SURGIFLO®
Hemostatic Matrix
simple preparation

You can use SURGIFLO® with or without thrombin.
Please refer to your thrombin IFU for preparation instructions.

Flowable Gelatin Matrix Preparation

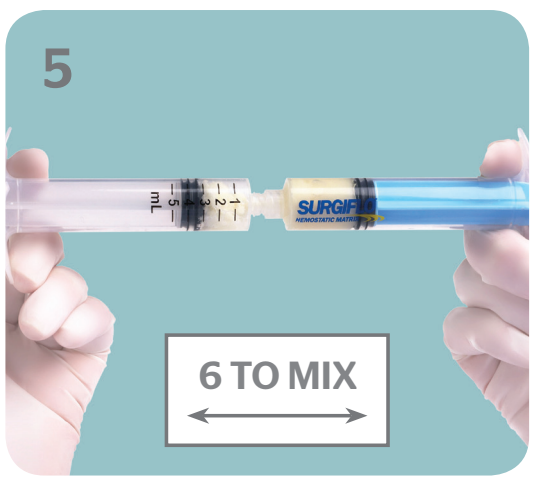
Prepare the sterile solution
(i.e. thrombin or sterile saline)

Measure the sterile solution and transfer into the sterile liquid transfer cup.

Draw up all the sterile solution from the sterile liquid transfer cup into the empty syringe.

For the same product consistency as SURGIFLO® Hemostatic Matrix Kit with thrombin use 2 mL of sterile solution.
NOTE: Use aseptic technique if solution is prepared outside the sterile field.

Connect the syringes
- Remove the blue cap from the syringe with the blue plunger containing the Gelatin Matrix.
- Attach this syringe to the sterile syringe containing the sterile solution.



Mix the contents of the two syringes
- Begin mixing by transferring the sterile solution into the sterile pre-filled syringe containing the Gelatin Matrix.
- Push the combined material between syringes 6 times (3 times back and forth) ending in the syringe with the blue plunger.

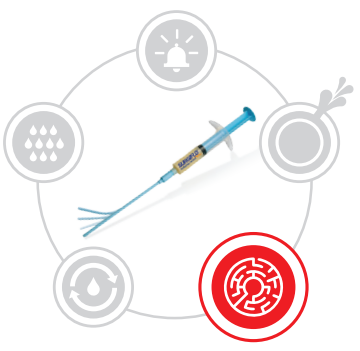
Attach the applicator tip.
The product is now ready for clinical use.

Do not inject SURGIFLO® Hemostatic Matrix into blood vessels.
See the Contraindications, Warnings, and Precautions.
For complete product details, see instructions for use.
For technical support, call 1-877-ETHICON.

Call 1-800-255-2500 to order.

Ordering Information		
Ordering Code	Size	Package
2991	8 mL SURGIFLO® Hemostatic Matrix	Case of 6
MS1995	34 cm Endoscopic Applicator	Case of 6

Situation
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.



Solution
SURGIFLO®
Part of the **Hemostasis Optimization Program** portfolio of adjunctive hemostats

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 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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