SURGIFLO® Hemostatic Matrix Kit

SURGIFLO® and Go

Bleeding won't wait.
Neither should you.

ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

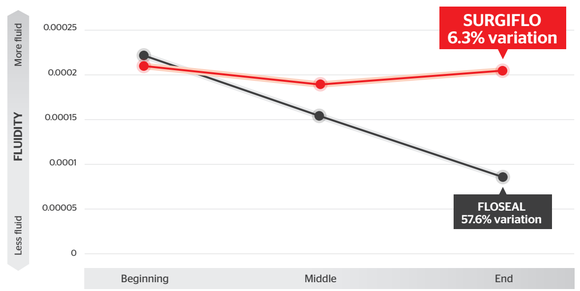
Shaping
the future
of surgery

SURGIFLO® Hemostatic Matrix Kit fills and envelops bleeding sites—**to stop bleeding fast**

SURGIFLO® **stays in place even during active bleeding**, so you can count on it to deliver fast hemostasis right where you need it.[1-3]

SURGIFLO® **maintains uniform viscosity** better from beginning to end than FLOSEAL[4]*

VARIATION IN MATRIX FLOWABILITY (as measured immediately after preparation)[4]**



SURGIFLO® with Thrombin achieved hemostasis in under a minute in an animal model[5]

*Based on in vitro viscosity testing of SURGIFLO® 8 mL and FLOSEAL Hemostatic Matrix 5 mL; each product was prepared following Instructions for Use.

References: 1. Zhang G. Gelatin paste density in SURGIFLO next generation product. Technical report. March 3, 2011. Ethicon, Inc. **2.** Werrlein S. Evaluation of the conformability of SURGIFLO (pre-filled flowable hemostat) vs. SURGIFOAM absorbable gelatin sponge. PSE Accession No. 04-0624, Project No. 6731.4. December 10, 2004, Ethicon, Inc. **3.** Werrlein S. Evaluation of the Hemostatic Efficacy of SURGIFLO (Pre-filled Flowable Hemostat) Plus Thrombin Compared to FLOSEAL Kit, PSE Accession No. 05-0015, Project No. 6731.4, February 14, 2005, Ethicon, Inc..

SURGIFLO® is backed by robust clinical data demonstrating **proven efficacy**, safety, and efficiency[6]

SURGIFLO® is backed by extensive clinical data. A systematic review and meta-analysis of **6 clinical studies across 39,660 patients** demonstrated efficacy and safety across the following endpoints[6]:

Blood transfusions

Minor/major complications

Surgical/ operating time

4. Wang A. Measurements of viscosity and thrombin activity of SURGIFLO 2993 as compared to FLOSEAL over time. Technical report. April 7, 2013. Ethicon, Inc. **5.** Langkilde S. Evaluation of the dose response curve for hemostatic efficacy of SURGIFLO next generation mixed with thrombin. Report NG-162. 2013. Ethicon, Inc. **6.** Valls M, Amazan R, Fernandez R, et al. Systematic revision and meta-analysis of hemostatic matrices for bleeding control. ISPOR Poster. 2016. Ethicon, Inc.

SURGIFLO® stops bleeding fast to help surgeries **flow faster**

SURGIFLO® is ready over **2 minutes faster** than FLOSEAL, so you can stop bleeding without interrupting the flow of your procedure.[7-9]

Ready to use in

30 seconds

or less once thrombin or saline solution is delivered to sterile field[10]

Reconstituting thrombin takes

13 seconds

vs. 136 seconds for FLOSEAL[9]

Stops bleeding before FLOSEAL is ready to use[9]

7. SURGIFLO Hemostatic Matrix Kit (2994) Instructions for Use. Ethicon, Inc. **8.** FLOSEAL Hemostatic Matrix. Instructions for Use. Baxter Healthcare. **9.** Comparison of thrombin reconstitution time in SURGIFLO Hemostatic Matrix Kit vs. FLOSEAL Hemostatic Matrix. 11052017. Ethicon, Inc. **10.** SURGIFLO® Technical Report, 2017. Ethicon, Inc.

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.
- Apply EVITHROM® on the surface of bleeding tissue only.
- 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. Hypersensitivity reactions, including anaphylaxis, may occur.
- 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®) 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.

021328-180430

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 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.

063756-161128

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

DESCRIPTION

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

ACTIONS

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

INTENDED USE/INDICATIONS

SURGIFLO® Hemostatic Matrix , mixed with with sterile saline or 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® Hemostatic Matrix in intravascular compartments because of the risk of embolization.
- Do not use SURGIFLO® Hemostatic Matrix in patients with known allergies to porcine gelatin.
- Do not use SURGIFLO® Hemostatic Matrix 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® Hemostatic Matrix should not be used in the presence of infection and should be used with caution in contaminated areas of the body
- SURGIFLO® Hemostatic Matrix should not be used in instances of pumping arterial hemorrhage. SURGIFLO® Hemostatic Matrix will not act as a tampon or plug in a bleeding site.
- SURGIFLO® Hemostatic Matrix 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® Hemostatic Matrix should be removed once hemostasis has been achieved.
- The safety and effectiveness of SURGIFLO® Hemostatic Matrix for use in ophthalmic procedures has not been established.
- SURGIFLO® Hemostatic Matrix should not be used for controlling post-partum intrauterine bleeding or menorrhagia.
- The safety and effectiveness of SURGIFLO® Hemostatic Matrix 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® Hemostatic Matrix is supplied as a sterile product and cannot be resterilized.
- SURGIFLO® Hemostatic Matrix should not be used for packing unless excess product that is not needed to maintain hemostasis is removed. SURGIFLO® Hemostatic Matrix may swell up to 20% upon contact with additional fluid.
- SURGIFLO® Hemostatic Matrix should not be used in conjunction with autologous blood salvage circuits.
- SURGIFLO® Hemostatic Matrix should not be used in conjunction with methylmethacrylate adhesives.
- In urological procedures, SURGIFLO® Hemostatic Matrix 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.

064302-161208

SURGIFLO® Hemostatic Matrix Kit—
helping surgeries flow faster

Ordering code	Size	Package
2994	8 mL SURGIFLO® Hemostatic Matrix Kit with thrombin (fully sterile)	Case of 6
2991	8 mL SURGIFLO® Hemostatic Matrix	Case of 6
MS1995	34 cm Endoscopic Applicator	Case of 6

For technical support, call 1-877-ETHICON.
For additional information, visit www.ethicon.com.

Call 1-800-255-2500 to order.

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Shaping the future of surgery

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

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

Do not inject into blood vessels.

DESCRIPTION

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

The Kit contains:

1. A sterile tray with *all* sterile components to prepare the Flowable Gelatin Matrix,
2. A sterile tray with *all* surface sterilized Thrombin kit components to prepare the Thrombin Solution.
    1. The Flowable Gelatin Matrix comes in a tray with *all* sterile components:
        - A sterile pre-filled blue plunger syringe containing the porcine Gelatin Matrix that is off-white in appearance,
        - A sterile empty syringe,
        - A sterile liquid transfer cup,
        - A sterile blue flexible applicator tip that is bendable in all directions, and
        - A sterile white applicator tip that can be trimmed to desired length
    2. The surface sterilized components to prepare the Thrombin Solution include:
        - A Thrombin vial, EVITHROM® Thrombin, Topical (Human), containing 2000 International Units (IU) of sterile lyophilized human thrombin powder for reconstitution,
        - A needle-free syringe containing 2 mL of Sterile Water for Injection (Sterile WFI),
        - A sterile vial adapter.

For prescribing information on the Thrombin component, please refer to the EVITHROM® Thrombin, Topical (Human) Prescribing Information on page 9.

Thrombin should be reconstituted using the vial adapter and the needle-free syringe with Sterile WFI.

The Thrombin Solution must be added to the Flowable Gelatin Matrix prior to use.

Once the hemostatic matrix is mixed with the Thrombin Solution, the appropriate applicator tip should be attached to the syringe for product delivery onto the bleeding site.

ACTIONS

SURGIFLO® Hemostatic Matrix Kit has hemostatic properties. When used in appropriate amounts SURGIFLO® Hemostatic Matrix is absorbed completely within 4 to 6 weeks. In an animal implantation study, tissue reactions were classified as minimal.

INTENDED USE/INDICATIONS

SURGIFLO® Hemostatic Matrix, 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® Hemostatic Matrix in intravascular compartments because of the risk of embolization.
- Do not use SURGIFLO® Hemostatic Matrix in patients with known allergies to porcine gelatin.
- Do not use SURGIFLO® Hemostatic Matrix 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

- Do not inject or compress SURGIFLO® Hemostatic Matrix into blood vessels.
- SURGIFLO® Hemostatic Matrix is not intended as a substitute for meticulous surgical technique and the proper application of ligatures or other conventional procedures for hemostasis.
- SURGIFLO® Hemostatic Matrix should not be used in the presence of infection. SURGIFLO® Hemostatic Matrix should be used with caution in contaminated areas of the body. If signs of infection or abscess develop where SURGIFLO® Hemostatic Matrix has been positioned, reoperation may be necessary in order to remove the infected material and allow drainage.
- SURGIFLO® Hemostatic Matrix should not be used in instances of pumping arterial hemorrhage. It should not be used where blood or other fluids have pooled or in cases where the point of hemorrhage is submerged. SURGIFLO® Hemostatic Matrix will not act as a tampon or plug in a bleeding site.
- SURGIFLO® Hemostatic Matrix 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. Care should be exercised to avoid overpacking. SURGIFLO® Hemostatic Matrix may swell, creating the potential for nerve damage.
- Excess SURGIFLO® Hemostatic Matrix should be removed once hemostasis has been achieved, because of the possibility of dislodgment of the device or compression of other nearby anatomic structures.
- The safety and effectiveness of SURGIFLO® Hemostatic Matrix for use in ophthalmic procedures has not been established.
- SURGIFLO® Hemostatic Matrix should not be used for controlling post-partum intrauterine bleeding or menorrhagia.
- The safety and effectiveness of SURGIFLO® Hemostatic Matrix 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. The tray can be used to contain the excess piece for discarding.

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® Hemostatic Matrix is supplied as a sterile product and cannot be resterilized. Unused open pouches of SURGIFLO® Hemostatic Matrix should be discarded.
- While packing a cavity for hemostasis is sometimes surgically indicated, SURGIFLO® Hemostatic Matrix should not be used in this manner unless excess product that is not needed to maintain hemostasis is removed. When incorporated into a fibrin clot, SURGIFLO® Hemostatic Matrix may swell up to 20% upon contact with additional fluid.
- Only the minimum amount of SURGIFLO® Hemostatic Matrix needed to achieve hemostasis should be used. Once hemostasis is achieved, any excess SURGIFLO® Hemostatic Matrix should be carefully removed.
- SURGIFLO® Hemostatic Matrix should not be used in conjunction with autologous blood salvage circuits. It has been demonstrated that fragments of collagen-based hemostatic agents may pass through 40 µm transfusion filters of blood scavenging systems.
- SURGIFLO® Hemostatic Matrix should not be used in conjunction with methylmethacrylate adhesives. Microfibrillar collagen has been reported to reduce the strength of methylmethacrylate adhesives used to attach prosthetic devices to bone surfaces.
- SURGIFLO® Hemostatic Matrix should not be used for the primary treatment of coagulation disorders.
- Although the safety and effectiveness of the combined use of SURGIFLO® Hemostatic Matrix with other agents such as topical thrombin, antibiotic solution, or antibiotic powder has not been evaluated in controlled clinical trials, if, in the physician's judgment, concurrent use of topical thrombin or other agents is medically advisable, the product literature for that agent should be consulted for complete prescribing information.
- The safety and effectiveness for use in urological procedures has not been established through a randomized clinical study.
- In urological procedures, SURGIFLO® Hemostatic Matrix 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. The most common adverse events recorded during and after the application of the device were fever, tachycardia, and asthenia (a general feeling of weakness). Table 1 lists those adverse events that occurred in greater than 5% of the SURGIFOAM® Sponge patients. The control patients are included for comparison. Other adverse events observed in less than 5% of the SURGIFOAM® Sponge patients were chest pain, somnolence, anorexia, anxiety, dizziness, ecchymosis, oliguria, abdominal pain, thrombocytopenia, agitation, bradycardia, confusion, depression, dyspnea, back pain, urine retention, abdominal enlargement, dry mouth, GI discomfort, dehydration, lung edema, flatulence, abnormal healing, hematuria, hiccups, hyperventilation, ileus, infection of the urinary tract, leukocytosis, vertigo, amblyopia, arrhythmia, cardiomegaly, cellulitis, chills, dysphagia, hyperglycemia, urinary incontinence, melena, mucous membrane discharge, eye pain, and pneumonia.

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.

Table 1: Incidence of treatment emergent adverse events by treatment group

TERM	SURGIFOAM® (n=142)	Control Sponge (n=139)	Total (n=281)
Fever	28 (19.7%)	34 (24.5%)	62 (22.1%)
Tachycardia	27 (19.0%)	28 (20.1%)	55 (19.6%)
Asthenia	25 (17.6%)	17 (12.2%)	42 (14.9%)
Peripheral Edema	20 (14.1%)	20 (14.4%)	40 (14.2%)
Hypertonia	20 (14.1%)	12 (8.6%)	32 (11.4%)
Anemia	19 (13.4%)	11 (7.9%)	30 (10.7%)
Nausea	18 (12.7%)	22 (15.8%)	40 (14.2%)
Constipation	17 (12.0%)	17 (12.2%)	34 (12.1%)
Hypertension	16 (11.3%)	12 (8.6%)	28 (10.0%)
Insomnia	16 (11.3%)	13 (9.4%)	29 (10.3%)
Pain	13 (9.2%)	17 (12.2%)	30 (10.7%)
Pharyngitis	13 (9.2%)	11 (7.9%)	24 (8.5%)
Vomiting	13 (9.2%)	8 (5.8%)	21 (7.5%)
Edema	12 (8.5%)	10 (7.2%)	22 (7.8%)
Pruritus	12 (8.5%)	10 (7.2%)	22 (7.8%)
Rash	12 (8.5%)	19 (13.7%)	31 (11.0%)
Headache	11 (7.7%)	9 (6.5%)	20 (7.1%)
Hypokalemia	11 (7.7%)	10 (7.2%)	21 (7.5%)
Hypomagnesemia	11 (7.7%)	11 (7.9%)	22 (7.8%)
Infection	11 (7.7%)	6 (4.3%)	17 (6.0%)
Paresthesia	11 (7.7%)	7 (5.0%)	18 (6.4%)
Dyspepsia	10 (7.0%)	4 (2.9%)	14 (5.0%)
Hypotension	10 (7.0%)	10 (7.2%)	20 (7.1%)
Diarrhea	9 (6.3%)	8 (5.8%)	17 (6.0%)
Hypocalcemia	9 (6.3%)	9 (6.5%)	18 (6.4%)
Cough Increased	8 (5.6%)	9 (6.5%)	17 (6.0%)
Edema General	8 (5.6%)	5 (3.6%)	13 (4.6%)
Hematoma	8 (5.6%)	9 (6.5%)	17 (6.0%)

CLINICAL STUDIES

Study Design: An open-label, randomized, controlled, multi-center, unmasked study was conducted to evaluate the safety and effectiveness of 2 hemostatic agents. The study compared the SURGIFOAM® Sponge to an absorbable gelatin sponge currently legally marketed in the U.S.A. The primary objective of the study was to examine the equivalence of the SURGIFOAM® Sponge to the control device as measured by hemostasis within 10 minutes of application. Cardiovascular, general surgical, and orthopedic patients were eligible for the study. The sponges were used either soaked with saline or dry. Patients were followed for2 months after surgery to assess the safety of the sponge.

Study Results: Two hundred eighty-one patients were enrolled into the study and received study treatment. The hemostasis data were collected immediately during surgery and the patients were examined at two to four weeks, and again at six to eight weeks, in order to obtain safety data. The study effectiveness results are summarized in Table 2 below.

Table 2: Summary of effectiveness results comparing SURGIFOAM® Sponge to another absorbable gelatin sponge (percent achieving hemostasis)

Minutes	Device	General Surgical	Cardiovascular	Orthopedic	Total
		% (Ratio)	% (Ratio)	% (Ratio)	% (Ratio)
3	SURGIFOAM® Sponge	65.6 (42/64)	57.4 (39/68)	100.0 (10/10)	64.0 (91/142)
	Control Sponge	66.2 (43/65)	62.9 (39/62)	91.7 (11/12)	66.9 (93/139)
6	SURGIFOAM® Sponge	98.4 (63/64)	80.9 (55/68)	100.0 (10/10)	90.1 (128/142)
	Control Sponge	95.4 (62/65)	91.9 (57/62)	100.0 (12/12)	94.2 (131/139)
10	SURGIFOAM® Sponge	100.0 (64/64)	89.7 (61/68)	100.0 (10/10)	95.1 (125/142)
	Control Sponge	95.4 (62/65)	96.8 (60/62)	100.0 (12/12)	96.4 (134/139)

A statistical analysis showed that SURGIFOAM® Sponge and the control sponge were equivalent in the ability to achieve hemostasis within 10 minutes. The study also collected hemostasis data at 3 and 6 minutes. These results are also summarized in Table 2.

Immune Response: Patient sera were tested for the presence of anti-porcine collagen immunoglobulins. Sera were collected prior to surgery, at 2 to 4 weeks post-surgery, and at 6 to 8 weeks following surgery. Two hundred six patients were tested at baseline, 2 to 4 weeks, and at 6 to 8 weeks. Only one of the 206 patients had antibodies at baseline, and 6 of the 206 patients had antibodies at the 6- to 8-week time point. Three of the patients were in the SURGIFOAM® Sponge group and 3 patients were in the control group. The analysis of the immunology data indicated that there was no difference in the ability of the SURGIFOAM® Sponge to induce anti-porcine collagen immunoglobulins when compared to the control sponge.

Use of SURGIFLO® Hemostatic Matrix as a hemostatic agent for nasal/sinus bleeding: SURGIFLO® Hemostatic Matrix has been successfully used with bovine thrombin intraoperatively as a hemostatic agent for the control of bleeding post-nasal sinus surgery in 30 patients (54 application sites).

Study Design: This was a multi-center, prospective, single-arm study. Thirty (30) subjects from three (3) US centers undergoing elective endoscopic sinus surgery (ESS), who met the eligibility criteria, were treated with SURGIFLO® Hemostatic Matrix and bovine thrombin post ESS. Subjects were followed at 7 days (± 3 days) and at 30 days (± 7 days) post-operatively. This was a single arm study with no control arm. Patients were followed for 30 days following surgery. Post-operative healing and all complications were recorded during this period.

Study Results: Intraoperative bleeding ceased in 29 out of 30 patients. One subject failed to achieve hemostasis within 10 minutes of product application. The median time to hemostasis for 54 operated sites, including manual compression, was 61 seconds. One patient had mild oozing after surgery. This patient was treated with local care with immediate resolution. No intraoperative complications, serious adverse events, or serious complications such as synechiae or infections were reported in this study.

HOW SUPPLIED

SURGIFLO® Hemostatic Matrix Kit consists of:

1. A sterile tray with *all* sterile components to prepare the Flowable Gelatin Matrix
2. A sterile tray with *all* surface sterilized Thrombin kit components to prepare the Thrombin Solution

SURGIFLO® Hemostatic Matrix Kit is provided in the configuration shown in the table below.

SURGIFLO® Hemostatic Matrix Kit with Thrombin	
Flowable Gelatin Matrix Components	**Thrombin Components**
• A sterile pre-filled syringe with blue plunger containing the sterile Gelatin Matrix. The syringe is labeled **SURGIFLO™ Hemostatic Matrix** • A sterile empty syringe • A sterile liquid transfer cup • A sterile blue flexible applicator tip that is bendable in all directions • A sterile white applicator tip that can be trimmed to desired length	• A Thrombin vial, EVITHROM® Thrombin, Topical (Human), containing 2000 International Units (IU) of sterile lyophilized human thrombin powder for reconstitution • A needle-free syringe containing 2 mL of Sterile Water for Injection (Sterile WFI) • A sterile vial adapter

The package also contains the SURGIFLO® Hemostatic Matrix Kit Instructions for Use and tracking labels.

STORAGE AND HANDLING

- SURGIFLO® Hemostatic Matrix Kit should be stored dry at controlled room temperature 36°-77°F (2°-25°C).
- The Flowable Gelatin Matrix may be used up to eight (8) hours after mixing with the Thrombin Solution.
- For prescribing information on the Thrombin component, please refer to the EVITHROM® Thrombin, Topical (Human) Prescribing Information on page 9.
- SURGIFLO® Hemostatic Matrix Kit is for single use only.

DIRECTIONS FOR USE

Before use

Inspect the packages for signs of damage. If the package is damaged or wet, sterility cannot be assured and the contents should not be used.

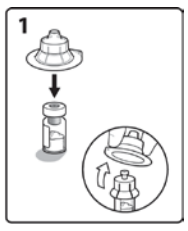
Open packages of SURGIFLO® Hemostatic Matrix Kit should be discarded, since they are not intended for reuse and/or resterilization.

Opening the tray with Flowable Gelatin Matrix and the tray with Thrombin kit components

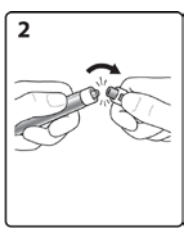
Open the outer packages and deliver the sterile inner trays to the sterile field using aseptic technique. Once placed in the sterile field, the sterile inner tray may be opened.

Preparing the Thrombin Solution inside the sterile field:

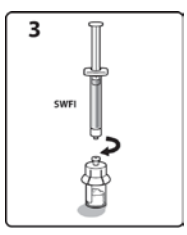
Flip off the cap from the *Thrombin vial*, leaving the aluminum ring and the rubber stopper in place. Peel off the lid from the vial adapter package.



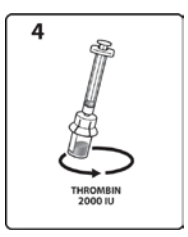
1. Place the *Thrombin vial* on a flat surface, seat the *vial adapter* on the center of the rubber stopper and push down until the spike penetrates the rubber stopper and the *vial adapter* snaps into place. Remove the blister package.



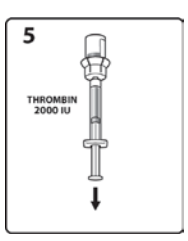
2. **Snap** off the tamper cap on the *needle-free syringe* containing the Sterile Water for Injection (Sterile WFI).



3. Connect and screw on the *needle-free syringe* to the *vial adapter*. Transfer the entire Sterile WFI into the *Thrombin vial*.



4. Gently swirl the *Thrombin vial* until the Thrombin Solution is clear.



5. Draw up the Thrombin Solution into the *needle-free syringe*. Label the *needle-free syringe*: "Thrombin 2000 IU".

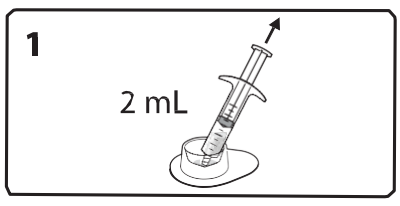
6. Disconnect the *needle-free syringe* from the *vial adapter* and transfer the Thrombin Solution into the sterile liquid transfer cup as shown in the next section (Figure 1).

After reconstitution, discard the components used for the thrombin reconstitution.

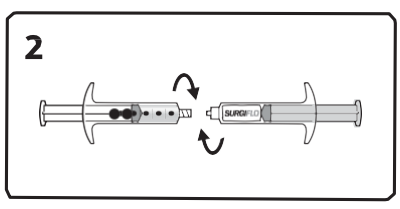
Alternatively, the Thrombin may be reconstituted **outside** the sterile field. Be careful not to touch the rubber stopper of the vial. After reconstitution the Thrombin Solution should be transferred into the sterile liquid transfer cup using aseptic technique.

Place the sterile liquid transfer cup near the edge of the sterile field to receive the Thrombin Solution transfer without contaminating the sterile field.

Preparing the Flowable Gelatin Matrix with sterile Thrombin Solution inside the sterile field:

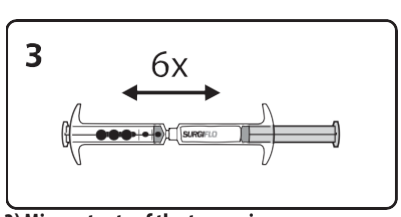


1) Draw up 2 mL sterile Thrombin Solution from the sterile liquid transfer cup into the empty sterile syringe.



2) Connect syringes

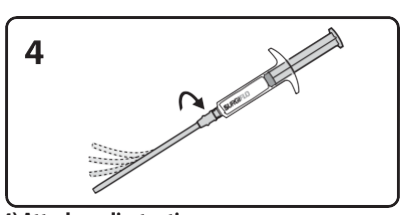
Remove the blue cap from the end of the sterile pre-filled syringe with blue plunger containing the Gelatin Matrix. Attach this syringe to the sterile syringe containing the sterile Thrombin Solution.



3) Mix contents of the two syringes

Begin mixing by transferring the sterile Thrombin Solution into the sterile pre-filled syringe containing the Gelatin Matrix. Push the combined material back and forth 6 times until the consistency is even.

Once mixed, the hemostatic matrix should reside completely in the syringe with the blue plunger that is labeled **SURGIFLO™ Hemostatic Matrix**. Remove the empty syringe and discard.



4) Attach applicator tip

The product is now ready for clinical use.

Do not inject SURGIFLO® Hemostatic Matrix into blood vessels. See the Contraindications, Warnings, and Precautions.

For open procedures:

a. Identify the source of bleeding.
b. Deliver SURGIFLO® Hemostatic Matrix to the source of bleeding. SURGIFLO® Hemostatic Matrix can be used with or without the applicator tip attached to the syringe labeled **SURGIFLO™ Hemostatic Matrix**. Apply sufficient SURGIFLO® Hemostatic Matrix to cover the entire bleeding surface.
c. For tissue defects (cavities, divots, or craters) apply SURGIFLO® Hemostatic Matrix at the deepest part of the lesion, and continue applying material as the syringe (or applicator tip) is withdrawn from the lesion.
d. Apply a sterile saline moistened gauze over the SURGIFLO® Hemostatic Matrix to ensure the material remains in contact with the bleeding tissue.
e. After 1-2 minutes, lift the gauze and inspect the wound site. Once bleeding has ceased, irrigate excess SURGIFLO® Hemostatic Matrix away gently so as not to disturb the new clot.
f. In cases of persistent bleeding indicated by saturation and bleeding through the material, repeat application of SURGIFLO® Hemostatic Matrix.

For endoscopic and/or laparoscopic surgical procedures:

a. Prepare the selected endoscopic applicator according to the product's labeling.
b. Attach the selected endoscopic applicator tip to the **SURGIFLO™ Hemostatic Matrix** syringe. Make sure that the luer connection is secure.
c. Express SURGIFLO® Hemostatic Matrix to the end of the cannula. Introduce the cannula into the trocar port. Insert the cannula using caution not to express SURGIFLO® Hemostatic Matrix.
d. Carefully position the distal end of the endoscopic applicator to the site where SURGIFLO® Hemostatic Matrix is to be delivered. Be careful to avoid damaging tissue with the cannula.
e. While holding the endoscopic applicator in place, express SURGIFLO® Hemostatic Matrix to the bleeding site.
f. If applicable, detach **SURGIFLO™ Hemostatic Matrix** syringe and introduce the stylet to dispense remaining product in the length of the cannula.
g. Observe bleeding and repeat application of SURGIFLO® Hemostatic Matrix if necessary.
h. Carefully remove the endoscopic applicator from the trocar port when sufficient SURGIFLO® Hemostatic Matrix has been delivered to the bleeding site.

For endoscopic sinus surgery and epistaxis:

a. Deliver SURGIFLO® Hemostatic Matrix to the source of bleeding using the selected applicator tip attached to the syringe that is labeled **SURGIFLO™ Hemostatic Matrix.**
b. Apply sufficient SURGIFLO® Hemostatic Matrix to cover the entire bleeding surface. Using forceps or an appropriate instrument, carefully layer a sterile saline moistened gauze over the SURGIFLO® Hemostatic Matrix for 1-2 minutes to ensure the material remains in contact with the bleeding tissue.
c. In cases of persistent bleeding, indicated by saturation and bleeding through the material, insert the applicator tip through the center of the mass of previously placed SURGIFLO® Hemostatic Matrix to deliver fresh material as close as possible to the tissue surface. After reapplication of SURGIFLO® Hemostatic Matrix, use a sterile saline moistened gauze to approximate the material to the tissue for another minute, and then inspect the site. Repeat reapplication if necessary.
d. Once hemostasis has been achieved, remove the gauze. If possible, excess SURGIFLO® Hemostatic Matrix should be removed with gentle irrigation or careful suction. Avoid disrupting the SURGIFLO® Hemostatic Matrix clot complex. The remaining SURGIFLO® Hemostatic Matrix does not have to be removed, as it will be bioresorbed.
e. Use of nasal packing is not necessary when satisfactory hemostasis is achieved.
f. If necessary, gentle irrigation and/or careful suction can be used in the post-operative period to remove the remaining SURGIFLO® Hemostatic Matrix.

Caution: The use of SURGIFLO® Hemostatic Matrix for mechanical support has not been studied.

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

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