



## D-Stat® Clamp Accessory Instructions For Use

### USA CAUTION

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

### DEVICE DESCRIPTION

Each D-Stat Clamp accessory hemostatic clamp (D-Stat Clamp accessory) consists of the following components:

- Connector for attachment to most commercially available femoral compression devices
- Translucent comfort pad
- Release tab
- Lyophilized pad consisting of thrombin, sodium carboxymethylcellulose and calcium chloride in a nonwoven gauze

**Note:** All of the above components come as a single unit in a sterile tray.

- 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. Calcium chloride is added to assist in the clotting cascade.

Control of surface bleeding is achieved by mechanical compression combined with the physiological coagulation-inducing properties of the lyophilized pad.

The D-Stat Clamp accessory has been sterilized with irradiation.

### INDICATIONS

The D-Stat Clamp accessory is indicated for use with the D-Stat Handle, CompressAR® Universal System (Advanced Vascular Dynamics) and the Femoral Artery Vascular Clamp (Pressure Products) compression devices or as a stand-alone device to assist in the control of bleeding following catheterization or cannulation procedures. Following achieving hemostasis the D-Stat Dry Bandage may be detached from the D-Stat Clamp accessory and left in place for up to 24 hours and is indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes.

### CONTRAINDICATIONS

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

### WARNINGS

Do not place the D-Stat Clamp accessory, or any component thereof 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 Clamp accessory is supplied sterile for single use only. Do not re-sterilize.

Do not use the D-Stat Clamp accessory with the CompressAR Strong Arm XL. The D-Stat Clamp accessory is not compatible with the CompressAR Strong Arm XL compression device.

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

### PRECAUTIONS

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

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

The D-Stat Clamp accessory 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 Clamp accessory lyophilized pad with wet gloves or expose the pad to liquid. The pad may absorb the liquid and become difficult to use.

The D-Stat Clamp accessory has been designed to fit with most commercially available mechanical compression devices. If the D-Stat Clamp accessory product does not securely attach to the compression device, remove the D-Stat Clamp accessory and use as a stand-alone device or use the compression disk provided by the manufacturer of the mechanical device.

### 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 Clamp accessory and mechanical compression devices and in the preparation and removal of arterial sheaths. 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.

### APPLICATION PROCEDURE

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

### USE WITH A MECHANICAL COMPRESSION DEVICE

1. Prepare and position the mechanical compression device according to the manufacturer's instructions for use. Omit attachment of the compressive pad supplied by the manufacturer.
2. Using sterile technique, open the foil pouch and transfer the tray into the sterile field.
3. Remove the tape from the packaging tray and attach the D-Stat Clamp accessory to the connection point provided on the compressive device. Remove the plastic tray protecting the lyophilized pad portion of the D-Stat Clamp accessory.

**Precaution:** D-Stat Clamp accessory has been designed to fit with the D-Stat Handle and most other commercially available mechanical compression devices. If the D-Stat Clamp accessory does not securely attach to the compression device, remove the D-Stat Clamp accessory and use as a stand-alone device or use the compressive pad provided by the manufacturer of the mechanical device.

**Precaution:** Do not touch the D-Stat Clamp accessory lyophilized pad with wet gloves or expose the pad to liquid. The pad may absorb the liquid and become difficult to use.

4. Apply the mechanical compression device to the patient as directed by the manufacturer and ensure that the D-Stat Clamp accessory is positioned directly over the source of the bleeding.

**Note:** Institutional protocol should be followed regarding compression time.

5. Observe for hemostasis by gradually decreasing the pressure obtained by the mechanical compression device. As pressure is released and full arterial flow is restored, confirm that the puncture site remains dry and no hematoma forms.

6. Once hemostasis is achieved either:

- Remove the D-Stat Clamp accessory and apply dressing of choice.

OR

- Remove the mechanical compression device and leave the D-Stat Clamp accessory in place. Apply downward pressure on the release tab with one hand, and with the other hand slowly peel the plastic and translucent comfort pad back leaving the D-Stat Dry pad in place. Apply adhesive bandage over the D-Stat Dry pad.

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

7. 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.

### USE AS A STAND-ALONE PRODUCT

If using the D-Stat Dry Clamp accessory alone, place unit directly over the source of the bleeding and apply manual compression.

**Note:** Institutional protocol should be followed regarding compression time.

Refer to item 6 in the above section (Use with a Mechanical Compression Device) for instructions once hemostasis is achieved.

### LIMITED WARRANTY

Vascular Solutions, Inc. warrants that the D-Stat Clamp accessory 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 Clamp accessory. Damage to the product through misuse, alteration, improper storage, or improper handling shall void this limited warranty.

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### PATENTS AND TRADEMARKS

International and U.S. patents pending.

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CompressAR® is a registered trademark of Advanced Vascular Dynamics, Inc.