Elite™

Expandable Interbody Fusion System

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A Note for Physicians:

As with any spinal fusion procedure, proper imaging and interpretation of the images are critical to safety. This technique manual describes the 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 Elite™ Expandable Interbody Fusion System for physicians experienced in interpreting biplanar fluoroscopic images of the lumbar spine and in image-guided instrument placement.

Proper aseptic technique, anesthesia and antibiotic use, prone patient positioning, and the ability to obtain proper anterior–posterior (AP) and lateral images are assumed. It is always good practice to verify the ability to obtain useable AP and lateral images before preparing the sterile field.

Elite™ Expandable Implant

Implant sizing and insertion occurs following discectomy and endplate preparation.

Note: A thorough discectomy is a critical and necessary element of any spinal fusion procedure.

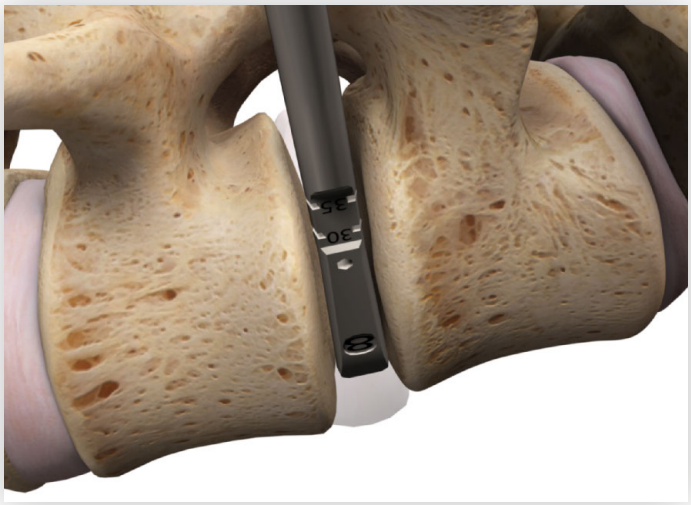

Figure 1

Implant Selection

Paddle Distractors are provided to select an appropriate Implant size. Starting with a relatively small height, so as not to damage the endplate, sequentially insert and rotate increasingly larger Paddle Distractors into the disc space until the desired annular tension is achieved (Fig. 1).

Use fluoroscopic imaging to assess the position of the Paddle Distractor and to aid in selecting the appropriate length and height Implant.

Note: The Paddle Distractors are marked for lengths and heights.

Select an Implant that, when expanded, is of the final desired disc height and appropriate length.

Starting - Expanded Height (mm) & Degree of Lordosis

Starting - Expanded Length (mm)	10mm and 12mm wide Elite Expandable Implant		Parallel	6° Lordosis				12° Lordosis	
			7-10	8-11	9-13	10-14	11-15	10-14	11-15
	10 mm wide	24-21	541-0001	541-0004	541-0007	541-0010	X	541-0019	X
		28-25	541-0002	541-0005	541-0008	541-0011	541-0014	541-0020	541-0023
		32-29	541-0003	541-0006	541-0009	541-0012	541-0015	541-0021	541-0024
	12 mm wide	28-25	541-0101	541-0302	541-0303	541-0304	541-0305	541-0504	541-0505
		32-29	541-0201	541-0402	541-0403	541-0404	541-0405	541-0604	541-0605

Implant Loading

Place the Inserter over the back of the Implant. Rotate the control knob on the Inserter Housing clockwise until the knob stops turning, securely connecting the Implant to the Inserter (Fig. 2).

Figure 2

Ensure the distal fingers of the Inserter Housing pass over the back end of the Implant (Fig. 3). Confirm secure connection of Inserter and Implant prior to insertion into the disc space.

Fill the selected Implant with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

Note: Spineology Incite™ Cortical Fibers provide excellent utility when paired with Elite. As the fibers hydrate in situ, they will swell to fill the expanded cage void.

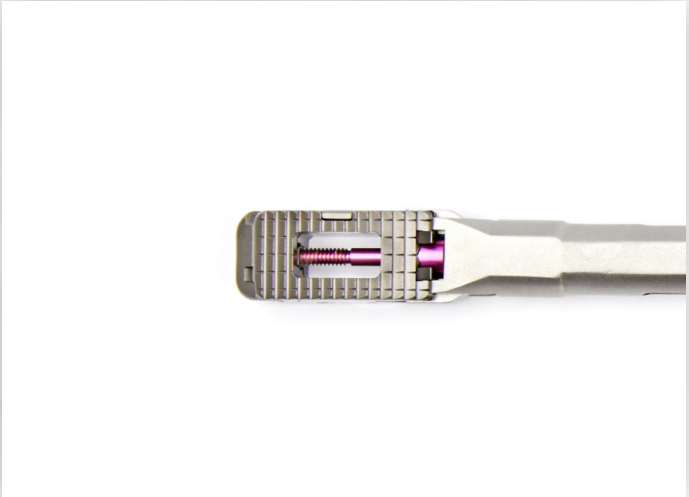

Figure 3

Implant Insertion

If desired, add bone graft to the disc space prior to Implant insertion.

Strike the proximal end of the Inserter to advance the Implant to the desired location within the disc space (Fig. 4).

Confirm Implant position using fluoroscopy.

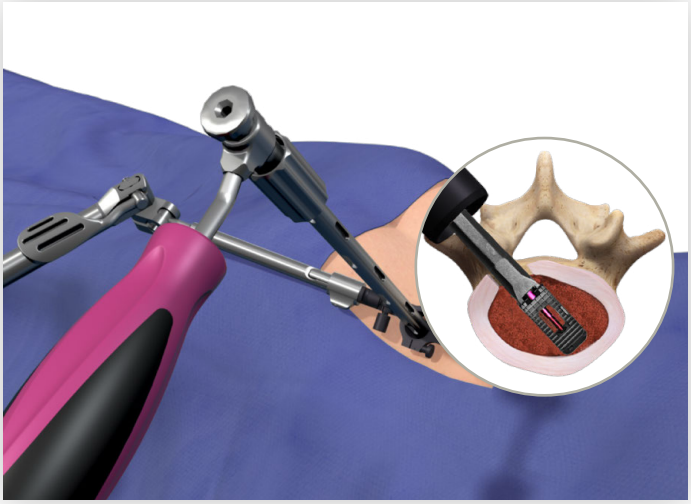

Figure 4

Implant Expansion

Rotate the control knob on the Inserter Housing counter-clockwise until the indicator pin is in-line with the recessed notch on the Inserter Housing shaft (Fig. 5). This confirms the distal fingers of the Inserter Housing are retracted and in position to allow Implant expansion.

Figure 5

Implant Expansion (continued)

Attach the Torque Handle to the Driver.

Note: Use only the Torque Handle provided.

Pass the Driver through the Implant Inserter cannula and engage the Implant expansion bolt.

Rotate the Driver clockwise to expand the Implant to the desired height (Fig. 6).

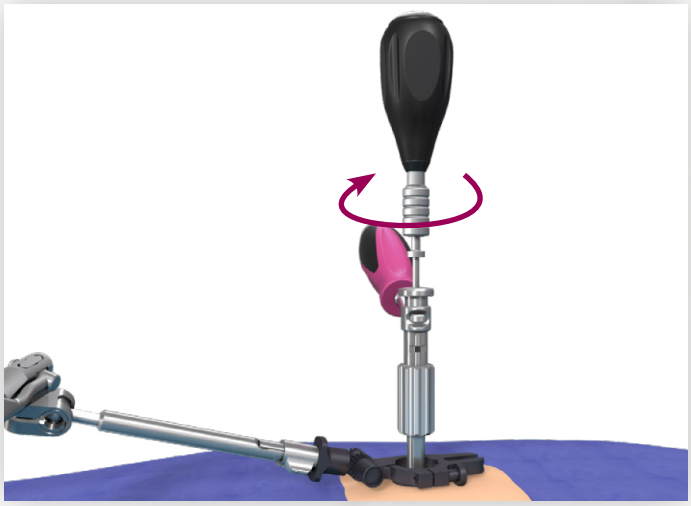

Figure 6

Cease expansion of the Implant when the desired height is visually achieved, or the maximum allowable torque is reached. This is evident when the Torque Handle clicks (Fig. 7).

Note: Use caution while expanding the Implant to avoid excessive distraction and damage to the vertebral endplates.

Note: Implant Driver revolutions can be visually tracked by observing the location of the laser mark on the driver shaft collar relative to a laser mark on the Implant Inserter. Rotating the Implant Driver one revolution results in 1/3mm of Implant expansion.

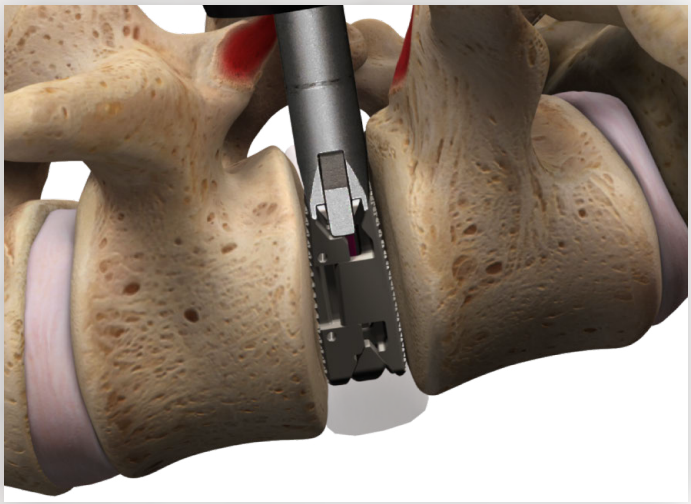

Figure 7

Implant Release

Note: Confirm final Implant position with fluoroscopy prior to release from the Inserter. In the event of Implant repositioning or removal, see Appendix C, page 12.

Turn the control knob counter-clockwise until the distal Inserter Fork releases from the Implant and remove the Implant Inserter (Fig. 8).

Place bone graft around the Implant if desired.

Figure 8

Implant Release Tool

In the event the Inserter does not immediately release from the Implant, press the button on the proximal end of the Inserter Housing and remove the Inserter Housing leaving the Inserter Fork attached to the Implant (Fig. 9).

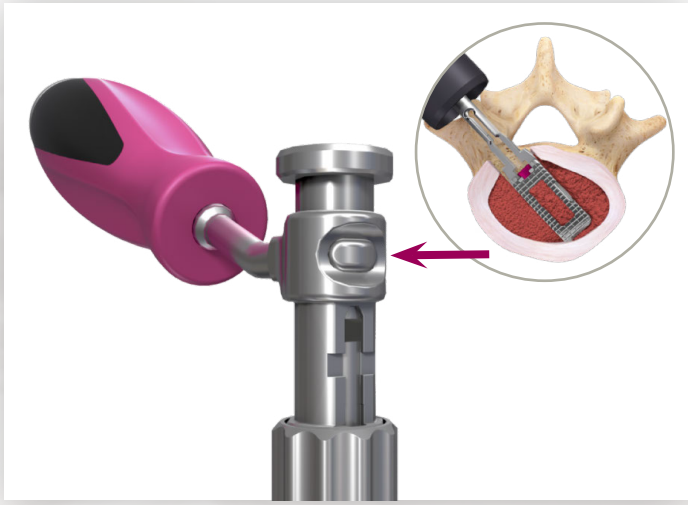

Figure 9

Implant Release Tool (continued)

Oscillate the Inserter Fork to release the Implant (Fig. 10).

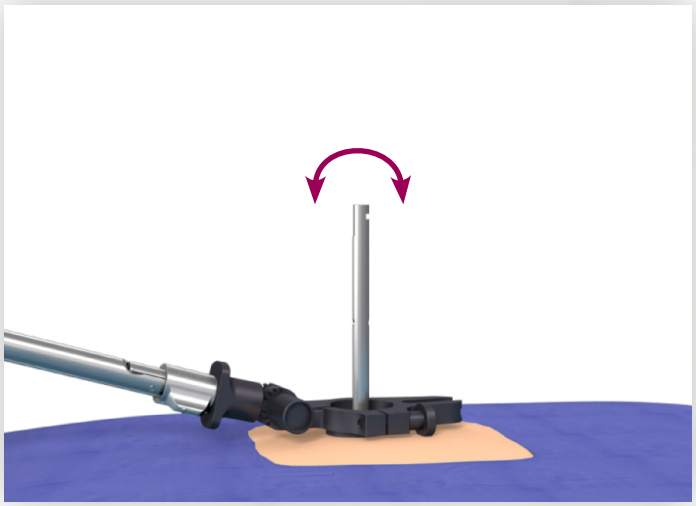

Figure 10

If the Inserter Fork will not release from the Implant, pass the Release Tool through the Inserter Fork (Fig. 11). Turn the knob of the Release Tool clockwise to expand the distal end of the tool and disengage the Inserter Fork from the Implant.

To disassemble the Release Tool from the Inserter Fork, turn the knob of the Release Tool counter-clockwise 6-7 turns. This will create a gap in the shaft at the proximal end of the Release Tool. Hit the proximal end of the Release Tool to advance the shaft.

Remove the Release Tool from the Inserter Fork.

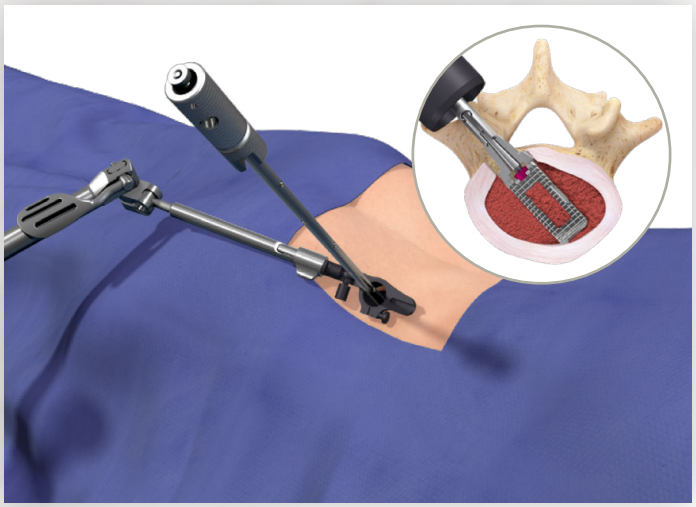

Figure 11

Appendix A: Implant Inserter Assembly

Identify the Inserter Housing and Inserter Fork (Fig. 12).

Turn the control knob of the Inserter Housing counter-clockwise until it stops turning.

Pass the 10mm or 12mm Implant-specific Inserter Fork into the Inserter Housing.

Note: Ensure the "flat" on the proximal end of the Inserter Fork is aligned with the button on the proximal end of the Inserter Housing.

Figure 12

Press the button near the proximal end of the Inserter Housing while continuing to pass the Inserter Fork into the Inserter Housing.

Confirm the Inserter Fork is locked inside the Inserter Housing with a light tug on the distal end of the Inserter Fork (Fig. 13).

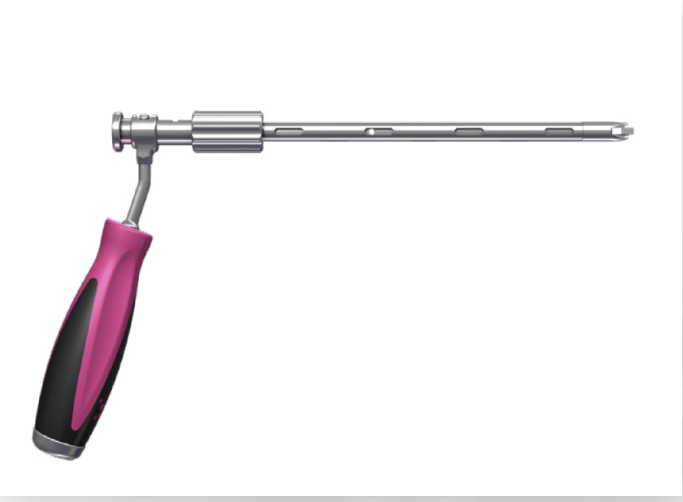

Figure 13

Appendix B:
Elite™ Expandable Interbody Fusion System

Instruments

CATALOG #	DESCRIPTION
540-9001	Inserter Housing
540-9101	Inserter Fork, 12mm
540-9102	Inserter Fork, 10mm
270-0020	Mallet
540-9401	Torque Handle
540-9501	Driver
301-0176	7mm Paddle Distractor
301-0094	8mm Paddle Distractor
301-0095	9mm Paddle Distractor
301-0025	10mm Paddle Distractor
301-0026	11mm Paddle Distractor
301-0027	12mm Paddle Distractor
301-0028	13mm Paddle Distractor
301-0029	14mm Paddle Distractor
301-0030	15mm Paddle Distractor
301-0031	16mm Paddle Distractor
280-0051	Slap Hammer
540-8951	Release Tool

10 mm-Wide Implants

CATALOG #	DESCRIPTION
541-0001	Elite Expandable, 10x24mm, Parallel, 7-10mm
541-0002	Elite Expandable, 10x28mm, Parallel, 7-10mm
541-0003	Elite Expandable, 10x32mm, Parallel, 7-10mm
541-0004	Elite Expandable, 10x24mm, 6° Lordosis, 8-11mm
541-0005	Elite Expandable, 10x28mm, 6° Lordosis, 8-11mm
541-0006	Elite Expandable, 10x32mm, 6° Lordosis, 8-11mm
541-0007	Elite Expandable, 10x24mm, 6° Lordosis, 9-13mm
541-0008	Elite Expandable, 10x28mm, 6° Lordosis, 9-13mm
541-0009	Elite Expandable, 10x32mm, 6° Lordosis, 9-13mm
541-0010	Elite Expandable, 10x24mm, 6° Lordosis, 10-14mm
541-0011	Elite Expandable, 10x28mm, 6° Lordosis, 10-14mm
541-0012	Elite Expandable, 10x32mm, 6° Lordosis, 10-14mm
541-0014	Elite Expandable, 10x28mm, 6° Lordosis, 11-15mm
541-0015	Elite Expandable, 10x32mm, 6° Lordosis, 11-15mm
541-0019	Elite Expandable, 10x24mm, 12° Lordosis, 10-14mm
541-0020	Elite Expandable, 10x28mm, 12° Lordosis, 10-14mm
541-0021	Elite Expandable, 10x32mm, 12° Lordosis, 10-14mm
541-0023	Elite Expandable, 10x28mm, 12° Lordosis, 11-15mm
541-0024	Elite Expandable, 10x32mm, 12° Lordosis, 11-15mm

Appendix B:
Elite™ Expandable Interbody Fusion System

12 mm-Wide Implants

CATALOG #	DESCRIPTION
541-0101	Elite Expandable, 12x28mm, Parallel, 7-10mm
541-0201	Elite Expandable, 12x32mm, Parallel, 7-10mm
541-0302	Elite Expandable, 12x28mm, 6° Lordosis, 8-11mm
541-0303	Elite Expandable, 12x28mm, 6° Lordosis, 9-13mm
541-0304	Elite Expandable, 12x28mm, 6° Lordosis, 10-14mm
541-0305	Elite Expandable, 12x28mm, 6° Lordosis, 11-15mm
541-0402	Elite Expandable, 12x32mm, 6° Lordosis, 8-11mm
541-0403	Elite Expandable, 12x32mm, 6° Lordosis, 9-13mm
541-0404	Elite Expandable, 12x32mm, 6° Lordosis, 10-14mm
541-0405	Elite Expandable, 12x32mm, 6° Lordosis, 11-15mm
541-0504	Elite Expandable, 12x28mm, 12° Lordosis, 10-14mm
541-0505	Elite Expandable, 12x28mm, 12° Lordosis, 11-15mm
541-0604	Elite Expandable, 12x32mm, 12° Lordosis, 10-14mm
541-0605	Elite Expandable, 12x32mm, 12° Lordosis, 11-15mm

Unique Device Identification (UDI)

All Spineology devices are labeled with UDI in human readable and/or Automatic Identification and Data Capture (AIDC) format. The human readable UDI is formatted starting with M740 and followed by device identifying characters.

The UDI of single use devices is found on the package label in both formats.

The UDI of reusable devices is directly marked on the device in human readable format or can be derived from the catalog number directly marked on the device. For example, a device with catalog number 123-4567 would have a UDI of M74012345670.

Appendix C:
Implant Repositioning and Removal

Implant Repositioning

With the Implant Inserter attached to the Implant, pass the Driver through the cannulation of the Implant Inserter and engage the Implant expansion bolt.

Apply force to the distal tip of the Driver when engaging the Implant expansion bolt and rotate the Driver counter-clockwise to reduce the Implant to its minimum height.

Rotate the control knob on the Inserter Housing clockwise until the knob stops turning, securely connect the Implant to the Inserter.
Note: Prior to repositioning, ensure the distal threads of the expansion bolt engage the nose of the Implant.

Reposition the Implant to the desired location and re-expand.

Implant Removal

With the Implant Inserter attached to the Implant, pass the Driver through the cannulation of the Implant Inserter and engage the Implant expansion bolt.

Apply force to the distal tip of the Driver when engaging the Implant expansion bolt and rotate the Driver counter-clockwise to reduce the Implant to its minimum height.

Rotate the control knob on the Inserter Housing clockwise until the knob stops turning, securely connect the Implant to the Inserter.
Note: Prior to removal, ensure the distal threads of the expansion bolt engage the nose of the Implant.

Remove the Implant.

DESCRIPTION

The Elite™ Expandable Interbody Fusion System is designed for use as a lumbar intervertebral body fusion device and consists of medical grade titanium alloy (Ti6AL4V) cages and implantation instrumentation. The cages are available in various geometries and sizes to accommodate patient anatomy. The cages have ridges or teeth that resist rotation and migration and have cavities to accept packing of bone graft. Components of the Elite™ IBF Expandable Lumbar Fusion System should not be used with components of any other system or manufacturer.

Spineology Inc. disclaims all warranties, express or implied, including but not limited to any implied warranty of merchantability or fitness for a particular use.

INDICATIONS

Elite™ Expandable implants are intervertebral body fusion devices indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Elite™ Expandable implants are designed for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft as an adjunct to fusion and are intended for use with supplemental fixation systems cleared by the FDA for use in the lumbar spine.

CONTRAINDICATIONS

1. Use of this system is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
2. Severe osteoporosis or osteopenia may prevent adequate fixation and thus preclude the use of these or any other orthopedic implants.
3. Conditions that may place excessive stresses on bone and implants, such as severe obesity, pregnancy or degenerative diseases, are relative contraindications. The decision to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
4. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
5. Prior fusion at the level(s) to be treated.
6. Any condition not described in the Indications for Use.

WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS CONCERNING SPINAL FIXATION IMPLANTS

Following are specific warnings, precautions and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations, particular to devices such as this system. General surgical risks should be explained to the patient prior to surgery. This system is intended to support the vertebral column while fusion is taking place. Not all implants are intended to be permanent. The recommendations for removal of hardware apply to the supplemental internal fixation implants used in this procedure. The decision to remove the supplemental fixation should be discussed with the patient taking into account the risks versus the benefits to the patient.

WARNINGS

1. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT.
2. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NON-UNION.
3. MR ENVIRONMENT: The Elite™ Expandable Interbody Fusion implant has not been evaluated for safety and compatibility in the MR environment. The Elite™ Expandable Interbody Fusion implant has not been tested for heating or migration in the MR environment.
4. The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrect operating techniques, the limitations of treatment methods or inadequate asepsis.
5. Patient compliance with post-operative instructions from his/her surgeon is very important for success of the treatment. Noncompliance could lead to failure of the device and/or of the surgery.
6. The instruments are provided non-sterile and must be sterilized prior to use.

PRECAUTIONS

1. SURGICAL IMPLANTS MUST NEVER BE REUSED

2. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT

- Implants are designed to support physiologic loads. Excessive torque, when applied to long-handle insertion tools, can cause deformation of the implant material. When implants are impacted or hammered into place, the broad surface of the insertion tool should be seated fully against the implant. Impaction forces applied directly to a small surface of the implant could cause damage to the implant.
- Pack the Elite™ Expandable Interbody Fusion Implant with bone graft until it flows out the opposite graft window. This will help ensure that the internal cavities of the implant are filled with bone graft material. Additional bone graft should be placed into the disc space after Elite™ Expandable is implanted using bone tamps, graft delivery systems or other instruments. Place autogenous bone graft around the Elite™ implant, filling the disc space on both sides of the implant.

3. ADEQUATELY INSTRUCT THE PATIENT
Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing.

4. CAUTERIZATION NEAR THE IMPLANT
When performing cauterization around an implant, care should be taken to avoid contact with the implant.

5. PATIENTS WITH PREVIOUS SURGERY
Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

6. PATIENT CONDITIONS
Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the intervertebral body fusion device.

7. METAL COMPATIBILITY – When selecting supplemental fixation, do not mix stainless steel with the titanium alloy found in the Elite™ Expandable Interbody Fusion implant. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Do not use implants or instruments from other systems or manufacturers, and do not mix stainless steel and titanium implant components together in the same spinal construct.

8. POTENTIAL RISKS IDENTIFIED WITH THIS DEVICE, WHICH MAY REQUIRE ADDITIONAL SURGERY INCLUDE: Device component failure (bending, loosening, or fracture of the implant), loss of fixation, non-union or delayed union, infection, fracture of the vertebrae, neurological injury and vascular or visceral injury.

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

ADVERSE EFFECTS

This list may not include all complications caused by the surgical procedure itself.

1. Bursitis.
2. Decrease in bone density due to stress shielding.
3. Degenerative changes or instability of segments adjacent to fused vertebral levels.
4. Fracture of bony structures.
5. Implant material sensitivity, or allergic reaction to a foreign body.
6. Infection, early or late.
7. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia.
8. Nonunion, delayed union.
9. Discomfort, or abnormal sensations due to the presence of the device.
10. Paralysis.
11. Spinal cord impingement or damage.
12. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late post-operative period.
13. Bending or fracture of the implant. Loosening of the implant.
14. Dural tears experienced during surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
15. Death.
16. Reflex sympathetic dystrophy.
17. There is an additional risk if there were to be long term in vivo degradation of the implant resulting in possible local or systemic adverse reactions from any potential degradation products.
18. If a pseudarthrodesis occurs coupled with the implant, a mechanical grinding action could possibly occur which might generate wear debris. Most types of wear debris have shown the potential of initiating local osteolysis in articulating joints.

IMPLANT HANDLING

Exercise care in handling implants. Protect the implants from contact with objects that may damage the surface. Inspect each implant prior to use and do not use if any damage is suspected.

IMPORTANT NOTE TO OPERATING SURGEON

The Elite™ Expandable device must be implanted only with the applicable Elite™ Expandable Interbody Fusion implant insertion instruments. The Elite™ Expandable Interbody Fusion implant expansion bolt must be engaged by and operated only with the applicable Elite™ Expandable Interbody Fusion torque-limiting bolt driver instrument. The Elite™ Expandable Interbody Fusion System instruments are available from the manufacturer at any time.

Interbody fusion procedures should only be undertaken after the surgeon has had hands-on training in these methods of spinal fixation, and has become thoroughly knowledgeable about spinal anatomy and biomechanics. Even for surgeons already experienced in spinal instrumentation, or interbody fusion procedures, new skills may be required that are best learned by working with an experienced surgeon or through a course of formal instruction with laboratory training. Lack of experience or expertise with these implants may result in complications.

POSTOPERATIVE MOBILIZATION

Postoperative external immobilization (such as bracing or casting) is recommended, at the surgeon's discretion. Instructions to the patient to reduce stress on the implants are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.

DEVICE RETRIEVAL

Contact Spineology to discuss Revision / Retrieval.

INSTRUMENTS

Surgical instruments must be handled with care. Improper handling may result in damage and may impair proper functioning of the device. Instruments which exhibit signs of damage or deterioration, including discoloration or corrosion, must be replaced. Ensure that all components of the system are available for use prior to surgery. Instruments must be sterilized before use and are to be cleaned and re-sterilized immediately after use.

- Note that these instruments are non-sterile.
- Spineology recommends using an FDA-cleared wrap for sterilizing.

All instruments must be cleaned and sterilized by the hospital before use as described below.

STERILIZATION

Instrument trays are provided for storing and sterilizing the instruments. Instrument trays do not provide a sterile barrier. Trays must be used with a sterilization wrap. Sterilization can be performed on wrapped trays with the following cycle parameters:

Method: Steam
Exposure Time: 4 Minutes
Cycle: Pre-Vacuum
Temperature: 270°F (132°C)
Drying Time: Minimum 30 Minutes

Deviations from the recommended methods of cleaning and decontamination are not advised. It is the sole responsibility of the user to qualify such deviations.

CLEANING AND DECONTAMINATION

- Cleaning and decontamination of surgical instruments are required before introduction into the sterile field.
- Following use, disassemble devices as instructed for cleaning. Preventing drying will facilitate later cleaning.
- Soak in enzymatic detergent (mixed per manufacturer's recommendations) for five (5) minutes or longer.
- Use a soft brush for manual cleaning and a soft bottle brush to clean tubes. Pay special attention to inner diameters and crevices during cleaning. Ultrasonic cleaning is acceptable.
- Rinse each part thoroughly under running water for one (1) minute or longer.

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

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Spineology, the innovator in anatomy-conserving spine surgery, develops surgical techniques, instruments and implants that conserve spinal bone, nerve and muscle tissues. Spineology is committed to increasing procedural efficiency, reducing surgical morbidity and accelerating patient recovery. Learn more at spineology.com.

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