

Histoacryl® Topical Skin Adhesive *Patient Instructions*



Purpose and 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.

For Histoacryl to work correctly, you must observe the *Patient Instructions* below.

Patient Instructions, Do's and don'ts:

- ***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.***
- ***Keep the wound dry and protected with a water resistant non-medicated bandage, per doctor's instructions. Change the bandage per doctor's instructions. Keep the adhesive part of the bandage off of the wound's edges.***
- ***Watch the wound's appearance as healing progresses. Swelling, pain, or redness is normal and common for wounds but this should go away as the wound heals.***

Cautions

- ***Never pick, pull, or scratch the wound or its bandage. 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 increased discomfort, redness, swelling, 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 thus how well the wound heals.

When is Histoacryl® used and when it should not be 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 (cuts). Histoacryl® may be used in conjunction with but not in place of stitches.

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 “dehiscence,” which is a splitting or opening of the wound. Studies have shown that the risk of dehiscence is no different from using stitches, the alternate method of wound closure. The benefits of using Histoacryl® include: speed of use, better cosmetic outcomes, and elimination of the need for a return visit to the doctor for the removal of stitches. Information on the clinical studies conducted on Histoacryl® is presented at the end of this brochure. See *Additional Information*.

Expectations of the device and 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. The wound will be “debrided” (removal of foreign material) when necessary. Your doctor may choose to use a local anesthetic. Your doctor will then open the 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 he/she wishes 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 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 safe, has a low complication rate, and produces excellent outcomes.

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 faster and probably less painful than sutures. It has the same complication rate and same cosmetic outcome when reviewed at 3 and 12 months. It has the advantages of being less expensive and not requiring a follow-up visit to remove sutures. It is important however, to apply it correctly and choose the wounds carefully. Wounds that may appear superficial initially are often deeper and require subcutaneous sutures. Glue is useful in many small superficial lacerations in children and should be the treatment of choice.

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 faster and less painful method of facial laceration repair that has cosmetic results similar to that of sutures.

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. In this study, the use of (Histoacryl® Blue) allowed for improved time efficiency, decreased pain to the child, and resulted in comparable cosmetic outcome to conventional suture repair. Also, the need for suture removal was eliminated.

BIBLIOGRAPHY

1. Amiel GE, Sukhotnik I, Kowar B, Siplovich L, Use of N-Butyl-2-cyanoacrylate in Elective Surgical Incisions- Longterm Outcomes. J Am Coll Surg Vol 189, No. 1, July 1999, 21-25
2. P Barnett, FC Jarman, J Goodge, G Silk, and R Aickin in Randomised trial of histoacryl blue tissue adhesive glue versus suturing in the repair of paediatric lacerations., J. Paediatr. Child Health (1998) 34, 548-550.
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 a Tissue Adhesive in a Children's Emergency Department , Pediatrics 1996;98:673-675