ZIMMER BIOMET

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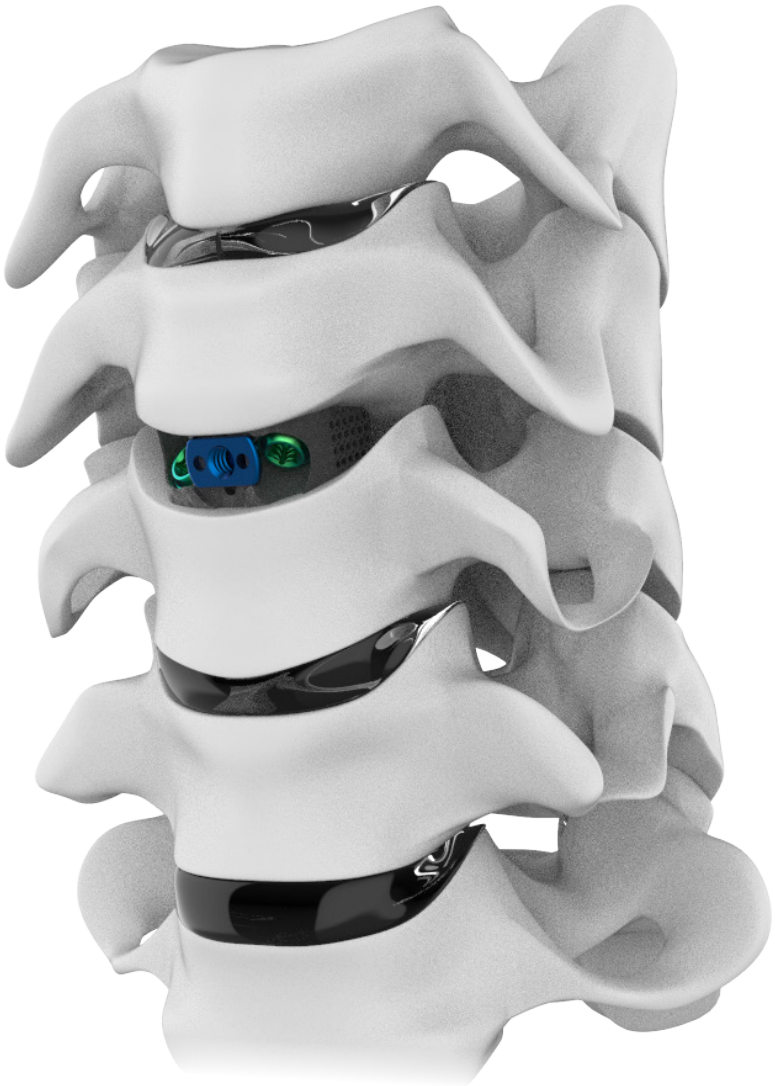
Cervical Solutions

Trell ss™ - C SA

Porous Ti Interbody System

Surgical Technique Guide



The TrellOss-C SA Porous Ti Interbody System is a stand-alone anterior cervical interbody fusion system intended for use at one or two contiguous levels.

TABLE OF CONTENTS

Zimmer Biomet Spine does not practice medicine. 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. Only those individuals with specialized training and experience in spinal surgery should attempt to use the TrellOss Porous Ti Interbody System. Detailed preoperative clinical and diagnostic evaluation followed by carefully executed surgical technique is essential.

Refer to the Instructions for Use (IFU) for a complete list of prescribing information. This technique guide was developed in conjunction with health care professionals.

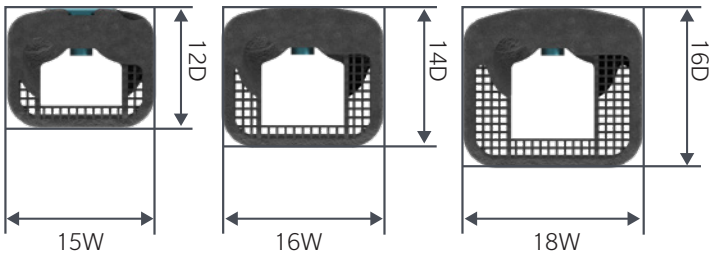
TRELLOSS-C SA POROUS TI INTERBODY SYSTEM OVERVIEW

TrellOss-C SA Porous Ti Interbody System possesses combined functionality and benefits of a cervical interbody and an anterior cervical plate. The implant is contained within the region of the excised disc space and is designed to not protrude past the mid-line edge of the vertebral bodies, reducing the amount of soft tissue damage or irritation. TrellOss-C SA implants are sterile packaged and comprised of various heights and footprints to accommodate individual patient anatomy.

Interbody

- 3D printed porous titanium alloy (Ti-6Al-4V ELI per ASTM F3001) material, integrated with TrellOss technology.
- Roughened surface provides initial stabilization.
- Integrated one-step turn lock (Ti-6Al-4V ELI per ASTM F136).
- Built-in 6° lordotic angle to accommodate anatomy of cervical spine.

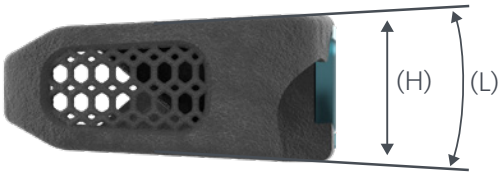
Footprint



Lordosis (L) + Height (H) Options

(L): 6°

(H): 5, 6, 7, 8, 9, 10, 11, and 12 mm



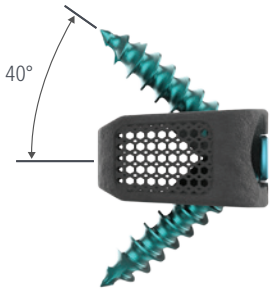
Implants in heights 5-6 mm utilize a Z-shape locking cover.

Implants in heights 7-12 mm utilize a rectangular locking cover.

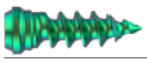
Screws

- Titanium alloy (Ti-6Al-4V ELI per ASTM F136) screws provide fixation to the adjacent superior and inferior vertebral bodies.
- Screws are designed as self- tapping and variable angle.
- Screw lengths are measured from the anterior to posterior of the footprint.
- Self-retaining T10 hexalobe feature.
- Cephalad/Caudal angulation: 40°.
- Medial/Lateral angulation: 12.5°.

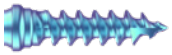
Cephalad / Caudal Angulation



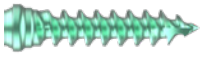
Screws are color-coded by length and diameter



109N3512 Ø3.5 x 12 mm Screw



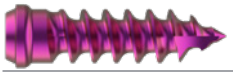
109N3514 Ø3.5 x 14 mm Screw



109N3516 Ø3.5 x 16 mm Screw

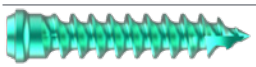
109N3518* Ø3.5 x 18 mm Screw

109N4012 Ø4.0 x 12 mm Screw



109N4014 Ø4 .0 x 14 mm Screw

109N4016 Ø4.0 x 16 mm Screw



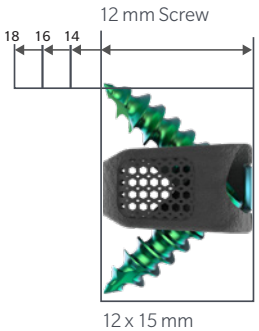
109N4018* Ø4.0 x 18 mm Screw

**By Request Only*

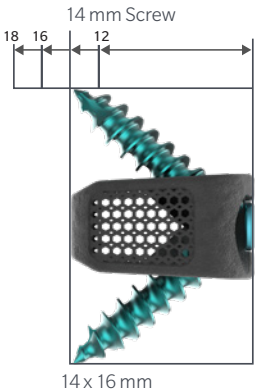
Medial Angulation

Constructs are designed to match screw depth with interbody depth. If utilizing a different screw length or diameter, proceed at surgeon's discretion.

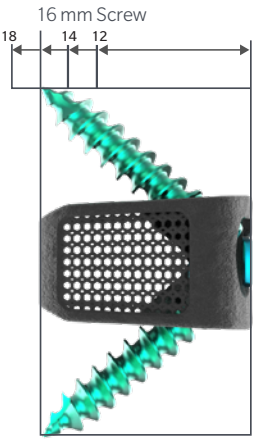
- *12 mm for the 12 x 15 mm footprint*
- *14 mm for the 14 x 16 mm footprint*
- *16 mm for the 16 x 18 mm footprint*



12 x 15 mm



14 x 16 mm



16 x 18 mm

Note: *The standard screw lengths above are recommended as each terminate with the posterior edge of their respective implant.*

SURGICAL APPROACH

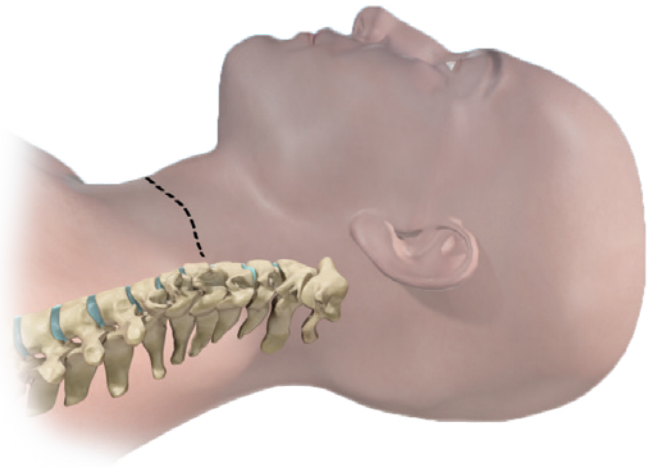


Figure 1

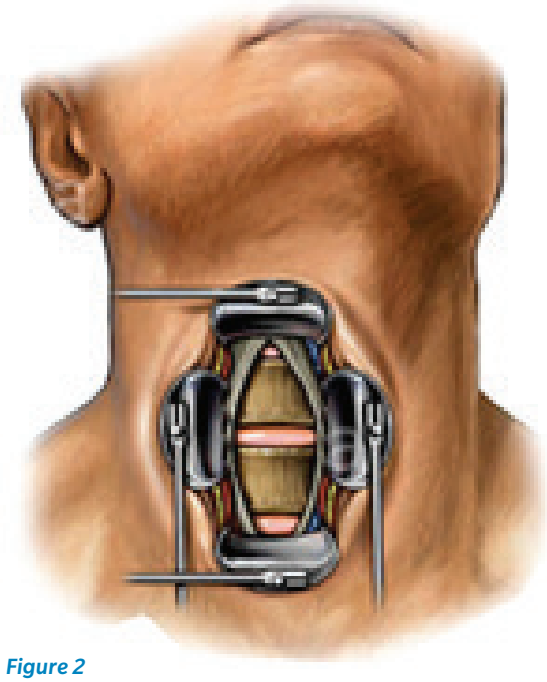


Figure 2

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 2). Insert a marker into the disc and confirm the correct operative level using a lateral radiograph.

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

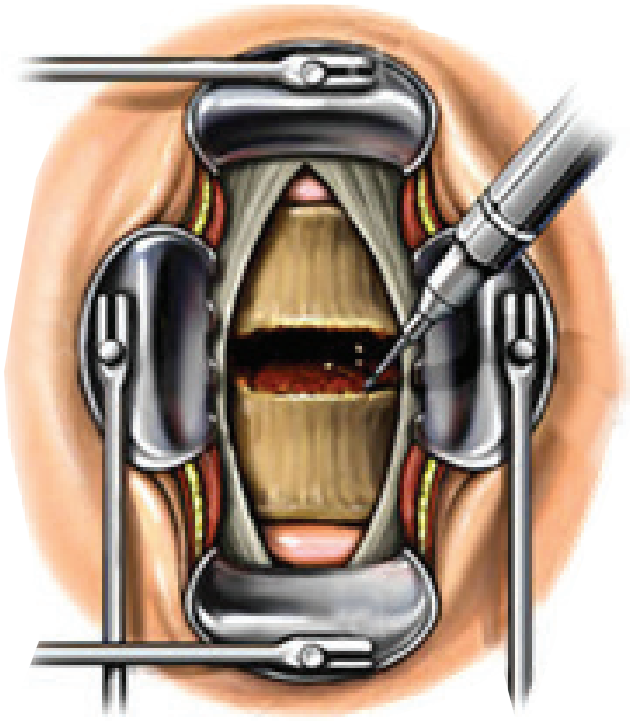


Figure 3

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 (Figure 3). 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.*

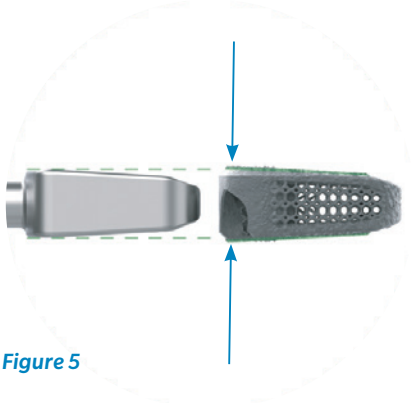


Figure 5

Figure 4

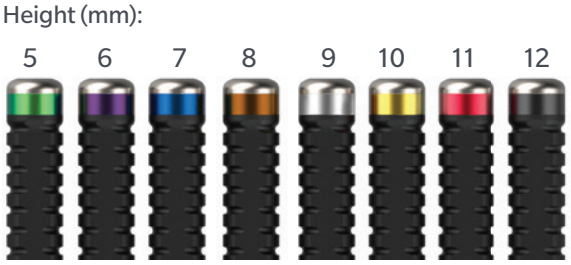


Figure 6

ENDPLATE PREPARATION

A 12 x 14 x 5 mm universal cervical rasp is included standard in the surgical set 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. Additional rasp sizes are available upon request.

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

TRIALING

Selection of interbody height and footprint is dependent on the trial spacer. A mallet may be used to aid in insertion of the trials. Trials should be used incrementally to determine the appropriate dimensions of the interbody to be implanted.

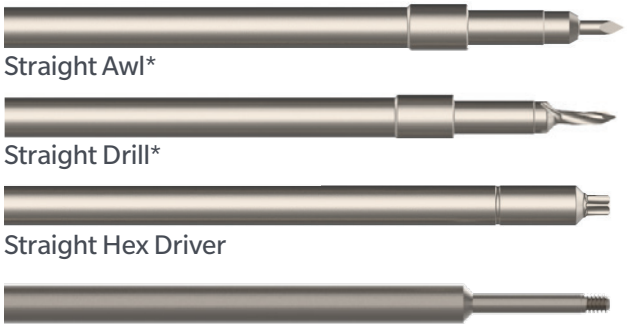
Notes:

- *All labeled heights are measured from the area representing the highest point on the anterior wall of the implant* (Figure 5).
- *The trials are color coded according to the height of the implant. Trials are line to line with the corresponding implant* (Figure 6).

IMPLANT INSERTION
- GUIDE HEAD METHOD

(For Free Hand Method Implant Insertion proceed to page 13)

Straight Instruments:



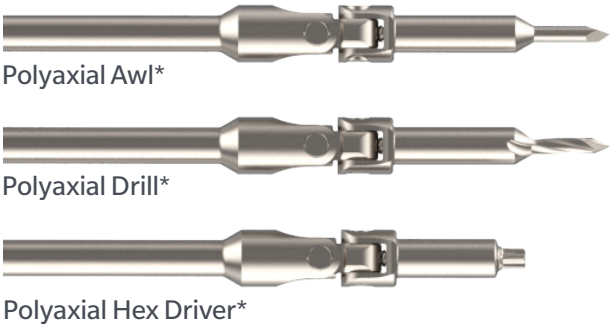
Straight Awl*

Straight Drill*

Straight Hex Driver

Straight Screw Remover

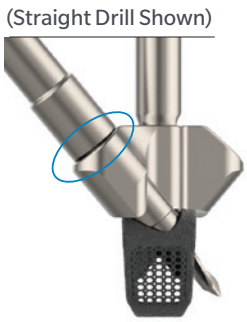
Polyaxial Instruments:



Polyaxial Awl*

Polyaxial Drill*

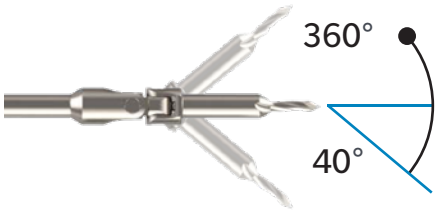
Polyaxial Hex Driver*



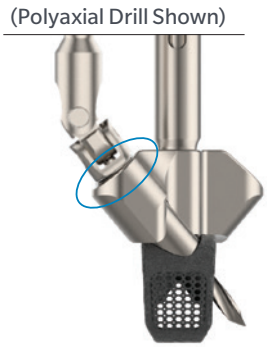
(Straight Drill Shown)

*Positive stop with guide head

Figure 7



Polyaxial tip movement with 40° maximum angulation



(Polyaxial Drill Shown)

*Positive stop with guide head

Figure 8

Notes:

- *The straight awl, straight drill, and straight hex driver work with and without the guide head.*
- *Drill and awl lengths match the shortest implant depth, 12 mm.*
- *Awl and drill diameters are ø2.0 mm.*

Note: *The polyaxial awl, polyaxial drill, polyaxial hex driver and polyaxial screw remover should only be used with the guide head.*

IMPLANT INSERTION
- GUIDE HEAD METHOD (CONTINUED)

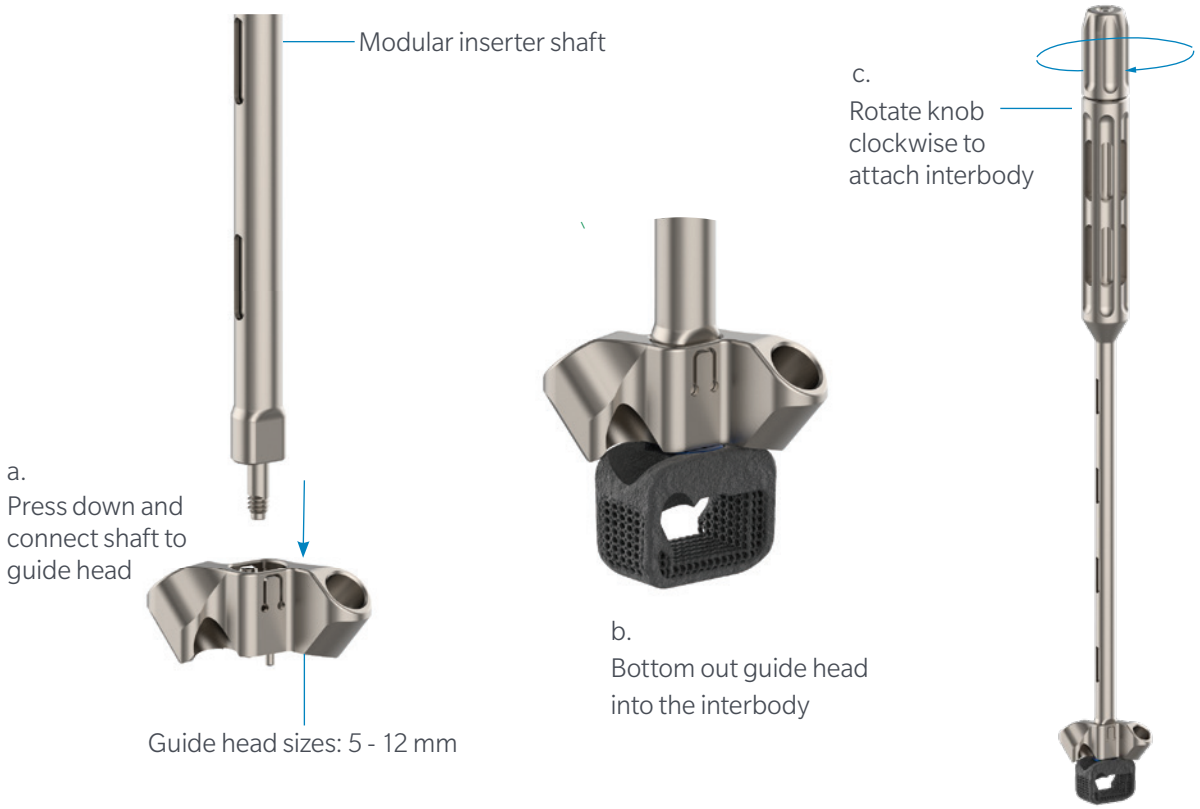


Figure 9

INTERBODY ATTACHMENT

- Select the appropriate interbody size determined by trialing and remove from sterile packaging.
- Connect the modular inserter shaft to the appropriate guide head via the integrated press-and-retain feature (Figure 9a) and align the guide head pins with the corresponding interbody footprint (Figure 9b).
- Rotate the knob on the modular inserter shaft clockwise until the thread bottoms out in the interbody (Figure 9c).

Note: *Each guide head height has a 1:1 precise interbody match for every footprint available. For example, the 5 mm guide head mates with all footprints of 5 mm interbodies; 12 x 15, 14 x 16, and 16 x 18 mm.*

INTERBODY PACKING & INSERTION

- Pack the center cavity of the interbody with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. Introduce the interbody into the disc space, mallet when necessary. Interbodies have been designed to have symmetric superior/inferior surfaces relative to the vertebral endplates. Verify placement of the interbody in the A/P and lateral direction before continuing the procedure.

Note: *Do not overpack the interbody with autograft and/or allograft to ensure the interbody screw pockets remain unobstructed.*

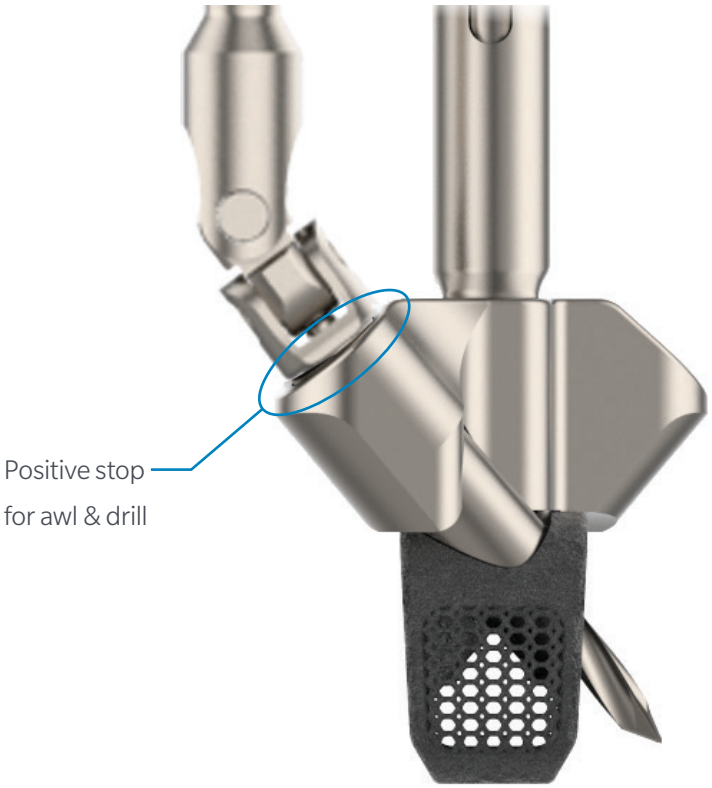


Figure 10

HOLE PREPARATION

- Use either the awl or drill (straight, or polyaxial) to penetrate the cortex of the endplate through the guide head and interbody pocket. Guide head method instruments outlined on pages 9 and 10 will encounter a physical stop on the face of the guide head to ensure the instrument tips do not protrude beyond the intended depth (Figure 10).

IMPLANT INSERTION
- GUIDE HEAD METHOD (CONTINUED)

Figure 11

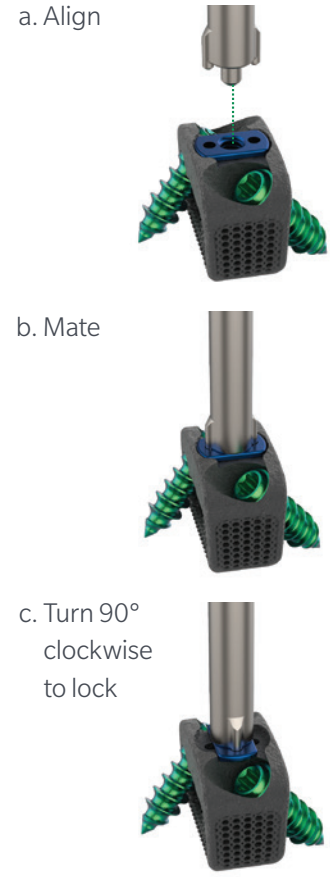


Figure 12

SCREW INSERTION

- Press the hex driver (straight or polyaxial) tip into the female drive feature of the screw in order to retain the screw onto the screw inserter. Guide the attached screw into the barrel of the guide head, then thread the screw into the pilot hole until fully seated. Verify screw placement and angulation via intraoperative imaging.
- Repeat the above steps for implanting the second screw. Upon finalizing screw placement, disengage the modular inserter and guide head by turning the proximal knob counterclockwise.

Notes:

- *If the turn lock does not rotate the full 90° range, ensure debris is clear of the turn lock path and that the screw is bottomed out into the interbody.*
- *Screws are color-coded by length and diameter.*

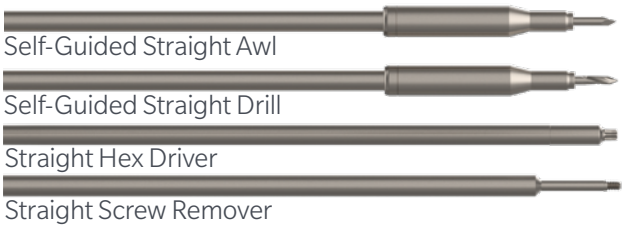
CONSTRUCT LOCKING

1. Align the center tip of the turn lock tool with the center hole on the interbody (Figure 12a).
2. Mate the pins into the superior and inferior holes (Figure 12b).
3. Turn lock tool 90° clockwise. The integrated turn lock will encounter a positive stop with the interbody confirming it has reached the locked position (Figure 12c).

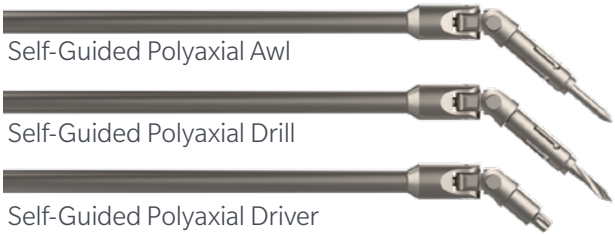
IMPLANT INSERTION
-FREE HAND METHOD

Zimmer Biomet strongly advises utilizing the guide head method for optimal alignment of screws in the interbody. In the event a free hand method (implantation of the interbody without the use of a guide head) is performed, the following technique is recommended for best screw placement.

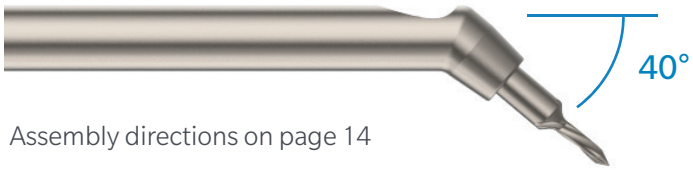
Self-Guided Straight Instruments:



Self-Guided Polyaxial Instruments:



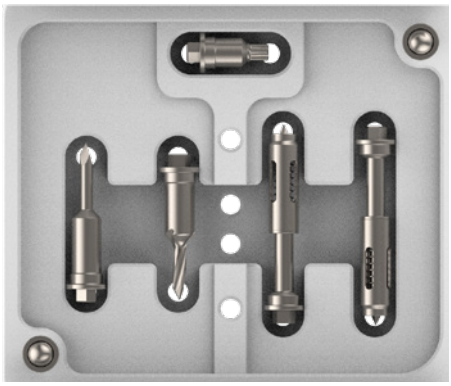
Fixed Angle Driver



Assembly directions on page 14

Notes:

- *Utilize the short tips when using the non-guided free hand method.*
- *Utilize the long tips when using the self-guided free hand method.*



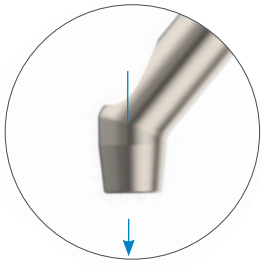
IMPLANT INSERTION
-FREE HAND METHOD (CONTINUED)

FIXED ANGLE DRIVER

The fixed angle driver comes unassembled. It is a modular device with several tip options. Self-guided and non-guided awl, drill, hex driver, and screw removal tips come standard in the fixed angle driver tip caddy.

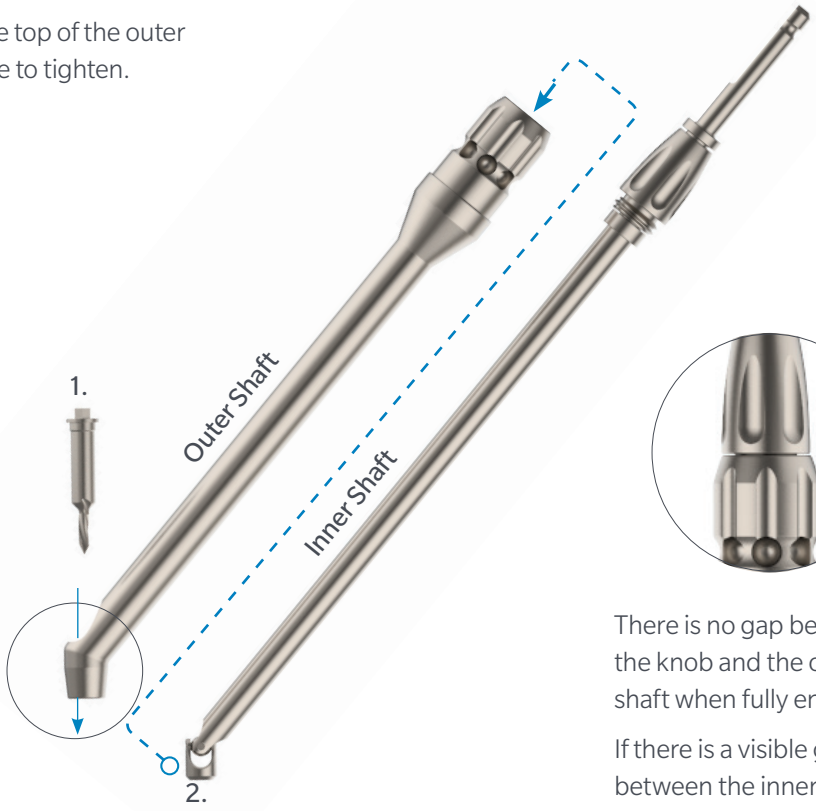
To Assemble:

1. Insert desired tip into outer shaft.
2. Insert inner shaft through the top of the outer shaft and turn knob clockwise to tighten.

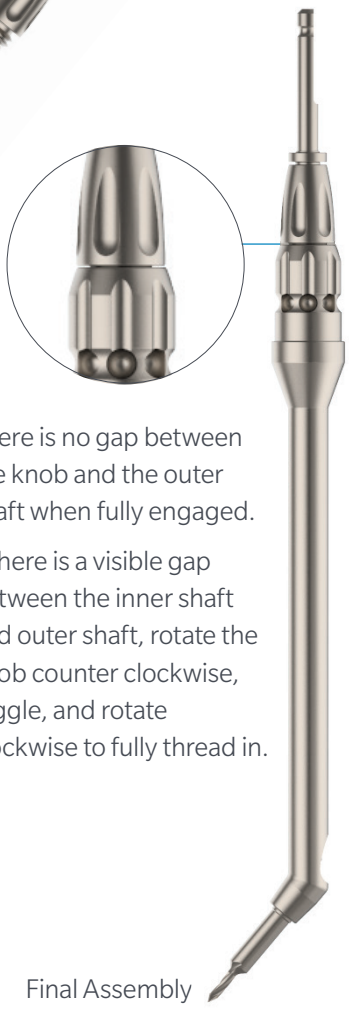


Distal Tip

While assembling, keep the distal tip of the outer shaft pointed down to ensure the tip does not fall out.



Optional Fixed Angle Driver Attachment is available for additional stability.



There is no gap between the knob and the outer shaft when fully engaged.

If there is a visible gap between the inner shaft and outer shaft, rotate the knob counter clockwise, toggle, and rotate clockwise to fully thread in.

Final Assembly

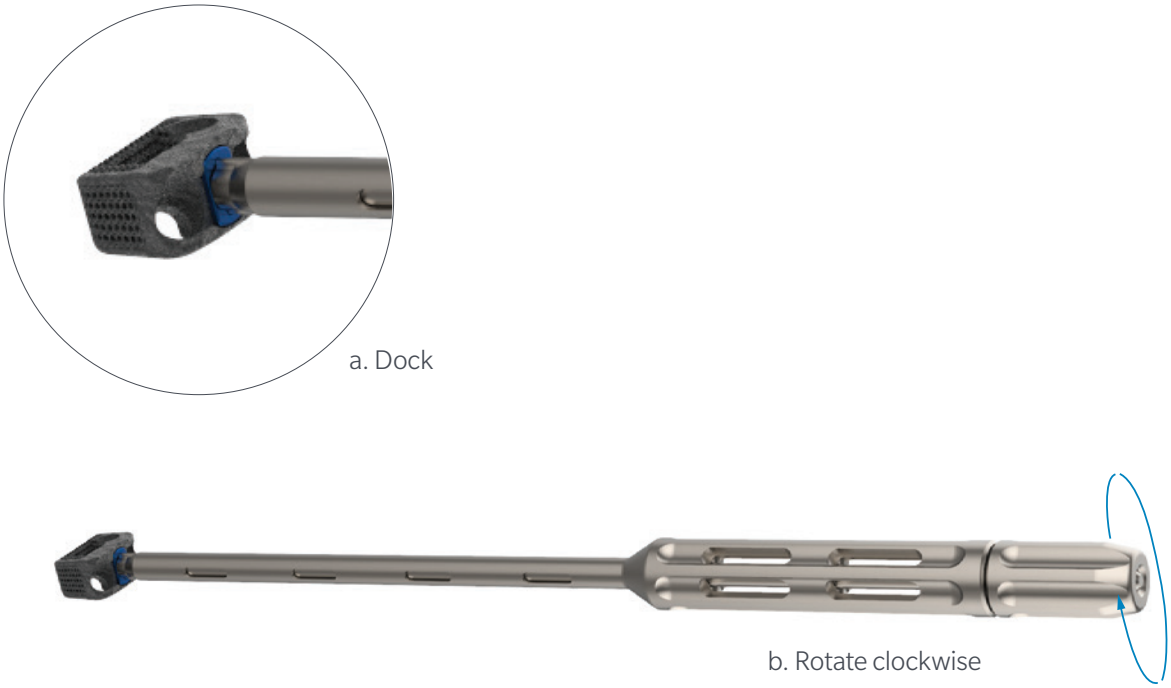


Figure 13

INTERBODY ATTACHMENT

Select the appropriate interbody size determined by trialing and remove from sterile packaging.

- Dock the fixed interbody Inserter to the chosen interbody (Figure 13a).
- Rotate the proximal knob of the fixed interbody inserter clockwise until the thread bottoms out in the interbody (Figure 13b).

Note: *Do not overpack the interbody with autograft and/or allograft to ensure the interbody screw pockets remain unobstructed.*

INTERBODY PACKING & INSERTION

- Pack the center cavity of the interbody with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. Introduce the interbody into the disc space, mallet when necessary. Interbodies have been designed to have symmetric superior/inferior surfaces relative to the vertebral endplates. Verify placement of the interbody in the A/P and lateral direction before continuing the procedure.

IMPLANT INSERTION
-FREE HAND METHOD (CONTINUED)

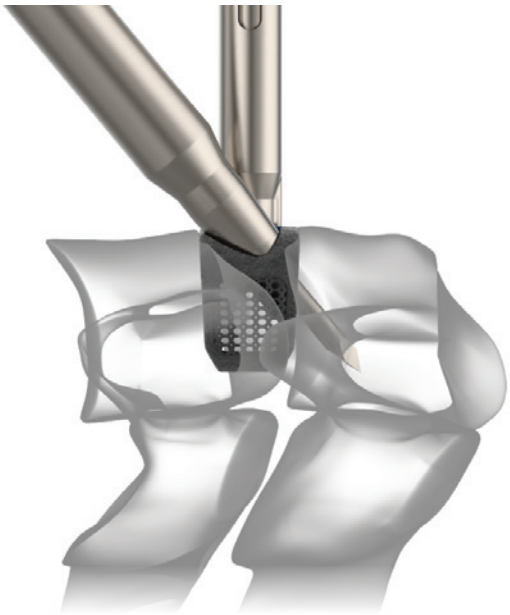


Figure 14

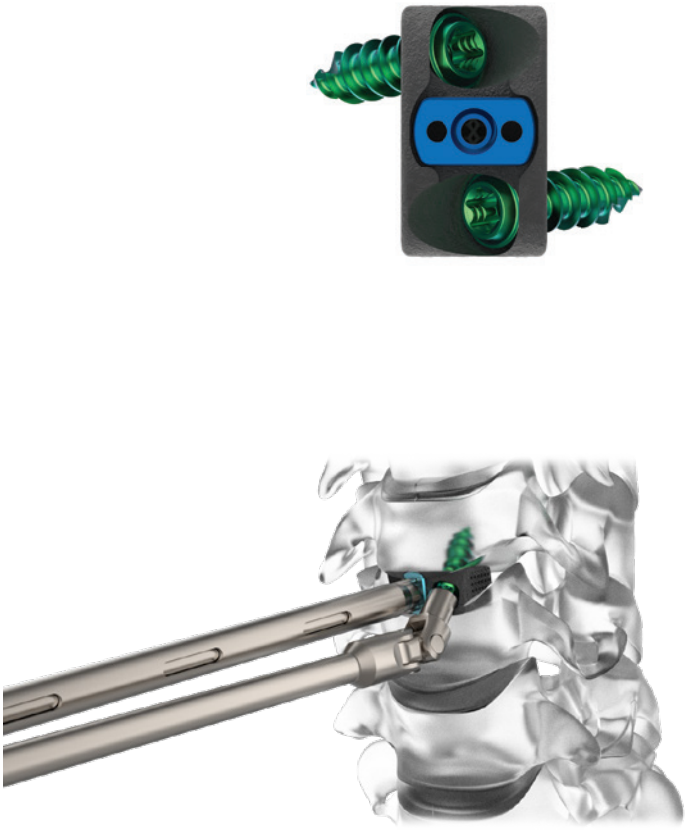


Figure 15

HOLE PREPARATION

- Use either self-guided straight or polyaxial instrumentation or the fixed angle driver with either an awl or drill tip to penetrate the cortex through the interbody pocket (Figure 14).

SCREW INSERTION

- Screws are color-coded by length and diameter. Press the hex driver (straight or polyaxial self-guided or fixed angle tip) into the female drive feature of the screw in order to retain the screw onto the screw inserter. Guide the attached screw into the pilot hole and thread until fully seated. Ensure screw is concentrically centered in screw pocket and aligned correctly. Verify screw placement and angulation via intraoperative imaging (Figure 15).
- Repeat the above steps for implanting the second screw. Upon finalizing screw placement, disengage the fixed interbody inserter by turning the proximal knob counterclockwise.

a. Align

b. Mate

c. Turn 90° clockwise to lock

Figure 16

CONSTRUCT LOCKING

- Align the center tip of the turn lock tool with the center hole on the interbody (Figure 16a).
- Mate the pins into the superior and inferior holes (Figure 16b).
- Turn lock tool 90° clockwise. The integrated turn lock will encounter a positive stop with the interbody confirming it has reached the locked position (Figure 16c).

Note: *If the turn lock does not rotate the full 90° range, ensure debris is clear of the turn lock path and that the screw is bottomed out into the interbody.*

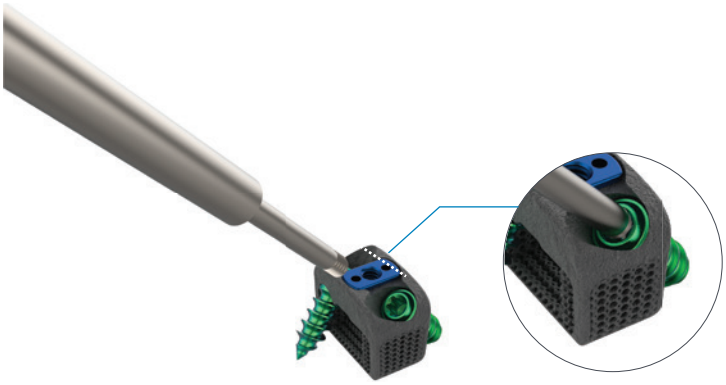
IMPLANT REMOVAL

Screw Removal: To remove the screws from the interbody, follow the outlined steps.

1. Align and turn 90° counterclockwise to unlock

2. Unlocked

3. Remove lock tool



4. Thread screw removal tool counterclockwise into screw head

5. Continue to rotate counterclockwise while pulling out screw to explant

Interbody Removal: Remove any debris from the center hole on the interbody.

1. Dock

2. Rotate clockwise to attach instrument to interbody
3. Toggle medial/lateral and pull out interbody

KIT CONTENTS

TrellOss-C SA Instrument Kit
Kit Number: PCR100N8100

DESCRIPTION	QTY	PART NUMBER
Fixed Angle Tip Awl, Self-guided	1	138N4038
Fixed Angle Tip Drill, Self-guided	1	138N4039
Straight Drill, Self-guided	1	138N4040
Straight Awl, Self-guided	1	138N4041
Polyaxial Angle Hex Driver, Self-guided	1	138N4042
Polyaxial Angle Drill, Self-guided	1	138N4043
Polyaxial Angle Awl, Self-guided	1	138N4044
Cervical Tamp	1	130N3003
Trial, 12 mm x 15 mm x 5 mm, 6°	1	135N1205
Trial, 12 mm x 15 mm x 6 mm, 6°	1	135N1206
Trial, 12 mm x 15 mm x 7 mm, 6°	1	135N1207
Trial, 12 mm x 15 mm x 8 mm, 6°	1	135N1208
Trial, 12 mm x 15 mm x 9 mm, 6°	1	135N1209
Trial, 12 mm x 15 mm x 10 mm, 6°	1	135N1210
Trial, 12 mm x 15 mm x 11 mm, 6°	1	135N1211
Trial, 12 mm x 15 mm x 12 mm, 6°	1	135N1212
Trial, 14 mm x 16 mm x 5 mm, 6°	1	135N1405
Trial, 14 mm x 16 mm x 6 mm, 6°	1	135N1406
Trial, 14 mm x 16 mm x 7 mm, 6°	1	135N1407
Trial, 14 mm x 16 mm x 8 mm, 6°	1	135N1408
Trial, 14 mm x 16 mm x 9 mm, 6°	1	135N1409
Trial, 14 mm x 16 mm x 10 mm, 6°	1	135N1410
Trial, 14 mm x 16 mm x 11 mm, 6°	1	135N1411
Trial, 14 mm x 16 mm x 12 mm, 6°	1	135N1412
Trial, 16 mm x 18 mm x 5 mm, 6°	1	135N1605
Trial, 16 mm x 18 mm x 6 mm, 6°	1	135N1606
Trial, 16 mm x 18 mm x 7 mm, 6°	1	135N1607
Trial, 16 mm x 18 mm x 8 mm, 6°	1	135N1608
Trial, 16 mm x 18 mm x 9 mm, 6°	1	135N1609
Trial, 16 mm x 18 mm x 10 mm, 6°	1	135N1610
Trial, 16 mm x 18 mm x 11 mm, 6°	1	135N1611
Trial, 16 mm x 18 mm x 12 mm, 6°	1	135N1612
Guide Head 5 mm	1	137N1205
Guide Head 6 mm	1	137N1206
Guide Head 7 mm	1	137N1207
Guide Head 8 mm	1	137N1208
Guide Head 9 mm	1	137N1209
Guide Head 10 mm	1	137N1210
Guide Head 11 mm	1	137N1211
Guide Head 12 mm	1	137N1212

DESCRIPTION	QTY	PART NUMBER
Fixed AO Handle	2	138N4001
Universal Rasp	1	138N4002
Fixed Interbody Inserter	1	138N4003
Guide Interbody Inserter	2	138N4004
Fixed Angle Tip Awl, Short	1	138N4009
Fixed Angle Tip Drill, Short	1	138N4011
Fixed Angle Tip Driver, Short	1	138N4013
Fixed Angle Driver Outer	2	138N4015
Fixed Angle Driver Shaft	2	138N4016
Fixed Angle Driver Handle	2	138N4017
Lock Tool	1	138N4020
Straight Awl	1	138N4021
Straight Drill	1	138N4022
Straight Hex Driver	2	138N4023
Straight Screw Remover	1	138N4024
Polyaxial Awl	1	138N4031
Polyaxial Drill	1	138N4032
Polyaxial Hex Driver	1	138N4033

TrellOss-C SA Standard Implant Kit
Kit Number: PCR100N6100

DESCRIPTION, D x W x H	QTY	PART NUMBER
Implant, 12 mm x 15 mm x 5 mm, 6°	3	108N1205
Implant, 12 mm x 15 mm x 6 mm, 6°	3	108N1206
Implant, 12 mm x 15 mm x 7 mm, 6°	3	108N1207
Implant, 12 mm x 15 mm x 8 mm, 6°	3	108N1208
Implant, 12 mm x 15 mm x 9 mm, 6°	2	108N1209
Implant, 12 mm x 15 mm x 10 mm, 6°	2	108N1210
Implant, 14 mm x 16 mm x 5 mm, 6°	3	108N1405
Implant, 14 mm x 16 mm x 6 mm, 6°	3	108N1406
Implant, 14 mm x 16 mm x 7 mm, 6°	3	108N1407
Implant, 14 mm x 16 mm x 8 mm, 6°	3	108N1408
Implant, 14 mm x 16 mm x 9 mm, 6°	2	108N1409
Implant, 14 mm x 16 mm x 10 mm, 6°	2	108N1410
Screw, ø3.5 mm x 12 mm	6	109N3512
Screw, ø3.5 mm x 14 mm	6	109N3514
Screw, ø3.5 mm x 16 mm	6	109N3516
Screw, ø4.0 mm x 12 mm	6	109N4012
Screw, ø4.0 mm x 14 mm	6	109N4014
Screw, ø4.0 mm x 16 mm	6	109N4016

TrellOss-C SA X-Large Implant Kit
Kit Number: PCR100N6101

DESCRIPTION, D x W x H	QTY	PART NUMBER
Implant, 16 mm x 18 mm x 5 mm, 6°	3	108N1605
Implant, 16 mm x 18 mm x 6 mm, 6°	3	108N1606
Implant, 16 mm x 18 mm x 7 mm, 6°	3	108N1607
Implant, 16 mm x 18 mm x 8 mm, 6°	3	108N1608
Implant, 16 mm x 18 mm x 9 mm, 6°	2	108N1609
Implant, 16 mm x 18 mm x 10 mm, 6°	2	108N1610
Implant, 16 mm x 18 mm x 11 mm, 6°	2	108N1611
Implant, 16 mm x 18 mm x 12 mm, 6°	2	108N1612
Screw, ø3.5 mm x 16 mm	6	109N3516
Screw, ø3.5 mm x 18 mm	6	109N3518
Screw, ø4.0 mm x 16 mm	6	109N4016
Screw, ø4.0 mm x 18 mm	6	109N4018

TrellOss-C SA Rasp Kit
Kit Number: PCR100N9100

DESCRIPTION, D x W x H	QTY	PART NUMBER
Rasp, 12 mm x 15 mm x 5 mm, 6°	1	136N1205
Rasp, 12 mm x 15 mm x 6 mm, 6°	1	136N1206
Rasp, 12 mm x 15 mm x 7 mm, 6°	1	136N1207
Rasp, 12 mm x 15 mm x 8 mm, 6°	1	136N1208
Rasp, 12 mm x 15 mm x 9 mm, 6°	1	136N1209
Rasp, 12 mm x 15 mm x 10 mm, 6°	1	136N1210
Rasp, 12 mm x 15 mm x 11 mm, 6°	1	136N1211
Rasp, 12 mm x 15 mm x 12 mm, 6°	1	136N1212
Rasp, 14 mm x 16 mm x 5 mm, 6°	1	136N1405
Rasp, 14 mm x 16 mm x 6 mm, 6°	1	136N1406
Rasp, 14 mm x 16 mm x 7 mm, 6°	1	136N1407
Rasp, 14 mm x 16 mm x 8 mm, 6°	1	136N1408
Rasp, 14 mm x 16 mm x 9 mm, 6°	1	136N1409
Rasp, 14 mm x 16 mm x 10 mm, 6°	1	136N1410
Rasp, 14 mm x 16 mm x 11 mm, 6°	1	136N1411
Rasp, 14 mm x 16 mm x 12 mm, 6°	1	136N1412
Rasp, 16 mm x 18 mm x 5 mm, 6°	1	136N1605
Rasp, 16 mm x 18 mm x 6 mm, 6°	1	136N1606
Rasp, 16 mm x 18 mm x 7 mm, 6°	1	136N1607
Rasp, 16 mm x 18 mm x 8 mm, 6°	1	136N1608
Rasp, 16 mm x 18 mm x 9 mm, 6°	1	136N1609
Rasp, 16 mm x 18 mm x 10 mm, 6°	1	136N1610
Rasp, 16 mm x 18 mm x 11 mm, 6°	1	136N1611
Rasp, 16 mm x 18 mm x 12 mm, 6°	1	136N1612

IMPORTANT INFORMATION ON THE TRELLOSS-C SA POROUS TI INTERBODY SYSTEM

Device Description

TrellOss is a collection of additively manufactured implants. The TrellOss-C SA Porous Ti Interbody System includes additively manufactured spacer and traditionally machined fixation screw implants. The spacer and screw components are available in an assortment of dimensional combinations to accommodate the individual anatomic and clinical circumstances of each patient. The basic shape of the spacer 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 300-700µm pores. The inferior/superior aspects of the spacer incorporate a vertical cavity which can be packed with bone graft material. Each interbody is preassembled with a turn lock mechanism that secures the screw to the spacer component.

Indications for Use

- The TrellOss-C SA Porous Ti Interbody System is a stand-alone anterior cervical interbody fusion system intended for use as an adjunct to fusion at one or two contiguous levels (C2-T1) in skeletally mature patients for the treatment of degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by history and radiographic studies). These patients should have received at least six weeks of non-operative treatment prior to treatment with the device. The TrellOss-C SA Porous Ti Interbody System is to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and implanted via an open, anterior approach. The TrellOss-C SA Porous Ti Interbody System is intended to be used with the bone screw fixation provided and requires no additional fixation.

Contraindications

The TrellOss-C SA 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 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-C SA 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.
- 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-C SA Porous Ti Interbody System is used to augment the development of a spinal fusion by providing temporary stabilization. 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.

Disclaimer: *This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part. 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 physician. Rx Only. Please see the product Instructions for Use for a complete listing of the indications, contraindications, precautions, warnings and adverse effects.*

Manufactured by:
Nexxt Spine, LLC
14425 Bergen Blvd, Suite B
Noblesville, IN 46060

Distributed by:
Zimmer Biomet Spine, Inc.
10225 Westmoor Dr.
Westminster, CO 80021 USA
+1 800.447.3625

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800.447.3625/zimmerbiomet.com

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