



INSTRUCTIONS FOR USE

TOPICAL SKIN ADHESIVE (2-Octyl Cyanoacrylate)

DESCRIPTION

DERMABOND ADVANCED™ 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 as a single-use applicator in a blister package. The pen style applicator is composed of a crushable ampoule contained within a plastic applicator. As it is applied to the skin, the liquid is syrup-like in viscosity and polymerizes within minutes. Studies have shown that following application, DERMABOND ADVANCED™ Adhesive acts as a barrier to prevent microbial penetration as long as the adhesive remains. See DIRECTIONS FOR USE.

INDICATIONS

DERMABOND ADVANCED™ Adhesive is intended for topical application only, to hold closed easily approximated skin edges of wounds from surgical incisions, including incisions from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. DERMABOND ADVANCED™ Adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

CONTRAINDICATIONS

- Do not use on any wound with evidence of active infection, gangrene, or wounds of decubitus etiology.
- Do not 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.
- Do not use on patients with a known hypersensitivity to cyanoacrylate or formaldehyde.

WARNINGS

- DERMABOND ADVANCED™ Adhesive is a fast setting adhesive capable of adhering to most body tissue and many other materials, such as surgical 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 DERMABOND ADVANCED™ Adhesive may be accelerated by water or fluids containing alcohol. DERMABOND ADVANCED™ Adhesive should not be applied to wet wounds.
- DERMABOND ADVANCED™ 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.
- When closing facial wounds near the eye with DERMABOND ADVANCED™ Adhesive, position the patient so that any runoff of adhesive is away from the eye. The eye should be closed and protected with gauze. Prophylactic placement of petroleum jelly around the eye, to act as a mechanical barrier or dam, can be effective in preventing inadvertent flow of adhesive into the eye. DERMABOND ADVANCED™ Adhesive will not adhere to skin pre-coated with petroleum jelly. Therefore, avoid using petroleum jelly on any skin area where DERMABOND ADVANCED™ Adhesive is intended to adhere.
- DERMABOND ADVANCED™ Adhesive should not be used below the skin because the polymerized material is not absorbed by tissue and can elicit a foreign body reaction. Avoid excessive pressure of the applicator tip against wound edges or surrounding skin. This can force the wound edges apart and allow adhesive into the wound. DERMABOND ADVANCED™ Adhesive should be applied with a light brushing motion of the applicator tip over easily approximated wound edges.
- DERMABOND ADVANCED™ Adhesive should not be used in areas of high skin tension or across areas in which tension may increase, such as knuckles, elbows, or knees, unless the joint will be immobilized during the skin healing period or unless skin tension has been removed by application of another wound closure device (e.g., sutures or skin staples) prior to application of DERMABOND ADVANCED™ Adhesive.
- As with all wounds, DERMABOND ADVANCED™ Adhesive treated wounds should be monitored for signs of infection. Wounds with signs of infection, such as erythema, edema, warmth, pain, and purulent exudate, should be evaluated and treated according to standard practice for infection.
- DERMABOND ADVANCED™ Adhesive should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction.

- DERMABOND ADVANCED™ Adhesive should only be used after wounds have been thoroughly and adequately cleaned and debrided in accordance with standard surgical practice.
- DERMABOND ADVANCED™ Adhesive polymerizes through an exothermic reaction in which a small amount of heat is released sometimes resulting in a sensation of warmth. Applying DERMABOND ADVANCED™ Adhesive in one continuous layer onto a dry wound and allowing time for polymerization, will minimize the warm sensation.
- DERMABOND ADVANCED™ Adhesive is packaged for single patient use. Discard remaining opened material after each wound closure procedure.
- Do not resterilize DERMABOND ADVANCED™ Adhesive.
- Do not place DERMABOND ADVANCED™ Adhesive in a procedure pack/tray that will be sterilized prior to use. Exposure of DERMABOND ADVANCED™ Adhesive, to excessive heat (as in autoclaves or ethylene oxide sterilization) or radiation (such as gamma or electron beam) will 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 ADVANCED™ Adhesive, as these substances can weaken the polymerized film and allow for skin edge separation. Prior to application, cleanse the application site thoroughly to remove any remaining topical medications/anesthetics.
- DERMABOND ADVANCED™ Adhesive, as a liquid, is syruplike in viscosity. To prevent inadvertent flow of liquid DERMABOND ADVANCED™ Adhesive to unintended areas, the wound should be maintained in a horizontal position, with DERMABOND ADVANCED™ Adhesive applied from above.
- DERMABOND ADVANCED™ Adhesive should be used immediately after crushing ampoule because the adhesive will polymerize in the applicator, rendering the device unusable.
- If unintended bonding of intact skin occurs, peel the adhesive from the skin, but do not pull the skin edges apart. Petroleum jelly or acetone may help loosen the bond. Other agents such as water, saline, or soap are not expected to immediately loosen the bond.

ADVERSE REACTIONS

- Reactions may occur in patients who are hypersensitive to cyanoacrylate or formaldehyde. See CONTRAINDICATIONS.
- Adverse reactions may be experienced following contact with the eye.

DIRECTIONS FOR USE

1. The application of DERMABOND ADVANCED™ Adhesive requires thorough wound cleansing. Follow standard surgical practice for wound preparation before application of DERMABOND ADVANCED™ Adhesive (i.e., anesthetize, irrigate, debride, assure hemostasis, and close deep layers making sure that the wound edges can be easily approximated).
2. Pat the wound dry with dry, sterile gauze to assure direct contact of the DERMABOND ADVANCED™ Adhesive to the skin. Moisture accelerates DERMABOND ADVANCED™ Adhesive's polymerization and may affect wound closure results.
3. To prevent inadvertent flow of liquid DERMABOND ADVANCED™ Adhesive to unintended areas of the body, the wound should be maintained in a horizontal position and the DERMABOND ADVANCED™ Adhesive should be applied from above the wound.
4. DERMABOND ADVANCED™ Adhesive should be used immediately after crushing the ampoule, since the liquid DERMABOND ADVANCED™ Adhesive will flow freely from the tip for only a few minutes.
5. Refer to the instructions on the package for crushing the ampoule and expressing the liquid adhesive. Remove the applicator from the blister package. Hold the applicator with the thumb and a finger, away from the patient to prevent any unintentional placement of the liquid DERMABOND ADVANCED™ Adhesive into the wound or on the patient. With the applicator tip pointing downward, apply pressure at the midpoint of the bulb to crush the ampoule. Gently squeeze the applicator sufficiently to moisten the internal filter with the liquid adhesive. Stop squeezing and allow the liquid DERMABOND ADVANCED™ Adhesive to draw back into the applicator.
6. Approximate the wound edges with gloved fingers or sterile forceps. Slowly apply the liquid DERMABOND ADVANCED™ Adhesive in one continuous layer to the surface of the approximated wound edges using a gentle brushing motion. Maintain manual approximation of the wound edges for approximately 60 seconds after the application. The width of the layer can be increased or decreased by adjusting the amount of pressure applied to the bulb during application. Full apposition strength is expected to be achieved within minutes after the adhesive is applied. Full polymerization is expected when the DERMABOND ADVANCED™ Adhesive layer is no longer sticky.
7. Do not apply liquid or ointment medications onto wounds closed with DERMABOND ADVANCED™ Adhesive because these substances can weaken the polymerized film, leading to skin edge separation.
8. Protective dry dressings such as gauze may be applied only after DERMABOND ADVANCED™ Adhesive film is completely polymerized: not tacky to the touch after a few minutes. Allow the DERMABOND ADVANCED™ Adhesive to fully polymerize before applying a bandage.

9. Patients should be instructed to not pick at the polymerized film of DERMABOND ADVANCED™ Adhesive. Picking at the film can disrupt its adhesion to the skin and cause skin edge separation.
10. Patients should be instructed that until the polymerized film of DERMABOND ADVANCED™ Adhesive has sloughed naturally (usually in 5–10 days), there should be only transient wetting of the treatment site. Patients may immediately shower or bathe the site gently as directed by their physician. The site should not be scrubbed, soaked, or exposed to prolonged wetness until after the film has sloughed naturally and the physician has determined that the wound is adequately healed. Patients should be instructed not to swim during this period.
11. If removal of DERMABOND ADVANCED™ Adhesive is necessary for any reason, carefully apply petroleum jelly or acetone to the DERMABOND ADVANCED™ Adhesive film to help loosen the bond. Peel off the film; do not pull the skin edges apart.

HOW SUPPLIED

DERMABOND ADVANCED™ Adhesive is supplied sterile, in a pre-filled, single-use applicator. The pen style applicator consists of a crushable ampoule contained within a plastic applicator. The applicator contains the liquid adhesive. The applicator is supplied in a blister package to maintain the sterility of the device until opened or damaged. DERMABOND ADVANCED™ Adhesive is available in boxes of 6 or 12 applicators.

STORAGE

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












STERILITY

DERMABOND ADVANCED™ Adhesive has been 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 each medical procedure.

STERILE SINGLE USE ONLY

REPORTING

Physicians should use the following toll-free number 1-800-255-2500 (valid in U.S.A. only), when reporting adverse reactions or potentially threatening complications involving DERMABOND ADVANCED™ Adhesive.

 30°C 86°F max		Rx only	
Store at room temperature. (Below 30°C, 86°F)	Keep away from sunlight	CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare practitioner.	Contents: Vial
	STERILE !		
Use by — year & month	Method of Sterilization — Dry Heat	See instructions for use	Crush Vial After Opening the Package
	STERILE EO		
Manufacturer	Method of Sterilization — Ethylene Oxide	Do not reuse	Reorder number
LOT			
Batch number	Do not use if package is damaged or open	Do not resterilize	

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TOPICAL SKIN ADHESIVE