130x193mm

Instructions for Use for Topical Tissue Adhesive

PerfectSeal®

PRODUCT NAME
Topical Tissue Adhesive

DESCRIPTION
This product is a sterile, topical tissue adhesive that holds wound edges together. The topical tissue adhesive will usually remain in place for 5 to 10 days and then naturally fall off the skin.No additional or special care is needed for wounds closed using the adhesive other than following the instructions below. The adhesive is a quick-setting glue made from cyanoacrylate which is a substance that bonds upon contact with a small amount of water as is found in human tissue.

INDICATIONS
The adhesive is intended for topical application only, to hold closed easily approximated skin edges of wounds, incisions closure of minimum-tension wounds from clean surgical incisions and simple, thoroughly cleansed, trauma-induced lacerations. The adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

CONTRAINDICATIONS
The tissue adhesive is not indicated for holding together wound surfaces on internal organs or on the brain surface, or in the central or peripheral nervous system, as such action could cause tissue damage and scarring, with the resultant problems.
Application to the intima and media of blood vessels must also be avoided, since this wound involve the risk of thrombosis and vessel wall damage.
The tissue adhesive for the topical approximation of skin should not be used:
- in the presence of infection, gangrene, or wounds of decubitus etiology
- in the presence of ongoing bleeding
- in the presence of incomplete debridement
- on mucosal (e.g., oral cavity, lips) or hair covered surfaces
- on patients with a known hypersensitivity to cyanoacrylate, formaldehyde or the dye D&C Violet 2.
- on patients with uncontrolled diabetes or diseases or conditions that are known to interfere with the wound healing process

Tissue adhesives for the topical approximation of skin should also not be used on wounds that are:
- wet
- dirty
- complex
- not easily approximated
- non-acute
- poorly perfused
- located in areas where device run-off into unintended sites cannot be prevented.

WARNINGS
The 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 the adhesive may be accelerated by water or fluids containing alcohol.The adhesive 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.
- When closing facial wounds near the eye with the 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.
- The adhesive will not adhere to skin pre-coated with petroleum jelly. Therefore, avoid using petroleum jelly on any skin area where the adhesive is intended to adhere. Use of the adhesive near the eye has inadvertently caused some patients' eyelids to be sealed shut. In some of these cases, general anesthesia and surgical removal has been required to open the eyelid.
- The adhesive should not be introduced into the wound since this would interfere with wound healing or cause 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. The adhesive should be applied with a light brushing motion of the dropper tip over easily approximated wound edges.
- The 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 the adhesive.
- As with all wounds, the 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. Patients should be instructed to contact the doctor if the such signs as well as wound reopen or the edges separation are found.
- The adhesive should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction.
- The wounds should not be exposed to long periods of sunlight or tanning lamps during the healing period.
- The adhesive should only be used after wounds have been thoroughly and adequately cleaned and debrided in accordance with standard surgical practice.
- The adhesive polymerizes through an exothermic reaction in which a small amount of heat is released, and thus should not be applied to tissues that may be affected by such heat. The adhesive is to be applied in one continuous layer.

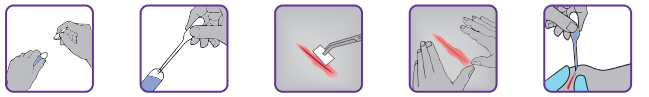
NOTE: Applying the adhesive in one continuous layer onto a dry wound will minimize the sensation of heat. Applying a second layer is not required or recommended.
If a second layer of the adhesive is applied or if large droplets of liquid are not spread thinly,the patient may experience an increased sensation of heat or discomfort.
NOTE: Excessive pressure of the dropper tip against the wound edges or surrounding skin can result in forcing the wound edges apart and allowing the adhesive into the wound.
The adhesive within the wound could delay wound healing and/or result in adverse cosmetic outcome.
- The adhesive is packaged for single patient use. Discard remaining opened material after each wound closure procedure.
- Do not resterilize the adhesive.
- Do not place the adhesive in a procedure pack/tray that will be sterilized prior to use.Exposure of the 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 the adhesive, as these substances can weaken the polymerized film and allow for dehiscence (skin edge separation). Prior to application, cleanse the application site thoroughly to remove any remaining blood, fluids or topical medications/anesthetics.
- The adhesive, as a liquid, is syrup-like in viscosity. To prevent inadvertent flow of liquid adhesive to unintended areas, the wound should be maintained in a horizontal position,with the adhesive applied from above.
- The adhesive should be used immediately after the ampoule is open.
- 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.

SIDE EFFECTS
Adverse reactions related to either the wound closure procedure or the use of the adhesive are possible. The following events have been identified as potentially associated with the wounds closed with the adhesive.
- Infection (redness more than 3-5 mm from the wound margin, swelling, purulent discharge,pain, increased skin temperature, fever)
- Acute inflammation (erythema, edema, pain, warmth)
- Dehiscence (Skin Edge Separation)
- Excessive itching or local irritation

Events potentially associated with the wound closure procedure include bleeding, skin edge necrosis, seroma, and hematoma.

DIRECTIONS FOR USE
1. The application of the adhesive requires thorough wound cleansing. Follow standard surgical practice for wound preparation before application of the adhesive (i.e., anesthetize, irrigate, debride, ensure hemostasis, and close deep layers making sure that the wound edges can be easily approximated). If necessary, subcutaneous suture is required. The subcutaneous suture is as close as possible to the dermis layer, so that the incision is flat and favorable for adhesion.
2. Pat the wound dry with dry, sterile gauze to ensure direct contact of the adhesive to the skin. Moisture accelerates the adhesive's polymerization and may affect wound closure results.
3. To prevent inadvertent flow of liquid the adhesive to unintended areas of the body, the wound should be maintained in a horizontal position and the adhesive should be applied from above the wound.
4. Clean the external surface of the ampoule with alcohol wipe. If there is adhesive above the neck, hold the ampoule in your non-dominant hand, and gently flip the top of the ampoule (with dominant hand) until all the fluids is in the base of ampoule. Orient the ampoule so that the blue dot is facing towards you. Protect the hands from broken glass by using a paper towel, light cloth or piece of gauze when opening the ampoule. Snap the ampoule neck by applying pressure while bending the neck away from dot (and away from yourself). Dispose of the broken off glass top in a medical waste bin.
Note: The adhesive should be used immediately after opening the ampoule. If the glass shatters when opening the ampoule, wrap all the pieces in a tissue and discard. Don't use the adhesive if the ampoule shatters.
5. Remove the dropper from the blister package. Immerse the dropper tip into the opened ampoule to draw up the liquid adhesive. The adhesive should be used immediately after the aspiration into the dropper, since the liquid adhesive will flow freely from the dropper tip for only a few minutes. Hold the dropper away from the patient to prevent any unintentional placement of the liquid adhesive into the wound or on the patient. After taken the adhesive, discard all the pieces of the ampoule by wrapping in a tissue or paper and discarding.
6. Approximate the wound edges with gloved fingers or sterile forceps. Slowly apply the liquid 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 15~60 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.
NOTE: The adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. The polymerization of the adhesive starts immediately after contact with tissue. Unless otherwise prescribed, as little adhesive as possible should be applied; the amount applied is already sufficient if slight colouring is visible.
The adhesive is to be applied in one continuous layer. Applying the adhesive in one continuous layer onto a dry wound will minimize the sensation of heat. Applying a second layer is not required or recommended. If too much adhesive is accidentally applied it can be removed within the first few seconds using a dry swab.
If a second layer of the adhesive is applied or if large droplets of liquid are not spread thinly, the patient may experience an increased sensation of heat or discomfort. Avoid excessive pressure of the dropper tip against the wound edges or surrounding skin to avoid forcing the wound edges apart and allowing the adhesive into the wound.
Full apposition strength is expected to be achieved within minutes after the adhesive is applied. Full polymerization is expected when the adhesive layer is no longer sticky.
7. Do not apply liquid or ointment medications onto wounds closed with the adhesive because these substances can weaken the polymerized film, leading to dehiscence (skin edge separation).
8. Protective dry dressings such as gauze may be applied only after adhesive film is completely polymerized: not tacky to the touch after a few minutes. Allow the adhesive to fully polymerize before applying a bandage.
9. Patients should be instructed to not pick at the polymerized film of the adhesive. Picking at the film can disrupt its adhesion to the skin and cause dehiscence (skin edge separation).
10. Patients should be instructed to keep the wound dry and protected with a water-resistant, non-medicated bandage, per doctor's instructions. Change the bandage per doctor's instructions. Keep the adhesive part of the bandage off of the wound's edges. Patients should be instructed that until the polymerized film of the adhesive has sloughed naturally (usually in 5–10 days), there should be only transient wetting of the treatment site.
If possible, the patients should avoid contact with water for the first 24 hours after treatment. Patients may shower or bathe as directed by their physician but allow only transient wetting of the treatment site. 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 the adhesive is necessary for any reason, carefully apply petroleum jelly or acetone to the adhesive film to help loosen the bond. Peel off the film; do not pull the skin edges apart.



HOW SUPPLIED
The adhesive is supplied sterile, in a glass ampoule. The dropper is supplied in a blister package to maintain the sterility of the device until opened or damaged.

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

STERILITY
The adhesive has been sterilized by moist heat and the dropper has been sterilized by EO sterilization. Do not resterilize. Do not use if package is opened or damaged. Discard any unused material following completion of each medical procedure.
The adhesive is intended for single use and should be applied immediately after opening the ampoule. Opened unused ampoules should be discarded. Do not re-use. Infection hazard for patients and/or users and impairment of product functionality due to re-use. Risk of injury, illness or death due to contamination and/or impaired functionality of the product.

Symbols used on labelling

Consult Instructions for use	Do not use if package is damaged	Sterilized using ethylene oxide	Sterilized using steam
Do not re-use	Caution	Do not resterilize	Use-by date
Batch code	Keep dry	Upper limit of temperature	Keep away from sunlight
Fragile, handle with care	Manufacturer	Caretechion GmbH Niederrheinstr 71, 40474 Duesseldorf, Germany	

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CE marking and identification number of Notified Body.
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