

SURGICEL® Powder Absorbable Haemostat

Managing continuous oozing bleeding in liver resection

Maintaining haemostasis in liver resection is the single most important factor in ensuring a favorable outcome,¹ but dissection of liver parenchyma often leads to continuous oozing over broad areas. This bleeding challenge can prolong the surgery, and it may not stop with compression and simple packing.

SURGICEL Powder is designed to address continuous oozing of this type:

- Efficient control of continuous oozing bleeding on broad surfaces, in minimally invasive and open procedures²
- Due to its structure and penetrating ability, SURGICEL Powder may not require manual compression, which may be optimal for minimally invasive procedures or open procedures where manual compression is difficult to achieve^{3,4}
- Has been demonstrated to **sustain haemostasis** even when it is irrigated^{5*}

SURGICEL™ Endoscopic Applicator

Flexible Tip:

Flexible tip on both the open and endoscopic applicators allows for delivery in any direction or orientation in open and *laparoscopic* procedures.

Rigid Tip:

The rigid component of the endoscopic applicator is designed for one-handed application and enables easy access in *laparoscopic procedures*.

Efficient Delivery:

Efficient aspirator keeps powder securely in place until surgeon is ready to deploy, and modulates the amount of powder per pump for consistent expression regardless of device orientation.⁶

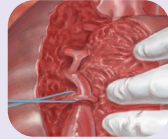


*Based on preclinical testing in a swine acute liver biopsy model

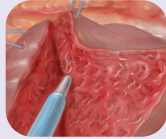
ADDRESSING SURGICAL BLEEDING IN LIVER RESECTION/HEPATOBIILIARY PANCREATIC (HPB) SURGERY

Will primary methods of haemostasis be effective or practical?

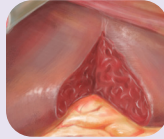
Potential bleeding sites



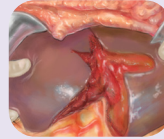
Hepatectomy



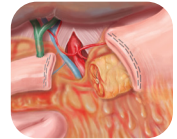
Subsegmental Resection



Wedge Resection



Liver Trauma



Pancreaticoduodenectomy (Soft Tissue)

Advanced Energy, Suture, and Clips

Compression/packaging

YES ▶

Primary methods of haemostasis

NO ▶

Bleeding challenges requiring an adjunctive haemostat

Can you see the source of the bleeding and apply an adjunctive haemostat?

YES



Continuous oozing

Will not stop with compression/simple packing. The solution for this bleeding is more time consuming than it is difficult.⁷



SURGICEL Powder

- Continuous oozing bleeding is frustrating during liver resections, and it can lead to unnecessary delays
- SURGICEL Powder provides efficient control of continuous oozing bleeding on broad surfaces²

YES



Problematic

Even though the bleeding is accessible, it could be trouble. It is more than routine and likely to be **resistant to conventional means**, and requires immediate attention causing disruption to the normal progression of surgery.⁷

Fibrin Patch

Is there intraoperative bleeding with a concern of postoperative rebleeding?

YES



Potential re-bleeding risk

Bleeding may be addressed intraoperatively, but could later **develop into more serious complications**, especially in high-risk patients.⁷



EVICEL® Solution for Fibrin Sealant Fibrinogen, Thrombin (Human)

NO



Difficult to access

Bleeding that **occurs in tight and irregular spaces** and you cannot see the exact source of the bleed. You are concerned accessing a tight space will cause more harm.⁷



SURGIFLO® Haemostatic Matrix

Closing SURGICEL® Absorbable Haemostat in a contaminated wound without drainage may lead to complications and should be avoided.

Although packing or wadding sometimes is medically necessary, SURGICEL® Absorbable Haemostat (oxidized regenerated cellulose) should not be used in this manner unless it is to be removed after haemostasis is achieved.

SURGICEL® Powder Absorbable Haemostat penetrates through the blood to stop bleeding at the source, for efficient control of continuous oozing during liver resections^{2,4}

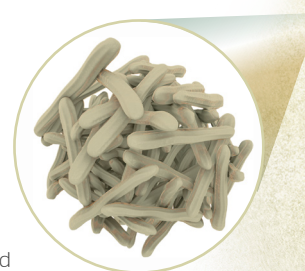
- SURGICEL Powder provides efficient control of continuous oozing bleeding on broad surfaces, such as liver parenchyma²
- Advanced applicator delivers consistent expression of powder for about 15 pumps, regardless of device orientation⁶
- Has been demonstrated to **sustain haemostasis** even when it is irrigated^{5*}

The next generation of SURGICEL® Absorbable Haemostat...

with everything you've come to expect from the world's #1 trusted brand of adjunctive hemostats with over 50 years of proven safety and efficacy⁸⁻¹⁰

- Can be stored at room temperature and is ready to use out of the package with no preparation required³
- Proven bactericidal in vitro against a broad range of gram-positive and gram-negative organisms, including various antibiotic-resistant bacteria (MRSA, VRE, PRSP and MRSE)³
- Fully absorbable within 7 to 14 days³
- ORC technology helps control capillary, venous, and small arterial haemorrhage³

*Based on preclinical testing in a swine acute liver biopsy model



SURGICEL Powder

is an aggregate of small oxidized regenerated cellulose (ORC) fiber fragments

EVICEL® Solutions for fibrin sealant. Fibrinogen, thrombin (human)

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 episodic 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.

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

PBS Information: This product is not listed on the PBS

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
128269-191123 Nov 2019

Manufacturer

Omxix Biopharmaceuticals, Ltd. Israel License No. 1603 US-2009/10/180

<https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2012-PI-02766-1122945-190911> Oct 2019

References: **1.** Poon RT. Current techniques of liver transection. *HPB*. 2007;9:166-73. **2.** MacDonald M. SURGICEL® Powder versus Competitive Powdered Hemostats. Final Report, PSE Accession No. 16-0006, Project No. 16438. March 8, 2016. Ethicon, Inc. **3.** SURGICEL® Powder Absorbable Hemostat. Instructions for Use. Ethicon, Inc. **4.** Wang A. Surface energy/tension analysis among ORC Aggregate, ORC Fine Fiber, and Arista - Project PIXIE. Ethicon, Inc. **5.** MacDonald M. SURGICEL® Powder versus ARISTA™ AH. Final Report, PSE Accession No. 15-0120, Project No. 16438. September 2, 2015. Ethicon, Inc. **6.** SURGICEL Powder vs. Arista AH Expression Testing. ADAPTIV document 100293850-1. Ethicon, Inc. **7.** S-Factors Faculty Training, May 2015. Ethicon, Inc. **8.** Hong YM, Loughlin KR. The use of hemostatic agents and sealants in urology. *J Urol*. 2006;176(6 Pt 1):2367-2374. **9.** SURGICEL® Absorbable Hemostat. Full Prescribing Information, Ethicon, Inc. **10.** Quarterly Report. Ethicon, Inc.