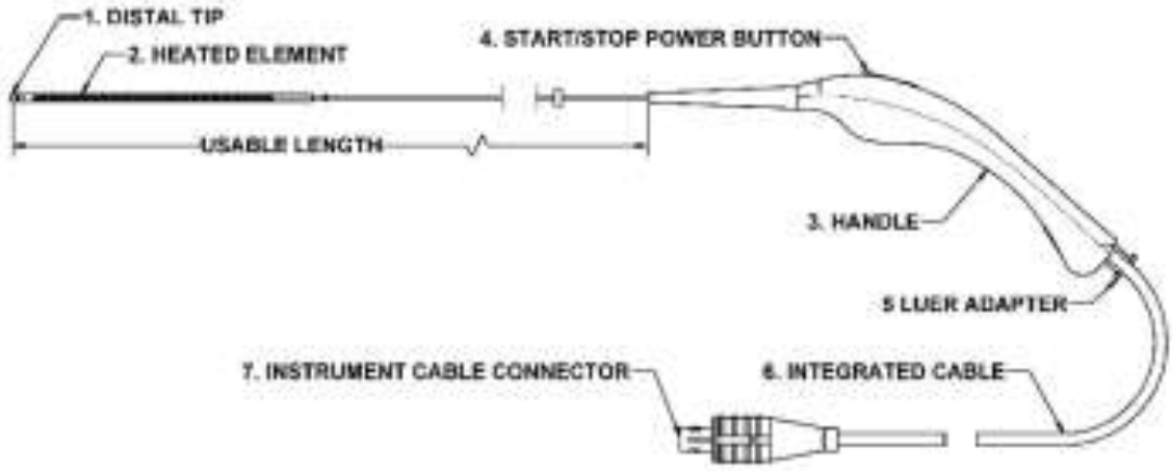
NES RF SMART®

NES Reprocessed Varicose Vein RF Catheter

R-CF7-3-60, R-CF7-7-60 & R-CF7-7-100

INSTRUCTIONS FOR USE



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Manufacturers:
Northeast Scientific, Inc.
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Waterbury, CT 06704 U.S.A.

Medtronic, Inc.
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NES RF SMART® - NES Reprocessed Varicose Vein Catheter

Instructions For Use

Lot Number


Do Not Reuse or Resterilize

Sterilization by Ethylene oxide


Caution Consult Enclosed Documents


Manufacturer


Use By

Federal (U.S.) law restricts this device to sale by or on the order of a physician

Note: Read all instructions carefully, including the Closure RFG™ RF generator Operator's Manual supplied by the Covidien™ company, prior to using the Reprocessed Varicose Vein Catheter and the system supplied by Covidien™. Observe all precautions, cautions and warnings stated in these instructions. Failure to do so may result in patient complications.


Single Use Only

Attention: Contents are sterile unless package is opened or damaged. For use with the Closure RFG™ RF generator only.


Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician.

Supplies and Equipment

- Closure RFG™ RF generator (software version 4.4.0 or higher)
- Tilt table
- Duplex ultrasound scanner
- Sterile ultrasound gel
- Sterile ultrasound transducer cover
- 19G ultra thin-walled needle for percutaneous access
- 7F introducer sheath (the Covidien™ company recommends 7 cm or 11 cm length)

Catheter Models:	OEM # CF7-7-60, CF7-100,CF7-3-60
Introducer sheath:	7F
Insertable length:	60cm, 100cm
Heating Element diameter:	2.25mm
Heating Element length:	7cm, 3cm

Indications For Use

The NES Reprocessed Varicose Vein RF Catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

Device Description

The Covidien™ closure system consists of two main components: The NES Reprocessed Varicose Vein RF Catheter and the Closure RFG™ RF generator. The NES Reprocessed Varicose Vein RF Catheter is provided sterile and is a single use disposal device. The function of the catheter is to provide thermal energy to the desired treatment site via radio frequency heating of the heating element and to relay that temperature back to the RF generator. The generator remains out of the sterile field and is provided non-sterile. The catheter is connected to the RF generator with the cable connector.

CONTRAINDICATION: PATIENTS WITH THROMBUS IN THE VEIN SEGMENT TO BE TREATED.

⚠ **CAUTION: THE VEINWALL MAY BE THICKER IN AN ANEURYSMAL SEGMENT. TO EFFECTIVELY OCCLUDE A VEIN WITH AN ANEURYSMAL SEGMENT, ADDITIONAL TUMESCENT INFILTRATION MAY BE NEEDED OVER THE ANEURYSMAL SEGMENT, AND THE TREATMENT OF THE VEIN SHOULD INCLUDE SEGMENTS PROXIMAL AND DISTAL TO THE ANEURYSMAL SEGMENT.**

⚠ **CAUTION: NO DATA EXISTS REGARDING THE USE OF THIS CATHETER IN PATIENTS WITH DOCUMENTED PERIPHEAL ARTERIAL DISEASE, THE SAME CARE SHOULD BE TAKEN IN THE TREATMENT OF PATIENTS WITH SIGNIFICANT PERIPHEAL ARTERIAL DISEASE AS WOULD BE TAKEN WITH A TRADITIONAL VEIN LIGATION AND STRIPPING PROCEDURE.**

Generator Set-up

Note: Refer to the Closure RFG™ RF generator Owner's Manual

1. Plug in RF generator.
2. Turn power "ON" using switch on rear of unit.
3. Confirm software version on screen: 4.4.0 or higher.
4. The temperature range for the catheter is between 95-120˚C. Reference the generator Owner's Manual for instructions on changing settings if desired.
5. Default settings will not be displayed until a catheter has been connected to the unit. Treatment settings may be adjusted according to physician preference.

DIRECTIONS FOR USE

USE ASEPTIC TECHNIQUE

CATHETER INSPECTION AND PREPERATION

1. Inspect the catheter and package before opening. The contents of the package are sterile unless the package is opened or damaged. If the package is damaged or if it was opened and the catheter not used, do not use the catheter. Return the catheter and packaging to Northeast Scientific, Inc. for resteriliztion by ethylene oxide (EtO) gas.
2. Do not attempt to resterilize. Northeast Scientific, Inc. will not accept catheters for reprocessing that have been reprocessed or sterilized by other facilities.
3. Remove the catheter from the package and place it in a sterile work area using aseptic technique.
4. Inspect the catheter for overall condition and physical integrity. **Do not use** the catheter if any damage is noted. If such problems exist, return the catheter and packaging to Northeast Scientific, Inc.
5. Keep cable connector out of sterile field and connect to RF generator.

⚠ **CAUTION: KEEP CABLE CONNECTORS CLEAN AND DRY AND AVOID CONTACT WITH ANY FLUIDS.**

6. Using sterile normal saline solution, flush and fill catheter lumen, cap lumen at handle and wipe outer surface of catheter shaft.

7. If using a guidewire, refer to the manufacturer's instructions for use. Following the removal of wire, reflush catheter lumen with sterile normal saline and cap lumen at handle.

⚠ **CAUTION: USE OF FLUSH THROUGH CATHETER WHILE HEATING ELEMENT IS ACTIVE WILL HEAT FLUID EXITING CATHETER TIP, AVOID FLUID DELIVERY THROUGH CATHETER WHEN TIP IS NEAR AREA THAT SHOULD NOT BE THERMALLY COAGULATED.**

PATIENT PREPERATION

1. Flush disposable accessories with sterile physiologic saline.
2. If local anesthesia is employed, administer at vein access site. Mild sedation may be administered.
3. Position patient for vein access. Lowering of patient's legs below level of heart will increase vein diameter which may make vein access easier.
4. Access the vein to be treated with a percutaneous stick using 19 gauge ultra thin-walled needle or by a small incision.
5. Prepare and insert introducer sheath per manufacturer's instructions for use.

TUMESCENT INFILTRATION AND CATHETER TIP POSITION

1. Use tumescent infiltration of dilute local anesthetic or saline into the perivascular space to create a fluid layer around the vessel to be treated. To ensure contact between catheter heating element and the vein wall, a volume of 10cc per cm of vein wall to be treated is suggested. Infiltrate up to 5cm distal to the Saphenofemoral Junction.
NOTE: When the vein to be treated is located near the skin surface, a subcutaneous distance of greater than or equal to 1cm between the anterior vein wall and skin should be created by tumescent infiltration of saline or dilute anesthetic solution.
2. Verify catheter tip location using ultrasound. When treating the Greater Saphenous Vein the catheter tip should be placed 2.0cm inferior to the Saphenofemoral Junction.
3. Infiltrate tumescent fluid over and beyond the Saphenofemoral Junction using ultrasound as guide.

TREATMENT

1. Place patient's legs above level of heart to facilitate vein collapse, apposition and exsanguinations.
2. Maintain catheter tip position and partially withdraw the introducer sheath until the sheath hub is aligned with first visible shaft marker. If desired, secure sheath to skin.

⚠ **WARNING: DO NOT TREAT WITH HEATING ELEMENT IN THE DEEP VENOUS SYSTEM**

3. Create near bloodless field by applying external compression along the full length of the heating element using the ultrasound transducer longitudinally aligned with the heating element, plus two fingertips of compression distal to the transducer.

⚠ **CAUTION; FAILURE TO COMPRESS THE VEIN OVER THE FULL LENGTH OF THE HEATING ELEMENT MAY RESULT IN INCONSISTENT EFFECTIVENESS AND/OR POSSIBLE CATHETER DAMAGE.**

4. Start the RF energy delivery by pressing the "RF POWER" button on the generator. This will cause the RF power button to start blinking. If the button does not light or start blinking, observe any displayed messages and respond. Refer to RF generator Owner's Manual.
5. Begin RF energy delivery by pressing the button on the catheter handle or by pressing the "Start RF" button below the screen on the RF generator. During treatment, energy delivery can be turned off by pressing the button on the catheter handle or by pressing the "Stop RF" button or the "RF Power" button.

Note: Power will typically begin at 40W and drop below 20W within 10 seconds if compression is located correctly and the vein segment has been properly exsanguinated.
Note: If set temperature is not reached in 5 seconds after pressing of the button or the power level is maintained above 20 watts, there may be flow within the vein that is cooling the treatment segment. Terminate RF energy delivery, verify compression and exsanguination methods and proper tip position, correct as necessary and re-initiate treatment to segment.
Note: Continuous temperature readings below the set temperature may result in treatment. If this occurs, stop treatment and reconfirm vessel apposition to the catheter heating element and absence of blood flow in the vessel segment to be treated. Apply more firm external compression if needed and retreat segment.

⚠ **CAUTION: IF TREATMENT IS HALTED DUE TO NON-UNIFORM TEMPERATURE, REMOVE CATHETER AND INSPECT THE HEATING ELEMENT FOR DAMAGE. IF DAMAGE IS FOUND, REPLACE CATHETER.**
CAUTION: FAILURE TO RESPOND TO ALERTS CAN RESULT IN SEVERE DAMAGE TO THE CATHETER.

6. RF Energy will terminate automatically after treatment time interval. Deliver a second energy cycle to the segment closest to the Saphenofemoral Junction.
7. RF Energy delivery may be repeated in a given vein segment at the physician's option.

⚠ **CAUTION: DO NOT ADMINISTER MORE THAN THREE ENERGY DELIVERY CYCLES AT ANY GIVEN VEIN SEGMENT**

8. Quickly withdraw the catheter until the next visible shaft marker is aligned with the hub of the sheath.
NOTE: Some friction between the vein wall and catheter after heating cycle is normal and may be noticed while withdrawing the catheter.
9. Treat next vein segment according to steps 3 through 8 above, repeating compression, treatment and indexing sequence until all segments are treated. Diagonal lines and printed numbers correlating to the introducer sheath length on the outside of the catheter shaft indicate the last full treatment segment when they are fully visible.
NOTE: The presence of a triple shaft mark located 3cm from the heating element may be used to determine the distance from the heating element to the puncture site.

⚠ **CAUTION: TREATMENT WITH THE HEATING ELEMENT INSIDE THE SHEATH OR OUTSIDE THE BODY MAY RESULT IN SKIN BURN OR CATHETER DAMAGE.**

10. Remove catheter and introducer sheath from vein and evaluate treated segment with ultrasound to determine treatment outcome.

⚠ **CAUTION: THERE IS NO RE-TREATMENT ALOGORITHM WITH THE REPROCESSED VARICOSE VEIN RF CATHETER; DO NOT RE-ADVANCE CATHETER THROUGH AN ACUTELY TREATED VEIN SEGMENT.**

11. Obtain hemostasis at the access site.
12. Apply a multilayer compression wrap from foot to groin.

FOLLOW UP CARE

1. Instruct patient to ambulate frequently and refrain from strenuous activities or heavy lifting for several days.
2. Post-operative compression for at least 1 week is recommended.
3. Follow up examination within 72 hours should include an assessment to ensure that there is no thrombus extension into the deep veins.

⚠ **POTENTIAL COMPLICATIONS: THE POTENTIAL COMPLICATIONS INCLUDE BUT ARE NOT LIMITED TO, THE FOLLOWING: VESSEL PERFORATION, THROMBOSIS, PULMONARY EMBOLISM, PHLEBITIS, HEMATOMA, INFECTION, ADJAVENT NERVE INJURY, SKIN BURN.**

⚠ **WARNING: TREATMENT OF A VEIN LOCATED NEAR THE SKIN SURFACE MAY RESULT IN A SKIN BURN IF THE SKIN IS NOT PROTECTED WITH FLUID INFILTRATION.**

WARNING: NERVE INJURY MAY OCCUR FROM THERMAL DAMAGE TO ADJACENT SENSORY NERVES. RISK OF NERVE INJURY MAY BE HIGHER WITH TREATMENT OR BELOW THE CALF, OR WITHOUT PERIVENOUS FLUID INFILTRATION.

WARNING: FOR SINGLE USE ONLY. DO NOT REUSE, REPROCESS OR RESTERILIZE.

WARNING: DO NOT TREAT WITH THE HEATING ELEMNT IN THE DEEP VENOUS SYSTEM.

CAUTION: DO NOT ADVANCE THE CATHETER AND/OR THE GUIDEWIRE AGAINST RESISTANCE, OR VEIN PERFORATION MAY OCCUR.

PRECAUTIONS

- Store in dry, cool place.
- Do not use catheter if package is opened or damaged, as sterility is not guaranteed.
- Do not bend catheter into a tight radius. Kinking of the shaft may damage the catheter.
- To prevent damage to the guidewire, ensure that the guidewire does not protrude from the catheter tip when inserting catheter into vein.
- Do not advance catheter and/or guidewire against resistance.
- Do not deliver RF energy with the heating element (tip) of the catheter within the introducer sheath or outside the body.
- Use the catheter only with the Closure RFG™ RF generator.
- Treatment of a vein located close to the skin surface may result in a skin burn if the skin is not protected with fluid infiltration.
- Nerve injury may occur from thermal damage to adjacent nerves. Risk of nerve injury may be higher with treatment at or below the calf or without perivenous fluid infiltration.

TECHNICAL DATA

ELECTRICAL RATINGS:

Recurring Peak Voltage: 99 V

RMS Voltage: 70 V

Frequency: 460 kHz

Crest Factor: 1.4 (sine wave)

OPERATING ENVIRONMENTAL RANGES:

Temperature: 10˚ C TO 40˚ C

Humidity: Non-condensing humidity conditions

TRANSPORT AND STORAGE ENVIRONMENTAL RANGES:

Temperature: -15˚ C TO 40˚ C

Humidity: 10 to 85% RH

DISPOSAL: Used devices shall be disposed of as medical waste in accordance with all applicable, local, state and federal laws and regulations.