

Gelfoam®

absorbable gelatin sponge, USP

DESCRIPTION

GELFOAM Dental Sponges are small, water-insoluble, off-white, nonelastic, porous, pliable, sterile, surgical sponges prepared from purified pork Skin Gelatin NF Granules and Water for Injection, USP and are able to absorb and hold within their interstices, many times their weight of blood and other fluids. GELFOAM Dental Sponge is a medical device intended for application to bleeding surfaces as a hemostatic.

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

GELFOAM Dental Sponge can be used either dry or saturated with sterile saline or thrombin* solution. Prior to GELFOAM Dental Sponge application, the target bleeding site should be visualized if feasible. **Always use sterile technique when handling GELFOAM Dental Sponge.**

For all applications, follow Steps 1 through 3:

1. Inspect the GELFOAM Dental Sponge package for signs of damage. DO NOT use if the package is damaged.
2. Remove GELFOAM Dental Sponge from packaging.
3. Cut to the desired size.

When applied dry:

1. Roll GELFOAM Dental Sponge between gloved fingers (optional).
2. Lightly compress to the approximate diameter of the cavity or socket to be filled.
3. Insert GELFOAM Dental Sponge and apply light pressure for 1 or 2 minutes.

When applied wet:

1. Immerse GELFOAM Dental Sponge in sterile saline or thrombin solution.
2. Remove from saline or thrombin solution and **squeeze between gloved fingers to expel air bubbles.**
3. Replace in saline or thrombin solution until needed.
(GELFOAM Dental Sponge should return to its original size.)

4. Remove GELFOAM Dental Sponge from saline or thrombin solution and blot the sponge on sterile gauze to remove excess fluid.
5. Apply to the cavity or wound and apply light pressure for 1 or 2 minutes.

Notes:

- Once hemostasis is achieved, GELFOAM Dental Sponge may be left at the bleeding site when necessary.
- **For use with thrombin, consult the thrombin insert for complete prescribing information and proper sample preparation.**

*Prepared as per thrombin label instructions.

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 must not be re-sterilized.

Although the safety and efficacy of the combined use of GELFOAM with other agents such as topical thrombin have 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 must not be re-sterilized. Unused, opened envelopes of GELFOAM must be discarded.

To prevent contamination, employ aseptic procedure in opening envelope and withdrawing GELFOAM. If the envelope is damaged, the contained GELFOAM must 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 & Upjohn Company LLC
7000 Portage Road
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