MicroCross™ Microcatheter

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

INDICATIONS
The MicroCross™ Microcatheter is intended for use as a conduit for the exchange/support of guidewires in the peripheral and coronary vasculatures. The MicroCross™ Microcatheter is also intended to infuse and deliver saline and contrast agents.

DESCRIPTION
The MicroCross™ Microcatheter is a single-lumen, braided shaft, variable stiffness catheter with a radiopaque marker on the distal end and a luer hub on the proximal end. The distal portion of the catheter shaft has a hydrophilic coating to reduce friction during use. The radiopaque distal marker facilitates fluoroscopic visualization. Device dimensions and configuration are shown on the product label.

HOW SUPPLIED
The MicroCross™ Microcatheter is supplied STERILE (using ethylene oxide gas) and NONPYROGENIC. Provided that the integrity of the sterile pouch is not compromised in any way, it serves as an effective sterile barrier until the “Use By” (expiration) date printed on the label.

CONTRAINDICATIONS
The MicroCross™ Microcatheter is contraindicated for use in the neuro- and cerebral vasculatures.

WARNINGS
- If the pouch is opened or has been damaged compromising the sterile barrier, please discard the product.
- Do not reuse. Discard after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning.
- Never advance or torque catheter against resistance without careful assessment of cause using fluoroscopy. If cause cannot be determined, withdraw catheter. Movement against resistance may result in damage to vessel or catheter.
- Do not use device that has been damaged in any way. Damaged device may cause complications.
- Do not exceed maximum recommended infusion pressure of 300psi. Excess pressure may result in catheter rupture or tip severance.
- Never advance the catheter into a vessel without a leading guidewire. Vessel dissection or perforation may result.
- Do not use device during an MRI procedure.
- This device has not been evaluated specifically for use in pediatric patients.

PRECAUTIONS
- Use by “Use By” date.
- Upon removal from package, inspect device to ensure it is not damaged. Do not use device if damaged.
- Use device with fluoroscopic visualization and proper anti-coagulation solution.
- Read and follow instructions for use of all agents or contrast media used with the device.
- While in the vascular system, the device should always be filled with either flushing solution or contrast medium.

- The MicroCross™ Microcatheter is not intended to be used in conjunction with high pressure injectors.

POTENTIAL ADVERSE EFFECTS
As with all catheterization procedures, adverse effects may occur when using the MicroCross™ Microcatheter. Possible adverse effects include, but are not limited to, the following:
- Vessel dissection
- Vessel occlusion
- Vessel perforation
- Embolus
- Spasm
- Local and/or systemic infection
- Pneumothorax
- Myocardial infarction
- Serious arrhythmias
- Death

INSTRUCTIONS FOR USE
These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

Note: Follow instructions for use for all equipment to be used with the MicroCross™ Microcatheter. For example: guiding catheters, introducer sheaths, catheters and guidewires.

Inspection
1. Carefully inspect the sterile packaging for damage. If there is any damage, replace with a new device.
2. Reference Table 1 for recommended introducer sheaths, guide catheters, guide wires and product specifications.

<table>
<thead>
<tr>
<th>MicroCross™ Device</th>
<th>Working Length</th>
<th>Max Shaft Diameter</th>
<th>Max Guide Wire</th>
<th>Min Guide Catheter</th>
<th>Min Introductor Sheath</th>
</tr>
</thead>
<tbody>
<tr>
<td>MicroCross™ 14</td>
<td>155cm</td>
<td>0.038&quot; (0.97mm)</td>
<td>0.014&quot; (0.36mm)</td>
<td>5F</td>
<td>4F</td>
</tr>
<tr>
<td>MicroCross™ 144ES</td>
<td>155cm</td>
<td>0.038&quot; (0.97mm)</td>
<td>0.014&quot; (0.36mm)</td>
<td>5F</td>
<td>4F</td>
</tr>
<tr>
<td>MicroCross™ 18</td>
<td>155cm</td>
<td>0.038&quot; (0.97mm)</td>
<td>0.018&quot; (0.46mm)</td>
<td>5F</td>
<td>4F</td>
</tr>
</tbody>
</table>

Preparation For Use
3. Flush package loop with saline before removing MicroCross™ Microcatheter.
4. Carefully remove catheter from package loop and inspect thoroughly, assuring that it is not kinked or otherwise damaged. If there is any damage, replace with a new device.
5. Flush MicroCross™ Microcatheter and guide catheter or sheath with heparinized saline prior to use.

Device Use
6. Place an appropriately selected guide catheter or sheath according to standard methods.
7. Insert an appropriately selected guidewire into catheter and advance catheter into guide catheter or sheath.
8. To maintain hydrophilic coating lubricity, provide continuous flow of appropriate solution between catheter and guide catheter or sheath.
9. Advance catheter over guidewire into desired vasculature using fluoroscopic visualization.
10. Follow warnings and precautions during use.

STORAGE CONDITION
The MicroCross™ Microcatheter should be stored in a clean, dry location at room temperature.
STERILE
EO

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