THROMBI-GEL®
(thrombin/gelatin foam hemostat)

Distributed by

Pfizer Inc
New York, NY 10017

Manufactured by:
Vascular Solutions, Inc.
Minneapolis, MN 55369

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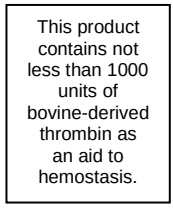
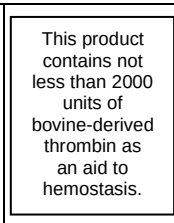
International Symbols Glossary

					
International Symbols Glossary	Contents of package	Latex Free	Keep Dry	This product contains not less than 1000 units of bovine-derived thrombin as an aid to hemostasis.	This product contains not less than 2000 units of bovine-derived thrombin as an aid to hemostasis.

Thrombi-Gel® thrombin/gelatin foam hemostat

Instructions For Use

USA CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician.

CAUTION

Application of the Thrombi-Gel thrombin/gelatin foam hemostat should be performed by physicians or physician-directed allied health care professionals with adequate training in the use of the device.

DEVICE DESCRIPTION

Each Thrombi-Gel consists of the following components:

- An off-white, inelastic, porous, pliable foam pad consisting of Thrombin-JMI (bovine-derived), sodium carboxylmethylcellulose and calcium chloride freezedried into a gelatin sponge/pad.

Thrombin is a protein substance produced through a conversion reaction in which prothrombin of bovine origin is activated by tissue thromboplastin of bovine origin in the presence of calcium chloride. Thrombin contains no preservative and has been chromatographically purified. Thrombin requires no intermediate physiological agent for its reaction. It converts fibrinogen directly to fibrin.

Thrombi-Gel 10 and Thrombi-Gel 40 contain not less than 1000 units of bovine-derived thrombin as an aid to hemostasis.

Thrombi-Gel 100 contains not less than 2000 units of bovine-derived thrombin as an aid to hemostasis.

Sodium carboxymethylcellulose, also known as cellulose gum or CMC, serves as a stabilizer for the lyophilized pad and as a suspension agent for the thrombin.

The gelatin sponge serves as the matrix for the lyophilized pad. It is prepared from purified Porcine Skin Gelatin, USP, granules and Water for Injection, and is able to absorb and hold within its interstices, many times its weight of blood and other fluids.

Hemostasis is achieved by the physiological coagulation-inducing properties of the gelatin sponge, USP, combined with the hemostatic properties of Thrombin and Calcium Chloride.

INDICATIONS

The Thrombi-Gel is applied topically and is indicated as a trauma dressing for temporary control of moderate to severely bleeding wounds and for the control of surface bleeding from vascular access sites and percutaneous catheters and tubes.

CONTRAINDICATIONS

The Thrombi-Gel is contraindicated in persons with known hyper-sensitivity to any of the components.

The Thrombi-Gel should not be used in the closure of skin incisions because it may interfere with the healing of skin edges. This is due to mechanical interposition of gelatin and is not secondary to intrinsic interference with wound healing.

WARNINGS

Do not place the Thrombi-Gel into blood vessels. Extensive intravascular clotting and even death may result.

WARNING: SEVERE BLEEDING AND THROMBOSIS COMPLICATIONS

- **THROMBIN- JMI can cause fatal severe bleeding or thrombosis.**
- **Thrombosis may result from the development of antibodies against bovine thrombin. Bleeding may result from the development of antibodies against factor V. These may cross-react with human factor V and lead to its deficiency.**
- **Do not re-expose patients to THROMBIN-JMI if there are known or suspected antibodies to bovine thrombin and/or factor V.**
- **Monitor patients for abnormal coagulation laboratory values, bleeding, or thrombosis.**

This product contains ≤0.20mg of residual formaldehyde.

The Thrombi-Gel is supplied sterile for single use only. Do not re-sterilize.

PRECAUTIONS

Do not use the Thrombi-Gel if the packaging has been damaged.

The safety and effectiveness of the Thrombi-Gel has not been established in children and pregnant women.

The Thrombi-Gel should not be used in the presence of infection. It should be used with caution in contaminated areas of the body.

ADVERSE EVENTS

A recognized rare potential reaction associated with the use of bovine-derived thrombin is the development of inhibitory antibodies, which interferes with hemostasis.

CLINICAL PROCEDURE

The following instructions provide technical direction but do not obviate the necessity of formal training in the use of the Thrombi-Gel. The techniques and procedures described do not represent ALL medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgment in treating any specific patient.

Carefully inspect the Thrombi-Gel packaging for damage prior to use.

APPLICATION PROCEDURE

1. Using sterile technique, open the foil pouch and transfer the tray into the sterile field.
2. Peel back the lid of the tray completely.
3. If desired, the Thrombi-Gel can be cut or rolled to desired shape before wetting.
4. Preparation of the Thrombi-Gel for use: Thrombi-Gel 10: Apply up to 3ml 0.9% Sterile, Normal Saline for injection or up to 3ml Sterile Water for injection.

   Thrombi-Gel 40: Apply up to 10ml 0.9% Sterile, Normal Saline for injection or up to 10ml Sterile Water for injection.

   Thrombi-Gel 100: Apply up to 20ml 0.9% Sterile, Normal Saline for injection or up to 20ml Sterile Water for injection.

   NOTE: Texture will vary depending on the amount of liquid added.

   NOTE: Thrombi-Gel may be used up to 3 hours after preparation.
5. The wetted Thrombi-Gel should be kneaded to thoroughly saturate the pad and remove trapped air bubbles.
6. Place the wetted Thrombi-Gel directly over the source of the bleeding and apply adjunct manual compression until hemostasis is achieved.

PACKAGING & STORAGE

The Thrombi-Gel has been sterilized with irradiation.

The Thrombi-Gel should be stored at temperatures between 20°C and 25°C.

Store in a cool, dry place.

Thrombi-Gel 10 is packaged in quantities of 10 units per box.

Thrombi-Gel 40 and Thrombi-Gel 100 are packaged in quantities of 5 units per box.

Individual units are not sold separately.

LIMITED WARRANTY

Vascular Solutions, Inc. warrants that the Thrombi-Gel thrombin/gelatin foam hemostat is free from defects in workmanship and materials prior to the stated expiration date. Liability under this warranty is limited to refund or replacement of any product which has been found by Vascular Solutions, Inc. to be defective in workmanship or materials. Damage to the product through misuse, alteration, improper storage or improper handling shall void this limited warranty.

THIS WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTIBILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER OBLIGATION OF VASCULAR SOLUTIONS, INC.

LIMITATIONS

Neither Vascular Solutions, Inc. nor Pfizer, Inc. shall be liable for any incidental, special or consequential damages arising from the use of the Thrombi-Gel thrombin/gelatin foam hemostat.

No Employee, agent or distributor of Vascular Solutions, Inc. or Pfizer, Inc. has any authority to alter or amend the limited warranty, set forth above, in any respect. Any purported alteration or amendment shall not be enforceable against either Vascular Solutions, Inc. or Pfizer, Inc.

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