STALIF L® / STALIF L® FLX

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The STALIF® L Portfolio consists of radiolucent lumbar intervertebral body fusion devices that are fixed to the superior and inferior vertebral bodies with cancellous lag bone screws augmented with an Anti Back-Out (ABO®) system.

The graft containment cavity is filled with bone graft (allograft and/or autograft) material. The STALIF L® Portfolio is available in two material options: PEEK (polyetheretherketone) and FLX™ (3D-printed osteoconductive porous titanium trabecular scaffold; FLX™ devices feature a combination of solid and porous, radiolucent FUSE-THRU® titanium sections for reduced mechanical stiffness and improved visibility compared to solid titanium implants).

STALIF L® is manufactured from Polyetheretherketone (PEEK) in accordance to the ASTM F2026. X-ray marker rods/spheres are manufactured from unalloyed Tantalum (Ta) per ASTM F-560. STALIF L® FLX is manufactured from Printed Titanium Alloy (Ti6Al4V) in accordance to the ASTM F3001 standard and ISO 5832-2-surfaced.

The STALIF L® Integrated Interbody™ Fusion Cages consist of varying heights, widths, lengths, and lordotic angles to accommodate individual pathology and anatomical conditions.

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 (ABO®) system that are offered in a variety of lengths. They are manufactured from Titanium Alloy (Ti-6Al-4V) to ASTM F-136 & ISO 5832 Part 3 and BS 7252 Part 3.

STALIF L® Portfolio devices are Integrated Interbody fusion devices and are required to be used with supplementary fixation systems (e.g., pedicle screws) that have been cleared for use in the lumbar spine.

INDICATIONS

The STALIF L® is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to L5. The STALIF L® FLX is indicated for use with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft) 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 I 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 may 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.

CONTRAINDICATIONS

- Osteoporosis, sepsis

- Infection or inflammation at or near the operative site
- Fever of undetermined origin
- Allergy to implant materials
- Patient is unable or unwilling to follow post-operative instructions
- Disease or condition which precludes the possibility of healing
- Prior fusion at the level to be treated
- Any conditions not described in the indications

WARNINGS and PRECAUTIONS

- Patients with previous spinal surgery at the levels to be treated may not experience the same clinical outcomes as those without a previous surgery.
- Selection of an appropriately sized device for the patient is important and increases the likelihood of a satisfactory outcome.
- 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.
- 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 implants 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.
- Re-usable surgical instruments must be re-sterilized prior to next use.
- Do not reuse the device even if the device shows no external signs of damage. Internal stresses from previous use may cause early failure.

POTENTIAL ADVERSE EVENTS with the STALIF L®/STALIF L® FLX

Potential risks or adverse effects identified with the use of this intervertebral body fusion device, which may require additional surgery are similar to those of other spinal systems, and include, but are not limited to:

- Early or late loosening of the components
- Bending or breakage of the components
- Foreign body (allergic) reaction
- Infection
- Bone loss due to resorption or stress shielding
- Loss of neurological function
- Neurological difficulties such as radiculopathy, paresthesia, new or continued pain, numbness/tingling, neuroma, dural tears, neuropathy and neurologic deficit
- Loss or impairment of bowel, sexual, and/or bladder function
- Vascular damage resulting in excessive blood loss
- Bone graft complications including pain, fracture or wound healing problems
- Spinal cord impingement or damage
- Fracture, damage, degenerative changes or instability of any bone above and/or below the level of surgery
- Additional surgery
- Rarely, some complications may be fatal

PACKAGING

Packaging of the components should be intact upon receipt. Damaged packages or products should not be used and should be returned to Centinel Spine.

STORAGE

The STALIF L®/STALIF L® FLX device can be shipped and stored at ambient conditions.

STERILITY

All components of the STALIF L®/STALIF L® FLX device are provided sterile for single use only. STALIF L®/STALIF L® FLX is supplied sterile by gamma irradiation with a SAL of 10-6. Dose mapping has been completed in accordance with ISO 11137. Sterilization validation has been completed in accordance with AAMI TIR27 (VDmax method).

System instrumentation must be sterilized per AAMI ST79. Complete instructions for cleaning and sterilization (LBL379) are available from Centinel Spine Customer Service [Call: +1 (484) 887-8810 or E-mail: cs@centinelspine.com].

INSTRUCTIONS FOR USE

Use of the STALIF L®/STALIF L® FLX device should only be considered when the following pre-operative, intra-operative and post-operative conditions exist:

Pre-operative

- Patient meets the indication criteria described and does not have any contraindications.
- The surgeon should determine the construct prior to surgery to ensure that the required components in the necessary sizes are available.

Intra-operative

- The surgeon follows the surgical technique and instructions for use of the device. The surgical technique guide is available through Centinel Spine Customer Service [Call: +1 (484) 887-8810 or E-mail: cs@centinelspine.com].
- All components are inspected and determined to be free of damage.
- Once the STALIF L®/STALIF L® FLX has been introduced and fixed by its screw fixation, additional anterior or posterior instrumentation is employed if deemed appropriate by the surgeon, who should consider factors such as the stability of the spinal column after fixation and potential risk associated with a subsequent surgical procedure to remove and/or replace these surgical appliances.
- For STALIF L®, autogenous bone graft is placed in the area to be fused.
- For STALIF L® FLX, bone graft (autograft and/or allograft) is placed in the area to be fused.

Post-operative

- The choice to administer post-operative antibiotics is at the discretion of the surgeon.
- Post-operative mobilization and rehabilitation is at the discretion of the surgeon dependent on clinical and radiological progress.
- The need for external orthotic support is not mandatory with the final choice based on surgeon preference, patient condition and intra-operative findings that might influence implant security.
- The patient is to be instructed to reduce undue stress on the implant as a precaution to avoid clinical problems that could result in fixation failure.
- The patient is to be instructed to follow the post-operative regime.

MRI SAFETY INFORMATION

Non-clinical testing demonstrated that the STALIF L®/STALIF L® FLX is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla and 3-Tesla only.
- Maximum spatial gradient magnetic field of 2,000-Gauss/cm (20-T/m)
- Maximum MR System reported whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.

Under the scan conditions defined, the STALIF L®/STALIF L® FLX implant is expected to produce a maximum temperature rise of 2.0°C after 15 minutes of continuous scanning.

- In non-clinical testing, the image artifacts caused by the STALIF L®/STALIF L® FLX implant extends approximately 10-mm from this implant when imaged using gradient echo pulse sequence and a 3-Tesla MR system.

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.

STERILE R Sterilized using irradiation.

Do not re-sterilize.

Do not reuse.

Do not use if package is damaged.

Patents Pending

CENTINEL SPINE®

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