Stronghold™ T

3D Titanium Interbody Device

SURGICAL TECHNIQUE

SpineWave

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STRONGHOLD™ T 3D TITANIUM INTERBODY DEVICE DEISGN RATIONALE

Featuring
TiCell™ 3D
Advanced Surface Technology

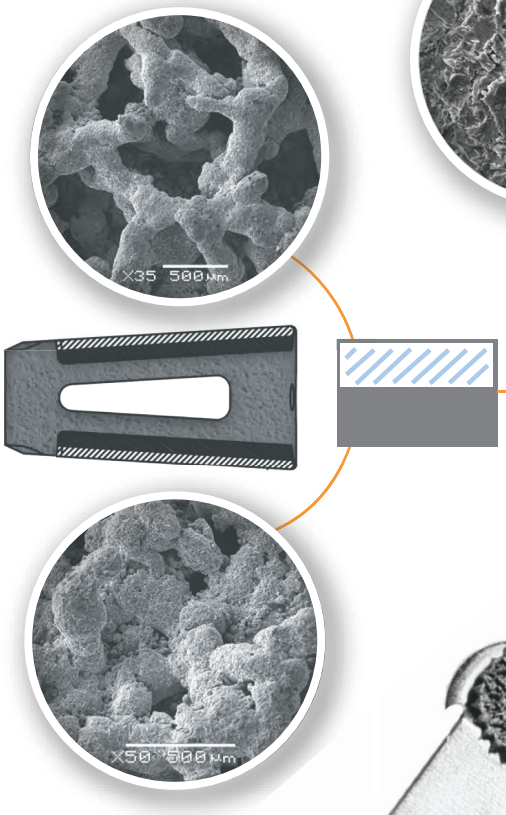
Dual Layer Organic Lattice Structure

Based on literature, 200 µm pore size is more suitable for earlier osseointergration, and 300 µm pore size supports lamellar bone formation (see Figure 1).*[27]

Surface Roughness with Peaks and Valleys

A surface roughness between 1-20 µm on the main body of the implant both on the outside and the inside where the bone graft is packed. A study showed, micro-rough Ti surfaces of the 1-3 µm range may contribute effectively to osteogenic differentiation and proliferation (see Figure 2).*[8]

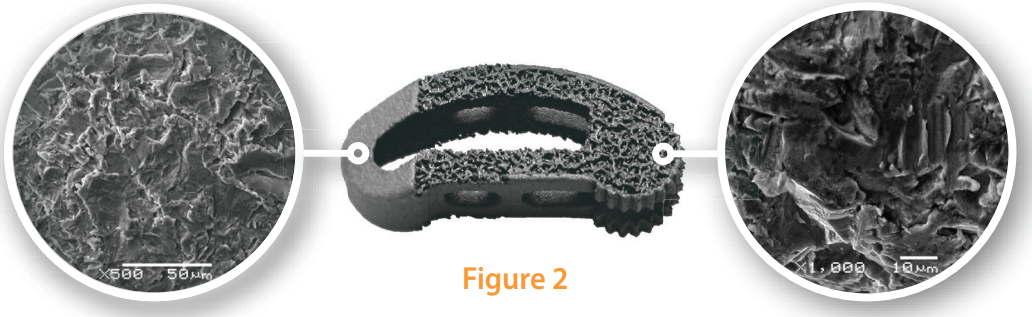
Figure 1

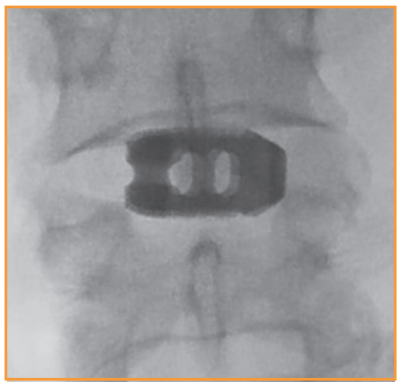


Outer Layer:
0.5 mm pores ranging from 600-1000 µm.

Inner Layer:
0.5 mm pores ranging from 50-500 µm.

Figure 2





Open Architecture

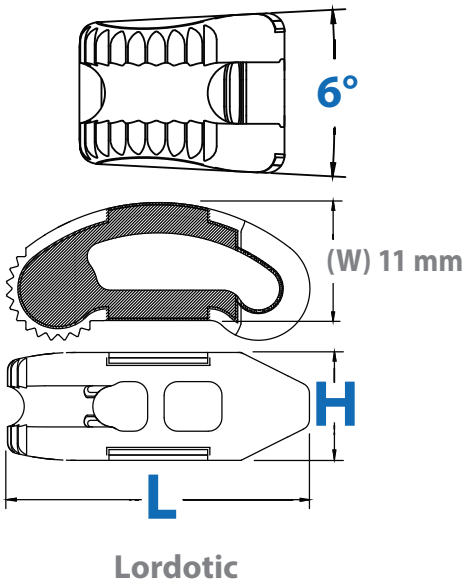
Open architecture designed to maximize grafting and reduce radiographic presence for clear imaging.

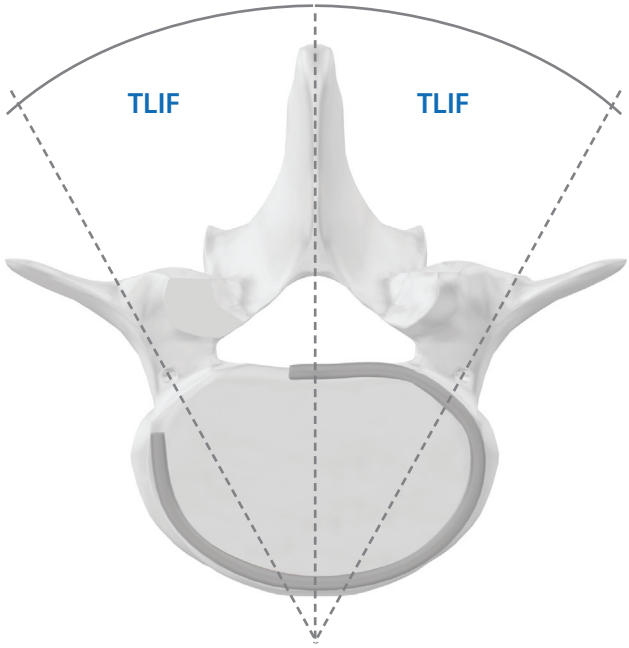
*Citations on file and available upon request

Stronghold™ T

3D Titanium Interbody Device

- Length (L): 30 mm
- Heights (H) ranging from 8-14 mm (1 mm increments)
- TLIF Curved Lordotic Width (W): 11 mm
- Lordosis: 6°





A Note for Physicians:

As with any Transforaminal Lumbar Interbody Fuison (TLIF) procedure, proper imaging and interpretation of the images are critical for safety. This technique describes suggested parameters for instrument trajectory selection, but does not purport to teach radiographic image interpretation. These instructions are intended as an outline for the use of the Stronghold™ T Interbody Device System, for physicians experienced in interpreting fluoroscopic images of the sacroiliac and in image-guided instrument placement.

STEP 1 PREOPERATIVE

Preoperative planning is recommended for the precise identification and selection of the Stronghold™ T 3D Titanium Cage. Determine an approximation for the implant height by measuring a lateral radiograph of a healthy disc space (see Figure 3).

The implant must be firmly seated with a secure fit between the endplates when the segment is fully distracted. It is essential to use the tallest possible implant to maximize segmental stability, as determined by the preoperative planning (see Figure 4).

Due to variations in radiographic magnification, the radiograph measurements only provide an estimate of the ideal implant size.

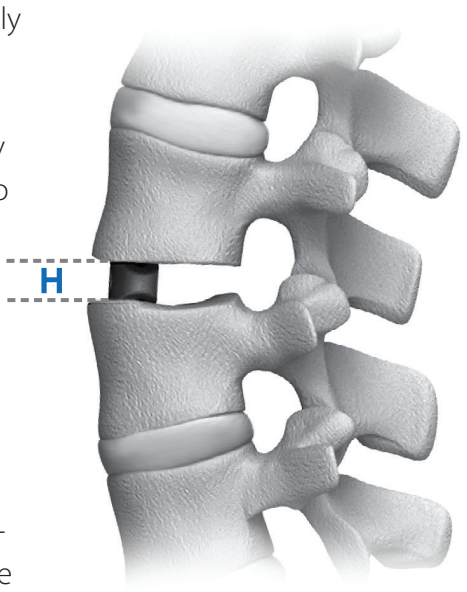


Figure 3

Figure 4

STEP 2 PATIENT POSITIONING

The patient is positioned prone on a lumbar frame that promotes suitable exposure and restores sagittal alignment (see Figure 5).

Intraoperative radiographic equipment can aid in confirming the precise position of the implant and minimize surgical exposure.

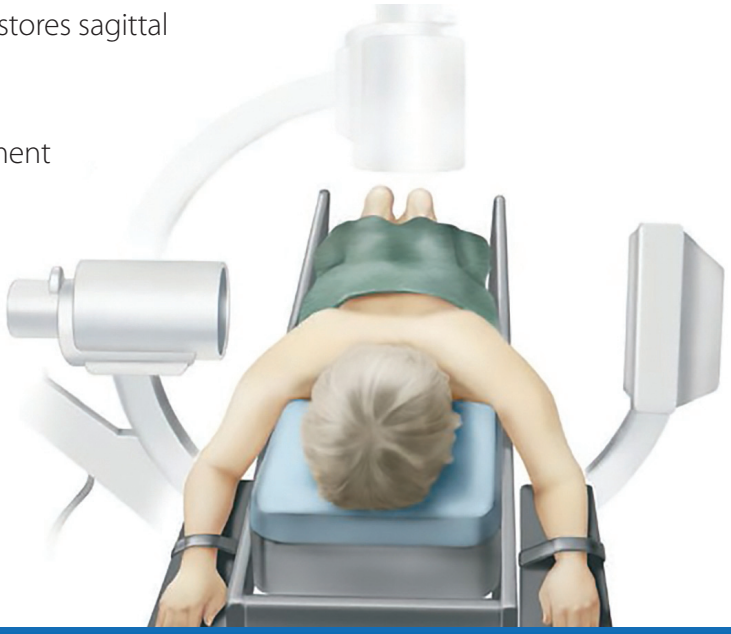


Figure 5

STEP 3 MAKE INCISION

Incise and identify anatomical landmarks. Locate the facets, pars interarticularis, lamina, spinous processes, and transverse processes (see Figure 6).

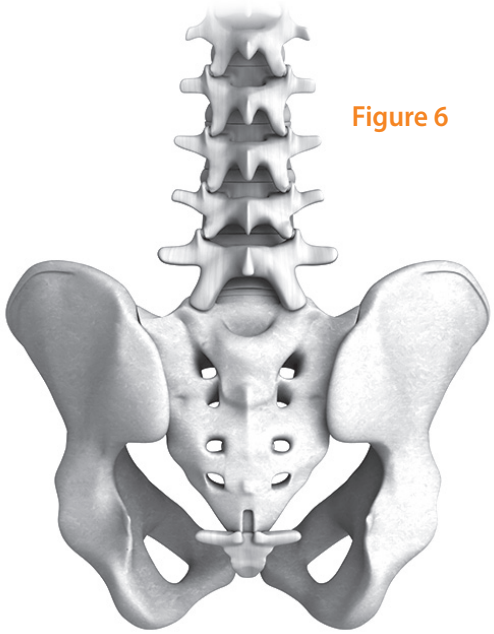


Figure 6

STEP 4 DISTRACT

Place the lamina spreader at the base of the spinous processes of the appropriate levels and apply distraction. This maneuver temporarily opens the posterior disc space and promotes increased exposure for both decompression and delivery of the implant.

STEP 5 CREATING THE TRANSFORAMINAL WINDOW

Remove the inferior facet of the cranial vertebra and the superior facet of the caudal vertebra of the appropriate levels (see Figure 7).

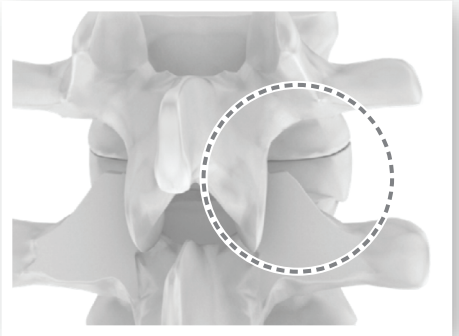


Figure 7

STEP 6 PERFORMING DISCECTOMY

Standard procedures should be taken when performing a discectomy upon surgeon preferences. Remove disc material from the intervertebral disc space using curettes.

The anterior and lateral walls of the annulus must be preserved to provide additional support for the implant (see Figure 8).

Additional distraction may be applied at this time.

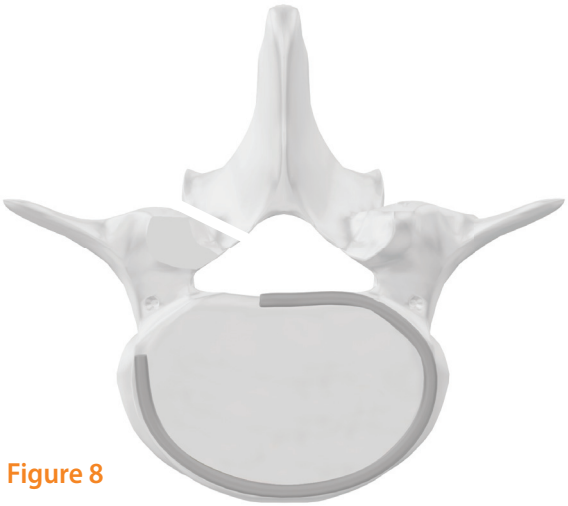


Figure 8

STEP 7A PREPARING ENDPLATES

After the discectomy is complete, remove the superficial layers of the entire cartilaginous endplates and expose bleeding bone. The superficial layers of the cartilaginous endplates are removed in order to promote bone growth and ultimately fusion of the vertebral. Excessive removal of subchondral bone may weaken the vertebral endplate. If the entire endplate is removed, subsidence and a loss of segmental stability may result.

STEP 7B PREPARING ENDPLATES (USING REAMERS)

The reamers are used to open the intervertebral space to allow placement of implants to maintain proper vertebral positioning. The reamers are used to loosen or remove disc material from the endplate. They come in a progression of sizes from 7 mm to 14 mm allowing the space to be gradually increased.

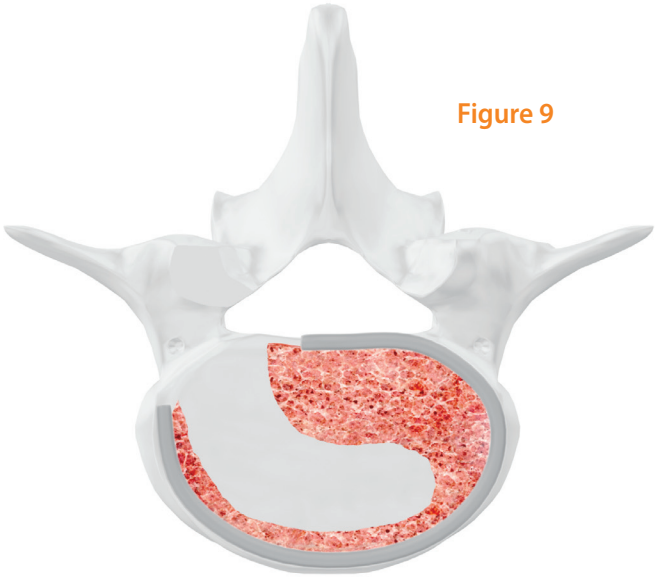
Note: *A full list of Reamers is available on page 15*

STEP 8 PREPARING INTERVERTEBRAL DISC SPACE

Prior to placement of the implant, autogenous cancellous bone should be placed in the anterior and lateral aspects of the intervertebral disc space (see Figure 9).

A bone funnel (Cat. #SW19319-2000) and bone funnel pusher (Cat. #SW19319-2001) may aid in the delivery of the graft.

Figure 9

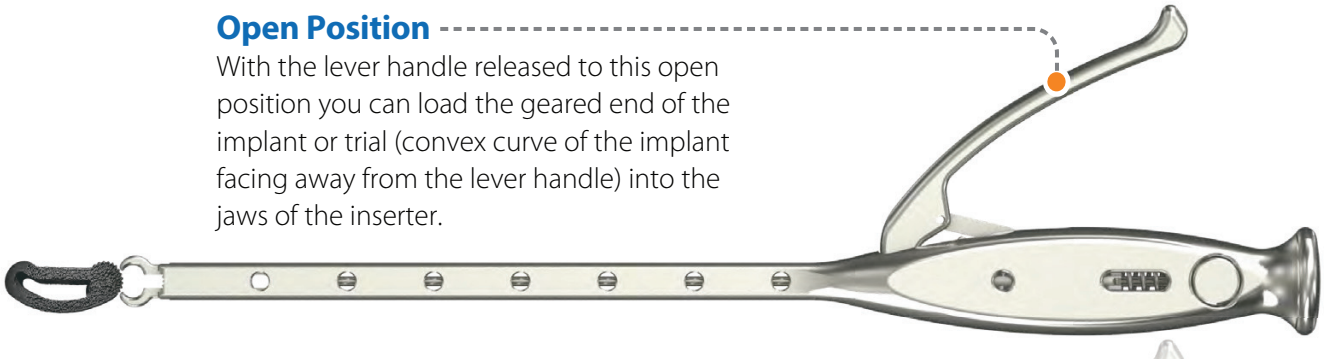


STRONGHOLD™ T PIVOTEC INSERTER OPERATION/IMPLANT ATTACHMENT

The Stronghold™ T Pivotec Inserter (Cat. #SW-PI-0100), connects to the implant or trial through a two-step grip action. The pictures below illustrate the inserter/implant assembly.

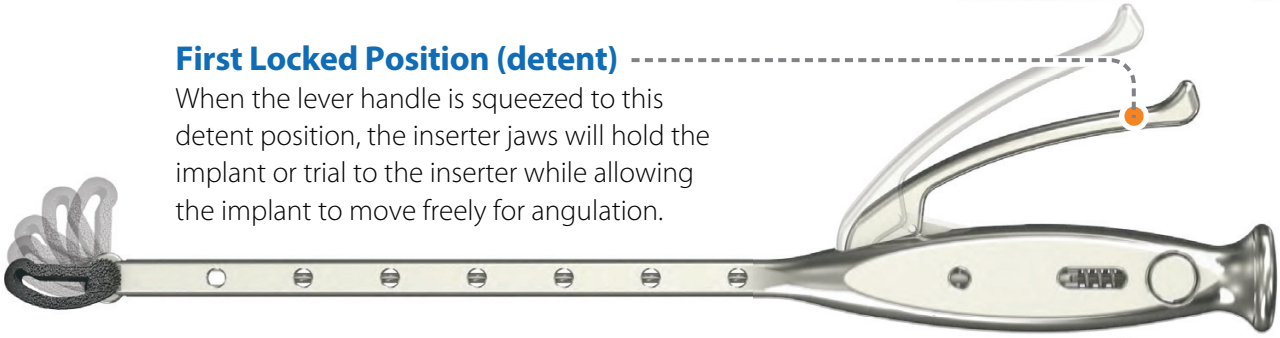
Open Position

With the lever handle released to this open position you can load the geared end of the implant or trial (convex curve of the implant facing away from the lever handle) into the jaws of the inserter.



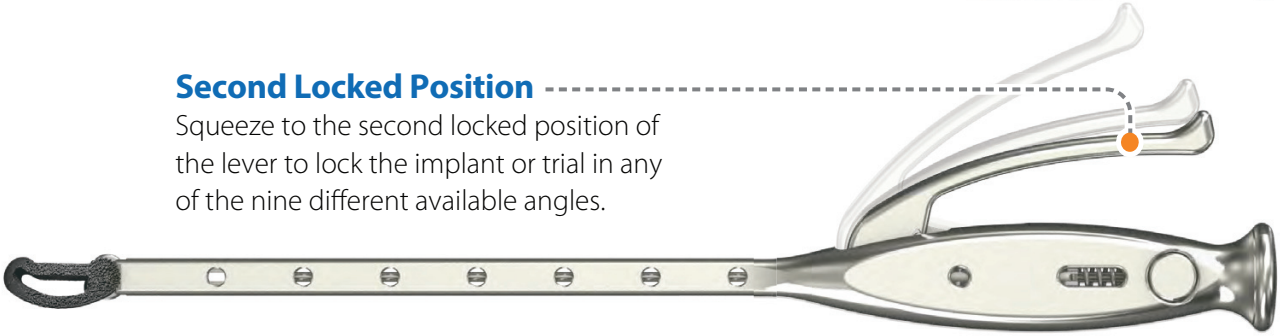
First Locked Position (detent)

When the lever handle is squeezed to this detent position, the inserter jaws will hold the implant or trial to the inserter while allowing the implant to move freely for angulation.



Second Locked Position

Squeeze to the second locked position of the lever to lock the implant or trial in any of the nine different available angles.



To change the angle of the implant without releasing the implant from the inserter, push the lever handle away from the second locked position back to the first locked position (see above "Second Locked Position" and "First Locked Position").

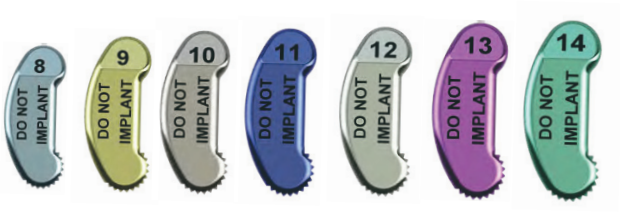
To release the inserter from the implant, press the release button on distal end of the inserter while in the detent position (see Figure 10).

Figure 10

STEP 9 DETERMINING IMPLANT SIZE

Select an appropriately-sized trial and attach to the Stronghold™ T Pivotec Inserter. Insert the trial into the intervertebral disc space using gentle impaction (see Figure 11).

Fluoroscopy can assist in confirming the fit and geometry of the trial spacer. If the trial spacer appears too small or too tight, try the next larger or smaller size until the most secure fit is achieved.



Select an implant that corresponds to the trial spacer height and remove the trial spacer.

Note: *To remove the trial, it may be necessary to use the slap hammer (Cat. #SW99301-0000) to back the trial out of the disc space. (See page 15)*

Note: *A full list of trials is available on page 16.*

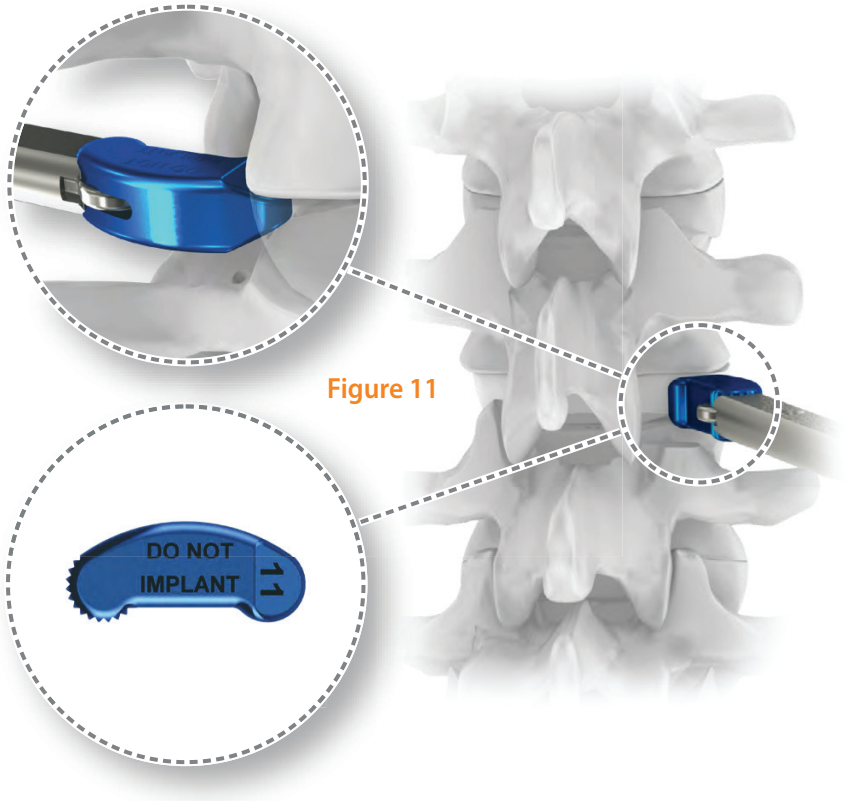
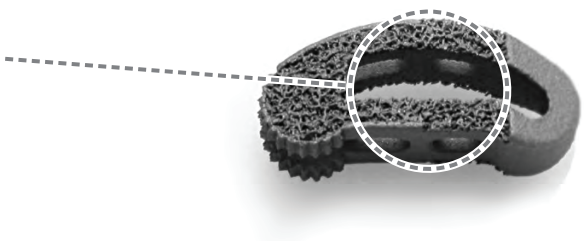


Figure 11

STEP 10 PREPARE IMPLANT BEFORE INSERTION

Pack the internal cavities of the implant with autogenous cancellous bone.



STEP 11 IMPLANT INSERTION

Introduce the implant into the intervertebral disc space, ensuring that the implant is locked in the desired orientation. It is recommended that the implant be recessed a minimum of 2 mm from the posterior edge of the vertebral body.

1. After initial insertion, to articulate the implant into position, the inserter handle may be released to the first locked position (detent) to allow for repositioning of the inserter angle to the implant
2. In this detent position, move the inserter medial
3. Reengaged the implant
4. Continue advancing implant to desired in vivo position and repeat these steps until the implant is in place (see Figure 12)

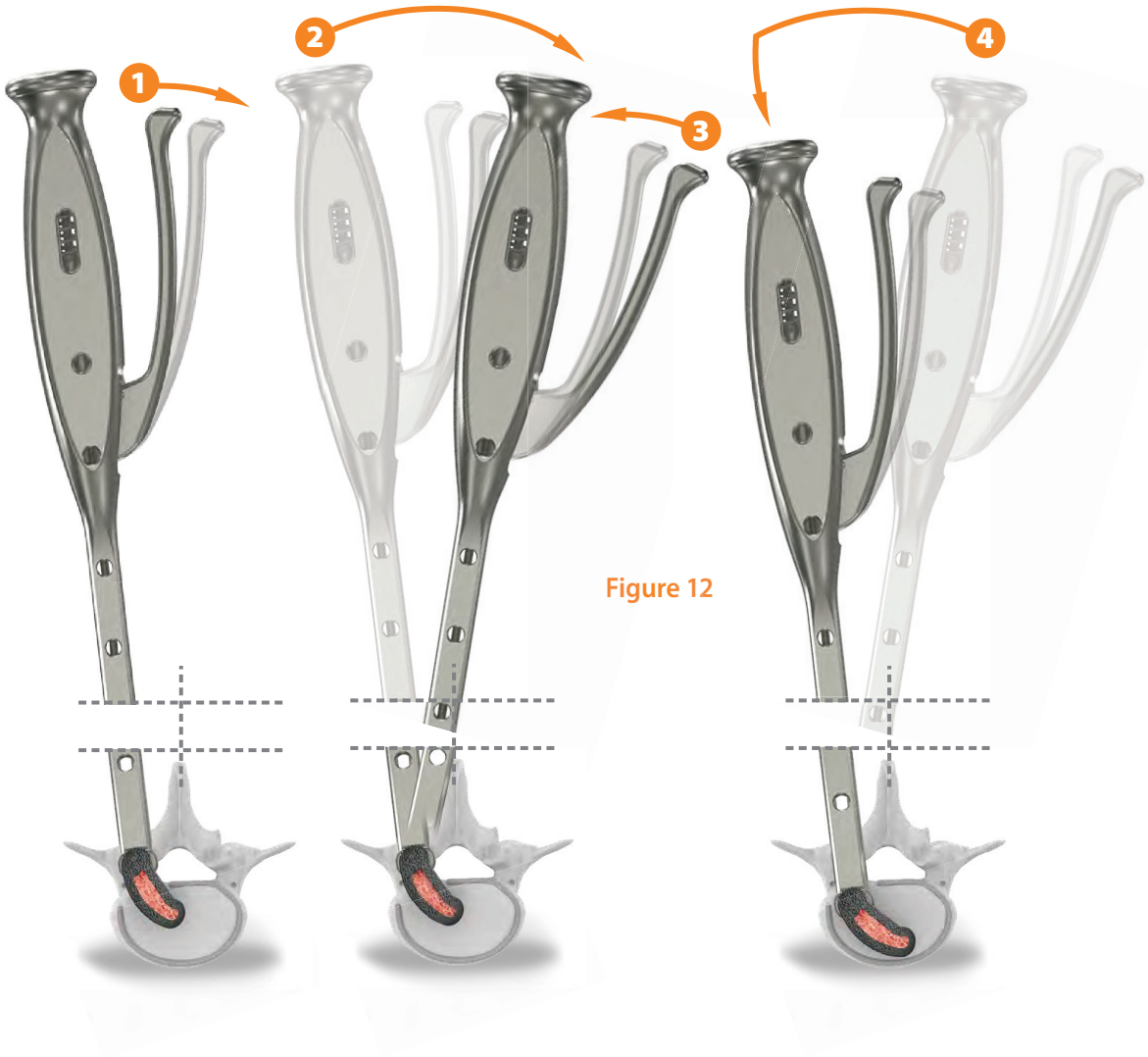


Figure 12

STEP 12 IMPLANT INSERTION (CONTINUED)

Note: The Stronghold™ T Pivotec Inserter allows you to release the cage and reengage the cage to reposition or remove.

Figure 13

To release the implant completely from the inserter, first release the handle lever to the first locked position, (detent) then depress the release button.

MALLET (IF NECESSARY)

If the implant is not in the correct orientation, a mallet can be used to slightly impact the Stronghold™ T Pivotec inserter or bone tamps (straight, Cat. #SW19319-2001 or curved, Cat. #SW19319-3000) to position the implant into the disc space as needed. In addition, the bone tamps can be used to better position the implant within the disc space. By tamping the implant at certain angles, the implant position can be adjusted. If the inserter is already removed, a bone tamp is recommended instead of the inserter (see Figure 14).

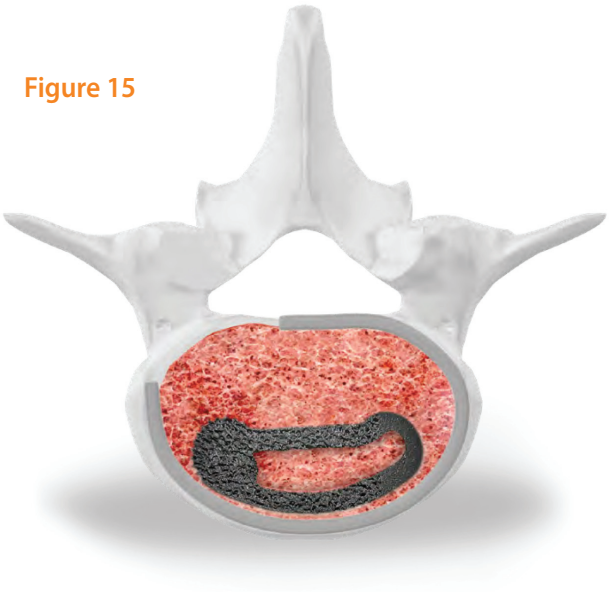
Note: *If the Pivotec inserter must be impacted, please be sure it is in the second locked postion.*

STEP 13 POST IMPLANT INSERTION

Once the implant is properly positioned and all instrumentation has been removed, the disc space may be filled with additional graft material posterior to the spacer (see Figure 15). Release of the distraction allows loading of the anterior column and restoration of sagittal alignment. Following final placement of the device, a supplemental fixation system cleared for use in the lumbar spine should be inserted. Please refer to the specific system's surgical technique manual for user instructions.

Figure 14

Figure 15



STEP 14 IMPLANT REMOVAL / REVISION

In the event the implant or trial needs to be removed, the slap hammer and Stronghold™ T Pivotec inserter may be used to remove the implant from the disc space.

Note: *When using the slap hammer, please be sure the Stronghold™ T Pivotec inserter is in the second locked position.*

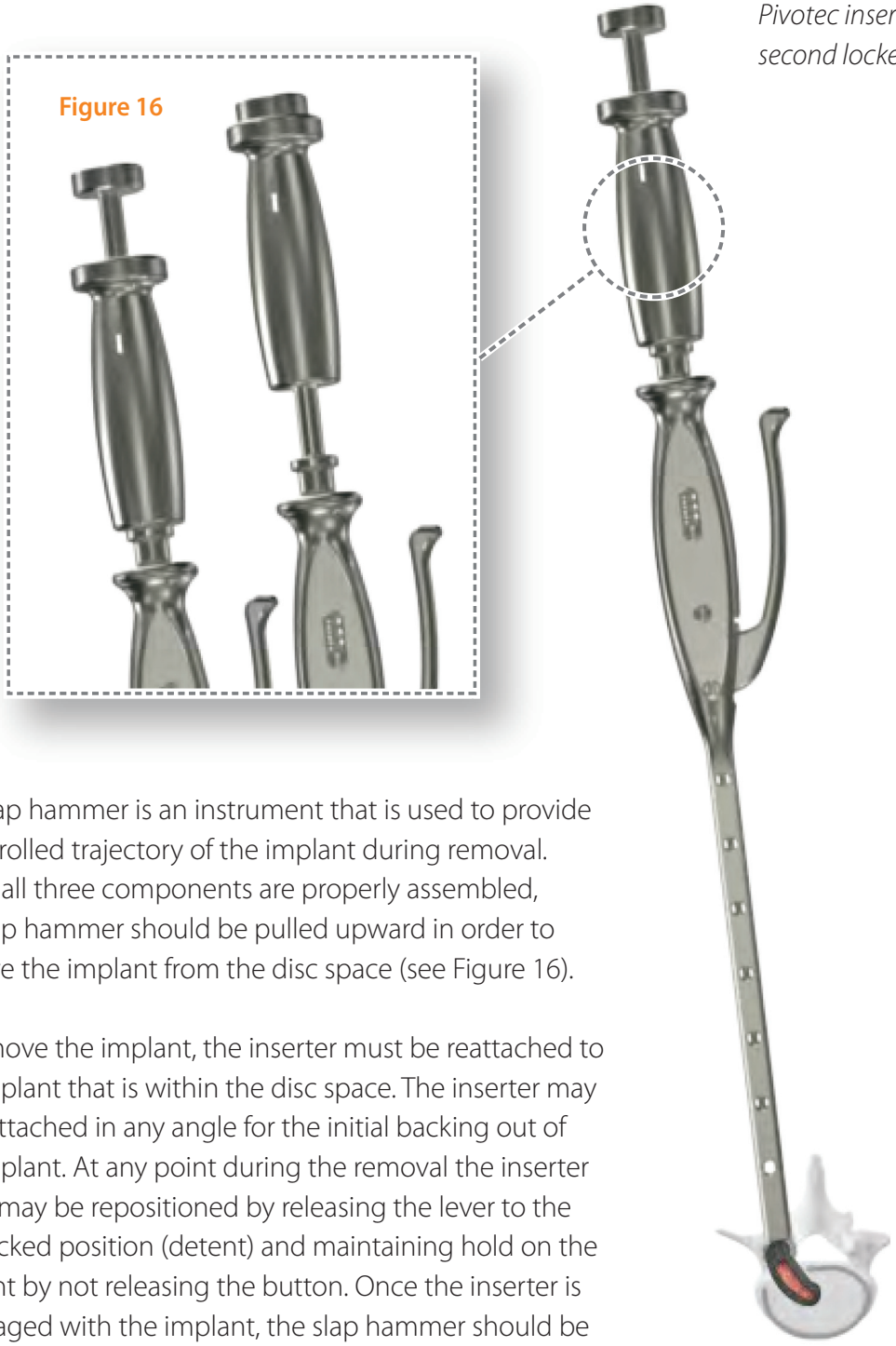


Figure 16

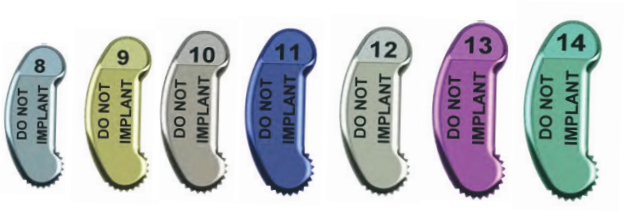
The slap hammer is an instrument that is used to provide a controlled trajectory of the implant during removal. When all three components are properly assembled, the slap hammer should be pulled upward in order to remove the implant from the disc space (see Figure 16).

To remove the implant, the inserter must be reattached to the implant that is within the disc space. The inserter may be reattached in any angle for the initial backing out of the implant. At any point during the removal the inserter angle may be repositioned by releasing the lever to the first locked position (detent) and maintaining hold on the implant by not releasing the button. Once the inserter is reengaged with the implant, the slap hammer should be threaded onto the back handle of the inserter.

STRONGHOLD™ T 3D TITANIUM INTERBODY DEVICE INSTRUMENT SET

ITEM	ITEM #	DESCRIPTION
	1 SWPI-0100	Stronghold™ T Pivotec Inserter
	2 SW99301-0000	Slap Hammer
	3 SWPI-0300	Non-Ratcheting T-Handle, 1/4" Square Connect
	4 Reamers: SW19305-0506 SW19305-0507 SW19305-0508 SW19305-0509 SW19305-0510 SW19305-0511 SW19305-0512 SW19305-0513 SW19305-0514	 Reamer H = 6 mm Reamer H = 7 mm Reamer H = 8 mm Reamer H = 9 mm Reamer H = 10 mm Reamer H = 11 mm Reamer H = 12 mm Reamer H = 13 mm Reamer H = 14 mm

INSTRUMENT SET (CONTINUED)

ITEM		ITEM #	DESCRIPTION
	5	Trials: SW19306-3008 SW19306-3009 SW19306-0010 SW19306-0011 SW19306-0012 SW19306-0013 SW19306-0514	 Trial CVD 30 x 8 mm Trial CVD 30 x 9 mm Trial CVD 30 x 10 mm Trial CVD 30 x 11 mm Trial CVD 30 x 12 mm Trial CVD 30 x 13 mm Trial CVD 30 x 14 mm
	6	SW19319-2001	Bone Tamp - Straight
	7	SW19319-3000	Curved Tamp (Not shown)
	8	SW19319-2000	Bone Funnel (Not shown)
		SW19319-2001	Bone Funnel Pusher (Not shown)

INDICATIONS FOR USE

GENERAL DESCRIPTION:

The Stronghold™ 3D Titanium Interbody Device System consists of intervertebral body fusion devices for use with autogenous bone graft in the intervertebral disc space to stabilize spinal segments and promote fusion. The Spine Wave Stronghold™ 3D Titanium Interbody Device System includes both the Stronghold™ and Stronghold™ T 3D Titanium Interbody Devices to provide multiple footprints to adapt to various patient anatomies.

Stronghold™ Lumbar Cage implants are manufactured from a Titanium Ti-6Al-4V ELI alloy powder through a Direct Metal Laser Sintering Process (3D-Printed).

These devices are provided in various configurations and heights, containing a hollow core to receive autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Placement is achieved with an insertion instrument that allows for manipulation of the implant within the intra-vertebral disc space. All implants are supplied single use only.

See the package insert for complete product information.

INDICATIONS FOR USE:

The Spine Wave Stronghold™ 3D Titanium Interbody Device System is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation and must be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The DDD patients may also have up to a Grade I spondylolisthesis or retrolisthesis at the involved level(s).

CONTRAINDICATIONS:

Including but not limited to:

- Systemic infection, infection or inflammation localized to the operative site
- Fever or leukocytosis
- Pregnancy
- Known Titanium allergy
- Rapid joint disease, bone absorption, and/or severe osteoporosis.
- Relative contraindications include conditions that preclude successful fusion (e.g., cancer, kidney dialysis, or osteopenia), foreign body sensitivity, morbid obesity, and certain degenerative diseases
- Any patient unwilling to cooperate with post-operative instructions
- Any case not described in the Indications
- Prior fusions at the level(s) to be treated

WARNINGS AND PRECAUTIONS:

- The implantation of this device should be performed only by experienced spinal surgeons with specific training in the use of this system because this is technically demanding procedure presenting a risk of serious injury to the patient.
- The following warnings and precautions should be understood by the surgeon and explained to the patient. These warnings are specific to spinal fixation implants and do not consider all adverse effects of surgery in general.
- Patient selection relative to both bone quality and stability is an important consideration for the proper application of this device. Patients who are obese, malnourished, smoke, abuse alcohol and/or other drugs are not good candidate for spinal fusion.
- Improper patient selection, implant selection, vertebral support, and/or postoperative care can result in increased stresses on the implant resulting in failure of the device. This device must be used with supplemental fixation.
- Stronghold™ 3D Titanium Interbody Device has not been evaluated for safety and compatibility in the MR environment.
- Stronghold™ 3D Titanium Interbody Device has not been tested for heating or migration in the MR environment.
- Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient condition, etc. which may impact on the performance of the device.
- Patient with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.
- Do not combine with products from other systems or manufacturers.
- Do not use with dissimilar metals e.g., titanium and stainless steel.
- Patients receiving the Stronghold™ 3D Titanium Interbody Device should have had at least six months of nonoperative treatment.
- Potential risks identified with the use of Stronghold™ 3D Titanium Interbody Device, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebrae, neurological injury, and/or vascular or visceral injury.
- Do not use if package is opened or damaged or if expiration date has passed.

SAFETY IN MRI NOT EVALUATED

The Stronghold™ 3D Titanium Interbody Device System has not been evaluated for safety and compatibility in the MR environment. The safety of the Stronghold™ Lumbar Cage implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

SPINE WAVE

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