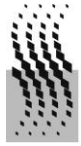


D-Stat Rad-Band

Topical Hemostat



Vascular SOLUTIONS



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D-Stat® Rad-Band Topical Hemostat Model 3501

Instructions For Use

USA CAUTION

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

CAUTION

The D-Stat Rad-Band 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 D-Stat Rad-Band consists of the following components:

- Application device consisting of a Lyophilized D-Stat Rad-Band pad containing thrombin, sodium carboxymethylcellulose and calcium chloride in a nonwoven gauze, an adjustable retention strap and attached foam comfort pads



- Adhesive bandage



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.

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

The D-Stat Rad-Band has been sterilized with irradiation.

INDICATIONS

The D-Stat Rad-Band is applied topically and is indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes.

CONTRAINDICATIONS

The D-Stat Rad-Band is contraindicated in persons with known sensitivity to bovine-derived materials.

WARNINGS

Do not place the lyophilized pad of the D-Stat Rad-Band into blood vessels. Extensive intravascular clotting and even death may result.

Do not apply occlusive pressure using the D-Stat Rad-Band. Arterial damage and thrombosis may result. Check pulses frequently to maintain arterial flow, and loosen the retention strap as necessary.

Do not leave the adhesive bandage attached for more than 24 hours. Skin irritation 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 D-Stat Rad-Band is supplied sterile for single use only. Do not re-sterilize.

STERILE | R

PRECAUTIONS

Do not use the D-Stat Rad-Band if the packaging has been damaged.

The D-Stat Rad-Band should not be used in the presence of infection.

It should be used with caution in contaminated areas of the body.

Do not touch the D-Stat Rad-Band lyophilized pad with wet gloves or expose the pad to liquid. Absorption of the liquid and destruction of the pad will result.

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. Other potential adverse events include allergic reaction or radial artery occlusion, local venous thrombosis, hematoma formation, recurrent bleeding, peripheral nerve damage and complex regional pain syndrome.

CLINICAL PROCEDURE

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

Carefully inspect the D-Stat Rad-Band packaging and components for damage prior to use.

APPLICATION PROCEDURE

1. Using sterile technique, open the foil pouch and transfer the D-Stat Rad-Band into the sterile field.

Precaution: Do not touch the D-Stat Rad-Band lyophilized pad with wet gloves or expose the pad to liquid. Absorption of the liquid and destruction of the lyophilized pad will result.

2. Place the D-Stat Rad-Band around the patient's forearm with the D-Stat Rad-Band pad over the access site and the clasp on the thumb side of the forearm.
3. Secure the D-Stat Rad-Band loosely around the forearm by threading the retention strap through the opening in the clasp and gently pulling the strap. The foam pads may be adjusted along the bony prominences of the patient's wrist to minimize patient discomfort when the band is tightened.
4. As the introducer sheath or needle is removed, apply non-occlusive manual compression by placing the D-Stat Rad-Band pad directly over the source of the bleeding.
5. Tighten the D-Stat Rad-Band by pulling on the retention strap until the device is secure on the patient's wrist and the cessation of bleeding is observed, but the presence of pulses are still present.

Warning: Do not apply occlusive pressure using the D-Stat Rad-Band. Arterial damage and thrombosis may result. Check pulses frequently to maintain arterial flow, and loosen the retention strap as necessary.

6. Monitor the site per institutional protocol.
7. Observe for hemostasis by loosening the retention strap gradually. To loosen or remove the retention strap, compress the protruding tab on the clasp and slowly loosen the strap to the desired tension.
8. Once hemostasis is achieved either:
 - Carefully remove the D-Stat Rad-Band, being careful not to disrupt the clot, and dispose of it properly. Apply dressing of choice.
 - OR
 - Secure the D-Stat Rad-Band pad by applying slight compression directly on the retainer while sliding the retention strap out of the side groove on the retainer. Apply downward pressure on the release tab of the D-Stat Rad-Band pad with one hand. With the other hand slowly pull the retainer back leaving the D-Stat Rad-Band pad in place and being careful not to disrupt the clot. Apply the adhesive bandage over the pad.

Warning: Do not leave the adhesive bandage attached for more than 24 hours. Skin irritation may result.

Upon removing the adhesive bandage, do not disrupt the clot by physical manipulation. If the adhesive bandage adheres to the placement site, gently irrigate the bandage with non-heparinized saline and carefully remove it.

3M™ Tegaderm™ Transparent Film Dressing Frame Style

1626, 1627, 1628, 1629, 1630, 1634, 1622W, 1623W, 1624W, 1626W, 9505W, 9506W

Description: Tegaderm™ Film consists of a thin film backing with a non-latex, hypoallergenic adhesive. Tegaderm™ Film with Border is notched and reinforced with soft cloth tape to provide a better seal around catheters and other devices. The dressing is breathable, allowing good oxygen and moisture vapor exchange. It is waterproof and impermeable to liquids, bacteria, and viruses. *An intact dressing protects the site from outside contamination.

*Laboratory testing has proven Tegaderm™ and Tegaderm™ HP Film provide a barrier against HIV-1 and HBV while the dressings remain intact without leakage.

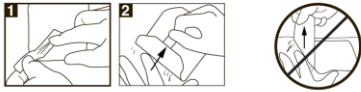
Indications: Tegaderm™ Film can be used to cover and protect catheter sites and wounds, to maintain a moist environment for wound healing or to facilitate autolytic debridement, as a secondary dressing, as a protective cover over at-risk skin, to secure devices to the skin, to cover first and second degree burns, and as a protective eye covering. Do not use the dressing as a replacement for sutures and other primary wound closure methods.

Precautions:

1. Stop any bleeding at the site before applying the dressing.
2. Do not stretch the dressing during application as tension can cause skin trauma.
3. Make sure the skin is clean, free of soap residue and lotion and allowed to dry thoroughly before applying the dressing to prevent skin irritation and to ensure good adhesion.
4. The dressing may be used on an infected site, only when under the care of a health care professional.
5. Antimicrobial ointments containing polyethylene glycols may compromise the strength of the Tegaderm™ HP Transparent Film Dressings.
6. Tegaderm™ Transparent Dressings should not be re-sterilized by gamma, E-beam or steam methods.

Instructions for Use: Refer to figures.

Low and Slow Removal



OR

Stretch Release Removal



If you have any questions or comments, contact the 3M Health Care Customer Help Line at **1-800-228-3957 OR GO TO WWW.3M.COM.**

LIMITED WARRANTY

Vascular Solutions, Inc. warrants that the D-Stat Rad-Band topical 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. Vascular Solutions, Inc. shall not be liable for any incidental, special, or consequential damages arising from the use of the D-Stat Rad-Band topical hemostat. Damage to the product through misuse, alteration, improper storage, or improper handling shall void this limited warranty.

No employee, agent, or distributor of Vascular Solutions, Inc. has any authority to alter or amend this limited warranty in any respect. Any purported alteration or amendment shall not be enforceable against Vascular Solutions, Inc.

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

PATENTS AND TRADEMARKS

International and U.S. patents pending.

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