MID-SEW™

SILICONE EXTENDER FOR WOUND

REF **MID300**

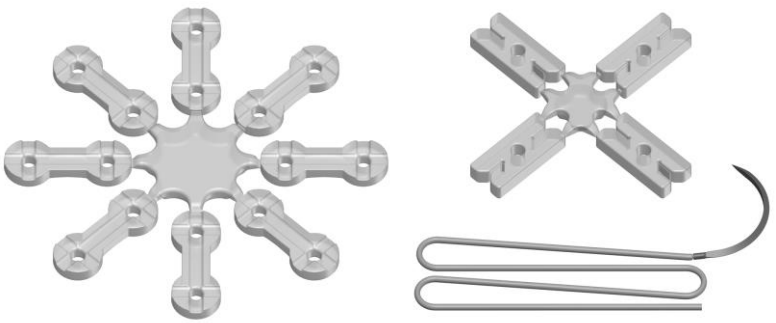


Figure 1: MID-SEW™

1 QUALIFICATION OF PRACTIONNERS

MID-SEW™ must be handled only by practitioners with experience of surgery of cutaneous extension.
Warning : Practitioners must fully familiarize themselves with these instructions before use. This IFU is not a textbook of surgical techniques. The figures show the set-up or the adjustment of the medical device.

2 IMPORTANT POINTS

- **The MID-SEW™ must not be used for longer than 29 days.** In case of replacement by an identical device, the total period of use should not exceed 29 days
- The devices could be returned to the distributor for expert analysis in accordance with MID returned goods policy with a brief description of the observation, to satisfy the manufacturer's quality assurance policy. Please contact MID before returning.
- Removal of this device must not compromise the safety or health of patients, users or any other person. The device must be removed and destroyed in accordance with current legislation in the country concerned.

WARNING: This product is a sharp device according to 2010/32/UE directive which may be contaminated after use. Handle and remove it with other sharp / cutting devices according to established medical protocols and other applicable regulations.

- When handling MID-SEW™, do not bring it into contact with any instrument that could damage the device.
- It is essential to keep **at least one spare device** available in the event of malfunction or other incidents.

WARNING: MID-SEW™ is NOT a safety medical device.

3 DESCRIPTION

The MID-SEW™, ref MID300 is a surgical suture in silicone intended to cutaneous extension.
It is composed of:

- Eight (8) silicone wedges with two orifices which assure the passing of the suture.
- An elastic silicone wire which is 100 cm long with one of its edge is set to a triangular curved needle.
- Four (4) silicone devices for blocking the suture with a reversible way.

4 INDICATIONS

The silicone extender for wound MID-SEW™ is intended to be used to facilitate closure of wounds that cannot be managed by primary wound closure.
MID-SEW™ is a dermato-traction medical device. MID-SEW™ is intended an adult patient.

5 CONTRINDICATIONS

Do not use this device on an injured skin.

6 INTERACTIONS

None known.

7 SECONDARY EFFECTS

Skin necrosis may occur next to the elastic suture and the silicone wedges if the tension set by the practitioner is excessive (skin whitening).

8 PRECAUTIONS:

- **The choice and the setting of the silicone suture is depending on the state of the patient, the experiment of the surgeons, the surgical technique and the type and size of the wound.**
- **Withdraw the suture from the cardboard carefully.**
- **The silicone wedges and the blockers are easily detachable by traction to rupture or with the use of surgical scissors.**

⚠ **Do not tighten the elastic silicon wire before cutting the needle.**

9 INSTRUCTIONS FOR USE

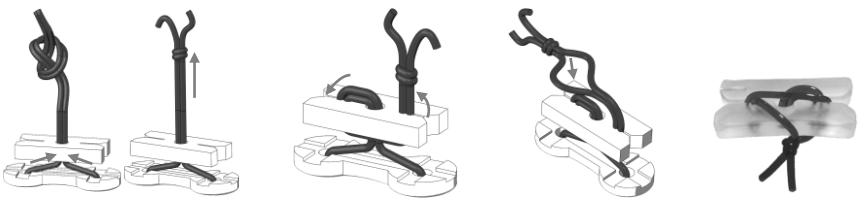
The set of the suture is realized with a needle holder. The silicone wedges are set between the suture (in the dedicated slot) and the cutaneous wall in order to reduce the pressure. The use of the wedges is facultative.

WARNING: Moisten the thread before stitching

The blocking system is placed at the two edges of the elastic suture once the needle removed and the tension set.
The choice of the adjustment in the following days after the surgery depends on the state of the patient and the experience of the surgeon. The device could be readjusted several times following the decision of the practitioner.

WARNING: The blocking system must NOT be in contact with the wound.

Figures : suture thread and wedges setting



Figures : Reversible locking

10 STORAGE AND STERILISATION CONDITIONS

10.1 Storage:

Keep products in their original packaging in a dry, cool location, sheltered from light and impact.

10.2 Sterilization:

- MID-SEW™ is delivered in a package that ensures a sterile probe (ethylene oxide sterilization). Check the integrity of the packaging before use. Do not use a product from a damaged package.
- **Do not use the product after the expiry date shown on the package.**
- This is a single-use product – **DO NOT RE-STERILISE / DO NOT REUSE**
- To do so would entail the following risks:
    - Sterile condition not guaranteed outside MID-approved methods.
    - Significant risk of cross-contamination or post-operative complications.
    - The expected performance characteristics of the device would not be guaranteed.

For single use only

Store in a cool, dark, dry place

Do not used if package is opened or damaged

Rx Only "Caution : Federal Law restricts this device to sale by or on the order of a physician or a licensed practitioner"

Not made with natural rubber latex – ne contient pas de latex – kein latex– No Latex – No Lattice – não latex- Latexvrij – Uden latex – Utan latex – Lateks içermez-本品不含有乳胶
از لاتکس لاستیک طبیعی ساخته نشده است.

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POLITIQUE de RETOURS/RETURNED Goods POLICY
Aucun retour produit ne peut se faire sans l'autorisation préalable de MID. Afin de connaitre les modalités de retour merci de nous contacter à :
Authorization must be received from MID prior to return of the medical device. For particular return indications, please contact us:

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