Purpose and Description

Your doctor has chosen to use Histoacryl as a method for closing your wound. Histoacryl is a sterile, topical tissue adhesive that holds wound edges together. The topical tissue adhesive 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, Dos and don’ts:

- If possible, you should avoid contact with water for the first 24 hours after treatment. You may shower or bathe but allow only transient wetting of the treatment site. The wound should not be soaked or exposed to prolonged wetness for 7-10 days or until topical tissue adhesive has sloughed off.

- You should not apply any medications or creams to the wound.

- You should 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.

- You should 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:

- You should never pick, pull or scratch the wound or its bandage. This may cause the wound to reopen.
- You should contact your doctor if the wound reopens or the edges separate.
- You should contact your doctor if you have increased discomfort, redness, swelling or if the wound feels warm to the touch.
- You should 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 follow the instructions.

When is Histoacryl used and when should it not be used?
Your doctor makes this decision. Histoacryl topical tissue 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, improved 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.

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 tissue 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 tissue adhesive and apply small amounts of tissue adhesive to the wound edges. Your doctor will push the wound edges together to close the wound. The tissue adhesive will “set” and hold the wound edges together in typically less than a minute. Your doctor will then give you any special instructions 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 study examined the use of Histoacryl in elective surgical incisions and the 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 cosmetic results.

**Barnett et al. 1998**
This was a randomized trial of Histoacryl tissue adhesive versus suturing in the repair of pediatric lacerations. The study demonstrated that the use of tissue adhesive is both faster and probably less painful than sutures. It has relatively similar complication rates and cosmetic outcomes as sutures 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. Tissue adhesive 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 and 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 for laceration repair is an acceptable alternative to conventional suturing. In this study, the use of Histoacryl allowed for improved time efficiency, decreased pain and resulted in comparable cosmetic outcome to conventional suture repair. Also, the need for suture removal was eliminated.
BIBLIOGRAPHY


