JULIET® Ti LL

LATERAL Ti CAGE

C O N T E N T

CONCEPT AND DESIGN

The JULIET® Lateral Lumbar System has been designed with surgeons in accordance with Spineart's philosophy: Quality, Innovation, Simplicity.

The JULIET®Ti LL platform consists of sterile-packed implants and streamlined instrumentation designed for the lateral, minimally invasive approach.

The JULIET®Ti LL interbody range is comprehensive to better address variable patient anatomy and surgeon preferences.

AT A GLANCE

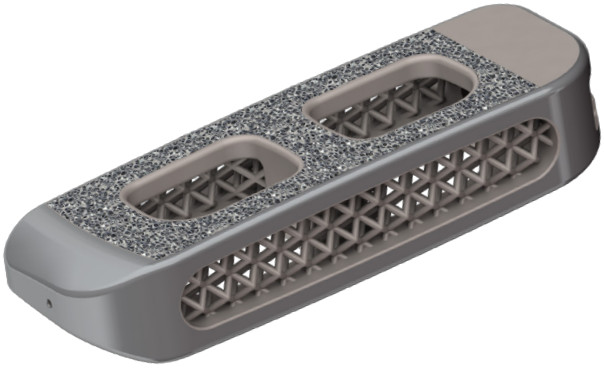
Ti-LIFE Technology
MIS Lateral Approach
Anatomical Shape
Optimal Visualization

INDICATIONS

JULIET® Ti LL Lumbar Interbody Device is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-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). The JULIET® Ti LL Lumbar Interbody Device 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.

Implants with 15 degree lordosis or greater are only indicated from levels L2-L5 and are to be used with at least two integrated fixation screws. The JULIET® Ti LL implants must be used with supplemental internal spinal fixation system that has been cleared by the FDA for use in the lumbosacral spine.

IMPLANTS



WIDTH : 17mm
LORDOSIS : 0°

HEIGHT	LENGTH	REFERENCE
H08	L40	JLT-S0 40 08-S
H10	L40	JLT-S0 40 10-S
H12	L40	JLT-S0 40 12-S
H14	L40	JLT-S0 40 14-S
H08	L45	JLT-S0 45 08-S
H10	L45	JLT-S0 45 10-S
H12	L45	JLT-S0 45 12-S
H14	L45	JLT-S0 45 14-S
H08	L50	JLT-S0 50 08-S
H10	L50	JLT-S0 50 10-S
H12	L50	JLT-S0 50 12-S
H14	L50	JLT-S0 50 14-S
H08	L55	JLT-S0 55 08-S
H10	L55	JLT-S0 55 10-S
H12	L55	JLT-S0 55 12-S
H14	L55	JLT-S0 55 14-S
H08	L60	JLT-S0 60 08-S
H10	L60	JLT-S0 60 10-S
H12	L60	JLT-S0 60 12-S
H14	L60	JLT-S0 60 14-S

WIDTH : 17mm
LORDOSIS : 8°

HEIGHT	LENGTH	REFERENCE
H08	L40	JLT-S8 40 08-S
H10	L40	JLT-S8 40 10-S
H12	L40	JLT-S8 40 12-S
H14	L40	JLT-S8 40 14-S
H08	L45	JLT-S8 45 08-S
H10	L45	JLT-S8 45 10-S
H12	L45	JLT-S8 45 12-S
H14	L45	JLT-S8 45 14-S
H08	L50	JLT-S8 50 08-S
H10	L50	JLT-S8 50 10-S
H12	L50	JLT-S8 50 12-S
H14	L50	JLT-S8 50 14-S
H08	L55	JLT-S8 55 08-S
H10	L55	JLT-S8 55 10-S
H12	L55	JLT-S8 55 12-S
H14	L55	JLT-S8 55 14-S
H08	L60	JLT-S8 60 08-S
H10	L60	JLT-S8 60 10-S
H12	L60	JLT-S8 60 12-S
H14	L60	JLT-S8 60 14-S

IMPLANTS

WIDTH : 21mm
LORDOSIS : 0°

HEIGHT	LENGTH	REFERENCE
H08	L40	JLT-M0 40 08-S
H10	L40	JLT-M0 40 10-S
H12	L40	JLT-M0 40 12-S
H14	L40	JLT-M0 40 14-S
H08	L45	JLT-M0 45 08-S
H10	L45	JLT-M0 45 10-S
H12	L45	JLT-M0 45 12-S
H14	L45	JLT-M0 45 14-S
H08	L50	JLT-M0 50 08-S
H10	L50	JLT-M0 50 10-S
H12	L50	JLT-M0 50 12-S
H14	L50	JLT-M0 50 14-S
H08	L55	JLT-M0 55 08-S
H10	L55	JLT-M0 55 10-S
H12	L55	JLT-M0 55 12-S
H14	L55	JLT-M0 55 14-S
H08	L60	JLT-M0 60 08-S
H10	L60	JLT-M0 60 10-S
H12	L60	JLT-M0 60 12-S
H14	L60	JLT-M0 60 14-S

WIDTH : 21mm
LORDOSIS : 8°

HEIGHT	LENGTH	REFERENCE
H08	L40	JLT-M8 40 08-S
H10	L40	JLT-M8 40 10-S
H12	L40	JLT-M8 40 12-S
H14	L40	JLT-M8 40 14-S
H08	L45	JLT-M8 45 08-S
H10	L45	JLT-M8 45 10-S
H12	L45	JLT-M8 45 12-S
H14	L45	JLT-M8 45 14-S
H08	L50	JLT-M8 50 08-S
H10	L50	JLT-M8 50 10-S
H12	L50	JLT-M8 50 12-S
H14	L50	JLT-M8 50 14-S
H08	L55	JLT-M8 55 08-S
H10	L55	JLT-M8 55 10-S
H12	L55	JLT-M8 55 12-S
H14	L55	JLT-M8 55 14-S
H08	L60	JLT-M8 60 08-S
H10	L60	JLT-M8 60 10-S
H12	L60	JLT-M8 60 12-S
H14	L60	JLT-M8 60 14-S

OPTIONAL IMPLANTS

HYPERLORDOTIC CAGES

WIDTH : 21 mm
LORDOSIS : 15°

HEIGHT	LENGTH	REFERENCE
H12	L40	JLT-MX 40 12-S
H14	L40	JLT-MX 40 14-S
H16	L40	JLT-MX 40 16-S
H18	L40	JLT-MX 40 18-S
H12	L45	JLT-MX 45 12-S
H14	L45	JLT-MX 45 14-S
H16	L45	JLT-MX 45 16-S
H18	L45	JLT-MX 45 18-S
H12	L50	JLT-MX 50 12-S
H14	L50	JLT-MX 50 14-S
H16	L50	JLT-MX 50 16-S
H18	L50	JLT-MX 50 18-S
H12	L55	JLT-MX 55 12-S
H14	L55	JLT-MX 55 14-S
H16	L55	JLT-MX 55 16-S
H18	L55	JLT-MX 55 18-S
H12	L60	JLT-MX 60 12-S
H14	L60	JLT-MX 60 14-S
H16	L60	JLT-MX 60 16-S
H18	L60	JLT-MX 60 18-S

WIDTH : 21 mm
LORDOSIS : 25°

HEIGHT	LENGTH	REFERENCE
H14	L40	JLT-MY 40 14-S
H16	L40	JLT-MY 40 16-S
H18	L40	JLT-MY 40 18-S
H20	L40	JLT-MY 40 20-S
H14	L45	JLT-MY 45 14-S
H16	L45	JLT-MY 45 16-S
H18	L45	JLT-MY 45 18-S
H20	L45	JLT-MY 45 20-S
H14	L50	JLT-MY 50 14-S
H16	L50	JLT-MY 50 16-S
H18	L50	JLT-MY 50 18-S
H20	L50	JLT-MY 50 20-S
H14	L55	JLT-MY 55 14-S
H16	L55	JLT-MY 55 16-S
H18	L55	JLT-MY 55 18-S
H20	L55	JLT-MY 55 20-S
H14	L60	JLT-MY 60 14-S
H16	L60	JLT-MY 60 16-S
H18	L60	JLT-MY 60 18-S
H20	L60	JLT-MY 60 20-S

OPTIONAL IMPLANTS

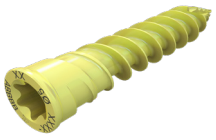
LATERAL PLATES

SMALL
2 HOLES
Width: 13 mm

LARGE
4 HOLES
Width: 17mm

	DESIGNATION	REFERENCE
SMALL	H08	JLT-PL 02 08-S
	H10	JLT-PL 02 10-S
	H12	JLT-PL 02 12-S
	H14	JLT-PL 02 14-S
	H16	JLT-PL 02 16-S
	H18	JLT-PL 02 18-S
	H20	JLT-PL 02 20-S
LARGE	H08	JLT-PL 04 08-S
	H10	JLT-PL 04 10-S
	H12	JLT-PL 04 12-S
	H14	JLT-PL 04 14-S
	H16	JLT-PL 04 16-S
	H18	JLT-PL 04 18-S
	H20	JLT-PL 04 20-S

BONE SCREWS



DIA. 5.0 mm

DIA. 5.5 mm

DIAMETER	LENGTH	REFERENCE
5.0	L35	SJT-LS 50 35-S
	L40	SJT-LS 50 40-S
	L45	SJT-LS 50 45-S
	L50	SJT-LS 50 50-S
	L55	SJT-LS 50 55-S
	L60	SJT-LS 50 60-S
5.5	L35	SJT-LS 55 35-S
	L40	SJT-LS 55 40-S
	L45	SJT-LS 55 45-S
	L50	SJT-LS 55 50-S
	L55	SJT-LS 55 55-S
	L60	SJT-LS 55 60-S

TECHNICAL FEATURES

MIS LATERAL APPROACH

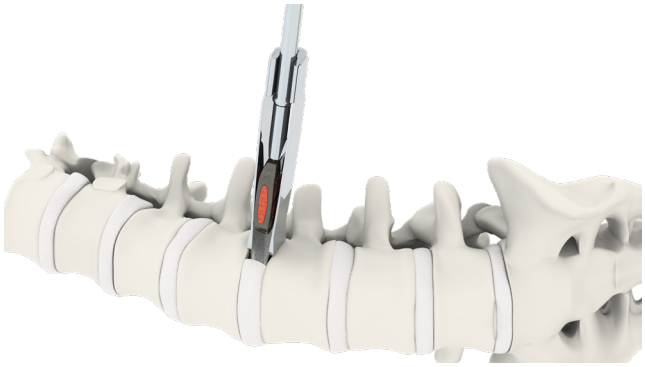
The retroperitoneal approach through a retractor minimizes soft tissue disruption and allows large footprint interbody placement for optimal endplate coverage. JULIET®Ti LL is made out of Titanium. It features the Ti-LIFE Technology, a porous, interconnected structure replicating the trabecular bone geometry.

JULIET®Ti LL IMPLANT

Anatomically shaped cages for optimal fit between endplates.
17 and 21mm widths.
0° & 8° of standard lordoses.
15° and 25° of optional lordoses.
Sterile packaged and barcoded implants.

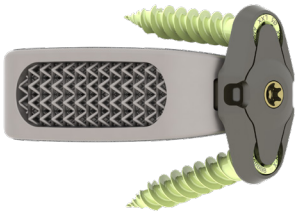
TECHNICAL FEATURES

INSTRUMENTS



Intuitive instruments housed in two compact sets.
Optional angled instrument set to accommodate anatomic challenges.
Optional plate and screws sets.
Straightforward instruments with working lengths
optimized for the lateral approach.

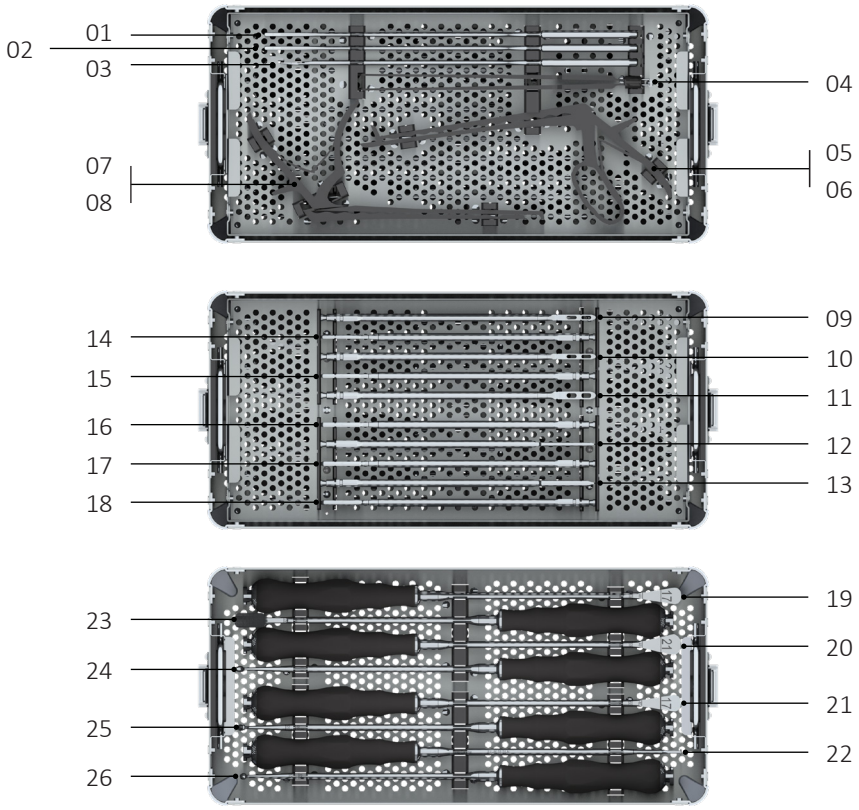
INTEGRATED FIXATION SYSTEM



Low-profile plate with 2 or 4-screw designs.
One-step locking mechanism with counter-plate : for screw back out prevention and minimal retractor exposure.
5.0 & 5.5mm screw diameter option.
Screw angulation limited by plate design.

INSTRUMENT SET

SET A - DISC PREPARATION INSTRUMENTS

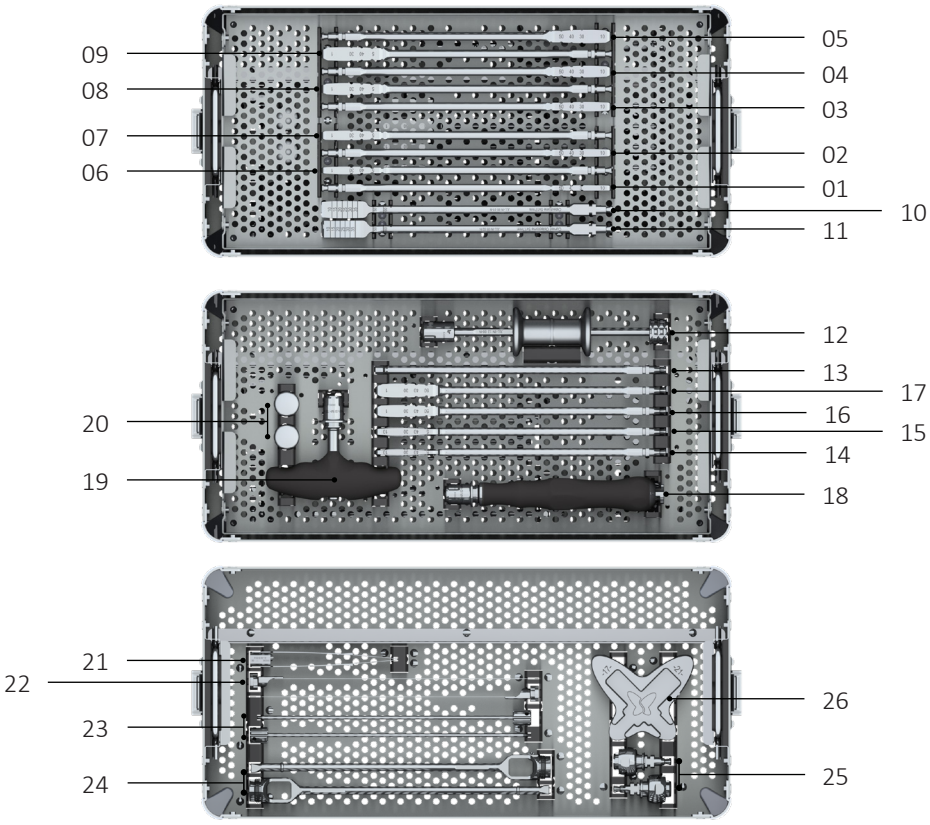


#	DESCRIPTION	REFERENCE
01	BAYONETED PENFIELD #4, TOE IN	JLL-IN 00 01-N
02	BAYONETED PENFIELD #4, TOE OUT	JLL-IN 00 02-N
03	BAYONETED BLADE HOLDER	JLL-IN 00 03-N
04	BIPOLAR FORCEPS WL10	S03-551NS
05	CLEAN WAVE RONGEUR WITH KERRISON RING HANDLE WL330 W4	18.23.24
06	CLEAN WAVE RONGEUR WITH KERRISON RING HANDLE WL330 W7	18.23.27
07	KERRISON WL330 W2	JLL-IN 14 02-N
08	KERRISON WL330 W5	JLL-IN 14 05-N
09	BOX CUTTER 4 X 17MM	JLL-IN 04 01-N
10	BOX CUTTER 6 X 17MM	JLL-IN 04 02-N
11	BOX CUTTER 8 X 17MM	JLL-IN 04 03-N
12	DISC DILATOR 4 X 17MM	JLL-IN 10 04-N
13	DISC DILATOR 6 X 17MM	JLL-IN 10 06-N

#	DESCRIPTION	REFERENCE
14	PADDLE DISTRACTOR H08	JLL-IN 08 08-N
15	PADDLE DISTRACTOR H10	JLL-IN 08 10-N
16	PADDLE DISTRACTOR H12	JLL-IN 08 12-N
17	PADDLE DISTRACTOR H14	JLL-IN 08 14-N
18	PADDLE DISTRACTOR H16	JLL-IN 08 16-N
19	FLAT COBB 17MM	JLL-IN 01 01-N
20	FLAT COBB 21MM	JLL-IN 01 03-N
21	FLAT COBB 10°	JLL-IN 01 02-N
22	RING CURETTE	JLL-IN 03 01-N
23	RASP	JLL-IN 02 01-N
24	CUP CURETTE STRAIGHT	JLL-IN 03 03-N
25	CUP CURETTE UP	JLL-IN 03 04-N
26	CUP CURETTE DOWN	JLL-IN 03 05-N
	BASE BOX A	JLL-BX 10 00-N

INSTRUMENT SET

SET B - TRIAL IMPLANT AND CAGE INSERTION INSTRUMENTS

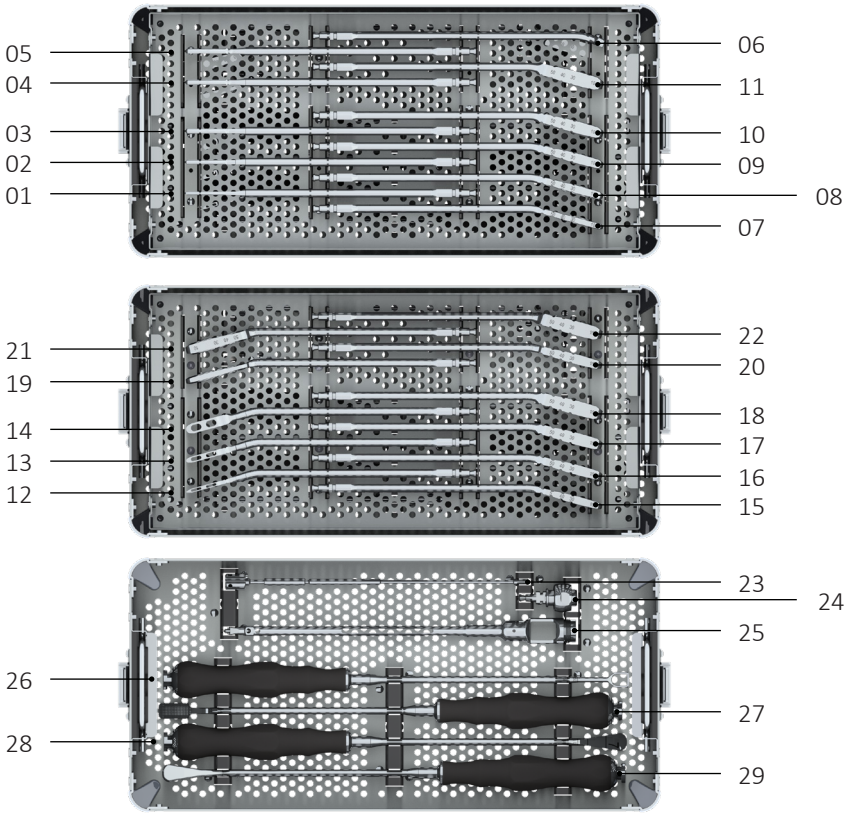


#	DESCRIPTION	REFERENCE
01	TRIAL 17MM H06 LORDOSIS 0°	JLL-IN 07 06-N
02	TRIAL 17MM H08 LORDOSIS 0°	JLL-IN 07 08-N
03	TRIAL 17MM H10 LORDOSIS 0°	JLL-IN 07 10-N
04	TRIAL 17MM H12 LORDOSIS 0°	JLL-IN 07 12-N
05	TRIAL 17MM H14 LORDOSIS 0°	JLL-IN 07 14-N
06	TRIAL 17MM H08 LORDOSIS 8°	JLL-IN 18 08-N
07	TRIAL 17MM H10 LORDOSIS 8°	JLL-IN 18 10-N
08	TRIAL 17MM H12 LORDOSIS 8°	JLL-IN 18 12-N
09	TRIAL 17MM H14 LORDOSIS 8°	JLL-IN 18 14-N
10	OSTEOTOME 5 X 17MM	JLL-IN 05 01-N
11	CURVED OSTEOTOME 5 X 17MM	JLL-IN 05 02-N
12	SLAP HAMMER	JLL-IN 12 00-N
13	STRAIGHT IMPACTOR	JLL-IN 11 01-N

#	DESCRIPTION	REFERENCE
14	TRIAL 21MM H08 LORDOSIS 8°	JLL-IN 28 08-N
15	TRIAL 21MM H10 LORDOSIS 8°	JLL-IN 28 10-N
16	TRIAL 21MM H12 LORDOSIS 8°	JLL-IN 28 12-N
17	TRIAL 21MM H14 LORDOSIS 8°	JLL-IN 28 14-N
18	STRAIGHT HANDLE	HAN-SI MH ST-N
19	T-HANDLE	HAN-SI MH TE-N
20	IMPACTION CAP	HAN-SS SH 02-N
21	IMPLANT DOUBLE SLIDE	JLL-IN 09 02-N
22	IMPLANT SINGLE SLIDE	JLL-IN 09 01-N
23 24 25	INSERTER	JLL-IN 07 01-N
26	COMPACTION BASE	JLL-IN 08 01-N
	BASE BOX B	JLL-BX 11 00-N

INSTRUMENT SET

SET C (OPTIONAL) - ANGLED INSTRUMENTS

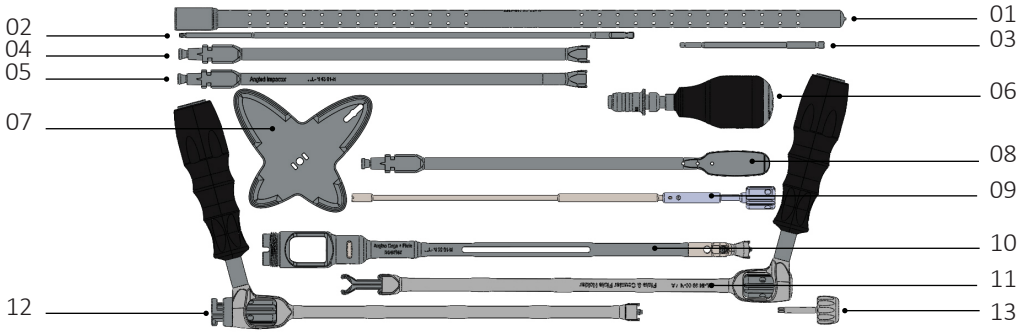


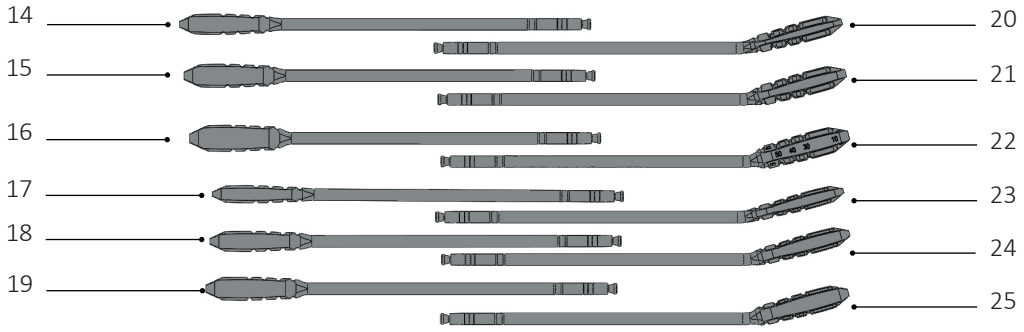
#	DESCRIPTION	REFERENCE
01	PADDLE SHAVER H08	JLL-IN 06 08-N
02	PADDLE SHAVER H10	JLL-IN 06 10-N
03	PADDLE SHAVER H12	JLL-IN 06 12-N
04	PADDLE SHAVER H14	JLL-IN 06 14-N
05	PADDLE SHAVER H16	JLL-IN 06 16-N
06	ANGULATED IMPACTOR	JLL-IN 11 02-N
07	ANGLED TRIAL 17MM H06 LORDOSIS 0°	JLL-IN 37 06-N
08	ANGLED TRIAL 17MM H08 LORDOSIS 0°	JLL-IN 37 08-N
09	ANGLED TRIAL 17MM H10 LORDOSIS 0°	JLL-IN 37 10-N
10	ANGLED TRIAL 17MM H12 LORDOSIS 0°	JLL-IN 37 12-N
11	ANGLED TRIAL 17MM H14 LORDOSIS 0°	JLL-IN 37 14-N
12	ANGLED BOX CUTTER 4X17MM	JLL-IN 04 04-N
13	ANGLED BOX CUTTER 6X17MM	JLL-IN 04 05-N
14	ANGLED BOX CUTTER 8X17MM	JLL-IN 04 06-N
15	ANGLED TRIAL 17MM H08 LORDOSIS 8°	JLL-IN 19 08-N

#	DESCRIPTION	REFERENCE
16	ANGLED TRIAL 17MM H10 LORDOSIS 8°	JLL-IN 19 10-N
17	ANGLED TRIAL 17MM H12 LORDOSIS 8°	JLL-IN 19 12-N
18	ANGLED TRIAL 17MM H14 LORDOSIS 8°	JLL-IN 19 14-N
19	ANGLED TRIAL 21MM H08 LORDOSIS 8°	JLL-IN 29 08-N
20	ANGLED TRIAL 21MM H10 LORDOSIS 8°	JLL-IN 29 10-N
21	ANGLED TRIAL 21MM H12 LORDOSIS 8°	JLL-IN 29 12-N
22	ANGLED TRIAL 21MM H14 LORDOSIS 8°	JLL-IN 29 14-N
23	ANGLED INSERTER	JLL-IN 07 02-N
26	ANGLED RING CURETTE	JLL-IN 03 02-N
27	ANGLED RASP	JLL-IN 02 02-N
28	UP ANGLE COBB 17MM	JLL-IN 01 04-N
29	DOWN ANGLE COBB 17MM	JLL-IN 01 05-N
	BASE BOX C	JLL-BX 12 00-N

INSTRUMENT SET

SET D (OPTIONAL) - HYPERLORDOTIC AND PLATE INSTRUMENTS



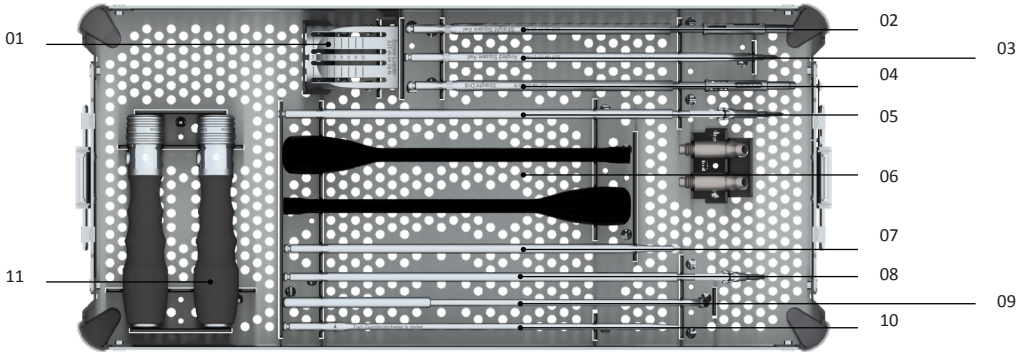


#	DESCRIPTION	REFERENCE
01	K-WIRE TUBE	MIS-IN 30 00-N
02	SCREWDRIVER T15	JLL-IN 40 00-N
03	SMALL SCREWDRIVER T15	JLL-IN 45 00-N
04	PUSHER	JLL-IN 43 00-N
05	ANGLED PUSHER	JLL-IN 43 01-N
06	1.3Nm HANDLE	HAN-SI DY 13-N
07	ASSEMBLY BASE	JLL-IN 44 00-N
08	PADDLE DISTRACTOR 18	JLL-IN 08 18-N
09	ANGLED INSERTER	JLL-IN 07 02-N
10	ANGLED CAGE + PLATE INSERTER	JLL-IN 38 01-N
11	PLATE + COUNTER PLATE HOLDER	JLL-IN 39 00-N
12	CAGE + PLATE INSERTER	JLL-IN 38 00-N
13	HEXAGONAL HANDLE	JLL-IN 42 00-N

#	DESCRIPTION	REFERENCE
14	TRIAL 21MM H14 LORDOSIS 25°	JLL-IN 25 14-N
15	TRIAL 21MM H16 LORDOSIS 25°	JLL-IN 25 16-N
16	TRIAL 21MM H18 LORDOSIS 25°	JLL-IN 25 18-N
17	TRIAL 21MM H12 LORDOSIS 15°	JLL-IN 15 12-N
18	TRIAL 21MM H14 LORDOSIS 15°	JLL-IN 15 14-N
19	TRIAL 21MM H16 LORDOSIS 15°	JLL-IN 15 16-N
20	ANGLED TRIAL 21MM H14 LORDOSIS 25°	JLL-IN 26 14-N
21	ANGLED TRIAL 21MM H16 LORDOSIS 25°	JLL-IN 26 16-N
22	ANGLED TRIAL 21MM H18 LORDOSIS 25°	JLL-IN 26 18-N
23	ANGLED TRIAL 21MM H12 LORDOSIS 15°	JLL-IN 16 12-N
24	ANGLED TRIAL 21MM H14 LORDOSIS 15°	JLL-IN 16 14-N
25	ANGLED TRIAL 21MM H16 LORDOSIS 15°	JLL-IN 16 16-N
	BASE BOX D	JLL-BX 13 00-N

INSTRUMENT SET

SCREW INSERTION INSTRUMENTS



#	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	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

DISSECTION

BAYONETED PENFIELD #4, TOE IN	JLL-IN 00 01-N
BAYONETED PENFIELD #4, TOE OUT	JLL-IN 00 02-N

BIPOLAR FORCEPS WL10	S03-551NS

BAYONETED BLADE HOLDER	JLL-IN 00 03-N

DISC SPACE PREPARATION

FLAT COBB 17mm	JLL-IN 01 01-N
FLAT COBB 21mm	JLL-IN 01 03-N
FLAT COBB 10°	JLL-IN 01 02-N

DISC DILATOR 4 x 17mm	JLL-IN 10 04-N
DISC DILATOR 6 x 17mm	JLL-IN 10 06-N

UP ANGLE COBB 17mm (OPTIONAL)	JLL-IN 01 04-N
DOWN ANGLE COBB 17mm (OPTIONAL)	JLL-IN 01 05-N

PADDLE DISTRACTOR H08	JLL-IN 08 08-N
PADDLE DISTRACTOR H10	JLL-IN 08 10-N
PADDLE DISTRACTOR H12	JLL-IN 08 12-N
PADDLE DISTRACTOR H14	JLL-IN 08 14-N
PADDLE DISTRACTOR H16	JLL-IN 08 16-N

PADDLE DISTRACTOR H18 (OPTIONAL)	JLL-IN 08 18-N

HANDLES

STRAIGHT HANDLE	HAN-SI MH ST-N

T-HANDLE	HAN-SI MH TE-N

INSTRUMENTS

DISCECTOMY

CLEAN WAVE RONGEUR WITH KERRISON RING HANDLE WL330 W4	18.23.24
CLEAN WAVE RONGEUR WITH KERRISON RING HANDLE WL330 W7	18.23.27

BOX CUTTER 4 x 17	JLL-IN 04 01-N
BOX CUTTER 6 x 17	JLL-IN 04 02-N
BOX CUTTER 8 x 17	JLL-IN 04 03-N

RING CURETTE	JLL-IN 03 01-N
CUP CURETTE STRAIGHT	JLL-IN 03 03-N
CUP CURETTE UP	JLL-IN 03 04-N
CUP CURETTE DOWN	JLL-IN 03 05-N

KERRISON WL330 W2	JLL-IN 14 02-N
KERRISON WL330 W5	JLL-IN 14 05-N

OSTEOTOME 5 x 17mm	JLL-IN 05 01-N
CURVED OSTEOTOME 5 x 17mm	JLL-IN 05 02-N

DISCECTOMY - OPTIONAL

ANGLED BOX CUTTER 4 x 17	JLL-IN 04 04-N
ANGLED BOX CUTTER 6 x 17	JLL-IN 04 05-N
ANGLED BOX CUTTER 8 x 17	JLL-IN 04 06-N

ANGLED RING CURETTE	JLL-IN 03 02-N

PADDLE SHAVER H08	JLL-IN 06 08-N
PADDLE SHAVER H10	JLL-IN 06 10-N
PADDLE SHAVER H12	JLL-IN 06 12-N
PADDLE SHAVER H14	JLL-IN 06 14-N
PADDLE SHAVER H16	JLL-IN 06 16-N

INSTRUMENTS

END PLATE PREPARATION

RASP	JLL-IN 02 01-N

ANGLED RASP (OPTIONAL)	JLL-IN 02 02-N

TRIAL IMPLANTS

TRIAL 17mm H08 Lordosis 8°	JLL-IN 18 08-N
TRIAL 17mm H10 Lordosis 8°	JLL-IN 18 10-N
TRIAL 17mm H12 Lordosis 8°	JLL-IN 18 12-N
TRIAL 17mm H14 Lordosis 8°	JLL-IN 18 14-N

TRIAL 21mm H08 Lordosis 8°	JLL-IN 28 08-N
TRIAL 21mm H10 Lordosis 8°	JLL-IN 28 10-N
TRIAL 21mm H12 Lordosis 8°	JLL-IN 28 12-N
TRIAL 21mm H14 Lordosis 8°	JLL-IN 28 14-N

TRIAL 17mm H06 Lordosis 0°	JLL-IN 07 06-N
TRIAL 17mm H08 Lordosis 0°	JLL-IN 07 08-N
TRIAL 17mm H10 Lordosis 0°	JLL-IN 07 10-N
TRIAL 17mm H12 Lordosis 0°	JLL-IN 07 12-N
TRIAL 17mm H14 Lordosis 0°	JLL-IN 07 14-N

INSTRUMENTS OPTIONAL

ANGLED TRIAL IMPLANTS

ANGLED TRIAL 17mm H06 Lordosis 0°	JLL-IN 37 06-N
ANGLED TRIAL 17mm H08 Lordosis 0°	JLL-IN 37 08-N
ANGLED TRIAL 17mm H10 Lordosis 0°	JLL-IN 37 10-N
ANGLED TRIAL 17mm H12 Lordosis 0°	JLL-IN 37 12-N
ANGLED TRIAL 17mm H14 Lordosis 0°	JLL-IN 37 14-N

ANGLED TRIAL 17mm H08 Lordosis 8°	JLL-IN 19 08-N
ANGLED TRIAL 17mm H10 Lordosis 8°	JLL-IN 19 10-N
ANGLED TRIAL 17mm H12 Lordosis 8°	JLL-IN 19 12-N
ANGLED TRIAL 17mm H14 Lordosis 8°	JLL-IN 19 14-N

ANGLED TRIAL 21mm H08 Lordosis 8°	JLL-IN 29 08-N
ANGLED TRIAL 21mm H10 Lordosis 8°	JLL-IN 29 10-N
ANGLED TRIAL 21mm H12 Lordosis 8°	JLL-IN 29 12-N
ANGLED TRIAL 21mm H14 Lordosis 8°	JLL-IN 29 14-N

HYPERLORDOTIC TRIAL IMPLANTS

TRIAL 21mm H12 Lordosis 15°	JLL-IN 15 12-N
TRIAL 21mm H14 Lordosis 15°	JLL-IN 15 14-N
TRIAL 21mm H16 Lordosis 15°	JLL-IN 15 16-N

TRIAL 21mm H14 Lordosis 25°	JLL-IN 25 14-N
TRIAL 21mm H16 Lordosis 25°	JLL-IN 25 16-N
TRIAL 21mm H18 Lordosis 25°	JLL-IN 25 18-N

ANGLED TRIAL 21mm H12 Lordosis 15°	JLL-IN 16 12-N
ANGLED TRIAL 21mm H14 Lordosis 15°	JLL-IN 16 14-N
ANGLED TRIAL 21mm H16 Lordosis 15°	JLL-IN 16 16-N

ANGLED TRIAL 21mm H14 Lordosis 25°	JLL-IN 26 14-N
ANGLED TRIAL 21mm H16 Lordosis 25°	JLL-IN 26 16-N
ANGLED TRIAL 21mm H18 Lordosis 25°	JLL-IN 26 18-N

INSTRUMENTS

IMPLANT INSERTION

INSERTER	JLL-IN 07 01-N

COMPACTION BASE	JLL-IN 08 01-N

IMPLANT SINGLE SLIDE	JLL-IN 09 01-N
IMPLANT DOUBLE SLIDE	JLL-IN 09 02-N

IMPACTION CAP	HAN-SS SH 02-N

SLAP HAMMER	JLL-IN 12 00-N

STRAIGHT IMPACTOR	JLL-IN 11 01-N

ANGLED INSERTER (OPTIONAL)	JLL-IN 07 02-N

ANGULATED IMPACTOR (OPTIONAL)	JLL-IN 11 02-N

INSTRUMENTS OPTIONAL

PLATE INSERTION

CAGE + PLATE INSERTER	JLL-IN 38 00-N
ANGLED CAGE + PLATE INSERTER	JLL-IN 38 01-N

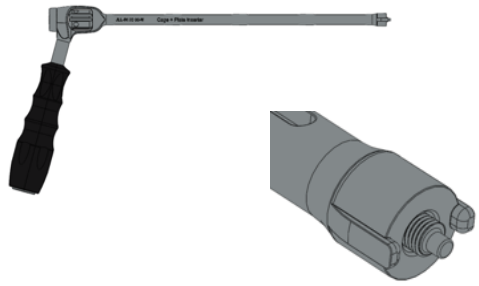
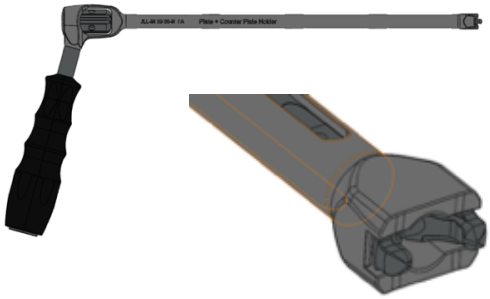


PLATE & COUNTER PLATE HOLDER	JLL-IN 39 00-N



K-WIRE	JLL-IN 41 00-N

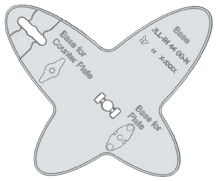
SCREWDRIVER T15	JLL-IN 40 00-N
SMALL SCREWDRIVER T15	JLL-IN 45 00-N

HEXAGONAL HANDLE	JLL-IN 42 00-N

PUSHER	JLL-IN 43 00-N
ANGLED PUSHER	JLL-IN 43 01-N

1.3Nm HANDLE	HAN-SI DY 13-N

ASSEMBLY BASE	JLL-IN 44 00-N

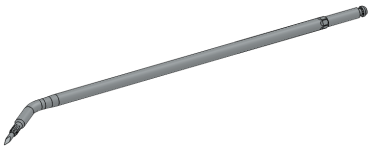


INSTRUMENTS OPTIONAL

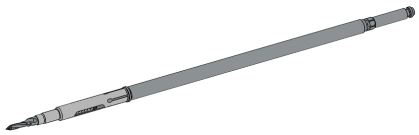
SCREW INSERTION

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

STRAIGHT HANDLE RATCHET	HAN-SI RA ST-N

U-JOINT SCREWDRIVER	SJT-IN 03 01-N

SCREW LOADER	SJT-IN 04 00-N

U-JOINT GUIDE	SJT-IN 05 00-N

UNIVERSAL-JOINT TUBE	SJT-IN 06 00-N

REVISION SCREWDRIVER	SJT-IN 03 02-N

INSTRUMENTS
OPTIONAL

15º/25º CAGE INSERTION

ALL PROTECTOR- CURVED 10MM X 90MM	SPE-US 01 15-N

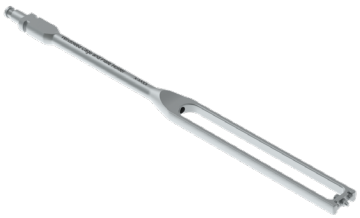
RING GUIDE	SPE-US 01 08-N

U-JOINT DRIVER, T15	SPE-US 00 80-N

15º ELBOW	SPE-US 00 89-N

ALL PROTECTOR- CURVED 16MM X 90MM	SPE-US 01 16-N

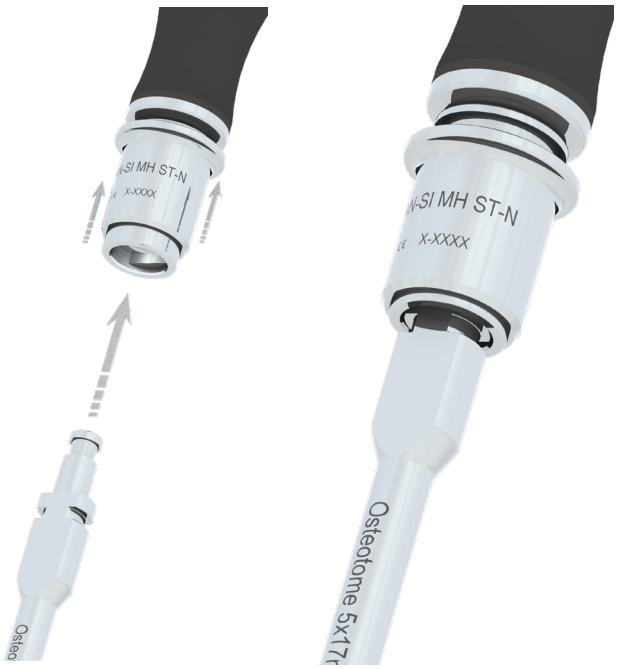
WINDOWED CAGE INSERTER	SPE-US 00 92-N



15º ANGLED AWL	SPE-US 00 90-N

SHORT TIP T20 U-JOINT SCREWDRIVER	SPE-US 00 91-N

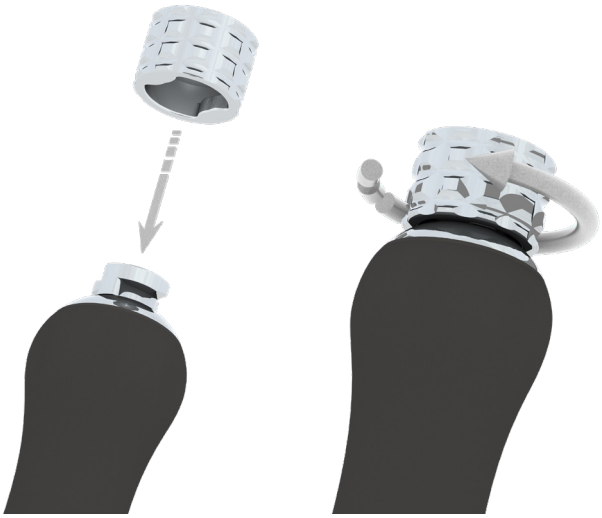
INSTRUMENT ASSEMBLY



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	HAN-SI MH ST-N
T-HANDLE	HAN-SI MH TE-N



PROTECTION CAP ATTACHMENT

The **Impactor Cap** is placed on instruments with handles to provide an impaction surface and protect the Slap Hammer attachment feature. Align and insert the proximal end of the handle into the Protection Cap recess. Rotate the **Impactor Cap** clockwise 90°.

INSTRUMENT	REFERENCE
IMPACTOR CAP	HAN-SS SH 02-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 90º.

HANDLE CONNECTION
Align and insert the proximal end of the straight handle into the **Slap Hammer** recess. Rotate the **Slap Hammer** shaft clockwise 90°.

INSTRUMENT	REFERENCE
SLAP HAMMER	JLL-IN 12 00-N

INSERTER ASSEMBLY

Insert the Inner Shaft of the **Inserter** into the Outer Shaft. Align the Handle Adaptor onto the Outer Shaft and turn clockwise to secure the assembly.

NOTE: When assembling the **Angled Inserter**, push the button on the outer shaft and insert the inner shaft.

INSTRUMENT	REFERENCE
INSERTER	JLL-IN 07 01-N
ANGLED INSERTER (OPTIONAL)	JLL-IN 07 02-N
ANGLED CAGE + PLATE INSERTER (OPTIONAL)	JLL-IN 38 01-N

INSTRUMENT ASSEMBLY

_WARNINGS AND PRECAUTIONS

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

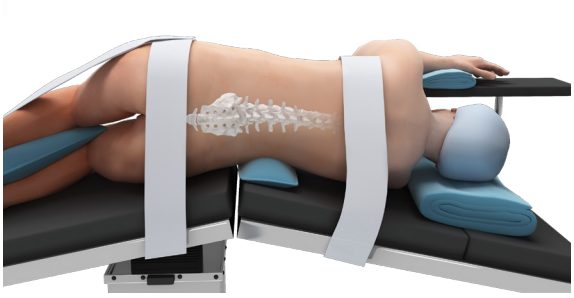
The surgeon is responsible for familiarizing him/herself with the surgical technique used for implanting these devices by studying the relevant published articles, consulting experienced colleagues, and receiving training in the methods appropriate to the particular implant being used.

It is strongly recommended to avoid excessive force when implanting any JULIET®Ti LL implants.

⚠ **WARNING: Spineart strongly recommends the use of neuromonitoring throughout the entire procedure. The lumbar plexus is a complex neural network and the visualization of the roots is difficult during lateral surgeries. A neural lesion could happen, especially during transpsoas dissection.**

SURGICAL TECHNIQUE

_STEP 1



PATIENT POSITIONING

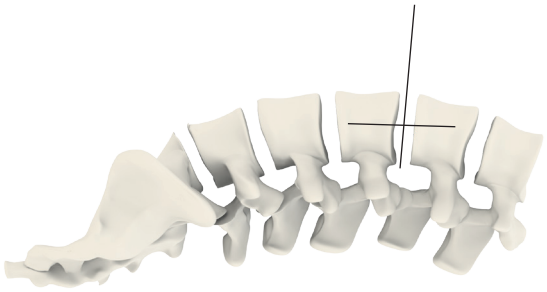
The patient is positioned on the table in the right lateral decubitus position as shown in the image.

A pillow or a gel bump may be placed between the legs to further relax the psoas muscle.

The patient is securely fastened to the surgical table using surgical tape at the axilla and pelvis.

Break the table at the level of the femoral head if needed. This may distance the ribs from the iliac crest, easing access to the disc.

_STEP 2



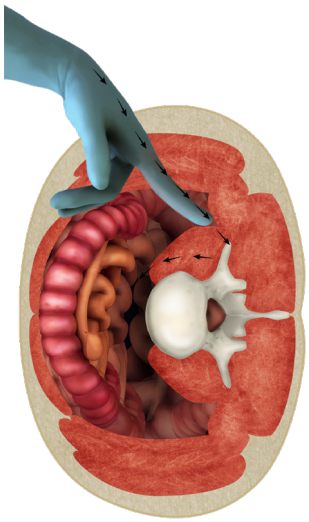
TARGET THE LEVEL TO BE TREATED

Once the patient is correctly positioned, an A/P and Lateral fluoroscopic image should be taken to allow clear visualization of the level to be treated.

Draw the skin landmarks for the incision.

NOTE: Matching the lordotic angle to the C-arm ensures optimal cage insertion and height assessment.

_STEP 3



DISSECTION

A skin incision is made corresponding to the level to be treated.

Blunt tissue dissection through the subcutaneous tissue allows visualization of oblique muscles.

Muscle fibers are bluntly dissected and separated posteriorly, aiming for the transverse process.

This allows access to the retroperitoneal space.

This allows access to the retroperitoneal space. The finger can be further advanced to the top of the psoas muscle, as shown in the image. Dissection of the psoas must be realized with neuro-surveillance though blunt dissection or using tubular dilators.

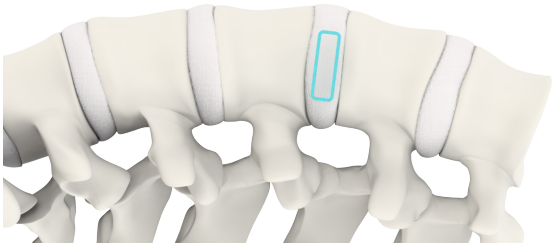
The underlying disk space is exposed.

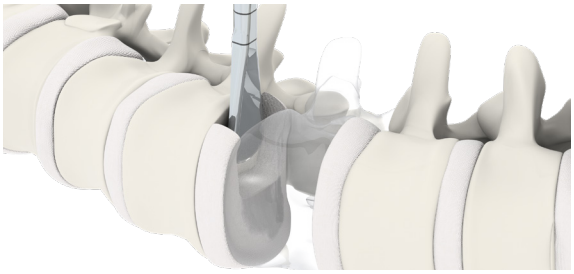
Once the disk level confirmed by fluoroscopy a self retaiing retractor is placed to maintain exposure.

⚠**WARNING**: Spineart strongly recommends the use of neuromonitoring throughout the entire procedure. Nerve roots are to be avoided, preventing accidental injury.

SURGICAL TECHNIQUE

_STEP 4

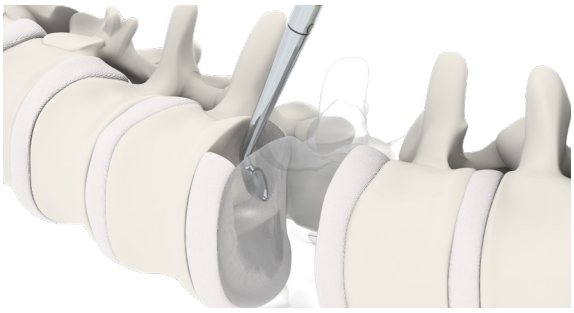




DISC SPACE PREPARATION

Create a rectangular incision in the annulus using the **Bayoneted Blade Holder**.
A **Cobb** can be used to release the contralateral annulus and loosen disc material from endplates. A disc dilator can be used to open a collapsed disc.

INSTRUMENT	REFERENCE
BAYONETED BLADE HOLDER	JLL-IN 00 03-N
FLAT COBB 17mm, 21mm, 10º UP	JLL-IN 01 0X-N
PADDLE DISTRACTORS H08-H16	JLL-IN 08 XX-N
DISC DILATOR 17mm x 4, 6mm	JLL-IN 10 0X-N
T-HANDLE	HAN-SI MH TE-N
PADDLE DISTRACTORS H18 (OPTIONAL)	JLL-IN 08 18-N

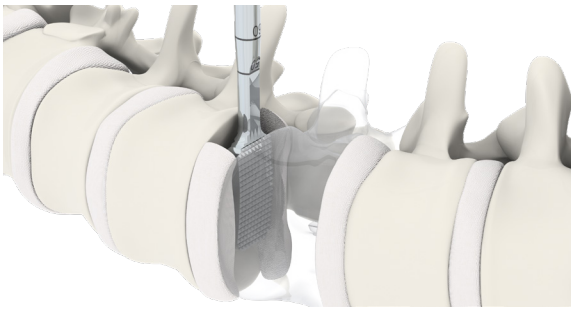


DISCECTOMY

Disc material is removed using various instruments: pituitary **Rongeurs**, **Kerrisons**, **Curettes**, Box Cutters, or **Osteotomes**.

INSTRUMENT	REFERENCE
CLEAN WAVE RONGEUR WITH KERRISON RING HANDLE WL330 W4/W7	18.23.24 / 18.23.27
KERRISON WL330 W2 / W5	JLL-IN 14 02-N/ JLL-IN 14 05-N
RING CURETTE	JLL-IN 03 01-N
CUP CURETTES: STRAIGHT, UP, DOWN	JLL-IN 03 0X-N
BOX CUTTERS 17 x 4, 6, 8mm	JLL-IN 04 0X-N
OSTEOTOME 5 x 17mm	JLL-IN 05 01-N
CURVED OSTEOTOME 5 x 17mm	JLL-IN 05 02-N
T-HANDLE	HAN-SI MH TE-N
PADDLE SHAVERS H08-H16 (OPTIONAL)	JLL-IN 06 XX-N

_STEP 4 BIS

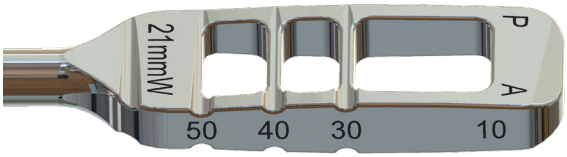


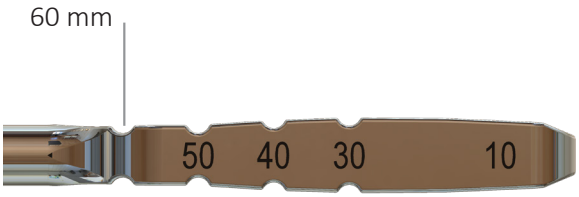
END PLATE PREPARATION

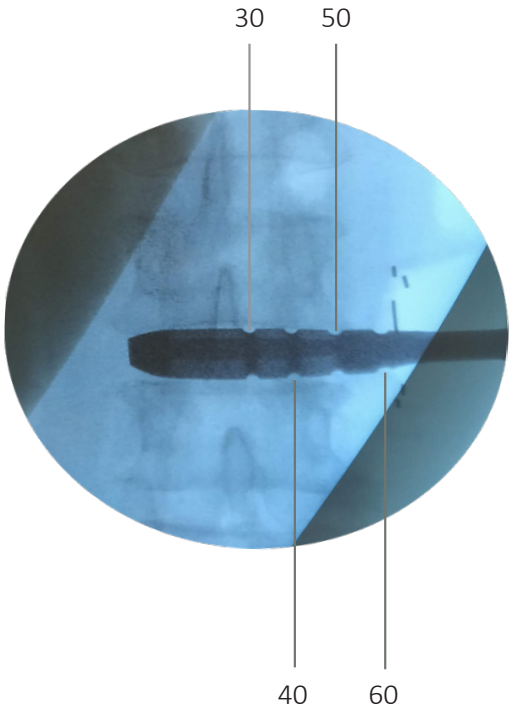
The **Rasp** is used to expose subchondral bone.
If access to the disc space is challenging to reach due to the iliac crest, angled instruments are optionally available.

INSTRUMENT	REFERENCE
RASP	JLL-IN 02 01-N
ANGLED RASP (OPTIONAL)	JLL-IN 02 02-N

_STEP 5







IMPLANT SELECTION (1/2)

Implant **Trials** help determine the appropriate cage width, length, height and lordotic angle. Notches on each trial indicate length inserted in the disc space.

NOTE: Notches are placed 30mm, 40mm, 50mm & 60mm from the tip of the trial, and are visible on AP fluoroscopy to ease the identification of the length required.

The shortest **Trial** height should be inserted first.

Connect the **Trial** to the T-Handle or Straight Handle.

Under AP fluoroscopy, the **Trial** is gently impacted into the disc space until centered to determine the desired implant size.

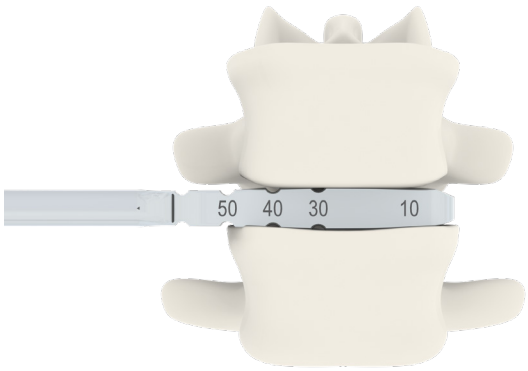
When satisfying position is obtained, the **Trial** can be removed, with the help of the **Slap Hammer** if needed.

The **Slap Hammer** can be connected to the **Trial** shaft or the **Straight Handle** for **Trial** removal.

INSTRUMENT	REFERENCE
TRIAL 17mm H08 - H14 LORDOSIS 8°	JLL-IN 18 XX-N
TRIAL 17mm H06 - H14 LORDOSIS 0°	JLL-IN 07 XX-N
TRIAL 21mm H08 - H14 LORDOSIS 8°	JLL-IN 28 XX-N
STRAIGHT HANDLE	HAN-SI MH ST-N
T-HANDLE	HAN-SI MH TE-N
SLAP HAMMER	JLL-IN 12 00-N
ANGLED TRIAL 17mm H08 - H14 LORDOSIS 8° (OPTIONAL)	JLL-IN 19 XX-N
ANGLED TRIAL 21mm H08 - H14 LORDOSIS 8° (OPTIONAL)	JLL-IN 29 XX-N
ANGLED TRIAL 17mm H08 - H14 LORDOSIS 0° (OPTIONAL)	JLL-IN 37 XX-N
TRIAL 21mm H14 - H18 LORDOSIS 25° (OPTIONAL)	JLL-IN 25 XX-N
TRIAL 21mm H12 - H16 LORDOSIS 15° (OPTIONAL)	JLL-IN 15 XX-N
ANGLED TRIAL 21mm H14 - H18 LORDOSIS 25° (OPTIONAL)	JLL-IN 26 XX-N
ANGLED TRIAL 21mm H12 - H16 LORDOSIS 15° (OPTIONAL)	JLL-IN 16 XX-N

_STEP 5

IMPLANT SELECTION (2/2)



Trial heights are progressively increased until a snug fit within the disc space. The implant height will correspond to the last trial size used.

Confirm correct placement of the trial using fluoroscopy.

NOTE: maximum endplate coverage and cage placement parallel to both anterior and posterior vertebral walls is necessary for mechanical stability. AP view: select a trial/cage that rests on the cortical ring of the endplates; Lateral view: ensure the cage is not rotated and select a trial/cage lordosis that maximizes endplate contact.

SURGICAL TECHNIQUE

_DIFFERENT METHODS FOR DIFFERENT ANATOMIES

The JULIET®Ti LL system versatility allows several surgical technique options.

For 0° and 8° cages (standard range):

Cage with supplemental fixation (Fig.A) :

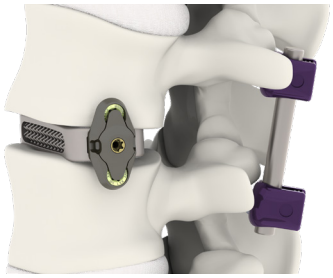
- Cage 0° or 8°.
- Supplemental fixation, e.g. ROMEO®2 posterior fixation.

Fig. A

Cage with integrated fixation (lateral plate) and supplemental fixation (Fig. B):

- Cage 0° or 8°.
- Lateral plate with integrated bone screws.
- Supplemental fixation, e.g. ROMEO®2 posterior fixation.

Fig. B

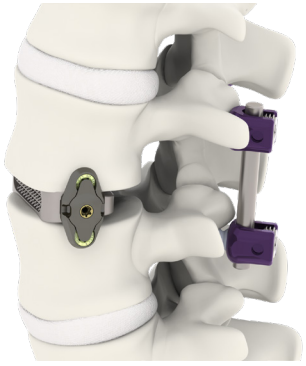


For 15° and 25° cages (optional range):

Cage with MANDATORY integrated fixation (lateral plate) and supplemental fixation (Fig C):

- Cage 15° or 25°.
- Lateral plate with integrated bone screws.
- Supplemental fixation, e.g. ROMEO®2 posterior fixation.

Fig. C



The cage can be inserted prior to the assembly with the plate or either with the plate pre-assembled. Both techniques are described in the following steps.

- **Cage insertion** is described on Step 6 to Step 8.
- **Plate insertion** is described on Step 9.
- **Cage + plate pre-assembled** insertion is described on Step 6A to Step 7A.
- **Screw insertion** is described on Step 10
- **Counter plate insertion** is described on Step 11

_STEP 6

CAGE ATTACHMENT ON IMPLANT HOLDER

To connect the selected cage to the **Inserter**, ensure the posterior side of the implant is aligned with the Outer Shaft marked “P” (posterior).

NOTE: The distal end of the implant is curved to ease the insertion between the endplates and the height of the implant is indicated on its anterior surface.

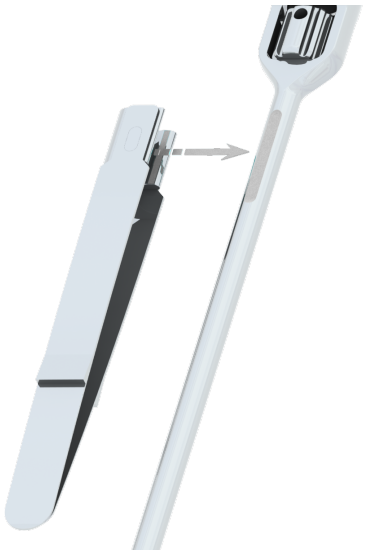
Align the **Inserter** tip tabs with the recess on the implant. Advance and rotate the **Inserter** knob clockwise to engage and secure the cage.

Attach the **T-Handle** or **Straight Handle**, (place an **Impactor Cap** onto the proximal end).

INSTRUMENT	REFERENCE
INSERTER	JLL-IN 07 01-N
STRAIGHT HANDLE	HAN-SI MH ST-N
T-HANDLE	HAN-SI MH TE-N
IMPACTOR CAP	HAN-SS SH 02-N
ANGLED INSERTER (OPTIONAL)	JLL-IN 07 02-N

_STEP 7

CAGE INSERTION



Place the cage into the respective slot on the **Compaction Base** to aid the placement of autograft material.

INSTRUMENT	REFERENCE
COMPACTION BASE	JLL-IN 08 01-N

The **Implant Slides** can be used to ease the insertion of the implant and ensure the retention of the bone graft in the cage.
To attach the **Double Slide** to the Inserter, mate the **Double Slide** opening to the flat portion of the Inserter and push inward.

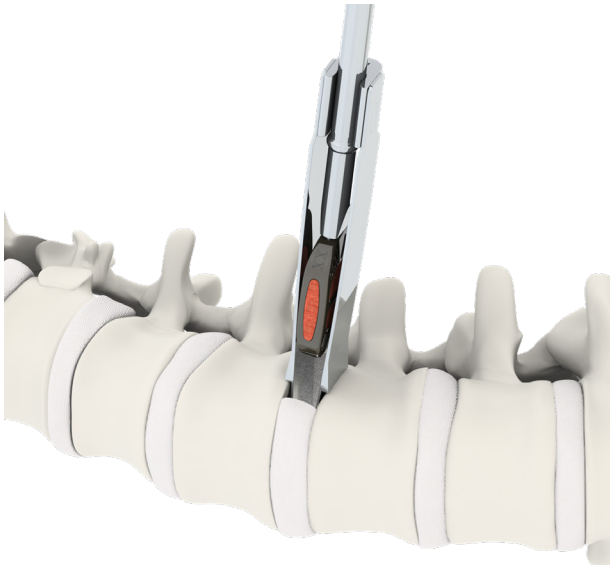
To attach the **Double Slide** to the Inserter, mate the **Double Slide** opening to the flat portion of the Inserter and push inward.

2 **Single Slides** or the **Double Slide** are placed in the disc space and held in place.

NOTE: The **Implant Double Slide** can not be used with the **Angled Inserter**.

INSTRUMENT	REFERENCE
IMPLANT SINGLE SLIDE	JLL-IN 09 01-N
IMPLANT DOUBLE SLIDE	JLL-IN 09 02-N

SURGICAL TECHNIQUE



Advance the cage into the disc space by impacting the Impactor Cap or T-Handle with a mallet.

Ensure correct orientation and monitor position using fluoroscopic images.

To separate the **Inserter** from the cage, rotate the **Inserter** knob counterclockwise.

NOTE: The **Double Slide** is removed along with the Inserter. **Single Slides** can be attached to the **Slap Hammer** and removed.

INSTRUMENT	REFERENCE
INSERTER	JLL-IN 07 01-N
SLAP HAMMER	JLL-IN 12 00-N
ANGLED INSERTER (OPTIONAL)	JLL-IN 07 02-N

_STEP 8

CAGE POSITIONING

If needed, a **Straight Impactor** can be used to complete the lateral positioning of the implant.

INSTRUMENT	REFERENCE
STRAIGHT IMPACTOR	JLL-IN 11 01-N
STRAIGHT HANDLE	HAN-SI MH ST-N
T-HANDLE	HAN-SI MH TE-N
ANGULATED IMPACTOR (OPTIONAL)	JLL-IN 11 02-N

At this point, the surgeon must decide whether to use the 0° and 8° lordosis JULIET®Ti LL interbody device with or without the integrated fixation (ie. plate + screw fixation).

Hyperlordotic implants (15°) or greater are to be used with the plate and the associated screws.

CAUTION: In case the cage is stabilized with the plate, a special care should be taken during cage insertion. The implant should be inserted progressively under fluoroscopic control to enable the good affixation of the plate on the lateral wall of the vertebrea and to ease its fixation.

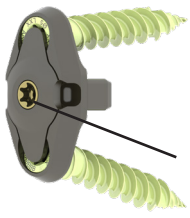
⚠**WARNING**: The JULIET®Ti LL Interbody Devices are to be used with supplemental fixation, such as ROMEO®2 Pedicle screw system.

PLATE

Plate screw: secures the plate to the cage

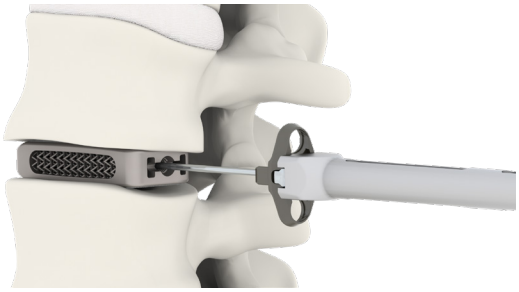
COUNTER PLATE

FINAL ASSEMBLY



Counter plate set screw: secures the counter plate to the plate

_STEP 9



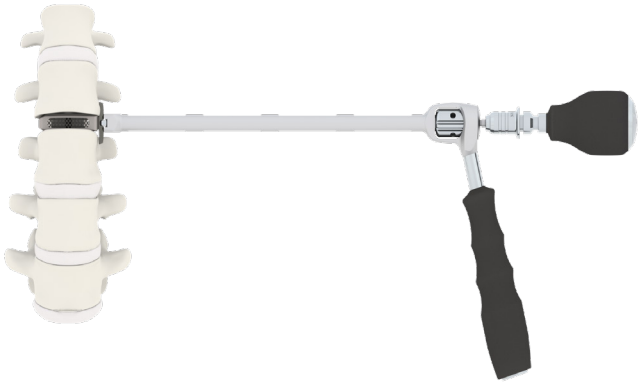


PLATE POSITIONING

OPTION A: ADDING ADDITIONAL FIXATION IF CAGE IS ALREADY IN PLACE

Place the **Plate** into the respective slot on the Assembly Base.

Tighten the **Plate & Counter Plate Holder** to the **Plate**.

Insert the **K-Wire** through the center of the cage.

Place the **Plate** over the **K-Wire** down into cage.

Remove the **K-Wire**, while the inserter stays in place.

The **Plate** screw pre-assembled in the center of the **Plate** should be tightened to the cage.

Assemble the **1.3Nm Handle** and **Screwdriver T15**. Pass the **Screwdriver** into the inserter.

Thread the **Plate** screw into the cage and tighten until it clicks.

Remove the inserter.

Use the Impactor to advance the implant until the **Plate** is in contact with the vertebral body.

Confirm correct positioning using fluoroscopy.

INSTRUMENT	REFERENCE
PLATE & COUNTER PLATE HOLDER	JLL-IN 39 00-N
1.3 Nm HANDLE	HAN-SI DY 13-N
SCREWDRIVER T15	JLL-IN 40 00-N
K-WIRE	JLL-IN 41 00-N
PUSHER	JLL-IN 43 00-N
ANGLED PUSHER (OPTIONAL)	JLL-IN 43 01-N
U-JOINT DRIVER, T15	SPE-US 00 80-N

SURGICAL TECHNIQUE

_STEP 10

CAGE + PLATE ASSEMBLY

OPTION B: INSERTION OF THE CAGE + PLATE ASSEMBLY

Before assembling the plate to the cage, place the cage into the respective slot on the compaction base and fill in the autograft material.

Assemble the device by selecting the appropriate size cage and the corresponding plate. Plate options include 2- and 4-hole plate configurations as determined by the patient's fixation needs.

Assemble the plate and cage using the **Small Screwdriver T15** and **1.3 Nm Handle** until it clicks.

NOTE: The cages are to be used with the corresponding plate or higher plate. Cage height is also laser marked on the plate.

Example: A H12 cage can be stabilized by a H12 plate or superior to H12.

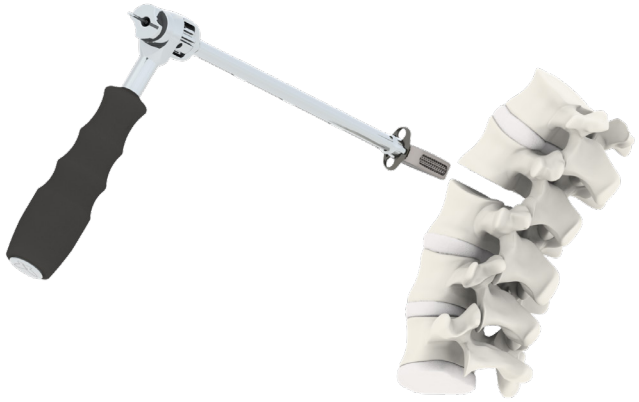
See corresponding table below.

INSTRUMENT	REFERENCE
SMALL SCREWDRIVER T15	JLL-IN 45 00-N
1.3Nm HANDLE	HAN-SI DY 13-N
COMPACTION BASE	JLL-IN 08 01-N

	CORRESPONDING PLATE TO USE						
CAGE HEIGHT	H08	H10	H12	H14	H16	H18	H20
H08	✔	✔	✔	✔	✔	✔	✔
H10		✔	✔	✔	✔	✔	✔
H12			✔	✔	✔	✔	✔
H14				✔	✔	✔	✔
H16					✔	✔	✔
H18						✔	✔
H20							✔

_STEP 11

CAGE + PLATE POSITIONING



Attach the **Cage + Plate Inserter** to the implant assembly by threading the inner shaft into the center of the plate.

Impact the implant assembly into the disc space until the plate is in contact with the vertebral body.

Confirm correct position using fluoroscopy.

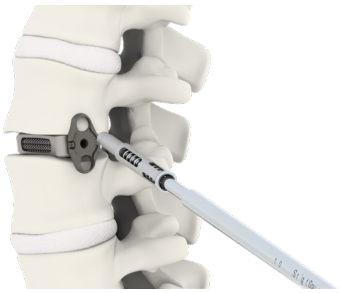
Adjust with the Impactor as necessary.

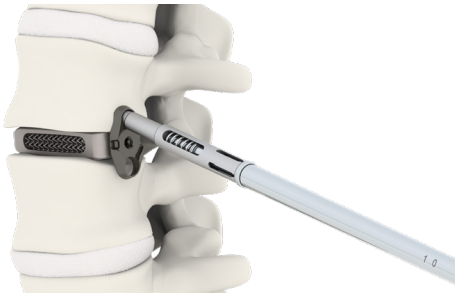
Remove the **Cage + Plate inserter**.

INSTRUMENT	REFERENCE
CAGE + PLATE INSERTER	JLL-IN 38 00-N
PUSHER	JLL-IN 43 00-N
ANGLED CAGE + PLATE INSERTER (OPTIONAL)	JLL-IN 38 01-N
ANGLED PUSHER (OPTIONAL)	JLL-IN 43 01-N
WINDOWED CAGE INSERTER	SPE-US 00 92-N

_STEP 12

SCREW INSERTION





NOTE: The **Drills** and **Square Awls** are available in both **Straight** and **Angled** configurations.

Assemble the appropriate combination of the **Drill** or **Square Awl** and the **Straight Handle Ratchet**.
Prepare the entry point of the screw with the **Square Awl**.

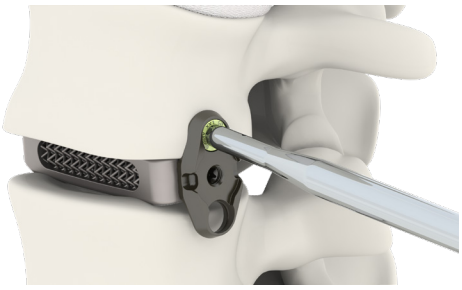
If needed, use the **Straight Drill** to complete the preparation.

NOTE: Both **Drills** and **Square Awls** tips measure 25mm. This helps estimating the final screw length using fluoroscopy.

Prepare the remaining screw holes using the same technique.

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	SJT-IN 06 00-N
U-JOINT GUIDE	SJT-IN 05 00-N
STRAIGHT HANDLE RATCHET	HAN-SI RA ST-N
15º ANGLED AWL	SPE-US 00 90-N
15º ELBOW	SPE-US 00 89-N
U-JOINT GUIDE, 15º ANGLE	SJT-IN 05 00-N

SURGICAL TECHNIQUE



Load the screw in the **Screw Loader**.

NOTE: It facilitates the connection between the screw and the self retaining **Screwdriver**. It also provides the length of the screw.

Assemble the selected **Screwdriver** to the handle.
Advance the screw into the vertebral body through appropriate screw hole in the plate.

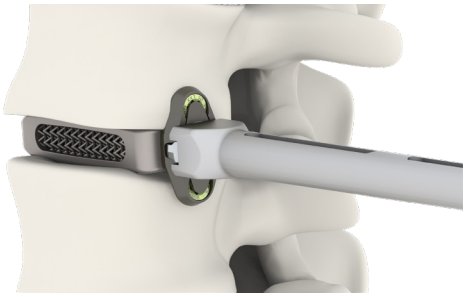
Use fluoroscopy to ensure appropriate screw placement.
Insert the other screw.

⚠**WARNING :** To avoid interference, plate screw placement should be considered when supplemental fixation are to be used.

INSTRUMENT	REFERENCE
SCREW LOADER	SJT-IN 04 00-N
STRAIGHT SCREWDRIVER	SJT-IN 03 00-N
U-JOINT SCREWDRIVER	SJT-IN 03 01-N
SHORT TIP T20 U-JOINT SCREWDRIVER	SPE-US 00 91-N

_STEP 13

COUNTER PLATE ASSEMBLY



Place the **Counter Plate** into the respective slot on the **Assembly Base**.

Assemble the **Counter Plate** onto the **Plate & Counter Plate Holder**.

Assemble the **1.3Nm Handle** and **Screwdriver T15**.
Pass the **Screwdriver** into the inserter.

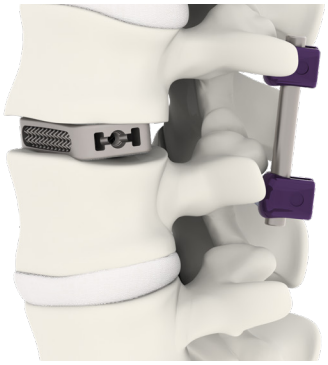
Secure the **Counter Plate** to the plate by aligning the set screw over the center hole of the **Plate**.

Tighten the set screw using the AO Connection dynamometric **Handle** until earing a click. .

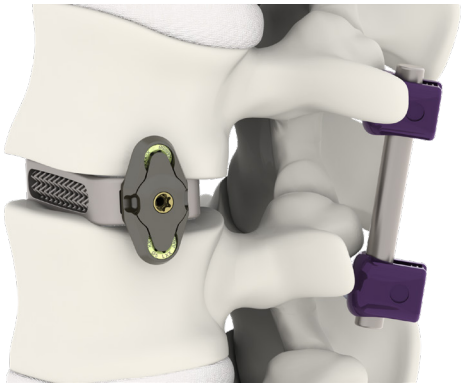
INSTRUMENT	REFERENCE
PLATE & COUNTER PLATE HOLDER	JLL-IN 39 00-N
ASSEMBLY BASE	JLL-IN 44 00-N
SCREWDRIVER T15	JLL-IN 40 00-N
1.3 Nm HANDLE	HAN-SI DY 13-N

⚠**WARNING** : The JULIET®Ti LL Interbody Devices are to be used with supplemental fixation, such as ROMEO®2 Pedicle screw system.

_FINAL CONSTRUCT



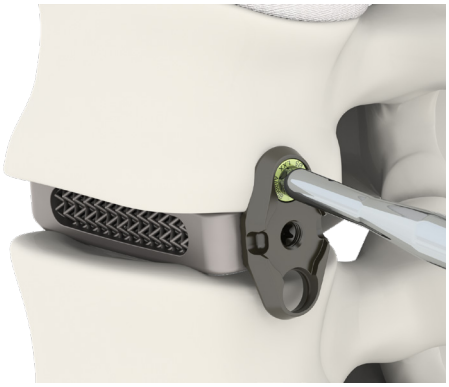
Final construct without integrated fixation (lateral plate), with supplemental fixation (pedicle screws) **allowed for 0° and 8° cages only**.



Final construct with integrated fixation (lateral plate), with supple mental fixation (pedicle screws) **allowed for 0° and 8° cages and mandatory for 15°**.

_REVISION

Removal of the Counter plate



Removal of the Plate

Use the **Screwdriver T15** to remove the Counter Plate.

Use the **Revision Screwdriver** to remove the screws.

Use the corresponding **Inserter** to remove the cage and the plate.

Clear tissue from the recesses and threads of the implant. To connect the implant to the **Inserter**, align the **Inserter** tip tabs with the recesses on the implant. Advance and rotate the **Inserter** knob clockwise to engage and secure the implant. Attach the Slap Hammer to the **Inserter** and slide the hammer upward. Repeat this motion until the implant is removed.

INSTRUMENT	REFERENCE
SCREWDRIVER T15	JLL-IN 40 00-N
1.3 Nm HANDLE	HAN-SI DY 13-N
REVISION SCREWDRIVER	SJT-IN 03 02-N
CAGE + PLATE INSERTER	JLL-IN 38 00-N
INSERTER	JLL-IN 07 01-N
ANGLED INSERTER (OPTIONAL)	JLL-IN 07 02-N
ANGLED CAGE + PLATE INSERTER (OPTIONAL)	JLL-IN 38 01-N

SURGICAL TECHNIQUE

OPTIONAL TECHNIQUE FOR 15º/25º CAGE INSERTION

_STEP 1

Surgeons may choose to release the **Anterior Longitudinal Ligament (ALL)** to allow lengthening of the anterior vertebral column.

ALL RELEASE

The **ALL Protector** can be temporarily inserted to prevent damage to soft tissue during an **ALL** release.

Insert the **ALL Protector** anterior to the **ALL** and posterior to the great vessels. Using fluoroscopy, carefully advance the **ALL Protector** until the tip extends beyond the width of the **ALL**.

Incise the **ALL** under direct visualization. Use fluoroscopy to monitor cutting tip location.

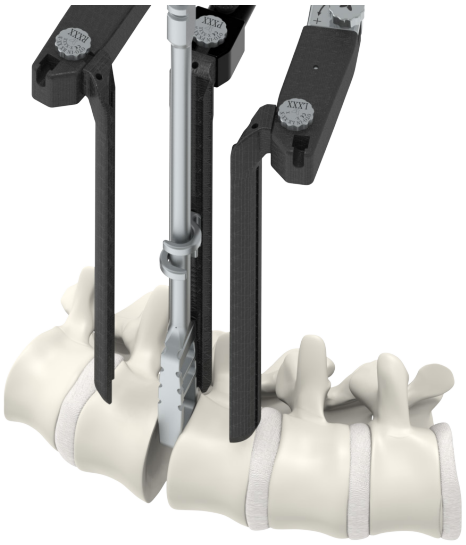
After the **ALL** is released, the **ALL Protector** is removed. A 4th blade can be introduced for additional tissue retraction anteriorly.

INSTRUMENT	REFERENCE
ALL PROTECTOR- CURVED 10MM X 90MM	SPE-US 01 15-N
ALL PROTECTOR- CURVED 16MM X 90MM	SPE-US 01 16-N

SURGICAL TECHNIQUE

OPTIONAL TECHNIQUE FOR 15º/25º CAGE INSERTION

_STEP 2



TRIALING

Hyperlordotic Implant Trials help determine the appropriate cage width, length, height and lordotic angle.
(See step 5, page 31)
The **Ring Guide**, affixed to the posterior blade can be used to prevent trials and disc prep instruments from anterior migration.

INSTRUMENT	REFERENCE
RING GUIDE	SPE-US 01 08-N

_STEP 3

CAGE INSERTION

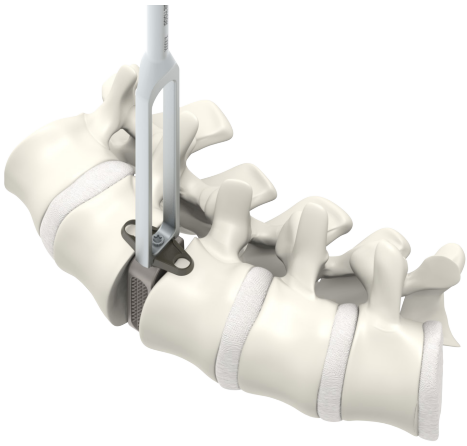
The **Ring Guide**, affixed to the posterior blade can be used to prevent the implant from anterior migration.

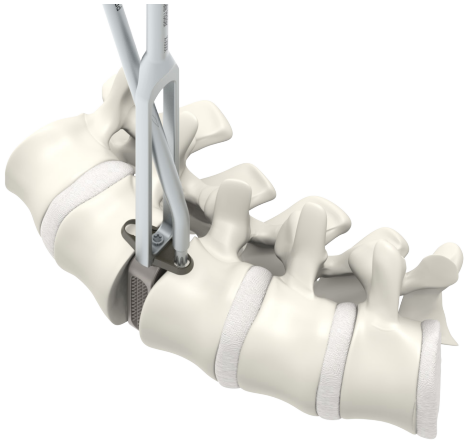
INSTRUMENT	REFERENCE
RING GUIDE	SPE-US 01 08-N

SURGICAL TECHNIQUE

OPTIONAL TECHNIQUE FOR 15º/25º CAGE INSERTION

_STEP 4





CAGE-PLATE INSERTION

The **Windowed Cage Inserter** can be used to implant the Cage-Plate assembly.

The **Windowed Cage Inserter** provides control and stability of the cage-plate assembly to prevent migration. The opening of the **Inserter** provides access for screw hole preparation and screw insertion.

INSTRUMENT	REFERENCE
WINDOWED CAGE INSERTER	SPE-US 00 92-N

GENERAL INFORMATION

REFERENCE OF THE IFU	JUT-LL-IF-WW	REVISION OF THE FINAL IFU	OCT-2019

_STERILITY

The implant is provided sterile.

Implants are double packaged in a PETG blister.

Each package is labeled and an IFU is included.

_CAUTION

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. Re-sterilization of the gamma sterilized implant is forbidden. The JULIET®Ti LL implants must only be used with JULIET®LL instruments.

US Caution Federal law restricts these devices to be sold by or on the order of a physician.

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.

Components of JULIET®Ti LL cage system should not be used with components of any other system or manufacturer.

_DESCRIPTION

The JULIET®Ti LL Lateral cage system has been designed to ensure the best possible adaptation to the patient's anatomic variations.

The JULIET®Ti LL Lumbar Lateral intersomatic cage, the plate and the screws are 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 lateral approach.

_INDICATIONS

JULIET®Ti LL Lumbar Interbody Device is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-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). The JULIET®Ti LL Lumbar Interbody Device 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.

Implants with 15 degree lordosis or greater are only indicated from levels L2-L5 and are to be used with at least two integrated fixation screws. The JULIET®Ti LL implants must be used with supplemental internal spinal fixation system that has been cleared by the FDA 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, 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

Neuromonitoring

Spineart® strongly recommends the use of a neuromonitoring device throughout the whole procedure. The nerve roots need to be avoided to prevent accidental injury.

_CAUTION – PRECAUTION FOR USE

An in-depth discussion of all possible complications associated with lumbar interbody fusion is beyond the scope of these instructions. 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.

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.

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. Surgeons should therefore take several factors into consideration, in order to achieve optimal results for each patient. It is therefore essential that each patient who must undergo this type of procedure be informed, with the supporting documentation available, of the potential complications.

_MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that SpineArt's Lumbar Interbody Cages system (with plates and screws) are MR Conditional. A patient with a SpineArt Lumbar Interbody Cage system 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 system 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 system extends approximately 5.3 cm from the devices when imaged in a 3 T MRI system.

_HANDLING

Spineart® ensures that only the highest-quality materials and expertise have been deployed in producing each implant. 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.

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. 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.

_SURGERY METHODS

Precaution: The implantation of a lumbar interbody cage 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.

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. We strongly recommend that excessive force should not be applied when implanting the JULIET® Ti LL implants.

A handbook on surgical techniques describing the standard implant procedure is available.

GENERAL INFORMATION

_PATIENT CARE FOLLOWING TREATMENT

Detailed instructions on the use and limitations of the device should be given to the patient. Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician. The patient should be instructed regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical problems. Surgeons must instruct patients to report any unusual changes of the operative site to his/her physician. The physician must closely monitor the patient.

_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 are specifically designed for use with JULIET®Ti LL implants.

They are delivered non-sterile.

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

_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 JULIET®LL 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 free cloth.

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 have 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

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

GENERAL INFORMATION

This 134°C – 18 minutes sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

"Do not stack trays during sterilization"

_PRODUCT USE LIFE

Spineart® instruments are validated for 150 steam sterilization runs.

Prior to use all components should be checked for functionality and the absence of defects such as wear, tear, corrosion, pitting and discoloration to ensure that there is no damage.

Damaged components must not be used and should be returned to Spineart®.

_MAINTENANCE AND REPAIRING

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.

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