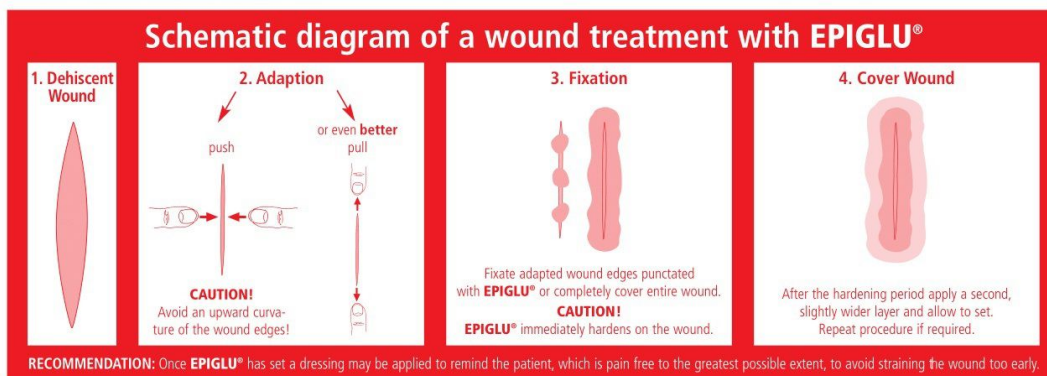


## Schematic diagram 2



Now the wound is closed secure of infection. The patient is immediately able to resume his personal daily hygiene like washing and showering (not too hot). Please advise the patient not to rub the place treated with EPIGLU® while foaming and wiping off but only dabbing it carefully. It is recommended not to take a full bath or a sauna.

**Recommendation:** Once the adhesive has fully set, a small dressing, band aid or sterile strips may be applied as a reminder to the patient to avoid straining the wound too early. As the wound is usually painless after the adhesion, the risk of scratching off the adhesive intentionally or unintentionally may occur.

**Attention:** The EPIGLU® layer must not be covered with a bandage of any type, as long as the adhesive **has not totally polymerized** as this can lead to an intense thermal reaction (heat development) which can, in the worst case, cause burning.

If a "throbbing" feeling appears a few hours after the wound has been adhered, it is advised to peel off the adhesive and to treat the wound otherwise. It might be assumed that at the time of adhesion the wound was already inflamed or foreign bodies were included.

If it should be noticed during a check-up that not enough EPIGLU® was applied and, therefore, the material peels off the surrounded healthy skin, another layer can be applied without any problem, because EPIGLU® provides no culture medium for germs, and even has an inhibitive effect on existing germs. The EPIGLU® solution is sterile (Medical Device Services May 2008 / MedCert October 2008).

After 5 to 10 days when the healing process is advanced, EPIGLU® detaches itself from the skin like scab. A further treatment of the wound is mostly not necessary.

#### Side effects:

If EPIGLU® is applied improperly or too thickly thermal tissue damage may occur due to the polymerization process. An extensive, too concentrated layer prevents the healing of connective tissue. Allergic reactions have not been observed so far. Local tolerance is excellent if the product is used according to the instructions. Hypersensitive reactions may occur with patients reacting anaphylactic to cyanoacrylate or formaldehyde (see: Contraindications).

**Should EPIGLU® unintentionally come in contact with healthy skin it will detach itself after setting.**

#### Storage instructions and shelf life of EPIGLU®:

Follow the storage instructions on the package and the single bags. The best way to store EPIGLU® is in the deep freezer or at least in the refrigerator. EPIGLU® can be used immediately after removal from the deep freezer because it does not freeze into a solid block. The expiry dates are mentioned on the aluminium pouches as well as on the outer package. Do not use EPIGLU® after these dates. Discontinue use if the solution does not drip in a clear watery consistency any longer. The material has then started to polymerize and an exact application is no longer possible. The adhesive must not be used any longer.

The mentioned maximum shelf life can only be guaranteed if stored in the deep freezer (-18°C / -0.4°F).

#### Properties:

The monomeric, liquid form of Ethyl-2-Cyanoacrylate turns rapidly into the polymeric form when in contact with water or tissue fluids, thus minimal quantities adhere the treated surfaces together.

#### Notes for health professionals:

##### Hazard statements:

Causes skin irritation.  
Causes serious eye irritation.  
May cause respiratory irritation.

##### Precautionary statements:

Avoid breathing in vapours.  
Wear protective gloves / protective clothing / eye protection / face protection.  
Wash thoroughly after handling.  
Use only outdoors or in a well-ventilated area.

**If in contact with eyes:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

**Take off contaminated clothing and wash before reuse.**

##### If accidentally inhaled:

Move victim to fresh air and keep at rest in a position comfortable for breathing.

##### Keep EPIGLU® locked up.

Store in a well-ventilated place. Keep container tightly closed Disposal of contents / container in accordance with local / regional / national / international regulations.

### Important Information:

- Cyanacrylate: Danger. Bonds skin and eyelids in seconds. Keep out of the reach of children.
- The Safety Data Sheet for EPIGLU® can be found on our website [www.meyer-haake.com](http://www.meyer-haake.com) under Download.
- Should any serious incidents arise in relation to the medical product EPIGLU® Single Dose they are to be reported to the manufacturer or the appropriate authorities.

#### Description of the pictograms on the primary and secondary packaging:



Observe instruction for use



Warning



Lot / Batch



Temperature limit



To be used by: year / month



Do not re-use!

CE 0482

CE mark and identification number of the Notified Body



Meyer-Haake GmbH Medical Innovations  
Daimlerstr. 4, 61239 Ober-Moerlen / Germany

#### To Re-Order:

##### EPIGLU®-Small package

1 Vial with 3 g, 20 application sets

##### EPIGLU®-Twin package

2 Vials each 3 g, 40 application sets

##### EPIGLU®-Economy package

4 Vials each 3 g, 80 application sets

##### EPIGLU®-OP-Package

1 Vial with 3 g, 20 sterile application sets

##### EPIGLU®-Single Dose

Package with 10 Dosettes each containing 0.3 ml

Package with 25 Dosettes each containing 0.3 ml

Package with 10 Dosettes each containing 0.5 ml

Package with 25 Dosettes each containing 0.5 ml

The packaging sets of all products may differ in certain countries!

**The packaging sets of all products may differ in certain countries!**

**For further information please contact your local dealer!**

Revision 10

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Manufacturer:

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# Instruction for Use

Please read carefully!  
Tissue Adhesive

**Composition:**  
EPIGLU® contains:  
Ethyl-2-Cyanoacrylate  
**Solution: Sterile**

# EPIGLU® Single Dose

Disposable product – intended for  
single use on a single patient only.

**EPIGLU®** is an Ethyl-2-Cyanoacrylate adhesive that is available for single use  
in either 0.3 ml or 0.5 ml Single Dose Dosettes

**EPIGLU®** provides no culture medium for germs and even has an inhibitive  
effect on existing germs.

#### Areas of application:

Tissue adhesive for external use and for the application in the oral cavity and at the external genital area. For the application to fresh lacerations, abrasion and surgical incisions and also for protection/closure after removal of skin lesions (nevi, warts, moles, senile freckles and many other more). For the closure of wounds after careful adaption of the wound edges, as a suture substitute, for additional suture support or as an anti-infective protection for sutured wounds.

#### Contraindications:

Do not use on infected or inflamed wounds and on wounds from bites. Do not use to close wounds of inner organs, the brain surface or the central or peripheral nervous system for EPIGLU® is not absorbable. An application to these areas might damage the tissue and the subsequent scarring may cause complications. The application to the intima and media of blood vessels should be avoided, because vascular thrombosis and damage of the vascular wall may occur. The tissue adhesive may come off if applied to extremely sweating patients. Do not use for patients with a known hypersensitivity to cyanoacrylate or formaldehyde (also see: Side effects).

#### Precautions for the application and warnings:

Adheres skin and eyelids within seconds. Avoid any contact with eyes and eyelids! EPIGLU® must not come in contact with the eyeball or conjunctival sac. Apply to external wounds, the oral mucosa and external genital area only. Ensure the exact adaption of wound edges prior to application. Surfaces to be adhered should be as dry and free of grease as possible. Liquid or pasty agents must not be applied before adhering. Do not drip into the depth of the wound, but apply in thin layers to skin surface. Apply to fresh wounds only (not older than 6 hours). Do not use on contaminated or inflamed wounds. Do not inhale fumes! Do not apply EPIGLU® to the breasts during lactation period.

**Hint:** The vapours which arise during the polymerization of the adhesive may irritate the conjunctiva of the eye and the mucous membrane of the nose. Therefore, we recommend protecting the patient's eyes and nose with humid cotton wool when wounds in the face are closed.

#### First aid actions to be taken in case of inadvertent contact of the adhesive with the eye:

Serious mechanical damage of the cornea may occur if eye or lid conjunctiva comes in contact with the adhesive. The affected eye must be rinsed thoroughly with a sterile, physiological solution (approx. 15 min) immediately after contamination. Should such a solution not be available the eye may be rinsed with tap water. Application of sterile medical neutral oils may be of advantage. An ophthalmologist should be consulted immediately.

#### Dosage and method of application:

- Wait until complete hemostasis.
- Remove possible foreign bodies from the wound.
- Clean the area around the wound with alcohol.
- Do not apply cream or ointment.
- Please be sure that no liquid film, e.g. of wound disinfection, remain.
- Do not use any aid with a pH-value <6.
- Do not use any powder before applying the adhesive and do not brush over the wound with soaked pads or swabs after cleaning.
- Remove the adhesive from the refrigerator or deep freezer.
- Tear the aluminium pouch open and take out the EPIGLU® Single Dose Dosette with the dispenser.
- Open the Dosette as shown on the aluminium pouch and attach the dispenser to the tip of the Dosette (see schematic diagram 1).
- Adapt the wound edges (see schematic diagram 2).
- Smooth out wrinkled skin before application.
- Bend injured joints, for example fingers, before application of the adhesive.
- Apply 1 to 2 drops, depending on length of the wound (see schematic diagrams 1 + 2).
- Spread the adhesive with the bend of the dispenser (see schematic diagram 1).
- Wait until the first layer of adhesive has set (approximately 10 seconds).
- The polymerization can be recognized when the adhesive appears less glossy.
- Apply again 1 to 2 drops adhesive and spread the solution in a wider layer than the first time – the adhesive must be spread thinly on the healthy skin.
- Wait again until the adhesive has set.
- If necessary apply a third layer – as described before.
- The final polymerization of all adhesive layers can take some minutes.
- A later correction of the wound edges is only possible by stripping off the totally polymerized adhesive.

**Important:** Apply the adhesive sparingly and spread it to the wound edges. It is not advisable to apply one thick layer, as this does not improve the adhesive strength, but causes the adhesive to peel off the healthy skin more easily. Avoid contact of the adhesive with gloves, instruments, gauze, etc. to prevent adhesion.

**Hint:** Injured joints, for examples fingers, should be bent before applying the adhesive. Wrinkled skin should be smoothed out.

#### Important notes for the use of Ethyl-2-Cyanoacrylate Wound Adhesive EPIGLU® in the Dental Practice:

1. Blow the area to be treated as dry as possible, so that the adhesive does not "float" on the wound.
2. Apply a little vaseline to the finger tip (of course over the glove); this avoids the glove later adhering (see 5.)
3. Carefully drop EPIGLU® onto the area to be treated by pressing the Single Dose packaging. Observe here how the adhesive runs into the pipette, to avoid too much adhesive getting onto the wound at one time.
4. After a few drops of the EPIGLU® adhesive (maximum 3, usually less) have been applied onto the area to be treated, spread the adhesive thinly with the bent tip of the pipette.
5. Immediately after, smooth over once again until completely flat with the finger tip on which the Vaseline has been applied. Thus preventing that the patient is later disturbed by protruding, hardened adhesive.
6. Please note that all acrylate adhesives, including EPIGLU®, due to the underlying damp environment do not adhere as long in the mouth as on treated areas of the skin.
7. However, as the wounds are deprived of disturbances by movement of the tongue, saliva or food, they heal considerably faster as untreated wounds or treatments made with other materials.
8. With a follow-up visit it can be decided whether EPIGLU® should be re-applied.
9. As EPIGLU® is not absorbable it may only be applied to the surface.

### Schematic diagram 1

