CURE OPEL-C

ANTERIOR CERVICAL PLATE

SURGICAL TECHNIQUE

CONTENT

CONCEPT AND DESIGN

The Cure™ OPEL-C Cervical Plate System is a next generation titanium plate and screw system designed by a group of tenured and practicing spine surgeons.

The design philosophy with the surgical team was to leverage their experience, keep things simple and yet be innovative. The system is designed to interface specifically with TALOS® C HA interbodies to provide mechanical support to the implanted level until biologic fusion is achieved. The system features low-profile plates and an integrated locking mechanism to prevent screw back out while placing either variable or fixed angle screws.

AT A GLANCE

Combines TALOS C HA Interbody with Cervical Plate

Allows minimal plate length

Perpendicular plate orientation

Tactile and Visual Locking Mechanism

INDICATIONS

The Cure™ OPEL-C System is intended to be used with TALOS®-C / TALOS®-C HA interbodies for anterior screw fixation to the C2 to C7 levels of the cervical spine. The system is indicated for use in skeletally mature patients for temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:

- Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e., fractures or dislocations)
- Deformity (defined as kyphosis, lordosis, or scoliosis)
- Pseudarthrosis
- Failed previous fusions

IMPLANTS

PLATES

ITEM SIZE	STERILE PART #	DESCRIPTION
16 MM	S1-11-0S001-16	OPEL-C (S), 16MM, 1 LEVEL PLATE
17 MM	S1-11-0S001-17	OPEL-C (S), 17MM, 1 LEVEL PLATE
18 MM	S1-11-0S001-18	OPEL-C (S), 18MM, 1 LEVEL PLATE
19 MM	S1-11-0S001-19	OPEL-C (S), 19MM, 1 LEVEL PLATE
20 MM	S1-11-0S001-20	OPEL-C (S), 20MM, 1 LEVEL PLATE
21 MM	S1-11-0S001-21	OPEL-C (S), 21MM, 1 LEVEL PLATE
22 MM	S1-11-0S001-22	OPEL-C (S), 22MM, 1 LEVEL PLATE *
23 MM	S1-11-0S001-23	OPEL-C (S), 23MM, 1 LEVEL PLATE *

* OPTIONAL

IMPLANTS

PLANAR/LORDOTIC CAGES

14X12MM FOOTPRINT
7° LORDOSIS

HEIGHTS	REFERENCES
5 MM	5-21205-07
6 MM	5-21206-07
7 MM	5-21207-07
8 MM	5-21208-07
9 MM	5-21209-07
10 MM	5-21210-07

16X14MM FOOTPRINT
7° LORDOSIS

HEIGHTS	REFERENCES
5 MM	5-21305-07
6 MM	5-21306-07
7 MM	5-21307-07
8 MM	5-21308-07
9 MM	5-21309-07
10 MM	5-21310-07

18X15MM FOOTPRINT
7° LORDOSIS

HEIGHTS	REFERENCES
5 MM	5-21605-07
6 MM	5-21606-07
7 MM	5-21607-07
8 MM	5-21608-07
9 MM	5-21609-07
10 MM	5-21610-07

14X12MM FOOTPRINT
14° LORDOSIS

HEIGHTS	REFERENCES
6 MM	5-21206-14
7 MM	5-21207-14
8 MM	5-21208-14
9 MM	5-21209-14
10 MM	5-21210-14

16X14MM FOOTPRINT
14° LORDOSIS

HEIGHTS	REFERENCES
6 MM	5-21306-14
7 MM	5-21307-14
8 MM	5-21308-14
9 MM	5-21309-14
10 MM	5-21310-14

18X15MM FOOTPRINT
14° LORDOSIS

HEIGHTS	REFERENCES
6 MM	5-21606-14
7 MM	5-21607-14
8 MM	5-21608-14
9 MM	5-21609-14
10 MM	5-21610-14

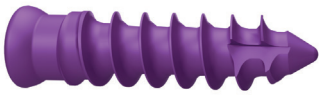
CONVEX / ANATOMIC CAGES

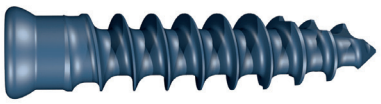
14X12MM FOOTPRINT 0° LORDOSIS	
HEIGHTS	**REFERENCES**
5 MM	5-22205-07
6 MM	5-22206-07
7 MM	5-22207-07
8 MM	5-22208-07
9 MM	5-22209-07
10 MM	5-22210-07

16X14MM FOOTPRINT 0° LORDOSIS	
HEIGHTS	**REFERENCES**
5 MM	5-22305-07
6 MM	5-22306-07
7 MM	5-22307-07
8 MM	**5-22308-07**
9 MM	5-22309-07
10 MM	5-22310-07

IMPLANTS

SCREWS





SELF-TAPPING SCREWS – VARIABLE Ø 4.1		
ITEM SIZE	**STERILE PART # BY 2**	**STERILE PART # BY 4**
12 MM	S2-7-42141-12	S4-7-42141-12
14 MM	S2-7-42141-14	S4-7-42141-14
16 MM	S2-7-42141-16	S4-7-42141-16
18 MM	S2-7-42141-18	S4-7-42141-18

SELF-DRILLING SCREWS – VARIABLE Ø 4.1		
ITEM SIZE	**STERILE PART # BY 2**	**STERILE PART # BY 4**
12 MM	S2-7-42241-12	S4-7-42241-12
14 MM	S2-7-42241-14	S4-7-42241-14
16 MM	S2-7-42241-16	S4-7-42241-16
18 MM	S2-7-42241-18	S4-7-42241-18

SELF-TAPPING SCREWS – VARIABLE Ø 4.5		
ITEM SIZE	**STERILE PART # BY 2**	**STERILE PART # BY 4**
12 MM	S2-7-42145-12	S4-7-42145-12
14 MM	S2-7-42145-14	S4-7-42145-14
16 MM	S2-7-42145-16	S4-7-42145-16
18 MM	S2-7-42145-18	S4-7-42145-18

SELF-DRILLING SCREWS – VARIABLE Ø 4.5		
ITEM SIZE	**STERILE PART # BY 2**	**STERILE PART # BY 4**
12 MM	S2-7-42245-12	S4-7-42245-12
14 MM	S2-7-42245-14	S4-7-42245-14
16 MM	S2-7-42245-16	S4-7-42245-16
18 MM	S2-7-42245-18	S4-7-42245-18

IMPLANTS

SCREWS

SELF-TAPPING SCREWS – FIXED Ø 4.1

ITEM SIZE	STERILE PART # BY 2	STERILE PART # BY 4
12 MM	S2-7-41141-12	S4-7-41141-12
14 MM	S2-7-41141-14	S4-7-41141-14
16 MM	S2-7-41141-16	S4-7-41141-16
18 MM	S2-7-41141-18	S4-7-41141-18

SELF-DRILLING SCREWS – FIXED Ø 4.1

ITEM SIZE	STERILE PART # BY 2	STERILE PART # BY 4
12 MM	S2-7-41241-12	S4-7-41241-12
14 MM	S2-7-41241-14	S4-7-41241-14
16 MM	S2-7-41241-16	S4-7-41241-16
18 MM	S2-7-41241-18	S4-7-41241-18

SELF-TAPPING SCREWS – FIXED Ø 4.5

ITEM SIZE	STERILE PART # BY 2	STERILE PART # BY 4
12 MM	S2-7-41145-12	S4-7-41145-12
14 MM	S2-7-41145-14	S4-7-41145-14
16 MM	S2-7-41145-16	S4-7-41145-16
18 MM	S2-7-41145-18	S4-7-41145-18

SELF-DRILLING SCREWS – FIXED Ø 4.5

ITEM SIZE	STERILE PART # BY 2	STERILE PART # BY 4
12 MM	S2-7-41245-12	S4-7-41245-12
14 MM	S2-7-41245-14	S4-7-41245-14
16 MM	S2-7-41245-16	S4-7-41245-16
18 MM	S2-7-41245-18	S4-7-41245-18

TECHNICAL FEATURES

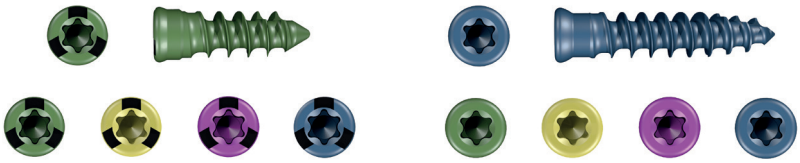
PLATE

Plate thickness is 2.2mm
16.5mm wide and 10mm waist
Composed of Ti Alloy (Ti-6AL-4V ELI)

*Lengths are measured end to end

**For screw hole to distal screw hole measurement: subtract 7mm

SCREWS

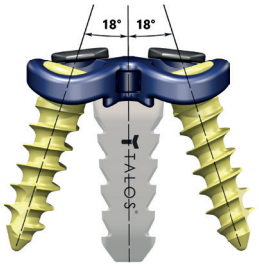


Color anodized to identify function and length
Composed of Ti Alloy (Ti-6AL-4V ELI)
2.8mm hexalobe (T10 torx) recess
Standard screw diameter: 4.1mm
Revision screw diameter: 4.5mm

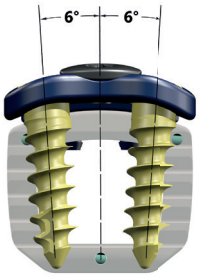
*Screw length is measured from the underside of the plate

TECHNICAL FEATURES

FIXED ANGLE SCREWS

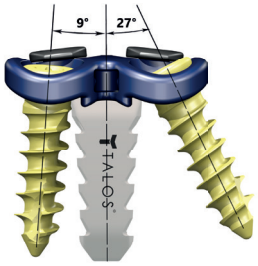


Cephalad/Caudal Angulation : 18°

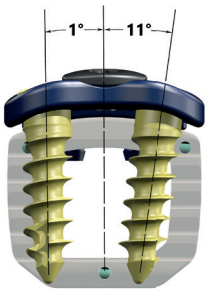


Medial/Lateral Angulation : 6°

VARIABLE ANGLE SCREWS



Cephalad/Caudal Angulation : 27°-9° Range

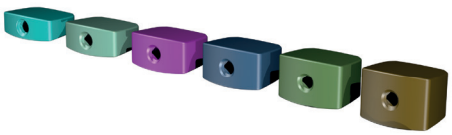


Medial/Lateral Angulation : 11°-1° Range

INSTRUMENTS

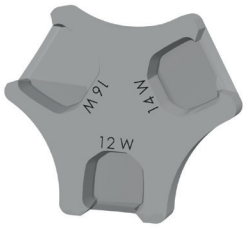
CURE OPEL-C TEMPLATES	T-11-0S001-XX

TALOS-C TRIALS	500-XXXXXX-XX



TRIAL INSERTER	510-200-00

PACKING BLOCK	520-205-50



BONE PACKING TOOL	520-205-55

OPEL-C INSERTER	1100-400-02

OPEL-C FORK, RESCUE	1100-400-02-02R

AO QUICK CONNECT HANDLE	700-405-RF

DRILLS	700-430-XX

SHEATHED AWL	700-460-00

INSTRUMENTS

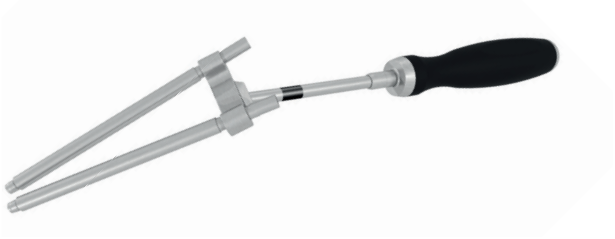
FIXED AWL SHEATH 700-461-00

VARIABLE AWL SHEATH 700-462-00

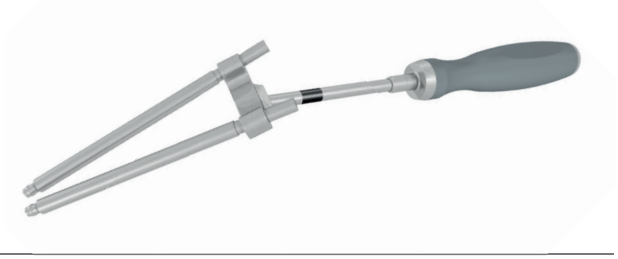
SINGLE BARREL DRILL GUIDE - FIXED 700-410-05

SINGLE BARREL DRILL GUIDE - VARIABLE 700-420-05

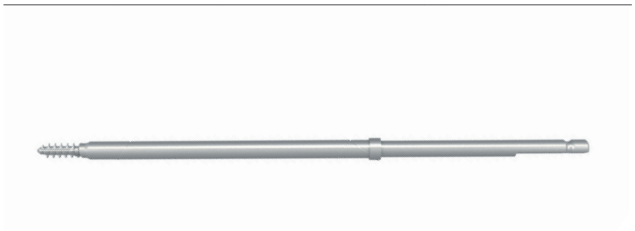
DOUBLE BARREL DRILL GUIDE, FIXED 1100-412-05



DOUBLE BARREL DRILL GUIDE, VARIABLE 1100-422-05



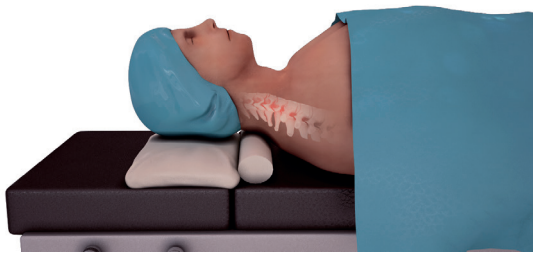
NON STERILE CURE ACP TAP 700-436-00



DRIVER 700-400-00

SURGICAL TECHNIQUE

_STEP 1



PATIENT POSITIONING

Standard anterior exposure techniques should be utilized to expose the spinal segment(s) to be fused.

A properly-sized plate should span the distance between the caudal and cephalad vertebrae. The surgeon should obtain an anterior exposure to the spine according to preference of incision, approach angle and side (left or right) of the patient.

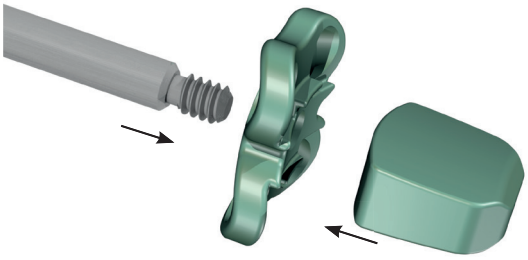
_STEP 2

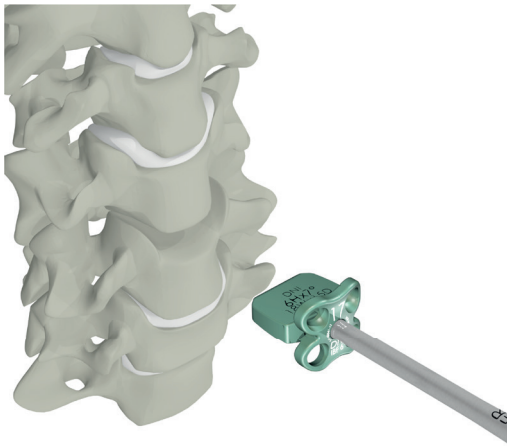
EXPOSURE OF SPINE

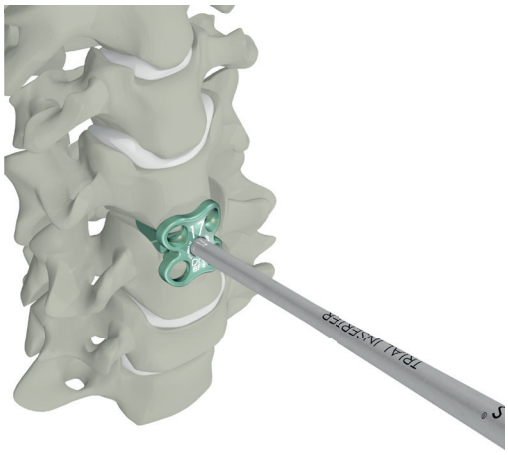
A multitude of retractors exist to provide adequate exposure during dissection, performing disc preparation and implanting the prosthesis. Depending on dissection preference, the surgeon should expose the mid-line of the intervertebral disc above and below the diseased level. Fluoroscopy should be used to verify position. Distractors, whether a spreader or distraction pins can be used to help with gentle distraction of the disc space. If used, distraction pins should be placed about 1cm from the edge of the endplate to allow clearance during implant insertion.

_STEP 3

CAGE & PLATE SELECTION / CONTOURING







After the appropriate disc has been removed, the TALOS-C interbody trial and the Cure™ OPEL-C template can be applied to the spine.

To ensure ideal anatomical fit, determine the appropriate cage & plate size using the supplied templates. TALOS®-C and OPEL-C implants are to be paired by height according to the following table:

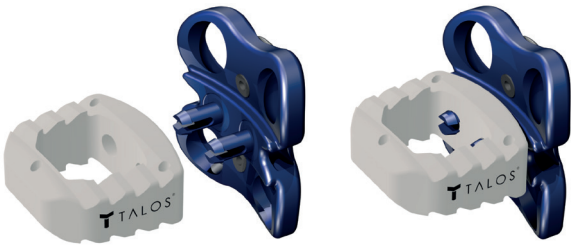
TALOS®-C IBF HEIGHT (MM)	5	6	7	8	9	10
OPEL-C PLATE LENGTH (MM)	16	17	18	19	20	21

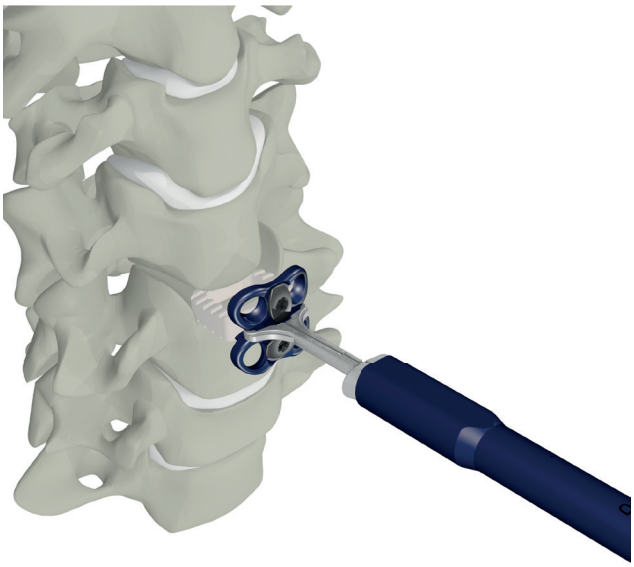
Insert the **trial inserter** on both the plate and cage template. Further insert it in the intervertebral space.

Check by fluoroscopy the adequate sizing of the templates

INSTRUMENT	**REFERENCE**
OPEL-C TEMPLATES	T-11-0S001-LL
TALOS-C TRIALS	500-XXXXXX-XX
TRIAL INSERTER	510-200-00

_STEP 4





IMPLANTS PREPARATION & POSITIONING

Once the adequate implants have been selected, pack the cage with bone graft using the **packing block** and the **bone packing tool**.

Assemble the outer tube to the knob by compressing the knob & inserting the proximal part of the tube in the knob's groove and releasing the knob. Insert the **OPEL-C fork** to the outer tube and turn the knob clockwise to engage the fork thread in the knob. Clip the fork on the plate and turn the knob clockwise to secure the implants in the inserter: the black line on the inserter should indicate lock.

Clip the cage onto the plate by aligning the two teeth of the plate with the two openings of the cage. A tactile and audible click will be felt and heard. Once fully assembled, hold the plate with the OPEL-C insertion tool.

Impact the cage into the intervertebral space until the plate is positioned onto the vertebral bodies.

To release the plate from the inserter, unscrew the knob of the instrument.

INSTRUMENT	REFERENCE
PACKING BLOCK	520-205-50
BONE PACKING TOOL	520-205-50

_STEP 5A

PREPARATION OF SCREW HOLES - FIXED ANGLE, SELF-TAPPING SCREWS

With the plate in proper position, select the **Single Barrel Fixed Drill Guide** or **Double Barrel Fixed Drill Guide** and place it into the desired screw hole of the plate.

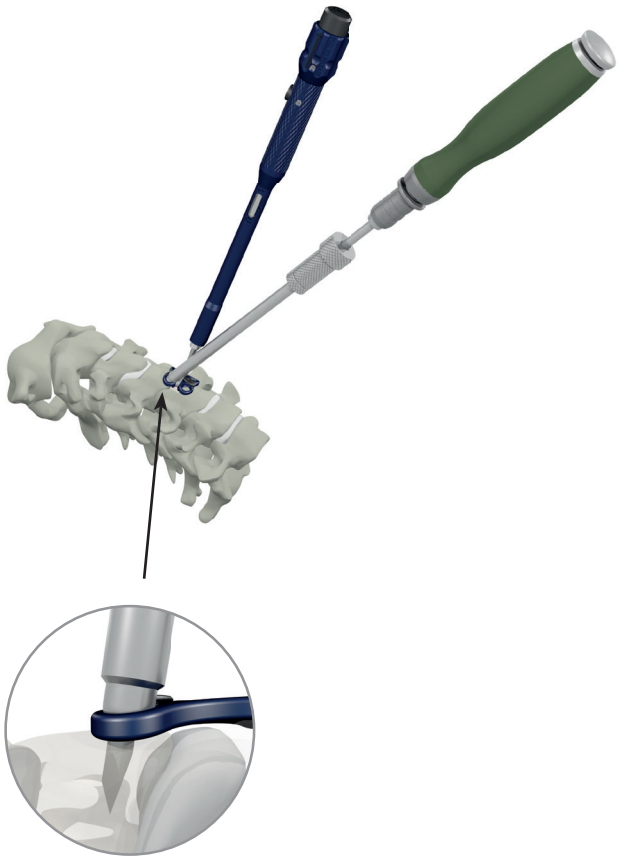
Securely seat the distal end of the drill guide into the hole of the plate so the correct, fixed angle screw trajectory is obtained.

Select the proper length **Drill** bit to match the chosen screw length and attach to the **Quick Connect Handle** (or the Drill bit may be attached to an appropriate power drill system). Once the Drill bit is attached to the handle, it may be introduced through the drill sleeve and advanced to its permitted depth stop when it meets the proximal end of the drill guide.

NOTE: Screw lengths are measured from the underside of the plate and does not include the screw head. Repeat this procedure for all additional holes in the plate.

INSTRUMENT	REFERENCE
SINGLE BARREL DRILL GUIDE - FIXED	700-410-05
DOUBLE BARREL DRILL GUIDE, FIXED	1100-412-05
DRILL	700-430-XX
AO QUICK CONNECT HANDLE	700-405-RF

_STEP 5B



Awl advances to the appropriate depth

PREPARATION OF SCREW HOLES - FIXED ANGLE, SELF-DRILLING SCREWS

Assemble the **Quick Connect Handle** with the **Sheathed Awl** and the **Fixed Awl Sheath**.

With the plate in the proper position, place the assembly into the desired screw hole of the plate.

Securely seat the distal end of **Fixed Awl Sheath** into selected hole of the plate.

Push down the handle to release the awl and so the correct fixed angle screw trajectory is obtained.

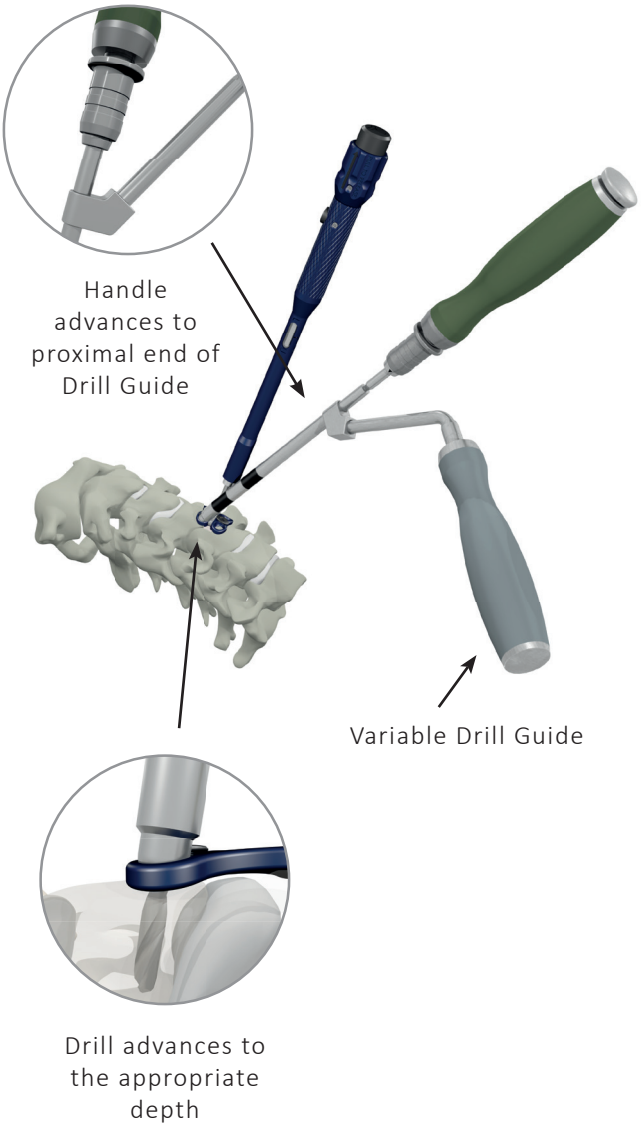
If necessary, a **drill** can be used to ease the screw insertion.

NOTE: Screw length are measured from the underside of the plate and does not include the screw head. The awl depth is 7mm when fully extended through the cortex.

Repeat this procedure for all additional holes in the plate.

INSTRUMENT	REFERENCE
SHEATHED AWL	700-460-00
FIXED AWL SHEATH	700-461-00
AO QUICK CONNECT HANDLE	700-405-00
DRILL	700-430-XX

_STEP 5C



PREPARATION OF SCREW HOLES - VARIABLE ANGLE, SELF-TAPPING SCREWS

With the plate in proper position, select the **Single Barrel Variable Drill Guide** or **Double Barrel Variable Drill Guide** and place it into the desired screw hole of the plate.

Securely seat the distal end of the Drill Guide into the hole of the plate so the correct, variable angle screw trajectory is obtained.

Select the proper length **Drill** bit to match the chosen screw length and attach to the **Quick Connect Handle** (or the Drill bit may be attached to an appropriate power drill system).

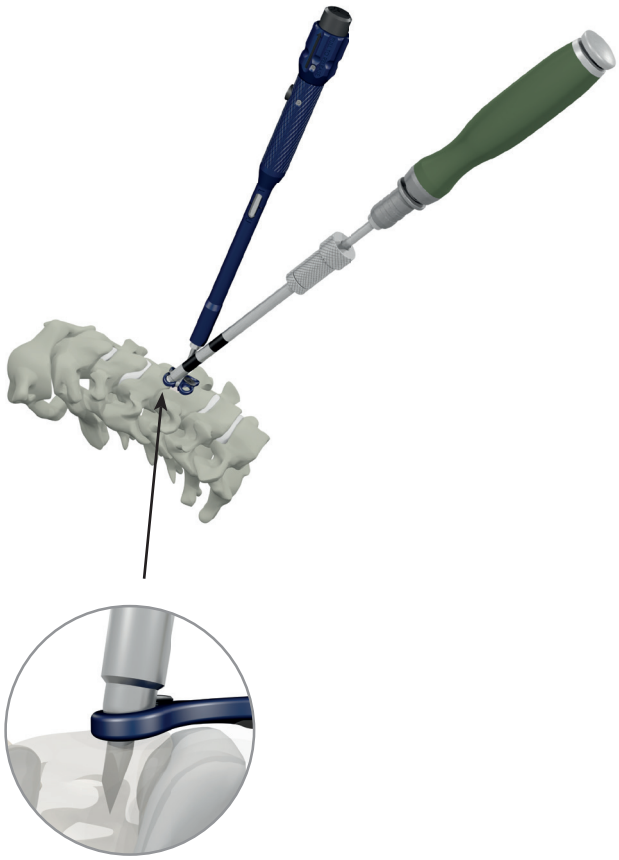
Once the **Drill** bit is attached to the handle, it may be introduced through the drill sleeve and advanced to its permitted depth stop when it meets the proximal end of the Drill Guide.

NOTE: Screw lengths are measured from the underside of the plate and does not include the screw head.

Repeat this procedure for all additional holes in the plate (Figure 6).

INSTRUMENT	REFERENCE
SINGLE BARREL DRILL GUIDE - VARIABLE	700-420-05
DOUBLE BARREL DRILL GUIDE, VARIABLE	1100-422-05
DRILL	700-430-XX
AO QUICK CONNECT HANDLE	700-405-RF

_STEP 5D



Awl advances to the appropriate depth

PREPARATION OF SCREW HOLES - VARIABLE ANGLE, SELF-DRILLING SCREWS

Assemble the **Quick Connect Handle** with the **Sheathed Awl** and the **Variable Awl Sheath**.

With the plate in the proper position, place the assembly into the desired screw hole of the plate.

Securely seat the distal end of **Variable Awl Sheath** into selected hole of the plate.

Push down the handle to release the awl and so the correct variable angle screw trajectory is obtained.

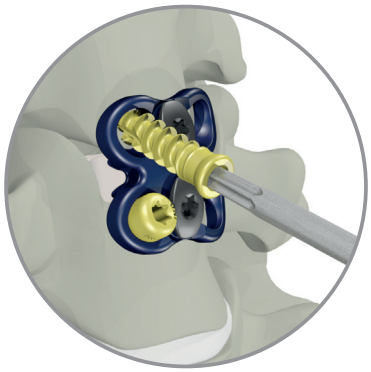
If necessary, a **drill** can be used to ease the screw insertion.

NOTE: Screw length are measured from the underside of the plate and does not include the screw head. The awl depth is 7mm when fully extended through the cortex.

Repeat this procedure for all additional holes in the plate.

INSTRUMENT	REFERENCE
SHEATHED AWL	700-460-00
VARIABLE AWL SHEATH	700-462-00
AO QUICK CONNECT HANDLE	700-405-00
DRILL	700-430-XX

_STEP 6



PLACEMENTS OF SCREWS

After each pilot has been prepared for the bone screws, the **Driver** should be attached to the **Quick Connect Handle** and the appropriate bone screw loaded to the promixal end of the Driver.

The Driver interface with the bone screw is a friction fit and care should be taken to ensure it is loaded securely onto the Driver.

The Cure bone screws can be identified by their color, tip configuration and laser markings.

The screw can be inserted through the hole on the plate taking care not to over-tighten (see figure).

To prevent possible Driver breakage or stripping in sclerotic bone, a tap should be used to prepare the screw holes.

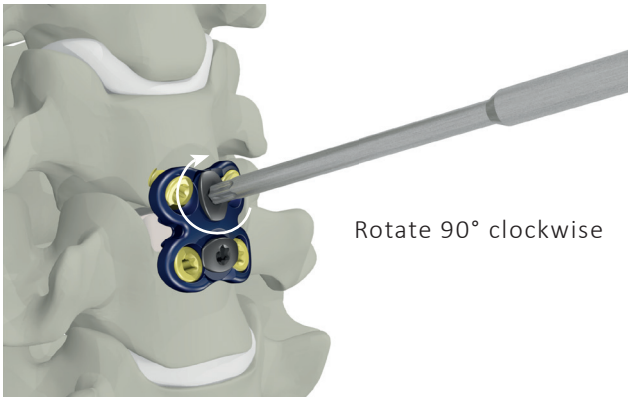
The underside of the screw head should sit flush into the plate (see figure).

Repeat the process for all screws.

INSTRUMENT	REFERENCE
DRIVER	700-400-00
AO QUICK CONNECT HANDLE	700-405-RF

SURGICAL TECHNIQUE

_STEP 7



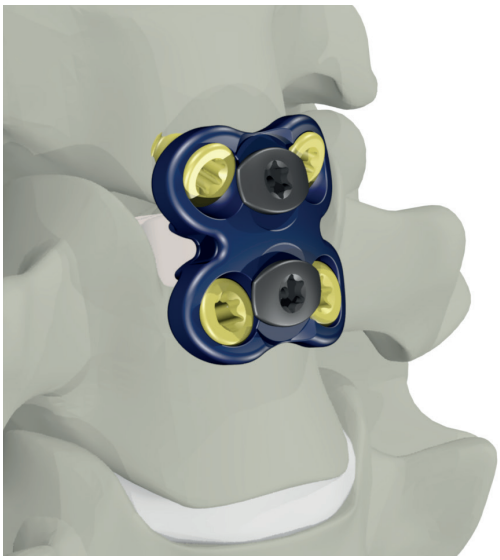
SECUREMENT OF SCREWS

Once all screws have been properly placed, use the **Driver** to rotate the central locking mechanism 90° clockwise into the locked position (see image below).

CAUTION: The central locking mechanism should not be rotated past 90°. Trying to rotate the locking mechanism past 90° will result in permanent damage and the plate should be discarded.

INSTRUMENT	REFERENCE
DRIVER	700-400-00

_FINAL CONSTRUCT



Once the Cure™ Opel-C plate is implanted, a final x-ray confirming proper placement may be performed and a standard closing technique should be utilized.

Depending on surgeon preference, a collar can be worn postoperatively

_IMPLANT REMOVAL

If a need to remove the screws from the plate occurs, use the screwdriver to rotate the central locking mechanism 90° counterclockwise.

Position the screwdriver into the hexalobe recess in the identified screw and rotate counterclockwise until the screw is completely removed from the plate.

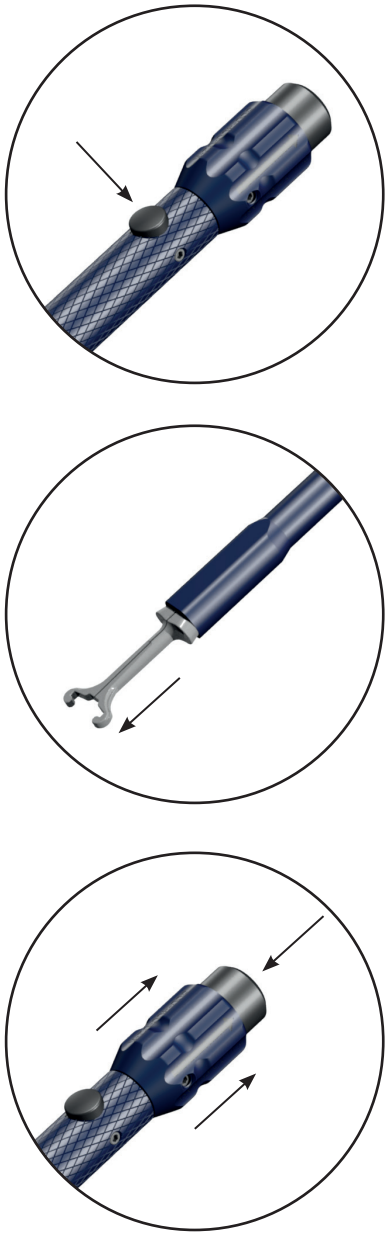
To remove the cage/plate assembly, use the **rescue fork** within the **inserter**. First disassemble the standard fork from the inserter by turning the knob anticlockwise to release the fork from the outer tube. Then insert the **OPEL-C rescue fork** into the outer tube and turn the knob clockwise to engage the fork thread in the knob.

Once assembled, position the rescue fork tips on the plate and turn the knob clockwise to seize it firmly before extracting it.

INSTRUMENT	REFERENCE
DRIVER	700-400-00
OPEL-C INSERTER	1100-400-00
RESCUE FORK	1100-400-02-02R

SURGICAL TECHNIQUE

_OPEL-C IBF INSERTER USAGE, ASSEMBLY AND DISASSEMBLY



DISASSEMBLY OF THE OPEL-C INSERTER

Rotate the knob in the counter-clockwise direction as indicated in Figure 3 so that the laser line is in the “U” or unlocked zone.

Depress the button on the body, pulling the forks away from the body. If the forks do not disengage, continue rotating the knob in the counter-clockwise direction.

DISENGAGING THE KNOB FROM THE BODY

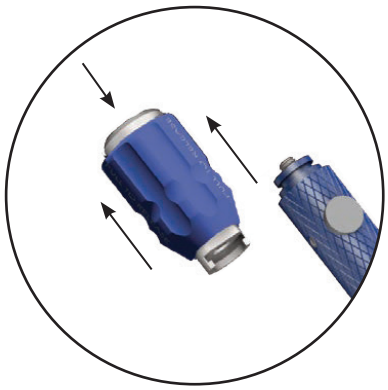
Hold the inserter body in one hand.

In the other hand, place your thumb at the end of the knob and your index finger and middle finger at opposite sides of the knob

Pull the knob up with your index finger and middle finger until the inner engagement portion of the knob and body is exposed.

Slide the body of the inserter away from the knob to disengage. with the button depressed until the forks pull away from the body.

SURGICAL TECHNIQUE



ASSEMBLY OF THE OPEL-C INSERTER

In one hand, place your thumb at the end of the knob and your index finger and middle finger at opposite sides of the knob.

Pull the spring loaded knob up with your index finger and middle finger until the inner portion is exposed.

Slide the end of the inserter body into the opening of the exposed portion inside the knob and release fingers to fully engage.

While depressing the button on the inserter body, slide the fork, threads first, into the inserter body opposite the knob end.

The fork should not fall out while the button is released. If it does, the fork may require rotation (with button depressed) so that it correctly mates with the inserter body.

GENERAL INFORMATION

REFERENCE OF THE IFU	OPE-CE-IF-US	REVISION OF THE FINAL IFU	APR-2022

INSTRUCTION FOR USE – IMPLANTS & INSTRUMENTS
CURE™ OPEL-C RANGE®

_STERILITY

The implants are provided sterile. The instruments are provided non-sterile.

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

_DESCRIPTION

The Cure™ OPEL-C is a plate and screw system composed of medical grade titanium (Ti-6Al-4V ELI) components. Titanium fixed and variable angle screws are available in various diameters and lengths. The titanium plate contains integrated mechanisms that secure the bone screws to the plate. The system is designed to interface specifically with Talos®-C and Talos® C (HA) interbodies to provide mechanical support to the implanted level until biologic fusion is achieved. Plates are available in a variety of lengths to accommodate normal cervical spine lordosis, The Cure™ Anterior Cervical Plate comes with a pre-machined lordotic curve. An array of appropriate instruments are available to facilitate the implantation of the device.

_INDICATIONS

The Cure™ OPEL-C System is intended to be used with Talos®-C / Talos®-C (HA) interbodies for anterior screw fixation to the C2 to C7 levels of the cervical spine. The system is indicated for use in skeletally mature patients for temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:

- Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e., fractures or dislocations)
- Deformity (defined as kyphosis, lordosis, or scoliosis)
- Pseudarthrosis
- Failed previous fusions

_INDICATIONS

This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine. Never reuse an implant under any circumstances. Even when a removed device appears undamaged, it may contain small defects or residual stresses. These defects and stresses may lead to implant failure. Any retrieved devices should be handled in a manner such that they may not be reused in another surgical procedure.

_CONTRAINDICATIONS

The contraindications include, but are not limited to:

1. Infection, local to the operative site.
2. Morbid obesity and patients who are unwilling to restrict activities or follow medical advice.
3. Pregnancy.
4. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
5. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis.
6. Suspected or documented metal allergy.
7. Any case not described in the indications
   - An active infection
   - Suspected or documented allergy to titanium

GENERAL INFORMATION

_SIDE EFFECTS

Possible adverse events or complications associated with the Cure™ OPEL-C System may include, but are not limited to:

Per Operative:

1. Nerve damage leading to decrease or loss of sensory and/or motor function, or paralysis
2. Incision related issues
3. Bleeding, significant blood loss
4. Pneumonia
5. ARDS
6. Atelectasis
7. Thrombophlebitis
8. Emboli
9. Heart attack
10. Stroke
11. Nerve or soft tissue damage
12. Death

Post-Operative:

13. Failure to relieve symptoms
14. Pseudarthrosis
15. Vocal paresis
16. Degeneration at adjacent level
17. Anesthesia or other drug reactions18. Dysphagia

Specific to implant:

19. Implant breakage
20. Implant migration
21. Revision, removal or supplemental fixation of original implant
22. Vertebral body damage

Additional surgery may be necessary to correct some of these potential adverse events.

_CAUTION – PRECAUTION FOR USE

An in-depth discussion of all possible complications associated with this procedure 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.

The following precautions must be followed:

Preoperative

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient's conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Significant implant overload 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. Fatigue testing of the Cure™ OPEL-C system cannot guarantee device performance in patients. Patient selection is important to minimize device failure.
4. Care should be used in the handling and storage of the implant components. The implant should not be scratched or damaged. Implants should be protected during storage especially from corrosive environments.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the device to verify that all parts and necessary instruments are present before surgery begins.
6. The type of construct to be assembled for the case should be determined prior to beginning of surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
7. Implants are provided clean and sterile. Instruments must be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

GENERAL INFORMATION

Intraoperative

1. The instructions in any available applicable surgical technique should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological function.
3. Implants are mechanical devices that can be worn, damaged or broken.Breakage, slippage or misuse of instrument or implant component may cause injury to the patient or operative personnel.
4. To assure proper fusion below and around the location of the instrumentation, a bone graft should be used. Bone graft must be placed in the area to be fused and graft material must extend from upper to lower vertebrae being fused. When using the Talos® C HA Cervical IBF Device, autologous bone graft should be used.
5. An implant site can become infected, painful, swollen, or inflamed.

Postoperative

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the device are complications which can occur as a result of excessive weight bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, demented, debilitated or otherwise unable to use crutches or other weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal positions.
2. To allow the maximum chances for successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume excessive alcohol during the bone graft healing process.
3. The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device. It is important that the immobilization of the union is established and confirmed by radiological examination. Where there is a non-union or if the components loosen, bend, and/or break, the device may need to be revised.
5. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.
6. 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 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.

_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.

GENERAL INFORMATION

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that Spineart's Cure OPEL-C systems are **MR Conditional**. A person with Spineart's Cure OPEL-C system may be safely scanned anywhere in the body at 1.5 T or 3.0 T under the following conditions. Failure to follow these conditions may result in injury.

PARAMETER	**CONDITION**
Static Magnetic Field Strength (B0)	1.5 T and 3 T
MR Scanner Type	Cylindrical
B0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	19.0 T/m (1,900 G/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
Operating Mode	Normal Operating Mode
RF Conditions	Maximum Whole-body SAR: 2 W/kg
Scan Duration	1.5T: Scanning at or above the shoulders must be limited to a maximum of 10 minutes of continuous scanning. Below the shoulders, up to 15 minutes of continuous scanning is permitted. 3 T: Scanning at or above the shoulders must be limited to a maximum of 4 minutes of continuous scanning. Below the shoulders, up to 15 minutes of continuous scanning is permitted. All scanners: If multiple scans are required, there must be a minimum of 13 minutes of cooling between successive scans.
Image Artifact	The presence of Spineart's Tryptik MC system may produce an image artifact of 4.8 cm. Some manipulation of scan parameters may be needed to compensate for the artifact.
RF Heating	Results of experimental heating testing indicated the largest measured temperature rise when scaled to 2.0 W/kg was 6.4 °C at 1.5 T and 11.6 °C at 3 T. After considering anatomical implantation location of the Tryptik MC System and accounting for uncertainty, the predicted maximum clinical temperature rise after 15 minutes of continuous scanning was determined to be 4.9 °C at 1.5 T and 6.7 °C at 3 T at whole body SAR of 2.0 W/kg (Normal Operating Mode). Therefore, the maximum allowable scan time was reduced for specific landmark locations, and a cooling period was introduced to allow for repeated scans. For 1.5 T and 3 T scanners, scanning is permitted at or below the shoulder for up to 15 minutes of continuous scanning. Scanning at or above the shoulders should be limited to 10 minutes and 4 minutes of continuous scanning in 1.5 T and 3 T scanners, respectively. If additional scanning is required, there should be a 13 minute of cool down period in between scans.

_SURGERY METHODS

The implantation of an implant should be performed only by experienced surgeons with specific training in the use of this implant 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.

Careful preparation of the surgical site and choosing an implant of the right size will increase the chances of a successful procedure. Surgeons are advised not to remove the device from its sterile packaging until the implant site has been properly prepared and precise measurements have been taken. The surgical procedure is standard for experienced surgeons. Your local representative should have communicated the

handbook describing the surgical technique. In any case, the handbook is readily available by contacting either your local representative or directly Spineart®.
We strongly recommend that excessive force should not be applied when installing any of the implants.
A handbook on surgical techniques, describing the standard implant procedure, is available.

_STORAGE CONDITIONS

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

_INSTRUMENTATION

The instruments were specifically designed for use when installing these implants. It is mandatory to use the Cure & Talos instruments for the OPEL-C devices implantations. Specific markings are engraved on each template instrument to facilitate identification of the corresponding implant size and type.

_CLEANING, DISINFECTION, DRYING AND STERILIZATION

Preparation before cleaning

Point-of-use: The instruments must, immediately after use, be cleaned, disinfected, dryed, inspected, and terminal sterilized as described below.

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

The instruments have been designed in order to avoid disassembly manipulation prior, cleaning and sterilization processes.

These methods and parameters have been validated following the AAMI TIR 30 Technical Report for reusable instruments.

In countries where reprocessing requirements are more stringent than those provided in this document it is the responsibility of the user/processor to comply with those prevailing laws and ordinances.

Follow the process below:

A - Automatic cleaning protocol

B - Thermal disinfection

C – Drying

D - Inspection

E - Sterilization trays cleaning and disinfection

F - Sterilization

A - AUTOMATIC CLEANING PROTOCOL

The washer-disinfector machine should be compliant with the last version of EN ISO 15883.

Pre-cleaning

- 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 tap water for 30 seconds. Devices with mobile parts must be 5 times activated during rinsing 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 tap water for 1 minute. Devices with mobile parts must be 5 times activated during rinsing through their full range of motion during rinsing.

Inspection and dry

- Visually inspect devices.
- Dry using a soft, lint free cloth.
- Load devices into the washer-disinfector.

WASHER-DISINFECTOR PARAMETERS

STEP	SOLUTION	TEMPERATURE	TIME
Pre-cleaning	Tap Water	<45°C	2 minutes
Cleaning	Tap Water + alkaline enzymatic cleaner (as example NEODISHER Mediclean Forte)	55°C	10 minutes
Neutralizing	Tap Water + Neutralizing agent (as exemple NEODISHER Z)	<45°C	2 minutes
Rinsing	Tap water	<45°C	2 minutes

B - THERMAL DISINFECTION

Following the cleaning step in the same washer-disinfector

WASHER-DISINFECTOR PARAMETERS

WASHER CYCLE	SOLUTION	TEMPERATURE	TIME
Disinfecting Rinse	Reversed osmosis water According to AAMI TIR 34	93°C	5 minutes

The thermal disinfection cycle should be performed to achieve a minimum value A0 = 3000 according to ISO 15883-1) and is compatible with Spineart instruments and not sterile implants.

C – DRYING

Following the disinfection step in the same washer-disinfector

WASHER-DISINFECTOR PARAMETERS

WASHER CYCLE	SOLUTION	TEMPERATURE	TIME
Drying	/	94.5°C	20 minutes

D - INSPECTION

Carefully inspect each device to ensure that all visible blood, soil and debris have been removed. Inspect lumens to confirm that all foreign material has been removed. Visually inspect for damage and/or wear. Check also the lack of humidity.

Note: If any damage or wear is noted that impairs the function of the instrument, contact your company representative for a replacement.

It is necessary to check the condition and functionality of the different instruments after each cleaning, disinfection and drying cycle.

In case of deterioration or wear that reduces the function of the instrument, it must be replaced.

The functionality of each instrument must be tested before using the instrument in surgery. In case of functionality issue or any doubt, do not use the instrument. Use a spare available in the ancillary instrumentation or in the OR.

Instrument should not be bent or damaged in any way.

Before sterilization, ensure that the instruments or implants are dry, otherwise use a soft, lint free cloth to dry them.

E - STERILIZATION TRAYS CLEANING, 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 tap 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 tap 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.

F - STERILIZATION

Preparation for sterilization

Instruments must be loaded into a dedicated tray, supplied by the manufacturer, and then double wrap the tray, using wrap compliant with ISO 11607-1, following AAMI ST 79 guidelines.

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

“Do not stack trays during sterilization”

The instruments are delivered non-sterile and must be sterilized by autoclave according to the instructions of the sterilizer manufacturer to ensure sterility.

Instruments delivered non-sterile must be sterilized in containers supplied by the manufacturer. Beforehand they must have followed a complete cycle of cleaning, disinfection and drying, as described in the previous steps. The sterilization cycle must be performed in a qualified steam sterilizer. Sterilization must be performed according to ISO 17665-1.

Sterilization parameters:

Method: Pre-vacuum cycle of Steam sterilization (moist heat - autoclave): 3 negatives pulses and 5 positives pulses

Cycle 2 (USA):

Exposure time: 4 minutes

Temperature: 132°C

Drying time: 30 minutes

_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.

NOTE

SPINEART

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