Late-Breaking Final Patency and Wound Healing Results with a 3-French Compatible Microstent (From Micro Medical) Versus POBA for Antegrade or Retrograde Insertion to Treat Tibial Artery Lesions: From the STAND RCT

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The MicroStent™ is limited to Investigational Use only in the US & has CE marking in the EEA

The Research Studies for:

MicroStent 3Fr System
Treatment of Tibioperoneal Arterial Lesions
The STAND RCT – US
The HEAL Registry - OUS

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Disclosures

Consultant:
Abbott, Bentley, BSCI, Cardinal Health/Cordis, Centerline BioMedical, Cook Medical, CR BARD/Becton Dickinson, CSI, Endologix, Inari, Medtronic, Micro Medical Solutions, Penumbra, Philips, Terumo, WL Gore

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STAND – Randomized, Multicenter US Trial

Evaluation of the Effectiveness and Safety of the MicroStent, Self-expanding Stent

Prospective, Randomized, Controlled – 25 US centers
177 patients
2:1 – MicroStent to PTA
Enrollment Complete

stand
NCT 03477604
A Clinical Evaluation of the MicroStent® PeripherAl Vascular SteNt in Subjects with Arterial Disease Below the Knee

Follow-up: 30D – 3M - 6M –1Y – 2Y – 3Y

National PI – Robert Beasley, MD, Palm Vascular

STAND – Randomized, Multicenter US Trial

- **Define STAND Trial and Endpoints Traditional in Design**
- **Share learning from STAND**
  STAND supports the growing evidence that we are seeing in our everyday treatment and management of CLTI patients

STAND – Randomized, Multicenter US Trial

- **Important to make distinctions between the endpoints of past and current BTK device studies**
- **Now give consideration to 'new' endpoints compatible with today's study outcomes**
- **This 'new' direction in study outcomes is vital to the evolving success of the CLTI patient management.**

STAND Endpoint Definitions – 'Traditional'

STAND Effectiveness and Safety – 'Traditional'

Effectiveness: Primary Patency at 6M

Defined as the composite of :
Freedom from *Target Lesion Occlusion*
With
1. NO *Clinically Driven Target Lesion Reintervention (CD-TLR)*
OR
2. *Major Amputation*

Safety
- *POD*
- *MALE at 6M*

Secondary Hypothesis Endpoints – 6M
- *Freedom from Amputation*
- *Wound Healing*

HEAL Registry – Post Market, Real World Evidence

Evaluation of Clinical Outcomes of the MicroStent Peripheral Stent System

All Comer's - 15 EU centers
300 patients
Enrollment 213 patients

heal – An All-Comers Registry of the MicroStent® PeripHeral Vascular StEnt in Subjects with PeripheraI Arterial Disease
NCT 04110327

Follow-up: 30D – 6M – 1Y – 2Y

Principle PI – Marco Manzi, MD, Abano, Terme

Effectiveness Outcomes: Primary Patency at 6M
Composite of :
Freedom from *target lesion occlusion*
AND
No *clinically driven target lesion reintervention (CD-TLR)*

MicroStent Use – Large Body of Research Data

stand – A Clinical Evaluation of the MicroStent® PeripheraI Vascular StENt in Subjects with Arterial Disease Below the Knee

390 Patients

heal – An All-Comers Registry of the MicroStent® PeripHeral Vascular StEnt in Subjects with PeripheraI Arterial Disease

IDE RCT Study

Randomized 2:1
177 Patients
6-month Primary Endpoint Data

2 Imaging Core Labs
Wound Healing Core lab
DUS follow-up

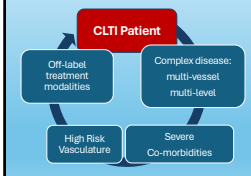
REAL WORLD EVIDENCE

De Novo, Restenosis, Bailout Use
213 Patients
6-month Primary Outcome Data

3rd party Verified and Monitored Data
Wound Healing Assessment
DUS follow-up

Lessons Learned: New Primary Study Endpoints?

The scientific community continues to learn and adapt treatment in this complex CLTI patient population.
❖ Increasingly aware and are now considering the impact of patient-centric outcomes.



Suggested Patient-Centric Outcomes:
- Freedom from Amputation - for as long as possible
- Wound Healing within 6-12 months
- Clinically Driven Reintervention – Understanding that 'maintaining perfusion of the entire limb (*inflow and outflow*) impacts wound healing and ultimately amputation.

STAND and HEAL – Baseline Characteristics

stand – A Clinical Evaluation of the MicroStent® PeripheraI Vascular StENt in Subjects with Arterial Disease Below the Knee

Pre-Existing Comorbidities	
Diabetes Mellitus	74.6%
Coronary Artery Disease	48.2%
Peripheral Artery Disease	100%
Previous Target Limb Intervention	82.5%
Prior Limb Amputation	17.5%
Chronic Renal Failure	5.3%

Complex Population:
- RC 4 – 55.3%
- RC 5 - 43.0%
- Baseline Wound/Ulcer – 38.0%

heal – An All-Comers Registry of the MicroStent® PeripHeral Vascular StEnt in Subjects with PeripheraI Arterial Disease

Pre-Existing Comorbidities	
Diabetes Mellitus	66.9%
Coronary Artery Disease	65.7%
Peripheral Artery Disease	83.7%
Previous Target Limb Intervention	51.2%
Prior Limb Amputation	20.3%
Chronic Renal Failure	18.0%

Complex Population:
- RC 4 – 16.4%
- RC 5 – 69.6%
- RC 6 – 1.8%
- Baseline Wound/Ulcer – 73.8%

Conclusions:

- STAND and HEAL provide a large cohort of CLTI patients treated under controlled clinical treatment and follow up through 2 years.
- Traditional endpoints need to be supplanted by clinically relevant, patient-centric outcomes.
- Maintaining inflow and outflow are critical for sustaining vessel patency, wound healing, and freedom from amputation.
- Close to 400 CLI patients have been studied with the MicroStent device under simultaneous IDE and post market studies.
- ***STAND data will be available to share in the first half of 2025.***