Manufacturers:
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Covidien™
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NES Reprocessed RF Stylet (RFS)

Instructions For Use

Batch code


Do not re-use

Sterilized using 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: Thoroughly read all instructions, including the ClosureRFG™ RF generator Operator's Manual, prior to using the NES Reprocessed RF Stylet (RFS). Observe all warnings, precautions and cautions noted throughout 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.

Recommended Supplies and Equipment

- Tilt Table
- Duplex ultrasound unit
- Sterile ultrasound transducer cover
- Sterile ultrasound gel
- 18G thin-wall or 19G ultra-thin wall needle (for use with Over-The-Wire access method)
- 0.035" (0.89 mm) x 45cm guidewire [GW] (optional for OTW access)
- 12G I.V. catheter (optional for I.V. catheter access)

Device Model #	RFS2-6-12
Shaft Type	Rigid
Working Length	12cm
Maximum Electrode Diameter	6F (2.0mm)
Minimum IV Catheter Gauge	12G

Device Description

The NES Reprocessed RF Stylet (RFS) is used with the ClosureRFG Generator. The RFS is provided sterile, and is a single-use, disposable device. The device's function is to deliver bipolar RF energy to the desired treatment site and relay temperature and other feedback to the RF Generator. The RF Generator remains out of the sterile field during use, and is provided non-sterile.

Indications

The NES Reprocessed RF Stylet (RFS) is intended for use in vessel and tissue coagulation including:

- Treatment of incompetent (i.e., refluxing) perforator and tributary veins.

Contraindications

Patients with thrombus in the vessel segment to be treated.

PRECAUTION: **For patients with a pacemaker, internal defibrillator or other active implanted device, consult the cardiologist and the manufacturer of the active implanted device. Continuous patient monitoring during the procedure is recommended. Evaluate the patient and the implanted active device post-procedure. Keep all power cords and the instrument cable away from the location of the pacemaker or leads, defibrillator or the implanted active device.**

CAUTION: **No data exists regarding the use of this device in patients with documented peripheral arterial disease. Care should be taken in using this device for occlusive venous surgery in patients with significant peripheral arterial disease.**

Potential Complications

The potential complications include, but are not limited to, the following: arteriovenous fistula, thrombosis, pulmonary embolism, phlebitis, hematoma, infection, nerve damage, skin burns.

WARNING: **TREATMENT OF A VESSEL LOCATED NEAR THE SKIN SURFACE MAY RESULT IN A SKIN BURN.**

WARNING: **NERVE INJURY MAY OCCUR FROM THERMAL DAMAGE TO ADJACENT NERVES. RISK OF NERVE INJURY IS HIGHER WITH TREATMENT AT OR BELOW THE KNEE.**

Generator Set-up and Operation

1) Plug in RF Generator.
2) Turn power "ON" using toggle switch on rear panel.

DEVICE INSPECTION AND PREPARATION

1) Inspect outer box for signs of visible damage.
2) Remove sterile pouch from box and inspect for damage (i.e., tears, punctures, etc.). **IF POUCH IS DAMAGED OR OPENED, DO NOT USE DEVICE.**
3) Peel pouch open from the end closest to the handle (chevron).
4) Using sterile technique, remove device and sharp from pouch and card.
5) Inspect the device and sharp for damage. **IF THE DEVICE OR SHARP ARE DAMAGED, DO NOT USE.**
6) Carefully insert the sharp into the Luer end of the device if needed. Lock the sharp into place by twisting the Luer cap of the sharp fully onto the Luer port of the device.
7) Pass the end of the attached cable out of the sterile field for connection to the RF Generator.
8) Flush device lumen and disposable accessories with sterile, physiologic saline (0.9% sodium chloride) or heparinized saline. Wipe outer surface of device with saline or heparinized saline.
9) Connect the device cable to the RF Generator. Default settings will not be displayed once a device is connected to the RG Generator.
10) Default settings for the RF Generator are 6 Watts and 85 ºC. Default settings may be adjusted according to physician preference. Device set temperature can be adjusted from 45 - 95 ºC. Reference the RF Generator Operator's Manual for instructions on changing the settings.

System Check

1) Immerse the device electrodes at the tip of the device in a bowl of sterile, physiologic saline or heparinized saline.
2) The ClosureRFG RF generator should display an impedance value of approximately 80 – 130 Ω and a temperature of approximately 20 ºC (room temperature).

Note: These stated values may vary due to the actual saline temperature.

PATIENT PREPARATION AND TREATMENT

1) Position the patient for vessel access.
2) Visualization of the target vessel and the device is required throughout the procedure and can be accomplished using ultrasound or alternative imaging technique.
3) Administer anesthesia in accordance with standard technique.
4) If required, local anesthesia can be administered subcutaneously into the tissue in proximity with the vessel to be treated using ultrasound guidance or other visualization technique.

Note: Vessel spasm may hinder the ability to access the target vessel and to perform the procedure. Therefore, factors that may induce vessel spasm such as certain drugs, a cold environment, or patient anxiety should be avoided.

Note: Too much fluid infusion in the treatment region may obscure ultrasound visualization.

5) Gain target vessel access using a technique appropriate for the particular anatomy. Recommended methods include:
   a) Direct percutaneous puncture of the vessel with the RFS (with sharp installed), or

b) Access the vessel with a 12G IV catheter, remove the needle from the catheter and advance the RFS (with sharp removed) through the catheter sheath, or

c) Access the vessel with an 18G TW or 19G UTW needle, exchange the needle with 0.035 in. guidewire, advance the stylet (with sharp removed) over the wire.

CAUTION: IF TREATING ENDOVASCULARY, DO NOT ADVANCE THE STYLET OR GUIDEWIRE AGAINST RESISTANCE.

CAUTION: IF TREATING ENDOVASCULARLY, DO NOT ADVANCE THE STYLET OR GUIDEWIRE WITHOUT ULTRASOUND OR OTHER VISUALIZATION.

CAUTION: DO NOT APPLY RF ENERGY IF THE STYLET TIP IS IN THE DEEP VENOUS SYSTEM, SUCH AS THE POPLITEAL, FEMORAL, ANTERIOR TIBIAL, POSTERIOR TIBIAL, PERONEAL OR ILIAC VEINS.

6) Prior to treatment, create a near-bloodless field for the RFS electrodes by occluding flow in the vessel to be treated. This can be accomplished with one or both of the following steps:
   - Position the legs of the patient above the heart to facilitate the exsanguination and vein collapse.
   - Apply external compression over the treatment area.

7) To help verify that electrodes are within the vessel to be treated, check impedance on the Closure RFG RF generator. Values greater than 400Ω usually suggest that the electrodes are extravascular or marginally endovascular. Test temperature values of 33 to 39 ºC, indicating body temperature, are acceptable.

Note: If the test impedance is less than 200Ω, verify that the electrodes are not within the deep venous system.

8) Remove the sharp prior to applying RF energy. Start the RF energy delivery by pressing the RF "ON/OFF" or "RF Power" button. Once operating temperature is reached, endovascular impedance levels are expected to be less than 350Ω. For a focal treatment, treat for approximately two to four minutes and then terminate RF energy. If treating a longer segment, maintain the target temperature while withdrawing the device (typically 1cm/min) after initial focal treatment is completed. Device shaft is marked with lines spaced 1 centimeter apart. Terminate RF energy when the desired length of vessel has been treated.

Note: If endovascular position is confirmed and the display indicates a high impedance condition during treatment, inject 1-2cc's of saline through the device flush lumen and restart treatment. If condition persists, remove device, clean any coagulum from electrodes using a saline wetted gauze or swab, reposition the device in contact with the vessel wall and restart treatment.

Note: If the set temperature is not reached within 10 to 15 seconds after RF energy delivery, there may be a flow within the vessel that is cooling the treatment segment or the electrodes may be in the deep venous system. Terminate RF energy delivery, verify effectiveness of flow occlusion and proper tip position, correct as necessary, and re-initiate treatment of the segment.

9) Evaluate the treated vessel segment using duplex ultrasound to determine the existence of residual flow. Retreat if necessary to further shrink vessel or occlude flow.
10) If a longer treatment length is required, multiple treatments can be performed on adjacent vessel segment.

CAUTION: DO NOT ADMINISTER MORE THAN TWO 4-MINUTE TREATMENTS AT ANY GIVEN FOCAL POINT.

11) If additional vessels are to be treated, repeat steps 4 through 10.

FOLLOW-UP CARE

1) Patient should be instructed to ambulate frequently after the procedure, not sit or stand for long periods of time and to avoid strenuous activity or lifting for up to 5 days.
2) Follow-up examination within 72 hours should include an assessment to ensure that there is no thrombus extension into non-targeted vessels, including the deep venous system.
3) Post-operative compression is recommended.

PRECAUTIONS

- Store in a dry, cool place.
- Do not use device if package is opened or damaged, as sterility cannot be guaranteed.
- To avoid kinking, do not bend device shaft.
- Do not advance device and/or guidewire against endovascular resistance.
- Use the NES Reprocessed RF Stylet (RFS) only with a RF Generator.
- Treatment of a vessel located near the skin surface may result in a skin burn.
- Nerve injury may occur from thermal damage to adjacent nerves. Risk of nerve injury is higher with treatment at or below the knee, especially at the lateral aspect.

THIS PRODUCT CANNOT BE ADEQUATELY CLEANED AND/OR STERILIZED BY THE USER IN ORDER TO FACILITATE SAFE REUSE, AND IS THEREFORE INTENDED FOR SINGLE USE. ATTEPMTS TO CLEAN OR STERILIZE THESE DEVICES MAY RESULT IN A BIO-INCOMPATIBILITY, INFECTION OR PRODUCT FAILURE RISKS TO THE PATIENT.