Inspire® TA

3D Printed Trabecular PEEK™ with HA FUSE®

CURITEVA®
POWER TO HEAL

Surgical Technique Guide

Table of Contents

Inspire® TA

TLIF Anterior

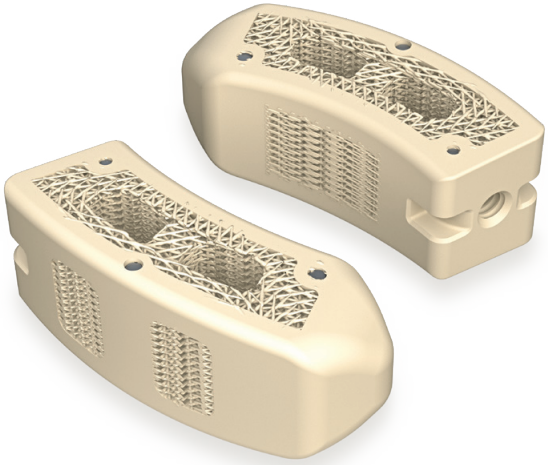
3D PRINTED TRABECULAR PEEK™ with HA FUSE®

Disclaimer

The surgical technique shown is for illustrative purposes only. Proper surgical procedure is the responsibility of the medical professional. Please reference the package insert for additional information and system instructions.

Inspire® TA TLIF Anterior

The Inspire TLIF Anterior System is indicated for use in skeletally mature patients with degenerative disc disease at one or two contiguous levels from L2 - S1. The implants are manufactured utilizing the Evonik VESTAKEEP® i4 3DF PEEK high-performance polymer on a proprietary, patented Fused Filament Fabrication 3D printer. Application of the patented HA^{FUSE} to this engineered PEEK structure presents a hydrophilic surface, which can lead to better bone apposition and enhanced Osseointegration, as observed in our animal study.[1]



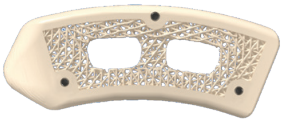
PEEK Interbody

Part Number: C434-XXXXYY-7

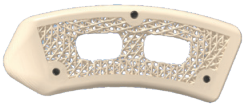
XXXX - Interbody Footprint, YY - Interbody Height

- Trabecular PEEK with HA^{FUSE}
- Footprints (mm): 28L x 9W, 32L x 9W
- Heights: 7-16mm, offered in 1mm increments
- Lordosis: 8°, 0°

32L x 9W



28L x 9W



Inspire Features

- Excellent fusion visualization
- 100% fully Interconnected porosity
- Pore size distribution between 100 – 600 microns designed to promote Osteoconduction[2,3,4]
- HA is bonded to 100% of the implant surface throughout the entire structure
- Titanium radiopaque markers to optimize visibility and placement
- Comprehensive discectomy instruments
- Robust Inserter engagement features to facilitate implant insertion
- Convex design offers a more accurate fit to the patients anatomy
- Simple instrumentation for reliable implant placement

References:

[1] Data is derived from ovine studies. Please note in vitro and in vivo testing may not be representative of clinical experience.

[2] Vijayavenkataraman, S., Kuan, L.Y., Lu, W.F., 2020. 3D-printed ceramic triply periodic minimal surface structures for design of functionally graded bone implants. Mater. Des. 108602.

[3] Liu, F., Mao, Z., Zhang, P., Zhang, D.Z., Jiang, J., Ma, Z., 2018b. Functionally graded porous scaffolds in multiple patterns: new design method, physical and mechanical properties. Mater. Des. 160, 849–860.

[4] Feng, B., Jinkang, Z., Zhen, W., Jianxi, L., Jiang, C., Jian, L., Guolin, M., Xin, D., 2011. The effect of pore size on tissue ingrowth and neovascularization in porous bioceramics of controlled architecture in vivo. Biomed. Mater. 6 (1), 015007.

*Additional references available by request

Inspire® TA 3D Printed Trabecular PEEK™ with HAFUSE®

Inspire TLIF Anterior Interbodies					
Height	**Catalog Number**	**Description**	**Height**	**Catalog Number**	**Description**
7mm	C434-280907-0	28 x 9 x 7mm, 0° TLIF Anterior*	7mm	C434-280907-8	28 x 9 x 7mm, 8° TLIF Anterior
8mm	C434-280908-0	28 x 9 x 8mm, 0° TLIF Anterior*	8mm	C434-280908-8	28 x 9 x 8mm, 8° TLIF Anterior
9mm	C434-280909-0	28 x 9 x 9mm, 0° TLIF Anterior*	9mm	C434-280909-8	28 x 9 x 9mm, 8° TLIF Anterior
10mm	C434-280910-0	28 x 9 x 10mm, 0° TLIF Anterior*	10mm	C434-280910-8	28 x 9 x 10mm, 8° TLIF Anterior
11mm	C434-280911-0	28 x 9 x 11mm, 0° TLIF Anterior*	11mm	C434-280911-8	28 x 9 x 11mm, 8° TLIF Anterior
12mm	C434-280912-0	28 x 9 x 12mm, 0° TLIF Anterior*	12mm	C434-280912-8	28 x 9 x 12mm, 8 TLIF Anterior
13mm	C434-280913-0	28 x 9 x 13mm, 0° TLIF Anterior*	13mm	C434-280913-8	28 x 9 x 13mm, 8° TLIF Anterior
14mm	C434-280914-0	28 x 9 x 14mm, 0° TLIF Anterior*	14mm	C434-280914-8	28 x 9 x 14mm, 8° TLIF Anterior
15mm	C434-280915-0	28 x 9 x 15mm, 0° TLIF Anterior*	15mm	C434-280915-8	28 x 9 x 15mm, 8° TLIF Anterior
16mm	C434-280916-0	28 x 9 x 16mm, 0° TLIF Anterior*	16mm	C434-280916-8	28 x 9 x 16mm, 8° TLIF Anterior

Height	**Catalog Number**	**Description**	**Height**	**Catalog Number**	**Description**
7mm	C434-320907-0	32 x 9 x 7mm, 0° TLIF Anterior*	7mm	C434-320907-8	32 x 9 x 7mm, 8° TLIF Anterior
8mm	C434-320908-0	32 x 9 x 8mm, 0° TLIF Anterior*	8mm	C434-320908-8	32 x 9 x 8mm, 8° TLIF Anterior
9mm	C434-320909-0	32 x 9 x 9mm, 0° TLIF Anterior*	9mm	C434-320909-8	32 x 9 x 9mm, 8° TLIF Anterior
10mm	C434-320910-0	32 x 9 x 10mm, 0° TLIF Anterior*	10mm	C434-320910-8	32 x 9 x 10mm, 8° TLIF Anterior
11mm	C434-320911-0	32 x 9 x 11mm, 0° TLIF Anterior*	11mm	C434-320911-8	32 x 9 x 11mm, 8° TLIF Anterior
12mm	C434-320912-0	32 x 9 x 12mm, 0° TLIF Anterior*	12mm	C434-320912-8	32 x 9 x 12mm, 8° TLIF Anterior
13mm	C434-320913-0	32 x 9 x 13mm, 0° TLIF Anterior*	13mm	C434-320913-8	32 x 9 x 13mm, 8° TLIF Anterior
14mm	C434-320914-0	32 x 9 x 14mm, 0° TLIF Anterior*	14mm	C434-320914-8	32 x 9 x 14mm, 8° TLIF Anterior
15mm	C434-320915-0	32 x 9 x 15mm, 0° TLIF Anterior*	15mm	C434-320915-8	32 x 9 x 15mm, 8° TLIF Anterior
16mm	C434-320916-0	32 x 9 x 16mm, 0° TLIF Anterior*	16mm	C434-320916-8	32 x 9 x 16mm, 8° TLIF Anterior

Interbody Details

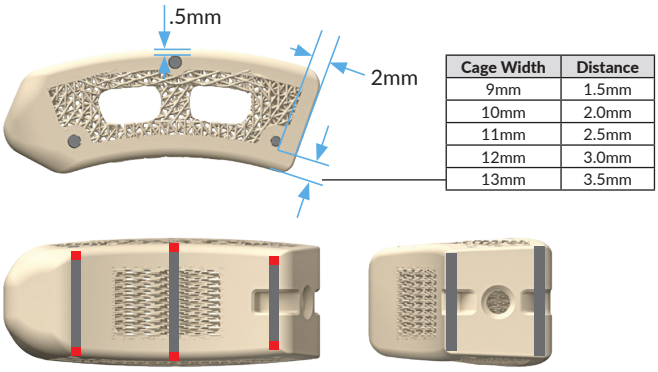
- Bulleted distracting nose
- Internal radius for 28 & 32mm length is 1.25”

Radiographic Markers

- 3 Pins per interbody – 2 lateral, 1 central, 1mm diameter
- Anterior pin centered on endplate contacting surface
- Lateral pins aligned in lateral view
- Pins offset .5mm (tooth depth) from endplate surface

Porous Windows

- Anterior Face - Split porous graft windows
- Posterior Face - Single porous graft window

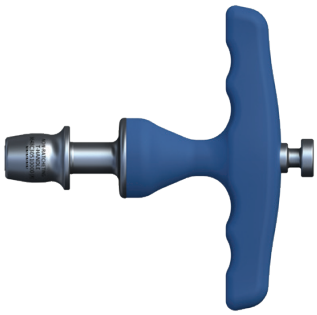


Cage Width	Distance
9mm	1.5mm
10mm	2.0mm
11mm	2.5mm
12mm	3.0mm
13mm	3.5mm

**Available by request*

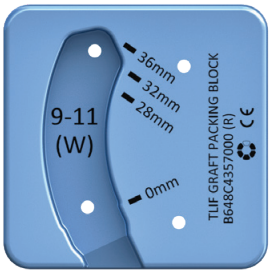
C305-100	TLIF/PLIF Inserter

C305-500	Straight Tamp



C305-1000	T-Handle, 1/4", Non-Ratcheting

	TLIF Anterior Trials
C405-300	6mm (H) x 9mm (W) TLIF Parallel Trial
C405-301	7mm (H) x 9mm (W) TLIF Parallel Trial
C405-302	8mm (H) x 9mm (W) TLIF Parallel Trial
C405-303	9mm (H) x 9mm (W) TLIF Parallel Trial
C405-304	10mm (H) x 9mm (W) TLIF Parallel Trial
C405-305	11mm (H) x 9mm (W) TLIF Parallel Trial
C405-306	12mm (H) x 9mm (W) TLIF Parallel Trial
C405-307	13mm (H) x 9mm (W) TLIF Parallel Trial
C405-308	14mm (H) x 9mm (W) TLIF Parallel Trial
C405-309	15mm (H) x 9mm (W) TLIF Parallel Trial
C405-310	16mm (H) x 9mm (W) TLIF Parallel Trial
C405-350	7mm (H) x 9mm (W) TLIF Lordotic Trial
C405-351	8mm (H) x 9mm (W) TLIF Lordotic Trial
C405-352	9mm (H) x 9mm (W) TLIF Lordotic Trial
C405-353	10mm (H) x 9mm (W) TLIF Lordotic Trial
C405-354	11mm (H) x 9mm (W) TLIF Lordotic Trial
C405-355	12mm (H) x 9mm (W) TLIF Lordotic Trial
C405-356	13mm (H) x 9mm (W) TLIF Lordotic Trial
C405-357	14mm (H) x 9mm (W) TLIF Lordotic Trial
C405-358	15mm (H) x 9mm (W) TLIF Lordotic Trial
C405-359	16mm (H) x 9mm (W) TLIF Lordotic Trial



C435-700	TLIF Anterior Graft Packing Block

Posterior Lumbar Disc Prep Instrument Guide

C445-100 8mm Straight Rasp, Bayoneted

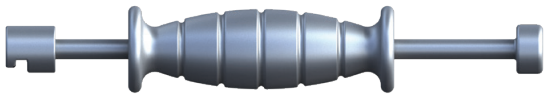
C445-105 8mm Angled Left Rasp, Bayoneted

C445-110 8mm Angled Right Rasp, Bayoneted

C445-115 10mm Straight Osteotome, Bayoneted

C445-120 10mm Curved Osteotome, Bayoneted

C445-210 Slotted Mallet



C445-220 Slap Hammer

C445-165 Nerve Root Retractor, Bayoneted

C445-125 4mm Straight Curette, Bayoneted

C445-130 4mm Angled Left Curette, Bayoneted

C445-135 4mm Angled Right Curette, Bayoneted

C445-140 4mm Push Curette, Bayoneted

C445-145 4mm Pull Curette, Bayoneted

C445-150 7mm Ring Curette, Bayoneted

C445-155 7mm Rake Curette, Bayoneted

C445-160 12mm Cobb Elevator, Bayoneted

C445-800 Shaver / Distractor, 6mm

C445-801 Shaver / Distractor, 7mm

C445-802 Shaver / Distractor, 8mm

C445-803 Shaver / Distractor, 9mm

C445-804 Shaver / Distractor, 10mm

C445-805 Shaver / Distractor, 11mm

C445-806 Shaver / Distractor, 12mm

C445-807 Shaver / Distractor, 13mm

C445-808 Shaver / Distractor, 14mm

C445-809 Shaver / Distractor, 15mm

C445-810 Shaver / Distractor, 16mm

Inspire® TA

TLIF Anterior
Interbody Fusion System

Surgical Technique

Step 1: Patient Positioning

Place the patient in a prone position on a radiolucent operating table that promotes suitable exposure and re-stores sagittal alignment. A/P and lateral fluoroscopy should be used to identify and target the appropriate levels. **(Figure 1)**

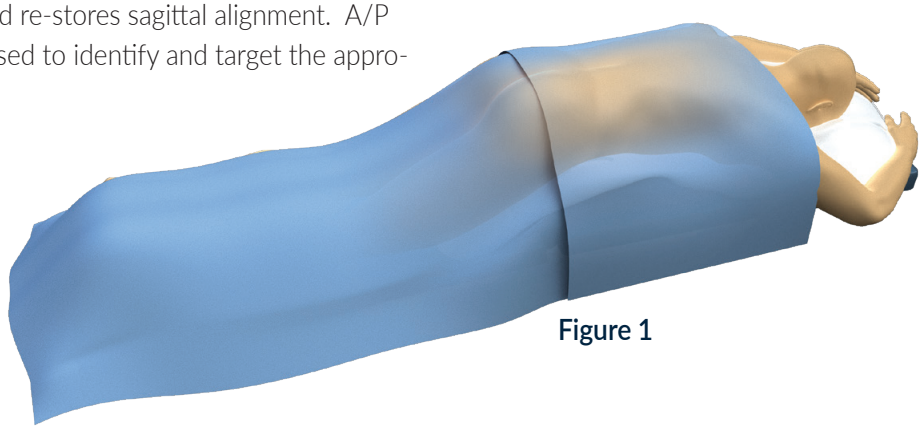
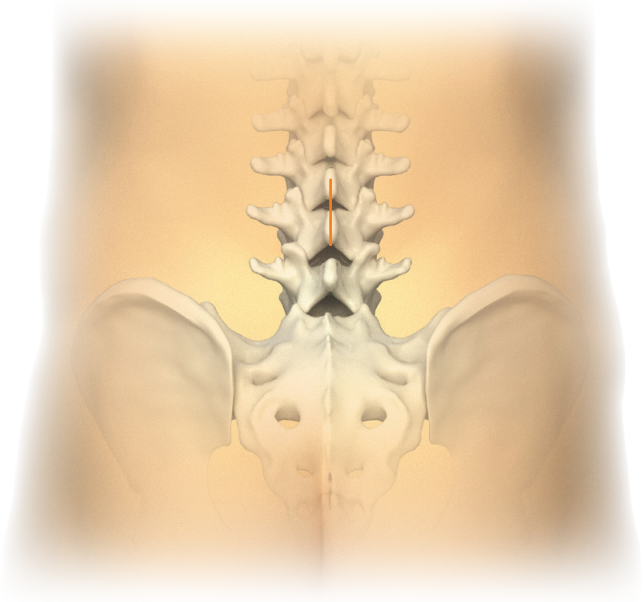


Figure 1

Step 2: Surgical Approach to the Disc (Posterior)

A midline incision provides exposure of the interlaminar space and facet joints at the indicated level. Pedicle screws of the surgeon's preference are inserted into the pedicles of the vertebrae adjacent to the disc space to be fused. Using a combination of surgical instruments appropriately selected by the surgeon, a laminotomy, laminectomy and/or facetectomy, is performed, along with the removal of the ligamentum flavum, to gain access to the disc space and identify neural and bony anatomy. **(Figure 2)**

Figure 2



Step 3: Discectomy and Endplate Preparation

Perform a standard discectomy using Paddle Shavers, Osteotomes, Curettes or Rasps to prepare the implant bed. **(Figure 3a, 3b)**

Note: Suggest shaving the cortical ring at the insertion window in the vertebral bodies.

Note: Adequate preparation of the endplates is important to facilitate vascularization of the bone graft.

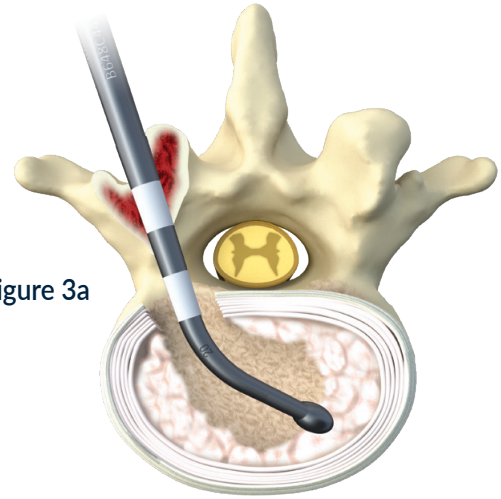


Figure 3a

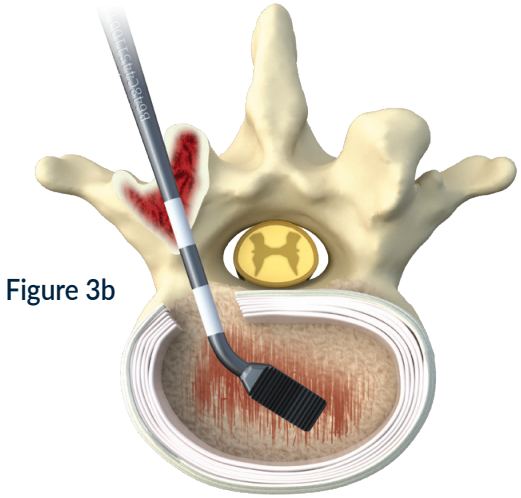


Figure 3b

Step 4: Distraction

Proper distraction is essential to restore desired disc height. Assemble the desired size of the Paddle Shaver/Distractor onto the T-Handle and insert into the disc space. **(Figure 4a)** Rotating the Paddle Shaver/Distractor clockwise will shave the endplates **(Figure 4b)** and rotating the Paddle Shaver/Distractor counterclockwise 90° will provide blunt distraction. **(Figure 4a)**

Note: The Distractors are depth marked from 20 – 40mm to aid in visualization.

Note: There are length indicators visible under fluoroscopy.

Figure 4a

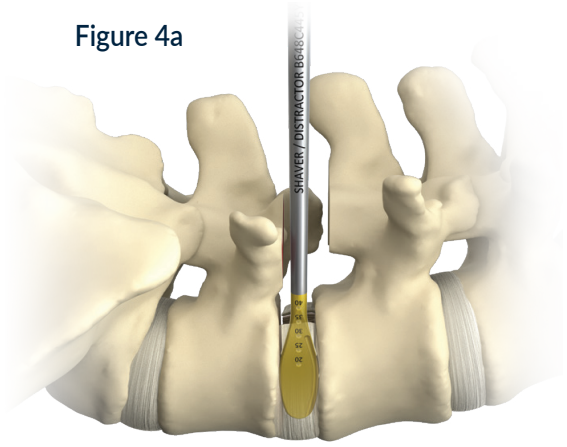
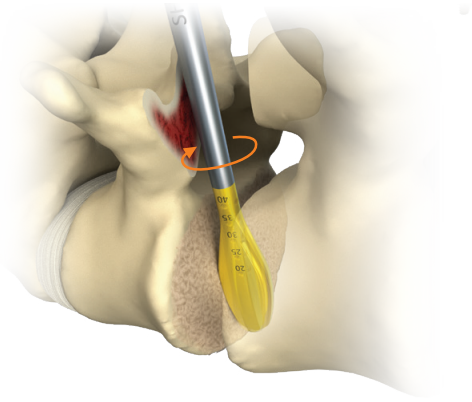


Figure 4b



Step 5: Implant Selection

Assemble the desired Trial onto the T-Handle. Trials are 9mm wide and 32mm long with length indicators that are visible with fluoroscopy. The vertical slot represents the 28mm implant and the end of the Trial body represents the 32mm implant. Heights start at 7mm and increase sequentially by 1mm increments. If necessary, impact the Trial assembly to confirm the position and fit of the Trial. Use A/P and lateral fluoroscopy to confirm proper placement and trajectory. Once the proper size is determined, remove the Trial from the intervertebral space.

A Slap Hammer is available in the Disc Preparation Set for assisting in removing the Trial assembly from the Disc Space. **(Figure 5a, 5b)**

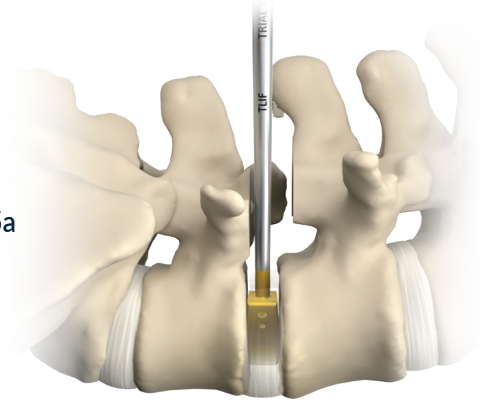


Figure 5a

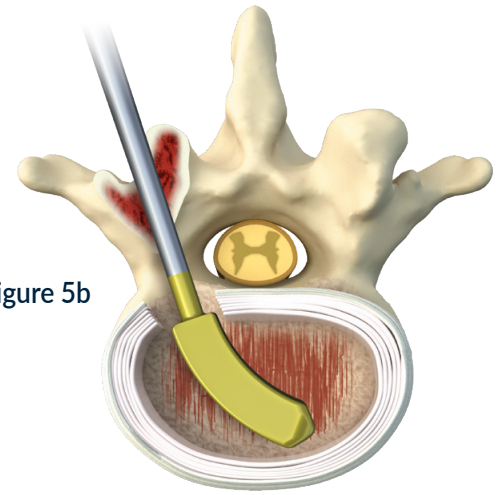


Figure 5b

Step 6: Implant Preparation

Select the appropriate implant size and attach to the Inserter. Load implant onto the inserter by aligning anti-rotation features and threading central stylus into implant. Once the implant is fully engaged on the Inserter, fill the implant with autologous bone, allograft or other bone grafting material. **(Figure 6a, 6b)**

Alternatively, utilize the Graft Block and Tamp to pack the implant with grafting material. **(Figure 6c)**

Note: The graft should be flush with the upper and lower surfaces of the implant.

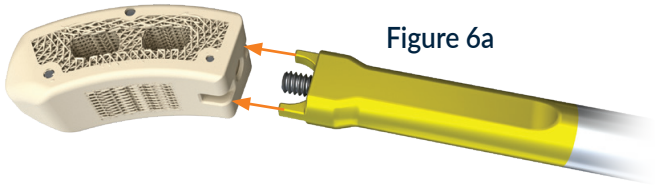


Figure 6a

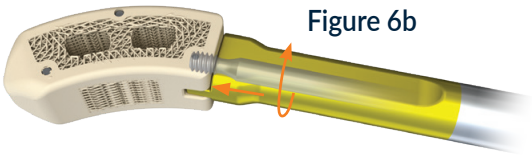


Figure 6b

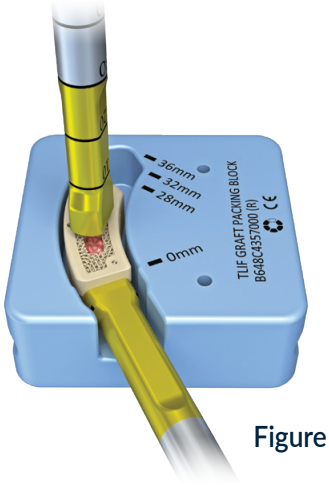


Figure 6c

Step 7: Implant Insertion

Prior to implant insertion, bone graft material may be placed anteriorly or contralaterally. Under fluoroscopy, insert the implant mounted on the Inserter into the disc space. The final position should be across the midline with the length of the device perpendicular to the midline. Once in position, remove all instruments and fill the remaining disc space with bone graft.

Note: Use asymmetrical malleting for implant insertion

Inserter as Tamp/Rotation Technique:
- Insert the implant using standard inserter
- Remove the inner threaded shaft
- Rotate the inserter to the 90 degree position while maintaining the posterior prong in the alignment cut
- Mallet the implant into position across the midline

To disengage the implant from the Inserter, unthread the knob on the end of the Inserter. **(Figure 7a, 7b)**

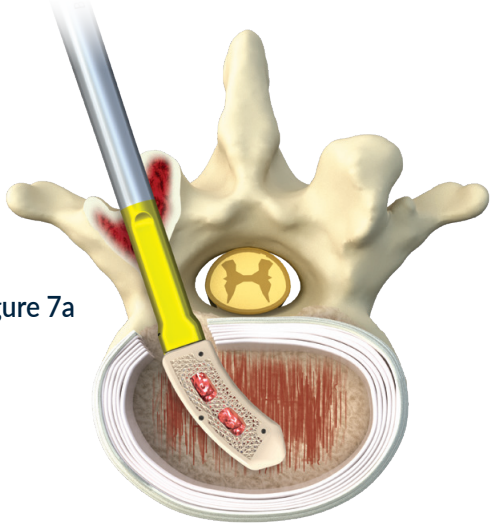


Figure 7a

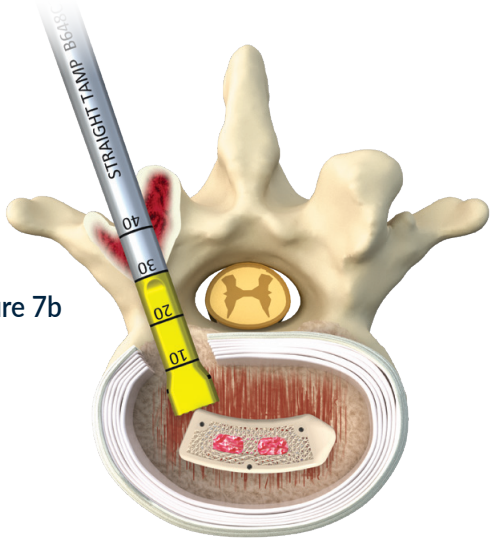


Figure 7b

Step 8: Implant Removal (optional)

Attach inserter into implant posteriorly and thread inserter into threads of implant until tightened. Gently remove implant from disc space. If the implant cannot be easily removed, a Cobb elevator, Slotted Mallet or Osteotome should be used to loosen the bone to implant interface. **(Figure 8)**

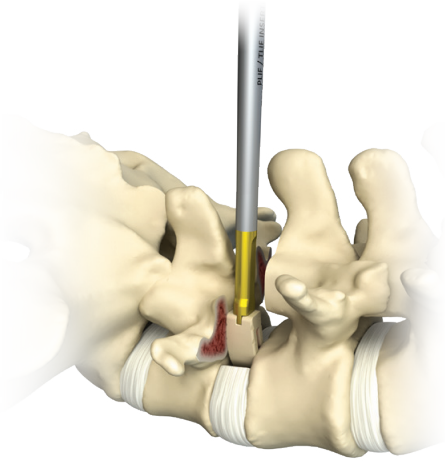


Figure 8

Description:

The Inspire Trabecular PEEK Lumbar Interbody Fusion System consists of interbody fusion cages that are generally rectangle-shaped with an open central chamber to permit packing with bone graft to facilitate fusion.

The Inspire Trabecular PEEK Lumbar Interbody Fusion System implants are manufactured from PEEK (per ASTM F2026) with Titanium alloy markers (Ti-6Al-4V) that conform to ASTM F136. Each implant has been surface treated with a thin hydroxyapatite (HA) coating. All implants are provided sterile-packed and are intended for single use only.

Indications for Use:

The Curiteva Inspire Trabecular PEEK Lumbar Interbody Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 – S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Implants are intended to be used with autograft and/or allograft bone (comprised of cancellous and/or corticocancellous bone graft) or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion and supplemental spinal fixation systems that have been cleared for use in the lumbar spine. Patients should receive at least six (6) months of non-operative treatment prior to treatment with the device.

Contraindications:

Contraindications for the Inspire Trabecular PEEK Lumbar Interbody Fusion System are comparable to those of other systems of similar design, and include, but are not limited to:

- Patients with probable intolerance to the materials used in the manufacture of this device.
- Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
- Patients unwilling or unable to follow post- operative restrictions on movement, especially in athletic and occupational activities.
- Use with components from other systems, or in any case requiring the mixing of metals from different components.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, the amount of mechanical fixation, and/or the quality of the bone graft.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any case not described in the indications for use.
- Reuse or multiple uses.

Cautions, Precautions and Warnings and Possible Adverse Effects:

Cautions:

Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium components must NOT be used together.

Do not use components of the INSPIRE TRABECULAR PEEK Lumbar Interbody Fusion System with components from any other manufacturer.

Care must be taken to protect the components from being marred, nicked or notched as a result of contact with other objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

As with all orthopedic implants, none of the INSPIRE TRABECULAR PEEK Lumbar Interbody Fusion System components should ever be reused under any circumstances.

Precautions:

The implantation of properly selected and placed system implants and components should be performed only by experienced spinal surgeons with specific training in the use of this spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of the consequences. Other poor candidates for spine fusion include obese, malnourished, those with poor muscle and bone quality, and nerve paralysis patients.

Due to the presence of implants, interference with roentgenographic, CT and/or MR imaging may result. The INSPIRE TRABECULAR PEEK Lumbar Interbody Fusion System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the INSPIRE TRABECULAR PEEK Lumbar Interbody Fusion System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Warnings:

The safety and effectiveness of lumbar interbody fusion systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. The safety and effectiveness of these devices for any other conditions are unknown.

This device system is not intended to be the sole means of spinal support. Its use without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand the loads of the body without maturation of a solid fusion mass, and in this case, bending, loosening or fracture of the implant will eventually occur. The proper selection and
compliance of the patient will greatly affect the results.

The implantation of spinal systems should be performed only by spinal surgeons fully experienced in the surgical techniques required for the use of such implants. Even with the use of spinal implants, a successful result in terms of pain, function, or fusion is not always achieved in every surgical case.

The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient. If requested, additional information, including surgical technique manuals, may be obtained through Curiteva customer support representatives.

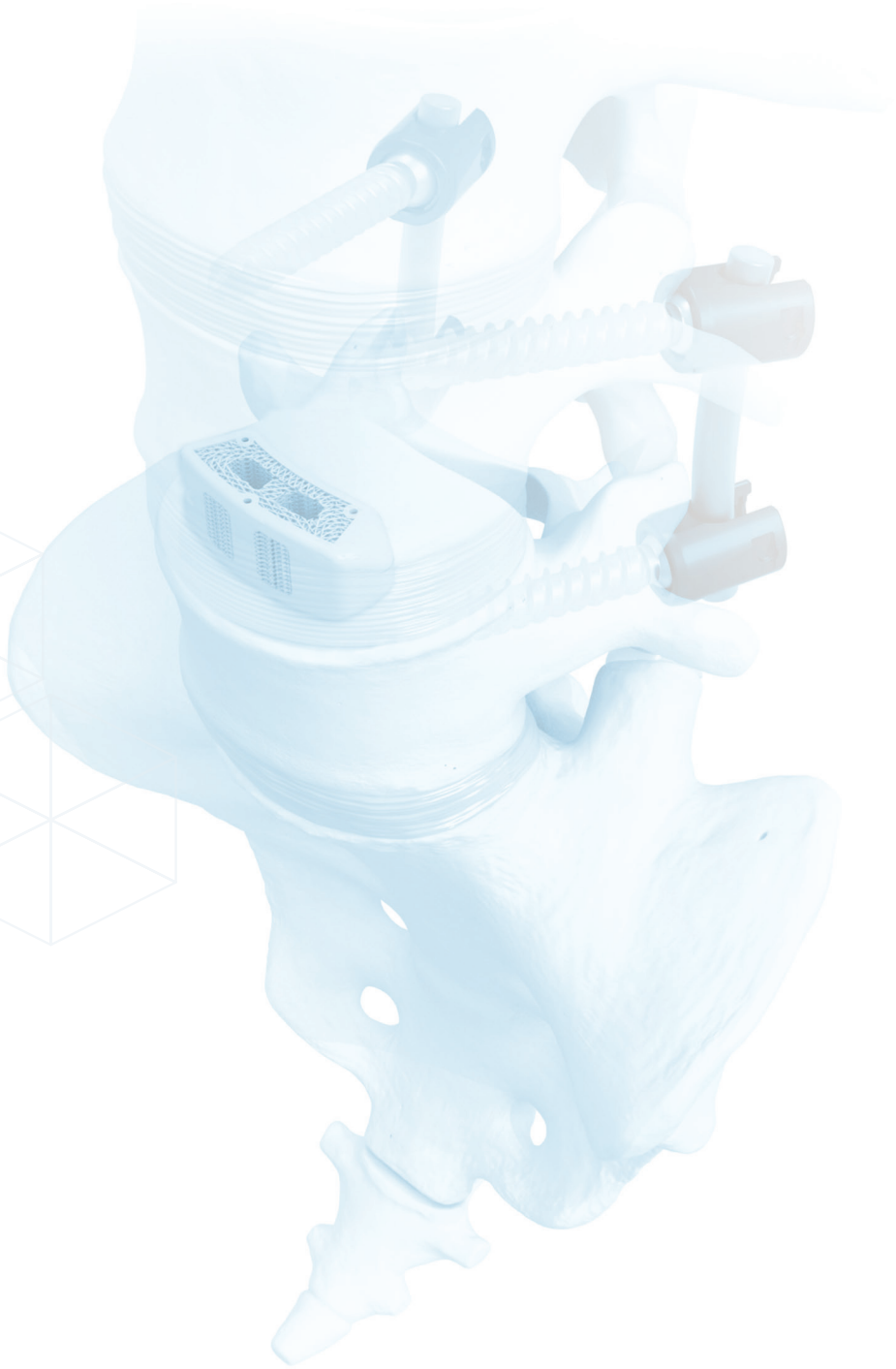
All implants are provided sterile-packed and are intended for single use only. Do not use the implant if the package is opened or damaged or if the expiration date has passed.

Possible Adverse Effects:

Pre-operatively, the patient should be made aware of the following possible adverse effects of spinal implant surgery. Additional surgery may be necessary to correct some of these effects, including but not limited to:

- Early or late loosening of the components
- Disassembly, bending, and/or breakage of any or all of the components
- Foreign body (allergic) reaction to the implants including possible tumor migration
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site which may result in skin breakdown and/or wound complications
- Pressure on the skin from components where there is inadequate tissue coverage
- Loss of proper spinal curvature, correction, height, and/or reduction
- Infection
- Hemorrhage of blood vessels and/or hematomas
- Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone at, above, and/or below the level of surgery
- Non-union (pseudarthrosis), mal-union or delayed union
- Loss of neurological function (e.g., bowel or bladder dysfunction), appearance of radiculopathy, and/or development of pain
- Neurovascular compromise including paralysis or other types of serious injuries
- Gastrointestinal and/or reproductive system compromise, including sterility
- Cessation of growth of the fused portion of the spine
- Death

Notes



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QMSF-1309 Rev 2.0