DERMAGLUE®
Topical Tissue Adhesive
Instructions for Use

I. DERMAGLUE® Topical Tissue Adhesive

1. Description

DERMAGLUE® Topical Tissue Adhesive is a sterile liquid topical tissue adhesive composed of a blended mixture of 2-octyl and n-butyl cyanoacrylate monomers. The product is supplied as a 0.6 g, single-patient-use, squeezable plastic tube with an applicator tip. Each applicator and tip is sealed in a blister pack to maintain sterility until the package is opened or damaged.

DERMAGLUE® Topical Tissue Adhesive remains liquid until applied to the skin. After application, it cures (polymerizes) and forms an adherent film on the underlying surface. Upon application, DERMAGLUE® Topical Tissue Adhesive polymerizes within approximately 60 seconds.

2. Indications

DERMAGLUE® Topical Tissue Adhesive is indicated for closure of skin wounds in areas with low skin tension, simple wound structure, thorough wound cleansing, and skin edges that can be easily approximated, including laparoscopic incision sites and lacerations resulting from trauma.

DERMAGLUE® Topical Tissue Adhesive may be used in conjunction with deep dermal sutures, but it is not intended to replace them.

In vitro studies have shown that DERMAGLUE® Topical Tissue Adhesive acts as a physical barrier to microbial penetration as long as the adhesive film remains intact. However, no clinical studies have been conducted to demonstrate microbial barrier properties, and a correlation between microbial barrier properties and reduction of infection has not been established.

DERMAGLUE® Topical Tissue Adhesive must be applied by trained medical or nursing personnel.

3. Contraindications

- Do not apply to: Internal organs, blood vessels, nerve tissue, mucosal surfaces or mucocutaneous junctions, areas with abundant natural hair, the conjunctival sac of the eye, or skin that is routinely exposed to body fluids.
- Infection and specific wounds: Do not apply to wounds showing signs of active microbial, bacterial, or fungal infection, or gangrene. Do not use on pressure ulcers, animal or human bites, or puncture wounds.
- Underlying patient conditions: Do not use in patients with a confirmed systemic infection before surgery, uncontrolled diabetes, or diseases or conditions known to interfere with the wound-healing process.
- Hypersensitivity: Do not use in patients with known hypersensitivity to cyanoacrylate or formaldehyde.

Warnings

- Wound preparation and hemostasis: DERMAGLUE® Topical Tissue Adhesive must be used only on wounds that have been thoroughly cleaned and debrided. Hemostasis must have been initiated before application of the adhesive.
- Heat-related precaution: DERMAGLUE® Topical Tissue Adhesive generates a small amount of heat during polymerization (curing) and must not be applied to tissues that may be affected by this heat.
- Do not apply to the eye and management of accidental eye closure: Do not apply the product to the ocular surface.

- If the eye becomes accidentally glued shut: Cover the eye with a pad moistened with warm water to allow the eyelashes to separate. The adhesive bonds to ocular proteins and may cause tearing for a period of time; tears can help separate the adhesive. Keep the eye covered until the adhesive has completely separated, usually within 1–3 days. Do not force the eye open. If adhesive residue remains after separation, seek evaluation by an ophthalmologist.
- Precautions for closure of facial wounds near the eye: Position the patient so that the adhesive flows away from the eye. The patient should keep the eye closed and the eye should be protected with gauze. Applying petroleum jelly around the eye before the procedure may be effective as a physical barrier to prevent the adhesive from accidentally flowing into the eye.
- Precaution regarding petroleum jelly: DERMAGLUE® Topical Tissue Adhesive will not adhere to skin that has been pre-coated with petroleum jelly. Therefore, do not apply petroleum jelly to areas of skin where DERMAGLUE® Topical Tissue Adhesive is intended to adhere.
- Do not use on high-tension or excision sites: Do not apply to wounds under high skin tension or areas subject to increased skin tension, such as elbows, knees, and finger joints. Do not use on skin excision sites.
- Excessive moisture and thick application: Do not apply to excessively wet wounds. Excess water, blood, or alcohol may accelerate polymerization and generate excessive heat. Applying the adhesive too thickly may increase polymerization time; always apply a thin layer along the wound edges to form a film.
- Do not apply to subdermal layers: Do not apply to subdermal tissue layers. Polymerized adhesive is not absorbed by tissue and may cause a foreign-body reaction.
- Monitor for adverse reactions and infection: Use of the product may cause localized hypersensitivity or irritation. As with other wounds, wounds treated with this product should be monitored for signs of infection. If signs such as erythema, edema, fever, pain, or purulent discharge occur, evaluate and treat according to standard infection-management guidelines.
- Single use and disposal: The product is packaged for single-patient use. Cross-use between multiple patients increases the potential for transmission of infectious agents. Any remaining product after the medical procedure must be discarded in a sharps container or biohazard waste container.
- Do not resterilize: Do not resterilize this product. Do not place the product in procedure packs or trays that will undergo sterilization before use. Sterilization may increase product viscosity and make it unusable.
- Use technique: When using the product, the user should place the fingertips on both sides of the plastic tube and control the pressure applied.

Adverse Reactions

Clinical use of cyanoacrylate-based topical tissue adhesives has suggested that the following adverse reactions may occur:

- Wound dehiscence
- Infection
- Acute inflammation, including erythema, edema, and exudate
- Bonding to unintended tissues, including the eye
- Thermal discomfort during polymerization (curing)
- Allergic reaction
- Foreign-body reaction

Clinical Studies

Published literature describing controlled clinical studies comparing cyanoacrylate-based topical tissue adhesives with sutures and staples has demonstrated the safety and effectiveness of these products for wound closure as described in this booklet.

7. Instructions for Use

1. Wound preparation
Before applying DERMAGLUE® Topical Tissue Adhesive, thoroughly clean the wound. Prepare the wound according to standard surgical procedures (i.e., anesthesia, cleansing, debridement, secure hemostasis, and closure of deep tissue layers). Confirm that the wound edges can be easily approximated.

2. Opening the product
Slowly peel open the blister pack with the label facing upward and remove the sterile, single-patient-use device.

3. Attaching the brush tip
If a broad application of adhesive is desired, attach the brush tip to the primary tip already fitted to the device.

4. Positioning
When ready to apply, hold the applicator with one hand with the applicator tip facing upward and away from the patient to prevent unintended contact.

5. Brush alignment
When using the brush tip, position the center of the brush directly over the wound so that the adhesive can be applied accurately.

6. Begin application
Apply light pressure to the tube to dispense DERMAGLUE® Topical Tissue Adhesive from the applicator tip.

7. Working time
The adhesive inside the applicator remains liquid for up to 20 minutes, allowing multiple applications to the same patient.

8. Skin approximation
During application, approximate the wound edges and hold them securely in position.

9. Thin application
Apply DERMAGLUE® Topical Tissue Adhesive as a thin film along the wound edges.

10. Curing (polymerization)
Maintain gentle pressure on the approximated wound line for approximately 60 seconds to allow the tissue adhesive to cure (polymerize). For wounds under tension, subcuticular sutures may be used for additional support before applying the topical tissue adhesive.

11. Dressing
A protective dry dressing, such as gauze, may be applied only after the DERMAGLUE® Topical Tissue Adhesive film has completely polymerized and is no longer tacky.

12. Disposal
After use, discard the device in a sharps container or biohazard waste container.

Patient Instructions
Wounds closed with DERMAGLUE® Topical Tissue Adhesive do not require additional or special care. However, the following information is recommended for patients when appropriate:

- Keeping the wound dry and clean: Keep the wound as dry as possible until the polymerized adhesive barrier naturally falls off after approximately 5–8 days. Contact with water should be limited to occasional exposure. The patient may shower immediately and gently wash the wound area. However, avoid directly rubbing the wound or prolonged immersion in water, including swimming, until the adhesive barrier has fallen off and the wound has healed.
- Do not apply medications or creams: Do not apply any medication or cream to the wound area.
- Dressings: As directed by the physician, use a non-adherent, non-medicated, waterproof dressing to keep the wound dry.
- Precautions: Do not pull or pick at the wound or dressing. Inform the physician of any discomfort or other concerns related to the wound.

How Supplied

DERMAGLUE® Topical Tissue Adhesive is supplied as a pre-filled, sterile, single-patient-use applicator. Each ampoule contains 0.6 g of liquid adhesive.

Storage

DERMAGLUE® Topical Tissue Adhesive should always be stored in its original sealed blister pack at a temperature between 4°C and 9°C (39°F–48°F), protected from direct sunlight and direct heat. Do not use the product after the expiration date indicated on the blister pack.

Sterility

DERMAGLUE® Topical Tissue Adhesive is sterilized by dry heat and ethylene oxide (EO) gas. The product is packaged for single-patient use. Do not resterilize, as resterilization may adversely affect product performance. Do not use the product if the package has been opened or damaged, as sterility cannot be assured. Discard all remaining product after completion of the medical procedure.

Note: This English document is a translation and clean formatting of the uploaded Korean Instructions for Use. It preserves the source document's content and terminology and is not intended to replace the officially approved labeling.