



SURGIFLO® Hemostatic Matrix with EVITHROM® Thrombin, Topical (Human)

Offering the same benefits and performance you've come to expect from SURGIFLO® with additional cost savings¹⁻³

Achieves visibility fast¹⁻³

- When mixed with 2mL of EVITHROM Thrombin Topical stops bleeding in less than 1 minute^{4*}

Simple preparation¹⁻³

- Ready to use in 30 seconds or less once liquid thrombin is delivered to the sterile field

Precision where you need it

- Blue Flex Tip: Can be bent to the desired angle
- Standard Long White Tip: Can be cut to the length you desire

*In animal models

Ordering Information		
Ordering Code	Size	Package
299102	SURGIFLO Hemostatic Matrix with 2ml Evithrom Thrombin Topical (8ml total yield)	Case of 6

For technical support, call 1-877-ETHICON (384-4266).
 For additional information, visit www.ethicon.com.
 Call 1-800-255-2500 to order.



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 ligation 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 post-partum 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.

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EVITHROM[®] Thrombin, Topical (Human) Topical Use Only, Frozen Solution

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

Important Safety Information

- For topical use only.
- Do not inject EVITHROM Thrombin Topical directly into the circulatory system.
- 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. There is a potential risk of thrombosis if absorbed systemically.
- 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 Thrombin Topical) were prolonged activated partial thromboplastin time, increased INR, decreased lymphocyte count, prolonged prothrombin time and increased neutrophil count. Adverse events were reported in the clinical trial with similar frequency in the two study groups (EVITHROM Thrombin Topical or bovine thrombin group).
- Anaphylactic reactions may occur.
- Immunogenicity was evaluated by testing for the development of antibodies to highly purified antigens: human thrombin, human Factor V/Va, bovine thrombin and bovine Factor V/Va. None of the patients treated with EVITHROM Thrombin Topical developed antibodies to human thrombin or to human Factor V/Va.

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

Surgiflo®



EVITHROM® Storage and Thawing

- EVITHROM Thrombin Topical comes ready to use directly from the vial (once thawed)²
- EVITHROM Thrombin Topical can be refrigerated for up to 30 days²
- EVITHROM Thrombin Topical is stable for up to 24 hours at room temperature²
- EVITHROM Thrombin Topical can be thawed by using one of the following methods²:
 - 2°C to 8°C (refrigerator) to thaw within 1 day
 - 20°C to 25°C (room temperature) to thaw within 1 hour
 - 37°C to thaw within 10 minutes and must not be left at this temperature for longer than 10 minutes

References: **1.** SURGIFLO® Assembly Time Data on File. Technical Report O5-0015 SURGIFLO® Plus Thrombin Compared to Floseal Kit Hemo Efficacy. Pdf. **2.** EVITHROM® Thrombin, Topical (Human) Prescribing Information, Ethicon, Inc. **3.** SURGIFLO® Technical Report.pdf. **4.** Langkild S. Evaluation of the Dose Response Curve for Hemostatic Efficacy of Surgiflo Next Generation Mixed with Thrombin. Ferrosan Medical Devices, Report NG 162, dated 7/10/2013.

Simple Preparation



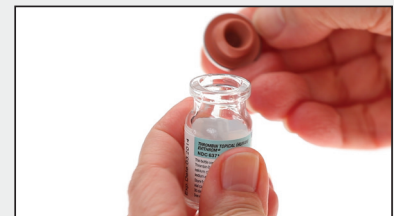
1. Remove flip-off plastic cap



2. Pull Tab



3. Remove Ring



4. Remove Stopper



5. Pour