
The following information is intended for healthcare professionals only:

INSTRUCTIONS FOR USE

Read this before you open the package

EVICEL comes in sterile packages and therefore it is important to use *only* undamaged packages which have not been opened (post-sterilisation is not possible).

Storage

The approved shelf life of EVICEL is 2 years storage at $\leq -18^{\circ}\text{C}$. Do not use after the expiry date stated on the carton.

Within the 2 years shelf life, after thawing, unopened vials can be stored at $2^{\circ}\text{C} - 8^{\circ}\text{C}$ (in a refrigerator) and protected from light, for up to 30 days. The date on which refrigerator storage was started should be marked on the carton in the space provided. Do not re-freeze. The fibrinogen and thrombin components are stable at room temperature for up to 24 hours but when they have been drawn up into the administration device, they must be used immediately.

The vials must be stored in an upright position.

Do not use after the expiry date stated on the carton and label.

Keep out of sight and reach of children.

The application device should be stored at room temperature, separately from the fibrinogen and thrombin.

Thawing

The vials should be thawed in one of the following ways:

$2^{\circ}\text{C} - 8^{\circ}\text{C}$ (refrigerator): vials thaw within 1 day,

$20^{\circ}\text{C} - 25^{\circ}\text{C}$ (room temperature): vials thaw within 1 hour,

37°C (e.g., water bath, using aseptic technique, or by warming vials in the hand): vials should be thawed within 10 minutes and must not be left at this temperature for longer than 10 minutes or until fully thawed.

The temperature must not exceed 37°C .

Before use, the product must reach $20^{\circ}\text{C} - 30^{\circ}\text{C}$.

Preparation

EVICEL should only be applied using the CE-marked EVICEL application device and optional use of a tip accessory to the device. Leaflets giving detailed instructions for use of EVICEL in conjunction with the application device and optional accessory tips are provided with the package of the application device and of the accessory tips. The accessory tips should only be used by persons adequately trained in laparoscopic, laparoscopic-assisted, or open surgical procedures. The product should only be reconstituted and administered according to the instructions and with the devices recommended for this product.

To avoid the risk of potentially life-threatening air or gas embolism EVICEL should be sprayed using pressurised CO_2 only.

The solutions should be clear or slightly opalescent. Do not use solutions that are cloudy or have deposits. Draw the contents of the two vials into the application device, following the instructions for use in the device package. Both syringes should be filled with equal volumes, and should not contain air bubbles. No needles are involved in the preparation of EVICEL for administration.

Prior to applying EVICEL the surface area of the wound needs to be dried by standard techniques (e.g., intermittent application of compresses, swabs, use of suction devices).

Application by dripping

Keeping the tip of the applicator as close to the tissue surface as possible, but without touching the tissue during application, apply individual drops to the area to be treated. If the applicator tip becomes blocked, the catheter tip can be cut back in 0.5 cm increments.

Spray application

EVICEL must be sprayed using pressurised CO₂ only.

Connect the short tube on the application device to the male luer-lock end of the long gas tube. Connect the female luer-lock of the gas tube (with the 0.2 µm bacteriostatic filter) to a pressure regulator. The pressure regulator should be used in accordance with the manufacturer’s instructions.

When applying EVICEL using a spray device, be sure to use a pressure and a distance from tissue within the ranges recommended by the manufacturer:

Surgery	Spray set to be used	Applicator tips to be used	Pressure regulator to be used	Distance from target tissue	Spray pressure
Open surgery	EVICEL Applicator Device	6 cm flexible tip	Omrix Pressure Regulator	10 – 15 cm (4 – 6 in)	20 – 25 psi (1.4 – 1.7 bar)
		35 cm rigid tip			
		45 cm flexible tip			
Laparoscopic procedures		35 cm rigid tip		4 – 10 cm (1.6 – 4 in)	15 – 20 psi (1.0 – 1.4 bar)
		45 cm flexible tip			20 psi (1.4 bar)

The product should then be sprayed onto the surface of the tissue in short bursts (0.1-0.2 ml) to form a thin, even layer. EVICEL forms a clear film over the area of application.

When spraying EVICEL, changes in blood pressure, pulse, oxygen saturation, and end tidal CO₂ should be monitored because of the possibility of occurrence of gas embolism.

Disposal

Any unused product or waste material should be disposed of in accordance with local requirements.