SCARLET® AL-T

SECURED LUMBAR ANTERIOR CAGE

C O N T E N T

CONCEPT AND DESIGN

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.

AT A GLANCE

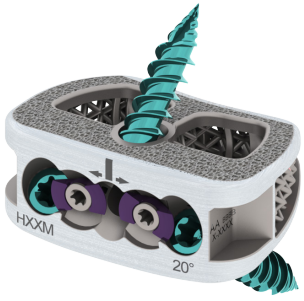
Ti-LIFE Technology
Integrated Screw Channel
High Performance Screw
One Step Cam Lock

INDICATIONS

The SCARLET® AL-T Hyperlordotic secured lumbar anterior cage system is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at various contiguous levels from L2 to 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 or retrolisthesis at the involved level(s). 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.

The SCARLET® AL-T Hyperlordotic secured lumbar anterior cages (≥ 20°) are to be used both with the integrated fixation by the mean of the bone screws provided and also additional supplemental fixation system that has been cleared for use in the lumbosacral spine.

IMPLANTS



Require supplemental fixation

SMALL FOOTPRINT
D24 MM X W32 MM
LORDOSIS: 20° (OPTIONAL)

HEIGHT	REFERENCE
H13	SCA-LS 20 13-S
H15	SCA-LS 20 15-S
H17	SCA-LS 20 17-S
H19	SCA-LS 20 19-S

MEDIUM FOOTPRINT
D27 MM X W36 MM
LORDOSIS: 20°

HEIGHT	REFERENCE
H14	SCA-LM 20 14-S
H16	SCA-LM 20 16-S
H18	SCA-LM 20 18-S
H20	SCA-LM 20 20-S

LARGE FOOTPRINT
D30 MM X W40 MM
LORDOSIS: 20°

HEIGHT	REFERENCE
H15	SCA-LL 20 15-S
H17	SCA-LL 20 17-S
H19	SCA-LL 20 19-S
H21	SCA-LL 20 21-S

Require supplemental fixation

SMALL FOOTPRINT
D24 MM X W32 MM
LORDOSIS: 25° (OPTIONAL)

HEIGHT	REFERENCE
H15	SCA-LS 25 15-S
H17	SCA-LS 25 17-S
H19	SCA-LS 25 19-S
H21	SCA-LS 25 21-S

MEDIUM FOOTPRINT
D27 MM X W36 MM
LORDOSIS: 25°

HEIGHT	REFERENCE
H18	SCA-LM 25 18-S
H20	SCA-LM 25 20-S
H22	SCA-LM 25 22-S
H24	SCA-LM 25 24-S

LARGE FOOTPRINT
D30 MM X W40 MM
LORDOSIS: 25°

HEIGHT	REFERENCE
H19	SCA-LL 25 19-S
H21	SCA-LL 25 21-S
H23	SCA-LL 25 23-S
H25	SCA-LL 25 25-S

Require supplemental fixation

SMALL FOOTPRINT
D24 MM X W32 MM
LORDOSIS: 30° (OPTIONAL)

HEIGHT	REFERENCE
H17	SCA-LS 30 17-S
H19	SCA-LS 30 19-S
H21	SCA-LS 30 21-S
H23	SCA-LS 30 23-S

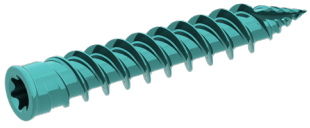
MEDIUM FOOTPRINT
D27 MM X W36 MM
LORDOSIS: 30° (OPTIONAL)

HEIGHT	REFERENCE
H19	SCA-LM 30 19-S
H21	SCA-LM 30 21-S
H23	SCA-LM 30 23-S
H25	SCA-LM 30 25-S

LARGE FOOTPRINT
D30 MM X W40 MM
LORDOSIS: 30° (OPTIONAL)

HEIGHT	REFERENCE
H20	SCA-LL 30 20-S
H22	SCA-LL 30 22-S
H24	SCA-LL 30 24-S
H26	SCA-LL 30 26-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*

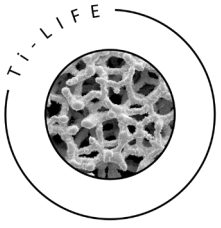
DIA 5.5 MM

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*

* CE 1250

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 SYSTEM

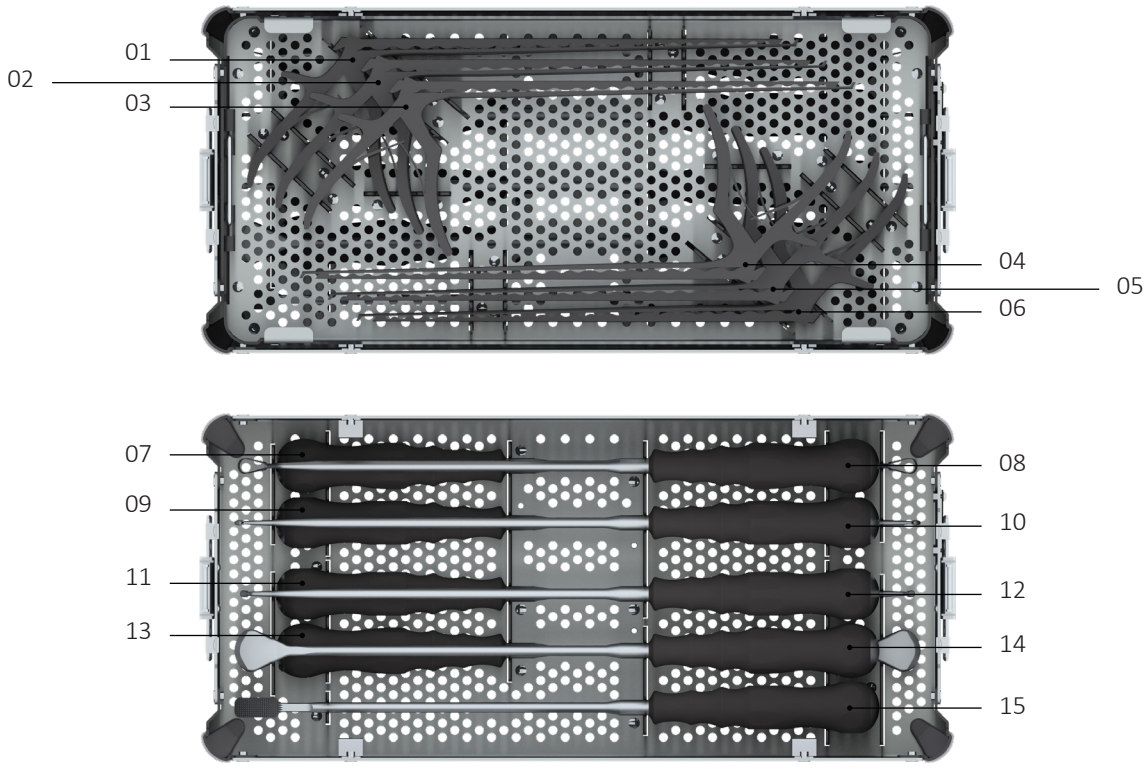
The cages feature a channel to ease screw insertion.
The zero-profile one-step locking mechanism with pre-assembled cam locks prevent screw migration.

COMPREHENSIVE RANGE

20°, 25° & 30° require supplemental fixation
3 footprints

INSTRUMENT SETS

DISC PREPARATION 1



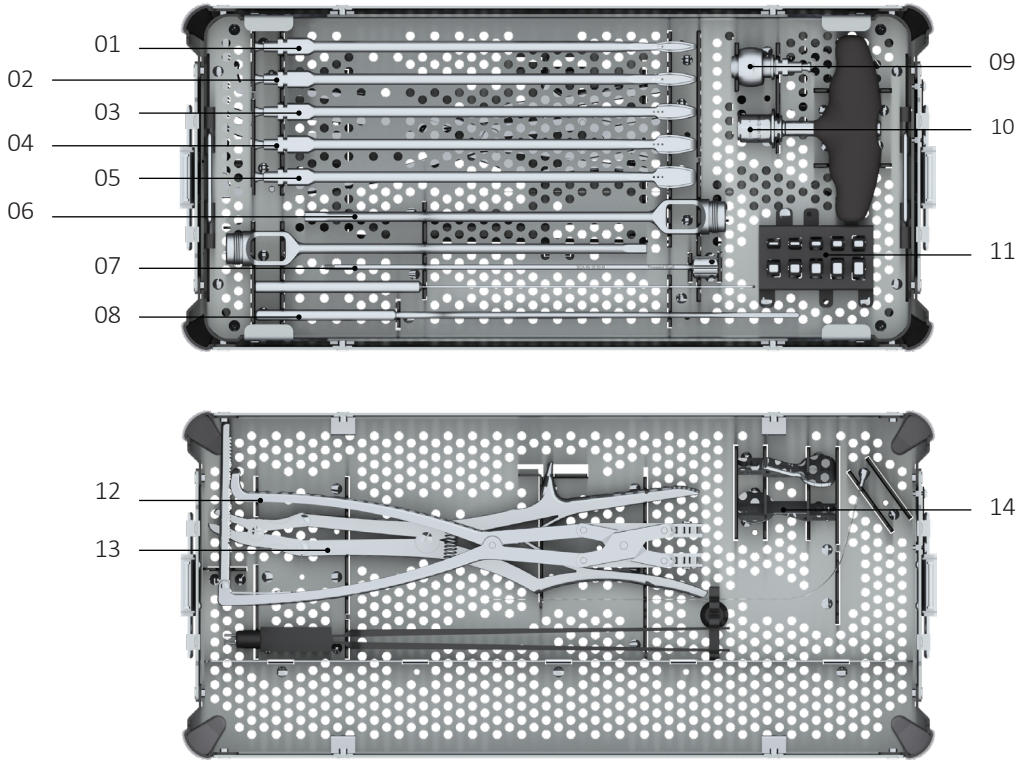
#	DESCRIPTION	REFERENCE
01	PITUITARY RONGEUR, STRAIGHT, 3MM	SCA-IN 21 00-N
02	PITUITARY RONGEUR, STRAIGHT, 5MM	SCA-IN 22 00-N
03	PITUITARY RONGEUR, 3MM, UP	SCA-IN 21 01-N
04	PITUITARY RONGEUR, 5MM, UP	SCA-IN 22 01-N
05	KERRISON RONGEUR, 5MM, 40DEG UP	JLL-IN 14 05-N
06	KERRISON RONGEUR, 3MM, 40DEG UP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

#	DESCRIPTION	REFERENCE
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
•	CUP CURETTE, ANGLED, DOWN, SIZE «0»	SCA-IN 11 01-N
•	CUP CURETTE, STRAIGHT, SIZE «0»	SCA-IN 11 00-N
•	STRAIGHT RING CURETTE, 11MM	SCA-IN 09 00-N
•	ANGLED RING CURETTE, 11MM	SCA-IN 09 01-N

• OPTIONAL

INSTRUMENT SETS

DISC PREPARATION 2

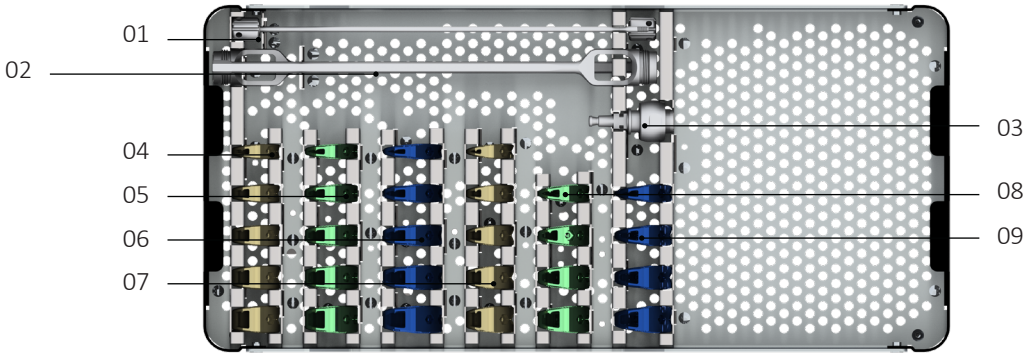


#	DESCRIPTION	REFERENCE
01	DISC SHAVER H08	SCA-IN 14 08-N
02	DISC SHAVER H10	SCA-IN 14 10-N
03	DISC SHAVER H12	SCA-IN 14 12-N
04	DISC SHAVER H14	SCA-IN 14 14-N
05	DISC SHAVER H16	SCA-IN 14 16-N
06	PADDLE DISTRACTOR HOLDER	SCA-IN 15 00-N
07	THREADED SHAFT	SCA-IN 18 00-N
08	BAYONETED PENFIELD #4, TOE IN	JLL-IN 00 01-N
09	HUDSON CONNECTOR	SCA-IN 17 00-N
10	T-HANDLE	HAN-SI MH TE-N

#	DESCRIPTION	REFERENCE
11	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
12	PARALLEL DISTRACTOR	ELL-IN 01 07-N
13	LEKSELL DOUBLE-ACTION RONGEUR, 8MM	SCA-IN 13 00-N
14	DISTRACTOR PARALLEL INTERSOMATIC ENDTIP	SCA-IN 01 00-N

INSTRUMENT SETS

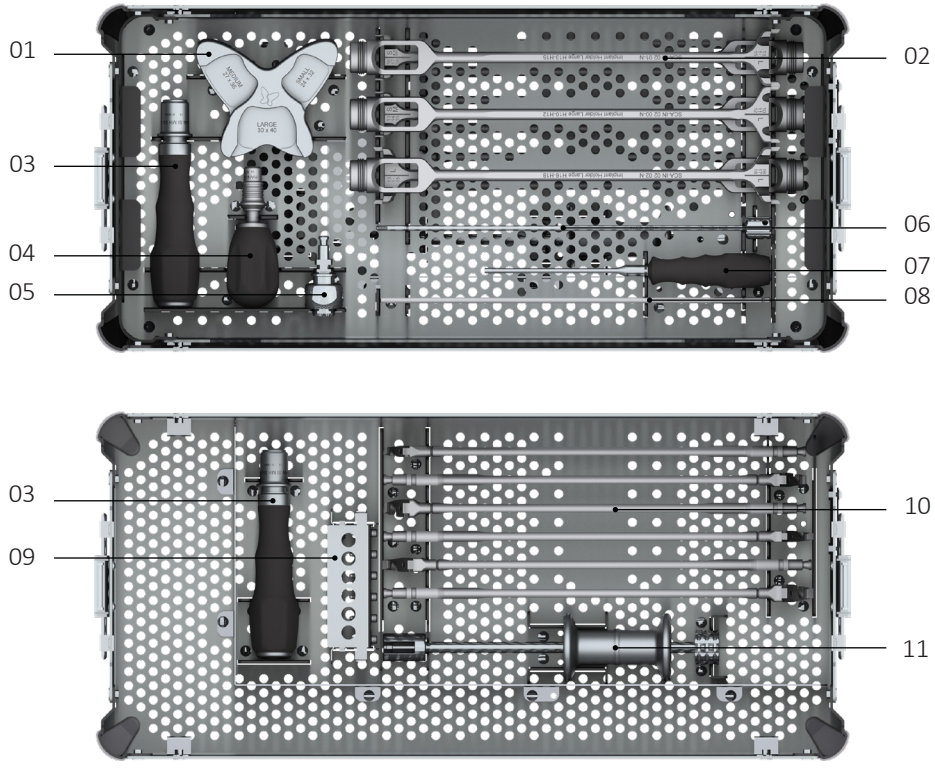
IMPLANT TRIALS AND CAGES



#	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° TRIAL SMALL H12 LORDOSIS 10° TRIAL SMALL H14 LORDOSIS 10° TRIAL SMALL H16 LORDOSIS 10°	SCA-TS 10 10-N SCA-TS 10 12-N SCA-TS 10 14-N SCA-TS 10 16-N
05	TRIAL MEDIUM H10 LORDOSIS 10° TRIAL MEDIUM H12 LORDOSIS 10° TRIAL MEDIUM H14 LORDOSIS 10° TRIAL MEDIUM H16 LORDOSIS 10°	SCA-TM 10 10-N SCA-TM 10 12-N SCA-TM 10 14-N SCA-TM 10 16-N
06	TRIAL LARGE H10 LORDOSIS 10° TRIAL LARGE H12 LORDOSIS 10° TRIAL LARGE H14 LORDOSIS 10° TRIAL LARGE H16 LORDOSIS 10°	SCA-TL 10 10-N SCA-TL 10 12-N SCA-TL 10 14-N SCA-TL 10 16-N
07	TRIAL SMALL H10 LORDOSIS 15° TRIAL SMALL H12 LORDOSIS 15° TRIAL SMALL H14 LORDOSIS 15° TRIAL SMALL H16 LORDOSIS 15°	SCA-TS 15 10-N SCA-TS 15 12-N SCA-TS 15 14-N SCA-TS 15 16-N
08	TRIAL MEDIUM H12 LORDOSIS 15° TRIAL MEDIUM H14 LORDOSIS 15° TRIAL MEDIUM H16 LORDOSIS 15°	SCA-TM 15 12-N SCA-TM 15 14-N SCA-TM 15 16-N
09	TRIAL LARGE H12 LORDOSIS 15° TRIAL LARGE H14 LORDOSIS 15° TRIAL LARGE H16 LORDOSIS 15°	SCA-TL 15 12-N SCA-TL 15 14-N SCA-TL 15 16-N

INSTRUMENT SETS

IMPLANT TRIALS AND CAGES

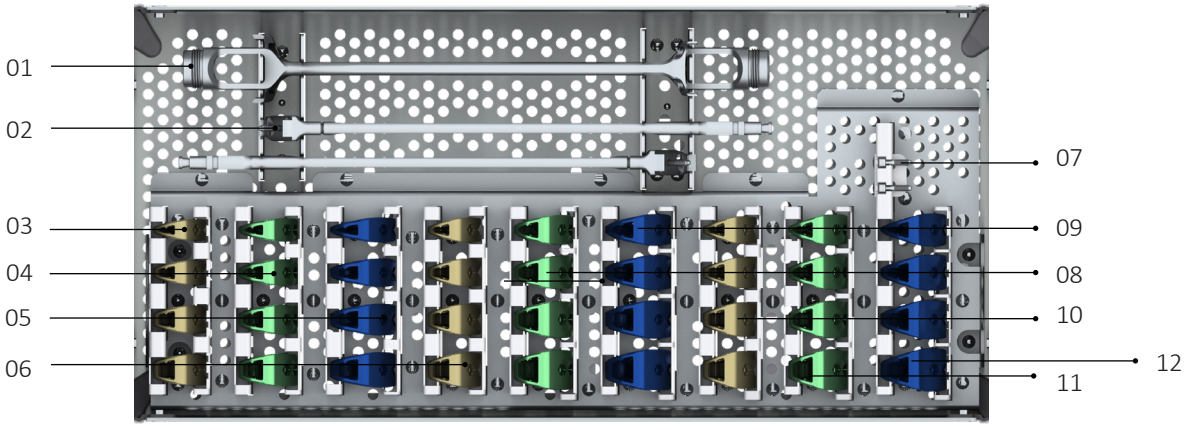


#	DESCRIPTION	REFERENCE
01	COMPACTION BASE	SCA-IN 07 00-N
02	IMPLANT HOLDERS: SMALL/MEDIUM H10-H12 SMALL/MEDIUM H13-H15 SMALL/MEDIUM H16-H18 LARGE H10-H12 LARGE H13-H15 LARGE H16-H18	 SCA-IN 01 01-N SCA-IN 01 02-N SCA-IN 01 03-N SCA-IN 02 00-N SCA-IN 02 01-N SCA-IN 02 02-N
03	STRAIGHT HANDLE (HUDSON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

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

INSTRUMENT SETS

HYPERLORDOTIC CAGES

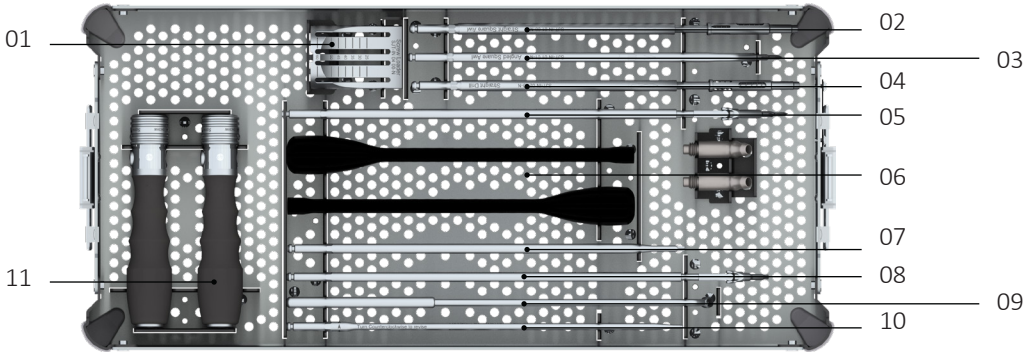


	DESCRIPTION		REFERENCE
03	TRIAL SMALL	H13 LORDOSIS 20°	SCA-TS 20 13-N
		H15 LORDOSIS 20°	SCA-TS 20 15-N
		H17 LORDOSIS 20°	SCA-TS 20 17-N
		H19 LORDOSIS 20°	SCA-TS 20 19-N
04	TRIAL MEDIUM	H14 LORDOSIS 20°	SCA-TM 20 14-N
		H16 LORDOSIS 20°	SCA-TM 20 16-N
		H18 LORDOSIS 20°	SCA-TM 20 18-N
		H20 LORDOSIS 20°	SCA-TM 20 20-N
05	TRIAL LARGE	H15 LORDOSIS 20°	SCA-TL 20 15-N
		H17 LORDOSIS 20°	SCA-TL 20 17-N
		H19 LORDOSIS 20°	SCA-TL 20 19-N
		H21 LORDOSIS 20°	SCA-TL 20 21-N
06	TRIAL SMALL	H15 LORDOSIS 25°	SCA-TS 25 15-N
		H17 LORDOSIS 25°	SCA-TS 25 17-N
		H19 LORDOSIS 25°	SCA-TS 25 19-N
		H21 LORDOSIS 25°	SCA-TS 25 21-N
08	TRIAL MEDIUM	H18 LORDOSIS 25°	SCA-TM 25 18-N
		H20 LORDOSIS 25°	SCA-TM 25 20-N
		H22 LORDOSIS 25°	SCA-TM 25 22-N
		H24 LORDOSIS 25°	SCA-TM 25 24-N

	DESCRIPTION		REFERENCE
09	TRIAL LARGE	H19 LORDOSIS 25°	SCA-TL 25 19-N
		H21 LORDOSIS 25°	SCA-TL 25 21-N
		H23 LORDOSIS 25°	SCA-TL 25 23-N
		H25 LORDOSIS 25°	SCA-TL 25 25-N
10	TRIAL SMALL	H17 LORDOSIS 30°	SCA-TS 30 17-N
		H19 LORDOSIS 30°	SCA-TS 30 19-N
		H21 LORDOSIS 30°	SCA-TS 30 21-N
		H23 LORDOSIS 30°	SCA-TS 30 23-N
11	TRIAL MEDIUM	H19 LORDOSIS 30°	SCA-TM 30 19-N
		H21 LORDOSIS 30°	SCA-TM 30 21-N
		H23 LORDOSIS 30°	SCA-TM 30 23-N
		H25 LORDOSIS 30°	SCA-TM 30 25-N
12	TRIAL LARGE	H20 LORDOSIS 30°	SCA-TL 30 20-N
		H22 LORDOSIS 30°	SCA-TL 30 22-N
		H24 LORDOSIS 30°	SCA-TL 30 24-N
		H26 LORDOSIS 30°	SCA-TL 30 26-N
01	IMPLANT HOLDER SMALL/MEDIUM H19-H25		SCA-IN 01 04-N
	IMPLANT HOLDER LARGE H19-H26		SCA-IN 02 03-N
02	LATERAL IMPLANT HOLDER SMALL/MEDIUM H19-H25		SCA-IN 03 03-N
	LATERAL IMPLANT HOLDER LARGE H19-H26		SCA-IN 04 03-N
07	LATERAL IMPLANT HOLDER SCREW M4 X 0.7		SCA-IN 16 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 RATCHETING HANDLE	HAN-SI RA ST-N

INSTRUMENTS

DISC PREPARATION

STRAIGHT RING CURETTE, 15MM	SCA-IN 09 02-N
STRAIGHT RING CURETTE, 11MM	SCA-IN 09 00-N

ANGLED RING CURETTE, 15MM	SCA-IN 09 03-N
ANGLED RING CURETTE, 11MM	SCA-IN 09 01-N

CUP CURETTE, STRAIGHT, SIZE «2»	SCA-IN 12 00-N
CUP CURETTE, STRAIGHT, SIZE «0»	SCA-IN 11 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 «0»	SCA-IN 11 01-N

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

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

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

COBB, 25MM, 10° UP	SCA-IN 10 01-N

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

PADDLE DISTRACTOR HOLDER	SCA-IN 15 00-N

THREADED SHAFT	SCA-IN 18 00-N

INSTRUMENTS

DISC PREPARATION

T-HANDLE (HUDSON CONNECTION)	HAN-SI MH TE-N

BALL TIP PROBE	SCA-IN 20 00-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

PITUITARY RONGEUR, STRAIGHT, 3MM	SCA-IN 21 00-N
PITUITARY RONGEUR, STRAIGHT, 5MM	SCA-IN 22 00-N
PITUITARY RONGEUR, 3MM, UP	SCA-IN 21 01-N
PITUITARY RONGEUR, 5MM, UP	SCA-IN 22 01-N

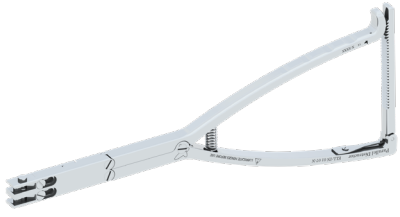
CUP CURETTE, STRAIGHT, SIZE «0» (OPTIONAL)	SCA-IN 11 00-N
CUP CURETTE, ANGED, SIZE «0» (OPTIONAL)	SCA-IN 11 01-N

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

INSTRUMENTS

DISC PREPARATION

PARALLEL DISTRACTOR	ELL-IN 01 07-N



BAYONETED PENFIELD #4, TOE IN	JLL-IN 00 01-N

DISTRACTOR PARALLEL INTERSOMATIC 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 AND CAGES

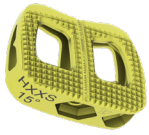
TRIAL INSERTER	SCA-IN 05 00-N

THREADED SHAFT	SCA-IN 18 00-N

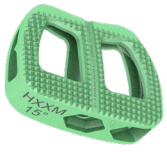
SLAP HAMMER	JLL-IN 12 00-N

HUDSON CONNECTOR	SCA-IN 17 00-N

TRIAL SMALL	H10 TO 16 LORDOSIS 10°	SCA-TS 10 XX-N
	H10 TO 16 LORDOSIS 15°	SCA-TS 15 XX-N
	H13 TO 19 LORDOSIS 20°	SCA-TS 20 XX-N
	H15 TO 21 LORDOSIS 25°	SCA-TS 25 XX-N
	H17 TO 23 LORDOSIS 30°	SCA-TS 30 XX-N



TRIAL MEDIUM	H10 TO 16 LORDOSIS 10°	SCA-TM 10 XX-N
	H12 TO 16 LORDOSIS 15°	SCA-TM 15 XX-N
	H14 TO 20 LORDOSIS 20°	SCA-TM 20 XX-N
	H18 TO 24 LORDOSIS 25°	SCA-TM 25 XX-N
	H19 TO 25 LORDOSIS 30°	SCA-TM 30 XX-N



TRIAL LARGE	H10 TO 16 LORDOSIS 10°	SCA-TL 10 XX-N
	H12 TO 16 LORDOSIS 15°	SCA-TL 15 XX-N
	H15 TO 21 LORDOSIS 20°	SCA-TL 20 XX-N
	H19 TO 25 LORDOSIS 25°	SCA-TL 25 XX-N
	H20 TO 26 LORDOSIS 30°	SCA-TL 30 XX-N

INSTRUMENTS

IMPLANT TRIALS AND CAGES

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 SMALL/MEDIUM H19-H25	SCA-IN 01 04-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
IMPLANT HOLDER LARGE H19-H26	SCA-IN 02 03-N

LATERAL IMPLANT HOLDER SCREW M4X0.7	SCA-IN 16 00-N

COMPACTION BASE	SCA-IN 07 00-N

STRAIGHT HANDLE (HUDSON CONNECTION)	HAN-SI MH SM-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 SMALL/ MEDIUM H19-H25	SCA-IN 03 03-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
LATERAL IMPLANT HOLDER LARGE H19-H26	SCA-IN 04 03-N

COMPACTOR	SCA-IN 19 00-N

CAMLOCKER DRIVER	SCA-IN 06 00-N

TORQUE LIMITING HANDLE (1NM) (PALM HANDLE)	HAN-SI AO PA-N

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 RATCHETING HANDLE	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

_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.

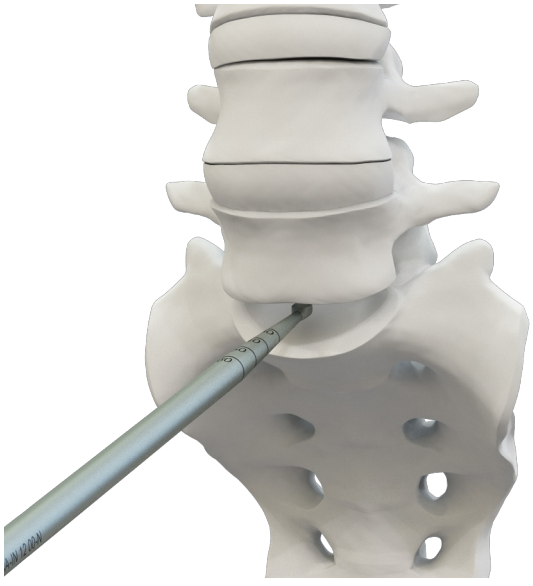
Through a standard retroperitoneal approach, dissect and retract the soft tissue to reach the operative disc level.

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

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.

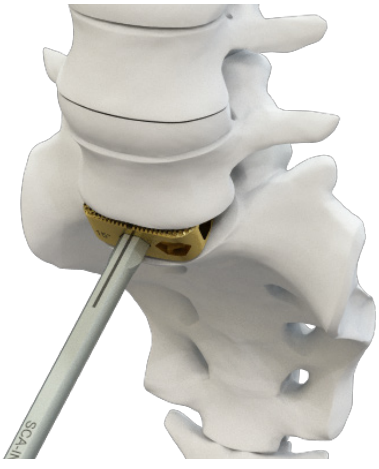
Complete endplate preparation with the rasp and disc shavers. Care must be taken to ensure excessive bone is not removed, which may weaken the endplate.

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
DISTRACTOR PARALLEL INTERSOMATIC 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

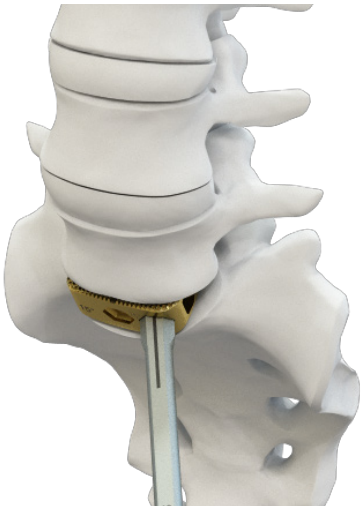
INSTRUMENT	REFERENCE
BAYONETED PENFIELD #4, TOE IN	JLL-IN 00 01-N
T-HANDLE (HUDSON CONNECTION)	HAN-SI MH TE-N
BALL TIP PROBE	SCA-IN 20 00-N
PITUITARY RONGEUR, STRAIGHT, 5MM	SCA-IN 21 00-N
PITUITARY RONGEUR, STRAIGHT, 3MM	SCA-IN 22 00-N
PITUITARY RONGEUR, 3MM, UP	SCA-IN 21 01-N
PITUITARY RONGEUR, 5MM, 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
CUP CURETTE, ANGLED, DOWN, SIZE «0» (OPTIONAL)	SCA-IN 11 01-N
CUP CURETTE, STRAIGHT, SIZE «0» (OPTIONAL)	SCA-IN 11 00-N
STRAIGHT RING CURETTE, 11MM (OPTIONAL)	SCA-IN 09 00-N
ANGLED RING CURETTE, 11MM (OPTIONAL)	SCA-IN 09 01-N

_STEP 3

DETERMINE THE IMPLANT SIZE



ANTERIOR APPROACH



ANTEROLATERAL APPROACH

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 H13 TO 19 LORDOSIS 20°	SCA-TS 20 XX-N
TRIAL SMALL H15 TO 21 LORDOSIS 25°	SCA-TS 25 XX-N
TRIAL SMALL H17 TO 23 LORDOSIS 30°	SCA-TS 30 XX-N
SLAP HAMMER	JLL-IN 12 00-N

INSTRUMENT	REFERENCE
TRIAL MEDIUM H14 TO 20 LORDOSIS 20°	SCA-TM 20 XX-N
TRIAL MEDIUM H18 TO 24 LORDOSIS 25°	SCA-TM 25 XX-N
TRIAL MEDIUM H19 TO 25 LORDOSIS 30°	SCA-TM 30 XX-N
TRIAL LARGE H15 TO 21 LORDOSIS 20°	SCA-TL 20 XX-N
TRIAL LARGE H19 TO 25 LORDOSIS 25°	SCA-TL 25 XX-N
TRIAL LARGE H20 TO 26 LORDOSIS 30°	SCA-TL 30 XX-N

SURGICAL TECHNIQUE

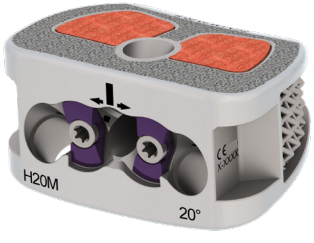
_STEP 4

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.

Tighten the cage onto the implant holder corresponding to the selected footprint and height.

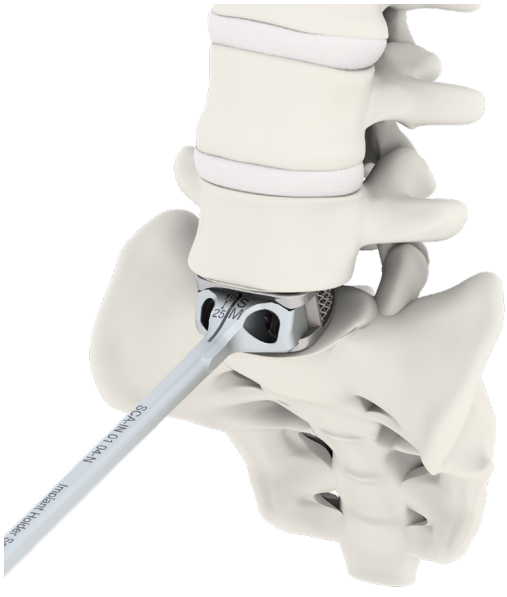
Place the cage onto the compaction base and fill it with bone graft.



INSTRUMENT	REFERENCE
IMPLANT HOLDER SMALL/MEDIUM H13-H15	SCA-IN 01 02-N
IMPLANT HOLDER SMALL/MEDIUM H16-H18	SCA-IN 01 03-N
IMPLANT HOLDER SMALL/MEDIUM H19-H25	SCA-IN 01 04-N
IMPLANT HOLDER LARGE H13-H15	SCA-IN 02 01-N
IMPLANT HOLDER LARGE H16-H18	SCA-IN 02 02-N
IMPLANT HOLDER LARGE H19-H26	SCA-IN 02 03-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 SMALL/ MEDIUM H19-H25	SCA-IN 03 03-N

INSTRUMENT	REFERENCE
LATERAL IMPLANT HOLDER LARGE H13-H15	SCA-IN 04 01-N
LATERAL IMPLANT HOLDER LARGE H16-H18	SCA-IN 04 02-N
LATERAL IMPLANT HOLDER LARGE H19-H26	SCA-IN 04 03-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	HAN-SI MH SM-N

_STEP 5



INSERTION OF THE FINAL IMPLANT

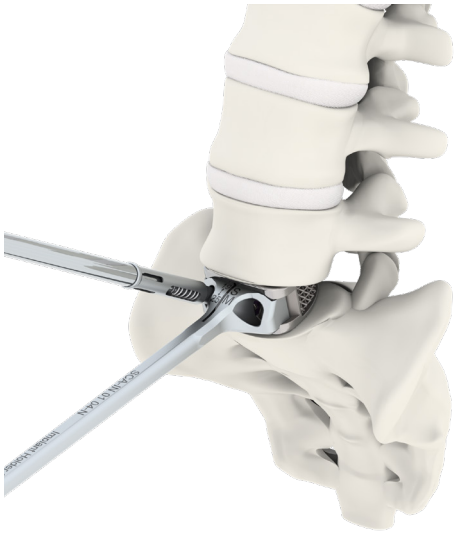
Insert the cage into the intervertebral space, according to preferred approach technique of the surgeon.

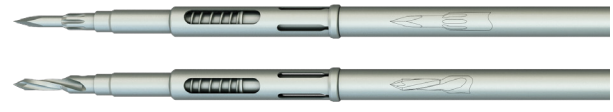
A mallet may be used to gently insert the final implant.

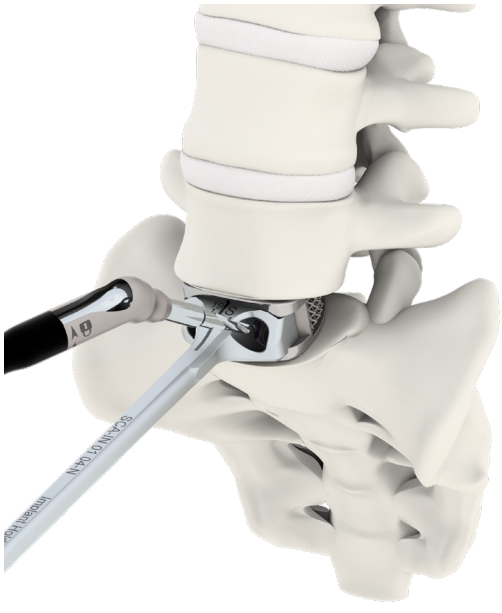
INSTRUMENT	REFERENCE
IMPLANT HOLDER SMALL/MEDIUM H13-H15	SCA-IN 01 02-N
IMPLANT HOLDER SMALL/MEDIUM H16-H18	SCA-IN 01 03-N
IMPLANT HOLDER SMALL/MEDIUM H19-H25	SCA-IN 01 04-N
IMPLANT HOLDER LARGE H13-H15	SCA-IN 02 01-N
IMPLANT HOLDER LARGE H16-H18	SCA-IN 02 02-N
IMPLANT HOLDER LARGE H19-H26	SCA-IN 02 03-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 SMALL/ MEDIUM H19-H25	SCA-IN 03 03-N

INSTRUMENT	REFERENCE
LATERAL IMPLANT HOLDER LARGE H13-H15	SCA-IN 04 01-N
LATERAL IMPLANT HOLDER LARGE H16-H18	SCA-IN 04 02-N
LATERAL IMPLANT HOLDER LARGE H19-H26	SCA-IN 04 03-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	HAN-SI MH SM-N
HUDSON CONNECTOR	SCA-IN 17 00-N
LATERAL IMPLANT HOLDER SCREW M4X0.7	SCA-IN 16 00-N

_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.

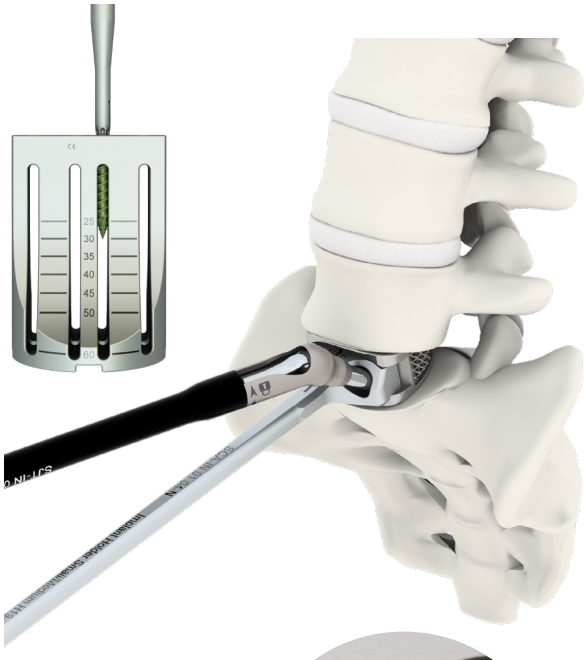
Insert preferred instrument into the guide hole of the implant holder to prepare each lateral screw hole.

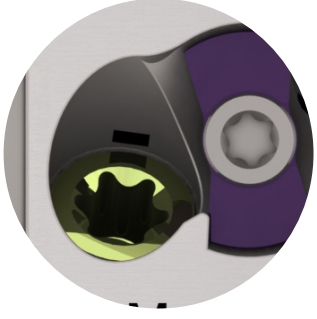
The U-joint guide may also be used during screw hole preparation to provide correct trajectory.

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

_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.

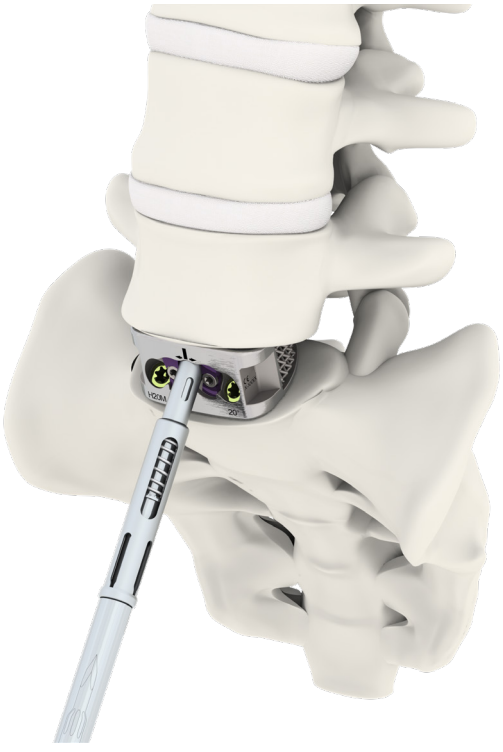
AP and Lateral images may be used to verify screw position.

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

_STEP 8



PREPARATION OF THE CENTRAL SCREW HOLE

Remove the implant holder.

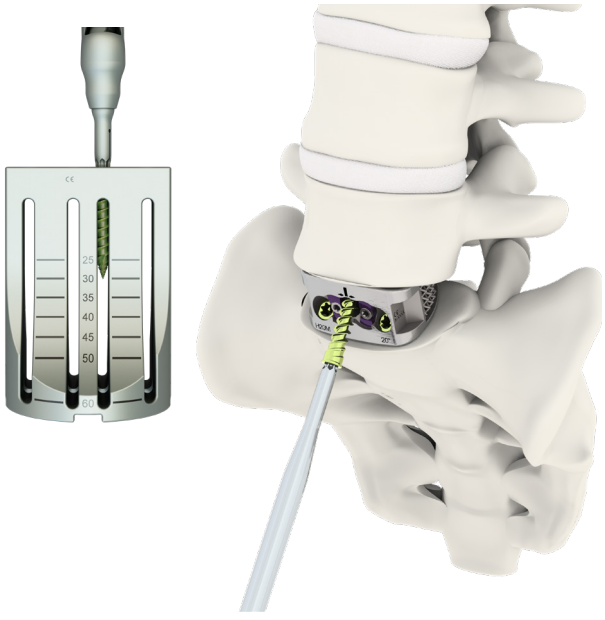
Prepare the central screw hole of the vertebra using the preferred instruments of the surgeon.
The U-Joint guide may also be used during central screw hole creation to provide correct trajectory of central screw hole.

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

NOTE: All screw hole preparation instruments can be used to create holes interchangeably according to surgeon preference.

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

_STEP 9



IMPLANTATION OF THE CENTRAL SCREW

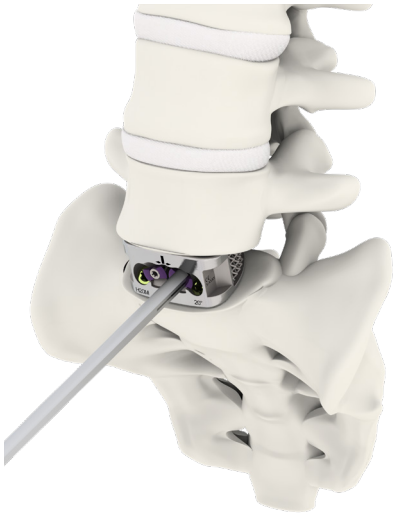
Load the screw into the screw loader. It will facilitate a secure connection between the screw and the self-retaining screwdriver. It also provides a verification of screw length.

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).

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

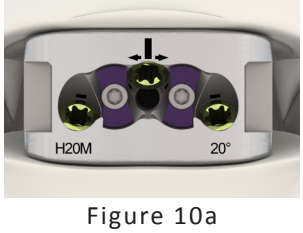


Figure 10a

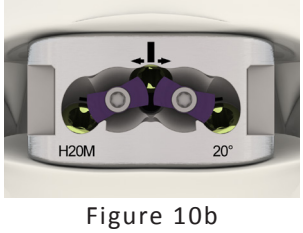
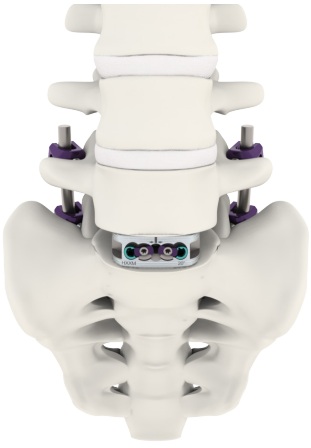


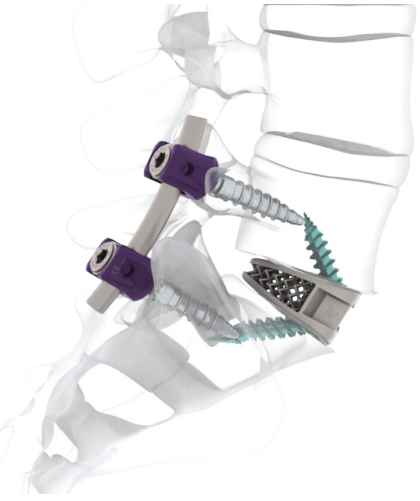
Figure 10b

SURGICAL TECHNIQUE

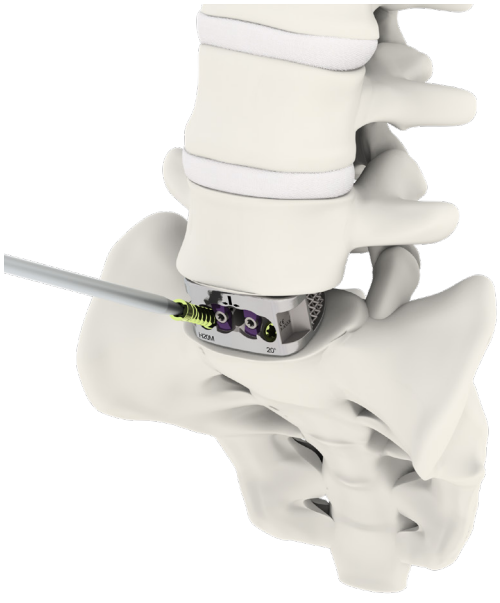
_ FRONTAL FINAL CONSTRUCT



_ LATERAL 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	HAN-SI MH SM-N
IMPLANT HOLDERS (see page 19)	

REFERENCE OF THE IFU	SCA-LH-IF-WW	REVISION OF THE FINAL IFU	JAN-2020

_STERILITY

The implant is provided sterile

Implants are double packaged in a PETG blister.

Each package is labeled and an IFU is included.

If the implant or its packaging seems to be damaged, if the expiry date is exceeded or if the sterility cannot be guaranteed for any reason, the implant must not be used.

Never use a damaged, explanted implant or one which has been used erroneously when it has come into contact with tissues, even after cleaning. The implant must be discarded. Re-use of a single use device does not make it possible to ensure structural integrity nor achievement of the assigned performances over time, and may result in premature rupture. Such re-use may also result in infection in the patient.

The re-sterilization of the gamma sterilized implant is forbidden.

The re-sterilization of the delivered sterilized instruments is forbidden.

Please refer to the individual package labeling.

_DESCRIPTION

The SCARLET® AL-T Hyperlordotic secured lumbar anterior cage system has been designed to ensure the best possible adaptation to the patient's anatomic variations.

The SCARLET® AL-T Hyperlordotic secured lumbar anterior cage system is in Titanium alloy. It is intended to perform fusion between lumbar vertebrae after discectomy. These implants may be implanted via an open or a minimally invasive anterior approach.

_INDICATIONS

The SCARLET® AL-T Hyperlordotic secured lumbar anterior cage system is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at various contiguous levels from L2 to 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 or retrolisthesis at the involved level(s). 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.

The SCARLET® AL-T Hyperlordotic secured lumbar anterior cages (≥ 20°) are to be used both with the integrated fixation by the mean of the bone screws provided and also additional supplemental fixation system that has been cleared for use in the lumbosacral spine.

_CONTRAINDICATIONS

- Mental illness.
- Infection.
- Severely damaged bone structures that could prevent stable implantation of the cage.
- Neuromuscular or vascular disorders or illness.
- Inadequate activity.
- Pregnancy
- Bone tumour in the region of implant
- Fractures

_SIDE EFFECTS

Operative:

Haemostatic problems, injuries to the nervous system resulting in temporary or permanent weaknesses, pain or functional handicap, fractures.

Post operative:

Venous thrombosis and pulmonary embolism, infection, cardio-vascular disorders, retrograde ejaculation, hematoma and late cicatrisation.

Specific to implant:

Implant migration, adhesion and fibrosis, limited range of movement, secondary fractures.

Potential risks identified with the use of this intervertebral body fusion device, which may require additional surgery, include: device component fracture, loss of fixation, pseudoarthrosis (i.e. non-union), fracture of the vertebra, neurological injury, and vascular or visceral injury.

GENERAL INFORMATION

_WARNINGS

Because this is a technically demanding procedure presenting a risk of serious injury to the patient, only experienced surgeons with adequate training should perform intervertebral body fusion.

Every surgeon who uses these implants must take each patient's clinical state and medical status into consideration, and be fully familiar with procedures involving the use of this type of implant and the potential complications in each case.

Abnormal use of the device may lead to risks of serious injury and/or health deterioration of the patient.

The soft tissue and the adjacent bones may deteriorate over time, or may not be in an adequate state to support the implant, thus causing instability and/or malformation. The benefits of this lumbar interbody fusion procedure may not meet the patient's expectations, thus requiring more surgery to replace or remove the implant, or other types of procedures.

Patients undergoing intervertebral body fusion shall, therefore, be informed.

Based on the dynamic testing result, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the intervertebral body fusion device.

Do not use titanium and stainless-steel components together.

Significant implant overload, patient hyperactivity or abnormal behavior may increase clinical risks and require secondary surgery. Patient who underwent this type of procedure shall, therefore, be informed of the residual clinical risks.

In rare cases, the patient may have or develop hypersensitivity to medical grade titanium alloys.

The SCARLET® AL-T Hyperlordotic implant must not be used with implant other than SCARLET® AL-T range.

The SCARLET® AL-T Hyperlordotic implant shall exclusively be implanted using SCARLET® AL-T Instrumentation.

_MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that SpineArt's Lumbar Interbody Cages are MR Conditional. A patient with a SpineArt Lumbar Interbody Cage can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).
- Maximum spatial field gradient of 3,160 G/cm (31.6 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg at 1.5 T and 3 T.

RF Heating

Under the scan conditions defined above, SpineArt's Lumbar Interbody Cages are expected to produce a maximum temperature rise of less than 1.0 ºC after 15 minutes of continuous scanning at 1.5 T and less than or equal to 1.2 ºC after 15 minutes of continuous scanning at 3 T.

Caution: The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

MR Artifact

In non-clinical testing, the image artifact caused by SpineArt Lumbar Interbody Cages extends approximately 5.3 cm from the devices when imaged in a 3 T MRI system.

_HANDLING

No effort has been spared to ensure that only the highest-quality materials and expertise have been deployed in producing each implant.

Implants are mechanical devices that can be worn, damaged or broken. An implant site can become infected, painful, swollen, or inflamed. Significant weight on the implant, an implant of inadequate size, and patient hyperactivity or a misuse will increase the risk of complications, including wear and tear or rupture.

When handling these implants, blunt instruments should be used in order to avoid scratching, cutting, or nicking the device. Sharp-edged, serrated or toothed instruments should not be used.

Surgeons are advised not to remove the device from its sterile packaging until after the implant site has been properly prepared and precise measurements have been taken.

We strongly recommend that excessive force should not be applied when installing any of the implants.

_SURGERY METHODS

The implantation of an implant should be performed only by experienced surgeons with specific training in the use of this lumbar interbody cage because this is a technically demanding procedure presenting a risk of serious injury to the patient.

GENERAL INFORMATION

The surgeon is responsible for familiarizing him/herself with the surgical technique used for implanting these devices, by studying the relevant published articles, consulting experienced colleagues, and receiving training in the methods appropriate to the particular implant being used.

Careful preparation of the surgical site and choosing an implant of the right size will increase the chances of a successful reconstruction.

Metallic trial implants provided can be used to assess disc space and help in making this selection.

The surgical procedure is standard for experienced surgeons. Your local representative should have communicated the handbook describing the surgical technique. In any case, the handbook is readily available by contacting either your local representative or directly Spineart®.

_STORAGE CONDITIONS

It is mandatory that the implants are stored in their original packaging, in a clean, dry location where atmospheric pressure is moderate.

_INSTRUMENTATION

The instruments were specifically designed for use when installing these implants.

They are delivered non-sterile.

Specific markings are engraved on each instrument to facilitate identification of the corresponding implant size and type.

_DECONTAMINATION, CLEANING, AND STERILIZATION

Point-of-instruction: The instruments must, immediately after use, be decontaminated, cleaned, and sterilized as described below.

Prior to starting the surgical procedure, all non-sterile reusable instruments must be properly cleaned, decontaminated and sterilized.

The SCARLET®AL-T instruments have been designed in order to avoid disassembly manipulation prior decontamination, cleaning and sterilization processes.

These methods and parameters have been validated following the AAMI TIR 30 Technical Report for reusable instruments and not sterile implants.

Manual disinfection/cleaning protocol

- Rinse soiled devices under running cold tap water for 1 minute, using soft-bristled brush to assist in the removal of gross soil debris. Devices that can be disassembled must be disassembled before cleaning.
- Soak devices in a bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and manually clean for 5 minutes using soft-bristled brush, at room temperature (+15/+25°C).
- Rinse devices under running cold water for 1 minute.
- Use a syringe to flush the devices with cannulation with 2x20 ml of neutral enzymatic cleaner at room temperature (+15/+25°C).
- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and clean ultrasonically for 10 minutes at room temperature (+15/+25°C).
- Rinse devices under running cold water for 1 minutes. Devices with mobile parts must be manipulated through their full range of motion during rinsing.
- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and manually clean for 2 minutes using soft-bristled brush at room temperature (+15/+25°C).
- Use a syringe to flush the devices with cannulation with 2x20 ml of deionized water at room temperature (+15/+25°C).
- Rinse thoroughly the devices with deionized water for 2 minutes. Devices with mobile parts must be manipulated through their full range of motion during rinsing.
- Visually inspect devices.
- Dry using a soft, lint free cloth.

Automatic disinfection/cleaning protocol

- Rinse soiled devices under running cold tap water for 30 seconds, using soft-bristled brush to assist in the removal of gross soil debris. Devices that can be disassembled must be disassembled before cleaning.
- Soak devices in a bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and manually clean for 1 minute using soft-bristled brush, at room temperature (+15/+25°C).
- Rinse devices under running cold water for 30 seconds. Devices with mobile parts must be manipulated through their full range of motion during rinsing.

- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and clean ultrasonically for 10 minutes at room temperature (+15/+25°C).
- Rinse devices under running cold water for 1 minute. Devices with mobile parts must be manipulated through their full range of motion during rinsing.
- Load devices into the washer-disinfector.
- Visually inspect devices.
- Dry using a soft, lint freecloth.

Sterilization trays cleaning and disinfection

All the trays must be thoroughly cleaned and disinfected after surgery completion.

Cleaning recommendations

- Remove all the instruments from the trays,
- Large and visible impurities must be removed from the trays,
- Use running water and rinse thoroughly for at least one minute,
- Use freshly prepared cleaning bath of the specified concentration for the period specified by the manufacturer,
- Use soft brush until there is no visible contamination,
- Dry trays with lint-free disposable cloths.

Disinfection recommendations

- Use a freshly disinfectant bath of the specified concentration for the period specified by the manufacturer. Rinse thoroughly three times,
- Rinse trays thoroughly with water as specified by the disinfectant manufacturer,
- Dry trays with lint-free disposable cloths.

Trays must be visually clean, if not, repeat the cleaning and disinfection protocol.

- Subsequent sterilization in containers is then recommended, using an autoclave and steam, and following a protocol that meets the minimum requirements or more, and is in compliance with current legislation (e.g., 134°C – 18 minutes) to obtain a guaranty of sterility of 10-6. The validation for sterilization has been done according to overkill/ half cycle method as described in the ISO 17664, ISO 17665 standards and of AAMI TIR 12 Technical Report.

Sterilization parameters

Method: Pre-vacuum cycle of Steam sterilization (moist heat - autoclave)

Cycle 1 (EU):

Exposure time: 18 minutes

Temperature: 134°C

Drying time: 30 minutes

Cycle 2 (USA):

Exposure time: 4 minutes

Temperature: 132°C

Drying time: 30 minutes

“Do not stack trays during sterilization”

_MAINTENANCE AND REPAIRING

Spineart instruments are guaranteed for at least 150 steam sterilization runs.

Spineart® instruments that need to be repaired must be decontaminated and cleaned, then sent to the address mentioned in this document.

_FURTHER INFORMATION

If further directions for use of this system are needed, please check with the SPINEART Customer Service.

If further information is needed or required, please see the addresses on this document.

WASHER-DISINFECTOR PARAMETERS

STEP	SOLUTION	TEMPERATURE	TIME
Pre-cleaning	Water	<45°C	2 minutes
Cleaning	Water + Neutral enzymatic cleaner (as example NEODISHER Mediclean Forte)	55°C	10 minutes
Neutralizing	Water	<45°C	2 minutes
Rinsing	Tap water	<45°C	2 minutes
Thermal disinfection	Reversed osmosis water	90 °C	5 minutes

NOTE

NOTE

S P I N E A R T

SPINEART SA
CHEMIN DU PRÉ-FLEURI 3
1228 PLAN-LES-OUATES
SWITZERLAND

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