

**DERMABOND\***  
Topical Skin Adhesive  
(2 Octyl Cyanoacrylate)

## **DESCRIPTION**

DERMABOND\* Topical Skin Adhesive is a sterile, liquid topical skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation and the colorant D & C Violet #2. It is provided in a single use applicator packaged in a blister pouch. The applicator is comprised of a crushable glass ampule contained within a plastic vial with attached applicator tip. As applied to the skin, the liquid adhesive is slightly more viscous than water and polymerizes within minutes. See DIRECTIONS FOR USE.

## **INDICATIONS**

DERMABOND Topical Skin Adhesive is intended for topical application to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. DERMABOND adhesive may be used in conjunction with, but not in place of, subcuticular sutures.

## **CONTRAINDICATIONS**

- Use on any wounds with evidence of active infection, gangrene, or wounds of decubitus etiology.
- Use on mucosal surfaces or across mucocutaneous junctions (e.g., oral cavity, lips), or on skin which may be regularly exposed to body fluids or with dense natural hair, (e.g., scalp).
- Use on patients with a known hypersensitivity to cyanoacrylate or formaldehyde.

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## WARNINGS

- DERMABOND adhesive is a fast setting adhesive capable of adhering to most body tissue and many other materials, such as latex gloves and stainless steel. Inadvertent contact with any body tissue, and any surfaces or equipment that are not disposable or that cannot be readily cleaned with a solvent such as acetone should be avoided.
- Polymerization of the adhesive may be accelerated by water or fluids containing alcohol: DERMABOND should not be applied to wet wounds.
- The adhesive should not be applied to the eye. If contact with the eye occurs, flush the eye copiously with saline or water. If residual adhesive remains, apply topical ophthalmic ointment to help loosen the bond and contact an ophthalmologist.
- This adhesive should not be used below the skin because the polymerized material is not absorbed by tissue and can elicit a foreign body reaction.
- This adhesive should not be used in high skin tension areas or across areas of increased skin tension, such as knuckles, elbows, or knees, unless the joint will be immobilized during the skin healing period.
- DERMABOND adhesive should only be used after wounds have been cleaned and debrided in accordance with standard surgical practice. Local anesthetic should be used when necessary to assure adequate cleansing and debridement.
- This adhesive should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction.
- Excessive pressure of the applicator tip against wound edges or surrounding skin can force the wound edges apart and allow adhesive into the wound. Adhesive within the wound could delay wound healing and/or result in adverse cosmetic outcome. Therefore, DERMABOND adhesive should be applied with a very light brushing motion of the applicator tip over easily approximated wound edges.
- The adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. With the proper technique of applying DERMABOND adhesive in multiple thin layers (at least three) onto a dry wound and allowing time for polymerization between applications, heat is released slowly and the sensation of heat or pain experienced by the patient is minimized. However, if DERMABOND adhesive is applied so that large droplets of liquid are allowed to remain unspread, the patient may experience a sensation of heat or discomfort.
- DERMABOND treated wounds should be monitored for signs of infection. Wounds with signs of infection, such as erythema, edema, warmth, pain, and pus, should be evaluated and treated according to standard practice for infection.

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- DERMABOND adhesive is packaged for single patient use. Discard remaining opened material after each wound closure procedure.
- Do not resterilize the adhesive.
- Do not place DERMABOND adhesive in a procedure pack/tray that is to be sterilized prior to use. Exposure of DERMABOND adhesive, after its final manufacture, to excessive heat (as in autoclaves or ethylene oxide sterilization) or radiation (such as gamma or electron beam), is known to increase its viscosity and may render the product unusable.

## PRECAUTIONS

- Do not apply liquid or ointment medications or other substances to the wound after closure with DERMABOND adhesive, as these substances can weaken the polymerized film and allow for wound dehiscence. DERMABOND permeability by topical medications has not been studied.
- DERMABOND permeability by fluids is not known and has not been studied.
- DERMABOND adhesive is a free flowing liquid slightly more viscous than water. To prevent inadvertent flow of liquid adhesive to unintended areas: (1) the wound should be held in a horizontal position, with DERMABOND adhesive applied from above, and (2) DERMABOND adhesive should be applied in up to three, thin layers rather than in a few large droplets.
- DERMABOND adhesive should be used immediately after crushing the glass ampule as the liquid adhesive will not flow freely from the applicator tip after a few minutes.
- If unintended bonding of intact skin occurs, peel, but do not pull the skin apart. Petroleum jelly or acetone may help loosen the bond. Other agents such as water, saline, betadine, Hibiclens, or soap, are not expected to immediately loosen the bond.
- Safety and effectiveness of DERMABOND adhesive on wounds of patients with peripheral vascular disease, insulin dependent diabetes mellitus, blood clotting disorders, personal or family history of keloid formation or hypertrophy, burst stellate lacerations, have not been studied.
- Safety and effectiveness of DERMABOND adhesive on the following wounds have not been studied: animal or human bites, puncture or stab wounds.
- Safety and effectiveness on wounds that have been treated with DERMABOND adhesive and then exposed for prolonged periods to direct sunlight or tanning lamps have not been studied.

- Safety and effectiveness of DERMABOND adhesive on wounds in vermilion surfaces has not been studied.

## ADVERSE REACTIONS

- o Adverse reactions encountered during clinical study:

<i>Clinical Study Outcomes</i>	<i>No</i>		<i>With</i>	
	<i>Subcuticular Sutures</i>		<i>Subcuticular Sutures</i>	
	DermaBond	Control	DermaBond	Control
	N (%)	N (%)	N (%)	N (%)
<b>Accounting</b>				
N, patients enrolled	240	243	167	168
N, patients treated	239	242	167	166
Patients completed	228 (95%)	215 (88%)	164 (98%)	162 (97%)
<b>Adverse Reactions:</b>				
<i>Suspected Infection*</i>	8 (3.6%)	2 (0.9%)	6 (3.6%)	2 (1.2%)
Wound type				
# Lacerations	8	2	1	0
# Incisions	0	0	5	2
<i>Dehiscence with Need for Retreatment</i>	6 (2.5%)	5(2.1 %)	3(1.8%)	0
<b>Acute Inflammation</b>				
Erythema	26 (11.5%)	74 (33.0%)	52 (31.3%)	75 (45.1%)
Edema	22 (9.7%)	28 (12.5) %	62 (37.3%)	71 (42.8%)
Pain	14 (6.1%)	13 (5.8%)	56 (33.7%)	57 (34.3%)
Warmth	3 (1.3%)	6 (2.6%)	3 (1.8%)	4 (2.4%)

\*In the clinical study, presence of infection was to be identified by observation of redness more than 3-5 mm from the repaired wound, swelling, purulent discharge, pain, increased skin temperature, fever, or other systemic signs of infection. (See clinical study). Confirmatory culture was not routinely obtained. Among cases of suspected infection for DERMABOND, 7/14 (50%) were in patients less than 12 years old with traumatic lacerations; overall, 8 of the 14 (approximately 60%) of DERMABOND wounds with suspected infections were associated with sub-optimal cosmetic outcome.

- Reactions may occur in patients who are hypersensitive to cyanoacrylate or formaldehyde. See CONTRAINDICATIONS.
- The polymerization of DERMABOND adhesive on the skin releases small amounts of heat which may cause a sensation of heat or discomfort in some patients.
- Adverse reactions may be experienced following DERMABOND contact with the eye.

## CLINICAL STUDY

**Description:** A prospective, randomized, controlled, unmasked study was conducted to evaluate the safety and effectiveness of closing the approximated skin edges of surgical incisions, including punctures from minimally invasive surgery, and trauma-induced lacerations using DERMABOND adhesive in comparison to USP size 5-0 or smaller suture, adhesive strips or staples, with or without dermal closure (subcuticular stitch) as per investigator judgment.

### Summary of Effectiveness Results Comparing DERMABOND to Sutures (U.S.P. size 5-0 and smaller diameter), Staples, and Adhesive Strips

<i>Clinical Study Outcomes</i>	<i>NSS</i>		<i>WSS</i>	
	DermaBond	Control	DermaBond	Control
	N (%)	N (%)	N (%)	N (%)
<i>Accounting</i>				
N, patients enrolled	240	243	167	168
N, patients treated	239	242	167	166
Patients completed	228 (95%)	215 (88%)	164 (98%)	162 (96%)
N, control: suture/strips/staples/missing		194/46/1/1		116/45/5/0
<i>Wound Closure Assessment</i>				
Immediate: Additional Devices	18 (7.5)	13 (5.4)	2 (1.2)	11 (6.6)
@ 5-10 days: 100% epidermal apposition	169 (75.1%)	199 (88.8%)	140 (84.3%)	160 (96.4%)
>50% epidermal apposition	205 (91.1%)	214 (95.5%)	163 (98.2%)	(165 (99.4%))
@ 3 months: Cosmesis Score*= 0 (optimal)	188 (82.5%)	180 (83.7%)	128 (78.0%)	128 (79.0%)
Median Time for Treatment (Minutes)	1.5	6.0	1.3	2.9

\* Cosmesis: modified Hollander Cosmesis Scale

The study population included patients at least one year of age, in good general health, who signed informed consent and agreed to follow-up visits. Patients were excluded if presenting with: significant multiple trauma, peripheral vascular disease, insulin dependent diabetes mellitus, blood clotting disorder, keloid formation or hypertrophy history (patient or family), cyanoacrylate or formaldehyde allergy, burst or stellate lacerations due to crush or hard blow, animal or human bite, and decubitus ulcer.

Follow-up was at 5-10 days and at 3 months. All wounds were assessed by visual inspection at 5-10 days after wound closure. The total kinds of wounds treated in the study were 46.1% lacerations and 53.9 % incisions. The incisions were comprised of 47.8% excisions of skin lesions, 27.4% minimally invasive surgery punctures, and 24.8% general surgery incisions.

For wounds closed without subcuticular stitches, mean wound length was 1.5cm, mean wound width was 2.5mm, and mean wound depth was 5.8mm. For wounds closed with

subcuticular stitches, mean wound length was 3.2cm, mean wound width was 5.3mm, and mean wound depth was 3.8 mm.

If the primary method of closure was insufficient for closure, an additional securing device was placed. The time to perform treatment included the time required later to remove the closure device when applicable.

The Modified Hollander Cosmesis Scale (MHCS), a validated scale, was used to evaluate cosmesis at three months: step-off borders, edge inversion, contour irregularities, excess inflammation, wound margin separation, and overall appearance.

## **DIRECTIONS FOR USE**

1. The application of DERMABOND requires thorough wound cleansing. Follow standard surgical practice for wound preparation before application of DERMABOND adhesive (i.e., anesthetize, irrigate, debride, obtain hemostasis and close deep layers).
2. Pat the wound dry with dry, sterile gauze to assure direct tissue contact for adherence of the DERMABOND adhesive to the skin. Moisture accelerates DERMABOND adhesive's polymerization and may affect wound closure results.
3. To prevent inadvertent flow of liquid adhesive to unintended areas of the body, the wound should be held in a horizontal position and the DERMABOND adhesive should be applied from above the wound.
4. DERMABOND adhesive should be used immediately after crushing the glass ampule, since the liquid adhesive will flow freely from the tip for only a few minutes. Remove the applicator from the blister pouch. Hold the applicator with the thumb and a finger and away from the patient to prevent any unintentional placement of the liquid adhesive into the wound or on the patient. While holding the applicator, and with applicator tip pointed upward, apply pressure at the midpoint of the ampule to crush the inner glass ampule. Invert and gently squeeze the applicator just sufficiently to express the liquid adhesive to moisten the applicator tip.
5. Approximate wound edges with gloved fingers or sterile forceps. Slowly apply the liquid adhesive in multiple (at least 3) thin layers to the surface of the approximated wound edges using a gentle brushing motion. Wait approximately 30 seconds between applications or layers. Maintain manual approximation of the wound edges for approximately 60 seconds after the final layer.

**NOTE:** DERMABOND adhesive polymerizes through an exothermic reaction. If the liquid adhesive is applied so that large droplets are allowed to remain without being evenly spread, the patient may experience a sensation of heat or discomfort. The sensation may be higher on sensitive tissues. This can be minimized by applying DERMABOND adhesive in multiple thin layers (at least 3).

**NOTE:** Excessive pressure of the applicator tip against the wound edges or surrounding skin can result in forcing the wound edges apart and allowing adhesive into the wound. Adhesive within the wound could delay wound healing and/or result in adverse cosmetic outcome.

**NOTE:** Full apposition strength is expected to be achieved about 2.5 minutes after the final layer is applied, although the top adhesive layer may remain tacky for up to

approximately 5 minutes. Full polymerization is expected when the top adhesive layer is no longer sticky.

6. Do not apply liquid or ointment medications onto closed wounds with DERMABOND adhesive because these substances can weaken the polymerized film, leading to wound dehiscence.
7. Protective dry dressings such as gauze, may be applied only after DERMABOND adhesive film is completely solid/polymerized: not tacky to the touch (approximately five minutes after application). Allow the top layer to fully polymerize before applying a bandage (see step 7. of DIRECTIONS FOR USE).

If a dressing: bandage, adhesive backing or tape is applied before complete polymerization, the dressing can adhere to the film, the film can be disrupted from the skin when the dressing is removed, and wound dehiscence can occur.

8. Patients should be instructed to not pick at the polymerized film of DERMABOND adhesive. Picking at the film can disrupt its adhesion to the skin and cause dehiscence of the wound. Picking at the film can be discouraged by an overlying dressing.
9. Apply a dry protective dressing for children or other patients who may not be able to follow instructions for proper wound care.
10. Patients treated with DERMABOND adhesive should be provided the printed instruction sheet entitled Proper Care For Your DERMABOND\* Topical Skin Adhesive Treated Wound. This instruction sheet should be reviewed with each patient or guardian to assure understanding of the proper care for the treatment site.
11. Patients should be instructed that until the polymerized film of DERMABOND adhesive has sloughed naturally (usually in 5-10 days), there should be only transient wetting of the treatment site. Patients may shower and bathe the site gently. The site should not be scrubbed, soaked, or exposed to prolonged wetness until after the film has sloughed naturally and the wound has healed closed. Patients should be instructed not to go swimming during this period.
12. If removal of DERMABOND adhesive is necessary for any reason, carefully apply petroleum jelly or acetone to the DERMABOND film to help loosen the bond. Peel off the film, do not pull the skin apart.



## **HOW SUPPLIED**

DERMABOND adhesive is supplied sterile, in a pre-filled, single-use applicator. The applicator is comprised of a crushable glass ampule contained within a plastic vial with attached applicator tip. The applicator contains 0.5 ml of liquid adhesive. The applicator is packaged in a blister pouch to maintain the device sterile until opened or damaged.

DERMABOND adhesive is available in boxes of 12 applicators.

## **STORAGE**

Recommended storage conditions: below 30° C, 86° F, away from moisture and direct heat. Do not use after expiry date.

## **STERILITY**

DERMABOND adhesive is originally sterilized by dry heat and ethylene oxide gas. Do not resterilize. Do not use if package is opened or damaged. Discard any unused material following completion of medical procedure.

## **STERILE SINGLE USE ONLY**

## **REPORTING**

Physicians should use the following toll free number listed below when reporting adverse reactions or potentially threatening complications involving DERMABOND adhesive.

## **CAUTION**

Federal (U.S.A) Law restricts this device to sale by or on the order of a physician.

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## **Proper Care For Your DERMABOND\* Topical Skin Adhesive Treated Wound**

**DERMABOND\* Topical Skin Adhesive** (2-octyl cyanoacrylate) is a sterile, liquid, skin adhesive that holds wound edges together. The film will usually remain in place for 5 to 10 days, then, naturally slough (fall) off your skin.

The following will answer some of your questions and provide instructions for proper care for your wound while it is healing:

### **CHECK WOUND APPEARANCE**

- Some swelling, redness and pain is common with all wounds and normally will go away as the wound heals. If swelling, redness or pain increase or if the wound feels warm to touch, contact a doctor. If the wound edges reopen or separate, contact a doctor.

### **BANDAGING**

- If bandaged, **keep the bandage dry.**
- Replace the dressing daily until the adhesive film has fallen off and if it should become wet unless otherwise instructed by your physician.
- Do not place tape directly over the DERMABOND adhesive film because removing the tape may also remove the film.
- **Do not scratch, rub, or pick** at the DERMABOND adhesive film. This may loosen the film before your wound is healed.
- Protect the wound from prolonged exposure to sunlight or tanning lamps while the film is in place.

### **TOPICAL MEDICATIONS**

- **Do not apply liquid or ointment medications** or any other product to your wound while the DERMABOND adhesive film is in place. This may loosen the film before your wound is healed.

### **KEEP WOUND DRY AND PROTECTED**

- Protect your wound from repeat injury until the skin has had sufficient time to heal.

- You may occasionally and briefly wet your wound in the shower or bath. **Do not soak or scrub your wound, do not swim,** and avoid periods of heavy perspiration until the DERMABOND adhesive has naturally fallen off. After showering or bathing, gently blot your wound dry with a soft towel. If a protective dressing is being used, apply a fresh, dry bandage keeping tape off the DERMABOND adhesive film.
- Apply a clean, dry bandage over the wound if necessary to protect the wound.

If you have any questions or concerns about this product, please consult your doctor.

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