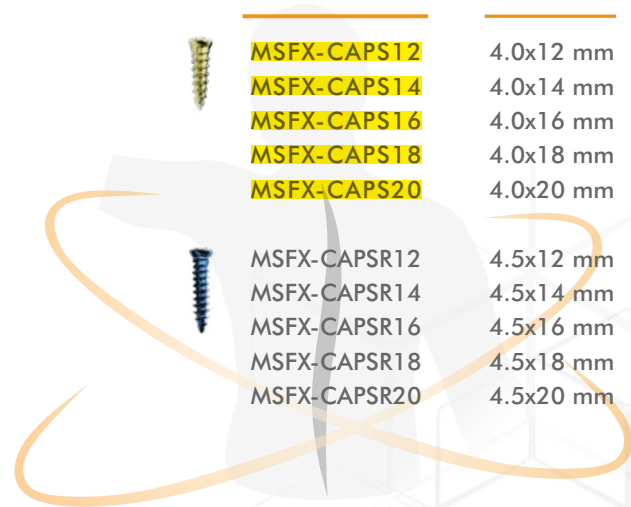


Code	Size
MSFX-CAP17	17
MSFX-CAP20	20
MSFX-CAP23	23
MSFX-CAP25	25
MSFX-CAP27	27
MSFX-CAP30	30
MSFX-CAP33	33
MSFX-CAP36	36
MSFX-CAP40	40
MSFX-CAP45	45
MSFX-CAP50	50
MSFX-CAP55	55
MSFX-CAP60	60
MSFX-CAP65	65
MSFX-CAP70	70
MSFX-CAP75	75
MSFX-CAP80	80
MSFX-CAP90	90
MSFX-CAP100	100



Width 20mm

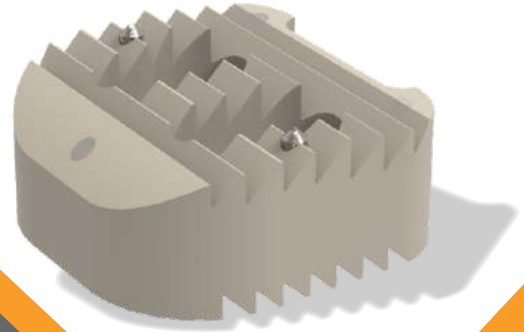
Cervical Plate Screws



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

AGENA

Cervical Cage



Features

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

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

