TALOS® T (HA)

TRANSFORAMINAL 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 and cages has been integrated into Spineart's existing range. More particularly, the TALOS® T HA Lumbar Cage perfectly brings synergies with the existing Lumbar Cage range. The implant is made of PEEK-OPTIMA™ HA Enhanced polymer, which is a bioactive material that has shown thru peer reviewed, preclinical trials to accelerate bony fusion.

AT A GLANCE

HA PEEK

Large Graft Window

Tapered Nose

Alignment guide

INDICATIONS

The TALOS® Lumbar (HA) PEEK IBF device is an intervertebral body device intended for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the lumbar spine with up to Grade 1 spondylolisthesis at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. TALOS® Lumbar (HA) PEEK IBF devices are intended to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

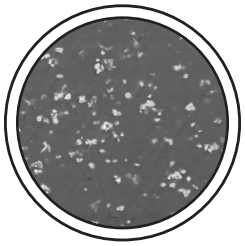
The TALOS® Lumbar (HA) PEEK IBF Device is to be used in patients who have had six months of non- operative treatment.

TALOS® Lumbar (HA) PEEK IBF devices are to be implanted via a transforaminal, anterior or anterolateral approach in the lumbosacral spine. The TALOS®-A (HA) , TALOS® T (HA) & TALOS® TL (HA) are intended to be used with supplemental fixation.

Additionally, the use of Hyperlordotic TALOS®-A (HA) devices (lordotic angle greater than 20°) are intended to be used exclusively with anterior supplemental fixation.

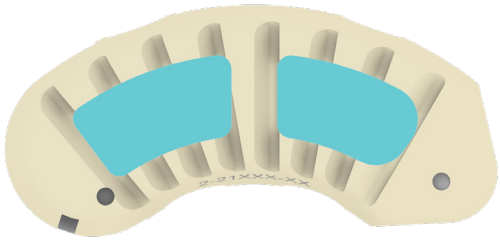
TECHNICAL FEATURES

HA PEEK



Osteoconductive* surface, biocompatible and radiolucent.
HA PEEK material provides a bioactive surface and environment for faster healing with increased bony apposition.

LARGE GRAFT WINDOW



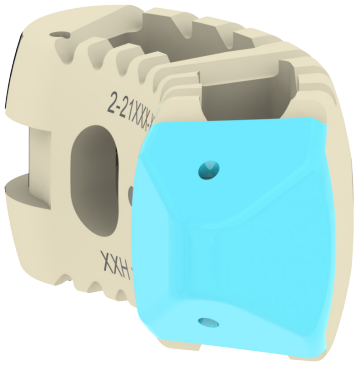
The large graft window allows for bone graft placement and permits bony in-growth.

* 1 Study evaluated the bone in-growth of PEEK-OPTIMA™ and PEEK-OPTIMA™ HA Enhanced in a bone defect model in sheep. Data on file at Invibio. This has not been correlated with human clinical experience.

2 Walsh WR, et al. Does PEEK/HA Enhance Bone Formation Compared With PEEK in a Sheep Cervical Fusion Model? Clin Orthop Relat Res. 2016 Nov; 474(11): 2364–2372.https://invibio.com/materials/peek-optima-ha-enhanced

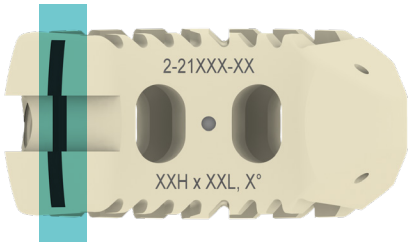
TECHNICAL FEATURES

TAPERED NOSE

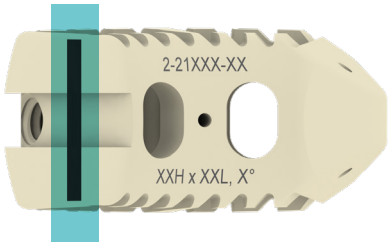


The implant's tapered nose helps facilitate distraction.

ALIGNMENT GUIDE



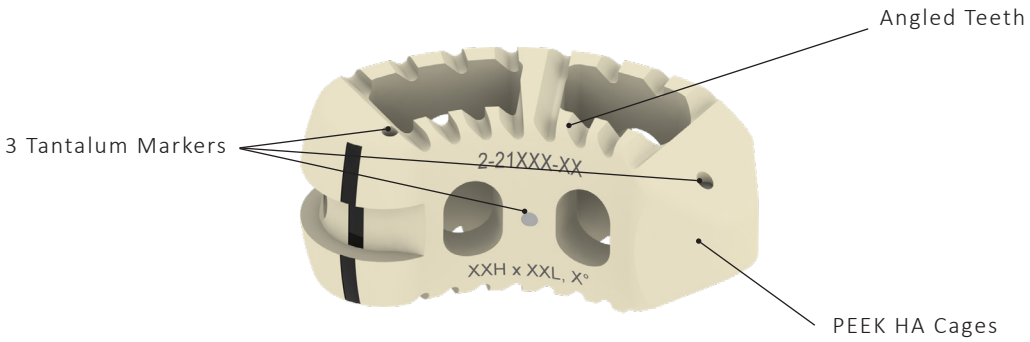
⊗ implant over-rotated or under-rotated



✓ implant in proper alignment

The unique patented alignment marks serve as a guide to aid positioning the implant and reduce X-Ray exposure.

IMPLANTS



STANDARD IMPLANTS

6° LORDOSIS			
HEIGHT	**LENGTH**	**WIDTH**	**REFERENCES**
H07	L28	10	2-21107-06
H08	L28	10	2-21108-06
H09	L28	10	2-21109-06
H10	L28	10	2-21110-06
H11	L28	10	2-21111-06
H12	L28	10	2-21112-06
H13	L28	10	2-22113-06
H14	L28	10	2-21114-06

* OPTIONAL

IMPLANTS

OPTIONAL IMPLANTS

6° LORDOSIS			
HEIGHT	**LENGTH**	**WIDTH**	**REFERENCES**
H07*	L32	10	2-21307-06*
H08*	L32	10	2-21308-06*
H09*	L32	10	2-21309-06*
H10*	L32	10	2-21310-06*
H11*	L32	10	2-21311-06*
H12*	L32	10	2-21312-06*
H13*	L32	10	2-22313-06*
H14*	L32	10	2-21314-06*

* OPTIONAL

INSTRUMENT SET

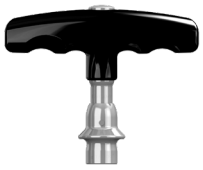
#	DESCRIPTION	REFERENCE
	HUDSON T HANDLE W/ IMPACTOR CAP	100-000-00
	INITIAL TRIAL STARTER, 5MM	100-100-05
	HUDSON SPORT GRIP LARGE	200-000-05
	DISC SHAVERS	100-300-07 100-300-08 100-300-09 100-300-10 100-300-11 100-300-12 100-300-13 100-300-14
	PADDLE DISTRACTORS	100-310-07 100-310-08 100-310-09 100-310-10 100-310-11 100-310-12 100-310-13 100-310-14
	1-8MM DILATOR	100-100-08
	T-HANDLE RETRIEVAL TOOL	100-461-00
	PISTOL GRIP INSERTER	200-427-00
	STRAIGHT TAMP	200-500-00

#	DESCRIPTION	REFERENCE
	STRAIGHT TAMP, 10°	200-500-10
	STRAIGHT TAMP, 20°	200-500-20
	SLAP HAMMER, SHORT	100-600-00
	SLAP HAMMER ADAPTOR-UNIVERSAL	924-21100-00
	ONE PIECE IMPLANT TRIAL; 10MM W x 28MM L x XXMM H, 6°	213-121107-06 213-121108-06 213-121109-06 213-121110-06 213-121111-06 213-121112-06 213-121113-06 213-121114-06
•	BAYONET TAMP	200-505-00

• : OPTIONAL

INSTRUMENTS

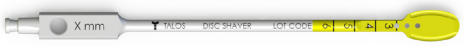
HUDSON T HANDLE W/ IMPACTOR CAP 100-000-00



HUDSON SPORT GRIP LARGE 200-000-05

INITIAL TRIAL STARTER, 5MM 100-100-05

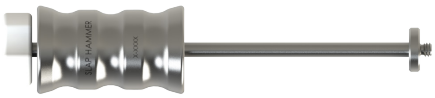
DISC SHAVERS 100-300-XX



PADDLE DISTRACTORS 100-310-XX

1-8MM DILATOR 100-100-08

SLAP HAMMER, SHORT 100-600-00



SLAP HAMMER ADAPTOR-UNIVERSAL 924-21100-00

ONE PIECE IMPLANT TRIAL; 10MM W X 28MM L X XXMM H, 6° 213-1211XX-06

• BAYONET TAMP 200-505-00

STRAIGHT TAMP, 10° 200-500-10

• : OPTIONAL

INSTRUMENTS

T-HANDLE RETRIEVAL TOOL	100-461-00

PISTOL GRIP INSERTER	200-427-00

STRAIGHT TAMP	200-500-00

STRAIGHT TAMP, 20°	200-500-20

COLOR CODE FOR PADDLE DISTRACTORS, DISC SHAVERS AND TRIALS

7MM	MAGENTA
8MM	LIGHT BLUE
9MM	GREEN
10MM	BRONZE
11MM	VECTOR PURPLE
12MM	GRAY TYPE
13MM	DARK BLUE
14MM	GOLD

SURGICAL TECHNIQUE

_STEP 1

POSITIONING

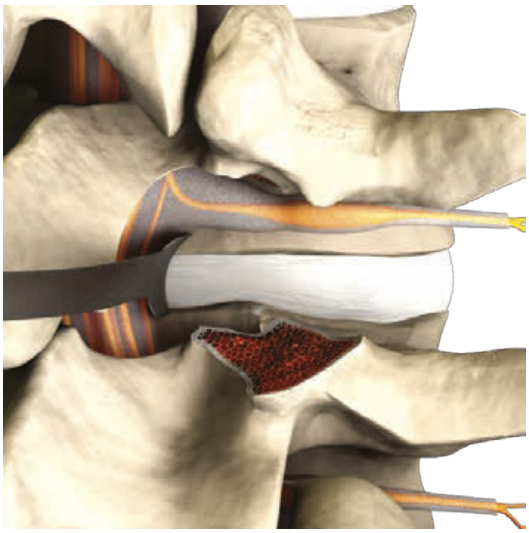
Place the patient in the prone position on a radiolucent surgical table.
The prone position:

- will create temporary segmental kyphosis and facilitates the approach to the spinal canal as well as to the disc space
- will allow a free abdomen to decrease abdominal pressure on the stomach vessels. This can be gained by the use of a positioning frame or by paddling.

Use a well-padded prone support table that replicates physiological lordosis. This positioning may be tolerated by the patient for many hours and therefore may be suitable for extended spinal surgeries.

To obtain optimal visualization of the spine, ensure adequate clearance around the surgical table for the fluoroscopic C-arm. It should be able to rotate freely to obtain AP, oblique, and lateral views.

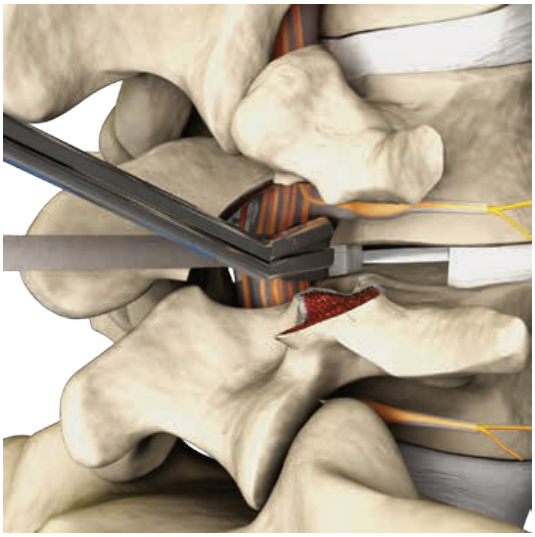
_STEP 2



ARTHRECTOMY

A facetectomy is performed on the appropriate side. The inferior articular process of the body above is removed along with the superior articular process of the body below. If necessary, the dura should be mobilized from the surrounding soft tissues in order to retract/ protect during disc removal. A retractor or nerve root protector can be used to ensure protection of the neural elements.

_STEP 3



DISCECTOMY AND PREPARATION OF THE ENDPLATES

Once the dissection and approach is complete, distraction of the disc space can be performed. To faciliate distraction, the **Paddle Distractors**, previously assembled with the **Hudson T-Handle** can be inserted and rotated 90° in the disc space.

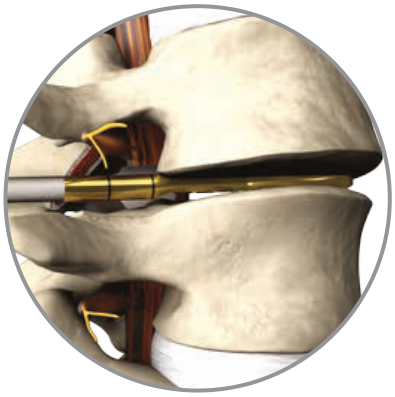
If there is a severely collapsed disc space, a small Initial Trial Starter 5mm or "wedge" **1-8mm Dilator** can be used before shavers are applied.

Remove additional disc material to prepare the space for bony fusion.

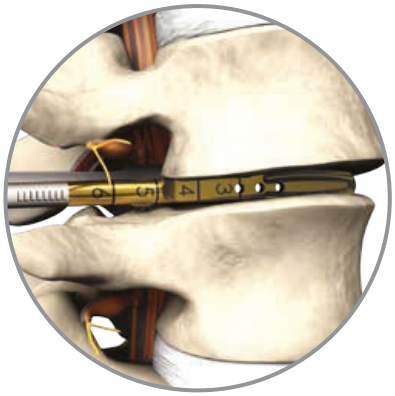
Prepare the endplates using **Disc Shavers**. **Disc Shavers** can be inserted into the disc space and rotated either 90° and 180° back and forth to remove residual disc material from the endplates. A curette can also be used to remove residual soft tissue from the endplates.

For protection of the dura, a nerve root retractor can be used.

NOTE: To maximize the chances of fusion, it is recommended to completely remove the superficial layers of cartilage plate until bleeding occurs.



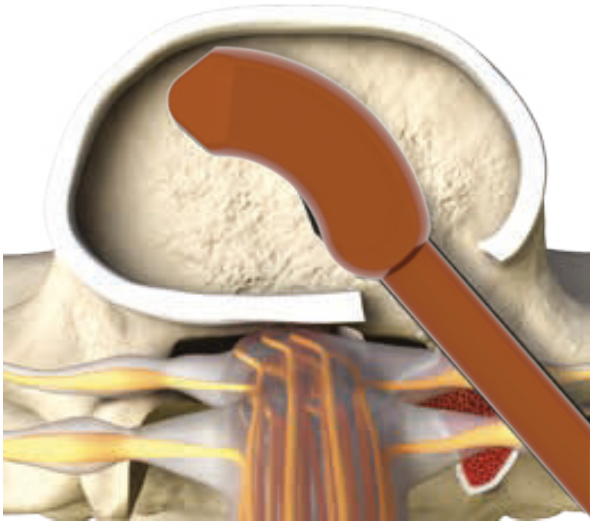
Disc Shaver upon insertion



Disc Shaver rotated 90º

INSTRUMENT	REFERENCE
1-8MM DILATOR	100-100-08
INITIAL TRIAL STARTER, 5MM	100-100-05
PADDLE DISTRACTORS	100-310-XX
HUDSON T HANDLE	100-000-00
DISC SHAVERS	100-300-XX
SLAP HAMMER, SHORT	100-600-00
SLAP HAMMER ADAPTOR-UNIVERSAL	924-21100-00

_STEP 4



SELECTION OF THE IMPLANT SIZE

To help determine the right cage to implant, additional dedicated TALOS® T **One Piece Implant Trial** are available. To insert the implant trials, connect the **Hudson Sport Grip** to the **One Piece Implant Trials** and gently hammer the assembly into the disc space.

It is recommended to start trialing with the smallest height available.

Footprint (length and width), lordosis and height of the trial match the footprint, lordosis and height of the implant. Use of a Trial will help to determine the height and length of the implant.

Perform fluoroscopic imaging during insertion of the trial to validate correct height.

If the Trial is too small, gently remove it and proceed with the next size until satisfactory results. You can use the **Slap Hammer** with the **Slap Hammer Adaptor-Universal** to remove the Implant Trial.

Once the size is assessed, gently remove the trial, and select the cage corresponding in height.

INSTRUMENT	REFERENCE
ONE PIECE IMPLANT TRIAL : 10MM W X 28MM L X XXMM H, 6°	213-1211XX-06
HUDSON SPORT GRIP LARGE	200-000-05
SLAP HAMMER, SHORT	100-600-00
SLAP HAMMER ADAPTOR-UNIVERSAL	924-21100-00

_STEP 5

CAGE PREPARATION

Select the corresponding cage.

Connect it with the **Pistol Grip Inserter** and fill it with bone graft*.

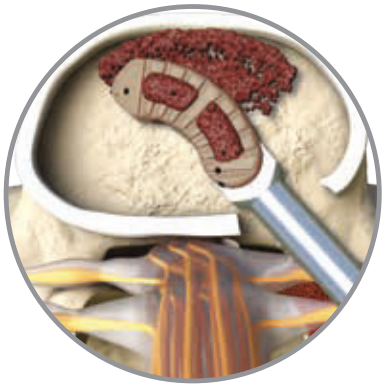
Bone graft can be placed on the anterior and contralateral side of the level being fused.

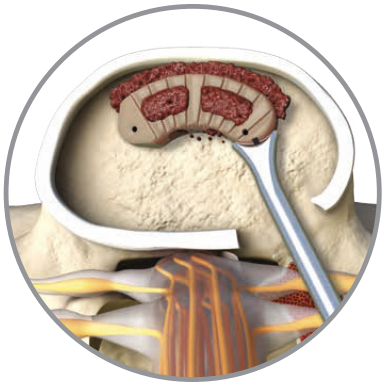
NOTE: Care should be taken not to cross thread or over tighten the implant on the inserter.

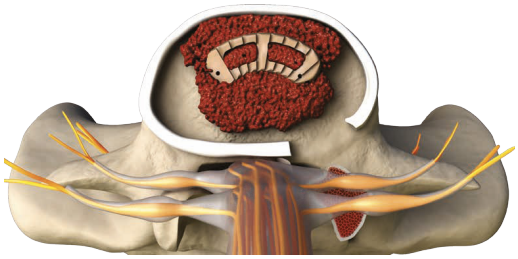
INSTRUMENT	REFERENCE
PISTOL GRIP INSERTER	200-427-00

_STEP 6

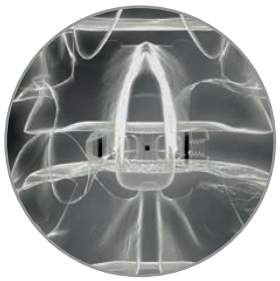
Axial View







Lateral View



AP View

INSERTION

Insert the cage into the disc space while protecting the dura with a nerve root retractor.

It is possible to gently hammer on the Implant holder Handle to ease the insertion of the implant.

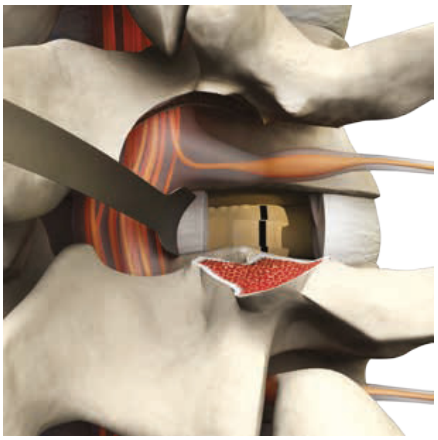
The TALOS® T implant can be impacted across the disc space with its convex anterior wall resting up against the anterior annulus.

Perform fluoroscopic controls to make sure the implant is correctly positioned.

Multiple **Tamps** are available to help push and position the implant into the anterior third of the disc space. The backside of the TALOS® T implant has a functional groove for the **Tamps** to rest during impacting and positioning.

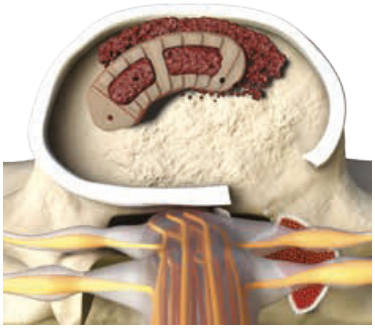
Proper orientation of the implant is with the teeth in the cadual-rostral position. The TALOS® T implant should be positioned with its convex anterior wall resting up against the anterior annulus in the anterior third of the disc space. Depending on the depth and how far the implant was placed across the disc space, more bone graft can be placed around or behind the TALOS® T implant. The tantalum markers can be seen on X-ray to aid in the final verification of implant position.

SURGICAL TECHNIQUE



As shown in the images, the implant also has a ledge with three alignment marks. When the implant is properly aligned, the three alignment marks will create a single axis to indicate to the surgeon that the TALOS® T implant has been rotated far enough within the cavity.

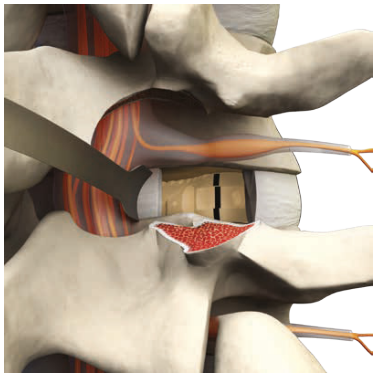
This image shows a view depicting the three alignment marks within the bone space when the TALOS® T implant has been over-rotated.



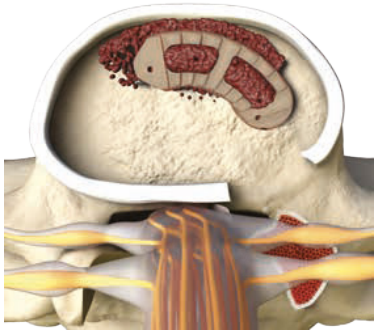
This image shows a top view of the surgical configuration of the TALOS® T implant after over-rotation.

The TALOS® T implant to the left shows a side view in isolation when the alignment marks indicate the implant has been over-rotated.

SURGICAL TECHNIQUE



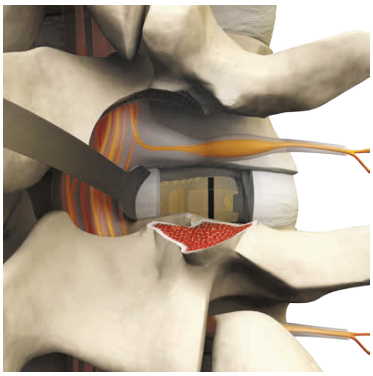
This image shows a view depicting the three alignment marks within the bone space when the TALOS® T implant has been under-rotated.



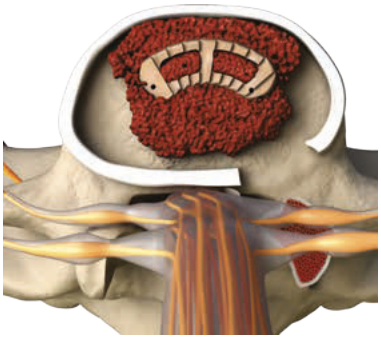
This image shows a top view of the surgical configuration after under-rotation.

The TALOS® T Implant to the left shows a side view in isolation when the alignment marks indicate the implant has been underrotated as shown in the previous image.

SURGICAL TECHNIQUE



This image shows a view depicting the three alignment marks within the bone space when the TALOS® T implant has been properly aligned and the three marks align along a single axis and form a single line.



This image shows a top view of the surgical configuration of the TALOS® T implant when the three guide lines are properly aligned.

The TALOS® T Implant to the left shows a side view of the implant in isolation when the alignment marks indicate the TALOS® T implant is in proper alignment.

The alignment marks serve as a guide to aid in positioning the implant. The ultimate decision on final position is determined by the surgeon performing the procedure as many factors might play into the decision making process.

INSTRUMENT	REFERENCE
PISTOL GRIP INSERTER	200-427-00
STRAIGHT TAMP	200-500-00
STRAIGHT TAMP, 10°	200-500-10
STRAIGHT TAMP,20°	200-500-20
BAYONET TAMP (OPTIONAL)	200-505-00

SURGICAL TECHNIQUE

_FINAL CONSTRUCT

The TALOS® T (HA) cages should be used with a supplemental posterior fixation system, as described in the ROMEO®2, ROMEO®2 MIS, ROMEO®2 PAD, PERLA® TL and PERLA® TL MIS surgical techniques, or an anterior fixation system.

Compression forceps should be used for final compression of the construct.

_IMPLANT REMOVAL

Should a cage need to be removed, the TALOS® T Pistol Grip Inserter can be re-attached to the implant and then removed either by connecting the slap hammer or with direct visualization. The T-HANDLE RETRIEVAL TOOL can also be used. In all instances of retrieval of TALOS® T implant, care should be taken to protect the neural structures.

REFERENCE OF THE IFU	TAL-AL-IF-US	REVISION OF THE FINAL IFU	NOV-2022

_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 TALOS® Lumbar (HA) PEEK IBF Devices are made of the polymer, polyetheretherketone (PEEK) impregnated (filled) with hydroxyapatite (HA). TALOS® Lumbar (HA) PEEK IBF devices are available in three configurations: TALOS®-A (HA), TALOS® T (HA) & TALOS® TL (HA). The devices are open devices with ridged teeth on superior and inferior ends to resist implant pullout. The TALOS® TL (HA) are rectangular devices and the TALOS® T (HA) & TALOS®-A (HA) have curved lateral walls and rounded edges. The implants are available in a range of sizes, as well as flat and lordotic angled implants to accommodate variations in patient's anatomy. In addition, tantalum markers at the opposite ends are offered which allow radiological confirmation for proper positioning. The instruments are provided clean and non-sterile for steam sterilization at the user's facility. The implantable devices are provided sterile. If the product package is intact and labeled "sterile" upon receipt, the device is ready for use in the operative field.

_INDICATIONS

The TALOS® Lumbar (HA) PEEK IBF device is an intervertebral body device intended for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the lumbar spine with up to Grade 1 spondylolisthesis at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. TALOS® Lumbar (HA) PEEK IBF devices are intended to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

The TALOS® Lumbar (HA) PEEK IBF Device is to be used in patients who have had six months of non- operative treatment.

TALOS® Lumbar (HA) PEEK IBF devices are to be implanted via a transforaminal, anterior or anterolateral approach in the lumbosacral spine. The TALOS®-A (HA) , TALOS® T (HA) & TALOS® TL (HA) are intended to be used with supplemental fixation.

Additionally, the use of Hyperlordotic TALOS®-A (HA) devices (lordotic angle greater than 20°) are intended to be used exclusively with anterior supplemental fixation.

_CONTRAINDICATIONS

Use of the TALOS® Lumbar (HA) PEEK IBF device is not intended for cervical or thoracic surgical implantation. Contraindications include, but are not limited to:

- Infection, local to the operative site.
- Morbid obesity.
- Pregnancy.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis.
- Suspected or documented metal or polymer allergy.
- Any case not described in the indications.

_SIDE EFFECTS

All of the possible adverse events or complications associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events or complications includes, but is not limited to:

Per Operative:

- Disassembly, bending, or breaking of any or all components.
- Tissue damage.
- Loss of neurological function, including paralysis.
- Urinary retention or loss of bladder control.

- Vascular damage resulting in excessive blood loss.
- Pain or loss of function.
- Vertebral endplate injury.
- Death.

Postoperative:

- Allergic reaction to foreign body.
- Infection.
- Bone loss, or decrease in bone density, possibly caused by stress shielding.
- Pseudoarthrosis.

Specific to implant:

- Implant migration.
- Possible local or systemic adverse reaction may occur if any long-term polymer degradation occurs.

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

_WARNINGS

These devices are to be used as indicated. The safety and effectiveness of these devices when implanted in the spine for any other indications has not yet been established. Do not use the implant if it appears damaged or the expiration date has passed.

_CAUTION – PRECAUTION FOR USE

An in-depth discussion of all possible complications associated with this procedure is beyond the scope of these instructions.

A successful result is not always achieved in every surgical case. Use of this product without a bone graft may not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device may occur.

The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of the device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

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 selection of proper size, shape and design of the implant is crucial to the success of the procedure. Plastic polymer implants are subject to repeated stresses in use, and their strength is limited by the need to adapt to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause polymer fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

The following precautions must be followed:

Per Operative:

- Only patients that meet the criteria described in the indications should be selected.
- Patient's conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
- 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 TALOS® Lumbar (HA) PEEK IBF device system cannot guarantee device performance in patients. Patient selection is important to minimize device failure.
- 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.
- 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.
- 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.

- 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.

Intraoperative:

- The instructions in any available applicable surgical technique should be carefully followed.
- 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.
- 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.
- 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® Lumbar (HA) PEEK IBF device, autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft should be used.
- 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.

- 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.
- 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.
- 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.
- 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.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.
- 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.

_MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that Spineart's lumbar interbody cages are MR Conditional. A person with Spineart's lumbar interbody cages 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.

GENERAL INFORMATION

PARAMETER	CONDITION
Device name	Spineart Lumbar Interbody Cages
Static Magnetic Field Strength (B0)	1.5 T and 3 T
MR Scanner Type	Cylindrical
B0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	31.6 T/m (3,160 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	Up to 1 hour without cooling period
Scan Regions	Any landmark is acceptable
Image Artifact	The presence of Spineart's Lumbar Interbody Cages may produce an image artifact of 5.3 cm. Some manipulation of scan parameters may be needed to compensate for the artifact.
RF Heating	Results of heating testing (utilizing both experimental and computational methods) indicate the largest temperature rise is expected to be less than or equal to 2.1 °C at 1.5 T and 2.7 °C at 3 T when scanned in Normal Operating Mode with a whole-body SAR of 2.0 W/kg.

_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

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 TALOS® instruments for the TALOS® Lumbar (HA) PEEK IBF device implantations. Specific markings are engraved on each

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 (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 REPAIR

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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