**TopClosure® - Tension Relief System**

**BEFORE USING THIS PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY**

**IMPORTANT!**
This instructions guide is designed to assist in using this product. It is not a reference to surgical techniques. The clinical application of this product should be based on specific clinical judgment, by a trained physician that takes into consideration all potential risks prior to application of the device.

TopClosure® intended use for Skin Stretching and Secure Wound Closure. This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury. Do not reuse, reprocess or re-sterilize this device. Reprocessing and/or re-sterilization of this device may create the risk of product malfunction, contamination and infection. Proper handling of the device ensures infection control and reduced contamination risk.

Do not use if the sterile packaging is damaged or opened.

Discard product after use.

Store away from light in a cool, dry place. Optimal storage conditions are at temperatures between 10-28°C and relative humidity between 40-70%.

This package insert is designed to provide instructions for use of TopClosure®. It is not a reference to skin stretching techniques.

- Please read all information carefully.
- Failure to properly follow the instructions may lead to serious surgical consequences.

**TopClosure® System Components (varies to specific model):**

- Flexible semi-transparent attachment plates with non-toxic hypoallergenic adhesive tape on its undersurface (Figure. 1).
- Approximation strap (of distinct sizes) (Figure. 2).
- Patch of hypo-allergenic transparent adhesive tape (Figure. 3).
- Liquid adhesive ampoule (Figure. 4).

**TopClosure® 1S-AD First-Aid Kit includes:**

- Two flexible semi-transparent attachment plates with non-toxic hypoallergenic undersurface.
- One approximation strap (of distinct sizes).
- Two patches of hypo-allergenic transparent adhesive tape.
- One liquid adhesive ampoule.

**TopClosure® TRS 1SM Rescue Kit includes:**

- Two flexible semi-transparent attachment plates with non-toxic hypoallergenic undersurface.
- One approximation strap (of distinct sizes).
- Two patches of hypo-allergenic transparent adhesive tape.
- One liquid adhesive ampoule.
- Provided in custom-made (waterproof, durable) packaging.

**Instructions for use**

**Preparations for TopClosure® Application**

- Prior to application assess the expected tension on the skin and choose the appropriate TopClosure® size orientation and number of sets to be used.
- Evaluate the proper positioning of the attachment plates across the wound or lesion.
- For curved surface – bend the attachment plates at the transverse indentation in order to accommodate skin surface curvature before application.
- If the TopClosure® is used on an open wound make sure you cover it with gauze or a bandage before the approximation strap is placed on it.
- **Important note:** Do not use TopClosure® in the following cases:
  - Known allergy to adhesives/tapes.
  - Thin, fragile sensitive skin.
  - Uncooperative patients.
- Do not apply excessive shearing forces at all TopClosure® usages. Always apply gentle gradual tension to the skin when approximating tissues.
The Applied Stress and the Recommended Application

<table>
<thead>
<tr>
<th>Wound closure intensity</th>
<th>Applied stress</th>
<th>Recommended mean for plate adhesion</th>
<th>Main means of wound edges approximation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low (non-invasive application)</td>
<td>≤0.6kg</td>
<td>AP's adhesive tape and covering medical adhesive tape</td>
<td>approximation straps</td>
</tr>
<tr>
<td>Moderate (non-invasive application)</td>
<td>0.6-1kg</td>
<td>liquid adhesive AP’s adhesive tape and covering medical adhesive tape</td>
<td>approximation straps</td>
</tr>
</tbody>
</table>

Choosing the TopClosure® Tension Relief System Size

<table>
<thead>
<tr>
<th>TopClosure® system size</th>
<th>Recommended use</th>
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<tbody>
<tr>
<td>4mm</td>
<td>Pediatric Applications, Facial Wounds, Fine to Minor Skin Lacerations</td>
</tr>
<tr>
<td>8mm</td>
<td>Adult High Tension Wounds, Adult Torso and Limb Trauma, Military Use</td>
</tr>
</tbody>
</table>

TopClosure® – Non Invasive Application

• Open the blister using sterile technique and remove the attachment plates and approximation straps required for the application.

• Apply on skin which has been shaven, cleansed with Isopropyl Alcohol sponge and dried thoroughly.

• Adjust the attachment plates to the skin surface by bending them along the designated horizontal indentations, as needed.

• Peel off the adhesive tape on the back of the attachment plates, avoid touching the adhesive.

• Place the attachment plates and attach them to the skin on both sides of the lesion or wound. The approximation plates should be positioned 1.5-2cm away from the wound edges.

• Firmly adhere to skin.

• Further secure the attachment plate to the skin with additional medical hypoallergenic tape, to prevent unintentional peeling of the attachment plate from the skin.

• Insert the approximation strap in the locking/release mechanism (LR/M) of one attachment plate and then to the remote attachment plate. While inserting the approximation strap through the LR/M of the remote attachment plate, be sure to press down on the proximal end of the attachment plate to avoid its detachment from the skin.

• Make sure that the approximation strap’s wing is interfaced with the locking/release mechanism of the first attachment plate.

• Tighten the approximation strap gradually to enable the skin stretching.

• In case of excessive pull and collapse of the LR/M and the approximation strap wings, re-insert the strap and pull gradually in order to maintain functionality of the system and avoid repeated failure of the approximation strap wings.

• Shorten the approximation strap as clinically indicated and secure the stump to the attachment plate with a tape.

• The adhesive is extremely durable under shear forces, yet can be easily peeled off when needed. In order to prevent inadvertent peel of the attachment plate from the skin and to further secure the attachment plate to the skin, apply an additional medical hypoallergenic drape.

• To further secure the system, it is advisable to circumferentially wrap it with an elastic bandage.

• The TopClosure® should be removed every 4 days, replaced and repositioned if necessary.
  • To release tension, gently lift the tab of the LR/M and then withdraw the approximation strap as necessary.
  • Detach the attachment plates from the patient’s skin (when an additional medical adhesive tape has been used- remove it first).

• Using TopClosure® in conjunction with liquid adhesive

Do not apply the liquid adhesive on a skin with prior known sensitivity or allergy to adhesive tapes or skin glues.

• Pat the skin dry with sterile gauze to assure good contact of the adhesive to a dry skin. Moisture accelerates the adhesive’s polymerization and may affect adhesion results.

• Prevent inadvertent flow of liquid adhesive into the wound and unintended areas of the body.

• Adhesive should be used immediately after crushing the ampoule, since the liquid adhesive will flow freely from the tip for only a few minutes. Notice that sterility is guaranteed until the ampoule is opened.

• Hold the applicator with the thumb and a finger, away from the patient to prevent any unintentional placement of the liquid adhesive on the patient. With the applicator tip pointing upward, at a slight angle or in a position that is comfortable to you, apply pressure at the midpoint of the plastic bulb to crush the ampoule. Gently squeeze the applicator sufficiently to moisten the applicator with the liquid adhesive. Stop squeezing and allow the liquid adhesive to draw back into the applicator.

• Slowly apply the liquid adhesive in one continuous layer to the skin covering the intended area where the attachment plates should be attached using a gentle brushing motion. Anchor the attachment plates to the skin approximately 60 seconds after the application of the liquid adhesive. Apply another thin layer of adhesive at the edges of the attachment plates to improve the bonding. Full apposition strength is expected to be achieved within minutes after the adhesive is applied. Full polymerization is expected when the adhesive layer is dry.

• Protective dry dressings such as gauze to an open wound may be applied only after adhesive film is completely polymerized and not sticky to the touch. Allow the adhesive to fully polymerize before applying a covering drape and dressings.

• Wait until the adhesive under the attachment plates is fully polymerized before inserting the approximation straps through the attachment plates.

• Do not apply liquid or ointment medications onto area of the adhesive because these substances can weaken the polymerized film, leading to detachment of the attachment plates from the skin.

• Patients should be instructed to not pick at the polymerized film of the adhesive. Picking at the film can disrupt its adhesion to the skin and cause the attachment plates detachment.

• Patients should be instructed that there should be only transient wetting of the attachment plates. Patients may immediately shower or bathe the site gently as directed by their physician. The site should not be scrubbed, soaked, or exposed to prolonged moisture until physician has determined that the attachment plates can be removed.
If removal of the attachment plates is necessary for any reason, wash repeatedly the adhesive film with soap and water to help loosen the bond. Then, gently peel off the attachment plate.

Contraindications

- The TopClosure® should not be applied for stretching of heavily scarred tissue, with minimal laxity of the skin.
- Special caution should be taken when stretching circular organs (e.g. limbs), to avoid and detect compartment syndrome, inflicted by excessive stretching of the skin. If compartment syndrome is suspected, immediately release the tension by releasing the straps and/or the sutures. As an invasive wound closing aid, the TopClosure® is designed to bring the skin margins together so that they may be safely sutured or stapled, using conventional methods. By applying a controlled amount of tension evenly along the wound margins, the TopClosure® uses the visco-elastic properties of skin to cause it to stretch and extend while minimizing its tendency to recoil. This process, known as "Mechanical Creep", does not impair the immediate or long-term viability of skin. The amount of tension applied by the device is controlled by the surgeon. As the skin expands and tension is reduced, additional tension can be applied incrementally in repeated cycles until the skin margins are brought into close apposition for suturing or skin grafting. The device is then removed.

Precautions and Warnings

- **A "pinch test" may be employed as a rough estimation of the potential effectiveness of the skin stretching technique. If the tissue doesn’t stretch at all on either side of the wound, the device may not be helpful in advancing the skin edges.**
- Devices which come in contact with bodily fluids may require special disposal handling to prevent biological contamination.
- The TopClosure® is packaged and sterilized for single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury or illness. also, reprocessing or re-sterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. The signs that indicate that the device was used are an open or damaged Blister package and/or an attachment plate missing its adhesive's cover.
- The development of post trauma or postoperative edema may cause severe degradation in adhesion quality, skin shearing, skin blistering and compartment syndrome.
- As with all skin adhesive products, a small percentage of individuals may experience hypo or hyper pigmentation following removal.
- Application of any surgical tape or medical adhesive may result in skin stripping upon removal.
- Excessive tension application may cause skin damage by shearing, skin blistering, or loss of adhesion.
- The surrounding area to be operated upon should also be prepared using sterile antiseptic cleansing solution, and should be appropriately draped.
- The polypropylene (PP) is chemically inert and does not interact with electric or magnetic sources or instruments. Chemical liquids such as soaps, detergents, alcohols, disinfectants and other chemicals may change the adhesive properties of the adhesive at the underside of TopClosure® attachment plates. The attachment surface for TopClosure® should be clean and dry for optimal performance of the adhering tape. Possible exposure to body fluids, cleansing liquids or wetting of the tape should be considered prior and during clinical use to determine means of proper securing of the device to the skin.
- Where there is tissue edema, the device should be used with caution.
- This device must be prescribed by a physician.
- The device should be handled after use as potentially contaminated material; therefore it must be disposed of and discarded accordingly.

Risks and Adverse Effects

- **Sensitivity to Adhesives**
  Application of liquid adhesive may result in allergic reaction in patients who are hypersensitive to cyanoacrylate and formaldehyde.
  Upon appearance of local redness, itching or stinging sensation, the attachment plate should be removed, the area should be washed using water and soap and the physician in-charge should be consulted. If needed, a new attachment plate may be relocated.

- **Local Infection**
  Local skin infection may complicate local irritation caused by adhesives and may require removal of attachment plate and topical or systemic treatment of local infection.

- **Local Pigmentation Changes and/or Scar formation**
  In rare occasions, the application of adhesives may result in severe skin irritation, with permanent change in local pigmentation and/or scar formation.

- **Excessive Tension on Anchoring Skin**
  Application of tension on the anchoring skin may result in excessive shear stress on the skin that may induce skin damage (blistering and/or scarring). Use the releasing mechanism knob to release the approximation strap in order to reduce local tension.

Adverse effects that could possibly result from the use of this device include skin irritation, change in pigmentation, local infection, blistering, scarring and compartment syndrome. In addition, it may not always be possible to completely close the wound.

Manufacturer's Warrantee:
Non-conforming products will be replaced without charge, as long as the product has been handled in accordance with the manufacturer's recommendations and instructions.

For more information visit [www.topclosure.com](http://www.topclosure.com)

Authorizations:

CE 1023
IMoH Registration No. 21380001
Exp. Date: see product label.

⚠️ PRIOR TO USE SEE INSTRUCTIONS.

 لهذا המוצר יש איסור עין אחת.

Latex Free

M-Leaflet-EU_FirstAid&Rescue, Issued July 2016