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GELFOAM®

absorbable gelatin sponge USP

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Sterile Sponge

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 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 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. 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

To open envelope:

1. With the hands folded into fists, grasp each flap between the thumb and index finger.
2. With a slow, rolling motion, carefully peel back the envelope sides until the sterile inner envelope is exposed.
3. Employing sterile technique, remove sterile inner envelope and sterile sponge.

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 dry or saturated with a physiologic saline solution.

When applied dry, GELFOAM should be manually compressed before application to the bleeding site. When used with saline, GELFOAM should be soaked in the solution, then withdrawn, squeezed between gloved fingers to expel air bubbles present in the interstices, replaced in saline, and kept there until needed.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 dropped into the solution. GELFOAM can be 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

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

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

Absorbable gelatin must not be placed into the intravascular compartment because of risk of embolization.

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 should not be resterilized by heat, because heating may change absorption time. 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.

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.

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.

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 used, it may be necessary 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 intravascular migration of gelatin and life-threatening thromboembolic events and should be avoided.

Gelfoam should not be placed in the vicinity of the cerebral ventricular space or where there is a possibility of a cerebral spinal 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 cerebral spinal fluid circulation. Hydrocephalus and cerebral spinal fluid retention, requiring a reintervention 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.

ADVERSE REACTIONS

GELFOAM Sterile Sponge may form a nidus of infection and abscess. 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.

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

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.

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

Adverse reactions reported from unapproved uses

Absorbable gelatin is not recommended for use other than for topical application to bleeding surfaces as a hemostatic agent.

When absorbable gelatin 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), 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 with or without bone dust for repair of dural and cranial defects encountered during burr-hole operations or craniotomies: cerebral spinal fluid retention and hydrocephalus leading to secondary intervention (see Precautions).

STORAGE AND HANDLING

GELFOAM Sterile Sponge should be stored at controlled room temperature 15 to 30 °C. 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.

HOW SUPPLIED

Size 12: 20 mm x 60 mm (12 cm sq.) x 7 mm in boxes of 4 sponges in individual envelopes.

Size 100: 80 mm x 125 mm (100 cm sq.) x 10 mm in boxes of 6 sponges in individual envelopes.

Manufactured by:
Pharmacia & Upjohn Company LLC
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Imported by:
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