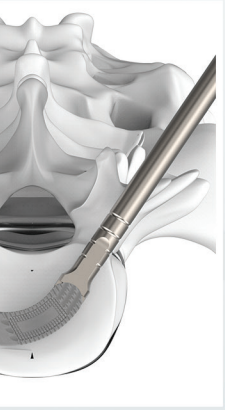
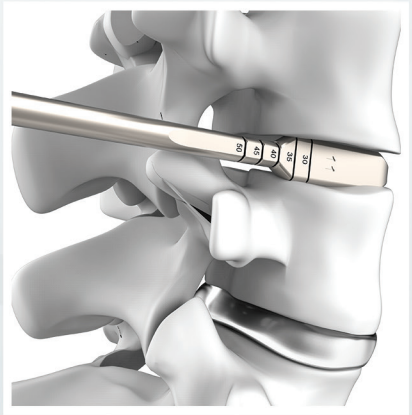
TrellOss™-TC

Porous Ti Interbody System

Surgical Technique Guide





ZimVie

TrellOss-TC (TLIF Curved) interbodies may be used in various posterior approaches to the anterior spine, and is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and with supplemental fixation.

Table Of Contents

ZimVie Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each physician should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training physicians have received.

The following general Surgical Technique Guide is for illustrative purposes only. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as to the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure. Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

Refer to the Instructions for Use (IFU) for a complete list of prescribing information.

Figure 1
Patient positioning

Patient Positioning

- Following adequate general anesthesia, the patient is placed in the prone position on a radiolucent spine table (Figure 1). Particular attention is applied to the positioning of the head and extremities to lessen the risk of ocular and nerve compression.

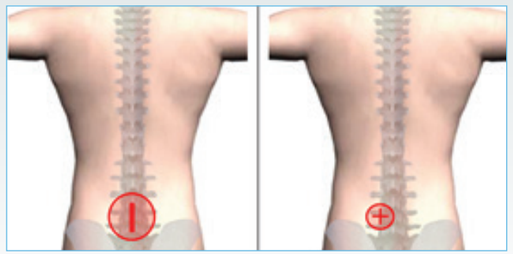


Figure 2
Confirm correct operative level(s)

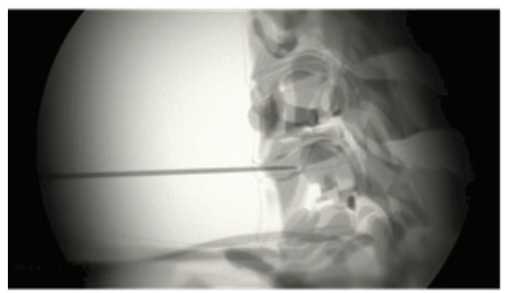
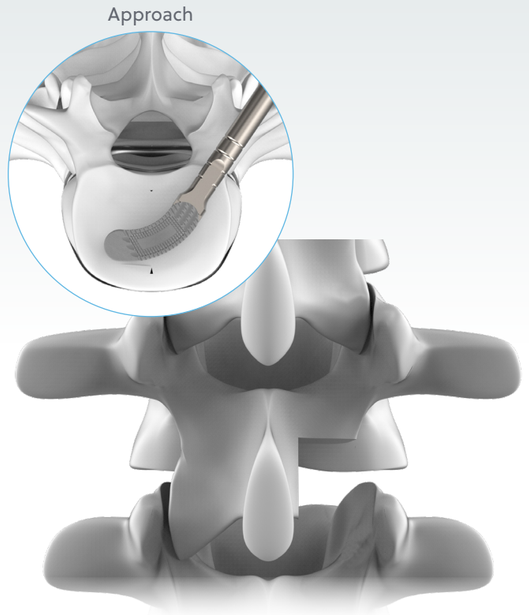


Figure 3
Confirm correct operative level(s)

Exposure Of Operative Level(S)

- Identify the affected level(s) using fluoroscopic imaging and palpation of the targeted anatomy (Figure 2). Access the operative site using preferred instruments. Tissues should be retracted enough to allow for exposure and visualization of the targeted disc space. Insert a marker into the disc(s) to confirm the correct operative level(s) using a lateral radiograph (Figure 3).

  Note: *TrellOss-TC interbodies are indicated for use at up to two contiguous levels in the lumbar spine, from L2-S1.*



TLIF Approach

Figure 4

Decompression

- Utilizing osteotomes and rongeurs, a small section of the lamina and facet(s) should be removed to create an appropriately sized bony window for access to the targeted disc space (Figure 4)

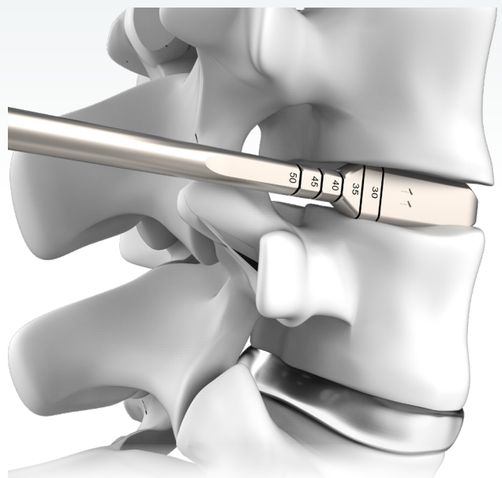
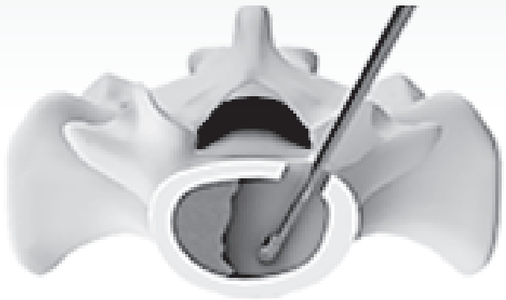


Figure 5

Distraction (optional)

- Effective distraction aids in removal of the superior articular process, decompression of the neuroforamen, preparation of the disc space and insertion of the implant. This may be accomplished through several techniques: pedicle screw distraction, distraction between boney elements, and/or distraction with paddle distractors (Figure 5).



TLIF Approach

Figure 6

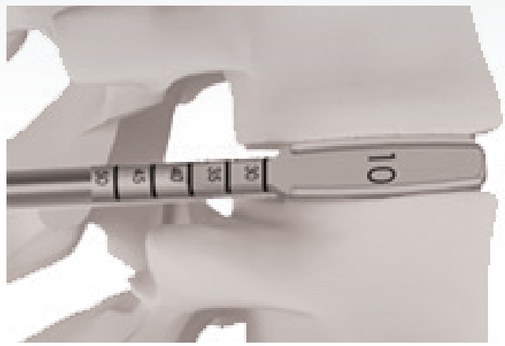


Figure 7

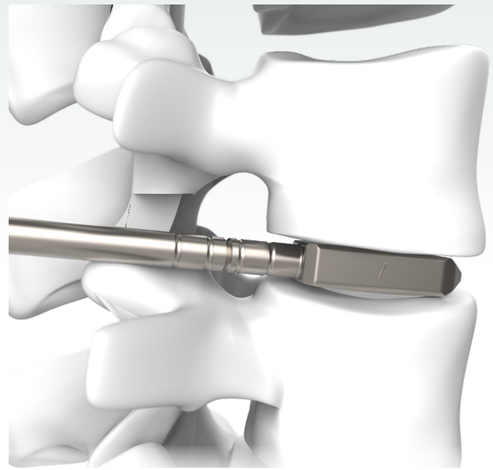


Figure 8

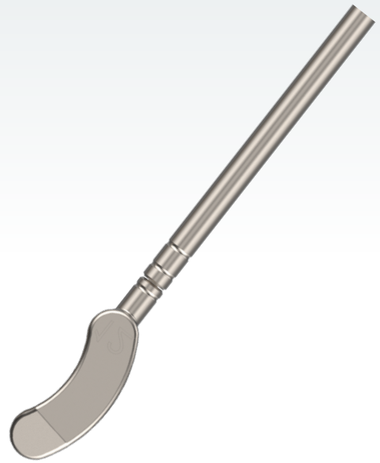


Figure 9

Discectomy And Endplate Preparation

- Access to the disc space is achieved through an annulotomy made lateral to the posterior longitudinal ligament.
- Using a scalpel, vertical cuts should be made parallel to the dura and laterally in the foramen between the superior and inferior endplate. Additional cuts extend horizontally along the endplates, connecting the vertical cuts.
- Perform a complete discectomy using preferred surgical instruments. Pituitaries, cup curettes (Figure 6), rongeurs and interspace shavers (Figure 7) may be used to remove the disc material. The discectomy is complete once superficial layers of the entire cartilaginous endplates are removed and bleeding bone is exposed. If there is significant disc space collapse, a complete discectomy may not be possible until disc space distraction is accomplished.
- Appropriate endplate preparation will optimize surface contact with the selected TrellOss-TC implant.

Warning: *Excessive removal of subchondral bone may weaken the vertebral endplate. If the entire endplate is removed, subsidence and a loss of segmental stability may result.*

Implant Size Selection

- Selection of the trial depends on the height, width, and depth of the intervertebral space. Based on the pre-operative imaging and surgical technique, connect an appropriately sized trial to the quick release T-handle and insert it into the annulotomy window (Figure 8).
- Each trial is labeled to differentiate height and should be used incrementally to determine the appropriate dimensions of the required TrellOss-TC implant (Figure 9).

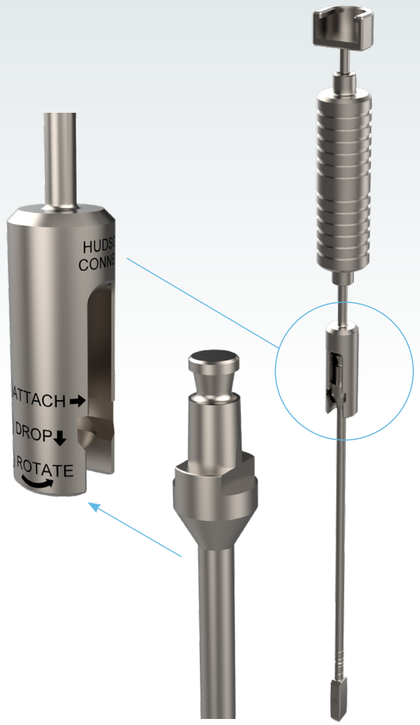


Figure 10

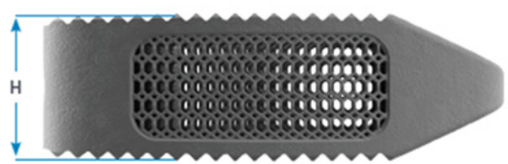


Figure 11

Figure 12

Implant Size Selection (Continued)

- Insert desired trial into the intervertebral disc space using gentle impaction of a mallet. Fluoroscopy can assist in confirming the fit and geometry of the trial. If the trial appears too small or too tight, try the next larger or smaller size until the most secure fit is achieved.
- The slap hammer can be used to facilitate the removal of the trial from the intervertebral disc space. The slap hammer includes laser etched steps (attach, drop and rotate) for attachment of the trial (Figure 10). To use, apply an upward force to the slap hammer. Repeat until trial is removed from the intervertebral disc space.

Notes:

Adequate preparation of the endplates is critical in facilitating vascular supply to promote fusion.

Trial sizes (d x w x h) are a line to line match to the corresponding implant, including implant teeth. There is no need to under-size or over-size the implant.

All implant heights are measured from the tallest point on the implant (Figure 11).

All implants have superior/inferior teeth to help resist implant migration and expulsion while providing a high degree of initial stability.

Implant Preparation And Graft Placement

- Open the sterile packaging of the TrellOss-TC Implant size (height and footprint) that was determined with the trial.
- Prior to insertion, pack the center cavity of the im autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. In addition, autograft or allograft may be placed in the anterior and lateral aspects of the intervertebral disc space.

Figure 13

Figure 14

Implant Insertion

Note: *The TrellOss-TC Porous Ti Interbody System comes complete with two articulating inserters specific to the needs of the individual procedure. A minimally invasive (offset) inserter and straight inserter are provided. Both instruments assemble to the implant and function in the same manner.*

- Place the end of the implant into the circular cup (Figure 12) and thread into the implant by turning the knob on the threaded shaft component clockwise (Figure 13). Confirm the implant is securely attached but DO NOT overtighten.

Articulating Inserter Technique

- Guide the implant into the intervertebral space, verifying placement via fluoroscopic imaging. The angle of insertion can be customized in situ to facilitate final positioning (Figure 14).
- Turn the knob at the proximal end of the inserter counterclockwise until inserter can be angled relative to the implant, typically 1/4 to 1/2 turn. Then move the inserter shaft to the desired angle, turn the knob clockwise until tight, and contiue to insert the implant.
- Repeat the steps until the implant has reached the desired position.
- Verify positioning with A/P and lateral fluoroscopy.
- Remove the inserter by turning the threaded knob at the proximal end of the inserter counterclockwise (Figure 13) until free from the implant (approximately four full revolutions).
- If the Implant requires further adjustment, a tamp may be used to carefully manipulate into desired position.
- Complete the procedure by following the surgical technique for the specific device to be used as supplemental fixation.

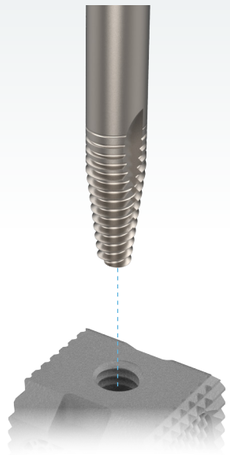


Figure 15

Implant Removal

- Attach either the inserter or universal removal instrument in a clockwise rotation to the implant (Figure 15). Be careful to avoid pushing the implant anteriorly. A slap hammer or slotted mallet may be used in conjunction with the inserter for removal of the implant if desired. To use, apply an upward force to the slap hammer. Repeat until implant is removed from the intervertebral disc space.
- If distraction was utilized during implantation, be sure to re-apply distraction to allow easier removal of the implant. Vertebral bone overgrowth or osteophytes may be removed to facilitate retrieval of the implant.

Notes:

An osteotome can be used at the interface between the Implant and endplates to disengage the construct.

Use of distraction is suggested to allow easier access to the implant/endplate interface.

Implant Sizing

10° Curved Implants

	ANTERIOR HEIGHT	POSTERIOR HEIGHT
8 mm x 10°	8 mm	6 mm
9 mm x 10°	9 mm	7 mm
10 mm x 10°	10 mm	8 mm
11 mm x 10°	11 mm	9 mm
12 mm x 10°	12 mm	10 mm
13 mm x 10°	13 mm	11 mm
14 mm x 10°	14 mm	12 mm
15 mm x 10°	15 mm	13 mm
16 mm x 10°	16 mm	14 mm

Kit Contents

TrellOss-TC Instrument Kit
Kit Number: PCR200M1111

DESCRIPTION	QTY	PART NUMBER
Release Wheel	1	230M0007
Lumbar Removal Tool	1	230M0008
Slap Hammer	1	230M0009
Straight Implant Tamp 90°	1	230M0010
Inline Articulating Inserter Inner Shaft	1	230M0012
Inline Articulating Inserter Outer Shaft	1	230M0013
MIS Articulating Inserter Outer Shaft	1	230M0014
MIS Articulating Inserter Inner Shaft	1	230M0015
TrellOss-TC Implant Tamp	1	230M0016
Hudson T-Handle	2	231M0001
Paddle Shaver 6 mm	1	231M0006
Paddle Shaver 7 mm	1	231M0007
Paddle Shaver 8 mm	1	231M0008
Paddle Shaver 9 mm	1	231M0009
Paddle Shaver 10 mm	1	231M0010
Paddle Shaver 11 mm	1	231M0011
Paddle Shaver 12 mm	1	231M0012
Paddle Shaver 13 mm	1	231M0013
Paddle Shaver 14 mm	1	231M0014
Paddle Shaver 15 mm	1	231M0015
Paddle Shaver 16 mm	1	231M0016
Paddle Distractor 6 mm	1	231M1006
Paddle Distractor 7 mm	1	231M1007
Paddle Distractor 8 mm	1	231M1008
Paddle Distractor 9 mm	1	231M1009
Paddle Distractor 10 mm	1	231M1010
Paddle Distractor 11 mm	1	231M1011
Paddle Distractor 12 mm	1	231M1012
Paddle Distractor 13 mm	1	231M1013
Paddle Distractor 14 mm	1	231M1014
Paddle Distractor 15 mm	1	231M1015
Paddle Distractor 16 mm	1	231M1016

TrellOss-TC 0° Trial Kit
Kit Number: PCR200M2111

DESCRIPTION	QTY	PART NUMBER
Hudson T-Handle	2	231M0001
Curved Trial 0° 28 x 10 x 7 mm	1	235M2807
Curved Trial 0° 28 x 10 x 8 mm	1	235M2808
Curved Trial 0° 28 x 10 x 9 mm	1	235M2809
Curved Trial 0° 28 x 10 x 10 mm	1	235M2810
Curved Trial 0° 28 x 10 x 11 mm	1	235M2811
Curved Trial 0° 28 x 10 x 12 mm	1	235M2812
Curved Trial 0° 28 x 10 x 13 mm	1	235M2813
Curved Trial 0° 28 x 10 x 14 mm	1	235M2814
Curved Trial 0° 28 x 10 x 15 mm	1	235M2815
Curved Trial 0° 28 x 10 x 16 mm	1	235M2816
Curved Trial 0° 32 x 10 x 7 mm	1	235M3207
Curved Trial 0° 32 x 10 x 8 mm	1	235M3208
Curved Trial 0° 32 x 10 x 9 mm	1	235M3209
Curved Trial 0° 32 x 10 x 10 mm	1	235M3210
Curved Trial 0° 32 x 10 x 11 mm	1	235M3211
Curved Trial 0° 32 x 10 x 12 mm	1	235M3212
Curved Trial 0° 32 x 10 x 13 mm	1	235M3213
Curved Trial 0° 32 x 10 x 14 mm	1	235M3214
Curved Trial 0° 32 x 10 x 15 mm	1	235M3215
Curved Trial 0° 32 x 10 x 16 mm	1	235M3216

Note: *There is not a TrellOss-TC 10° Trial Kit. The 0° Trial Kit is intended for use with parallel or lordotic implants.*

Kit Contents *(continued)*

TrellOss-TC 28 mm Implant Kit
Kit Number: PCR200M8101

DESCRIPTION	QTY	PART NUMBER
Curved 28D X 10W X 7H 0°	2	204M2807
Curved 28D X 10W X 8H 0°	2	204M2808
Curved 28D X 10W X 9H 0°	2	204M2809
Curved 28D X 10W X 10H 0°	2	204M2810
Curved 28D X 10W X 11H 0°	1	204M2811
Curved 28D X 10W X 12H 0°	1	204M2812
Curved 28D X 10W X 13H 0°	1	204M2813
Curved 28D X 10W X 14H 0°	1	204M2814
Curved 28D X 10W X 8H 10°	2	206M2808
Curved 28D X 10W X 9H 10°	2	206M2809
Curved 28D X 10W X 10H 10°	2	206M2810
Curved 28D X 10W X 11H 10°	2	206M2811
Curved 28D X 10W X 12H 10°	2	206M2812
Curved 28D X 10W X 13H 10°	1	206M2813
Curved 28D X 10W X 14H 10°	1	206M2814
Curved 32D X 10W X 12H 0°	1	204M3207
Curved 32D X 10W X 12H 0°	1	204M3208
Curved 32D X 10W X 12H 0°	1	204M3209
Curved 32D X 10W X 12H 0°	1	204M3210
Curved 32D X 10W X 12H 0°	1	204M3211
Curved 32D X 10W X 12H 0°	1	204M3212

TrellOss-TC 32 mm Implant Kit
Kit Number: PCR200M0111

DESCRIPTION	QTY	PART NUMBER
Curved 32D X 10W X 8H 10°	2	206M3208
Curved 32D X 10W X 9H 10°	2	206M3209
Curved 32D X 10W X 10H 10°	2	206M3210
Curved 32D X 10W X 11H 10°	2	206M3211
Curved 32D X 10W X 12H 10°	2	206M3212
Curved 32D X 10W X 13H 10°	1	206M3213
Curved 32D X 10W X 14H 10°	1	206M3214

Important Information On The Trelloss Porous Ti Interbody System

Device Description

The TrellOss Porous Ti Interbody System is a collection of additively manufactured spacers for cervical, lumbar/lumbosacral and thoracolumbar implantation. The basic shape of these implants is a structural column to provide surgical stabilization of the spine. Each device comprises an external structural frame having a roughened surface (~7 µm). The intervening geometric lattices have pores 300-700 µm. The inferior/superior aspects of the TrellOss open devices incorporate a large vertical cavity which can be packed with bone graft material. The open and solid devices are available in an assortment of height, length, width and lordotic angulation combinations to accommodate the individual anatomic and clinical circumstances of each patient.

Materials

The TrellOss Porous Ti Interbody System implants are manufactured from Titanium Alloy (Ti6Al4V) as described by ASTM F3001.

Indications for Use

- When used as a cervical intervertebral fusion device, the TrellOss-C Porous Ti Interbody System open devices are indicated for use at up to two contiguous levels in the cervical spine, from C2-T1, in skeletally mature patients who have had six weeks of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and with supplemental fixation.
- When used as a lumbar intervertebral fusion device, the TrellOss-TS and TrellOss-TC Porous Ti Interbody System open devices are indicated for use at one or two contiguous levels in the lumbar spine, from L2-S1, in skeletally mature patients who have had six months of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Additionally, the TrellOss Porous Ti Interbody System lumbar implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The device is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and with supplemental fixation.
- When used as a vertebral body replacement device, the TrellOss Porous Ti Interbody System open and solid devices are indicated for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors or trauma/fracture in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The device is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and with supplemental fixation.

Contraindications

The TrellOss Porous Ti Interbody System contraindications include, but are not limited to:

- The presence of infection, pregnancy, metabolic disorders of calcified tissues, grossly distorted anatomy, inadequate tissue coverage, any demonstrated allergy or foreign body sensitivity to any of the implant materials, drugs/alcohol abuse, mental illness, general neurological conditions, immunosuppressive disorders, obesity, patients who are unwilling to restrict activities or follow medical advice, and any condition where the implants interfere with anatomical structures or precludes the benefit of spinal surgery.
- Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
- Any condition not described in the Indications for Use.
- Prior fusion at the level(s) to be treated.

Warnings and Precautions

- Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct.
- The TrellOss Porous Ti Interbody System devices should be implanted only by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Prior to use, surgeons should be trained in the surgical procedures recommended for use of these devices.
- The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of

Important Information On The Trelloss Porous Ti Interbody System *(continued)*

the implant. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the device.

- The TrellOss solid devices are not intended for interbody fusion as bone growth through the device has not been demonstrated.
- These devices are provided as single use only implants and are not to be reused or reimplanted regardless of an apparent undamaged condition.
- The TrellOss Porous Ti Interbody System is used to augment the development of a spinal fusion by providing temporary stabilization. This device is not intended to be the sole means of spinal support – supplemental internal fixation must be used. If fusion is delayed or does not occur, material fatigue may cause breakage of the implant. Damage to the implant during surgery (i.e., scratches, notches) and loads from weight bearing and activity will affect the implant's longevity.
- The correct handling of the implant is extremely important. Use care in handling and storage of devices. Store the devices in a clean, dry area away from radiation and extreme temperatures and corrosive environments such as moisture, air, etc
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
- Components of this system should not be used with components of any other system or manufacturer.
- Potential risks identified with the use of this system, which may require additional surgery, include: device component breakage, loss of fixation/loosening, non-union, vertebral fracture, neurologic, vascular or visceral injury.

POTENTIAL ADVERSE EFFECTS

Potential complications and adverse effects for this system are similar to those of other spinal instrumentation systems and include but are not limited to: pseudarthrosis, insufficient bone stock, painful bursa, pressure necrosis, palpable components, early or late loosening of the components; disassembly, bending or breakage of any or all of the components; foreign body (allergic) reaction to the implants: possible infections requiring removal of devices; loss of neurological function, including paralysis, spinal cord impingement or damage.

Reference:
Mirkovic SR, Schwartz DG, and Glazier KD. 1995. Anatomic Considerations in Lumbar Posterolateral Percutaneous Procedures. Spine 20 (18): 1965-1971.

For more information, visit ZimVie.com

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