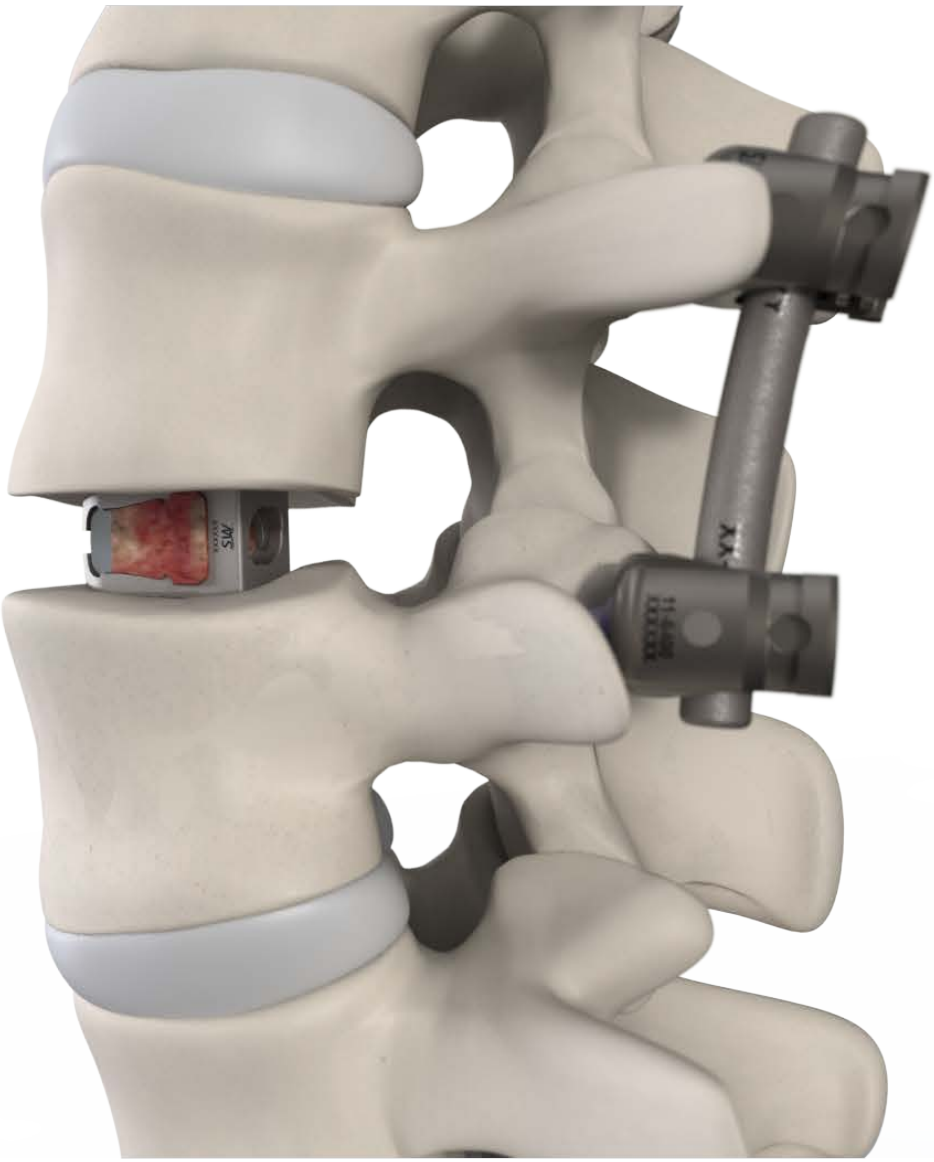
Exceed®

Biplanar Expandable Interbody Device

SURGICAL TECHNIQUE



SpineWave

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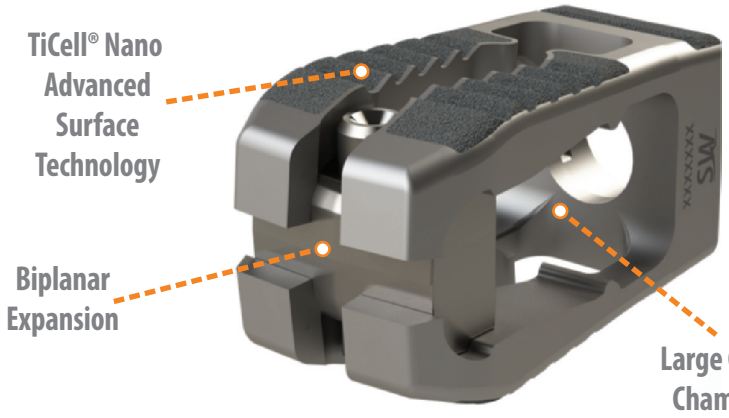
EXCEED® BIPLANAR EXPANDABLE INTERBODY DEVICE DESIGN RATIONALE

Dual Taper

- Dual taper design reduces profile in two planes for easy implant insertion

Biplanar Expansion

- The implant offers biplanar expansion with a simple, confirmable technique designed to enhance stability and reduce subsidence



Integrated Grafting Technique

- Simple instrumentation and open implant architecture facilitate a streamlined, integrated grafting technique using Graftmag® EX Graft Delivery System

Open Architecture

- Large graft portal and open architecture provide for unrivaled graftability
- Designed to reduce overall implant stiffness
- Less implant material provides improved radiographic visibility of the fusion mass

Featuring TiCell® Nano

Advanced Surface Technology

- TiCell® Nano is a patented, proprietary advanced surface technology that combines porosity, micro roughness, and nanoscale features

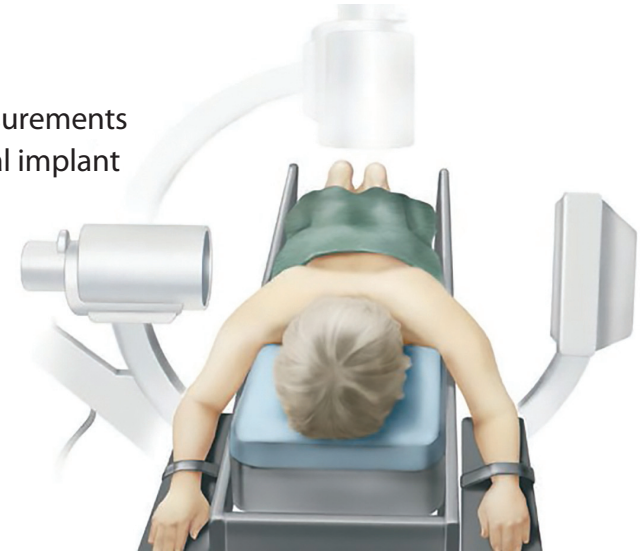
STEP 1 PREOPERATIVE PLANNING AND APPROACH

Preoperative planning is recommended for the selection of the Exceed® Biplanar Expandable 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.

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



STEP 2 DISC PREPARATION

Remove the inferior facet of the cranial vertebra and the superior facet of the caudal vertebra of the appropriate levels. Standard procedures should be taken when performing 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.

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 3 SIZING

All sizers insert at 7 mm in height, and have features at 22 mm and 25 mm to help assess length (Figure 1).

Begin with the smallest sizer and insert into the disc space. Sizers are inserted into the disc space with the laser marked size towards the endplates (Figure 2).

Rotate sizers 90 degrees to distract and assess the disc height (Figure 3).

Sequentially use larger sizers until the optimal fit is achieved based on tactile feedback. The final sizer should fit snugly in the disc space. A secure fit is desirable in order to maintain disc height and stabilize the segment and should be confirmed using fluoroscopy and tactile feel.

The Exceed® Biplanar Expandable Interbody Device is recommended to be sized to final height.

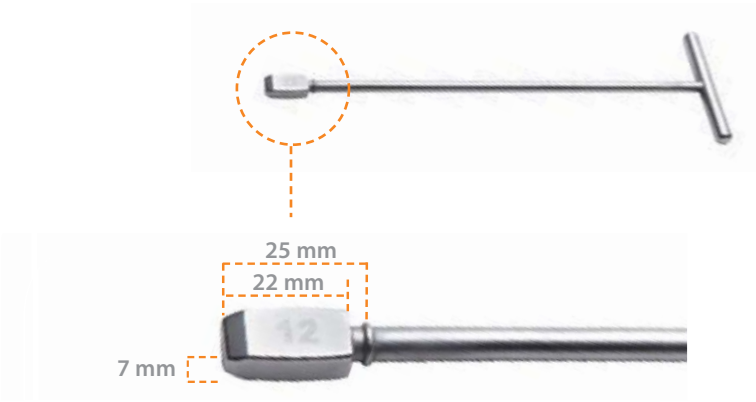


FIGURE 1

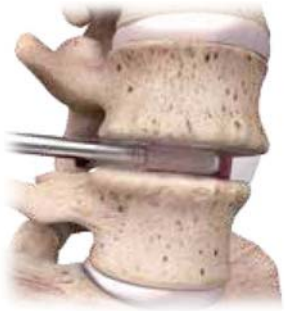


FIGURE 2

Caution:
Using an implant that is smaller than the available disc space may result in less than optimal stability. Using an implant that is larger than the available disc space may result in difficult expansion, incomplete expansion and/or disruption of the vertebral endplate.

FIGURE 3

STEP 4 LOADING THE EXCEED® IMPLANT

Once the appropriately sized trial is determined, select the corresponding implant. Implant heights are offered in 1 mm increments to restore natural disc height.

Press and hold the Release Button on the Exceed® Inserter. While holding, rotate the Lock Handle to the unlock position (Figure 4).

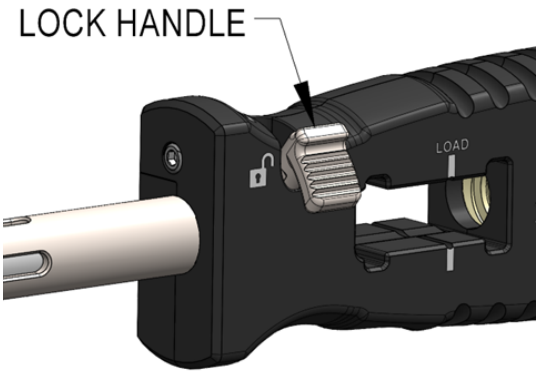


FIGURE 4

Align the Locking Lugs of the Exceed® Inserter with the mating notches on the implant and slide the implant onto the Exceed® Inserter (Figure 5a and 5b).

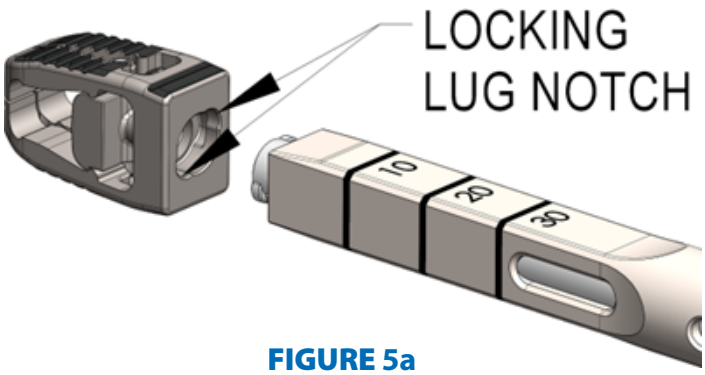


FIGURE 5a

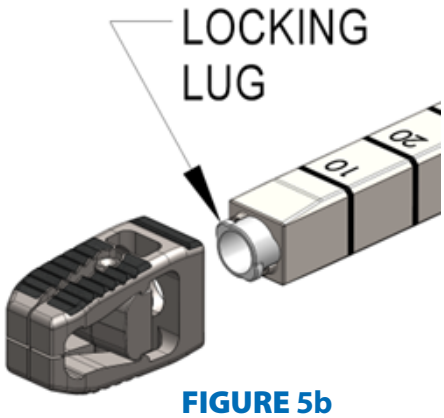


FIGURE 5b

Rotate the Lock Handle fully until a click is heard and it aligns with the lock symbol (Figure 6). Attempt to rotate the Lock Handle to the unlock symbol to ensure that the implant is properly locked.

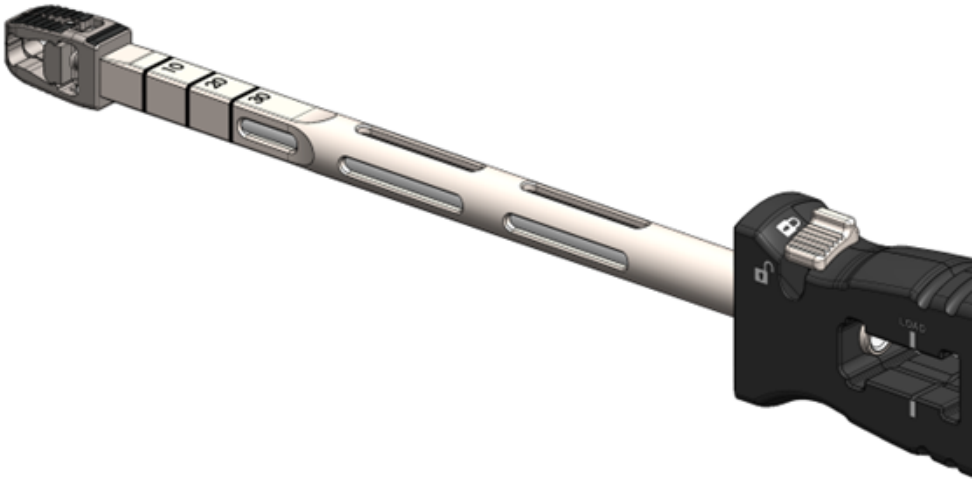


FIGURE 6

STEP 4 LOADING THE EXCEED® IMPLANT (CONTINUED)

Insert the Push Rod into the circular opening at the proximal end of the Exceed® Inserter and slide the Push Rod into the lumen of the Exceed® Inserter inner tube.

Engage the Push Rod Inserter into the hex socket of the Push Rod and turn clockwise to completely thread the Push Rod to the Wedge. Finger-tighten only. DO NOT OVERTORQUE.

Confirm there is no gap present between the Push Rod and Wedge; the black line on the Push Rod should be aligned with the "LOAD" line on the Exceed® Inserter (Figure 7).

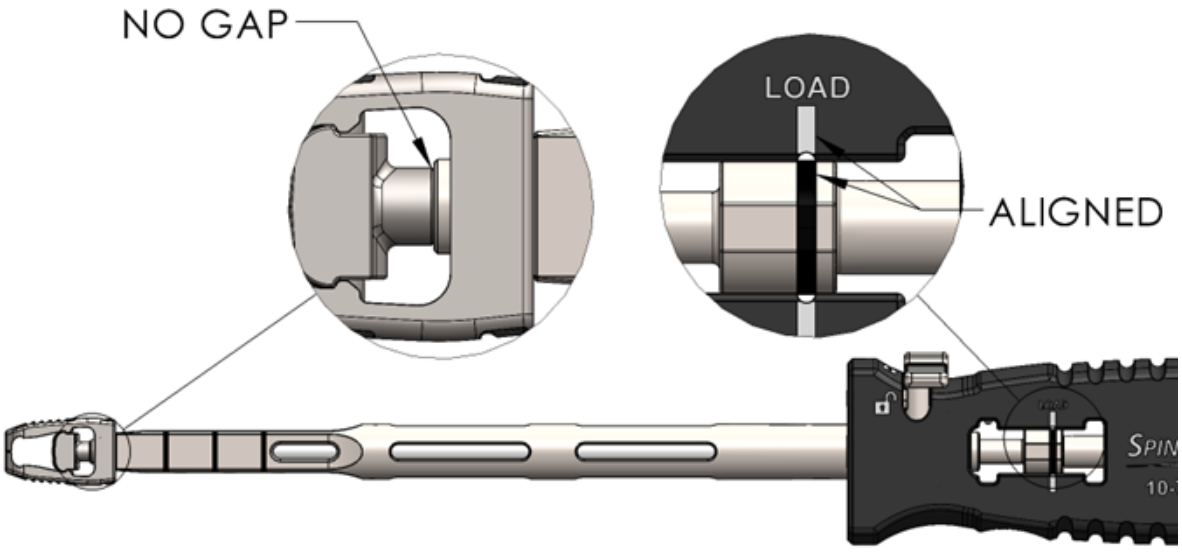


FIGURE 7

Remove the Push Rod Inserter.

STEP 5 IMPLANT INSERTION

Once properly loaded, the implant is inserted into the desired position in the disc space. If necessary, the Inserter may be impacted on to facilitate insertion. The TiCell® Nano textured surfaces of the implant should be positioned against the endplates. The Exceed® Inserter has depth markings in 10 mm increments from the tip of the instrument.

Use intraoperative x-ray and/or fluoroscopy to confirm proper position in the A/P and lateral planes as well as the orientation of the device within the boundaries of the vertebral column. The proximal edge of the side fenestration of the implant is approximately 4 mm from the distal tip of the Exceed® Inserter.

Prior to expansion, ensure that the black line on the Push Rod is aligned with the "LOAD" line on the Exceed® Inserter.

Warning: Positioning of the Exceed® Implant should only be performed using the Exceed® Inserter.

STEP 6 EXPANDING THE EXCEED® IMPLANT

Assemble the Wedge Driver onto the T-Handle (1/4" Square Drive). Insert the Wedge Driver into the circular opening at the proximal end of the Exceed® Inserter. To expand the Exceed® Implant, advance the wedge by turning the T-Handle clockwise. It is important to apply counter torque to the Exceed® Inserter handle during expansion. An optional Counter Torque Handle is available to order separately. A tactile and audible click will occur at full expansion. Stop rotating the T-Handle once a hard stop is reached and confirmation of full expansion is verified using the next steps.

Visually confirm the Implant Wedge is fully forward and locked in position by verifying there is no gap present between the Push Rod and the Exceed® Inserter's inner tube and/or the use of fluoroscopy (Figure 8a and 8b).

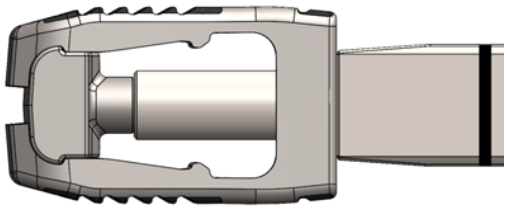


FIGURE 8a

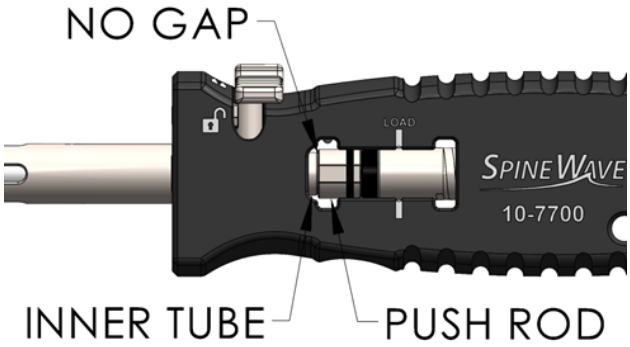


FIGURE 8b

Remove the Wedge Driver by rotating the T-Handle counterclockwise to unthread from the Exceed® Inserter.

Assemble the Push Rod Removal Tool to the Push Rod Inserter by inserting the Push Rod Removal Tool into the Push Rod Inserter and threading together until the threaded tip of the Push Rod Removal Tool is exposed.

To remove the Push Rod from the deployed Exceed® Implant, engage the Push Rod Inserter/Removal Tool Assembly into the hex socket of the Push Rod and thread together by rotating the Push Rod Removal Tool clockwise (Figure 9). Finger-tighten only. DO NOT OVERTORQUE.

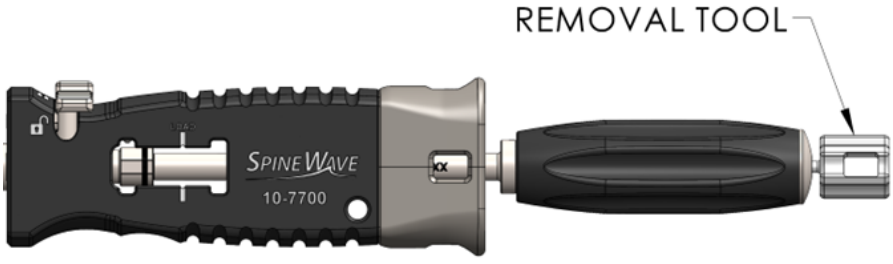


FIGURE 9

Rotate the Push Rod Inserter Handle counterclockwise until the Push Rod is released from the deployed Implant Wedge.

Remove the assembled Push Rod Instrument from the Exceed® Inserter.

STEP 7 GRAFTING THE EXCEED® IMPLANT

The Exceed® System features an integrated grafting technique that streamlines graft delivery. With the Exceed® Implant expanded and the Push Rod removed, post expansion grafting is performed directly through the Exceed® Inserter using one of two techniques.

Technique 1 - USING GRAFTMAG® EX GRAFT DELIVERY SYSTEM

When grafting with the GraftMag® EX Delivery System, use the Exceed® Graft Plunger and Exceed® Graft Tamp (Black Handles)

FIGURE 10

The GraftMag® EX Graft Delivery System allows the surgeon to deliver a large amount of bone graft quickly and efficiently. The surgeon is able to deliver a known amount of bone graft while eliminating funnel jamming with no additional instrument passes in and out of the disc space.

Open the sterile pouch and leave the grafting block attached to the graft clip for loading graft material. Load the bone graft into each of the five chambers of the graft clip. Each chamber holds 0.5cc for graft material.

Slide the filled GraftMag® EX clip into the handle of the Exceed® Inserter. Use the Exceed® Graft Plunger to deliver graft material into the implant. Ensure that the plunger is bottomed out to a hard stop, and remove Graft Plunger to index the graft clip to the next position.

The Exceed® Graft Tamp may be used to sweep graft material from the implant into the surrounding disc space. Repeat until desired amount of graft is delivered (Figure 10).

Note: It is important to use the Graft Plunger and Graft Tamp (black handles) with the GraftMag® EX Delivery System and not the Graft Funnel Plunger and Graft Funnel Tamp (gray handles) as they are not interchangeable.

Note: The Exceed® System comes with an optional Plunger Guide to help align the Plunger with the GraftMag® EX clip. When using the Plunger Guide, use the Graft Funnel Plunger and Graft Funnel Tamp (gray handles).

STEP 7 GRAFTING THE EXCEED® IMPLANT (CONTINUED)

TECHNIQUE 2 - USING EXCEED® INSERTER FUNNEL

When grafting with the Exceed® Inserter Funnel, use the Exceed® Graft Funnel Plunger and Exceed® Graft Funnel Tamp (Gray Handles)

Thread the Exceed® Inserter Funnel into the proximal hole of the Exceed® Inserter Handle. Ensure that the Exceed® Inserter Funnel is bottomed out on the inner tube of the Exceed® Inserter. Load the Exceed® Inserter Funnel with graft material.

Use the Exceed® Graft Funnel Plunger to deliver graft material into the implant. Ensure that the plunger is bottomed out to a hard stop, and remove Graft Plunger to add additional graft material into the Exceed® Inserter Funnel.

The Exceed® Graft Funnel Tamp may be used to sweep graft material from the implant into the surrounding disc space. Repeat until desired amount of graft is delivered (Figure 11). The Exceed® Graft Funnel Tamp should only be used with the Exceed® Graft Funnel. The back of the Exceed® Graft Funnel Tamp is laser marked "USE WITH FUNNEL ONLY."

FIGURE 11

Note: It is important to use the Graft Funnel Plunger and Graft Funnel Tamp (gray handles) with the Exceed® Inserter Funnel and not the Graft Plunger and Graft Tamp (black handles) as they are not interchangeable.

STEP 8 DISENGAGING THE EXCEED® IMPLANT

Disengage the Exceed® Inserter from the implant by pressing the Release Button on the Exceed® Inserter and simultaneously rotating the Lock Handle towards the unlock symbol. Pull the Exceed® Inserter straight back to remove (Figures 12a-c).

Note: If grafting was performed with the Exceed® Inserter Funnel, rotate the Funnel counterclockwise to unthread prior to removal of the Exceed® Inserter.

FIGURE 12a

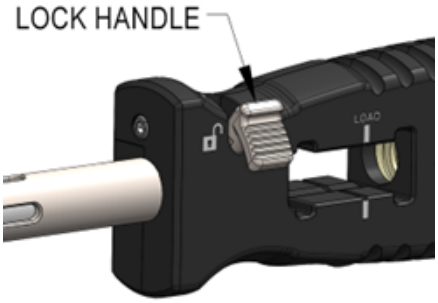


FIGURE 12b

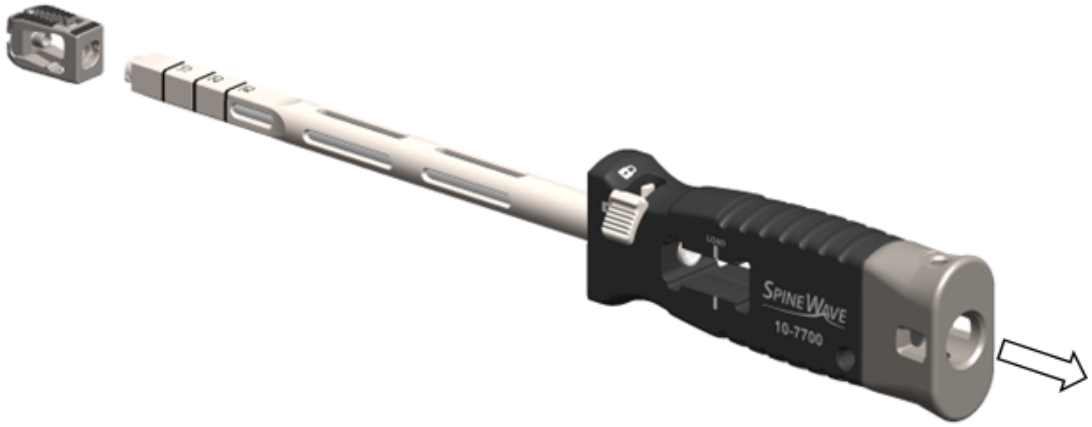


FIGURE 12c

STEP 9 IMPLANT REMOVAL

The Exceed® Implant is intended to be a permanent implant. If the Implant is to be removed, reattach the Exceed® Inserter and remove the Implant. A Slap Hammer may be used to facilitate removal. DO NOT reuse an Implant that has been deployed.

EXCEED® INSTRUMENT OFFERING

Catalog #	Description
10-7700	Exceed® Inserter
10-7701	Exceed® Push Rod Inserter
10-7706	Exceed® Push Rod Removal Tool
10-7707	Exceed® Push Rod
10-7702	Exceed® Wedge Driver
10-7532	Exceed® Graft Plunger
10-7533	Exceed® Graft Tamp
10-7703	Exceed® Graft Funnel Plunger
10-7704	Exceed® Graft Funnel Tamp
10-7710	Exceed® Inserter Funnel
10-7708	8° Lordotic Trial
10-7709	15° Lordotic Trial
10-7801	Sizer, 9 mm
10-7802	Sizer, 10 mm
10-7803	Sizer, 11 mm
10-7804	Sizer, 12 mm
10-7805	Sizer, 13 mm
10-7806	Sizer, 14 mm
10-7129*	Counter Torque Handle*
10-7705	Slap Hammer
10-7799	T-Handle
10-7534**	Curved Cannula, EX**
10-7537**	Obturator, EX**
10-7523**	Flexible Plunger, EX**
10-7530**	Straight Grafting Cannula, EX**
10-7517**	Graft Plunger, Mini**
10-7519**	Small Tamp, Mini**
10-7232**	Obturator, Mini**
14-0295X	Plunger Guide

* Optional instrument to be ordered separately
** Only available in 10-7800 Exceed® Instrument Set

EXCEED® IMPLANTS

Catalog #	Description
11-5339	Exceed® Interbody Device, 22 mm (L) x 10 mm (W) x 9 mm (H), 0° Lordotic
11-5340	Exceed® Interbody Device, 22 mm (L) x 10 mm (W) x 10 mm (H), 0° Lordotic
11-5341	Exceed® Interbody Device, 22 mm (L) x 10 mm (W) x 11 mm (H), 0° Lordotic
11-5342	Exceed® Interbody Device, 22 mm (L) x 10 mm (W) x 12 mm (H), 0° Lordotic
11-5343	Exceed® Interbody Device, 22 mm (L) x 10 mm (W) x 13 mm (H), 0° Lordotic
11-5344	Exceed® Interbody Device, 22 mm (L) x 10 mm (W) x 14 mm (H), 0° Lordotic
11-5354	Exceed® Interbody Device, 22 mm (L) x 10 mm (W) x 10 mm (H), 8° Lordotic
11-5355	Exceed® Interbody Device, 22 mm (L) x 10 mm (W) x 11 mm (H), 8° Lordotic
11-5356	Exceed® Interbody Device, 22 mm (L) x 10 mm (W) x 12 mm (H), 8° Lordotic
11-5357	Exceed® Interbody Device, 22 mm (L) x 10 mm (W) x 13 mm (H), 8° Lordotic
11-5412	Exceed® Interbody Device, 22 mm (L) x 10 mm (W) x 14 mm (H), 8° Lordotic
11-5415	Exceed® Interbody Device, 22 mm (L) x 10 mm (W) x 12 mm (H), 15° Lordotic
11-5416	Exceed® Interbody Device, 22 mm (L) x 10 mm (W) x 13 mm (H), 15° Lordotic
11-5417	Exceed® Interbody Device, 22 mm (L) x 10 mm (W) x 14 mm (H), 15° Lordotic
11-5331	Exceed® Interbody Device, 25 mm (L) x 10 mm (W) x 9 mm (H), 0° Lordotic
11-5332	Exceed® Interbody Device, 25 mm (L) x 10 mm (W) x 10 mm (H), 0° Lordotic
11-5333	Exceed® Interbody Device, 25 mm (L) x 10 mm (W) x 11 mm (H), 0° Lordotic
11-5334	Exceed® Interbody Device, 25 mm (L) x 10 mm (W) x 12 mm (H), 0° Lordotic
11-5335	Exceed® Interbody Device, 25 mm (L) x 10 mm (W) x 13 mm (H), 0° Lordotic
11-5336	Exceed® Interbody Device, 25 mm (L) x 10 mm (W) x 14 mm (H), 0° Lordotic
11-5348	Exceed® Interbody Device, 25 mm (L) x 10 mm (W) x 10 mm (H), 8° Lordotic
11-5349	Exceed® Interbody Device, 25 mm (L) x 10 mm (W) x 11 mm (H), 8° Lordotic
11-5350	Exceed® Interbody Device, 25 mm (L) x 10 mm (W) x 12 mm (H), 8° Lordotic
11-5351	Exceed® Interbody Device, 25 mm (L) x 10 mm (W) x 13 mm (H), 8° Lordotic
11-5430	Exceed® Interbody Device, 25 mm (L) x 10 mm (W) x 14 mm (H), 8° Lordotic
11-5433	Exceed® Interbody Device, 25 mm (L) x 10 mm (W) x 12 mm (H), 15° Lordotic
11-5434	Exceed® Interbody Device, 25 mm (L) x 10 mm (W) x 13 mm (H), 15° Lordotic
11-5435	Exceed® Interbody Device, 25 mm (L) x 10 mm (W) x 14 mm (H), 15° Lordotic

EXCEED® SETS

Catalog #	Description
10-7800	Exceed® Instrument Set
10-7900	Exceed® Instrument Set Without GraftMag® EX Instruments
11-5440	Exceed® 22 mm Implant Set (0° & 8°)
11-5441	Exceed® 25 mm Implant Set (0° & 8°)
11-5442	Exceed® 22 mm Implant Set (0°, 8°, & 15°)
11-5443	Exceed® 25 mm Implant Set (0°, 8°, & 15°)

IMPORTANT INFORMATION ON EXCEED® BIPLANAR EXPANDABLE INTERBODY SYSTEM

PRODUCT DESCRIPTION:

The Exceed® Biplanar Expandable Interbody System is a lumbar intervertebral body fusion device fabricated from titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The implant is provided unexpanded with a bullet nose tapered in both the lateral and vertical planes and expanded in situ using the Exceed® Inserter. The implant has a microscopic roughened surface with micro and nano-scale features on the superior and inferior surfaces. The implant is provided in different heights, lengths, and lordotic angles to accommodate the anatomical needs for a range of patients, and is designed to accommodate autogenous and/or allogenic bone graft material.

Covered by one or more U.S. patents or patent applications.

See www.spinewave.com/legal-notice.html for details.

INDICATIONS FOR USE:

The Exceed® Biplanar Expandable Interbody System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The Exceed® Biplanar Expandable Interbody System is to be used with autograft bone and/or allogenic bone graft composed of cancellous, and/or corticocancellous bone. The Exceed® Biplanar Expandable Interbody System is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral body fusion device.

CONTRAINDICATIONS:

The Exceed® Biplanar Expandable Interbody System is contraindicated for:

- Morbid obesity
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery
- Degenerative disease, other than Degenerative Disc Disease (DDD)
- Any case where the implants or components selected would be too large or too small to achieve a successful result
- Uncorrectable coagulopathy or hemorrhagic diathesis
- Allergy to any component of the treatment procedure
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation
- Fever or leukocytosis
- Inadequate tissue coverage over the operative site or inadequate bone stock, or bone quality
- Anatomy or other factor that prohibits safe surgical access to the surgical body
- Spondylolisthesis unable to reduce to Grade 1
- Pediatric case or case where patient still has general skeletal growth
- Active infection
- Any patient unwilling or unable to follow postoperative instructions
- Mental illness
- Pregnancy
- Any case in which fusion is not needed
- Prior fusion at level to be treated
- Any case not described in the indications

HOW SUPPLIED - STERILIZATION

Please refer to corresponding instructions for use for information on sterility, cleaning, and sterilization.

WARNINGS AND PRECAUTIONS:

- Surgical implants must never be reused. SINGLE-USE ONLY.
- Never reuse a surgical implant under any circumstances. Even when a removed implant appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage.
- The Exceed® Implant is only intended to be deployed once.
- Do not use if package is opened or damaged or if use-by date has passed.
- This device is not intended to be the sole means of spinal support. The Exceed® Biplanar Expandable Interbody System must be used with additional internal spinal instrumentation.
- Potential risks identified with the use of this intervertebral body fusion device, which may require additional surgery, include device component fracture, loss of fixation, pseudoarthrosis (i.e., non-union), fracture of the vertebra, neurological injury, and vascular or visceral injury.
- The implantation of this intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting risk of serious injury to the patient.
- Placement and adjustment of the Exceed® Implant must only be performed with the Exceed® Inserter Instrument supplied with the system.
- The implant is not to be left in the unexpanded state.
- Based on dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the intervertebral body fusion device.
- Provide the patient with adequate instructions for postoperative care. The patient must be made aware of the limitations of the implants. The patient should be encouraged to ambulate to tolerance as soon as possible after surgery, and instructed to limit and restrict lifting and twisting motions and any type of sports participation until the bone is healed. The patient should understand that implants are not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on them in the absence of complete bone healing. Implants displaced or damaged by improper activities may experience migration and damage to nerves or blood vessels.
- A successful result is not always achieved in every surgical case. This is especially true in spinal surgery where other patient conditions may compromise the results.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous spinal surgery.
- Preoperative and operative procedures, including knowledge of surgical techniques, proper selection and placement of the implant, and good reduction are important considerations in the success of the surgery.
- Proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spinal fusion.

For more complete information on the implants and instruments, refer to respective package inserts.

IMPORTANT INFORMATION ON EXCEED® BIPLANAR EXPANDABLE INTERBODY SYSTEM

POTENTIAL ADVERSE EFFECTS:

All the potential adverse events or complications associated with spinal fusion surgery with internal instrumentation are possible.

Possible adverse events with the use of this system include but are not limited to:

- Early or late loosening of components.
- Implant migration.
- Disassembly, bending, and/or breakage of any or all the components.
- Implant material sensitivity or allergic reaction to a foreign body including tumor formation and/or autoimmune disease.
- Infection, early or late.
- Dural tears, psuedomeningocele, fistula, persistent CSF leak, meningitis.
- Tissue or nerve damage, irritation and/or pain caused by improper positioning and placement of implants or instruments.
- Loss of neurological function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or development or continuation of pain, numbness, neuroma, tingling sensation, sensory loss, and/or spasms.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, arachnoiditis, and/or muscle loss.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Bone loss or decrease in bone density due to stress shielding.
- Subsidence of the device into the vertebral body or bodies.
- Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of spinal mobility or function resulting in inability to perform the activities of daily living.
- Pseudarthrosis, delayed union, and/or malunion.
- Fracture, microfracture, resorption, damage, penetration, and/or retropulsion of any spinal bone, of the bone graft or at the bone graft harvest site.
- Autograft donor site complications including pain, fracture, infection, or wound healing problems.
- Herniated nucleus pulposis, disc disruption or degeneration at, above, or below the level of surgery.
- Ileus, gastritis, bowel obstruction or other types of gastrointestinal system compromise.
- Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise.
- Wound necrosis or wound dehiscence.
- Reproductive system compromise, including sterility. Loss of consortium, sexual disfunction and retrograde ejaculation.
- Development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
- Change in mental status.
- Death.

MRI SAFETY INFORMATION:

The Exceed® Biplanar Expandable Interbody System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Exceed® Biplanar Expandable Interbody System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

PRODUCT COMPLAINTS:

Any health care professional who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness, and/or performance, should notify Spine Wave, Inc. If any Spine Wave, Inc. product ever “malfunctions” and may have caused or contributed to the death or serious injury to a patient, Spine Wave, Inc. should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name, catalog number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report is requested.

For more complete information on the implants and instruments, refer to respective package inserts.

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