Medtronic

Prep and Procedure Guide

ClosureFast™ Radiofrequency Ablation 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.

ClosureRFG™ Radiofrequency Generator
Indications for Use: The ClosureRFG generator is used with radiofrequency catheters intended for vessel and tissue coagulation.

Contraindications: Refer to the applicable radiofrequency catheter instructions for use for a list of contraindications related to a ClosureFast system procedure.

Potential Adverse Effects of the Device on Health: Refer to the applicable radiofrequency catheter instructions for use for a list of potential complications related to a ClosureFast system procedure.

IMPORTANT: Please reference the Operation Manual for a complete listing of indications, warnings, precautions safety notices, and operational information.

ClosureRFS™ Endovenous Radiofrequency Stylet
Indications for Use: The ClosureRFS stylet is intended for use in vessel and tissue coagulation, including treatment of incompetent (i.e., refluxing) perforator and tributary veins.

Contraindications: The ClosureRFS stylet is contraindicated for use in patients with thrombus in the vein segment to be treated.

Potential Adverse Effects of the Device on Health: The potential complications include, but are not limited to, the following: arteriovenous fistula, infection, phlebitis, skin burns, hematoma, nerve damage, pulmonary embolism, and thrombosis.

IMPORTANT: Please reference the Instructions For Use (IFU) for a complete listing of indications, contraindications, warnings and precautions, adverse effects, and suggested procedure.

ClosureFast™ Endovenous Radiofrequency (RFA) Ablation Catheter
Indications for Use: The ClosureFast endovenous radiofrequency ablation (RFA) catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

Contraindications: The ClosureFast catheter is contraindicated for use in patients with thrombus in the target vein segment.

Potential Adverse Effects of the Device on Health: The potential complications include, but are not limited to, the following: adjacent nerve injury, hematoma, pulmonary embolism, thrombosis, infection, phlebitis, skin burn or discoloration, and vessel perforation.

IMPORTANT: Please reference the Instructions For Use (IFU) for a complete listing of indications, contraindications, warnings and precautions, adverse effects, and suggested procedure.

24-hour technical support
Toll free: +1.800.551.5544

medtronic.com/ClosureFast

System inspection and preparation

ClosureRFG radiofrequency generator

- Plug in radiofrequency generator.
- Push “on” button located on lower left corner. Green light will illuminate.
- Confirm software version on screen. For RFG3 with any ClosureFast heating length, software must be version 1.11.0 or higher. For the RFG2 with 8 cm heating element, it must be 4.0.0 or higher, and with 3 cm heating element it must be 4.4.0 or higher.
- Using the touchscreen, touch the settings icon and review default settings.
- Target temperature for the catheter is 120° C.

Note: Default settings will not be displayed until a catheter is connected to the generator.

- To return to the home screen, touch the home icon.

Patient preparation

- Prep leg in sterile fashion.

Anesthesia

- Physician choice.

Access vein

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

Catheter preparation

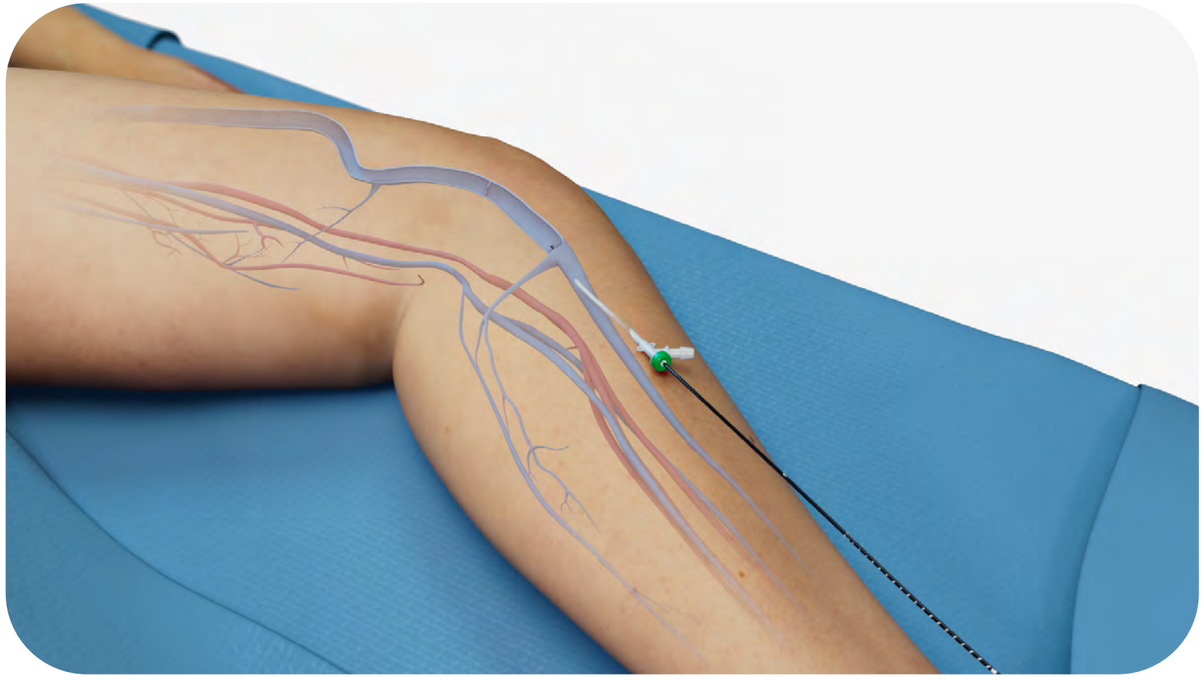
- Attach the ClosureFast catheter cable to ClosureRFG generator.
- Flush the catheter with sterile physiologic saline (0.9% sodium chloride) or heparinized saline and cap the Luer port.

Caution: Avoid putting any flush through the wire port while there is active heating of the element.

Position catheter

- Insert the catheter and advance to most proximal treatment site.

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



Tumescent infiltration and catheter tip positioning

Tumescent fluid infiltration

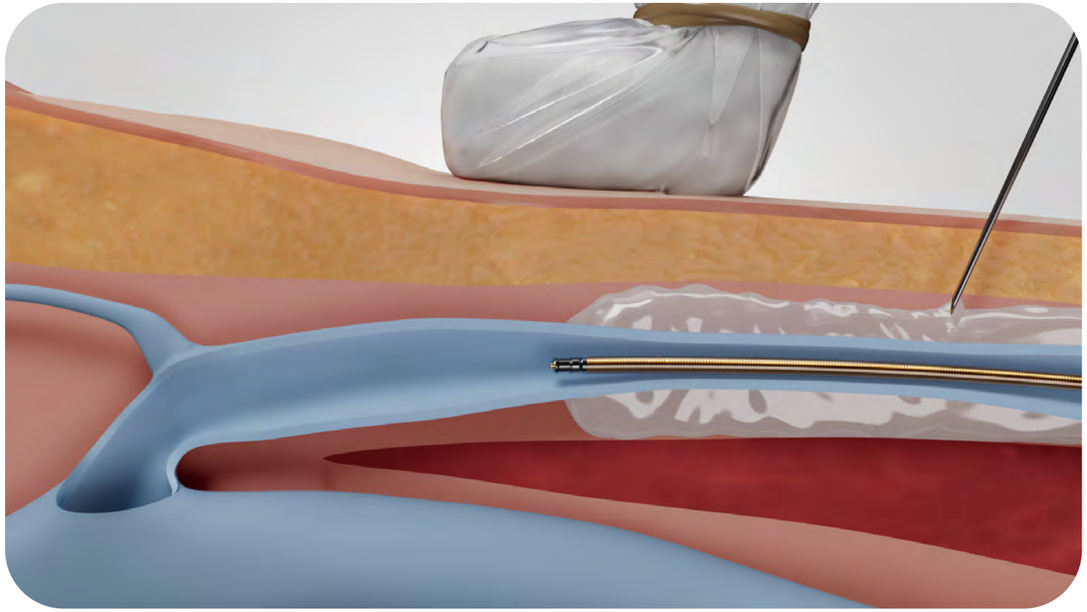
- Administer tumescent into the perivascular space along the treatment length.†
- Administer tumescent solution up to approximately 5 cm distal to the saphenofemoral junction (SFJ) or saphenopopliteal junction (SPJ) .

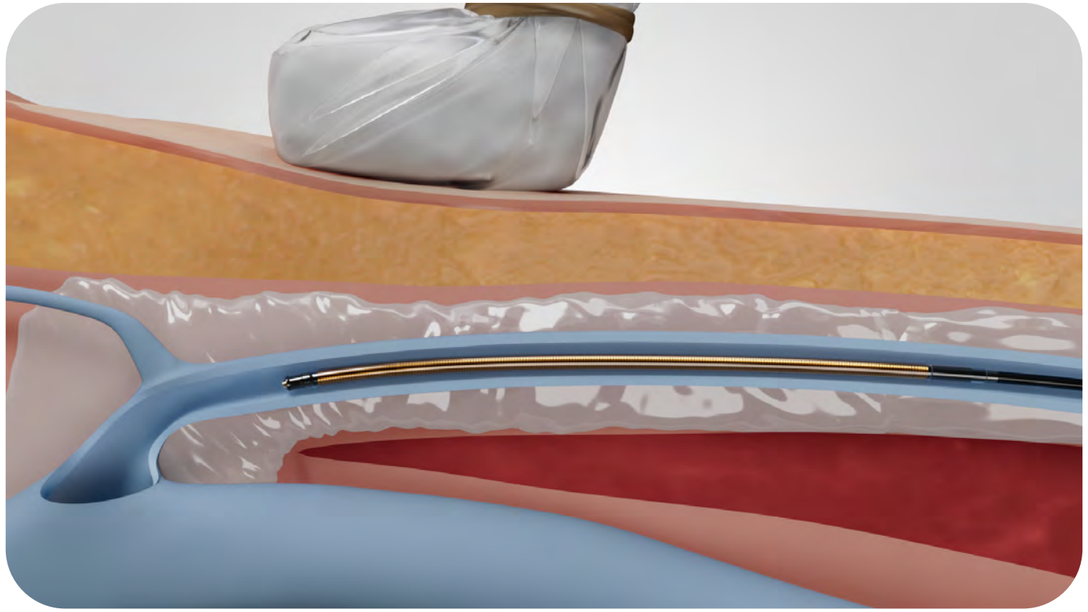
Note: When the vein is located near the skin surface, a subcutaneous distance of > 1 cm between the anterior vein wall and skin should be created by tumescent fluid infiltration.

Final catheter position and tumescent infiltration

- Confirm final tip position with ultrasound guidance; tip should be at least 2 cm inferior to junction when treating great saphenous vein (GSV) or small saphenous vein (SSV).
- Infiltrate tumescent fluid above and beyond the junction using ultrasound guidance.

Note: If leg position changes, reconfirm tip position before RF delivery.





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

Treatment

Position the patient

- Place patient in Trendelenburg position with legs above heart level to facilitate vein collapse, apposition and exsanguination.

Establish indexing

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

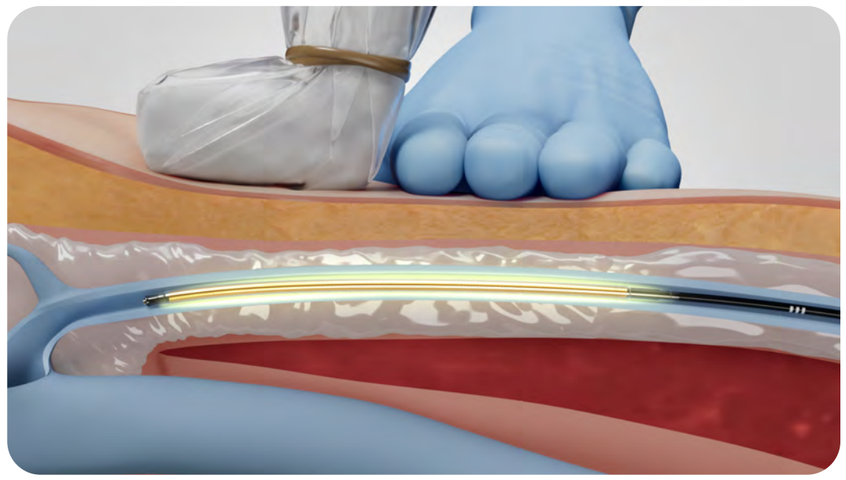
Caution: Do not treat with heating element in deep venous system.

Apply compression

- Create a near-bloodless field by applying even compression over the full heating element length to establish good contact between the vein wall and heating element.

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

- Use the ultrasound probe in longitudinal view plus a minimum of three fingertips distal to the probe's end (recommended).



Treat the vein

- 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 ClosureFast 7 cm (7F) and 8 cm (6F) catheters, under normal conditions, power will typically begin at 40 W and drop below 20 W within 10 seconds. For the ClosureFast 3 cm (7F) catheter, under normal conditions, power will typically begin at 18 W and drop below 10 W within 10 seconds.

Caution: Do not administer more than three energy cycles at any given vein segment.

- When a treatment cycle is complete, RF power automatically stops.
- When using ClosureFast catheter with 7 cm or 8 cm heating element, deliver a second energy cycle to the one segment closest to the SFJ. When using ClosureFast catheter with 3 cm heating element, a second energy cycle may be given at physician's discretion if sufficient treatment length is available.
- Quickly index the catheter to the next shaft mark position using 7.5 cm index markings if using 8 cm catheter, 6.5 cm markings if using 7 cm catheter, and 2.5 cm markings if using 3 cm catheter.
- Apply even compression over entire heating element and start the next treatment.
- Repeat withdrawal, compression, and treatment until desired vein length is treated.

Note: The presence of a triple shaft mark located 3 cm from the heating element may be used to determine minimum distance from heating element to puncture site.

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

- Remove external compression and withdraw the catheter quickly.
- Evaluate treated vein segments with ultrasound to determine treatment outcome.

Caution: There is no re-treatment algorithm with the ClosureFast catheter; do not re-advance the catheter through an acutely treated vein segment.

Conclude procedure

- Remove the introducer sheath and obtain hemostasis. Apply a compression bandage.
- Review post-operative instructions with the patient.

The importance of compression

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

After vein access is completed, the use of Trendelenburg position will assist in emptying the vein

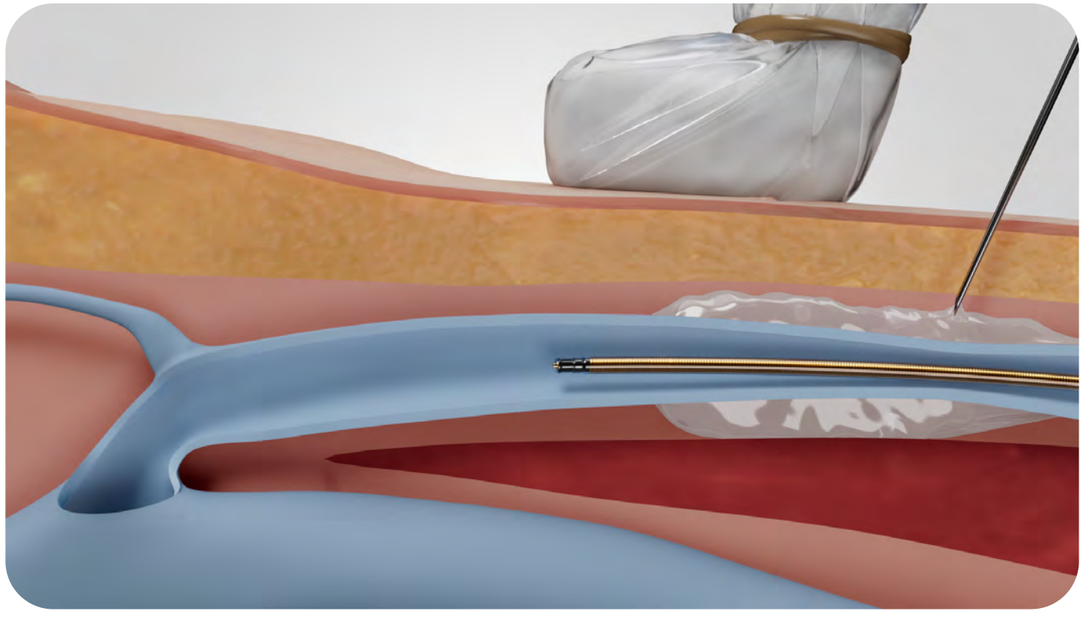
- Confirm final tip position.
- Administer tumescent infiltration above and beyond the SFJ region.

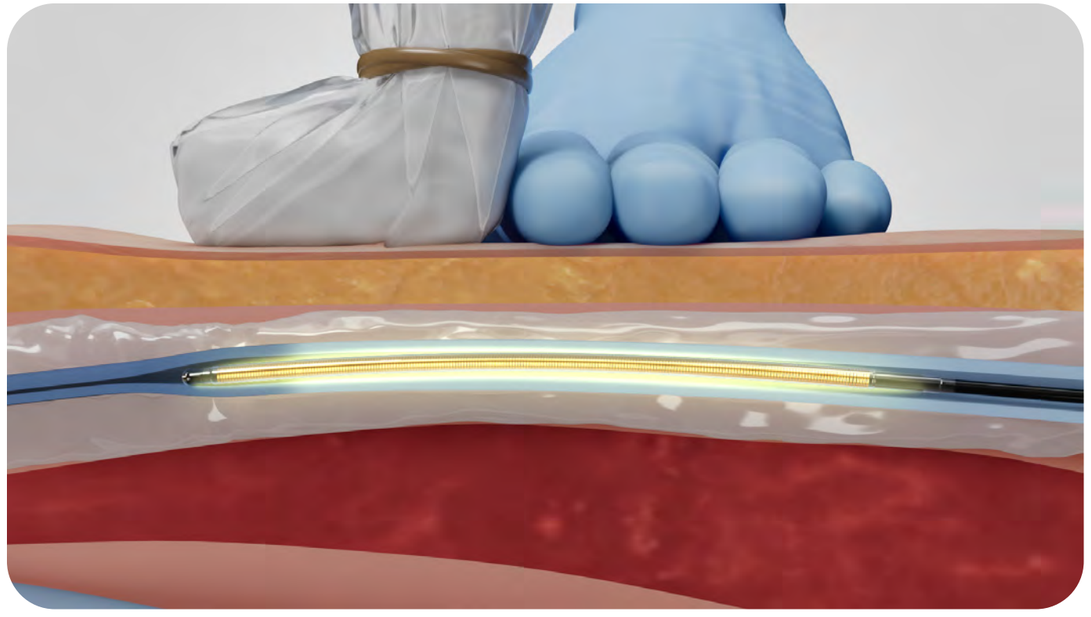
Deliver perivenous tumescent into the saphenous compartment

- Create a 360˚ halo of fluid around the treatment vein.
- A general guideline is to infiltrate 10 cc of tumescent fluid per 1 cm of vein to be treated.

Apply external compression evenly over the entire heating element during each treatment cycle

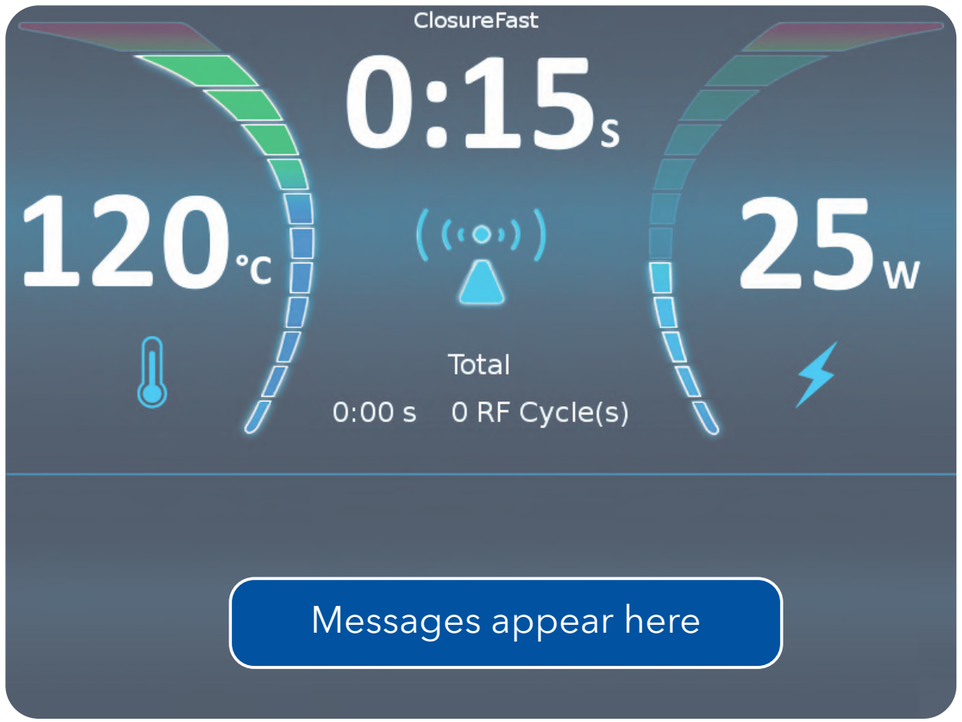
- The recommended external compression technique involves use of the ultrasound transducer aligned with the heating element plus additional compression with a minimum of three fingertips just distal to the probe when using the 8 cm (6F) catheter and two fingertips for other lengths.
- Insufficient external compression during treatment may result in under-treatment of a segment, advisory messages on the ClosureRFG generator screen, treatment interruptions, or damage to the catheter heating element.





ClosureRFG generator messages and alerts

For a complete list of messages and alerts, please see operation manual.



“Low temperature, high power – adjust compression”

Indicates there may be fluid surrounding and cooling the heating element. Compression should be improved.

“Target temperature not reached”

Indicates the set temperature was not reached. This may be caused by substantial fluid surrounding the heating element. The heating element location should be verified and compression should be improved.

“Treatment halted: Non-uniform temperature”

Indicates the heating element is not heating uniformly along its length. Withdraw catheter and check heating element for damage (if damage is found, replace catheter). Reassess alignment of heating element and external compression.

“Low temp. Verify device is in body – press OK to proceed”

Indicates device has not observed 30° C at least once prior to starting treatment.