Rely on EVICEL® Fibrin Sealant

For sustained hemostasis, demonstrated in high-risk patients.[1]

Storage

Freezer (-18ºC for up to two years)

Refrigerator (2-8ºC for up to 30 days)

EVICEL® ready for when you need it.*

Outside of Sterile Field Preparation[2]

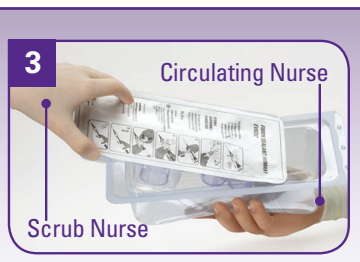
1

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

2

Remove the cover of the outer packaging without touching the contents.

3



Using sterile technique, empty the inner package onto the sterile field.

4

Ensure that the two vials of product (thrombin and BAC2) **have been thawed** according to package insert instructions.

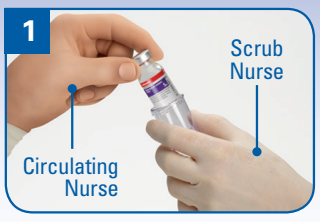
- Flip off plastic caps of the two vials of product.
- Do not touch sterile rubber stoppers.

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.

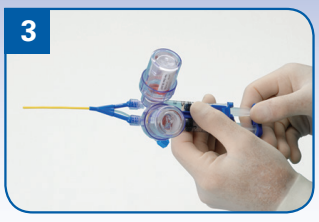
Non-sterile field: Do not touch vial cups.

2

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

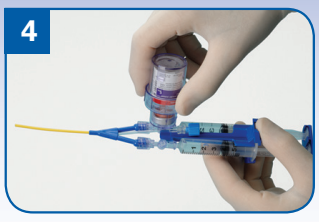
Holding the vials upright, the person who has scrubbed should press each vial connector firmly into the exposed portion of the rubber stopper on each vial.

3



Hold the syringe barrels with vials facing upward and slowly aspirate both products into the syringes. If necessary to expel air, product may be slowly injected back into vials and aspirated again.

4



Hold the syringe barrels with one hand, and gently turn the vial counter-clockwise with the other hand. The vial connector, vial and vial cup combination will disconnect automatically. Discard within the sterile field.

5

The device is now ready for drip use.

Spraying with Evicel™ Airless Spray Accessory-Open and Laparoscopic

1

Detach the 6cm yellow tip by holding the syringe barrel and loosening the luer nuts by turning them counter clockwise.

2

3

Attach the EVICEL™ Open or Laparoscopic Airless Spray Accessory and tighten the luer nuts by rotating them in a clockwise fashion.

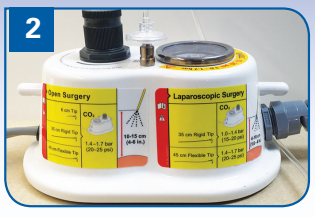
Spraying with Gas Assistance

1

If spraying required connect male luer-lock to the short gas tube on the device in the sterile field.

The long gas tube with the 0.2um filter is then connected by inserting the female luer-lock onto the EVICEL® Fibrin Sealant (Human) pressure regulator.

2



To spray, set pressure on pressure regulator at 15 to 25 psi and hold tip 10 to 15 cm from tissue surface during open procedures and 4 to 10 cm from tissue surface during laparoscopic procedures.

* When stored in refrigerator, after thawing (24 hours).

References 1. Chalmers RT, Darling RC III, Wingard JT, et al. Randomized clinical trial of tranexamic acid-free fibrin sealant during vascular surgical procedures. *Br J Surg.* 2010;97(12):1784–1789. **2.** Fibrin Sealant (Human) EVICEL Application Device, Product Assembly Guide 2009.

PBS Information: This product is not listed on the PBS

https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2012-PI-02766-1

Manufacturer: Omrix Biopharmaceuticals, Ltd. Israel License No. 1603 US-2009/10/180

Australian Sponsor: Johnson & Johnson Medical Pty Ltd 1-5 Khartoum Road, North Ryde 2113, NSW, Australia AUST R 266221, AUST R 181318, AUST R 181319

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MINIMUM PRODUCT INFORMATION

Fibrinogen Solution: 1mL contains Fibrinogen 80-120mg/mL total protein (clottable protein (human) 50-90mg); and Thrombin Solution: 1mL contains 800 to 1,200 IU Thrombin (human).

INDICATIONS Supportive treatment in surgery where standard surgical techniques are insufficient, for improvement of haemostasis. As suture support for haemostasis in large vessel vascular surgery. For suture line sealing in dura mater closure.

DOSAGE AND ADMINISTRATION Before use, the product must reach 20-30°C. The volume and frequency is dependent on the clinical needs of the patient. The initial volume should be sufficient to entirely cover the intended application area. The application can be repeated, if necessary. EVICEL® is for epilesional use only. Before application, the surface of the wound should be as dry as possible. See full PI.

CONTRAINDICATIONS Hypersensitivity to the actives or excipients. Injection into tissues is contraindicated. EVICEL® should only be applied topically. Soft tissue injection of EVICEL® carries the risk of an anaphylactic reaction and/or local tissue damage and/or thromboembolic complications. Spray application of EVICEL® should not be used in endoscopic procedures. Must not be used for sealing the suture line in dura mater if there are gaps of greater than 2mm after suturing. Must not be used as a glue for the fixation of dural patches. Must not be used as a sealant when the dura mater cannot be sutured. See full PI.

PRECAUTIONS Viral and Prion Risk: Products made from human plasma may contain infectious agents which can cause disease, such as viruses and theoretically Creutzfeldt-Jakob Disease (CJD) agents. See full PI. General: The PI gives guidance on the use of the spray device. Air or gas embolism, tissue rupture, or gas entrapment with compression, which may be life-threatening, have occurred with the use of spray devices. Cover areas outside application to prevent tissue adhesion at undesired sites. 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 pressure should be within the ranges recommended by the manufacturer. Adequate data are not available to support administration of EVICEL® through a flexible endoscope for the treatment of bleeding or in gastrointestinal anastomoses. Not to be used for treatment of massive and brisk arterial or venous bleeding. Avoid injection into the nasal mucosa as severe allergic/anaphylactoid reactions can occur and thromboembolic complications may occur in the area of the ophthalmic artery. The use of EVICEL® in patients undergoing radiotherapy within 7 days after surgery, and the use as a sealant in transphenoidal otoneurosurgical procedures and spinal procedures has not been evaluated. Complete haemostasis should be achieved before application of EVICEL® to seal the dural suture line. See full PI.

USE IN PREGNANCY Category B2. See full PI.

ADVERSE EVENTS Hypersensitivity, allergic reactions, severe anaphylaxis. Antibodies to active components may occur rarely. Intravascular injection could lead to thromboembolic events, disseminated intravascular coagulation (DIC). See full PI.

PRESENTATION 2mL composite pack containing Fibrinogen Solution 1mL and Thrombin Solution 1mL. 4mL composite pack containing Fibrinogen Solution 2mL and Thrombin Solution 2mL. 10mL composite pack containing Fibrinogen Solution 5mL and Thrombin Solution 5mL. Store in a freezer at or below -18°C. Keep the vials upright in the outer carton protect from light. Do not refreeze. After thawing, unopened vials can be stored at 2-8°C and protected from light for up to 30 days, the components are stable at or below 25°C for up to 24 hours.

PLEASE REVIEW FULL PRODUCT INFORMATION BEFORE PRESCRIBING (available from Johnson & Johnson Medical Pty Ltd 1-5 Khartoum Rd, North Ryde NSW 2113 Australia). Date of preparation 11 January 2017. *122944-190911 Oct 2019*