THROMBI-PAD™
(3x3 hemostatic pad)

Thrombi-Pad™ 3x3 Hemostatic Pad

Instructions For Use

USA CAUTION

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

CAUTION

The Thrombi-Pad™ 3x3 procedure 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-Pad™ 3x3 hemostatic pad consists of a lyophilized pad consisting of thrombin, sodium carboxylmethylcellulose and calcium chloride in a nonwoven gauze.

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. This product contains not less than 200 units of bovine-derived thrombin.

Sodium carboxymethylcellulose, also known as cellulose gum or CMC, serves as the matrix for the lyophilized pad and as a suspension agent for the thrombin. Calcium chloride is added to assist in the clotting cascade.

Hemostasis is achieved by the physiological coagulation-inducing properties of the lyophilized pad combined with manual compression.

INDICATIONS

The Thrombi-Pad™ 3x3 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-Pad™ 3x3 is contraindicated in persons with known sensitivity to bovine-derived materials.

WARNINGS

Do not place the Thrombi-Pad™ 3x3 into blood vessels. Extensive intravascular clotting and even death may result.

The use of topical bovine thrombin preparations has occasionally been associated with abnormalities in hemostasis ranging from asymptomatic alterations in laboratory determinations, such as prothrombin time (PT) and partial thromboplastin time (PTT), to severe bleeding or thrombosis which rarely have been fatal. These hemostatic effects appear to be related to the formation of antibodies against bovine thrombin and/or factor V, which in some cases may cross react with human factor V, potentially resulting in factor V deficiency. Repeated clinical applications of topical bovine thrombin increase the likelihood that antibodies against thrombin and/or factor V may be formed. Consultation with an expert in coagulation disorders is recommended if a patient exhibits abnormal coagulation laboratory values, abnormal bleeding, or abnormal thrombosis following the use of topical thrombin. Any interventions should consider the immunologic basis of this condition. Patients with antibodies to bovine thrombin preparations should not be re-exposed to these products.

The Thrombi-Pad™ 3x3 is supplied sterile for single use only. Do not re-sterilize.

Do not use Thrombi-Pad™ 3x3 as a replacement for absorbable hemostats. This product contains non-absorbable materials and is not intended to be left in the body.

PRECAUTIONS

Do not use the Thrombi-Pad™ 3x3 if the packaging has been damaged.

The safety and effectiveness of the Thrombi-Pad™ 3x3 have not been established in children and pregnant women.

The Thrombi-Pad™ 3x3 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-Pad™ 3x3. 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-Pad™ 3x3 packaging for damage prior to use.

APPLICATION PROCEDURE

1. Using sterile technique, open the foil pouch and remove the Thrombi-Pad™ 3x3 pad.
2. The Thrombi-Pad™ 3x3 may be used dry or wet. If wetting the Thrombi-Pad™ 3x3, apply up to 10ml of 0.9% sterile, normal saline to the pad.

   NOTE: If 0.9% sterile, normal saline is applied to the Thrombi-Pad™ 3x3, it may be used for up to 1 hour after preparation.
3. Apply the Thrombi-Pad™ 3x3 directly over the source of the bleeding. Apply adjunct manual pressure.
4. If desired, the Thrombi-Pad™ 3x3 may be left in place for up to 24 hours.
5. Upon removal, do not disrupt the clot by physical manipulation. If the Thrombi-Pad™ 3x3 adheres to the placement site, gently irrigate the pad with non-heparinized saline and carefully remove it.

PACKAGING & STORAGE

The Thrombi-Pad™ 3x3 has been sterilized with irradiation. The Thrombi-Pad™ 3x3 should be stored at temperatures between 20°C and 25°C. Store in a cool, dry place.

LIMITED WARRANTY

Vascular Solutions, Inc. warrants that the Thrombi-Pad™ 3x3 hemostatic pad 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 King Pharmaceuticals, Inc. shall be liable for any incidental, special or consequential damages arising from the use of Thrombi-Pad™ 3x3 hemostatic pad.

No Employee, agent or distributor of Vascular Solutions, Inc. or King Pharmaceuticals, 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 King Pharmaceuticals, Inc.

King Pharmaceuticals

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