Stronghold® C

3D Titanium Interbody Device

SURGICAL TECHNIQUE

SpineWave

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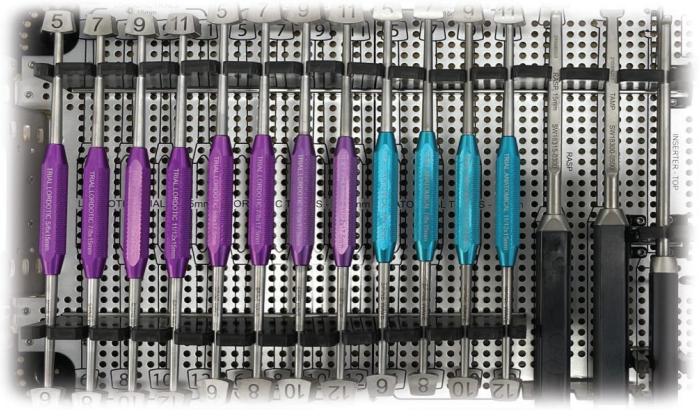
ORDERING GUIDE

Instrument Set

Catalog Number	Set
16-7102	Stronghold® C Instrument Set



Instrument Set Includes:

- Lordotic and anatomic trials without stops
- Single -sided rasp, 15 mm wide
- Tamp
- Inserter

Implant Sets

Catalog Number	Set
15-7105	Stronghold® C Anatomic Implant Set
15-7205	Stronghold® C Lordotic Implant Set

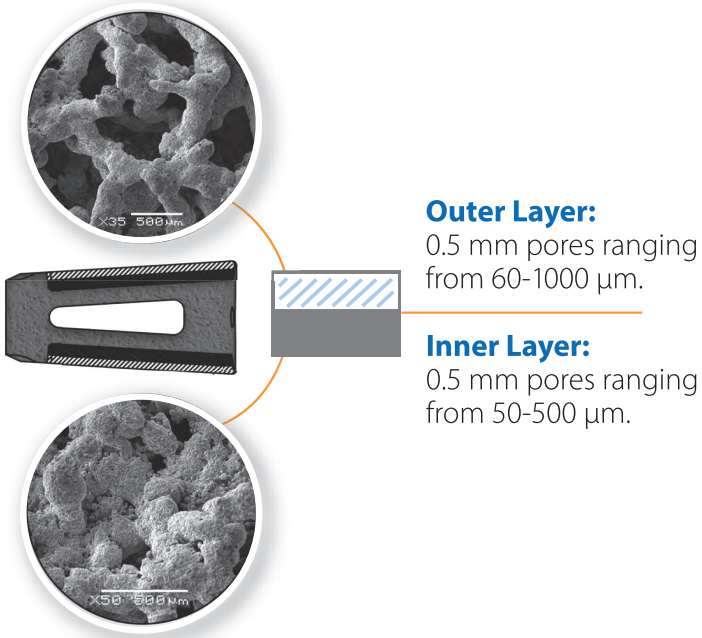
Optional Items (ship loose)

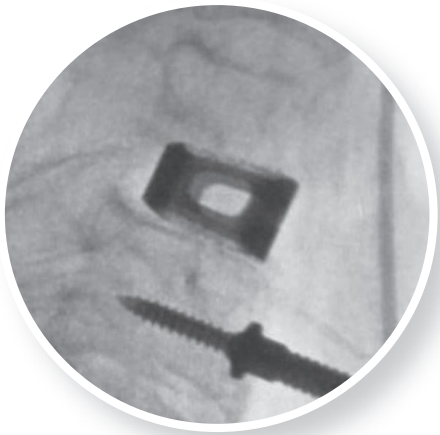
Catalog Number	Description
SW18357-0506	Anatomic Trial (W) 17.5 mm x (H) 5/6 mm
SW18357-0708	Anatomic Trial (W) 17.5 mm x (H) 7/8 mm
SW18357-0910	Anatomic Trial (W) 17.5 mm x (H) 9/10 mm
SW18357-1112	Anatomic Trial (W) 17.5 mm x (H) 11/12 mm

IMPLANT SPECIFICATIONS

Featuring TiCell® 3D

- A dual-layer organic lattice structure intended to incorporate optimally sized interconnected pores



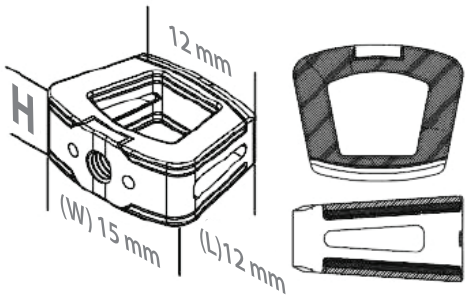


Open Architecture

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

Lordotic Implants

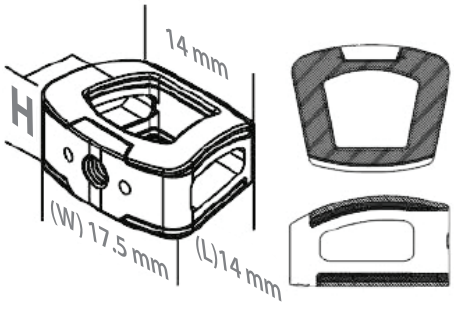
- 7°of lordosis
- Height is measured at the anterior aspect of the cage
- Height includes surface technology and matches corresponding trial size



Lordotic • 15 mm

Anatomic Implants

- Height is measured at the peak of the anatomic curve
- Height includes surface technology and matches corresponding trial size



Anatomic • 17.5 mm

EXPOSURE & SITE PREPARATION

Exposure

Identify the intervertebral disc to be treated, then use standard anterior exposure techniques to access the disc to be treated.

Discectomy

Perform an anterior incision over the selected segment(s). Prepare the muscles laterally considering the anatomic conditions. Cut a window matching the width of the chosen implant in the anterior longitudinal ligament and annulus fibrosus and remove the disc material through this window.

Distraction

Distract the segment using preferred distraction method. Distraction of the segment is essential for restoration of disc height and for providing good access to the intervertebral space for subsequent preparation of the endplates.

Endplate Preparation

Remove the cartilaginous layers from the surface of the vertebral endplates using the rasp (see Figure 1) until bleeding bone is attained. Clean the endplates. These techniques are intended to preserve the cortical bone beneath the cartilaginous layer and the natural shape of the bone.

Note: Do not over-penetrate rasps into the disc space to avoid spinal cord damage and do not over-expose the endplate to avoid implant subsidence.

Note: The removal of any osteophytes is very important for achieving complete decompression of the neural structures and avoiding the risk of partial compression after implant insertion.

FIGURE 1: End Plate Preparation

DISC SPACE CONFIGURATION

The set contains three sets of trials; lordotic, in both 15 mm and 17.5 mm widths (purple handles), and anatomic, in 15 mm width (blue handles). Select the appropriately sized lordotic or anatomic trial to determine the width and height of the desired implant.

Note: 17.5 mm anatomic trials are available if needed. These items do not come in the instrument set and must be ordered separately.

Note: The trials do not contain a depth marker. Use tactile confirmation or fluoroscopy when needed. A comprehensive list of available trial sizes is available at the end of this surgical technique.

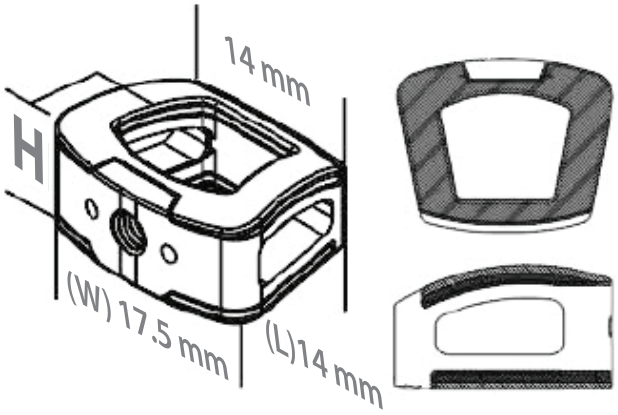
Position the implant trial in the correct cranial/caudal alignment and carefully slide the implant trial into the disc space. With the segment fully distracted, the implant trial must fit tightly between the endplates (see Figure 2). Repeat until satisfactory fit is found and remove trial.

FIGURE 2:
Stronghold® C Implant Trial

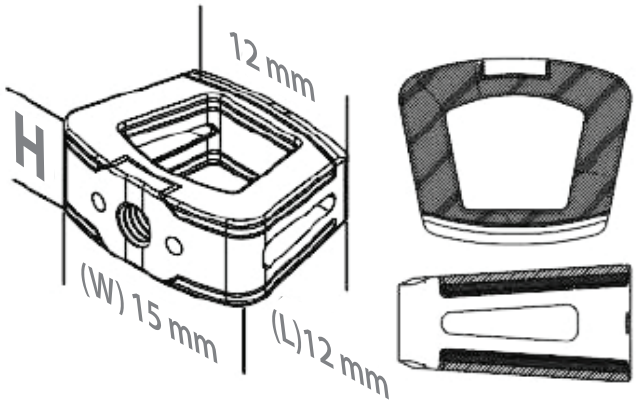
IMPLANT SELECTION

Confirm the size and placement of the implant trial in the disc space using fluoroscopy. Once appropriately sized trial is determined, select the corresponding sterile packed implant.

FIGURE 3 & 4: Implant Measurements



Anatomic • 17.5 mm



Lordotic • 15 mm

Anatomic Implants

All anatomic implants are available in (H) 5-10 mm in 1 mm increments. Footprints are available in 15 mm x 12 mm and 17.5 mm x 14 mm (see Figure 3).

Lordotic Implants

All lordotic implants are available in (H) 5-12 mm in 1 mm increments. Footprints are available in 15 mm x 12 mm (see Figure 4) and 17.5 mm x 14 mm.

IMPLANT INSERTION

Assemble the implant inserter by threading the inserter rod into the inserter sleeve. Turn the inserter rod clockwise until it is past the proximal threads and has movement without being able to remove from the inserter sleeve.

The implant inserter engages the implant using a threaded shaft and two alignment pins (see Figure 5). Care should be taken to avoid over-tightening the inserter, which could result in stripping of the implant threads. Completely fill the implant with autogenous bone graft composed of cancellous and/or corticocancellous bone.

Note: It is recommended to connect the implant to the inserter before filling the implant with autogenous bone graft as the graft may be dislodged during the connection process.

FIGURE 5:
Stronghold® C Inserter connected to implant

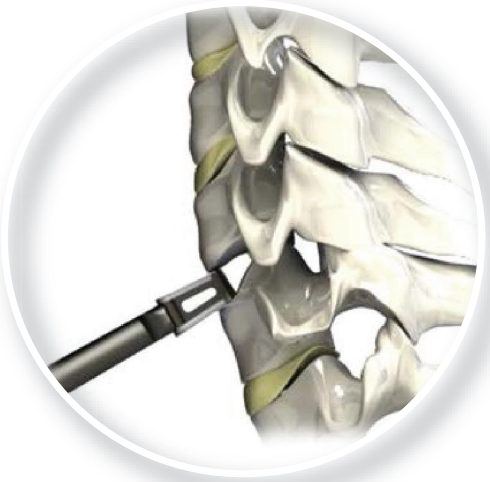


FIGURE 6:
Stronghold® C implant being inserted into the disc space

Position the implant and inserter in the correct cranial/caudal alignment and carefully insert into the distracted segment. If necessary, use a mallet to lightly tamp the implant fully into the disc space (see Figure 6).

The optimal position is centered on the midline with respect to the vertebral bodies. Depending on the size of the vertebrae, the anterior edge of the implant should be recessed approximately 2 mm within the anterior edges of the vertebrae.

RADIOGRAPHIC CONFIRMATION & INSERTER REMOVAL

With inserter still connected to the implant, use fluoroscopy to verify implant placement. Once the implant is in the desired position, remove the inserter by unthreading it. Implant position should be confirmed by anterior-posterior (AP) and lateral fluoroscopy (see Figure 7 & 8)

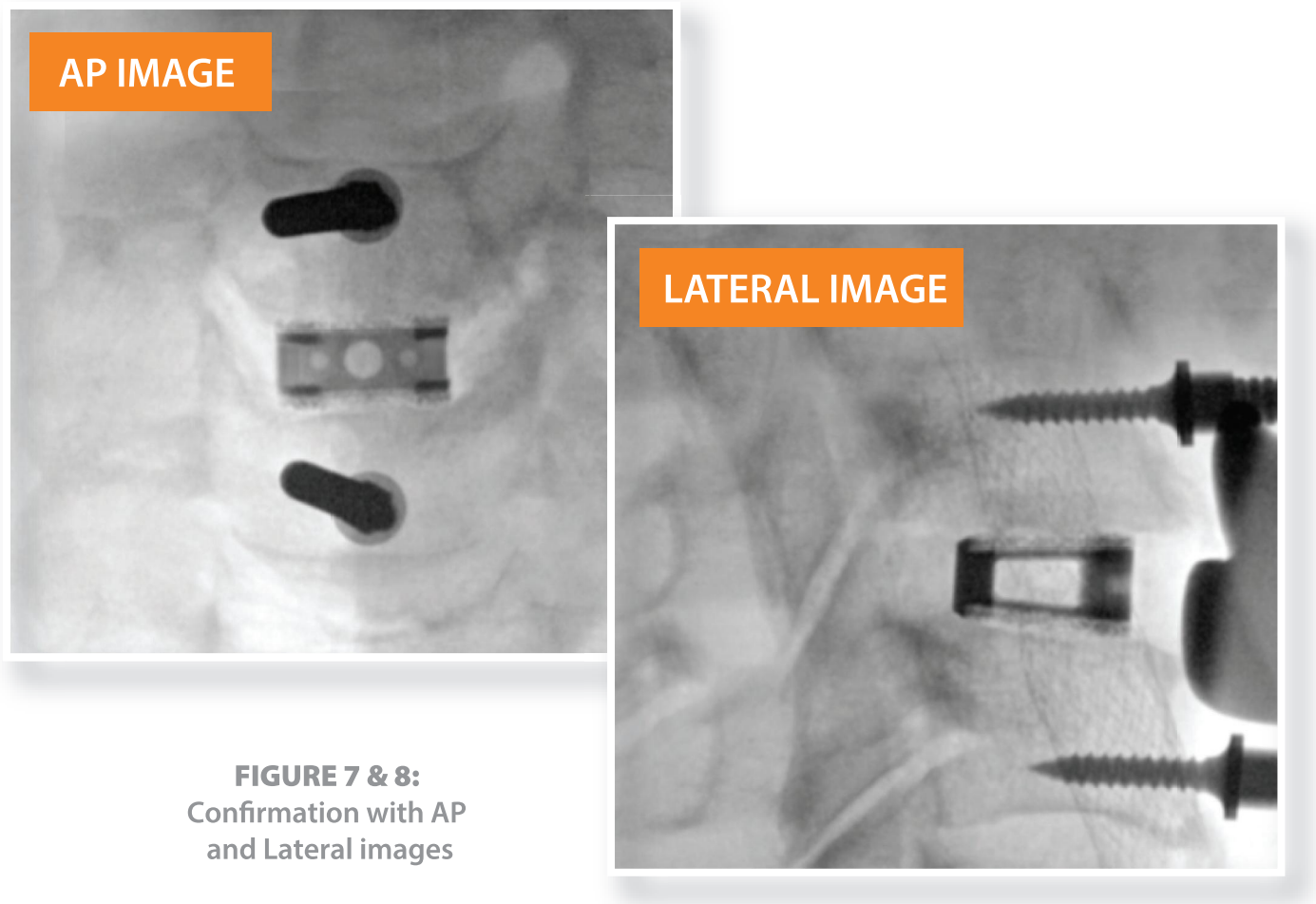


FIGURE 7 & 8:
Confirmation with AP and Lateral images

Note: If the implant needs to be repositioned after the inserter has been removed, a tamp can be used to adjust the implant.

SUPPLEMENTAL FIXATION & IMPLANT REMOVAL

Supplemental Fixation

Stronghold® C is indicated with anterior supplemental fixation. Complete anterior fixation procedure by following the steps indicated in the respective surgical technique (see Figure 9).

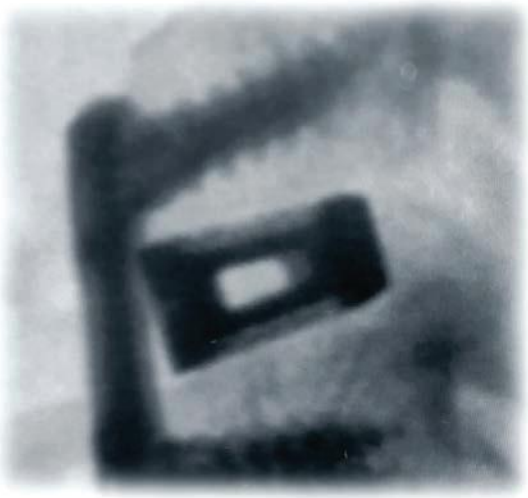


FIGURE 9:
Stronghold® C implant with supplemental fixation

Implant Removal

Removal of the implant, if needed, is performed by re-engaging the threaded inserter instrument and carefully withdrawing the implant (see Figure 10). Care should be taken to avoid inadvertently displacing the implant posteriorly during re-engagement.

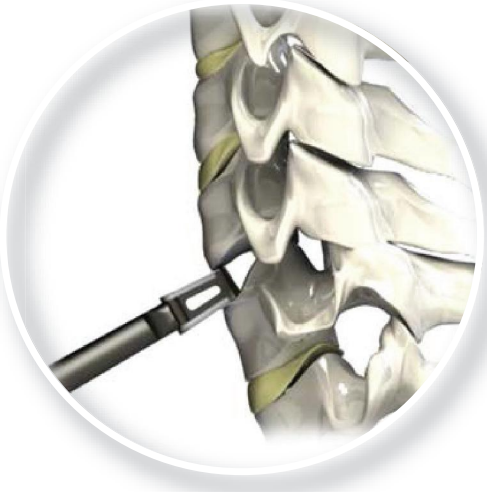
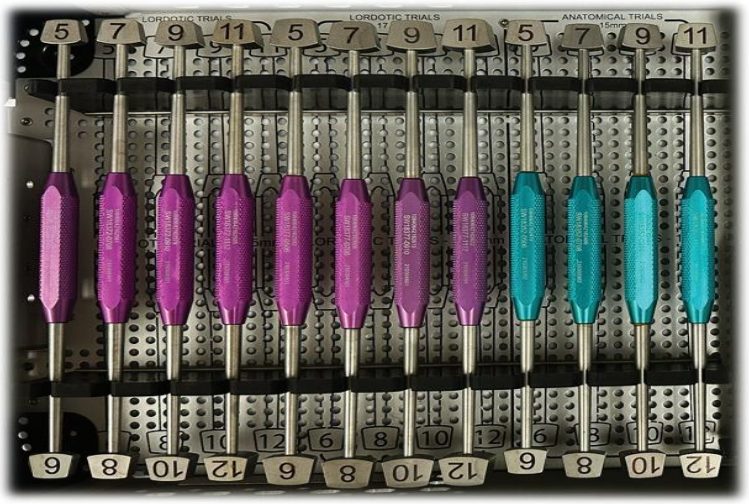


FIGURE 10:
Removal of implant

TRIAL OFFERING

Instrument Set

Catalog #	Description
SW18352-0506	Anatomic Trial (W) 15 mm x (H) 5/6 mm
SW18352-0708	Anatomic Trial (W) 15 mm x (H) 7/8 mm
SW18352-0910	Anatomic Trial (W) 15 mm x (H) 9/10 mm
SW18352-1112	Anatomic Trial (W) 15 mm x (H) 11/12 mm
SW18372-0506	Lordotic Trial (W) 15 mm x (H) 5/6 mm
SW18372-0708	Lordotic Trial (W) 15 mm x (H) 7/8 mm
SW18372-0910	Lordotic Trial (W) 15 mm x (H) 9/10 mm
SW18372-1112	Lordotic Trial (W) 15 mm x (H) 11/12 mm
SW18377-0506	Lordotic Trial (W) 17.5 mm x (H) 5/6 mm
SW18377-0708	Lordotic Trial (W) 17.5 mm x (H) 7/8 mm
SW18377-0910	Lordotic Trial (W) 17.5 mm x (H) 9/10 mm
SW18377-1112	Lordotic Trial (W) 17.5 mm x (H) 11/12 mm



Optional Items

Catalog #	Description
SW18357-0506	Anatomic Trial (W) 17.5 mm x (H) 5/6 mm
SW18357-0708	Anatomic Trial (W) 17.5 mm x (H) 7/8 mm
SW18357-0910	Anatomic Trial (W) 17.5 mm x (H) 9/10 mm
SW18357-1112	Anatomic Trial (W) 17.5 mm x (H) 11/12 mm

IMPLANT OFFERING

Lordotic Cages

Catalog #	Description
SW18107 -0515	Lordotic Cage (W) 15 mm x (L) 12 mm x (H) 5 mm
SW18107 -0615	Lordotic Cage (W) 15 mm x (L) 12 mm x (H) 6 mm
SW18107 -0715	Lordotic Cage (W) 15 mm x (L) 12 mm x (H) 7 mm
SW18107 -0815	Lordotic Cage (W) 15 mm x (L) 12 mm x (H) 8 mm
SW18107 -0915	Lordotic Cage (W) 15 mm x (L) 12 mm x (H) 9 mm
SW18107 -1015	Lordotic Cage (W) 15 mm x (L) 12 mm x (H) 10 mm
SW18107 -1115	Lordotic Cage (W) 15 mm x (L) 12 mm x (H) 11 mm
SW18107 -1215	Lordotic Cage (W) 15 mm x (L) 12 mm x (H) 12 mm
SW18107 -1405	Lordotic Cage (W) 17.5 mm x (L) 14 mm x (H) 5 mm
SW18107 -1406	Lordotic Cage (W) 17.5 mm x (L) 14 mm x (H) 6 mm
SW18107 -1407	Lordotic Cage (W) 17.5 mm x (L) 14 mm x (H) 7 mm
SW18107 -1408	Lordotic Cage (W) 17.5 mm x (L) 14 mm x (H) 8 mm
SW18107 -1409	Lordotic Cage (W) 17.5 mm x (L) 14 mm x (H) 9 mm
SW18107 -1410	Lordotic Cage (W) 17.5 mm x (L) 14 mm x (H) 10 mm
SW18107 -1411	Lordotic Cage (W) 17.5 mm x (L) 14 mm x (H) 11 mm
SW18107 -1412	Lordotic Cage (W) 17.5 mm x (L) 14 mm x (H) 12 mm

Anatomic Cages

Catalog #	Description
SW18105 -0515	Anatomic Cage (W) 15 mm x (L) 12 mm x (H) 5 mm
SW18105 -0615	Anatomic Cage (W) 15 mm x (L) 12 mm x (H) 6 mm
SW18105 -0715	Anatomic Cage (W) 15 mm x (L) 12 mm x (H) 7 mm
SW18105 -0815	Anatomic Cage (W) 15 mm x (L) 12 mm x (H) 8 mm
SW18105 -0915	Anatomic Cage (W) 15 mm x (L) 12 mm x (H) 9 mm
SW18105 -1015	Anatomic Cage (W) 15 mm x (L) 12 mm x (H) 10 mm
SW18125 -1405	Anatomic Cage (W) 17.5 mm x (L) 14 mm x (H) 5 mm
SW18125 -1406	Anatomic Cage (W) 17.5 mm x (L) 14 mm x (H) 6 mm
SW18125 -1407	Anatomic Cage (W) 17.5 mm x (L) 14 mm x (H) 7 mm
SW18125 -1408	Anatomic Cage (W) 17.5 mm x (L) 14 mm x (H) 8 mm
SW18125 -1409	Anatomic Cage (W) 17.5 mm x (L) 14 mm x (H) 9 mm
SW18125 -1410	Anatomic Cage (W) 17.5 mm x (L) 14 mm x (H) 10 mm

IMPORTANT INFORMATION ON STRONGHOLD® C 3D TITANIUM INTERBODY DEVICE

GENERAL DESCRIPTION

The Stronghold® C 3D Titanium Interbody Device is intended to facilitate fusion between vertebrae in patients requiring anterior cervical interbody fusion (ACIF). The Spine Wave Stronghold® C 3D Titanium Interbody Device includes multiple footprints to adapt to various patient anatomies.

Stronghold® C 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.

INDICATIONS

The Spine Wave Stronghold® C 3D Titanium Interbody Device is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one-disc level. DDD is defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. The Spine Wave Stronghold® C 3D Titanium Interbody Device is used to facilitate fusion in the cervical spine and is placed via an anterior approach at the C3 to C7 disc levels with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral body fusion device. The device must be used with supplemental fixation.

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

Potential Complications and Adverse Effects

Including but not limited to:

- Non-union (pseudoarthrosis) or delayed union
- Failure of the implant
- Sensitivity or allergic reaction to the implant
- Infection (early or delayed)
- Degenerative damage or instability at vertebral segments, above, and/or below the level of surgery
- Changes in spinal curvature, correction, and/or height
- Neurological damage including spinal cord damage or neurological compromise around nerves resulting in radicular pain, muscle weakness, and/or paralysis (partial or complete)
- Dural tears, chronic CSF leak or fistula, and/or possible meningitis
- Vascular damage including excessive or fatal bleeding, hemorrhage, hematoma, embolism, edema, and/or stroke
- Loss of spinal mobility or function
- Death

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 a 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 candidates 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.
- 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.
- Patients 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® C interbody device should have had at least six weeks of non-operative treatment.
- Potential risks identified with the use of Stronghold® C interbody device implant, 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® C 3D Titanium Interbody Device has not been evaluated for safety and compatibility in the MR environment. The safety of the Stronghold® C 3D Titanium Interbody Device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Product Handling

Implants should not be cleaned or resterilized, and should be disposed of following contact with bodily fluids. Implants should be used only if received with packaging and labeling intact. Protect the implants from contact with objects that may damage the surface finish. Inspect each implant prior to use for visual damage. Damaged packaging and implants should not be used and should be returned to Spine Wave.

IMPORTANT INFORMATION ON STRONGHOLD® C 3D TITANIUM INTERBODY DEVICE (CONTINUED)

Decontamination, Cleaning, and Sterilization

All Stronghold® C ancillary instruments are delivered non-sterile; therefore, all ancillary instruments must be decontaminated, thoroughly cleaned and sterilized prior to surgical use.

Decontamination and cleaning reduces the population of microorganisms and facilitates subsequent sterilization. Ancillary instruments are provided clean, but not sterile.

Limitations on Reprocessing

Repeated processing has minimal effects on instrument life and function. End of useful life is generally determined by wear or damage in surgical use. Carefully inspect instruments between uses to verify proper function. Return damaged instruments to Spine Wave.

Pre-Cleaning

The decontamination and cleaning process should begin as soon as possible following completion of the surgical procedure. Keep instruments moist and do not allow blood, body fluids, tissue, bone fragments, or other debris to dry on the instruments prior to cleaning. Remove gross debris from instruments with a water-moistened, disposable gauze pad. Pass a wire brush through all cannulated devices.

Multi-component instruments, such as the Inserter (shaft and base) assembly, must be disassembled for appropriate cleaning, reference Figure 1. To disassemble the inserter for cleaning turn the cap at the proximal end of the instrument counter-clockwise and pull back to remove shaft, reference Figure 2. Care must be exercised to avoid losing small screws and components.

Figure 1. Assembled Inserter (shaft and base)

Figure 2. Disassembled Inserter (shaft and base)

Decontamination and Cleaning Process

Immerse device in a neutral pH enzymatic cleaning solution such as "Enzol enzymatic cleaner" or equivalent, prepared in tap water (approximately 40°C), per the instructions of the enzymatic solution manufacturer. Manufacturer's instructions for preparation and use of these solutions should be explicitly followed. During the soaking period of fifteen (15) minutes, actuate any working mechanisms a minimum of 3 times. Change the soaking solution often if grossly soiled. While still in the soaking solution, use a soft brush or cloth to gently scrub the device until all visible soil and contamination has been removed. Ensure passage through all cannulated devices. Each lumen should be brushed a minimum of 5 times.

Engage instrument-working mechanisms during cleaning to access any interfacing areas within the device. After the enzymatic soak, rinse the device thoroughly with clean, free-flowing water for at least sixty (60) seconds until the water runs clear, while operating any movable parts to ensure thorough rinsing (deionized water preferred) through all lumens and crevices. Place instrument in an ultrasonic bath containing fresh, neutral pH enzymatic detergent solution. Verify that all surfaces are in contact with detergent solution. Actuate any working mechanism a minimum of 3 times. Sonicate the instruments for at least 15 minutes.

Rinse each instrument thoroughly for at least one minute with clean warm water actuating any mechanisms at least 3 times. Repeat until all visible residue has been removed and water runs clear. If the instruments are not visibly clean, repeat the cleaning steps from the beginning.

Dry instruments with a sterile gauze pad and use clean compressed air or 70% isopropyl to dry the lumens. Reassemble any instrument that was taken apart, and visually inspect instruments. Verify that the instrument is clean, dry, and in proper working order prior to sterilization.

NOTE: Spine Wave does not define the maximum number of uses appropriate for reusable instruments. The useful life of these devices depends on many factors, including the method and duration of each use, and the handling between uses. If any visual corrosion, discoloration, pitting or cracking is noticed on a device, the device must be replaced.

Inspection

Instruments should be inspected for completeness, damage, corrosion, and excessive wear. If contamination cannot be removed after repeated cleaning or the instrument is not complete, damaged, excessively worn or has corrosion, please return it to the address listed below.

NOTE: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage instruments; these solutions should not be used. All products should be treated with care; improper use or handling may lead to damage and possible improper functioning of the device.

Sterilization

The Spine Wave Stronghold® C ancillary instruments are provided non-sterile.

A sterilization cycle to achieve a sterility assurance level of 10^{-6} is required. Suggested cycles include:

Packaging

Instruments are intended to be loaded into dedicated sterilization trays. Do not stack trays during sterilization.

Double-wrap the trays for sterilization and handling, with an FDA-cleared wrap using standard wrapping techniques such as those described in ANSI/AAMI ST79: 2010 and A1:2010 and A2:2011.

Method Cycle	Temperature	Exposure Time	Minimum Drying Time
Steam Pre-Vacuum	270°F (132°C)	4 minutes	20 minutes

Sterile Implant Packaging

Sterile implant components are provided sterile by gamma radiation in accordance with AAMI/ANSI/ISO 11137, with a sterility assurance level of 10^{-6} Sterile implants are provided individually packaged in double barrier double tray configuration for aseptic presentation. Do not resterilize any implant. Do not use any implant from an opened or damaged package. Do not use implants after the expiration date. Wrappings should not be removed by receiving personnel.

MPORTANT INFORMATION ON STRONGHOLD® C 3D TITANIUM INTERBODY DEVICE (CONTINUED)

Traceability

Implants are identified by a part number or size and lot number, or both, on the package and surface of the device. Record these control numbers and retain for transfer to patient records, to facilitate inventory, stock rotation, medical device reporting and/or possible traceability to the manufacturer.

Storage

Instruments should be stored to avoid rusting. Store instruments in the operating room in such a manner as to isolate and protect the instruments surface, sterility, and configuration. Store the instruments in the operating room in such a manner as to isolate the instruments from the implants. Transport in a manner to preclude any damage or alteration to the received condition of the implant or instrument.

Instructions for Use

A successful result is not achieved in every surgical case, especially in spinal surgery where many extenuating circumstances may compromise results. This device is intended for temporary immobilization of the spine in order to obtain a solid fusion mass using autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The durability and success of the implant will be compromised in cases where a non-union develops, or when used without autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant, are critical considerations in achieving a successful result. Use of the system should only be considered when the following preoperative, intraoperative and postoperative conditions exist.

Preoperative

- The components should be handled with great care to avoid damaging them. The components should not be scratched or notched. The components should be stored in a non-corrosive environment.
- The surgeon should be familiar with the components, their function, and method of insertion. Refer to the surgical technique manual for specific instructions.
- Verify that all the components and required instruments are present.

Intraoperative

- The implant must be used with autogenous and/or allogenic bone graft inserted in the implant. The autogenous and/or allogenic bone graft must contact the upper and lower surfaces of the space to be fused.
- Supplemental fixation must be used to support the vertebrae until complete fusion is confirmed.

Postoperative

- The limitations of the device should be explained to the patient. The patient must be warned that excessive or early weight-bearing or physical activity can result in failure of the device before the fusion process is complete.
- The patient should be advised not to smoke or consume alcohol during the healing process. Also, to increase the chance of success the patient should be advised to restrict physical activity, especially lifting or twisting motions, and any sporting activity.
- The patient should be informed of these hazards and should be monitored to ensure cooperation until bone fusion has been confirmed.

The device should be removed or revised a.) in cases in which a solid boney fusion fails to occur, b.) in cases of discitis, epidural abscess, or any infection of tissue adjacent to the implant, or c.) in cases in which the implant is found to have migrated from its intended position within the disc space.

Product Complaints

Any complaint or dissatisfaction with product quality, performance, labeling, and/or safety should be reported to Spine Wave. If any of the implants or instruments "malfunction" (i.e. do not meet any of their performance specifications or do not perform as intended), and/or are suspected to have caused or contributed to the death or serious injury of the patient, Spine Wave should be notified immediately by phone, fax or written correspondence.

When filing a complaint, please provide the product description, product number, lot number, complainant's name and address, and the nature of the complaint.

For more complete information, refer to the package insert.

SPINE WAVE

Manufactured For:
Spine Wave, Inc.
Three Enterprise Drive
Suite 210
Shelton, CT 06484

Direct: 877-844-4225 | Fax: 203-944-9493
Email: info@spinewave.com | www.spinewave.com

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Symbol Translation

	SINGLE USE ONLY
LOT	BATCH CODE
REF	CATALOG NUMBER
	USE BY: YYYY-MM-DD
STERILE R	STERILIZED USING IRRADIATION
	DO NOT USE IF PACKAGE IS DAMAGED
	CONSULT INSTRUCTIONS FOR USE
	NON-PYROGENIC
℞ ONLY	FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

SPINE WAVE

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