REFLOW coraForce® MICROCATHETER

REFLOW MEDICAL® THE PULSE OF MEDICAL INGENUITY

REFLOW coraFlex® MICROCATHETER

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

CoraForce & CoraFlex Microcatheter
Instructions For Use

Description
The CoraForce and the CoraFlex Microcatheters (Cora Microcatheters) 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 Microcatheters 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 Microcatheters 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 Microcatheters are contraindicated for use in the cerebral vasculature.

How Supplied
The Cora Microcatheters 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 Microcatheters are 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 Microcatheters. Damage to the Cora Microcatheters 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
- The Cora Microcatheter should never be advanced without guidewire support. Failure to advance over a guidewire may result in device damage.

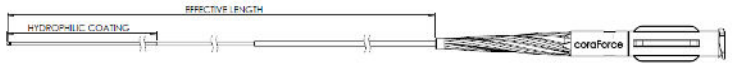
Precautions
- Store in a cool, dry place. Protect from direct sunlight and high temperature.
- Use only appropriately sized ancillary device, as shown in the Specifications below.
- Use the catheter prior to the "Use By" date specified on the package
- The catheter should only be used by physicians qualified 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.
- Do not exceed Maximum Infusion Pressure: 300 psi (2070kpa)

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

Device Preparation
Use aseptic technique. Remove the Cora Microcatheter 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 Microcatheter with saline solution to activate the hydrophilic coating.
Catheter Insertion
Through a previously inserted, appropriately sized guiding catheter or introducer sheath, introduce the distal end of the Cora Microcatheter over an appropriately sized guidewire (see specifications) using standard technique.
Advancement
Use fluoroscopic guidance when advancing the Cora Microcatheter to the desired location within the vasculature. In the case that a different guidewire is needed, retract the guidewire while holding the hub of the Cora Microcatheter 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.
Removal
Fix the guidewire using standard guidewire exchange techniques and carefully withdraw the Cora Microcatheter
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)	Distal Outer Diameter	Proximal Outer Diameter	Sheath Compatibility	Max Pressure psi(kpa)	Hydrophilic Coating Length
FRC14135US	MIN 5F (1.7mm)	.014" (.36mm)	135cm	.029" (.74mm/2.2F)	.050" (1.27mm/3,8F)	MIN 4F (1.3mm)	300 (2070)	60cm
FRC14150US	MIN 5F (1.7mm)	.014" (.36mm)	150cm	.029" (.74mm/2.2F)	.050" (1.27mm/3,8F)	MIN 4F (1.3mm)	300 (2070)	60cm
FLX14135US	MIN 5F (1.7mm)	.014" (.36mm)	135cm	.029" (.74mm/2.2F)	.050" (1.27mm/3,8F)	MIN 4F (1.3mm)	300 (2070)	60cm
FLX14150US	MIN 5F (1.7mm)	.014" (.36mm)	150cm	.029" (.74mm/2.2F)	050" (1.27mm/3,8F)	MIN 4F (1.3mm)	300 (2070)	60cm

Manufacturer:
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Standard Symbol Legend

LOT	Batch Code		Use By Date		Do not use if package is damaged		Do not reuse		Keep away from sunlight		Keep away from rain		Consult instructions for use	MD	Medical Device
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	UDI	Unique Device Identifier		Non-pyrogenic		

Patents: This product is covered by U.S Patent No. 11,565,079 and other pending applications, and foreign patents.