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

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

**DESCRIPTION**
The CenterCross ULTRA LV Catheter (“CenterCross ULTRA LV”) 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”-0.035” in diameter, while maintaining access to the distal vasculature. The device allows microwiretahers 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 LV has a hydrophilic coating on the distal portion of the catheter.

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

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

**WARNINGS**
- Never advance the CenterCross ULTRA LV 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 LV catheter, withdraw the CenterCross ULTRA LV immediately.
- Never advance or retract the CenterCross ULTRA LV 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, rotate, or reposition the CenterCross ULTRA LV with the scaffold deployed.
- For single use only. Do not re-use, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization 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 re-sterilization 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. Treatment of the patient 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 ULTRA LV 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.
- The device must be used prior to the expiration date.
- For single patient use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization 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, clinically appropriate priming solution, such as heparinized saline prior to use. Flush 5cc of heparinized saline solution every 10 minutes through the 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.
- CenterCross ULTRA LV has not been evaluated for thrombus formation from multiple deployments and resterilizations.
- 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 more than 360 degrees in any one direction, when advancing or retracting the device.
- Upon detaching the handle/inner shaft assembly, do not reinsert it into the outer shaft hub.
- CenterCross ULTRA LV should be used where emergency bypass surgery can be immediately performed.
- The CenterCross ULTRA LV is not intended for dilation of vessels.
- The CenterCross ULTRA LV is not intended to be used in conjunction with high pressure injectors.
- CenterCross ULTRA LV has not been evaluated in patent vessel lumens greater than 8.0mm in diameter.
  - CenterCross ULTRA LV may be optimal for vessel sizes 2.5 – 6.5 mm

**POTENTIAL ADVERSE EFFECTS**
As with all catheterization procedures, adverse effects may occur when using the CenterCross ULTRA LV. 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 LV. For example: guiding catheters, introducer sheaths, microwires, catheters, and guidewires.
Preparation For Use
3. Carefully inspect the scaffold at the distal portion to ensure it is intact without any damage.
4. Through the prime port, purge each 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 LV 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 location of the catheter tip.
10. When the thumb lever is pushed fully forward in the handle, the scaffold is retracted about 1cm. To deploy the scaffold, slowly pull back on the thumb lever/prime port, while keeping the handle fixed.
11. When the inner shaft marker band aligns with the marker bands 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 CenterCross ULTRA LV with the scaffold deployed.
12. While deploying the scaffold, attempt to ensure a landing zone of at least 20mm.
13. The scaffold is deployed once the longer inner shaft radiopaque section is distal of the outer shaft marker band.
14. If warranted, an appropriately sized microcatheter may be loaded onto the guidewire and advanced through the inner shaft of the CenterCross ULTRA LV.
   • If difficulty is encountered while tracking the catheter in the peripheral vasculature (for example Anterior Tibial artery), use CenterCross ULTRA LV with a microcatheter.
   **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 Scaffold
15. To resheath the scaffold, push forward on the thumb lever/prime port, while keeping the handle fixed.
16. 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**
17. 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.
18. 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).
19. If warranted, an appropriately sized catheter may be loaded onto the guidewire and advanced through the outer shaft of the CenterCross ULTRA LV. 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.
20. Upon completion of procedure, under fluoroscopic guidance, slowly withdraw the outer shaft while holding the guidewire fixed.

B) **To Remove entire Catheter**
21. Under fluoroscopic guidance, slowly withdraw the CenterCross ULTRA LV while holding the guidewire fixed.

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

**GRAPHIC SYMBOLS GLOSSARY**

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**CenterCross ULTRA LV Catheter**

**Instructions For Use**

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