

Gelfoam[®]

absorbable gelatin sponge, USP

DESCRIPTION

GELFOAM Sterile Sponge 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 NF Granules and Water for Injection, USP. It may be cut without fraying and is able to absorb and hold within its interstices, many times its weight of blood and other fluids.

ACTION

GELFOAM Sterile Sponge 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 upon 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 within 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 Sponge, used dry or saturated with sterile sodium chloride solution, is indicated in surgical procedures 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 Sponge can be used either dry or saturated with sterile saline or thrombin* solution. Prior to GELFOAM Sterile Sponge application, the target bleeding site should be visualized if feasible.

Use only the minimum amount of GELFOAM Sterile Sponge necessary to produce hemostasis. The first application of GELFOAM Sterile Sponge will usually control bleeding; if not, repeat the steps below using a new piece of GELFOAM Sterile Sponge.

Always use sterile technique in handling GELFOAM Sterile Sponge.

For all applications, follow Steps 1 through 3:

1. Inspect the GELFOAM Sterile Sponge package for signs of damage. DO NOT use if the package is damaged.
2. Remove GELFOAM Sterile Sponge from packaging.
3. Cut to the desired size.

When applied dry:

1. **Manually compress** a single piece of GELFOAM Sterile Sponge.
2. Apply to the bleeding site. Hold GELFOAM Sterile Sponge in place with **moderate pressure** until hemostasis is achieved. Use a pledget of cotton or small gauze sponge as necessary.
3. If used, wet the pledget or gauze with a few drops of sterile saline before removing.
(Wetting the pledget or gauze will prevent pulling up the GELFOAM Sterile Sponge, which by then should enclose a firm clot.)

When applied wet:

1. Immerse GELFOAM Sterile Sponge in sterile saline or thrombin solution.
2. Remove from saline or thrombin solution and **squeeze between gloved fingers to expel air bubbles.**
3. Replace in saline or thrombin solution until needed.
(GELFOAM Sterile Sponge should promptly return to its original size and shape in the solution. If it does, go to Step 7. If it does not, follow Steps 4 and 5.)
4. Remove from saline or thrombin solution again and **knead vigorously until all air is expelled.**
5. Return GELFOAM Sterile Sponge to saline or thrombin solution and ensure it expands to its original size and shape.
6. **If desired, blot to dampness on gauze to remove excess fluid.**
7. Apply to the bleeding site. Hold in place with **moderate pressure** using a pledget of cotton or small gauze until hemostasis is achieved.
8. Remove the pledget or gauze by wetting it with a few drops of sterile saline.
(Wetting the pledget or gauze will prevent pulling up the GELFOAM Sterile Sponge, which by then should enclose a firm clot.)

Notes:

- It is not necessary to use suction over the pledget of cotton or gauze to draw blood into the GELFOAM Sterile Sponge as the GELFOAM Sterile Sponge will draw up sufficient blood by capillary action.
- Once hemostasis is achieved, GELFOAM Sterile Sponge may be left at the bleeding site when necessary. GELFOAM Sterile Sponge may be left in place when applied to mucosal surfaces until it liquefies.
- Since GELFOAM Sterile Sponge causes little more cellular reaction than does the blood clot, the wound may be closed over it.
- **For use with thrombin, consult the thrombin insert for complete prescribing information and proper sample preparation.**

* Prepared as per thrombin label instructions.

CONTRAINDICATIONS

GELFOAM Sterile Sponge 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 must not be placed in intravascular compartments because of the risk of embolization.

Do not use GELFOAM Sterile Sponge in patients with known allergies to porcine collagen (see **WARNINGS**).

WARNINGS

Life-threatening anaphylactic reactions, including death, have been reported after exposure to absorbable gelatin. Patients with history of allergies to porcine products may be at risk of serious acute hypersensitivity reactions, including anaphylaxis (see **CONTRAINDICATIONS**). If an anaphylactic reaction is observed, absorbable gelatin administration should be immediately discontinued and any applied product removed.

GELFOAM Sterile Sponge 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 must not be re-sterilized. Unused, opened envelopes of GELFOAM must be discarded.

To prevent contamination, employ aseptic procedure in opening envelope and withdrawing GELFOAM. If the envelope is damaged, the contained GELFOAM must 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 to its original size on absorbing fluids, and produce nerve damage by pressure within confined bony spaces.

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

PRECAUTIONS

GELFOAM should not be placed in the vicinity of the cerebral ventricular space or where there is a possibility of a cerebrospinal fluid fistula to the target bleeding site. GELFOAM should also not be used as a tissue substitute to repair tissue defects of the dura or the cranium. GELFOAM may migrate from central nervous system (CNS) surgical sites into the cerebral ventricular space and compromise the cerebrospinal fluid circulation. Hydrocephalus and cerebrospinal fluid retention, requiring a re-intervention to remove GELFOAM residue, have been reported in adult and pediatric patients (see **ADVERSE REACTIONS**). In some cases, these complications occurred several months after use of GELFOAM.

Use only the minimum amount of GELFOAM Sterile Sponge needed for hemostasis, holding it at the site until bleeding stops and then removing the excess.

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

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

Microfibrillar collagen has been reported to reduce the strength of methyl-methacrylate 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 intravascular migration of gelatin and life-threatening thromboembolic events and should be avoided.

ADVERSE REACTIONS

Life-threatening anaphylactic reactions, including death, have been reported after exposure to absorbable gelatin (see **WARNINGS**).

Product migration to the cerebral ventricular space followed by hydrocephalus or cerebrospinal fluid retention leading to secondary intervention, has been reported following neurosurgery in the vicinity of the ventricular space (see **PRECAUTIONS**).

There have been reports of fever associated with the use of GELFOAM, without demonstrable infection. GELFOAM Sterile Sponge may serve as a nidus of infection and abscess formation¹, 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,² as has compression of the brain and spinal cord resulting from the accumulation of sterile fluid.³

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

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

Pseudoinfection/pseudoabscess has also been reported in the literature.

Pseudotumor/pseudomass and pseudoinfection/pseudoabscess may result in additional invasive procedures, reoperations, and prolonged hospital stays.

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 for topical application to bleeding surfaces as a hemostatic agent.

While some adverse medical events following the unapproved use of GELFOAM have been reported (see **ADVERSE REACTIONS**), other potential harms 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; vessel recanalization, intravascular gelatin migration, fever, end organ ischemia and infarction, pancreatitis, post-embolization syndrome, ischemia and infarction at unintended locations (such as duodenum and pancreas), duct stenosis (such as bile duct stenosis), gangrene, infection, necrosis, organ dysfunction, infertility, embolization of extremities, pulmonary embolization, splenic abscess, asterixis, and death.

The following 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.

The following adverse medical events have been associated with the use of GELFOAM with or without bone dust for repair of dural and cranial defects encountered during burr-hole

operations or craniotomies: cerebrospinal fluid retention and hydrocephalus leading to secondary intervention (see **PRECAUTIONS**).

DOSAGE AND ADMINISTRATION

Sterile technique should always be used in removing the inner envelope containing the GELFOAM Sterile Sponge from the outer printed sealed envelope. The minimum amount of GELFOAM of appropriate size and shape should be applied dry or wet (see **DIRECTIONS FOR USE**) to the bleeding site and held firmly in place until hemostasis is observed. Opened envelopes of unused GELFOAM must always be discarded.

HOW SUPPLIED

GELFOAM Sterile Sponge is supplied in a sterile envelope enclosed in an outer peelable envelope. Sterility of the product is assured unless the outer envelope has been damaged or opened. It is available in the following sizes:

Sponge-Size 12—7 mm	Box of 12	GTIN 00300090315085 (0009-0315-08)
Sponge-Size 50	Box of 4	GTIN 00300090323011 (0009-0323-01)
Sponge-Size 100	Box of 6	GTIN 00300090342012 (0009-0342-01)
Sponge-Size 100	(Individual) One Sterile Sponge	GTIN 00300090342104 (0009-0342-10)
Sponge-Size 200	Box of 6	GTIN 00300090349035 (0009-0349-03)
GELFOAM-JMI™ Sponge Kit (GELFOAM Absorbable Gelatin Sponge USP and Thrombin, Topical (Bovine) USP, Thrombin- JMI®, 5,000 International Units)-Size 100	Kit includes GELFOAM Absorbable Gelatin Sponge, USP, One Sterile Sponge	GTIN 00360793310107 (60793-310-10)

Storage and Handling

GELFOAM Sterile Sponge should be stored at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature]. Once the package is opened, contents are subject to contamination. It is recommended that GELFOAM be used as soon as the package 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.

CLINICAL STUDIES

GELFOAM Sterile Sponge is a water-insoluble, hemostatic device prepared from purified skin gelatin, and capable of absorbing up to 45 times its weight of whole blood.¹⁰ The

absorptive capacity of GELFOAM is a function of its physical size, increasing as the size of the gelatin sponge increases.¹¹

The mechanism of action of surface-mediated hemostatic devices is supportive and mechanical.¹¹ 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.⁴ Jenkins et-al⁸ 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 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.⁸ The spongy physical properties of the gelatin sponge hasten clot formation and provide structural support for the forming clot.^{4,5}

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.^{7,10,12,13,14} Barnes¹³ reviewed experiences with GELFOAM in gynecologic surgery. No excessive scar tissue, attributable to the absorption of GELFOAM, could be palpated at postoperative examination.

ANIMAL PHARMACOLOGY

Surface-acting hemostatic devices, when applied directly to bleeding surfaces, arrest bleeding by providing a mechanical matrix that facilitates clotting.^{4,5,6,7} 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.^{4,5,6,8} MacDonald and Mathews⁹ studied GELFOAM implants in canine kidneys and reported that it assisted in healing, with no marked inflammatory or foreign-body reactions.

Jenkins and Janda⁵ 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 al⁷ studied the histology of GELFOAM Sterile Sponge when implanted in rat muscle and reported no significant tissue reaction.

REFERENCES

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This product's label may have been updated. For current full prescribing information, please visit www.pfizer.com.



DO NOT RE-USE



Method of sterilization using steam or dry heat



Attention, see instructions for use



CONSULT Instructions for Use



DO NOT RESTERILIZE



DO NOT USE IF PACKAGE IS DAMAGED



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