CENTINEL SPINE®

STERILE R

Sterilized using irradiation.

Do not re-sterilize.

Do not use if package is damaged.

Do not reuse.

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.

INSTRUCTIONS FOR USE

STALIF MIDLINE® SCREW

Device Description: STALIF MIDLINE® screws are to be used in conjunction with the MIDLINE II®, MIDLINE II-Ti®, or 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.

Indications for Use: Consult MIDLINE II®, Midline II-Ti®, or STALIF M FLX™ cage instructions for use.

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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.

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 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.
- MIDLINE II®, MIDLINE II-Ti®, and 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® 35mm screws can extend beyond the back wall of the cage to a maximum as shown in Figure 1. STALIF MIDLINE® 35mm screws must not be used with 30mm MIDLINE II®, MIDLINE II-Ti®, or STALIF M FLX™ cages. Caution should be exercised when using STALIF MIDLINE® 35mm screws with 33mm MIDLINE II®, MIDLINE II-Ti®, or STALIF M FLX™ cages.

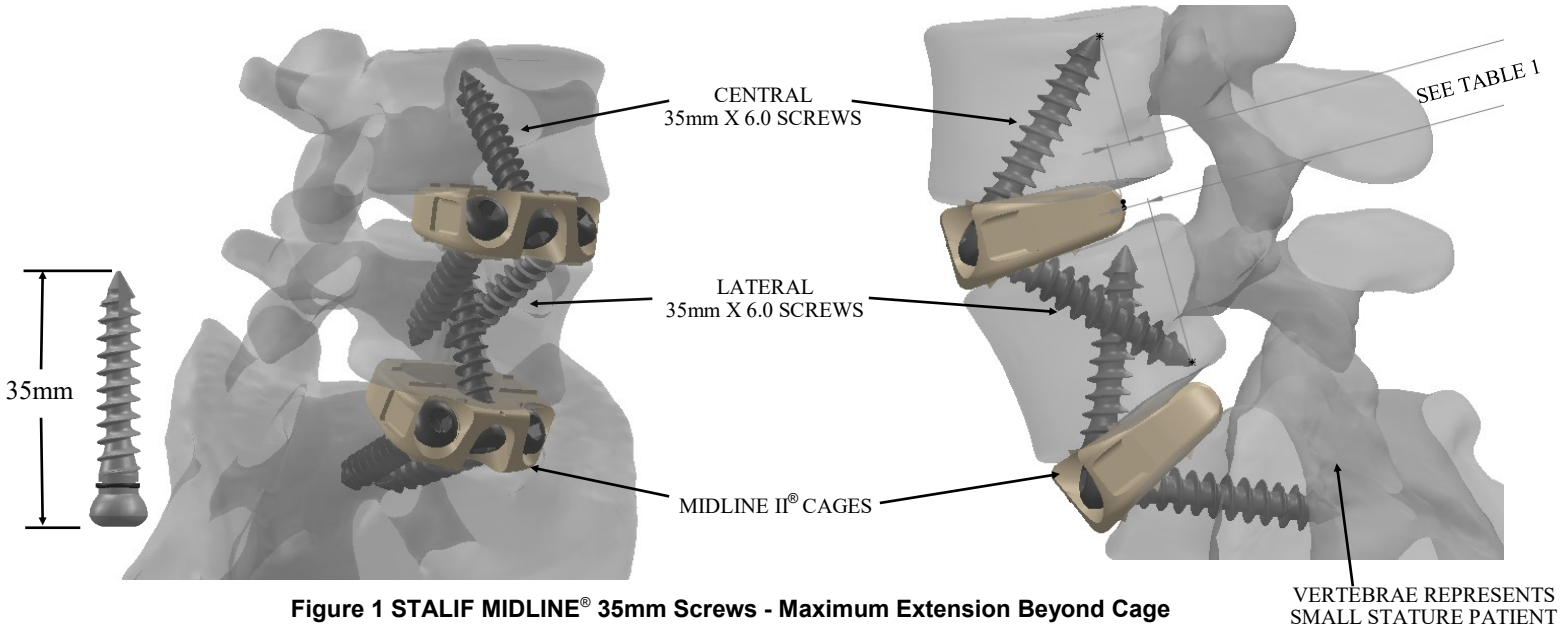

Figure 1 STALIF MIDLINE® 35mm Screws - Maximum Extension Beyond Cage

	LATERAL 35mm SCREW - MAX. DISTANCE BEYOND BACK WALL	CENTRAL 35mm SCREW - MAX. DISTANCE BEYOND BACK WALL
33mm MIDLINE II®, MIDLINE II-Ti®, and STALIF M FLX ™ CAGES (M33xxxx / M33xxxxc / SMF33xxxx)	1.5mm	1mm

Table 1 Maximum Extension Beyond Cages Using 35mm Screws

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