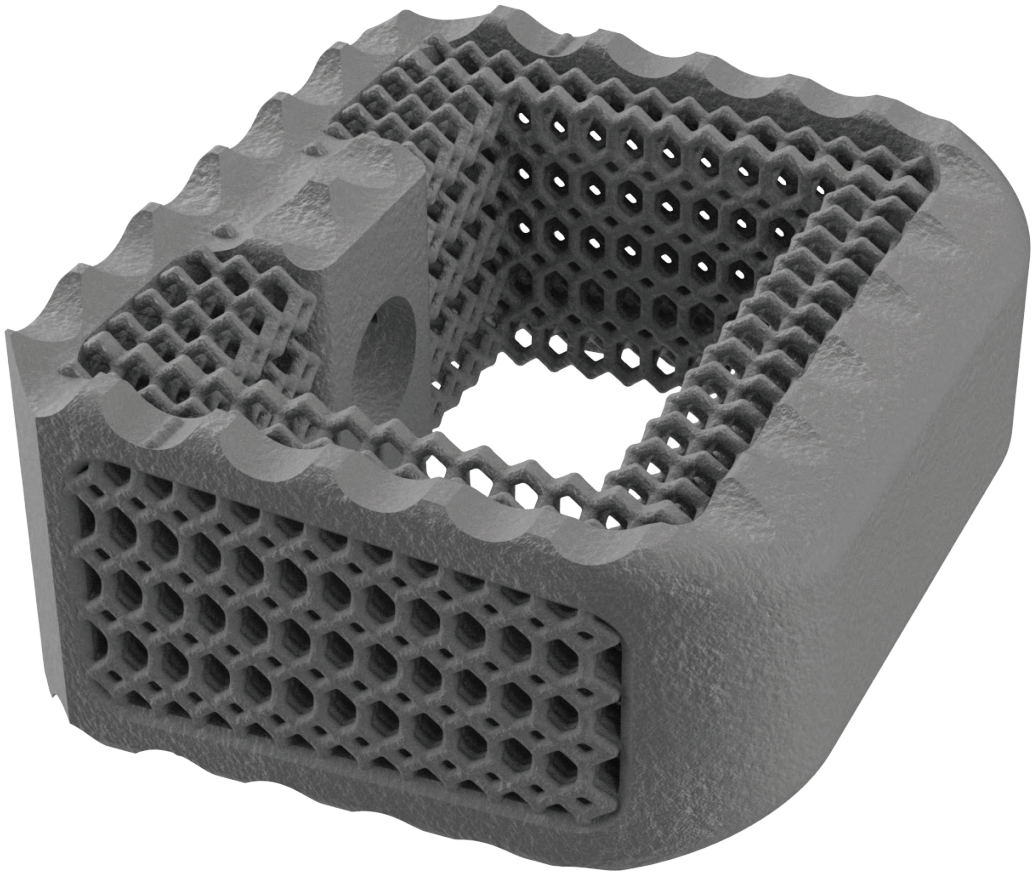
TrellOss™-C
Porous Ti Interbody System

Surgical Technique Guide

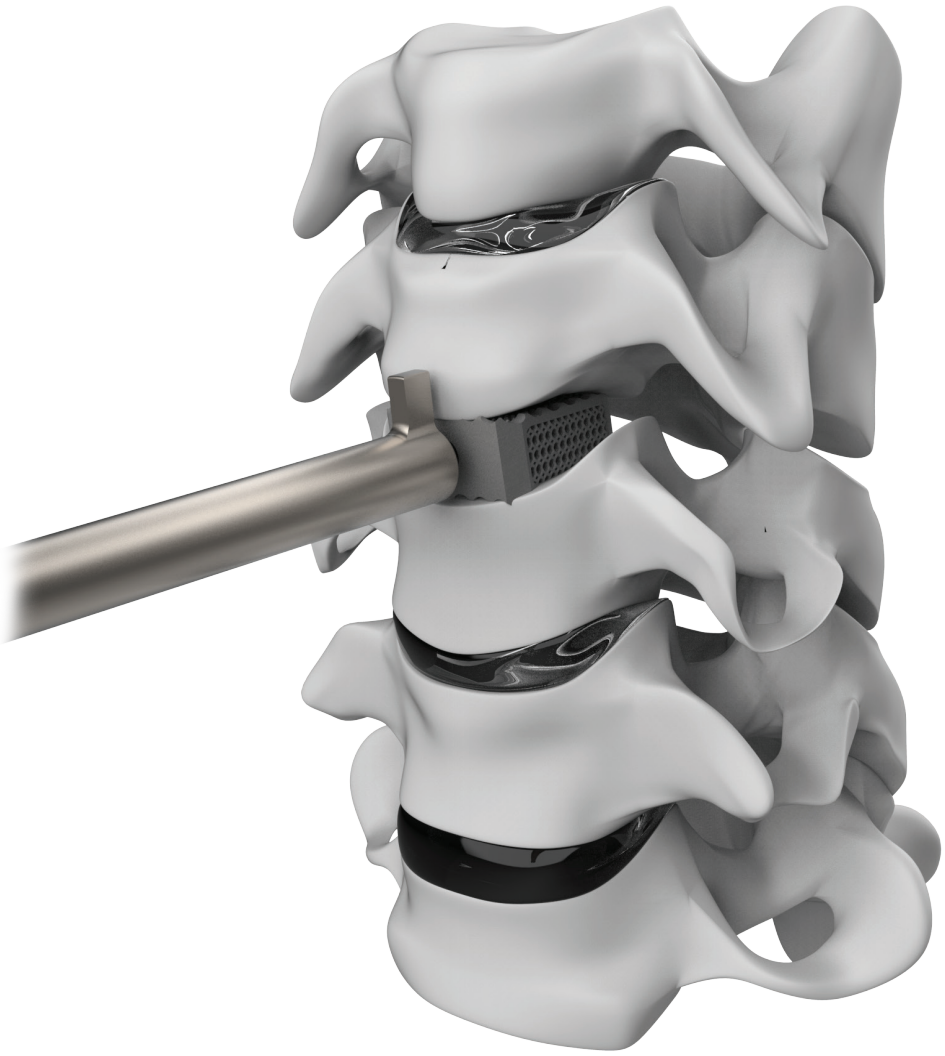


ZimVie

TrellOss-C

Porous Ti Interbody System

TrellOss-C is an additively manufactured spacer
for implantation in up to two levels in the cervical spine.



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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.

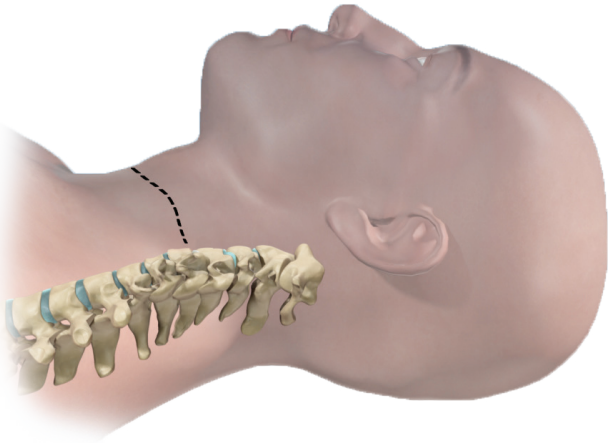

Figure 1
Patient positioning

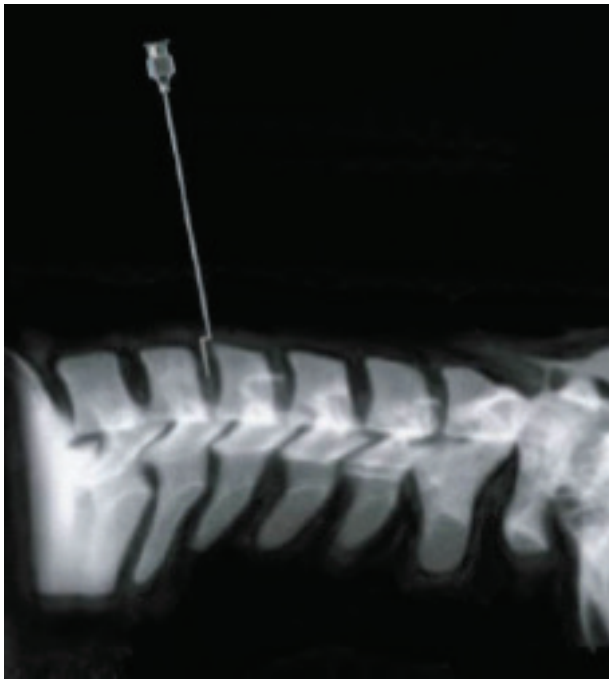

Figure 2
Lateral radiograph

Patient Positioning

- Following adequate general anesthesia, the patient is placed in the supine position with the head in slight extension (Figure 1). The mandible is tilted out of the surgical field. The posterior cervical spine is supported to establish and maintain normal lordosis.

Exposure of Operative Level(s)

- Access the operative site and retract the tissues using preferred instruments. Retract the muscles, trachea, esophagus and carotid artery to clearly see the vertebral bodies and discs (Figure 3).
- Insert a marker into the disc(s) and confirm the correct operative level(s) using a lateral radiograph (Figure 2).

  Note: *TrellOss-C Cervical Interbodies are indicated for use at up to two contiguous levels in the cervical spine from C2-T1.*

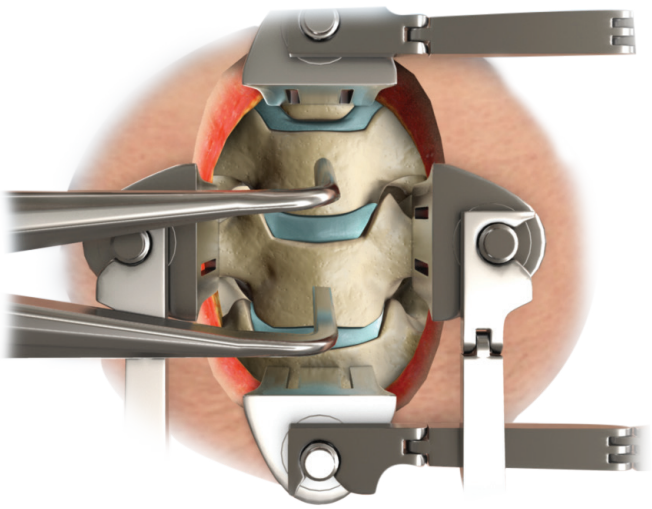

Figure 3
Retraction/distraction of operative level

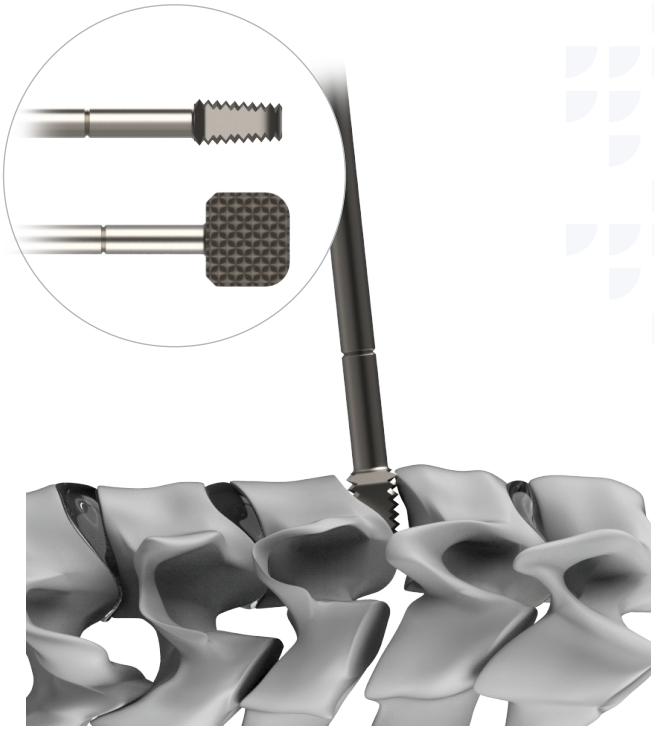

Figure 4
Endplate preparation

Discectomy

- Perform a complete discectomy using preferred surgical instruments. Pituitaries, curettes, and rongeurs may be used to remove the disc material and cartilage to expose the posterior longitudinal ligament and endplates. A high-speed burr may be used for removal of posterior osteophytes to achieve neural decompression. The posterior longitudinal ligament may be removed to access and remove any disc material that may be pressing on the neural elements.

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

  Warning: *Excessive removal of subchondral bone during endplate preparation may weaken the bone, resulting in subsidence and/or segmental instability.*

Endplate Preparation

- Rasps can be used sequentially, in 1 mm increments, to remove the superficial layer on the endplates (Figure 4). This will aid in creating bleeding bone to promote spinal fusion. Appropriate endplate preparation will optimize surface contact with the selected interbody.

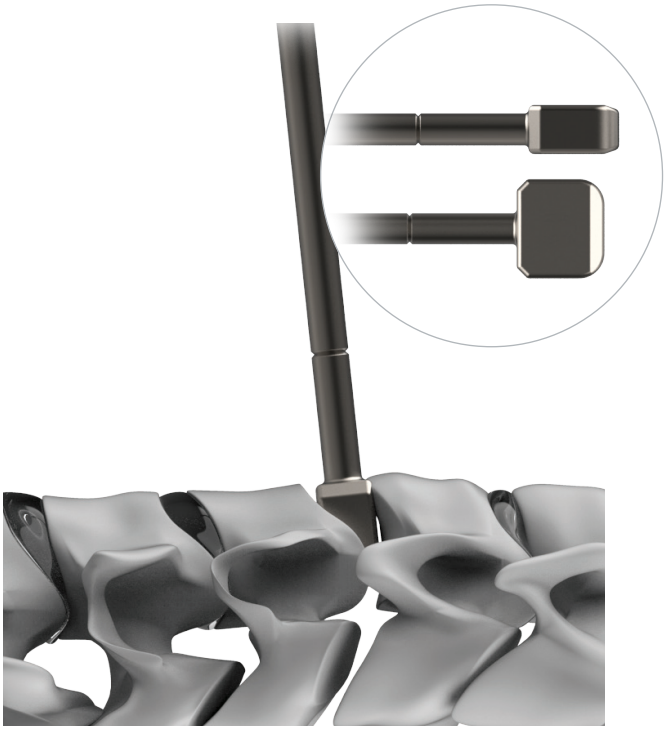

Figure 5
Trial selection

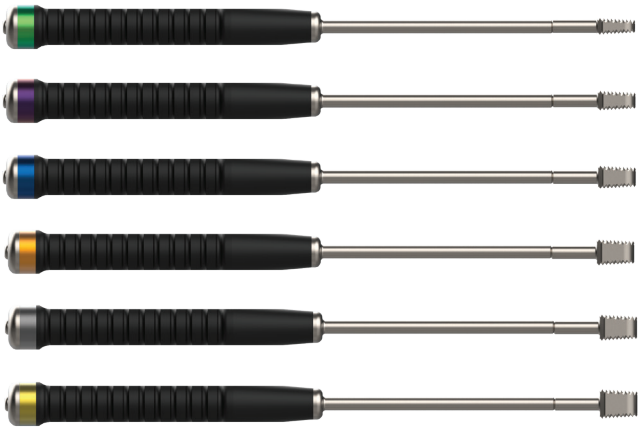

Figure 6
Trials are color coded to differentiate height

Implant Size Selection

- Selection of the trial depends on the height, width, and depth of the intervertebral space. Based on preoperative imaging and surgical technique, select a trial of appropriate height (Figure 5).
- Each trial is color coded to differentiate height and should be used incrementally to determine the appropriate dimensions of the interbody required (Figure 6).

Notes:

- Rasp and trial sizes (w x d x h) are a line-to-line match to the corresponding interbody.
- Standard angulation (Lordosis) of rasps, trials and corresponding interbodies is 6°. 0° versions are also available.
- All labeled heights are measured from the area representing the highest point on the anterior wall of the implant.

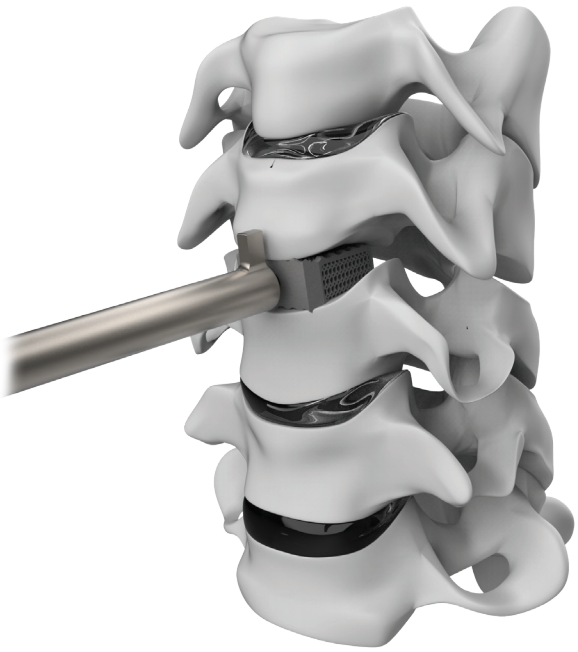

Figure 7
Implant insertion

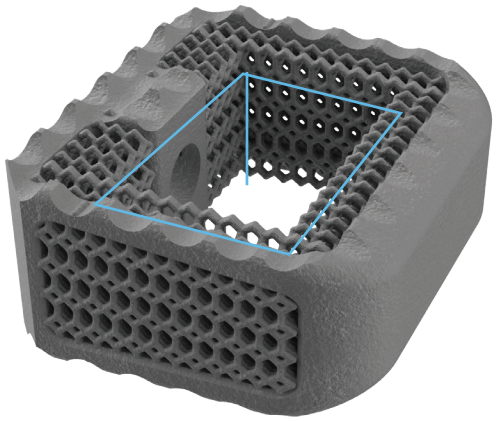

Figure 8

Implant Preparation and Insertion

- Open the sterile packaging of the interbody (height and footprint) that was determined with the trial. There is no need to undersize or oversize the Implant.
- Attach the Interbody to the Inserter by aligning the male/female thread components while rotating the instrument handle clockwise. Confirm the Implant is securely attached but DO NOT overtighten.
- If desired, a modular sleeve with a 2 mm safety stop can be attached to the shaft of the Inserter prior to loading the implant. The safety stop will contact the anterior edge of the vertebral body when the Interbody is inserted 2 mm beyond the anterior edge of the vertebral body (Figure 7).
- Adjust the position of the safety stop on the modular Inserter sleeve if utilized. Safety stop should be positioned in the cephalad orientation.
- Pack the center cavity of the implant with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft (Figure 8).
- Gently insert the implant into the intervertebral disc space. It is important to ensure the implant is seated in the midline of the disc space and slightly recessed (approximately 2 mm).

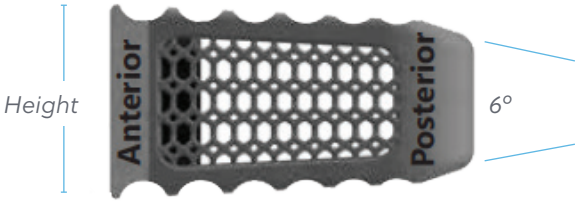

Figure 9
Standard implant

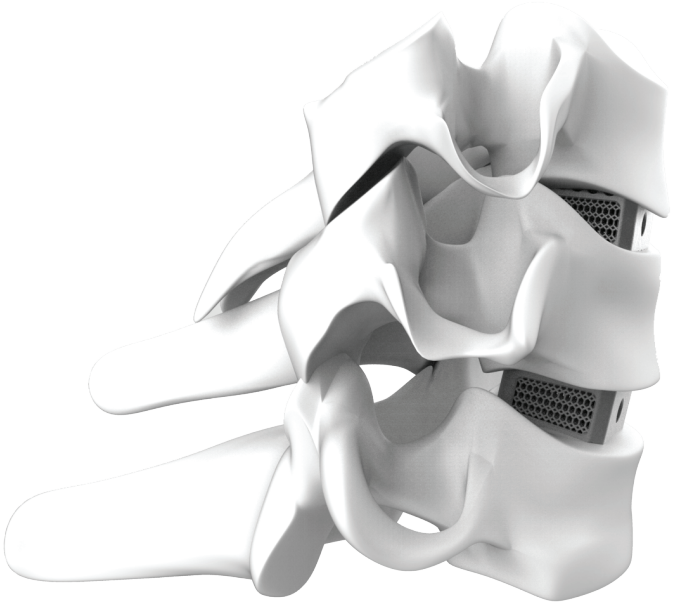

Figure 10
Final implant positioning

Implant Preparation and Insertion *(continued)*

- If necessary, controlled and light tamping with a mallet can be used to help advance the implant to the desired position within the intervertebral disc space.

  Notes:

  - *Use caution when tightening the Implant to the Inserter to avoid stripping threads or overtightening where detachment of implant from instrument becomes difficult.*
  - *Standard implants have a 6° angle of lordosis. 0° versions are also available.*
  - *Implant heights are measured from the area representing the highest point on the anterior wall of the implant (Figure 9).*

- The use of fluoroscopy is recommended during any or all of the implantation steps to ensure proper positioning (Figure 10).
- Rotate the inserter handle in a counterclockwise direction to release the implant from the Inserter.
- If the implant requires further adjustment, use the cervial tamp to carefully manipulate the implant into desired position.
- Complete the procedure by following the surgical technique for the specific device to be used as supplemental fixation, such as the MaxAn® Anterior Cervical Plate System.

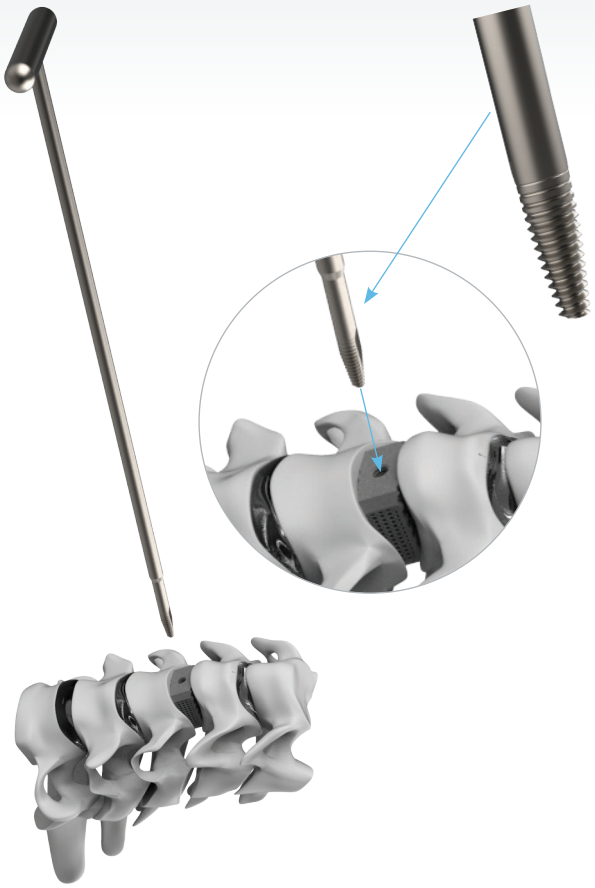

Figure 11
Implant removal

Implant Removal

- Either the Inserter or Universal Removal Instrument may be used for Implant removal by attachment via clockwise rotation to the implant threads (Figure 11). Be careful to avoid pushing the implant posteriorly. Once the implant is firmly attached, remove the implant from the disc space.
- Vertebral bone overgrowth or osteophytes may be removed to facilitate implant retrieval.

Kit Contents

Cervical 0° Implant Kit
Kit Number: PCR100N1101

DESCRIPTION, D x W x H	QTY	PART NUMBER
Cervical Implant Soft Case	1	100N1100
Cervical, 12 mm x 14 mm x 5 mm, 0°	3	106N1205
Cervical, 12 mm x 14 mm x 6 mm, 0°	3	106N1206
Cervical, 12 mm x 14 mm x 7 mm, 0°	3	106N1207
Cervical, 12 mm x 14 mm x 8 mm, 0°	3	106N1208
Cervical, 12 mm x 14 mm x 9 mm, 0°	2	106N1209
Cervical, 12 mm x 14 mm x 10 mm, 0°	2	106N1210
Cervical, 14 mm x 16 mm x 5 mm, 0°	3	106N1405
Cervical, 14 mm x 16 mm x 6 mm, 0°	3	106N1406
Cervical, 14 mm x 16 mm x 7 mm, 0°	3	106N1407
Cervical, 14 mm x 16 mm x 8 mm, 0°	3	106N1408
Cervical, 14 mm x 16 mm x 9 mm, 0°	2	106N1409
Cervical, 14 mm x 16 mm x 10 mm, 0°	2	106N1410

Cervical 6° Implant Kit
Kit Number: PCR100N2101

DESCRIPTION, D x W x H	QTY	PART NUMBER
Cervical Implant Soft Case	1	100N2100
Cervical, 12 mm x 14 mm x 5 mm, 6°	3	107N1205
Cervical, 12 mm x 14 mm x 6 mm, 6°	3	107N1206
Cervical, 12 mm x 14 mm x 7 mm, 6°	3	107N1207
Cervical, 12 mm x 14 mm x 8 mm, 6°	3	107N1208
Cervical, 12 mm x 14 mm x 9 mm, 6°	2	107N1209
Cervical, 12 mm x 14 mm x 10 mm, 6°	2	107N1210
Cervical, 14 mm x 16 mm x 5 mm, 6°	3	107N1405
Cervical, 14 mm x 16 mm x 6 mm, 6°	3	107N1406
Cervical, 14 mm x 16 mm x 7 mm, 6°	3	107N1407
Cervical, 14 mm x 16 mm x 8 mm, 6°	3	107N1408
Cervical, 14 mm x 16 mm x 9 mm, 6°	2	107N1409
Cervical, 14 mm x 16 mm x 10 mm, 6°	2	107N1410

Cervical 0° Instrument Kit
Kit Number: PCR100N3101

DESCRIPTION, D x W x H	QTY	PART NUMBER
Cervical Inserter Outer Shaft	2	130N3001
Cervical Tamp	1	130N3003
Universal Remover	1	130N3004
Cervical Trial 0°, 12 x 14 x 5 mm	1	132N1205
Cervical Trial 0°, 12 x 14 x 6 mm	1	132N1206
Cervical Trial 0°, 12 x 14 x 7 mm	1	132N1207
Cervical Trial 0°, 12 x 14 x 8 mm	1	132N1208
Cervical Trial 0°, 12 x 14 x 9 mm	1	132N1209
Cervical Trial 0°, 12 x 14 x 10 mm	1	132N1210
Cervical Trial 0°, 12 x 14 x 11 mm	1	132N1211
Cervical Trial 0°, 12 x 14 x 12 mm	1	132N1212
Cervical Rasp 0°, 12 x 14 x 5 mm	1	131N1205
Cervical Rasp 0°, 12 x 14 x 6 mm	1	131N1206
Cervical Rasp 0°, 12 x 14 x 7 mm	1	131N1207
Cervical Rasp 0°, 12 x 14 x 8 mm	1	131N1208
Cervical Rasp 0°, 12 x 14 x 9 mm	1	131N1209
Cervical Rasp 0°, 12 x 14 x 10 mm	1	131N1210
Cervical Rasp 0°, 12 x 14 x 11 mm	1	131N1211
Cervical Rasp 0°, 12 x 14 x 12 mm	1	131N1212
Cervical Trial 0°, 14 x 16 x 5 mm	1	132N1405
Cervical Trial 0°, 14 x 16 x 6 mm	1	132N1406
Cervical Trial 0°, 14 x 16 x 7 mm	1	132N1407
Cervical Trial 0°, 14 x 16 x 8 mm	1	132N1408
Cervical Trial 0°, 14 x 16 x 9 mm	1	132N1409
Cervical Trial 0°, 14 x 16 x 10 mm	1	132N1410
Cervical Trial 0°, 14 x 16 x 11 mm	1	132N1411
Cervical Trial 0°, 14 x 16 x 12 mm	1	132N1412
Cervical Rasp 0°, 14 x 16 x 5 mm	1	131N1405
Cervical Rasp 0°, 14 x 16 x 6 mm	1	131N1406
Cervical Rasp 0°, 14 x 16 x 7 mm	1	131N1407
Cervical Rasp 0°, 14 x 16 x 8 mm	1	131N1408
Cervical Rasp 0°, 14 x 16 x 9 mm	1	131N1409
Cervical Rasp 0°, 14 x 16 x 10 mm	1	131N1410
Cervical Rasp 0°, 14 x 16 x 11 mm	1	131N1411
Cervical Rasp 0°, 14 x 16 x 12 mm	1	131N1412

Cervical 6° Instrument Kit
Kit Number: PCR100N4101

DESCRIPTION, D x W x H	QTY	PART NUMBER
Cervical Inserter Outer Shaft	2	130N3001
Cervical Tamp	1	130N3003
Universal Remover	1	130N3004
Cervical Trial 6°, 12 x 14 x 5 mm	1	134N1205
Cervical Trial 6°, 12 x 14 x 6 mm	1	134N1206
Cervical Trial 6°, 12 x 14 x 7 mm	1	134N1207
Cervical Trial 6°, 12 x 14 x 8 mm	1	134N1208
Cervical Trial 6°, 12 x 14 x 9 mm	1	134N1209
Cervical Trial 6°, 12 x 14 x 10 mm	1	134N1210
Cervical Trial 6°, 12 x 14 x 11 mm	1	134N1211
Cervical Trial 6°, 12 x 14 x 12 mm	1	134N1212
Cervical Rasp 6°, 12 x 14 x 5 mm	1	133N1205
Cervical Rasp 6°, 12 x 14 x 6 mm	1	133N1206
Cervical Rasp 6°, 12 x 14 x 7 mm	1	133N1207
Cervical Rasp 6°, 12 x 14 x 8 mm	1	133N1208
Cervical Rasp 6°, 12 x 14 x 9 mm	1	133N1209
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Cervical Rasp 6°, 12 x 14 x 11 mm	1	133N1211
Cervical Rasp 6°, 12 x 14 x 12 mm	1	133N1212
Cervical Trial 6°, 14 x 16 x 5 mm	1	134N1405
Cervical Trial 6°, 14 x 16 x 6 mm	1	134N1406
Cervical Trial 6°, 14 x 16 x 7 mm	1	134N1407
Cervical Trial 6°, 14 x 16 x 8 mm	1	134N1408
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Cervical Rasp 6°, 14 x 16 x 5 mm	1	133N1405
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Cervical Rasp 6°, 14 x 16 x 7 mm	1	133N1407
Cervical Rasp 6°, 14 x 16 x 8 mm	1	133N1408
Cervical Rasp 6°, 14 x 16 x 9 mm	1	133N1409
Cervical Rasp 6°, 14 x 16 x 10 mm	1	133N1410
Cervical Rasp 6°, 14 x 16 x 11 mm	1	133N1411
Cervical Rasp 6°, 14 x 16 x 12 mm	1	133N1412

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 (~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.

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 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 and with supplemental internal 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 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; infections possible requiring removal of devices; loss of neurological function, including paralysis, spinal cord impingement or damage.

For more information visit ZimVie.com

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