

# Gelfoam®

## absorbable gelatin powder

(absorbable gelatin powder from absorbable gelatin sponge, USP)

### DESCRIPTION

GELFOAM is a medical device intended for application to bleeding surfaces as a hemostatic. It is a water-insoluble, off-white, nonelastic, porous, pliable product prepared from purified pork Skin Gelatin USP Granules and Water for Injection, USP and is able to absorb and hold within its interstices, many times its weight of blood and other fluids. GELFOAM Sterile Powder is a fine, dry, heat-sterilized light powder prepared by milling absorbable gelatin sponge.

### ACTION

GELFOAM has hemostatic properties. While its mode of action is not fully understood, its effect appears to be more physical than the result of altering the blood clotting mechanism.

When not used in excessive amounts, GELFOAM is absorbed completely, with little tissue reaction. This absorption is dependent on several factors, including the amount used, degree of saturation with blood or other fluids, and the site of use. When placed in soft tissues, GELFOAM is usually absorbed completely in from four to six weeks, without inducing excessive scar tissue. When applied to bleeding nasal, rectal or vaginal mucosa, it liquefies within two to five days.

### INDICATIONS

**Hemostasis:** GELFOAM Sterile Powder, saturated with sterile sodium chloride solution, is indicated in surgical procedures, including those involving cancellous bone bleeding, as a hemostatic device, when control of capillary, venous, and arteriolar bleeding by pressure, ligature, and other conventional procedures is either ineffective or impractical. Although not necessary, GELFOAM can be used either with or without thrombin to obtain hemostasis.

### DIRECTIONS FOR USE

GELFOAM Sterile Powder must be saturated with sterile, isotonic sodium chloride solution (sterile saline) or a solution of thrombin<sup>1</sup>, before use as an adjunct to hemostasis. The envelope of GELFOAM Sterile Powder should be opened and the contents (1 gram) poured carefully into a sterile beaker, avoiding contamination. Using sterile technique, a puttylike paste is prepared by adding a total of approximately 3-4 mL of sterile saline or thrombin solution<sup>1</sup> to the GELFOAM. If a mixture of less viscosity is desired, 7-10 mL of sterile saline or thrombin solution may be utilized. Dispersion of the powder can be avoided by initially compressing it with the gloved fingers into the bottom of the beaker and then kneading it into the desired consistency. The resulting doughy paste may be smeared or pressed against the bleeding surface to control bleeding. When bleeding stops the excess should be removed.

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<sup>1</sup> Prepared as per label recommendations.

Use only the minimum amount of GELFOAM, necessary to produce hemostasis. The GELFOAM may be left in place at the bleeding site, when necessary. Since GELFOAM causes little more cellular reaction than does the blood clot, the wound may be closed over it. GELFOAM may be left in place when applied to mucosal surfaces until it liquefies. For use with thrombin, consult the thrombin insert for complete prescribing information and proper sample preparation.

### **CONTRAINDICATIONS**

GELFOAM should not be used in closure of skin incisions because it may interfere with healing of the skin edges. This is due to mechanical interposition of gelatin and is not secondary to intrinsic interference with wound healing.

GELFOAM should not be placed in intravascular compartments, because of the risk of embolization.

Do not use GELFOAM Sterile Powder in patients with known allergies to porcine collagen.

### **WARNINGS**

GELFOAM is not intended as a substitute for meticulous surgical technique and the proper application of ligatures, or other conventional procedures for hemostasis. GELFOAM is supplied as a sterile product and cannot be resterilized. Unused, opened envelopes of GELFOAM should be discarded.

To prevent contamination, employ aseptic procedure in opening envelope and withdrawing GELFOAM. If the envelope is torn or punctured, the contained GELFOAM should not be used.

Only the minimum amount of GELFOAM necessary to achieve hemostasis should be used. Once hemostasis is attained, excess GELFOAM should be carefully removed.

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

Although the safety and efficacy of the combined use of GELFOAM with other agents such as topical thrombin has not been evaluated in controlled clinical trials, if in the physician's judgment concurrent use of other agents is medically advisable, the product literature for that agent should be consulted for complete prescribing information.

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

Whenever possible, it should be removed after use in laminectomy procedures and from foramina in bone, once hemostasis is achieved. This is because GELFOAM may swell on absorbing fluids, and produce nerve damage by pressure within confined bony spaces.

The packing of GELFOAM, particularly within bony cavities, should be avoided, since swelling may interfere with normal function and/or possibly result in compression necrosis of surrounding tissues.

### **PRECAUTIONS**

The minimum amount of GELFOAM Sterile Powder needed for hemostasis should be applied together with pressure until the bleeding stops. The excess should then be removed.

GELFOAM should not be used for controlling postpartum hemorrhage or menorrhagia.

It has been demonstrated that fragments of another hemostatic agent, microfibrillar collagen, pass through the 40 $\mu$  transfusion filters of blood scavenging systems.

GELFOAM should not be used in conjunction with autologous blood salvage circuits since the safety of this use has not been evaluated in controlled clinical trials.

Microfibrillar collagen has been reported to reduce the strength of methylmethacrylate adhesives used to attach prosthetic devices to bone surfaces. As a precaution, GELFOAM should not be used in conjunction with such adhesives.

GELFOAM is not recommended for the primary treatment of coagulation disorders.

It is not recommended that GELFOAM be saturated with an antibiotic solution or dusted with antibiotic powder.

Positioning of the patient resulting in negative peripheral venous pressure during a procedure has been reported to be a contributing factor resulting in life-threatening thromboembolic events.

### **ADVERSE REACTIONS**

There have been reports of fever associated with the use of GELFOAM, without demonstrable infection. GELFOAM may serve as a nidus for infection and abscess formation<sup>1</sup>, and has been reported to potentiate bacterial growth. Giant-cell granuloma has been reported at the implantation site of absorbable gelatin product in the brain<sup>2</sup>, as has compression of the brain and spinal cord resulting from the accumulation of sterile fluid.<sup>3</sup>

Foreign body reactions, "encapsulation" of fluid and hematoma have also been reported.

When GELFOAM was used in laminectomy operations, multiple neurologic events were reported, including but not limited to cauda equina syndrome, spinal stenosis, meningitis, arachnoiditis, headaches, paresthesias, pain, bladder and bowel dysfunction, and impotence.

Excessive fibrosis and prolonged fixation of a tendon have been reported when absorbable gelatin products were used in severed tendon repair.

Toxic shock syndrome has been reported in association with the use of GELFOAM in nasal surgery.

Fever, failure of absorption, and hearing loss have been reported in association with the use of GELFOAM during tympanoplasty.

#### **ADVERSE REACTIONS REPORTED FROM UNAPPROVED USES**

GELFOAM is not recommended for use other than as an adjunct for hemostasis.

While some adverse medical events following the unapproved use of GELFOAM have been reported to Pharmacia & Upjohn Company (see ADVERSE REACTIONS), other hazards associated with such use may not have been reported.

When GELFOAM has been used during intravascular catheterization for the purpose of producing vessel occlusion, the following adverse events have been reported; fever, duodenal and pancreatic infarct, embolization of lower extremity vessels, pulmonary embolization, splenic abscess, necrosis of specific anatomic areas, asterixis, and death.

These adverse medical events have been associated with the use of GELFOAM for repair of dural defects encountered during laminectomy and craniotomy operations: fever, infection, leg paresthesias, neck and back pain, bladder and bowel incontinence, cauda equina syndrome, neurogenic bladder, impotence, and paresis.

#### **ADVERSE EVENTS ASSOCIATED WITH BONE HEMOSTASIS**

In a clinical study, 108 patients received GELFOAM Sterile Powder on the cut surface of the sternum during cardiopulmonary bypass surgery, while 107 patients received no treatment on the cut surface of the bone. Table 1 is a summary of medical events reported by at least 1.0% of patients in a treatment group. The most frequently reported events were atrial fibrillation, perioperative event, and wound infection. Events occurring in less than 1.0% of the patients were as follows: anaphylaxis, cardiogenic shock, delirium tremens, infection at the vascular catheter site, unevaluable reaction, sepsis, angina pectoris, atrial arrhythmia, nodal arrhythmia, arteriosclerosis, cardiac insufficiency, cardiac tamponade, cardiomyopathy, deep vein thrombosis, mitral valve disorder, endocarditis, ventricular extrasystoles, heart arrest, hypotension, mesenteric occlusion, supraventricular tachycardia, thrombophlebitis, thrombosis, gastrointestinal disorder, gastrointestinal bleeding, increased serum creatinine, dehydration, anemia, thrombocytopenia, abnormal healing, hypovolemia, hypoxia, metabolic acidosis, cerebral infarction, visual hallucinations, stupor, aspiration pneumonia, chest congestion, pleural effusion, pulmonary infiltration, retinal artery occlusion, anuria, UG disorder, abnormal kidney function and menorrhagia.

**Table 1: Summary of Medical Events for GELFOAM Sterile Powder when used as a Bone Hemostatic Agent During Cardiopulmonary Bypass Surgery**

Medical Event	GELFOAM N=108		Control N=107		Total N=215	
	n	%	n	%	n	%
Atrial Fibrillation	14	(13)	12	(11)	26	(12)
Wound Infection	6	(6)	1	(0.9)	7	(3.3)
Perioperative Event	4	(4)	5	(4.7)	9	(4.2)
Congestive Heart Failure	4	(4)	0	(0)	4	(1.9)
Ventricular Tachycardia	2	(2)	3	(2.8)	5	(2.3)
Atrial Flutter	2	(2)	0	(0)	2	(0.9)
Peripheral Vascular Disorder	2	(2)	0	(0)	2	(0.9)
Pneumothorax	2	(2)	3	(2.8)	5	(2.3)
Respiratory Failure	2	(2)	2	(1.9)	4	(1.9)
Respiratory Arrest	2	(2)	1	(0.9)	3	(1.4)
Fever	1	(1)	2	(1.9)	3	(1.4)
Heart Block	1	(1)	2	(1.9)	3	(1.4)
Prolonged Wound Drainage	0	(0)	1	(0.9)	1	(0.5)
Cellulitis	0	(0)	2	(1.9)	2	(0.9)
Dyspnea	0	(0)	2	(1.9)	2	(0.9)
Pneumonia	0	(0)	2	(1.9)	2	(0.9)

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.
- After placement, absorbable hemostatic agents may be visible on imaging studies until they are fully absorbed, which could be interpreted as pseudotumor appearance.
- 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 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 hemotoma 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

GELFOAM Sterile Powder is a water-insoluble, hemostatic device prepared from purified skin gelatin, and capable of absorbing up to 45 times its weight of whole blood.<sup>4</sup> The absorptive capacity of GELFOAM is a function of its physical size, increasing as the amount of the gelatin powder increases.<sup>5</sup>

The mechanism of action of surface-mediated hemostatic devices is supportive and mechanical.<sup>5</sup> Surface acting devices, when applied directly to bleeding surfaces, arrest bleeding by the formation of an artificial clot and by producing a mechanical matrix that facilitates clotting.<sup>6</sup> Jenkins et al<sup>7</sup> have theorized that the clotting effect of GELFOAM may be due to release of thromboplastin from platelets, occurring when platelets entering the sponge become damaged by contact with the walls of its myriad of interstices. Thromboplastin interacts with prothrombin and calcium to produce thrombin, and this sequence of events initiates the clotting reaction. The authors suggest that the physiologic formation of thrombin in the sponge is sufficient to produce formation of a clot, by its action on the fibrinogen in blood.<sup>7</sup> The spongy physical properties of the gelatin sponge hasten clot formation and provide structural support for the forming clot.<sup>6,8</sup>

Several investigators have claimed that GELFOAM becomes liquefied within a week or less and is completely absorbed in four to six weeks, without inducing excessive scar formation.<sup>4,7,9,10,11</sup> Barnes<sup>10</sup> reviewed experiences with GELFOAM in gynecologic surgery. No excessive scar tissue, attributable to the absorption of GELFOAM, could be palpated at postoperative examination.

### **Bone Hemostasis Study:**

The efficacy of GELFOAM Sterile Powder as a bone hemostatic agent during cardiopulmonary bypass surgery was evaluated.

#### Study Design

Two randomized open-label clinical studies were conducted at separate investigative sites. The objectives were as follows:

- To evaluate the effectiveness of GELFOAM Sterile Powder as a hemostatic agent in the treatment of sternal bone bleeding during cardiopulmonary bypass surgery.
- To identify any deleterious effects of GELFOAM Sterile Powder on interference with bone healing.
- To determine any systemic or local wound side effects from leaving GELFOAM Sterile Powder *in situ*.

Patients between the ages of 18 to 74 years old undergoing cardiopulmonary bypass surgery were randomly assigned to either a GELFOAM group or a Control group. The GELFOAM group (composed of 108 patients) had a paste made up of sterile saline solution and GELFOAM Sterile Powder applied to the cut sternal surface immediately following sternotomy. The Control group (composed of 107 patients) received no treatment applied to the cut surface.

Blood loss was monitored both during surgery and postoperatively. Blood loss during surgery was determined by measuring the weight of the powder before and after application to the cut edge of the sternum. Postoperative blood loss was collected

from the mediastinal drainage tubes. The total blood loss (in milligrams) over 72 hours was determined for each patient.

#### Study Endpoints

Patients were evaluated upon admission (preoperative), during surgery (intraoperative), after surgery (postoperative), upon hospital discharge (7 to 10 days after surgery), and at the 3-month follow-up visit. An additional poststudy follow-up was required if a patient reported an ongoing medical event at the 3-month follow-up visit.

#### Study Results

In both studies, the amount of blood loss was significantly less in the GELFOAM group than in the Control group. In Study 001, the mean blood loss in the GELFOAM group was 13727.7 mg while the mean blood loss in the Control group was more than double at 27712.0 mg. Similar results were found in Study 002, where the mean blood loss in the GELFOAM group was 9514.8 mg while the mean blood loss in the Control group was 22687.5 mg.

**Table 2: Blood Loss in Sternotomy Patients**

	Site 001		Site 002	
	<b>GELFOAM</b>	<b>Control</b>	<b>GELFOAM</b>	<b>Control</b>
Mean Blood Loss (mg)	13727.7	27712.0	9514.8	22687.5
Median Blood Loss (mg)	11561.0	24798.0	6950.0	16900.0
Minimum Blood Loss (mg)	2922.0	10748.0	800.0	900.0
Maximum Blood Loss (mg)	87448.0	61535.0	46000.0	89800.0

Patients in the GELFOAM and Control groups were similar with regard to sternal bone healing. At hospital discharge, normal bone healing was reported for 105 patients (97%) in the GELFOAM group and 104 patients (97%) in the Control group. At the 3-month follow-up, 103 patients (95%) in the GELFOAM group and 100 patients (93%) in the Control group were healed.

Few patients in either treatment group had sternotomy infection or other postoperative infection complications related to sternotomy. At hospital discharge, two patients treated with GELFOAM had mediastinitis. No Control patients had any infections at hospital discharge. One patient treated with GELFOAM had a non-infection related complication.

At the 3-month follow-up, one of the original patients treated with GELFOAM who had mediastinitis still showed signs of infection. In addition, two additional patients treated with GELFOAM developed mediastinitis at the 3-month follow-up.

One patient in the Control group experienced sternal osteomyelitis at the 3-month follow-up but recovered with no residual effects. No patients from the GELFOAM arm of the study had reported complications of sternal osteomyelitis.

There was a total of four Control patients who had non-infection-related complications.

One Control patient had serous/sanguineous wound drainage from the left leg and sternum incisions at hospital discharge. This complication was non-infectious and the patient recovered with no residual side effects.

Three Control patients all experienced chronic pain syndrome, a symptom which can occur following thoracic/cardiac surgery. Evaluation sternal bone healing at the 3-month follow-up for these patients showed no evidence of non-union of the sternum. In all three cases, bone healing at the 3-month follow-up was reported as being normal. A summary of sternotomy infection information is located in Table 3.

**Table 3: Summary of Postoperative Infection Complications**

	Hospital Discharge				3-Month Follow-up			
	GELFOAM		Control		GELFOAM		Control	
	N	%	N	%	N	%	N	%
<b>Any Infection</b>								
yes	1	(1)	0	(0)	5	(5)	0	(0)
no	104	(99)	106	(100)	95	(95)	105	(100)
<b>Superficial Wound</b>								
yes	0	(0)	0	(0)	2	(2)	0	(0)
no	105	(100)	106	(100)	98	(98)	105	(100)
<b>Sternal Osteomyelitis</b>								
yes	0	(0)	0	(0)	1	(1)	1	(1)
no	105	(100)	106	(100)	99	(99)	105	(99)
<b>Mediastinitis</b>								
yes	1	(1)	0	(0)	2	(2)	0	(0)
no	104	(99)	106	(100)	98	(98)	105	(100)
<b>Complication Related to Sternotomy</b>								
yes	0	(0)	0	(0)	1	(1)	3	(3)
no	105	(100)	106	(100)	99	(99)	102	(97)

### Study Conclusions

These studies demonstrate that a paste made from GELFOAM Sterile Powder is safe and effective in treating intraoperative bleeding when applied to the cut surface of cancellous bone and has shown superior hemostasis versus no treatment at all to the cut bone surface. The benefit to patients is that a reduction in bleeding will make surgery easier to perform by reducing the time the surgeon needs to revisit cut bone surfaces to clean up the bleeding. This study also demonstrated that GELFOAM Sterile Powder could be left *in situ* without increased risk of bone infection or non-union of the sternum.

### DOSAGE AND ADMINISTRATION

Sterile technique should always be used. The minimum amount of GELFOAM should be applied to the bleeding site (see DIRECTIONS FOR USE) with pressure until hemostasis is observed. Opened envelopes of unused GELFOAM should always be discarded.

### HOW SUPPLIED

GELFOAM Sterile Powder (absorbable gelatin powder) is supplied in envelopes containing 1 gram:

Carton of 6 Envelopes: GTIN 00300090433048 (0009-0433-04).



(Individual) One Gram Single-Patient-Use Sterile Powder Envelope: GTIN 00300090433109 (0009-433-10).

The GELFOAM One Gram Single-Patient-Use Sterile Powder Envelope is supplied in the following kit presentation:

GELFOAM-JMI™ Powder Kit (GELFOAM Absorbable Gelatin Powder and Thrombin, Topical (Bovine) USP, Thrombin-JMI®, 5,000 International Units): GTIN 00360793410104 (60793-410-10).

#### **STORAGE AND HANDLING**

GELFOAM Sterile Powder should be stored at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature]. Once the envelope is opened, contents are subject to contamination. It is recommended that GELFOAM be used as soon as the envelope is opened and unused contents discarded. This product is prepackaged sterile and intended only for single use. Reuse can result in transmission of bloodborne pathogens (including HIV and hepatitis), potentially endangering patients and health care providers. Adherence to the principles of aseptic technique when using this product is essential.

**Caution:** Federal law restricts this device to sale by or on the order of a physician.

#### **ANIMAL PHARMACOLOGY**

##### **Thrombin Concentration Study<sup>12</sup>**

In a blinded pre-clinical study conducted on a liver lesion model in swine, an inverse dose related response was observed between the visual bleeding scores and the thrombin\* concentration within the absorbable gelatin powder syringe delivery system, GEL-FLOW™ NT (a device containing 550 mg of GELFOAM Sterile Powder). Bleeding was assigned scores according to a visual scale (Adams et al. 2009<sup>13</sup>), with scores of 0 (no bleeding), 0.5 (ooze), 1 (very slight), 2 (slight), 3 (moderate), and 4 (severe). Scores of 1 and less were considered clinically acceptable. The 770 IU/mL thrombin concentration provided statistically significant lower bleeding scores than either 375 IU/mL or 250 IU/mL thrombin concentrations\*\* (Table 4). The results of this study showed that higher concentrations of thrombin within the GEL-FLOW NT syringe resulted in improved hemostasis as measured by lower bleeding scores.

\*Thrombin-JMI® (Thrombin, Topical (Bovine) USP) was used for all thrombin concentrations tested in this study. \*\*Per the Thrombin-JMI® prescribing information, for routine use THROMBIN-JMI is reconstituted with sterile isotonic saline at a recommended concentration of 1,000 to 2,000 International Units per mL.

**Table 4: Comparison of Effect on Hemostasis of Varying Thrombin Concentrations in GEL-FLOW NT as Measured by Bleeding Scores in Swine Liver Lesion Model**

Comparison of Effect on Bleeding Scores of Varying Thrombin Concentrations in GEL-FLOW NT in Animal Model using Repeated Measures Logistic Regression			
Parameter	250 IU/mL Mean (Standard Error)	375 IU/mL Mean (Standard Error)	770 IU/mL Mean (Standard Error)
3 Minute Bleeding Score	1.8 (0.2)	1.6 (0.2)	0.7 (0.2)**
6 Minute Bleeding Score	1.7 (0.2)	1.5 (0.2)	0.6 (0.2)**
9 Minute Bleeding Score	1.5 (0.2)	1.2 (0.2)	0.5 (0.2)**
12 Minute Bleeding Score	1.4 (0.2)	1.0 (0.2)*	0.4 (0.2)**

\*Significantly different from 250 IU/mL at the 0.05 significance level. Tukey adjusted p-value for multiple comparisons.

\*\*Significantly different from both 250 and 375 IU/mL at <0.001 significance level. Tukey adjusted p-values for multiple comparisons.

Surface-acting hemostatic devices, when applied directly to bleeding surfaces, arrest bleeding by providing a mechanical matrix that facilitates clotting.<sup>6,8,14,15</sup> Due to their bulk, surface-acting hemostatic agents slow the flow of blood, protect the forming clot, and offer a framework for deposition of the cellular elements of blood.<sup>6,7,8,14</sup> MacDonald and Mathews<sup>16</sup> studied GELFOAM implants in canine kidneys and reported that it assisted in healing, with no marked inflammatory or foreign-body reactions.

Jenkins and Janda<sup>14</sup> studied the use of GELFOAM in canine liver resections and noted that the gelatin sponge appeared to offer a protective cover and provide structural support for the reparative process.

Correll et al<sup>15</sup> studied the histology of GELFOAM Sterile Sponge when implanted in rat muscle and reported no significant tissue reaction.

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This product's label may have been updated. For current full prescribing information, please visit [www.pfizer.com](http://www.pfizer.com).



DO NOT RE-USE



Method of sterilization using steam or dry heat



Attention, see instructions for use



CONSULT Instructions for Use



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