Gelfoam®

absorbable gelatin sponge, USP

DESCRIPTION

GELFOAM Dental Sponges are small, sterile, surgical sponges prepared from specially treated and purified gelatin solution which is beaten to desired porosity, dried, sectioned, packaged, sealed, and sterilized by dry heat. GELFOAM is pliable, and is capable of absorbing and holding within its meshes many times its weight in whole blood. It is used as a hemostatic device.

ACTIONS

When implanted in tissues, GELFOAM Dental Sponges are completely absorbed within four to six weeks without inducing excessive scar tissue.

INDICATIONS AND USAGE

Hemostasis: In oral and dental surgery, GELFOAM Dental Sponges are an aid in providing hemostasis. GELFOAM may be used either dry or moistened, depending upon conditions present at operation and preference of the surgeon. Isotonic saline is suitable for use with GELFOAM. Although not necessary, GELFOAM can be used either with or without thrombin to obtain hemostasis.

DIRECTIONS FOR USE

When used dry, GELFOAM Dental Sponges, cut to desired size, are rolled between the fingers and lightly compressed to the approximate diameter of the cavity or socket to be filled. Following insertion of the rolled pack, light finger pressure should be applied for one or two minutes.

When used moistened, GELFOAM, cut to desired size, is immersed in the solution of sodium chloride. The piece is then removed from the solution, squeezed thoroughly to remove air bubbles present in the meshes, and replaced in the solution where it will swell to its original size. It is then taken from the solution, blotted on sterile gauze to remove excess fluid, and placed in the cavity or wound. For use with thrombin, consult the thrombin insert for complete prescribing information and proper sample preparation.

CONTRAINDICATIONS

GELFOAM Dental Sponges should not be used in closure of skin incisions because they may interfere with the healing of skin edges.

Do not use GELFOAM Dental Sponges 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.

This product should not be re-sterilized by heat, because heating may change absorption time. Ethylene oxide is not recommended for re-sterilization because it may be trapped in the interstices of the foam. Although not reported for GELFOAM Dental Sponges, the gas is toxic to tissue and in trace amounts may cause burns or irritation.

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.

GELFOAM is supplied as a sterile product and cannot be re-sterilized. 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.

PRECAUTIONS
Use of GELFOAM Dental Sponges is not recommended in presence of frank infection. If signs of infection or abscess develop in an area where GELFOAM has been placed, reoperation may be necessary to remove infected material and allow drainage.

By absorbing fluid, GELFOAM 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 exercised to avoid over packing.

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

Although sterile, GELFOAM Dental Sponges may form a nidus of infection and abscess.

HOW SUPPLIED
GELFOAM Dental Sponges are available in
Size 4 (2 x 2 cm) envelopes of 2 sponges GTIN 00300090396053 (0009-0396-05)

STORAGE AND HANDLING
GELFOAM Dental Sponges 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 dentist or physician.

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

Manufactured by:
Pharmacia and Upjohn Company
7000 Portage Road
Kalamazoo, Michigan 49001
USA
1-800-253-8600

Pfizer Injectables

Distributed by
Pharmacia & Upjohn Co
Division of Pfizer Inc
New York, NY 10017

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