Specifications

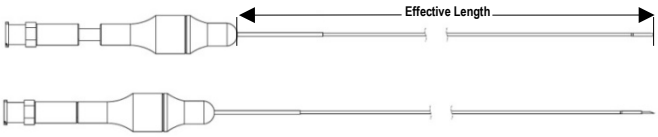
Model (Ref.)	Guide Compatibility	Sheath Compatibility	Guidewire Compatibility	Effective Length	Max Outer Diameter	Max Pressure psi(kpa)	Extendable Tip Diameter	Tip Extension
WGM14065US	MIN 4F (1.3mm)	MIN 3F (1.0mm)	0.014" (0.35mm)	65 cm	0.035" (0.89mm/2.7F)	360 (2482)	0.022" (0.56mm)	0.20" (5mm)
WGM14135US				135 cm				
WGM14150US				150 cm				
WMC14090US				90 cm			0.024" (0.61mm)	
WMC14135US				135 cm				
WMC14150US				150 cm				
WGM18090US	MIN 5F (1.7mm)	MIN 4F (1.3mm)	0.018" (0.46mm)	90 cm	0.05" (1.3mm/3.8F)		0.032" (0.81mm)	
WGM18135US				135 cm				
WGM18150US				150 cm				
WGM35065US	MIN 6F (2mm)	MIN 5F (1.7mm)	0.035" (0.89mm)	65 cm	0.06" (1.5mm/4.6F)		0.050" (1.27mm)	
WGM35090US				90 cm				
WGM35135US				135 cm				

Instructions for Use

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

Description

Wingman Crossing Catheters consis of a support catheter, with an extendable tip and activating handle. The support catheter is tracked over a guidewire to the occluded lesion. 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. Wingman Crossing catheters 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 catheters in the Wingman Family of Crossing Catheters (14/14C/18/35 – see specification table above) are intended to be used in conjunction with steerable guidewires to access discrete regions of the peripheral vasculature. Any one of these catheters may be used to facilitate placement and exchange of guidewires and other interventional devices, including facilitation of the intraluminal placement of diagnostic/interventional devices beyond peripheral stenotic lesions (including chronic total occlusions [CTOs]) and provide a conduit for delivery of saline solutions or diagnostic/therapeutic agents.

The Wingman 14C Crossing Catheters are also intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary vasculature. In that area, they may also be used to facilitate placement and exchange of guidewires and other interventional devices and provide a conduit for delivery of saline solutions or diagnostic/therapeutic agents.

Contraindications

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

Warnings

Hydrophilic wires prone to excessive swelling (e.g., ZipWire) should not be used with Wingman Crossing Catheters.
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.
This device contains nickel and should not be used in patients with known allergies to nickel.

Precautions

Store in a cool, dry place. Protect from direct sunlight and high temperatures.
Use only appropriately sized ancillary device, as shown in the Specifications below.
Maximum Infusion Pressure: 360 psi (2482 kpa)
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

Note: Follow instructions for use on all equipment to be used with Wingman Crossing Catheters

1. Preparation for Use:
a. Using sterile technique, remove a Wingman Crossing catheter dispenser coil from its packaging and transfer it to the sterile field.
b. Remove this Wingman 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 this catheter and thoroughly flush the catheter.
d. For the Wingman 14C/18/35 catheters: Prior to use, wet the distal 40cm of these catheters with Heparinized saline solution to activate the hydrophilic coating.

2. Insertion
Through a previously inserted, appropriately sized guiding catheter or introducer sheath, introduce the distal end of the selected Wingman Crossing catheter over an appropriately sized guidewire (see specifications) using standard technique.

3. Advancement
Use fluoroscopic guidance when advancing the selected Wingman Crossing catheter to the desired location within the vasculature.

4. Activation
a. Continue advancing the selected Wingman Crossing catheter until the lesion is reached. Using fluoroscopic guidance, confirm that the catheter and guidewire are at the lesion.
b. Once position is confirmed, slightly retract the guidewire within the 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.
Note: The handle should only be directed in a forward and backward motion. A side-to-side motion will not actuate the tip.
Note: rotation of the outershaft will not advance the extendable tip and is not recommended during lesion penetration as resistance may be encountered.
Note: Excessive grip should not be placed on the outer shaft during advancement, as this will restrict the movement of the extendable tip.
CAUTION: Never advance, withdraw, or rotate a Wingman Crossing catheter against resistance until the cause is determined by fluoroscopy.
c. Once penetrated, advance the guidewire through the lesion, and gently retract the catheter.
d. Repeat as needed until the catheter and guidewire have passed the lesion.

5. Infusion
To perform infusion, withdraw the guidewire and reference the specifications for maximum infusion pressure.

6. Removal
Fix the guidewire using standard guidewire exchange techniques and carefully withdraw the Catheter you are using.

Complications

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

- Vessel dissection, perforation, rupture, or total occlusion
- Infection
- Hematoma
- Unstable angina
- Embolism
- Hypo/hypertension
- Acute myocardial infarction
- Arrhythmia, including ventricular fibrillation
- Death

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.

Clinical Study Results:
A prospective, multi-center, non-randomized single-arm study of the Wingman Catheter to cross infrainguinal peripheral CTO's. The study was conducted at 12 investigational sites; 9 in the United States and 3 in Europe. Safety and effectiveness were evaluated during the index procedure and through 30-day follow up.

Inclusion Criteria:
Patient willing and able to provide informed consent. Patient willing and able to comply with the study protocol. Patient >18 years old. Patient with PAD requiring revascularization as evidence by contrast computed tomography (CT) or magnetic resonance (MR) angiography. A maximum of 2 lesions per subject, as identified by the Investigator, involving occluded infrainguinal arteries without flow is observed in the distal lesion except the flow from collateral circulation. Target lesion(s) ≥1 cm and <30 cm in length, by visual estimate. Target vessel ≥2.0 mm in diameter. Rutherford Classification of 2-5. Lesion unable to be crossed with conventional guidewire(s). Reconstruction of the vessel at least 2 cm above bifurcation/trifurcation. Occlusion could be within a previously implanted stent.

Exclusion Criteria:
Patient had known sensitivity or allergy to contrast materials that could not be adequately pre-treated. Patient had known sensitivity or allergy to all antiplatelet medications. Patient was pregnant or lactating. Patient had a co-existing disease or medical condition contraindicating percutaneous intervention. Target lesion in a bypass graft. Patient had a failed crossing attempt without an intervening intervention on the target limb within the past 14 days. Patient had a planned surgical or interventional procedure within 30 days after the study procedure.

Primary Safety Endpoint:
Freedom from: significant in-hospital or 30-day MAEs, clinically significant perforation, clinically significant embolization, or ≥ Grade C dissections as adjudicated by the CEC.

Primary Effectiveness Endpoint:
Successful CTO crossing- successful guidewire placement in the distal true lumen confirmed by angiography, without clinically significant perforations.

Patient Demographics:

Demographics and History	Value ± Stdev	N Reporting
Average Age (yrs)	71.4 ± 9.3	85
Gender (male)	65.9%	(56/85)
History of CABG	19.0%	(16/84)
History of PCI	25%	(21/84)
History of Peripheral Intervention	63.5%	(54/85)
History of Amputation	4.7%	(4/85)
Rutherford Category		
0	0%	(0/85)
1	0%	(0/85)
2	2.4%	(2/85)
3	70.6%	(60/85)
4	14.1%	(12/85)
5	12.9%	(11/85)
6	0%	(0/85)

Lesion Characteristics:

Lesion Characteristics	Value ± Stdev	N Reporting*
Target Lesion Side		
Right	57.0%	(49/86)
Left	43.0%	(37/86)
Vessel		
Superficial Femoral Artery	70.9%	(61/86)
Popliteal Artery	15.1%	(13/86)
Below the Knee Artery	14.0%	(12/86)
Type of Occlusion		
DeNovo	75.6%	(65/86)
Restenotic	24.4%	(21/86)
Number of Lesions Treated (by subject)		
1	98.8%	(84/85)
2	1.2%	(1/85)
Calcification		
None	30.2%	(26/86)
Mild	41.9%	(36/86)
Moderate	9.3%	(8/86)
Severe	18.6%	(16/86)

* 86 lesions treated in 85 patients.

Study Results:

Endpoint	Value ± Stdev	N Reporting	95% CI
Primary Safety Composite Endpoint Rate†	4.8%	(4/83)	10.7 UCL
Major Adverse Events	4.8%	(4/83)	1.3% - 11.9%
All-Cause Mortality	1.2%	(1/83)	0% - 6.5%
Unplanned Target Limb Major Amputation	1.2%	(1/83)	0% - 6.5%
Emergent Target Vessel Revascularization	2.4%	(2/83)	0.3% - 8.4%
Clinically Significant Perforation	1.2%	(1/83)	0% - 6.5%
Clinically Significant Embolization	0.0%	(0/83)	N/A
Grade C or Greater Dissection	0.0%	(0/83)	N/A
Primary Efficacy Endpoint †			
Successful CTO Crossing	89.5%	(77/86)	82.5% LCL
Lesion Success	92.8%	(77/83)	84.9%-97.3%
Procedure Success	91.5%	(75/82)	83.2% - 96.5%

† All events were adjudicated by the independent Clinical Events Committee, all angiographic measures were made by an independent core laboratory.

Definitions:

Clinically Significant Perforation – Clinically significant perforation defined as a perforation requiring intervention (e.g., angioplasty, covered stent, bypass or other interventional procedures).

Clinically Significant Embolization – Clinically significant embolization defined as those events that result in distal ischemia (e.g., occlusion of run-off vessel resulting in pain or foot discoloration) and/or require rescue intervention.

Successful CTO Crossing – while using the Wingman device, successful CTO crossing was identified by successful guidewire placement in the distal true lumen confirmed by angiography with no clinically significant perforation. Requires successful delivery and retrieval of the study device.

Lesion success – defined as attainment of <50% final residual stenosis of the target lesion using any percutaneous method.

Procedure success – defined as lesion (device) success and the absence of in-hospital major adverse events, clinically significant perforation, clinically significant embolization or Grade C or greater dissection.

Warranty and Limitation of Warranty
Manufacturer warrants that the Wingman 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 Crossing Catheter. Damage to the Wingman 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.

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

Manufacturer:
Reflow Medical
208 Avenida Fabricante #100
San Clemente, CA 92672, USA