2) In removing the device, a light oil, alcohol or ketone may be applied to facilitate the removal. To remove, the device should be peeled slowly from each side toward the middle and then peeled off front to back so as to carefully remove it from the skin. Surrounding skin should be held down while removing to minimize the possibility of skin trauma while peeling off the adhesive. **NEVER REMOVE THE DEVICE BY PULLING IT UP FROM THE SKIN AS DAMAGE TO, OR REOPENING OF, THE HEALED WOUND OR INCISION MAY RESULT. PEEL; DON'T PULL!**

Storage, Shelf Life and Packaging:
The product should be stored under normal indoor conditions at room temperature. The expiration date in such conditions is indicated on the package.

Devices are supplied in packages with a white front with printing and a clear, transparent back. The devices are sterilized using EtO.

For more information, visit the DermaClip® website (DermaClip.com) or contact the DermaClip® team.

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Link to Training Videos
(via DermaClip Website)

DermaClip®
Non-Invasive Skin Closure Device
Instructions for Use (IFU)

Symbols used:

STERILE EO	Sterilized using ethylene oxide		Expiration date		Do not use if package is damaged or open	Rx only	Federal law (USA) restricts this device to use by or on the order of a physician. (Rx Only)
LOT	Lot Number	2	Single use only		Keep away from sun and heat		
REF	Catalog number		Keep dry		Not made with natural rubber latex.		
CONF	Configuration identifier		See Instructions for Use				

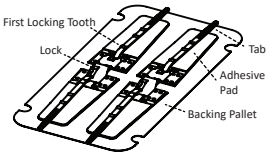
DermaClip®
Non-Invasive Skin Closure Device

Regular Clip, 2 Pack
Instructions for Use (IFU)

BEFORE APPLYING TO A PATIENT, SUFFICIENTLY PRACTICE WITH THE DEVICE TO ASSURE FAMILIARITY WITH THE LOCKING OF THE DEVICE .

Product Description:
The DermaClip® device is a single use, extended wear device that employs proprietary technology designed to evert skin edges and maintain wound approximation with minimum tension on the wound. Each device is composed of two strips of breathable medical adhesive joined together by a polypropylene closure device. The DermaClip® device utilizes an acrylic, non-benzoin, non-latex, pressure-sensitive medical adhesive that has been shown to have a minimal incidence of skin reaction.

The package contains two (2) regular-sized devices and closes up to 25 to 30 mm (1.0 inch) of incision length.



Caution: Federal law (USA) restricts this device to use by or on the order of a physician. (Rx Only)

Indications for Use:
Devices are intended for use for skin closure of lacerations, wounds and surgical incisions on patients.

Contraindications:
1) The device should not be used on patients with known allergies to skin adhesives.

2) Do not apply the device under excessive tension or on wounds that cannot be easily approximated, as skin shearing, blistering, or device release may result.

3) Do not use on infected wounds unless specifically determined appropriate by the attending physician.

4) Do not use in areas on wounds where the device cannot be fully adhered to the skin.

5) Do not use within the hairline unless the area has been depilated before applying.

Warnings:
1) Do not use the devices in a package if the package is damaged or the seal of the package has been broken prior to the intended use, as such damage renders the devices non-sterile.

2) Do not use with petroleum-based creams, lotions, ointments (such as Bacitracin®), salves or other oil- or petroleum-based products. Contact with these substances may result in device failure or release.

3) Use of adhesive enhancers may increase the risk of dermatitis and is not required to maintain good adhesion.

4) If applying to wounds or incisions subject to high stress, extra care should be taken to assure proper adhesion. If used on a joint that is not immobilized, use caution to ensure mobility does not compromise the integrity of the device or the adhesion of the device adhesive to the skin. Allow sufficient spacing between the devices to allow the flexing of the joint without causing the devices to come into contact with each other.

5) Do not use a device if it is damaged or destroyed during application, including breaking of a pull tab, or if there has been excessive handling of, or fully applied skin contact with, the adhesive surface of the device.

6) In applying any wound dressing, ensure that none of the dressing adhesive contacts the device adhesive as removal of the dressing where the two adhesives are overlapping may result in the release of the device.

7) Devices are single use and cannot be reused. Once locked, the device cannot be unlocked and cannot be reapplied. Reuse of the adhesive involves a high risk of infection.

8) DermaClip® devices utilize non-sensitizing adhesives; however, it is still possible that patients may experience allergic reactions to the adhesive, skin sensitivities or stripping upon removal. If allergic reactions occur during the wearing of the device, remove and replace with an alternative skin closure if required.

9) Swallowing the device could present a choking hazard, so care should be taken to ensure the device

is not swallowed.

Skin Preparation:

1) Depilatory removal of any surface hair on the surrounding skin is recommended and will enhance the adhesion of the device adhesive to the skin.

2) Any loose or damaged skin should be removed, if possible under the circumstances.

3) The wound or incision and the surrounding skin should be carefully cleaned with approved, non-petroleum based antiseptic, preferably with alcohol or an alcohol-based cleanser, so as to be free of dirt, oils, biological materials or other impediments to adhesion.

4) The surrounding skin should be dry prior to application of the devices.

Instructions for Use:

1) Prepare skin according to the prior instructions.

2) Determine how many devices will be needed to close the wound or incision. The individual device is 11 mm (0.43") in width. Each package of 2 will cover approximately 25 to 30 mm (1.0") in laceration, wound or incision length.

3) Open and remove the backing pallet with devices from the packaging. (*FIG. 1*)

4) Approximate the edges of the wound or incision as close together as possible, ensuring that the skin alignment is as close to the original positioning (e.g., pre-incision) as possible. If needed, perform a final cleansing of the area prior to applying the device.

5) Remove the device from the backing pallet by grasping the two tabs between your thumb and forefinger and peeling the device down the pallet. Using this method avoids handling the adhesive of the device. (*FIG. 2*)

6) Apply the adhesive halves of the DermaClip® device on either side of the wound/incision as close as possible to each wound edge without overlapping the wound edge. (*FIG. 3*)

Adjusting the opening (e.g., expanding the gap between the sides of the device) before application so that the edges of the adhesive can reach the wound's edges (without extending into the center of the wound) may require touching of the device adhesive; if so, minimize the touching to preserve the robustness of the adhesive.

7) Press down firmly on the adhesive pads and smooth the pads into the skin to fully engage the pressure sensitive adhesive.

8) Place the next DermaClip® device close to the one just applied (1 to 4 mm apart). The ends of pads may overlap in curving wounds, but the center portion of the device where wound closure occurs should not be overlapped.

For joints that are not immobilized, assure adequate spacing so that the devices do not come into contact with each other due to flexion and extension.

9) Once all the devices have been applied to the wound or incision, close each device by grasping it at the first locking tooth (as noted in the part diagram) and pulling it straight out. (*FIG. 4*) **PULL THE TABS ON EACH DermaClip® DEVICE UNTIL A CLICK IS HEARD.** Then proceed to the next, immediately adjacent device and close it. However, in the physician's discretion, each device may be pulled closed and locked as applied.

WHEN PULLING THE TABS, THERE IS AN INITIAL RESISTANCE AS THE DEVICE ENGAGES. THIS IS NOT THE DEVICE LOCKING! CONTINUE TO PULL THE TABS OF THE DEVICE UNTIL A "CLICK" IS HEARD, WHICH OCCURS AFTER THE TWO EDGES OF THE DEVICE HAVE FORCED EACH OTHER, AND THE ATTACHED SKIN, INTO AN UPWARD, FULLY EVERTED POSITION. ONLY THEN IS THE DEVICE CLOSED AND LOCKED SHUT.

To manually check if the devices are locked, simply push down on the top center of each device. When the device is properly locked, the device remains rigid

Figure 1 - Open

Figure 2 - Pick

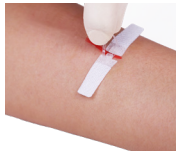


Figure 3 - Place

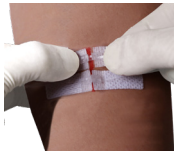


Figure 4 - Pull

and everted when the top center is pushed down. The faces will remain in full contact. If the device is not locked, the center of the device will be pushed down and out. The tabs on any device not properly locked should be re-pulled to achieve proper locking of the device.

Device Remains Rigid, Locked & Everted

Device Slides Opened

10) If an individual device is not applied correctly or has a tab break off during the closure process, remove and replace it. **DO NOT ATTEMPT TO REUSE A DEVICE IF A TAB HAS BROKEN OFF, IF THE DEVICE HAS ALREADY BEEN PROPERLY LOCKED PRIOR TO REMOVAL OR IF, PRIOR TO REMOVAL, THE DEVICE WAS FULLY ADHERED TO THE SKIN.**

11) Once all the devices have been closed and confirmed locked, cut the tabs off at least 5 mm beyond the locking tooth and discard the pieces. *N.B.* Complete cure and bonding of the adhesive takes approximately 30 minutes but does not affect the interim efficacy of the device.

12) After closure, some form of absorbent or protective dressing should be applied to the wound or incision both to protect the wound and to protect the device from catching on external objects, which can cause the device to separate from the wound. **WHEN PLACING A DRESSING, ENSURE THAT THE DRESSING'S TAPE OR ADHESIVE DOES NOT COME INTO CONTACT WITH THE DEVICE ADHESIVE TO AVOID ACCIDENTALLY PULLING THE DermaClip® DEVICE OFF WHEN THE DRESSING IS REMOVED**. Any dressing should be changed regularly to avoid infection.

DO NOT USE PETROLEUM-BASED OINTMENTS (SUCH AS BACITRACIN®), SKIN CREAMS, LOTIONS, SALVES OR OTHER OIL- OR PETROLEUM-BASED PRODUCTS WITH OR ON THE DEVICES. THESE PRODUCTS WILL BREAK DOWN THE ADHESIVE, WHICH COULD RESULT IN DEVICE FAILURE.

13) Devices may be applied to a healed wound in accordance with the preceding instructions after removal of stitches or staples to reinforce the newly formed scar and protect against reopening.

Patient Care of Device:

1) Patient must avoid using ointments (such as Bacitracin®), skin creams, lotions, salves or other oil- or petroleum-based products with or on the devices, as these products can cause device failure.

2) Patients can rinse and dry the device carefully after 24 hours with physician approval. Use of a plastic waterproof covering is recommended if showering to avoid wetting the area of the wound or incision as much as possible. Do not allow water to flow directly onto the devices. Patient should not submerge the device in a bathtub or swim until after the devices have been removed.

3) To dry, gently blot the area of the wound or incision dry with a soft clean towel to remove any wetness. Any previously applied dressing should be removed (following the healthcare professional's instructions) and a new, clean dressing reapplied, using caution to ensure that the adhesive of the dressing does not come into contact with the adhesive of the devices. Maintaining a dressing is important both to protect the wound and to avoid catching the device on external objects, which can cause the device to separate from the wound prematurely.

4) The patient should take care not to stress, flex, rub or put undue pressure on the area of the wound, as tension on the skin and the wound area will stress the adhesive and can lead to device failure.

5) Patient should call the healthcare professional if the adhesive of any of the devices closing the wound or incision has released (unless the device has been on the wound for an extended period of at least 7 days), if the wound or incision appears not to be healing after several days, or if any sign of redness or infection appears either while the devices are on the skin or after removal.

Separate skin care instructions reflecting the above instructions are available for distribution to the patient.

Device Removal:

The device normally should be left on the wound at least 7 days or as directed by the healthcare professional.

1) Devices should be removed at such time as directed by the healthcare professional if not otherwise removed by the healthcare professional.