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-cleaned, 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 debrided 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® 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 opthalmic 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.

**PATIENT INSTRUCTIONS**

- 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, diabetes 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 applicator packaged in a protective foil pouch, preceded by the expiration symbol.
4. Hold the applicator in your dominant hand, and check the tip with your nondominant hand to force the adhesive away from the tip. Keep the applicator upright and twist and snap off the winged cap. Retain the cap for rescaling 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 applicator. The wound edges should be held apposed for approximately 30 seconds to allow full curing of the adhesive.
6. Following application, recap the applicator 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.

**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**

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.

**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.