Spineology®

# Elite™ Expandable Interbody Fusion System

## 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.

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## 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 implants are provided sterile by ethylene oxide and 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 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 on 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 SALES 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 pseudoarthrosis 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.

## POST OPERATIVE 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 | Exposure Time | Cycle | Temperature | Drying Time |
|---|---|---|---|---|
| Steam | 4 Minutes | Pre-Vacuum | 270°F (132°C) | 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) minute 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.

## FURTHER INFORMATION OR PRODUCT COMPLAINTS

Contact Spineology at:

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Please contact your local Spineology representative for a complete surgical technique manual or further cleaning instructions.

Manufactured by:
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STERILE EO Sterilized by ethylene oxide

Do not reuse