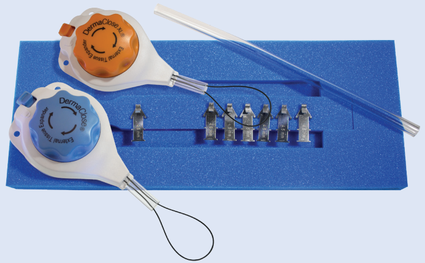
PACKAGE CONTENTS



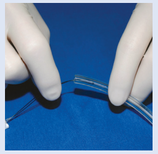
Tension Controller (1200 gram force):

The tension controller is 1.7" wide, 2.6" long, 0.8" high, and is made of ABS plastic. The USP 2 monofilament nylon line is 66 cm in length for the DERMACLOSE and 95.25 cm in length for the DERMACLOSE XL. The 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. The DERMACLOSE is intended to be used with six skin anchors and one tension controller for each 10 cm of length of wound. Use multiple devices for longer wounds.

Skin Anchor:

The package contains seven sterile skin anchors. Six skin anchors are used for skin expansion per DERMACLOSE device, the seventh anchor is provided in the event of accidental loss or drop. One DERMACLOSE device should be used for every 10 cm wound length. Each skin anchor is made of 316L surgical stainless steel with sharp flat barbs that penetrate the skin 4.5 mm. They are held in place with two (or more) standard wide (6-7 mm) skin staples. A skin stapler is included with the DERMACLOSE kit.

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 folded tight and then is threaded through the bridge tubing before application of the DERMACLOSE device. When remote positioning is desired, the use of a DERMACLOSE XL is recommended as this device provides extra tension line length.

Symbols Referenced on Labeling

Symbol Glossary per US FD&C Act:

Standard	Symbol	Symbol Title	Symbol Meaning	Symbol Number
ISO 15223-1		Consult instructions for use	Consult instructions for use	5.4.3
ISO 15223-1		Caution	Caution, Consult instructions for use for warning and precaution information	5.4.4
ISO 15223-1	LOT	Batch code	Lot number	5.1.5
ISO 15223-1		Use by date	Use by date	5.1.4
ISO 15223-1	REF	Catalogue Number	Catalogue Number	5.1.6
ISO 15223-1	STERILE R	Sterilized using irradiation	Sterilized using irradiation	5.2.4
ISO 15223-1		Do not use if package is damaged	Do not use if the product sterilization barrier or its packaging is compromised	5.2.8
ISO 15223-1		Do not re-use	Do not re-use	5.4.2
ISO 15223-1		Do not re-sterilize	Do not re-sterilize	5.2.6
ISO 15223-1		Manufacturer	Manufacturer	5.1.1
ISO 15223-1		Date of manufacture	Date of manufacture	5.1.3
ISO 15223-1	EC REP	Authorized representative in the European Community	Authorized representative in the European Community	5.1.2
	CONTENT		Content	
	Rx Only		US law restricts the device to sale by or on the order of a licensed practitioner	

Additional Symbols Not Required by the US FD&C act:

Symbol	Symbol Meaning
MADE IN THE U.S.A.	Made in USA
PN	Manufacturer Part Number

DISCLAIMER OF WARRANTIES:

Synovis Micro Companies Alliance, Inc., (SMCA), a subsidiary of Baxter International Inc., warrants that reasonable care has been used in the manufacture of this device. This warranty is exclusive and in lieu of all other warranties whether expressed, implied, written or oral, including, but not limited to, any implied warranties of merchantability or fitness. Since SMCA has no control over the conditions under which the device is used, diagnosis of the patient, methods of administration or its handling after it leaves its possession, SMCA does not warrant either a good effect or against an ill effect following its use. The manufacturer shall not be liable for any incidental or consequential loss, damage or expense arising directly or indirectly from the use of this device. SMCA will replace any device which is defective at the time of shipment. No representative of SMCA may change any of the foregoing or assume any additional liability or responsibility in connection with this device.

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DERMACLOSE
Continuous External Tissue Expander
dermaclose.com

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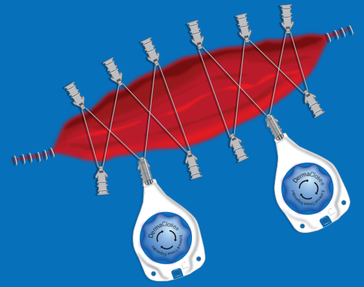
14069 Rev B

INSTRUCTIONS FOR USE

DERMACLOSE Continuous External Tissue Expander
DERMACLOSE XL Continuous External Tissue Expander

Product Description:

The DERMACLOSE is a continuous external tissue expander that facilitates rapid tissue movement to reduce or reapproximate wounds. The DERMACLOSE XL model contains 29.25 cm more line than the standard DERMACLOSE and is intended for large wounds that are greater than 8 cm in width. After 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 can be sutured or stapled closed.



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.

PRIOR TO USING

Please read entire contents prior to using the DERMACLOSE Continuous External Tissue Expander

Potential Complications:

- 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
- Do not reprocess or resterilize. Attempts to resterilize and/or reuse this device may result in product failure and increased risks to the patient.
- Skin anchors left in place for more than seven days increase the risk of scarring the skin

Cautions/Precautions:

All wounds:

- Open this package using appropriate sterile procedures
- Skin anchors have sharp skin engagement barbs. Handle carefully and dispose of in a sharps container
- 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 at the health care provider's discretion
- Excise wound margins when indicated
- The wound edges should be surgically undermined as needed to mobilize the dermis
- Dispose of used device appropriately

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:
  - 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 1.5 cm deep) that exhibit deep tunneling

APPLICATION

Application of the DERMACLOSE® Device

Prior to Application:

Before application, ensure that the wound is thoroughly cleaned, debrided and that the wound edges are undermined (Fig 1).

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. Prior to applying DERMACLOSE, close as much of the wound distal and proximal ends as possible. 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. One DERMACLOSE device should be used for every 10 cm wound length.

Step 1 - Inserting the Skin Anchors:

Position the tips of the skin anchors approximately 0.5 to 1 cm from the wound edge (Fig 2) and a maximum of 2 cm apart (Fig 3) with the 'anchor loop tab' facing the wound. (The anchors may be positioned up to 3 cm from the wound margins and 3 cm apart when clinically indicated for applications such as off-loading high-tension sutures or abdominal wounds.) Press firmly so that the barbs fully penetrate the skin. Secure the skin anchor in place with two standard wide (6-7 mm) skin staples (Fig 4). Additional skin staples may be used if deemed necessary. Staples should be placed in the gaps provided on the skin anchors. Repeat this step until the six skin anchors are inserted and affixed.

Step 2 - Protect the Wound:

To help protect the wound bed from the tension controller line, it may be helpful to put petrolatum impregnated or similar non-adhering wound dressing on the wound bed and, if desired, under the wound margins before attaching the tension controller line to the tabs on the skin anchors (Fig 5).

If used for high tension offloading:

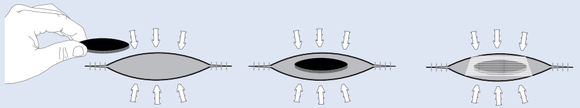
When using the DERMACLOSE device for high tension offloading, apply a petrolatum impregnated or similar non-adhering wound dressing over the closed suture before lacing the tension line from the tension controller.

If Used with Negative Pressure Wound Therapy (NPWT):

DERMACLOSE can be used successfully with NPWT. However, DERMACLOSE works very well alone and does NOT require the use of NPWT to be effective. If the surgeon determines the wound requires NPWT, following the NPWT tips in these instructions will help ensure a successful outcome.

Abdominal wounds with NPWT:

Cut the NPWT foam 50% smaller than the wound, insert within the wound, and place a layer of petrolatum impregnated or similar non-adhering wound dressing over the foam. This enables the tissue to easily glide over the foam after the tension line has been tightened. This is important to keep mobility of tissue under pressure of the NPWT.



Step 3- Positioning the Tension Controller:

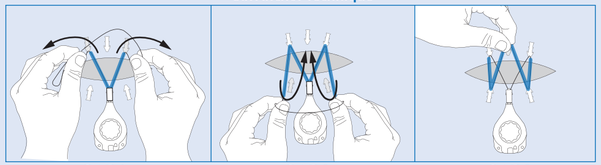
Once all the required skin anchors have been secured in place it is recommended to position the tension controller at the center skin anchor. If the tension controller is to be seated close to the wound (Fig 6), leave the existing short bridge tubing in place. If the tension controller is to be placed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

Step 4 -Attaching the Tension Line:

The tension controller is shipped with all available line extended. Caution: When all available line is extended do not turn the tension control knob 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, using both hands, separate the two strands of the tension line and place over the respective off-set opposing skin anchors under the anchor tabs from the inside out (Fig 9). Next, guide the tension line around the tabs of the opposing two outer anchors from the outside in (Fig 10). Finally, guide the tension line over the final anchor tab opposite the "home anchor" (Fig 11) and gently pull on the tension controller to remove any slack in the line. See the Six Anchor Technique graphic and figures 9 through 11.
Caution: do not create any eyelets or loops around the skin anchors.

Six Anchor Technique



Step 5 - Winding the Tension Controller:

Once the tension line has been attached around the skin anchors, tension is applied by turning the tension control knob clockwise (Fig 12) until a clicking sound is heard (approximately 22 half rotations). This indicates that the tension controller is fully tightened and that the internal clutch mechanism is preventing additional force from being applied. During application, if adjustment or tension release is needed, the line may be released by depressing the control knob and pulling line out.

When using the DERMACLOSE device for high tension offloading, the tension controller knob is turned clockwise only until sufficient offloading has been achieved, as determined by the clinician. This is typically less than 11 half rotations.

Once the full tension has been achieved, the tension controller should be locked to prevent accidental tension line release by pushing in the locking button on the rear of the device (Fig 13). The internal mechanism maintains a constant pulling force of 1.2kg on the tension line. No additional tightening of the device is required.

Step 6 - 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 may be placed between the patient's skin and the tension controller device to protect the skin. The tension controller may also be secured beneath the final wound wrap.

If Used with Negative Pressure Wound Therapy (NPWT):

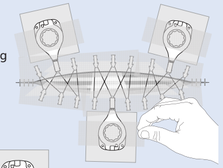
Place a closed cell membrane or two layers of hydrocolloid dressing beneath the tension controller and bridge tubing to prevent the vacuum pressure from causing tissue damage under the controller and tubing. Caution: Do not place gauze under the tension controller when using NPWT. This will result in skin blistering under the tension controller.

Step 7 - Dressing the Wound:

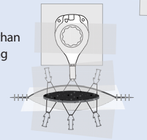
Apply a suitable dressing to the wound as indicated. Please note that the pulling force on the skin may result in additional exudate. The tension controller may also be secured beneath the final gauze wrap. The DERMACLOSE device will immediately begin to mobilize the tissue and can be left in place until the desired tissue expansion has occurred. This can take anywhere from hours to days depending on wound location, size, and type of tissue. Evaluate tissue movement after 48 to 72 hours. If scarring from the anchors and skin staples is a concern, remove or reposition them prior to day seven.

If Used with Negative Pressure Wound Therapy (NPWT):

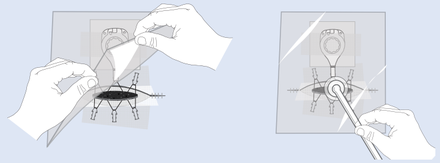
Place a layer of petrolatum impregnated or similar non-adhering wound dressing over the tension line and all skin anchors; the anchors are sharp and can pierce the VAC drape. Also, place the dressing material over the controller to keep the NPWT drape from sticking to the controller.



For extremity wounds, cut NPWT foam 50% smaller than the wound and place the foam over the non-adhering wound dressing in the center of the wound.



Place the NPWT drape over the wound (abdominal or extremity) and the entire DERMACLOSE device, including controller.
Poke hole in NPWT drape to place suction over the foam.



Step 8 - 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 any of the following methods:

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

Use a skin staple remover to remove the staples from the skin.

Remove each skin anchor and dispose of appropriately in a sharps container.
The wound should then be sutured or stapled closed.