Reflow Medical Wingman Catheter Wing-IT Clinical Trial
RFM-CTO-13001
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PROTOCOL SUMMARY

Title:	A Non-Randomized Study Evaluating the Use of the ReFlow Medical **Wing**man Catheter to Cross Chronic Total Occlusions in **I**nfrainguinal Peripheral Ar**T**eries (Wing-IT)
Design:	Prospective, multi-center, non-randomized single-arm study of the Wingman Catheter to cross a single infrainguinal peripheral chronic total occlusion (CTO). Safety and effectiveness will be evaluated during the index procedure through 30-day follow-up.
Purpose:	To evaluate the safety and effectiveness of the ReFlow Medical Wingman Catheter used to cross *de novo* or restenotic infrainguinal CTOs that cannot be crossed with a standard guidewire.
Enrollment and Sites:	A maximum of 85 patients will be enrolled and treated with the investigational device at up to twelve (12) centers in North America and three (3) centers in Europe.
Time Course:	Initial enrollment: Q1 2018 Last enrollment: Q1 2019 Last follow-up: Q1 2019
Primary Efficacy and Safety Endpoints:	*Primary Efficacy:* While using the Wingman device, successful CTO crossing is identified by successful guidewire placement in the distal true lumen confirmed by angiography with no clinically significant perforations. *Primary Safety:* No evidence of significant in-hospital or 30-day MAEs. No evidence of clinically significant perforation, clinically significant embolization or ≥ Grade C dissection, after Wingman CTO crossing and prior to adjunctive interventions, confirmed by angiography. Components of the composite primary safety endpoint include: • Major Adverse Events (MAEs) defined as death, unplanned target limb major amputation, and emergent target vessel revascularization. • Clinically significant perforation defined as all perforations requiring intervention (e.g., covered stent, bypass or other surgery) [1] • 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 requires rescue intervention.

- Grade C Dissection or greater with a minimum of a dissection protruding outside the lumen of the vessel persisting after passage of the contrast material.[1]

The components of the primary and secondary safety endpoints will be adjudicated by an independent CEC with angiographic elements assessed by an independent core laboratory.

Secondary Endpoints:

1) Lesion success, defined as attainment of <50% final residual stenosis of the target lesion using any percutaneous method.
2) Procedure success, defined as device success and the absence of in-hospital MAEs, clinically significant perforation, clinically significant embolization or Grade C or greater dissection not resolved by visual estimate.
3) Procedure safety, defined as any in-hospital AE or MAE following use of a therapeutic interventional device.
4) Evaluation of total procedural and fluoroscopic time and contrast volume.
5) Evaluation of procedure time associated with use of the investigational device.
6) Evaluation of utility of ancillary device in addition to investigational device.

Inclusion Criteria:

1) Patient is willing and able to provide informed consent.
2) Patient is willing and able to comply with the study protocol.
3) Patient is > 18 years old.
4) Patient has peripheral arterial disease requiring revascularization as evidenced by contrast, CT or MR angiography.
5) Patient has at least one but not more than two occluded infrainguinal arteries that are 99-100% stenosed and no flow is observed in the distal lesion except the flow from collateral circulation.
6) Target lesion(s) is ≥ 1 cm and ≤ 30 cm in length by visual estimate.
7) Target vessel is ≥ 2.0 mm in diameter.
8) Patient has Rutherford Classification of 2-5.
9) Lesion cannot be crossed by concurrent conventional guidewire.
10) Reconstitution of vessel at least 2cm above bifurcation/trifurcation.
11) Occlusion can be within previously implanted stent.

Exclusion Criteria:

1) Patient has a known sensitivity or allergy to contrast materials that cannot be adequately pre-treated.
2) Patient has a known sensitivity or allergy to all anti-platelet medications.
3) Patient is pregnant or lactating.
4) Patient has a co-existing disease or medical condition contraindicating percutaneous intervention.
5) Target lesion is in a bypass graft.

6) Patient has had a failed crossing attempt without an intervening intervention on the target limb within the past 14 days.
7) Patient has a planned surgical or interventional procedure within 30 days after the study procedure.

Data Analysis Center:	Syntactx 4 World Trade Center 150 Greenwich Street / 44th Floor New York, NY 10007
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