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**Important Safety Information for GELFOAM Sterile Sponge, GELFOAM Sterile Compressed Sponge, and GELFOAM Sterile Powder**

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 in patients with known allergies to porcine collagen.

Unused, opened envelopes of GELFOAM should be discarded and cannot be re-sterilized.

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.

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.

Important Safety Information for Gelfoam Sterile Sponge, Gelfoam Sterile Compressed Sponge, and Gelfoam Sterile Powder continued on next page.
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. GELFOAM should not be used for controlling postpartum bleeding or menorrhagia.

GELFOAM should not be used in conjunction with autologous blood salvage circuits or methylmethacrylate adhesives.

There have been reports of the following events associated with the use of GELFOAM: fever (without demonstrated infection), infection, abscess formation, giant cell granuloma, CNS compression, foreign body reaction, encapsulation of fluid, hematoma, excessive fibrosis, prolonged fixation of a tendon, toxic shock syndrome, and hearing loss (in tympanoplasty surgeries).

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.

**Indication for GELFOAM Sterile Sponge and GELFOAM Sterile Compressed Sponge**

GELFOAM Sterile Sponge and GELFOAM Sterile Compressed Sponge, used dry or saturated with sterile sodium chloride solution, are indicated in surgical procedures as hemostatic devices, 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.

**Indication for GELFOAM Sterile Powder**

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.

Please see accompanying Instructions for Use for Gelfoam Sterile Sponge, Gelfoam Sterile Compressed Sponge, and Gelfoam Sterile Powder beginning on page 4.

Important Safety Information for Gelfoam Sterile Sponge, Gelfoam Sterile Compressed Sponge, and Gelfoam Sterile Powder continued from previous page.

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

GELFOAM should not be used in conjunction with autologous blood salvage circuits or methylmethacrylate adhesives.

There have been reports of the following events associated with the use of GELFOAM: fever (without demonstrated infection), infection, abscess formation, giant cell granuloma, CNS compression, foreign body reaction, encapsulation of fluid, hematoma, excessive fibrosis, prolonged fixation of a tendon, toxic shock syndrome, and hearing loss (in tympanoplasty surgeries).

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.

**Indication for GELFOAM Sterile Sponge and GELFOAM Sterile Compressed Sponge**

GELFOAM Sterile Sponge and GELFOAM Sterile Compressed Sponge, used dry or saturated with sterile sodium chloride solution, are indicated in surgical procedures as hemostatic devices, 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.

**Indication for GELFOAM Sterile Powder**

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.

Please see accompanying Instructions for Use for Gelfoam Sterile Sponge, Gelfoam Sterile Compressed Sponge, and Gelfoam Sterile Powder beginning on page 4.

Gelfoam® is a registered trademark of Pharmacia & Upjohn Company, LLC, a Pfizer company.

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**References**

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 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 4μ transfer 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 formation, and has been reported to potentiate bacterial growth. Giantcell granuloma has been reported at the implantation site of absorbable gelatin product in the brain, as has compression of the brain and spinal cord resulting from the accumulation of sterile fluid.

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.

Tissue 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 during tympanoplasty.

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.

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.

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 during tympanoplasty.

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.

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.
HISTORY AND USE

GELFOAM Sterile Sponge is supplied in a sterile envelope enclosed in an outer peable 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 200**
  - Box of 6
  - GTIN 00300090349035
  - (0009-0349-03)

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

REFERENCES

Gelfoam® absorbable gelatin compressed sponge, USP

DESCRIPTION
GELFOAM Sterile Compressed 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 porcine skin gelatin, 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.

ACTIONS
GELFOAM Sterile Compressed 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 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 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.

CLINICAL STUDIES
GELFOAM Sterile Compressed Sponge is a water-insoluble, hemostatic device prepared from purified porcine 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.

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ANIMAL PHYSIOPHARMACOLOGY
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 studied the histology of GELFOAM Sterile Compressed Sponge when implanted in rat muscle and reported no significant tissue reaction.

INDICATIONS
HEMOSTASIS. GELFOAM Sterile Compressed 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 Compressed 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 applied to the bleeding site, and 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, with slight expansion in thickness 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, with slight increases in thickness and shape when returned to the sterile saline.

GELFOAM if used wet it may be 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 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. For additional applications, fresh pieces should be used and prepared as previously described.

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 Compressed Sponge should not be used in closure of skin incisions because it may interfere with the healing of 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 Compressed Sponge in patients with known allergies to porcine collagen.

WARNINGS
GELFOAM Sterile Compressed 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 laminecctomy 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 bedding of GELFOAM, particularly in 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 Compressed Sponge needed for hemostasis, holding it at the site until bleeding stops, then removing the excess.

GELFOAM should not be used for controlling postpartum bleeding 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 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 Sterile Compressed Sponge may form a nidus of infection and abscess formation, and has been reported to potentiate bacterial growth.

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.

There have been reports of fever associated with the use of GELFOAM, without demonstrable infection. GELFOAM Sterile Compressed Sponge may form a nidus of infection and abscess formation, 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, and compression of the brain and spinal cord resulting from an accumulation of sterile fluid has been reported following use of absorbable gelatin sponge in closed space.
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 USE
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 (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 abscesses, 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 craniootomy operations: fever, infection, leg paresthesias, neck and back pain, bladder and bowel incontinence, cauda equina syndrome, neurogenic bladder, impotence, and paresis.

DOSEAGE 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 should always be discarded.

HOW SUPPLIED
GELFOAM Sterile Compressed Sponge is supplied in an individual 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 as follows

- **Sponge-Size 100 Box of 6** GTIN 00300090353018 (0009-0353-01) (100 sq cm [8X12.5 cm], 15 5/8 sq in [3 1/8 X 5 in])

STORAGE AND HANDLING
GELFOAM Sterile Compressed 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.

REFERENCES


This product's label may have been updated. For current full prescribing information, please visit [www.pfizer.com](http://www.pfizer.com).
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 hemostat. 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 can be saturated with sterile, isotonic sodium chloride solution (sterile saline) or a solution of thrombin1, 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 solution1 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.

1 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 technique 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 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 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 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, 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.

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

Toxic shock syndrome has 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 anatomical 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 paraparesis.

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, cardiacogenic shock, delirium tremens, infection at the vascular catheter site, un evaluable 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.

PRECAUTIONS ASSOCIATED WITH BONE HEMOSTASIS
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To determine any systemic or local wound side effects from leaving GELFOAM Sterile Powder in situ, the study objectives were as follows:

**Study Design**

- **Cardiopulmonary Bypass Surgery:** The efficacy of GELFOAM Sterile Powder as a bone hemostatic agent during cardiopulmonary bypass surgery was evaluated.

- **Bone Hemostasis Study:** Several investigators have claimed that GELFOAM becomes liquefied within a week or less and may not provide support for the forming clot. It has been 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.

- **CLINICAL STUDIES**

  GELFOAM Sterile Powder is a water-insoluble, hemostatic device prepared from purified porcine gelatin-based hemostatic agents. It has been observed that when used in laminecтомy operations, including cauda equina syndrome, a high incidence of permanent neurologic dysfunction and impotence was reported. Several investigators have used absorbable gelatin-based sponges in nasal surgery. Absorbable gelatin-based sponges were used in severed tendon repair. Foreign body reactions, "encapsulation" of fluid, and hematoma have been observed at implant sites.

- **Complications:**
  - Fever, failure of absorption, and hearing loss have been observed when absorbable gelatin-based hemostatic agents were used during tympanoplasty.
  - Toxic shock syndrome was reported in association with the use of absorbable gelatin-based sponges in nasal surgery.
  - Excessive fibrosis and prolonged fixation of a tendon have been reported when absorbable gelatin-based sponges were used in severed tendon repair.
  - Foreign body reactions, "encapsulation" of fluid, and hematoma have been observed at implant sites.

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

<table>
<thead>
<tr>
<th>Medical Event</th>
<th>GELFOAM N=108</th>
<th>Control N=107</th>
<th>Total N=215</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Atrial Fibrillation</td>
<td>14 (13)</td>
<td>12 (11)</td>
<td>26 (12)</td>
</tr>
<tr>
<td>Wound Infection</td>
<td>6 (6)</td>
<td>1 (0.9)</td>
<td>7 (3.3)</td>
</tr>
<tr>
<td>Perioperative Event</td>
<td>4 (4)</td>
<td>5 (4.7)</td>
<td>9 (4.2)</td>
</tr>
<tr>
<td>Congestive Heart Failure</td>
<td>4 (4)</td>
<td>0 (0)</td>
<td>4 (1.9)</td>
</tr>
<tr>
<td>Ventricular Tachycardia</td>
<td>2 (2)</td>
<td>3 (2.8)</td>
<td>5 (2.3)</td>
</tr>
<tr>
<td>Atrial Flutter</td>
<td>2 (2)</td>
<td>0 (0)</td>
<td>2 (0.9)</td>
</tr>
<tr>
<td>Peripheral Vascular Disorder</td>
<td>2 (2)</td>
<td>0 (0)</td>
<td>2 (0.9)</td>
</tr>
<tr>
<td>Pneumononox</td>
<td>2 (2)</td>
<td>3 (2.6)</td>
<td>5 (2.3)</td>
</tr>
<tr>
<td>Respiratory Failure</td>
<td>2 (2)</td>
<td>2 (1.9)</td>
<td>4 (1.9)</td>
</tr>
<tr>
<td>Respiratory Arrest</td>
<td>2 (2)</td>
<td>1 (0.9)</td>
<td>3 (1.4)</td>
</tr>
<tr>
<td>Fever</td>
<td>1 (1)</td>
<td>2 (1.9)</td>
<td>3 (1.4)</td>
</tr>
<tr>
<td>Heart Block</td>
<td>1 (1)</td>
<td>2 (1.9)</td>
<td>3 (1.4)</td>
</tr>
<tr>
<td>Prolonged Wound Drainage</td>
<td>0 (0)</td>
<td>1 (0.9)</td>
<td>1 (0.5)</td>
</tr>
<tr>
<td>Cellulitis</td>
<td>0 (0)</td>
<td>2 (1.9)</td>
<td>2 (0.9)</td>
</tr>
<tr>
<td>Dysepsia</td>
<td>0 (0)</td>
<td>2 (1.9)</td>
<td>2 (0.9)</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>0 (0)</td>
<td>2 (1.9)</td>
<td>2 (0.9)</td>
</tr>
</tbody>
</table>

### Table 2: Blood Loss in Sternotomy Patients

<table>
<thead>
<tr>
<th>Site</th>
<th>Mean Blood Loss (mg)</th>
<th>Median Blood Loss (mg)</th>
<th>Minimum Blood Loss (mg)</th>
<th>Maximum Blood Loss (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>001</td>
<td>13727.7</td>
<td>27712.0</td>
<td>2922.0</td>
<td>87448.0</td>
</tr>
<tr>
<td>002</td>
<td>11561.0</td>
<td>24798.0</td>
<td>1048.0</td>
<td>61535.0</td>
</tr>
</tbody>
</table>

### Table 3: Summary of Postoperative Infection Complications

<table>
<thead>
<tr>
<th>Complication Related to Sternotomy</th>
<th>Site 001</th>
<th>Site 002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>GELFOAM</td>
<td>Control</td>
</tr>
<tr>
<td>Any Infection</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>yes</td>
<td>1 (1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>no</td>
<td>104 (99)</td>
<td>105 (100)</td>
</tr>
<tr>
<td>Superficial Wound</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>yes</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>no</td>
<td>105 (100)</td>
<td>106 (100)</td>
</tr>
<tr>
<td>Sternal Osteomyelitis</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>yes</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>no</td>
<td>105 (100)</td>
<td>106 (100)</td>
</tr>
<tr>
<td>Mediastinitis</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>yes</td>
<td>1 (1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>no</td>
<td>104 (99)</td>
<td>105 (100)</td>
</tr>
</tbody>
</table>

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 has been observed.
- Multiple neurologic events were reported when absorbable gelatin-based hemostatic agents were used in laminecтомy operations, including cauda equina syndrome, spinal stenosis, meningitis, arachnoiditis, headaches, paresthesia, pain, bladder and bowel dysfunction, and impotence and paraparesis.
- 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, laminecтомy 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.

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</tr>
</tbody>
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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 sterna. 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.
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 nonunion of the sternum.

DOSEAGE 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: GTIN 00300090433048 (0009-0433-04).

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

REFERENCES

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