Gelfoam®
Sterile Sponge

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, non-elastic, 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. However, in case of brisk arterial bleeding, the pressure of the flow may prevent the sponge from remaining securely anchored, and bleeding is likely to continue.

DIRECTIONS FOR USE

Always use sterile technique when handling GELFOAM Sterile Sponge.

GELFOAM should be cut to the minimum size required to attain hemostasis. GELFOAM may be applied either dry or saturated with sterile, isotonic sodium chloride solution (sterile saline).

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 When used with sterile saline, GELFOAM should be soaked in the solution, then withdrawn, squeezed between gloved fingers to expel air bubbles present in the interstices, replaced in saline, and kept there until needed. GELFOAM should immediately return to its original size and shape when returned to the solution. If it does not swell, it should be removed and kneaded vigorously until all air is expelled and it does expand to its original shape when returned to the sterile saline.

GELFOAM is used wet or blotted to dampness on gauze before application to the bleeding site. GELFOAM should be applied to the bleeding surface and held in place with
moderate pressure until hemostasis is attained. It is not necessary to apply suction to GELFOAM, since GELFOAM will draw up blood into its interstices by capillary action.

Usually, the first application of GELFOAM will control bleeding, but if not, additional applications may be made, using fresh pieces of GELFOAM.

When bleeding is controlled, the pieces of GELFOAM may be left in place; otherwise, bleeding may start again. Since GELFOAM causes little more cellular infiltration than the blood clot, the wound may be closed over it. When applied to bleeding mucosa, GELFOAM will stay in place until it liquefies.

CONTRAINDICATIONS

GELFOAM Sterile Sponge should not be used in closure of skin incisions because it may interfere with the healing of skin edges.

WARNINGS

GELFOAM Sterile Sponge is supplied as a sterile product and cannot be resterilized by heat, because heating may change absorption time.

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. Ethylene oxide is not recommended for resterilization because it may be trapped in the interstices of the foam. Although, not reported for GELFOAM, the gas is toxic to tissue, and in trace amounts may cause burns or irritation.

GELFOAM should not be used intravascularly due to the risk of embolization.

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 the physician determines that concurrent use of GELFOAM with other agents is medically advisable, the product literature for the other agent should be consulted for complete prescribing information.

PRECAUTIONS

Use of GELFOAM Sterile Sponge 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 in an area where GELFOAM has been positioned, reoperation may be necessary in order to remove the infected material and allow drainage.

GELFOAM should not be used to control postpartum bleeding or menorrhagia. Because GELFOAM absorbs fluid, it may expand and impinge on neighboring structures. Therefore, when placed into cavities or closed tissue spaces, minimal preliminary compression is advised and care should be taken to avoid overpacking.

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

GELFOAM Sterile Sponge may serve as a nidus of infection and abscess formation, and has been reported to potentiate bacterial growth. Fever, without a proven site of infection, has been reported with the use of GELFOAM. Toxic shock syndrome has been reported with the use of GELFOAM during nasal surgery. Fever, failure of absorption, and hearing loss have been reported with the use of GELFOAM during tympanoplasty.

Foreign body reactions, encapsulation of fluid and hematoma formation have been reported with the use of GELFOAM. Giant-cell granuloma has been reported at the implantation site of absorbable gelatin product in the brain, as well as compression of the brain and spinal cord resulting from the accumulation of sterile fluid. Multiple neurologic events have been reported when GELFOAM is used during laminectomy operations, 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 to repair severed tendons.

STORAGE AND HANDLING

GELFOAM Sterile Sponge should be stored at controlled room temperature (20°C to 25°C) [see USP]. 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 be discarded. GELFOAM is supplied as a sterile product and cannot be resterilized. Unused, opened packages of GELFOAM should be 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.

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

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