Instruction for Use (IFU051) – STALIF L® Screws Spinal Implants

Important Information – please read before use!

These Instructions for Use apply to the STALIF L Screws. Other sets of manufacturer's instructions are available containing information required for application of the systems:

- Reprocessing Instructions for Instruments (LBL379)
- Instrumentation Guide (STG019)

The system-specific product information can also be viewed at the following links:

- https://elabeling.silony-medical.com
- www.silonyspine.com

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1 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 self-drilling 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.

2 Indications

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.

3 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.

4 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.

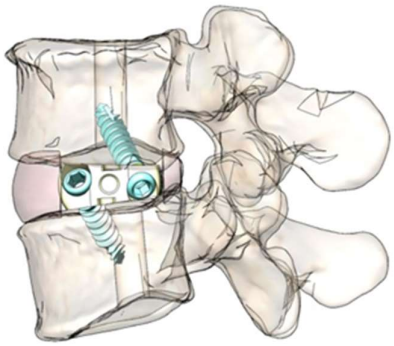

Figure 1. STALIF L®

STALIF L SCREW	RESTRICTIONS ON USE ACCORDING TO CAGE HEIGHT
Ø4.5mm (All lengths)	**STALIF L: Use with 8mm and 10mm height cages only** **STALIF L FLX: DO NOT USE**
Ø5.5mm x 25mm	**STALIF L: Use with 12mm and 14mm height cages only** **STALIF L FLX: Use with 8mm-14mm height cages only**
Ø5.5mm x 30, 35, 40mm	**STALIF L: Use with 12mm and taller height cages only** **STALIF L FLX: Use with 8mm and taller height cages only**

Table 1. RESTRICTIONS ON SCREW LENGTH ACCORDING TO CAGE HEIGHT

5 Glossary of Symbols

Symbols according to ISO 15223-1 (Recognition number: 5-134) and 21 CFR 801.109:

Symbol	Explanatory Text
	Manufacturer
REF	Catalog number
LOT	Batch code
	Do not use if the packaging is damaged
	Consult instructions for use
	Caution
	Do not reuse
	Do not resterilize
	Use by date *Including the year and month in the following format: YYYY-MM-DD*
STERILE R	Sterilized using irradiation
Rx only	Federal law in the USA restricts this device to sale by or on the order of a physician
QTY	Quantity
	Contact
	Conditional MR* safe
Ø	Diameter

*The term MR is synonymous with MRI and means magnetic resonance imaging

Patents Pending

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