

PRIOR TO USING

Please read entire contents prior to using the DermaClose® Continuous External Tissue Expander.

All Wounds:

- Ensure wound bed has been thoroughly cleaned, debrided and is free of any foreign material prior to application
- Thoroughly cleanse the area around the wound using an appropriate anti-microbial agent
- Utilize local, regional or general anesthesia as indicated
- Excise wound margins when indicated
- The wound edges should be surgically undermined as needed to mobilize the dermis

Chronic Wounds:

- Devitalized tissue along wound margins should be excised before application of the DermaClose device
- Wound edges that are attached at the margin will require surgical undermining as needed in order to mobilize the dermis

Use precautions when considering DermaClose with chronic wounds, for example:

- Certain diabetic foot ulcers where skin is thin and in difficult locations
- Areas of ischemic tissue surrounding the wound bed
- Skin that is friable and not amenable to tissue expansion
- Inadequate vascularity of the affected tissue
- Irradiated skin may not respond to tissue expansion
- Presence of extensive scar tissue
- Extensive debridement and deroofing of the wound should be considered for decubitus ulcers (more than 1.5cm deep) that exhibit deep tunneling
- Closing wounds with heavy bacterial burdens or infected wounds is not recommended

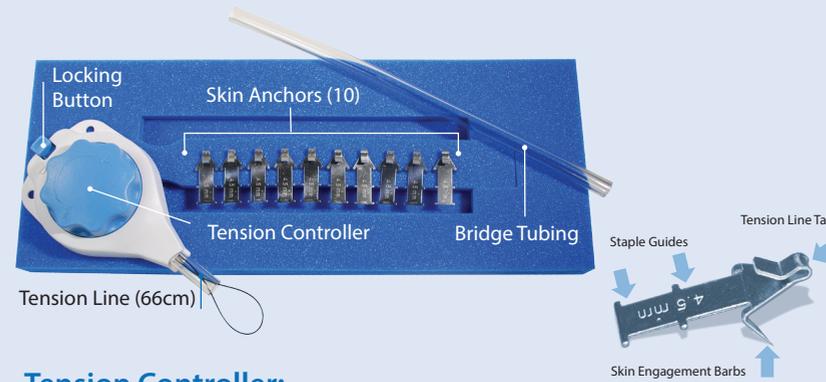
Potential complications may include:

- Minor to moderate pain
- Infection
- Inflammation
- Tissue expansion may lead to increased levels of exudate (without appropriate dressing management, maceration of the surrounding tissue may occur)

Warnings:

- For single patient use only
- Do not use if sterile packaging is open or compromised
- By federal law this device is restricted for use by or on the order of a physician
- Open this package using appropriate sterile procedures
- Do not reprocess or resterilize
- Dispose of appropriately
- Skin anchors left in place for more than seven days increase the risk of scarring the skin
- Skin anchors have sharp skin engagement barbs. Handle carefully and dispose of in a sharps container

PACKAGE CONTENTS



Tension Controller:

The tension controller is 1.7" wide and 2.6" long and 0.8" high and is made of ABS plastic. The USP 2 monofilament nylon line is 66cm in length and is housed in the base of the component. The blue tension control knob is turned clockwise until a clicking sound is heard which indicates the appropriate force is being applied to the line. A lock button is located on the rear of the tension controller and is used to prevent unintended release of tension force. It must be in the 'out' position to release or rotate the tension control knob. The tension controller comes with a small section of tubing already attached which may be exchanged for the longer bridge tube if the tension controller is to be situated remotely (see Tension Line Bridge Tubing below).

Skin Anchor:

The package contains ten skin anchors. Each skin anchor is made of 316L surgical stainless steel with sharp flat barbs that penetrate the skin 4.5mm. They are held in place with two (or more) standard wide (6-7mm) skin staples (skin stapler is included with DermaClose kit – item code: 204010-K).

Tension Line Bridge Tubing:

Fifteen centimeters of sterile tubing is included in the package so that the tension controller may be positioned remotely from the wound site. If necessary, the tubing should be cut to the desired length. After removing the preinstalled short tubing, the tension line is threaded through the bridge tubing before application of the DermaClose device. It may be advisable to use the DermaClose XL when remote positioning is desired.

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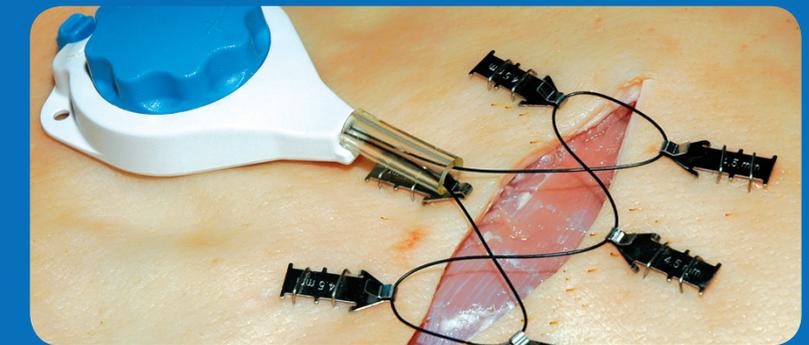
INSTRUCTIONS FOR USE



Product Description:

The DermaClose® Continuous External Tissue Expander is designed to be used on full thickness wounds of the skin. Once the initial application has been completed the DermaClose device does not require any additional tightening. Depending on the location and size of the wound, one or more DermaClose may be left in place for hours to days to provide the needed tissue expansion.

Once the desired tissue expansion has occurred the device(s) can be removed and the wound either closed primarily or the resulting smaller wound allowed to heal by secondary intention.



Indications for Use: The DermaClose Continuous External Tissue Expander is indicated for use in reducing or assisting with the closure of full-thickness wounds of the skin.

Contraindications: The DermaClose Continuous External Tissue Expander should not be used on ischemic or infected tissue. It should not be used on fragile tissue at the edges of a wound.

APPLICATION

Application of the DermaClose® Device

Before application, ensure that the wound is thoroughly cleaned, debrided and that the wound edges are elevated (please see Prior to Using section).

Prior to Application:

It is necessary to create a tissue plane prior to applying the device. Undermine or elevate wound margins on a supra-fascial plane by approximately half the width of the wound when clinically indicated. Close as much of the wound primarily as possible before placing the skin anchors. Pre-marking the skin may be useful to ensure that the anchors are placed evenly along the opposing wound edges. More effective wound edge approximation can be achieved when each anchor has an opposing anchor on the opposite side of the wound.

Step 1 – Inserting the Skin Anchors:

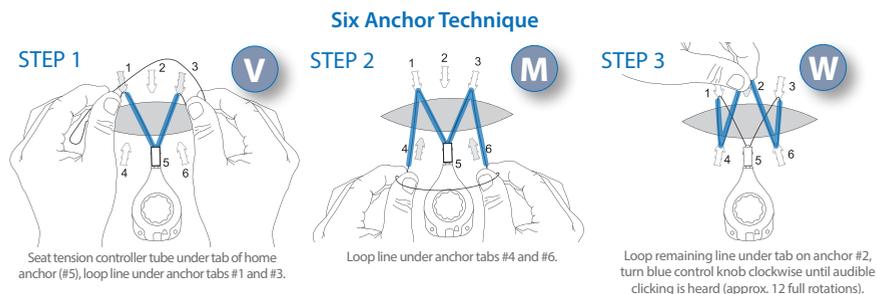
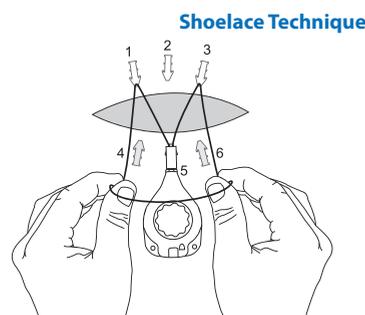
Position the tips of the skin anchors approximately 0.5 to 1 cm from the wound edge and 2-3cm apart with the 'anchor loop tab' facing the wound. (The anchors may be positioned up to 3cm from the wound margins when clinically indicated for applications such as off-loading high-tension sutures and abdominal uses.) Press firmly so that the barbs fully penetrate the skin (Fig 1). To help protect the wound bed from the tension controller line put Xeroform® (petrolatum impregnated gauze) on the wound bed and under the wound margins before attaching the tension controller line to the tabs on the skin anchors. Secure the skin anchor in place with two standard wide (6-7mm) skin staples (Fig 2). Additional skin staples may be used if deemed necessary. Staples should be placed in the gaps provided on the skin anchors (Fig 3). Repeat this step until the appropriate number of anchors are inserted and affixed. A minimum of six skin anchors should be used.

Step 2 – Positioning the Tension Controller:

Once all the required skin anchors have been secured in place it is recommended to position the tension controller at the widest part of the wound. If the tension controller is to be seated close to the wound (Fig 6), leave the existing short bridge tubing in place. If the tension controller is to be placed remotely (Fig 7), remove the short section of bridge tubing from the tension line and cut a new section to fit from the enclosed 15cm section of bridge tubing. Once the desired tube length has been determined, thread the line through the bridge tubing (Fig 5).

Step 3 – Attaching the Tension Line:

The tension controller is shipped with all available line out. If during application adjustment or re-release is needed, the line may be released by depressing the blue control knob with your thumb and pulling line out (Fig 4). (**Caution: Once all line has been released do not continue to turn counter-clockwise as this may damage the tension controller.**) Seat the distal end of the bridge tubing on the "Home Anchor" by firmly pressing the lumen of the tubing into the top of the skin anchor tab (Fig 8). Once this has been seated, separate the two strands of the tension line and place over the respective off-set opposing skin anchors from the inside out (Fig 9). Continue to attach the Tension Line to the skin anchors using a shoelace technique as illustrated (Fig 9). Be careful not to create any eyelets or loops around the skin anchors. For more information please visit dermaclose.com/product-tutorial.php or study the enclosed 'Shoelace Technique Guide'.



Step 4 – Winding the Tension Controller:

Once the tension line has been attached around the skin anchors, tension is applied by turning the blue tension control knob clockwise (Fig 11) until a clicking sound is heard (approximately 12 full rotations). This indicates that the tension controller is fully tightened and that the internal clutch mechanism is preventing additional force from being applied. Once the full tension has been achieved, the tension controller can be locked by pushing in the locking button on the rear of the device (Fig 12). The internal mechanism maintains a constant pulling force of 1.2kg on the tension line until the tension controller device is removed. **No additional tightening of the device is required.**

Step 5 – Securing the Tension Controller:

Secure the tension controller to the skin by loosely suturing through the holes located on the rear of the device. You may also use tape to secure the tension controller; padding such as DuoDERM® may be placed between the patient's skin and the tension controller device to protect the skin.

Step 6 – Dressing the Wound:

Apply a suitable dressing to the wound as indicated. Please note that the pulling force on the skin may result in additional exudate. The tension controller may also be secured beneath the final gauze wrap. If Negative Pressure Wound Therapy (NPWT) is indicated please see the enclosed Negative Pressure Wound Therapy Guide. When using NPWT cut the foam 50% smaller than the wound and place Adaptic over the skin anchors and tension line. Also place DuoDERM under the tension controller to avoid blistering. If the skin edges will be gliding across the NPWT foam, place Adaptic over the foam. The DermaClose device will immediately begin to mobilize the tissue and can be left in place until the desired tissue expansion has occurred. This can take anywhere from hours to days depending on wound location, size, and type of tissue. If scarring from the anchors and skin staples is a concern, remove or reposition them prior to day seven.

Step 7 – Removing the DermaClose:

After the desired tissue expansion has occurred, remove the DermaClose device. Remove the sutures and/or tape that is securing the tension controller. Release the line tension by either:

- Cutting the tension line
- Pulling out the locking button, pressing down on the blue control knob and turning counter-clockwise. (Note: when under tension the blue tension control knob may automatically spin counter-clockwise when depressed)
- Removing the tension line from the skin anchors
- Using a skin staple remover to remove the staples from the skin

Remove each skin anchor and dispose of appropriately in a sharps container

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DuoDERM is a registered trademark of Convatec, Inc.
Xeroform is a registered trademark of Covidien, Inc.

