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

INDICATIONS
The CenterCross ULTRA 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 ULTRA Catheter ("CenterCross ULTRA") is an over-the-wire 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" to 0.035" in diameter, while maintaining access to the distal vasculature. The device allows microcatheters to be delivered through the central lumen, which has a 3F inner diameter. Furthermore, the handle/inner shaft assembly is removable, leaving the outer shaft in place and allowing interventional devices to be delivered through the outer shaft, which has a 4.4F inner diameter. The CenterCross ULTRA has a hydrophilic coating on the distal portion of the catheter.

The distal portion of the CenterCross ULTRA inner and outer shafts are radiopaque (Figure 1). Under fluoroscopy, the radiopaque sections identify the location of the distal tip of the catheter as well as indicate the deployment or retraction of the scaffold (Figure 2).

Figure 1. Distal Tip of CenterCross ULTRA

The proximal end of the catheter includes a handle (Figure 3), which has a 4.4F inner diameter. The CenterCross ULTRA has a radiopaque (Figure 1) marker band & radiopaque section.

Figure 2(a) Figure 2(b)

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

The proximal end of the catheter includes a handle (Figure 3), which incorporates 6 main functions:

- Hemostasis valve to secure guidewire or microcatheter
- 2 prime ports to prime catheter
- Thumb lever to deploy and reshape the scaffold
- Button to release the handle/inner shaft assembly
- Strain relief
- Introducer

Figure 3. Proximal portion of CenterCross ULTRA

The proximal end of the catheter includes a handle (Figure 3), which has a 4.4F inner diameter. The CenterCross ULTRA includes a handle (Figure 3), which has a 4.4F inner diameter. The CenterCross ULTRA has a radiopaque marker band & radiopaque section.

Figure 4. Thumb Lever/Prime Port detached from Handle

Contents
1 CenterCross ULTRA Device

HOW SUPPLIED
The CenterCross ULTRA 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 CenterCross ULTRA is contraindicated for:

- Vessels less than 2.5mm in diameter
- Carotid vessels
- Vessels in the neurovasculature
- Venous system

Warnings
- Never advance the CenterCross ULTRA 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 ULTRA catheter, withdraw the CenterCross ULTRA immediately.
- Never advance or retract the CenterCross ULTRA 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 ULTRA with the scaffold deployed.
- For single use only. Do not reuse, reprocess or resterilize.
- Exercise care while handling the catheter during alignment of an intervention or guidewire against resistance may result in separation of the catheter or guidewire tip, damage to the catheter and/or to the vessel wall.

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POTENTIAL ADVERSE EFFECTS
As with all catheterization procedures, adverse effects may occur when using the CenterCross ULTRA. 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
- 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 ULTRA. For example: guiding catheters, introducer sheaths, microcatheters, catheters, 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, guidewires and product specifications.

<table>
<thead>
<tr>
<th>Working Length</th>
<th>Scaffold OD</th>
<th>Max Shaft OD</th>
<th>Max Guide-wire</th>
<th>Min ID</th>
<th>Min Guide Catheter</th>
<th>Min Introducer Sheath</th>
</tr>
</thead>
<tbody>
<tr>
<td>90, 125 cm</td>
<td>4.5mm</td>
<td>0.073” (1.9mm)</td>
<td>0.035” (0.90mm)</td>
<td>Inner Shaft: 3F</td>
<td>Outer Shaft: 4.4F</td>
<td>7F/6F</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. 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 lumen
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 ULTRA over a 280cm minimum guidewire using standard technique.
8. Load the guidewire 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 radiopaque distal sections of the catheter to assess the annular space between the inner and outer shafts.
10. To deploy the scaffold, slowly pull back on the thumb lever/prime port, while keeping the handle fixed.
11. The scaffold is deployed once the longer inner shaft radiopaque section is 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 ULTRA.

**Resheathing Scaffold**

13. To resheath the scaffold, push forward on the thumb lever/prime port, while keeping the handle fixed.
14. Confirm the scaffold is fully sheathed with the outer shaft marker band distal of the inner shaft marker band.

A) **To Remove Handle/Inner Shaft Assembly Only:**
15. Depress and hold down the release button. While keeping the outer shaft hub fixed, slowly retract and withdraw the handle/inner shaft assembly from the outer shaft. Once the thumb lever has disengaged from the handle, the Button can be released.
16. Once handle/inner shaft assembly has been retracted beyond the Outer Shaft hub, the Introducer may be pushed fully distal to open the valves and facilitate removal of the inner shaft assembly. To close valves and resume hemostasis, pull Introducer proximal until the hard stop.

  **Caution:** Do not reinsert handle/inner shaft assembly into the outer shaft hub once it has been detached (see Figure 4).
17. If warranted, an appropriately sized catheter may be loaded onto the guidewire and advanced through the outer shaft of the CenterCross ULTRA. To facilitate easier introduction of a catheter through the hemostatic valves, the Introducer can be pushed fully distal to open the valves. To close valves and resume hemostasis, pull Introducer proximal until the hard stop.
18. Upon completion of procedure, under fluoroscopic guidance, slowly withdraw the outer shaft while holding the guidewire fixed.

B) **To Remove entire Catheter:**

19. Under fluoroscopic guidance, slowly withdraw the CenterCross ULTRA while holding the guidewire fixed.

**STORAGE CONDITION**
The CenterCross ULTRA 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