

BEFORE USING THIS PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY

DESCRIPTION

exofin[®] Precision Pen High Viscosity 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 squeezable pen body and applicator packaged in a rigid PETG blister with Tyvek[®] lid. The applicator is comprised of a self-puncturing cap and a soft elastomeric brush, which allows the adhesive to spread uniformly. As applied to skin, the liquid is syrup-like in viscosity and polymerizes within minutes.

exofin[®] Precision Pen has a syrup-like viscosity. The increased viscosity 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 **exofin[®] Precision Pen** 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

exofin[®] Precision Pen 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. **exofin[®] Precision Pen** 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, formaldehyde or benzethonium chloride.

WARNINGS

- **exofin[®] Precision Pen** 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 **exofin[®] Precision Pen** may be accelerated by water or fluids containing alcohol: **exofin[®] Precision Pen** should not be applied to wet wounds.
- **exofin[®] Precision Pen** 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 **exofin[®] Precision Pen**, 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. **exofin[®] Precision Pen** will not adhere to skin pre-coated with petroleum jelly. Therefore, avoid using petroleum jelly on any skin area where **exofin[®] Precision Pen** is intended to adhere.
- **exofin[®] Precision Pen** should not be used below the skin because the polymerized material is not absorbed by tissue and can elicit a foreign body reaction.
- **exofin[®] Precision Pen** 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 **exofin[®] Precision Pen**.
- **exofin[®] Precision Pen** 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.
- **exofin[®] Precision Pen** should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction.
- **exofin[®] Precision Pen** 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 an adverse cosmetic outcome. Therefore, **exofin[®] Precision Pen** should be applied with a very light brushing motion of the applicator tip over easily approximated wound edges.
- **exofin[®] Precision Pen** polymerizes through an exothermic reaction in which a small amount of heat is released. With the proper application technique of **exofin[®] Precision Pen** any potential sensation of heat or pain experienced by the patient is minimized.
- **exofin[®] Precision Pen** is packaged for single patient use. Discard remaining opened material after each wound closure procedure.
- Do not resterilize **exofin[®] Precision Pen**.
- Do not place **exofin[®] Precision Pen** in a procedure pack/tray that is to be sterilized prior to use. Exposure of **exofin[®] Precision Pen**, 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 **exofin[®] Precision Pen**, as these substances can weaken the polymerized film and allow for wound dehiscence. **exofin[®] Precision Pen** permeability by topical medications has not been studied.
- exofin[®] Precision Pen** permeability by fluids is not known and has not been studied.
- exofin[®] Precision Pen**, as a liquid, is syrup-like in viscosity. Hold the pen horizontal and away from yourself and the patient and squeeze the grooved grips until adhesive is visible in applicator tip. To prevent inadvertent flow of liquid **exofin[®] Precision Pen** to unintended areas the patient should be positioned so that inadvertent flow would be away from unwanted areas.
- exofin[®] Precision Pen** should be used immediately after tightening the pre-assembled applicator tip onto the pen body because the adhesive will polymerize in the applicator, rendering the device unusable.
- 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[®] antiseptics, HIBICLENS (chlorhexidine gluconate), or soap, are not expected to immediately loosen the bond.
- Safety and effectiveness of **exofin[®] Precision Pen** 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 **exofin[®] Precision Pen** 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 **exofin[®] Precision Pen** and then exposed for prolonged periods to direct sunlight or tanning lamps have not been studied.
- Safety and effectiveness of **exofin[®] Precision Pen** 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.
- Adverse reactions may be experienced following **exofin[®] Precision Pen** contact with the eye.

DIRECTIONS FOR USE

- The incision or trauma site must be clean and dry before applying adhesive. Ensure that the wound edges are easily approximated (Fig. 1).
- Tighten the pre-assembled Applicator Tip onto the pen body in a clockwise direction until the applicator is tight. The applicator will puncture the foil membrane inside the pen once seated and adhesive will be allowed to flow (Fig. 2).
- Hold the pen horizontal and squeeze until adhesive appears in the clear applicator tip (Fig. 3).
- Immediately begin to apply **exofin[®] Precision Pen** to the wound site brushing in a back and forth motion "painting the surface" until completely covered. Squeeze pen to dispense additional adhesive as needed. If additional sites require adhesive, move to those sites and repeat (Fig. 4).
- The adhesive should be tack free approximately 30 seconds after application, but is dependent upon the thickness of the adhesive layer. Care should be taken to create a smooth even layer of adhesive to prevent thick edges which may lead to inadvertent bond breakage of the adhesive (Fig. 5).
- Once adhesive has completely polymerized (non-tacky) you may cover the site with a secondary bandage. If a secondary bandage is used, DO NOT apply to the adhesive area until it is completely tack free. Applying while tacky may result in adhesive removal when removing secondary bandage and possibly dehiscence of the wound site.
- Discard adhesive device according to normal protocol after use (Fig. 6).

ADDITIONAL INFORMATION

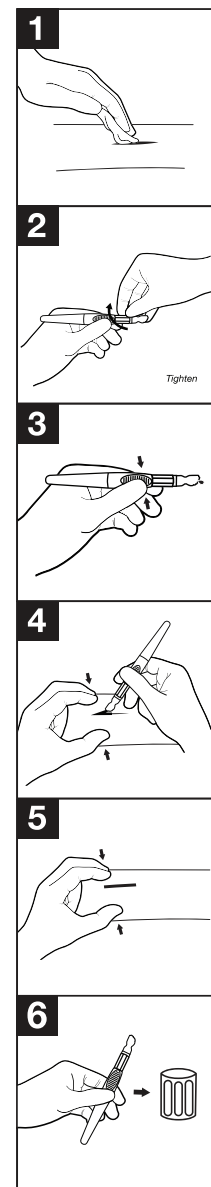
NOTE: **exofin[®] Precision Pen** polymerizes through an exothermic reaction. If the liquid **exofin[®] Precision Pen** is applied so that large droplets are allowed to remain without being evenly spread, the patient may experience a sensation of heat or discomfort. The sensation may be higher on sensitive tissues.

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

NOTE: Full apposition strength is expected to be achieved within minutes after the adhesive is applied. Full polymerization is expected when the **exofin[®] Precision Pen** layer is no longer sticky.

NOTE: Do not apply liquid or ointment medications onto wounds closed with **exofin[®] Precision Pen** because these substances can weaken the polymerized film, leading to wound dehiscence.

NOTE: Protective dry dressings such as gauze may be applied only after **exofin[®] Precision Pen** film is completely solid/polymerized: not tacky to the touch (approximately five minutes after application). Allow the adhesive to fully polymerize



before applying a bandage. 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.

NOTE: Patients should be instructed not to pick at the polymerized film of **exofin[®] Precision Pen**. 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.

NOTE: Apply a dry protective dressing for children or other patients who may not be able to follow instructions for proper wound care.

NOTE: Patients should be instructed that until the polymerized film of **exofin[®] Precision Pen** 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.

NOTE: If removal of **exofin[®] Precision Pen** is necessary for any reason, carefully apply petroleum jelly or acetone to the **exofin[®] Precision Pen** film to help loosen the bond. Peel off the film, do not pull the skin apart.

HOW SUPPLIED

exofin[®] Precision Pen is supplied sterile, in a pre-filled, single-use squeezable pen body and applicator. The pen body contains the liquid adhesive. The applicator, pen and tip are packaged in a rigid PETG blister with Tyvek[®] lid so the device remains sterile until opened or damaged. **exofin[®] Precision Pen** may be available in a box of 12 devices.

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

STERILITY — **exofin[®] Precision Pen** 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 — Healthcare Professional should use the following number 844-633-4583, when reporting adverse reactions or potentially threatening complications involving **exofin[®] Precision Pen**.

CAUTION — This product is meant for external dermal application only and should not contact the eyes. This product should not be ingested, applied internally, or injected intravascularly.

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

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