EVICEL®
Solutions for Sealant

- <1 minute from refrigeration storage to application ready[a]

WHEN SPRAYING EVICEL®

- There is a risk of air or gas embolism when the spray device is used at closer proximity to the tissue surface and/or at higher pressure than recommended in the instructions.
- Closely monitor blood pressure, pulse rate, oxygen saturation, and end tidal CO_2 when spraying the product, for the occurrence of gas embolism.
- To avoid the risk of potentially life threatening air or gas embolism EVICEL® should be sprayed using **pressurised CO_2 gas only.**
- Spray application of EVICEL® should only be used if it is possible to accurately judge the spray distance, especially during laparoscopy.
- Spray application of EVICEL® should **not** be used in **endoscopic** procedures
- Prior to applying EVICEL®, dry the surface area of the wound using standard techniques (e.g., intermittent application of compresses, swabs, use of suction devices)

[a] When stored in refrigerator, after thawing.

Outside of Sterile Field Preparation

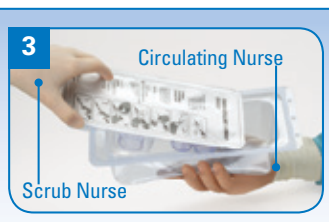
1

- **Select package** by size (1,2 ml or 5 ml).
- Open the box containing the device and take out the inner packaging.

2

- **Remove the cover** of the outer device packaging without touching the contents.

3



- Open the applicator box and remove the tray packaging. Remove the cover of the outer tray without touching the sterile inner tray. Empty the sterile tray into the sterile field.

4

- **Ensure that the two vials** of product (thrombin and fibrinogen) **have been thawed** according to package insert instructions.*
- Flip off plastic caps of the two vials of product.
- Do not touch sterile rubber stoppers.

* Thawing: The vials should be thawed in one of the following ways: 2°C-8°C (refrigerator): vials thaw within 1 day, or 20°C-25°C (room temperature): vials thaw within 1 hour, or 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. Once thawed, EVICEL® must not be refrozen. Once at room temperature, EVICEL® must not be refrigerated. **Before use, the product must reach 20°C-30°C.**

Sterile Field Preparation

Remove the cover of the inner packaging and empty contents onto the sterile field.

Note: Device assembly and product aspiration into the device MUST take place in a sterile operating room.

1

- **Place each vial securely** into the sterile vial cup held by a person who has scrubbed.

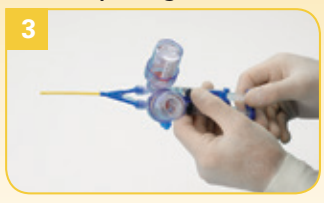
  Non-sterile field: Do not touch vial cups.

2

- **Loosen the syringe pistons** of the device by sliding them back and forth.

  Holding the vials upright, the person who has scrubbed should press each vial cup into a vial connector, being careful not to contaminate sterile cup and cup connector.

3



- **Hold the syringe barrels** with vials facing upward and slowly aspirate both products into the syringes. Aspirate slowly to minimize formation of air bubbles.

4

- Grasp each vial cup holder at the base, where the holder connects to the device, and remove entire assembly by turning counterclockwise until assembly disconnects. Discard vial cups, vials and vial connector.

5

- **The device is now ready for drip use.**

6

- **If spraying is required** connect the short gas tube on the application device to the long gas tube provided. Hand the circular filter end to the circulating nurse to connect to the pressure regulator.

7

- **Use only Omrix Pressure Regulator, in line with manufacturer recommendations and the SmPC instructions for use.**

8

- **To spray**, set pressure on pressure regulator to the level indicated in the SmPC for the tip and surgery type (see information below).

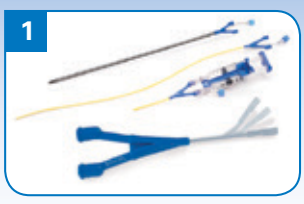
  EVICEL® spray application should only be used if it is possible to accurately judge the spray distance, especially during laparoscopy. Spray distance from tissue and CO_2 pressure should be within the ranges recommended by the manufacturer

The use of EVICEL™ is restricted to experienced surgeons who have been trained in the use of EVICEL®

Connecting Accessory Tip Options within Sterile Field

Note: Assemble this device in the OR using proper sterile technique.

1



- **Circulating Nurse:** Open the pouch and empty the respective accessory tip onto the sterile field.

2

- **Scrub Nurse:** To remove the short tip, hold the syringe barrels and loosen luer connectors by turning nuts anti-clockwise. Discard short tip. To minimize risk of device clogging, the short tip should not be reattached.

3

- **Attach the Respective Accessory Tip** to the syringe body by rotating the luer connectors clockwise to tighten.
- EVICEL® should be sprayed using **pressurised CO_2 gas ONLY.**

4

- **Ensure tip is firmly connected** before use.

  If the tip should become clogged during use, any visible clot at the end of the tip can be wiped off or removed using sterile gauze.
- When dripping, if the applicator tip becomes blocked, the catheter tip can be cut back in 0.5cm increments.

SUMMARY FOR SPRAYING IN OPEN PROCEDURES

Pressure: 1.4 - 1.7 bar (20 - 25 psi)

Distance: 10 - 15cm (4 - 6 in)

SUMMARY FOR SPRAYING IN LAPAROSCOPIC PROCEDURES

Pressure: 35cm rigid tip: 1.0 - 1.4 bar (15 - 20 psi)
45cm flexible tip: 1.4 bar (20 psi)

Distance: 4 – 10 cm (1.6 – 4 in)

Airless spray device options are also available for EVICEL® which remove the need for spraying with gas connected systems.

EVICEL® Solutions for Sealant, Abbreviated Prescribing Information:
Please read Summary of Product Characteristics (SmPC) before prescribing.
COMPOSITION: Component 1:Human clottable protein (mainly fibrinogen and fibronectin): 50-90 mg/ml. Component 2: Human thrombin: 800-1200 IU/ml.
INDICATIONS: Indicated in adults as supportive treatment in surgery where standard surgical techniques are insufficient, for improvement of haemostasis. Suture support for haemostasis in vascular surgery and for suture line sealing in dura mater closure.
POSOLOGY & ADMINISTRATION: For epilesional use. Use restricted to experienced trained surgeons. Use by dripping or spraying. **To avoid the risk of potentially life-threatening air or gas embolism s**pray using pressurised CO_2 only. See the table below for spray pressure and distance from tissue recommendations. Dose applied governed by several variables and must be individualised. In controlled clinical trials in vascular surgery, individual dosage was up to 4 ml whereas in retroperitoneal or intra-abdominal surgery individual dosage used was up to 10 ml. For suture line sealing in dura mater closure, doses of up to 8 ml were used. For some procedures (eg liver traumata) larger volumes may be required. Initial volume applied should be sufficient to cover intended application area. Application can be repeated, if necessary.
CONTRAINDICATIONS: Must not be applied intravascularly. Hypersensitivity to active substances or any excipient. Spray application should not be used in endoscopic procedures. For laparoscopy, spray only if the spray distance can be judged accurately. Not for use for sealing the suture line in dura mater if there are gaps of greater than 2 mm after suturing. Not for use as a glue for fixation of dural patches. Not for use as a sealant when the dura mater cannot be sutured.
SPECIAL WARNINGS & PRECAUTIONS: Life threatening thromboembolic complications if applied intravascularly. Life-threatening air or gas embolism has occurred with spray devices employing a pressure regulator. This may be related to use of spray devices at higher than recommended pressures and/or in close proximity to tissue. Apply Evicel only with CE-marked Evicel application devices and accessory tips and OMRIX pressure regualtor. Spray only if able to accurately judge spray distance.

Surgery	Tip	Distance	Pressure
Open	6 cm flexible	10-15 cm (4 - 6 in)	1.4 - 1.7 bar (20 - 25 psi)
Open	35 cm rigid	10-15 cm (4 - 6 in)	1.4 - 1.7 bar (20 - 25 psi)
Open	45 cm flexible	10-15 cm (4 - 6 in)	1.4 - 1.7 bar (20 - 25 psi)
Laparoscopic	35 cm rigid	4-10 cm (1.6 - 4 in)	1.0 - 1.4 bar (15 - 20 psi)
Laparoscopic	45 cm flexible	4-10 cm (1.6 - 4 in)	1.4 bar (20 psi)

When spraying EVICEL, changes in blood pressure, pulse, oxygen saturation, and end tidal CO2 should be monitored because of the possibility of occurrence of a gas embolism. Apply as thin layer; excessive clot thickness may impede efficacy and wound healing. Inadequate data to support use in tissue gluing, application through a flexible endoscope for treatment of bleeding or in gastrointestinal anastomoses. Concomitant use for dural suture line sealing with implants from synthetic materials or dural patches not evaluated in clinical studies. Use in patients undergoing radiotherapy within 7 days after surgery not evaluated. Not known if radiation therapy could affect the efficacy of fibrin sealant when used for suture line sealing in dura mater closure. Complete haemostasis required before sealing the dural suture line. Use as a sealant in transphenoidal and otoneurosurgical procedures not studied.

Before administration, adjacent areas should be protected. Allergic type hypersensitivity reactions possible. If these occur, discontinue immediately. The possibility of transmitting infectious agents including unknown or emerging viruses and other pathogens cannot be excluded. It is strongly recommended that name and batch number of the product are recorded to maintain a link between patient and product batch. There is not enough information available to know whether any particular risks are associated with the use of EVICEL during pregnancy or whilst breast-feeding - the product should be administered to pregnant and breast-feeding women only if clearly needed.
UNDESIRABLE EFFECTS: Hypersensitivity or allergic reactions (which may include angioedema, burning and stinging at the application site, bronchospasm, chills, flushing, generalised urticaria, headache, hives, hypotension, lethargy, nausea, restlessness, tachycardia, tightness of the chest, tingling, vomiting, wheezing) may occur in rare cases in patients treated with fibrin sealants/haemostatics. In isolated cases, these reactions have progressed to severe anaphylaxis. Such reactions may especially be seen if the preparation is applied repeatedly, or administered to patients known to be hypersensitive to constituents of the product.. Antibodies against product components may occur. Inadvertent intravascular injection could lead to thromboembolic event, disseminated intravascular coagulation and a risk of anaphylactic reaction. In abdominal clinical trials, abdominal abscess was reported commonly. In vascular clinical trials the following events were reported uncommonly: graft infection, staphylococcal infection, haematoma, oedema peripheral, decreased haemoglobin, peripheral oedema, incision site haemorrhage, vascular graft occlusion, wound, post procedural haematoma, post-operative wound complication. In a neurological study the following events were reported commonly: meningitis, intracranial hypotension, CSF rhinorrhoea, headache, hydrocephalus, subdural hygroma, haematoma.
LEGAL CATEGORY: POM
COST: 2ml – EVB02DE €250 and 5ml – EVB05DE €487.36
MA HOLDER: Omrix Biopharmaceuticals NV, Leonardo Da Vinci Laan 15, B-1831 Diegem, Belgium.
MA NUMBER(S): EU/1/08/473/001, EU/1/08/473/002, EU/1/08/473/003.
Date of Preparation: April 2019

PHARMACOVIGILANCE: Adverse events should be reported. Reporting forms and information can be found at the HPRA online reporting system https://www.hpra.ie/homepage/about-us/report-an-issue . Adverse events should also be reported to Omrix Biopharmaceuticals Ltd by one of the following methods:
Fax number: +972-3-5350265
Email address: RA-OMRILPV@its.jnj.com Tel: +972 3 5316 531

ETHICON
PART OF THE Johnson&Johnson FAMILY OF COMPANIES
Shaping the future of surgery

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