ETHICON



Nothing is more important than **your patients**.

Balancing the requirements of your patients, the needs of your surgical team, and budget constraints can be challenging.

You need a portfolio of adjunctive hemostats that can help you achieve positive patient outcomes while minimizing hospital resource utilization.

DISCLAIMER: This brochure contains healthcare economic information intended for evaluation by formulary committees, pharmacy and therapeutics committees, medical advisory boards, technology assessment panels, medical directors, or other individuals or entities who have responsibility for the selection of drugs/medical devices or who advise those with such responsibility. The information contained herein is not intended for evaluation by medical practitioners making prescribing decisions for individual patients.

Your Patients Are Complex

A growing number of surgical **patients** are considered **high risk** because of **existing comorbidities**, **coagulopathies** (bleeding conditions), or the use of **anticoagulants**.¹⁻⁴



High-risk patients are more likely to experience **rebleeding events.**¹⁻³



As many as

32% to 68%

of procedures involve a major bleeding event.⁵



Up to **25%**

of procedures may result in bleeding because of patient medications.¹⁵

The Value of Adjunctive Hemostats

Challenging and uncontrollable bleeding during surgery is associated with high rates of morbidity.¹

When adjunctive hemostats are used,*



Up to 40% fewer patients require transfusion⁶⁻¹⁴



Length of hospital stay is reduced by up to **4 days**^{6,15,16}



Operating room time is reduced by **15 to 25**

15 to 25 minutes¹⁶⁻¹⁸



The rate of readmission is

significantly reduced^{19,†}

*Results may vary by specific adjunctive hemostat used.

†As per a retrospective matched cohort study.

Controlling surgical bleeding reduced hospital costs from

20% to 53%

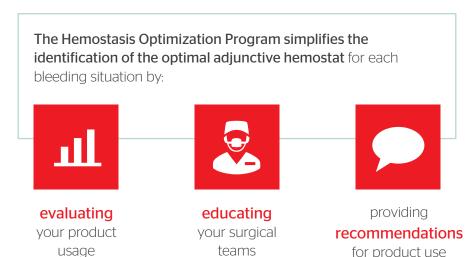
across procedure types based on a retrospective data analysis.^{5,‡}

†Including cardiac revascularization and valve surgery, hepatic resection, and radical abdominal hysterectomy.

Your Partner in Patient Care

At Ethicon we understand that the selection and purchase of adjunctive hemostats can be confusing.

We Can Help



A Systematic Approach to Bleeding

Different types of bleeding situations require unique solutions. Ethicon's portfolio of adjunctive hemostats has solutions for a variety of bleeding situations.²⁰

Bleeding Situation	ETHICON's Solution
Continuous oozing ²⁰	SURGICEL® Family of Absorbable Hemostats
Problematic ²⁰	EVARREST® Fibrin Sealant Patch
Potential rebleeding risk ²⁰	EVICEL® Fibrin Sealant (Human)
Difficult-to-access ²⁰	SURGIFLO® Hemostatic Matrix

The products within the portfolio can help promote **optimal outcomes** for your patients while supporting **cost-effective utilization**.





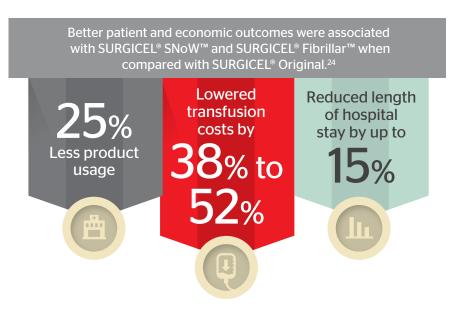
Family of Absorbable Hemostats



Continuous oozing. Will not stop with compression/ simple packing. The solution for this bleeding is more time consuming than it is difficult.²⁰

SURGICEL has more than 150 million uses worldwide, ²¹ a proven record of safety and clinical efficacy, ^{21,22} and is the leader in managing a broad spectrum of continuous-oozing situations. ^{23,24}

SURGICEL® SNoW™ and SURGICEL® Fibrillar™, when compared with SURGICEL® Original, were associated with a reduction in total hospital costs of up to 18%.²⁴



One layer of SURGICEL® SNoW™ and SURGICEL® Fibrillar™ is each more effective than four layers of SURGICEL® Original.²⁵



EVARREST®

Fibrin Sealant Patch



Problematic bleeding. 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.²⁰

The EVARREST® Fibrin Sealant Patch innovation offers **superior hemostatic efficacy** on the first attempt.*

Prospective clinical trials have suggested that you may save more per patient with EVARREST®, when compared with Tachosil®, during a cardiovascular procedure.²⁶⁻³¹



As the complexity of a bleeding situation increases, so do the **potential savings** associated with EVARREST®. ²⁶⁻³¹

*EVARREST demonstrated hemostatic superiority across 4 clinical trials. **Trial 1:** Soft tissue hemorrhage (per protocol efficacy measured at n=87, safety assessed at n=141) 100% vs 53.3% for Surgicel, 0.46.7%, R-0001; **Trial 2:** Normal and abnormal liver resection hemorrhage (per protocol efficacy measured at n=77, safety assessed at n=104), 94.3% vs 28.6% for conventional adjunctive methods, Δ 65.7%, R-0001; **Trial 3:** Anatomic and nonanatomic liver resection hemorrhage (per protocol efficacy measured at n=48, safety assessed at n=102), 97.9% vs 44.4% for conventional adjunctive methods, Δ 53.5, R-0001; **Trial 4:** Aortic reconstruction (per protocol efficacy measured at n=141, safety assessed at n=156), 78.8% vs 46.7% for Tachosil, Δ 32.1%, R-0001.



EVICEL®

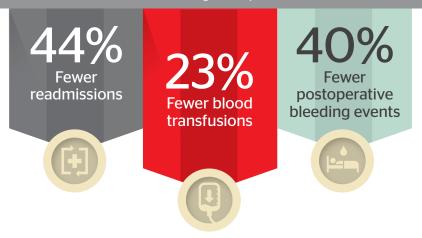
Fibrin Sealant (Human)



Potential rebleeding risk. Bleeding may be addressed intraoperatively, but could later develop into more serious complications, especially in high-risk patients.²⁰

Fibrin sealants work independently of a patient's coagulation system, making them an effective adjunctive hemostat in high-risk patients. Studies have suggested, however, that all fibrin sealants do not perform equally.¹⁻⁴

A retrospective database analysis has suggested that you may save up to \$5500 more per patient with EVICEL®, when compared with Tisseel®, during CABG procedures.32



Better patient outcomes were associated with **FVICFI** * than with Tisseel*

EVICEL® and TISSEEL® have not been determined by adequate and well-controlled studies to be equivalent in safety or efficacy. The study only compares economic impacts associated with the products.

CABG=coronary artery bypass graft.

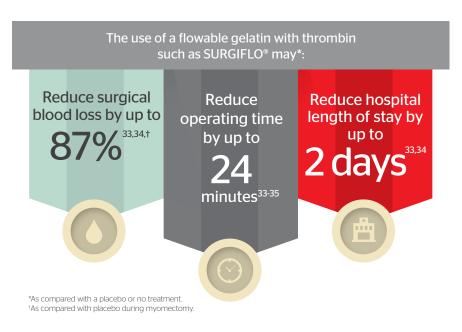




Hemostatic Matrix



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.²⁰



Effective performance and utilization

The use of SURGIFLO®, when compared to Floseal®, was associated with:

- Preferred product consistency that remains uniformly flowable for 8 hours^{36,37}
- Quicker and easier preparation^{38,39}
- A cost reduction of \$150 per surgery for an average 4-hour spinal surgery⁴⁰

With Ethicon's portfolio of adjunctive hemostats, you can help achieve positive patient outcomes while minimizing hospital resource utilization.

EVARREST® Fibrin Sealant Patch

IMPORTANT SAFETY INFORMATION INDICATIONS AND USAGE

EVARREST® is a fibrin sealant patch indicated for use with manual compression as an adjunct to hemostasis in adult patients undergoing surgery, when control of bleeding by conventional surgical techniques (such as suture, ligature, and cautery) is ineffective or impractical.

LIMITATIONS FOR USE

- Cannot be used in place of sutures or other forms of mechanical ligation in the treatment of major arterial or venous bleeding.
- Not for use in children under one month of age
- Laparoscopic and other minimally invasive surgeries where manual compression would be difficult to achieve.

IMPORTANT SAFETY INFORMATION

For topical use only. Apply immediate manual compression over the entire surface of the patch and maintain contact pressure for 3 minutes to control the bleeding.

Do not apply intravascularly. This can result in life threatening thromboembolic events.

Do not use to treat bleeding from large defects in arteries or veins where the injured vascular wall requires conventional surgical repair and maintenance of vessel patency or where there would be persistent exposure of EVARREST® to blood flow and/or pressure during absorption of the product. Thrombosis can occur if absorbed systemically.

Do not use in individuals known to have anaphylactic or severe systemic reaction to human blood products. EVARREST® can cause hypersensitivity reactions including anaphylaxis.

Avoid application to contaminated areas of the body or in the presence of active infection. Infection can occur.

EVARREST contains oxidized regenerated cellulose which adheres to bleeding surfaces. Inadvertent adhesions can occur.

Avoid use in, around, or in proximity to, foramina in bone or areas of bony confines where swelling may cause compression.

Use the least number of patches required to cover the entire bleeding area. Portions of excess patch material can become dislodged and migrate to other areas of the body.

Do not use more than eight 2x4 inch $(5.1 \times 10.2 \text{ cm})$ or more than four 4x4 inch $(10.2 \times 10.2 \text{ cm})$ patches.

Use in patients who have been previously exposed to EVARREST® has not been studied.

May carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

The adverse reactions reported during clinical trials occurred in less than 1% of all cases and included deep venous thrombosis, pulmonary embolism, blood fibrinogen increase, anastomotic hemorrhage,

post procedural and intra-abdominal hemorrhage, abdominal distension, anemia, gastrointestinal hemorrhage, thoracic cavity drainage, pleural effusion, abdominal abscess, ascites, localized intra-abdominal fluid collection, cardiac failure, operative hemorrhage, and ischemic bowel

Pediatrics: Safety and effectiveness in pediatric patients have not been established. Use in children under the age of one month may be unsafe or ineffective due to small size and limited ability to apply the patch as recommended.

Please see package insert for EVARREST® Full Prescribing Information.

To report SUSPECTED ADVERSE REACTIONS, contact ETHICON Customer Support Center at 1-877-384-4266 or FDA at 1-800-FDA-1088 or www.fda. gov/medwatch.

030813-171115

EVICEL® Fibrin Sealant (Human)

IMPORTANT SAFETY INFORMATION

INDICATION

EVICEL® Fibrin Sealant (Human) is indicated as an adjunct to hemostasis for use in patients undergoing surgery, when control of bleeding by standard surgical techniques (such as suture, ligature, or cautery) is ineffective or impractical.

CONTRAINDICATIONS

- Do not inject directly into the circulatory system. Intravascular application of EVICEL® may result in life-threatening thromboembolic events.
- Do not use in individuals known to have anaphylactic or severe systemic reaction to human blood products.
- Do not use for the treatment of severe or brisk arterial bleeding.
- Do not use EVICEL® for spraying in endoscopic or laparoscopic procedures where the minimum recommended distance from the applicator tip to the target site cannot be ensured.

WARNINGS AND PRECAUTIONS

- Life-threatening air or gas embolism has occurred with the use of spray devices employing a pressure regulator to administer EVICEL®. This event appears to be related to the use of the spray device at pressures higher than recommended and/or at distances closer than recommended to the surface of the tissue.
- Monitor changes in blood pressure, pulse, oxygen saturation, and end-tidal CO₂ when spraying EVICEL® because of the possibility of gas embolism.
- To reduce the risk of potentially life-threatening gas embolism, spray EVICEL® using only pressurized CO₂ gas at the pressures and distances recommended for the specific tips.
- Use EVICEL® spray application only if it is possible to accurately judge the spray distance, especially during endoscopic or laparoscopic procedures.
- Prior to applying EVICEL®, dry surface areas of the wound by standard techniques (e.g. intermittent)

application of compresses, swabs, use of suction devices). Prepare and administer EVICEL® according to the instructions and with only devices recommended for this product.

 May carry a risk of transmitting infectious agents, e.g. viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

The most common adverse reactions reported in clinical trials are peripheral edema, abdominal abscess, infection, hematoma, incision site hemorrhage, vascular graft occlusion, postoperative wound complication and decreased hemoglobin.

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

021323-170803

EVITHROM® Thrombin, Topical (Human) for Topical Use Only

Lyophilized Powder for Solution

EVITHROM® is a topical thrombin indicated as an aid to hemostasis whenever oozing blood and minor bleeding from capillaries and small venules is accessible and control of bleeding by standard surgical techniques (such as suture, ligature or cautery) is ineffective or impractical.

EVITHROM® may be used in conjunction with an Absorbable Gelatin Sponge, USP.

IMPORTANT SAFETY INFORMATION

- For topical use only.
- · Do not inject.
- There is a potential risk of thrombosis if absorbed systemically.
- The amount of EVITHROM® required depends upon the area of tissue to be treated and the method of application. In clinical studies, volumes up to 10 ml were used in conjunction with Absorbable Gelatin Sponge.
- Do not use for the treatment of severe or brisk arterial bleeding.
- Do not use in individuals known to have anaphylactic or severe systemic reaction to human blood products. May carry a risk of transmitting infectious agents such as viruses and theoretically, the Creutzfeldt-Jakob disease (CJD) agent, despite manufacturing steps designed to reduce the risk of viral transmission.
- The most common adverse reactions during clinical trial (reported in at least 2% of subjects treated with EVITHROM®) were prolonged activated partial thromboplastin time, increased INR, decreased lymphocyte count, prolonged prothrombin time and increased neutrophil count.
- None of the patients treated with EVITHROM developed antibodies to human thrombin or to human Factor V/Va. The clinical significance of these findings is unknown.

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

021328-140912

SURGICEL Essential Product Information INDICATIONS

SURGICEL® Absorbable Hemostat (oxidized regenerated cellulose) is used adjunctively in surgical procedures to assist in the control of capillary, venous, and small arterial hemorrhage when ligation or other conventional methods of control are impractical or ineffective. SURGICEL® ORIGINAL, SURGICEL® FIBRILLAR™ and SURGICEL® NU-KNIT® Hemostats can be cut to size for use in endoscopic procedures.

PRECAUTIONS

Use only as much SURGICEL® Absorbable Hemostat as is necessary for hemostasis, holding it firmly in place until bleeding stops. Remove any excess before surgical closure in order to facilitate absorption and minimize the possibility of foreign body reaction.

In urological procedures, minimal amounts of SURGICEL® Absorbable Hemostat should be used and care must be exercised to prevent plugging of the urethra, ureter, or a catheter by dislodged portions of the product.

Since absorption of SURGICEL® Absorbable Hemostat could be prevented in chemically cauterized areas, its use should not be preceded by application of silver nitrate or any other escharotic chemicals.

If SURGICEL® Absorbable Hemostat is used temporarily to line the cavity of large open wounds, it should be placed so as not to overlap the skin edges. It should also be removed from open wounds by forceps or by irrigation with sterile water or saline solution after bleeding has stopped.

Precautions should be taken in otorhinolaryngologic surgery to assure that none of the material is aspirated by the patient. (Examples: controlling hemorrhage after tonsillectomy and controlling epistaxis.)

Care should be taken not to apply SURGICEL®
Absorbable Hemostat too tightly when it is used as a wrap during vascular surgery (see Adverse Reactions).

ADVERSE EVENTS

"Encapsulation" of fluid and foreign body reactions have been reported.

There have been reports of stenotic effect when SURGICEL® Absorbable Hemostat has been applied as a wrap during vascular surgery.

Paralysis and nerve damage have been reported when SURGICEL® Absorbable Hemostat was used around, in, or in proximity to foramina in bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm.

Blindness has been reported in connection with surgical repair of a lacerated left frontal lobe when SURGICEL® Absorbable Hemostat was placed in the anterior cranial fossa.

Possible prolongation of drainage in cholecystectomies and difficulty passing urine per urethra after prostatectomy have been reported.

For more information, please consult your doctor or for product quality and technical questions, call 1-800-795-0012.

063768-161128

SURGIFLO® Hemostatic Matrix Kit Essential Product Information (Made from Absorbable Gelatin Sponge, USP) with Thrombin

DESCRIPTION

SURGIFLO® with Thrombin (SURGIFLO® Hemostatic Matrix Kit) is intended for hemostatic use by applying to a bleeding surface.

ACTIONS

When used in appropriate amounts SURGIFLO® is absorbed completely within 4 to 6 weeks.

INTENDED USE/INDICATIONS

SURGIFLO®, mixed with thrombin solution, is indicated in surgical procedures (other than ophthalmic) as an adjunct to hemostasis when control of bleeding by ligature or other conventional methods is ineffective or impractical.

CONTRAINDICATIONS

- Do not use SURGIFLO® in intravascular compartments because of the risk of embolization.
- Do not use SURGIFLO® in patients with known allergies to porcine gelatin.
- Do not use SURGIFLO® in closure of skin incisions because it may interfere with the healing of skin edges. This interference is due to mechanical interposition of gelatin and is not secondary to intrinsic interference with wound healing.

WARNINGS

- SURGIFLO® should not be used in the presence of infection and should be used with caution in contaminated areas of the body
- SURGIFLO® should not be used in instances of pumping arterial hemorrhage. SURGIFLO® will not act as a tampon or plug in a bleeding site.
- SURGIFLO® should be removed from the site of application when used in, around, or in proximity to foramina in bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm because it may swell resulting in nerve damage.
- Excess SURGIFLO® should be removed once hemostasis has been achieved.
- The safety and effectiveness of SURGIFLO® for use in ophthalmic procedures has not been established.
- SURGIFLO® should not be used for controlling postpartum intrauterine bleeding or menorrhagia.
- The safety and effectiveness of SURGIFLO® has not been established in children and pregnant women.
- The blue flexible applicator tip should not be trimmed to avoid exposing internal guidewire.
- The white straight applicator tip should be trimmed away from the surgical area. Cut a square angle to avoid creating a sharp tip.

PRECAUTIONS

 Safe and effective use of SURGIFOAM® Sponge has been reported in a published neurologic retrospective study involving 1700 cases in Europe.
 Safe and effective use in neurosurgery has not been proven through randomized, controlled clinical studies in the United States.

- SURGIFLO® is supplied as a sterile product and cannot be resterilized.
- SURGIFLO® should not be used for packing unless excess product that is not needed to maintain hemostasis is removed. SURGIFLO® may swell up to 20% upon contact with additional fluid.
- SURGIFLO® should not be used in conjunction with autologous blood salvage circuits.
- SURGIFLO® should not be used in conjunction with methylmethacrylate adhesives.
- In urological procedures, SURGIFLO® should not be left in the renal pelvis or ureters to eliminate the potential foci for calculus formation.

ADVERSE EVENTS

A total of 142 patients received SURGIFOAM® Sponge during a clinical trial comparing SURGIFOAM® Sponge to another absorbable gelatin sponge. In general, the following adverse events have been reported with the use of absorbable porcine gelatin-based hemostatic agents:

- Gelatin-based hemostatic agents may serve as a nidus for infection and abscess formation and have been reported to potentiate bacterial growth.
- Giant cell granulomas have been observed at implant sites when used in the brain.
- Compression of the brain and spinal cord resulting from the accumulation of sterile fluid have been observed.
- Multiple neurologic events were reported when absorbable gelatin-based hemostatic agents were used in laminectomy operations, including cauda equina syndrome, spinal stenosis, meningitis, arachnoiditis, headaches, paresthesias, pain, bladder and bowel dysfunction, and impotence.
- The use of absorbable gelatin-based hemostatic agents during the repair of dural defects associated with laminectomy and craniotomy operations, has been associated with fever, infection, leg paresthesias, neck and back pain, bladder and bowel incontinence, cauda equina syndrome, neurogenic bladder, impotence, and paresis.
- The use of absorbable gelatin-based hemostatic agents has been associated with paralysis, due to device migration into foramina in the bone around the spinal cord, and blindness, due to device migration in the orbit of the eye, during lobectomy, laminectomy, and repair of a frontal skull fracture and lacerated lobe.
- Foreign body reactions, "encapsulation" of fluid, and hematoma have been observed at implant sites.
- Excessive fibrosis and prolonged fixation of a tendon have been reported when absorbable gelatin-based sponges were used in severed tendon repair.
- Toxic shock syndrome was reported in association with the use of absorbable gelatin-based hemostats in nasal surgery.
- Fever, failure of absorption, and hearing loss have been observed when absorbable hemostatic agents were used during tympanoplasty.

063756-161128

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To learn more about **Ethicon's portfolio of adjunctive hemostats** or implementing the Hemostasis Optimization Program, please contact your Ethicon Sales representative or call **1-877-ETHICON**.









For more information visit

http://www.ethicon.com/healthcare-professionals/products/biosurgery

