

D-Stat[®] Handle

Hemostat Accessory



Vascular SOLUTIONS



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D-Stat[®] Handle 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 Handle should be used by physicians and/or operators with adequate training in the use of the device.

Please see the D-Stat Clamp Accessory Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions specific to the D-Stat Clamp Accessory.

DEVICE DESCRIPTION

Each D-Stat Handle consists of the following components:

- Stainless steel handle and shaft with a configured press-fit attachment for the D-Stat Dry Clamp Accessory.

INDICATIONS

The D-Stat Handle is indicated for use with the D-Stat Clamp Accessory to assist in the control of bleeding following catheterization or cannulation procedures.

CONTRAINDICATIONS

None identified.

WARNINGS

Do not apply excessive adjunctive compression or suddenly release compression, as occlusion of the vessel may occur.

Serious bleeding may occur if arterial hemostasis is not achieved.

PRECAUTIONS

Periodically monitor pedal pulses during use of the D-Stat Handle to confirm adequate arterial flow to the arterial vessels.

The D-Stat Handle should be thoroughly cleaned as directed between uses.

ADVERSE EVENTS

As with all medical procedures, complications may occur. For this procedure, these events may occur:

- Bleeding or hematoma
- Compression injuries to nerves
- Pseudoaneurysm
- Femoral artery or venous thrombosis

CLINICAL PROCEDURE

The following instructions provide technical direction but do not obviate the necessity of formal training in the use of the D-Stat Handle and D-Stat Clamp Accessory. The techniques and procedures described do not represent

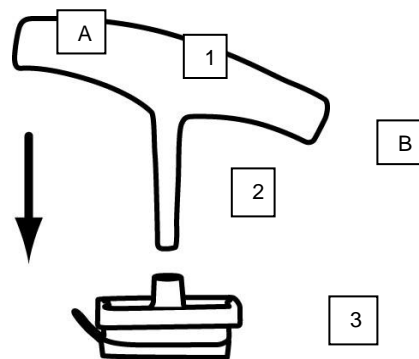
ALL medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgment in treating any specific patient.

APPLICATION or DEPLOYMENT PROCEDURE

Please see the D-Stat Clamp Accessory Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions specific to the D-Stat Clamp Accessory.

1. Locate the clean D-Stat Handle.
2. Using sterile technique, open the D-Stat Clamp Accessory 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 configured connection point on the D-Stat Handle. Remove the plastic tray protecting the lyophilized pad portion of the D-Stat Clamp Accessory. See Figure 1.

Figure 1

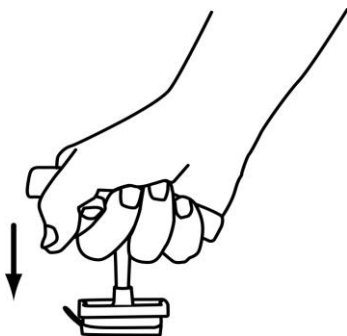


- | |
|----------------------------|
| 1 – Handle |
| 2 – Shaft |
| 3 – D-Stat Clamp Accessory |
| A – Thumb Side |
| B – Pinky Side |

4. Grip the D-Stat Handle with the highest point of the angled handle on the thumb side of the operator's hand. Use the mechanical compression device to apply the D-Stat Clamp Accessory directly over the source of the bleeding. See Figure 2.

Note: Institutional protocol should be followed regarding compression time to achieve hemostasis.

Figure 2



5. Observe for hemostasis by gradually decreasing the pressure applied with the D-Stat Handle. As pressure is released and full arterial flow is restored, confirm that the arterial puncture site remains dry and that no hematoma forms.
6. Once hemostasis is achieved, either:
 - a. Remove the D-Stat Handle and the D-Stat Clamp Accessory and apply dressing of choice.

OR

 - b. Remove the D-Stat Handle from the D-

Stat Clamp Accessory. 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.

7. Clean the D-Stat Handle with an alcohol wipe or other institutional approved disinfectant.

PACKAGING & STORAGE

The D-Stat Handle is supplied non-sterile.

This is a reusable device.

Thoroughly clean with alcohol wipes or other institutional approved disinfectant between every use.

LIMITED WARRANTY

Vascular Solutions, Inc. warrants that the D-Stat Handle is free from defects in workmanship and materials. 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 Handle. Damage to the product through misuse, alteration, improper storage or improper handling shall void this limited warranty.

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PATENTS AND TRADEMARKS

U.S. patents pending.

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