TALOS® C (HA)

CERVICAL PEEK HA CAGE

SURGICAL TECHNIQUE

CONTENT

CONCEPT AND DESIGN

In each product development, Spineart is relentlessly driven by the same phIlosophy : Quality, Innovation, Simplicity.

It is with this in mind that Meditech's portfolio of sterile-packed, barcoded plates and cages has been integrated into Spineart's existing range. More particularly, the TALOS® C HA Cervical Cage perfectly brings synergies with the existing Cervical Cage range.

AT A GLANCE

HA PEEK

Anatomical and Lordotic Shape

Large Graft Window

Angle Teeth

INDICATIONS

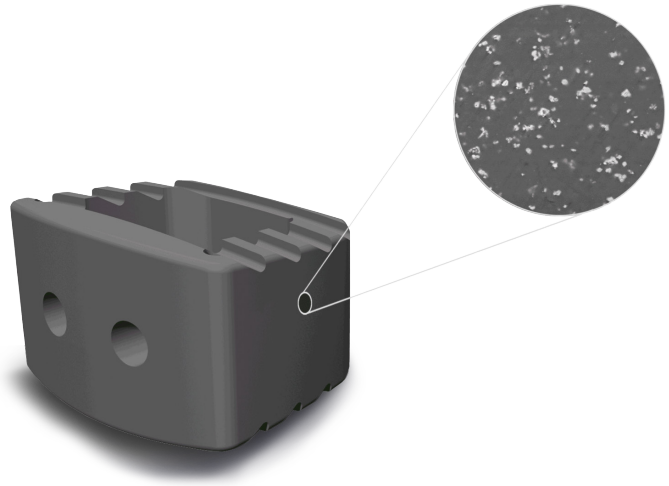
The TALOS® C/(HA) Cervical Intervertebral Body Fusion Device is an intervertebral body device intended for use in skeletally mature patients with Degenerative Disc (DDD) of the cervical spine at one level from C2-T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on the posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by history and radiographic studies. TALOS® C/(HA) Cervical IBF Devices are intended to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

Non-operative treatment prior to treatment with TALOS® C/(HA) Cervical Intervertebral Body Fusion Devices is six (6) weeks.

TALOS® C/(HA) Cervical IBF Devices are to be implanted via an open anterior approach. TALOS® C/(HA) Cervical IBF Devices are also to be used with supplemental fixation.

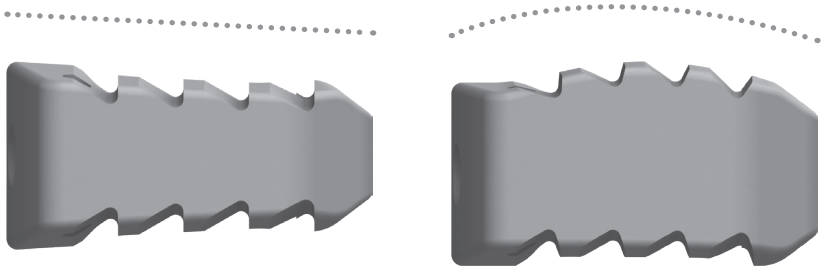
TECHNICAL FEATURES

HA PEEK



Osteoconductive surface, biocompatible and radiolucent.

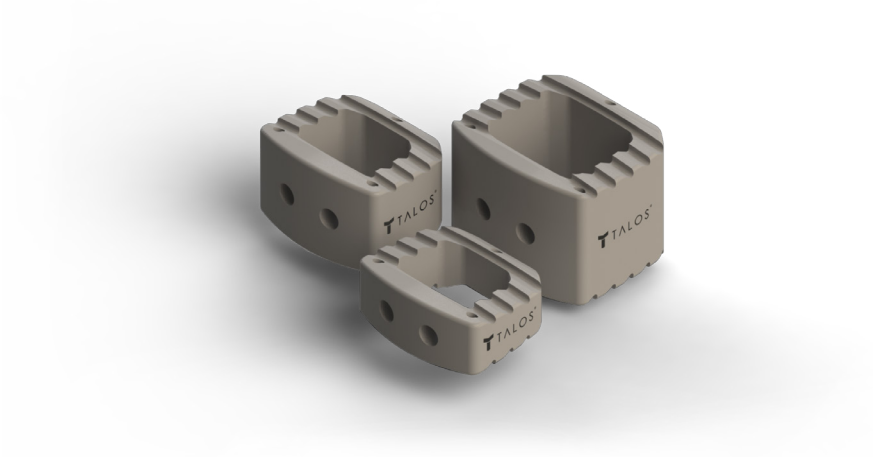
ANATOMICAL AND LORDOTIC SHAPE



Convex and lordotic profiles to address patient anatomy and surgeon preferences.

TECHNICAL FEATURES

LARGE GRAFT WINDOW



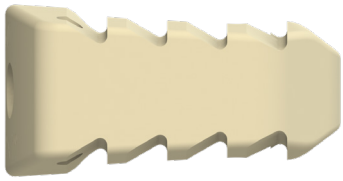
The large graft window allows for bone graft placement and permits boney in-growth.

ANGLED TEETH

Angled teeth provide primary stability.

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

PLANAR/LORDOTIC CAGES - OPTIONAL

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

IMPLANTS

CONVEX/ANATOMIC CAGES - OPTIONAL

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

INSTRUMENTS

* TRASPS PLANAR 14MM W X 12 MM D	509-3122XX-07

TRIALS	500-XXXXXX-XX

* TRIAL INSERTER	510-200-00

INSERTER	500-400-02

INSERTER WITH 1/2/3MM DEPTH STOP	515-120X00

PACKING BLOCK	520-205-50

BONE PACKING TOOL	520-205-55

* TAMP	520-205-00

* PICKLE FORK	530-205-00

*Shorter Trial Inserters and Tamps are available for surgeons working under a microscope.

INSTRUMENT DISASSEMBLY

Figure 6

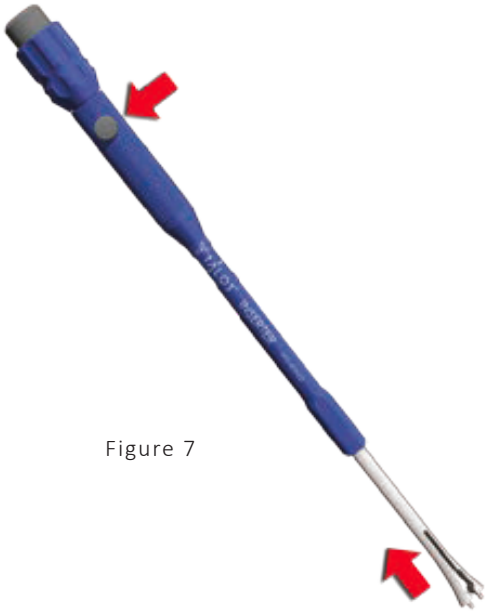


Figure 7

ASSEMBLY OF THE TALOS® C INSERTER

1. 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. (See Figure 6)

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

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

4. While depressing the button on the inserter body, slide the fork, threads first, into the inserter body opposite the knob end. (See Figure 7)

   A. 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.

INSTRUMENT ASSEMBLY

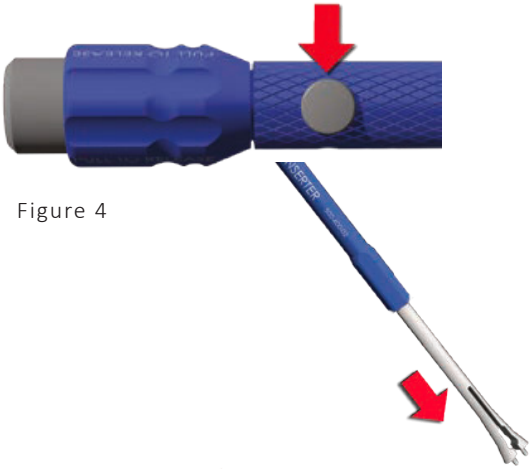


Figure 4

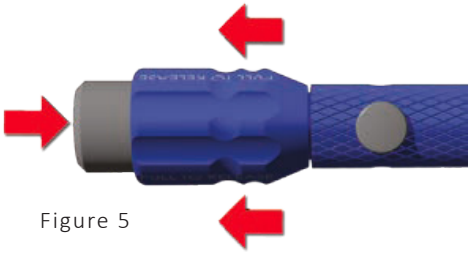


Figure 5

DISASSEMBLY OF THE TALOS® C INSERTER

1. Disengaging the fork from the body:

A. 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.

B. 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 with the button depressed until the forks pull away from the body. (See Figure 4)

2. Disengaging the knob from the body:

A. Hold the inserter body in one hand.

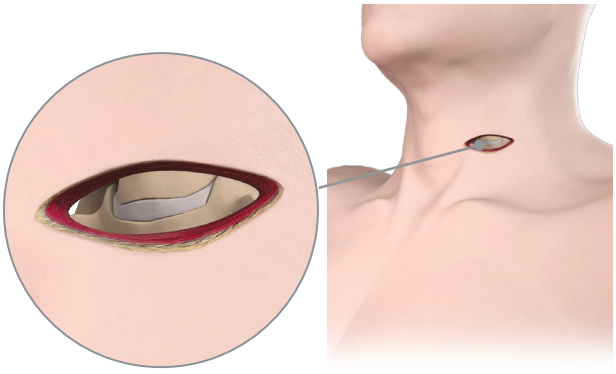
B. In the other hand, place your thumb at the end of the knob and your index finger and middle finger at opposite sides of the knob.

C.Pull the knob up with your index finger and middle finger until the inner engagement portion of the knob and body is exposed. (See Figure 5)

D. Slide the body of the inserter away from the knob to disengage.

SURGICAL TECHNIQUE

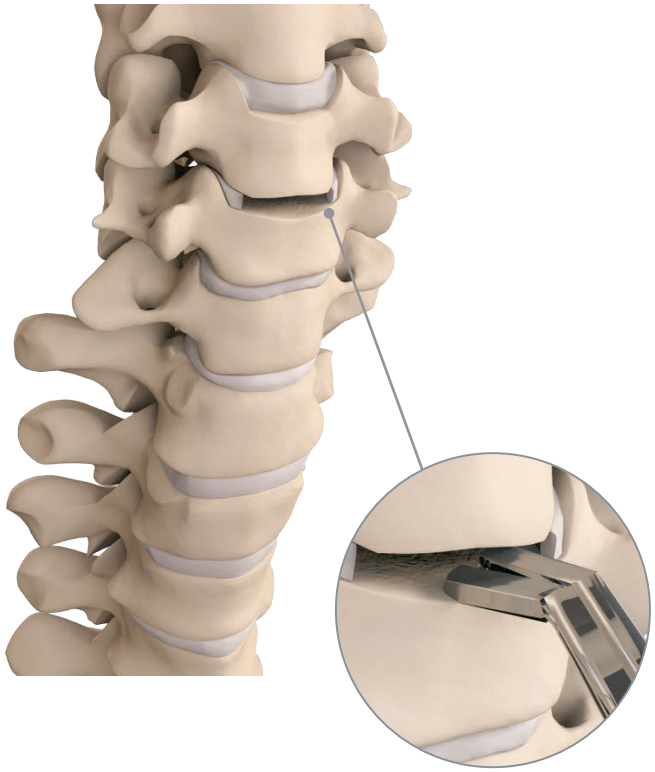
_STEP 1



PATIENT POSITIONING & DISSECTION

Proper patient positioning should be obtained using a frame or spine table.
The patient is placed in the supine position.
Maintain normal lordosis using proper support.
The surgeon should obtain an anterior exposure to the spine according to preference of incision, approach angle and side (left or right).

_STEP 2



EXPOSURE OF SPINE AND DISC REMOVAL

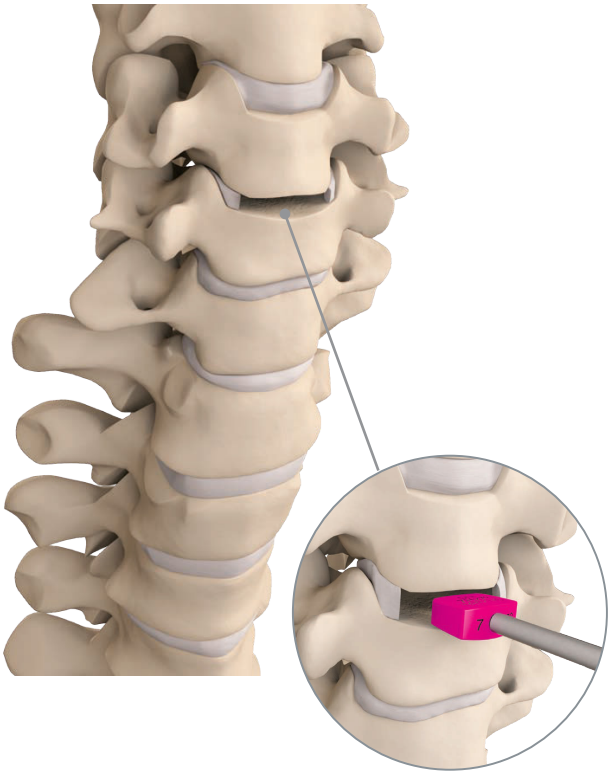
A cervical retractor is used to provide adequate exposure during dissection, disc preparation and prothesis implantation.

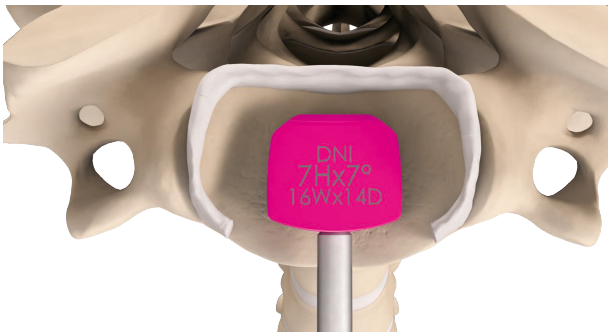
Depending on dissection preference, the surgeon should expose the midline of the diseased intervertebral disc.
Fluoroscopy should be used to verify the correct level.

A cervical spreader or cervical distraction pins can be used to help with gentle distraction of the disc space.

Once the annulus is incised, ronguers and curettes can be used to remove disc material. Kerrisons and/or a high speed burr can be utilized to remove posterior disc and osteophytes to expose the posterior longintudinal ligament (PLL). It is surgeon discretion to remove the PLL and/or osteophytes to achieve neural decompression.

_STEP 3





ENDPLATE PREPARATION & TRIALING

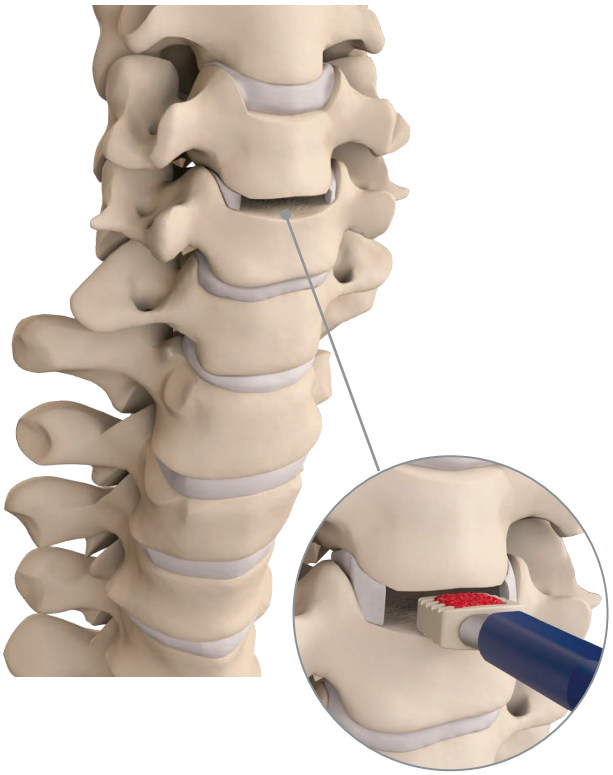
After the disc is removed and decompression is achieved; curettes, rasps or a high speed burr can be used to prepare the end-plates. Care should be taken to not remove too much bone from the end-plates. Trials can be used to template the disc space.

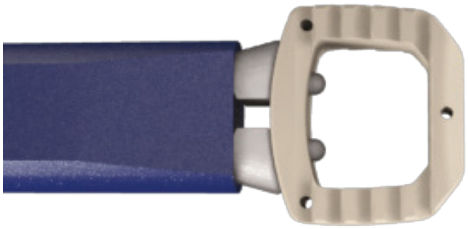
To template for the final implant, thread a trial onto the trial inserter and gently tap into the disc space. Sequential trialing can be utilized to achieve the proper height and fit of the disc space. If implanting a convex trial, ensure the convex surface is oriented cephalically (arrows on the anterior face of trial towards superior endplate)

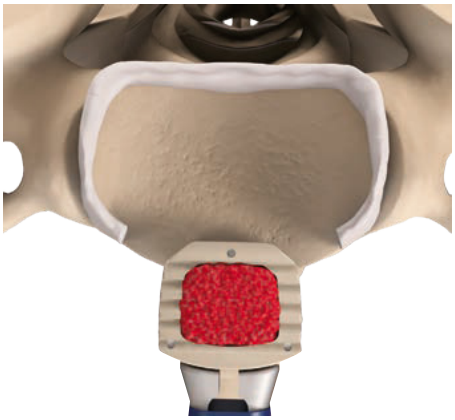
Care should be taken to not over distract the disc space or impact the trial too far posteriorly into the neural canal.

INSTRUMENT	REFERENCE
TALOS-C TEMPLATES	500-XXXXXX-XX(-A)
TRIAL INSERTER	510-200-00
TRASPS	509-3122XX-07

_STEP 4





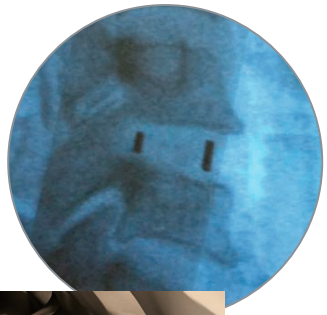


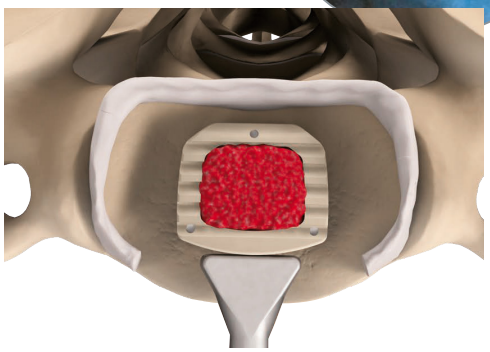
TALOS® C IMPLANT INSERTION

Once the proper size implant is determined, the TALOS® C Implant can be attached to the inserter by placing the fork tips into the two holes on the implant and turning the knob on the inserter in the clockwise direction.
If desired, fork tips with positive depth stops are available in 1, 2 and 3mm increments.
The implant can be filled with bone graft material before or after attaching to the inserter.
If implanting a convex cage, ensure the convex surface is oriented cephalically (UP marking on the anterior face of the cage placed towards the superior endplate)
The implant can then be placed into the disc space and tamped into position.
Care should be taken not to impact the implant too far posteriorly into the neural canal.

INSTRUMENT	REFERENCE
INSERTER	500-400-02
PACKING BLOCK	520-205-50
BONE PACKING TOOL	520-205-55
INSERTER WITH 1/2/3MM STOP	515-120X00
TAMP	520-205-00
PICKLE FORK	530-205-00

Sagittal View





SURGICAL TECHNIQUE

_STEP 4

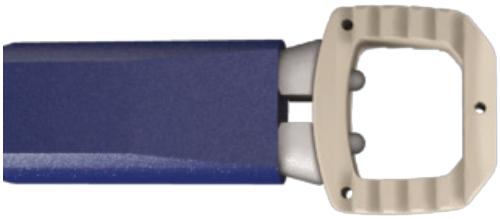


Figure 1

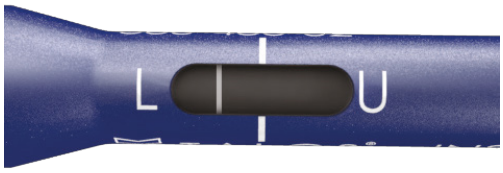


Figure 2

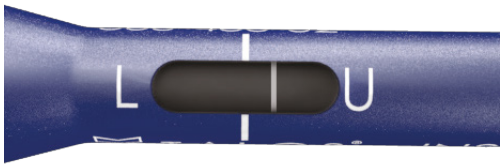


Figure 3

USING THE TALOS® C INSERTER

1. Engaging Talos®- C IBF Implant with Talos®- C Inserter:

A. Interface the fork tips with the holes of the implant and begin rotating the knob in a clockwise direction until the implant is securely fastened (See Figure 1).

A1. To determine when the implant is “securely fastened”, the laser line will move past the dashed laser marks and into the “L” (locked) side of the window (See Figure 2).

A2. Check that the implant is secure by gently pulling it away from the forks. If it disengages, repeat the above steps until it is firmly locked in place.

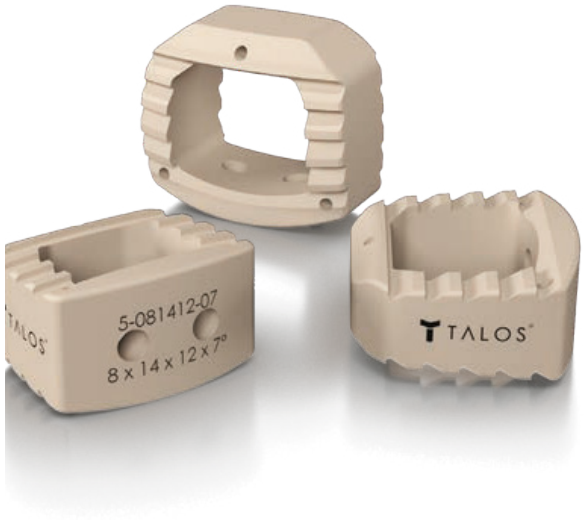
2. Inserting the Talos®- C IBF Implant into the cervical disc space:

A. When the implant is positioned correctly, the surgeon shall rotate the knob counter-clockwise to release the implant from the inserter.

A1. Once the marker in the window of the inserter body shifts to the “U” (unlocked) side, the inserter can be removed from the implant (See Figure 3).

A2. If the surgeon cannot see the window from his perspective, it usually takes 1-2 revolutions of the knob in the counter clockwise direction to release the implant from the inserter.

_STEP 5



EXPLANTATION OR REMOVAL OF THE TALOS® C DEVICE

The Talos® IBF device is made of Peek Polymer and has similar biomechanical strength to cortical bone.
If excessive leverage (that which is greater than physiological loads) is placed on the implant, a crack or breakage may occur. If this does happen, the implant should be retrieved. Distraction can be utilized on the vertebral bodies to retrieve the implant with a surgical clamp such as a Kocher or hemostat. Also, the inserter can be attached to the implant and removed from the disc space. Gentle distraction may be necessary to facilitate the removal of the implant.
In all instances of retrieval of the TALOS® C device, care should be taken to protect to the neural structures.

GENERAL INFORMATION

REFERENCE OF THE IFU	TEK-IF VF ST-E	REVISION OF THE FINAL IFU	APR-2022

_STERILITY

The TEKTONA®2 system comprises sterile single-use devices only.

Reprocessing of single use devices is strictly forbidden and would expose the patient to risks of serious health deterioration. Re-use of a single use device does not make it possible to ensure structural integrity nor achievement of the assigned performances over time and may result in premature rupture. Such re-use may also result in infection in the patient.

If sterile devices or their packaging seems to be damaged, if the expiry date is exceeded or in the event that sterility cannot be guaranteed, the device shall not be used.

The Vertebral Fracture Reduction instrument is delivered sterile. Please refer to the individual package labeling.

_DESCRIPTION

The TEKTONA®2 system was designed to assist in the reduction of vertebral body fractures in a percutaneous surgical approach. It is used in combination with bone cement marketed for vertebroplasty or kyphoplasty procedures. The TEKTONA®2 system comprises a flexible Lamella (Nickel-Titanium) that can be expanded by the action of a Vertebral Fracture Reduction instrument (VFR instrument). The VFR instrument has a ratchet mechanism that can maintain the shape of the Lamella during the fracture reduction procedure. The TEKTONA®2 system comprises a cement filler device (cannula) with a standard luer-lock connection. Specific information is indelibly marked on the devices.

_INDICATIONS

The TEKTONA®2 system is indicated to treat moderate to severe pain caused by vertebral body compression fractures (VCF) located between T7 and L5, secondary to osteopenia, multiple myeloma and/or trauma, and presenting kyphotic deformities and risk of progressive vertebral height loss.

_CONTRAINDICATIONS

- Inadequate pedicle dimension affecting safe passage of the instrumentation;
- Instability of posterior wall and/or pedicles;
- Consolidated fractures ;
- Fractures of B or C according to Magerl classification;
- Vertebral compression fracture with neurological disorder;
- Need for spinal decompression;
- Systemic and/or spinal infections;
- Known allergies to bone cement material and/or nickel-titanium;
- Cardiovascular disease which is not controlled by the treatment;
- Patient at risk with a spontaneous or therapeutical coagulation trouble that cannot be treated;
- Pregnancy or breast-feeding female;

We recommend to check if the treated fracture is considered as fresh and not consolidated. Consolidated fracture could limit the efficacy of the TEKTONA®2 system in repositioning interbody bone fractures.

_SIDE EFFECTS

Perioperative:

Symptomatic cement leak, hemostatic problems, neurologic and/or vascular injury.

Postoperative:

Secondary fracture, pulmonary embolism, neurological disorder, cardiovascular or vascular disorder, lymphatic disorders, deep infection.

Serious adverse device effects:

GENERAL INFORMATION

Secondary fracture, symptomatic cement leak, pulmonary embolism, motor loss, epidural hematoma.

_WARNINGS

Because this is a technically demanding procedure presenting a risk of serious injury to the patient, only experienced surgeons with adequate training should perform this procedure. Every surgeon who uses TEKTONA®2 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 instrumentation and the potential complications in each case. Abnormal use of the device may lead to risks of serious injury, health deterioration of the patient.

The performance and safety of TEKTONA®2 was not yet confirmed for treatments of more than two adjacent levels, or for fractures of A2, A3.2 or A3.3 according to Magerl classification. Clinical experience of TEKTONA®2 in combination with bone cements specifications other than those of TEKTONA® HV Bone Cement or Mendec Spine HV System (TECRES Medical, Verona, Italy) is limited. Please refer to the cement manufacturer's instructions for use for more information.

The benefits of this surgical procedure may not meet the patient's expectations, possibly requiring more surgeries. Patients undergoing this surgical procedure shall, therefore, be informed.

_SURGERY METHODS

The surgeon is responsible for familiarizing him/herself with the surgical technique, by studying the relevant published articles, consulting experienced colleagues, and receiving training in the surgical technique.

Precautions:

Preoperative planning by magnetic resonance imaging (MRI) and/or computed tomography (CT) are required to assess the fragmentation of the fracture, as well as to verify suitable dimensions of the vertebral body and pedicle, and the integrity of the vertebral body posterior wall. The pedicle shall allow passage of the working cannula (Size Small: diameter 4.8mm or Size Large: diameter 5.6mm) and the integrity of the posterior wall of the vertebral body shall be confirmed.

The patient shall be placed in a prone and hyper-lordotic position. Fluoroscopic monitoring is required to control the safe trajectory, operation and removal of the instrumentation.

If needed, two vertebral fracture reduction instruments are used to achieve effective reduction of the fracture.

Always use fluoroscopy to control cement flow during the delivery. Injection of the cement may only be executed after removal of the VFR instruments from the body. Always check with fluoroscopic control when using the Drill.

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®.

_HANDLING PRECAUTIONS

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

Prior to usage, the surgeon shall verify the proper functioning of the VFR instrument and the intended behavior of the Lamella.

If required, the Lamella may be extracted by connecting the removal handle to the VFR instrument and pulling it out of the instrument. This may happen if morsels of bone are preventing the Lamella to collapse.

_STORAGE CONDITION

It is mandatory that sterile-delivered devices are stored in their original packaging, in a clean, dry location under normal conditions.

_FURTHER INFORMATION

Should you need further directions regarding the use of TEKTONA®2, please contact Spineart Customer Service or your Spineart representative.

NOTE

SPINEART

MEDITECH SPINE, LLC
1447 PEACHTREE STREET NE SUITE 440
ATLANTA, GA 30309

DISTRIBUTED BY:
SPINEART USA INC
23332 MILL CREEK DR. SUITE 150
LAGUNA HILLS, CA 92653
USA

MAY-2022-REF-TAL-CE-ST-US