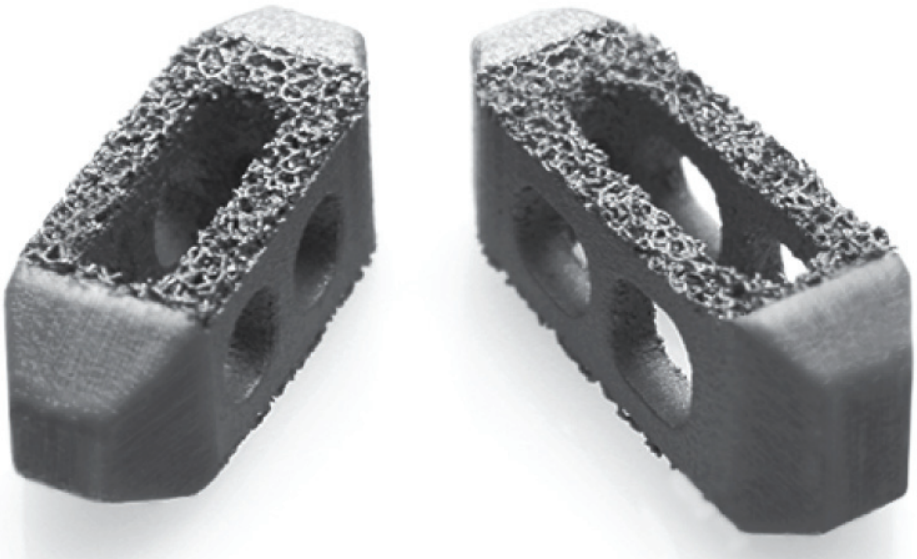
Stronghold™

3D Titanium Interbody Device

SURGICAL TECHNIQUE



SpineWave

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STRONGHOLD™ 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]

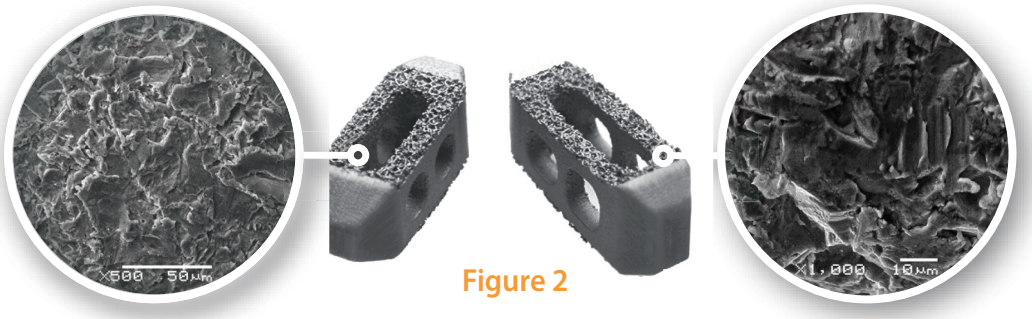
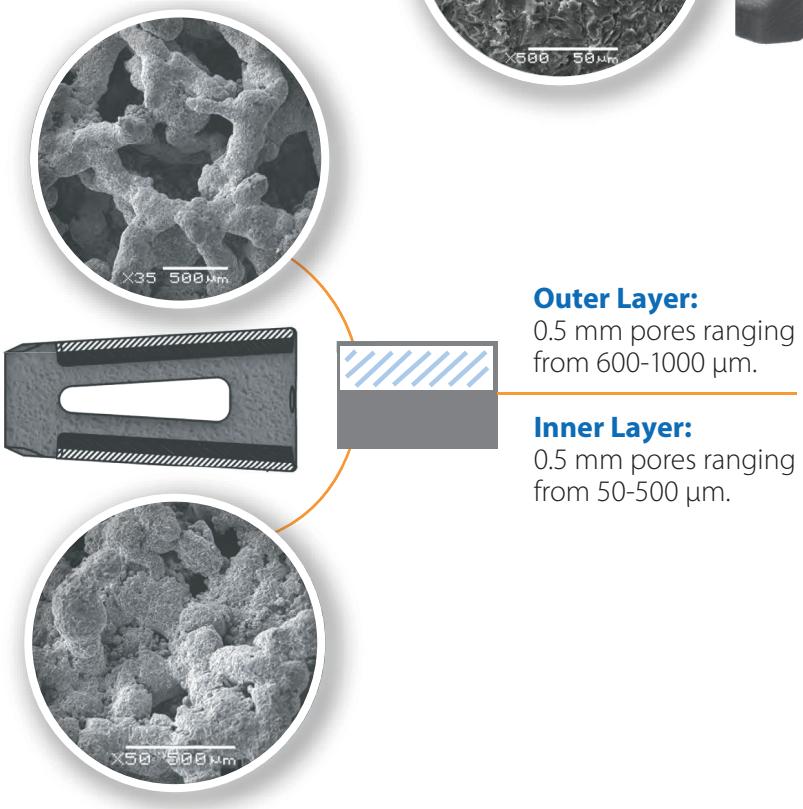


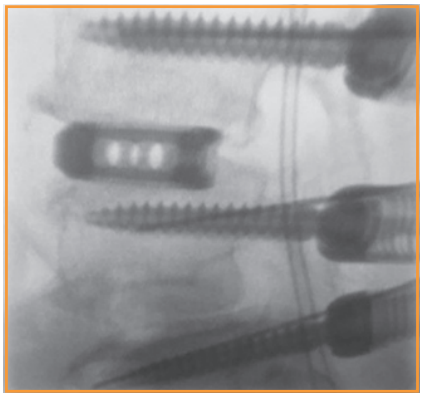
Figure 2

Figure 1



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

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



Open Architecture

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

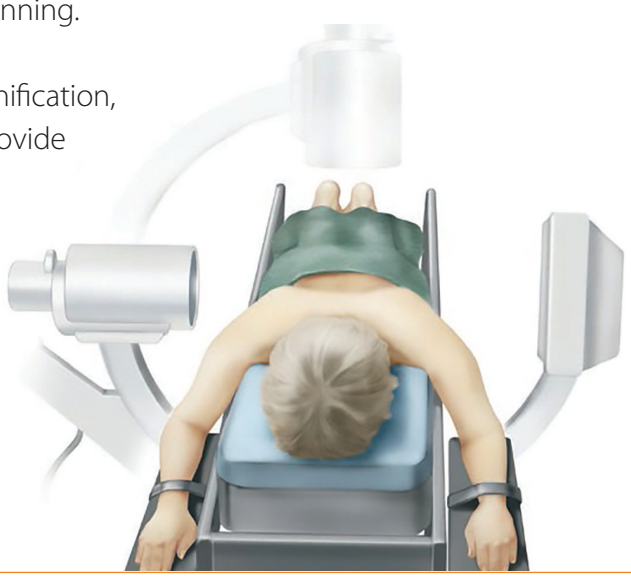
*Citations on file and available upon request

STEP 1 PRE-OPERATIVE

Preoperative planning is recommended for the selection of the Stronghold™ 3D Titanium Interbody Device. Determine an approximation for the implant height by measuring a lateral radiograph of a healthy disc space.

The implant must be firmly secured 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.

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



STEP 2 PATIENT POSITIONING

The patient is positioned prone on a lumbar frame that promotes suitable exposure and restores sagittal alignment.

STEP 3 MAKE INCISION

Incise and identify anatomical landmarks. Locate the facets, pars interarticularis, lamina, spinous processes, and transverse processes.

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 CREATE THE TRANSFORAMINAL WINDOW

Remove the inferior facet of the cranial vertebra and the superior facet of the caudal vertebra of the appropriate levels.

STEP 6 PERFORM DISCECTOMY

Standard procedures should be taken when preforming a discectomy. Remove disc material from the intervertebral disc space. The anterior and lateral walls of the annulus must be preserved to provide additional support for the implant. Additional distraction may be applied at this time.

STEP 7 PREPARE 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 vertebra. 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 8 STRONGHOLD™ IMPLANT TRIAL SELECTION AND INSERTION

The trial holder assembly (Cat.# SW19300-0200) is used to insert the trial into the disc space. Begin by selecting an appropriately sized trial and attach it to the trial holder. To attach the trial to the trial holder, align the trial to the trial holder base and thread the trial holder shaft into the trial. This will pull the trial flush with the trial holder base.

Insert the trial into the intervertebral disc space using gentle impaction.

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

Note: *A full list of trials can be found on page 13.*

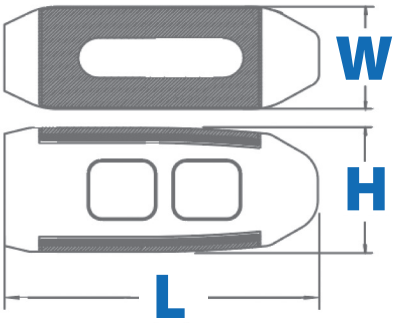
Note: *A Stronghold™ inserter handle or side handle (Cat.# SWFPT0201) is also available for the trial holder assembly.*

STEP 9 IMPLANT SELECTION

Once the appropriately sized trial is determined, select the corresponding implant. Implants have different configurations to achieve the desired sagittal alignment of the spine. Implant heights are offered in 1 mm increments to restore natural disc height.

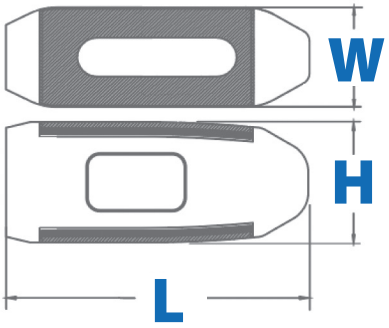
Note: *Actual height includes the texture and matches with corresponding implant trial size. Height of lordotic implant is measured at the posterior portion (closest to the inserter/implant interface) of the implant.* ***For Lordotic Implants: Anterior height (H2) is greater than posterior height (H).***

Convex (L) 25 mm/30 mm

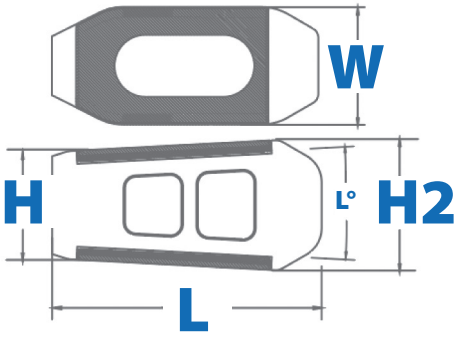


(W) Width Available: 9.5 mm
(L) Length Available: 22 mm, 25 mm, 30 mm
(H) Height Available: 7-14 mm (1 mm Increments)

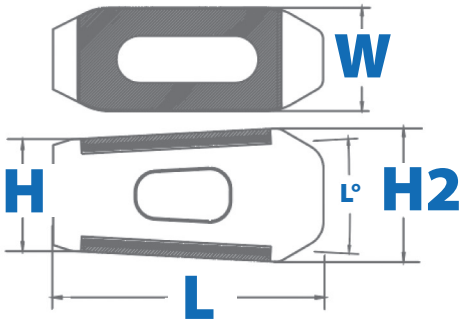
Convex (L) 22 mm



Lordotic (L) 25 mm/30 mm (L°) 6°/15°



Lordotic (L) 22 mm (L°) 6°/15°



(W) Width Available: 9.5 mm
(L) Lengths Available: 22 mm, 25 mm, 30 mm (30 mm only available in 6° Lordotic)
(H) Height Available: 7-14 mm (1mm Increments)
(L°) Lordosis Available: 6°/15°
(H2) Anterior Height

STEP 10 ASSEMBLY OF THE PLIF INSERTER 2.0 TO IMPLANT

FIGURE 3

Stronghold™ PLIF Inserter 2.0 (Cat.# SW19319-1000) and retention shaft (Cat.# SW19400-0105) (Figure 3), is used to insert the Stronghold™ 3D Titanium Interbody Device into the disc space. Attach to the Inserter.

To attach the implant to the inserter, align the implant to the inserter outer handle and thread the retention shaft into the implant. Continue threading the inserter until the implant is flush with the inserter base. (Figure 4).

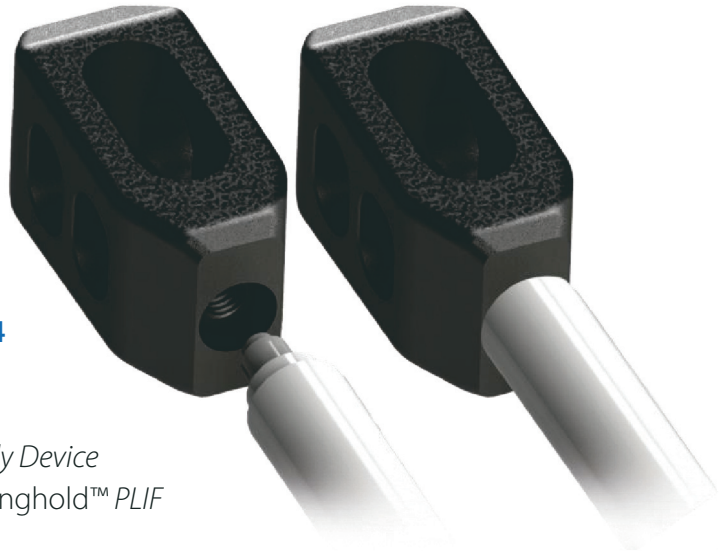


FIGURE 4

Note: *The Stronghold™ 3D Titanium Interbody Device is only to be used in conjunction with the* Stronghold™ *PLIF Inserter 2.0 (Cat.# SW19319-1000).*

STEP 11 PREPARING DISC SPACE BEFORE INSERTION

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

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

Note: *Pre-pack the graft chamber with bone graft.*

STEP 12 IMPLANT INSERTION

Introduce the implant into the intervertebral disc space, ensuring that the implant is aligned in the proper orientation. It is recommended that the implant be recessed a minimum of 2 mm from the posterior edge of the vertebral body (if necessary, a mallet is included in the set) (Figure 5). When final position is reached the implant should be released and the inserter extracted. While holding the inserter outer handle stationary, unthread the retention shaft from the implant. When removing the inserter be sure to hold both pieces (PLIF inserter 2.0 and retention shaft, Cat.# SW19400-0105).

Repeat these steps on the other side of the spine if two implants are required.

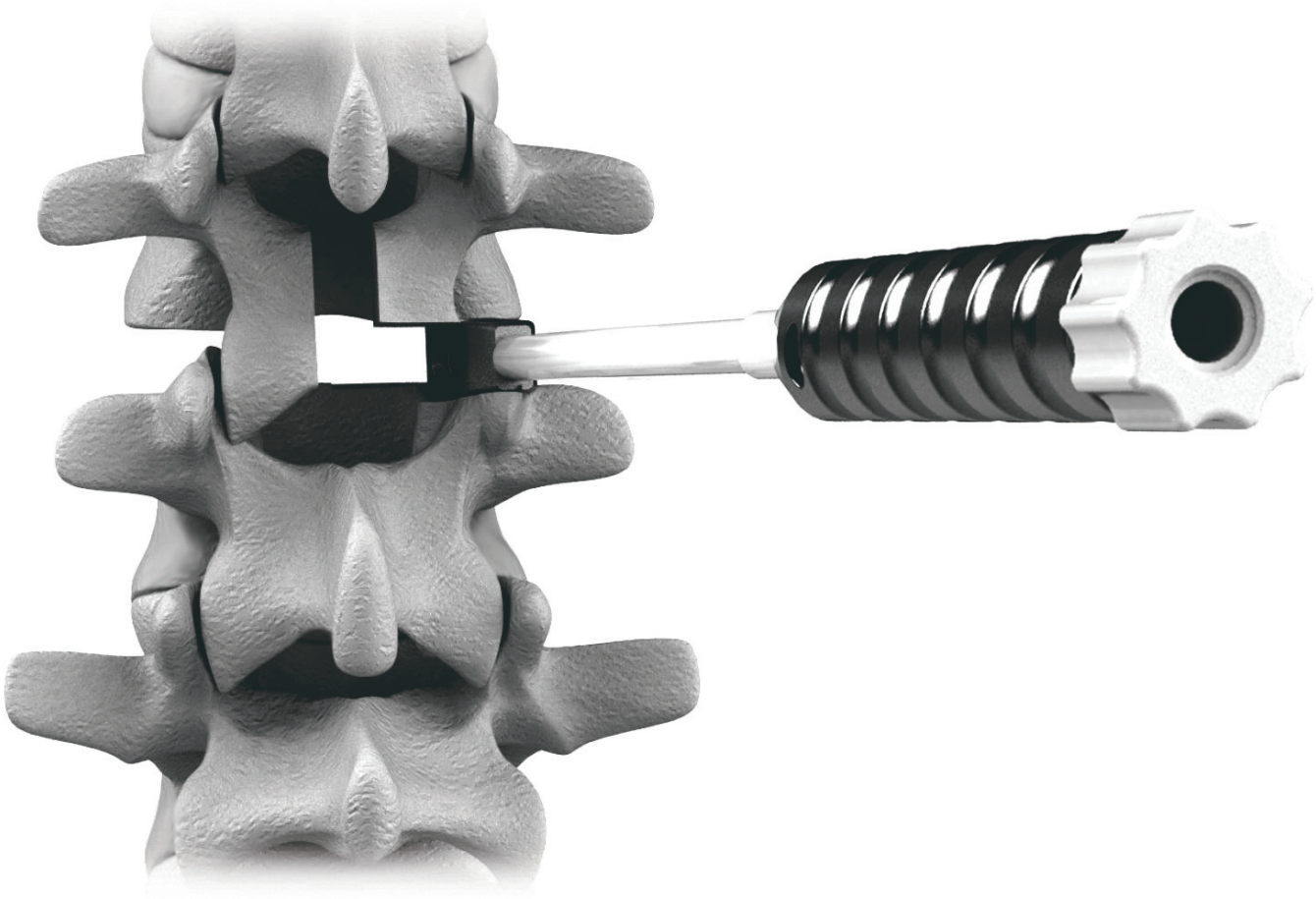


FIGURE 5

Adjusting the Position of the Implant

If the implant is not in the desired orientation, and the PLIF Inserter 2.0 is already removed, a bone tamp is recommended to adjust the implant position. There are two tamps located in the instrument set: bone tamp-curved (Cat.# SW19319-3000) or bone tamp-straight (Cat.# SW19319-2001).

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. 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.

STEP 14 IMPLANT REMOVAL/REVISION

In the event the implant needs to be removed or revised, the slap hammer (Cat.# SW99301-0000) and PLIF inserter 2.0 may be used to remove the implant from the disc space. To remove the implant, the inserter must be threaded back onto the implant that is within the disc space. Once the inserter is re-engaged with the implant, the slap hammer should be threaded onto the back handle of the inserter (Figure 5). 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.

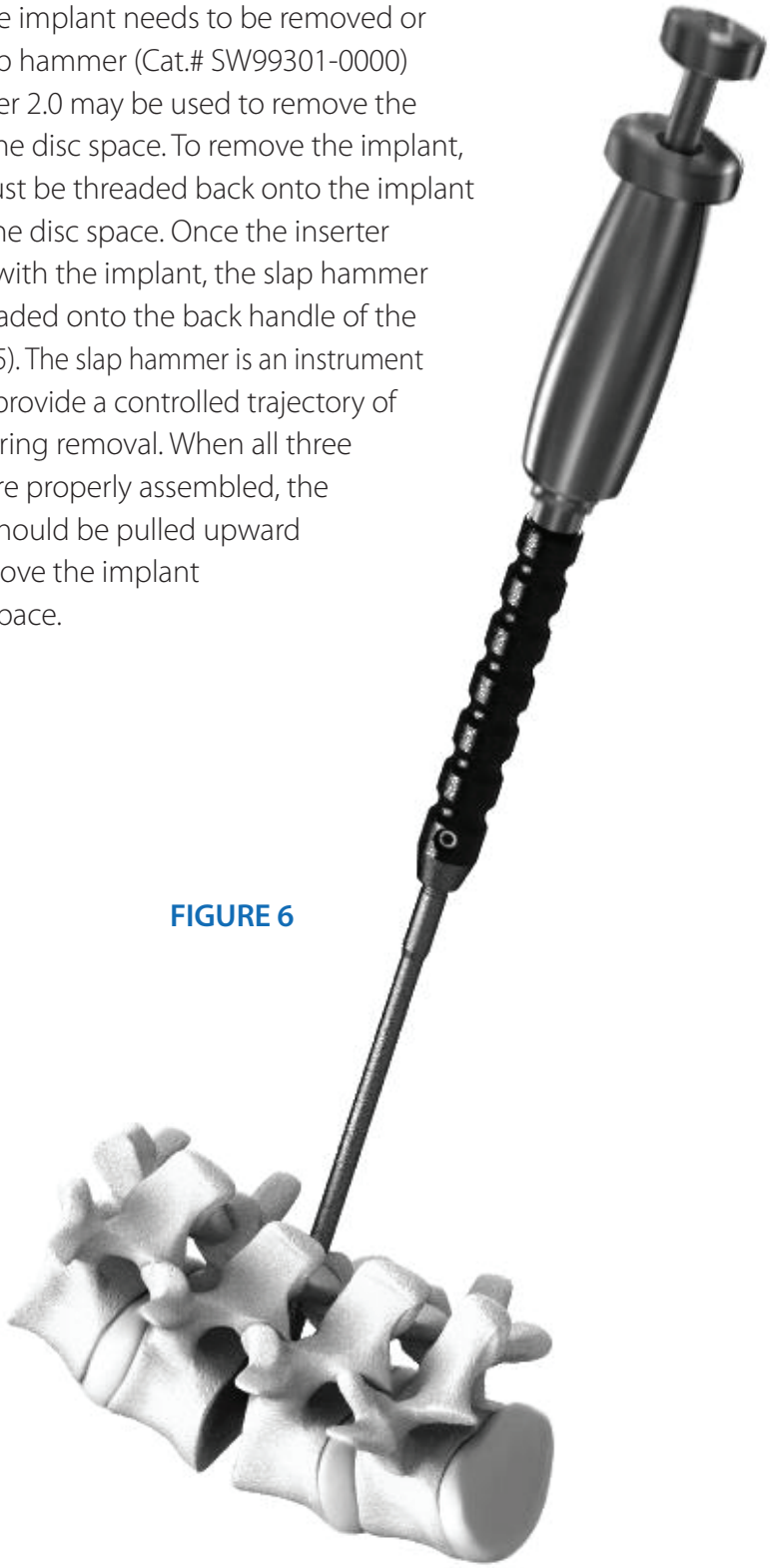


FIGURE 6

STRONGHOLD™ 3D TITANIUM INTERBODY DEVICE INSTRUMENT SET

Catalog #	Description
SW19319-1000	Stronghold™ PLIF Inserter 2.0
SW19300-0200	Stronghold™ Trial Holder Assembly
SW19400-0105	Stronghold™ Retention Shaft
SW19319-2000	Stronghold™ Bone Funnel
SW19319-2001	Stronghold™ Bone Pusher/Bone Tamp-Straight
SW19319-3000	Stronghold™ Bone Tamp-Curved
SW99301-0000	Stronghold™ Slap Hammer, Large
SWFPT0201	Stronghold™ Inserter Handle (side handle)
SWPI-0300	Stronghold™ Non-Ratcheting T-Handle, 1/4" Square Connect
SW19305-0506	Stronghold™ 6 mm Reamer
SW19305-0507	Stronghold™ 7 mm Reamer
SW19305-0508	Stronghold™ 8 mm Reamer
SW19305-0509	Stronghold™ 9 mm Reamer
SW19305-0510	Stronghold™ 10 mm Reamer
SW19305-0511	Stronghold™ 11 mm Reamer
SW19305-0512	Stronghold™ 12 mm Reamer
SW19305-0513	Stronghold™ 13 mm Reamer
SW19305-0514	Stronghold™ 14 mm Reamer

STRONGHOLD™ LUMBAR TRIALS - CONVEX

Catalog #	Description
SW19309-2207	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 22 x (H)7 mm
SW19309-2208	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 22 x (H) 8 mm
SW19309-2209	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 22 x (H) 9 mm
SW19309-2210	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 22 x (H) 10 mm
SW19309-2211	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 22 x (H) 11 mm
SW19309-2212	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 22 x (H) 12 mm
SW19309-2213	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 22 x (H) 13 mm
SW19309-2214	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 22 x (H) 14 mm
SW19309-2507	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 25 x (H) 7 mm
SW19309-2508	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 25 x (H) 8 mm
SW19309-2509	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 25 x (H) 9 mm
SW19309-2510	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 25 x (H) 10mm
SW19309-2511	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 25 x (H) 11mm
SW19309-2512	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 25 x (H) 12mm
SW19309-2513	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 25 x (H) 13 mm
SW19309-2514	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 25 x (H) 14 mm
SW19309-2807	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 30 x (H) 7 mm
SW19309-3008	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 30 x (H) 8 mm
SW19309-3009	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 30 x (H) 9 mm
SW19309-3010	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 30 x (H) 10 mm
SW19309-3011	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 30 x (H) 11 mm
SW19309-3012	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 30 x (H) 12 mm
SW19309-3013	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 30 x (H) 13 mm
SW19309-3014	Stronghold™ Lumbar Trial - Convex (W) 9.5 x (L) 30 x (H) 14 mm

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.

*Please refer to the package insert for the Stronghold™ 3D Titanium Interbody Device for more complete information regarding the StrongholdTM system.

SPINE WAVE

Three Enterprise Drive, #210
Shelton, CT 06484

877-844-4225
www.spinewave.com

Cat. #19-5676 Rev. 2/21