CENTINEL SPINE®

STALIF L®

INSTRUCTIONS FOR USE – for OUS ONLY

GENERAL DESCRIPTION

The STALIF L® is a radiolucent lumbar intervertebral body fusion device that is fixed to the superior and inferior vertebral bodies with cancellous bone screws augmented with an anti back-out system (ABO®). THE STALIF L® device is manufactured from polyetheretherketone (PEEK) to ASTM F2026.

The graft containment cavity is filled with bone graft material. The STALIF L® IBF system consists of varying heights, widths and angles of lordosis to accommodate individual pathology and anatomical conditions.

INDICATIONS

The STALIF L® is indicated for use with autogenous bone graft and/or allogenic bone graft comprised 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 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® system 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.

WARNINGS and PRECAUTIONS (Continued)

- 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 EFFECTS with the STALIF L®

Potential adverse effects for this system 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.

STERILITY

All components of the STALIF L® device are provided sterile for single use only. STALIF L ® 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).

INSTRUCTIONS FOR USE

Use of the STALIF L® 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. Care should be taken to determine the correct size implant using the trial sizers in-line with the lateral surgical approach.
- All components are inspected and determined to be free of damage.
- Once the STALIF L® 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.•

INSTRUCTIONS FOR USE (Continued)

- Bone graft 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.
- The STALIF L® device is considered MR conditional. A patient with this device can be scanned immediately after placement under the following conditions: Static magnetic field of 3-Tesla or less, Maximum spatial gradient magnetic field of 720-Gauss/cm or less.
- Optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The MR image quality of artifacts may be compromised if the area of interest is in the exact same area or relatively close to the position of the implant.
- MRI-related heating may occur with a highest temperature change of +1.9°C.

STORAGE CONDITIONS

The device should be stored at ambient temperatures

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.

Caution: Do not re-sterilize

Do not use if package is damaged.

Do not reuse.

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