

# SKIN AFFIX™ Topical Skin Adhesive

MSC091040

## INSTRUCTIONS FOR USE

### BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

**CAUTION:** Federal (USA) law restricts this device to sale and use by, or on the order of, a physician.

**IMPORTANT!** This insert is designed to assist in using SKIN AFFIX™ topical skin adhesive. It is not a reference to surgical techniques.

### DESCRIPTION

SKIN AFFIX™ 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 patient use applicator packaged in a paper pouch. The SKIN AFFIX™ product is comprised of a crushable glass ampoule contained within a plastic applicator with attached applicator tip. SKIN AFFIX™ remains liquid until it is applied to the skin. Upon application SKIN AFFIX™ topical skin adhesive polymerizes within minutes. In vitro studies have shown that SKIN AFFIX™ topical skin adhesive acts as a barrier to microbial penetration as long as the adhesive film remains intact. Clinical studies were not conducted to demonstrate microbial barrier properties and a correlation between microbial barrier properties and a reduction in infection have not been established.

### INDICATIONS

SKIN AFFIX™ topical skin adhesive is intended for topical applications only, 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. SKIN AFFIX™ topical skin adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

### CONTRAINDICATIONS

- DO NOT use on any wounds with evidence of microbial, bacterial or fungal infections or gangrene.
- DO NOT use on mucosal surfaces or across mucocutaneous junctions, or on skin which may be regularly exposed to body fluids.
- DO NOT use on patients that have a hypersensitivity to cyanoacrylates or formaldehyde.
- DO NOT apply internally, inject intravascularly, or ingest.
- DO NOT use on decubitus ulcers, animal or human bite wounds, or stab wounds.

### WARNINGS

- SKIN AFFIX™ topical skin adhesive is a fast setting adhesive capable of adhering to most body tissues and many other materials, such as latex gloves and stainless steel. Inadvertant contact with any body tissue, surface and/or equipment that are not disposable or that can not be readily cleaned with a solvent such as acetone should be avoided.
- Polymerization of SKIN AFFIX™ topical skin adhesive may be accelerated by water or fluids containing alcohol: SKIN AFFIX™ topical skin adhesive should not be applied to wet wounds.
- SKIN AFFIX™ topical skin 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 using SKIN AFFIX™, adjust the patients position so that any flow of the adhesive is away from the eye. The eye should be closed and protected with gauze. Strategic placement of petroleum jelly near the eye can be effective at preventing inadvertant flow of the adhesive into the eye. Use of adhesives near the eye has inadvertently caused some patients' eyelids to be sealed shut. In some of these cases, general anesthesia and surgical intervention has been needed to open the eyelid.
- SKIN AFFIX™ topical skin adhesive will not adhere to skin pre-coated with petroleum jelly. Therefore, avoid using petroleum jelly on any skin area where SKIN AFFIX™ is intended to adhere.
- SKIN AFFIX™ topical skin adhesive is not absorbable and therefore should not be used below the skin as it may cause a foreign body reaction.

SKIN AFFIX™ topical skin adhesive should not be used in areas with high or increased skin tension, such as knuckles, elbows, or knees, unless the joint will be immobilized during the skin healing period or the skin tension has been decreased by application of another wound closure device (e.g., sutures or skin staples) prior to application of SKIN AFFIX™ topical skin adhesive.

- SKIN AFFIX™ topical skin adhesive treated wounds should be monitored for signs of infection. Wounds with signs of infection such as, erythema, edema, warmth, pain and/or drainage should be evaluated and treated according to standard practice for infection.
- SKIN AFFIX™ topical skin adhesive should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction.
- SKIN AFFIX™ topical skin adhesive should be used only on wounds that have easily apposed edges which have been thoroughly cleaned, debrided, and otherwise closed in accordance with standard surgical practice. Local anesthetic should be used when necessary to assure adequate cleansing and debridement.
- SKIN AFFIX™ topical skin adhesive should always be applied sparingly, bridging the wound and the aligned wound edges. Avoid pressure on the applicator to prevent wound edge separation, which could cause the topical skin adhesive to be interposed between the wound edges. Application and/or migration (leak) of the topical skin adhesive below the surface of the skin between the wound edges may impair the healing process by forming a barrier.
- SKIN AFFIX™ topical skin adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. With the proper technique of applying SKIN AFFIX™ topical skin adhesive sparingly onto a dry wound, heat is released slowly and the sensation of heat or pain experienced by the patient is minimized. However, if SKIN AFFIX™ topical skin adhesive is applied so that large droplets of liquid are allowed to remain unspread, the patient may experience a sensation of heat or discomfort.
- SKIN AFFIX™ topical skin adhesive is packaged for a single patient use. Discard remaining opened material after each wound closure procedure.
- DO NOT re-sterilize SKIN AFFIX™ topical skin adhesive or include it in a procedure pack/tray that is to be sterilized prior to use. Exposure of SKIN AFFIX™ topical skin 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 viscosity and may render the product unusable.

### PRECAUTIONS

- This product is meant for external dermal application only.
- Hold applicator away from yourself and the patient and break ampoule close to it's centre one time only. Do not crush the contents of the applicator tube repeatedly as further manipulation of the applicator may cause glass shard penetration of the plastic tube.
- Safety and effectiveness of SKIN AFFIX™ topical skin adhesive has not been evaluated for use on wounds of patients with uncontrolled diabetes mellitus, diseases or conditions that are known to interfere with the wound healing process, or a personal or family history of keloid formation or hypertrophic scarring.
- Safety and effectiveness has not been evaluated on wounds that have been treated with SKIN AFFIX™ topical skin adhesive and then exposed for prolonged periods of time to direct sunlight and tanning lamps.
- SKIN AFFIX™ topical skin adhesive permeability by topical medications or other fluids is not known and has not been studied.
- Liquid, ointment, or cream medications should not be applied to the wound after closure with SKIN AFFIX™, as these substances may weaken the polymerized film which may allow for wound dehiscence.
- If unintended bonding of intact skin with SKIN AFFIX™ should occur, removal may be accomplished by using either acetone or petroleum jelly. Typical cleansers such as soap and other agents such as water, saline, Betadine® or chlorhexidine gluconate are not expected to loosen the bond. Peel, do not pull skin apart.
- SKIN AFFIX™ topical skin adhesive is a viscous liquid prior to polymerization. To prevent inadvertant flow of SKIN AFFIX™ topical skin adhesive to unintended areas the wound should be placed in a horizontal position, with SKIN AFFIX™ topical skin adhesive applied from above.

## ADVERSE REACTIONS

Clinical use of cyanoacrylate-based topical skin adhesives has suggested that the following adverse events may occur: wound dehiscence; infection; acute inflammation including erythema, edema, and drainage; bonding to unintended tissues such as the eye; thermal discomfort during polymerization; allergic reaction; foreign body reaction; and chronic non-healing of a wound.

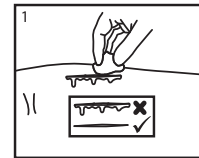
## CLINICAL STUDIES

Topical skin adhesives comprised of monomeric 2-Octyl-cyanoacrylate have been evaluated in controlled clinical studies in comparison to sutures, staples, adhesive strips and other cyanoacrylate-based topical skin adhesives to close incisions and trauma-induced lacerations. This Instructions for Use has been generated based on these studies.

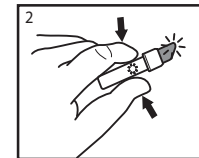
## DIRECTIONS FOR USE

1. Before using SKIN AFFIX™, the wound must be thoroughly cleansed. When necessary, debride the wound.
2. Use standard wound preparation procedures prior to using SKIN AFFIX™ topical skin adhesive.
3. Wounds that are subject to tension should be secured by subcuticular sutures prior to the topical application of the skin adhesive.
4. Dry the wound area with sterile gauze, removing all moisture to ensure proper bonding of SKIN AFFIX™.
5. To prevent inadvertent flow of SKIN AFFIX™ topical skin adhesive to the unintended areas of the body, the wound should be positioned horizontally and SKIN AFFIX™ topical skin adhesive should be applied from above the wound.
6. Remove the applicator from the paper pouch. Hold the applicator with finger and thumb in the centre of the body with the tip pointed upward and away from the patient to avoid unintentional placement of the topical skin adhesive into the wound or on the patient. Squeeze the applicator body to apply sufficient pressure to crush the inner glass ampoule. Invert and gently squeeze the applicator body just sufficiently to express the liquid SKIN AFFIX™ to moisten the applicator tip. It will appear to darken as it is moistened by the adhesive.
7. Approximate the wound edges together using either a gloved finger or sterile forceps. Maintain the wound edges in apposition during the application of SKIN AFFIX™ topical skin adhesive.
8. Apply SKIN AFFIX™ topical skin adhesive sparingly, along the edges of the wound. Avoid heavy application.
9. Maintain manual approximation of the apposed wound edges for approximately 60 seconds after the application. Full apposition strength is expected to be achieved within minutes after the adhesive is applied. Full polymerization is expected when the SKIN AFFIX™ topical skin adhesive layer is no longer sticky.  
**NOTE:** Excessive pressure of the applicator tip against the wound edges or surrounding skin can force the wound edges apart, allowing adhesive into the wound. Adhesive within the wound could act as a barrier and delay wound healing and/or result in adverse cosmetic outcomes.
10. Liquid, ointment or cream medications should not be applied onto wounds following closure with SKIN AFFIX™ topical skin adhesive.
11. Protective dry dressings, such as gauze, may be applied over wounds closed with SKIN AFFIX™ topical skin adhesive once the adhesive has completely polymerized and is no longer tacky.
12. If removal of SKIN AFFIX™ topical skin adhesive is necessary for any reason, carefully apply petroleum jelly or acetone to the SKIN AFFIX™ topical skin adhesive film to help loosen the bond. Peel off the film, do not pull the skin apart.

## DIRECTIONS FOR USE



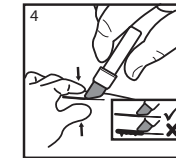
Thoroughly clean and dry wound, ensure wound edges are easily apposed.



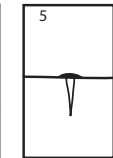
Squeeze the applicator body with the tip pointing upward to activate the device.



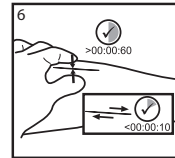
Approximate the wound edges together, maintain the wound edges in apposition.



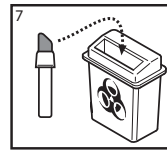
Apply topical skin adhesive sparingly as a thin film along the edges of the wound. Avoid heavy application.



Apply topically, do not allow applicator tip or adhesive into the wound.



Hold together for approximately 60 seconds.

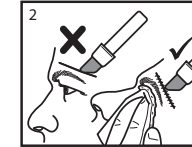


Dispose to clinical waste.

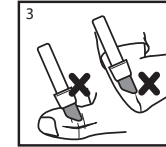
## WARNINGS



Avoid inadvertent contact with wet adhesive.

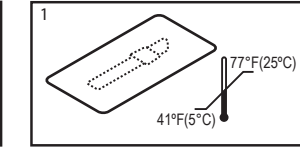


When closing facial wounds near the eye, adjust the patient's position. The eye should be closed and protected with petroleum jelly and gauze.



Do not use on wounds under high tension.

## STORAGE



Store in original packaging at ambient room temperatures between 41°F (5°C) and 77°F (25°C).

## PATIENT INSTRUCTIONS:

No additional or special care is needed for wounds closed using SKIN AFFIX™ topical skin adhesive; however, it is recommended that the following information be shared with the patient as necessary. A dry protective dressing should be applied for children or other patients who may not be able to follow these instructions for proper wound care.

- Do not pick or pull at the wound or polymerized film of SKIN AFFIX™ topical skin adhesive. Picking at the film can disrupt its adhesion to the skin and cause dehiscence of the wound.
- Light showering or bathing is permitted, however do not scrub, soak, or expose the wound site to prolonged wetness (including swimming) until after the film has sloughed off naturally (usually in 5 - 10 days).
- Do not apply any liquid, ointment or cream medication to the wound.
- Report any discomfort or other concerns regarding your wound to your doctor.

## HOW SUPPLIED:

SKIN AFFIX™ topical skin adhesive is supplied sterile, in a pre-filled, single use applicator. SKIN AFFIX™ topical skin adhesive is comprised of a crushable glass ampoule contained within a plastic applicator tip with tip attached. The applicator contains 0.4mL of the liquid adhesive. The applicator is packaged in a pouch to maintain the device sterile until opened or damaged. SKIN AFFIX™ topical skin adhesive is supplied in boxes of 12 applicators.

## STORAGE:

Recommended storage conditions: between 41°F (5°C) and 77°F (25°C), away from moisture, direct heat and direct light.

Avoid prolonged exposure to elevated temperatures.

SKIN AFFIX™ topical skin adhesive should always be stored in its original packaging. DO NOT use after the expiration date shown on the packaging, preceded by the expiration symbol.

## STERILITY:

SKIN AFFIX™ topical skin adhesive is terminally sterilized by dry heat and ethylene oxide gas. SKIN AFFIX™ topical skin adhesive is packaged for single patient use. Do not resterilize. Do not use if package is opened or damaged. Discard any unused material following completion of medical procedure.

To Order Call: 1-800 Medline.

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