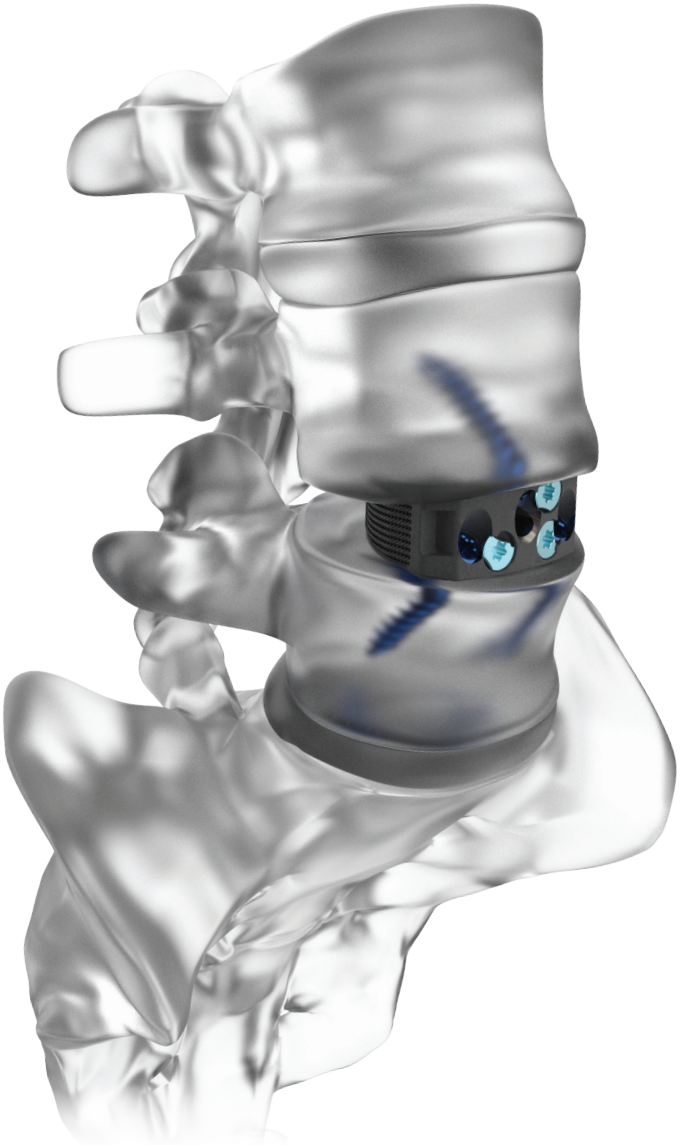
TrellOss®-A SA

Porous Ti Interbody System

Surgical Technique Guide



ZimVie

TrellOss-A SA

Porous Ti Interbody System

TrellOss-A SA is a 3D printed, porous titanium interbody device with aligned 300, 500, and 700 µm pores and a 7 µm roughened surface; TrellOss-A SA is designed to provide appropriate endplate coverage with three footprint offerings, and allow for consistent bone purchase with optimized location of screw pockets.

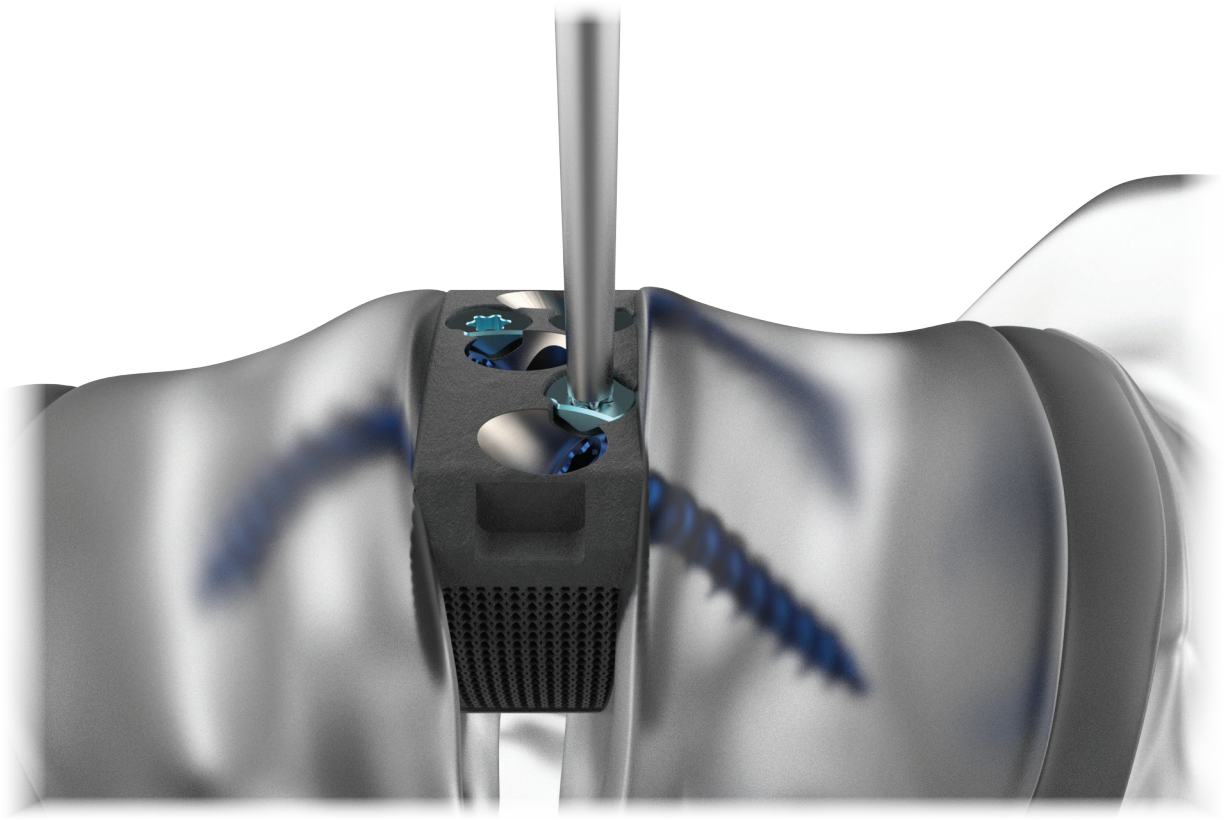


Table Of Contents

ZimVie 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. Animations and virtual reality are provided as a visual guide based on surgical techniques. A written copy of the surgical technique is available at www.zimvie.com. 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. Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

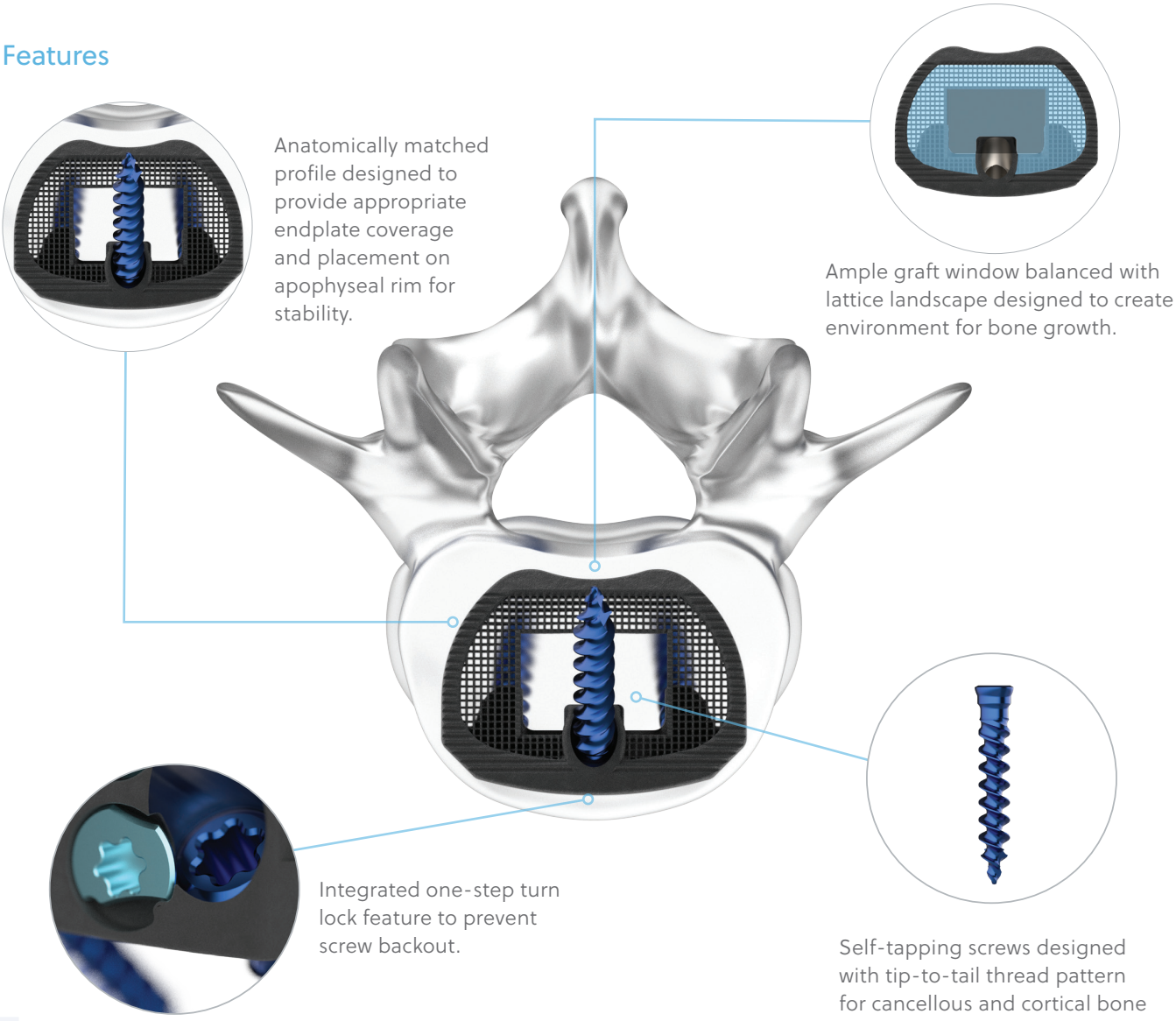
TrellOss-A SA Porous Ti Interbody System

Introduction

The TrellOss-A SA Porous Ti Interbody System is a stand-alone lumbar interbody fusion system intended for use as an adjunct to fusion at one or two contiguous levels (L2-S1) in skeletally mature patients for the treatment of degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels and should have received at least six months of nonoperative treatment prior to treatment with the device.

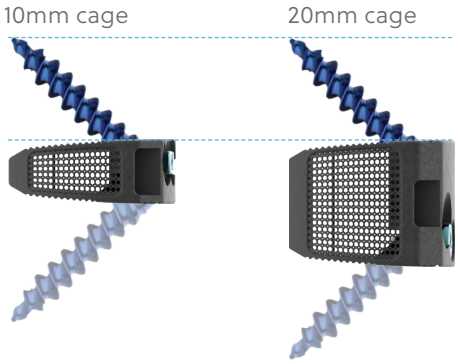
The TrellOss-A SA Porous Ti Interbody System is to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone, the bone screw fixation provided and requires no additional fixation. Hyperlordotic interbody devices (>20° lordosis) must be used with supplemental fixation (e.g. posterior fixation). Each interbody fusion device having a lordotic angle 20° or less is intended to be used with the bone screws provided and requires no additional fixation.

Features



Optimized location of Screw Pockets:

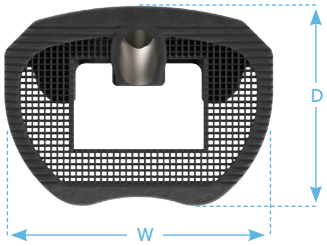
Allows for consistent bone purchase per screw regardless of cage height.



Cage Specifications

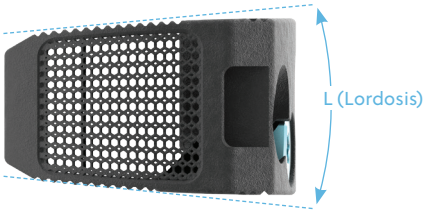
Footprints

24D x 32W, 27D x 36W, and 30D x 40W mm



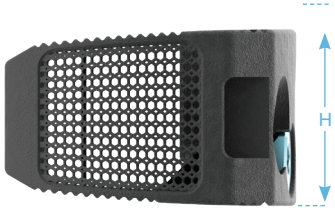
Lordoses

8°, 14°, 20°, and 25°



Heights

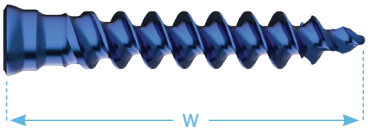
10, 12, 14, 16, 18, and 20 mm



Screw Specifications

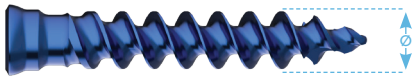
Lengths

20, 25, 30, and 35 mm



Diameters

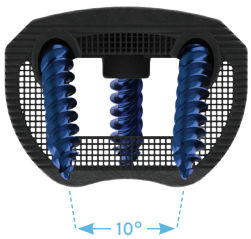
5.0 and 5.5 mm

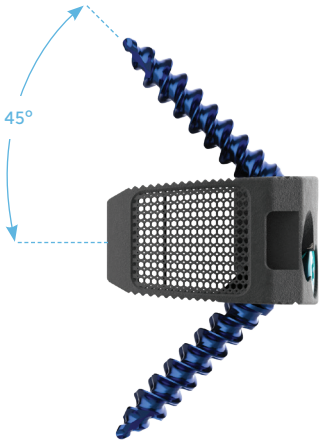


Construct Specifications

Angulation

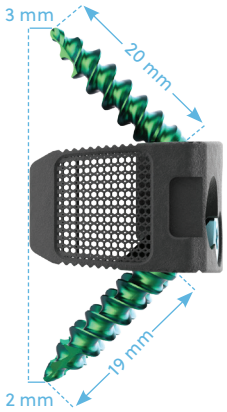
Fixed angle, no toggle



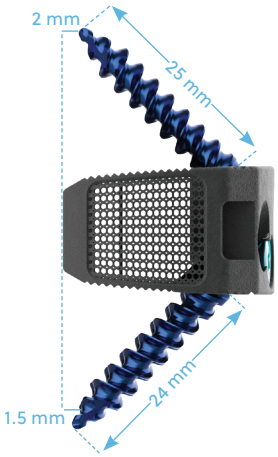


Bone Purchase

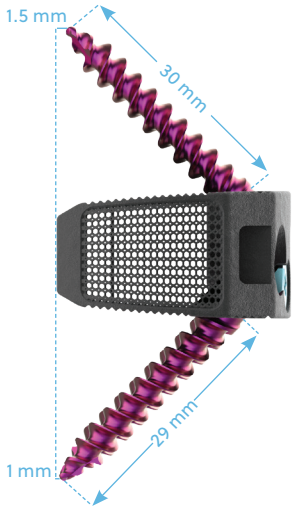
Cage: 24D x 32W
Screw: 25 mm



Cage: 27D x 36W
Screw: 30 mm

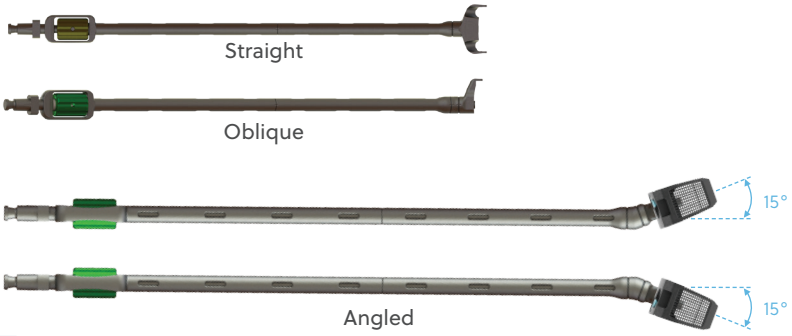


Cage: 30D x 40W
Screw: 35 mm



Multiple insertion instrumentation options:

Accommodate patient anatomy and spinal pathology that is being treated



Preoperative Planning

The following Surgical Technique Guide describes the recommended placement and use of the TrellOss-A SA Porous Ti Interbody System components.

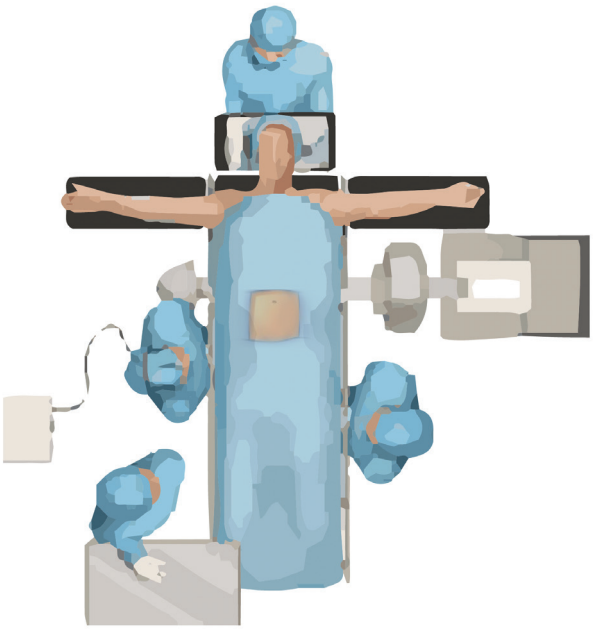


Figure 1

Patient Positioning

Approach to the Surgery

- Perform the customary approach for an ALIF as chosen by the surgeon (Figure 1).

  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.*

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.

Retractor Insertion

- Using fluoroscopy, identify the middle of the disc space.
- Mark the skin to indicate the intended incision location.
- Approach the desired disc space level and place the retractor. Use of the intraoperative neuromonitoring is recommended to ensure patient safety. It is especially critical during approach and retractor placement.

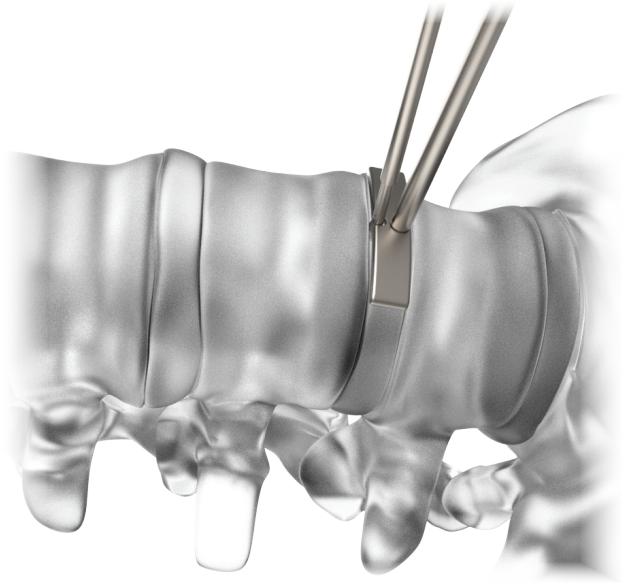


Figure 2

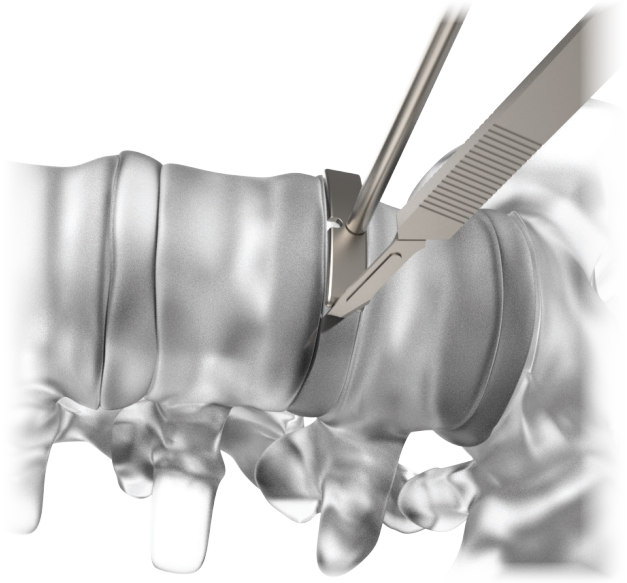


Figure 3

Midline Verification

- Position the annulotomy template (32, 36, or 40 mm wide) on the disc space and insert the centering pin in the midline (Figure 2).

  Note: *Utilize A/P fluoroscopy to verify midline and lateral fluoroscopy to verify depth.*

  Note: *Centering pin depth is 23 mm.*

Disc Removal

- Use an annulotomy knife to make incisions in the annulus along the lateral edges of the annulotomy template. (Figure 3).

  Note: *The width of the annulotomy template matches the width of the trial/cage.*

Figure 4

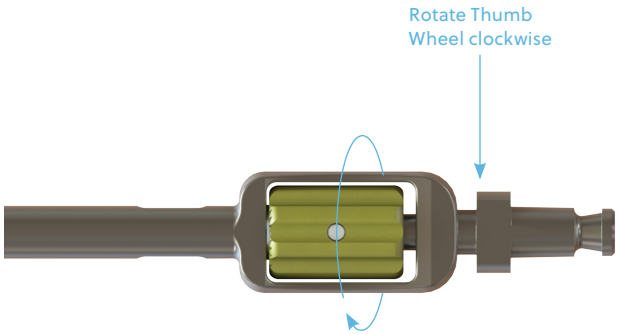


Figure 5

Cage Inserter + Trial/Cage Attachment

Note: *Trial and cage follow the same process of attachment/detachment.*

- Align the cage Inserter to the trial/cage. When aligning with the cage, ensure proper orientation by matching the laser etched icon and the cage face hole(s) (Figure 4). Trials may be loaded to the cage Inserter in both orientations.
- Turn the thumb wheel on the cage inserter clockwise to tighten to the trial/cage (Figure 5).

  Note: *Verify assembly before insertion. Due to their biased orientation, oblique and angled inserter verification is especially important to ensure correct screw placement.*

Figure 6

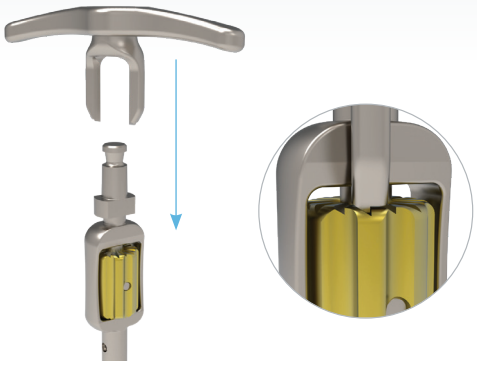


Figure 7

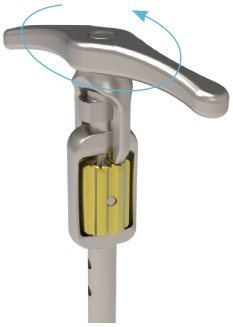


Figure 8

Cage Inserter + Trial/Cage Detachment

- To disconnect the trial/cage, rotate the thumb wheel counterclockwise until trial/cage is released.

Thumb Wheet Rotater

A thumb wheel rotator may be used in the event that additional leverage is required to loosen the thumb wheel.

- To use the thumb wheel rotator, first remove the handle from the inserter (Figure 6).
- Slide the thumb wheel rotator over the adapter (Figure 7) and align the two prongs over the thumb wheel.
- Verify successful merge of the thumb wheel rotator to the inserter (Figure 5c).
- Rotate the thumb wheel rotator counter-clockwise to loosen while exerting slight downward pressure to allow for ratcheting (Figure 8).

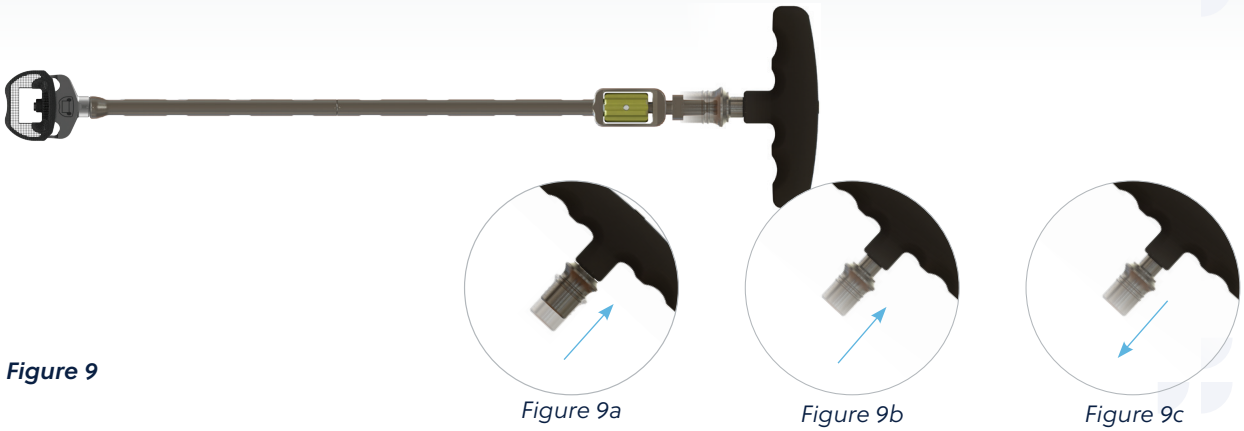


Figure 9a

Figure 9b

Figure 9c

Figure 9

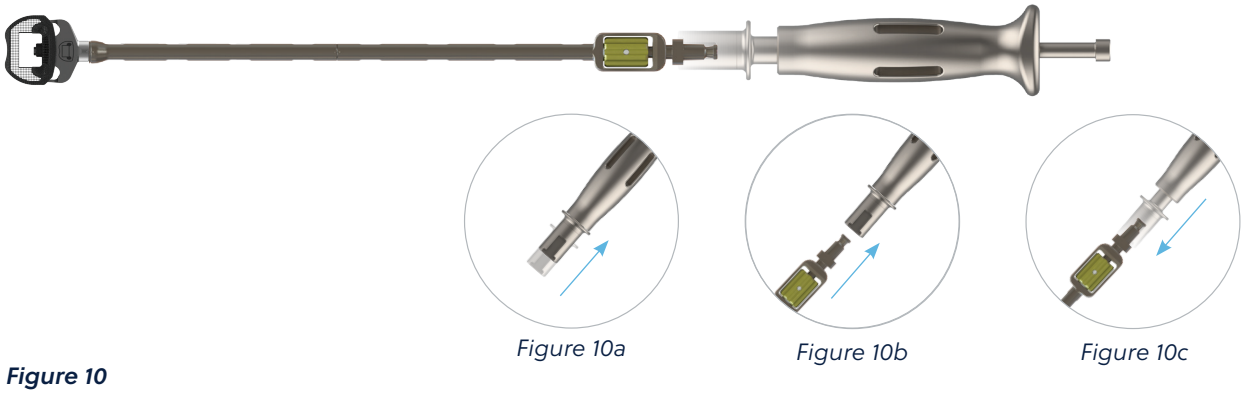


Figure 10a

Figure 10b

Figure 10c

Figure 10

Cage Inserter + T-Handle Attachment

- Pull the Hudson connect sleeve up (Figure 9a).
- Align and connect the Hudson connect sleeve to the cage inserter (Figure 9b).
- Release the Hudson connect sleeve (Figure 9c).

Cage Inserter + Slap Hammer Attachment

- Pull Hudson connect sleeve up (Figure 10a).
- Align Hudson connect sleeve with cage inserter (Figure 10b).
- Release Hudson connect sleeve (Figure 10c).

  Note: *A slap hammer adapter is provided and allows the slap hammer to be connected to the inline handle. The slap hammer adapter is threaded into the inline handle and the slap hammer is connected to the slap hammer adapter via Hudson connect.*

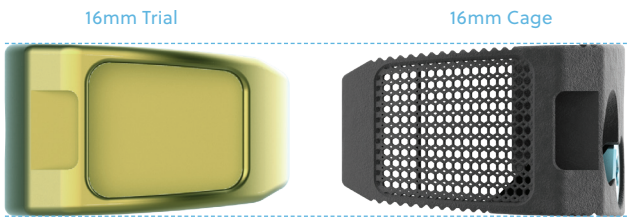


Figure 11

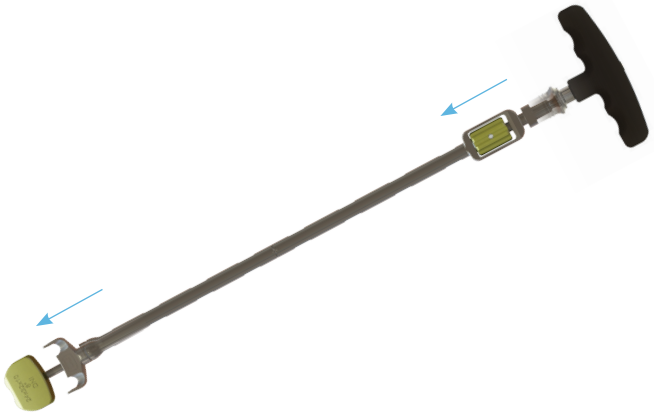


Figure 12

Figure 13

Trialing

Cage Selection

- Once the disc space and endplates are adequately prepared, the optimal cage footprint and height can be determined by trialing. Anodization colors differentiate trials by lordosis.

  Note: *The height of the trial is line-to-line with the cage (Figure 11).*

- Attach the trial to the cage Inserter or trial inserter.

Cage Inserter

- Attach a T-handle Hudson connect to the proximal end of the cage inserter and verify the security of the assembly (Figure 12).
- Center the trial in the vertebral cavity.

Trial Inserter

- Attach a T-handle Hudson connect to the proximal end of the cage Inserter and verify the security of the assembly (Figure 12). Center the trial in the vertebral cavity.
- To determine the appropriate cage size, gently impact the trial into the disc space until it is centered under medial/lateral fluoroscopy (Figure 13). Use incrementally taller sizes until a tight fit is achieved; there should be no gap between the prepared site and the trial.
- Once the optimal placement and fit of the trial is determined, the trial can be removed from the disc space. The slap hammer can be used, if necessary, to facilitate trial removal.

  Note: *Trials can be loaded directly from the caddy.*

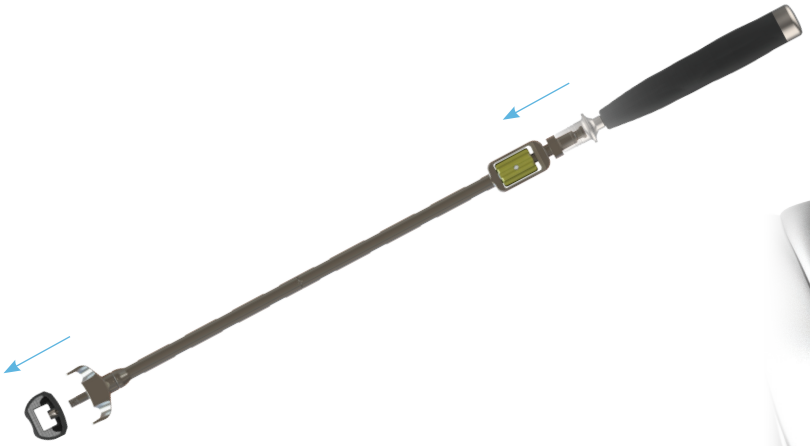


Figure 14

Figure 15

Cage Insertion

Cage + Cage Inserter Attachment

- Pack the central graft cavity with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft prior to insertion.
- Attach the cage to the cage inserter (Figure 14). Attach an inline handle to proximal end of cage Inserter and verify security of the assembly.
- Center the cage in the vertebral cavity.

Cage Placement

- Impact the cage into the prepared disc space (Figure 15). Placement of the cage is dictated by patient anatomy and the spinal pathology that is being treated. Fluoroscopy should be used to verify cage is positioned properly.
- Remove the cage inserter.

Note: *Cage inserter may remain attached during preparation of lateral holes, however, Inserter must be removed to allow access to the medial hole.*

- A tamp may be used to adjust placement of the cage. Generally, the cage spans the apophyseal rim and is centered across the disc space from an anterior/posterior perspective, and is near the center of the disc space from a medial/lateral perspective.

Note: *Anterior midline or anterolateral positioning of the cage may be determined by anatomy and by surgeon preference. At L5-S1, the cage may be implanted anteriorly and directly midline, below the level of the bifurcation of the vessels.*

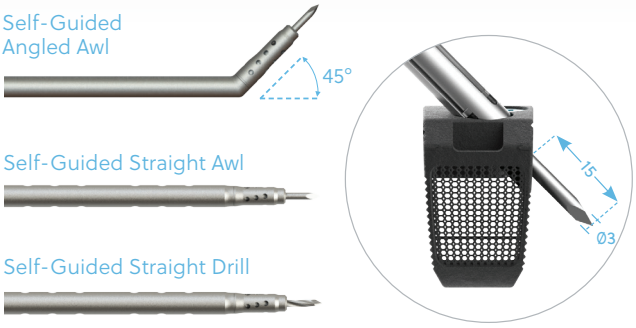
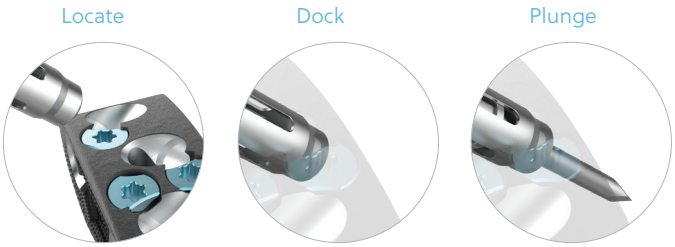


Figure 16



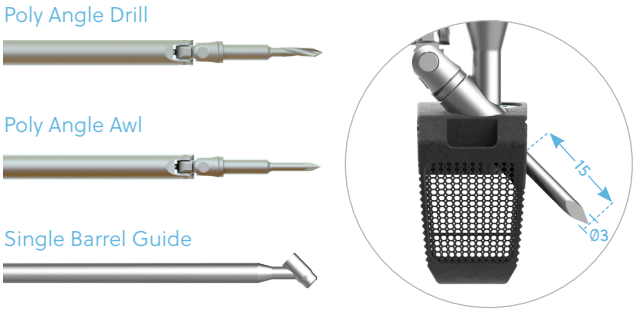


Figure 17

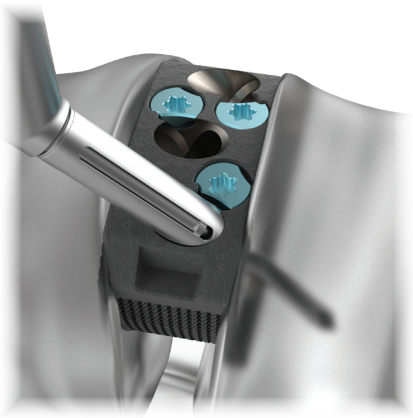


Figure 18

Hole Preparation

Option 1: Self-Guided

- Self-guided instrumentation includes the self-guided angled awl, self-guided straight awl, and self-guided straight drill (Figure 16).
- The self-guided angled awl offers a fixed 45° angle.
- Both self-guided awls feature a proximal threaded hole for the slap hammer adapter.
- Awl and drill diameter is 2.5 mm, and depth is 10 mm.

Option 2: Poly Angle + Single Barrel Guide

- Poly angle instrumentation includes the poly angle awl, the poly angle drill, and the single barrel guide (Figure 17).
- The poly angle awl features a proximal threaded hole for the slap hammer adapter.
- Awl and drill diameter is 2.5 mm, and depth is 10 mm.

Pilot Hole Execution

- Using the self-guided angled awl, self-guided straight awl, and self-guided straight drill or the poly angle awl, poly angle drill, and the single barrel guide, locate the screw pocket within the cage and dock. Plunge/drill to create the pilot hole. Repeat for all pilot holes (Figure 18).

  Note: *Use of power with hole preparation instrumentation is not recommended.*

  Note: *The cage Inserter may remain attached to the cage to provide additional support while creating pilot holes using self-guided instrumentation options for the lateral screw pockets.*

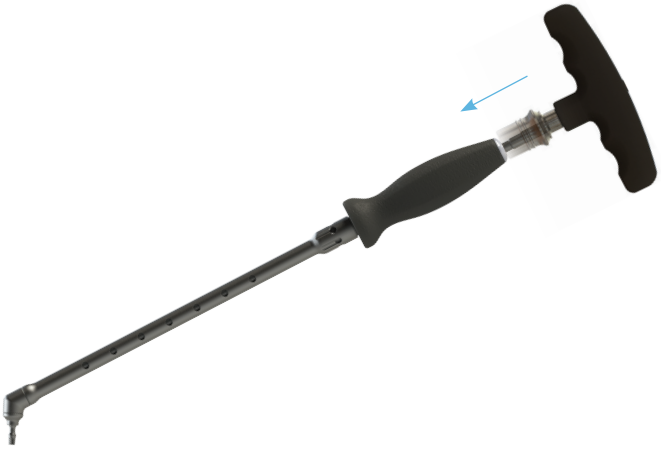


Figure 19

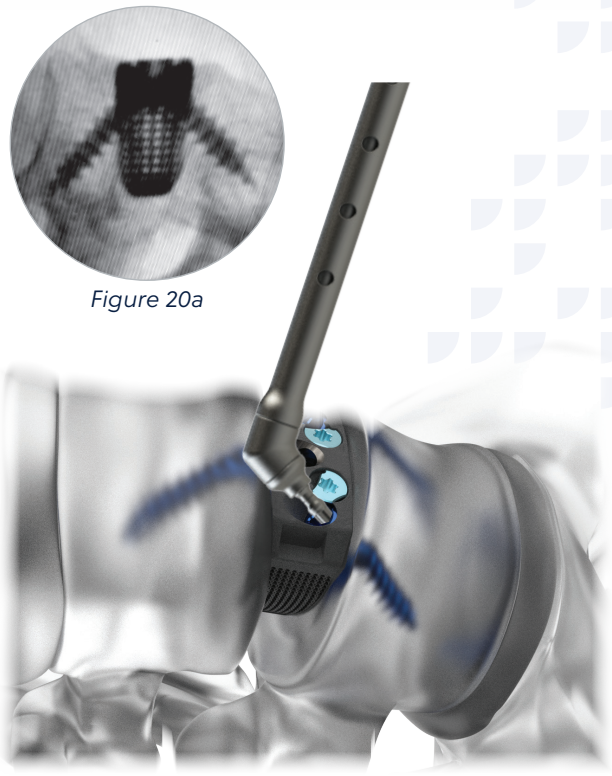


Figure 20a

Figure 20

Screw Insertion

Instrument Options

- Connect a ratcheting T-handle to either the straight driver (T20) or fixed angle driver (T20) (Figure 19).
- Determine the desired screw length and attach the Screw to the tip of the selected driver.

  Note: *The fixed angle driver tip is fixed at 60°.*

  Note: *The straight driver and fixed angle driver have a self-retaining, press-fit connection with the screw.*

Screw Placement

- Insert the screw into the desired screw pocket and advance the screw by turning the axial ratcheting handle clockwise until bottomed out (Figure 20). Repeat for all screws to complete the construct.
- Verify screw placement via fluoroscopy (Figure 20a).

  Note: *Ensure all screws are fully seated within the screw pockets.*

Figure 21

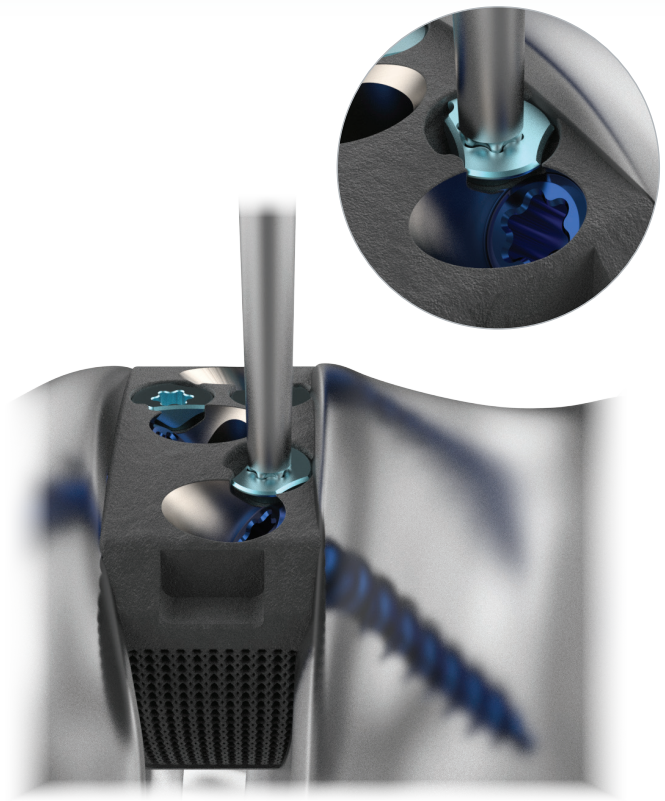


Figure 22

Locking

Turn Lock Tool

- The turn lock tool (T15) is designed for use exclusively with the cage turn locks (Figure 21).

Cage Turn Lock Locking

- Mate the tip of the turn lock tool to the turn lock. Rotate clockwise, approximately 90°, until turn lock encounters hard-stop with cage (Figure 22).
- Repeat for all turn locks.

  Note: *In the event a turn lock does not clear the screw head, drive the screw deeper until bottomed out in the screw pocket. Rotate the turn lock.*

Closure

- The skin is closed using standard surgical techniques.
- Hyperlordotic interbody devices (>20° lordosis) must be used with supplemental fixation (e.g. posterior fixation). Each interbody fusion device having a lordotic angle 20° or less is intended to be used with the bone screws provided and requires no additional fixation.

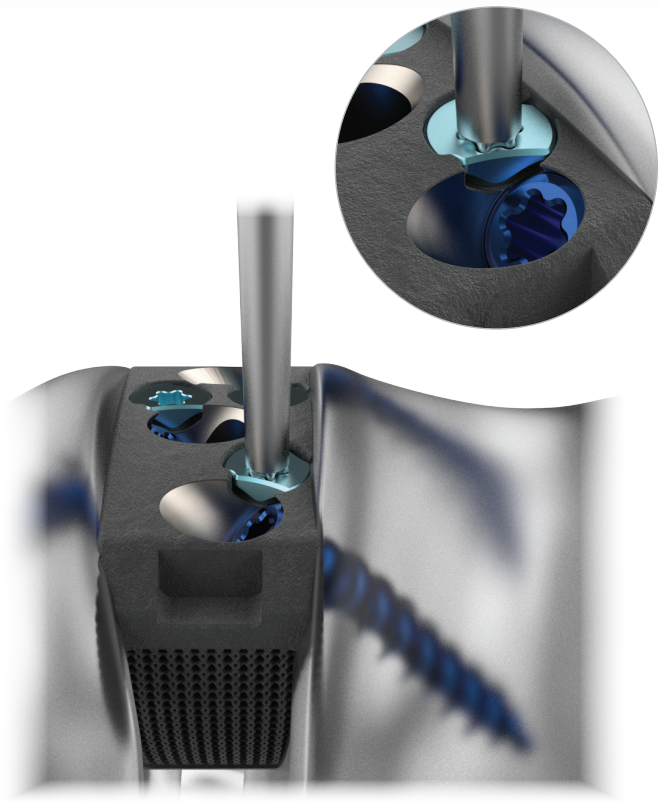


Figure 23

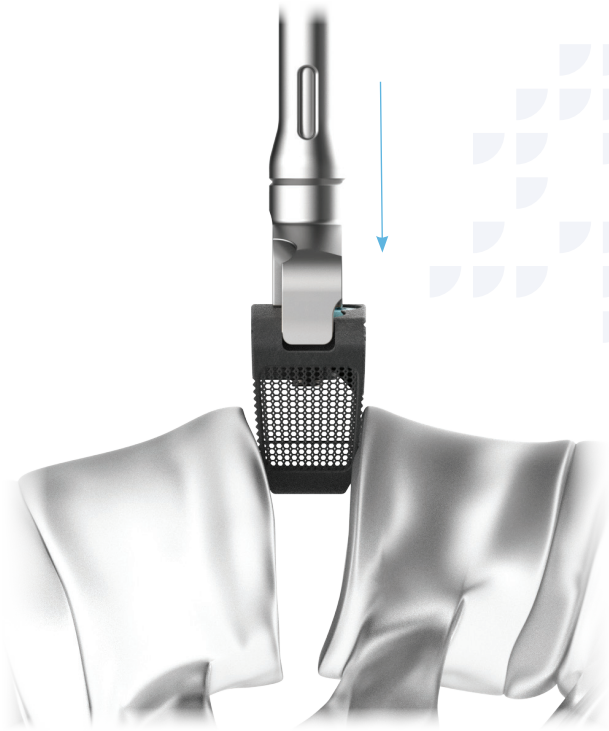


Figure 24

Removal (as needed)

Cage Turn Lock Unlocking

- If it becomes necessary to revise the implanted construct, access to the implantation site can be achieved in a similar fashion to the original access.
- Mate the tip of the turn lock tool to the turn lock. Rotate counterclockwise, approximately 90°, until turn lock encounters hard-stop with cage (Figure 23). Repeat for all turn locks.

Screw Removal

- Attach the axial ratcheting handle to the straight driver or fixed angle driver and remove the screw by rotating the axial ratcheting handle counterclockwise until the screw can be safely removed from the surgical site. Repeat for all screws.

Cage Removal

- Reattach the cage inserter to the cage and attach either the inline handle or slap hammer, if desired, to the cage inserter and proceed to remove (Figure 24).
- If the cage is difficult to remove, additional engagement or dislodging may be achieved with the cage removal tool. To do so, thread the cage removal tool clockwise into the central hole of the cage until tightly attached and remove. Separation from the inferior and superior endplate and removal of bony ongrowth should be completed so as to limit iatrogenic damage.
- All supplemental instrumentation should be revised in accordance with its respective product technique guide.

Implant Kits

TrellOss-A SA Implant Set – 24 x 32
Kit Number: PCR400H2432

DESCRIPTION	QTY	PART NUMBER
TrellOss-A SA, 24 x 32, Implant Case	1	400H2432
TrellOss-A SA 24D x 32W x 10H, 8°	2	424H0810
TrellOss-A SA 24D x 32W x 12H, 8°	2	424H0812
TrellOss-A SA 24D x 32W x 14H, 8°	2	424H0814
TrellOss-A SA 24D x 32W x 16H, 8°	1	424H0816
TrellOss-A SA 24D x 32W x 18H, 8°	1	424H0818
TrellOss-A SA 24D x 32W x 10H, 14°	2	424H1410
TrellOss-A SA 24D x 32W x 12H, 14°	2	424H1412
TrellOss-A SA 24D x 32W x 14H, 14°	2	424H1414
TrellOss-A SA 24D x 32W x 16H, 14°	1	424H1416
TrellOss-A SA 24D x 32W x 18H, 14°	1	424H1418
TrellOss-A SA 24D x 32W x 20H, 14°	1	424H1420
TrellOss-A SA 24D x 32W x 12H, 20°	1	424H2012
TrellOss-A SA 24D x 32W x 14H, 20°	1	424H2014
TrellOss-A SA 24D x 32W x 16H, 20°	1	424H2016
TrellOss-A SA 24D x 32W x 18H, 20°	1	424H2018
TrellOss-A SA 24D x 32W x 20H, 20°	1	424H2020

TrellOss-A SA Implant Set – 27 x 36
Kit Number: PCR400H2736

DESCRIPTION	QTY	PART NUMBER
TrellOss-A SA, 27 x 36, Implant Case	1	400H2736
TrellOss-A SA 27D x 36W x 10H, 8°	2	427H0810
TrellOss-A SA 27D x 36W x 12H, 8°	2	427H0812
TrellOss-A SA 27D x 36W x 14H, 8°	2	427H0814
TrellOss-A SA 27D x 36W x 16H, 8°	1	427H0816
TrellOss-A SA 27D x 36W x 18H, 8°	1	427H0818
TrellOss-A SA 27D x 36W x 10H, 14°	2	427H1410
TrellOss-A SA 27D x 36W x 12H, 14°	2	427H1412
TrellOss-A SA 27D x 36W x 14H, 14°	2	427H1414
TrellOss-A SA 27D x 36W x 16H, 14°	1	427H1416
TrellOss-A SA 27D x 36W x 18H, 14°	1	427H1418
TrellOss-A SA 27D x 36W x 20H, 14°	1	427H1420
TrellOss-A SA 27D x 36W x 12H, 20°	1	427H2012
TrellOss-A SA 27D x 36W x 14H, 20°	1	427H2014
TrellOss-A SA 27D x 36W x 16H, 20°	1	427H2016
TrellOss-A SA 27D x 36W x 18H, 20°	1	427H2018
TrellOss-A SA 27D x 36W x 20H, 20°	1	427H2020

TrellOss-A SA Implant Set – 30 x 40
Kit Number: PCR400H3040

DESCRIPTION	QTY	PART NUMBER
TrellOss-A SA, 30 x 40, Implant Case	1	400H3040
TrellOss-A SA 30D x 40W x 10H, 8°	2	430H0810
TrellOss-A SA 30D x 40W x 12H, 8°	2	430H0812
TrellOss-A SA 30D x 40W x 14H, 8°	2	430H0814
TrellOss-A SA 30D x 40W x 16H, 8°	1	430H0816
TrellOss-A SA 30D x 40W x 18H, 8°	1	430H0818
TrellOss-A SA 30D x 40W x 10H, 14°	2	430H1410
TrellOss-A SA 30D x 40W x 12H, 14°	2	430H1412
TrellOss-A SA 30D x 40W x 14H, 14°	2	430H1414
TrellOss-A SA 30D x 40W x 16H, 14°	1	430H1416
TrellOss-A SA 30D x 40W x 18H, 14°	1	430H1418
TrellOss-A SA 30D x 40W x 20H, 14°	1	430H1420
TrellOss-A SA 30D x 40W x 14H, 20°	1	430H2014
TrellOss-A SA 30D x 40W x 16H, 20°	1	430H2016
TrellOss-A SA 30D x 40W x 18H, 20°	1	430H2018
TrellOss-A SA 30D x 40W x 20H, 20°	1	424H2020

TrellOss-A SA Hyperlordotic Implant Set*
Kit Number: PCR400H2500

DESCRIPTION	QTY	PART NUMBER
TrellOss-A SA, Hyperlordotic Implant Case	1	400H2500
TrellOss-A SA 24D x 32W x 14H, 25°	1	425H2414
TrellOss-A SA 24D x 32W x 16H, 25°	1	425H2416
TrellOss-A SA 24D x 32W x 18H, 25°	1	425H2418
TrellOss-A SA 24D x 32W x 20H, 25°	1	425H2420
TrellOss-A SA 27D x 36W x 14H, 25°	1	425H2714
TrellOss-A SA 27D x 36W x 16H, 25°	1	425H2716
TrellOss-A SA 27D x 36W x 18H, 25°	1	425H2718
TrellOss-A SA 27D x 36W x 20H, 25°	1	425H2720
TrellOss-A SA 30D x 40W x 14H, 25°	1	425H3014
TrellOss-A SA 30D x 40W x 16H, 25°	1	425H3016
TrellOss-A SA 30D x 40W x 18H, 25°	1	425H3018
TrellOss-A SA 30D x 40W x 20H, 25°	1	425H3020

**Must order PCR400H1001 Hyperlordotic Trial Caddy*

TrellOss-A SA Screws
Kit Number: PCR400H5055

DESCRIPTION	QTY	PART NUMBER
TrellOss-A SA Screw Case	1	400H5055
TrellOss-A SA Screw 5.0 x 20 mm	6	405H5020
TrellOss-A SA Screw 5.0 x 25 mm	7	405H5025
TrellOss-A SA Screw 5.0 x 30 mm	7	405H5030
TrellOss-A SA Screw 5.0 x 35 mm	4	405H5035
TrellOss-A SA Screw 5.5 x 20 mm	4	405H5520
TrellOss-A SA Screw 5.5 x 25 mm	4	405H5525
TrellOss-A SA Screw 5.5 x 30 mm	4	405H5530
TrellOss-A SA Screw 5.5 x 35 mm	4	405H5535

Screw Overview

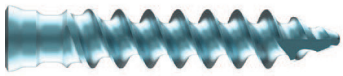
SA ALIF, Ø5.0 x 20 mm Screw	PART NUMBER
	405H5020

SA ALIF, Ø5.5 x 20 mm Screw	PART NUMBER
	405H5520

SA ALIF, Ø5.0 x 25 mm Screw	PART NUMBER
	405H5025

SA ALIF, Ø5.5 x 25 mm Screw	PART NUMBER
	405H5525

SA ALIF, Ø5.0 x 30 mm Screw	PART NUMBER
	405H5030



SA ALIF, Ø5.5 x 20 mm Screw	PART NUMBER
	405H5530

SA ALIF, Ø5.0 x 35 mm Screw	PART NUMBER
	405H5035

SA ALIF, Ø5.5 x 25 mm Screw	PART NUMBER
	405H5535

Instrument Kits

TrellOss-A SA Instrument Kit 1
Kit Number: PCR400H1000

DESCRIPTION	QTY	PART NUMBER
TrellOss-A SA Interbody and Trial Case	1	400H1000
TrellOss-A SA Interbody and Trial Tray	1	400H1100
TrellOss Case Lid	1	400H1101
TrellOss Inserter Release Tool	1	431H0001
TrellOss Thumb Wheel Rotator	1	431H0016
TrellOss-A SA Straight Inserter	2	431H0002
TrellOss-A SA Oblique Inserter	2	431H0003
TrellOss-A SA Angled Inserter	2	431H0004
TrellOss-A SA Trial Inserter	2	431H0005
T-Handle Silicone Hudson Connect	2	231M0001
TrellOss-A SA Implant Remover	1	431H0007
TrellOss-A SA Tamp	1	431H0008
TrellOss-A SA Annulotomy Template, 32 mm	1	431H0009
TrellOss-A SA Annulotomy Template, 36 mm	1	431H0010
TrellOss-A SA Annulotomy Template, 40 mm	1	431H0011
TrellOss-A SA Annulotomy Centering Pin	1	431H0012
TrellOss-A SA 24x32 Trial Caddy Base	1	400H1200
TrellOss-A SA Trial Caddy Lid	3	400H1201
TrellOss-A SA Trial 24D x 32W x 10H, 8°	1	442H0810
TrellOss-A SA Trial 24D x 32W x 12H, 8°	1	442H0812
TrellOss-A SA Trial 24D x 32W x 14H, 8°	1	442H0814
TrellOss-A SA Trial 24D x 32W x 16H, 8°	1	442H0816
TrellOss-A SA Trial 24D x 32W x 18H, 8°	1	442H0818
TrellOss-A SA Trial 24D x 32W x 10H, 14°	1	442H1410
TrellOss-A SA Trial 24D x 32W x 12H, 14°	1	442H1412
TrellOss-A SA Trial 24D x 32W x 14H, 14°	1	442H1414
TrellOss-A SA Trial 24D x 32W x 16H, 14°	1	442H1416
TrellOss-A SA Trial 24D x 32W x 18H, 14°	1	442H1418
TrellOss-A SA Trial 24D x 32W x 20H, 14°	1	442H1420
TrellOss-A SA Trial 24D x 32W x 12H, 20°	1	442H2012
TrellOss-A SA Trial 24D x 32W x 14H, 20°	1	442H2014
TrellOss-A SA Trial 24D x 32W x 16H, 20°	1	442H2016
TrellOss-A SA Trial 24D x 32W x 18H, 20°	1	442H2018
TrellOss-A SA Trial 24D x 32W x 20H, 20°	1	442H2020

DESCRIPTION	QTY	PART NUMBER
TrellOss-A SA 27D x 36W Trial Caddy Base	1	400H1300
TrellOss-A SA Trial 27D x 36W x 10H, 8°	1	443H0810
TrellOss-A SA Trial 27D x 36W x 12H, 8°	1	443H0812
TrellOss-A SA Trial 27D x 36W x 14H, 8°	1	443H0814
TrellOss-A SA Trial 27D x 36W x 16H, 8°	1	443H0816
TrellOss-A SA Trial 27D x 36W x 18H, 8°	1	443H0818
TrellOss-A SA Trial 27D x 36W x 10H, 14°	1	443H1410
TrellOss-A SA Trial 27D x 36W x 12H, 14°	1	443H1412
TrellOss-A SA Trial 27D x 36W x 14H, 14°	1	443H1414
TrellOss-A SA Trial 27D x 36W x 16H, 14°	1	443H1416
TrellOss-A SA Trial 27D x 36W x 18H, 14°	1	443H1418
TrellOss-A SA Trial 27D x 36W x 20H, 14°	1	443H1420
TrellOss-A SA Trial 27D x 36W x 12H, 20°	1	443H2012
TrellOss-A SA Trial 27D x 36W x 14H, 20°	1	443H2014
TrellOss-A SA Trial 27D x 36W x 16H, 20°	1	443H2016
TrellOss-A SA Trial 27D x 36W x 18H, 20°	1	443H2018
TrellOss-A SA Trial 27D x 36W x 20H, 20°	1	443H2020
TrellOss-A SA 30D x 40W Trial Caddy Base	1	400H1400
TrellOss-A SA Trial 30D x 40W x 10H, 8°	1	444H0810
TrellOss-A SA Trial 30D x 40W x 12H, 8°	1	444H0812
TrellOss-A SA Trial 30D x 40W x 14H, 8°	1	444H0814
TrellOss-A SA Trial 30D x 40W x 16H, 8°	1	444H0816
TrellOss-A SA Trial 30D x 40W x 18H, 8°	1	444H0818
TrellOss-A SA Trial 30D x 40W x 10H, 14°	1	444H1410
TrellOss-A SA Trial 30D x 40W x 12H, 14°	1	444H1412
TrellOss-A SA Trial 30D x 40W x 14H, 14°	1	444H1414
TrellOss-A SA Trial 30D x 40W x 16H, 14°	1	444H1416
TrellOss-A SA Trial 30D x 40W x 18H, 14°	1	444H1418
TrellOss-A SA Trial 30D x 40W x 20H, 14°	1	444H1420
TrellOss-A SA Trial 30D x 40W x 14H, 20°	1	444H2014
TrellOss-A SA Trial 30D x 40W x 16H, 20°	1	444H2016
TrellOss-A SA Trial 30D x 40W x 18H, 20°	1	444H2018
TrellOss-A SA Trial 30D x 40W x 20H, 20°	1	444H2020

TrellOss-A SA Instrument Kit 2
Kit Number: PCR400H2000

DESCRIPTION	QTY	PART NUMBER
TrellOss-A SA Instrument Case 2 Base	1	400H2000
TrellOss Case Lid	1	400H1101
TrellOss-A SA Straight Awl	1	432H0001
TrellOss-A SA Fixed Angle Awl	1	432H0002
TrellOss-A SA Straight Drill	1	432H0003
TrellOss-A SA Poly Angle Awl	1	432H0004
TrellOss-A SA Poly Angle Drill	1	432H0005
TrellOss-A SA Single Barrel Guide	1	432H0006
TrellOss-A SA Straight Driver	2	432H0007
TrellOss-A SA Poly Angle Driver	1	432H0008
TrellOss-A SA Fixed Angle Driver	1	432H0009
TrellOss-A SA Lock Tool	2	432H0010
TrellOss-A SA Ratchet T-Handle	1	432H0011
Slap Hammer	1	330H0004
Slap Hammer Adapter	1	330H0005

TrellOss-A SA Hyperlordotic Trial Caddy
Kit Number: PCR400H1001

DESCRIPTION	QTY	PART NUMBER
TrellOss-A SA 25° Hyperlordotic Trial Caddy	1	400H1500
TrellOss-A SA Hyperlordotic Trial Caddy Lid	1	400H1501
TrellOss-A SA Trial, 24D x 32W x 14H, 25°	1	445H2414
TrellOss-A SA Trial, 24D x 32W x 16H, 25°	1	445H2416
TrellOss-A SA Trial, 24D x 32W x 18H, 25°	1	445H2418
TrellOss-A SA Trial, 24D x 32W x 20H, 25°	1	445H2420
TrellOss-A SA Trial, 27D x 36W x 14H, 25°	1	445H2714
TrellOss-A SA Trial, 27D x 36W x 16H, 25°	1	445H2716
TrellOss-A SA Trial, 27D x 36W x 18H, 25°	1	445H2718
TrellOss-A SA Trial, 27D x 36W x 20H, 25°	1	445H2720
TrellOss-A SA Trial, 30D x 40W x 14H, 25°	1	445H3014
TrellOss-A SA Trial, 30D x 40W x 16H, 25°	1	445H3016
TrellOss-A SA Trial, 30D x 40W x 18H, 25°	1	445H3018
TrellOss-A SA Trial, 30D x 40W x 20H, 25°	1	445H3020

Instrument Overview

Straight Inserter PART NUMBER 431H0002

Self-Guided Straight Awl PART NUMBER 432H0001

Oblique Inserter PART NUMBER 431H0003

Self-Guided Straight Drill PART NUMBER 432H0003

Self-Guided Angled Awl PART NUMBER 432H0002

Straight Driver, T20 PART NUMBER 432H0007

Turn Lock Tool PART NUMBER 432H0010

Slap Hammer PART NUMBER 432H0012

Cage Remover PART NUMBER 431H0007

Tamp PART NUMBER 431H0008

Angled Inserter PART NUMBER 431H0004

Fixed Angle Driver PART NUMBER 432H0009

Ratchet T-Handle	PART NUMBER
	432H0011

Annulotomy Template, 32mm	PART NUMBER
32 mm	431H0009
36 mm	431H0010
40 mm	431H0011

Single Barrel Awl Guide	PART NUMBER
	432H0006

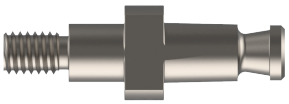
Poly Angle Driver	PART NUMBER
	432H0008

T-Handle Silicone Hudson Connect	PART NUMBER
	231M001

Annulotomy Centering Pin	PART NUMBER
	431H0012

Poly Angle Awl	PART NUMBER
	432H0004

Poly Angle Drill	PART NUMBER
	432H0005



Slap Hammer Adapter	PART NUMBER
	432H0013

Thumb Wheel Rotator	PART NUMBER
	432H0016

Important Information on TrellOss-A SA Porous Ti Interbody System

Device Description

TrellOss-A SA Porous Ti Interbody System is a collection of additively manufactured implants. The TrellOss-A SA Porous Ti Interbody System implants include additively manufactured spacers and traditionally machined fixation screws. 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 incorporates a vertical cavity which can be packed with bone graft material. Each interbody is preassembled with turn lock mechanisms which secure the screws to the spacer component.

Materials

TrellOss-A SA Porous Ti Interbody System spacers are manufactured from Ti-6Al-4V ELI titanium alloy per ASTM F3001. The fixation screws and turn lock subcomponents are manufactured from Ti- 6Al-4V ELI titanium alloy per F136.

Indications for Use

The TrellOss-A SA Porous Ti Interbody System is a stand-alone anterior lumbar interbody fusion system intended for use as an adjunct to fusion at one or two contiguous levels (L2-S1) in skeletally mature patients for the treatment of degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels and should have received at least six months of nonoperative treatment prior to treatment with the device. The TrellOss-A 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. Hyperlordotic interbody devices (>20° lordosis) must be used with supplemental fixation (e.g. posterior fixation). Each interbody fusion device having a lordotic angle 20° or less is intended to be used with the bone screws provided and requires no additional fixation.

Contraindications

The TrellOss-A 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, 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.
- Prior fusion at the level(s) to be treated.
- Any condition not described in the Indications for Use.

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-A 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 reimplanted regardless of an apparent undamaged condition.
- The TrellOss-A 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 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

MRI Safety Information

The TrellOss-A SA Porous Ti Interbody System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the TrellOss-A SA Porous Ti Interbody System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

For more information visit ZimVie.com

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