

EN English

DESCRIPTION

SURGISEAL[®] Topical Skin Adhesive is a sterile, professional liquid topical skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation and the colorant D & C Violet #2. Each applicator consists of a thermoformed blister tray with a heat sealed lid with an attached applicator sponge tip. This applicator with sponge tip is contained in an outer Tyvek pouch.

INDICATIONS

SURGISEAL 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. SURGISEAL may be used in conjunction with, but not in place of, deep dermal sutures.



1. Fold over the SURGISEAL[®] adhesive applicator at the sponge. You will hear a snap.



2. Hold with the sponge facing downward. No squeezing is necessary in normal application.
If you require greater flow, you may very gently squeeze.



3. Approximate the wound edges together & apply in one thick layer or two thin layers.
If two thin layers applied, allow 30 seconds dry time in between layers.

DIRECTIONS FOR USE

1. Before the use of SURGISEAL the wound must be thoroughly cleaned.
2. Use normal surgical protocol for wound preparation before treatment of SURGISEAL topical skin adhesive and be certain to suture deep subcutaneous layers.
3. Dry the injured area with sterile gauze, removing all moisture for proper tissue bonding of SURGISEAL to the skin.
4. To prevent inadvertent flow of SURGISEAL topical skin adhesive to unintended areas of the body, the wound should be held in a horizontal position and the SURGISEAL topical skin adhesive should be applied from above the wound.
5. Remove the applicator from the blister pouch. Hold the applicator with the thumb and forefinger away from patient to prevent any unintentional placement of the liquid SURGISEAL topical skin adhesive into the wound or on the patient.
6. While holding the applicator, and with the applicator sponge facing upward, snap at tip along the perforated line and fold over.
7. Gently squeeze the liquid SURGISEAL adhesive from the applicator bubble while saturating the sponge.
8. Approximate the wound edges together using either gloved fingers or sterile forceps.
9. Slowly apply the liquid SURGISEAL topical skin adhesive in one thick, continuous layer or two thin layers. If two thin layers are applied, allow 30 seconds dry time in between layers.
10. Maintain manual approximation of the opposed wound edges together for approximately 60 seconds once the final coat of SURGISEAL is applied.

NOTE: Excessive pressure of the applicator tip against the wound edges or surrounding skin can result in forcing the wound edges apart and allowing SURGISEAL topical skin adhesive into the wound. SURGISEAL topical skin adhesive within the wound could delay wound healing and/or result in adverse cosmetic outcome.

NOTE: Full apposition strength is expected to be achieved about 1.0 minute after the final layer is applied. Full polymerization is expected when the top SURGISEAL topical skin adhesive layer is no longer tacky.

11. Protective dry dressings, such as gauze, may be applied only after SURGISEAL topical skin adhesive film is

completely solid/polymerized and not tacky to the touch (approximately five minutes after application). Allow the top layer 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.

12. Patients should be instructed to not pick at the polymerized film of SURGISEAL topical skin adhesive. 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.
13. Apply a dry protective dressing for children or other patients who may not be able to follow instructions for proper wound care.
14. Patients should be instructed that until the polymerized film of SURGISEAL topical skin adhesive 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.
15. If removal of SURGISEAL topical skin adhesive is necessary for any reason, carefully apply petroleum jelly or acetone to the SURGISEAL topical skin adhesive film to help loosen the bond. Peel off the film, do not pull the skin apart.
16. Once the surface is tack-free, full polymerization has generally occurred.

ANTIBACTERIAL ACTIONS

SURGISEAL has been shown with in vitro studies to provide a strong holding strength of approximated wound skin edges.

Studies have shown in vitro that SurgiSeal has bactericidal activity against gram- and gram+ bacteria; *Escherichia coli*, *Methicillin-resistant Staphylococcus aureus*, *P aeruginosa*, *Klebsiella pneumoniae*, *Staphylococcus epidermidis*, *Corynebacterium pseudodiphtheriticum*, *Staphylococcus aureus*, known to contribute to surgical site infections. These evaluations have shown that a 7 log or greater bacterial challenge of these microorganisms do not survive on contact when incorporated within the adhesive on application. However, the clinical relevance of this activity has not been demonstrated.

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 or with dense natural hair.
- DO NOT use on patients that have a hypersensitivity to cyanoacrylates or formaldehyde.

WARNINGS

- SURGISEAL topical skin 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.
- SURGISEAL topical skin adhesive is not intended as a substitute for systemically administered therapeutic or prophylactic antimicrobial agents to control or prevent post-operative infections.
- Polymerization of SURGISEAL topical skin adhesive may be accelerated by water or fluids containing alcohol: SURGISEAL topical skin adhesive should not be applied to wet wounds.
- SURGISEAL 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 with a tissue adhesive for topical approximation of skin, 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 at preventing inadvertent flow of adhesive into the eye.
- SURGISEAL topical skin adhesive will not adhere to skin pre-coated with petroleum jelly. Therefore, avoid using petroleum jelly on any skin area where SURGISEAL adhesive is intended to adhere.
- SURGISEAL topical skin adhesive is not absorbable and therefore should not be used below the skin as it may cause a foreign body reaction.
- SURGISEAL topical skin 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 or skin staples) prior to application of SURGISEAL topical skin adhesive.
- SURGISEAL topical skin 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.
- SURGISEAL topical skin adhesive should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction.
- SURGISEAL topical skin 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.
- SURGISEAL should always be applied as a light coating bridging the wound and the aligned approximated wound edges. Avoid pressure on the applicator or wound edge separation, which could cause the topical adhesive to be interposed between wound edges. Topical adhesive between wound edges interfere with wound healing.
- SURGISEAL topical skin adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. With the proper technique of applying SURGISEAL topical skin adhesive in one thick, continuous layer or two thin layers onto a dry wound and allowing time for polymerization between applications, heat is released slowly and the sensation of heat or pain experienced by the patient is minimized. However, if SURGISEAL 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.
- SURGISEAL topical skin adhesive is packaged for single patient use. Discard remaining opened material after each wound closure procedure.
- Do not resterilize SURGISEAL topical skin adhesive in a procedure pack/tray that is to be sterilized prior to use. Exposure of SURGISEAL 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 its viscosity and may render the product unusable. Use of the tissue adhesive may result in localized sensitization or irritation reactions.
- SURGISEAL topical skin adhesive should not be applied to decubitus ulcers.
- SURGISEAL topical skin adhesive should be used only on wounds that have been thoroughly cleaned debrided and have easily apposed wound edges.
- Application and/or migration (leak) of either version of the product below the surface of the skin will impair the healing process by forming a barrier between tissue edges.
- If Chlorhexidine gluconate (CHG) is used preoperatively on the affected area, it must be completely dry before applying SURGISEAL adhesive. The adhesive may not cure properly and prematurely flake if the adhesive is applied before the Chlorhexidine gluconate is completely dry¹.

PRECAUTIONS

- Tissue adhesives for the topical approximation of skin should also not be used on wounds that are: wet, dirty, complex, not easily approximated, under dynamic stress (e.g. knuckles or elbows), non-acute, poorly perfused, located in areas where device run-off into unintended sites cannot be prevented.
- Tissue adhesives intended for the topical approximation of skin should not be used in the presence of infection, ongoing bleeding, incomplete debridement and on mucosal or hair covered surfaces.
- This product should not be ingested, applied internally, or injected intravascularly.

- DO NOT apply liquid or ointment medications or other substances to the wound after closure with SURGISEAL, as these substances weaken the polymerized film and allow for wound dehiscence.
- SURGISEAL topical skin adhesive permeability by topical medications has not been studied.
- If mistaken placement of SURGISEAL should occur then removal may be accomplished by using either acetone or petroleum jelly. Typical cleaners such as soap do not work well. However, petroleum jelly or acetone will immediately help the release of the adhesive from the skin.
- SURGISEAL topical skin adhesive, as a liquid, is viscous. To prevent inadvertent flow of liquid SURGISEAL topical skin adhesive to unintended areas: (1) the wound should be held in a horizontal position, with SURGISEAL topical skin adhesive applied from above, and (2) SURGISEAL topical skin adhesive should be applied in one thick, continuous layer or two thin layers rather than in a few large droplets.
- SURGISEAL topical skin adhesive should be used immediately after breaking along the perforated opening as the liquid adhesive will not flow freely from the applicator sponge tip after a few minutes.
- 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, Chlorhexidine gluconate (CHG), or soap, are not expected to immediately loosen the bond.
- Safety and effectiveness of SURGISEAL topical skin adhesive on the following wounds have not been studied: animal or human bites, puncture or stab wounds.
- Safety and effectiveness of SURGISEAL topical skin 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 on wounds that have been treated with SURGISEAL topical skin adhesive and then exposed for prolonged periods to direct sunlight or tanning lamps have not been studied.
- Vermillion surfaces have not been tested for effectiveness and safety.

ADVERSE REACTIONS

- Adverse reactions may occur if adhesive makes contact with the eye.
- Adverse reactions may occur to patients that have a hypersensitivity to cyanoacrylates or formaldehyde.
- SURGISEAL topical skin adhesive should always be applied in one thick, continuous layer or two thin layers so that large amounts of liquid are not allowed to collect, resulting in thermal discomfort for the patient.

HOW SUPPLIED

SURGISEAL is a sterile, easy to use, single-dose applicator, packaged in a thermal formed blister pouch. The applicators are packaged in a box that fits precisely on the skin shelf. The applicator has a perforation in the middle allowing for ease of application. The applicator contains a topical skin adhesive.

STORAGE

Recommended storage conditions are at or below 30°C, 86 °F, away from moisture, direct heat and direct light. DO NOT use after expiration date.

STERILITY

SURGISEAL topical skin adhesive is terminally sterilized by irradiation.
STERILE SINGLE USE ONLY

CAUTIONS

Federal (USA) law restricts this device to sale by or on the order of a physician.

¹ Adhezion Biomedical, LLC Data on File.



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