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 USP 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.

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
Sterile technique should always be used to remove GELFOAM Sterile Sponge from its packaging. Cut to the desired size, a piece of GELFOAM, either dry or saturated with sterile, isotonic sodium chloride solution (sterile saline), can be applied with pressure directly to the bleeding site. When applied dry, a single piece of GELFOAM should be manually compressed before application to the bleeding site, and then held in place with moderate pressure until hemostasis results. When used with sterile saline, GELFOAM should be first immersed in the solution and then withdrawn, squeezed between gloved fingers to expel air bubbles, and then replaced in saline until needed. The GELFOAM sponge should promptly return to its original size and shape in the solution. If it does not, it should be removed again and kneaded vigorously until all air is expelled and it does expand to its original size and shape when returned to the sterile saline.

GELFOAM is used wet or blotted to dampness on gauze before application to the bleeding site. It should be held in place with moderate pressure, using a pledget of cotton or small gauze sponge until hemostasis results. Removal of the pledget or gauze is made easier by wetting it with a few drops of sterile saline, to prevent pulling up the GELFOAM which by then should enclose a firm clot. Use of suction applied over the pledget of cotton or gauze to draw blood into the GELFOAM is unnecessary, as the GELFOAM will draw up sufficient
blood by capillary action. The first application of GELFOAM will usually control bleeding, but if not, additional applications may be made using fresh pieces, prepared as described above.

Use only the minimum amount of GELFOAM, cut to appropriate size, 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 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 should 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.

WARNINGS
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 cannot be resterilized. Unused, opened envelopes of GELFOAM should be discarded. WARNING: 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 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**

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.

It has been demonstrated that fragments of another hemostatic agent, microfibrillar collagen,
pass through the 40μ 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 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 life-threatening thromboembolic
events.

**ADVERSE REACTIONS**

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. Giantcell 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.

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.

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.

**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 INDICATIONS AND USAGE, Directions for Use) to the bleeding site and held firmly in place until hemostasis is observed. Opened envelopes of unused GELFOAM should 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:

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

The mechanism of action of surface-mediated hemostatic devices is supportive and mechanical. 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. Jenkins et-al 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. The spongy physical properties of the gelatin sponge hasten clot formation and provide structural support for the forming clot.

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. Barnes 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. 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. MacDonald and Mathews studied GELFOAM implants in canine kidneys and reported that it assisted in healing, with no marked inflammatory or foreign-body reactions.

Jenkins and Janda 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\textsuperscript{7} studied the histology of GELFOAM Sterile Sponge when implanted in rat muscle and reported no significant tissue reaction.

\textbf{REFERENCES}


This product’s label may have been updated. For current full prescribing information, please visit \texttt{www.pfizer.com}.