

PRODUCT DESCRIPTION

Derma+Flex® QS™ High Viscosity Tissue 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 aluminum collapsible tube packaged in a Tyvek pouch also containing 2 Indothene HD Grade HD50MA180 applicator tips. The dauber applicator is comprised of a self-puncturing cap and a foam surface, which allows spreading of the adhesive with uniformity. The nozzle applicator is also a self-puncturing cap with an elongation that enables detailed application of the adhesive. As applied to skin, the liquid is syrup-like in viscosity and polymerizes within minutes.

Derma+Flex® QS™ High Viscosity Tissue Adhesive has a syrup-like viscosity. The increased viscosity **Derma+Flex® QS™** is intended to reduce the risk of unintended placement of the adhesive during application due to migration of the liquid adhesive from the wound site. In vitro studies have shown that **Derma+Flex® QS™** High Viscosity Tissue 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.

Indications

Derma+Flex® QS™ High Viscosity Tissue Adhesive is intended for topical application 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. **Derma+Flex® QS™** High Viscosity Tissue Adhesive may be used in conjunction with, but not in place of, deep dermal sutures.

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, (e.g., scalp).
- Do not use on patients with a known hypersensitivity to cyanoacrylate or formaldehyde.

WARNINGS

- **Derma+Flex® QS™** High Viscosity Tissue 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 **Derma+Flex® QS™** High Viscosity Tissue Adhesive may be accelerated by water or fluids containing alcohol. **Derma+Flex® QS™** High Viscosity Tissue Adhesive should not be applied to wet wounds.
- **Derma+Flex® QS™** High Viscosity Tissue 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 **Derma+Flex® QS™** High Viscosity Tissue Adhesive,

position the patient so that any run-off 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. **Derma+Flex® QS™** High Viscosity Tissue Adhesive will not adhere to skin pre-coated with petroleum jelly. Therefore, avoid using petroleum jelly on any skin area where **Derma+Flex® QS™** High Viscosity Tissue Adhesive is intended to adhere.

- **Derma+Flex® QS™** High Viscosity Tissue Adhesive should not be used below the skin because the polymerized material is not absorbed by tissue and can elicit a foreign body reaction.
- **Derma+Flex® QS™** High Viscosity Tissue 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 or unless skin tension has been removed by application of another wound closure device (e.g., sutures, skin staples, or adhesive wound closure strips) prior to application of **Derma+Flex® QS™** High Viscosity Tissue Adhesive.
- **Derma+Flex® QS™** High Viscosity Tissue Adhesive 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.
- **Derma+Flex® QS™** High Viscosity Tissue Adhesive should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction.
- **Derma+Flex® QS™** High Viscosity Tissue Adhesive should only be used after wounds have been cleaned, debrided and are otherwise closed in accordance with standard surgical practice. Local anesthetic should be used when necessary to assure adequate cleansing and debridement.
- 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, **Derma+Flex® QS™** High Viscosity Tissue Adhesive should be applied with a very light brushing motion of the applicator tip over easily approximated wound edges.
- **Derma+Flex® QS™** High Viscosity Tissue Adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. With the proper application technique of **Derma+Flex® QS™** High Viscosity Tissue Adhesive any potential sensation of heat or pain experienced by the patient is minimized.
- **Derma+Flex® QS™** High Viscosity Tissue Adhesive is packaged for single patient use. Discard remaining opened material after each wound closure procedure.
- Do not resterilize **Derma+Flex® QS™** High Viscosity Tissue Adhesive.
- Do not place **Derma+Flex® QS™** High Viscosity Tissue Adhesive in a procedure pack/tray that is to be sterilized prior to use. Exposure of **Derma+Flex® QS™** High Viscosity Tissue Adhesive, after its final manufacture, to excessive heat (as in autoclaves) or radiation (such as gamma or electron beam), is known to increase its viscosity and may render the product unusable.
- Potential systemic toxicity of this product is unknown

PRECAUTIONS

- Do not apply liquid or ointment medications or other substances to the wound after closure with **Derma+Flex® QS™** High Viscosity Tissue Adhesive, as these substances can weaken the polymerized film and allow for wound dehiscence. **Derma+Flex® QS™** High Viscosity Tissue Adhesive permeability by topical medications has not been studied.
- **Derma+Flex® QS™** High Viscosity Tissue Adhesive permeability by fluids is not known and has not been studied.
- **Derma+Flex® QS™** High Viscosity Tissue Adhesive, as a liquid, is syrup-like in viscosity. To prevent inadvertent flow of liquid **Derma+Flex® QS™** High Viscosity Tissue Adhesive to unintended areas the patient should be positioned so that inadvertent flow would be away from unwanted areas.
- Hold applicator upward and away from yourself and the patient and squeeze the contents of the tube from the bottom of the tube towards the applicator.
- **Derma+Flex® QS™** High Viscosity Tissue Adhesive should be used within 30 minutes after attaching the self-puncture applicator on the tube to avoid premature polymerization. The adhesive may be used as long as it remains in liquid form and has not been allowed to become contaminated.
- 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® Antibiotics, HIBICLENS® (chlorhexidene gluconate), or soap, are not expected to immediately loosen the bond.
- Safety and effectiveness of **Derma+Flex® QS™** High Viscosity Tissue 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, or burst stellate lacerations, have not been studied.
- Safety and effectiveness of **Derma+Flex® QS™** High Viscosity Tissue Adhesive on the following wounds has not been studied: animal or human bites; puncture or stab wounds.
- Safety and effectiveness on wounds that have been treated with **Derma+Flex® QS™** High Viscosity Tissue Adhesive and then exposed for prolonged periods to direct sunlight or tanning lamps have not been studied.
- Safety and effectiveness of **Derma+Flex® QS™** High Viscosity Tissue Adhesive on wounds in vermilion surfaces has not been studied.

ADVERSE REACTIONS

Reactions may occur in patients who are hypersensitive to cyanoacrylate or formaldehyde. See CONTRAINDICATIONS above.

Adverse reactions may be experienced following **Derma+Flex® QS™** High Viscosity Tissue Adhesive contact with the eye.