

INSTRUCTIONS FOR USE
Tissuelink™ Flex Topical Skin Adhesive

READ INSTRUCTIONS FOR USE **FOR SINGLE USE ONLY**

MEDICAL DEVICE **REVIEW CAUTIONS**

TEMPERATURE LIMITS
25°C / 77°F

STERILE MEDICAL DEVICE PROCESSED USING ASEPTIC TECHNIQUES
Skin Adhesive

SYMBOL FOR STERILIZATION USING ETHYLENE OXIDE
Applicator Tip

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

TissueLink™ Flex Topical Skin Adhesive

I. DESCRIPTION

TissueLink™ Flex is a sterile, liquid Topical Skin Adhesive composed of n-Butyl-2-Cyanoacrylate monomer with Myristic acid and Triacetin added to allow the film to remain flexible. TissueLink™ Flex is colored with D&C Violet #1 dye in order to make it easier to see the thickness of the layer being applied. TissueLink™ Flex Topical Skin Adhesive is supplied in 0.5 ml single patient use plastic ampoules. Each ampoule is sealed within an aluminum pouch so the ampoule can remain sterile. TissueLink™ Flex remains liquid until exposed to acidic, basic, alcohol, water or water-containing substances, including tissues. TissueLink™ Flex cures (polymerizes exothermically) and forms a film that bonds to the underlying surface.

TissueLink™ Flex may be used with an optional applicator tip. The applicator tip attaches to the open cannula of the TissueLink™ Flex ampoule. The adhesive can then be applied to the skin surface.

In vitro studies have shown that TissueLink™ Flex 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 and a correlation between microbial barrier properties and a reduction in infection have not been established. See **INSTRUCTIONS FOR USE** section for further information.

II. INDICATIONS

TissueLink™ Flex Topical Skin Adhesive is intended for topical application to hold closed easily approximated skin edges of minimum-tension wounds from clean surgical incisions and simple, thoroughly cleansed, trauma-induced lacerations. TissueLink™ Flex may be used in conjunction with, but not in place of, deep dermal sutures.

III. CONTRAINDICATIONS

- TissueLink™ Flex Topical Skin Adhesive is not to be applied below the surface of the skin. The liquid adhesive will react exothermically with tissue; the polymerized adhesive is not absorbed by any tissues and may elicit a foreign body reaction.
- TissueLink™ Flex is not to be applied to any internal organs, blood vessels, nerve tissue, mucosal surfaces or mucocutaneous junctions, areas with dense natural hair, or within the conjunctival sac of the eye.
- TissueLink™ Flex is not to be applied to the surface of the eye. If the eyelids are accidentally bonded closed, release eyelashes with warm water by covering with a wet pad. The adhesive will bond to eye protein and will cause periods of weeping which will help to debond the adhesive. Keep the eye covered until debonding is complete—usually within 1 to 3 days. Do not force the eye open.
- TissueLink™ Flex is not to be applied to wounds subject to high skin tension or on areas of increased skin tension such as the elbows, knees, or knuckles. TissueLink™ Flex is not to be used in areas of skin excision.
- TissueLink™ Flex is not to be applied to wounds that show evidence of infection, gangrene or wounds of decubitus etiology.

Before using product, read through the following information thoroughly

CAUTION: Federal law restricts this device to sale and use by, or on the order of, a physician.

IMPORTANT! This insert is designed to assist in using TissueLink™ Flex Topical Skin Adhesive. It is not a reference to surgical techniques.

- TissueLink™ Flex is not to be used on patients with known preoperative systemic infections, uncontrolled diabetes, or diseases or conditions that are known to interfere with the wound healing process.
- TissueLink™ Flex is not to be used on patients with a known hypersensitivity to cyanoacrylate, formaldehyde, or the dye D&C Violet #2.

III. WARNINGS

- TissueLink™ Flex Topical Skin Adhesive should only be used on wounds that have been thoroughly cleaned, debrided and have easily apposed wound edges.
- TissueLink™ Flex generates a small amount of heat during polymerization and should not be applied to tissues that may be affected by such heat.
- TissueLink™ Flex should always be applied very sparingly, either as minute drops or as a very thin film along the edges of the wound. Heavy application may cause thermal damage to tissues, and delayed healing may result.
- TissueLink™ Flex should not be applied to wet wounds. Excess moisture, such as water or alcohol, may accelerate polymerization, resulting in localized sensitization or irritation reactions.
- Application and/or migration of TissueLink™ Flex below the surface of the skin will impair the healing process by forming a barrier between tissue edges.
- TissueLink™ Flex migration (leaking) below the epidermal surface may result in “tattooing” of the underlying tissue.
- TissueLink™ Flex will readily adhere to most substrates. Care should be taken to avoid unwanted contact with the adhesive during polymerization. Polymerized adhesive can be removed from metal instruments with acetone. Accidental bonding of materials other than tissues may be reversed by peeling apart the adhered surfaces with the aid of warm soapy water, petroleum gel, saline solution, or 5% solution of sodium bicarbonate.
- Accidental bonding of unwanted skin may occur. Do not pull apart skin. Instead, accidental bonding of unintended areas of skin of the body can be corrected with the use of acetone or by soaking in warm water until the skin may be separated.

IV. PRECAUTIONS

- Wounds should be kept dry following closure with TissueLink™ Flex. Do not apply topical medications following closure.
- In the event of spillage, TissueLink™ Flex can be absorbed with talc. Flush area with water to solidify the adhesive.
- TissueLink™ Flex has not been evaluated in patients with a history of hypertrophic scarring or keloid information.
- Small quantities of TissueLink™ Flex should be used during wound repair because of use of excess TissueLink™ Flex can result in tissue damage due to the cumulative heat dissipated during device polymerization.

V. POSSIBLE ADVERSE EVENTS

Clinical experience with TissueLink™ Flex used outside the United States suggests that the following adverse events may occur:

- Dehiscence with the need for re-closure
- Suspected infection
- Bonding to unintended tissues
- Thermal discomfort during polymerization
- Allergic reaction
- Foreign body reaction
- Tattooing
- Chronic non-healing of a wound.

VI. HOW SUPPLIED

TissueLink™ Flex Topical Skin Adhesive is supplied in 0.5ml single patient use ampoules. Each ampoule is sealed within an aluminum pouch so the exterior of the ampoule can remain sterile. TissueLink™ Flex is supplied in boxes of 5 or 10 individual ampoules.

VII. INSTRUCTIONS FOR USE

1. Inspect and clean the wound, provide local anesthesia for adequate cleansing and debridement of any devitalized structures, assure hemostasis, close the dermis as needed, and assure that surface edges are easily apposable before applying TissueLink™ Flexible.
2. For wounds at risk for tension, provide relief of potential stress along the wound line by approximating wound edges with subcuticular sutures before applying TissueLink™ Flex to the skin surface.
3. Open the aluminum pouch to expose the sterile, single patient use ampoule.
4. The ampoule is held at its tip and rigorously shaken downwards to ensure that no adhesive remains within the cannula. Then the ampoule is opened by twisting off the ribbed tip of the cannula. It is advisable to hold the yellow part of the ampoule between two fingers, holding it vertically with the thin end pointing upward, while opening the ampoule. This will prevent any lost TissueLink™ Flex from escaping from the ampoule when opening.
5. To express TissueLink™ Flex from the ampoule tip, apply light pressure to the ampoule.
6. Appose the tissue edges and hold in apposition while applying TissueLink™ Flex tissue adhesive. Hold in apposition for approximately 60 seconds for TissueLink™ Flex to polymerize and to prevent migration between wound edges.
7. Apply TissueLink™ Flex to the easily apposed wound edges very sparingly, either as minute drops or as a very thin film along the top edges of the wound. Avoid heavy application.
8. After applying TissueLink™ Flex, maintain light pressure along the wound line to maintain apposition for approximately 60 seconds to allow the adhesive to cure.
9. After TissueLink™ Flex application is completed; discard the ampoule with any remaining adhesive by putting the ribbed tip over the thin end of the cannula.

VIII. PATIENT INSTRUCTIONS

The following information should be shared with the patient:

- Patients may shower and/or bathe but only allow transient wetting of the treatment site. The site should not be soaked or exposed to prolonged wetness for 7-10 days or until polymerized film has sloughed off.
- Do not apply any medications or cream to the wound.
- Do not pull or pick at the wound.
- Avoid extreme physical activity that might dislodge or impact the wound surface.
- Report any unusual discomfort, redness, drainage, swelling and/or other concerns regarding your wound to your doctor.
- If they are recommended by your doctor, you should keep the wound dry with a non-stick, non-medicated and water-resistant bandage. While not required specifically for this product, your doctor in his/her expert opinion may recommend the use of a bandage as special precaution for your individual circumstance.

IX. STORAGE

- TissueLink™ Flex must be stored in its original sealed aluminum pouch.
- TissueLink™ Flex should be kept in the aluminum pouch to maintain stability of the liquid adhesive at room temperature.
- TissueLink™ Flex should be stored at ambient conditions in temperatures at or below 77°F (25°C) away from moisture and direct heat.
- Do not expose TissueLink™ Flex to elevated temperatures (i.e., 104-140°F, 40-60°C) for more than eight hours.
- Do not use TissueLink™ Flex after the expiration date shown on the aluminum pouch, preceded by the expiration symbol.

X. STERILITY

TissueLink™ Flex is packaged for single patient use. Do not resterilize. Do not use if package is opened or damaged.

XI. CUSTOMER SERVICE

For further information regarding TissueLink™ Flex please contact **Nissha Medical Technologies - Healthcare Solutions** Customer Service at: **800.669.6905**.