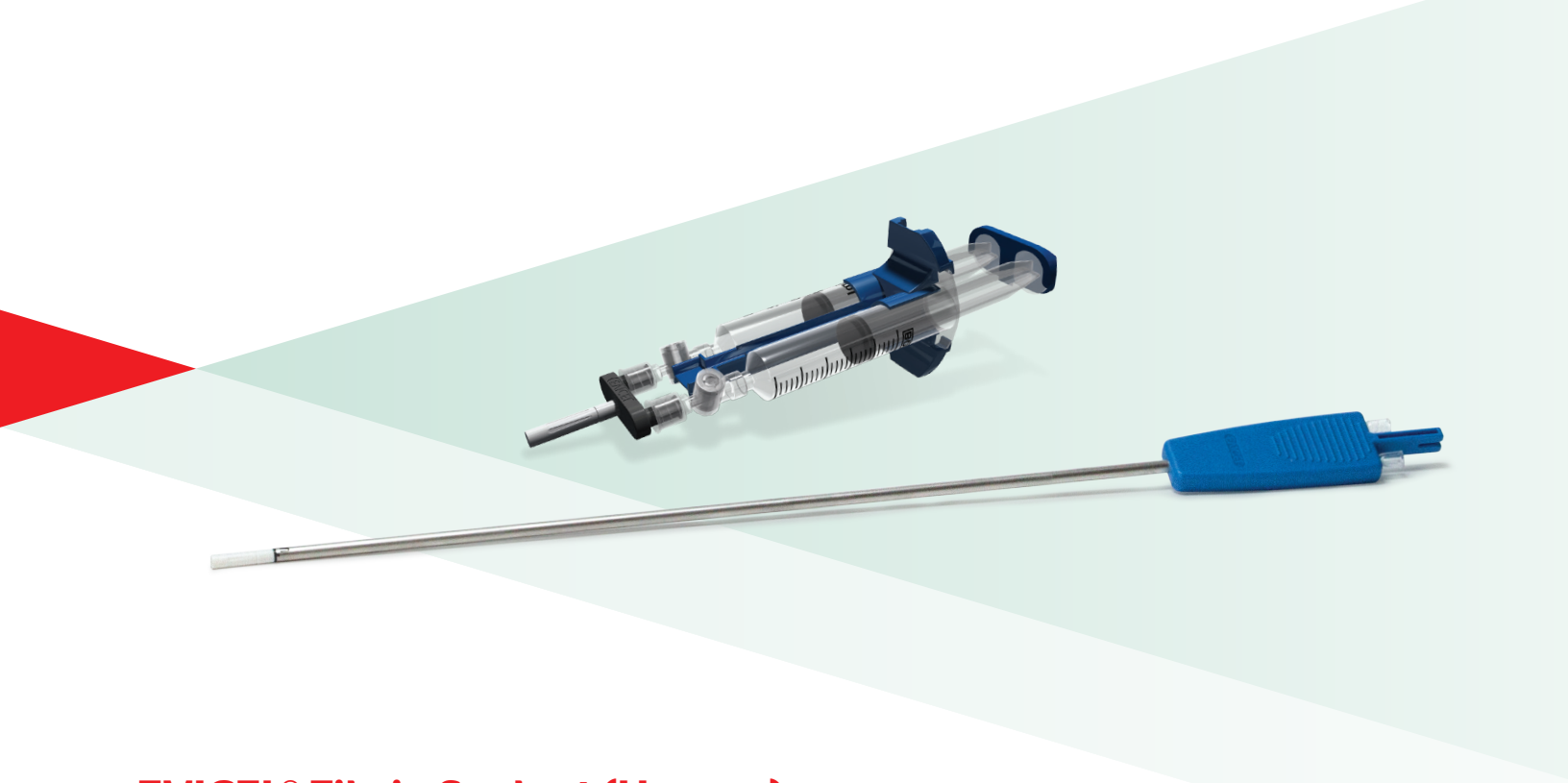


EVICEL® Fibrin Sealant (Human)

Excels in Burst Pressure Testing

EVICEL™ Airless Spray Accessory showed better clot strength and adherence vs TISSEEL® CO_2 assisted Spray[1]

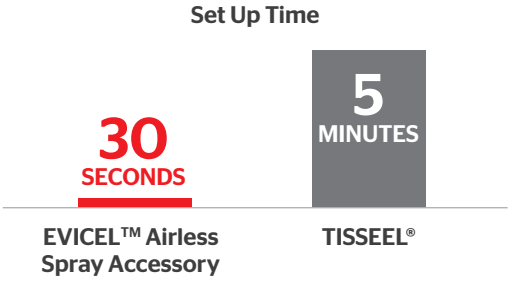
- Risk of potential bleeding complications in high-risk patients calls for a highly effective and time-efficient option[2,3]

EVICEL™ AIRLESS SPRAY TECHNOLOGY DEMONSTRATED 80% HIGHER MEAN BURST PRESSURE VS TISSEEL® CO_2 ASSISTED SPRAY IN BENCHTOP STUDY[1]

Biologic	Burst Pressure Mean (mmHg)	Standard Deviation (mmHg)
EVICEL®	355.0	147.1
TISSEEL®	197.6	112.1

P value=0.005 (statistically significant)

EVICEL™ AIRLESS SPRAY ACCESSORY AVERAGES 4.5 MINUTES FASTER SET-UP TIME THAN TISSEEL® DUPLOSPRAY SYSTEM[2]



With this technology, seeing is believing — ask your rep for a sample today!

EVICEL™ Airless Spray Accessory and gas-assisted TISSEEL® were sprayed onto tissue to test for burst-pressure failure.

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EVICEL® Solutions for Fibrin Sealant. Fibrinogen, Thrombin (Human)
MINIMUM PRODUT 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.

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

Please review the Product information before prescribing. Evicel is registered in Australia.

PBS Information: This product is not listed on the PBS

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

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

References: 1. Ghodbane, S. Burst Pressure Testing of Evicel and Tisseel Fibrin Sealant Sprays, March 8, 2019. Ethicon, Inc. **2.** ASA Design Validation Marketing Claims, August 2017. Ethicon, Inc. **3.** 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

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