Haemostasis Optimisation Program
A systematic approach to bleeding

Addressing Surgical Bleeding Situations With Adjunctive Haemostats*

	Continuous oozing	Problematic	Difficult to access	Potential re-bleeding risk	High-pressure vessel bleeding
Bleeding Situations	**Will not stop with compression/simple packing.** The solution for this bleeding is more time consuming than it is difficult.[1]	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.[1]	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.[1]	Bleeding may be addressed intraoperatively, but could later **develop into more serious complications,** especially in high-risk patients.[1]	A **leak in a high-pressure vessel** (aortic or peripheral vascular suture line) that has been stopped but could be catastrophic if it leaks post-op.[1]
Category Solutions	**Oxidized regenerated cellulose (ORC)** An absorbable plant-based biomaterial that expedites the hemostasis process by serving as a scaffold for platelet adhesion and aggregation that aids clot formation.[2,3]	**Fibrin patch** Fibrinogen/thrombin patch provides mechanical integrity and supports clot formation independently of the patient coagulation profile.[3,]	**Flowable gelatin** A gelatin-based foam that flows into the bleeding area and serves as a scaffold for platelet adhesion and can be combined with thrombin to expedite clot formation.[3,4]	**Fibrin sealant** Fibrinogen and thrombin, when mixed, create a fibrin clot independent of the patient coagulation profile.[5,6]	**Vascular sealant** A surgical adhesive that secures suture lines and provides a mechanical seal.[3]
	SURGICEL™ Absorbable Haemostats	**SURGIFLO™ Haemostatic Matrix**		**EVICEL™ Solutions for Sealant** (Human Thrombin, Human Fibrinogen)	

***The bleeding situations identified reflect customer insights/market research on optimal adjunctive hemostat utilization. The product solutions should only be used in accordance with their instructions for use. Product recommendations should not supplant medical judgment. Surgeon preference, experience, and patient needs may dictate alternate technique. Review all relevant precautions, especially the indications, contraindications, warnings, and information for use. Please see package inserts for Full Prescribing Information.**
The visual does not reflect any sequential order in use.

References: 1. Ethicon, 20130614, Hemostasis Optimization Program and Next Steps Meeting, June 2014, Data on File, 2. SURGICEL Fibrillar Instructions for Use, Ethicon Inc, 3. Spotnitz WD. Hemostats, Sealants, and Adhesives: A Practical Guide for the Surgeon. The American Surgeon 2012; 78: 1305-1321. 4. SURGIFLO™ Hemostatic Matrix Kit with Thrombin Instructions for use, Ethicon, Inc 5. Ethicon, EVICEL® Solutions for Sealant (Human Thrombin, Human Fibrinogen). Summary of Product Characteristics, December 2014. Data on File. 6. Dickneite G et al. A comparison of fibrin sealants in relation to their in vitro and in vivo properties. Thrombosis Research 112 (2003) 73– 82..

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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: 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. Spray using 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 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.

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 device at higher than recommended pressures and/or in close proximity to tissue. Spray only with CE-marked EVICEL application device or accessory tip. Spray only if able to accurately judge spray distance. Use only Omrix Pressure Regulator.

Surgery	Tip	Distance	Pressure
Open	6cm flexible	10 – 15 cm	1.4 – 1.7 bar
Open	35 cm rigid	10 – 15 cm	1.4 – 1.7 bar
Open	45 cm Flexible	10 – 15 cm	1.4 – 1.7 bar
Laparoscopic	35 cm rigid	4 – 10 cm	1.0 – 1.4 bar
Laparoscopic	45 cm flexible	4 – 10 cm	1.4 bar

When spraying EVICEL, monitor for air or gas embolism. Apply as thin layer; excessive thickness may impede efficacy and wound healing. Inadequate data to support use in tissue gluing, application through an 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 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.

UNDESIRABLE EFFECTS: (See SmPC for full listing). 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. Mild reactions can be managed with anti-histamines. Severe hypotensive reactions require immediate intervention using current principles of shock therapy. In abdominal clinical trials, abdominal abscess was reported commonly. In vascular clinical trials the following events were reported commonly: graft infection, staphylococcal infection, haematoma, 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.

SUPPLY CLASSIFICATION: Medicinal product subject to restricted medical prescription

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.

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PHARMACOVIGILANCE:

Adverse events should be reported via the appropriate national reporting system. 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