**Gelfoam® (absorbable gelatin sponge from absorbable gelatin, USP)**

**DESCRIPTION**

Gelfoam® PLUS is a sterile, absorbable gelatin sponge hemostatic agent containing Thrombin (Human). It is a foam of microfibrillar collagen, pass through the 40µm transfusion filters of all blood. It is a non-antigenic material which contains the active component, human Thrombin (Human). Gelfoam® PLUS, and contains 10 units of Thrombin (Human) per gram of absorbable gelatin sponge. Gelfoam® PLUS is available as a sterile, absorbable gelatin sponge in a convenient, disposable, premeasured foam packet.

**Thrombin (Human)** is included in the manufacture of Thrombin. The virus reduction vapor-heated, solvent/detergent-treated powder preparation made from human plasma. Products made from human plasma may contain such substances as fungi, viruses, bacteria, and other microorganisms. It has been demonstrated that fragments of another hemostatic agent, random-covalent collagen, pass through the 40µm transfusion filters of all blood. It is a non-antigenic material which contains the active component, human Thrombin (Human).

**PRECAUTIONS**

Use only the minimal amount of Gelfoam® PLUS needed to achieve hemostasis. Leaving Gelfoam® PLUS in position for more than 5 minutes may result in compression of the cellular elements of blood. Leaving Gelfoam® PLUS should not be used in conjunctive with multiple viruses or other agents effective.

**ADVERSE REACTIONS**

There have been rare reports of localized pain associated with the use of Gelfoam®, without demonstrable infection. Gelfoam® was also used in a study to evaluate the potential of Thrombin to enhance hemostasis. In a clinical study, 108 patients received Gelfoam Sterile Powder. The components of Gelfoam® PLUS are supplied as a sterile aqueous solution of human Thrombin and calcium to produce Thrombin. The virus reduction vapor-heated, solvent/detergent-treated powder preparation made from human plasma. Products made from human plasma may contain such substances as fungi, viruses, bacteria, and other microorganisms. It has been demonstrated that fragments of another hemostatic agent, random-covalent collagen, pass through the 40µm transfusion filters of all blood. It is a non-antigenic material which contains the active component, human Thrombin (Human).

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DIRECTIONS FOR USE
GELFOAM Plus Sterile Powder is now ready for use.

Preparing the Thrombin Solution
1. Remove the protective cap from the Thrombin vial. Disrupt the
vial stopper with a gestincidal solution and allow to dry. Do not
use solution-based preservatives for sterilisation.
2. Remove the Tyvek cover from the Thrombin Vial Access Device
(VAD) retaining the VAD in the rigid packaging. Attach the VAD to
the Thrombin vial stopper.
3. Reconstitute the Thrombin with Saline Solution aseptically as
described below prior to transferring the solution to the sterile
operating field.
4. Remove the protective cap from the prefilled NaCl syringe. If
necessary, add sterile water for injection or sterile water for
injection containing any remaining diluent.
5. Affix the “Thrombin” label provided in the kit to the syringe which
contains any remaining diluent.
6. For stability, hold the vial and VAD with one hand while injecting
the reconstituted Thrombin.
7. Carefully to avoid loss of GELFOAM PLUS Sterile Powder. Holding
the syringe upright, eject as much air from the syringe as possible
into the barrel of the syringe and re-insert the syringe plunger
receptacle containing the reconstituted Thrombin.
8. Using the same technique, combine the GELFOAM Powder with the
reconstituted Thrombin.
9. Reconstitute the Thrombin with sterile saline for injection as
described below prior to transferring the solution to the sterile
operating field.

Reconstituting the Thrombin
1. Reconstitute the Thrombin with sterile saline for injection as
described below prior to transferring the solution to the sterile
operating field.
2. Remove the empty syringe plunger and insert the mixed product
into the barrel of the syringe receptacle from the sterile operating
field.
3. Reconstitute the Thrombin with sterile saline for injection as
described below prior to transferring the solution to the sterile
operating field.
4. Secure the applicator tip to the luer connector on the syringe hub.
5. Gently mix the contents of the GELFOAM Powder aseptically as
reconstituting the reconstituted Thrombin.
6. Using sterile technique, combine the GELFOAM Powder with the
reconstituted Thrombin.
7. Reconstitute the Thrombin with sterile saline for injection as
described below prior to transferring the solution to the sterile
operating field.
8. For stability, hold the vial and VAD with one hand while injecting
the reconstituted Thrombin.
9. Minimise the amount of GELFOAM PLUS - POWDER necessary in
preparing hemostatic sponges. The GELFOAM PLUS - POWDER may
be left in place at the bleeding site, when necessary.

Use
1. Place the contents of the GELFOAM Powder aseptically as
reconstituting the reconstituted Thrombin.
2. Using sterile technique, combine the GELFOAM Powder with the
reconstituted Thrombin.
3. Reconstitute the Thrombin with sterile saline for injection as
described below prior to transferring the solution to the sterile
operating field.

Storage and Handling
Sterile GELFOAM PLUS - POWDER kit at 15-25°C (59-77°F).

Caution:
Do not use the kit if the label code or the case code (located on the
label) is not as shown below:

Distributor
Baxter Healthcare Corporation
2186 Alexander Court
Hayward, CA 94545 USA
LA5-MER-2-0
Peer Code: 00128
Label Code: 077171, Rev: 0

REFERENCES
1. Lindstrom PA: Complications from the use of absorbable
2. Khawam SD: Softball perforations in the brain— A
American Association for the Surgery of Trauma
Astrup A: In vivo evaluation of absorbable
5. Jenkins HP, Senz EH, Owen H, et al: Observations upon the
6. Barnes AC: The use of gelatin foam sponges in obstetrics and
7. Brown AC: The use of gelatin foam sponges in obstetrics and
8. Rarig HR: Successful use of gelatin foam sponge in surgical
Astrup A: In vivo evaluation of absorbable
10. Barnes AC: The use of gelatin foam sponges in obstetrics and
11. MacDonald SA, Mathews WH: Fibrin foam and GELFOAM
12.  MacDonald SA, Mathews WH: Fibrin foam and GELFOAM
13.  Barnes AC: The use of gelatin sponges or foam in surgical
15.  Correll JT, Prentice HR, Wise EC: Biologic investigations of a new
16.  Data on File: Acute In-Vivo Evaluation, Effect on Bleeding of
Gelfoam+Human Thrombin Solution to Gelfoam+Saline in The
Liver Square Lesion Model in the Pig. November 2006.

Symptomatic Reference Key for Product Labels
- 1 x Applicator Tip
- 1 x 10 mL Prefilled Saline Syringe, 0.9% Sodium Chloride
- 1 x vial Thrombin (Human), Vapor Heated, Solvent/Detergent
- 1 x Envelope Absorbable Gelatin Powder, 1 gram.

*Note: 95.1% of the kit is sterile, 4.9% is non-sterile.

Do not use if package is damaged.
Temperature Limitation

DISTRIBUTED FREE OF CHARGE