EPIGLU® SINGLE DOSE
Disposable product – intended for single use on a single patient only.

Composition:
EPIGLU® contains:
Ethyl-2-Cyanoacrylate

Solution: Sterile

Each EPIGLU® Single Dose Dosette contains 0.3 ml/cc Ethyl-2-Cyanoacrylate tissue adhesive and is sufficient for an approximately 10 cm long wound, even if the tissue adhesive is applied in several layers.

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 (next, 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, 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. 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.
- Remove the adhesive from the refrigerator or deep freezer.
- 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.
- 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 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 example fingers, should be bent before applying the adhesive. Wrinkled skin should be smoothed out.
Attach the dispenser to the drip opening of the EPIGLU®-Dosette.

Squeeze the reservoir of the Dosette carefully to avoid getting too much adhesive. Drip the adhesive onto the wound. Smooth the adhesive thinly out on the wound with the bend of the dispenser.

Important: In order to avoid any leakage whilst opening, do not press the adhesive container.

Hold the Peel-Off-Bag upright, open it and take out carefully the Single Dose Dosette with the applied dispenser.

Remove the dispenser.

Hold the lower part of the Dosette firmly and twist the upper seal off.

Important:
In order to avoid any leakage whilst opening, do not press the adhesive container.

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.

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.

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 aluminium pouch. 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.


Re-Order Items/Accessories:

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
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<tbody>
<tr>
<td>EPIGLU® Test Package</td>
<td>1 Tube with 3 g of solution, 20 application aids</td>
</tr>
<tr>
<td>EPIGLU® Twin Package</td>
<td>2 Tubes of 3 g solution each, 40 application aids</td>
</tr>
<tr>
<td>EPIGLU® Economy Package</td>
<td>4 Tubes of 3 g solution each, 80 application aids</td>
</tr>
<tr>
<td>EPIGLU® Package for the Operation Theater</td>
<td>1 Tube with 3 g of solution, 20 sterile application aids</td>
</tr>
<tr>
<td>EPIGLU® Single Dose</td>
<td>Carton containing 10 Dosettes of 0.3 ml/cc each</td>
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<tr>
<td></td>
<td>Carton containing 25 Dosettes of 0.3 ml/cc each</td>
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<tr>
<td>Dispensing Pipettes</td>
<td>100 pcs.</td>
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<td></td>
<td>200 pcs.</td>
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<tr>
<td></td>
<td>500 pcs.</td>
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<tr>
<td>Bars with 4 pcs. Drop-In Trays</td>
<td>20 bars</td>
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<tr>
<td>Sterile Application Sets</td>
<td>20 pcs.</td>
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The delivery forms of all products may differ in some countries!

For further information please contact your local dealer!

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