**CenterCross Catheter**

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

**INDICATIONS**
The CenterCross Catheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary and peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices.

**DESCRIPTION**
The CenterCross Catheter (“CenterCross”) is an Over-The-Wire, single lumen catheter with a supportive nitinol scaffold to maintain distal position while deployed. The catheter is designed for use in the arterial vasculature to provide guidewire support during interventional procedures. It allows for the exchange of guidewires from 0.014”-0.035” in diameter, while maintaining access to the distal vasculature. Further, it allows microcatheters up to 3F to be delivered through the central lumen. The CenterCross has a hydrophilic coating on the distal portion of the catheter.

The CenterCross has two radiopaque marker bands on the distal portion of catheter (Figure 1), which correspond to inner and outer shafts. Under fluoroscopy, the radiopaque marker bands identify the location of distal tip of the catheter as well as indicate the deployment or retraction of the scaffold (Figure 2).

**CONTRAINDICATIONS**
The CenterCross is contraindicated for:
- Vessels less than 2.5mm in diameter
- Carotid vessels
- Vessels in the neurovasculature
- Venous system

**WARNINGS**
- Never advance the CenterCross into a vessel without a leading guidewire or without confirming location using fluoroscopic guidance. Vessel dissection or perforation may result.
- If pressure in a vessel dampens after inserting the CenterCross catheter, withdraw the CenterCross immediately.
- Never advance or retract the CenterCross with the scaffold deployed or against any other resistance until the cause of the resistance is determined by fluoroscopy. Movement of the catheter or guidewire against resistance may result in separation of the catheter or guidewire tip, damage to the catheter and/or to the vessel wall.
- Never insert, withdraw or rotate the CenterCross with the scaffold deployed.
- 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.
- For single insertion only. Upon withdrawal of the device, do not reintroduce the same device into the vasculature.

**PRECAUTIONS**
The CenterCross should be used by physicians with adequate training in the use of the device.
- Device is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization of the device creates a potential risk of patient or user infections. Contamination of the device may lead to illness or serious patient injury.
- The device must be used prior to the expiration date.
- Inspect the catheter prior use for any bends or kinks. Do not use a damaged catheter because vessel damage and/or inability to advance or withdraw the catheter may occur.
- All catheter lumens must be flushed with sterile, appropriately priming solution, such as heparinized saline solution. Flush 5cc of heparinized saline solution every 10 minutes through the thumb lever/annular prime port.

**HOW SUPPLIED**
The CenterCross is supplied STERILE (using ethylene oxide gas) and “Use By” (expiration) date printed on the label.

**POTENTIAL ADVERSE EFFECTS**
As with all catheterization procedures, adverse effects may occur when using the CenterCross. Possible adverse effects include, but are not limited to, the following:
- Intimal disruption
- Pseudoaneurysm
- Arterial spasm
- Sepsis
- Arterial thrombosis
- Distal embolization
- Local or systemic infection
- Myocardial infarction
- Neurological deficit
- Angina
- Stroke
- Ventricular failure
- Allergic reaction to contrast medium
- Death
- Puncture site hemorrhage or hematoma
- Arterial dissection, perforation or rupture
- Pain and tenderness at insertion site

**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 CenterCross. For example: guiding catheters, introducer sheaths, microcatheters and guidewires.

**Table 1. CenterCross Dimensions and Recommended Accessories**

<table>
<thead>
<tr>
<th>Working Length</th>
<th>Max Shaft Diameter</th>
<th>Max Guide Wire</th>
<th>Max Microcatheter Diameter</th>
<th>Min Guide Catheter</th>
<th>Min Introducer Sheath</th>
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<tr>
<td>125 or 130 cm</td>
<td>0.073” (1.9mm)</td>
<td>0.035” (0.90mm)</td>
<td>3F (1.0mm)</td>
<td>7F</td>
<td>6F</td>
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Preparation For Use

3. Carefully inspect the scaffold at the distal portion to ensure it is intact without any damage.

4. Through each prime port, purge out of the lumens using 5cc of sterile, clinically appropriate priming solution, such as heparinized saline:
   - The annular space between the inner and outer shafts
   - The center shaft

5. Slowly push the thumb lever on the handle forward until the scaffold is covered by the outer shaft of the catheter.

6. Check the catheter shaft for functionality of the hydrophilic coating. When wetted with sterile saline, the catheter shaft should feel slippery.

Note: To facilitate catheter handling, the proximal portion of shaft is not coated.

Insertion & Deployment

7. Through a previously inserted, appropriately sized guiding catheter or introducer sheath, introduce the CenterCross over a 280cm minimum guidewire using standard technique.

8. Load the guide wire into the inner shaft.

9. Under fluoroscopic guidance, advance the catheter to the desired location within the vasculature, while keeping the guidewire fixed. Use the distal radiopaque markers to assess the location of the catheter tip.

10. To deploy the scaffold, slowly pull back on the thumb lever/annular prime port towards the “OPEN” icon on the handle, while keeping the handle fixed.

11. The scaffold is deployed once the inner shaft marker band is 15 mm distal of the outer shaft marker band.

12. If warranted, an appropriately sized microcatheter may be loaded onto the guidewire and advanced through the inner shaft of the CenterCross.

Caution: Do not sharply bend or kink the catheter shaft during handling as this could damage the device and impair its function. Should the catheter become kinked or damaged during use, replace the damaged catheter with a new catheter and notify your Roxwood Medical representative immediately.

Resheathing & Extraction

13. To resheath the scaffold, push forward on the thumb lever/annular prime port away from the “OPEN” icon on the handle, while keeping the handle fixed.

14. Confirm the scaffold is fully sheathed with the outer shaft marker being distal of the inner shaft marker band.

15. Remove all, but the desired guidewire from the CenterCross.

16. Under fluoroscopic guidance, slowly withdraw the catheter while holding the guidewire fixed.

STORAGE CONDITION
The CenterCross should be stored in a clean, dry location at room temperature.