SKIN AS DAMAGE TO THE HEALED WOUND OR INCISION AND REOPENING OF THE WOUND OR INCISION MAY RESULT. "PEEL; DON'T PULL!"

17) The DermaClip® device should normally be left on the wound no longer than 14 days. If it has not been peeled off or fallen off in 14 days, consult your physician about removal.

18) A healthcare professional should be consulted if the wound or incision appears not to have healed or if any sign of redness or infection appears either while the DermaClip® devices are on the skin or after removal.

19) DermaClip® devices may be utilized in accordance with the preceding instructions after removal of stitches or staples to reinforce the newly formed scar and protect against reopening.

United States federal law restricts this device to sale by or on the order of a physician.

For inquiries or questions, please contact:

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Document: IFU-R5-2017-0006
Rev. 6 (04/07/2017)

DermaClip®

Non-Invasive Skin Closure Device

Instructions for Use (IFU)

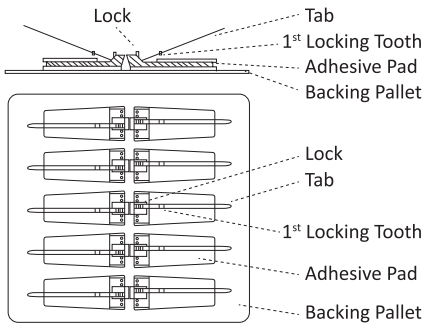
DermaClip®
Non-Invasive Skin Closure Device

Regular Clip, 5 Pack (LK-V)

Instructions for Use (IFU)

IMPORTANT NOTE ON USE: ***AS WITH ANY MEDICAL DEVICE, BEFORE APPLYING TO A PATIENT, THE MEDICAL PROFESSIONAL SHOULD SUFFICIENTLY PRACTICE WITH THE DEVICE TO ASSURE FAMILIARITY WITH THE CLOSURE OF THE DEVICE. WHEN PULLING THE DEVICE CLOSED, THERE IS A FIRST RESISTANCE. THIS IS NOT THE LOCKING OF THE DEVICE! THE DermaClip® DEVICE IS CLOSED AND LOCKED SHUT ONLY WHEN A CLICK OCCURS AFTER THE 2 EDGES OF THE DEVICE HAVE MADE CONTACT AND THEN FORCED EACH OTHER INTO AN UPWARD, EVERTED POSITION.***

Product Description:
The DermaClip® device is single use and is composed of two strips of non-latex, breathable, hypoallergenic, pressure-sensitive medical adhesive joined together by a polypropylene closure device; this model is packaged in an envelope of five (5) regular-sized devices. The DermaClip® device employs proprietary technology to evert skin edges with minimum tension on the surrounding skin. The DermaCLIP® device utilizes an alkylate, non-benzoin based adhesive, which has been shown to be hypoallergenic, minimizing allergic skin reactions.



Indications for Use:
DermaClip® devices are intended for use for non-invasive skin closure of lacerations, wounds and surgical incisions.

Contraindications:

Benzoin-based adhesive enhancers should not be used with this product.

The device should not be used on patients with known allergic reactions to skin adhesives.

Do not apply the DermaClip® device under excessive tension as skin shearing or blistering may result.

Warnings:
Additional care in application should be taken if infection is indicated, particularly in the presence of exudate. In such cases, the physician should determine whether to use DermaClip® devices for wound or incision closure. If the physician determines to utilize DermaClip® devices, the physician should consider whether debridement of the wound is warranted.

The wound or incision should be carefully cleaned with approved antiseptic, and any clearly infected skin surrounding the wound or incision should be removed prior to applying the DermaClip® device, if feasible.

When applying to wounds or incisions subject to high stress, extra care should be taken to assure proper adhesion. In these circumstances, depilatory removal of any surface hair and close placement of the DermaClip® devices is highly recommended.

Precautions:
Prior to application of the DermaClip® devices, the wound/incision should be thoroughly cleansed, preferably with alcohol or an alcohol based cleanser, so as to be free of dirt, oils or other impediments to adhesion; if possible in the circumstances, any loose or damaged skin should be removed; and any antibiotic and/or clotting medication to stop bleeding should be applied.

Depilatory removal of any surface hair is recommended unless otherwise indicated by the nature of the wound/incision.

The skin should be dry prior to application of the DermaClip® devices.

The wound/incision should be approximated as much as reasonably possible prior to applying the DermaClip® device(s) so that the two sides of the incision are close together with no overlapping so that eversion of the skin edges may occur upon closure of the DermaClip® devices.

Patient may shower, if approved by a healthcare professional, but the patient should not soak in a bathtub and/or swim or allow the water of a shower or faucet to run directly onto the DermaClip® device and the wound. Applying a water resistant material, such as plastic, to cover the DermaClip® device is recommended during any exposure to water, including showering. In any event, patient should take care not to apply direct water pressure to the wound area.

Storage, Shelf Life and Packaging:

The product should be stored at room temperature. Expiration date in such conditions is 2 years.

DermaClip® devices are supplied in packages with a white front with printing and a clear, transparent back. The DermaClip® devices are sterilized using ETO.

CAUTION: If the package is damaged or the seal of the package has been broken, the contents of the package should NOT be used and should be returned to the distributor.

Instructions for Use:

1) Completely clean the wound/incision according to standard technique; alcohol or an alcohol-based cleanser is generally effective for such purposes. All surrounding skin should be clean, dry and free of dirt or oils. If possible, any loose skin should be removed, and the skin should be depilated, as better adhesion results when the surrounding skin to which the adhesive is applied has been depilated.

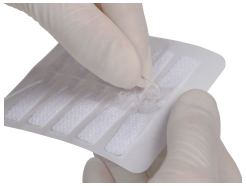
2) Place subcutaneous sutures where needed for layered closure or to decrease tension prior to applying DermaClip®.

3) Determine how many DermaClip® devices will be needed to close the wound or incision. The individual device is 11 mm (0.43") in width. Each package of 5 will cover approximately 65 to 75 mm (2.5" to 3.0") in laceration, wound or incision length.

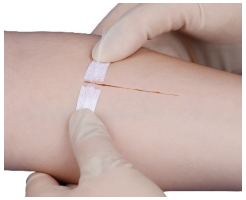
4) Approximate the edges of the wound/incision as close together as possible, without any overlapping of the skin. If needed, perform a final cleansing of the wound/incision to which the DermaClip® devices is to be applied prior to applying the device.

5) Open and remove the pallet of five (5) DermaClip® devices from the packaging.

6) To remove the DermaClip® device from the backing, grasp the two tabs between your thumb and forefinger and lift the DermaClip® from the backing.



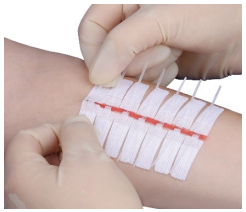
7) As you remove each individual device, apply it to the wound/incision so as to have one of the adhesive halves of the DermaClip® device on either side of the wound/incision as close as possible to the wound edge.



8) Place the next DermaClip® device close to the one just applied (~1 to 4 mm), without overlapping the adhesive, so as to close the wound securely and to maximize healthy healing.

9) During this process, carefully handle the DermaClip® device so as not to touch the adhesive as this may adversely affect the adhesion of the DermaClip® device to the skin and, thereby, its intended performance. Ensure that the adhesive strip is placed similarly on each side of the edge of the wound or incision. Complete cure and bonding of the adhesive takes approximately 20 minutes, but healthcare professionals may proceed with the following steps to achieve tissue approximation and eversion prior to complete bonding. **IF AN ADHESIVE ENHANCER IS USED, DO NOT UTILIZE A BENZOIN-BASED ENHANCER BECAUSE OF RISK OF ALLERGIC REACION.**

10) Once all the DermaClip® devices have been applied to the wound/incision, close each DermaClip® by grasping it at the first locking tooth and pulling it closed. **PULL EACH DermaClip® DEVICE UNTIL A CLICK IS HEARD TO ENSURE FULL CLOSURE OF THE DEVICE.**



THE DermaClip® DEVICE IS ONLY LOCKED SHUT WHEN A CLICK IS HEARD. WHEN PULLING THE DEVICE CLOSED, THERE IS A FIRST RESISTANCE AS THE DEVICE IS INITIALLY PULLED CLOSED. *THIS IS NOT THE LOCKING OF THE DEVICE!* IT IS VERY IMPORTANT TO THE PROPER FUNCTIONING OF THE DEVICE THAT YOU CONTINUE TO PULL UNTIL YOU HEAR THE CLICK THAT OCCURS AFTER THE TWO EDGES OF THE DEVICE HAVE CONTACTED EACH OTHER AND THEN FORCED EACH OTHER, AND THE ATTACHED SKIN, INTO AN UPWARD, EVERTED POSITION. ONLY THEN WILL THE DEVICE BE CLOSED AND LOCKED SHUT.

Then proceed to the next, immediately adjacent DermaClip® and close it. However, in the physician's discretion, each DermaClip® may be closed as applied. However, if the physician determines that a staged closure is appropriate, the DermaClip® may be left open until the physician determines skin closure is appropriate, even if such period is longer than one (1) day.

11) If an individual DermaClip® device is not applied correctly, or does not clearly click shut, remove and replace it. **DO NOT ATTEMPT TO REUSE A DermaClip® DEVICE IF IT HAS BEEN EITHER PARTIALLY OR FULLY CLOSED.**

12) Once all the individual DermaClip® devices have been locked closed, cut the excess pieces of the tabs (beyond the locking tooth) and discard them.

13) After closure of the DermaClip® devices, a light film of dressing may be applied to the wound or incision. A light gauze or breathable gauze and adhesive covering may be combined with or substituted for the light film of dressing. If a covering is utilized, it should also be changed regularly to avoid infection.

14) Patients can shower upon physician approval. Use of a plastic waterproof covering during such showering is recommended to avoid wetting the area of the wound or incision as much as possible. If not covered, do not allow water to flow directly onto the DermaClip® devices. After showering, gently blot the area of the wound or incision dry with a soft clean towel to remove any wetness. If a dressing has been applied, the dressing may be reapplied.

15) DermaClip® devices should be removed at such time as directed by the physician if not otherwise removed by the physician. At the direction of the physician, the DermaClip® devices may be removed by the patient.

16) In removing the device, apply a light oil to facilitate the removal and protect the skin. To remove, the device should be peeled from one side of the closed wound or incision to the other so as to carefully remove it from the skin. **NEVER REMOVE THE DEVICE BY PULLING IT FROM THE**