

Medtronic

Prep and Procedure Guide

VenaSeal™ Closure System



This document is to be used as a guide only. Refer to the Instructions for Use (IFU) for detailed information regarding use of this device.

VenaSeal™ closure system brief statement

Intended Use/Indications: The VenaSeal™ closure system (VenaSeal™ system) is indicated for use in 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).

Contraindications: Separate use of the individual components of the VenaSeal closure system is contraindicated. These components must be used as a system. The use of the VenaSeal system is contraindicated when any of the following conditions exist: previous hypersensitivity reactions to the VenaSeal™ adhesive or cyanoacrylates, acute superficial thrombophlebitis, thrombophlebitis migrans, acute sepsis.

Potential Adverse Effects of the Device on Health: The potential adverse effects (e.g., complications) associated with the use of the VenaSeal system include, but are not limited to, adverse reactions to a foreign body (including, but not limited to, nonspecific mild inflammation of the cutaneous and subcutaneous tissue), arteriovenous fistula, bleeding from the access site, deep vein thrombosis (DVT), edema in the treated leg, embolization, including pulmonary embolism (PE), hematoma, hyperpigmentation, hypersensitivity or allergic reactions to cyanoacrylates, such as urticaria, shortness of breath, and anaphylactic shock, infection at the access site, pain, paresthesia, phlebitis, superficial thrombophlebitis, urticaria, erythema, or ulceration may occur at the injection site, vascular rupture and perforation, visible scarring.

Warnings, precautions, and instructions for use can be found in the product labeling at <http://manuals.medtronic.com>.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

24-hour technical support
Toll free: +1.800.551.5544

medtronic.com/venaseal

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Prep and procedure guide Venaseal™ closure system

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Prep of system components

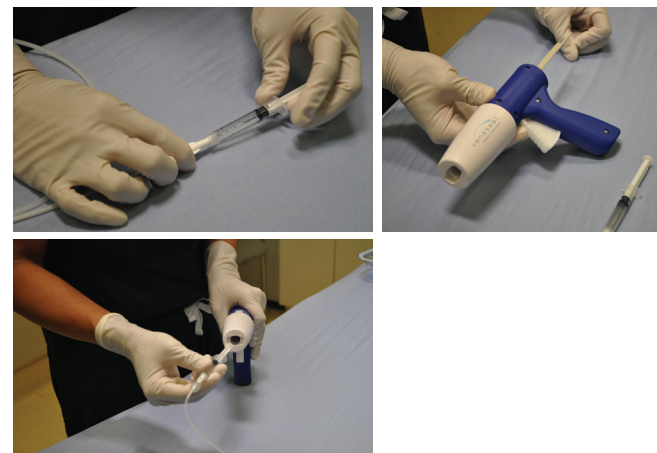
- 1 Separate flushable vs. non-flushable VenaSeal system components. Flush blue introducer (through the luer injection port) with sterile saline using a flushing syringe. Leave syringe in place. **Do not** flush adhesive delivery catheter.

Refer to the next page for a list of flushable (wet) vs. non-flushable (dry) VenaSeal system components.

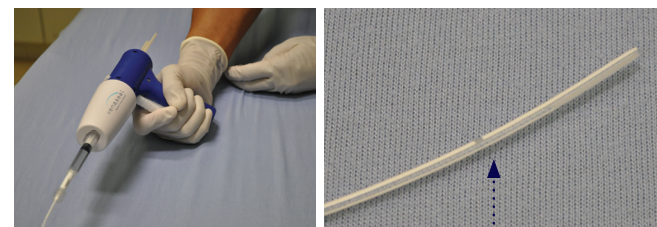
- 2 Use dispensing tip to fill one 3 cc syringe with VenaSeal adhesive.
- 3 Hold syringe upright to allow air bubble to float toward dispensing tip. Purge air from syringe and wipe clean with a dry gauze.



- 4 Attach adhesive-filled syringe to delivery catheter. Turn clockwise to lock into place.
- 5 Prep dispenser gun by pressing the top release button and pulling back the plunger.
- 6 Place syringe in dispenser assembly. Lock dispenser assembly by turning ¼ clockwise.



- 7 Prime delivery catheter by pulling and holding the trigger for 3 second intervals to advance the adhesive to the distal laser mark located 3 cm from the delivery catheter tip. A full 3 second trigger hold delivers 0.10 cc (range 0.06-0.12 cm) of adhesive.



Distal laser mark

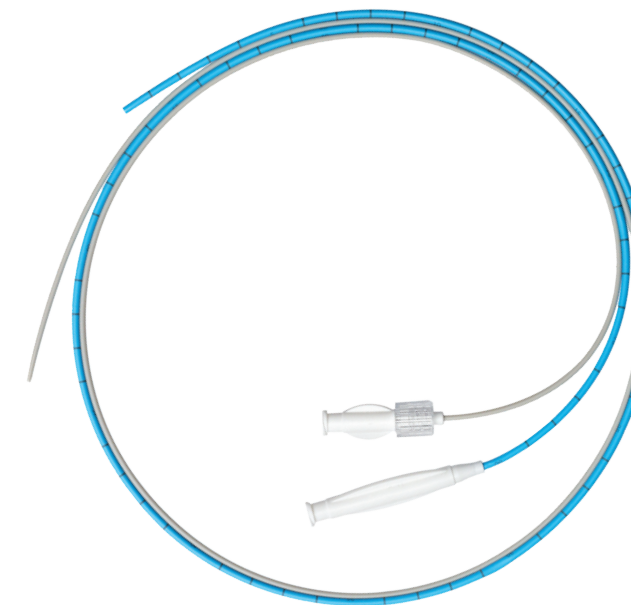
Caution: Prime delivery catheter slowly to avoid advancing adhesive past distal laser mark.



Dry components

- Delivery Catheter (inert)
- Dispensing gun
- Adhesive (bottle)
- Syringe
- Dispenser tip

These components remain dry before and during the procedure.



Wet components

- Blue introducer
- Dilator
- Straight-tip guidewire (not pictured)

These components are exposed to fluids before or during the procedure.

Vein access

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Access vein

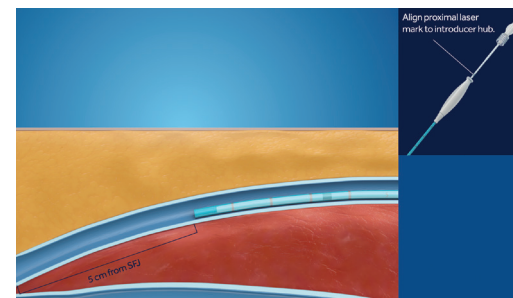
- 1 Locate vein and determine access site using ultrasound guidance (as necessary). Gain and confirm access. Exchange access kit for 0.035 inch straight floppy-tip guidewire and remove micro-access sheath. Advance guidewire just caudal of saphenofemoral junction (SFJ). Advance the 7 F blue introducer/gray dilator over the straight-tip guidewire just caudal to the SFJ. Remove 0.035 inch straight-tip guidewire and gray dilator.

Note: Ensure blue introducer has been flushed with sterile saline using a flushing syringe (see step 1 in Prep of System Components). Leave syringe attached to introducer until next step. Under ultrasound guidance, position blue introducer 5 cm from the SFJ.

Advance primed catheter into introducer

- 2 Remove flushing syringe from the blue introducer. Insert and advance primed delivery catheter into the blue introducer up to the proximal laser mark.

Note: Use short throws to advance the primed delivery catheter into the blue introducer, to avoid kinking of the catheter.



Pull back and lock catheter with introducer

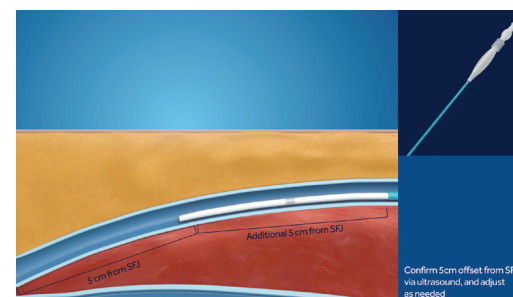
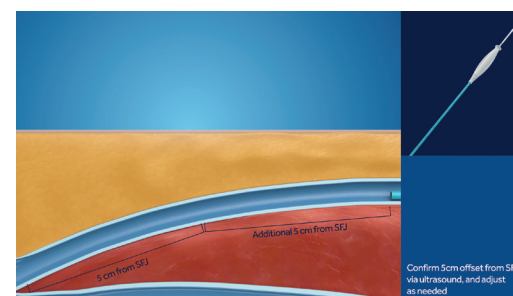
- 3 Pull the blue introducer back 5 cm.

Note: This will position the entire system 10 cm back from the SFJ.

- 4 Holding the blue introducer in place, advance the delivery catheter assembly into the blue introducer. Use spinlock mechanism to lock together the blue introducer and delivery catheter.

Note: This will position the catheter tip approximately 5 cm from the SFJ.

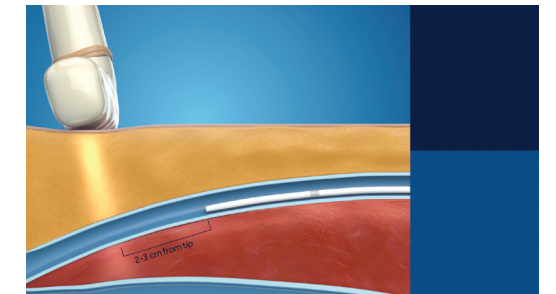
Verify delivery catheter tip is 5 cm from SFJ with ultrasound imaging.



First treatment

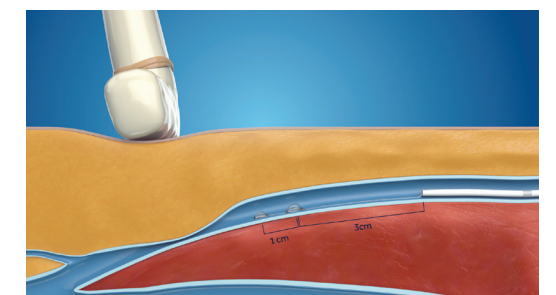
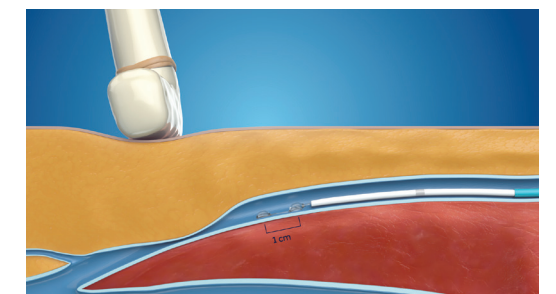
Apply pressure with ultrasound transducer

- 1 Using transverse ultrasound plane, position transducer 2-3 cm cephalad to the delivery catheter tip and apply compression 90 degrees to the vein.



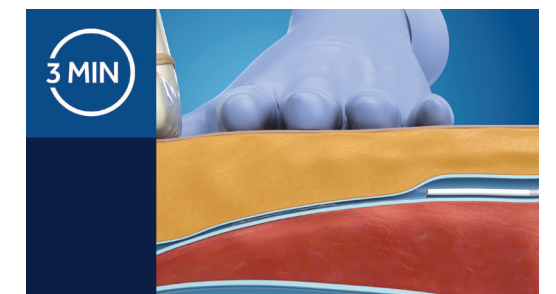
Deliver adhesive and pull back 3 cm

- 2 Continue to compress the vein with ultrasound probe and initiate delivery of the adhesive. Hold dispenser gun trigger for 3 full seconds. Immediately pull back the system 1 cm.
- 3 Pull and hold dispenser gun trigger for 3 full seconds. Immediately pull back the system 3 cm.



Compress for 3 minutes

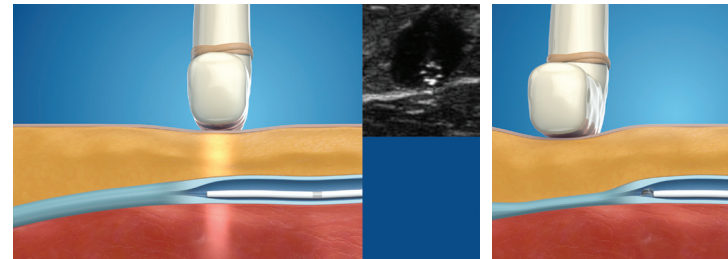
- 4 Following second injection of adhesive, continue to apply transverse compression with ultrasound probe and use the fingers of your free hand to compress the delivered adhesive for 3 minutes.



Three approved segmental treatment lengths to close vein

Locate catheter tip and push down with transducer

- 1 Relocate catheter tip by viewing the (delivery catheter) star under ultrasound guidance. Using transverse plane, position the ultrasound probe above the catheter tip and compress.

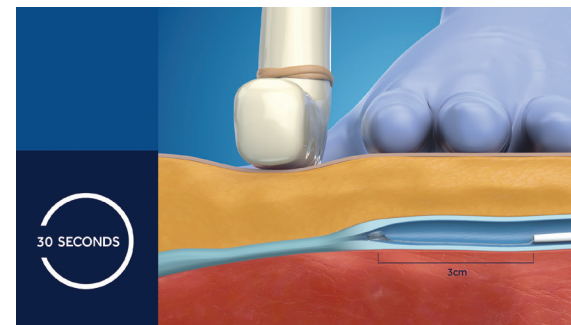


Single, double, and triple segment options

Option 1:

Deliver adhesive, pull back 3 cm, and compress 30 seconds

- 2a Single segment method. Pull and hold dispenser gun trigger for full 3 seconds. Immediately pull back the system 3 cm. Continue to apply transverse compression with ultrasound probe and use the fingers of your free hand to compress the delivered adhesive for 30 seconds.



Option 2:

Deliver adhesive (x2), pull back 3 cm (x2), and compress 30 seconds

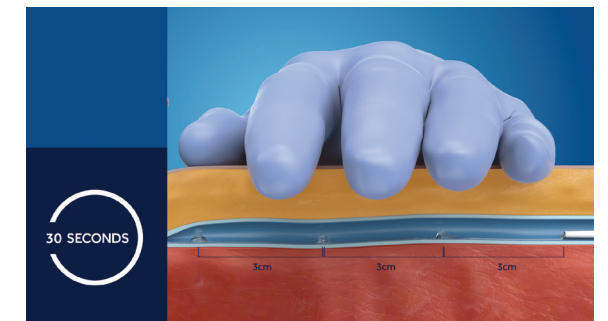
- 2b Double segment method. Pull and hold dispenser gun trigger for 3 full seconds. Immediately pull back the system 3 cm, and then pull and hold dispenser gun trigger for another 3 full seconds. Again, immediately pull back the system another 3 cm, for a total of 6 cm. Continue to apply transverse compression with ultrasound probe and use the fingers of your free hand to compress the entire 6 cm length of the delivered adhesive for 30 seconds.



Option 3:

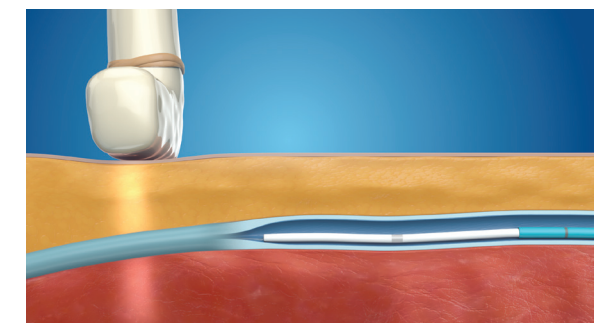
Deliver adhesive (x3), pull back 3 cm (x3), and compress 30 seconds

- 2c Triple segment method. Pull and hold dispenser gun trigger for 3 full seconds. Immediately pull back the system 3 cm, and then pull and hold dispenser gun trigger for another 3 full seconds. Again, immediately pull back the system another 3 cm, and hold dispenser gun trigger for another 3 full seconds, and then pull back the system 3 cm, for a total of 9 cm. Continue to apply transverse compression with ultrasound probe and use the fingers of your free hand to compress the entire 9 cm length of the delivered adhesive for 30 seconds.



Repeat steps 1 and 2 for length of vein to be treated

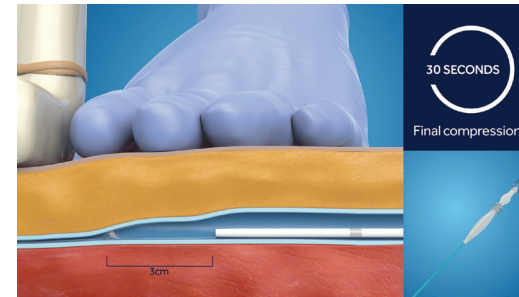
- 3 Depending on whether you chose the single, double, or triple segment method, repeat appropriate steps 1 and 2 to treat the entire length of the target vein segment.
Note: Additional drops of adhesive plus compression can be applied during treatment at the site of tributaries or focal dilatation.



Final treatment and device removal

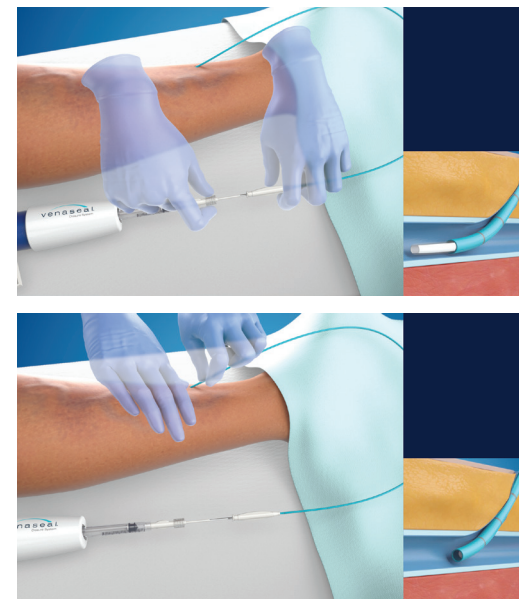
Deliver final adhesive, pull back 3 cm, and compress 30 seconds

- 4 Treat the entire length of the target vein segment to a point where the 5 cm laser mark of the introducer is visible outside of the access site.
After delivery of the final adhesive, pull back 3 cm and apply compression for 30 seconds.
Note: The introducer should also remain within the vein.



Withdraw catheter into introducer, remove and apply bandage

- 5 After the 30 seconds of compression associated with the final injection of adhesive within the target vein, unlock the spin-lock mechanism of delivery catheter from the introducer. Maintain introducer position within target vessel. While holding introducer stationary, recapture catheter by retracting it through introducer until catheter's proximal laser mark is visible 1 cm to 5 cm outside of introducer hub. Remove introducer and catheter together.
Apply hand pressure as long as needed to achieve hemostasis at access site. Bandage as necessary and confirm vein closure with ultrasound.



Primed catheter withdrawal prior to procedural completion

In the event the primed catheter needs to be withdrawn from the introducer prior to completion, take the following steps:

- 1 If the VenaSeal adhesive has not been injected through the distal end of the catheter: (see vein access | steps 1-4)
 - a. Check to make sure there is no adhesive that has been injected out the catheter tip.
 - b. If (a) has not occurred, the catheter can be unscrewed from the introducer and withdrawn.
- 2 If the adhesive has been injected through the distal end of the catheter: (see vein access | steps 2)
 - a. Withdraw delivery catheter so that it is completely inside the blue introducer before removing from vein. The following steps are performed outside the body.
 1. Push the white button on top of the dispenser gun and pull back the plunger rod.
 2. Unlock and release the syringe with attached catheter from the dispenser gun.
 3. Pull back gently on the syringe plunger to draw the adhesive back in to the catheter.
 4. Adhesive should be drawn at least 5-10 cm from the distal laser mark on the catheter.
 5. Using sterile gauze, repeatedly wipe any residual adhesive off the tip of the catheter.
 6. After confirming the tip is cleaned of adhesive, the catheter can be unscrewed from the introducer and withdrawn.
 7. Flush the introducer sheath with sterile saline prior to advancing over the guidewire.
- 3 To reintroduce the catheter back into the introducer: (see vein access | steps 2-4)

Locating the catheter under ultrasound guidance

The VenaSeal catheter is designed to be easily seen under ultrasound guidance. When looking at the short axis, the catheter has specially designed microchannels that present as a "star pattern" and assist in finding the end of the catheter.

