TopClosure® 3S System - Skin Stretching and Secure Wound Closure System

BEFORE USING THIS PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY

IMPORTANT!
This user instructions document is designed to assist in using this product. It is not a reference to surgical techniques.

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 resterilize this device. Reprocessing and/or resterilization 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: at temperatures between 10-27°C and relative humidity between 40-60%.

Failure to properly follow the instructions may lead to serious surgical consequences.

TopClosure® 3S System package components

The TopClosure™ 3S System is supplied sterile for single use only.

Illustrations 1 and 2 demonstrate the TopClosure® 3S System components structure.
Attachment Plate

Approximation Strap

Illustrations 1 and 2: TopClosure® 3S System components.

Device description

The TopClosure® 3S System is a sterile single-patient-use device which is comprised of two attachment plates with adhesive surface attached to the bottom and an approximation strap. The system may be adhered to the skin by gluing (non-invasive) or by using staples, sutures and/or KW. Each attachment plate consists of a series of oval opening pairs and a horizontal opening at the proximal edge of the attachment plate. One approximation strap connects each pair of attachment plates. An additional approximation strap is provided for extending the approximation strap if needed. The attachment plates and the approximation strap are made of Polypropylene. The double sided tape at the bottom of the attachment plates is a double-sided hypoallergenic, non-toxic medical grade adhesive, which is FDA and CE approved. The TopClosure® 3S System product line consists of three size options: 4mm, 6mm and 8mm. Each size of the system is packaged in a sealed blister which is differentiated by specific color card from the other systems' sizes.
**Intended use**

The TopClosure® 3S, Skin Stretching and Secure Wound Closure System, is a dynamic skin closure system that enables skin closure for low to high tension wounds. The TopClosure® 3S System is intended to temporarily stretch skin tissues to aid closure and healing of post traumatic, surgical, acute and chronic skin wounds. In addition, the TopClosure® 3S System may be used as reinforcement for securing wounds after early suture or staple removal. The TopClosure® 3S System enables a gradual regulated skin closure, without additional anesthesia.

- The system is a **non-invasive** mean for skin stretching. It can be used:
  - Prior to a surgical procedure for removal of skin lesions where direct skin closure is anticipated to take place under tension, or
  - Following surgery to secure wound closure where the skin has closed under tension.
  - For treatment of hypertrophic or keloid scars.

- The TopClosure® 3S System can also be attached to the skin **invasively** during surgery for:
  - The gradual approximation of wound edges when the edges are under significant tension that prevents primary closure, or:
  - As a substitute for tension sutures.

- The TopClosure® 3S System can be applied for management of traumatic, surgical, acute or chronic wounds, to ease and to secure reconstructive procedures and to improve the healing and aesthetics of wound closure.

- The TopClosure® 3S System can be applied simultaneously with Regulated Negative Pressure wound Treatment (RNPT) to promote healing in acute or chronic wounds.

- The TopClosure® 3S System- Skin Stretching and Secure Wound Closure System can be indicated for extended wound lengths by applying a series of pairs of TopClosure® 3S Systems along the suture line (in various directions as clinically indicated).

**Indications:**

- Specific indications for invasive use include:
  - Closure of large wounds with significant skin and soft tissue loss.
  - Wound closure when skin loss or retraction prevents an edge-to-edge apposition.
  - Approximation of wound edges over poorly vascularized structures, such as tendons and bones.
For improved aesthetics of wound closure as an alternative to skin grafts, by mobilizing skin and subcutaneous tissue.

- Closure of open fasciotomies.
- Wound closure over open fractures.
- Preoperative skin expansion in preparation for dermal extirpation (e.g. skin lesions).

**Contraindications:**

- Non-invasive application of TopClosure® 3S System is contraindicated for patients with very thin, delicate sensitive skin (in these patients, anchoring with staples or sutures is indicated exclusively with extra caution to the stress applied when stretching the skin). If the skin surrounding the treated site is delicate, thin or fragile, evaluate again the need for TopClosure® 3S System application. If absolutely needed, apply the TopClosure® 3S System at a slightly distant location away from the problematic area.

- This device is not intended for use with the applied adhesive surface in patients with a known sensitivity to adhesives. Other methods of application should be considered.

- Attachment using staples or KW should not be used when it is impossible to maintain a 7mm distance between stapled skin surface and underlying vital structures such as vessels, major nerves, internal organs, bones and connective tissue such as tendons and ligaments.

- Extra caution should be taken when applying the TopClosure® 3S System in the following cases:
  - When non-viable or atrophic tissue is present at or near the wound edges.
  - When the patient has received localized radiation treatment at the wound site.
  - When the patient is receiving chemotherapy.

- Special consideration should be made for application of TopClosure® 3S System in areas of repetitive motion as in areas adjacent to joints. Application of TopClosure® 3S System for these areas may be considered for each individual patient, and may require limb affixing.

- The TopClosure® 3S System application is contraindicated when the designated adherent area is infected.

As an invasive wound closing aid, the TopClosure® 3S System 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® 3S System 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.

**Instructions for use**

**Preparations for TopClosure® 3S System Application**

- Prior to application assess the expected tension on the skin and choose the appropriate TopClosure® 3S System size orientation and number of systems 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® 3S System is used on an open wound make sure you cover it with gauze or a bandage before the strap is placed on it.
- **Important note: Do not** use TopClosure® 3S System in the following cases:
  - Known allergy to adhesives.
  - Thin, fragile sensitive skin
  - Uncooperative patients.
- Do not apply excessive sheering forces at all TopClosure® 3S System usages. Always apply gentle gradual tension to the skin when approximating tissues.

**TopClosure® 3S System – 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 liner on the back of the attachment plates.
• Place the plates and attach them to the skin on both sides of the lesion or wound (see illustration 3, step 1). The plates should be located at a minimal distance of 1 cm from wound edges.
• Firmly adhere to skin.
• Insert the strap to the locking/release mechanism of one plate and then to the remote plate (see illustrations 3, steps 1, 2). While inserting the strap through the LR/M of the remote plate, be sure to press down on the proximal end of the 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 plate.
• Tighten the approximation strap gradually to enable the skin stretching (see illustration 3, step 4).
• Cut short the approximation strap as clinically indicated and secure stump to the plate with a tape.
• The adhesive is extremely durable under sheer forces, yet can be easily peeled off when needed. To further secure the distal end of the attachment plate to the skin with additional medical hypoallergenic drape (provided by IVT Medical Ltd. as an accessory), to prevent unintentional peeling of the plate from the skin.
• To further secure the system, it is advisable to circumferentially wrap it with an elastic bandage.
• The TopClosure® 3S System should be removed every 4 days, replaced and repositioned if necessary.
  o Cut the approximation strap.
  o Gently remove the attachment plates from the patient skin.
TopClosure® 3S System Invasive Application

**Note:** when applying the TopClosure® 3S System invasively a possibility of tissue scarring is inevitable. Before applying the TopClosure® 3S System invasively, evaluate the need Vs. the consequences of this invasive application. The care provider should evaluate the amount of stress that is anticipated during closure of the wound and carefully judge wound suturing methods and materials prior to making decision as to the application of the appropriate TopClosure® 3S System and means of application. Only CE or FDA APPROVED staples, sutures, KW and tapes should be applied.

- **Using TopClosure® 3S System in conjunction with Staples or Sutures**
  - 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 liner from the back of each attachment plate. **Important Note:** Skip this step for patients with known allergy to adhesives.
  - Place the plates and attach them to the skin on both sides of the wound.
  - Firmly adhere to skin. The plates should be located at a minimal distance of 1cm from wound edges.
  - Staple or suture the plates to the skin using the designated pairs of oval openings on each plate.
  - Insert the strap to the locking/ release mechanism of one plate and then to the remote plate. While inserting the strap through the LR/M of the remote plate, be sure to press down on the proximal end of the 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 plate.
  - Tighten the approximation strap gradually to enable skin stretching for reduction of wound edges’ gap.
- Cut short the approximation strap as clinically indicated and secure stump to the plate with a tape.

- The adhesive is extremely durable under sheer forces, yet can be easily peeled off when needed. To further secure the distal end of the attachment plate to the skin with additional medical hypoallergenic drape (provided by IVT Medical Ltd. as an accessory), to prevent unintentional peeling of the plate from the skin.

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

- The TopClosure® 3S System should be removed and replaced according to the surgeon's judgment.
  - Gently remove the staples/sutures from the patient's skin.
  - Cut the approximation strap.
  - Detach the attachment plates from the patient's skin.

Illustration 4 demonstrates the application of TopClosure® 3S System in conjunction with staples, in 3 steps.

Illustration 4: TopClosure® 3S System Invasive application demonstration in 3 steps.

This simulated illustration is for demonstration only. When applying the system invasively, a dressing must be placed underneath the strap.

- Using TopClosure® 3S System in conjunction with Kirschner Wires (KW)
  - Open the blister using sterile technique and remove the attachment plates and approximation straps required for the application.
o Apply on skin which has been shaven, cleansed with Isopropyl Alcohol sponge and dried thoroughly.

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

o Peel off the liner on the back of each attachment plate. Important Note: Skip this step for patients with known allergy to adhesives.

o Place the plates and attach them to the skin on both sides of the lesion or wound. The plates should be located at a minimal distance of 1cm from wound edges.

o Firmly adhere to skin.

o On both skin edges, insert a 1.8 or 1.6mm K Wire through the wound edges, into the designated horizontal opening across the base of the attachment plate, and then back into the skin.

o Apply additional staples or sutures as above if indicated.

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

o Tighten the approximation strap gradually to enable skin stretching for reduction of wound edges' gap.

o Make sure that the approximation strap's wing is interfaced with the locking/release mechanism of the first plate.

o Cut short the approximation strap as clinically indicated and secure stump to the plate with a tape.

o The adhesive is extremely durable under sheer forces, yet can be easily peeled off when needed. To further secure the distal end of the attachment plate to the skin with additional medical hypoallergenic drape (provided by IVT Medical Ltd. as an accessory), to prevent unintentional peeling of the plate from the skin.

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

o The TopClosure® 3S System should be removed and replaced according to the surgeon's judgment.
- Gently remove the Kirschner wire from the patient's skin.
- Cut the approximation strap.
- Detach the attachment plates from the patient's skin.

**Sterilization**

- Each TopClosure® 3S System is guaranteed sterile unless the blister is open or damaged.
- The products enclosed in the package are disposable and should not be resterilized or reused.
- TopClosure® 3S System sterilization process is performed using Gamma radiation.
- Sterility is confirmed by color change of the Gamma indicator located at the products' label.
- The device can be used both as a sterile product when needed and for non sterile indications.

**TopClosure® 3S System Safety Features**

The TopClosure® 3S System is intended for clinical use with force in the range of 0.7 to 1.3 Kg onto the stretched skin.

- The TopClosure® 3S System is designated to avoid excessive tension to the skin by having pre-determined collapse mechanism to the locking/ release mechanism and strap’s wing. There are two safety features that are set to break in case that excessive shear tension is unintentionally applied to the skin by the care provider:
  - The Locking/Release Mechanism (LRM) is designed to avoid extreme tension and was designed to collapse first, under an applied force of 2.4 Kg.
  - The approximation strap's wing is designed to avoid extreme tension and was designed to collapse under an applied force of 2.7 Kg.

These two mechanisms ensure a collapse of the system in a case of applying excessive force, thus minimizing the chance for damaging the skin.

- The TopClosure® 3S System is designed with no sharp edges and has smooth and round surface, thus inflicting no harm to the patient when applied according to the recommended clinical application as indicated in the instructions for use.

- In case of over stretching of the skin by approximating the attachment plates, tension can be released easily by lifting the lock/ release mechanism of the remote plate and loosen the strap gently.
• TopClosure® 3S System adheres to the skin by semitransparent attachment plate and tape, enabling early detection of irritation or local infection of the skin underneath the device and immediate cessation of treatment if indicated. The device was designed smooth at its borders, thus imposing no risk to the care provider and patient if properly used.

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 into contact with bodily fluids may require special disposal handling to prevent biological contamination.

• The TopClosure® 3S System is packaged and sterilized for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing, or resterilization 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 resterilization 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 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, or skin blistering.

• As with all skin adhesive products, a small percentage of individuals may experience hypopigmentation or hyperpigmentation 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 TopClosure® 3S System may be used when the patient is under local, regional or general anesthetic, as the surgeon judges appropriate.

• When local anesthesia is the method selected, the anesthetic solution used should NOT contain adrenalin or other known vasoactive agents.
• Prior to using the device, the wound should be prepared for closure using clinical practices known to support the healing process (e.g. debridement, freshening of skin edges, etc.).
• It is NOT advisable to undermine the skin edges beyond the position of the intradermal needles.
• The surrounding area to be operated upon should also be prepared using sterile antiseptic cleansing solution, and should be appropriately draped.
• The 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 surface at the underside of TopClosure® 3S System attachment plates. The attachment surface for TopClosure® 3S System 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 sold by or on the order of a physician.
• The device should be handled after use as a potentially contaminated material; therefore it must be disposed of and discarded accordingly.

**Risks and Adverse Effects**

- **Sensitivity to Adhesives**
  Sensitivity to adhesives is not common when medical tapes or drapes are used. 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 irreversible 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. Use the releasing mechanism knob to release the approximation strap in order to reduce local tension.

- When skin loss is extensive or when wound gap is substantial, the application of staples, sutures, KW or a combination of anchoring methods would be clinically justified, although local scarring or skin damage at the anchoring site is expected.

- Adverse effects that could possibly result from the use of this device include skin irritation, local infection, blistering of the skin due to excessive shear forces that are applied by the device and wound dehiscence due to unintended failure of the device. In addition, it may not always be possible to completely close the wound.

**How supplied**
The TopClosure® 3S System is supplied in a carton box containing 10 sealed blister packages. Each blister contains 7 attachment plates and 5 approximation straps: one spare plate and 2 extra straps for further elongation of the system when applying it over large or wide wounds or as needed. The elongation is performed by inserting one strap through the opening in the wing of the other strap. The carton box also contains an elaborated leaflet.

Shelf life: 3 years.

**Additional information**
Reasonably foreseeable incorrect or improper use of the device

- **A general note:**
  - The product label includes the symbol and text: "prior to use see instructions".
  - The leaflet inside the carton box which contains the TopClosure® 3S Systems includes all the relevant instructions in order to avoid the following cases.

- **Tightening the strap too fast (instead of incremental stretching)**
  - The skin should be incrementally stretched in order to avoid blenching of skin and pain (instructed in user instructions). This is based on the limitation of usage by experienced medical staff (nurses and doctors).
  - Over-stretching may be corrected by lifting the release tab on the locking/releasing mechanism.
• **Application of TopClosure on unsuitable skin surface**
  
o Plates should not be glued to wet or potentially wet surfaces such as burns, in close proximity to heavily discharging wounds.

  ❖ User instructions state that in these cases the user should apply sutures, staples, KW or combination of them.

  o Plates should not be applied on hairy skin surface.

  ❖ Shave the area before the treatment.

  o TopClosure® 3S System should not be used when there is lack of anchoring surfaces for the attachment plates.

  ❖ Do not apply (user instructions).

• **Using the TopClosure® 3S System on contra-indicated patients**
  
o User must identify known hypersensitivity to adhesives and avoid the usage of TopClosure® 3S System on these patients.

  o The application of TopClosure® 3S System requires patient cooperation. Usage should be avoided in case the patient is uncooperative.

**Manufacturer's warrantee:**

IVT Medical Ltd is committed to providing products that meet or exceed the requirements and expectations of its customers, as well as all applicable regulatory and statutory requirements.

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, please visit [www.topclosure.com](http://www.topclosure.com)
Exp. Date: see product label.

PRIOR TO USE SEE INSTRUCTIONS.
FOR SINGLE PATIENT USE.

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