PRECAUTIONS

1. The *SiteSeal SV* vascular closure device should be used only by operators trained in diagnostic and interventional catheterization procedures.

2. The *SiteSeal SV* vascular closure device is provided sterile and non-pyrogenic in unopened undamaged packaging. Products are sterilized with ethylene oxide and intended for single use only. Do not resterilize. Store in a cool, dry place.

3. Prior to use, inspect the *SiteSeal SV* vascular closure device to ensure that the sterile packaging has not been damaged during shipment.

ADVERSE EVENTS

Potential adverse effects that may result from the use of this device include, but not limited to:

• Artery and/or vein thrombosis • Embolization • Bleeding or hematoma • Arteriovenous fistula or pseudoaneurysm
• Hematoma (≥ 6 cm) • Late Access Site-related Bleeding • Anaphylaxis • Death

POST-PROCEDURE PATIENT MANAGEMENT

Assess the insertion site as per hospital or doctor protocol.

RECOMMENDATION FOR PATIENT AMBULATION AND DISCHARGE

In determining whether to ambulate or discharge an individual patient, it is important to consider thrombolytic agents administered, oozing or bleeding from the access site, adequate hemostasis of the access site, the general cardiovascular condition of the patient, anesthetic levels, and the overall clinical condition of the patient.

PRODUCT INFORMATION DISCLOSURE

Ensite Vascular LLC has exercised reasonable care in manufacture of this device. Ensite Vascular excludes all warranties, whether expressed or implied, by operation of law or otherwise, including but not limited to, any implied warranties of merchantability or fitness, since handling and storage of this device, as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond the control of Ensite Vascular LLC, directly affect this device and the results obtained from its use. Ensite Vascular LLC shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of this device. Ensite Vascular LLC neither assumes, nor authorizes any other person to assume for it, any other additional liability or responsibility in connection with this device.

HOW SUPPLIED

The *SiteSeal SV* vascular closure device is provided sterile and non-pyrogenic in unopened, undamaged packaging. Products are sterilized using ethylene oxide and intended for single use only. The device and the primary packaging are not made with natural rubber latex. Store in a cool, dry place.

Mfg for ENSITE Vascular™

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SiteSeal® SV™

SV™ (Small Vessel) CLOSURE DEVICE

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The *SiteSeal SV* vascular closure device is designed to close an access site following endovascular catheterization procedures. The *SiteSeal SV* vascular closure device consists of a spring assisted incline plane and completely adjustable strap, which can be used on either extremity.

INDICATIONS FOR USE

The *SiteSeal SV* vascular closure device is a compression device to assist hemostasis of vascular access sites after an endovascular catheterization procedure.

IMPORTANT!

This package insert is designed to assist in using the *SiteSeal SV* vascular closure device. It is not a reference to surgical techniques. To ensure proper use of this device and to prevent injury to patients, read all information contained in these instructions for use.

CAUTION

Federal law restricts this device to sale by or on the order of a physician who is trained in diagnostic and therapeutic catheterization procedures. Prior to use, the operators must review this Instructions for Use and be familiar with the deployment techniques associated with the use of this device.

WARNING

Do not use the *SiteSeal SV* vascular closure device if the packaging or sterile barrier has been previously opened or damaged or if the components appear to be damaged or defective.

DO NOT RESTERILIZE OR REUSE.

The *SiteSeal SV* vascular closure device is intended for single use only. Do not use the *SiteSeal SV* vascular closure device if the sterile field has been broken. In case the SiteSeal SV is unable to achieve hemostasis, use standard of care, external manual compression, for closing vascular access site.

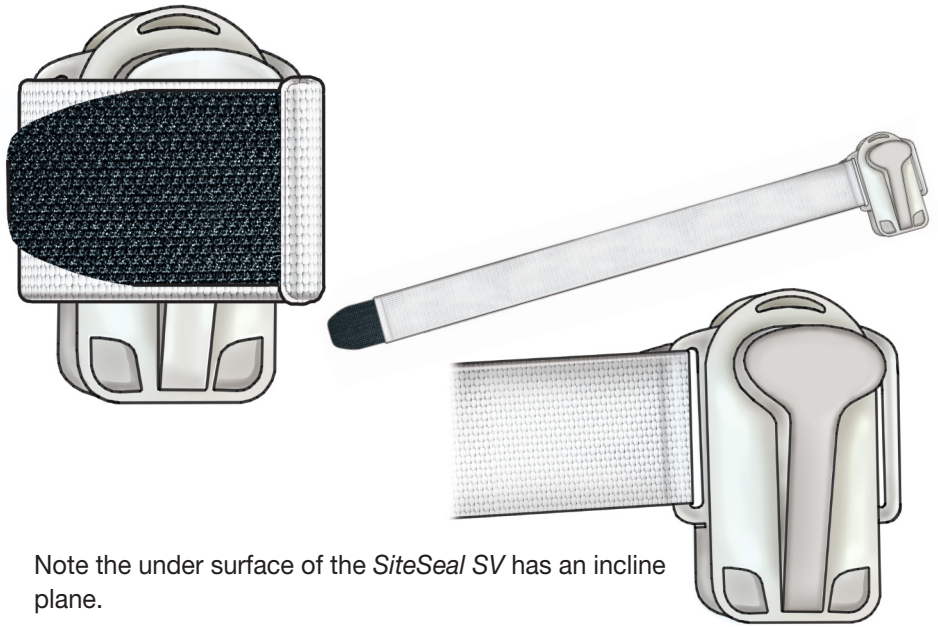
Graphical Symbols Glossary for Medical Device Labeling

	Manufactured for		Sterilized using ethylene oxide
	Caution/see Instructions For Use		Do not resterilize
	Consult Instructions For Use		Date of Manufacture
	Do not reuse/ single use only	REF	Catalog number/ reference number/ re-0rder number
	Do not use if package is damaged	LOT	Lot number/ batch code/ batch number
Rx Only	Prescription Only		Use by

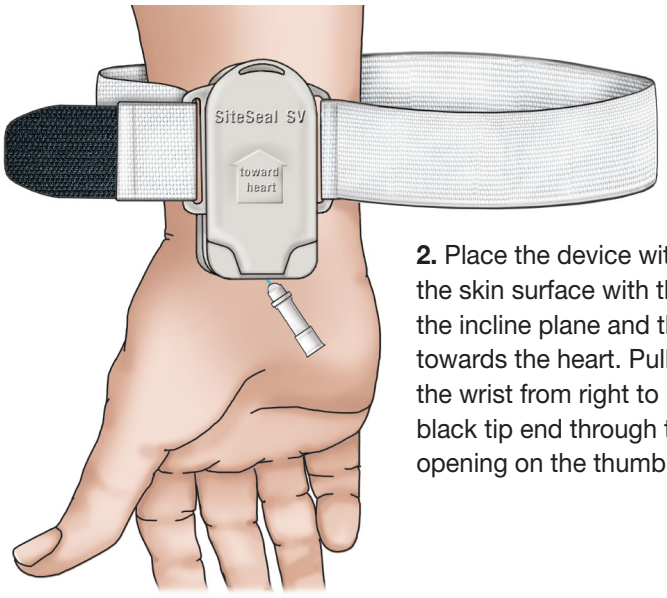
CONTINUED ON BACK

APPLICATION

1. Release the black tip end and unroll the soft elastic band to its fullest extent.

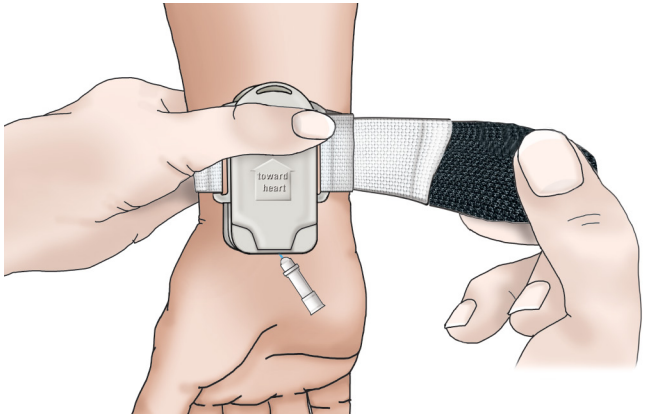


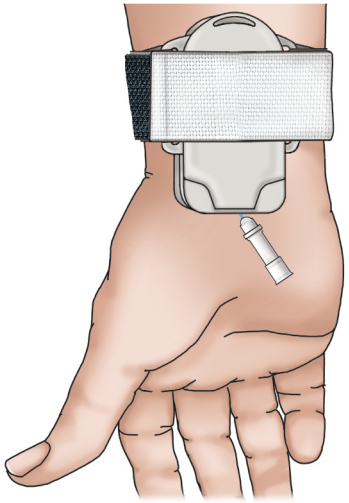
Note the under surface of the *SiteSeal SV* has an incline plane.



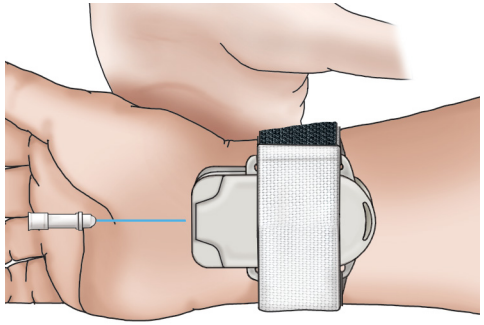
2. Place the device with the incline plane on the skin surface with the raised portion of the incline plane and the curved end pointing towards the heart. Pull the elastic band under the wrist from right to left. Then insert the black tip end through the strap support opening on the thumb side of the wrist.

3. Place the *SiteSeal SV* device on top of the access sheath, centered over the access site, and with the incline plane just above the access site. Using your thumb, apply pressure to the *SiteSeal SV* device to load the spring. Pull the elastic band up and over the device.





4. Continue to wrap the elastic band around the wrist until adequate pressure is applied to establish hemostasis of the access site and to secure the spring.



5. With *SiteSeal SV* securely in place, remove the sheath from the access site. Recheck distal pulses for adequate blood flow. Adjust the pressure on the *SiteSeal SV* device as necessary to control bleeding or inadequate blood flow by increasing or decreasing elastic band pressure.

Remove the *SiteSeal SV* device when adequate hemostasis of the access site is accomplished, which will be determined by the attending physician. Ensite Vascular recommends leaving the device in place for a minimum of 30 minutes.