

DEVICE SPECS

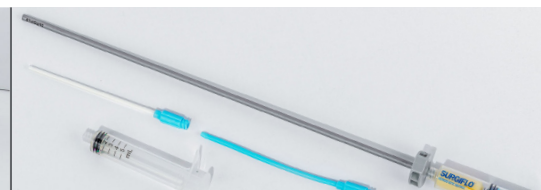
SURGIFLO® Hemostatic Matrix



SURGIFLO® Hemostatic Matrix with Thrombin



SURGIFLO® Hemostatic Matrix



SURGIFLO® Endoscopic Applicator

Codes	2994	2991	MS1995
Description	Flowable gelatin matrix with thrombin	Flowable gelatin matrix	Delivery device for minimally invasive procedures
Indication	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.	SURGIFLO Hemostatic Matrix, mixed 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.	The SURGIFLO Endoscopic Applicator is intended for use in delivering hemostatic agents to bleeding surgical sites through a 5 mm trocar or larger.
Size	8 mL	8 mL	34cm
Hemostatic Agent & Accessory	Hemostatic Agent	Hemostatic Agent	Accessory
Absorption Time	4-6 weeks	4-6 weeks	4-6 weeks
Storage Requirements	Stored dry at controlled room temperature 36°-77°F (2°-25°C).	Stored dry at controlled room temperature 36°-77°F (2°-25°C).	Store at controlled room temperature 59°-86°F (15°-30°C)
Preparation Time	Ready to use in 30 seconds or less once liquid thrombin is delivered to sterile field	Ready to use in 30 seconds or less once liquid thrombin or saline is delivered to sterile field	Ready out of package
Shelf Life	2 years	2 years	5 years
Material/Composition	Porcine Gelatin and Human Thrombin	Porcine Gelatin	Stainless Steel Cannula and Plastic Obturator
Mechanism of Action	SURGIFLO Hemostatic Matrix with thrombin provides a matrix for platelet adherence, accelerating the formation of the platelet plug and aids in fibrin clot formation	SURGIFLO Hemostatic Matrix without thrombin provides a matrix for platelet adherence, accelerating the formation of the platelet plug	--
NDC/Distributor Code	63713-461 (Lyophilized)	63713-0029-91	63713-MS19-95
Qty./Box	6	6	6

ESSENTIAL PRODUCT INFORMATION

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

DESCRIPTION

SURGIFLO® Hemostatic Matrix 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 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.

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ESSENTIAL PRODUCT INFORMATION

SURGIFLO® Hemostatic Matrix (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.

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- 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.

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- Fever, failure of absorption, and hearing loss have been observed when absorbable hemostatic agents were used during tympanoplasty.

ESSENTIAL PRODUCT INFORMATION

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

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.

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