See Separate Package Insert for:

- Kit Contents
- Description
- Indication for Use
- Contraindications
- Adverse Events
- Warnings
- Precautions
- Explanation of Symbols
- Warrantee Disclaimer (US)

IMPORTANT!

This package insert is designed to assist in using the SiteSeal™ Adjunctive Compression 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 - Investigational Device

Limited by Federal (or United States) Law to Investigational Use.

FOR SINGLE USE ONLY; DO NOT RE-STERILIZE OR REUSE THIS DEVICE.

Manufactured by

ENSITE Vascular™

10900 South Clay Blair Blvd.
Olathe, KS 66061
Phone: 913-777-5277

Made in U.S.A. Ver: 1.12

SiteSeal™

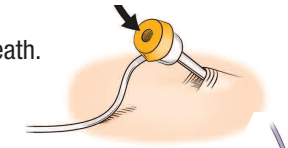
Adjunctive Compression Device

INSTRUCTIONS FOR USE*

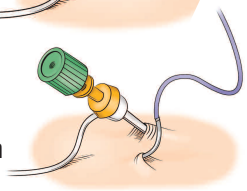
SiteSeal™ Placement:

Using the suture provided, a Z stitch will be placed.

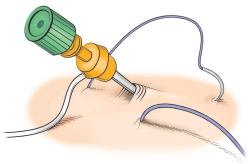
1) Insert obturator back into sheath.



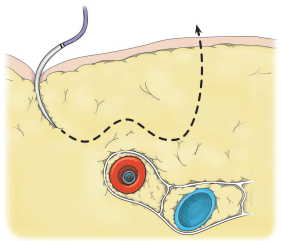
2) Enter subcutaneous tissue one centimeter lateral to and just inferior to the sheath. If there is a physician-concern of arterial puncture, the sheath/obturator can be raised vertically away from the common femoral artery and then enter the subcutaneous tissue.



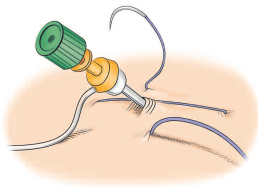
3) Exit subcutaneous tissue one centimeter medial to the sheath.
4) Re-enter subcutaneous tissue one centimeter above and one centimeter lateral to the sheath.



5) Direct suture needle medial toward sheath/obturator and CFA.
6) Direct needle up and over sheath/obturator and CFA, remaining beneath the skin, and back into subcutaneous tissue medially.



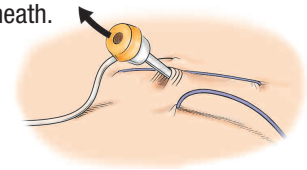
7) Exit subcutaneous tissue one centimeter medial to sheath, completing the Z stitch.



*See also separate PACKAGE INSERT enclosed.

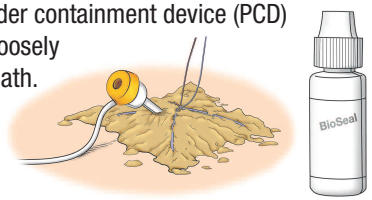
SiteSeal™ Placement Continued

8) Obturator is removed from sheath.

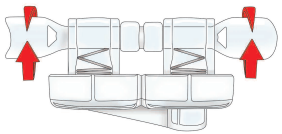


9) The two ends of the Z stitch are loosely closed around the sheath with a double half knot.

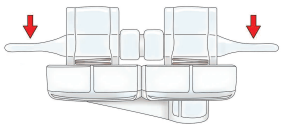
10) The BioSeal CVC powder containment device (PCD) is placed around the loosely closed suture and sheath.
11) The PCD is filled with BioSeal CVC powder.



12) The crossbar of the SiteSeal™ device is rotated from a vertical to horizontal position.

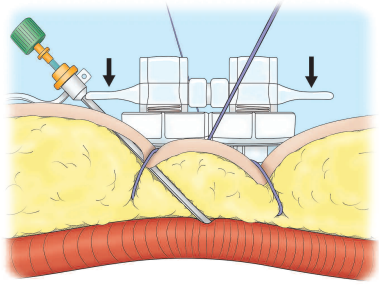


13) Downward pressure is applied to both ends of the crossbar until locked in place.



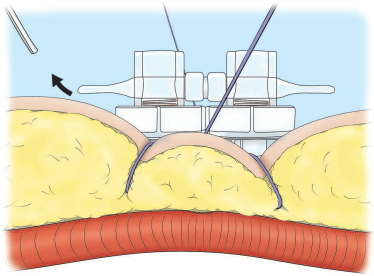
Steps 14 through 23 are executed with two pairs of hands.

14) The double half knot is pulled around the sheath and continuously held while the SiteSeal™ device is positioned.
15) The SiteSeal™ device is placed over the sheath parallel to the common femoral artery, with medial and lateral grooves positioned directly over the entry site. Continuous downward pressure is applied to both ends of the crossbar.

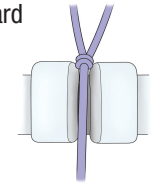


16) The two ends of the double half knot are maximally pulled tight around the sheath.

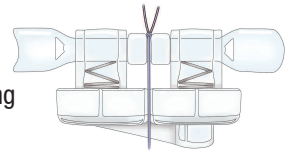
17) The sheath is removed.



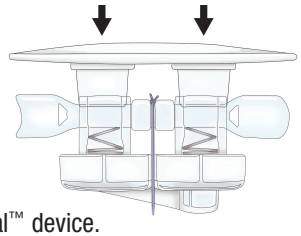
18) The two ends of the suture are pulled upward through the medial and lateral grooves and over the groove in the crossbar.
19) A complete knot is placed over the groove, while continuous pressure is applied to the crossbar.



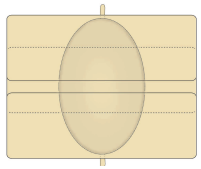
20) The crossbar is rotated from horizontal to vertical, releasing the locked position, maximizing spring effect.



21) The roof top is positioned over the anterior and posterior columns with continuous downward pressure.
22) Tincture of Benzoin is applied to the skin around the SiteSeal™ device.



23) Tegaderm™ strips are placed to stabilize the device north, south, east and west; one over center of roof top, a second anterior and a third inferior. Check the pedal pulses and compare them to the pre-procedure exam. If increased flow is required, decrease the applied pressure by readjusting the Tegaderm™ pressure until adequate pedal pulse is established.

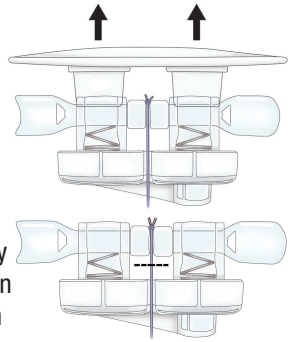


24) Move the patient off the angiographic table and elevate the head of the stretcher for patient's comfort up to a maximum of 30 degrees. There are no restrictions for leg movement and patient may turn on side.

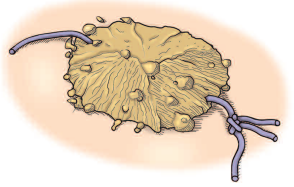
25) The physician determines the actual time the SiteSeal™ device remains in place.

SiteSeal™ Removal:

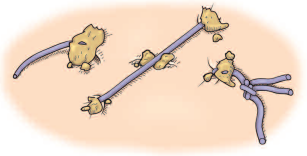
1) The doctor determines when to remove the SiteSeal™ device. Considerations include: catheter size, male versus female, diagnostic versus interventional, patient body mass, length of cannulation procedure, anticoagulation blood chemistry, etc. Remove Tegaderm strips.



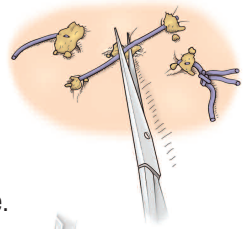
2) Remove roof top.
3) Cut suture and remove SiteSeal™ device.



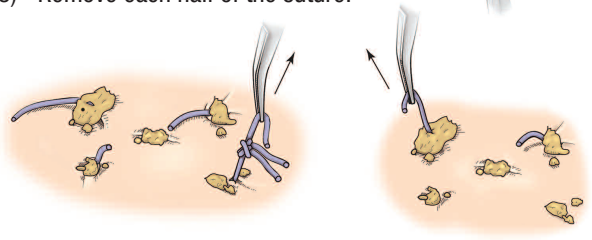
4) Remove PCD.
5) Gently brush away residual powder.
6) Do not remove powder that is sealing the skin penetration sites.



7) Cut the long axis of the Z stitch.



8) Remove each half of the suture.



9) If there is any ooze from the penetration sites, add additional powder and apply pressure for approximately 30 seconds.
10) No dressing is required, as the powder seals the penetration sites.
11) Ambulate the patient.