SURGIFOAM® Absorbable Gelatin Family

Gelatin used by surgeons during hemostasis for **over 60 years**

- Proven in surgery and clinical trial to facilitate rapid hemostasis[1,2]
- Absorbs completely within 4 to 6 weeks[1]
- Available in both powder and sponge
- Bovine free
- Indicated for use with thrombin or sterile saline

For Use in Broad Range of Procedures:

- Neurosurgery (Spine; Craniotomy)
- Urologic Surgery
- Cardiovascular Surgery
- General Surgery

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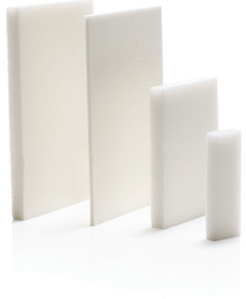
Shaping the future of surgery

SURGIFOAM®—from ETHICON, your one source provider of Biosurgery products

Sponge Options



SURGIFOAM®

Absorbable Gelatin Sponge

- Available in a variety of sizes to meet your needs
- Indicated for use with either saline or thrombin

Size	Code	Packaging
1 cm x 1 cm x 1 cm	1969	24 eaches / box
2 cm x 6 cm x 7 mm (12-7)	1972	12 eaches / box
8 cm x 6.25 cm x 10 mm (50)	1973	4 eaches / box
8 cm x 12.5 cm x 10 mm (100)	1974	6 eaches / box
8 cm x 12.5 cm x 2 mm (100C)	1975	6 eaches / box

SURGIFOAM®

Absorbable Gelatin Sponge Hemorrhoidectomy Sponge

- Pre-shaped for ease of use—conforms to anatomy
- Will not adhere to wound surface
- Ideal for temporary packing of traumatic puncture wounds

Size	Code	Packaging
8 cm x 3 cm	1977	5 eaches / box

Powder Options

SURGIFOAM®

Absorbable Gelatin Powder

- Mixes easily to form a paste, ball or roll
- Add thrombin or saline to achieve desired consistency

Size	Code	Packaging
1.0g	1978	6 eaches / box

SURGIFOAM®

Absorbable Gelatin Powder Kit

- Convenient kit includes syringe and tip
- Conforms to irregular surfaces to stop bleeding fast

Size	Code	Packaging
1.0g	1979	6 eaches / box

SURGIFOAM® — Part of the comprehensive Ethicon Biosurgery portfolio for bleeding management

To place an order, call 1-800-255-2500 For technical support, call 1-877-384-4266 www.ethicon.com

SURGIFOAM® Essential Product Information

DESCRIPTION

SURGIFOAM® is a sterile, water-insoluble, malleable, porcine gelatin absorbable sponge or powder intended for hemostatic use by applying to a bleeding surface.

ACTIONS

.When used in appropriate amounts, SURGIFOAM® is absorbed completely within 4 to 6 weeks. When applied to bleeding mucosal regions, it liquefies within 2 to 5 days.

INTENDED USE/INDICATION

SURGIFOAM®, used dry or saturated with sterile sodium chloride solution, is indicated for surgical procedures (except ophthalmic) for hemostasis, when control of capillary, venous and arteriolar bleeding by pressure, ligature and other conventional procedures is ineffective or impractical. Although not necessary, SURGIFOAM® can be used with thrombin to achieve hemostasis

CONTRAINDICATIONS

- Do not use SURGIFOAM® 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.
- Do not use SURGIFOAM® in intravascular compartments because of the risk of embolization. Do not use SURGIFOAM® in patients with known allergies to porcine collagen

WARNINGS

- SURGIFOAM® should not be used in the presence of infection and should be used with caution in contaminated areas of the body
- SURGIFOAM® should not be used in instances of pumping arterial hemorrhage
- SURGIFOAM® will not act as a tampon or plug in a bleeding site.
- SURGIFOAM® should be removed if possible once hemostasis has been achieved because of the possibility of dislodgment of the device or compression of other nearby anatomic structures.
- SURGIFOAM® 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.
- The safety and effectiveness of SURGIFOAM® for use in ophthalmic procedures have not been established.
- SURGIFOAM® should not be used for controlling post-partum bleeding or menorrhagia.
- The safety and effectiveness of SURGIFOAM® have not been established in children and pregnant women.

PRECAUTIONS

- Safe and effective use of this product has been reported in a published neurologic retrospective study involving 1700 cases in Europe. Safe and effective use has not been proven through randomized, controlled clinical studies in the United States.
- SURGIFOAM® is supplied as a sterile product and cannot be resterilized. When placed into cavities or closed tissue spaces, care should be exercised to avoid overpacking. SURGIFOAM® Sponge may swell to its original size on absorbing fluids, creating the potential for nerve damage.
- SURGIFOAM® should not be used for packing a cavity unless excess product not needed to maintain hemostasis is removed.
- Once hemostasis is achieved, any excess SURGIFOAM® should be carefully removed.
- SURGIFOAM® should not be used in conjunction with autologous blood salvage circuits. • SURGIFOAM® should not be used in conjunction with methyl methacrylate adhesives. The safety and effectiveness for use in urological procedures have not been established through a randomized clinical study.
- In urological procedures, SURGIFOAM® 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® Gelatin 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 has 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.

The SURGIFOAM® family can be included in both traditional and advanced hemostatic contracts

References: 1. SURGIFOAM® Absorbable Gelatin Powder Instructions for Use. Ethicon, Inc. **2.** Sabel M, Stummer W. The use of local agents: Surgicel and Surgifoam. *Eur Spine J.* 2004;13(Suppl 1):S97-S101.

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