

Histoacryl® Topical Skin Adhesive

Patient Instructions



Biosurgicals

Patient Care

Your doctor has chosen to use Histoacryl® as a method for closing your wound. Histoacryl® is a sterile, liquid skin glue that holds wound edges together. The film will usually remain in place for 5 to 10 days, and then naturally fall off your skin. No additional or special care is needed for wounds closed using Histoacryl® other than following the instructions below. Histoacryl® is a quick setting glue made from cyanoacrylate which is a substance that bonds upon contact with a small amount of water as is found in human tissue.

Contraindications, warnings and precautions relevant to patient care

- Use of the topical skin adhesive may result in localized sensitization or irritation reactions.
- Wounds should be kept dry following closure with the topical skin adhesive. Do not apply topical medications following closure.
- Histoacryl® topical skin adhesive has not been evaluated in patients with a history of hypertrophic scarring or keloid information.

Risks and benefits

As with any wound, there is always a risk of infection. Studies have shown that the risk of infection using Histoacryl® is not different from the risk of using stitches, the alternative method of wound closure. Another risk is the splitting or opening of the wound (dehiscence).

Studies have shown that the risk of dehiscence is not different from using stitches, the alternative method of wound closure. Information of the clinical studies conducted on with Histoacryl® is presented at the end of this brochure. See Additional Information.

For Histoacryl® to work correctly, please observe these important patient guidelines

- If possible, avoid contact with water for the first 24 hours after treatment and minimize contact with water for an additional 7–10 days. Patients may shower 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 the polymerized film has sloughed off.
- Do not apply any medications or creams to the wound.
- Watch the wound's appearance as healing progresses. A small amount of swelling, pain, or redness that goes away within a few days is common during wound healing. If these symptoms worsen or persist, please contact your doctor.

Cautions

Cautions

- Never pick, pull, or scratch the wound. This may cause the wound to reopen.
- Contact your doctor if the wound reopens or the edges separate.
- Contact your doctor if you have an infection. The signs are: increased discomfort, redness, swelling, discharge from the wound or if the wound feels warm to the touch.
- Do not expose the wound to long periods of sunlight or tanning lamps during the healing period.

Importance of the need to adhere to the care regimen

The instructions above are designed to optimize your healing and prevent infection. Also, the final appearance of the wound may depend on how well you followed the instructions and how well the wound heals.

How Histoacryl® is used

Your doctor makes this decision. Histoacryl® topical skin adhesive is intended for topical application to approximate and close skin edges of minimum-tension wounds from clean surgical incisions and simple, thoroughly cleansed, trauma-induced lacerations. Histoacryl® may be used along with but not in place of stitches.

Description of the procedure associated with the device

Before using Histoacryl® your doctor will decide if it is appropriate to use the tissue adhesive or whether stitches would be more appropriate. The wound will then be cleaned and dried prior to the application of the adhesive. Your doctor will remove any foreign material in the wound (debride) when necessary. Your doctor may choose to use a local anesthetic. Your doctor will then open the container (vial) of the adhesive and while squeezing the vial, apply small amounts of adhesive to the wound edges. Your doctor will push the wound edges together to close the wound. The adhesive will "set" and hold the wound edges together in typically less than a minute. Your doctor will cover the wound according to standard procedure. Your doctor will then give you any special instructions for you to follow.

Additional Information

Clinical Studies

Clinical Studies

Histoacryl® has been shown to be safe and effective in multiple clinical studies. Extensive chemical and mechanical testing has been performed as well. Four of the clinical studies are summarized here.

Amiel et al. 1999

The use of Histoacryl® in elective surgical incisions and long term outcomes were studied. The results demonstrated that administration of Histoacryl® for the closure of small low-tension surgical incisions in the pediatric population is both safe and effective.

Barnett et al. 1998

A randomized trial comparing Histoacryl® tissue adhesive glue versus suturing in the repair of pediatric lacerations. The study demonstrated that the use of glue is both safe and effective.

Farion et al. 2002

In this metanalysis, the effect of tissue adhesives in the management of traumatic lacerations in children and adults was evaluated. Reviewers concluded that tissue adhesives are an acceptable alternative to standard wound closure for repairing simple traumatic laceration. They offer the benefit of decreased procedure time and less pain, compared to standard wound close.

Göktas et al. 2002

In this study, 92 consecutive adult patients with lacerations equal to or shorter than 5 cm were enrolled. The application of Histoacryl® Blue resulted in greater satisfaction of the patient and the physician.

Quinn et al. 1993

A randomized, controlled trial assessing the use of a tissue adhesive versus suturing in the repair of pediatric facial lacerations. This study concluded that Histoacryl® is a safe and effective method for closing wounds.

Bruns et al. 1996

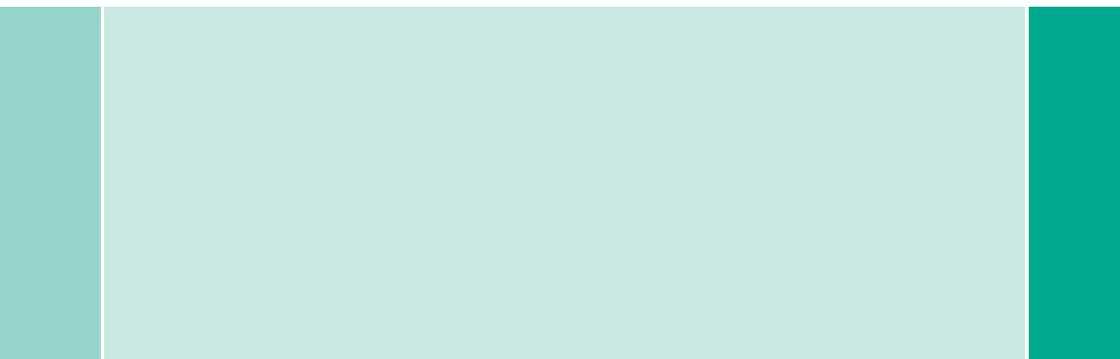
This study evaluated the application of a tissue adhesive for laceration repair in a children's emergency department. It concluded that the use of (Histoacryl® Blue) for laceration repair is an acceptable alternative to conventional suturing.

Literature

Selected references

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5. Quinn JV, Drezwiecki A, Li MM, Stiell IG, Sutcliffe, Elmsie TJ, Wood WE. A randomized, controlled trial comparing tissue adhesive with suturing in the repair of pediatric facial lacerations. *Ann Emerg Med.* 1993; 22(7): 1130-5.
6. Bruns TB, Simon HK, McLario DJ, Sullivan KM, Wood RJ, Anand KJ. Laceration repair using a tissue adhesive in a children's emergency department. *Pediatrics.* 1996; 93: 673-5.

■ **More than 2000 publications support the use of Histoacryl®.**



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