



SCARLET<sup>®</sup> AL-T  
SECURED LUMBAR ANTERIOR CAGE



# C O N T E N T

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GENERAL INFORMATION

# C O N C E P T   A N D   D E S I G N

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

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





## AT A GLANCE

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

## INDICATIONS

The SCARLET® AL-T system is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one 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). 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.

When used with the integrated fixation by the mean of the bone screws provided, the SCARLET® AL-T is a stand-alone system and requires no additional supplemental fixation system.

When used as a lumbar intervertebral fusion device (i.e. without the bone screws provided), the SCARLET® AL-T interbody device must be used with supplemental internal spinal fixation system that has been cleared by the FDA for use in the lumbosacral spine.

# IMPLANTS



SMALL FOOTPRINT D24 MM X W32 MM  
LORDOSIS: 10°

| HEIGHT | REFERENCE      |
|--------|----------------|
| H10    | SCA-LS 10 10-S |
| H12    | SCA-LS 10 12-S |
| H14    | SCA-LS 10 14-S |
| H16    | SCA-LS 10 16-S |

MEDIUM FOOTPRINT D27 MM X W36 MM  
LORDOSIS: 10°

| HEIGHT | REFERENCE      |
|--------|----------------|
| H10    | SCA-LM 10 10-S |
| H12    | SCA-LM 10 12-S |
| H14    | SCA-LM 10 14-S |
| H16    | SCA-LM 10 16-S |

LARGE FOOTPRINT D30 MM X W40 MM  
LORDOSIS: 10°

| HEIGHT | REFERENCE      |
|--------|----------------|
| H10    | SCA-LL 10 10-S |
| H12    | SCA-LL 10 12-S |
| H14    | SCA-LL 10 14-S |
| H16    | SCA-LL 10 16-S |



SMALL FOOTPRINT D24 MM X W32 MM  
LORDOSIS: 15°

| HEIGHT | REFERENCE      |
|--------|----------------|
| H10    | SCA-LS 15 10-S |
| H12    | SCA-LS 15 12-S |
| H14    | SCA-LS 15 14-S |
| H16    | SCA-LS 15 16-S |

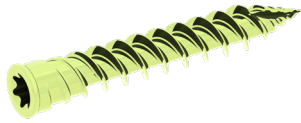
MEDIUM FOOTPRINT D27 MM X W36 MM  
LORDOSIS: 15°

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

LARGE FOOTPRINT D30 MM X W40 MM  
LORDOSIS: 15°

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

# IMPLANTS



DIA 5.0 MM

| LENGTH | REFERENCE      |
|--------|----------------|
| L25    | SJT-LS 50 25-S |
| L30    | SJT-LS 50 30-S |
| L35    | SJT-LS 50 35-S |
| L40    | SJT-LS 50 40-S |

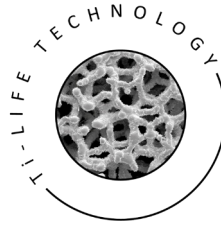


DIA 5.5 MM

| LENGTH | REFERENCE      |
|--------|----------------|
| L25    | SJT-LS 55 25-S |
| L30    | SJT-LS 55 30-S |
| L35    | SJT-LS 55 35-S |
| L40    | SJT-LS 55 40-S |

# TECHNICAL FEATURES

## Ti-LIFE TECHNOLOGY



The structure mimics the bone trabecular geometry and is designed to allow bone in-growth. This technology is based on a propriety algorithm associated with a unique additive manufacturing process, commonly referred to as 3D printing.

## ZERO PROFILE



The screw heads are completely integrated within the cage. Zero-profile implants may limit the risk of damage to vessels and adjacent soft tissues.

## SCREW ANTI-BACKOUT SYTEM



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

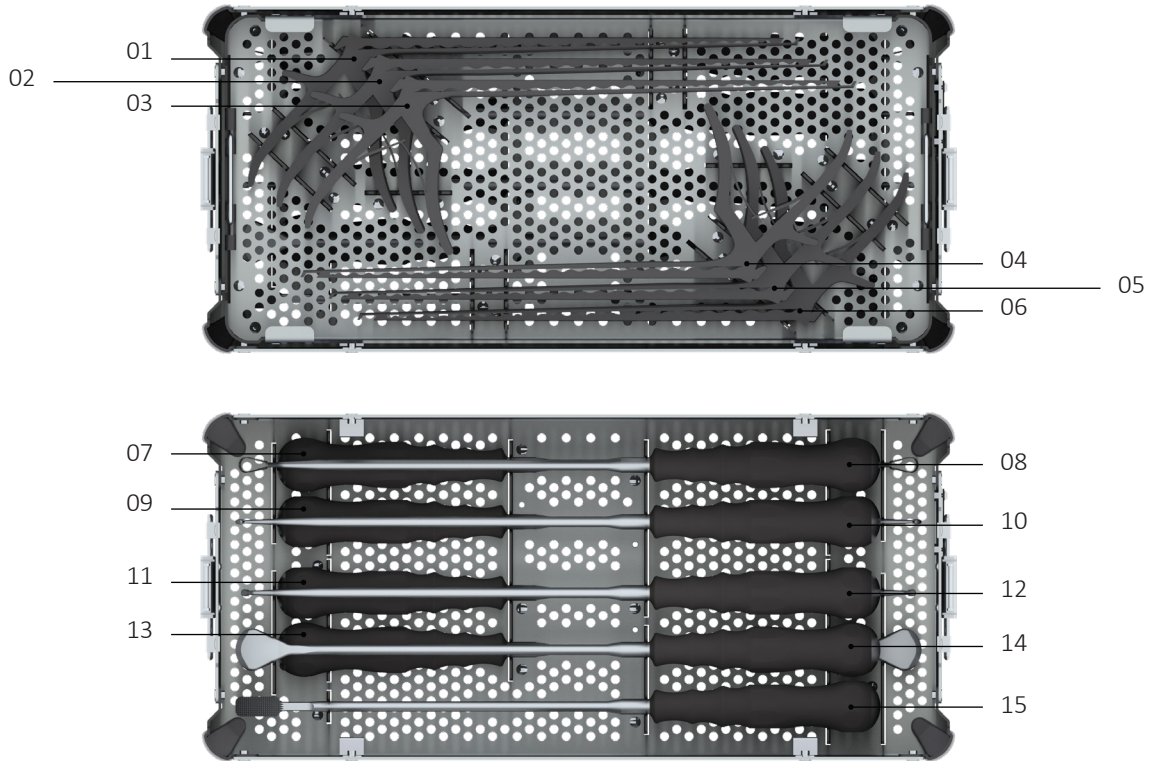
## COMPREHENSIVE RANGE



10° and 15° lordosis  
3 footprints

# INSTRUMENT SETS

## DISC PREPARATION 1

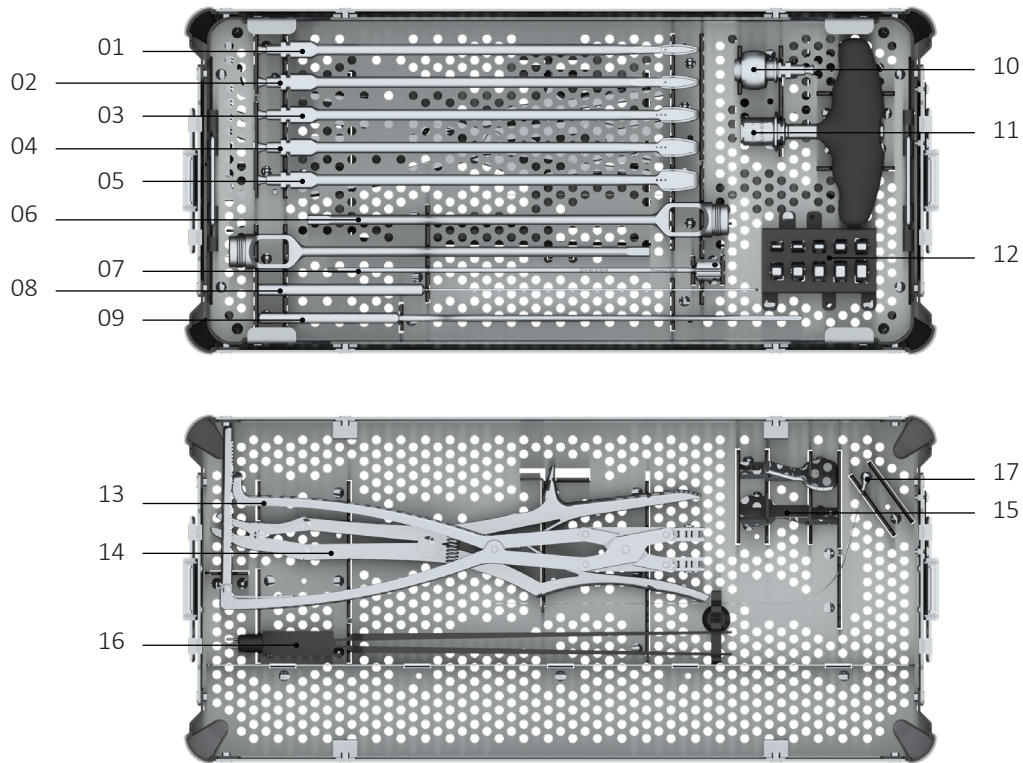


| #  | DESCRIPTION                      | REFERENCE      |
|----|----------------------------------|----------------|
| 01 | PITUITARY RONGEUR, STRAIGHT, 5MM | SCA-IN 21 00-N |
| 02 | PITUITARY RONGEUR, STRAIGHT, 3MM | SCA-IN 22 00-N |
| 03 | PITUITARY RONGEUR, 3MM, UP       | SCA-IN 21 01-N |
| 04 |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

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

# INSTRUMENT SETS

## DISC PREPARATION 2

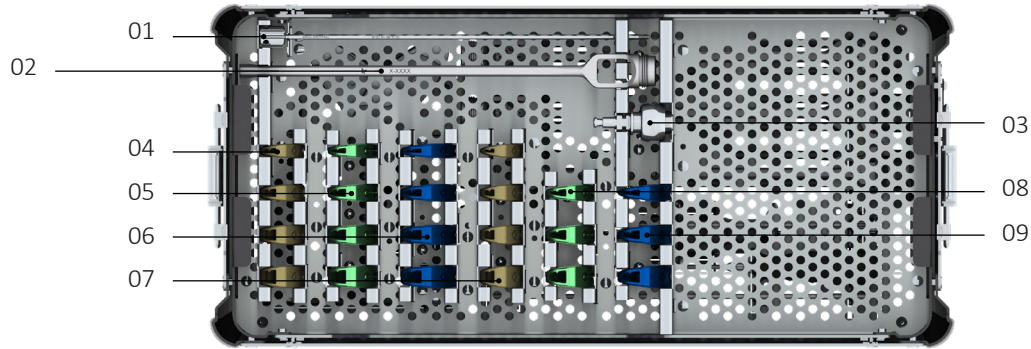


| #  | DESCRIPTION                     | REFERENCE      |
|----|---------------------------------|----------------|
| 01 | DISC SHAVER H08                 | SCA-IN 14 08-N |
| 02 | DISC SHAVER H10                 | SCA-IN 14 10-N |
| 03 | DISC SHAVER H12                 | SCA-IN 14 12-N |
| 04 | DISC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

| #  | DESCRIPTION                           | REFERENCE      |
|----|---------------------------------------|----------------|
| 12 | PADDLE DISTRACTOR H07                 | SCA-IN 15 07-N |
|    | PADDLE DISTRACTOR H08                 | SCA-IN 15 08-N |
|    | PADDLE DISTRACTOR H09                 | SCA-IN 15 09-N |
|    | PADDLE DISTRACTOR H10                 | SCA-IN 15 10-N |
|    | PADDLE DISTRACTOR H11                 | SCA-IN 15 11-N |
|    | PADDLE DISTRACTOR H12                 | SCA-IN 15 12-N |
|    | PADDLE DISTRACTOR H13                 | SCA-IN 15 13-N |
|    | PADDLE DISTRACTOR H14                 | SCA-IN 15 14-N |
|    | PADDLE DISTRACTOR H15                 | SCA-IN 15 15-N |
|    | PADDLE DISTRACTOR H16                 | SCA-IN 15 16-N |
| 13 | PARALLEL DISTRACTOR                   | ELL-IN 01 07-N |
| 14 | LEKSELL DOUBLE-ACTION<br>RONGEUR, 8MM | SCA-IN 13 00-N |
| 15 | PARALLEL DISTRACTOR / ENDTIP          | SCA-IN 01 00-N |
| 16 | BIPOLAR FORCEPS                       | S03-551NS      |
| 17 | LONG SUCTION                          | GS 75.9312     |

# INSTRUMENT SETS

## IMPLANT TRIALS AND CAGES INSERTION

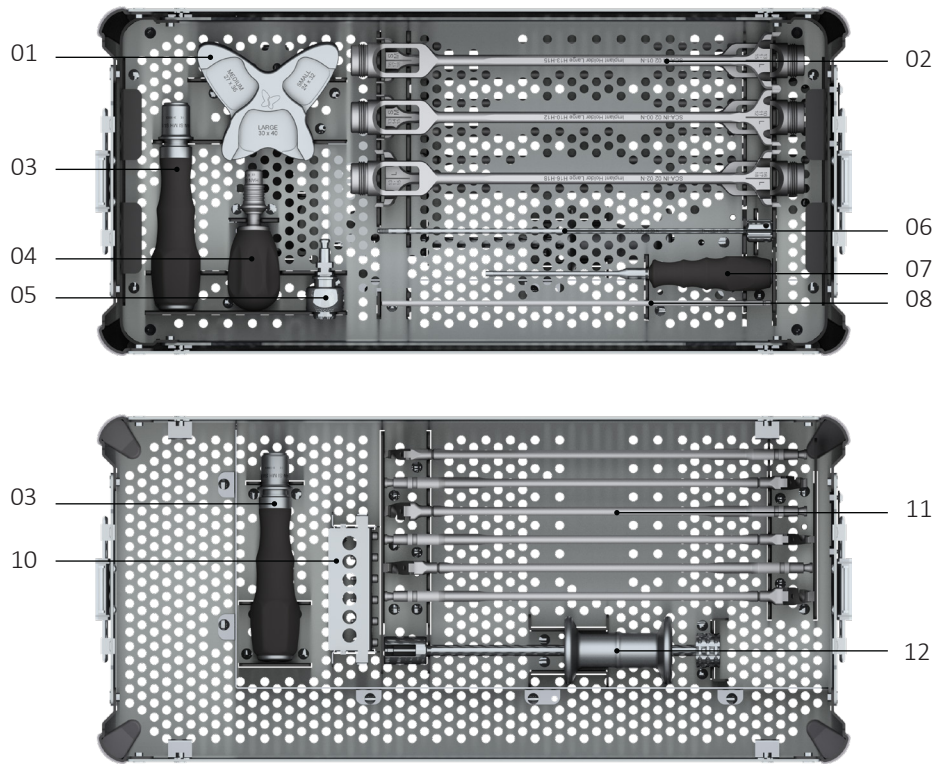


| #  | DESCRIPTION                   | REFERENCE      |
|----|-------------------------------|----------------|
| 01 | THREADED SHAFT                | SCA-IN 18 00-N |
| 02 | TRIAL INSERTER                | SCA-IN 05 00-N |
| 03 | HUDSON CONNECTOR              | SCA-IN 17 00-N |
| 04 | TRIAL SMALL H10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



# INSTRUMENT SETS

## IMPLANT TRIALS AND CAGES INSERTION



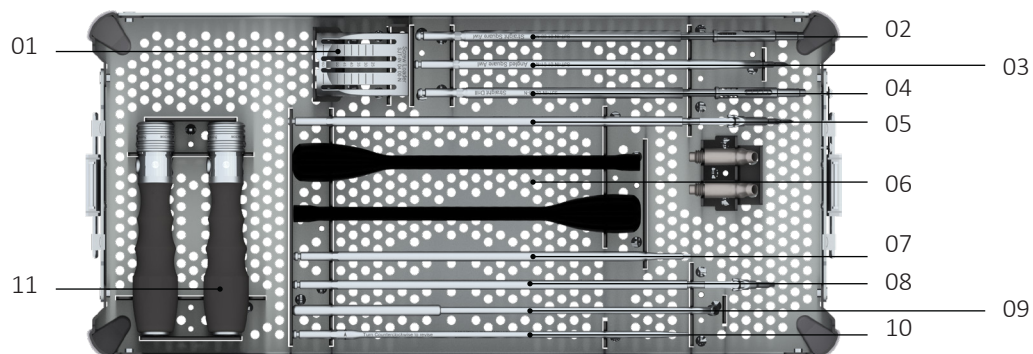
| #  | DESCRIPTION                                   | REFERENCE      |
|----|-----------------------------------------------|----------------|
| 01 | COMPACTION BASE                               | SCA-IN 07 00-N |
| 02 | IMPLANT HOLDERS:                              |                |
|    | SMALL/MEDIUM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

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



# INSTRUMENT SETS

## SCREW INSERTION



| #  | DESCRIPTION                                             | REFERENCE      |
|----|---------------------------------------------------------|----------------|
| 01 | SCREW LOADER                                            | SJT-IN 04 00-N |
| 02 | STRAIGHT SQUARE AWL                                     | SJT-IN 01 00-N |
| 03 | ANGLED SQUARE AWL                                       | SJT-IN 01 01-N |
| 04 | STRAIGHT DRILL                                          | SJT-IN 02 00-N |
| 05 | U-JOINT DRILL                                           | SJT-IN 02 01-N |
| 06 | UNIVERSAL-JOINT TUBE AND<br>UNIVERSAL JOINT ANGLED PART | SJT-IN 06 00-N |
| 07 | STRAIGHT SCREWDRIVER                                    | SJT-IN 03 00-N |
| 08 | U-JOINT SCREWDRIVER                                     | SJT-IN 03 01-N |
| 09 | U-JOINT GUIDE                                           | SJT-IN 05 00-N |
| 10 | REVISION SCREWDRIVER                                    | SJT-IN 03 02-N |
| 11 | STRAIGHT HANDLE RATCHET                                 | HAN-SI RA ST-N |

# INSTRUMENTS

## DISC PREPARATION

STRAIGHT RING CURETTE, 15MM

SCA-IN 09 02-N



CUP CURETTE, ANGLED, DOWN, SIZE «4»

SCA-IN 24 01-N



ANGLED RING CURETTE, 15MM

SCA-IN 09 03-N



FLAT COBB, 30 MM

SCA-IN 10 02-N



CUP CURETTE, STRAIGHT, SIZE «2»

SCA-IN 12 00-N



COBB, 25MM, 10° UP

SCA-IN 10 01-N



CUP CURETTE, STRAIGHT, SIZE «4»

SCA-IN 24 00-N



RASP, STRAIGHT, 14MM

SCA-IN 08 00-N



CUP CURETTE, ANGLED, DOWN, SIZE «2»

SCA-IN 12 01-N



PADDLE DISTRACTOR HOLDER

SCA-IN 15 00-N



PADDLE DISTRACTORS H07 TO H16

SCA-IN 15 07-N  
TO SCA-IN 15 16-N



THREADED SHAFT

SCA-IN 18 00-N



# INSTRUMENTS

## DISC PREPARATION

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



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



|                |                |
|----------------|----------------|
| BALL TIP PROBE | SCA-IN 20 00-N |
|----------------|----------------|



|                 |           |
|-----------------|-----------|
| BIPOLAR FORCEPS | S03-551NS |
|-----------------|-----------|



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



|              |            |
|--------------|------------|
| LONG SUCTION | GS 75.9312 |
|--------------|------------|



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



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

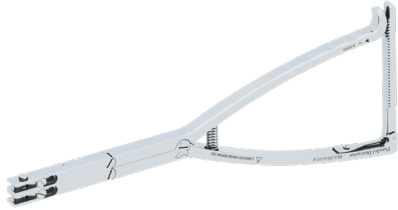


# INSTRUMENTS

## DISC PREPARATION

PARALLEL DISTRACTOR

ELL-IN 01 07-N



BLUNT DISSECTOR

JLL-IN 00 01-N



PARALLEL DISTRACTOR / ENDTIP

SCA-IN 01 00-N



HUDSON CONNECTOR

SCA-IN 17 00-N



DISC SHAVERS

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



# INSTRUMENTS

## IMPLANT TRIALS

|                |                |
|----------------|----------------|
| TRIAL INSERTER | SCA-IN 05 00-N |
|----------------|----------------|



|                |                |
|----------------|----------------|
| THREADED SHAFT | SCA-IN 18 00-N |
|----------------|----------------|



|             |                |
|-------------|----------------|
| SLAP HAMMER | JLL-IN 12 00-N |
|-------------|----------------|

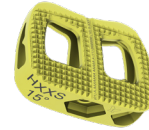


|                  |                |
|------------------|----------------|
| HUDSON CONNECTOR | SCA-IN 17 00-N |
|------------------|----------------|



|                                     |                |
|-------------------------------------|----------------|
| TRIAL SMALL H10 TO H16 LORDOSIS 10° | SCA-TS 10 XX-N |
|-------------------------------------|----------------|

|                                     |                |
|-------------------------------------|----------------|
| TRIAL SMALL H10 TO H16 LORDOSIS 15° | SCA-TS 15 XX-N |
|-------------------------------------|----------------|



|                                      |                |
|--------------------------------------|----------------|
| TRIAL MEDIUM H10 TO H16 LORDOSIS 10° | SCA-TM 10 XX-N |
|--------------------------------------|----------------|

|                                      |                |
|--------------------------------------|----------------|
| TRIAL MEDIUM H12 TO H16 LORDOSIS 15° | SCA-TM 15 XX-N |
|--------------------------------------|----------------|



|                                     |                |
|-------------------------------------|----------------|
| TRIAL LARGE H10 TO H16 LORDOSIS 10° | SCA-TL 10 XX-N |
|-------------------------------------|----------------|

|                                     |                |
|-------------------------------------|----------------|
| TRIAL LARGE H12 TO H16 LORDOSIS 15° | SCA-TL 15 XX-N |
|-------------------------------------|----------------|



# INSTRUMENTS

## CAGES INSTRUMENTS

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



|                                             |                |
|---------------------------------------------|----------------|
| LATERAL IMPLANT HOLDER SMALL/MEDIUM H10-H12 | SCA-IN 03 00-N |
| LATERAL IMPLANT HOLDER SMALL/MEDIUM H13-H15 | SCA-IN 03 01-N |
| LATERAL IMPLANT HOLDER SMALL/MEDIUM H16-H18 | SCA-IN 03 02-N |
| LATERAL IMPLANT HOLDER LARGE H10-H12        | SCA-IN 04 00-N |
| LATERAL IMPLANT HOLDER LARGE H13-H15        | SCA-IN 04 01-N |
| LATERAL IMPLANT HOLDER LARGE H16-H18        | SCA-IN 04 02-N |



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



|           |                |
|-----------|----------------|
| COMPACTOR | SCA-IN 19 00-N |
|-----------|----------------|



|                 |                |
|-----------------|----------------|
| COMPACTION BASE | SCA-IN 07 00-N |
|-----------------|----------------|



|                  |                |
|------------------|----------------|
| CAMLOCKER DRIVER | SCA-IN 06 00-N |
|------------------|----------------|



|                                     |                |
|-------------------------------------|----------------|
| STRAIGHT HANDLE (HUDSON CONNECTION) | HAN-SI MH SM-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 HANDLE RATCHET

HAN-SI RA ST-N



# INSTRUMENT ASSEMBLY



TRIALS AND CAGES INSERTION  
HUDSON CONNECTION HANDLES



SCREWS INSERTION  
RATCHET HANDLE



TORQUE LIMITING  
HANDLE



## HUDSON CONNECTION HANDLE ATTACHMENT

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

| INSTRUMENT                             | REFERENCE      |
|----------------------------------------|----------------|
| STRAIGHT HANDLE<br>(HUDSON CONNECTION) | HAN-SI MH SM-N |
| T-HANDLE<br>(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      |
|-----------------------------|----------------|
| TRIAL INSERTER              | SCA-IN 05 00-N |
| THREADED SHAFT              | SCA-IN 18 00-N |
| HUDSON CONNECTOR            | SCA-IN 17 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

# SURGICAL TECHNIQUE

## \_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.

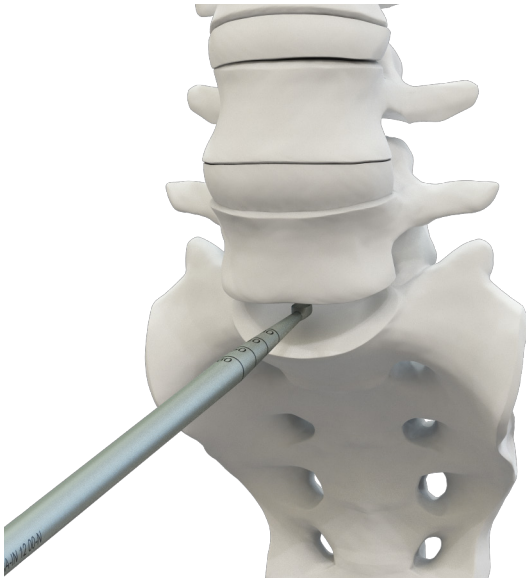
Through a standard retroperitoneal approach, dissect and retract the soft tissue to reach the operative disc level.

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.

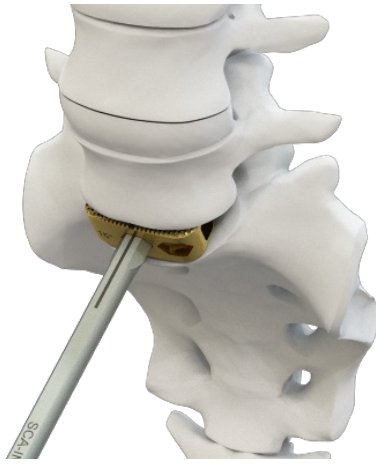
Distract the discectomy site, using the parallel distractor and/or paddle distractors.

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.

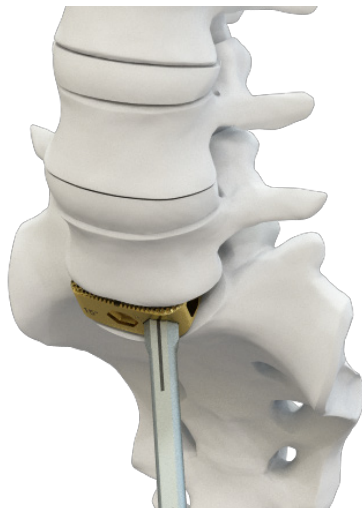
| INSTRUMENT                          | REFERENCE                           |
|-------------------------------------|-------------------------------------|
| STRAIGHT RING CURETTE, 15MM         | SCA-IN 09 02-N                      |
| ANGLED RING CURETTE, 15MM           | SCA-IN 09 03-N                      |
| 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                      |
| PARALLEL DISTRACTOR / ENDTIP        | SCA-IN 01 00-N                      |
| PADDLE DISTRACTOR HOLDER            | SCA-IN 15 00-N                      |
| PADDLE DISTRACTORS H07 TO H16       | SCA-IN 15 07-N TO<br>SCA-IN 15 16-N |
| RASP, STRAIGHT, 14MM                | SCA-IN 08 00-N                      |
| DISC SHAVERS                        | SCA-IN 14 08-N TO<br>SCA-IN 14 16-N |
| BLUNT DISSECTOR                     | JLL-IN 00 01-N                      |
| T-HANDLE (HUDSON CONNECTION)        | HAN-SI MH TE-N                      |
| BALL TIP PROBE                      | SCA-IN 20 00-N                      |
| PITUITARY RONGEUR, STRAIGHT, 5MM    | SCA-IN 21 00-N                      |
| PITUITARY RONGEUR, STRAIGHT, 3MM    | SCA-IN 22 00-N                      |
| PITUITARY RONGEUR, 3MM, UP          | SCA-IN 21 01-N                      |
| PITUITARY RONGEUR, 5MM, UP          | SCA-IN 22 01-N                      |
| KERRISON RONGEUR, 3MM, 40DEG UP     | SCA-IN 23 00-N                      |
| KERRISON RONGEUR, 5MM, 40DEG UP     | JLL-IN 14 05-N                      |
| LEKSELL DOUBLE-ACTION RONGEUR, 8MM  | SCA-IN 13 00-N                      |
| BIPOLAR FORCEPS                     | S03-551NS                           |
| LONG SUCTION                        | GS 75.9312                          |
| HUDSON CONNECTOR                    | SCA-IN 17 00-N                      |
| THREADED SHAFT                      | SCA-IN 18 00-N                      |

# SURGICAL TECHNIQUE

## \_STEP 3



ANTERIOR APPROACH



ANTEROLATERAL APPROACH

## SELECTION OF THE IMPLANT SIZE

**Straight Anterior Approach:**

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

**Anterolateral Approach:**

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

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

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

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

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

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

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

# SURGICAL TECHNIQUE

## \_STEP 4



## CAGE PREPARATION

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

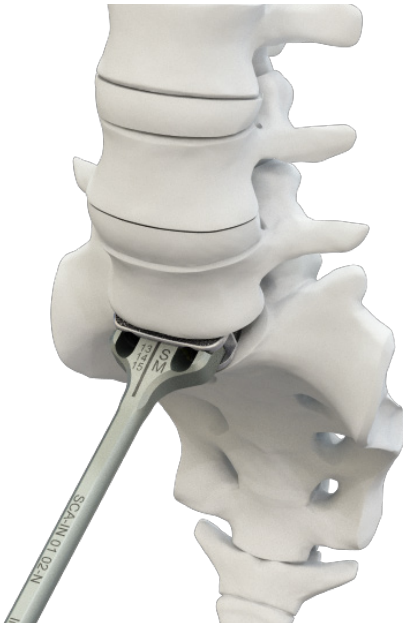
Tighten the cage onto the implant holder corresponding to the selected footprint and height.

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

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

# SURGICAL TECHNIQUE

## \_STEP 5



## INSERTION OF THE FINAL IMPLANT

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

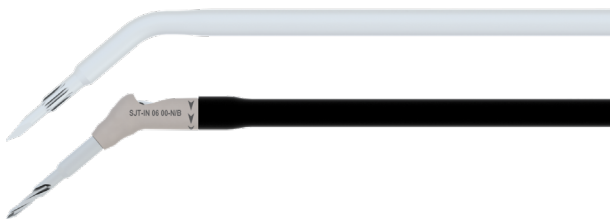
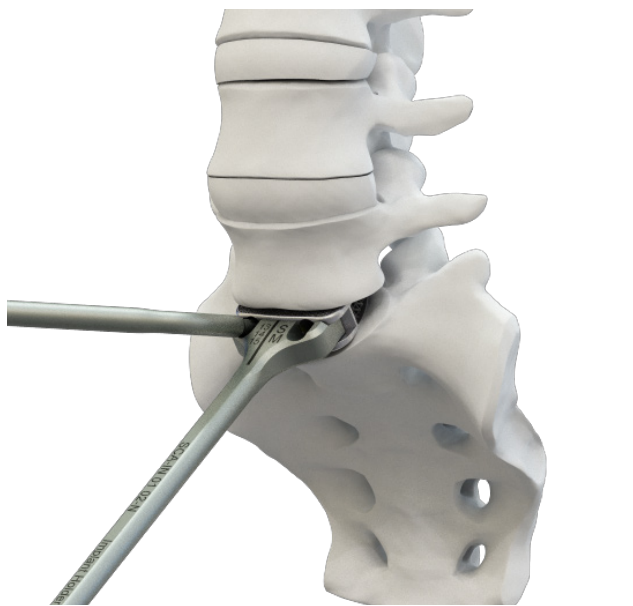
A mallet may be used to gently insert the final implant.

**At this point the surgeon must decide whether to use integrated screw fixation or a supplemental fixation. The integrated screw fixation technique is described on Step 6 to Step 10.**

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

# SURGICAL TECHNIQUE

## \_STEP 6



## PREPARATION OF LATERAL SCREW HOLES

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

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

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

Begin hole preparation with the two lateral screw holes.

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

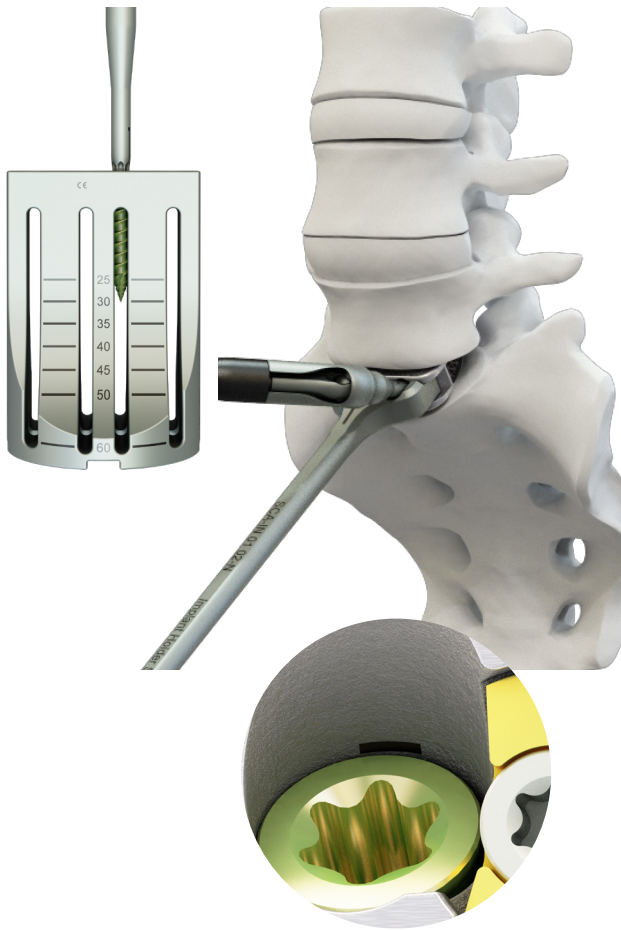
The U-joint guide may also be used during screw hole preparation to provide correct trajectory.

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

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

# SURGICAL TECHNIQUE

## \_STEP 7



Laser mark should be visible

## IMPLANTATION OF THE LATERAL SCREWS

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

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

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

Repeat this step to insert the second lateral screw.

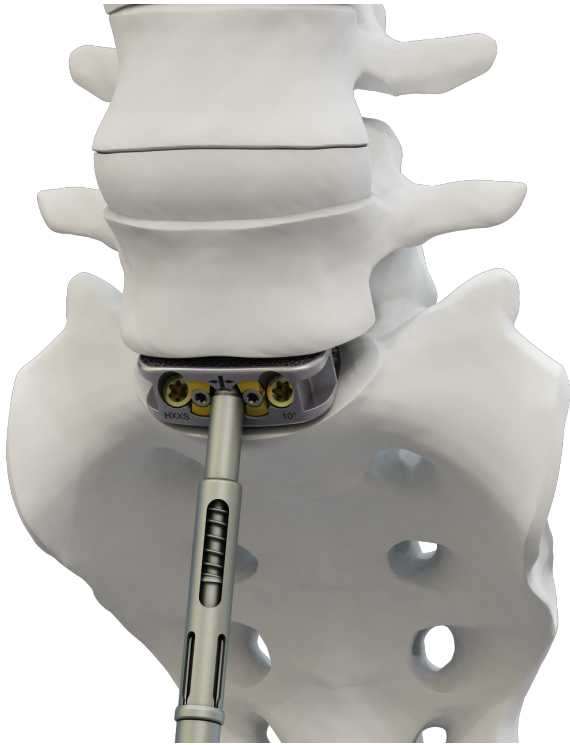
For visual confirmation of correct screw depth, a laser mark is positioned within the screw holes. The head of the screw should be inserted beyond this landmark.

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



# SURGICAL TECHNIQUE

## \_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.

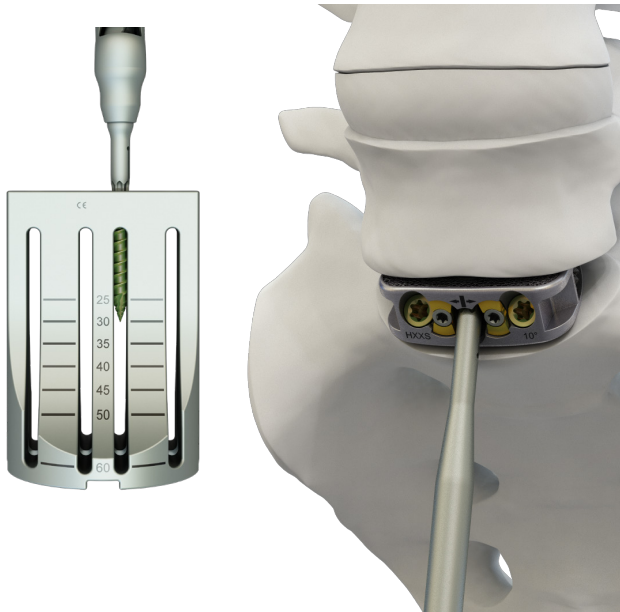
The screw hole preparation instruments all have a tip length of 25 mm, which represents the shortest length screw available. Lateral imaging during hole creation may assist with determining the appropriate screw length.

**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<br>UNIVERSAL JOINT ANGLED PART | SJT-IN 06 00-N |
| U-JOINT GUIDE                                           | SJT-IN 05 00-N |
| U-JOINT SCREWDRIVER                                     | SJT-IN 03 01-N |
| STRAIGHT SCREWDRIVER                                    | SJT-IN 03 00-N |

# SURGICAL TECHNIQUE

## \_STEP 9



## IMPLANTATION OF THE CENTRAL SCREW

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<br>UNIVERSAL JOINT ANGLED PART | SJT-IN 06 00-N |

## \_STEP 10

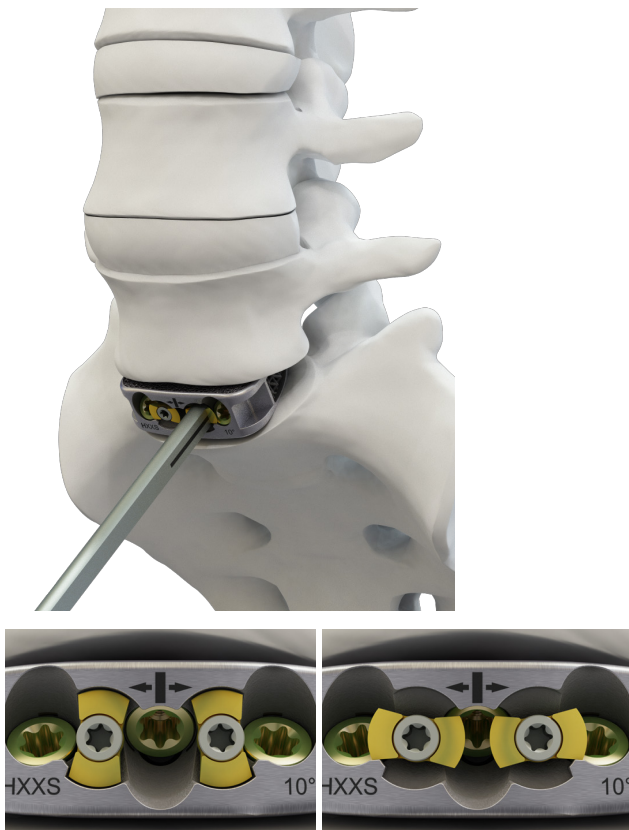


Figure 10a

Figure 10b

## 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).

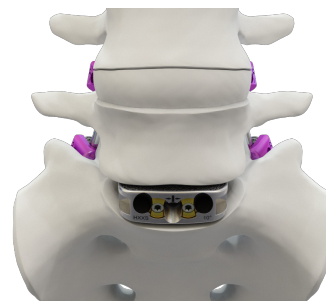
| INSTRUMENT             | REFERENCE      |
|------------------------|----------------|
| CAM LOCK DRIVER        | SCA-IN 06 00-N |
| TORQUE LIMITING HANDLE | HAN-SI AO PA-N |

# SURGICAL TECHNIQUE

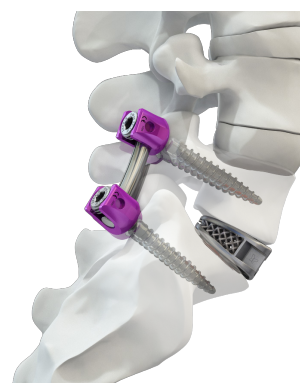
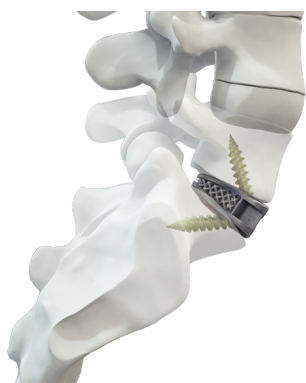
## \_FINAL CONSTRUCT



With integrated screws



Without integrated screws  
+ supplemental fixation system  
(e.g. Posterior spinal fixation system)



## \_REVISION



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

Remove the screws using the revision screwdriver.

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 |
| CAM LOCK DRIVER                               | SCA-IN 06 00-N |
| TORQUE LIMITING HANDLE<br>(1Nm) (PALM HANDLE) | HAN-SI AO PA-N |
| STRAIGHT HANDLE<br>(HUDSON CONNECTION)        | HAN-SI MH SM-N |
| IMPLANT HOLDERS (see page 18 & 19)            |                |

# GENERAL INFORMATION

|                      |                |                           |          |
|----------------------|----------------|---------------------------|----------|
| REFERENCE OF THE IFU | SCA-IF AL 01-W | REVISION OF THE FINAL IFU | MAR-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 SCARLET® AL-T implants must only be used with SCARLET® AL-T 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 SCARLET® AL-T cage system should not be used with components of any other system or manufacturer.

## DESCRIPTION

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

The SCARLET® AL-T Lumbar Anterior intersomatic cage 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 system is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine 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). 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.

When used with the integrated fixation by the mean of the bone screws provided, the SCARLET® AL-T is a stand-alone system and requires no additional supplemental fixation system.

When used as a lumbar intervertebral fusion device (i.e. without the bone screws provided), the SCARLET® AL-T interbody device 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, 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

## \_CAUTION - PRECAUTIONS 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

The SCARLET® AL-T Lumbar Interbody Device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of SCARLET® AL-T Lumbar Interbody Device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

## \_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 SCARLET® AL-T implants.

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

## \_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 CONDITION

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 SCARLET® AL-T implants. They are delivered non-sterile.

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



# GENERAL INFORMATION

## 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 free cloth.

| WASHER-DISINFECTOR PARAMETERS |                                                                             |             |            |
|-------------------------------|-----------------------------------------------------------------------------|-------------|------------|
| Step                          | Solution                                                                    | Temperature | Time       |
| Pre-cleaning                  | Water                                                                       | <45°        | 2 minutes  |
| Cleaning                      | Water + Neutral enzymatic cleaner<br>(as example NEODISHER Mediclean Forte) | 55°C        | 10 minutes |
| Neutralizing                  | Water                                                                       | <45°        | 2 minutes  |
| Rinsing                       | Tap water                                                                   | <45°        | 2 minutes  |
| Thermal disinfection          | Reversed osmosis water                                                      | 90°C        | 5 minutes  |

# GENERAL INFORMATION

## 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

Exposure temperature: 134°C

Drying Time: 30 minutes

#### Cycle 2 (USA):

Exposure time: 4 minutes

Temperature: 132°C

Drying Time: 30 minutes

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

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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