DEVICE SPECS

SURGIFOAM® Absorbable Gelatin Products

	 **SURGIFOAM® Absorbable Gelatin Powder**	 **SURGIFOAM® Absorbable Gelatin Sponge**	 **SURGIFOAM® Absorbable Gelatin Sponge, Hemhorrhoidectomy Sponge**
Codes	1978, 1979	1969, 1972, 1973, 1974, 1975	1977
Description	Sterile, porcine gelatin absorbable powder	Sterile, water-insoluble, malleable, porcine gelatin absorbable sponge	Sterile, water-insoluble, malleable, porcine gelatin absorbable sponge
Indication	SURGIFOAM® Powder, 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® Powder can be used with thrombin to achieve hemostasis.	SURGIFOAM® Sponge, 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® Sponge can be used with thrombin to achieve hemostasis.	SURGIFOAM® Sponge, 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® Sponge can be used with thrombin to achieve hemostasis.
Size	1.0g	1cm x 1cm x 1cm (1969), 2cm x 6cm x 7mm (1972), 8cm x 6.25cm x 10mm (1973), 8cm x 12.5cm x 10mm (1974), 8cm x 12.5cm x 2mm (1975)	8cm x 3cm
Absorption Time	4-6 weeks	4-6 weeks	4-6 weeks
Storage Requirements	Store at controlled room temperature 59°-86°F (15°-30°C)	Store at controlled room temperature 59°-86°F (15°-30°C)	Store at controlled room temperature 59°-86°F (15°-30°C)
Preparation Time	Ready out of package	Ready out of package	Ready out of package
Shelf Life	2 years	4 years	4 years
Material/Composition	Porcine Gelatin	Porcine Gelatin	Porcine Gelatin
Mechanism of Action	Provides a matrix for platelet adhesion and aggregation	Provides a matrix for platelet adhesion and aggregation	Provides a matrix for platelet adhesion and aggregation
NDC/Distributor Code	63713-0019-78, 63713-0019-79	63713-0019-69, 63713-0019-72, 63713-0019-73, 63713-0019-74, 63713-0019-75	63713-0019-77
Qty./Box	6	4 (1973), 6 (1974, 1975), 12 (1972), 24 (1969)	5

ETHICON

Johnson & Johnson SURGICAL TECHNOLOGIES

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

ESSENTIAL PRODUCT INFORMATION

SURGIFOAM®

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.

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