REFLOW MEDICAL

WINGMAN™ CTO Crossing Catheters: 14, 14C, 18 and 35 Instructions for Use (IFU)

Specifications Table

Model (Ref.)	Guidewire Compatibility	Effective Length	Max Outer Diameter	Sheath Compatibility	Max Pressure (psi/kpa)	Extendable Needle Tip Diameter	Max Needle Tip Extension	Hydrophilic Coating Length (Distal)
WGM14065CE	.014" (.36mm)	65cm	.035" (.89mm/2.7F)	MIN 4F (1.3mm)	360(2482)	.022" (.56mm)	0.20" (5mm)	N/A
WGM14135CE	.014" (.36mm)	135 cm	.035" (.89mm/2.7F)	MIN 4F (1.3mm)	360 (2482)	.022" (.56mm)	0.20" (5mm)	N/A
WGM14150CE	.014" (.36mm)	150cm	.035" (.89mm/2.7F)	MIN 4F (1.3mm)	360 (2482)	.022" (.56mm)	0.20" (5mm)	N/A
WGM18090CE	.018" (.46mm)	90 cm	.05" (1.3mm/3.8F)	MIN 4F (1.3mm)	360 (2482)	.032" (.81mm)	0.20" (5mm)	30cm
WGM18135CE	.018" (.46mm)	135cm	.05" (1.3mm/3.8F)	MIN 4F (1.3mm)	360 (2482)	.032" (.81mm)	0.20" (5mm)	30cm
WGM18150CE	.018" (.46mm)	150cm	.05" (1.3mm/3.8F)	MIN 4F (1.3mm)	360 (2482)	.032" (.81mm)	0.20" (5mm)	30cm
WGM35065CE	.035" (.89mm)	65 cm	.06" (1.5mm/4.6F)	MIN 5F (1.7mm)	360 (2482)	.050" (1.27mm)	0.20" (5mm)	40cm
WGM35090CE	.035" (.89mm)	90cm	.06" (1.5mm/4.6F)	MIN 5F (1.7mm)	360 (2482)	.050" (1.27mm)	0.20" (5mm)	40cm
WGM35135CE	.035" (.89mm)	135cm	.06" (1.5mm/4.6F)	MIN 5F (1.7mm)	360 (2482)	.050" (1.27mm)	0.20" (5mm)	40cm
WMC14090CE	.014" (.36mm)	90cm	.035" (.89mm/2.7F)	MIN 4F (1.3mm)	360 (2482)	.024" (.61mm)	0.20" (5mm)	30cm
WMC14135CE	.014" (.36mm)	135cm	.035" (.89mm/2.7F)	MIN 4F (1.3mm)	360 (2482)	.024" (.61mm)	0.20" (5mm)	30cm
WMC14150CE	.014" (.36mm)	150cm	.035" (.89mm/2.7F)	MIN 4F (1.3mm)	360 (2482)	.024" (.61mm)	0.20" (5mm)	30cm

Device Description

The Wingman CTO Crossing Catheter is a beveled (needle) tip recanalization device intended to provide additional support to a steerable guidewire when accessing discrete regions of the peripheral vasculature. The Wingman CTO Crossing Catheter consists of a support catheter, with a user controlled radiopaque guide tip (extendable needle tip) and activating handle. Using the activating handle, the 5mm extendable needle tip may be rotated 90-degrees to penetrate the cap of total occlusions and difficult-to-cross vasculature. The advancement and retraction of the extendable needle tip supports and allows the wire to penetrate and cross the lesion. When the extendable needle tip is in the normal mode it is retracted just flush to the support catheter. When the extendable tip is activated, it is extended up to 5mm just distal to the support catheter body. The Wingman CTO crossing catheter will also allow for exchange of guidewires and other interventional devices and provide a conduit for delivery of saline solutions or diagnostic contrast.

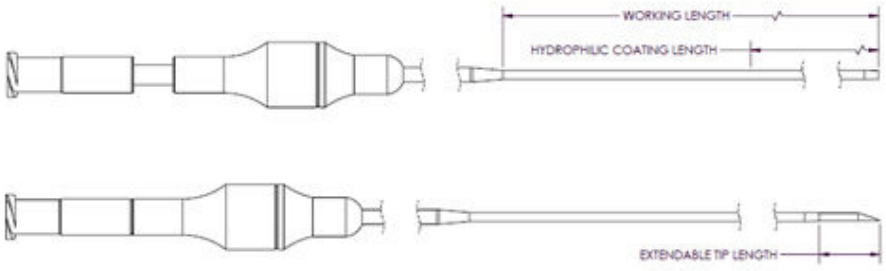

Figure 1. Wingman™ CTO Crossing Catheter

Indications for Use

The Wingman CTO Crossing Catheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the peripheral vasculature and to penetrate and recanalize a lesion intraluminal or subintimal using the extendable needle tip with the activating handle. 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.

Intended Use

The Wingman CTO Crossing Catheter is intended to treat peripheral artery disease (PAD) and chronic total occlusions (CTO).

Intended User

The Wingman CTO Crossing Catheter should only be used by physicians qualified to perform percutaneous vascular interventions.

Target Population
The device is intended for use in patients undergoing therapeutic or diagnostic peripheral endovascular procedures.

Contraindications
The Wingman 14, 14C, 18, and 35 Crossing Catheters are contraindicated for use in the coronary and cerebral vasculature.

Warnings
- Hydrophilic wires prone to excessive swelling (e.g. ZipWire) should not be used with the Wingman CTO Crossing Catheter.
- Single Use only. Do not reuse/resterilize. Reusing the device could result in compromised device performance, cross-infection and other safety related hazards including patient injury.
- Do not use if device is open or packaging is damaged
- Never advance, withdraw or rotate the Wingman CTO Crossing Catheter against resistance until the cause is determined by fluoroscopy.
- DO NOT turn the handle more than 90 degrees during advancement of the extendable needle 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.
- The guidewire should always stay within the catheter as this can cause damage to it.
- This device contains nickel and should not be used in patients with known allergies to nickel.
- If the catheter is damaged, this product may cut into a blood vessel wall. Extreme caution needs to be taken when removing a damaged device. In the case of complications resulting from the removal of the entire system, stop immediately the procedure, and perform appropriate treatment at the discretion of the physician.

Precautions
- Store in a cool, dry, dark place. Storage of the device in extreme conditions may damage the device and/or affect device performance that could lead to patient injury.
- Use only appropriately sized ancillary device, as shown in the Specifications above.
- Maximum Injection pressure: 360 psi (2482kpa).
- 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.

Expected Clinical Benefit
The Wingman CTO Crossing Catheters have an over-the-wire extendable-tip stainless-steel braided structure and tapered design which translates into greater support and pushability, as well as higher flexibility, to move quickly through tortuous vessels. This type of shaft design, combined with the Control Point™ activation and engagement handle, allows simultaneous push and twist of the beveled tip to anchor and provides the extra push needed for a guidewire to penetrate lesions and chronic total occlusions, e.g. subintimal recanalization, that cannot be crossed with a balloon dilation catheter. Additionally, the Wingman CTO Crossing Catheters facilitate guidewire exchange during the procedure.

Complications/Foreseeable events:
Vascular catheterization and/or vascular intervention may result in complications including but not limited to:
- Catheter related: Adverse reaction to device materials, device malfunction/ fracture, infection, distal embolization, vessel thrombosis/ clot formation, vascular damage/ dissection requiring surgical repair, incompatibility with accessories

Complications usually associated with endovascular procedures and percutaneous access including but not limited to:
- Unstable angina, Hypo/hypertension, Acute myocardial infarction, Hemorrhage at puncture site, False aneurysm formation, Renal dysfunction, Hematoma, Embolism, Arrhythmia, Death

How Supplied
The Wingman 14C/18/35 CTO Crossing Catheters are supplied sterile via ethylene oxide (EO) sterilization and are intended for single use (one patient) only. The Wingman 14 CTO Crossing catheter is supplied sterile via e-beam radiation and is intended for single use (one patient) only.

Required Devices for the Wingman

Contents: Wingman CTO Crossing Catheter
The Wingman CTO Crossing Catheters are intended to be used in conjunction with devices as shown in the Specification table.

Procedural Steps

Note: Follow instructions for use on all equipment to be used with the Wingman CTO Crossing Catheter

1. Carefully inspect all packaging for damage or defects prior to use. Do not use the device if there is any sign of breach of sterile barrier, as this would indicate loss of sterility that could result in patient injury.
2. Preparation for Use:
   a. Using sterile technique, remove the CTO Crossing Catheter dispenser coil from its packaging and transfer it to the sterile field.
   b. Remove the CTO Crossing Catheter from the dispenser coil and inspect for any bends or kinks.
   c. Attach a 10ml syringe filled with sterile, heparinized saline to the luer-lock guidewire entry port of the CTO Crossing Catheter and thoroughly flush the catheter.
   d. For the Wingman 14C/18/35 catheters: Prior to use, wet the distal 40cm of the catheter shaft with Heparinized saline solution to activate the hydrophilic coating.
3. Insertion
   a. Through a previously inserted, appropriately sized guiding catheter or introducer sheath, introduce the distal end of the CTO Crossing Catheter over an appropriately sized guidewire (see specifications) using standard technique.
4. Advancement
   a. Use fluoroscopic guidance when advancing the CTO Crossing Catheter to the desired location within the vasculature.
5. Activation
   a. Continue advancing the CTO Crossing Catheter until lesion is reached. Using fluoroscopic guidance, confirm that CTO Crossing Catheter and guidewire are at the lesion.
   b. Once in position is confirmed, slightly retract the guidewire within the CTO Crossing catheter and advance the extendable needle tip by depressing the handle down while turning ~ 90 degrees in a clockwise motion. This will extend the needle tip beyond the catheter, penetrating the lesion and providing support for the guidewire. **CAUTION: DO NOT turn the handle more than 90 degrees during advancement of the extendable needle tip. The needle tip will not advance further by turning more than 90 degrees; continuing to rotate the handle beyond 90 degrees may lead to device breakage. Ensure the guidewire remains within the catheter at all times when needle is activated.**
   Note: The handle should only be directed in a forward and backward motion. A side-to-side motion will not actuate the needle tip.
   Note: Excessive grip should not be placed on the outer shaft during advancement, as this will restrict the movement of the extendable needle tip. **CAUTION: Never advance, withdraw or rotate the CTO Crossing catheter against resistance until the cause is determined by fluoroscopy.**
   c. Once the CTO cap is penetrated, advance the guidewire through the lesion and gently retract the CTO Crossing Catheter.
   d. Repeat as needed until the CTO Crossing Catheter and guidewire have passed the lesion.
6. Injection
   a. To perform injection, withdraw the guidewire and reference the specifications for maximum injection pressure.
7. Removal
   a. Fix the guidewire using standard guidewire exchange techniques and carefully withdraw the CTO Crossing Catheter.
   b. If a device malfunction occurs or any defects are noted on the inspection, flush the guidewire lumen and clean the outer surface of the device with saline, store the device in a sealed biohazard plastic bag, and contact Reflow Medical, Inc. at complaints@reflowmedical.com for further instructions.
   c. After use this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices applicable laws and regulation.

Device Feedback and Return of Devices

If any portion of the Wingman CTO Crossing Catheter fails prior to or during a procedure, discontinue use and contact your local representative and/or Reflow Medical, Inc. at complaints@reflowmedical.com or www.reflowmedical.com.

Additionally, for a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices): if, during the use of this device or because of its use, a serious incident has occurred, this must be reported to the EU member state.

Warranty: Manufacturer warrants that the Wingman CTO Crossing Catheter 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 Wingman CTO Crossing Catheter. Damage to the Wingman CTO Crossing Catheter 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.

Patents: This product is covered by U.S. Patent No. 9,204,893; EPO 2473122 and other pending applications, and foreign patents.

Basic UDI-DI: 856492005SupportCathKP

Electronic IFU: www.reflowmedical.com

Symbols:

LOT	Batch code		Non-pyrogenic
REF	Catalogue number		Keep dry
	Use by date		Keep away from sunlight
MD	Medical device		Consult instructions for use
	Manufacturer	1	Contains 1 unit (Contents: 1)
STERILE EO	Sterilized using ethylene oxide gas; single sterile barrier with protective packaging outside	UDI	Indicates a carrier that contains Unique Device Identifier information
STERILE R	Sterilized using e-beam radiation	CE	Conformité Européenne
	Single sterile barrier system with protective packaging outside	EC REP	Authorized Representative in the European Community/European Union
	Do not re-sterilize	**UK RESPONSIBLE PERSON**:	Authorized Representative in the United Kingdom
	Do not re-use	CH REP	Authorized Representative in Switzerland
	Do not use if package is damaged and consult instructions for use		Date of Manufacture
	Single sterile barrier system		

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