

Product and Procedure

VenaSeal™ Closure System Procedure



Medtronic
Further, Together

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Introduction

To successfully sell the VenaSeal™ closure system, you must understand how it is intended to be used in a clinical setting.



Objectives

After completing this module, you will be able to:

- Identify the components in the VenaSeal™ system
- Describe the procedure steps necessary to facilitate a successful outcome



Key point

United States, Trinidad and Puerto Rico – The VenaSeal™ closure system is indicated for the permanent closure of lower extremity superficial truncal veins, such as the great saphenous vein (GSV), through endovascular embolization with **coaptation**. The VenaSeal™ system is intended for use in adults with clinically symptomatic venous reflux as diagnosed by duplex ultrasound (DUS).

All other approved countries – The VenaSeal™ closure system is intended for the permanent, complete, endovascular adhesive closure of the great saphenous vein (GSV) and associated **varicosities** in the treatment of venous reflux disease.

This module is **not** a substitute for the Instructions for Use (IFU). Refer to the VenaSeal™ closure system IFU for full product information.

System Overview



Key point

As with the ClosureFast™ system, the VenaSeal™ closure system closes various truncal veins to treat patients suffering from symptomatic chronic venous insufficiency (CVI).

The VenaSeal™ system consists of a small quantity of VenaSeal™ **adhesive** and a delivery system for delivering a controlled quantity of the adhesive to various truncal veins. The adhesive is a permanent implant.



Figure 1: VenaSeal™ Closure System

Components

All of the components for the VenaSeal™ system procedure are supplied in a single package. Additional surgical accessories are required (e.g., micro access kit, ultrasound system, etc.).

The VenaSeal™ system is made up of the following components:

- (1) 5 cc vial of VenaSeal™ adhesive
- (1) dispenser gun
- (1) 7 Fr, introducer (blue)
- (1) 5 Fr, delivery catheter (white)
- (1) 5 Fr, dilator (gray)
- (2) 3 cc syringes
- (2) 14 gauge dispenser tips
- (1) 0.035 inch, 180 cm J-wire guidewire

Provided sterile, the VenaSeal™ system is a single-use device.

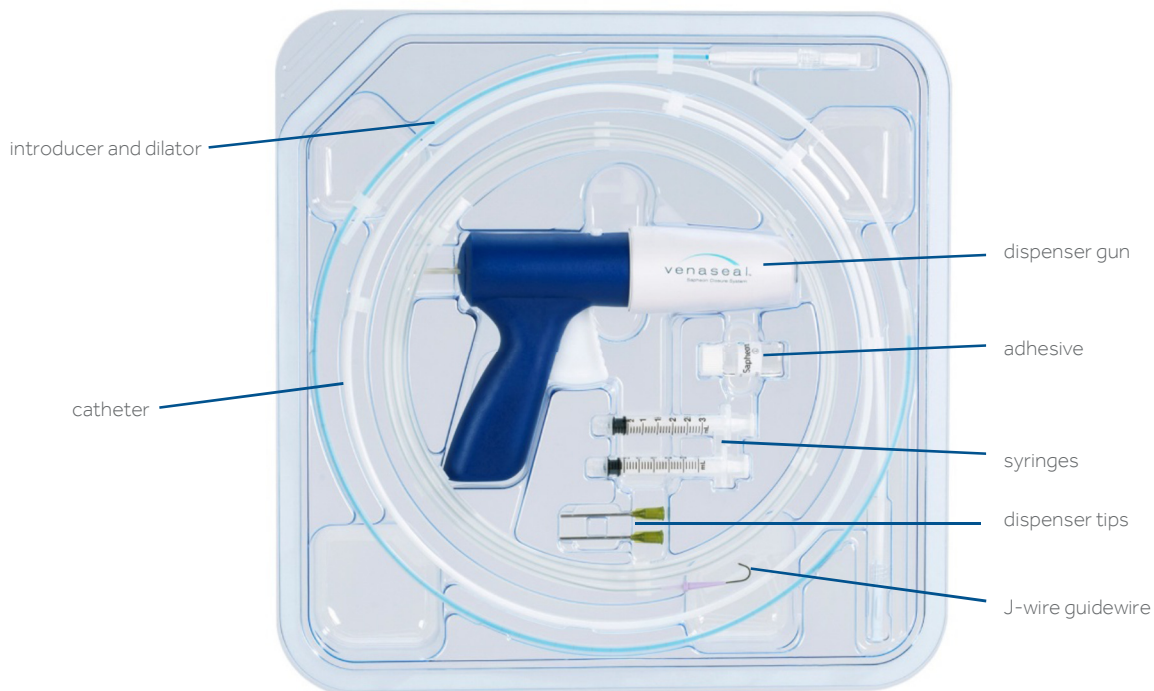


Figure 2: VenaSeal™ System Tray and Contents

Adhesive

The VenaSeal™ adhesive is a proprietary cyanoacrylate-based formula specifically designed to treat symptomatic venous reflux disease in the lower extremity superficial venous system, often the underlying cause of painful varicose veins. **The adhesive is a permanent implant.** Initially it creates a foreign body inflammatory response, which becomes encapsulated to form a chronic fibrotic closure of the vein. The VenaSeal™ adhesive is formulated not to migrate from the treatment area and not to embolize.



Figure 3: VenaSeal™ Adhesive

The VenaSeal™ adhesive was tested for **biocompatibility** following the guidance in ISO 10993-1 and FDA G95-1 Bluebook Memorandum. Based on the test results on file, the VenaSeal™ adhesive is biocompatible for the intended use.¹



Key point

For more information about the VenaSeal™ adhesive, refer to the *VenaSeal™ Adhesive module*.

¹ Data on file

Dispenser Gun

The dispenser gun precisely controls the amount of VenaSeal™ adhesive delivered. With each 3 second trigger pull, 0.10 cc of adhesive is delivered to the target vessel. (Note: Because the VenaSeal™ adhesive is **viscous**, the trigger is pulled back **and held for 3 seconds** to dispense 0.10 cc of the adhesive.)



Figure 4: Dispenser Gun

Introducer and Dilator

The VenaSeal™ system includes a blue introducer and gray dilator (which are packaged coupled together).

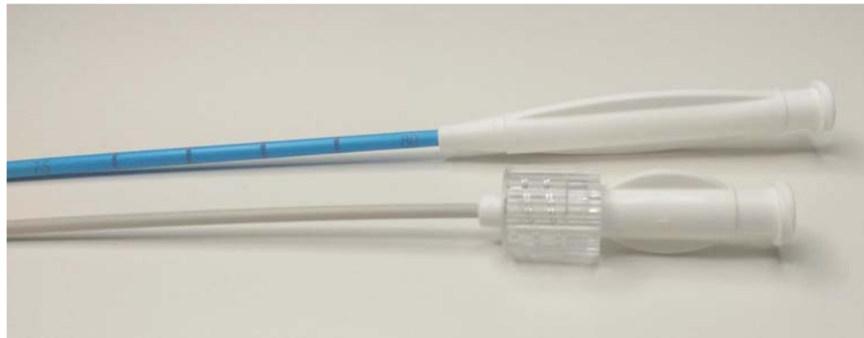


Figure 5: Introducer (top) and Dilator (bottom)

Once access is gained, the combined blue introducer and gray dilator are passed over the guidewire and into the GSV.

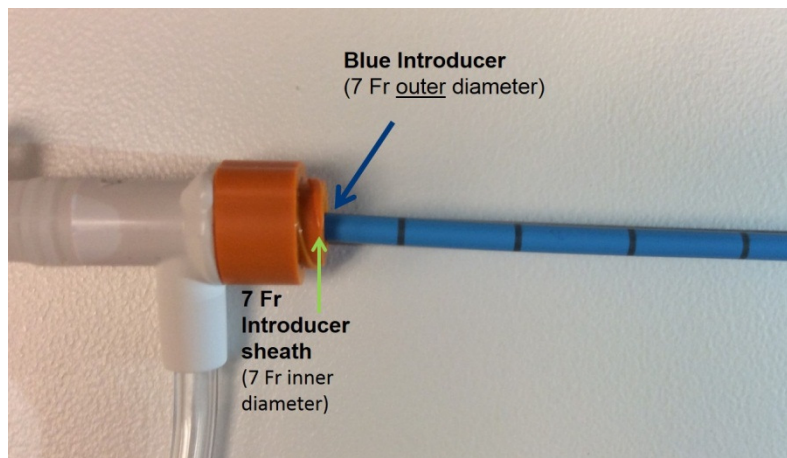


Figure 6: Introducer and Dilator

The gray dilator and guidewire are then removed and the blue introducer is flushed with saline, leaving the flushing syringe in place coupled with the blue introducer. The blue introducer is used as a tool to appropriately place the white delivery catheter. The blue introducer has markings spaced every 10 mm, with every 5th mark showing a number, to aid in positioning and pulling back the white delivery catheter appropriate distances.

Delivery Catheter

Once properly positioned within the blue introducer, the white delivery catheter dispenses the VenaSeal™ adhesive to the diseased vessel for closure. The proprietary white delivery catheter is engineered to be **inert** to the adhesive. Its tip extends beyond that of the blue introducer to prevent the adhesive from gluing the delivery tools to the vessel wall.

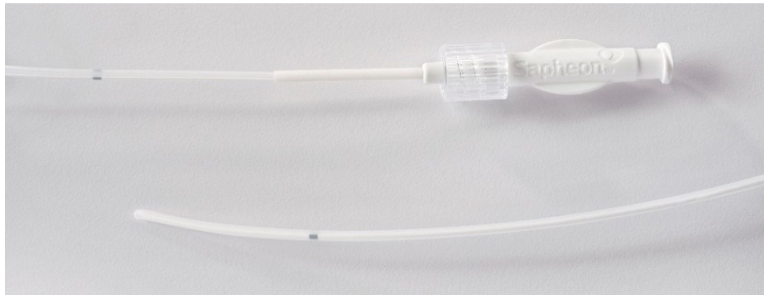
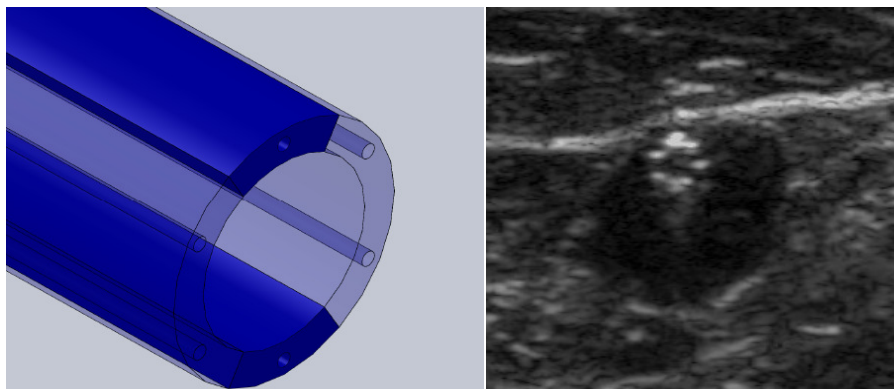


Figure 7: Delivery Catheter

The white delivery catheter has 6 micro-lumens that are highly visible under ultrasonic guidance, allowing for precise delivery of the adhesive.



micro-lumens

catheter in transverse view

Figure 8: Echogenic Delivery Catheter



Key point

Do not flush the white delivery catheter with saline or any solution – the only substance to enter the white delivery catheter should be the VenaSeal™ adhesive.

Syringes and Dispenser Tips

The 3 cc dispensing syringes included in the VenaSeal™ closure system are graduated and include a Luer Lock connector. The syringes are designed to mate with the dispenser gun.



Figure 9: Dispensing Syringes with Dispenser Tip

The syringes hold the VenaSeal™ adhesive before it is injected by the dispenser gun to the delivery site. Dispenser tips are included to allow the user to easily fill the syringes with VenaSeal™ adhesive. Once a syringe is filled with the adhesive, the air is removed. Then the tip is removed from the syringe and the adhesive-filled syringe is connected to the white delivery catheter and loaded into the dispenser gun, ready for use.

Procedure



Key points

- While the VenaSeal™ system procedure is not complicated, it is technique dependent. Users must complete physician training prior to the physician's first VenaSeal™ system procedure.
- It is important to follow ALL steps for a successful procedure.
- The VenaSeal™ procedure is administered without the use of tumescent anesthesia. Tumescent anesthesia is not required because the VenaSeal™ system uses an adhesive (not heat) to close the vein.

The VenaSeal™ closure system procedure can be broken into four steps:

1. Gain access and position the blue introducer
2. Prepare the VenaSeal™ Closure System and position the white delivery catheter
3. Execute the adhesive delivery and compression sequences
4. Remove the system and close the access site

Gain Access and Position Introducer

1. Prepare the leg per standard endovascular procedure protocol.
Note: Do not flush the white/clear adhesive delivery catheter. Only flush the blue introducer and gray dilator.
2. Administer topical lidocaine at the selected access site.
3. Under ultrasound guidance, access the target venous structure with a 21-gauge guidewire insertion needle from a 5 Fr micro-access kit or equivalent using **Seldinger technique**.

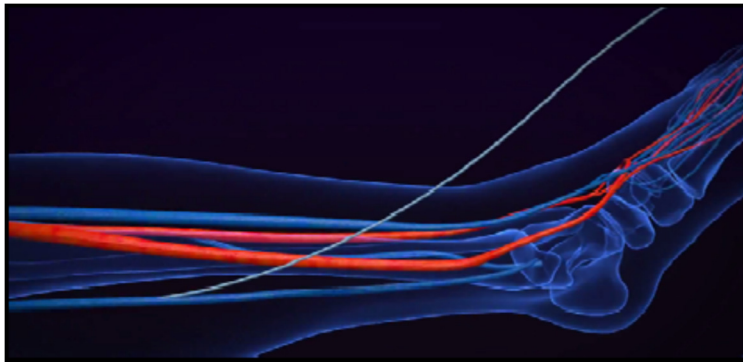


Figure 10: GSV Access

4. Advance an 0.018 inch (0.457 mm) micro-access kit guidewire (or equivalent) into the vein and confirm placement using ultrasound.

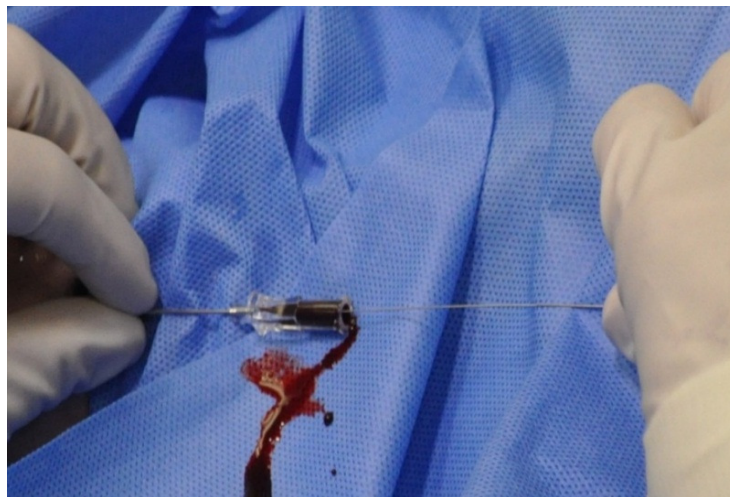


Figure 11: Advance Guidewire

5. Remove the guidewire insertion needle and advance the micro-access sheath/dilator over the micro-access kit guidewire and into the vein.

Note: Vein access methods will vary according to individual practice protocols and the device used. The VenaSeal™ system IFU offers one suggestion.

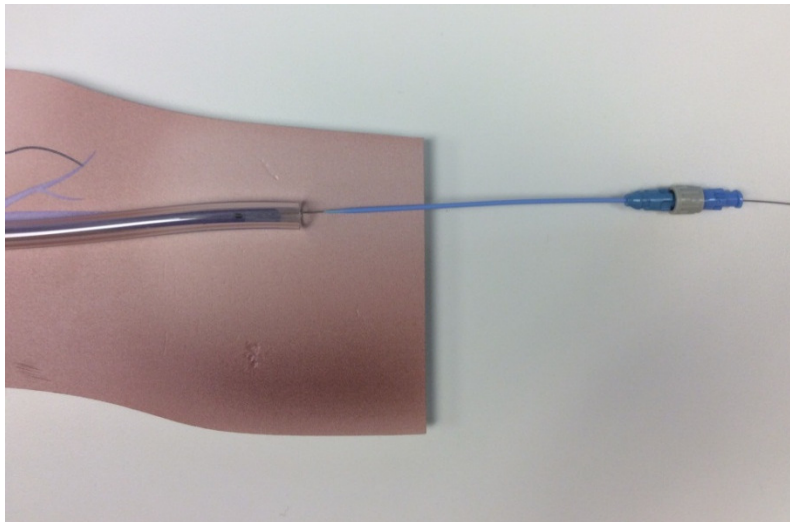


Figure 12: Advance Introducer/Dilator

6. Remove the micro-access kit guidewire and micro-access dilator, leaving the micro-access sheath in place.

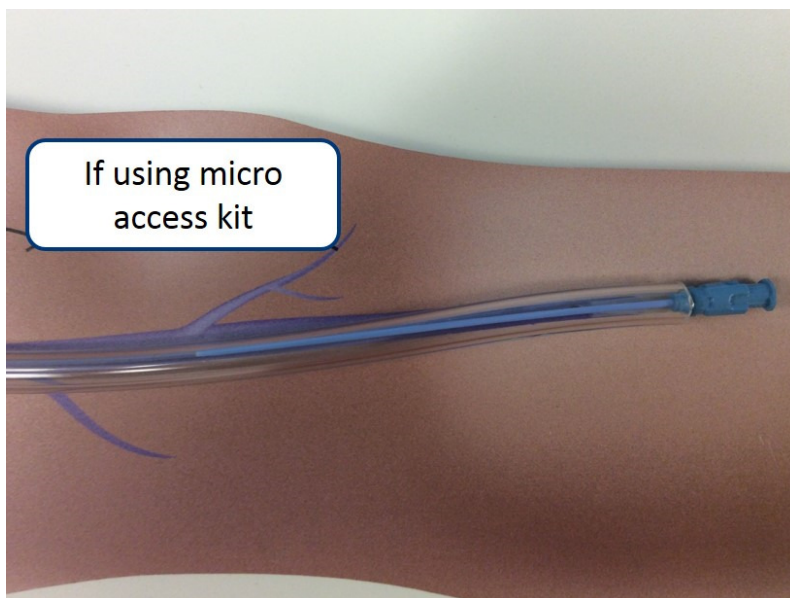


Figure 13: Remove Guidewire and Dilator

7. Advance the 0.035 inch (0.89 mm) J-wire guidewire through the access sheath and into the lumen of the vein.



Figure 14: Advance J-Wire Guidewire

8. Under real-time ultrasound, position the J-wire guidewire just **caudal** to the saphenofemoral junction (SFJ).
9. Confirm J-wire guidewire positioning with ultrasound.

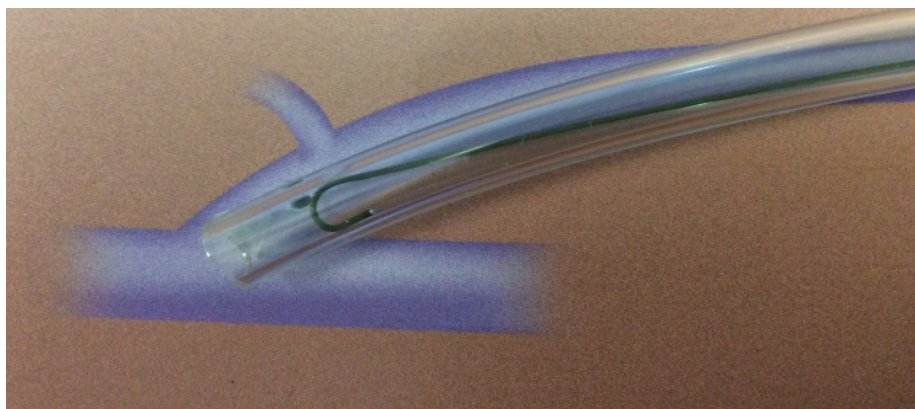


Figure 15: J-Wire Guidewire Position

10. If using a micro-access introducer, after ultrasound confirmation, remove the access sheath, leaving the guidewire in place.
11. Advance the blue introducer/gray dilator over the 0.035 J-wire guidewire toward the SFJ.

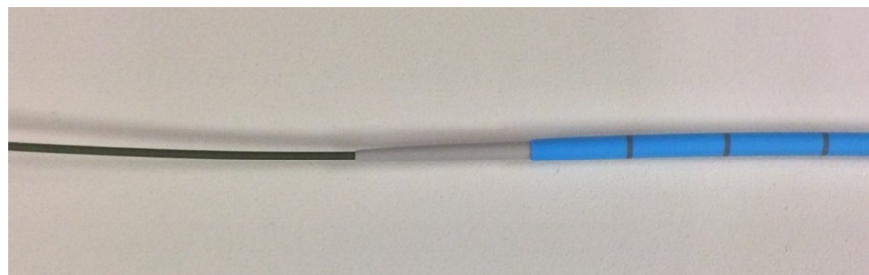


Figure 16: Advanced Introducer/Dilator

12. Position the blue introducer at the SFJ.
13. Remove the J-wire guidewire and gray dilator at the same time.
14. Flush the blue introducer through the luer injection port with sterile saline using a flushing syringe. Leave the flushing syringe in place.



Figure 17: Flush Introducer

15. Using ultrasound and the cm markings at the access site, pull the blue introducer back 5 cm. This action will position the blue introducer tip 5 cm from the SFJ.

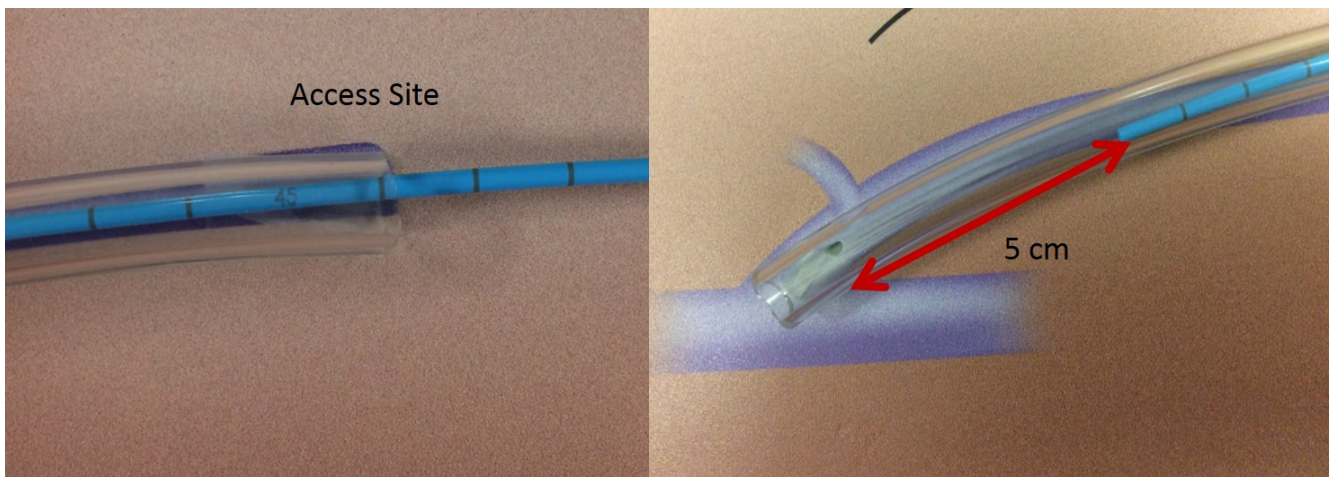


Figure 18: Introducer Position

Prepare the VenaSeal™ Closure System and Position the Catheter

1. Place the patient flat or with the head slightly lower than the feet.
2. Using the dispenser tip, fill a 3 cc syringe with VenaSeal™ adhesive.



Figure 19: Fill Syringe

3. Allow air to float toward the dispenser tip. Purge air from the syringe and wipe clean.
Note: Due to viscosity, the bubbles will move slowly.
4. Remove the dispenser tip from the syringe.



Figure 20: Dispenser Tip Removal

- Attach the VenaSeal™ adhesive-filled syringe to the white delivery catheter. Be sure the connection is tight.

Note: Never flush the white delivery catheter with saline.

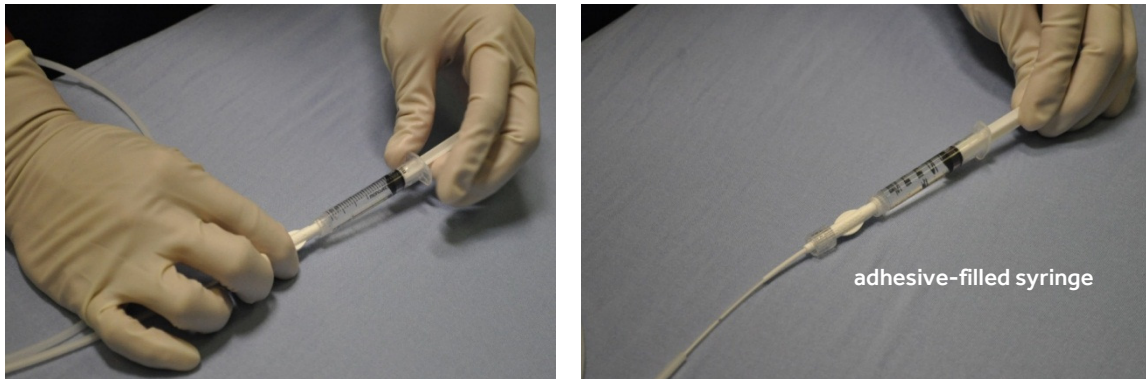


Figure 21: Syringe and Delivery Catheter Attachment

- Prepare the dispenser gun by pushing the top release button and pulling back the plunger.



Figure 22: Dispenser Gun Prep

7. Place the VenaSeal™ adhesive-filled syringe in the dispenser gun and turn it one-quarter of the way clockwise to lock the assembly.

Caution: Do not kink the white delivery catheter. Handle with care.



Figure 23: Clockwise Turn

8. Pull and hold the trigger to advance the adhesive.

Note: During the procedure, it is very important to pull the trigger for a FULL 3 seconds to deliver the full amount of adhesive.



Figure 24: Trigger Pull

9. Advance the adhesive to the distal laser mark, which is 3 cm from tip of the white delivery catheter.

Note: Near the end of the priming process, you may need to use a shorter trigger pull to avoid going past the distal laser mark and inadvertently ejecting adhesive out of the delivery catheter prematurely.

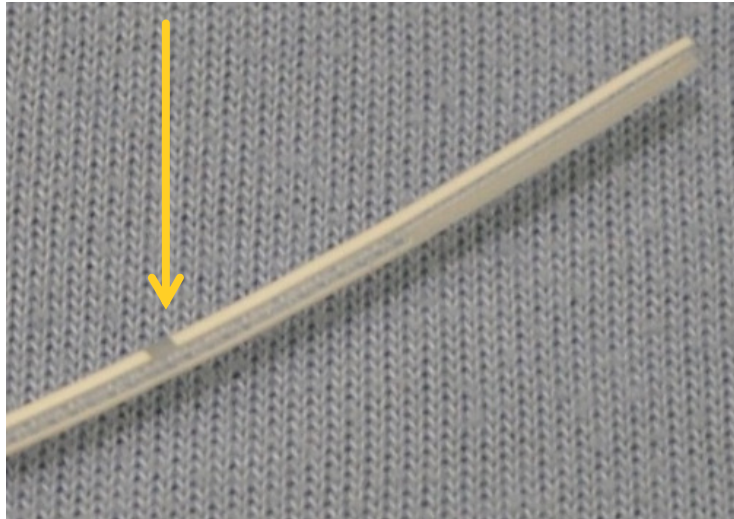


Figure 25: Distal Laser Mark

10. Remove the saline-filled flushing syringe and insert the primed white delivery catheter into the blue introducer.

Note: Be careful to keep the blue introducer in place.



Figure 26: Primed Catheter Insertion

11. Carefully advance the white delivery catheter to the proximal laser mark using **short throws** to avoid kinking the catheter.

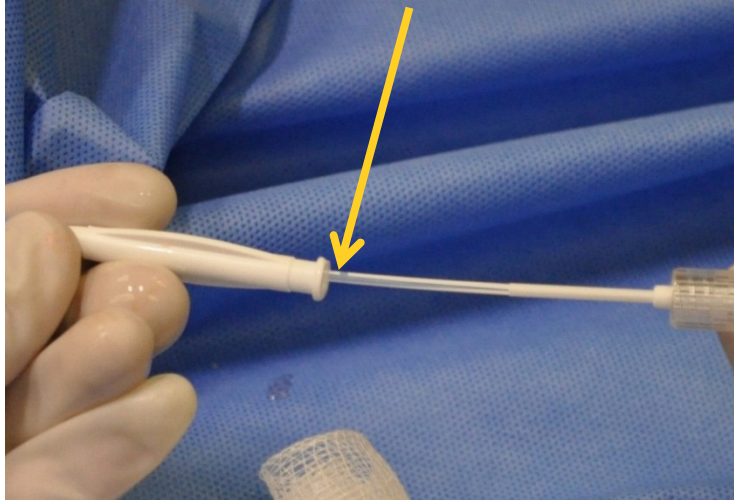
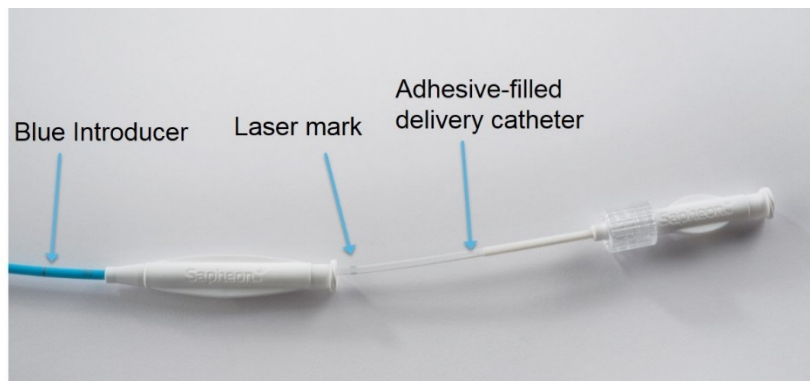


Figure 27: Proximal Laser Mark



Key point

The white delivery catheter inserted into the blue introducer should appear as follows:



12. The tip of the blue introducer is now 5 cm from the SFJ. Under ultrasound guidance, pull back the blue introducer **another** 5 cm.

Note: This action brings the tip of the blue introducer 10 cm from the SFJ.

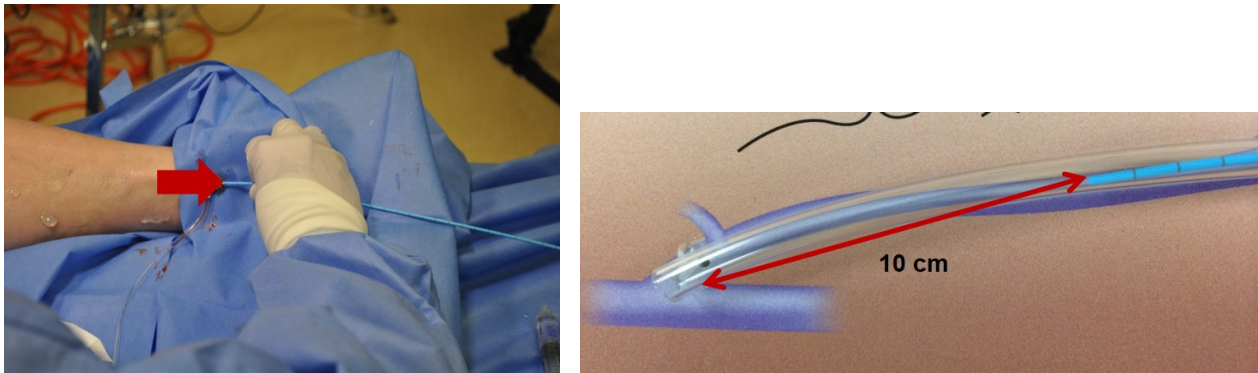


Figure 28: Pull Back Using Markings

13. While holding the blue introducer stationary, advance the white delivery catheter/dispenser gun into the blue introducer. Use the spinlock to lock the white delivery catheter and blue introducer together.

Note: This action will expose the catheter tip and position it 5 cm caudal to the SFJ.

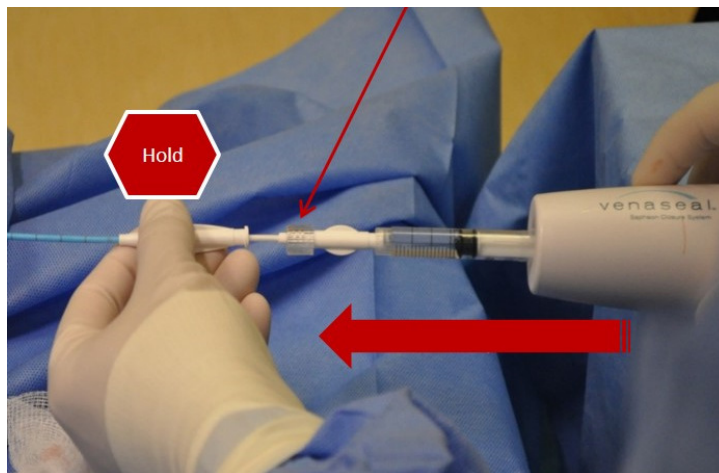
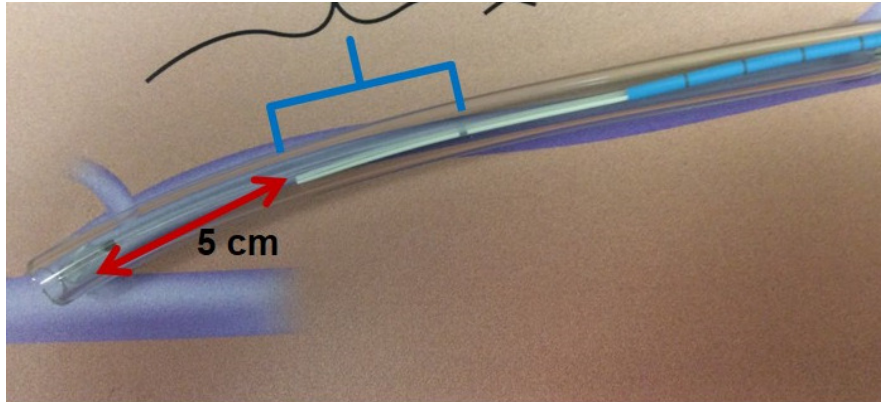


Figure 29: Advance and Lock



Key point

At this point, the primed catheter is visible outside the blue introducer in the proximal GSV.



14. **IMPORTANT:** Verify the white delivery catheter tip is 5 cm from the SFJ with ultrasound imaging. Slight adjustments may be needed.

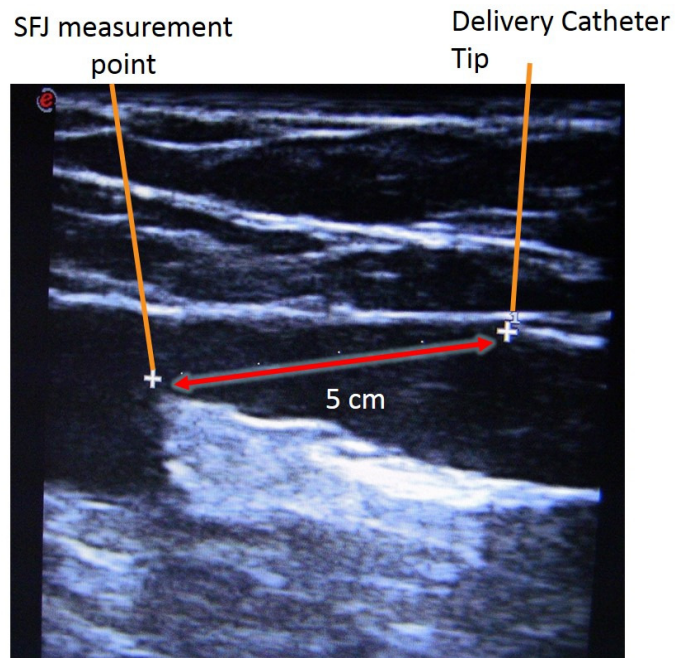


Figure 30: Primed Catheter Position

Execute Adhesive Delivery and Compression Sequences

1. Using transverse ultrasound plane, position the ultrasound transducer just **cephalad** (2-3 cm) to the catheter tip (which is 5 cm from SFJ) and apply adequate pressure to compress the GSV near the SFJ.

Note: The ultrasound probe should be positioned in the transverse/axial plane.

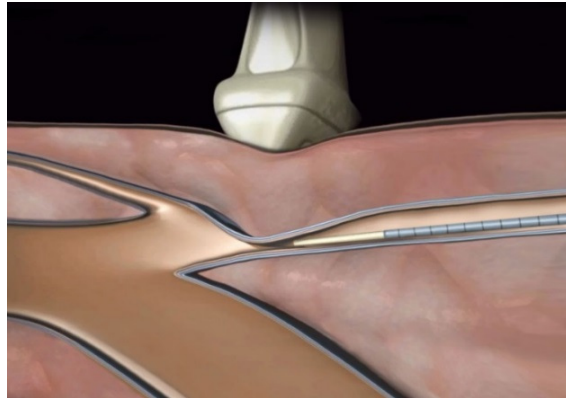


Figure 31: Catheter and Transverse Probe Position

2. While applying pressure with the transducer:
 - a. Deliver the first allotment (0.10 cc) of adhesive by completely depressing the trigger and holding for a FULL **3 seconds**.
 - b. Immediately pull the white delivery catheter/blue introducer assembly back **1 cm**.
 - c. Deliver the second allotment (0.10 cc) of adhesive by completely depressing the trigger and holding for **3 seconds**.
 - d. Immediately pull the white delivery catheter/blue introducer assembly back **3 cm**.

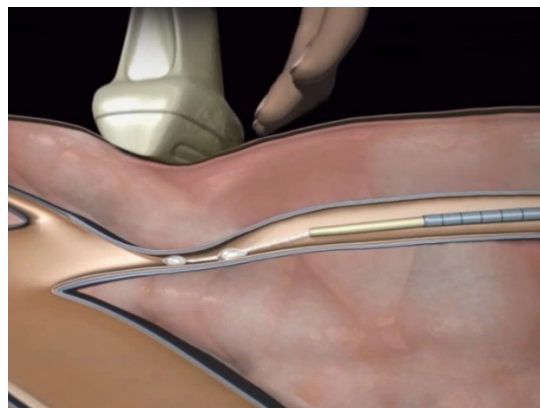


Figure 32: VenaSeal™ Adhesive Delivery



Key points

- External compression over the deposited adhesive is **BEST** performed by using the ultrasound probe with a transverse orientation. **DO NOT** use a longitudinal orientation of the ultrasound probe.
 - Compression times should be timed with a timer that has a second hand for accuracy.
 - Light manual compression is enough to coapt the vein; excessive pressure is not needed.
3. Maintaining transverse compression with the transducer, add light compression with the free hand over the area with the deposited adhesive for a minimum of **3 minutes**.

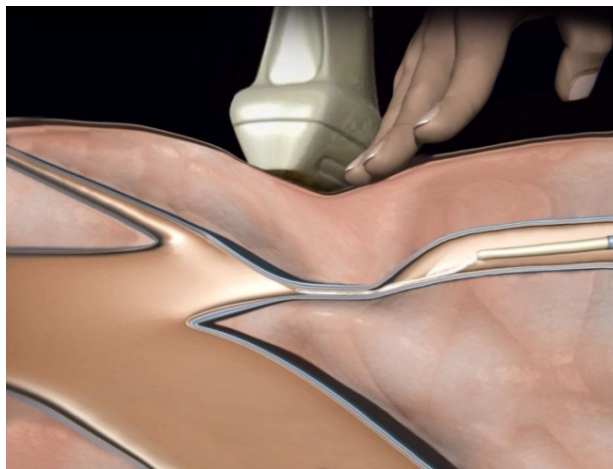


Figure 33: Vein Compression Post-Adhesive Delivery



Key point

The VenaSeal™ adhesive is formulated to not migrate from the treatment site and to not embolize.

4. Locate the white delivery catheter tip under ultrasound guidance.

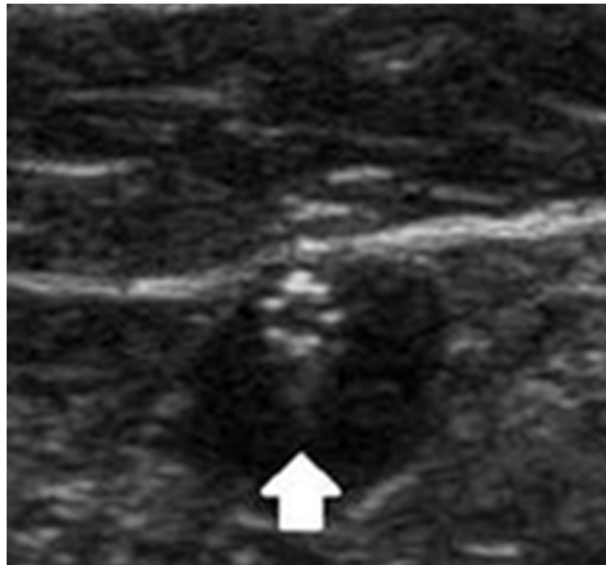


Figure 34: Catheter Tip Location

5. Compress the vein with the ultrasound probe transverse and cephalad to the catheter tip.

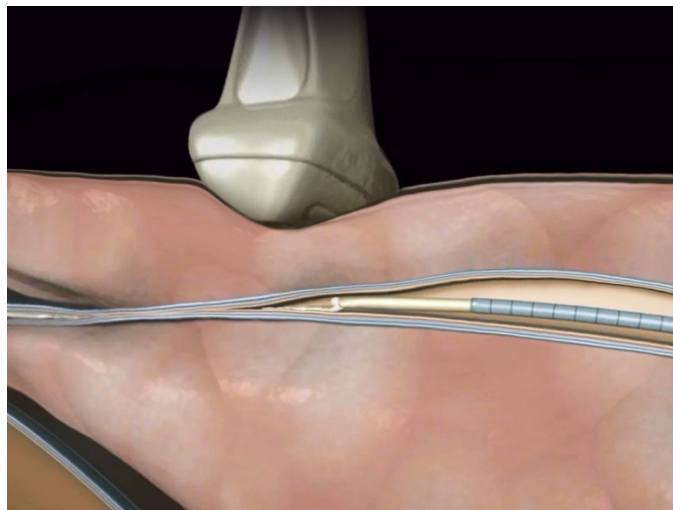


Figure 35: Vein Compression

6. While applying pressure with the transducer, deliver the third allotment (0.10 cc) of adhesive by completely depressing the trigger and holding for **3 seconds**. Immediately pull the white delivery catheter/blue introducer assembly back **3 cm**.

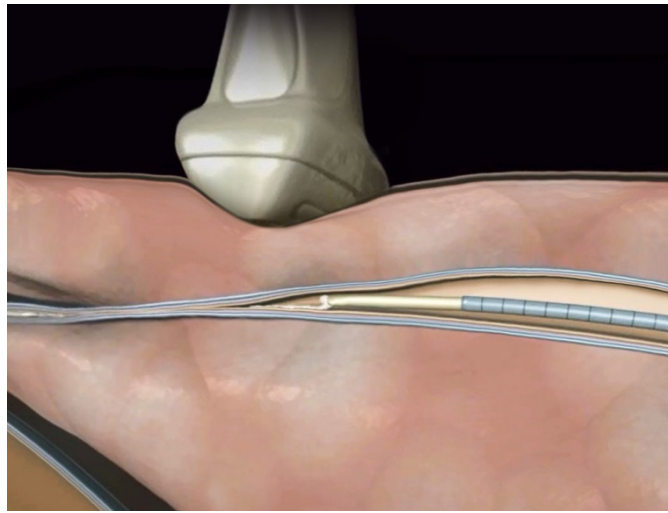


Figure 36: Dispense and Pull Back

7. Hold transverse compression with the ultrasound transducer for a minimum of **30 seconds**. Use a free hand caudal to the transducer to add light compression.

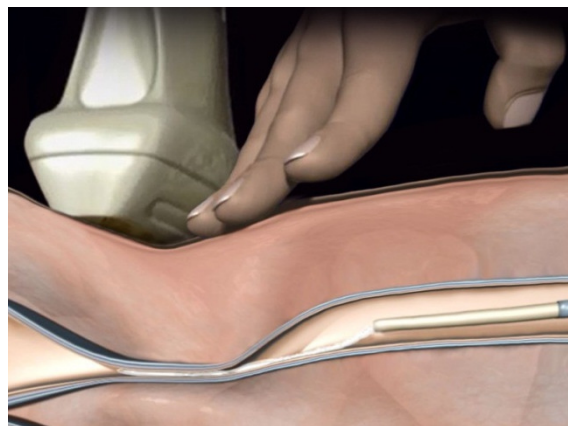


Figure 37: Vein Compression Post-Adhesive Delivery

- Repeat this process to continue to treat the target vein. Additional injections can be given during treatment at the site of tributaries or focal dilatation.



Key point

Ensure VenaSeal™ adhesive is delivered within the target vein (as opposed to outside the target vein in the subcutaneous tissue).

- Remove the access sheath when approximately two-thirds of the way down the target vein. (**Note:** Use the markers on the blue introducer, as the distance is dependent on the length of the blue introducer.) This action will prevent the adhesive catheter from coming in contact with the access sheath.

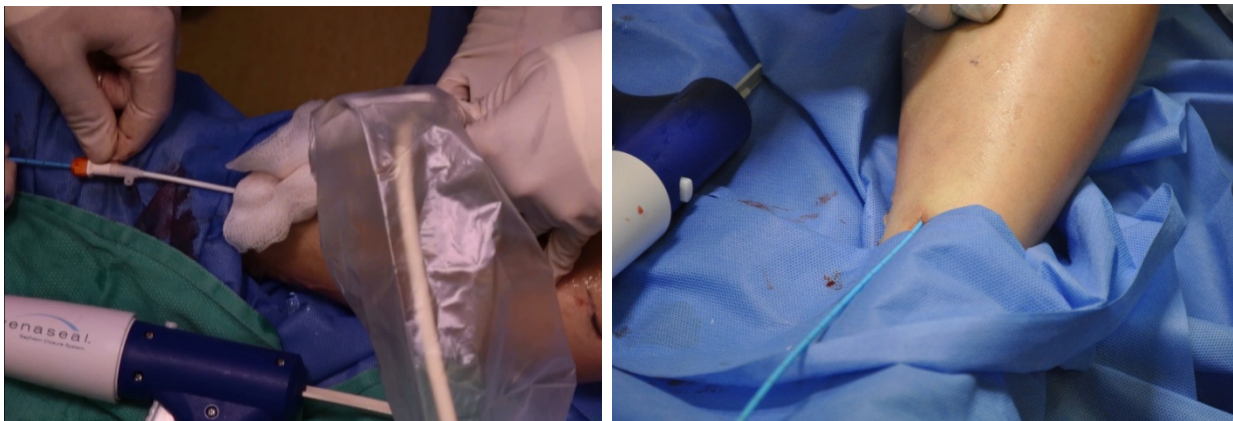
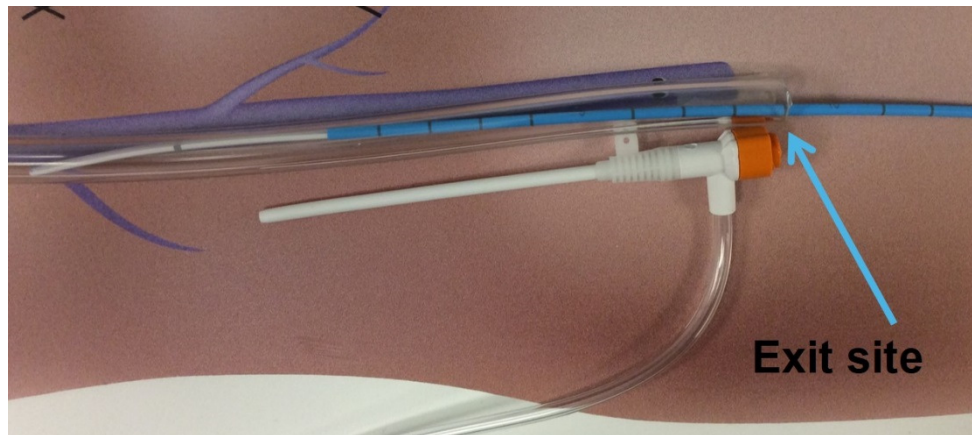


Figure 38: Access Sheath Removal



Key point

The image below shows the approximate position of a 7 Fr x 7 cm blue introducer relative to the end of the white delivery catheter. Longer blue introducers need to be withdrawn even earlier.



Model overlay for reference purposes

Remove System and Close Access Site

1. Treat the entire length of the target vein until the white delivery catheter tip is 5 cm from the access site. Injections should all be located within the target vein (as opposed to outside the target vein in the subcutaneous tissue).

Note: You will see the end of the blue introducer and the white delivery catheter will be showing (see *Figure 39*).



Figure 39: Visualization of Blue Introducer and White Delivery Catheter

2. If you have ultrasound confirmation that the white delivery catheter is still **inside** the target vein, administer the final injection.
Note: Vein depth varies among patients.
3. Pull back the white delivery catheter up to 3 cm.
4. Compression is then held for 30 seconds. This allows for polymerization of the adhesive and avoids getting adhesive outside the target vein.
5. Remove the blue introducer/white delivery catheter.
6. Hold hand pressure as long as necessary at the access site to achieve **hemostasis**.
7. Inspect the access site to ensure no adhesive is left in the access site.
8. Confirm vein closure with ultrasound.



Key points

- The follow-up procedure is determined by the medical provider. With venous procedures, post-operative instructions vary per physician choice. Some examples may include:
 - Verbally ask the patient pain score at X timepoint.
 - Post-treatment, the patient should be encouraged to walk around, in addition to following the site's usual post-operative practice.
 - Compression stockings are not required post-procedure, per the VenaSeal™ system IFU. However, the treating physician may prescribe compression stockings to patients as desired.
 - Patients should be provided pain or allergy medication at the treating physician's discretion.
 - Upon discharge, patients should be provided with the site's standard discharge instructions.
 - Follow-up visits should be scheduled according to site protocol. Utilize patient appointment reminder cards, as applicable.
- The VenaSeal™ system is a single-use device. Dispose of all components per facility protocol for biohazardous medical devices.

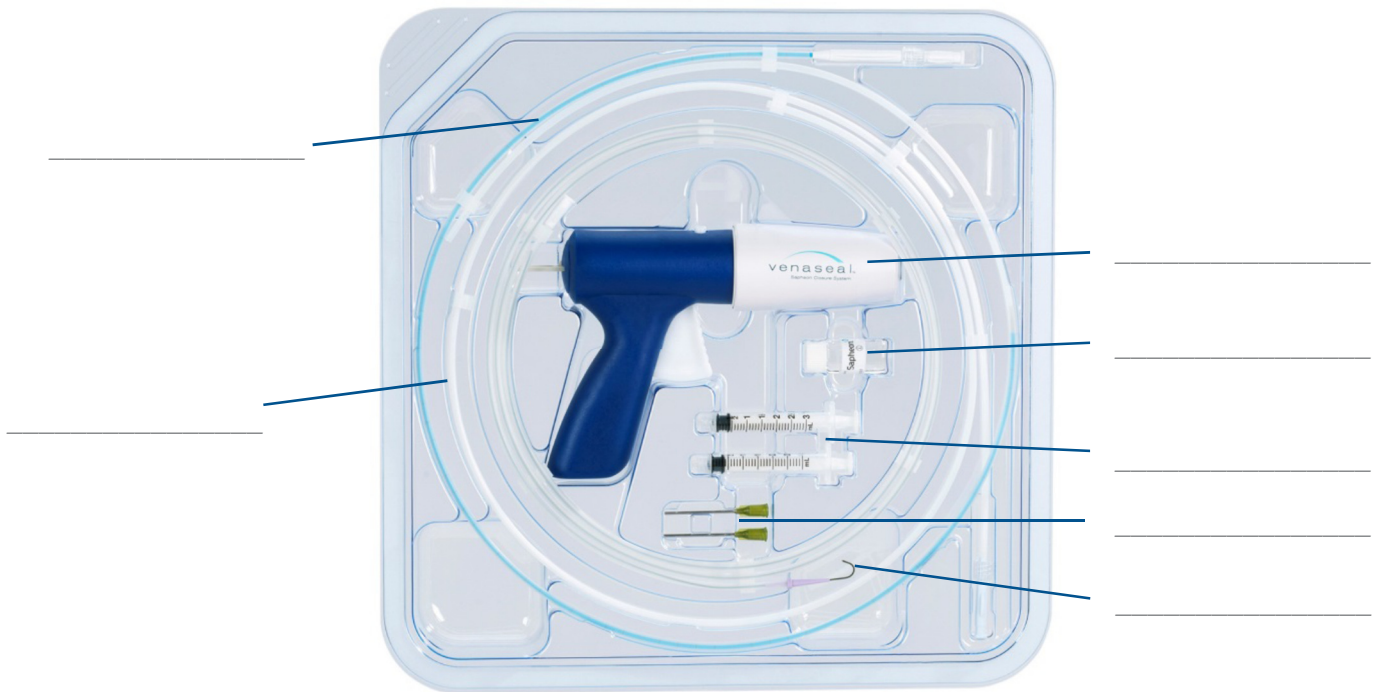


Key points

- The primed white delivery catheter can be withdrawn from the blue introducer only if no adhesive has exited the white delivery catheter tip.
- In the event the primed catheter would need to be withdrawn from the blue introducer prior to completion of the procedure (i.e., the delivery catheter needs to be used again), take the following steps:
 1. If the adhesive has not been injected through the distal end of the white delivery catheter (IFU Procedure Steps 21 – 23).
 - a. Check to make sure there is no adhesive that has been injected out the white delivery catheter tip.
 - b. If a. has not occurred, the white delivery catheter can be unscrewed from the blue introducer and withdrawn.
 2. If the adhesive has been injected through the distal end of the white delivery catheter (After IFU Procedure Step 23).
 - a. Withdraw the blue introducer with attached catheter. The following steps are performed outside the body.
 - b. Push the white button on top of the dispenser gun and pull back the plunger rod.
 - c. Unlock and release the syringe with attached catheter from the dispenser gun.
 - d. Pull back gently on the syringe plunger to draw the adhesive back in to the catheter.
 - e. Adhesive should be drawn at least 5-10 cm from the distal laser mark on the catheter.
 - f. Using sterile gauze repeatedly wipe any residual adhesive off the tip of the catheter.
 - g. After confirming the tip is cleaned of adhesive, the white delivery catheter can be unscrewed from the blue introducer and withdrawn.
 - h. Flush the blue introducer with sterile saline prior to advancing over the guidewire.
 3. To re-introduce the white delivery catheter back into the blue introducer, follow IFU Steps 10 - 23.

Progress Check

1. Identify the components in VenaSeal™ system below.



2. Identify the parts of the dispenser gun below.



3. Any medical-grade, cyanoacrylate-based adhesive may be used in the VenaSeal™ system.
- a. True
 - b. False

Progress Check Answers

1. Identify the components in VenaSeal™ system below.



2. Identify the parts of the dispenser gun below.



3. Any medical-grade, cyanoacrylate-based adhesive may be used in the VenaSeal™ system.

b. False

4. Where should the blue introducer tip be positioned in relation to the SFJ?

c. 5 cm caudal

5. The VenaSeal™ adhesive is a permanent implant.
 - a. *True*

6. The white delivery catheter should only be flushed with VenaSeal™ adhesive.

7. What is the best technique for avoiding catheter kinks?
Insert the white delivery catheter using short throws.

8. Describe the process for delivering the first and second allotment of adhesive.
 - *Deliver the first allotment (0.10 cc) of adhesive by completely depressing the trigger and holding for a FULL **3 seconds**.*
 - *Immediately pull the white delivery catheter/blue introducer assembly back **1 cm**.*
 - *Deliver the second allotment (0.10 cc) of adhesive by completely depressing the trigger and holding for **3 seconds**.*
 - *Immediately pull the white delivery catheter/blue introducer assembly back **3 cm**.*

9. The VenaSeal™ closure system is a single-use product and should be disposed of per proper protocol for biohazard devices following each patient case.
 - a. *True*

Glossary

adhesive	substance that binds materials together and resists separation
biocompatibility	quality of not having toxins or injurious effects on biological functions
caudal	away from the head
cephalad	toward the head
coapt (for VenaSeal™ procedure)	temporary compression of a vein using the ultrasound probe (Longer term, the ablated vein will appear to have returned to a more circular cross section with adhesive chemically and mechanically bonded to the intimal layer of the vein.)
hemostasis	stoppage of blood circulation through a vessel
inert	deficient in active properties; lacking the ability to react with other elements
monomer	a molecule that may bind chemically to other molecules to form a polymer
polymer	large molecule composed of many repeated subunits
polymerization	chemical process in which simple molecules combine to create a more complex structure or compound
Seldinger technique	method of percutaneous insertion of a catheter into a blood vessel or space A needle is used to puncture the structure and a guidewire is threaded through the needle; when the needle is withdrawn, a catheter is threaded over the wire; the wire is then withdrawn, leaving the catheter in place.
substrate	tissue to which the adhesive bonds
varicosities	vessels in a state of unnatural and permanent distention
viscosity	measure of flow resistance; substances with high viscosity tend to be thicker than substances with low viscosity

DISCLAIMER

Please reference the instructions for use for a complete listing of indications, contraindications, warnings and precautions, adverse effects and a full set of instructions for the procedure.

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