



BEFORE USING THE PRODUCT, PLEASE READ THE FOLLOWING INFORMATION THOROUGHLY

IMPORTANT: This information sheet is designed to assist in using GluStitch® Twist topical tissue adhesive. It is not a reference to surgical techniques.

DESCRIPTION

GluStitch® Twist is a sterile, topical tissue adhesive composed of a monomeric n-butyl-2-cyanoacrylate formulation. GluStitch® Twist is provided in a single-use applicator packaged in a protective foil pouch. GluStitch® Twist remains liquid until it is applied to the skin and spread into a thin layer. Upon exposure, GluStitch® Twist polymerizes rapidly and forms a film that bonds to the underlying surface.

INDICATIONS/INTENDED USE

GluStitch® Twist Tissue Adhesive is intended for the topical closure of surgical skin incisions and trauma-induced lacerations in areas of low skin tension that are simple, thoroughly-cleansed, and have easily approximated skin edges. GluStitch® Twist 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, including the eye, or across mucocutaneous junctions, or on skin which may be regularly exposed to body fluids.
- DO NOT use on patients with a known 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

- Polymerization of GluStitch® Twist may be accelerated by water or fluids containing alcohol: GluStitch® Twist should not be applied to wet wounds.
- GluStitch® Twist 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. Cover the eye and contact an ophthalmologist immediately.
- When closing facial lacerations near the eye, position the patient so that any inadvertent adhesive flow is away from the eye. Before beginning the procedure, the eye should be closed and protected using a surgical covering. Prophylactic placement of petroleum jelly around the eye, to act as a mechanical barrier or dam, can be effective in preventing inadvertent adhesive flow into the eye.
- GluStitch® Twist will not adhere to surfaces pre-coated with petrolatum, therefore avoid using ointments or creams containing this material as they will cause GluStitch® Twist to lose its ability to adhere to the tissue.
- GluStitch® Twist is not absorbable and therefore should not be used below the skin as it may cause a foreign body reaction.
- GluStitch® Twist 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, such as sutures or staples, prior to the application of GluStitch® Twist.
- Wounds treated with GluStitch® Twist should be monitored for signs of infection. Wounds with signs of infection or erythema, edema, warmth, pain and/or drainage should be evaluated and treated according to standard practice.
- GluStitch® Twist should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction.
- GluStitch® Twist should be used only on wounds that have easily approximated edges. The treatment site must be 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.
- GluStitch® Twist should be applied sparingly, by expelling minute drops and spreading into a thin film bridging the wound and the aligned wound edges. Application and/or migration of GluStitch® below the surface of the skin and between the wound edges should be avoided since it may impair the healing process.
- GluStitch® Twist polymerizes through an exothermic reaction which releases a small amount of heat. By using the proper application technique, the amount of heat released will be minimized, and the sensation of heat or pain experienced by the patient will be insignificant.
- GluStitch® Twist is packaged for a single patient use. Discard remaining opened material after each wound closure procedure.

PRECAUTIONS

- Do not apply topical medications following closure.
- GluStitch® Twist tissue adhesive is a rapidly setting adhesive capable of adhering to most body tissues and many other materials, such as latex gloves and stainless steel. Acetone may be used to remove unintended application of GluStitch® to body tissues, instruments or equipment.
- This product is intended for external dermal applications only.
- Safety and effectiveness of GluStitch® Twist has not been evaluated for use on wounds with uncontrolled diabetes mellitus, diseases or conditions that are known to interfere with the 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 GluStitch® Twist and then exposed for long periods of time to direct sunlight or tanning lamps.
- The permeability of GluStitch® Twist by topical medications or other fluids is not known and has not been studied.

DIRECTIONS FOR USE

1. Prepare the treatment area by ensuring the wound is clean and dry. When necessary, debride the wound and remove excess blood.
2. To prevent inadvertent flow of GluStitch® Twist to unintended areas, the wound should be positioned horizontally and GluStitch® Twist should be applied from above the wound. Wounds under tension should be secured by using sub-dermal sutures prior to the application of the tissue adhesive.
3. Peel open the foil pouch to expose the sterile, single-use ampoule.
4. Hold the ampoule vertically, and flick the tip with forefinger to force the adhesive away from the tip. Keep the ampoule pointed upright and twist and snap off the winged cap. Retain the cap for resealing the tip after use and prior to disposal.
5. Approximate the wound edges and while holding together, apply GluStitch® Twist in a thin film along the apposed edges. This is accomplished by inverting the applicator and applying GluStitch® Twist along the edges of the wound by gently compressing the back of the ampoule. The wound edges should be held apposed for approximately 30 seconds to allow full curing of the adhesive.
6. Following application, recap the ampoule with the retained cap, and dispose.
7. If desired, a dry protective dressing may be applied over repaired wounds once the adhesive has completely polymerized and is no longer tacky (approximately 2 minutes after application).
8. If removal of GluStitch® Twist is necessary for any reason, carefully apply petroleum jelly or acetone to the GluStitch® Twist film to help loosen the bond. Gently peel off the film, do not pull the skin apart.

PATIENT INSTRUCTIONS

No additional or special care is needed for wounds closed using GluStitch® Twist topical tissue 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 pull or pick at the wound or the polymerized film of GluStitch® Twist. Picking at the film can disrupt its adhesion to the skin and cause wound dehiscence.
- Do not shower, bathe or swim for 48 hours following wound closure.
- Do not scrub or soak the wound in water for 7-10 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.

SUPPLIED

GluStitch® Twist Tissue Adhesive should always be stored in its original sealed foil pouch. During prolonged periods, GluStitch® Twist should be kept refrigerated at a temperature < 8°C. Shorter storage periods at ambient conditions 22°C for a total of 4 weeks will not adversely affect product performance. Avoid prolonged exposure to elevated temperatures. GluStitch® Twist should not be used after the expiration date shown on the foil pouch, preceded by the expiration symbol.

ADVERSE REACTIONS

Historical clinical use of cyanoacrylate-based topical tissue 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.

STORAGE

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STERILITY

GluStitch® Twist topical tissue adhesive is terminally sterilized using irradiation. GluStitch® Twist is packaged for single patient use. Do not re-sterilize. Do not use if package is opened or damaged. Discard any unused material following completion of medical procedure.



GluStitch Inc.
307-7188 Progress Way
Delta, BC Canada V4G 1M6



MT Promedt Consulting GmbH,
Altenhofstr. 80
66386 St. Ingbert, Germany
Ph: 06894 5824580