Rist™

071 Radial Access Guide Catheter
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Rist™ 071 Radial Access Guide Catheter

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Instructions for Use

CAUTION
• Federal (USA) Law restricts this device to sale, distribution, and use by or on the order of a physician.
• This device should be used only by physicians with a thorough understanding of angiography and percutaneous interventional procedures.

DESCRIPTION
The Rist™ 071 Radial Access Guide Catheter is a single lumen, flexible, variable stiffness guide catheter. It has a radiopaque marker band on the distal end and a Luer hub at the proximal end. The Rist™ 071 Radial Access Guide Catheter shaft has a 25 cm lubricious coating at the distal end to reduce friction during use.

DEVICE COMPATIBILITY
The inner lumen of the Rist™ 071 Radial Access Guide Catheter is compatible with 5.5F (0.070 inch or 1.78 mm Outer Diameter) or smaller catheters. The Rist™ 071 Radial Access Guide Catheter is compatible with radial short sheaths with an Inner Diameter of 6F (0.087 inch or 2.21 mm) or greater.

INTENDED PURPOSE / INDICATIONS FOR USE
The Rist™ 071 Radial Access Guide Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

CONTRAINDICATIONS
The Rist™ 071 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.

PREPARATION FOR USE
1. Select the appropriately sized device based on procedure type and patient anatomy.
3. Inspect the product for kinks or other damage. If any damage is observed, replace with a new device.
4. Flush the inner lumen and outer surface with saline and connect a Hemostasis valve to the hub of the Rist™ 071 Radial Access Guide Catheter.

IF USING DILATOR:
• Flush and wet the dilator with saline.
• Insert the dilator completely into the Rist™ 071 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™ 071 Radial Access Guide Catheter/dilator assembly over the guide wire (0.038 inches or smaller) and advance products into vasculature. Remove the dilator.

IF USING A SHORT SHEATH:
• Advance the Rist™ 071 Radial Access Guide Catheter over the guide wire into the short sheath. It is recommended to use a shaped catheter/dilator with the Rist™ 071 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™ 071 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.

WARNINGS
• Visually inspect all sterile barrier systems, that are labeled as sterile, immediately prior to use. Do not use the device if breaches in the sterile barrier system integrity are evident.
• Carefully inspect the device packaging prior to use. Do not use if package appears open or damaged or if any of its components is missing. If damage is found, call your Medtronic representative.
• This device is intended 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.

POTENTIAL COMPLICATIONS
Potential complications of the device and the endovascular procedure include or are synonymous with, but may not be limited to:
• Access site complications, including sterile inflammation or granulomas
• Air Embolism
• Allergic Reaction, including anaphylaxis from contrast media and contrast media related risks (e.g., kidney damage)
• 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
• Pathological Hand Cold Intolerance
• 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
• Hand Dysfunction
• Complications of radiation exposure such as alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia
• Tissue necrosis

HOW SUPPLIED
This device is supplied STERILE using ethylene oxide. This device is non-pyrogenic.

STORAGE AND DISPOSAL
• This device should be stored in a dry place, away from sunlight.
• Dispose of device in accordance with hospital, administrative, and/or local government policy.
### Symbol Glossary

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="sterile_icon" alt="Sterilized" /></td>
<td>Sterilized using ethylene oxide</td>
<td>Keep away from sunlight</td>
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<tr>
<td><img src="sterile_barrier_icon" alt="Single sterile barrier system" /></td>
<td>Single sterile barrier system with protective packaging outside</td>
<td>Keep dry</td>
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<td>Do not re-use</td>
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<td>Do not resterilize</td>
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<td>Batch code</td>
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<td>Caution</td>
<td>Contents of Package</td>
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