REFLOW coraCross™

REFLOW MEDICAL

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

Description

The coraCross Catheters are single lumen catheters designed to cross lesions in the coronary and peripheral vasculature. The device consists of an extendable tip, activating handle, and support catheter with 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 extendable tip is in the retracted position during tracking over the guidewire. Upon reaching the occlusion, the tip is advanced forward, rotated, and retracted using the advancer on the handle. The advancement and retraction of the tip supports and allows the wire to penetrate and cross the lesion. This step can be repeated until the occlusion is crossed. When the tip is in the normal mode it is retracted just flush to the support catheter. When it is activated it is extended just distal to the catheter body.The coraCross 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

The coraCross Catheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary and peripheral vasculature. It 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 coraCross Catheter is contraindicated for use in the cerebral vasculature.

How Supplied

The coraCross Catheter is 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

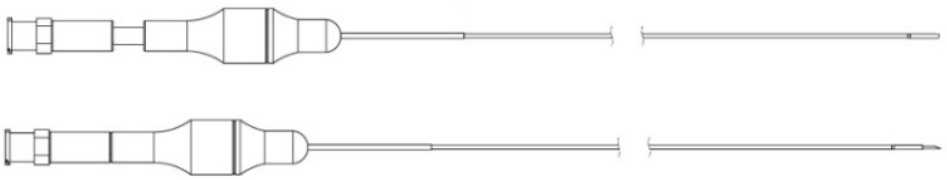
- Single Use only. Do not reuse/resterilize. Reusing the device could result in compromised device performance, cross-infection and other safety related hazards.
- Do not use if device is open or packaging is damaged
- Never advance, withdraw or rotate an intravascular device against resistance until 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.
- The performance of the coraCross device has not been assessed in crossing CTOs, especially in the coronary vasculature.

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.

Disposal

After use, dispose of all equipment in accordance with applicable requirements relating to hospital waste, and potentially bio-hazardous materials.



Model (Ref.)	Guide Compatibility	Guidewire Compatibility	Effective Length (cm)	Max Outer Diameter	Sheath Compatibility	Max Pressure psi(kpa)	Hydrophilic Coating Length	Distal Tip Diameter	Tip Extension
CRX14135US	MIN 5F (1.7mm)	.014" (.36mm)	135cm	.042" (1.07mm/3.2F)	MIN 4F (1.3mm)	300 (2070)	60cm	0.029" (.74mm)	0.20 (5mm)
CRX14150US	MIN 5F (1.7mm)	.014" (.36mm)	150cm	.042" (1.07mm/3.2F)	MIN 4F (1.3mm)	300 (2070)	60cm	0.029" (.74mm)	0.20 (5mm)

Manufacturer:
Reflow Medical
208 Avenida Fabricante #100
San Clemente, CA 92672, USA
(949) 481-0399

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

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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 coraCross 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 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
Continue advancing the catheter until lesion is reached. Using fluoroscopic guidance, confirm that the catheter and guidewire are at the lesion.
Crossing
Once position is confirmed, slightly retract the guidewire within the coraCross catheter and advance the extendable tip by depressing the handle down while turning ~ 90 degrees in a clockwise motion. This will extend the tip beyond the catheter, penetrating the lesion and providing support for the guidewire. **CAUTON: DO NOT turn the handle more than 90 degrees during advancement of the extendable tip. The tip will not advance further by turning more than 90 degrees; continuing to rotate the handle beyond 90 degrees may lead to device breakage. Never advance, withdraw or rotate the CROSSING catheter against resistance until the cause is determined by fluoroscopy.** Notes: The handle should only be directed in a forward and backward motion. A side to side motion will not actuate the tip. Rotation of the outershaft will not advance the extendable tip,and is not recommended during lesion penetration as resistance may be encountered. Excessive grip should not be placed on the outer shaft during advancement, as this will restrict the movement of the extendable tip. Once penetrated, advance the guidewire through the lesion and gently retract the coraCross. Repeat as needed until the coraCross and guidewire have passed the lesion.
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 coraCross

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

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