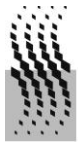


D-Stat² Dry

Hemostatic Bandage Topical Hemostat



Vascular
SOLUTIONS



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D-Stat[®] 2 Dry Hemostatic Bandage 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 2 Dry 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 2 Dry hemostatic bandage (D-Stat 2 Dry) consists of the following components:

- One (1) scored lyophilized pad consisting of thrombin, sodium carboxymethylcellulose and calcium chloride
- Two (2) adhesive bandages

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.

The D-Stat 2 Dry has been sterilized with irradiation.

INDICATIONS

The D-Stat 2 Dry 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 2 Dry is contraindicated in persons with known sensitivity to bovine-derived materials.

WARNINGS

Do not place the D-Stat 2 Dry 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 D-Stat 2 Dry is supplied sterile for single use only. Do not re-sterilize.

STERILE | R

Do not use D-Stat 2 Dry as a replacement for absorbable hemostats. This product contains non-absorbable materials and is not intended to be left in the body.

Do not leave the D-Stat 2 Dry adhesive bandage attached for more than 24 hours. Skin irritation may result.

PRECAUTIONS

Do not use the D-Stat 2 Dry if the packaging has been damaged.

The safety and effectiveness of the D-Stat 2 Dry have not been established in children and pregnant women.

The D-Stat 2 Dry 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 2 Dry 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 2 Dry. 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 2 Dry packaging (foil pouch and tyvek sealed inner tray) and components for damage prior to use.

APPLICATION PROCEDURE

- Using sterile technique, open the foil pouch and transfer the tray into the sterile field.
- Peel back the lid of the tray completely. On a sterile drape, turn the tray upside down and tap on the bottom to detach the D-Stat 2 Dry pad from the tray. The single pad may be broken into two separate pads by bending the pad along the center.

Precaution: Do not touch the D-Stat 2 Dry lyophilized pad with wet gloves or expose the D-Stat 2 Dry pad to liquid. Absorption of the liquid and destruction of the pad will result.

- Using sterile technique, open the adhesive bandage packaging and transfer the bandage(s) into the sterile field.
- Peel back the release layers on the bandages to expose approximately one-half of the adhesive portion of the bandages. Place the center of the bandage over the center of each half of the lyophilized pad, and gently push to attach the lyophilized pad to the adhesive bandage.
- Apply the D-Stat 2 Dry directly over the source of the bleeding. In cases of active bleeding, apply adjunct manual compression.

- If desired, the D-Stat 2 Dry may be left in place for up to 24 hours.

Warning: Do not leave the D-Stat 2 Dry 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.

LIMITED WARRANTY

Vascular Solutions, Inc. warrants that the D-Stat 2 Dry 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 2 Dry. 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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