VasoStat™ HEMOSTASIS DEVICE
INSTRUCTIONS FOR USE

CAUTION: Rx only: U.S. federal law restricts this device to sale to or on the order of a licensed health care practitioner.

DEVICE DESCRIPTION: The VasoStat™ Hemostasis Device is used to augment hemostasis through a ratcheting pressure mechanism.

INTENDED USE: The VasoStat™ Hemostasis Device is indicated for use by medical professionals to promote hemostasis following a catheterization or other puncture into a blood vessel in a patient's arm or lower leg, including radial artery catheterization, pedal or tibial artery catheterization, arterial or venous line removal, hemodialysis, and in patients on anticoagulation therapy.

CONTRAINDICATIONS: Allergy to medical adhesives.

PRECAUTIONS:

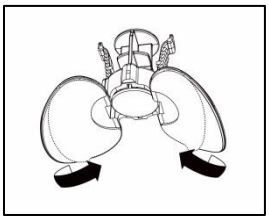
- The device is intended for single use only. Do not sterilize and/or reuse this device.
- Do not use this product if there is doubt as to whether the product is sterile.
- Store in a dark, dry, cool place. Avoid extended exposure to light.
- Upon removal of the product from packaging, inspect product to ensure no damage has occurred.

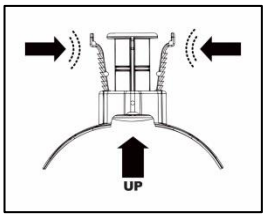
POTENTIAL ADVERSE EVENTS:

- Undesired bleeding at the puncture site could occur if care is not used when securing the device at puncture site
- Hematoma
- Radial artery or tibial artery thrombosis if the device is tightened excessively without checking for the presence of a pulse and/or hand/foot perfusion distal to the site of device application
- Vascular thrombosis if the device is tightened excessively over a hemodialysis access without checking for the presence of a thrill
- As in common with skin adhesives, slight irritation of the skin may occur with prolonged use

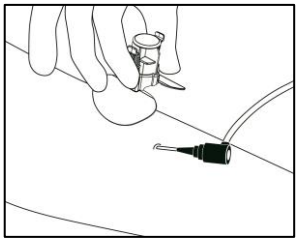
INSTRUCTIONS FOR USE:

1. Remove the paper strips on the adhesive wings of the VasoStat™ Hemostasis Device to expose the adhesive surfaces on the base of the device. Ensure the plunger of the device is in the up position. If needed, gently squeeze the wings of the plunger together to move the plunger to the 'up' position.

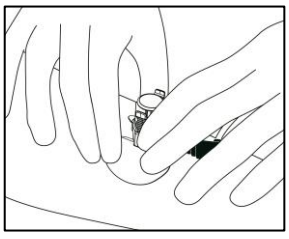


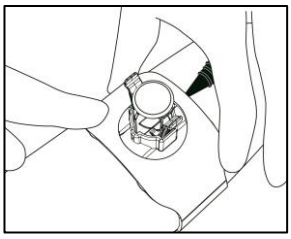


2. Align the central plunger of the device above the vascular puncture site of the patient's skin while the vascular sheath or needle is still in place. If needed, partially withdraw the vascular sheath or needle to provide sufficient room for positioning and securement of the device.

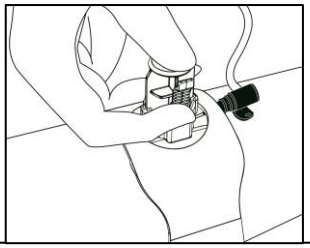


3. Secure the adhesive wings of the VasoStat™ device to the patient's skin with manual pressure. Ensure the adhesive pads completely contact the patient's skin. Next, remove the paper strips and apply the SeeCure™ adhesive pad over the wings of the VasoStat™ device and surrounding skin.

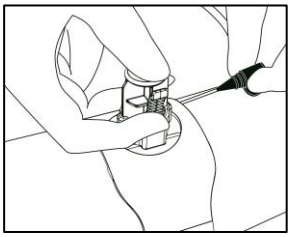
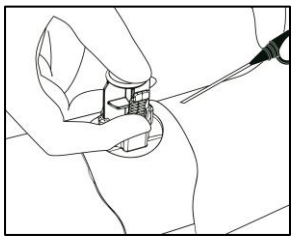




4. While stabilizing the base of the device with index and middle fingers, depress the plunger of the VasoStat™ device with gentle thumb pressure until it is just contacting the patient's skin.

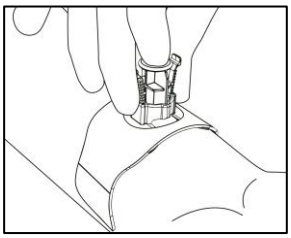
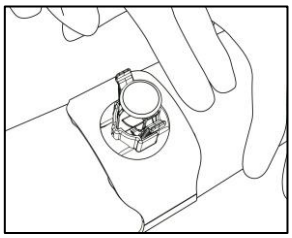


5. **Vascular sheath removal:** gently remove sheath while simultaneously depressing plunger of VasoStat™ to apply desired amount of compression force to the puncture site.

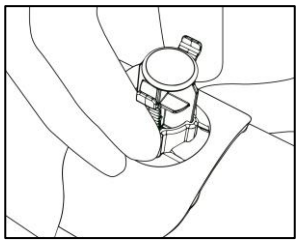



6. If bleeding is not controlled, apply additional pressure by further depressing the plunger against the puncture site.

7. Ensure a pulse or thrill can still be felt beyond the device so that an excessive amount of force is not being applied. If unsure, loosen the device (see steps 8-9 below) and check for the presence of a pulse or thrill before re-tightening the plunger.

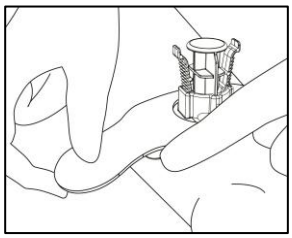
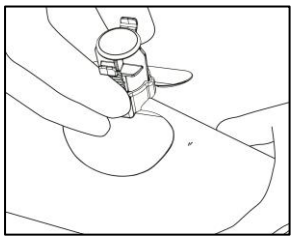



8. After sufficient time has elapsed to achieve hemostasis, release the plunger by squeezing the wings on each side to disengage them from the center of the device.



9. Withdraw the central plunger until it no longer contacts the skin and/or no longer produces pressure on the skin. Verify hemostasis has occurred by visually inspecting the puncture site underneath the plunger.

10. Remove the VasoStat™ Hemostasis Device and SeeCure™ pad by gently peeling the adhesive surfaces free from the patient's skin. Isopropyl alcohol swab(s) may also be used to assist in removal. Discard the device in appropriate receptacle. A sterile dressing may be applied to the puncture site.

HOW SUPPLIED:
The VasoStat™ Hemostasis Device and SeeCure™ adhesive pad are supplied sterile in peel open packages, intended for one time use. Sterile if package is unopened or undamaged.

Please report any defects or adverse events to 877-466-0109.

Manufactured for Forge Medical, Inc.
701 W Broad Street, Suite 102
Bethlehem, Pennsylvania, USA
18018

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