MultiCross Support Catheter

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

INDICATIONS
The MultiCross Support Catheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary or peripheral vasculature and for guidewire exchange.

DESCRIPTION
The MultiCross Support Catheter ("MultiCross") is an Over-The-Wire, tri-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 up to three guidewires, while maintaining access to the distal vasculature. The MultiCross has a hydrophilic coating on the distal portion of the catheter and is compatible with 0.014" diameter guidewires.

The MultiCross has radiopaque marker bands on the distal portion of each guidewire lumen (Figure 1), which correspond to three proximal ports, color-coded red, white and blue. Under fluoroscopy, the radiopaque marker bands identify each guidewire lumen. The outer shaft has a distal marker band to indicate the deployment or retraction of the scaffold (Figure 2).

The MultiCross is packaged with three non-vented luer caps to close the unused proximal lumens during the procedure.

Red Luer Lumen

White Luer Lumen

Blue Luer Lumen

Figure 1. Distal Tip of MultiCross

Figure 2(a)

Figure 2(b)

Figure 2. Fluoroscopic images of distal tip (a) Retracted (b) Deployed

The proximal end of the catheter includes a handle (Figure 3), which incorporates 4 main functions:
- Three (3) luers corresponding to each guidewire lumen
- Prime port to prime catheter
- Thumb lever to deploy and resheath the scaffold
- Strain relief

Strain Relief

3 Proximal Guidewire Lumens

Thumb Lever/Catheter Prime Port

Outer Shaft

Outer Shaft Marker Band

Figure 3. Proximal portion of MultiCross

Contents
1 MultiCross Support Catheter
3 Luer Caps

How Supplied
The MultiCross 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 MultiCross is contraindicated for:
- Vessels less than 2.5mm in diameter
- Carotid vessels
- Vessels in the neurovasculature
- Venous system

Precautions
The MultiCross 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 reuse, if the package seal is broken.
- The device must be used prior to the expiration date.
- If 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.

- Inspect the catheter prior to 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, heparinized saline prior to use. Flush 5cc of heparinized saline solution every 10 minutes through the catheter thumb lever/prime port.

- Precautions to prevent or reduce clotting should be taken when any catheter is used in the vascular system. Use of systemic heparinization and heparinized sterile solution should be considered.
- MultiCross has not been evaluated for thrombus formation from multiple deployments and resheathings.

- Exercise care while handling the catheter during a procedure to reduce the possibility of accidental breakage, bending or kinking.

- Excessive tightening of a hemostatic valve onto the catheter shaft may result in damage to the catheter shaft or difficulty translating the catheter.

- When the catheter is in the body, it should be manipulated only under fluoroscopy. Do not attempt to move the catheter without observing the resultant tip response.

- When the catheter is in the body, take care to not torque the catheter handle more than 360 degrees in any one direction, when advancing or retracting the device.

- In coronary applications, MultiCross should only be used where emergency coronary bypass surgery can be immediately performed.

- The MultiCross is not intended for dilation of vessels.

- The MultiCross is not intended to be used in conjunction with high pressure injectors.

- Do not inject diagnostic or therapeutic agents through the MultiCross luer ports.

Potential Adverse Effects
As with all catheterization procedures, adverse effects may occur when using the MultiCross. Possible adverse effects include, but are not limited to, the following:
- Intimal disruption
- Arterial spasm
- Arterial thrombosis
- Local or systemic infection
- Neurological deficit
- Stroke
- Allergic reaction to contrast medium
- Death
- Puncture site hemorrhage of 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 MultiCross. For example: guiding catheters, introducer sheaths, and guidewires.

Inspection
1. Prior to use, carefully inspect the catheter to verify that neither the sterile packaging nor the device has been damaged.
2. Reference Table 1 for recommended introducer sheaths, guide catheters, guide wires and product specifications.

Table 1. MultiCross Dimensions and Recommended Accessories

<table>
<thead>
<tr>
<th>Working Length</th>
<th>Scaffold OD</th>
<th>Total Scaffold Length</th>
<th>Max Shaft OD</th>
<th>Max Guide Wire</th>
<th>Min Guide Catheter</th>
<th>Min Introducer Sheath</th>
</tr>
</thead>
<tbody>
<tr>
<td>135 cm</td>
<td>4.7mm</td>
<td>16mm</td>
<td>0.073&quot;/1.9mm</td>
<td>0.014&quot;/0.36mm</td>
<td>7 F</td>
<td>6 F</td>
</tr>
</tbody>
</table>

Preparation For Use

3. Carefully inspect the scaffold at the distal portion to ensure it is intact without any damage.
4. Slowly push the thumb lever on the handle forward until the scaffold is covered by the outer shaft of the catheter.
5. Using a syringe filled with heparinized saline, gently purge the air out of the following using 5cc per luer or port:
   - The three guidewire lumens indicated by the red, white and blue luer at the proximal end
   - The catheter using the catheter prime port
6. Cap the lumens not to be used for initial use with the luer caps provided.
7. 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

8. Through a previously inserted, appropriately sized guiding catheter or introducer sheath, introduce the MultiCross over a 290cm minimum, 0.014" guidewire using standard technique.
9. Load the initial guide wire onto the lumen aligned with the most distal portion of the outer tip, as shown in Figure 4.

Figure 4. Loading of initial guidewire onto MultiCross

10. 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.
11. When the thumb lever is pushed fully forward in the handle, the scaffold is recessed about 1cm. To deploy the scaffold, slowly pull back on the catheter thumb lever/prime port, while keeping the handle fixed.
12. When the inner shaft marker band aligns with the marker band on the outer shaft, reposition the catheter if needed to ensure the scaffold deploys near the proximal cap of the lesion.

Warning: Never insert, withdraw, rotate, or reposition the MultiCross with the scaffold deployed.
13. While deploying the scaffold, attempt to ensure a landing zone of at least 20mm
14. The scaffold is deployed once the three lumen markers are distal of the outer shaft marker (Figure 2b).
15. As necessary, the remaining two guidewire lumens of the MultiCross may be used to introduce 0.014" guidewires to the target location.

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

16. To resheath the scaffold, push forward on the handle prime port, while keeping the handle fixed.
17. Confirm the scaffold is fully sheathed with the outer shaft marker being distal of the 3 lumen markers (Figure 2a).
18. Remove all, but the desired guidewire from the MultiCross.
19. Under fluoroscopic guidance, slowly withdraw the catheter, while holding the guidewire fixed.

STORAGE CONDITION

The MultiCross should be stored in a clean, dry location at room temperature.

GRAPHIC SYMBOLS GLOSSARY

- Catalog Number
- Batch Code
- Use By Date
- Contents
- Sterilized using ethylene oxide
- Caution: Consult Instructions For Use
- Single Use Only
- Do not resterilize
- CAUTION: Federal law restricts this device to sale by or on the order of a physician
- Do not use if packaging is damaged
- Manufacturer

MultiCross Support Catheter

Instructions For Use

Manufacturer:
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