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Closure of large soft tissue defects following ablative surgery or trauma, constitutes a substantial and common reconstructive challenge. Immediate primary suture closure of wounds is commonly the optimal solution because of its simplicity and acceptable outcome, yet it may be impeded by high-tension closure. The alternative application of skin grafts, flaps, or tissue expansion is often associated with relatively more complex surgical procedures, significant morbidity and extended hospitalization and recovery periods. Previous reports of external tissue expanders are inherently limited by the size of the defects that can be managed and the need for staged surgical procedures for the closure of large wounds.

The TopClosure® Tension-Relief System (TRS) is an innovative method that enables the employment of both mechanisms of stress-relaxation and mechanical creep for skin stretching. Its use has been previously reported to enable the primary closure of medium to large soft tissue defects. The representative case below documents the use of TopClosure® in such circumstances.



#### 41 year old female with a large recurrent spindle cell sarcoma

**Tumor size:** 25×18cm

**Defect size following tumor ablation:** 26cm

**Protocol:** Six pairs of APs (TopClosure®, 8mm sets) were attached by adhesive to the skin, 2cm away from the wound margins, and reinforced by skin staples. Direct primary closure of wound achieved under ultra high tension in just over two hours

Primary closure of huge defect with no undermining, flap or graft

**Watch Video:** <http://bit.ly/TCTumorvideo>

#### Conclusions:

By using TopClosure on this case, the conservative savings were as follows:

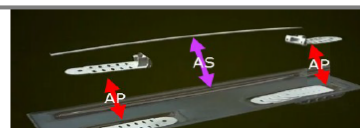
- At minimum, 1 hour OR time on the primary wound
- 5-15 days in hospital
- Possible graft failure
- Possible infection in primary and donor site

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#### The Applied Stress and the Recommended Application

Wound Closure Intensity	Applied Stress	Recommended Means for Plate Adherence	Primary Means of Wound Edge Approx'n	Types of Procedures
LOW	≤0.6kg	AP's adhesive tape and covering medical adhesive tape	AS	Closure of minor skin defects, Secure wound closure
MODERATE	0.6 - 1kg	Liquid adhesive or staples/ sutures, AP's adhesive tape and covering medical adhesive tape	AS	Closure of moderate to large skin defects
HIGH	1 - 2.4kg	AP's adhesive tape and liquid adhesive or staples/sutures	TS and AS	Closure of moderate to large skin defects
EXTREMELY HIGH	>2.4kg	AP's adhesive tape staples/ sutures	TS	Large to extremely large skin defects

AP= ATTACHMENT PLATE  
AS= APPROXIMATION STRAP  
TS= TENSION SUTURE



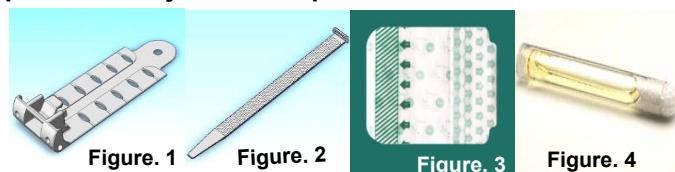
#### Preparations for TopClosure® Application

- 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 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:
  - o Known allergy to adhesives/tapes.
  - o Thin, fragile sensitive skin
  - o Uncooperative patients
- Do not apply excessive shearing forces at all for TopClosure® usages. Always apply gentle gradual tension to the skin when approximating tissues.
- TopClosure® should not be applied for stretching of heavily scarred tissue, with minimal laxity of the skin.

#### TOPCLOSURE COMES IN MULTIPLE PACKAGING CONFIGURATIONS AND ARE COLOR CODED

4mm-Pink 6mm-Green 8mm-Gray	Approximation Plate & Strap Size	Henry Schein Order Number	Unit of Measure
TopClosure® 1S - Clinic Pack Includes: o Two attachment plates o One approximation strap (of distinct sizes) o Two patches of hypo-allergenic transparent adhesive tape	4mm	776-0212	Each
	8mm	776-0205	Each
TopClosure® 3S - @Hospital Pack includes: o Three sets of TopClosure Tension Relief System o An additional attachment plate o Two approximation straps (of distinct sizes)	6mm	776-0208	Each
	8mm	776-0204	Each
TopClosure® 1S - AD® First Aid includes: o Two attachment plates o One approximation strap (of distinct sizes) o One liquid adhesive ampule	4mm	776-0210	Each
	8mm	776-0207	Each

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



**Figure 1-** Attachment plate (AP) of distinct sizes (4mm, 6mm, 8 mm).

**Figure 2-** Approximation strap (AS) of distinct sizes (4mm, 6mm, 8 mm).

**Figure 3-** Patch of hypo-allergenic transparent adhesive tape.

**Figure 4-** Liquid adhesive ampule.

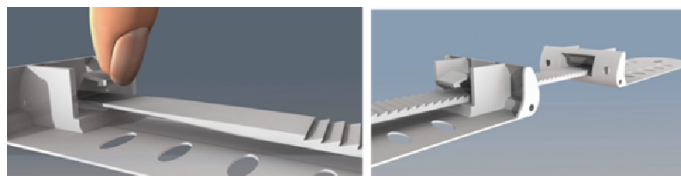
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**TopClosure® Tension Relief System (TRS)** is an innovative new technology for the management of simple and complex wounds is now available for skin stretching and secure wound closure.

This system is easy to apply, safe to use and leads to excellent results by providing simple solutions for complex problems. It is intended to temporarily stretch skin tissues to aid closure and healing of post traumatic, surgical, acute and chronic skin wounds.



FEATURES		BENEFITS	
Effective means of tension reduction	Serves as a topical tension-relief platform for tension sutures, alleviating the typical tearing and scarring inflicted by this method		
Wide scope of disciplines and indications	<ul style="list-style-type: none"><li>◆ Preoperative noninvasive external skin stretching</li><li>◆ Post-operative skin secure wound closure</li></ul>		
A multipurpose, simple surgical tool	<ul style="list-style-type: none"><li>◆ Ability to apply before (non-invasive), and following surgery</li><li>◆ Zipper-like, reversible closure of wound edges</li><li>◆ Versatile therapeutic areas and diverse wound severity levels</li></ul>		
Advances mechanical creep	Skin can be stretched allowing safe primary closure of wound margins alleviating the need for skin grafts and flaps		
Avoids extensive undermining of the skin edges and adjacent tissue	<ul style="list-style-type: none"><li>◆ Minimizing compromise of skin viability</li><li>◆ Eliminates dead space, seroma, hematoma accumulation, and the need for drainage</li><li>◆ Reduces the risk of infection</li><li>◆ Suitable for use on delicate tissues</li></ul>		
Breadth of application approaches	<b>Non-invasive Application can be affixed in one of the following manners:</b> With the Underlying Adhesive • Transparent Adhesive Tapes • Transparent Dressing • Liquid Adhesive <b>Minimally Invasive Application:</b> Staples • Sutures • Tension Sutures		

#### 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 by sutures
- ◆ Approximation of wound edges over poorly vascularized structures, such as tendons and bones
- ◆ For improved aesthetics of wound closure or as an alternative to skin grafts and flaps, by en-block mobilizing skin and subcutaneous tissue
- ◆ Primary closure of fasciotomy wounds
- ◆ Wound closure over open fractures
- ◆ Preoperative skin expansion in preparation for dermal extirpation (e.g. skin lesions)

This is just a partial list of TopClosure® applications.

#### Comparison Of Wound Closure Methods

Indications	TopClosure®	Butterfly Closures	Sterile Wound Closure Strips	Montgomery Straps	DermaClose®	ZipLine®
LOW TENSION	Yes	Yes	Yes	Yes	Yes	Yes
MEDIUM TENSION	Yes	No	No	Yes	Yes	No
HIGH TENSION	Yes	No	No	No	No	No
APPLICATION INVASIVENESS	Both	Non Invasive	Non Invasive	Non Invasive	Invasive Only	Non Invasive
SECRETING WOUNDS	Yes	No	No	No	Yes	No
WEIGHT BEARING	2.8.Kg w/ APStraps High w/ Tension Sutures	Limited Application	Limited Application	High	1.2 Kg	Low Only
PRIMARY CLOSURE FOR LARGE WOUNDS	Yes	No	No	No	Limited Size	No
CAN BE REOPENED	Yes	No	No	Yes	Yes	No
PRESSURE SPREAD OVER LARGE AREA	Yes	Not Applicable	Not Applicable	Not Applicable	No	Yes
WOUND EDGES UNDERMINING	Not Required	Not Applicable	Not Applicable	Not Applicable	Necessary	Not Applicable
PRE-OPERATIVE NON-INVASIVE SKIN STRETCHING	Yes	Not Applicable	Not Applicable	Yes	Not Applicable	Not Applicable
INTRA-OPERATIVE STRESS RELAXATION	Yes	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable