

Frequently Asked Questions for TopClosure® Tension Relief System (TRS)

1. How does TopClosure® TRS works?

TopClosure® TRS designed is to optimally utilize the visco-elastic properties of the skin in both stress-relaxation and mechanical creep for dynamic closure of moderate to large skin defects, by both non-invasive and invasive application in a reversible, zipper-like manner.

2. What are the advantages of TopClosure® TRS?

- Easy to apply- simple yet creative and effective manner of treating diverse and complex skin wounds.
- The TopClosure® TRS is a relatively low cost disposable device.
- The TopClosure® TRS enables simplified surgical procedures, reducing the need for skin graft, flaps or tissue expansion, allowing simple primary closure. This may substantially reduce surgical morbidity, operating time, hospital stay and costs.
- The tension is distributed over a wider area due to the size of the plates.
- Designed for versatility- The system is a non-invasive mean for skin stretching. The TopClosure® TRS can also be attached to the skin invasively during surgery.
- Flexible device can accommodate body curvatures.
- The TopClosure® TRS serves as a tension-relief platform that allows primary wound closure.

3. When and how is TopClosure® TRS used?

May be applied invasively and non-invasively as a fast way to manage acute trauma wounds, where conventional primary wound closure treatment must be deferred. TopClosure® TRS is designed for wide scope of applications:

- Orthopedic surgery (traumatic wounds)
- Plastic surgery (substitute for tissue expander, scar revisions)
- Vascular surgery (primary closure of fasciotomy wounds)
- Pediatric surgery
- Dermato-surgery (Skin tumor resection)
- Cardiology (control of pacemaker hematoma)
- General surgery (closure of dehisced wounds)
- Esthetic Plastic Surgery (abdominoplasty, face lift)

4. Is TopClosure® TRS available in different sizes and configurations?

Yes. TopClosure® TRS is available in various sizes (4/6/8 mm width), in order to allow usage on extremely large wounds. TopClosure® TRS is available in the following configurations:

- TopClosure® TRS 1S Clinic Pack- single set
- TopClosure® TRS 1S-AD TRS First-Aid Kit- single set with liquid adhesive
- TopClosure® TRS 3S TRS Hospital Pack- Triple set
- TopClosure® TRS 1S-M TRS Military Kit- single set, custom made

5. Who is authorized to use the TopClosure® TRS?

Medical personnel (Doctors, nurses, paramedics etc...).

6. What is the optimal distance of the plates away from wound edges?

Generally, as the gap is larger the plates should be placed further away from the margin of wound/excision. The plates should be attached in line with the vector of pull, at least 1.5- 2 cm away from the margins of the wound/excision.

7. How many sets of TopClosure® TRS should be applied?

The number of sets to be applied for wound closure should be related to the amount of tension that is needed to approximate the wound edges. This would be related to the elasticity of the skin and to the gap that needs to be closed. The treating physician should have the ability to evaluate the number of sets needed.

8. How much tension can the attachment plates take?

Detachment force (aligned with the vector of pull) for plate $\geq 7kg$.

Notice that if removal of the attachment plates is necessary gently peel off in a perpendicular direction from which it was applied.

9. How much tension can the Lock/Release mechanism (L/RM) take?

Tearing force of the L/RM $\geq 2.4kg$.

10. Is there any limitation to dimensions of a wound that TopClosure® TRS can be applied to?

Practically there is no limitation to dimensions of the treated wound as additional TopClosure® TRS sets can be applied along the wound edges. The length of the 6mm and 8mm straps is 25cm and the length of the 4mm strap is 16cm. This length can be extended by threading 2 straps together through the hole in the wing of the strap, thus doubling the original length, enabling treatment of even huge skin gaps. The effectiveness of the TopClosure® TRS for these kinds of wounds should be evaluated individually.

11. Are there cases where the TopClosure is not recommended?

The TopClosure® TRS should not be applied in areas of heavy scarring, where skin elasticity is reduced and in areas where the skin is firmly attached to the bone or non-elastic tissues. Skin elasticity can be tested prior to the application of the TopClosure® TRS by manual stretching of the skin. If the skin is not compliant it will not be recommended to use the TopClosure® TRS.