REFLOW coraForce™

REFLOW MEDICAL

REFLOW coraFlex™

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

Description
The coraForce and the coraFlex Catheters are single lumen catheters designed to access the coronary and peripheral vasculature. Each configuration has a polymer and metal support matrix and hydrophilic coating on the distal 60cm segment of the catheter for lubricity. The proximal luer allows for connection for flushing delivery of saline solutions or diagnostic contrast. The distal tip of the coraForce catheter is metallic while the distal tip of the coraFlex catheter is polymer. The Cora Catheters will also allow for exchange of guidewires and other interventional devices, and provide a conduit for delivery of saline solutions or diagnostic contrast.

Indications for Use
Cora Catheters are intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary and peripheral vasculature. They may be used to facilitate placement and exchange of guidewires and other interventional devices, and provide a conduit for delivery of saline solutions or diagnostic contrast.

Contraindications
The Cora Catheter is contraindicated for use in the cerebral vasculature.

How Supplied
The Cora Catheters are supplied sterile and are designated for single use only and are not permitted to be resterilized and/or reused.

Warranty and Limitation of Warranty
Manufacturer warrants that the Cora Catheters is free from defects in material and workmanship when used by the stated Use By date and when package is unopened and undamaged immediately before use. Manufacturer's liability under this warranty is limited to replacement or refund of the purchase price of any defective Cora Catheters. Damage to the Cora Catheters caused by misuse, alteration, improper storage or handling, or any other failure to follow these Instructions for Use will void this limited warranty. THIS LIMITED WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. No person or entity, including any authorized representative or reseller of Manufacturer, has the authority to extend or expand this limited warranty and any purported attempt to do so will not be enforceable against Manufacturer.

Warnings
- Single Use only. Do not reuse/resterilize. Reusing the device could result in compromised device performance, cross-infection and other safety related hazards.
- Do not use if device is open or packaging is damaged
- Never advance, withdraw or rotate an intravascular device against resistance until the cause is determined by fluoroscopy.
- Manipulation, advancement, and/or withdrawal past sharp or beveled edges may result in destruction and/or separation of the outer coating, which may lead to clinical adverse events, resulting in coating material remaining in the vasculature or device damage. This may result in adverse events requiring additional intervention.
- Avoid wiping the device with dry gauze as this may damage the device coating. Avoid excessive wiping of the coated device.
- Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the device because this may cause unpredictable changes in the coating which could affect the device safety and performance.
- Avoid pre-soaking devices, as this may impact the coating performance and has not been tested.
- The safety and effectiveness of the coated device has not been established, or is unknown, in vascular regions other than those specifically indicated

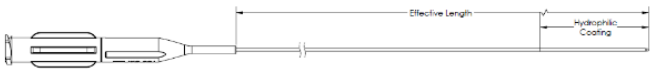
Precautions
- Store in a cool, dry place. Protect from direct sunlight and high temperature.
- Use only appropriately sized ancillary device, as shown in the Specifications below.
- Use the catheter prior to the "Use By" date specified on the package
- The catheter should only be used by physicians qualified to perform percutaneous, vascular interventions.
- Precautions to prevent or reduce clotting should be taken when any catheter is used in the vascular system. Use of systemic heparinization and heparinized saline solution should be considered.
- Exercise care while handling the catheter during procedure to reduce the possibly of accidental damage, kinking or bending.
- Manipulation of the catheter should only occur under fluoroscopy.

Directions for Use
Follow instructions for use on all accessory equipment to be used with the Cora Catheters

Device Preparation
Use aseptic technique. Remove the Cora catheter from the dispenser coil and inspect for any bends or kinks.
Fill a sterile standard luer-lock syringe with sterile saline and flush the lumen.
Wet the distal 60cm of the Cora catheter with saline solution to activate the hydrophilic coating. **Warning: Failure to abide by the warnings related to coating in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.**
Catheter Insertion
Through a previously inserted, appropriately sized guiding catheter or introducer sheath, introduce the distal end of the Cora catheter over an appropriately sized guidewire (see specifications) using standard technique. **Caution: The Cora Catheter should never be advanced without guidewire support. Failure to advance over a guidewire may result in device damage.**
Advancement
Use fluoroscopic guidance when advancing the Cora catheter to the desired location within the vasculature. **Caution: Never advance the Cora catheter against strong resistance until the cause of the resistance is determined by fluoroscopy. If the cause cannot be determined, withdraw the catheter. Movement against unidentified resistance may result in damage to the vessel.** In the case that a different guidewire is needed, retract the guidewire while holding the hub of the Cora catheter in place. Once guidewire has been removed from the patient, a different guidewire can be introduced into the hub of the catheter and advanced to the distal tip.
Infusion
To perform infusion, withdraw the guidewire and reference the specifications for maximum infusion pressure. **Warning: Do not exceed Maximum Infusion Pressure: 300 psi (2070kpa)**
Removal
Fix the guidewire using standard guidewire exchange techniques and carefully withdraw the Cora Catheter
Disposal
After use, dispose of all equipment in accordance with applicable requirements relating to hospital waste, and potentially bio-hazardous materials.

Complications
Vascular catheterization and/or vascular intervention may result in complications including but not limited to:

- Vessel dissection, perforation, rupture or total occlusion
- Arrhythmia, including ventricular fibrillation
- Hypo/hypertension
- Acute myocardial infarction
- Additional surgical or percutaneous intervention
- Hematoma
- Unstable angina
- Thrombosis/Embolism
- Renal Dysfunction
- Radiation Exposure
- Hemorrhage
- False Aneurysm
- Infection
- Blood Loss
- Death



Model (Ref.)	Guide Compatibility	Guidewire Compatibility	Effective Length (cm)	Outer Diameter	Sheath Compatibility	Max Pressure psi(kpa)	Hydrophilic Coating Length
FRC14135US	MIN 5F (1.7mm)	.014" (.36mm)	135cm	.029" (.74mm/2.2F)	MIN 4F (1.3mm)	300 (2070)	60cm
FRC14150US	MIN 5F (1.7mm)	.014" (.36mm)	150cm	.029" (.74mm/2.2F)	MIN 4F (1.3mm)	300 (2070)	60cm
FLX14135US	MIN 5F (1.7mm)	.014" (.36mm)	135cm	.029" (.74mm/2.2F)	MIN 4F (1.3mm)	300 (2070)	60cm
FLX14150US	MIN 5F (1.7mm)	.014" (.36mm)	150cm	.029" (.74mm/2.2F)	MIN 4F (1.3mm)	300 (2070)	60cm

Manufacturer:
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(949)-481-0399
ART-100511 Rev C 2022-04-01

Standard Symbol Legend

LOT	Batch Code		Use By Date		Do not use if package is damaged		Do not reuse	⚠	Caution: See instructions for use	STERILE R	Sterilized using irradiation		Consult instructions for use
REF	Catalogue Number		Manufacturer	STERILE EO	Sterilized using ethylene oxide		Do not resterilize	RX ONLY	**Caution**: Federal (USA) law restricts this device to sale by or on the order of a physician	EC REP	Authorized representative in the European Community		Non-pyrogenic