

D-Stat[®] Radial

Hemostat Band

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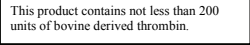


vascular
SOLUTIONS



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Symbols Glossary

				
Symbols Glossary	Contents of package	Latex Free	Keep Dry	This product contains not less than 200 units of bovine derived thrombin.

D-Stat® Radial Hemostat Band 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 Radial 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 Radial hemostatic band (D-Stat Radial) consists of the following components:

- Lyophilized pad consisting of thrombin, sodium carboxymethylcellulose and calcium chloride in a nonwoven gauze
- Application device consisting of an adjustable retention strap and attached foam 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.

The adhesive bandage is comprised of a polyvinyl chloride foam material and is supplied sterile attached to the outside of the foil pouch.

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

INDICATIONS

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

WARNINGS

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

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

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 Radial is supplied sterile for single use only. Do not re-sterilize.

STERILE | R

Do not leave the D-Stat Radial attached for more than one hour, arterial damage and thrombosis may result.

PRECAUTIONS

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

The safety and effectiveness of the D-Stat Radial have not been established in children and pregnant women.

The D-Stat Radial 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 Radial 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.

CLINICAL PROCEDURE

The following instructions provide technical direction but do not obviate the necessity of formal training in the use of the D-Stat Radial. 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 judgement in treating any specific patient.

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

APPLICATION PROCEDURE

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

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

2. Wrap the D-Stat Radial around the patient's forearm with the D-Stat Radial pad over the artery and the clasp on the thumb side of the forearm.
3. Secure the D-Stat Radial loosely around the forearm by pulling the narrow end through the opening in the retention strap.
4. As the introducer sheath or needle is removed, slide the D-Stat Radial pad over the bleeding site, placing the center of the D-Stat Radial pad directly over the source of the bleeding. Apply non-occlusive manual pressure and observe for the cessation of bleeding.
5. Tighten the retention strap by pulling on the narrow end of the strap. The foam pads may be moved along the back side of the patient's wrist to minimize patient discomfort.

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

6. Observe for hemostasis by loosening the retention strap gradually. To loosen or remove the retention strap, compress the protruding tab on the larger end of the strap.
7. Once hemostasis is achieved either:
 - Remove the D-Stat Radial and dispose of it properly. Apply dressing of choice.
 - OR
 - Release the retention strap and apply downward pressure on the lyophilized pad with one hand. With the other hand slowly peel the translucent pad back leaving the D-Stat Dry pad in place and being careful not to disrupt the clot. Apply the adhesive bandage over the pad.

Warning: Do not leave the D-Stat Radial attached for more than one hour. Arterial damage and thrombosis may result.

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.

PACKAGING AND STORAGE

The D-Stat Radial has been sterilized with irradiation.

The D-Stat Radial should be stored at temperatures between 2°C and 25°C.

LIMITED WARRANTY

Vascular Solutions, Inc. warrants that the D-Stat Radial sealing device 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 Radial sealing device. 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.

D-Stat[®] is a registered trademark of Vascular Solutions, Inc.

See the Symbols Glossary on page 3.



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