



REFLOW

wingman™

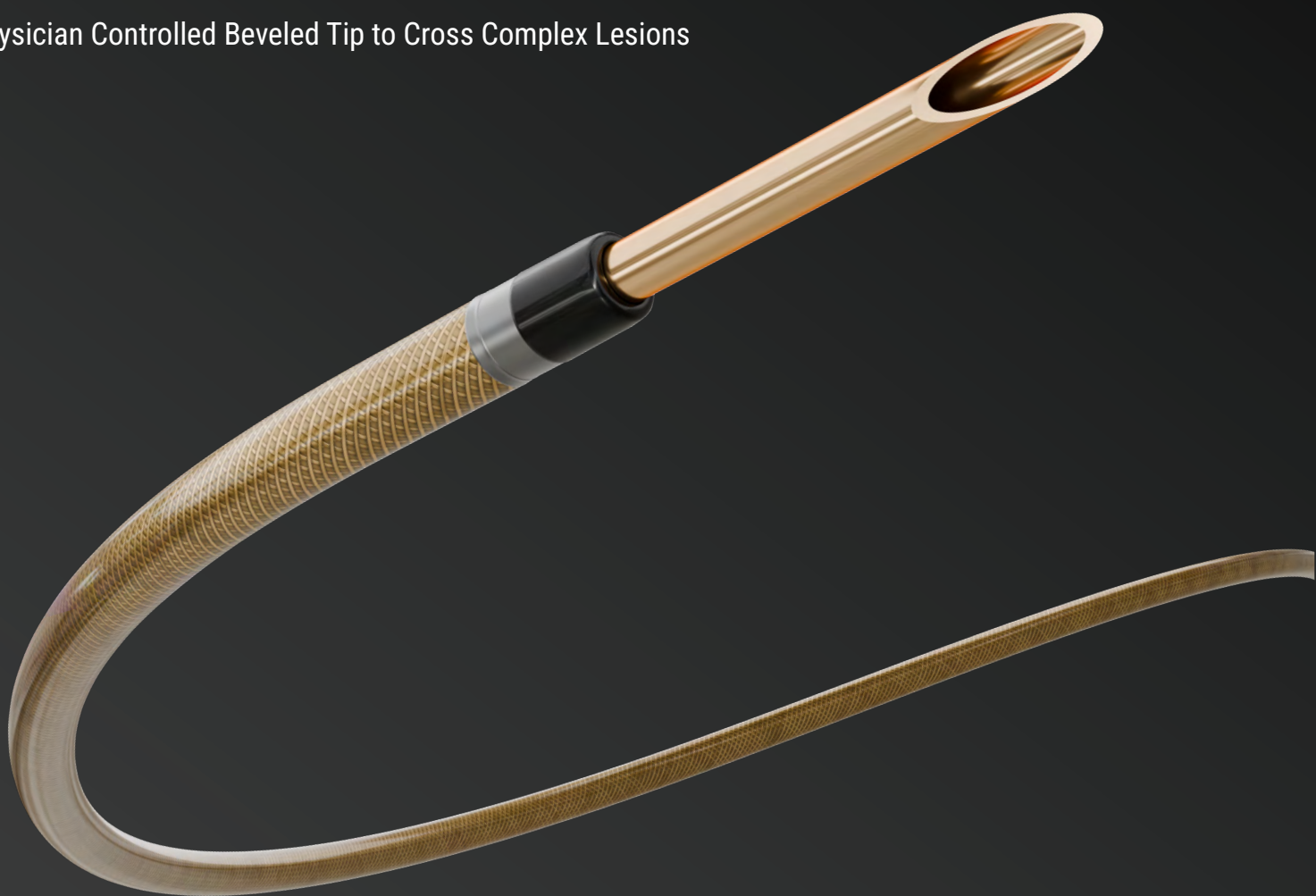
14 14^c 18 35

CTO CROSSING CATHETER

PERIPHERAL
CTO INDICATION

CLINICALLY PROVEN CTO CROSSING SUCCESS

Physician Controlled Beveled Tip to Cross Complex Lesions



REFLOW MEDICAL™
THE PULSE OF MEDICAL INGENUITY

90% CTO Crossing Success

In the Wing-It clinical trial, following failed crossing attempts with a standard guidewire, the rate of successful CTO* crossing with the Wingman catheter was 90%.

Unique Extendable Beveled Tip

Improves crossing through extremely tight occlusions and difficult-to-cross vasculature

Physician Controlled with Activation and Engagement Handle

Allows you to simultaneously “push and twist” the beveled tip to anchor and penetrate the lesion

Telescoping Compatibility

Wingman 14/14C are compatible with Spex LP 35 and Spex 35 Shapeable Support Microcatheters

Spex 35

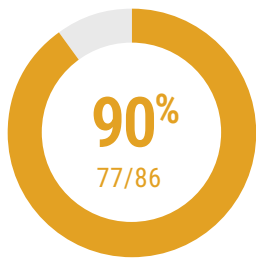
*CTO: Chronic Total Occlusion

Clinically Proven

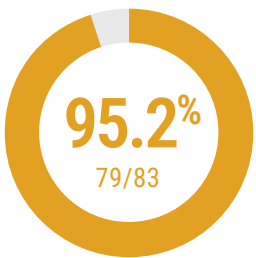
WING-IT CTO CLINICAL TRIAL¹

Prospective, international, single-arm study of a novel crossing catheter used in peripheral artery CTOs after failed crossing attempts with standard guidewires

PRIMARY ENDPOINTS



CTO Crossing Success



Primary Safety at 30 days*

“REAL WORLD” STUDY DESIGN

Patients with a peripheral artery CTO that was uncrossable with standard guidewires (up to 2 conventional guidewires were attempted and failed for up to 5 minutes) were treated with Wingman CTO Crossing Catheter.

MEAN CROSSING TIME: 12 minutes

STUDY DEVICES

Wingman™ used in peripheral artery CTOs after failed crossing attempts with standard guidewires.

STUDY SIZE

- ✋ 85 patients enrolled
- 🏢 12 centers (US + Germany + Austria)

PERFORMANCE GOAL

70.7% crossing success

BASELINE CHARACTERISTICS

- 27%** CLTI patients (Rutherford 4 and 5)
- 28%** moderately/severely calcified lesions
- 188mm** mean lesion length

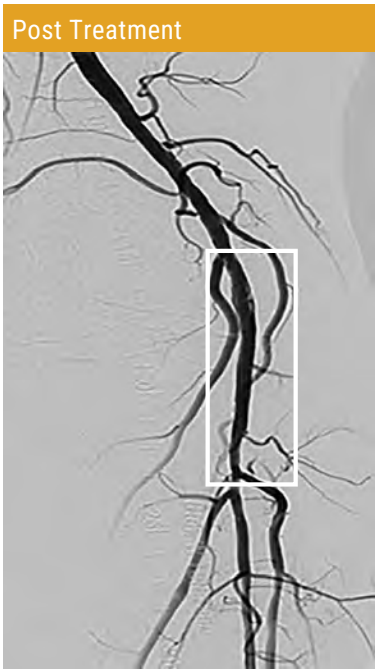
Wingman Case Experience



Popliteal artery (P2) chronic total occlusion (located between P2 and TPT, left panel)



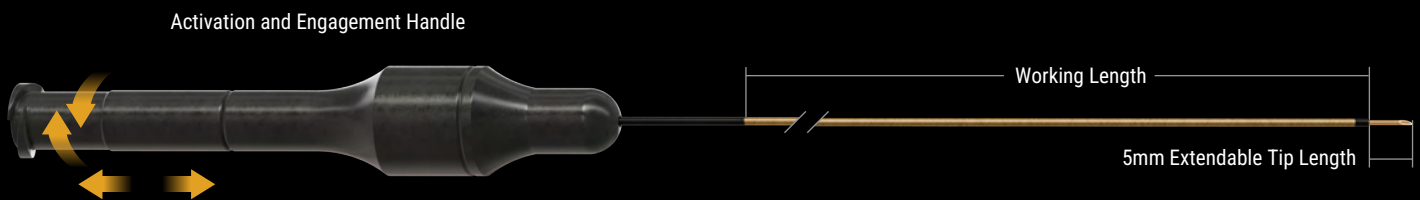
After failure to cross with a standard guidewire, the Wingman catheter successfully crossed the occlusion



Wingman facilitated endovascular treatment with balloon angioplasty resulting in 17% final diameter stenosis

Images courtesy of Dr. Jay Matthews, MD

	14	14 ^C	18	35
Model Number	WGM14065CE WGM14135CE WGM14150CE	WMC14090CE WMC14135CE WMC14150CE	WGM18090CE WGM18135CE WGM18150CE	WGM35065CE WGM35090CE WGM35135CE
Effective Length (cm)	65, 135, 150	90, 135, 150	90, 135, 150	65, 90, 135
Introducer Sheath Compatibility (F/mm)	3/1	3/1	4/1.33	5/1.67
Max Outer Diameter (in/F/mm)	0.035/2.7/0.89	0.035/2.7/0.89	0.050/3.8/1.27	0.060/4.6/1.52
Max Pressure (psi/kpa)	360/2482	360/2482	360/2482	360/2482
Extendable Tip Diameter (in/mm)	0.022/0.56	0.024/0.61	0.032/0.81	0.050/1.27
Tip Extension (in/mm)	0.20/5	0.20/5	0.20/5	0.20/5
Hydrophilic Coating - Distal (cm)	N/A	30	30	40



1 Laird JR, Mathews SJ, Brodmann M, Soukas PA, Schmidt A, The Wing-It Trial Investigators. Performance of the Wingman catheter in peripheral artery chronic total occlusions: Short-term results from the international Wing-It trial. Catheter Cardiovasc Interv. 2021;97:310–316. 10.1002/ccd.29366
 * Freedom from major adverse event [MAE], clinically significant perforation or embolization, or grade C or greater dissection.

Indications for Use

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

Intended 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.

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.
- 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; the guidewire should always stay within the catheter to reduce the possibility of accidental damage, kinking or bending.
- Manipulation of the catheter should only occur under fluoroscopy.

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