QUICK

Reference Guide For The Venefit™ Procedure

A step-by-step process for getting you started right away.
The Venefit procedure, delivered by the Covidien ClosureFast™ endovenous radiofrequency ablation (RFA) Catheter.

Venefit™
Targeted Endovenous Therapy

COVIDIEN

QUICK REFERENCE GUIDE

System & Patient Preparation

Covidien ClosureRFG™ Radiofrequency Generator

- Plug in radiofrequency generator.
- Push on button located on lower left corner. Green light will illuminate on button.
- Using the touchscreen, touch the settings icon and review default settings. Adjust the settings accordingly.
- To return to the home screen, touch the home icon.

Patient Preparation

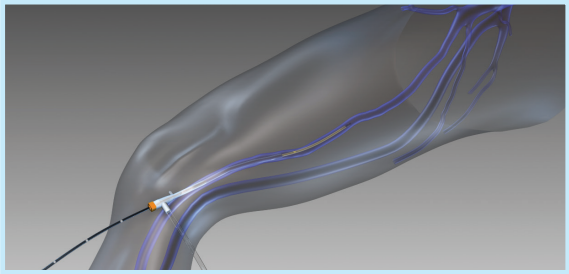
- Prep leg in sterile fashion.

Anesthesia

- Physician choice.

Access Vein

- Use percutaneous or cutdown technique.
- Flush the introducer sheath with saline and place it in the vein.



Catheter Preparation

- Attach the Covidien ClosureFast™ catheter cable to ClosureRFG™ generator.
- Flush the catheter with sterile physiologic saline (0.9% sodium chloride) or heparinized saline and cap the luer port.

CAUTION: Use of a flush through the catheter while the heating element is active will heat the fluid coming out of the end of the catheter. Avoid fluid delivery through the catheter during energy delivery when tip of catheter is near an area that should not be thermally coagulated.

Catheter Advancement & Vessel Exsanguination

Position Catheter

- Insert catheter and advance to most proximal treatment site.

CAUTION: Do not advance the catheter or guidewire against resistance or vein perforation may occur.

Tumescent Fluid Infiltration

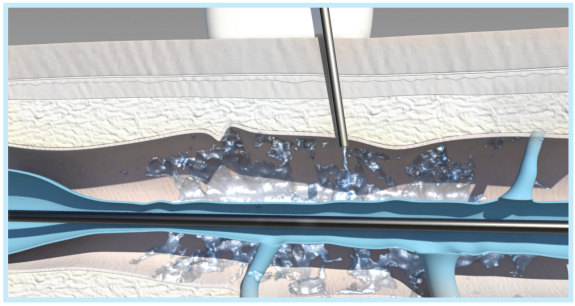
- Administer tumescent fluid into saphenous compartment along treatment region.*
- Do not administer tumescent solution up to approximately 5 cm distal to the Saphenofemoral Junction (SFJ) or Saphenopopliteal Junction (SPJ) until final catheter tip position has been confirmed.

NOTE: When the vein is located near the skin surface, a subcutaneous distance of >1 cm between the anterior vein wall and skin should be created by tumescent fluid infiltration.

Final Catheter Position & Tumescent Infiltration

- Confirm final tip position with ultrasound guidance; tip should be at least 2 cm inferior to the junction when treating the Great Saphenous Vein (GSV) or Small Saphenous Vein (SSV).
- Administer tumescent at most proximal treatment site.

NOTE: If leg position changes, re-confirm tip position before RF delivery.



Trendelenburg Position

- Position patient's legs above the level of the heart to facilitate vein collapse, apposition and exsanguination.

Establish Indexing

Reference Point

- Establish reference point for shaft marker indexing by withdrawing introducer sheath while holding the catheter stationary to align with the nearest visible shaft mark or by marking a line on skin at nearest visible shaft mark.

CAUTION: Do not treat with the heating element in the deep venous system.

Treatment

Compress

- Apply even compression over full length of heating element to establish good contact between vein wall and heating element.
- Use ultrasound probe in longitudinal view plus two fingertips distal to end of probe (recommended).

Treat

- Press the white device button on the catheter handle to initiate treatment.
- Blue lights on upper left and right corners of the generator will illuminate with the start of treatment.
- For the Covidien ClosureFast™ catheter, under normal conditions, power will typically begin at 40W and drop below 20W within 10 seconds. For the Covidien ClosureFast™ 3cm catheter, under normal conditions, power will typically begin at 18W and drop below 10W within 10 seconds.

CAUTION: If treatment is halted due to non-uniform temperature, remove the catheter and inspect the heating element for damage. If damage is found, replace the catheter.

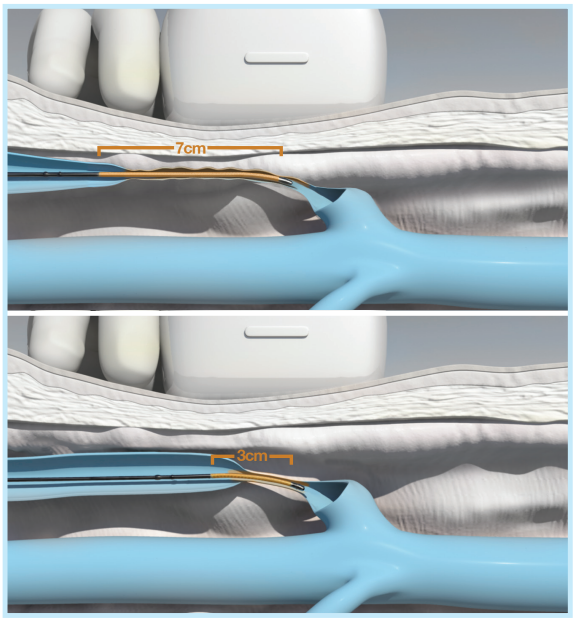
- When using the Covidien ClosureFast™ catheter, deliver a second energy cycle to the one segment closest to the SFJ. When using the Covidien ClosureFast™ 3cm catheter, a second energy cycle may be given at the physician's discretion if sufficient treatment length is available.

*Use and dilutions of tumescent anesthesia are at the physician's sole judgment and discretion. Covidien does not recommend specific tumescent anesthesia mixtures or dilutions. Please refer to the drug package insert prior to use for important warnings, prescribing, and risk information.

CAUTION: Do not administer more then three energy delivery cycles at any given vein segment.

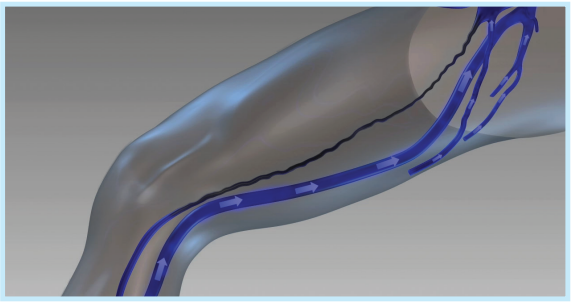
- When treatment cycle is complete and RF Power automatically stops, quickly index catheter to next shaft mark position, apply even compression over entire heating element and start next treatment.
- Repeat withdrawal, compression and treatment until desired length of vein is treated.

CAUTION: Do not deliver RF energy with the heating element (tip) of the catheter within the introducer sheath or outside the body.



Confirm Vessel Occlusion

- Remove external compression and withdraw catheter quickly.
- Place patient in supine position and perform post-operative duplex scan of treated vein segment to confirm vessel occlusion.
- There is no retreatment protocol; THE CATHETER SHOULD NOT BE RE-ADVANCED THROUGH A PREVIOUSLY TREATED SEGMENT.



Procedure End

- Remove introducer sheath; apply compression bandage.
- Review post-operative instructions with patient.

The Importance of Compression

Good procedural outcomes for the Venefit procedure are dependent on the ability to bring the vein wall in contact with the full length of the heating element. This contact is created through several techniques, all of which should be employed during treatment.

1. Perivenous tumescent infiltration into the saphenous compartment
   a. From vein access point to beyond the SFJ to effectively stem flow from junctional tributaries
   b. Create a 360˚ halo of fluid around the treatment vein
   c. A general guideline is to infiltrate 10 cc of tumescent fluid per 1 cm of vein to be treated
2. Trendelenburg position to empty the superficial venous system and collapse the treatment vein after final tip position and tumescent infiltration at the SFJ region
3. External compression applied evenly in a medial-to-lateral direction over the entire heating element during each treatment cycle
   - The recommended external compression technique involves use of the ultrasound transducer aligned with the heating element plus additional compression with two fingertips just distal to the probe
   - Insufficient external compression during treatment may result in under-treatment of a segment, advisory messages on the RFGPlus screen, treatment interruptions or damage to the catheter heating element

CAUTION: Failure to compress the vein over the full length of the heating element may result in inconsistent effectiveness and/or possible catheter damage.