SCARLET® AC-T

CERVICAL SECURED CAGE

C O N T E N T

CONCEPT AND DESIGN

For over 10 years, Spineart has acquired expertise in Cervical Spine thanks to the success of its cervical disc prosthesis BAGUERA® C * and its TRYPTIK® cervical range known worldwide. To sustain this expertise, Spineart's Marketing and Research & Development teams have worked hand in hand to develop a unique secured cervical cage, the SCARLET® AC-T.

Inspired by « Gone with the Wind » from Margaret Mitchell, Scarlet is a person with a strong character, proud of her atypical beauty.
Our cage has been developed following that philosophy, a perfect design that makes the SCARLET® AC-T system a cutting-edge technology.

This device respects Spineart's philosophy : Quality, Innovation and Simplicity.

* Not FDA approved.

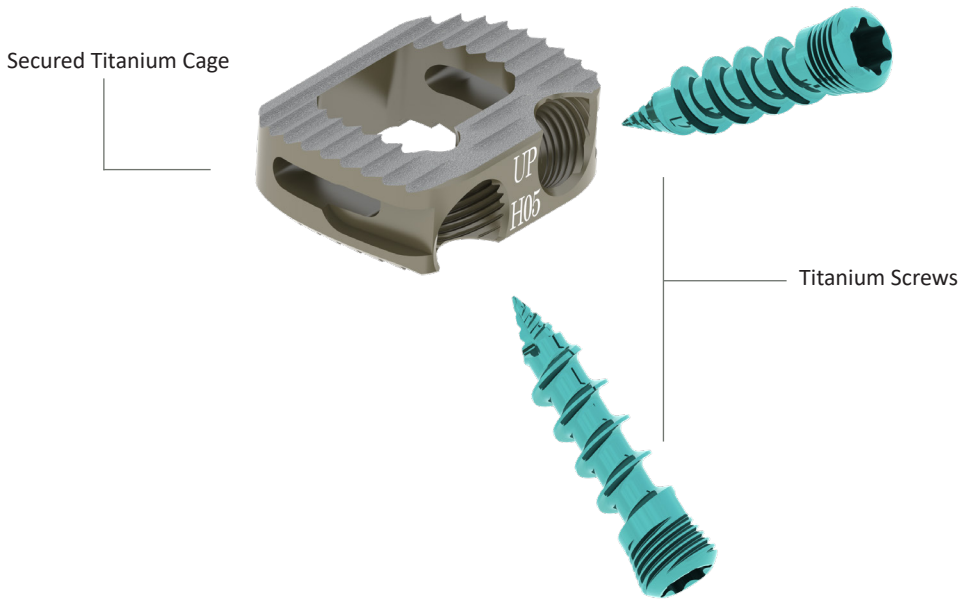
AT A GLANCE

Secured Cage
Zero Profile
Simplicity Of Use
Titanium

INDICATIONS

SCARLET®AC-T cages are indicated for use in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage. SCARLET®AC-T cages are intended to be used at one level from the C2-C3 disc to the C7-T1 disc to facilitate intervertebral body fusion with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The SCARLET®AC-T Secured Anterior Cervical Cage is intended to be used as a standalone system used with the two bone screws provided and requires no additional supplementary fixation systems. When used without the two bone screws, SCARLET®AC-T cages are to be used with supplemental fixation which has been cleared by the FDA for use in the cervical spine.

IMPLANTS



ANATOMICAL CAGE	SMALL FOOTPRINT 12X15mm
HEIGHT	**REFERENCE**
5mm	SCA-AC TS 05-S
6mm	SCA-AC TS 06-S
7mm	SCA-AC TS 07-S
8mm	SCA-AC TS 08-S
9mm	SCA-AC TS 09-S
10mm	SCA-AC TS 10-S

ANATOMICAL CAGE	LARGE FOOTPRINT 14X17mm
HEIGHT	**REFERENCE**
5mm	SCA-AC TL 05-S
6mm	SCA-AC TL 06-S
7mm	SCA-AC TL 07-S
8mm	SCA-AC TL 08-S
9mm	SCA-AC TL 09-S
10mm	SCA-AC TL 10-S

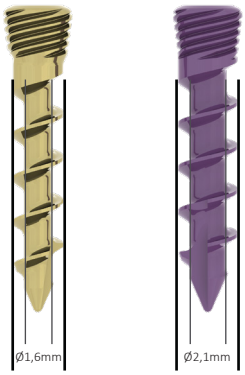
LORDOTIC CAGE	SMALL FOOTPRINT 12X15mm
HEIGHT	**REFERENCE**
5mm	SCA-AC LS 05-S
6mm	SCA-AC LS 06-S
7mm	SCA-AC LS 07-S
8mm	SCA-AC LS 08-S
9mm	SCA-AC LS 09-S
10mm	SCA-AC LS 10-S

LORDOTIC CAGE	LARGE FOOTPRINT 14X17mm
HEIGHT	**REFERENCE**
5mm	SCA-AC LL 05-S
6mm	SCA-AC LL 06-S
7mm	SCA-AC LL 07-S
8mm	SCA-AC LL 08-S
9mm	SCA-AC LL 09-S
10mm	SCA-AC LL 10-S

IMPLANTS

STANDARD RANGE

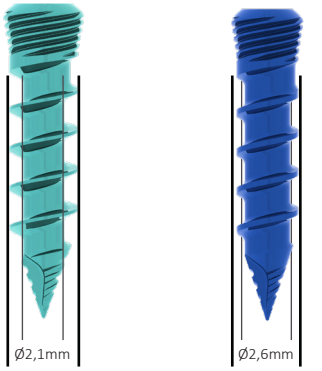
L12 L14 L16 L18



Ø 3mm Ø 3,5mm

SELF-DRILLING RANGE

L12 L14 L16 L18



Ø 3,5mm Ø 3,5mm

SCREWS Ø 3mm

LENGTH	REFERENCE
12mm	SCA-CS 30 12-S
14mm	SCA-CS 30 14-S
16mm	SCA-CS 30 16-S
18mm	SCA-CS 30 18-S

SCREWS Ø 3.5mm

LENGTH	REFERENCE
12mm	SCA-CS 35 12-S
14mm	SCA-CS 35 14-S
16mm	SCA-CS 35 16-S
18mm	SCA-CS 35 18-S

SELF-DRILLING SCREWS Ø 3,5mm (core Ø 2.1mm)

LENGTH	REFERENCE
12mm	SCA-FI 35 12-S
14mm	SCA-FI 35 14-S
16mm	SCA-FI 35 16-S
18mm	SCA-FI 35 18-S

SELF-DRILLING REVISION SCREWS Ø 3.5mm (core Ø 2.6mm)

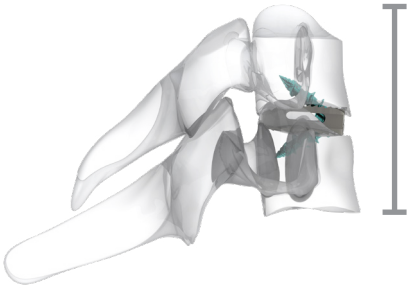
LENGTH	REFERENCE
12mm	SCA-RE 35 12-S
14mm	SCA-RE 35 14-S
16mm	SCA-RE 35 16-S
18mm	SCA-RE 35 18-S

TECHNICAL FEATURES

SECURED CAGE

The screws allow stabilization of the device.
The screw head is micro-threaded and has a conical shape. This feature secures the screw controlling potential risk of expulsion once locked into the cage.

ZERO PROFILE IMPLANT



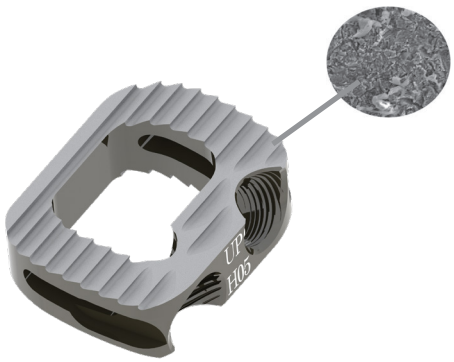
The screw heads are completely integrated in the cage. Implantation of a zero-profile implant has shown to reduce the incidence rate of dysphagia.

SIMPLICITY OF USE

The anatomical profile of SCARLET® AC-T system allows for an anatomical fit between endplates.
The SCARLET® AC-T system also offers a lordotic option of 7°.

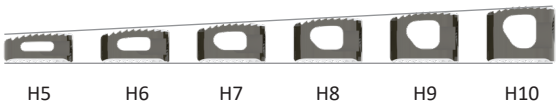
TECHNICAL FEATURES

TITANIUM



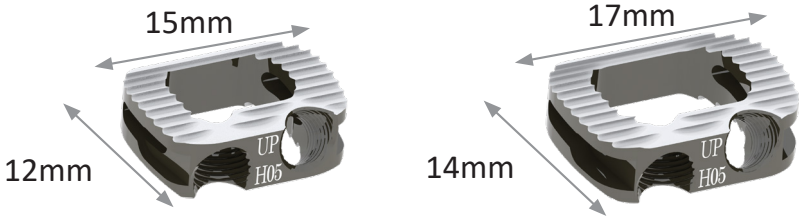
The device features a large graft window. The Titanium sandblasted surfaces of the implant facilitate primary stability and osseointegration.

24 SIZES OF CAGE



ANATOMICAL PROFILE

LORDOTIC PROFILE

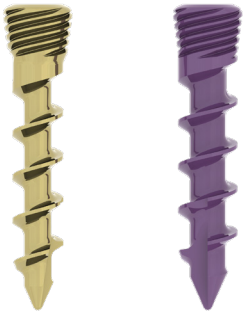


For an optimal fit, the SCARLET® AC-T is proposed in 6 heights, 2 footprints, and 2 profiles.

TECHNICAL FEATURES

TWO TYPES OF SCREWS

STANDARD RANGE

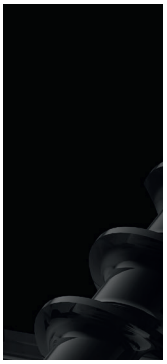


Screw Ø 3mm Screw Ø 3,5mm

L12 L14 L16 L18

SELF-DRILLING RANGE

Self-drilling
Screw Ø 3,5mm
(core Ø 2,1mm)



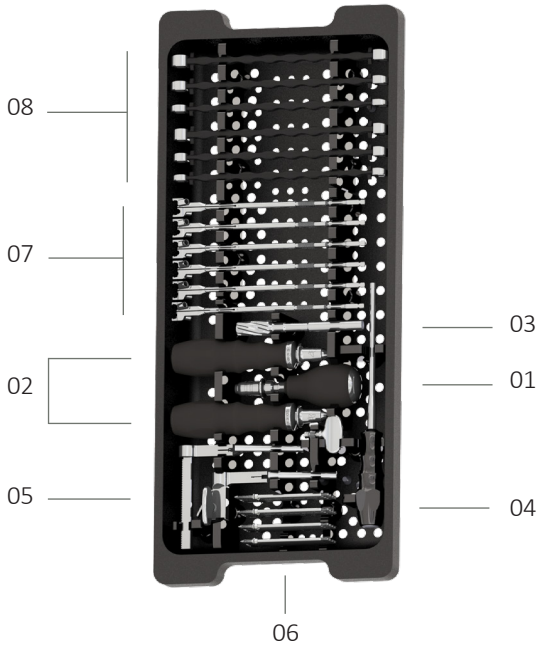
Self-drilling revision
Screw Ø 3,5mm
(core Ø 2,6mm)

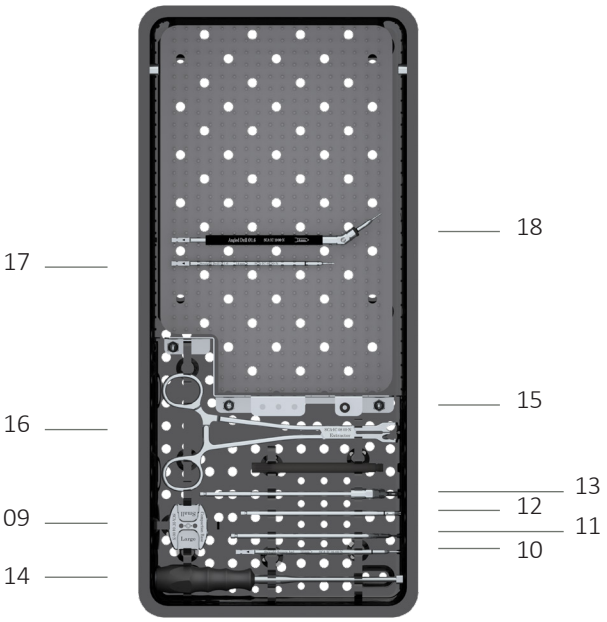
L12 L14 L16 L18

Two types of screw are available: standard and self-drilling.
The standard screws are available in 4 lengths from 12mm to 18mm and two diameters (Ø3mm and Ø3.5mm) for an optimal fit.

The self-drilling screws feature sharper threaded, are available in 4 lengths from 12mm to 18mm and diameter Ø3.5mm. Revision screws with bigger core diameters are also available.

INSTRUMENT SET





#	DESCRIPTION	REFERENCE
01	AO CONNECTION DYNAMOMETRIC HANDLE 1.3 NM	HAN-SI DY 13-N
02	AO HANDLE	HAN-SI AO 08-N
03	IMPLANT HOLDER TUBE	SCA-IC 03 00-N
04	SCREWDRIVER FOR PINS	SCA-IC 07 00-N
05	ARTICULATED CERVICAL DISTRACTOR	CDP-IN 50 00-N
06	PINS DIA. 3.6 MM	CDP-IN 30 12-N CDP-IN 30 14-N CDP-IN 30 16-N CDP-IN 30 18-N
07	LOW-PROFILE IMPLANT HOLDERS	SCA-IC 11 05-N SCA-IC 11 06-N SCA-IC 11 07-N SCA-IC 11 08-N SCA-IC 11 09-N SCA-IC 11 10-N
08	ANATOMICAL RASP TRIALS	SCA-IC 2S 05-N SCA-IC 2S 07-N SCA-IC 2S 09-N SCA-IC 2L 05-N SCA-IC 2L 07-N SCA-IC 2L 09-N
09	COMPACTION BASE	SCA-IC 04 00-N
10	STRAIGHT CUTTING SQUARE AWL	SCA-IC 13 00-N
11	ANGLED CUTTING SQUARE AWL	SCA-IC 13 01-N
12	STRAIGHT SCREWDRIVER	SCA-IC 06 00-N

#	DESCRIPTION	REFERENCE
13	ANGLED SCREWDRIVER	SCA-IC 06 01-N
14	COMPACTOR	TRY-IN 01 00-N
15	NUT FOR PINS	CDP-IN 30 02-N
16	EXTRACTOR	SCA-IC 08 00-N
17	STRAIGHT DRILL	SCA-IC 09 00-N
18	ANGLED DRILL	SCA-IC 10 00-N
	INSTRUMENT CONTAINER	SCA-BX 10 01-N
	OPTION	
	ANATOMICAL SMOOTH TRIALS	SCA-IC 1S 05-N SCA-IC 1S 07-N SCA-IC 1S 09-N SCA-IC 1L 05-N SCA-IC 1L 07-N SCA-IC 1L 09-N
	LORDOTIC SMOOTH TRIALS	SCA-IC 3S 05-N SCA-IC 3S 07-N SCA-IC 3S 09-N SCA-IC 3L 05-N SCA-IC 3L 07-N SCA-IC 3L 09-N
	PINS DIA. 4.2 MM	CDP-IN 40 12-N CDP-IN 40 14-N CDP-IN 40 16-N CDP-IN 40 18-N

INSTRUMENTS

AO CONNECTION DYNAMOMETRIC HANDLE 1.3 NM	HAN-SI DY 13-N

AO HANDLE	HAN-SI AO 08-N

IMPLANT HOLDER TUBE	SCA-IC 03 00-N

ARTICULATED CERVICAL DISTRACTOR	CDP-IN 50 00-N

SCREWDRIVER FOR PINS	SCA-IC 07 00-N

PINS Ø3.6 L12	CDP-IN 30 12-N
PINS Ø3.6 L14	CDP-IN 30 14-N
PINS Ø3.6 L16	CDP-IN 30 16-N
PINS Ø3.6 L18	CDP-IN 30 18-N

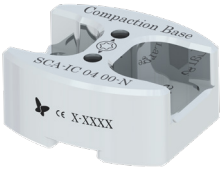
PINS Ø4.2 L12	CDP-IN 40 12-N
PINS Ø4.2 L14	CDP-IN 40 14-N
PINS Ø4.2 L16	CDP-IN 40 16-N
PINS Ø4.2 L18	CDP-IN 40 18-N

DISPOSABLE PINS Ø3.6 L12	SCA-IN 30 12-S
DISPOSABLE PINS Ø3.6 L14	SCA-IN 30 14-S
DISPOSABLE PINS Ø3.6 L16	SCA-IN 30 16-S
DISPOSABLE PINS Ø3.6 L18	SCA-IN 30 18-S

DISPOSABLE PINS Ø4.2 L12	SCA-IN 40 12-S
DISPOSABLE PINS Ø4.2 L14	SCA-IN 40 14-S
DISPOSABLE PINS Ø4.2 L16	SCA-IN 40 16-S
DISPOSABLE PINS Ø4.2 L18	SCA-IN 40 18-S

INSTRUMENTS

COMPACTION BASE	SCA-IC 04 00-N



ANGLED CUTTING SQUARE AWL	SCA-IC 13 01-N

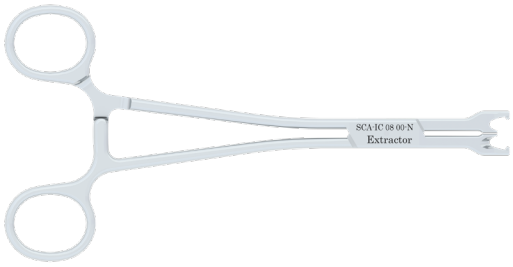
ANGLED SCREWDRIVER	SCA-IC 06 01-N

ANGLED DRILL	SCA-IC 10 00-N

LOW-PROFILE IMPLANT HOLDERS	SCA-IC 11 XX-N

COMPACTOR	TRY-IN 01 00-N

EXTRACTOR	SCA-IC 08 00-N



NUT FOR PINS	CDP-IN 30 02-N

STRAIGHT CUTTING SQUARE AWL	SCA-IC 13 00-N

STRAIGHT SCREWDRIVER	SCA-IC 06 00-N

STRAIGHT DRILL	SCA-IC 09 00-N

DISPOSABLE STRAIGHT DRILL	SCA-IC 09 01-S

LORDOTIC SMOOTH TRIALS	SCA-IC 3S XX-N SCA-IC 3L XX-N

ANATOMICAL SMOOTH TRIALS	SCA-IC 1S XX-N SCA-IC 1L XX-N

ANATOMICAL RASP TRIALS	SCA-IC 2X XX-N

SURGICAL TECHNIQUE

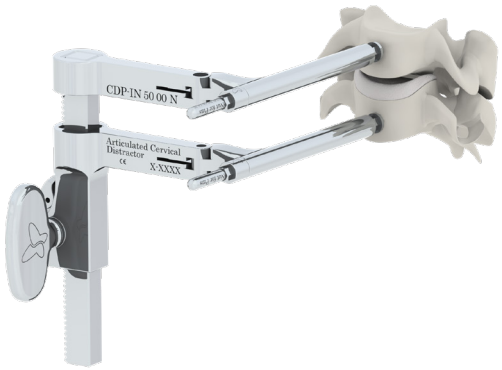
_STEP 1

PATIENT POSITIONING

Place the patient in a supine position on the operating table.

A pillow can be positioned under the neck of the patient to preserve the lordosis.

_STEP 2



DISTRACTION

Place the **Pins** parallel to the endplates.
Once the **Pins** are correctly placed, position the **Articulated Cervical Distractor** on the **Pins**.
Attach the **Nuts** to the **Screwdriver for Pins** and secure **Articulated Cervical Distractor** on the **Pins**.

INSTRUMENT	REFERENCE
PINS	CDP-IN 30 XX-N
ARTICULATED CERVICAL DISTRACTOR	CDP-IN 50 00-N
NUT FOR PINS	CDP-IN 30 02-N
SCREWDRIVER FOR PINS	SCA-IC 07 00-N

_STEP 3

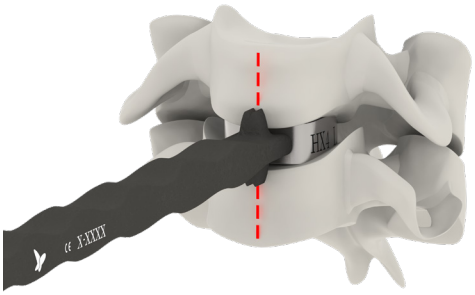
PREPARATION OF THE ENDPLATES

The **Anatomical Rasp Trials** can be used to further prepare the endplates.
A mallet can be used to gently advance the **Anatomical Rasp Trials**.

NOTE: that the «depth stopper» on the **Anatomical Rasp Trial** can be used for midline positioning.
The **Anatomical Rasp Trials** are 0.5mm smaller than the cage.

INSTRUMENT	REFERENCE
ANATOMICAL RASP TRIALS	SCA-IC 2S XX-N
ANATOMICAL RASP TRIALS	SCA-IC 2L XX-N

_STEP 3 BIS



SELECTION OF THE IMPLANT SIZE

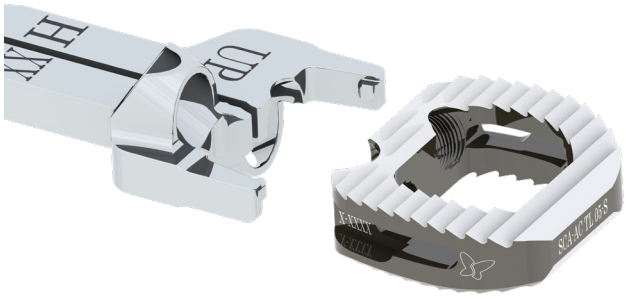
Use the appropriate **Trial** to determine the height and footprint (depth and width) of the implant.
The selection of the implant size depends on the intervertebral space, patient anatomy and preparation technique.

The appropriate **Trial** must be placed in a correct cranio-caudal position centered as shown in the picture.
A mallet can be used to gently insert the trial, note that the «depth stopper» on the appropriate **Trial** can be used for midline positioning.

Perform an AP and Lateral control, release the **Articulated Cervical Distractor** to verify the stability of the appropriate **Trial** implant.

INSTRUMENT	REFERENCE
ANATOMICAL RASP TRIALS	SCA-IC 2S XX-N SCA-IC 2L XX-N
ANATOMICAL SMOOTH TRIALS	SCA-IC 1S XX-N SCA-IC 1L XX-N
LORDOTIC SMOOTH TRIALS	SCA-IC 3S XX-N SCA-IC 3L XX-N

_STEP 4



ASSEMBLY OF THE IMPLANT HOLDER

Select the **Low Profile Implant Holder** according to the height previously selected.
Assemble the **Implant Holder Tube** on the **Low Profile Implant Holder** and turn the **Implant Holder Tube** until it passes the first set of threads.

Attach the **AO Handle** to the **Low Profile Implant Holder**.
To facilitate the assembly of the two elements ensure that the two arrows are correctly aligned.
Pull and twist the **AO Handle** to ensure it is fixed properly.

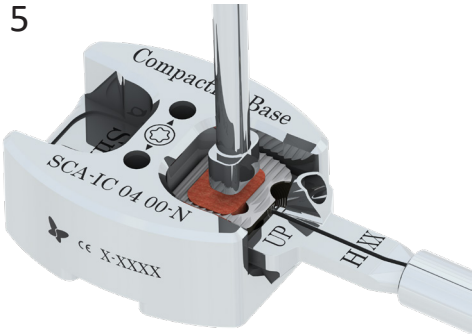
SURGICAL TECHNIQUE

_STEP 4

Align the UP markings on the **Low Profile Implant Holder** with the top of the implant and attach the implant into the **Low Profile Implant Holder**. Turn the tube down towards the implant to lock it in place. Do not over tighten.

INSTRUMENT	REFERENCE
LOW PROFILE IMPLANT HOLDER	SCA-IC 11 05-N TO SCA-IC 11 10-N
IMPLANT HOLDER TUBE	SCA-IC 03 00-N
AO CONNECTION HANDLE	HAN-SI AO 08-N

_STEP 5



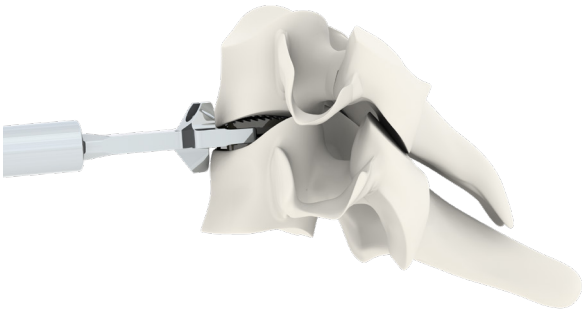
CAGE PREPARATION

Place the cage on the **Compaction Base** and fill it with bone graft by using the **Compactor**.

NOTE: Use the **Compaction Base** as a base for screws, to facilitate the connection between screws and self retaining screwdriver.

INSTRUMENT	REFERENCE
COMPACTION BASE	SCA-IC 04 00-N
COMPACTOR	TRY-IN 01 00-N

_STEP 6



INSERTION

Insert the implant in the intervertebral space.
The **Low Profile Implant Holder** is equipped with a depth stop.
Impact gently with a hammer if needed.
Remove the **Articulated Cervical Distractor** and **Pins**.

OPTION: Place a small amount of bone wax in the holes created by the Pins.

INSTRUMENT	REFERENCE
LOW-PROFILE IMPLANT HOLDER	SCA-IC 11 XX-N

SURGICAL TECHNIQUE

_STEP 7

PREPARATION OF THE FIRST SCREW SITE

Prepare the insertion hole for the cervical screw in the superior vertebra by inserting the **Straight or Angled Cutting Square Awl** into the guide hole of the **Low Profile Implant Holder**.

Both **Square Awls** measure 14mm length. This helps to estimate the final screw length with a lateral image control

INSTRUMENT	REFERENCE
STRAIGHT CUTTING SQUARE AWL	SCA-IC 13 00-N
ANGLED CUTTING SQUARE AWL	SCA-IC 13-01-N
LOW-PROFILE IMPLANT HOLDER	SCA-IC 11 XX-N

_STEP 8

FIRST SCREW INSERTION

Assemble the selected screwdriver.
While keeping in place the **Low Profile** Implant **Holder**, insert the superior screw using the **Straight or Angled Screwdriver**.

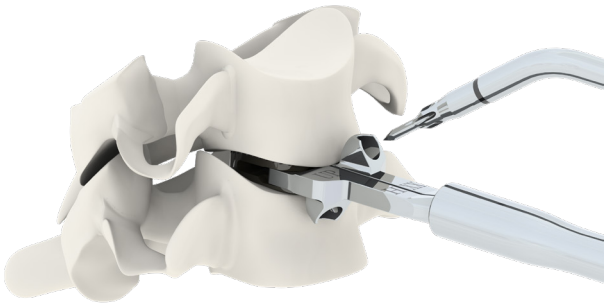
Use AP and Lateral images to verify the implant position.
It is necessary to create pilot holes prior to insert the SCARLET®AC-T screws.

NOTE : No instrument other than the **AO Connection Dynamometric Handle 1.3 NM** shall be used to tighten and secure the cervical screws to final position.

INSTRUMENT	REFERENCE
LOW-PROFILE IMPLANT HOLDER	SCA-IC 11 XX-N
STRAIGHT SCREWDRIVER	SCA-IC 06 00-N
ANGLED SCREWDRIVER	SCA-IC 06 01-N
AO CONNECTION DYNAMOMETRIC HANDLE 1.3 NM	HAN-SI DY 13-N

SURGICAL TECHNIQUE

_STEP 9

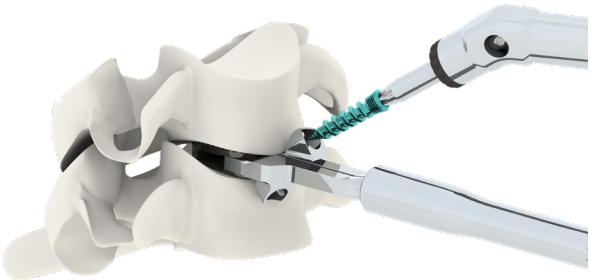


PREPARATION OF THE SECOND SCREW SITE

Prepare the insertion hole of the screws in the inferior vertebra by inserting the **Straight or Angled Cutting Square Awl** in the guide holes on the **Low Profile Implant Holder**.

INSTRUMENT	REFERENCE
STRAIGHT CUTTING SQUARE AWL	SCA-IC 13 00-N
ANGLED CUTTING SQUARE AWL	SCA-IC 13 01-N
LOW PROFILE IMPLANT HOLDER	SCA-IC 11 XX-N

_STEP 10



SECOND SCREW INSERTION

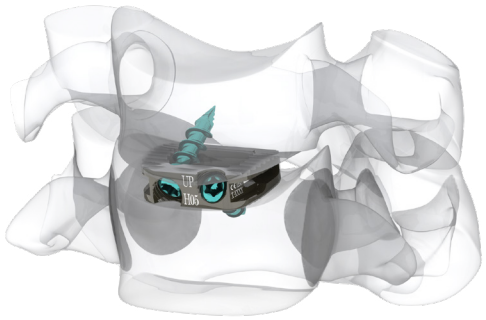
Insert the inferior screw using the **Straight** or **Angled Screwdriver**.

Verify implant placement with AP and lateral image.

NOTE : No instrument other than the **AO Connection Dynamometric Handle 1.3 NM** shall be used to tighten and secure the cervical screws to final position.

INSTRUMENT	REFERENCE
AO CONNECTION DYNAMOMETRIC HANDLE 1.3 NM	HAN-SI DY 13-N
STRAIGHT SCREWDRIVER	SCA-IC 06 00-N
ANGLED SCREWDRIVER	SCA-IC 06 01-N
LOW-PROFILE IMPLANT HOLDER	SCA-IC 11 XX-N

_FINAL CONSTRUCT



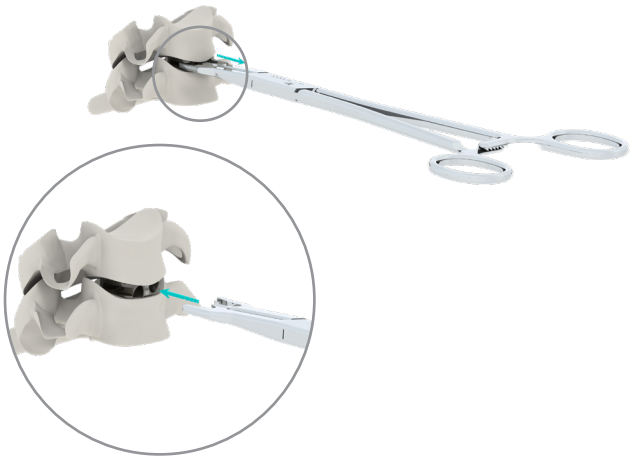
_REVISION

In case of revision, remove both screws using the **Straight or Angled Screwdriver** by turning them counter-clockwise.

Use the **Extractor** to remove the implant.

Gently pull the implant out of the vertebral space.

INSTRUMENT	REFERENCE
STRAIGHT SCREWDRIVER	SCA-IC 06 00-N
ANGLED SCREWDRIVER	SCA-IC 06 01-N
AO HANDLE	HAN-SI AO 08-N
EXTRACTOR	SCA-IC 08 00-N



GENERAL INFORMATION

REFERENCE OF THE IFU	SCA-IF AC 01-W	REVISION OF THE FINAL IFU	OCT-2017

_STERILITY

The implant is provided sterile. Under sterile condition, implants are packaged in a first polyethylene pouch, put in a second PETG blister. Each of these packaging are 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 mustn't be used. The re-sterilization of the gamma sterilized implant is forbidden. The SCARLET®AC-T implant must not be used with implant other than SCARLET®AC-T range. The SCARLET®AC-T implant must only be used with the SCARLET®AC-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 results, 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®AC-T cage system should not be used with components of any other system or manufacturer.

_DESCRIPTION

The SCARLET®AC-T implant range was designed to ensure the best possible adaptation to the patient's anatomic variations.

Intersomatic SCARLET®AC-T cage: Titanium cervical implant used to perform fusion between cervical vertebras after discectomy.

Screw SCARLET®cs: Titanium fixation implant associated to the SCARLET®AC-T cage.

_INDICATIONS

SCARLET®AC-T cages are indicated for use in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage. SCARLET®AC-T cages are intended to be used at one level from the C2-C3 disc to the C7-T1 disc to facilitate intervertebral body fusion with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The SCARLET®AC-T Secured Anterior Cervical Cage is intended to be used as a standalone system used with the two bone screws provided and requires no additional supplementary fixation systems. When used without the two bone screws, SCARLET®AC-T cages are to be used with supplemental fixation which has been cleared by the FDA for use in the cervical spine.

_CONTRAINDICATIONS

Include but not limited to:

- 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 tumor in the region of implant.

_SIDE EFFECTS

Per operative:

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

GENERAL INFORMATION

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 risk 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.

_CAUTION - PRECAUTION FOR USE

An in-depth discussion of all possible complications associated with cervical interbody fusion with cage 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 cervical 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.

The SCARLET®AC-T cage system has not been evaluated for safety and compatibility in the MR environment. The SCARLET®AC-T cage system has not been tested for heating or migration in the MR environment.

_HANDLING

No effort has been spared to ensure 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.

_SURGERY METHODS

Precaution: the implantation of cervical interbody cage should be performed only by experienced surgeons with specific training in the use of this cervical interbody cage because this is a technically demanding procedure presenting 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 installing any of the SCARLET®AC-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.

GENERAL INFORMATION

_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 were specifically designed for use when installing the SCARLET®AC-T 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 SCARLET®AC-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.

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

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):

Minimum exposure time: 18 minutes

Minimum temperature: 134°C

Drying time: 30 minutes

Cycle 2 (USA):

Minimum exposure time: 4 minutes

Minimum 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"

GENERAL INFORMATION

_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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