SURGIFOAM* Sponge (Sterile)
(absorbable gelatin sponge, USP)

Caution: **Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).**

DESCRIPTION

The SURGIFOAM Sponge is a sterile, water-insoluble, malleable, porcine gelatin absorbable sponge intended for hemostatic use by applying to a bleeding surface. The sponge is off-white and porous in appearance.

INTENDED USE/INDICATIONS

SURGIFOAM Sponge, used dry or saturated with sterile sodium chloride solution, is indicated for surgical procedures (except urologic, ophthalmic and neurologic) for hemostasis, when control of capillary, venous and arteriolar bleeding by pressure, ligature and other conventional procedures is ineffective or impractical.

CONTRAINDICATIONS

Do not use SURGIFOAM Sponge 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 Sponge in intravascular compartments because of the risk of embolization.

Do not use SURGIFOAM Sponge in patients with known allergies to porcine collagen.

WARNINGS

- SURGIFOAM Sponge is not intended as a substitute for meticulous surgical technique and the proper application of ligatures or other conventional procedures for hemostasis.

- SURGIFOAM Sponge should not be used in the presence of infection. SURGIFOAM Sponge should be used with caution in contaminated areas of the body. If signs of infection or abscess develop where SURGIFOAM Sponge has been positioned, reoperation may be necessary in order to remove the infected material and allow drainage.

- SURGIFOAM Sponge 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. SURGIFOAM Sponge will not act as a tampon or plug in a bleeding site, nor will it close off an area of blood collecting behind a tampon.

- 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 Sponge for use in neurosurgical, ophthalmic, and urological procedures has not been established.

- SURGIFOAM Sponge should not be used for controlling post-partum bleeding or menorrhagia.

- The safety and effectiveness of SURGIFOAM Sponge has not been established in children and pregnant women.

PRECAUTIONS

Caution: SURGIFOAM Sponge is supplied as a sterile product and cannot be resterilized. Unused open envelopes of SURGIFOAM Sponge should be discarded.

Caution: When placed into cavities or closed tissue spaces, minimal preliminary compression is advised and care should be exercised to avoid overpacking (the sponge expands upon absorption of liquid). SURGIFOAM may swell to its original size on absorbing fluids creating the potential for nerve damage.

Caution: While packing a cavity for hemostasis is sometimes surgically indicated, SURGIFOAM Sponge should not be used in this manner unless excess product not needed to maintain hemostasis is removed.

Caution: Only the minimum amount of SURGIFOAM Sponge needed to achieve hemostasis should be used. Once hemostasis is achieved any excess SURGIFOAM Sponge should be carefully removed.

Caution: SURGIFOAM Sponge 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 40μ transfusion filters of blood scavenging systems.

Caution: SURGIFOAM Sponge 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.

Caution: SURGIFOAM Sponge should not be used for the primary treatment of coagulation disorders.

Caution: The safety and effectiveness of the combined use of SURGIFOAM Sponge with other agents such as topical thrombin, antibiotic solution or antibiotic powder has not been established.

ADVERSE EVENTS

A total of 281 patients received SURGIFOAM gelatin sponge or 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 patients. The control patients are included for comparison.

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%)	41 (14.6%)
Peripheral Edema	20 (14.1%)	20 (14.4%)	40 (14.2%)
Hypertonia	20 (14.1%)	12 (8.6%)	31 (11.0%)
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%)

Other adverse events observed in less than 5% of the SURGIFOAM 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, have 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 have 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.

CLINICAL STUDIES

Study Design:

An open label, randomized, controlled, multi-center, unmasked study was conducted to evaluate the safety and effectiveness of two hemostatic agents. The study compared the SURGIFOAM Absorbable Gelatin Sponge, USP to an absorbable gelatin sponge currently legally marketed in the US. 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 for two 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 was 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 to Another Absorbable Gelatin Sponge, USP (Percent achieving hemostasis).

Minutes	Device	General Surgical	Cardiovascular	Orthopedic	Total
		% (Ratio)	% (Ratio)	% (Ratio)	% (Ratio)
3	SURGI-FOAM	65.6 (42/64)	57.4 (39/68)	100.0 (10/10)	64.0 (91/142)
	Control Sponge	67.2 (43/65)	63.9 (39/62)	91.7 (11/12)	67.9 (93/139)
6	SURGI-FOAM	98.4 (63/64)	80.9 (55/68)	100.0 (10/10)	90.1 (128/142)
	Control Sponge	96.9 (62/65)	93.4 (57/62)	100.0 (12/12)	95.6 (131/139)
10	SURGI-FOAM	100.0 (64/64)	89.7 (61/68)	100.0 (10/10)	95.1 (135/142)
	Control Sponge	96.9 (62/65)	98.4 (60/62)	100.0 (12/12)	97.8 (134/139)

A statistical analysis showed that SURGIFOAM 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, 2-4 weeks, and at 6-8 weeks. Only one of the 206 patients had antibodies at baseline and 6 of the 206 patients had antibodies at the 6-8 week time point. Three of the patients were in the SURGIFOAM 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 to induce anti-porcine collagen immunoglobulins when compared to the control sponge.

HOW SUPPLIED

SURGIFOAM is supplied sterile in a variety of sizes, both standard and compressed.

Model	Size
SURGIFOAM 50-10	8 cm x 6.25 cm (50 cm sq.) x 10 mm (thickness)
SURGIFOAM 100-C	8 cm x 12.5 cm (100 cm sq.) x 2 mm (thickness)
SURGIFOAM 100-10	8 cm x 12.5 cm (100 cm sq.) x 10 mm (thickness)
SURGIFOAM 200-10	8 cm x 25 cm (200 cm sq.) x 10 mm (thickness)

STORAGE AND HANDLING

SURGIFOAM Sponge should be stored dry at controlled room temperature 15°-30° C (59°-86° F). It is recommended that SURGIFOAM Sponge be used as soon as the package is opened.

DIRECTIONS FOR USE

Before using, inspect the package for signs of damage. If the package is damaged or wet, sterility cannot be assured and the contents should not be used. Sterile technique should always be used to remove the SURGIFOAM Sponge from its packaging. Cut the sponge to the desired size. Use only the minimum amount necessary to achieve hemostasis. This piece of SURGIFOAM Sponge can be applied to the bleeding site either dry or saturated with sterile isotonic sodium chloride solution (sterile saline). Open packages of SURGIFOAM Sponge should be discarded, since they are not intended for reuse and/or resterilization. When used in appropriate amounts the sponge is absorbed completely within 4-6 weeks. In an animal implantation study, tissue reactions were classified as negligible when observed macroscopically and moderate when observed microscopically. When applied to bleeding mucosal regions it liquefies within 2-5 days.

A) <u>Dry Use:</u>

1. Cut the SURGIFOAM Sponge to desired size and shape.
2. Manually compress the SURGIFOAM Sponge prior to applying to the bleeding site.
3. Hold the SURGIFOAM Sponge in place with moderate pressure until hemostasis is achieved.

4. Removal of excess SURGIFOAM Sponge upon achieving hemostasis can be accomplished by gentle irrigation of the site with sterile saline solution to completely wet the sponge.
5. The portion of the SURGIFOAM Sponge that is adhering to the bleeding site may be left *in situ*. Use only the amount required to achieve hemostasis and remove any excess.

B) Use With Sterile Saline Preparation:

1. Cut the SURGIFOAM Sponge to desired size and shape.
2. Immerse the SURGIFOAM Sponge cut to size in the saline solution.
3. Withdraw sponge and squeeze between gloved fingers to expel air bubbles.
4. Return sponge to the solution until needed. The SURGIFOAM sponge should promptly return to its original size and shape in the solution. If it does not, remove the sponge from the solution and vigorously knead it between gloved fingers until all air is expelled and it can return to its original size and shape when placed in the solution.
5. Blot sponge to desired dampness on gauze before applying to the bleeding site.
6. Hold the SURGIFOAM Sponge in place with gauze using moderate pressure until hemostasis is achieved.
7. Removal of gauze is aided by wetting with a few drops of saline, which helps to prevent removal of the SURGIFOAM Sponge and clot.
8. Removal of excess SURGIFOAM upon achieving hemostasis can be accomplished by gentle irrigation of the site with sterile saline solution to completely wet the sponge.
9. The portion of the SURGIFOAM Sponge that is adhering to the bleeding site may be left *in situ*. Use only the amount required to achieve hemostasis and remove any excess.

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