Caution: Do not re-sterilize

STERILE R Sterilized using irradiation

Do not reuse

Do not use if package is damaged

INSTRUCTIONS FOR USE

STALIF L® SCREW

Device Description: STALIF L® screws are to be used in conjunction with the STALIF L® and STALIF L FLX™ cages. They are 4.5mm or 5.5mm outside diameter cancellous, self tapping type screws, augmented with an anti back-out system (ABO®). They are manufactured from Titanium Alloy (Ti -6Al-4V) to ASTM F-136 & ISO 5832 Part 3 and BS 7252 Part 3.

Indications for Use: The STALIF L®/ STALIF L FLX™ is indicated for use with autogenous bone graft (and/or allogenic bone graft for STALIF L FLX®) in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to L5. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These implants should be implanted via a laparoscopic or an open lateral approach. The STALIF L®/ STALIF L FLX™ is required to be used with supplementary fixation systems (e.g., pedicle screws) that have been cleared for use in the lumbar spine. The STALIF L® system should be used with bone grafting material (autograft) only.

Contraindications:

- Osteoporosis, sepsis, infection or inflammation at or near the operative site.
- Fever of undetermined origin or allergy to screw material.
- Patient is unable or unwilling to follow post operative instruction.
- Disease or condition which precludes the possibility of healing.
- Any condition not described in the indications.

Warnings and Precautions:

- Do not intermix implants of different metallic alloy types in the same construct. Premature device failure and / or infection in the patient may occur.
- Selection of an appropriately sized device for the patient is important and increases the likelihood of a satisfactory outcome.
- Do not use if the package is damaged or opened. Contents may not be sterile.
- Do not use if current date exceeds label expiry date.
- Do not re-sterilize sterile implants.
- Instrumentation provided with the implant must be used in accordance with the approved surgical technique.
- Do not use excessive force when introducing and positioning the implant within the intervertebral body space to avoid damaging the implant.
- On insertion of the screw into the STALIF L® / STALIF L FLX™ device, ensure soft tissue is not trapped between the head of the screw and the device.
- Re-usable surgical instruments must be decontaminated and sterilized prior to next use.
- Do not reuse the device even if the device shows no external signs of damage. Internal stresses from a previous use may cause early failure.
- The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this type of device.
- STALIF L® screws must be used in accordance with table 1, to ensure minimum depth of screw in bone is greater than 12mm.
- Use caution when using STALIF L® / STALIF L FLX™ devices at contiguous levels to avoid screw interaction between adjacent level STALIF L® screws, particularly when using the longer length screws (30mm—40mm) with the smaller height cages (8mm—12mm).
- When using the STALIF L® / STALIF L FLX™ system, the physician/surgeon should consider the height of the patient vertebral bodies in the selection of STALIF L® screw lengths, particularly in contiguous level use.

Rx Only

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Please refer to your sales representative for further information about this device.

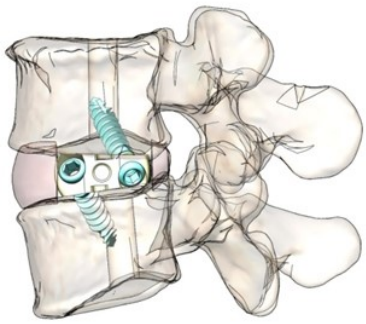

Figure 1 STALIF L®

STALIF L® SCREW	RESTRICTIONS ON USE ACCORDING TO CAGE HEIGHT
Ø4.5mm (All lengths)	To be used with 8mm and 10mm height cages only (STALIF L® only)
Ø5.5mm x 25mm	To be used with 12mm and 14mm height STALIF L® cages and 8mm-14mm STALIF L FLX™ cages only
Ø5.5mm x 30, 35, 40mm	To be used with 12mm and taller height cages only (STALIF L® and STALIF L FLX™)

TABLE 1: RESTRICTIONS ON SCREW LENGTH ACCORDING TO CAGE HEIGHT

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