

VIPERCATH™ XC

PERIPHERAL EXCHANGE CATHETER

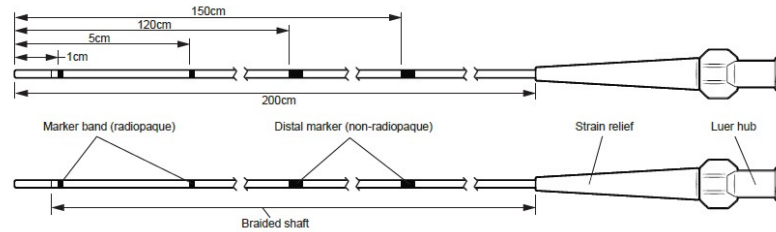
Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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1. Description

The Cardiovascular Systems, Inc. (CSI) VIPERCATH XC Peripheral Exchange Catheter (exchange catheter) is designed to support use of a guide wire during access of the peripheral vasculature. The exchange catheter allows for exchanges of guide wires, up to diameters of 0.035" during interventional and diagnostic peripheral arterial procedures. Both straight and angled models are available in order to accommodate a variety of vasculature and procedural needs (Figure 1).

Figure 1: Labeled diagram of the Exchange Catheter



2. Contents of package

The VIPERCATH XC Peripheral Exchange Catheter is supplied sterile and is for single-use only. Each package contains the following:

- 1 Model 035-XC-200-0 (straight) or Model 035-XC-200-1 (angled) exchange catheter

3. Indications

The VIPERCATH XC Peripheral Exchange Catheter is intended to guide and support a guide wire during access of the vasculature, allow for wire exchanges, and provide a conduit for the delivery of saline or diagnostic contrast agents.

4. Contraindications

Use of the VIPERCATH XC Peripheral Exchange Catheter is contraindicated in the following:

- The exchange catheter cannot be used in coronary or cerebral arteries
- The exchange catheter cannot be used in women who are pregnant.
- The exchange catheter cannot be used in patients with a contraindication to antiplatelet and/or anticoagulant therapy.

5. Restrictions

The exchange catheter should only be used by physicians who are experienced in peripheral vascular intervention and who are trained on the use of this exchange catheter. Contact a CSI representative for information on training.

6. Warnings

- Do **not** skip flushing the exchange catheter with saline step prior to use. Skipping this step could cause an air embolism in the patient as the air would not have been removed from the exchange catheter prior to use.
- Do **not** use the exchange catheter if the sterile package barrier is compromised or damaged. If the sterile package barrier is compromised or damaged, obtain a new exchange catheter and contact a CSI representative.
- Do **not** re-sterilize or reuse the exchange catheter. The exchange catheter is for **single-use** only. Reuse of the single-use exchange catheter creates a potential risk of patient or user infection.
- Do **not** advance or withdraw the exchange catheter against resistance. Determine the cause of the resistance using fluoroscopy as movement of the exchange catheter against resistance may result in vessel or catheter damage.
- Do **not** use excessive force while using the exchange catheter. Vessel perforation, patient injury, or exchange catheter dissection may occur.
- Do **not** use a maximum infusion pressure above 600 psi. The exchange catheter may rupture and vessel dissection may occur.
- Do **not** torque the device excessively (more than 3 rotations) during use. Exchange catheter damage may occur.
- Do **not** heat or bend the catheter tip. Exchange catheter damage may occur.
- Be careful when inserting/withdrawing the device through a stent or its struts. Exchange catheter damage may occur.
- Perform appropriate anticoagulant or antiplatelet therapy according to the patient's condition to avoid complications, such as thrombotic embolization.
- Before inserting/withdrawing the device, clean the surface of the guidewire with gauze moistened with saline solution. Advancing/withdrawing the product over a guidewire with residual blood on its surface or a guidewire which is not fully wet may result in damage to the exchange catheter.

7. Precautions

- Do not use the exchange catheter if there is damage to the packaging or if the exchange catheter has reached its use-by date.
- Inspect the exchange catheter prior to use.
- Do not use the exchange catheter if there is any sign of kinking or damage.
- Prior to use, be sure to flush the exchange catheter to ensure it is free from any debris entering the patient.
- Use care to not kink or crush the exchange catheter while removing the exchange catheter from the dispenser coil.
- Use care in handling the exchange catheter during a procedure in order to reduce the possibility of kinking, bending, or breaking of the exchange catheter.
- If using a hemostasis valve, ensure that the valve is sufficiently open so that there is no resistance when inserting the exchange catheter.
- If injecting contrast media through the catheter, contrast media should be injected at 37°C.
- Consider the use of systemic heparinization.

8. Storage and handling

- Store the exchange catheter at room temperature and in a clean environment.
- The exchange catheter is intended to be used in typical operating room/catheterization laboratory environments.
- Do not reuse or resterilize the exchange catheter as the exchange catheter is designed for single-use only.
- Do not use the exchange catheter if the sterile package barrier is compromised or damaged.
- Do not use the exchange catheter if there is damage to the exchange catheter package or if the exchange catheter has reached its use-by date.

9. Adverse events

Potential adverse events that may occur and/or require intervention include, but are not limited to:

- Access site complications, including bleeding and pain
- Allergic reaction to medication/media/device components
- Arrhythmia
- Catheter fracture with tip separation and distal embolization
- Death
- Distal embolization
- Hemorrhage or hematoma
- Hypotension/hypertension
- Infection/Sepsis
- Myocardial infarction
- Thrombosis
- Vessel injury, including rupture, dissection, and perforation
- Vessel occlusion
- Vessel spasm

10. Instructions for use

10.1. Preparing the exchange catheter

Note: Have the following items available prior to preparing the exchange catheter. These items are required for preparing the exchange catheter, but are not provided in the exchange catheter package:

- Catheter or sheath with an internal diameter large enough to accommodate the outer diameter of the exchange catheter.
 - A guide wire with an outer diameter small enough to accommodate the inner diameter of the exchange catheter.
 - Sterile syringe and sterile heparinized saline for flushing the exchange catheter.
1. Inspect the exchange catheter packaging and components for damage prior to use. If the packaging and components are damaged, obtain a new exchange catheter and contact a CSI representative.
 2. Using sterile techniques, open the exchange catheter pouch, remove the catheter dispenser coil, and transfer the catheter dispenser coil to the sterile field.
 3. Grasp the exchange catheter by the female luer and gently remove the exchange catheter from the catheter dispenser coil.
 4. Fill a sterile syringe with sterile heparinized saline, attach the syringe to the female luer hub on the exchange catheter, and thoroughly flush the exchange catheter prior to use. Remove the syringe once flushing is complete.

10.2. Using the exchange catheter

1. Slide the distal end of the exchange catheter over a previously inserted guide wire and within a previously inserted guide catheter, guide sheath, or introducer.
2. Using fluoroscopy, carefully advance the exchange catheter to the desired location within the patient's vasculature.
3. Exchanging guide wires:
 - a. Exchange one guide wire with another guide wire by first confirming that the catheter is in the desired location within the patient's vasculature.
 - b. Slowly remove the guide wire from the exchange catheter.
 - c. Insert the desired length guide wire into the female luer hub on the exchange catheter and slowly advance the guide wire until it exits the tip of the exchange catheter.
4. If injecting contrast media:
 - a. Carefully withdraw the guide wire.











- b. Inject the contrast media into the female luer hub on the exchange catheter or into an available hemostasis valve
- 5. Removing the exchange catheter:
 - a. Using fluoroscopy, confirm that the guide wire is sufficiently advanced distally into the patient's vasculature.
 - b. Grasp the exchange catheter by the female luer hub and gently withdraw the exchange catheter.
 - c. After use, dispose of all equipment in accordance with applicable requirements relating to hospital waste, and potentially bio-hazardous materials.


11. Disclaimer of warranty

Cardiovascular Systems, Inc. (CSI) disclaims all warranties whether expressed or implied, written or oral, including but not limited to any warranties of merchantability of fitness for a particular purpose. CSI does not warrant either for a good effect or against any ill effect following use. CSI shall not be liable for any direct, indirect, incidental or consequential loss, damage, or expense arising from or related to the use of this device.

CSI may, at its sole discretion, replace any device that is determined to have been out of specification at the time of shipment.

Explanation of symbols on the package labels

 Rx Only	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician		Use by
	Model number		Sterilized with Ethylene Oxide
	Caution: Consult IFU. www.csi360.com (USA)		Do not reuse
	Lot number		Do not re-sterilize
	Quantity per box (this example = 1 per box)		Manufacturer

 Manufacturer:
 Cardiovascular Systems, Inc.
 1225 Old Highway 8 NW
 St. Paul, MN 55112 USA
 +01-651-259-1600
 +1-877-274-0360 (USA)

