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SURGIFOAM®

Absorbable Gelatin Sponge, U.S.P.

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

DESCRIPTION

The SURGIFOAM® Absorbable Gelatin Sponge, U.S.P. (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.

ACTIONS

SURGIFOAM® Sponge has hemostatic properties. SURGIFOAM® Sponge absorbs completely, with little tissue reaction, when excessive amounts are not used. When used in appropriate amounts, SURGIFOAM® Sponge is absorbed completely within 4 to 6 weeks. In an animal implantation study, tissue reactions were classified as negligible when observed macroscopically, and moderate when observed microscopically with SURGIFOAM® Sponge. When applied to bleeding mucosal regions, it liquefies within 2 to 5 days.

INTENDED USE/INDICATIONS

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.

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 (See Adverse Events section). 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® Sponge 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® Sponge 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 ophthalmic procedures have not been established.
- SURGIFOAM® Sponge should not be used for controlling post-partum bleeding or menorrhagia.
- The safety and effectiveness of SURGIFOAM® Sponge have not been established in children and pregnant women.

PRECAUTIONS

Caution: 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.

Caution: SURGIFOAM® Sponge is supplied as a sterile product and cannot be resterilized. If the individual package is opened or the seal has been breached, the unused 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® Sponge 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 methyl methacrylate adhesives. Microfibrillar collagen has been reported to reduce the strength of methyl methacrylate adhesives used to attach prosthetic devices to bone surfaces.

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

Caution: Although the safety and effectiveness of the combined use of SURGIFOAM® Sponge with other agents such as topical thrombin, antibiotic solution or antibiotic powder have not been evaluated in controlled clinical trials, if in the physician's judgment, concurrent use of topical thrombin or other agents is medically advisable, the product literature for that agent should be consulted for complete prescribing information.

Caution: The safety and effectiveness for use in urological procedures have not been established through a randomized clinical study.

Caution: In urological procedures, SURGIFOAM® Sponge should not be left in the renal pelvis or ureters to eliminate the potential foci for calculus formation.

Caution: Precautions should be taken to assure that none of the material is aspirated by the patient.

ADVERSE EVENTS

Gelatin-Based Hemostatic Agents Adverse Events

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.

Adverse Reactions Reported from Unapproved Uses

- As with any other collagen/gelatin-based topical hemostats used for catheter embolization there is a risk of thromboembolism, pseudoaneurysms and delayed bleeding events, if product is used to obliterate or seal a tract communicating with large vessels.

Adverse Events Reported in Clinical Trial

A total of 142 patients received SURGIFOAM® Sponge during a clinical trial comparing SURGIFOAM® Sponge to another absorbable gelatin sponge (control 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® Sponge patients. The control patients are included for comparison. Other adverse events observed in less than 5% of the SURGIFOAM® Sponge 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.

Table 1: Incidence of Treatment Emergent Adverse Events by Treatment Group.

TERM	SURGIFOAM® Sponge (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%)	42 (14.9%)
Peripheral Edema	20 (14.1%)	20 (14.4%)	40 (14.2%)
Hypertonia	20 (14.1%)	12 (8.6%)	32 (11.4%)
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%)

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CLINICAL STUDIES

Study Design:

An open-label, randomized, controlled, multicentre, unmasked study was conducted to evaluate the safety and effectiveness of two hemostatic agents. The study compared the SURGIFOAM® Sponge to an absorbable gelatin sponge currently legally marketed in the U.S.A. The primary objective of the study was to examine the equivalence of the SURGIFOAM® Sponge to the control sponge as measured by hemostasis within 10 minutes of application. Cardiovascular, general surgical, and orthopaedic 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.

Table 2: Summary of Effectiveness Results Comparing SURGIFOAM® Sponge to a control sponge (Percent achieving hemostasis.)

Minutes	Device	General Surgical	Cardiovascular	Orthopedic	Total
		% (Ratio)	% (Ratio)	% (Ratio)	% (Ratio)
3	SURGIFOAM® Sponge	65.6 (42/64)	57.4 (39/68)	100.0 (10/10)	64.0 (91/142)
	Control Sponge	66.2 (43/65)	62.9 (39/62)	91.7 (11/12)	66.9 (93/139)
6	SURGIFOAM® Sponge	98.4 (63/64)	80.9 (55/68)	100.0 (10/10)	90.1 (128/142)
	Control Sponge	95.4 (62/65)	91.9 (57/62)	100.0 (12/12)	94.2 (131/139)
10	SURGIFOAM® Sponge	100.0 (64/64)	89.7 (61/68)	100.0 (10/10)	95.1 (125/142)
	Control Sponge	95.4 (62/65)	96.8 (60/62)	100.0 (12/12)	96.4 (134/139)

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

HOW SUPPLIED

SURGIFOAM® Sponge is supplied sterile in both standard and compressed sponges.

Model	Size
SURGIFOAM® Sponge 100-C	8 cm x 12.5 cm (100 cm sq.) x 2 mm (thickness)
SURGIFOAM® Sponge 100-10	8 cm x 12.5 cm (100 cm sq.) x 10 mm (thickness)
SURGIFOAM® Sponge 12-7	2 cm x 6 cm (12 cm sq.) x 7 mm (thickness)
SURGIFOAM® Sponge 50-10	8 cm x 6.25 cm (50 cm sq.) x 10 mm (thickness)
SURGIFOAM® Hemorrhoidectomy Sponge	8 cm x 3 cm (cylindrical)
SURGIFOAM® Oral Sponge	1 cm x 1 cm x 1 cm

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) or sterile topical thrombin solution. Each sponge is individually sealed in a sterile package. If the individual package is opened or the seal has been breached, the unused sponge should be discarded, since they are not intended for reuse and/or resterilization.

A) Dry Use:

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. Use only the amount required to achieve hemostasis and remove any excess.

B) Use With Sterile Saline or Thrombin Preparation:

1. Cut the SURGIFOAM® Sponge to desired size and shape.
2. Immerse the SURGIFOAM® Sponge cut to size in the 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 prevent removal of the SURGIFOAM® Sponge and clot.
8. 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.
9. Use only the amount required to achieve hemostasis and remove any excess.

SURGIFOAM® Hemorrhoidectomy Sponge:

Following completion of the Hemorrhoidectomy, an anal retractor or anoscope is used to visualize the surgical site and aid in the placement of the Hemorrhoidectomy Sponge. Rapid decomposition and spontaneous discharge of the sponge can be expected.

SURGIFOAM® Oral Sponge:

To be used in oral surgery and slightly compressed to secure hemostatic effect in cavities after tooth extractions etc. May also be used in areas where the small size of the sponge is an advantage, e.g., Epistaxis.

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

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SYMBOLS USED ON LABELING

- = Store at controlled room temperature 15°-30° C (59°-86° F).
- = Do not reuse.
- = Do not resterilize.
- = Do not use if package is damaged or open.
- = Latex free.
- = Designates the packaging material to which it is applied is recyclable. Recycling programs may not exist in your area.
- = Sterile.
- = Distributed by.
- = Manufacturer.
- = Re-order number.
- = Use by: year, month and day.
- = Date of manufacture: year, month and day.
- = Batch number.
- = Do not cut.

SURGIFOAM®

Absorbable Gelatin Sponge, U.S.P.

3/9/20 3:15 PM

BNO

FEMD MATERIAL NO: 4548626
PRODUCT CODE / REORDER NUMBER: 1969/1972/1973/1974/1975/1977
VERSION: Master V1
DATE: 2020.03.09
PRODUCT NAME: SURGIFOAM® Absorbable Gelatin Sponge, U.S.P.
PACKAGE TYPE: Instructions for use (IFU)
LANGUAGES: English
SIZE: Sheet: 114 mm (H) x 700 mm (W) / Folded: 114 mm (H) x 100 mm (W)
COLORS: PMS 287 Blue
BARCODE(S): 2D datamatrix
Content: 4548626
Size: 8,127 mm x 8,127 mm

2D Datamatrix Scan:

4548626

Note: Scan produced in this document has been produced by Handheld Products 4600g scan gun and reflects the exact data encoded.

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