Medtronic

Rist™ 079

Radial Access Guide Catheter

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Table Of Contents

Rist™ 079 Radial Access Guide Catheter

English en
Instructions for Use

CAUTION
Federal Law (USA) restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION
The Rist™ 079 Radial Access Guide Catheter is a single lumen, flexible, variable stiffness long sheath. It has a radiopaque marker band on the distal end and a Luer hub at the proximal end. The Rist™ 079 Radial Access Guide Catheter shaft has a 25 cm lubricious coating at the distal end to reduce friction during use.

Each package includes one Rist™ 079 Radial Access Guide Catheter and one Dilator. Dimensions of the Rist™ 079 Radial Access Guide Catheter are included on the individual device label.

DEVICE COMPATIBILITY
The inner lumen of the Rist™ 079 Radial Access Guide Catheter is compatible with 6F (0.078 inch OD or 1.99 mm OD) or smaller catheters.

INTENDED PURPOSE/INDICATIONS FOR USE
The Rist™ 079 Radial Access Guide Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

CONTRAINDICATIONS
The Rist™ 079 Radial Access Guide Catheter is contraindicated for use with liquid embolic agents, such as n-butyl cyanoacrylate, ethylene vinyl alcohol, and dimethyl sulfoxide (DMSO) based materials.

PREPARATIONS FOR USE
1. Select the appropriately sized device based on procedure type and patient anatomy.
2. Grasp the hub and gently remove the Rist™ 079 Radial Access Guide Catheter from its protective tubing.
3. Inspect the product for kinks or other damage. If any damage is observed, replace with a new device.
4. Flush the inner lumen with saline and connect a Hemostasis valve to the hub of the Rist™ 079 Radial Access Guide Catheter.

IF USING DILATOR:
- Flush and wet the dilator with saline.
- Insert the dilator completely into The Rist™ 079 Radial Access Guide Catheter.

DIRECTIONS FOR USE
1. Gain primary radial artery access using standard technique.
   IF NOT USING A SHORT SHEATH:
   - Advance the Rist™ 079 Radial Access Guide Catheter/dilator assembly over the guide wire (0.037 inches or 0.94 mm or smaller) and advance products into vasculature. Remove the dilator.

   IF USING A SHORT SHEATH:
   - Advance the Rist™ 079 Radial Access Guide Catheter over the guide wire into the appropriately sized short sheath. It is recommended to use a shaped catheter/dilator with the Rist™ 079 Radial Access Guide Catheter to aid insertion into a short sheath.

   Insert appropriately sized catheters as needed and advance products to the intended vascular site under fluoroscopic guidance.
2. When use of the Rist™ 079 Radial Access Guide Catheter is complete, remove the product using standard technique.
3. After use, the device may be a potential biohazard. Handle and dispose of product in accordance with facility protocol and applicable local, state, and federal laws and regulations.

POTENTIAL COMPLICATIONS
- Air Embolism
- Allergic Reaction
- Death
- Embolism
- False Aneurysm Formation
- Fistula
- Hemorrhage
- Hypersensitivity
- Hypotension
- Infection
- Inflammation
- Intracranial hemorrhage
- Ischemia
- Material Left in Patient
- Neurological deficit/ dysfunction
- Occlusion
- Organ failure
- Pain And Tenderness
- Radial Artery Occlusion
- Stenosis
- Stroke/ Cerebral infarction
- Therapeutic response decreased
- Thromboembolism
- Thrombus/ Thrombosis
- Vessel Collapse
- Vessel Dissection
- Vessel Perforation or Rupture
- Vessel Spasm/ Vasoconstriction
- Vision symptoms

WARNINGS
- Contents supplied sterile using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Medtronic Neurovascular representative.
- Do not use if labeling is incomplete or illegible.
- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- When the Guide Catheter is introduced to the vascular system, it should be manipulated while under high- quality fluoroscopic observation. Do not advance or retract the Guide Catheter if resistance is met during manipulation; determine the cause of the resistance before proceeding.
- Torquing or moving the device against resistance may result in damage to the vessel or device.
- This device is coated with a hydrophilic coating at the distal end of the device for a length of 25cm. Please refer to the preparation and directions sections for further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the warnings in this labeling may result in damage to the device coating, which may necessitate intervention or result in serious adverse events.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

PRECAUTIONS
1. The Rist™ 079 Radial Access Guide Catheter must only be used by physicians trained in intravascular intervention.
2. Use the device prior to the "Use By" date specified on the package.
3. Maintain a constant infusion of appropriate flush solution.
4. If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.
5. Examine the device to verify functionality and to ensure that its size and shape are suitable for the specific procedure for which it is to be used.
6. The Rist™ 079 Radial Access Guide Catheter should be used only by physicians trained in percutaneous procedures and/or interventional techniques.
7. Prior to beginning radial artery access, perform an assessment of the collateral circulation of the hand to ensure that radial access is appropriate for the patient.
8. Limit the exposure to X-ray radiation doses to patients and physicians by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors when possible.
9. Avoid wiping the device with dry gauze as this may damage the device coating.
10. Avoid excessive wiping of the coated device.
11. Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the device because this may cause unpredictable changes in the coating which could affect the device safety and performance.
12. Use an appropriate hemostasis valve during the procedure.

HANDLING AND STORAGE
This device should be stored in a dry place, away from sunlight.

Symbol Glossary

STERILE EO	Sterilized using ethylene oxide	REF	Catalogue number
	Do not re-use		Manufacturer
Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician		Use-by date
	Do not resterilize	LOT	Batch code
 www.medtronic.com/manuals	Consult instructions for use at this website		Date of manufacture
	Caution	CONTENTS	Contents of Package
	Do not use if package is damaged		Contains biological material of animal origin
	Non-pyrogenic		Radial Access Guide Catheter
	Keep away from sunlight		Dilator
	Keep dry		

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