Instruction for Use (IFU044)

Implants of the STALIF M® portfolio

STALIF M
STALIF M Ti
STALIF M FLX

Important Information – please read before use!

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This Instruction for use covers cages of the STALIF M, STALIF M-Ti and STALIF M FLX systems.
Other sets of manufacturer's instructions are available containing information required for application of the systems:

- Reprocessing Instructions for Instruments (LBL379)
- Surgical Technique Guide (STG012)

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

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

Any manufacturer liability is excluded in the event of non-compliance with the manufacturer's product information.

Prior to using a product distributed by Silony Spine, the surgeon is expected to carefully study the following indications/contraindications, recommendations, warnings, and advice as well as the product specific information. Silony Spine also recommends participation in appropriate user training.

Users and/or patients are required to report any (serious) incidents related to the device to the manufacturer and to the state competent authority.

Caution: Federal Law (USA) resctricts these devices to sale by or on the order of a physician.

1 Device Description

1.1 General Information

The STALIF M Portfolio consists of 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 M portfolio is available in three material options: PEEK (polyetheretherketone), Ti-ACTIVE™ (3-dimensional inter-digitated microporous texturized titanium surface), 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).

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

STALIF MIDLINE/STALIF M screws are to be used in conjunction with the STALIF M, STALIF M-Ti and STALIF M FLX cages. They are 6mm outside diameter cancellous, self-tapping type screws, augmented with an Anti-BackOut (ABO) system that are offered in a variety of lengths.

STALIF M Portfolio devices are Integrated Interbody fusion devices and do not require supplementary fixation.

1.2 Material

STALIF M is manufactured from polyetheretherketone (PEEK) in accordance to ASTM F2026. STALIF M-Ti is manufactured from polyetheretherketone (PEEK) to ASTM F2026 with commercially pure titanium (CP Ti) coating (Ti-ACTIVE) to ASTM F1580. X-ray marker rods/spheres are manufactured from unalloyed tantalum (Ta) per ASTM F560. STALIF M FLX is manufactured from printed titanium alloy (Ti6Al4V) in accordance to ASTM F3001.
STALIF M Screws are manufactured from titanium alloy (Ti-6Al-4V) to ASTM F136 and ISO 5832-3.

2 Indications for use

The STALIF M/ STALIF M-Ti/ STALIF M 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 S1. 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 anterior approach.

The STALIF M/ STALIF M-Ti/ STALIF M FLX is a stand-alone system intended to be used with the bone screws provided and requires no additional supplementary fixation systems. The STALIF M FLX with lordotic angles greater than or equal to 20 degrees are required to be used with FDA-cleared supplemental fixation for use in the lumbar spine.

3 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

4 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 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 previous use may cause early failure.
- Should not be used with components of any other system or manufacturer.
- Do not intermix implants of different metallic alloy types in the same construct. Premature device failure and/or infection in the patient may occur.
- Based on fatigue testing results, when using the STALIF M/ STALIF M-Ti/ STALIF M FLX system, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may have an impact on the performance of this system.
- On insertion of the screw into the STALIF M/ STALIF M-Ti/ STALIF M FLX device, ensure soft tissue is not trapped between the head of the screw and the device.
- STALIF M/ STALIF M-Ti/ STALIF M FLX cages are recommended for use with 25mm or 30mm long screws. If patient pathology requires 35mm screws, use imaging to ensure unicortical fixation occurs only. STALIF MIDLINE/ STALIF M 35mm screws can extend beyond the back wall of the cage to a maximum as shown in Figure 1. **STALIF MIDLINE/ STALIF M 35mm screws must not be used with 30mm STALIF M/ STALIF M-Ti/ STALIF M FLX cages.**

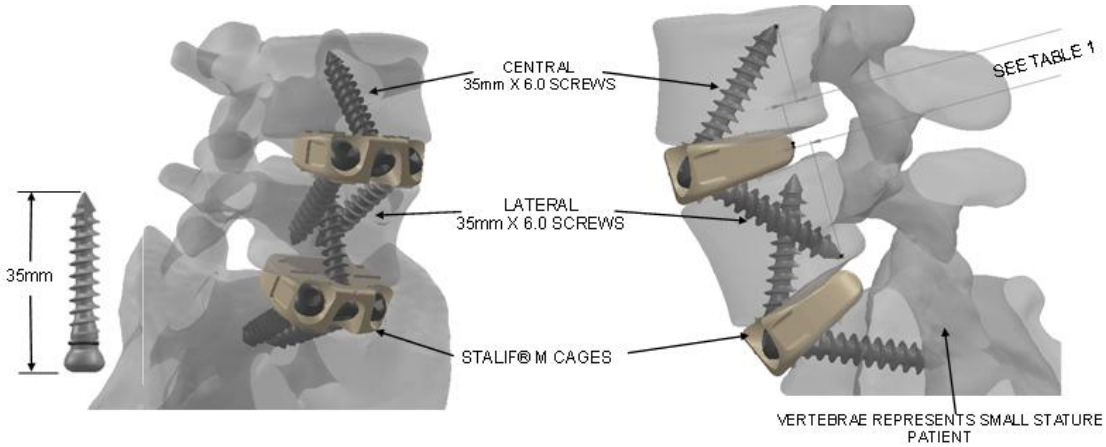

Figure 1. STALIF MIDLINE/ STALIF M 35mm screws – Maximum extension beyond cage

Table 1: Maximum extension beyond cage using 35mm screws

	Lateral 35 mm screw – max. distance beyond back wall	Central 35mm screw – max. distance beyond back wall
33mm STALIF M/ STALIF M-Ti/ STALIF M FLX cage (M33xxxx / M33xxxxc / SMF33xxxx)	1.5mm	1mm

5 Potential adverse events

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
- Pseudoarthrosis (i.e., non-union)
- 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
- Death

6 Packaging, sterility and storage

6.1 Packaging

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

6.2 Storage

- The STALIF M/ STALIF M-Ti/ STALIF M FLX device can be shipped and stored at ambient conditions.

6.3 Sterility

- All components of the STALIF M/ STALIF M-Ti/ STALIF M FLX device are provided sterile by gamma irradiation for single use only.
- System instrumentation must be sterilized per AAMI ST79. Complete instructions for cleaning and sterilization as indicated in instruction for use for cleaning and sterilization (LBL379).

7 Notes for application

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

7.1 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.

7.2 Intra-operative

- The surgeon follows the surgical technique and instructions for use of the device.
- All components are inspected and determined to be free of damage.
- Once the STALIF M/ STALIF M-Ti/ STALIF M 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.
- Bone graft (autograft and/or allograft) is placed in the area to be fused.

7.3 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.

8 Magnetic Resonance Imaging (MRI) Safety Information

- Non-clinical testing demonstrated that the STALIF M/ STALIF M-Ti/ STALIF M FLX implants are 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 M/ STALIF M-Ti/ STALIF M 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 M/ STALIF M-Ti/ STALIF M FLX implant extends approximately 10mm from this implant when imaged using gradient echo pulse sequence and a 3 Tesla MR system.

9 Labeling and Symbols

Symbols according to ISO 15223-1 and 21 CFR 801 Labeling.

Symbol	Explanatory Text
	Manufacturer
	Date of manufacture *Including the date in the following format: YYYY-MM-DD*
REF	Article number
LOT	Lot number
QTY	Number of items
MD	Medical device
UDI	Unique device identification
	Use by date *Including the year and month in the following format: YYYY-MM-DD*
	Consult instruction for use
	Caution
STERILE R	Sterilized using irradiation
	Do not reuse
	Do not resterilize
	Do not use if the packaging is damaged

	Keep dry
	Keep away from sunlight
	MR conditional (The term MR is synonymous with MRI and means magnetic resonance imaging.)
	Metal detectors can trigger alarm due to the implant
	Patient Identification
	Health care centre or doctor
	Date (of implantation)
	Contact
	Silony Logo (for identification of the legal manufacturer in the course of direct marking of products)

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