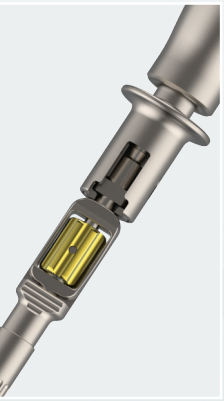
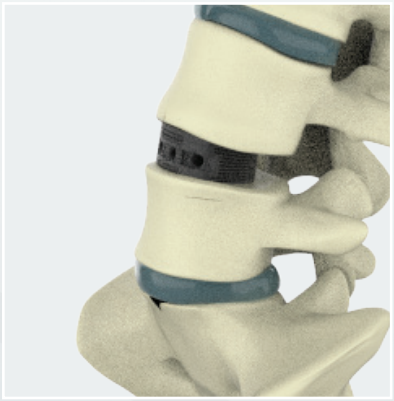
TrellOss®-A

Porous Ti Interbody system

Surgical Technique Manual





ZimVie

TrellOss®-A

Porous Ti Interbody System

TrellOss-A is a 3D printed, Porous Titanium Interbody device with aligned 300 µm, 500 µm, and 700 µm pores with a 7 µm roughened surface; TrellOss-A is designed to help achieve sagittal alignment goals with three lordotic offerings, and allow insertion versatility with three insertion options.

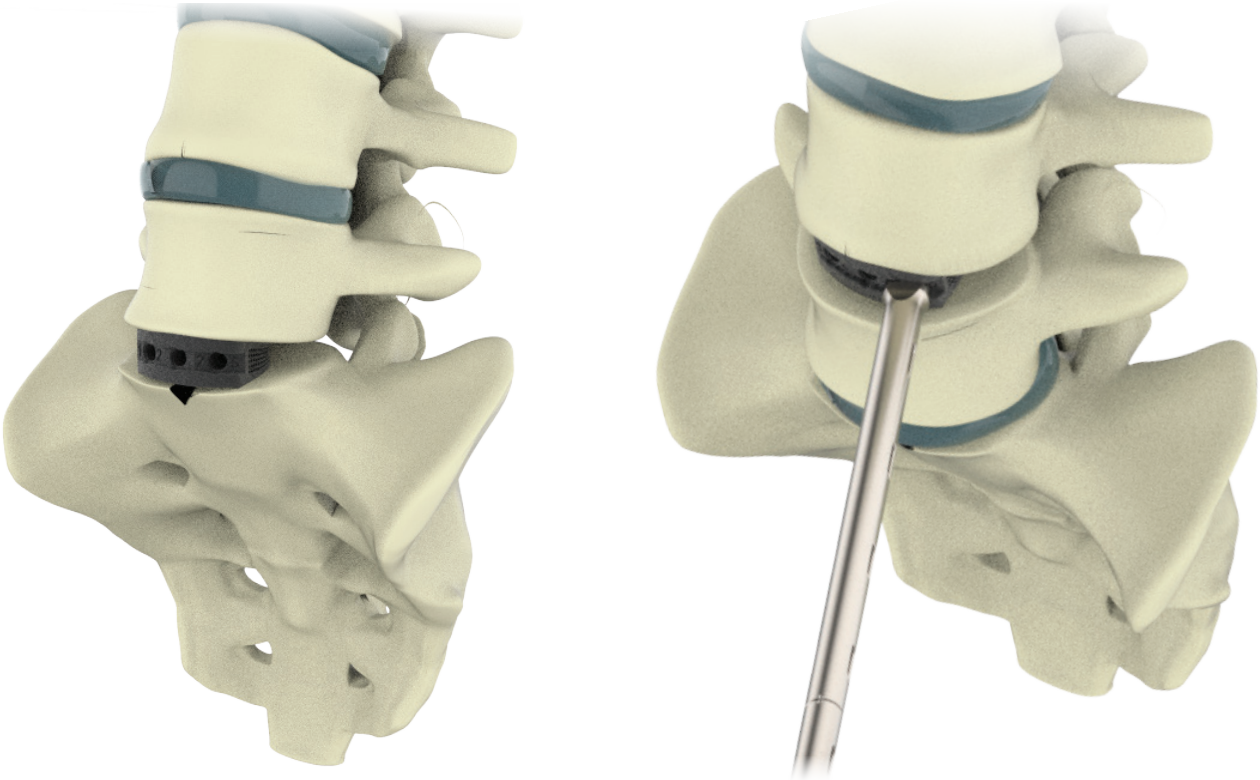
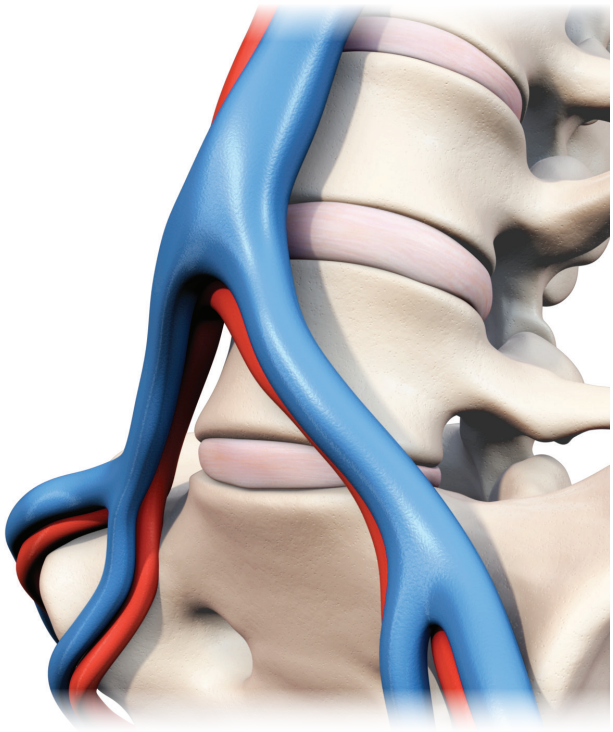


Table of Contents

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 surgeon 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 surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as 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.

Patient Positioning and Oblique Surgical Approach

The TrellOss-A (ALIF) device is designed to offer a roughened titanium surface with an aligned pattern of three pore sizes for optimum fluoroscopy imaging, and three insertion angles to allow versatility when facing challenging anatomy.



Step 1

Approach to the Surgery

- Perform the customary approach for an ALIF as chosen by the surgeon.

Oblique Surgical Approach

- The disc space can be reached through a left sided retroperitoneal approach. Generally, access may be gained by a:
  - Flank incision - Make a horizontal incision, 2-3 inches long, lateral to the midline at the appropriate level; OR
  - Paramedian incision - Start two finger breadths to the left of the umbilicus to 2-3 inches cephalad.

Note: *While cleared for use at L5-S1, the anatomic position of the iliac crest or left femoral artery can make an oblique approach challenging at the L5-S1 level.*

- The vena lumbalis ascendens and/or the intersegmental vessels may be sutured, as necessary, to mobilize the major vessels medially. The exposure may be secured using appropriate retractors.

Confirm Disc Location with Fluoroscopy

- A disc marker may be inserted into the affected disc and a radiographic image taken to confirm the appropriate level.

Discectomy

Figure 1

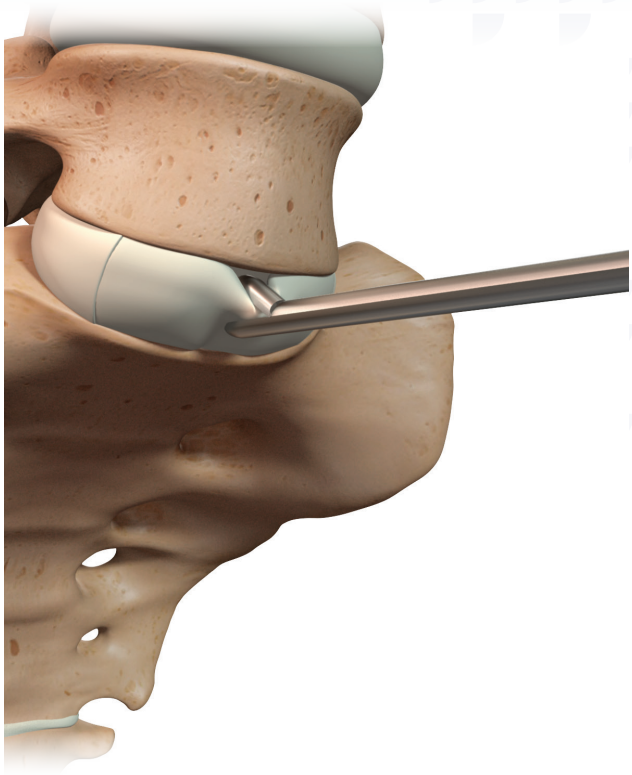


Figure 2

Step 2

- After the patient has been properly positioned for an anterior lumbar interbody fusion and the operative level(s) has been exposed, perform a discectomy. Begin the box discectomy by incising the annulus with a scalpel. The "box" should be centered around the midline and of sufficient width to accommodate the desired implant. Begin by making a transverse incision between the inferior annulus and the vertebra as well as the superior annulus and the vertebra. Then, complete the box incision by making perpendicular incisions at the end of the superior and inferior incisions (Figure 1).
- Pituitary rongeurs and curettes can be used to perform the discectomy (Figure 2). Continue to remove disc material until the posterior longitudinal ligament (PLL) is exposed. If necessary, incise the pll to obtain additional distraction or to facilitate removal of herniated disc material from the spinal canal.

  Caution: *Care should be taken to ensure that all exposed blood vessels are properly retracted prior to discectomy to avoid unintended contact with the curettes and rongeurs.*

Assemble the Inserter to the Trial

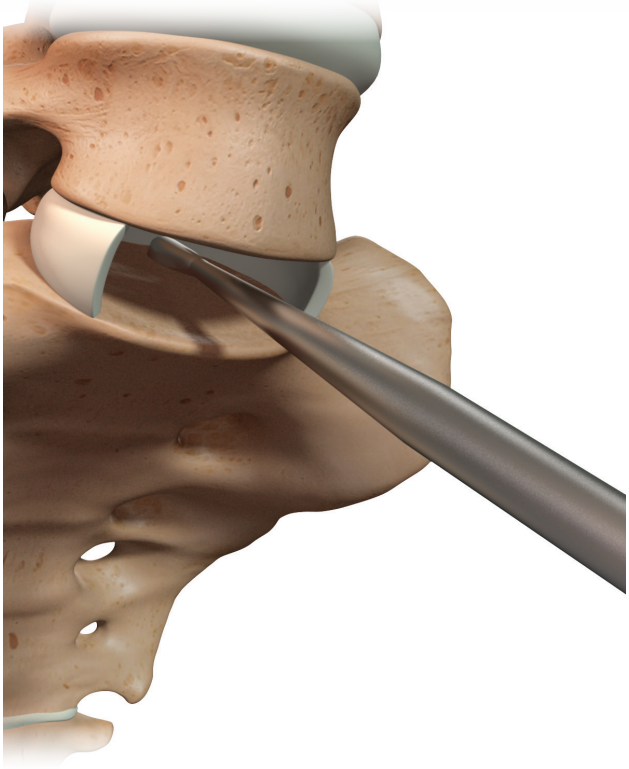


Figure 3

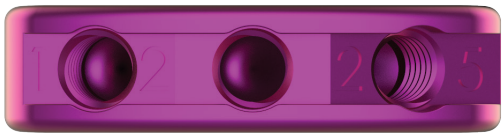


Figure 4a

Figure 4b

Step 3

- Use the surgeons preferred anterior discectomy instruments and distraction method. Use a curette to clean the disc space. Scrape the cartilaginous endplates without perforating the boney endplates. Move the curette from side to side to avoid slipping out of the disc space and causing damage to vessels or intra-abdominal structures. Make certain the endplates are well cleaned and bleeding bone has been exposed laterally, posteriorly and on the anterior lip (Figure 3).

  Note: *Prepare the endplates just enough to create a surface that will encourage vascularization between the endplates and the graft, without weakening the cortical bone.*

Step 4

- When selecting the trial, consider the three sizing parameters: footprint, lordosis, and height. An ideal trial fit provides full endplate coverage and takes into account the disc height and lordosis of healthy adjacent levels to ensure primary stability. The trials have the same dimensions as the implants.
- Start with a small trial height and footprint (Figure 4a). Use progressively increasing heights of the trials until the appropriate height distraction is achieved. Radiographic confirmation will determine the appropriate Trial height, lordosis, and footprint for the anatomical conditions. Select a trial and attach it to the inserter (330H0001): (Figure 4b).

Trial Position

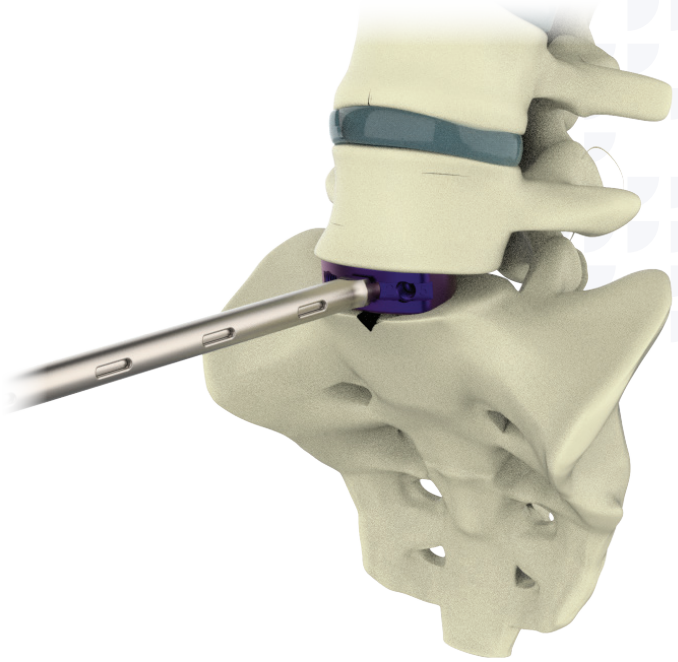


Figure 5a

Step 4 *(continued)*

- Ensure the inserter is in the unlocked position by turning the sleeve below the gold thumb-wheel to the unlock position.
- Position the threads of the inserter over one of the three thread options of the trial based on the desired angulation the surgeon requests. The two distal prongs of the inserter will fit longitudinally in the trial slot along the anterior face. Engage the threads using the gold thumb-wheel until the trial is securely attached to the inserter.
- Turn the lock sleeve to the lock position until audible clicks are heard.

Step 5

- After the trial is locked on the inserter, it may be inserted into the disc space (Figure 5a). Under lateral fluoroscopy confirm the:
  - Trial depth, height, and lordosis.
  - Endplate coverage (anterior-posterior).
  - Trial rotation.

  Under anterior-posterior fluoroscopy confirm the:
  - Midline placement.
  - Endplate coverage (medial-lateral).
  - Trial rotation.
- Continue with trials until correct fit is determined. Increase footprint, lordosis, and height incrementally as necessary until the ideal combination for distraction is determined. There should be no gaps between the prepared site and the trial. Use the largest size possible to ensure maximum stability.

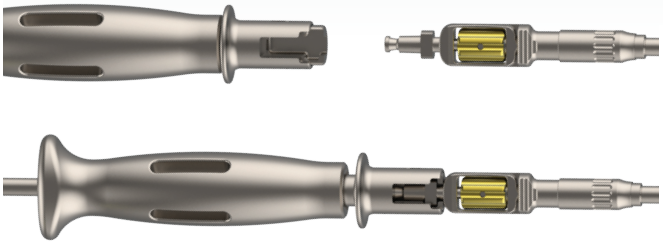


Figure 6a

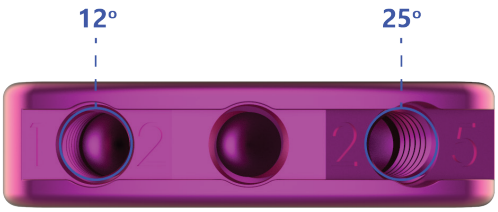


Figure 5b

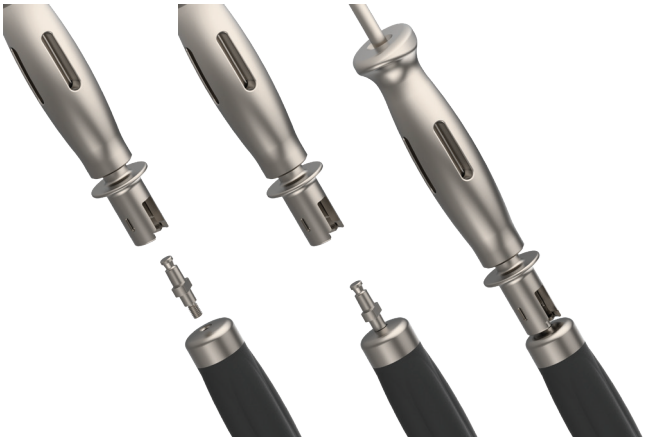


Figure 6b

Step 5 *(continued)*

Oblique Implants

- If anatomy necessitates an oblique implant, each trial can be inserted in a 12° oblique offset and/or 25° oblique offset (Figure 5b).
- The anterior face of the trials are labeled with 12° and 25° to indicated the offset from the trial midline. Use the same assembly technique as described in step 4 to attach the inserter to the oblique insertion points.

Step 6

- Once the proper size has been determined, remove the trial. Use of the slap hammer (330H0004) may be required.
- **Option A.** Remove the inline handle (330H0009) and connect the slap hammer directly to the inserter (Figure 6a).
- **Option B.** Insert a hudson adapter (330H0005) to the inline handle (300H0009), and connect the slap hammer to remove the trial (Figure 6b).

Implant Insertion

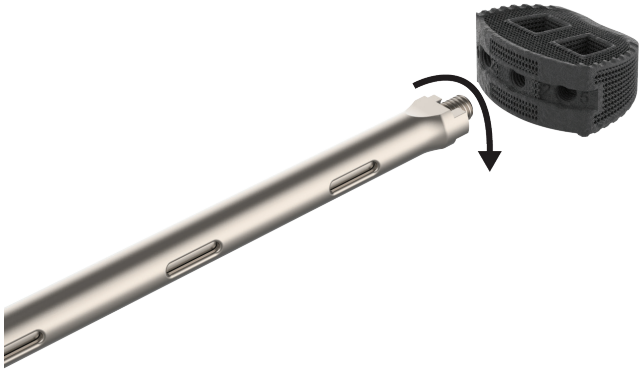


Figure 7a-1

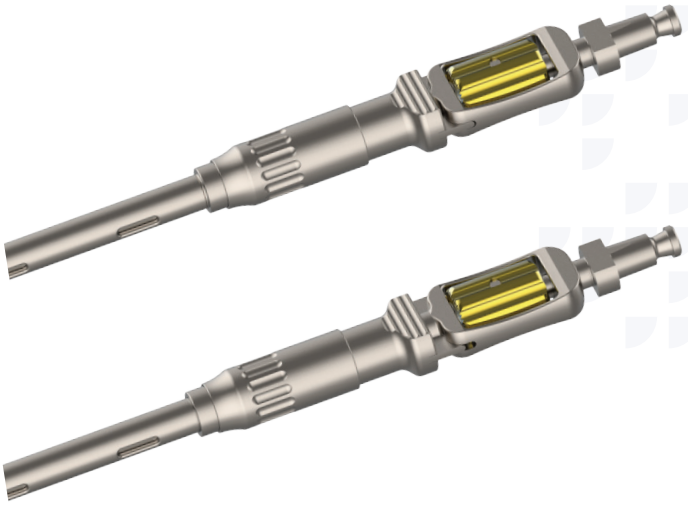


Figure 7a-2

STEP 7a: (Using the Standard Inserter)

- Choose the corresponding implant to the trial that gave the best anatomical fit.
- Open the implant from its sterile packaging. After packing the lumens with autogenous bone graft, place the inserter (330H0001) onto the anterior face of the implant. The central hole accommodates inline insertion.
- Ensure the inserter is in the unlocked position by turning the sleeve below the gold thumb-wheel to the unlock position.
- Position the threads of the inserter over one of the three thread options of the implant based on the desired angulation the surgeon requests. The two distal prongs of the inserter will fit longitudinally in the implant slot along the anterior face. Engage the threads using the gold thumb-wheel until the implant is securely attached to the inserter. (Figure 7a-1).
- Turn the lock sleeve to the lock position until audible clicks are heard.

  Note: *The locking inserter is designed to prevent unwanted loosening and disengagement when passing by the vascular structures.*
- For oblique insertion, attach the inserter to either the 12° oblique offset or the 25° oblique offset threads. Each implant is stamped with a 12 and a 25 to help identify the correct oblique offset.

  Note: *The implant may be flipped and inserted upside down if necessary for oblique insertion.*
- Turn the lock sleeve counterclockwise to unlock (there will be a hard stop). Once fully unlocked, turn the gold thumb-wheel counterclockwise until the inserter is released from the implant (Figure 7a-2).

Alternate Implant Insertion

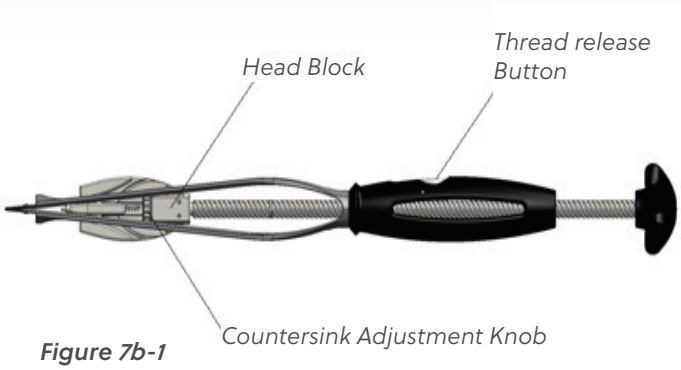
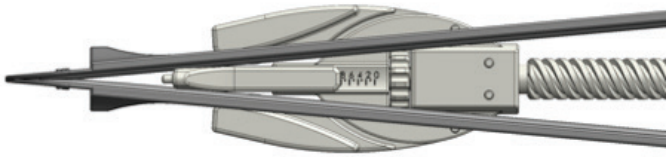


Figure 7b-1



Countersink depth graphics

Figure 7b-2

Figure 7b-3

Figure 7b-4

STEP 7b: (Using the Distractor Inserter)

- Retract the distractor inserter (330H0007) head block by pressing the thread release button on the main handle and pulling back on the T-handle (Figure 7b-1). Set the implant countersink depth by rotating the knob on the head block until the desired depth is showing (depth is adjustable between 0 and 8 mm) (Figure 7b-2).
- Load the desired implant between the blades, making sure that the channels on the implant align with the features on the blades, and advance the head block by pushing forward on the T-handle until the pusher tip engages with the implant (Figure 7b-3).
- Position the Distractor Inserter (330H0007) into the disc space as shown and advance the implant by rotating the T-handle. Once the implant reaches the pre set countersink depth the distractor inserter blades will pull out of the disc space as the T-handle is rotated. Continue to rotate the T-handle until the distractor inserter is fully disengaged from the implant (Figure 7b-4).

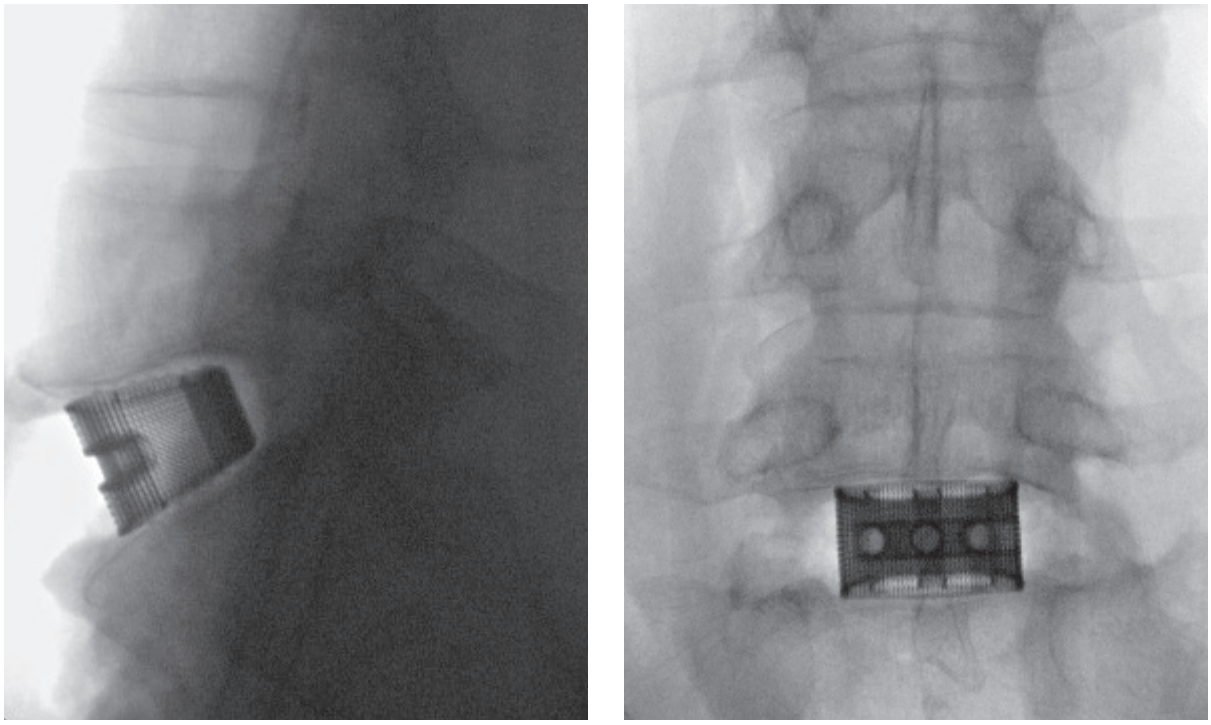


Figure 8

STEP 8

- Radiographically confirm the position and placement of the Implant. Fine tuning of implant position is optional by using the tamp (300H0002) (Figure 8).

Procedure Completion

- Compress vertebral bodies on the implant and secure with supplemental fixation system.

Closure

- Close wound and dress in the usual fashion.

Removal or Revision Procedure

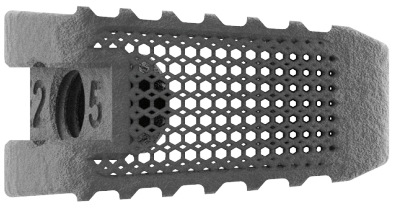
Figure 9a

Figure 9b

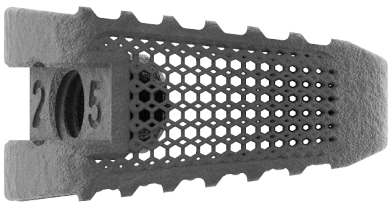
- Attach inserter (300H0001) (Figure 9a) or ALIF implant remover (300H0006) (Figure 9b) instrument to the implant.
- Attach slap hammer (300H0004) to instrument or use mallet to tap instrument until implant is removed from disc space.
- Attach the inserter (300H0001) to the threads of the implant. Refer to step 6 for slap hammer options.
- Alternatively use the implant remover (300H0006) to engage the threads of the implant. Attach the hudson adapter and slap hammer or carefully use a mallet to tap the instrument until the implant is removed from the disc space.

TrellOss-A Implants

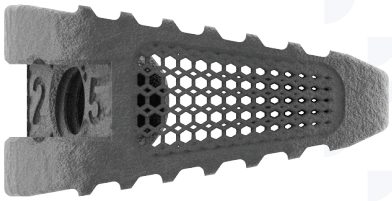
Lordosis Options



8 degrees

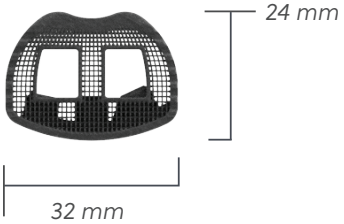


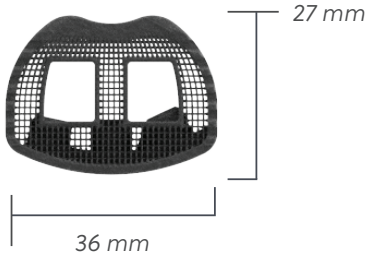
14 degrees



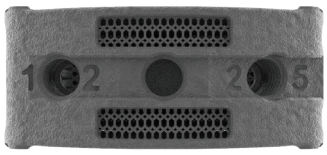
20 degrees

Footprint Options





Insertion Options



Instrument Kit

TrellOss-A Instruments Kit
Kit Number: PCR300H2000

- Small Footprint 8°
- Small Footprint 14°
- Small Footprint 20°
- Medium Footprint 8°
- Medium Footprint 14°
- Medium Footprint 20°

Small Footprint 8°	
Trial 24D x 32W x 8H 8°	332H0808
Trial 24D x 32W x 10H 8°	332H0810
Trial 24D x 32W x 12H 8°	332H0812
Trial 24D x 32W x 14H 8°	332H0814
Trial 24D x 32W x 16H 8°	332H0816
Trial 24D x 32W x 18H 8°	332H0818

Medium Footprint 8°	
Trial 27D x 36W x 8H 8 °	336H0808
Trial 27D x 36W x 10H 8 °	336H0810
Trial 27D x 36W x 12H 8°	336H0812
Trial 27D x 36W x 14H 8°	336H0814
Trial 27D x 36W x16H 8°	336H0816
Trial 27D x 36W x 18H 8°	336H0818

Small Footprint 14°	
Trial 24D x 32W x 10H 14°	332H1410
Trial 24D x 32W x12H 14°	332H1412
Trial 24D x 32W x 14H 14°	332H1414
Trial 24D x 32W x 16H 14°	332H1416
Trial 24D x 32W x 18H 14°	332H1418
Trial 24D x 32W x 20H 14°	332H1420

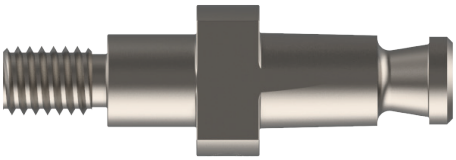
Medium Footprint 14°	
Trial 27D x 36W x 10H 14°	336H1410
Trial 27D x 36W x 12H 14°	336H1412
Trial 27D x 36W x 14H 14°	336H1414
Trial 27D x 36W x 16H 14°	336H1416
Trial 27D x 36W x 18H 14°	336H1418
Trial 27D x 36W x 20H 14°	336H1420

Small Footprint 20°	
Trial 24D x 32W x 12H 20°	332H2012
Trial 24D x 32W x 14H 20°	332H2014
Trial 24D x 32W x 16H 20°	332H2016
Trial 24D x 32W x 18H 20°	332H2018
Trial 24D x 32W x 20H 20°	332H2020

Medium Footprint 20°	
Trial 27D x 36W x 12H 20°	336H2012
Trial 27D x 36W x 14H 20°	336H2014
Trial 27D x 36W x 16H 20°	336H2016
Trial 27D x 36W x 18H 20°	336H2018
Trial 27D x 36W x 20H 20°	336H2020

ALIF Inserter	PART NUMBER
	330H0001

Note: *The inserter can be used for both the implants and trials.*



Slap Hammer Adapter	PART NUMBER
	330H0005

ALIF Distractor Inserter	PART NUMBER
	330H0007

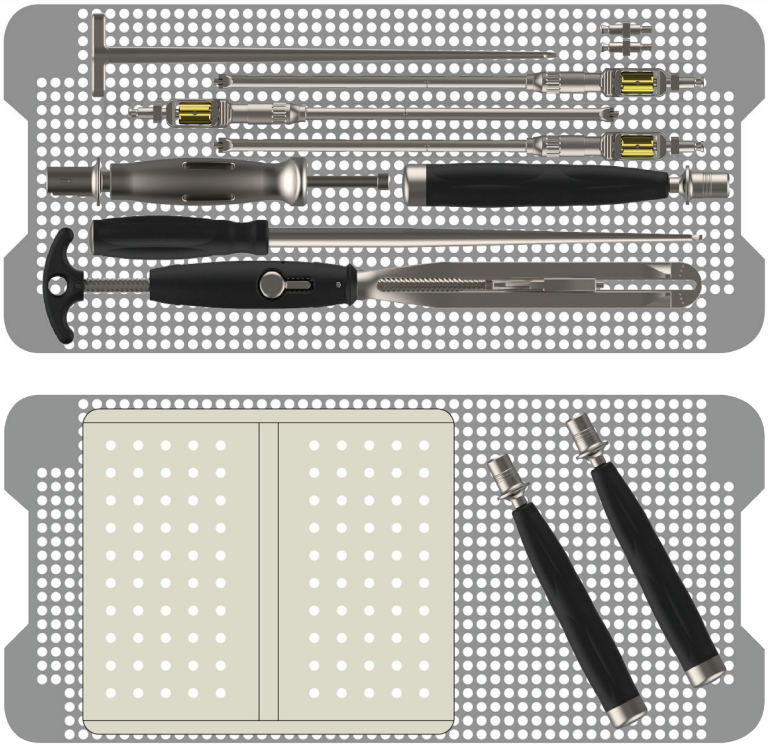
Slap Hammer	PART NUMBER
	330H0004

ALIF Implant Remover	PART NUMBER
	330H0006

Tamp	PART NUMBER
	330H0002

Inline Handle Hudson Connection	PART NUMBER
	330H0009

Kit Contents



TrellOss-A instrument Kit
Kit Number: PCR300H2000

Description	Qty	Part Number
ALIF Inserter	3	330H0001
Tamp	1	330H0002
Slap Hammer	1	330H0004
Slap Hammer Adaptor	2	330H0005
ALIF Implant Remover	1	330H0006
ALIF Distractor Inserter	1	330H0007
Inline Handle Hudson Connection	3	330H0009
Trial 24D x 32W x 8H, 8°	1	332H0808
Trial 24D x 32W x 10H, 8°	1	332H0810
Trial 24D x 32W x 12H, 8°	1	332H0812
Trial 24D x 32W x 14H, 8°	1	332H0814
Trial 24D x 32W x 16H, 8°	1	332H0816
Trial 24D x 32W x 18H, 8°	1	332H0818
Trial 24D x 32W x 10H, 14°	1	332H1410
Trial 24D x 32W x 12H, 14°	1	332H1412
Trial 24D x 32W x 14H, 14°	1	332H1414
Trial 24D x 32W x 16H, 14°	1	332H1416
Trial 24D x 32W x 18H, 14°	1	332H1418
Trial 24D x 32W x 20H, 14°	1	332H1420
Trial 24D x 32W x 12H, 20°	1	332H2012
Trial 24D x 32W x 14H, 20°	1	332H2014

Description	Qty	Part Number
Trial 24D x 32W x 16H, 20°	1	332H2016
Trial 24D x 32W x 18H, 20°	1	332H2018
Trial 24D x 32W x 20H, 20°	1	332H2020
Trial 27D x 36W x 8H, 8°	1	336H0808
Trial 27D x 36W x 10H, 8°	1	336H0810
Trial 27D x 36W x 12H, 8°	1	336H0812
Trial 27D x 36W x 14H, 8°	1	336H0814
Trial 27D x 36W x 16H, 8°	1	336H0816
Trial 27D x 36W x 18H, 8°	1	336H0818
Trial 27D x 36W x 10H, 14°	1	336H1410
Trial 27D x 36W x 12H, 14°	1	336H1412
Trial 27D x 36W x 14H, 14°	1	336H1414
Trial 27D x 36W x 16H, 14°	1	336H1416
Trial 27D x 36W x 18H, 14°	1	336H1418
Trial 27D x 36W x 20H, 14°	1	336H1420
Trial 27D x 36W x 12H, 20°	1	336H2012
Trial 27D x 36W x 14H, 20°	1	336H2014
Trial 27D x 36W x 16H, 20°	1	336H2016
Trial 27D x 36W x 18H, 20°	1	336H2018
Trial 27D x 36W x 20H, 20°	1	336H2020

TrellOss-A Implant Kit
Kit Number: PCR300H1000

Part Number	Description	Qty	Anterior Height [mm]	Posterior Height [mm]	Graft Volume [cc's]
SMALL FOOTPRINT					
32 mm width, 8° Lordosis					
308H3208	24D x 32W x 8H, 8°	2	8.2	5.6	0.7
308H3210	24D x 32W x 10H, 8°	2	10.1	7.6	1.0
308H3212	24D x 32W x 12H, 8°	2	12.1	9.6	1.3
308H3214	24D x 32W x 14H, 8°	2	14.1	11.6	1.5
308H3216	24D x 32W x 16H, 8°	1	16.1	13.6	1.8
308H3218	24D x 32W x 18H, 8°	1	18.1	15.6	2.1
32 mm width, 14° Lordosis					
314H3210	24D x 32W x 10H, 14°	2	9.9	5.6	0.9
314H3212	24D x 32W x 12H, 14°	2	12.1	7.8	1.2
314H3214	24D x 32W x 14H, 14°	2	14.1	9.8	1.4
314H3216	24D x 32W x 16H, 14°	1	16.1	11.8	1.7
314H3218	24D x 32W x 18H, 14°	1	18.1	13.8	2.0
314H3220	24D x 32W x 20H, 14°	1	20.1	15.8	2.2
32 mm width, 20° Lordosis					
320H3212	24D x 32W x 12H, 20°	1	11.9	5.8	1.0
320H3214	24D x 32W x 14H, 20°	1	14.1	8.0	1.3
320H3216	24D x 32W x 16H, 20°	1	16.1	10.0	1.6
320H3218	24D x 32W x 18H, 20°	1	18.1	12.0	1.8
320H3220	24D x 32W x 20H, 20°	1	20.1	14.0	2.1

Part Number	Description	Qty	Anterior Height [mm]	Posterior Height [mm]	Graft Volume [cc's]
MEDIUM FOOTPRINT					
36 mm width, 8° Lordosis					
308H3608	27D x 36W x 8H, 8°	2	8.4	5.6	0.9
308H3610	27D x 36W x 10H, 8°	2	10.1	7.2	1.1
308H3612	27D x 36W x 12H, 8°	2	12.1	9.2	1.3
308H3614	27D x 36W x 14H, 8°	2	14.1	11.2	1.6
308H3616	27D x 36W x 16H, 8°	1	16.1	13.2	1.9
308H3618	27D x 36W x 18H, 8°	1	18.1	15.2	2.2
36 mm width, 14° Lordosis					
314H3610	27D x 36W x 10H, 14°	2	10.4	5.6	1.0
314H3612	27D x 36W x 12H, 14°	2	12.1	7.1	1.3
314H3614	27D x 36W x 14H, 14°	2	14.1	9.1	1.5
314H3616	27D x 36W x 16H, 14°	1	16.1	11.1	1.8
314H3618	27D x 36W x 18H, 14°	1	18.1	13.1	2.0
314H3620	27D x 36W x 20H, 14°	1	20.1	15.1	2.3
36 mm width, 20° Lordosis					
320H3612	27D x 36W x 12H, 20°	1	12.4	5.6	1.2
320H3614	27D x 36W x 14H, 20°	1	14.2	7.0	1.4
320H3616	27D x 36W x 16H, 20°	1	16.1	9.0	1.6
320H3618	27D x 36W x 18H, 20°	1	18.1	11.0	1.9
320H3620	27D x 36W x 20H, 20°	1	20.1	13.0	2.2

Important Information on the TrellOss-A 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 (~7µm). The intervening geometric lattices have pores 300-700µm. 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.

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, TrellOss-TC and TrellOss-A 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 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, morbid 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 Precaution

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 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 re-implanted 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.

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