

HISTOACRYL® FLEXIBLE TOPICAL SKIN ADHESIVE
Package Insert



Before using product, read 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 Histoacryl® Flexible Topical Skin Adhesive. It is not a reference to surgical techniques.

DESCRIPTION:

Histoacryl® Flexible 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. Histoacryl® Flexible is colored with D&C Violet #2 dye in order to make it easier to see the thickness of the layer being applied. Histoacryl® Flexible 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. Histoacryl® Flexible remains liquid until exposed to acidic, basic, alcohol, water or water-containing substances, including tissues. Histoacryl® Flexible cures (polymerizes exothermically) and forms a film that bonds to the underlying surface.

Histoacryl® Flexible may be used with an optional applicator tip. The applicator tip attaches to the open cannula of the Histoacryl® Flexible ampoule. The adhesive can then be applied to the skin surface.

In vitro studies have shown that Histoacryl® 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.

INDICATIONS:

Histoacryl® Flexible 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. Histoacryl® Flexible may be used in conjunction with, but not in place of, deep dermal sutures.

CONTRAINDICATIONS:

- Histoacryl® Flexible 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.
- Histoacryl® Flexible 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.
- Histoacryl® Flexible 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.

- Histoacryl® Flexible 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. Histoacryl® is not to be used in areas of skin excision.
- Histoacryl® Flexible is not to be applied to wounds that show evidence of infection, gangrene or wounds of decubitus etiology.
- Histoacryl® Flexible 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.
- Histoacryl® Flexible is not to be used on patients with a known hypersensitivity to cyanoacrylate, formaldehyde, or the dye D&C Violet #2.

WARNINGS:

- Histoacryl® Flexible Topical Skin Adhesive should be used only on wounds that have been thoroughly cleaned, debrided and have easily apposed wound edges.
- Histoacryl® Flexible generates a small amount of heat during polymerization and should not be applied to tissues that may be affected by such heat.
- Histoacryl® Flexible 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.
- Histoacryl® Flexible should not be applied to wet wounds. Excess moisture, such as water or alcohol, may accelerate polymerization, resulting in the generation of excess heat.
- Use of Histoacryl® Flexible may result in localized sensitization or irritation reactions.
- Application and/or migration of Histoacryl® Flexible below the surface of the skin will impair the healing process by forming a barrier between tissue edges.
- Histoacryl® Flexible migration (leaking) below the epidermal surface may result in “tattooing” of the underlying tissue.
- Histoacryl® Flexible 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.

PRECAUTIONS:

- Wounds should be kept dry following closure with Histoacryl® Flexible. Do not apply topical medications following closure.
- In the event of spillage, Histoacryl® Flexible can be absorbed with talc. Flush area with water to solidify the adhesive.
- Histoacryl® Flexible has not been evaluated in patients with a history of hypertrophic scarring or keloid information.

- Small quantities of Histoacryl® Flexible should be used during wound repair because use of excess Histoacryl® Flexible can result in tissue damage due to the cumulative heat dissipated during device polymerization.

POSSIBLE ADVERSE EVENTS:

Clinical experience with Histoacryl® Flexible 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.

HOW SUPPLIED:

Histoacryl® Flexible 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. Histoacryl® Flexible is supplied in boxes of 5 or 10 individual ampoules.

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 Histoacryl® 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 Histoacryl® Flexible 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 Histoacryl® Flexible from escaping from the ampoule when opening.
5. To express Histoacryl® Flexible from the ampoule tip, apply light pressure to the ampoule.
6. Appose the tissue edges and hold in apposition while applying Histoacryl® Flexible tissue adhesive. Hold in apposition for approximately 60 seconds for Histoacryl® Flexible to polymerize and to prevent migration between wound edges.

7. Apply Histoacryl® Flexible 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 Histoacryl® Flexible, maintain light pressure along the wound line to maintain apposition for approximately 60 seconds to allow the adhesive to cure.
9. After Histoacryl® Flexible application is completed; discard the ampoule with any remaining adhesive by putting the ribbed tip over the thin end of the cannula.

PATIENT INSTRUCTIONS:

The following information should be shared with the patient:

- Patients may shower and/or bathe but allow only 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 a special precaution for your individual circumstance.

STORAGE:

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

STERILITY:

Histoacryl® Flexible is packaged for single patient use. Do not resterilize. Do not use if package is opened or damaged.

CUSTOMER SERVICE:

For further information regarding Histoacryl® Flexible please contact Tissue Seal, LLC. Customer Service at: 1-877-754-6458.



Tissue Seal, LLC.
4401 Varsity Drive
Suite D
Ann Arbor, MI 48108
Phone: 877-754-6458
E-mail: customerservice@tissue seal.com
www.tissue seal.com