

Histoacryl® Topical Skin Adhesive Patient Instructions

Histoacryl® Description

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 no different from the risk of using stitches, the alternate method of wound closure. Another risk is the splitting or opening of the wound (dehiscence). Studies have shown that the risk of dehiscence is no different from using stitches, the alternate method of wound closure. Information on the clinical studies conducted on 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 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

- *Never pick, pull, or scratch the wound. This may cause the wound to re-open.*
- *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 hold closed easily approximated 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 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 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

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

This studied the Use of Histoacryl® in elective surgical incisions- long term outcomes. 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

This was a randomized trial of 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.

Quinn et al, 1993

This was a randomized, controlled trial comparing a tissue adhesive with suturing in the repair of pediatric facial lacerations. This study concluded that Histoacryl® is a safe and effective method of closing wounds.

Bruns et al, 1996

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

BIBLIOGRAPHY

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3. Quinn JV, Drezwiecki A, Li MM, Stiell IG, Sutcliffe, Elmsie TJ, Wood WE: A Randomised, Controlled Trial Comparing Tissue Adhesive With Suturing in the Repair of Pediatric Facial Lacerations. Annals of Emergency Medicine 1993; 22 (7): 1130-1135
4. Bruns Thomas B. Simon Harold K. McLario David J. Sullivan Kevin M. Wood Robert J. Anand K.J.S. Laceration Repair Using aTissue Adhesive in a Children's Emergency Department , Pediatrics 1996;98:673-675