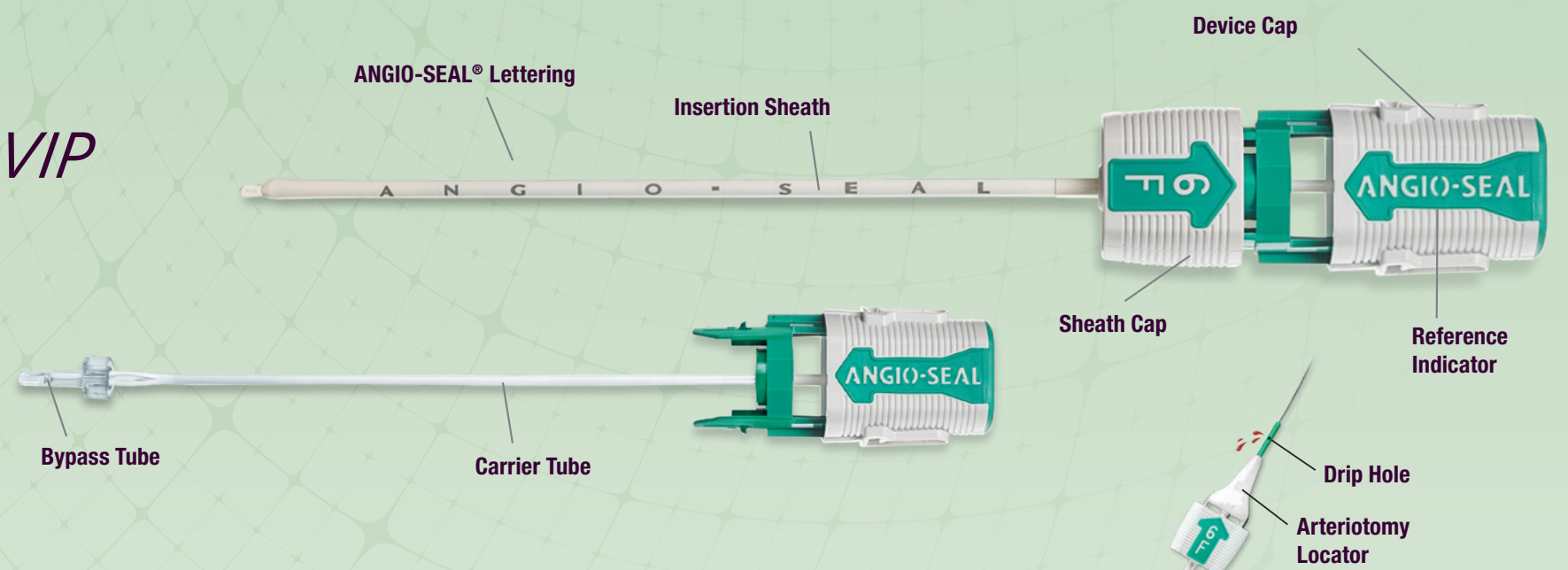


Angio-Seal[®] VIP

Vascular Closure Device



ANGIO-SEAL[®] VIP Quick Deployment Guide¹

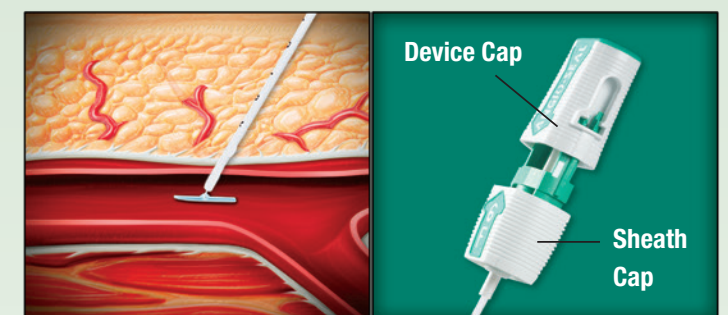
LOCATE the Artery

1. Begin by exchanging the procedure sheath with the ANGIO-SEAL[®] sheath and locator system.
2. Confirm entry into the artery with blood flow through the locator.
3. Withdraw the locator system until blood flow stops; re-insert until blood flow resumes, confirming correct intra-arterial position.
4. Hold the sheath in place and remove the locator and wire.



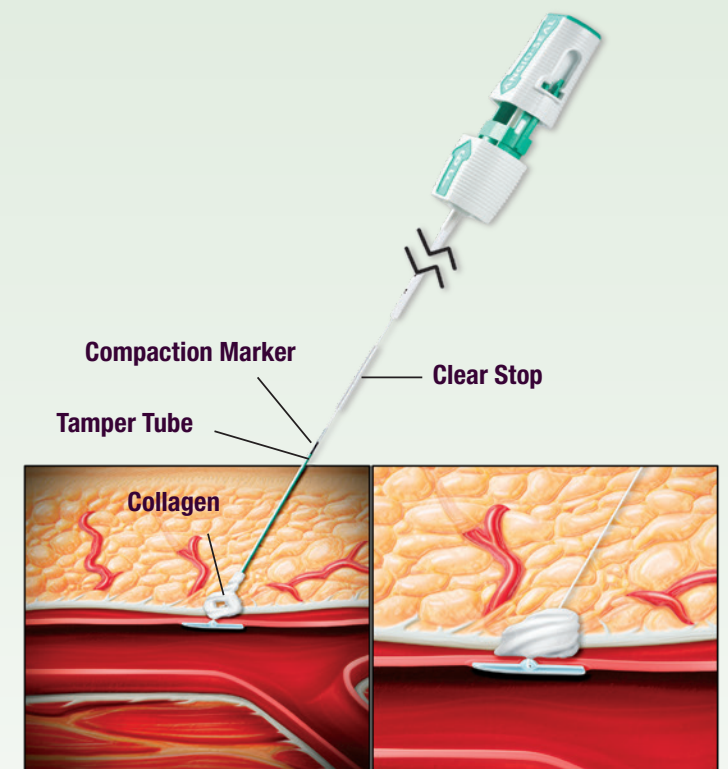
SET the Anchor

1. Carefully grasp the ANGIO-SEAL[®] device just behind the bypass tube and slowly insert into the sheath until the sheath cap and device cap snap together; you will hear a click when this occurs. Be sure the arrow on the sheath and device sleeve align.
2. Maintaining a grip on the sheath cap, grasp the device cap and gently pull back until the device handle and sheath cap audibly click into rear-lock position.



SEAL the Puncture

1. Slowly withdraw the device assembly along the angle of the puncture tract until the clear stop appears.
2. Maintain tension and advance the knot and collagen with the tamper tube. A seal occurs when resistance is felt and hemostasis is achieved. As a guide, a black compaction marker will appear in most cases.
3. Cut the suture below the clear stop and remove the tamper tube.
4. Gently pull up on the suture. Push down on the skin using a sterile instrument. Cut the suture below the skin level, making sure to cut below the black compaction marker.



ORDERING INFORMATION

ANGIO-SEAL [®] VIP		
PRODUCT CODE	FRENCH SIZE	GUIDEWIRE DIAMETER (in)
610132	6	0.035
610133	8	0.038

Contents: Vascular Closure Device, Insertion Sheath, Arteriotomy Locator and 70 cm Guidewire with "J" Straightener (10 units per box).

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Indications:
The Angio-Seal Vascular Closure Device is indicated for use in closing and reducing time to hemostasis of the femoral arterial puncture site in patients who have undergone diagnostic angiography procedures or interventional procedures using an 8 French or smaller procedural sheath for the 8 F Angio-Seal device and a 6 French or smaller procedural sheath for the 6 F Angio-Seal device. Angio-Seal is also indicated for use to allow patients who have undergone diagnostic angiography to safely ambulate as soon as possible after sheath removal and device placement, as well as to allow patients who have undergone an interventional procedure to safely ambulate after sheath removal and device placement.

Important Safety Information:
Possible adverse events for vascular closure devices include, but are not limited to: bleeding or hematoma, AV fistula or pseudoaneurysm, infection, allergic reaction, foreign body reaction, inflammation or edema. This device should only be used by physicians with training qualifying them to perform arterial access and closure for endovascular procedures through the common femoral artery and have participated in a Terumo Medical Corporation Angio-Seal physician instruction program.

Exception (applicable to US and China only):
This device should only be used by a licensed physician (or other health care professional authorized by or under the direction of such physician) possessing adequate instruction in the use of the device, e.g., participation in an Angio-Seal physician instruction program or equivalent.

RX ONLY. The advertisement is directed to physicians only, and not to consumers. Refer to product labels and packaging insert for complete warnings, precautions, potential complications, and instructions for use.

References
1. ANGIO-SEAL[®] VIP Instructions for Use. ASIN0015. 2023-05-09.

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