English

ENROUTE® TRANSCAROTID 0.014" GUIDEWIRE

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

CAUTIONS
This device should be used only by physicians trained in angiography and percutaneous transluminal angioplasty (PTA).

- Read all instructions prior to use. Failure to do so may result in complications.
- Read the instructions supplied with any interventional product to be used in conjunction with the ENROUTE Transcarotid Guidewire to ensure compatibility.
- Do not use if the package or sterile barrier is damaged or open.
- Use the guidewire prior to the "Use by" date on the package label, preceded by the symbol
- The ENROUTE Transcarotid Guidewire is for Single Use Only
  - Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient.
  - Cleaning, disinfection and sterilization may compromise essential material and design characteristics leading to device failure.

Refer to the instructions supplied with any interventional devices to be used in conjunction with the guidewire for their intended uses, contraindications, and potential complications.

DESCRIPTION
The ENROUTE Transcarotid 0.014" Guidewire is a hydrophilic coated stainless steel steerable guidewire. The shapeable distal tip has a radiopaque coil.
Refer to the product label for product specifications (e.g. wire length, diameter and length of tip radiopacity).

HOW SUPPLIED
Sterilized using ethylene oxide gas.

HOW SUPPLIED
One guidewire

STORAGE
Store in a cool, dark, dry place.

INDICATIONS FOR USE
The ENROUTE Transcarotid 0.014" Guidewire is intended for use in the peripheral vasculature, inclusive of the carotid artery.

CONTRAINDICATIONS
The ENROUTE Transcarotid 0.014" Guidewire **is not** intended for use in:
- The cerebral or coronary vasculature.
- Patients judged not acceptable for percutaneous intervention.

PRECAUTIONS
Failure to follow the instructions may compromise guidewire performance and result in complications.

- Do not withdraw or manipulate the coated wire in a metal cannula or sharp -edged object.
- Avoid wiping the device with dry gauze as this may damage the device coating.
- Avoid using alcohol, antiseptic solutions or other solvents to pre-treat the guidewire as this may cause unpredictable changes in the coating which can affect the device safety and performance.
- Always inspect the guidewire carefully for bends, kinks or other damage prior to insertion or re-insertion. Do not use damaged guidewires.

DIRECTIONS FOR USE
1. Prepare the catheter and any interfacing devices according to the manufacturer's directions.
2. Using sterile aseptic technique, remove the guidewire dispenser with the guidewire from the package and place onto a sterile field.
3. Flush the guidewire dispenser through the injection port with saline to increase surface lubricity of the guidewire.
4. To remove the guidewire from the dispenser, gently push the proximal end of the guidewire starting from the window of the dispenser, so that the tip and a potion of the shaft is being exposed out of the luer lock flush port. Push until the PTFE coated section exits the luer flush port. Pull gently at the distal guidewire shaft, which is then protruding out of the luer lock until the entire wire is removed out of the dispenser. Do not grasp the distal tip of the guidewire while removing it from the dispenser.
5. The tip section of the guidewire may be manually shaped. Identify the flexing plane before shaping. Gently shape in the same plane as that for flexure.
6. Always introduce the guidewire into the guiding catheter or sheath hemostasis valve using a guidewire introducer.
7. Remove the guidewire introducer by sliding it over the proximal end of the guidewire. Secure the guidewire within the hemostatic valve being careful not to over-tighten the compression fitting.
8. Advance the guidewire into the target vessel and across the lesion using fluoroscopy to facilitate proper guidewire placement. A torque application device may be applied to the proximal end of the guidewire.
9. The catheter may be advanced over the guidewire according to manufacturer's instructions.
10. Holding the guidewire in position, advance the catheter over the guidewire and into the target lesion.
11. Complete the procedure and remove the guidewire and catheter according to the procedural protocol.
12. Dispose of the guidewire according to your facilities hazardous waste policy.

WARNING
A guidewire is a delicate instrument and must not be advanced, withdrawn, or torqued if resistance is met. Guidewire manipulations must always be observed under fluoroscopy.
If the guidewire is removed and is to be re-inserted, it must be gently wiped with saline soaked gauze or placed in a bowl of sterile saline and inspected for signs of damage (weakened or kinked segments) prior to re-introduction.
Do not re-introduce if guidewire is weakened or kinked.
If the wire is removed and not immediately reinserted, store the wire in a bowl of sterile saline in order to avoid particulate adhering to the activated hydrophilic coating of the guidewire.

Explanation of symbols used on the package labels:

	Do not reuse	REF	Catalog number
LOT	Lot number		Use by date
	Manufacturer		Date of Manufacture
	Do not re-sterilize		Do not use if package is damaged
	Keep dry		Consult instructions for use
	Keep away from direct sunlight	LATEX	Not made with natural rubber latex
STERILE EO	Sterilized with ethylene oxide gas		

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