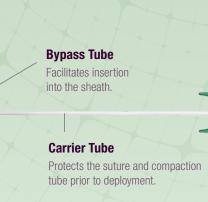


Vascular Closure Device





Reference Indicator

Sheath Cap

Aligns with the reference indicator on the sheath hub. Indicates proper device orientation when inserting into sheath.

ANGIO-SEAL® Evolution™ 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 handle snap together; you will hear a click when this occurs. Be sure the arrow on the sheath and device align.
- 2. Maintaining a grip on the sheath cap, grasp the device handle and gently pull back until the device handle and sleeve sheath cap audibly click into rear-lock position.

SEAL the Puncture

- 1. Carefully pull back on the ANGIO-SEAL® Evolution device handle along the angle of the puncture tract.
- 2. While pulling back on the device, maintain a steady, uninterrupted motion until light resistance is felt. As a guide, a colored compaction marker will appear in most cases. Pause and assess for hemostasis.

RELEASE the Suture

- 1. Press and hold down the suture release button.
- 2. Pull back on the device handle until the suture is exposed and light resistance is felt.
- **3.** While maintaining tension on the suture, push down on the skin using a sterile instrument. Cut the suture below the skin level.

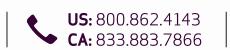
ORDERING INFORMATION

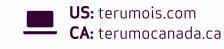
ANGIO-SEAL° EVOLUTION™			
PRODUCT CODE	FRENCH SIZE	GUIDEWIRE DIAMETER (in)	
C610134	6	0.035	
C610135	8	0.038	

ANGIO-SEAL° VIP			
PRODUCT CODE	FRENCH SIZE	GUIDEWIRE DIAMETER (in)	
610130	6	0.035	
610131	8	0.038	

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

FIND OUT MORE





Indications:

The Angio-Seal Vascular Closure Device product family, including the STS Plus, VIP and Evolution platforms, is indicated for use in closing and reducing time to hemostasis of the femoral arterial puncture site inpatients 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. The Angio-Seal STS Plus, VIP and Evolution platform devices are 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 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. Products may not have regulatory approval in all countries. Please contact your local sales representative if you have questions about the availability of products in your area.

Reference

1. Per Instructions For Use ARTEN600051890 A revison 2018-09-01





