CONCIERGE CATALYST™

English

Specialty Catheter

INSTRUCTIONS FOR USE

Read Instructions Prior To Use

℞ ONLY: Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.Sterile (Ethylene Oxide). Non-pyrogenic. For one time use only. Do not autoclave.

Clinical Benefits
These Guiding Catheters are intended for use for intravascular introduction of interventional/diagnostic devices into coronary or peripheral vascular systems.

Contraindications
None known for guiding catheters.

Warnings
Discard guiding catheters after one procedure. Structural integrity and/or function may be impaired through reshaping, reuse, or resterilization. Use catheters prior to the expiration date on the package.

Precautions
- Store in a cool dark place.
- Do not use open or damaged packages.
- Do not resterilize the catheter.
- Do not autoclave. Exposure to temperatures above 54°C (130°F) may damage the catheter.
- Do not expose to solvents or ionizing radiation.
- Inspect the guiding catheter before use to verify that its size, shape, and condition are suitable for the specific procedure.
- Before use, flush all devices entering the blood vessel with sterile heparinized saline or a similar isotonic solution.
- If strong resistance is met during manipulation, discontinue the procedure and determine the cause of the resistance before proceeding. If the cause of the resistance cannot be determined, withdraw the catheter.
- Torquing the guiding catheter while kinked may cause damage which could result in possible separation along the catheter shaft. Should the guiding catheter shaft become kinked, withdraw the entire system (guiding catheter, guidewire, and catheter sheath introducer).
- Advancement, manipulation, and withdrawal of the guiding catheter should always be performed under fluoroscopic guidance.
- Extreme care must be taken to avoid damage to the vasculature through which the guiding catheter passes. The guiding catheter may occlude smaller vessels. Care must be taken to avoid complete blood flow blockage.
- Large internal lumen guiding catheters require less force on the syringe during injection.
- In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State.

Complications
Use of guiding catheters should be restricted to those specialists trained to perform procedures for which the product is indicated. Complications may occur at any time during or after the procedure and may include, but are not limited to, the following: hemorrhage, hematoma, allergic reaction, infection, embolism, blood vessel dissection or occlusion.

Recommended Procedure
1. Remove the guiding catheter from its packaging using sterile techniques.
2. Flush the guiding catheter lumen with a heparinized saline solution.
3. Appropriate anticoagulation and vasodilation therapy should be used.
4. Introduce the guiding catheter into the vasculature through the catheter sheath introducer, and/or over an indwelling guidewire using a percutaneous entry technique of choice.
5. Under fluoroscopic guidance, advance the guiding catheter over the guidewire or introducer until the desired position is attained.
6. Remove the guidewire prior to introduction of other intravascular devices or infusion of contrast agents.

For a copy of this device's current European Summary of Safety and Clinical Performance (SSCP), please go to www.merit.com/EU-SSCP.

Warning: After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal.

For electronic copy scan QR code or go to www.merit.com/ifu and enter IFU ID Number. For printed copy, call U.S.A or E.U Customer Service

REUSE PRECAUTION STATEMENT

For single patient 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.

SYMBOL	DESIGNATION
	Use By: YYYY-MM-DD
LOT	Lot Number
REF	Catalog Number
STERILE EO	Sterilized Using Ethylene Oxide
	Do Not Use if Package is Damaged
	Single Use
Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Do Not Re-sterilize
	Caution: Consult accompanying documents
	Date of Manufacture
	Non-pyrogenic
	For electronic copy scan QR code or go to www.merit.com/ifu and enter IFU ID Number. For printed copy, call U.S.A or E.U Customer Service.
MD	Medical Device.
Sterile Package.	Sterile Package.

MERIT MEDICAL®

www.merit.com

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