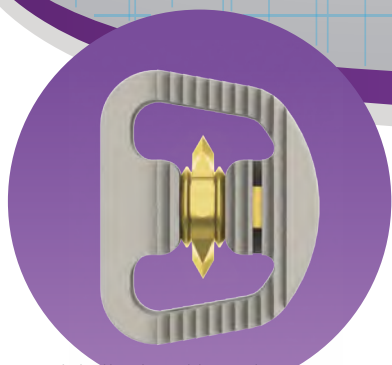
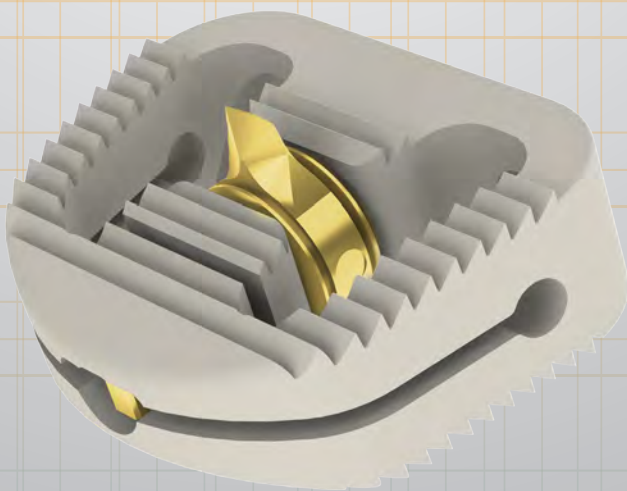


LorX[®]

NEW

expandable cervical peek cage with blade



LOT 2, 35

Digitally signed by Bolocan Roman
Date: 2022.03.15 17:02:06 EET
Reason: MoldSign Signature
Location: Moldova



...evolution of spine

design features

Better stability

Enhanced instrumentation for secure insertion



Anatomical shape

Original and anatomical design for a secure and better placement

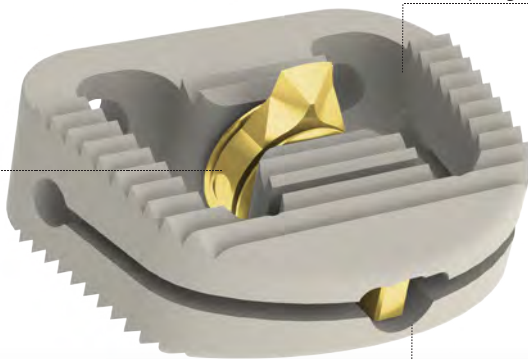


Biocompatibility

Radiolucent and biocompatible PEEK material (VESTAKEEP by Evonik, ASTM F2026) which provides modulus of elasticity similar to the bone

Enhanced bone fusion

Two adequate graft spaces for bone fusion



Special blade design

Specially designed (patent pending) titanium (ASTM F136) blade, positioned in the middle of the cage for perfect fixation
No need of extra fixation implants (plates etc.)

Improved mechanism

Improved mechanism for secure expanding and placement

Expandable Cervical PEEK Cage with Blade

Ref LX-03-525	:	12X15 mm	5 mm
Ref LX-03-526	:	12X15 mm	6 mm
Ref LX-03-527	:	12X15 mm	7 mm
Ref LX-03-528	:	12X15 mm	8 mm

LorX[®] TLIF Titanium Cage



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

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

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

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

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

**WE
SERVE LIFE**

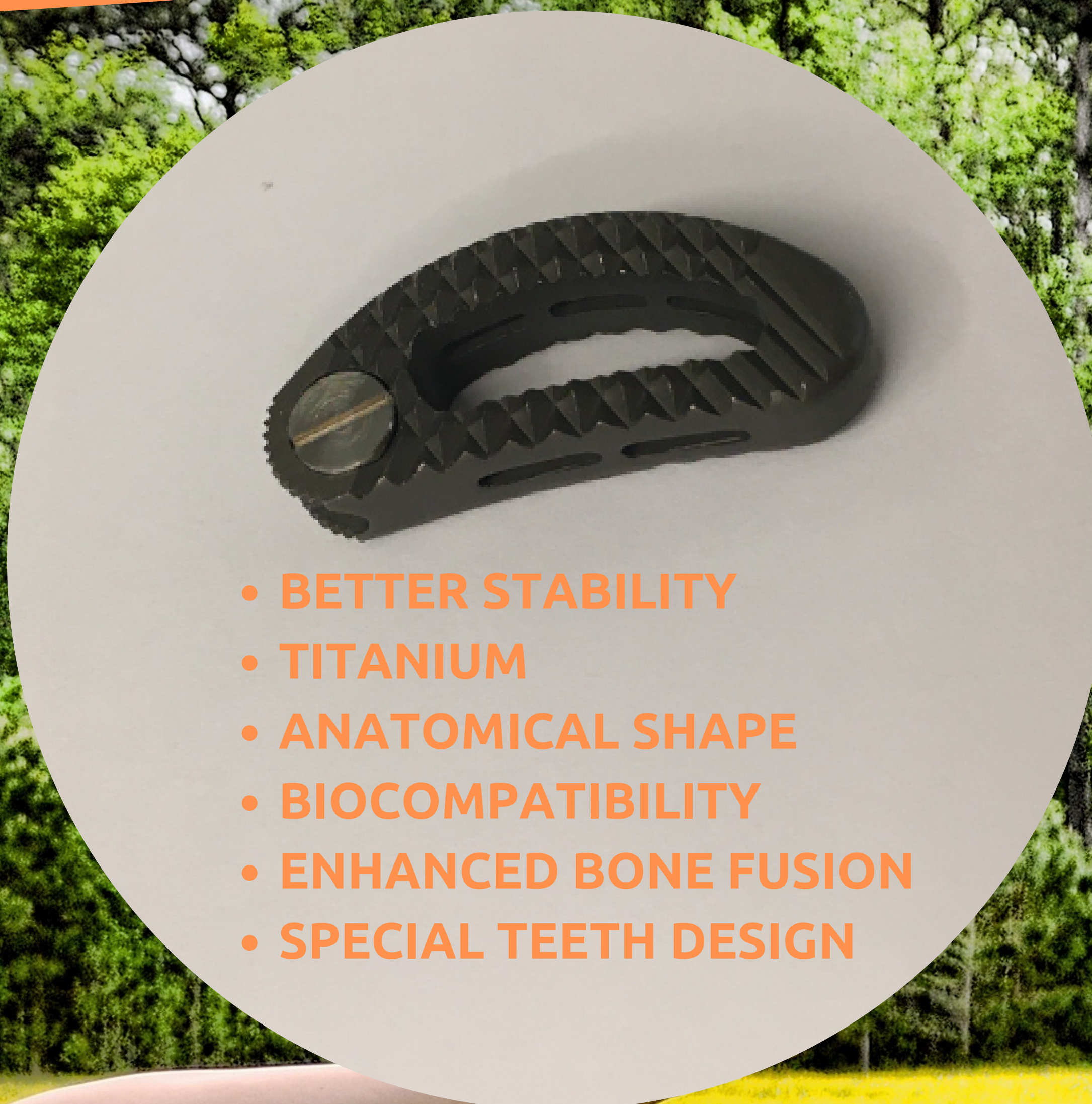
www.triaspine.com



Ostim O.S.B., 1208 Sokak No: 5/1, 06374
Yenimahalle - Ankara / TURKEY

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@ : info@triaspine.com

LorX[®] TLIF Titanium Cage

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

LorX[®] TLIF Titanium Cage Rotating 4° / 8°

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

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C O N C E P T A N D D E S I G N

Building on the success and experience acquired with our Posterior Lumbar Titanium range, Spineart developed a new Titanium secured lumbar anterior cage, featuring the Ti-LIFE Technology, a state-of-the-art porous, interconnected structure replicating the trabecular bone geometry.

With each product development, Spineart is relentlessly driven by the same philosophy: Quality, Innovation and Simplicity.

LOT 9



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°

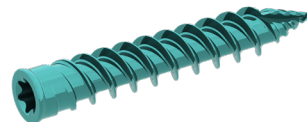
HEIGHT	REFERENCE
H12	SCA-LL 15 12-S
H14	SCA-LL 15 14-S
H16	SCA-LL 15 16-S

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

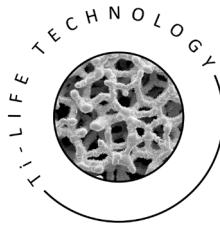


DIA 5.5 MM

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

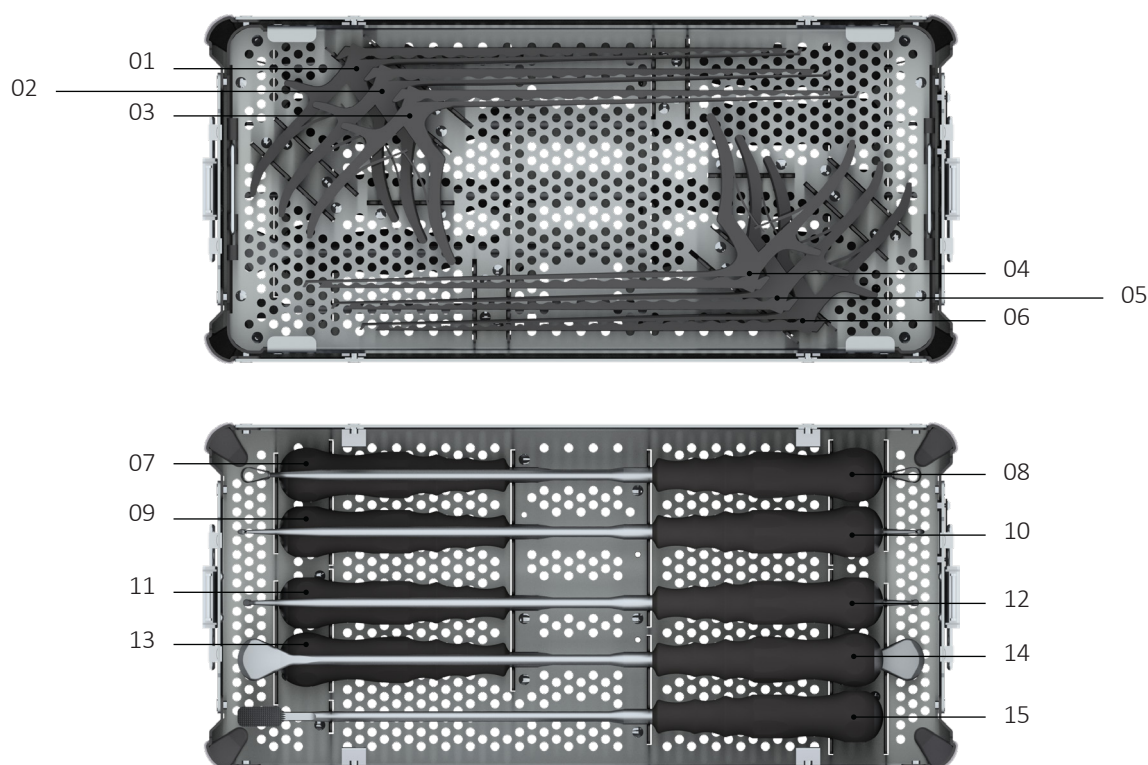
COMPREHENSIVE RANGE



10° and 15° lordosis
3 footprints

INSTRUMENT SETS

DISC PREPARATION 1

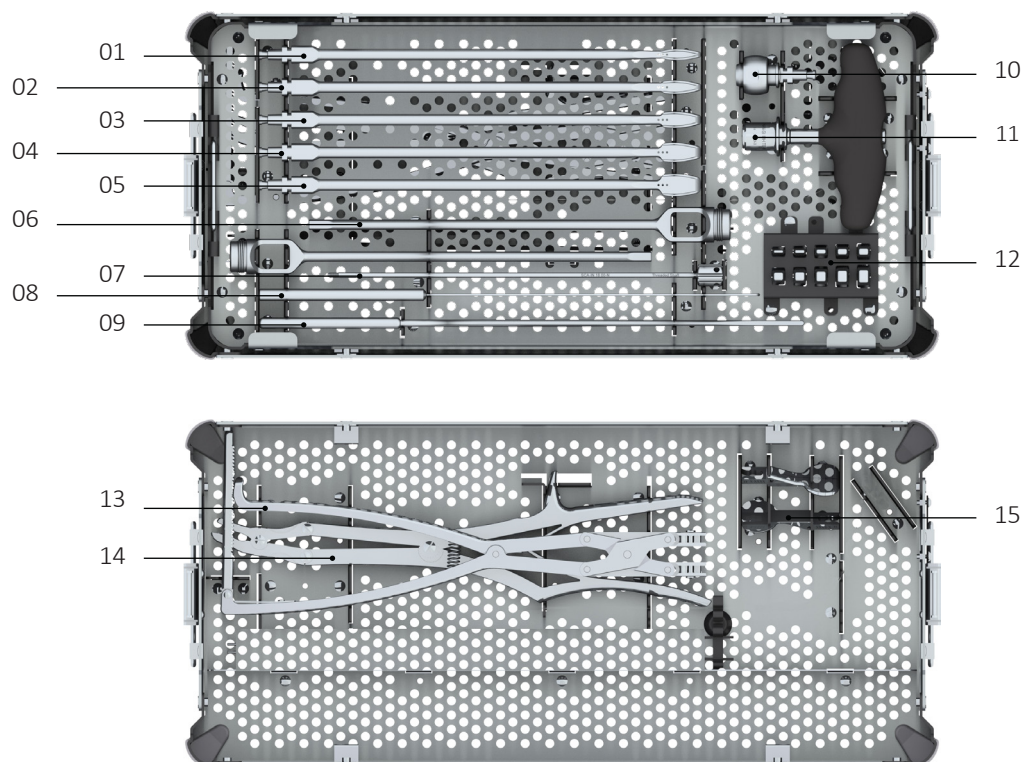


#	DESCRIPTION	REFERENCE
01	PITUITARY RONGEUR, STRAIGHT, 5MM	SCA-IN 21 00-N
02	PITUITARY RONGEUR, STRAIGHT, 3MM	SCA-IN 22 00-N
03	PITUITARY RONGEUR, 3MM, UP	SCA-IN 21 01-N
04	PITUITARY RONGEUR, 5MM, UP	SCA-IN 22 01-N
05	KERRISON RONGEUR, 5MM, 40DEG UP	JLL-IN 14 05-N
06	KERRISON RONGEUR, 3MM, 40DEG UP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

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

INSTRUMENT SETS

DISC PREPARATION 2

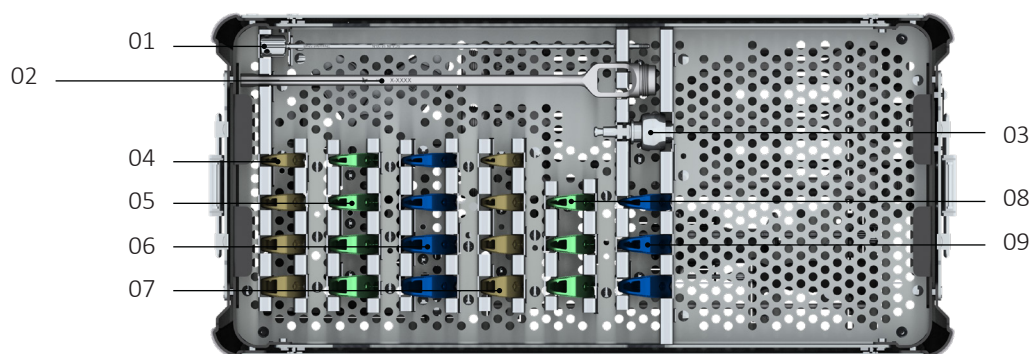


#	DESCRIPTION	REFERENCE
01	DISC SHAVER H08	SCA-IN 14 08-N
02	DISC SHAVER H10	SCA-IN 14 10-N
03	DISC SHAVER H12	SCA-IN 14 12-N
04	DISC SHAVER H14	SCA-IN 14 14-N
05	DISC SHAVER H16	SCA-IN 14 16-N
06	PADDLE DISTRACTOR HOLDER	SCA-IN 15 00-N
07	THREADED SHAFT	SCA-IN 18 00-N
08	BALL TIP PROBE	SCA-IN 20 00-N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

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

INSTRUMENT SETS

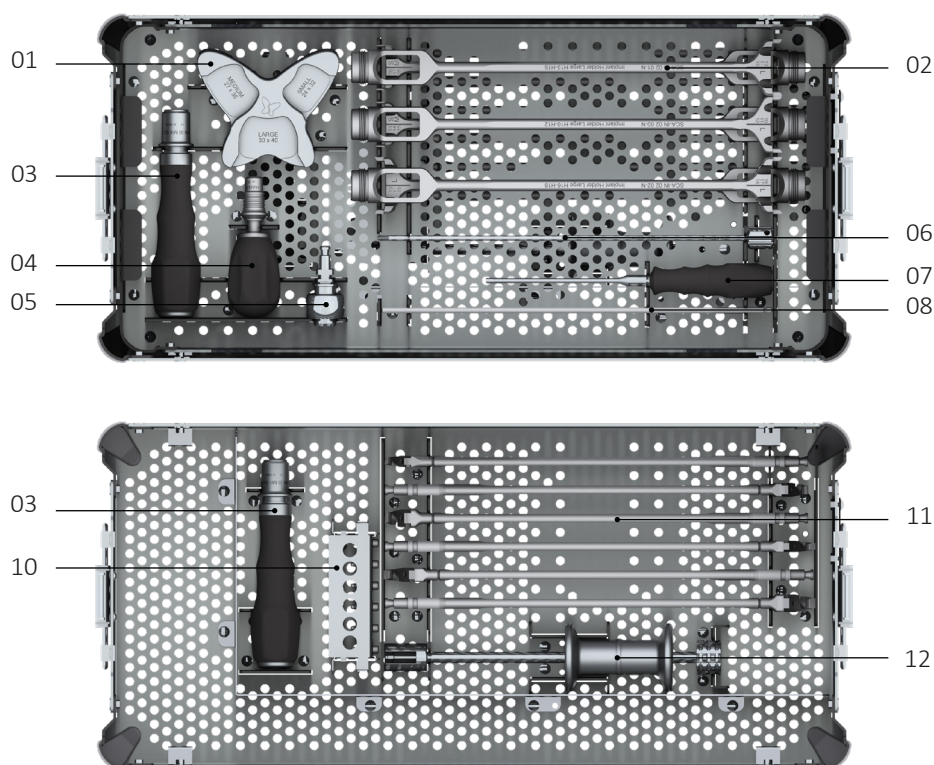
IMPLANT TRIALS AND CAGES INSERTION



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

INSTRUMENT SETS

IMPLANT TRIALS AND CAGES INSERTION

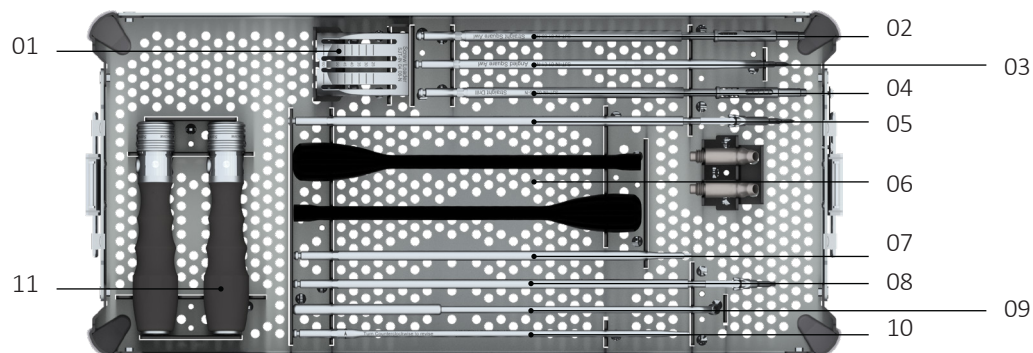


#	DESCRIPTION	REFERENCE
01	COMPACTION BASE	SCA-IN 07 00-N
02	IMPLANT HOLDERS:	
	SMALL/MEDIUM H10-H12	SCA-IN 01 01-N
	SMALL/MEDIUM H13-H15	SCA-IN 01 02-N
	SMALL/MEDIUM H16-H18	SCA-IN 01 03-N
	LARGE H10-H12	SCA-IN 02 00-N
	LARGE H13-H15	SCA-IN 02 01-N
	LARGE H16-H18	SCA-IN 02 02-N
03	STRAIGHT HANDLE (HUDSON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

INSTRUMENTS

DISC PREPARATION

STRAIGHT RING CURETTE, 15MM SCA-IN 09 02-N



CUP CURETTE, ANGLED, DOWN, SIZE «4» SCA-IN 24 01-N



ANGLED RING CURETTE, 15MM SCA-IN 09 03-N



FLAT COBB, 30 MM SCA-IN 10 02-N



CUP CURETTE, STRAIGHT, SIZE «2» SCA-IN 12 00-N



COBB, 25MM, 10° UP SCA-IN 10 01-N



CUP CURETTE, STRAIGHT, SIZE «4» SCA-IN 24 00-N



RASP, STRAIGHT, 14MM SCA-IN 08 00-N



CUP CURETTE, ANGLED, DOWN, SIZE «2» SCA-IN 12 01-N



PADDLE DISTRACTOR HOLDER SCA-IN 15 00-N



PADDLE DISTRACTORS H07 TO H16 SCA-IN 15 07-N TO SCA-IN 15 16-N



THREADED SHAFT SCA-IN 18 00-N



INSTRUMENTS

DISC PREPARATION

T-HANDLE (HUDSON CONNECTION)	HAN-SI MH TE-N
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PITUITARY RONGEUR, STRAIGHT, 5MM	SCA-IN 21 00-N
PITUITARY RONGEUR, STRAIGHT, 3MM	SCA-IN 22 00-N
PITUITARY RONGEUR, 3MM, UP	SCA-IN 21 01-N
PITUITARY RONGEUR, 5MM, UP	SCA-IN 22 01-N



BALL TIP PROBE	SCA-IN 20 00-N
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CUP CURETTE, STRAIGHT, SIZE «0» (OPTIONAL)	SCA-IN 11 00-N
CUP CURETTE, ANGLED, SIZE «0» (OPTIONAL)	SCA-IN 11 01-N



KERRISON RONGEUR, 3MM, 40DEG UP	SCA-IN 23 00-N
KERRISON RONGEUR, 5MM, 40DEG UP	JLL-IN 14 05-N



STRAIGHT AND ANGLED RING CURETTE, 11MM (OPTIONAL)	SCA-IN 09 00-N
	SCA-IN 09 01-N



LEKSELL DOUBLE-ACTION RONGEUR, 8MM	SCA-IN 13 00-N
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INSTRUMENTS

DISC PREPARATION

PARALLEL DISTRACTOR

ELL-IN 01 07-N



BLUNT DISSECTOR

JLL-IN 00 01-N



PARALLEL DISTRACTOR / ENDTIP

SCA-IN 01 00-N



HUDSON CONNECTOR

SCA-IN 17 00-N



DISC SHAVERS

SCA-IN 14 08-N TO
SCA-IN 14 16-N



INSTRUMENTS

IMPLANT TRIALS

TRIAL INSERTER	SCA-IN 05 00-N
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THREADED SHAFT	SCA-IN 18 00-N
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SLAP HAMMER	JLL-IN 12 00-N
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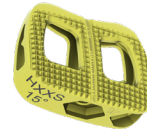


HUDSON CONNECTOR	SCA-IN 17 00-N
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TRIAL SMALL H10 TO H16 LORDOSIS 10°	SCA-TS 10 XX-N
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TRIAL SMALL H10 TO H16 LORDOSIS 15°	SCA-TS 15 XX-N
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TRIAL MEDIUM H10 TO H16 LORDOSIS 10°	SCA-TM 10 XX-N
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TRIAL MEDIUM H12 TO H16 LORDOSIS 15°	SCA-TM 15 XX-N
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TRIAL LARGE H10 TO H16 LORDOSIS 10°	SCA-TL 10 XX-N
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TRIAL LARGE H12 TO H16 LORDOSIS 15°	SCA-TL 15 XX-N
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INSTRUMENTS

CAGES INSTRUMENTS

IMPLANT HOLDER SMALL/MEDIUM H10-H12	SCA-IN 01 01-N
IMPLANT HOLDER SMALL/MEDIUM H13-H15	SCA-IN 01 02-N
IMPLANT HOLDER SMALL/MEDIUM H16-H18	SCA-IN 01 03-N
IMPLANT HOLDER LARGE H10-H12	SCA-IN 02 00-N
IMPLANT HOLDER LARGE H13-H15	SCA-IN 02 01-N
IMPLANT HOLDER LARGE H16-H18	SCA-IN 02 02-N



LATERAL IMPLANT HOLDER SCREW M4X0.7	SCA-IN 16 00-N
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COMPACTION BASE	SCA-IN 07 00-N
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STRAIGHT HANDLE (HUDSON CONNECTION)	HAN-SI MH SM-N
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LATERAL IMPLANT HOLDER SMALL/MEDIUM H10-H12	SCA-IN 03 00-N
LATERAL IMPLANT HOLDER SMALL/MEDIUM H13-H15	SCA-IN 03 01-N
LATERAL IMPLANT HOLDER SMALL/MEDIUM H16-H18	SCA-IN 03 02-N
LATERAL IMPLANT HOLDER LARGE H10-H12	SCA-IN 04 00-N
LATERAL IMPLANT HOLDER LARGE H13-H15	SCA-IN 04 01-N
LATERAL IMPLANT HOLDER LARGE H16-H18	SCA-IN 04 02-N



COMPACTOR	SCA-IN 19 00-N
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CAMLOCKER DRIVER	SCA-IN 06 00-N
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TORQUE LIMITING HANDLE (1NM) (PALM HANDLE)	HAN-SI AO PA-N
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INSTRUMENTS

SCREW INSERTION

STRAIGHT SQUARE AWL

SJT-IN 01 00-N



ANGLED SQUARE AWL

SJT-IN 01 01-N



STRAIGHT DRILL

SJT-IN 02 00-N



U-JOINT DRILL

SJT-IN 02 01-N



STRAIGHT SCREWDRIVER

SJT-IN 03 00-N



U-JOINT SCREWDRIVER

SJT-IN 03 01-N



REVISION SCREWDRIVER

SJT-IN 03 02-N



U-JOINT GUIDE

SJT-IN 05 00-N



SCREW LOADER

SJT-IN 04 00-N



UNIVERSAL-JOINT TUBE AND
UNIVERSAL JOINT ANGLED PART

SJT-IN 06 00-N



STRAIGHT HANDLE RATCHET

HAN-SI RA ST-N



INSTRUMENT ASSEMBLY



TRIALS AND CAGES INSERTION
HUDSON CONNECTION HANDLES



SCREWS INSERTION
RATCHET HANDLE



TORQUE LIMITING
HANDLE



HUDSON CONNECTION HANDLE ATTACHMENT

Align parallel flat surfaces of the instrument shaft with corresponding handle recess. Pull the adaptor barrel while inserting the shaft. Release the adaptor barrel.

INSTRUMENT	REFERENCE
STRAIGHT HANDLE (HUDSON CONNECTION)	HAN-SI MH SM-N
T-HANDLE (HUDSON CONNECTION)	HAN-SI MH TE-N



TRIAL INSERTER & IMPLANT HOLDER ASSEMBLY

Insert the threaded shaft into the implant holder or trial inserter. Align the Hudson connector onto the implant holder or trial inserter and turn clockwise to secure the assembly.

INSTRUMENT	REFERENCE
THREADED SHAFT	SCA-IN 18 00-N
HUDSON CONNECTOR	SCA-IN 17 00-N
TRIAL INSERTER	SCA-IN 05 00-N
IMPLANT HOLDER SMALL/MEDIUM	SCA-IN 01 XX-N
IMPLANT HOLDER LARGE	SCA-IN 02 XX-N
PADDLE DISTRACTOR HOLDER	SCA-IN 15 00-N

INSTRUMENT ASSEMBLY



SLAP HAMMER ATTACHMENT

The Slap Hammer can be used if additional force is needed for instrument removal. Attach instruments per respective connection end:

Hudson Connection

Align and insert the proximal end of the instrument shaft into the Slap Hammer slot. Rotate the slap hammer shaft clockwise 90°.

INSTRUMENT	REFERENCE
SLAP HAMMER	JLL-IN 12 00-N



ASSEMBLY OF THE U-JOINT INSTRUMENTS

1. Connect the U-Joint instrument with the universal U joint angled part
2. Thread the U-Joint Tube onto the universal U joint angled part using a counter clockwise rotation

S U R G I C A L T E C H N I Q U E

_STEP 1



PATIENT POSITIONING AND EXPOSURE

For an anterior approach of the lower lumbar levels, place the patient supine in a slight Trendelenburg position, per surgeon preference.

Locate the operative disc level and incision location via lateral fluoroscopy.

Determine surgical approach (anterior or anterolateral) based on the surgeon preference.

Through a standard retroperitoneal approach, dissect and retract the soft tissue to reach the operative disc level.

Cut an appropriately sized window through the anterior longitudinal ligament and the annulus fibrosus, to access the target disc space.

SURGICAL TECHNIQUE

_STEP 2



DISCECTOMY AND DISTRACTION

Begin discectomy and endplate preparation with a curette.

Use a Cobb elevator to clearly define the endplates.

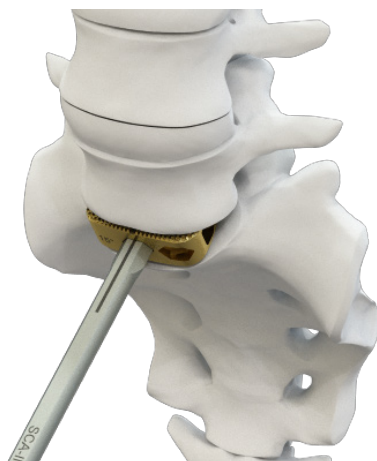
Distract the discectomy site, using the parallel distractor and/or paddle distractors.

Complete endplate preparation with the rasp and disc shavers. Care must be taken to ensure excessive bone is not removed, which may weaken the endplate.

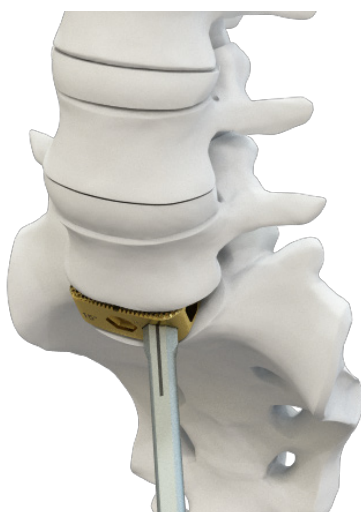
INSTRUMENT	REFERENCE
STRAIGHT RING CURETTE, 15MM	SCA-IN 09 02-N
ANGLED RING CURETTE, 15MM	SCA-IN 09 03-N
CUP CURETTE, STRAIGHT, SIZE «2»	SCA-IN 12 00-N
CUP CURETTE, STRAIGHT, SIZE «4»	SCA-IN 24 00-N
CUP CURETTE, ANGLED, DOWN, SIZE «2»	SCA-IN 12 01-N
CUP CURETTE, ANGLED, DOWN, SIZE «4»	SCA-IN 24 01-N
FLAT COBB, 30MM	SCA-IN 10 02-N
COBB, 25MM, 10° UP	SCA-IN 10 01-N
PARALLEL DISTRACTOR	ELL-IN 01 07-N
PARALLEL DISTRACTOR / ENDTIP	SCA-IN 01 00-N
PADDLE DISTRACTOR HOLDER	SCA-IN 15 00-N
PADDLE DISTRACTORS H07 TO H16	SCA-IN 15 07-N TO SCA-IN 15 16-N
RASP, STRAIGHT, 14MM	SCA-IN 08 00-N
DISC SHAVERS	SCA-IN 14 08-N TO SCA-IN 14 16-N
BLUNT DISSECTOR	JLL-IN 00 01-N
T-HANDLE (HUDSON CONNECTION)	HAN-SI MH TE-N
BALL TIP PROBE	SCA-IN 20 00-N
PITUITARY RONGEUR, STRAIGHT, 5MM	SCA-IN 21 00-N
PITUITARY RONGEUR, STRAIGHT, 3MM	SCA-IN 22 00-N
PITUITARY RONGEUR, 3MM, UP	SCA-IN 21 01-N
PITUITARY RONGEUR, 5MM, UP	SCA-IN 22 01-N
KERRISON RONGEUR, 3MM, 40DEG UP	SCA-IN 23 00-N
KERRISON RONGEUR, 5MM, 40DEG UP	JLL-IN 14 05-N
LEKSELL DOUBLE-ACTION RONGEUR, 8MM	SCA-IN 13 00-N
HUDSON CONNECTOR	SCA-IN 17 00-N
THREADED SHAFT	SCA-IN 18 00-N

SURGICAL TECHNIQUE

_STEP 3



ANTERIOR APPROACH



ANTEROLATERAL APPROACH

SELECTION OF THE IMPLANT SIZE

Straight Anterior Approach:

Thread the trial implant onto the trial inserter using the midline hole of the trial implant.

Anterolateral Approach:

Thread the trial implant onto the trial inserter using the appropriate lateral hole of the trial implant.

Insert the trial implant into the intervertebral space to determine the cage height, footprint and angulation.

If the chosen trial implant is too small, use incrementally larger trials until a tight fit is achieved.

A mallet may be used to gently insert the trial. Verify correct size with AP and Lateral imaging.

Implant size selection is dependent on the intervertebral space, patient anatomy and technical preparation.

With appropriate size verified, open the corresponding cage footprint and height and thread it onto the implant holder.

INSTRUMENT	REFERENCE
TRIAL INSERTER	SCA-IN 05 00-N
THREADED SHAFT	SCA-IN 18 00-N
HUDSON CONNECTOR	SCA-IN 17 00-N
STRAIGHT HANDLE (HUDSON CONNECTION)	HAN-SI MH SM-N
TRIAL SMALL H10 TO H16 LORDOSIS 10°	SCA-TS 10 10-N TO SCA-TS 10 18-N
TRIAL SMALL H10 TO H16 LORDOSIS 15°	SCA-TS 15 10-N TO SCA-TS 15 18-N
TRIAL MEDIUM H10 TO H16 LORDOSIS 10°	SCA-TM 10 10-N TO SCA-TM 10 18-N
TRIAL MEDIUM H12 TO H16 LORDOSIS 15°	SCA-TM 15 12-N TO SCA-TM 15 18-N
TRIAL LARGE H10 TO H16 LORDOSIS 10°	SCA-TL 10 10-N TO SCA-TL 10 18-N
TRIAL LARGE H12 TO H16 LORDOSIS 15°	SCA-TL 15 12-N TO SCA-TL 15 18-N
SLAP HAMMER	JLL-IN 12 00-N

SURGICAL TECHNIQUE

_STEP 4



CAGE PREPARATION

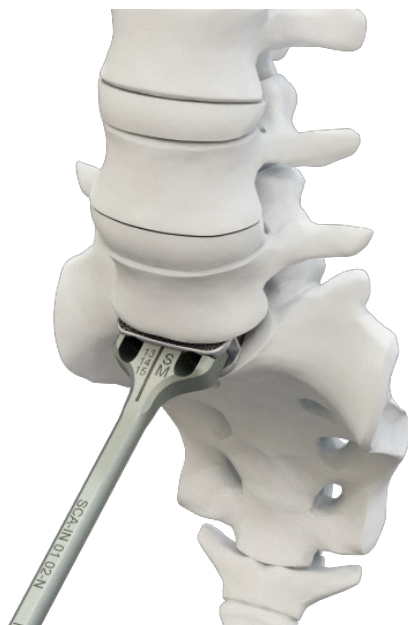
Please refer to the instrument assembly section of this guide to determine proper instrument selection and assembly instructions based on preferred approach technique of the surgeon.

Place the cage onto the compaction base and fill it with bone graft.

INSTRUMENT	REFERENCE
IMPLANT HOLDER SMALL/MEDIUM H10-H12	SCA-IN 01 01-N
IMPLANT HOLDER SMALL/MEDIUM H13-H15	SCA-IN 01 02-N
IMPLANT HOLDER SMALL/MEDIUM H16-H18	SCA-IN 01 03-N
IMPLANT HOLDER LARGE H10-H12	SCA-IN 02 00-N
IMPLANT HOLDER LARGE H13-H15	SCA-IN 02 01-N
IMPLANT HOLDER LARGE H16-H18	SCA-IN 02 02-N
LATERAL IMPLANT HOLDER SMALL/MEDIUM H10-H12	SCA-IN 03 00-N
LATERAL IMPLANT HOLDER SMALL/MEDIUM H13-H15	SCA-IN 03 01-N
LATERAL IMPLANT HOLDER SMALL/MEDIUM H16-H18	SCA-IN 03 02-N
LATERAL IMPLANT HOLDER LARGE H10-H12	SCA-IN 04 00-N
LATERAL IMPLANT HOLDER LARGE H13-H15	SCA-IN 04 01-N
LATERAL IMPLANT HOLDER LARGE H16-H18	SCA-IN 04 02-N
U-JOINT SCREWDRIVER	SJT-IN 03 01-N
STRAIGHT SCREWDRIVER	SJT-IN 03 00-N
THREADED SHAFT	SCA-IN 18 00-N
LATERAL IMPLANT HOLDER SCREW M4X0.7	SCA-IN 16 00-N
COMPACTION BASE	SCA-IN 07 00-N
COMPACTOR	SCA-IN 19 00-N
HUDSON CONNECTOR	SCA-IN 17 00-N
STRAIGHT HANDLE (HUDSON CONNECTION)	HAN-SI MH SM-N

SURGICAL TECHNIQUE

_STEP 5



INSERTION OF THE FINAL IMPLANT

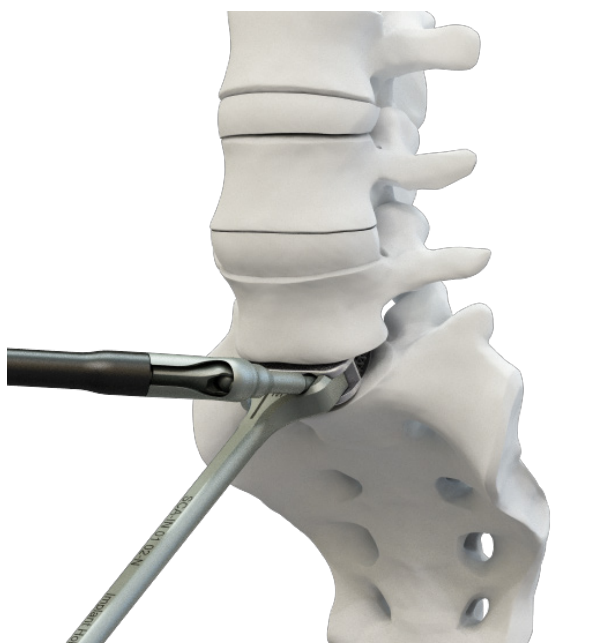
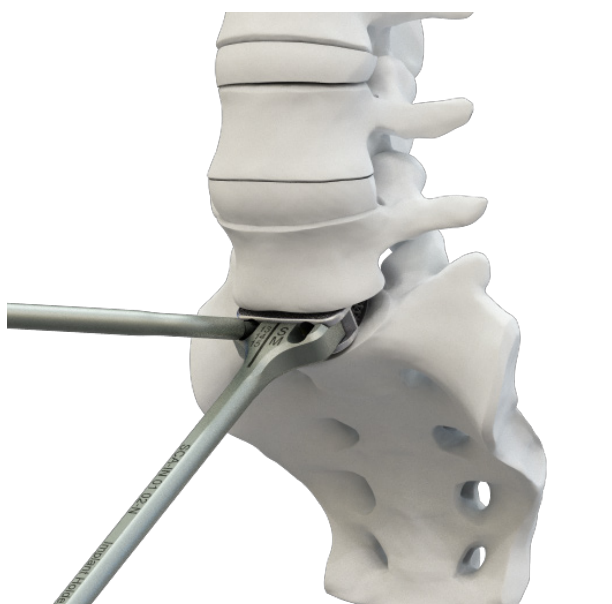
Insert the cage into the intervertebral space, according to preferred approach technique of the surgeon.

A mallet may be used to gently insert the final implant.

INSTRUMENT	REFERENCE
IMPLANT HOLDER SMALL/MEDIUM H10-H12	SCA-IN 01 01-N
IMPLANT HOLDER SMALL/MEDIUM H13-H15	SCA-IN 01 02-N
IMPLANT HOLDER SMALL/MEDIUM H16-H18	SCA-IN 01 03-N
IMPLANT HOLDER LARGE H10-H12	SCA-IN 02 00-N
IMPLANT HOLDER LARGE H13-H15	SCA-IN 02 01-N
IMPLANT HOLDER LARGE H16-H18	SCA-IN 02 02-N
LATERAL IMPLANT HOLDER SMALL/MEDIUM H10-H12	SCA-IN 03 00-N
LATERAL IMPLANT HOLDER SMALL/MEDIUM H13-H15	SCA-IN 03 01-N
LATERAL IMPLANT HOLDER SMALL/MEDIUM H16-H18	SCA-IN 03 02-N
LATERAL IMPLANT HOLDER LARGE H10-H12	SCA-IN 04 00-N
LATERAL IMPLANT HOLDER LARGE H13-H15	SCA-IN 04 01-N
LATERAL IMPLANT HOLDER LARGE H16-H18	SCA-IN 04 02-N
U-JOINT SCREWDRIVER	SJT-IN 03 01-N
STRAIGHT SCREWDRIVER	SJT-IN 03 00-N
THREADED SHAFT	SCA-IN 18 00-N
STRAIGHT HANDLE (HUDSON CONNECTION)	HAN-SI MH SM-N
HUDSON CONNECTOR	SCA-IN 17 00-N
LATERAL IMPLANT HOLDER SCREW M4X0.7	SCA-IN 16 00-N

SURGICAL TECHNIQUE

_STEP 6



PREPARATION OF LATERAL SCREW HOLES

The SCARLET® AL-T system offers four instruments for screw hole preparation:

- Straight square awl
- Angled square awl
- Straight drill
- U-Joint drill

NOTE: Straight and angled hole preparation instruments can be used interchangeably according to surgeon preference.

Begin hole preparation with the two lateral screw holes.

Insert preferred instrument into the guide hole of the implant holder to prepare each lateral screw hole.

The U-joint guide may also be used during screw hole preparation to provide correct trajectory.

NOTE: The screw hole preparation instruments have a tip length of 25mm, which represents the shortest length screw available. Lateral imaging during hole creation may assist with determining the appropriate screw length.

INSTRUMENT	REFERENCE
STRAIGHT SQUARE AWL	SJT-IN 01 00-N
ANGLED SQUARE AWL	SJT-IN 01 01-N
STRAIGHT DRILL	SJT-IN 02 00-N
U-JOINT DRILL	SJT-IN 02 01-N
UNIVERSAL-JOINT TUBE AND UNIVERSAL JOINT ANGLED PART	SJT-IN 06 00-N
U-JOINT GUIDE	SJT-IN 05 00-N

SURGICAL TECHNIQUE

_STEP 7



Laser mark should be visible

IMPLANTATION OF THE LATERAL SCREWS

Load the screw into the screw loader. It will facilitate a secure connection between the screw and the screwdriver. It also provides a verification of screw length.

While keeping the implant holder in place, insert the first lateral screw using the straight or U-joint screwdriver.

AP and Lateral images may be used to verify screw position.

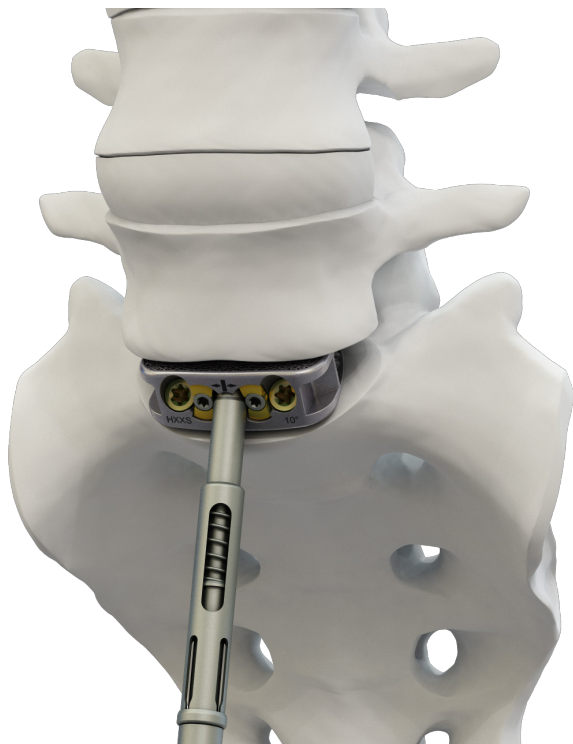
Repeat this step to insert the second lateral screw.

For visual confirmation of correct screw depth, a laser mark is positioned within the screw holes. The head of the screw should be inserted beyond this landmark.

INSTRUMENT	REFERENCE
SCREW LOADER	SJT-IN 04 00-N
STRAIGHT SCREWDRIVER	SJT-IN 03 00-N
U-JOINT SCREWDRIVER	SJT-IN 03 01-N
U-JOINT GUIDE	SJT-IN 05 00-N
UNIVERSAL-JOINT TUBE AND UNIVERSAL JOINT ANGLED PART	SJT-IN 06 00-N

S U R G I C A L T E C H N I Q U E

_STEP 8



PREPARATION OF THE CENTRAL SCREW HOLE

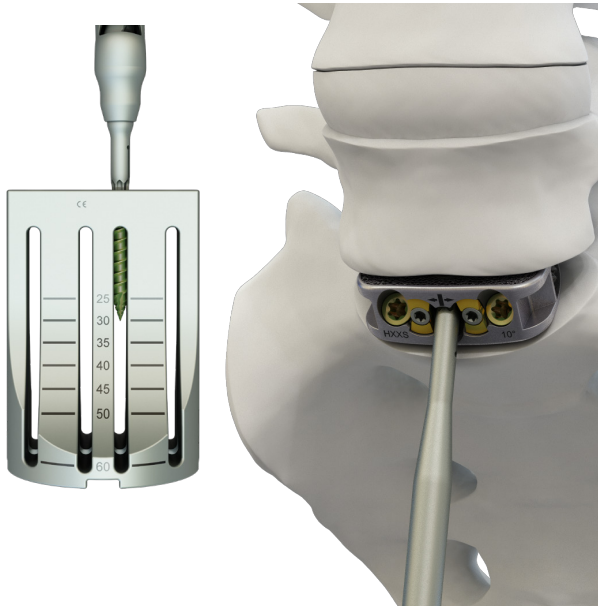
Remove the implant holder.

Prepare the central screw hole of the vertebra using the preferred instruments of the surgeon. The U-Joint guide may also be used during central screw hole creation to provide correct trajectory of central screw hole.

INSTRUMENT	REFERENCE
STRAIGHT SQUARE AWL	SJT-IN 01 00-N
ANGLED SQUARE AWL	SJT-IN 01 01-N
STRAIGHT DRILL	SJT-IN 02 00-N
U-JOINT DRILL	SJT-IN 02 01-N
UNIVERSAL-JOINT TUBE AND UNIVERSAL JOINT ANGLED PART	SJT-IN 06 00-N
U-JOINT GUIDE	SJT-IN 05 00-N
U-JOINT SCREWDRIVER	SJT-IN 03 01-N
STRAIGHT SCREWDRIVER	SJT-IN 03 00-N

SURGICAL TECHNIQUE

_STEP 9



IMPLANTATION OF THE CENTRAL SCREW

Insert the central screw using the straight or U-joint screwdriver.

AP and Lateral images may be used to verify screw position.

INSTRUMENT	REFERENCE
SCREW LOADER	SJT-IN 04 00-N
STRAIGHT SCREWDRIVER	SJT-IN 03 00-N
U-JOINT SCREWDRIVER	SJT-IN 03 01-N
U-JOINT GUIDE	SJT-IN 05 00-N
UNIVERSAL-JOINT TUBE AND UNIVERSAL JOINT ANGLED PART	SJT-IN 06 00-N

_STEP 10



SECURING OF THE SCREWS

The screws are secured with cam locks.

The cage is delivered with the cams unlocked in the open position (Figure 10a).

Using the cam lock driver with the torque limiting handle the cam locking mechanism is activated by rotating the cams in the direction indicated by the arrows laser marked on the front of the cage. The cams are now locked in the closed position (Figure 10b).

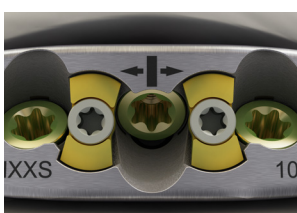


Figure 10a

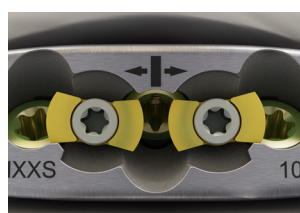


Figure 10b

INSTRUMENT	REFERENCE
CAMLOCKER DRIVER	SCA-IN 06 00-N
TORQUE LIMITING HANDLE (1Nm) (PALM HANDLE)	HAN-SI AO PA-N

S U R G I C A L T E C H N I Q U E

_FINAL CONSTRUCT



_REVISION



In the case of a revision, unlock the cam locks using the camlocker driver and torque limiting handle.

Remove the screws using the revision screwdriver.

Screw the revision screwdriver counter clockwise into the screw while taking it out.

Connect the corresponding implant holder to remove the implant

Gently pull the implant out of the vertebral space.

INSTRUMENT	REFERENCE
REVISION SCREWDRIVER	SJT-IN 03 02-N
CAMLOCKER DRIVER	SCA-IN 06 00-N
TORQUE LIMITING HANDLE (1Nm) (PALM HANDLE)	HAN-SI AO PA-N
STRAIGHT HANDLE (HUDSON CONNECTION)	HAN-SI MH SM-N
IMPLANT HOLDERS (see page 18)	

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

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

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

ANNEX II

Directive 93/42/EEC (without section 4)

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

The scope of validity covers the products

Sterile and non sterile spine instruments

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

CE 1250

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

Reg. no. 45886

Validity 24.01.2020–25.05.2024
 Issue 24.01.2020

Approved Medical Responsible
 24.01.2020



F. Müller, CEO SQS



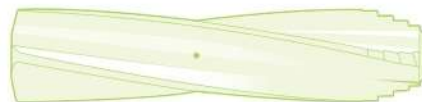
D. Taddeo, Medical Responsible



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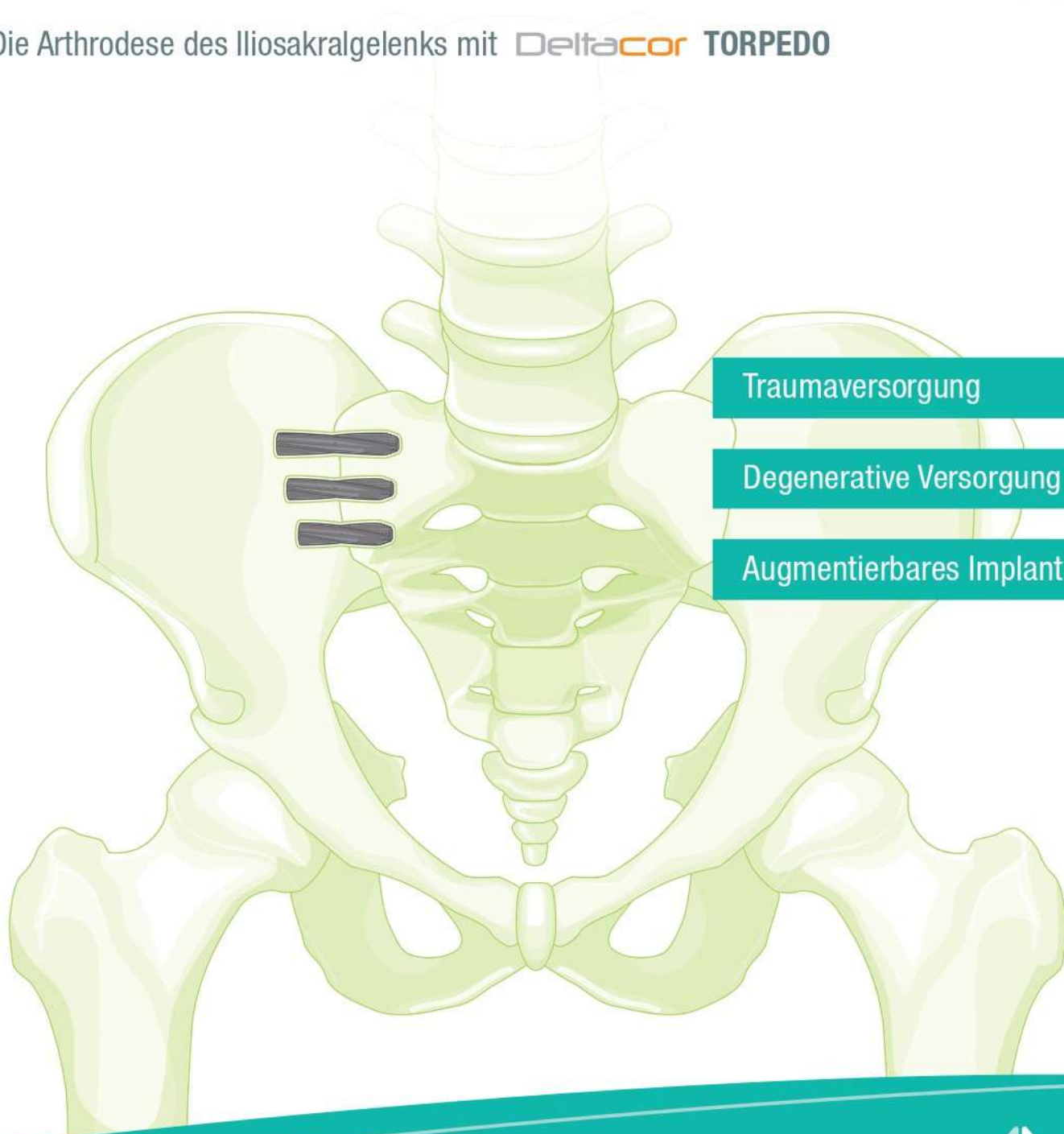
Swiss Association for Quality
 and Management Systems (SQS)
 Bernstrasse 103, 3052 Zollikofen, Switzerland





LOT 11

Die Arthrodesese des Iliosakralgelenks mit **DeltaCor TORPEDO**



Traumaversorgung

Degenerative Versorgung

Augmentierbares Implantat



DeltaCor
TORPEDO
Made in Germany

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

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

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



Torpedo und seine Eigenschaften:

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

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

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

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



Deltacor TORPEDO Instrumente



Abstandhalter



Gewebeschutzhülse



Vorböhrer



Trokarnadel



Einschläger



Schlitzhammer



Längenmesser



Stabhaltezeange

Ein etablierter Weg der richtigen Diagnosestellung beinhaltet unter anderem:

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



DeltaCOR TORPEDO Implantationsschritte



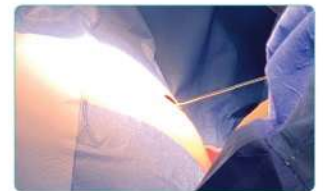
Schritt 1



Schritt 2



Schritt 3



Schritt 4



Schritt 5



Schritt 6



Schritt 7



Schritt 8



Schritt 9



Schritt 10



Schritt 11



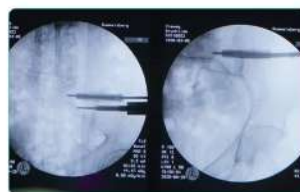
Schritt 12



Schritt 13



Schritt 14



Schritt 15

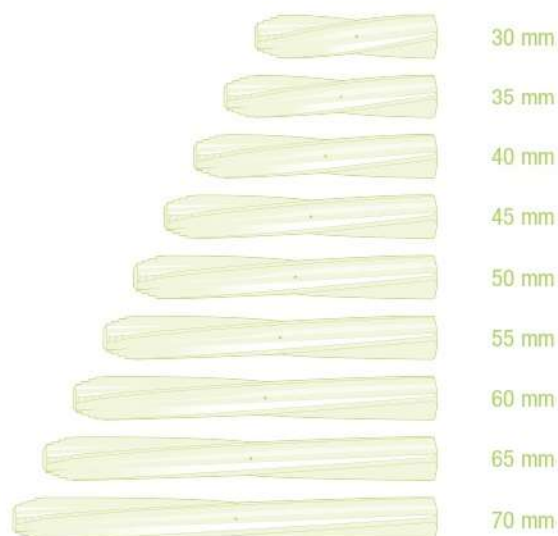


Schritt 16



Produktliste **DeltaCor** TORPEDO

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



EC CERTIFICATE AT SERTİFİKA

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

Full Quality Assurance System Tam Kalite Güvencesi

Certificate Number: 2195-MED-1404201
Sertifika Numarası

Manufacturer:
Üretici

TRİA SPİNE MEDİKAL LTD. ŞTİ.

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

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

Product(s):
Ürün(ler)

Sterile and Non-Sterile Spinal System Implants
Steril ve Steril Olmayan Spinal Sistem Implantları

Model(s):
Model(ler)

Product specifications are given on the second page.
Ürün detayları ikinci sayfada verilmiştir.

Reference Report No:
Referans Rapor No

MM0572-P005-R01, MM0572-P005-R02, MM0572-P005-R03

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

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

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

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

This EC certificate is valid till 2024-05-26.

Bu AT Sertifikası 2024-05-26 tarihine kadar geçerlidir.

Issue Date/Yayın Tarihi:

2014-02-11

Revision No./ Revizyon No.:

05 Recertification/Yeniden Belgelendirme

Revision Date/ Revizyon Tarihi:

2020-03-27

Rukiye BALKAN

Deputy General Manager
Genel Müdür Yardımcısı

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

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

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

ANNEX II

Directive 93/42/EEC (without section 4)

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

The scope of validity covers the products

Sterile and non sterile spine implants

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

CE 1250

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

Reg. no. 33159

Validity 24.01.2020–25.05.2024
 Issue 24.01.2020

Approved Medical Responsible
 24.01.2020



F. Müller, CEO SQS



D. Taddeo, Medical Responsible



sqs.ch

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





Certificate

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



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

Scope of certification

According to appendix

Field of activity

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

Normative base

**EN ISO 13485:2016 Medical devices –
Quality Management System**

Validity 03.10.2017 – 02.2022
Issue 27.06.2018

Reg. no. H31786

X. Edelmann, President SQS

R. Glauser, CEO SQS



sqs.ch



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



Swiss Made





EG – Konformitätserklärung

Entsprechend der Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte

Deltacor GmbH

Rudolf-Diesel-Strasse 10, D – 97440 Werneck,

erklärt hiermit in alleiniger Verantwortung, dass die Produkte der Produktgruppe
zur ISG Versorgung
TORPEDO
(Klasse IIb, Regel 8)

den einschlägigen Bestimmungen der Richtlinie 93/42/EWG über Medizinprodukte entspricht.

EG - Zertifikat

Nr. G1 18 07 50746

Benannte Stelle:

TÜV SÜD Product Service GmbH (0123)
Ridlerstrasse 65, D – 80339 München

Konformitätsbewertung gemäß RL 93/42/EWG Anhang II ohne Nr. 4
Die Konformität endet spätestens mit dem Ablaufdatum des Zertifikates nach Anhang
II (ohne 4), RL 93/42/EWG. (2023-09-30)

Die alleinige Verantwortung zur Ausstellung dieser EG-Konformitätserklärung liegt beim
oben genannten Hersteller.

Werneck, den 03.12.2018

DELTACOR
GMBH

Rudolf-Diesel-Str. 10 · 97440 Werneck
Phone 09722 9220 · Fax 9221

Kilian Kraus, Geschäftsführer



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 18 06 05033 001

Manufacturer:

OSARTIS GmbH

Lagerstraße 11-15
64807 Dieburg
GERMANY

Facility(ies):

OSARTIS GmbH
Lagerstraße 11-15, 64807 Dieburg, GERMANY

OSARTIS GmbH
Nordring 29, 64807 Dieburg, GERMANY

OSARTIS GmbH
Benzstraße 4, 64807 Dieburg, GERMANY



Product

Category(ies):

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

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

713127557

Valid from:

2018-07-02

Valid until:

2022-07-01

Date, 2018-07-02

Stefan Preiß



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

Page 1 of 1

CERTIFICATE



Medical Devices Quality Management System
CERTIFICATE NO: 31910501

Tria Spine Medical Ltd. Şti.

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

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

EN ISO 13485:2016

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

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

Issue Date 15.04.2019
Expiry Date 14.04.2023



TÜRKAK BDS NO
YS-79CB-B206



Deputy General Manager

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



Product Service

CERTIFICATE

No. Q5 18 06 05033 002

Holder of Certificate: OSARTIS GmbHLagerstraße 11-15
64807 Dieburg
GERMANY**Facility(ies):**OSARTIS GmbH
Lagerstraße 11-15, 64807 Dieburg, GERMANYOSARTIS GmbH
Nordring 29, 64807 Dieburg, GERMANYOSARTIS GmbH
Benzstraße 4, 64807 Dieburg, GERMANY**Certification Mark:****Scope of Certificate:**Design and development, production and distribution
of bone cements, mixing and delivery devices for
bone cements (including accessories),
bone substitute materials including application devices,
collagen products**Applied
Standard(s):**EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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

Report No.:

713127557

Valid from:

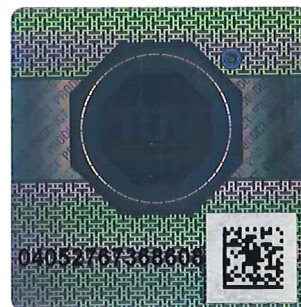
2018-07-02

Valid until:

2022-07-01

Date, 2018-07-02

Stefan Preiß



Page 1 of 1