TALOS® A (HA)

ANTERIOR LUMBAR 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 cages has been integrated into Spineart's existing range. More particularly, the TALOS® A 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 through peer reviewed, preclinical trials to accelerate bony fusion.

The TALOS® A HA Lumbar Cage system consists of sterile-packed implants and a single compact instrument set.

TALOS® A HA, in addition to CURE™ LP (lumbar plate) and SCARLET® AL-T (secured interbody) provides a comprehensive solution for anterior lumbar fusion procedures.

AT A GLANCE

HA PEEK

Large Graft Window

Multiple Insertion

Lordotic and Hyper-Lordotic Profiles

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.

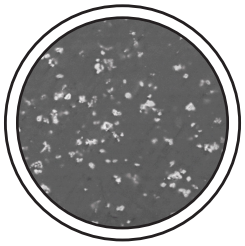
TALOS® A (HA) PEEK IBF devices are to be implanted via an anterior or anteriolateral approach in the lumbosacral spine.

The TALOS®-A (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.

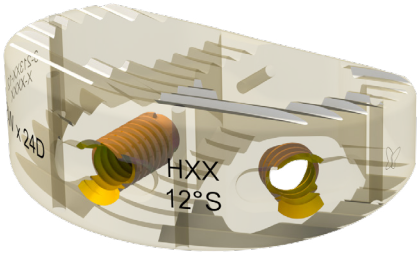
TECHNICAL FEATURES

HA PEEK



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

ANTERIOR AND ANTEROLATERAL INSERTION



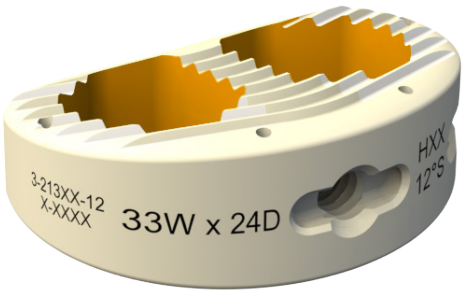
Address variable patient anatomy and surgeon technique preferences.

* 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

LARGE GRAFT WINDOW

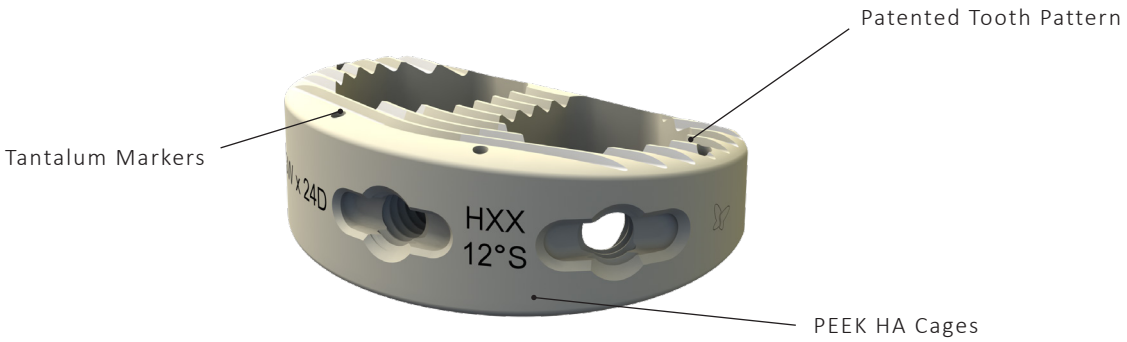


The large graft window allows for bone graft placement and permits bony in-growth.

MULTIPLE LORDOTIC PROFILES

Options to aid in restoration of sagital alignment.

IMPLANTS



PLANAR SYMMETRIC CAGES

12° LORDOSIS

HEIGHT	LENGTH	WIDTH	REFERENCES
H10	L24	W33	3-21310-12
H12	L24	W33	3-21312-12
H14	L24	W33	3-21314-12
H16	L24	W33	3-21316-12
H10	L26	W36	3-21410-12
H12	L26	W36	3-21412-12
H14	L26	W36	3-21414-12
H16	L26	W36	3-21416-12
H18*	L26	W36	3-21418-12*
H10	L28	W39	3-21510-12
H12	L28	W39	3-21512-12
H14	L28	W39	3-21514-12
H16	L28	W39	3-21516-12
H18*	L28	W39	3-21518-12*

16° LORDOSIS

HEIGHT	LENGTH	WIDTH	REFERENCES
H10	L24	W33	3-21310-16
H12	L24	W33	3-21312-16
H14	L24	W33	3-21314-16
H16	L24	W33	3-21316-16
H10	L26	W36	3-21410-16
H12	L26	W36	3-21412-16
H14	L26	W36	3-21414-16
H16	L26	W36	3-21416-16
H18*	L26	W36	3-21418-16*
H10	L28	W39	3-21510-16
H12	L28	W39	3-21512-16
H14	L28	W39	3-21514-16
H16	L28	W39	3-21516-16
H18*	L28	W39	3-21518-16*

* OPTIONAL

IMPLANTS

20° LORDOSIS			
HEIGHT	**LENGTH**	**WIDTH**	**REFERENCES**
H10*	L24	W33	3-21310-20*
H12*	L24	W33	3-21312-20*
H14*	L24	W33	3-21314-20*
H16*	L24	W33	3-21316-20*
H18*	L24	W33	3-21318-20*
H20*	L24	W33	3-21320-20*
H12*	L26	W36	3-21412-20*
H14*	L26	W36	3-21414-20*
H16*	L26	W36	3-21416-20*
H18*	L26	W36	3-21418-20*
H20*	L26	W36	3-21420-20*
H12*	L28	W39	3-21512-20*
H14*	L28	W39	3-21514-20*
H16*	L28	W39	3-21516-20*
H18*	L28	W39	3-21518-20*
H20*	L28	W39	3-21520-20*

25° LORDOSIS			
HEIGHT	**LENGTH**	**WIDTH**	**REFERENCES**
H14*	L24	W33	3-21314-25*
H16*	L24	W33	3-21316-25*
H18*	L24	W33	3-21318-25*
H20*	L24	W33	3-21320-25*
H14*	L26	W36	3-21414-25*
H16*	L26	W36	3-21416-25*
H18*	L26	W36	3-21418-25*
H20*	L26	W36	3-21420-25*
H14*	L28	W39	3-21514-25*
H16*	L28	W39	3-21516-25*
H18*	L28	W39	3-21518-25*
H20*	L28	W39	3-21520-25*

PLANAR ASYMMETRIC CAGES

11° LORDOSIS			
HEIGHT	**LENGTH**	**WIDTH**	**REFERENCES**
H10*	L26	W36	3-22410-11*
H12*	L26	W36	3-22412-11*
H14*	L26	W36	3-22414-11*
H16*	L26	W36	3-22416-11*
H18*	L26	W36	3-22418-11*

* OPTIONAL

INSTRUMENT SET

#	DESCRIPTION	REFERENCE
	PLANAR, SYMMETRIC MODULAR TI TRIAL, 33 MM W X 24 MM L, 12 °	310-123310-12 310-123312-12 310-123314-12 310-123316-12
	PLANAR, SYMMETRIC MODULAR TI TRIAL, 33 MM W X 24 MM L, 16°	310-123310-16 310-123312-16 310-123314-16 310-123316-16
	PLANAR, SYMMETRIC MODULAR TI TRIAL , 33 MM W X 24 MM L, 20°	310-123310-20* 310-123312-20* 310-123314-20* 310-123316-20* 310-123318-20* 310-123320-20*
	PLANAR, SYMMETRIC MODULAR TI TRIAL , 33 MM W X 24 MM L, 25°	310-123314-25* 310-123316-25* 310-123318-25* 310-123320-25*
	PLANAR, SYMMETRIC MODULAR TI TRIAL , 36 MM W X 26 MM L, 12°	310-124410-12 310-124412-12 310-124414-12 310-124416-12 310-124418-12*
	PLANAR, ASYMMETRIC MODULAR TI TRIAL , 36 MM W X 26 MM L, 11°	310-224410-11* 310-224412-11* 310-224414-11* 310-224416-11* 310-224418-11*

#	DESCRIPTION	REFERENCE
	PLANAR, SYMMETRIC MODULAR TI TRIAL , 36 MM W X 26 MM L, 16°	310-124410-16 310-124412-16 310-124414-16 310-124416-16 310-124418-16*
	PLANAR, SYMMETRIC MODULAR TI TRIAL , 36 MM W X 26 MM L, 20°	310-124412-20* 310-124414-20* 310-124416-20* 310-124418-20* 310-124420-20*
	PLANAR, SYMMETRIC MODULAR TI TRIAL, 36 MM W X 26 MM L, 25°	310-124414-25* 310-124416-25* 310-124418-25* 310-124420-25*
	PLANAR, SYMMETRIC MODULAR TI TRIAL , 39 MM W X 28 MM L, 12°	310-125510-12 310-125512-12 310-125514-12 310-125516-12 310-125518-12*
	PLANAR, SYMMETRIC MODULAR TI TRIAL , 39 MM W X 28 MM L, 16°	310-125510-16 310-125512-16 310-125514-16 310-125516-16 310-125518-16*
	PLANAR, SYMMETRIC MODULAR TI TRIAL , 39 MM W X 28 MM L, 20°	310-125512-20* 310-125514-20* 310-125516-20* 310-125518-20* 310-125520-20*
	PLANAR, SYMMETRIC MODULAR Ti TRIAL , 39 MM W x 28 MM L, 25°	310-125514-25* 310-125516-25* 310-125518-25* 310-125520-25*

* : OPTIONAL

INSTRUMENT SET

#	DESCRIPTION	REFERENCE
	STRAIGHT INSERTER, GEN II, YELLOW HANDLE	921-310001-00
	SLAP HAMMER ADAPTER	924-211100-00
	SLAP HAMMER, SHORT	100-600-00
	TAMP, STRAIGHT	302-110000-00
	TAMP, 15° DEG ANGLE	302-110000-15
	TEMPLATE TRIAL, 33 X 24MM	312-113300-00
	TEMPLATE TRIAL, 36 X 26MM	312-114400-00
	TEMPLATE TRIAL, 39 X 28MM	312-115500-00
	INSTRUMENT CASE	300-950-00
	RASP, BLUE HANDLE	300-500-00
	CURE DISC TEMPLATE 33 MM	900-300-33
	CURE DISC TEMPLATE 36 MM	900-300-36
	CURE DISC TEMPLATE 39 MM	900-300-39

• : OPTIONAL

INSTRUMENTS

STRAIGHT INSERTER	921-310001-00

SLAP HAMMER ADAPTER	924-211100-00

SLAP HAMMER, SHORT	100-600-00

TAMP, STRAIGHT	302-110000-00

TAMP, 15° DEG ANGLE	302-110000-15

RASP, BLUE HANDLE	300-500-00

CURE DISC TEMPLATE	900-300-33 900-300-36 900-300-40

	10MM	BRONZE
	12MM	GRAY TYPE
	14MM	GOLD
	16MM	TEAL
	18MM	LIGHT BLUE
	20MM	BRONZE

INSTRUMENTS

OPTIONS

PLANAR, SYMMETRIC MODULAR TI TRIAL	310-12XXXX-12 310-12XXXX-16 310-12XXXX-20 310-12XXXX-25 310-12XXXX-30

TEMPLATE TRIAL	312-113300-00 312-114400-00 312-115500-00

PLANAR, ASYMMETRIC MODULAR TI TRIAL	310-2244XX-11

SURGICAL TECHNIQUE

_STEP 1

PATIENT POSITIONING AND EXPOSURE

For an anterior approach of the lower lumbar levels, place the patient supine in a slight Trendelenburg position, per surgeon preference.

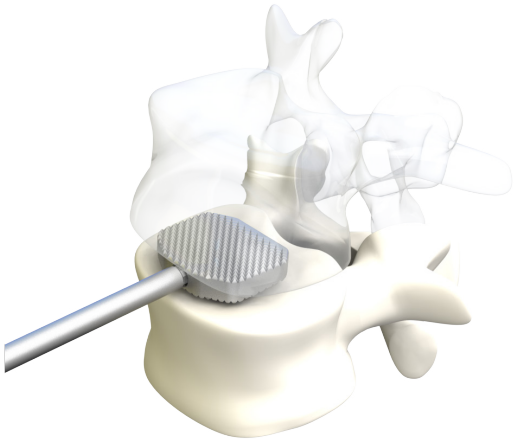
Locate the operative disc level and incision location via lateral fluoroscopy.

Determine surgical approach (anterior or anterolateral) based on the surgeon preference.

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

Cut an appropriately sized window through the anterior longitudinal ligament and the annulus fibrosus, to access the target disc space.

_STEP 2



PREPARATION OF THE ENDPLATES

The **Disc Template** can be used to help determine cage size and as a guide for annulotomy incisions. Place the template on the annulus and use an annulotomy knife to make incisions along the lateral edges of the template.

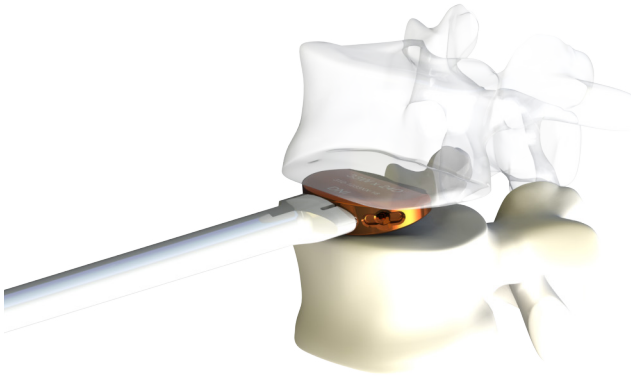
Rongeurs can be used to remove nucleus material from the disc space. In addition, curettes, shavers and soft tissue elevators can be used to aid in removal. Care should be taken to leave the lateral annulus intact so proper tensioning can be achieved. Cartilaginous endplates of the superior and inferior bodies should be removed but not the bony material (removal of too much bony material may increase the risk of subsidence). The **Rasp** can be used to aid in endplate preparation.

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

All nucleus material of the disc should be removed to ensure a healthy fusion bed for the bone graft. Further distraction with other instruments such as disc spreaders or “flip up” distractors may aid in the disc space preparation.

INSTRUMENT	REFERENCE
RASP, BLUE HANDLE	300-500-00
CURE DISC TEMPLATE	900-300-XX

_STEP 3



SELECTION OF THE IMPLANT SIZE

Templates Trials help measure disc space width and depth. Place the **Template Trial** into the disc space to determine appropriate implant footprint.

The selection of the implant's lordosis and size, depends on the intervertebral space, patient anatomy and preparation technique. The lordosis of the cage will depend on the patient's anatomy and surgeon's preferences for treatment. The lordotic cages are used to better restore lordosis at the treated level.

Once the lordosis is chosen, use a **Trial** to determine the height of the implant.

Lordosis, footprint (depth and width) and height of the **Trial** match the lordosis, footprint and height of the implant.

NOTE : Spineart provides different **Trials** that represent the footprint, lordosis and height of each implant. Footprint, lordosis and height are written on the **Trial**.

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

Trials are threaded onto the **Inserter**. Under fluoroscopy, the **Trial** is safely impacted into the disc space. Orientation and position is monitored. **Trial** heights are sequentially increased until the desired height and lordosis is achieved. (Inset of Templates and Trials)

A **Slap Hammer** and **Adaptor** are available to connect onto the Inserter to remove the **Trials** from the disc space.

Care should be taken to not cross thread the **Trials** on the **Inserter** and over impact the disc space.

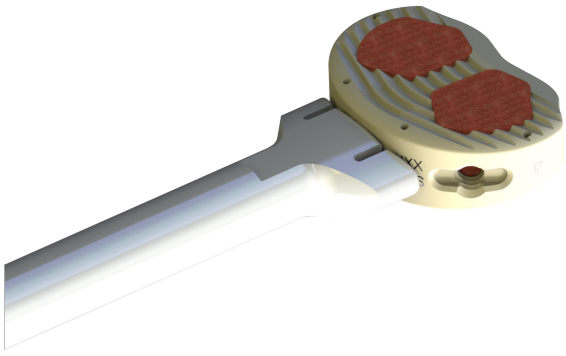
SURGICAL TECHNIQUE

Once the size is assessed, gently remove the **Trial**, and select the cage corresponding to footprint, height and lordosis.

The choice of the configurations/variants, listed page 6, 7 and 8, depends on the anatomy of the patient and the level to be treated. All implants are suitable for any of the indication reported in the IFU. Implant trials are available to assess the disc space and help the surgeon decide which implant is the most appropriate.

INSTRUMENT	REFERENCE
TEMPLATE TRIALS	312-11XX00-00
PLANAR, SYMMETRIC MODULAR TI TRIAL,	310-12XXXX-XX
PLANAR, ASYMMETRIC MODULAR TI TRIAL	310-2244XX-11
STRAIGHT INSERTER	921-310001-00
SLAP HAMMER ADAPTER	924-211100-00
SLAP HAMMER, SHORT	100-600-00

_STEP 4



CAGE PREPARATION

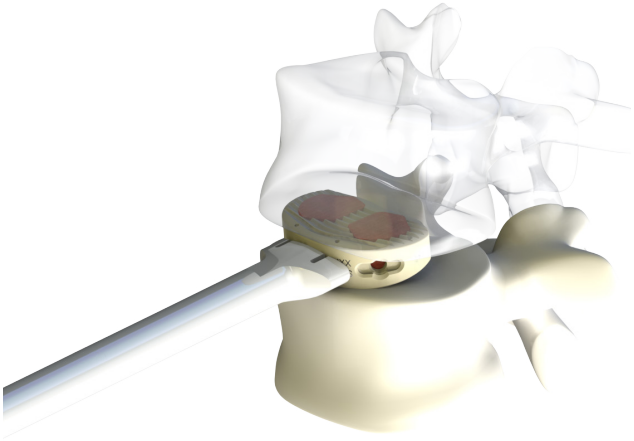
Once the proper cage is determined, fill the graft window with bone graft.

Thread the cage onto the **Inserter**. Over tightening or cross threading of the inserter to the implant should be avoided.

Bone graft can be placed around the implant.

INSTRUMENT	REFERENCE
STRAIGHT INSERTER	921-310001-00

_STEP 5



INSERTION

Insert the cage in the intervertebral space. Fluoroscopy should be used to verify the final position of the implant.

Two surgical approaches are possible: anterior or anterolateral.

Vascular structures should be protected prior to cage insertion. Orient the cage with the teeth in the caudal-raustral position. Adequately recess the implant within the disc space. The TALOS® A (HA) is designed to fill the middle anterior third of the spinal column. Special Tamps are available to help manipulate the implant across the disc space. Depending on the depth and how far the implant is placed across the disc space, more bone graft can be placed around or behind the TALOS® A (HA) cage.

ANTEROLATERAL APPROACH

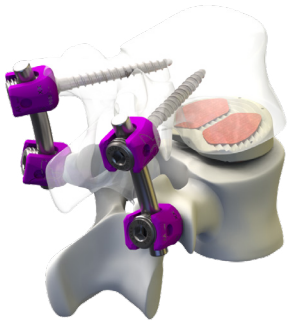
An oblique, threaded insertion hole is available to facilitate an anterolateral approach. Care should be taken not to over torque the threaded insertion hole. Additionally, during the anterolateral approach, excessive leverage should be avoided as not to damage the implant.

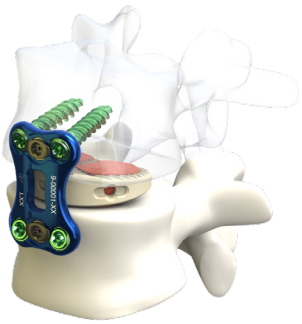
Should a cage need to be repositioned, the **Straight Inserter** can be re-attached to the implant.

INSTRUMENT	REFERENCE
STRAIGHT INSERTER	921-310001-00
TAMP, STRAIGHT	302-110000-00
TAMP, 15° DEG ANGLE	302-110000-15

SURGICAL TECHNIQUE

_FINAL CONSTRUCT





Supplemental fixation should be utilized to provide additional support for the spinal column. Additionally, the use of a Hyperlordotic TALOS® A (HA) (lordotic angle greater than 20°) requires use of anterior supplementation fixation in order to prevent implant migration. CURE™ LP system is an available option.

_IMPLANT REMOVAL

The TALOS® A (HA) PEEK IBF Device is made of PEEK-OPTIMA® HA ENHANCED and has similar biomechanical strength to cortical bone. If excessive leverage (that which is greater than physiological loads) is placed on the Inserter and implant interface, 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. If the surgeon determines upon insertion of the TALOS®A (HA) device that the implant is not positioned correctly, the threaded insertion tool can be attached to the implant and then removed either by connecting the Slap Hammer or with direct visualization and manipulation. In all instances of retrieval, care should be taken to protect the neural and vascular structures.

GENERAL INFORMATION

REFERENCE OF THE IFU	TAL-AL-IF-US	REVISION OF THE FINAL IFU	MAR-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 two configurations: Talos®-TL (HA), and Talos®-A (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® –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 anteriolateral approach in the lumbosacral spine. The Talos®-TL (HA) and Talos®-A (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 Cervical 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 Cervical 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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