Instruction for Use (IFU049) – STALIF MIDLINE®/ STALIF® M Screws Spinal Implants

Important Information – please read before use!

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

- Reprocessing Instructions for Instruments (LBL379)
- Instrumentation Guide (STG012)

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 MIDLINE®/ STALIF® M screws are to be used in conjunction with the STALIF® M/ STALIF® M-Ti/ STALIF® M FLX cage. They are 6mm 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.

2 Indications

Consult STALIF M/ STALIF M-Ti/ STALIF M FLX cage instructions for use (IFU044).

3 Contraindications

- Osteoporosis, sepsis, infection or inflammation at or near the operative site.
- Fever of undetermined origin or allergy to screw materials.
- 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 M/ STALIF M-Ti/ STALIF M 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 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.**

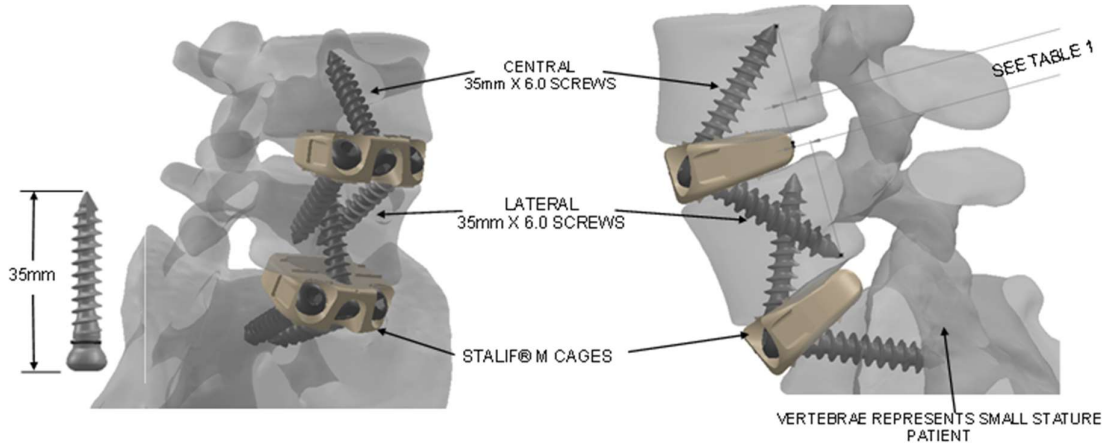

Figure 1. STALIF MIDLINE/ STALIF M 35mm Screws – Maximum Extension Beyond Cage

	LATERAL 35mm 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**

Table 1. Maximum Extension Beyond Cage Using 35mm Screws

5 Labelling and 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

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