



Instruction for use

Please read carefully!

EPIGLU®

TUBES

Tissue Adhesive

Composition:

0.1 g EPIGLU® solution contains:
Ethyl-2-Cyanoacrylate 95.45 mg
Polymethylmethacrylate

Each tube EPIGLU® contains 3 g Ethyl-2-Cyanoacrylate tissue adhesive and is sufficient for the treatment of 20 wounds.

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, abrasions 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 and for protection of infections after sutures.

Contraindications:

Do not use on infected, inflamed or extensive (e.g. abraded) wounds or 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. In case of a hypersensitivity to one of the ingredients EPIGLU® is contraindicated.

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. Keep surfaces to be adhered as dry and free of grease as possible. Liquid or pasty agents must not be applied before adhering. Do not drip EPIGLU® into the depth of the wound, but apply in thin layers to skin surface. Apply to fresh and clean 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 to protect the patient's eyes and nose with moistened 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. Afterwards an ophthalmologist should be consulted immediately.

Dosage and method of application:

1. Remove EPIGLU® from the freezer or the refrigerator just before use. EPIGLU® is immediately ready for use.
2. 2.1 Unscrew the tube cap completely.
2.2 Hold the tube upright at the top.
2.3 Punch the tube seal with the tip of the cap. Avoid squeezing the tube during this process.
2.4 Screw the complete cap on the tube again.
2.5 Unscrew the upper cap and remove EPIGLU®.
2.6 If the tip should stick together after several uses, cut this area off.
- 2.7 Place the upper cap on the tube again loosely (do not screw it on) and store the tube upright in the gap of the package at least in the refrigerator, or even better in the deep freezer. **The mentioned maximum shelf life can only be guaranteed if stored in the deep freezer (-18°C).**
3. Apply EPIGLU® with the dispensing pipettes.
 - 3.1 Break off one drop-in tray from the bar. Drip the desired amount of EPIGLU® (approximately 1 – 3 drops) into the depression. Soak up the solution with the dispensing pipette by squeezing the pipette approximately 1 – 2 cm behind the bend with thumb and index finger, dip pipette into the liquid and release your hold. Throw the drop-in tray away after the tissue adhesive has polymerized.
 - 3.2 It is also possible to cut off a dispensing pipette approximately 1 cm below the bend and affix the cutted pipette directly to the tube's opening. EPIGLU® will be applied in this case directly from the tube by pressing it slightly.
4. Wait until the wound stops bleeding. Remove possible foreign bodies from the wound. Clean the area around the wound with alcohol. Do not apply any creams or ointments. Adapt the wound edges (see schematic diagram) and apply a thin layer of EPIGLU®. The wound edges might also be fixated with EPIGLU® initially. EPIGLU® sets very quickly. The first layer of adhesive on the wound polymerizes in approximately 10 seconds. The solution should be applied in several thin layers. Allow each layer to set. The less glossy the adhesive appears the more the adhesive has polymerized. It can take some minutes until all layers of EPIGLU® have set. A later correction of the adapted wound edges is only possible by stripping off the totally polymerized adhesive.

Important: It is not advisable to apply one thick layer as the adhesive strength would not be improved but this could risk that EPIGLU® peels off the healthy skin quicker.

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

Avoid contact of the adhesive with gloves, instruments, gauze, etc. to prevent adhesion.

Once the wound is closed with the first layer of EPIGLU® the dropped adhesive for further layers can be smoothed out with the angular extension of the pipette. Therefore, the extension of the pipette must be laid plainly onto the skin and the adhesive must be smoothed out without any pressure. This measure gives additional stability to the wound closure and the thinly smoothed out adhesive layers do not peel off from the healthy skin so easily.

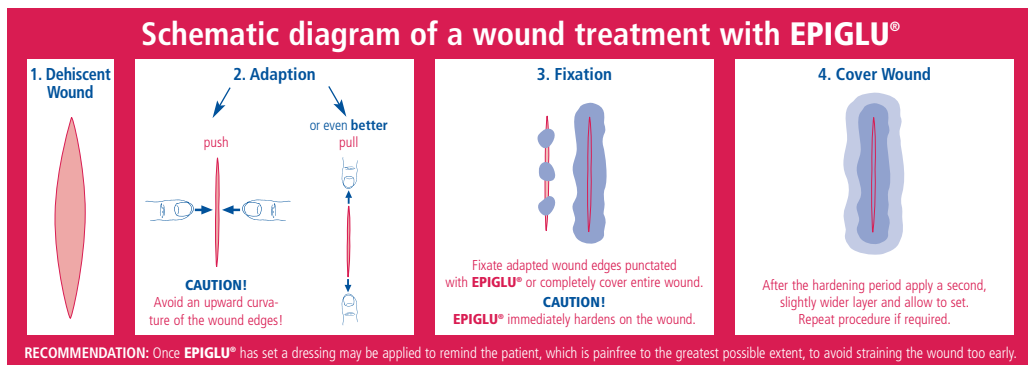
5. After the wound treatment all used application aids have to be thrown away.
6. Now the wound is closed secure of infection. The patient is immediately able to resume his personal daily hygiene like washing and showering (not too hot). Please advise the patient not to rub the place treated with EPIGLU®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

Once **EPIGLU®** has set, a small dressing or band-aid may be applied to remind the patient, who is almost painfree, to avoid straining the wound too early. This is recommended especially for small children or nervous persons. As the wound mostly does not cause any pain after the adhesion the risk of scratching off the adhesive intentionally or unintentionally may occur.

If it should be noticed during a check-up that the material peels off the surrounded healthy skin, another layer of **EPIGLU®** can be applied without any problem, because **EPIGLU®** provides no culture medium for germs, and even has an inhibitive effect on existing germs. **EPIGLU®-Solution** is sterile (Medical Device Services May 2008 / MedCert October 2008).

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.

After 5 – 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 improperly or too thickly applied thermal tissue damage may occur due to the polymerization process. An extensive, too concentrated layer prevents the healing of connective tissue. Allergic reactions were not observed so far. Local tolerance is excellent if the product is used according to the instructions.

Should EPIGLU® unintentionally come in contact with healthy skin and polymerize it will detach itself after a while without damaging the skin.

Storage instructions and shelf life of EPIGLU®:

Pay attention to the terms of storage on the package and on the tubes. The expiry date is printed on the tube as well as on the outer package. Do not use **EPIGLU®** after this date! Discontinue use of the opened tube if the solution does not drip from the tube in a clear watery consistency any longer. The material has then started to polymerize and an exact adaption is no longer possible. The adhesive must not be used any longer.

Store EPIGLU® protected from light in the deep freezer (-18°C) or refrigerator (+6°C). Store opened tubes vertically. The mentioned maximum shelf life can only be guaranteed if stored in the deep freezer (-18°C). EPIGLU® can be used immediately after removal from the deep freezer because it does not freeze into a solid block. If EPIGLU® is used several times a day, e.g. in emergency rooms, it is not necessary to store the adhesive in the deep freezer between the applications.

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.

EPIGLU® can be removed from healthy skin, textiles and work counters with CYANO-EX.

Keep out of the reach of children!

CE 0482

Re-Order Items / Accessories:

EPIGLU® Test Package	1 Tube with 3g of solution, 20 application aids
EPIGLU® Twin Package	2 Tubes with 3g of solution each, 40 application aids
EPIGLU® Economy Package	4 Tubes with 3g of solution each, 80 application aids
EPIGLU® Package for the Operation Theatre	1 Tube with 3g of solution, 20 sterile application aids
EPIGLU® Single Dose	Carton containing 5 dosettes of 0.3 ml/cc each Carton containing 10 dosettes of 0.3 ml/cc each Carton containing 25 dosettes of 0.3 ml/cc each

Dispensing Pipettes	100 pcs. 200 pcs. 500 pcs.
Bars with 4 pcs. Drop-In Trays	20 bars
Sterile Application Sets	20 pcs.
CYANO-EX	20 g Cyanoacrylate Remover

The delivery forms of all products may differ in some countries!

For further information please contact your local dealer!

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