TopClosure® Tension Relief 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.

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 is 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 resterilize 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.

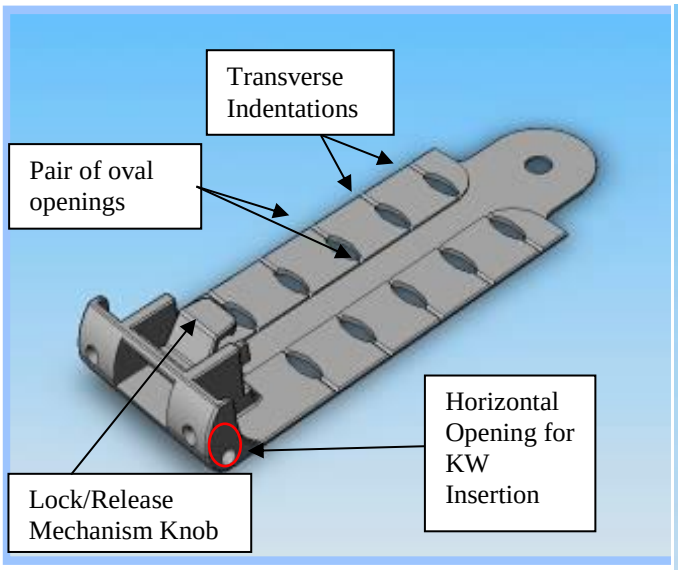
Store away from light in a cool, dry place. Optimal storage conditions at temperatures between 10-28°C and relative humidity between 40-70%.

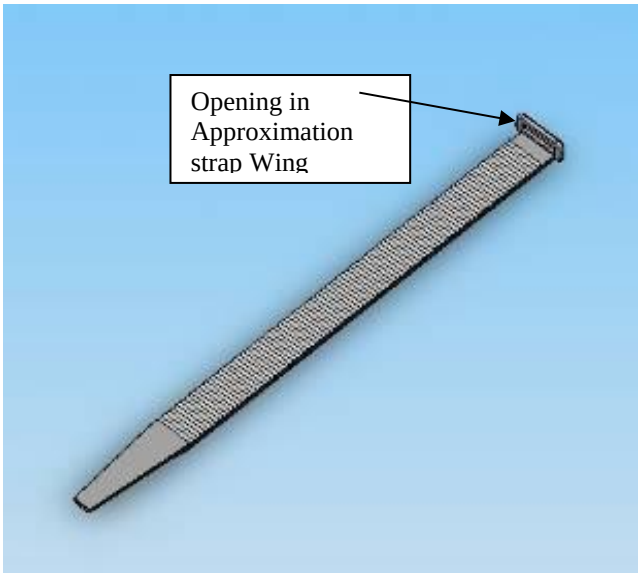
Failure to properly follow the instructions may lead to serious surgical consequences.

TopClosure® package components

The TopClosure® is supplied sterile for single use only.

Illustrations 1 and 2 demonstrate the TopClosure® components structure.





Attachment Plate

Approximation Strap

Illustrations 1and 2: TopClosure® components.

Device description

The TopClosure® 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 adhesive attachment plates. An additional approximation strap is provided for extending the approximation strap if needed. The attachment plates are made of Polypropylene (PP) and the approximation strap are made of LDPE (Low Density Polyethylene). The adhesive 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® 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.

TopClosure® System Components (varies to specific model):

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

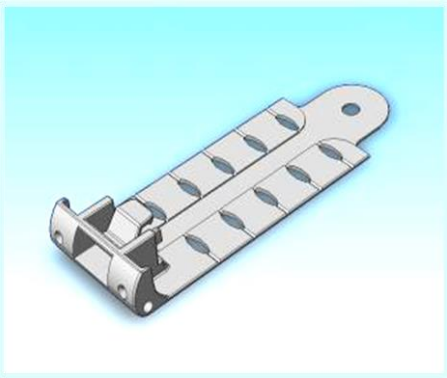


Figure. 1

Figure. 2

Figure. 3

Figure. 4

TopClosure® TRS 1S Clinic Pack 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.


TopClosure® TRS 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 3S Hospital Pack includes:

- 3 sets of TopClosure® Tension Relief System with extra flexible attachment plates with non-toxic hypoallergenic adhesive tape on its undersurface and two approximation straps (of distinct sizes).

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.

Intended use

The TopClosure®, 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® 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® may be used as reinforcement for securing wounds after early suture or staple removal. The TopClosure® 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® 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® 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® can be used for Applying topical pressure over silicone gel sheeting for possible prevention, reduction and/or treatment of keloid or hypertrophic scars.
- The TopClosure® can be applied simultaneously with Regulated Negative Pressure wound Treatment (RNPT) to promote healing in acute or chronic wounds.
- The TopClosure® - Skin Stretching and Secure Wound Closure System can be indicated for extended wound lengths by applying a series of pairs of TopClosure® 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® 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, re-evaluate the need for TopClosure® application. If absolutely needed, apply the TopClosure® 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 blood vessels, major nerves, internal organs, bones and connective tissue such as tendons and ligaments.
- Extra caution should be taken when applying the TopClosure® 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® in areas of repetitive motion as in areas adjacent to joints. Application of TopClosure® for these areas may be considered for each individual patient, and may require limb and joint immobilization.

- The TopClosure® application is contraindicated when the designated adherent area is infected.
- 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) with the TopClosure®, to avoid inducing 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.

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 systems to be used.
- Evaluate the proper positioning of the adhesive 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 an attachment plate 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

Wound closure intensity	Applied stress	Recommended mean for plate adherence	Main means of wound edges approximation
Low (non-invasive application)	≤0.6kg	AP's adhesive tape and covering medical adhesive tape	approximation straps
Moderate (non-invasive or invasive application)	0.6-1kg	liquid adhesive or staples/sutures, AP's adhesive tape and covering medical adhesive tape	approximation straps
High (invasive or non-invasive application)	1-2.4kg	AP's adhesive tape and liquid adhesive or staples/sutures	Tension sutures and approximation straps. For extra pull to assist in closure.
ex. High (invasive application)	2.4-5kg	AP's adhesive tape staples/sutures	Tension sutures

Choosing the TopClosure® Tension Relief System Size

TopClosure® system size	Recommended use
4mm	Pediatric Applications, Facial Wounds, Fine to Minor Skin Lacerations
6mm	Child and Adolescent High Tension Wounds, Child and Adolescent Torso and Limb Trauma
8mm	Adult High Tension Wounds, Adult Torso and Limb Trauma, Military Use

TopClosure® – Non Invasive Application

- Open the blister using sterile technique and pick the attachment plates and approximation straps required for the intended application.
- Apply on skin which has been shaven, cleansed with Isopropyl Alcohol sponge and dried thoroughly.
- Adjust the adhesive 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.
- Place the adhesive attachment plates and attach them to the skin on both sides of the lesion or wound (see illustration 3, step1). The attachment plates should be positioned 1.5-2 cm away from the wound edges.

- Firmly adhere to skin.
- Insert the approximation strap to the locking/release mechanism (LR/M) of one attachment plate and then to the remote attachment plate (see illustrations 3, steps 2, 3). 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 (see illustration 3, step 4).
- Shorten the approximation strap as clinically indicated and secure 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 (provided by IVT Medical Ltd. as an accessory in the TopClosure® 1S & 1SM System packages).
- Further secure the distal end of the attachment plate to the skin with additional medical hypoallergenic tape, to prevent unintentional peeling of the attachment plate from the skin.
- 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).

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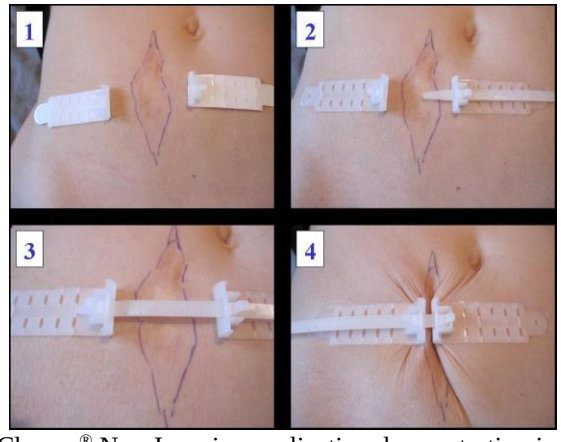

Illustration 3: TopClosure® Non-Invasive application demonstration in 4 steps.

- 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 adhesive . 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.

TopClosure® Invasive Application

Note: When applying the TopClosure® invasively a possibility of tissue scarring is inevitable.

Before applying the TopClosure® 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® and means of application. Only CE or FDA APPROVED/DESIGNATED staples, sutures, KW and tapes should be applied.

- Using TopClosure® in conjunction with Staples or Sutures

1) Open the blister using sterile technique and pick the adhesive attachment plates and approximation straps required for the intended application.
2) Apply on skin which has been shaven, cleansed with Isopropyl Alcohol sponge and dried thoroughly.
3) Adjust the attachment plates to the skin surface by bending them along the designated horizontal indentations, as needed.
4) Peel off the adhesive tape from the back of each attachment plate. Important Note: Skip this step and the following step 6 for patients with known allergy to adhesives or tapes.
5) Place the attachment plates and attach them to the skin on both sides of the wound. The adhesive attachment plates should be positioned 1.5-2 cm away from the wound edges.
6) Firmly adhere to skin.
7) Use staples (Weck Visistat with 35 wide staples) with dimensions of: 6.5mm X 4.7mm. (IVT Medical Ltd. cannot assure the safety of using the stainless steel skin staples under MRI conditions) or sutures (35 mm cutting needle) to secure the adhesive

attachment plates to the skin using the designated pairs of oval openings on each attachment plate.

8) Insert the approximation strap to 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.

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

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

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

12) 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 (provided by IVT Medical Ltd. as an accessory in TopClosure® 1S System packages).

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

14) The TopClosure® should be removed and replaced according to the surgeon's judgment.

- Gently remove the staples / sutures from the patient's skin.
- To release tension, gently lift the tab of the LR/M and then withdraw the approximation strap as necessary.
- Detach the adhesive attachment plates from the patient's skin (when an additional medical adhesive tape has been used- remove it first).

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

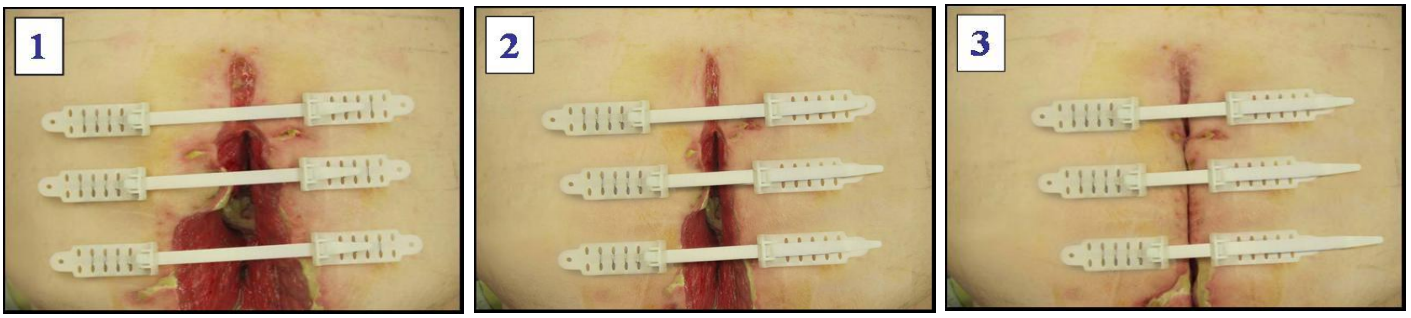

Illustration 4: TopClosure® Invasive application demonstration in 3 steps.

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

- TopClosure® as a topical tension-relief platform for tension sutures (TS)

  1) Heavy nylon TS (Syneture MONOSOF CN-290 Cutting needle 3/8 77 mm) can be applied to overcome high tension closure during stress-relaxation. The TS can be inserted through one of the designated oval holes in the attachment plate, gripping the deep subcutaneous tissue on both sides of the wound, and exiting through the attachment plate on the counter side of the wound. The suture is then threaded through the opening at the front of both attachment plates for firm, high tension tightening of the subcutaneous tissue by stress-relaxation.

- Using TopClosure® in conjunction with Kirschner Wires (KW) (Kirschner wires not included)

  1) Open the blister using sterile technique and pick the adhesive attachment plates and approximation straps required for the intended application.
  2) Apply on skin which has been shaven, cleansed with Isopropyl Alcohol sponge and dried thoroughly.
  3) Adjust the attachment plates to the skin surface by bending them along the designated horizontal indentations, as needed.
  4) Peel off the adhesive tape on the back of each attachment plate. Important Note: Skip this step and the following step 6 for patients with known allergy to adhesives or tapes.

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

6) Firmly adhere to skin.

7) 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.

8) Apply additional staples and/or sutures as above if indicated.

9) Insert the approximation strap to 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.

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

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

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

15) 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 (provided by IVT Medical Ltd. as an accessory in TopClosure® 1S System packages).

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

14) The TopClosure® should be removed and replaced according to the surgeon's judgment.

- Gently remove the Kirschner wire from the patient's skin.
- 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® application in conjunction with silicone gel sheeting. **Indicated only for the patient who has no known allergy to the adhesive and glue.** (silicone gel sheeting not included)

  Note: ONLY CE or FDA APPROVED SILICONE GEL SHEETING SHOULD BE APPLIED.

  1) Open the blister using sterile technique and pick the attachment plates and approximation straps required for the intended application.
  2) Apply on skin which has been shaven, cleansed with Isopropyl Alcohol sponge and dried thoroughly.
  3) Adjust the attachment plates to the skin surface by bending them along the designated horizontal indentations, as needed.
  4) Peel off the adhesive tape on the back of each attachment plate. Important Note: Skip this step for patients with known allergy to adhesives or tapes.
  5) Place the adhesive attachment plates and attach them to the skin on both sides of the lesion or wound. The attachment plates should be positioned 1.5-2 cm away from the wound edges.
  6) Attach the attachment plates **non-invasively** in accordance with the directions outlined in the appropriate section on Instructions for Use.
  7) Place the silicone gel sheeting directly on the scar/lesion.
  8) Insert the approximation strap, above the silicone gel sheeting, to the locking/release mechanism (LR/M) of one attachment plate and then to the remote attachment plate (see illustrations 3, steps 2, 3). 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.
  9) Tighten the approximation strap gradually to enable the skin stretching (see illustration 3, step 4).
  10) Make sure that the approximation strap's wing is interfaced with the locking/ releasing mechanism of the first attachment plate.
  11) Shorten the approximation strap as clinically indicated and secure stump to the attachment plate with a tape.

16) 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 (provided by IVT Medical Ltd. as an accessory in TopClosure® 1S System packages).

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

13) The TopClosure® should be removed and replaced according to the surgeon's judgment.

- 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).
- Remove the Silicone gel sheeting from the patient's skin.

Sterilization

- Each TopClosure® is guaranteed sterile unless the blister is opened or damaged.
- The products enclosed in the package are disposable and should not be resterilized or reused.
- TopClosure® 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® Safety Features

The TopClosure® is intended for clinical use with force in the range of 6.8N to 12.7N onto the stretched skin.

- The TopClosure® is designated to avoid excessive tension to the skin by having pre-determined collapse mechanism to the locking/ release mechanism and approximation 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 according to applied force. The locking force range is as follows:

Specification	4mm	6mm	8mm
Locking Force	23.5N-34.4N	23.5N-26.5N	23.5N-29.5N

- The approximation strap's wing is designed to avoid extreme tension and was designed to collapse under an applied force beyond the range of 26.5N – 55N.

These two mechanisms ensure a collapse of the system bellow 29.5N in a case of applying excessive force, thus minimizing the chance for damaging the skin.

- The TopClosure® 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, tension can be released easily by lifting the lock/ release mechanism of the remote attachment plate and loosen the approximation strap gently.
- TopClosure® 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® 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 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 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® 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® 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 a potentially contaminated material; therefore it must be disposed of and discarded accordingly.

Risks and Adverse Effects

- **Sensitivity to Adhesives and/or Silicone Gel Sheeting**

  Application of liquid adhesive may result in allergenic reaction in patients who are hypersensitive to cyanoacrylate and formaldehyde. Upon appearance of local redness, itching or stinging sensation, the attachment plate or silicone gel sheeting 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, staples or sutures may result in severe skin irritation, with permanent changes 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, scaring and/or compartment syndrome). 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 large, 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, change in pigmentation, local infection, blistering, scaring and compartment syndrome. In addition, it may not always be possible to primary close the wound by the TopClosure®.

How supplied

The TopClosure product line consists several systems:

TopClosure® 3S TRS Hospital Pack includes 3 sets of TopClosure® TRS with additional extra two flexible semi-transparent attachment plates with non-toxic hypoallergenic adhesive tape on its undersurface and 2 approximation straps (of distinct sizes);
When applying the TopClosure® over large or wide wounds you may use the extra approximation strap for elongation. The elongation is performed by inserting one approximation strap through the opening in the wing of the other approximation strap.
Hospital Pack is provided in a sterile color coded packaging of 8, 6 and 4 mm;
Each carton contains 10 boxes of 10 Hospital Packs (100 Hospital Packs) and elaborated leaflet.
Shelf life: 3 years.

TopClosure® 1S TRS Clinic Pack includes two flexible semi-transparent attachment plates with non-toxic hypoallergenic adhesive tape on its undersurface, one approximation strap (of distinct sizes), and two patches of hypo-allergenic transparent adhesive tape. Clinic Pack is provided in a sterile, color coded packaging of 8 and 4 mm; Each carton contains 10 boxes of 10 Clinic Packs (100 Clinic Packs) and elaborated leaflet.
Shelf life: 3 years.

TopClosure® TRS 1S-AD First-Aid Kit includes two flexible semi-transparent attachment plates with non-toxic hypoallergenic adhesive tape on its undersurface, one approximation strap (of distinct sizes), two patches of hypo-allergenic transparent adhesive tape and one liquid adhesive ampoule. First-Aid-Kit is provided in a sterile, color coded packaging of 8 and 4 mm. Each carton contains 10 boxes of 10 First Aid Kits (100 kits) and elaborated leaflet.
Shelf life: 3 years.

TopClosure® TRS 1SM Rescue Kit is provided in a waterproof, durable packaging to comply with extreme rescue needs in the civilian scenarios. The Rescue Kit includes two flexible semi-transparent attachment plates with non-toxic hypoallergenic adhesive tape on its undersurface, one approximation strap, two patches of hypo-allergenic transparent adhesive tape and one liquid adhesive ampoule. The Rescue Kit is provided in a sterile packaging of 8 mm.
Each carton contains 10 boxes of 10 Rescue Kits (100 kits) and 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® Systems includes all the relevant instructions in order to avoid the following cases.
- Tightening the approximation 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

  - Attachment 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 this case the user should apply sutures, staples, KW or combination of them.

  - Adhesive attachment plates should not be applied on hairy skin surface.

    ❖ Shave the area before the treatment.

  - TopClosure® should not be used when there is lack of anchoring surfaces for the attachment plates.

    ❖ Do not apply (user instructions).

- Using the TopClosure® on contra-indicated patients

  - User must identify known hypersensitivity to adhesives and avoid the usage of TopClosure® on these patients.

  - The application of TopClosure® 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

IMoH Registration No. 21380001

CE 1023

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Exp. Date: see product label.

PRIOR TO USE SEE INSTRUCTIONS.

FOR SINGLE PATIENT USE.

Do not re-sterilize.

STERILE R

Sterility guaranteed unless package is damaged or opened.

Latex Free

Manufactured by IVT Medical Ltd.
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