2018 MID-ATLANTIC
CONFERENCE

8th ANNUAL CURRENT CONCEPTS IN
VASCULAR THERAPIES

2018

**Samuel N. Steerman, MD, FACS, RPVI**

**EVMS Assistant Professor of Surgery**

**Sentara Vascular Specialists**

# Endovascular Widgets: What Are the New Toys, and Do They Work?

# Disclosure

- No relevant disclosure
- Many widgets are not FDA approved and not available in the US

# Outline

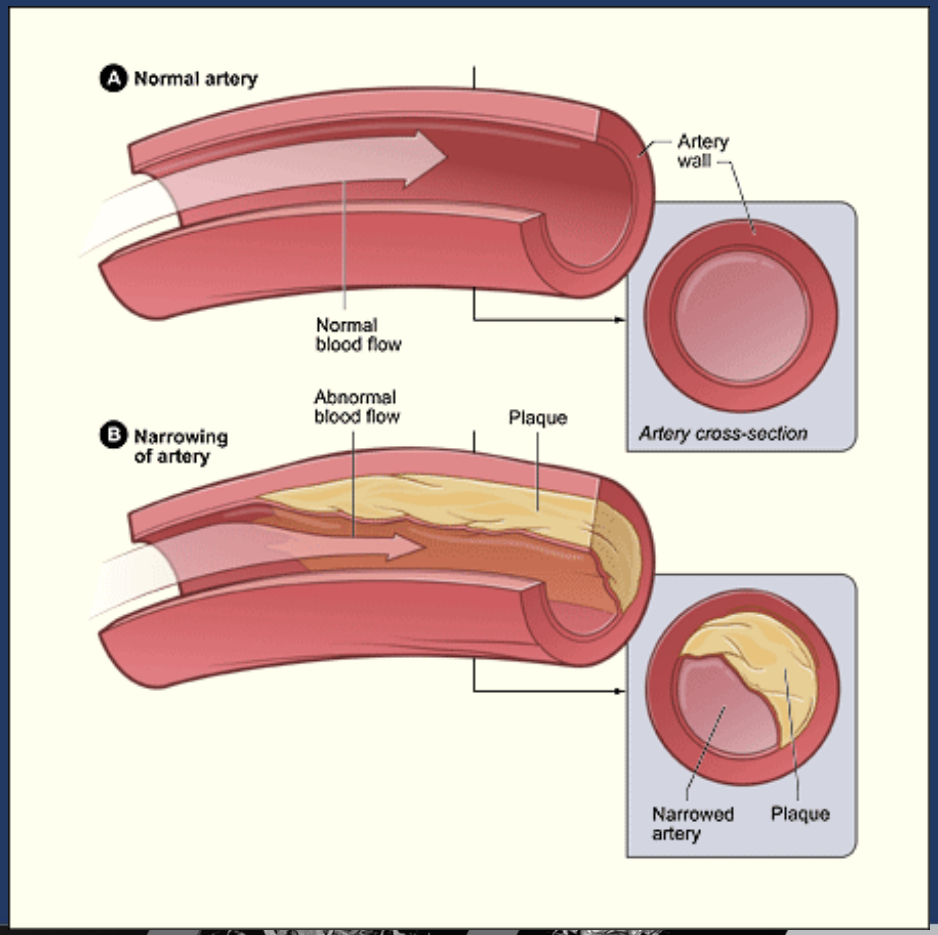
- Extra-Arterial Endovascular Bypass
- Robots
- Mercator drug delivery device
- Percutaneous Deep Vein Arterialization
- Cagent Vascular Serranator

# Extra-Arterial Endovascular Bypass

# Peripheral Artery Disease

Relieve the obstruction

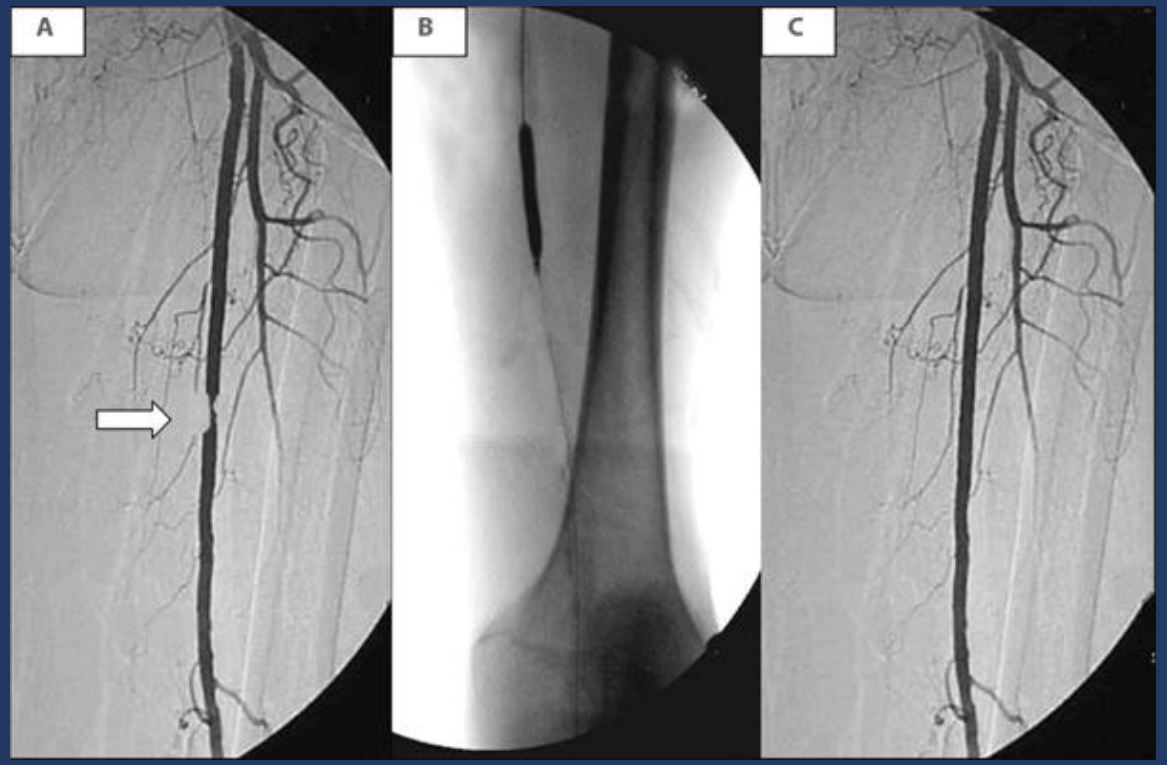
Avoid further harm

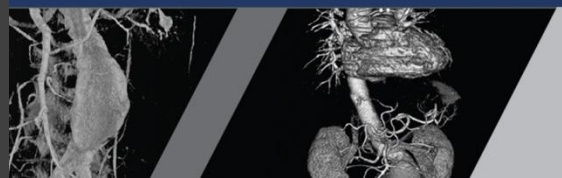



Improve the perfusion

# Innovation

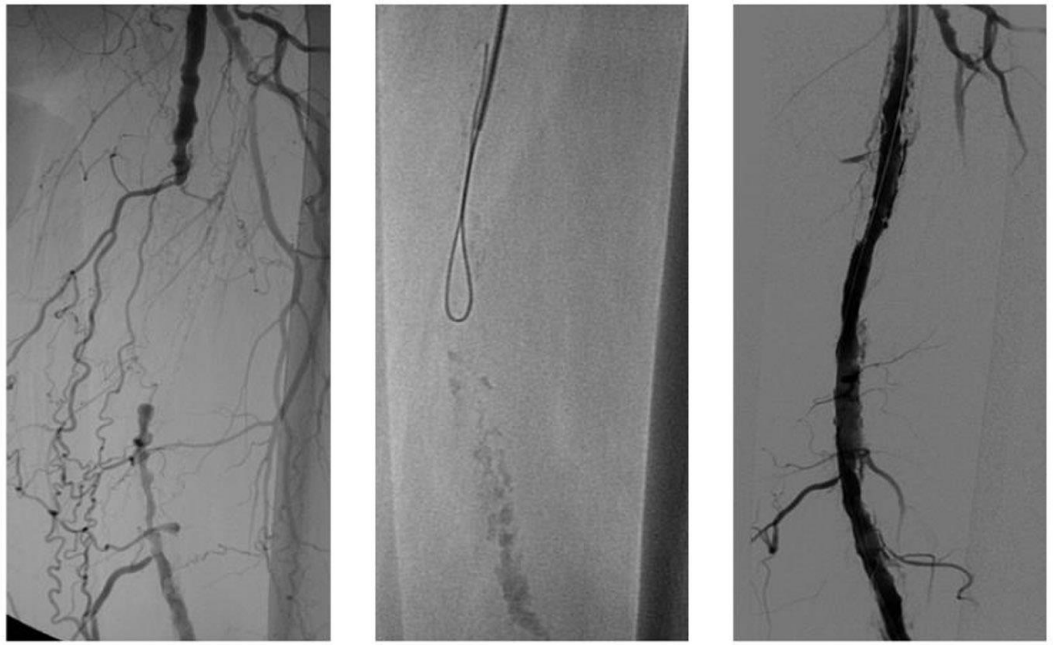
Short stenosis



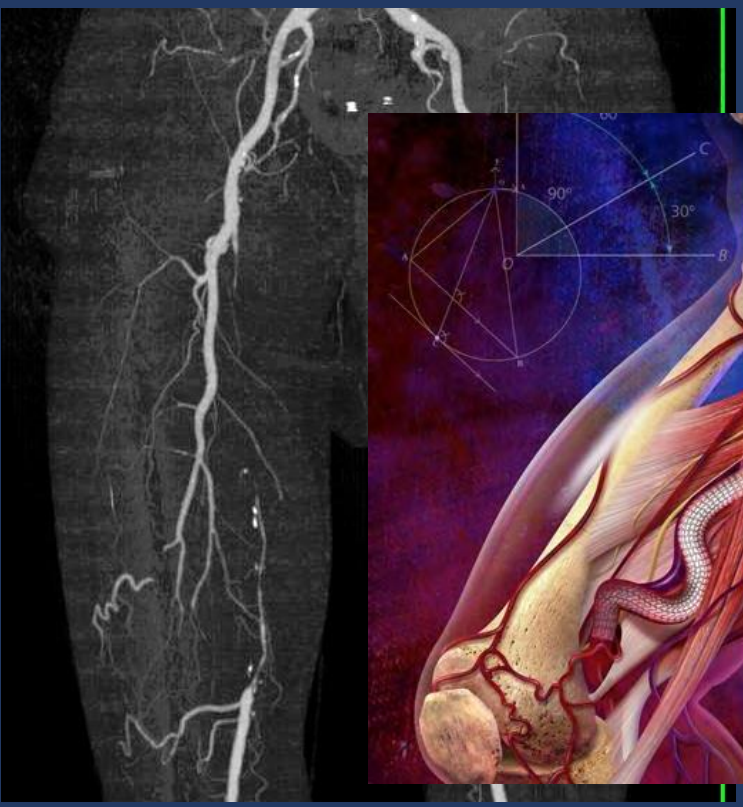
# Innovation

Moderate length occlusion

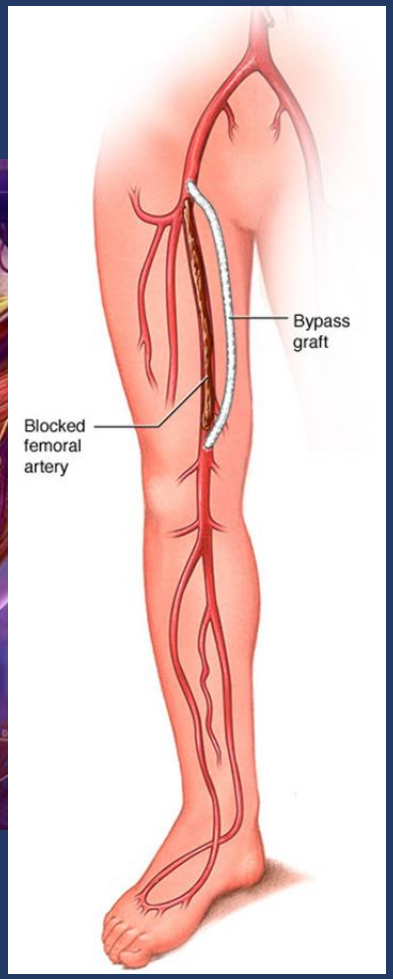


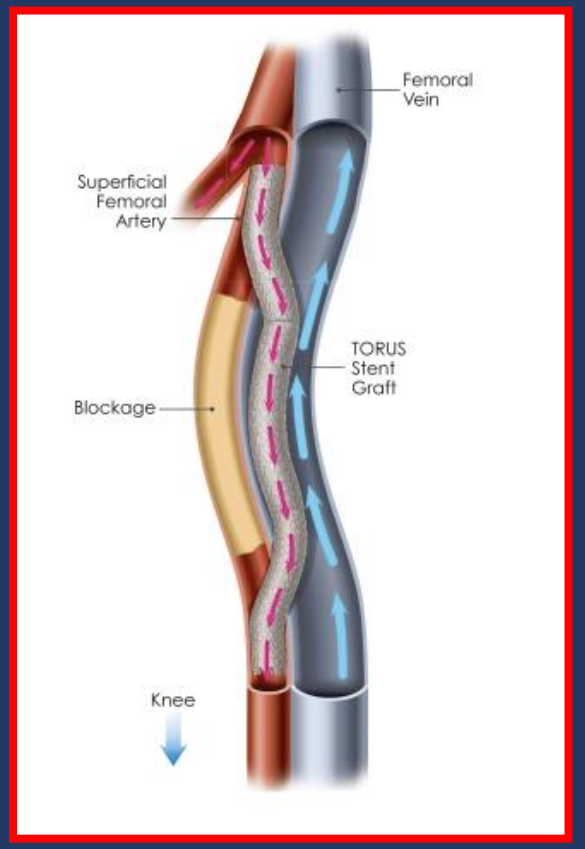
(A) (B) (C)

Figure 1. Subintimal angioplasty of a superficial femoral artery occlusion. (A) Angiogram demonstrating level of occlusion. (B) Subintimal guidewire advanced in “wide loop” configuration toward distal end. (C) Post-procedural angiogram demonstrates restoration of flow.








# Long segment occlusion

# Components

## PQ Snare

The PQ Snare is an over-the-wire, dual-nitinol-caged endovascular scaffold created to present a destination and snare for guidewires, then extract them through the tibial vein scaffold.

## PQ Crossing Device

The PQ Crossing Device is a spring-loaded guidewire support and delivery system. During the PQ DETOUR procedure, it is designed to create initial artery-vein-artery communication.

## TORUS Stent Graft System

The TORUS Stent Graft System features a flexible, self-expanding composite structure made of a nitinol wire frame encapsulated in ePTFE. Designed for flexibility and robust durability to help maintain an open lumen, the PQ Stent Graft System is under investigation in Europe for both standard intra-arterial placement and for use in the PQ Bypass procedure.

**Not available for sale in the United States, E.U. or E.E.A.**
**Not cleared or approved in the United States.**

# PQ Bypass

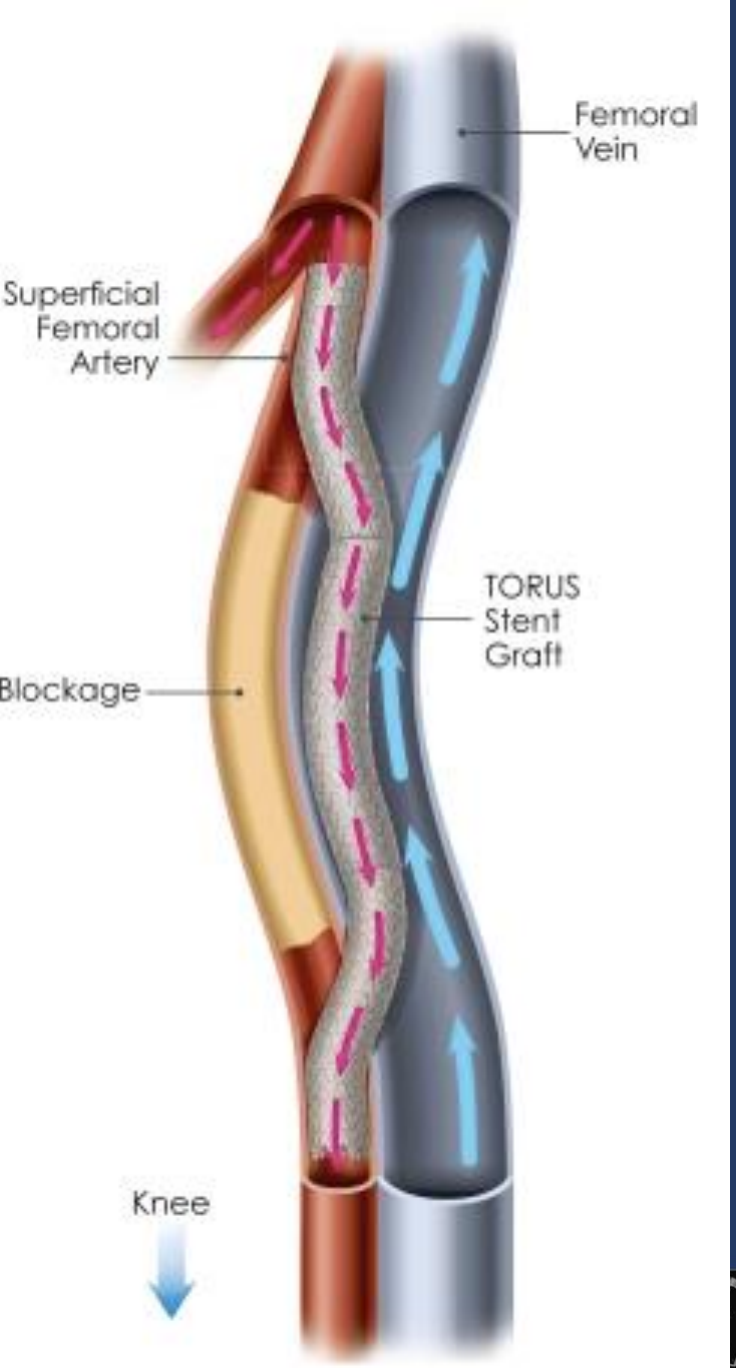
# DETOUR I study

Percutaneous treatment of femoropopliteal blockages with lengths of 25-45 cm (mean of 33.8 cm).

The six-month outcomes from 50 patients

- Primary safety endpoint: 2 percent MAEs – defined as death, target vessel revascularization (TVR) or amputation at 30 days. There were no deaths or amputations and one TVR
- Primary patency of 88.9 percent at six months with optimal placement, overall primary patency of 76.9 percent;
- Successful delivery of devices in 100 percent of lesions (53/53);
- Improvement in ABI: 0.64 to 0.92 ($p<0.0001$)
- No impact on venous function and no device-related deep vein thrombosis in treated vessels

PQ Bypass




# DETOUR II


- Prospective, single-arm clinical trial designed to evaluate the DETOUR™ System
- To enroll 292 patients at up to 40 centers in the U.S. and Europe
- Follow-up out to 36 months
- Includes a prospective economic study to collect quality-of-life outcome measures and cost data, including rehospitalizations

# Robots

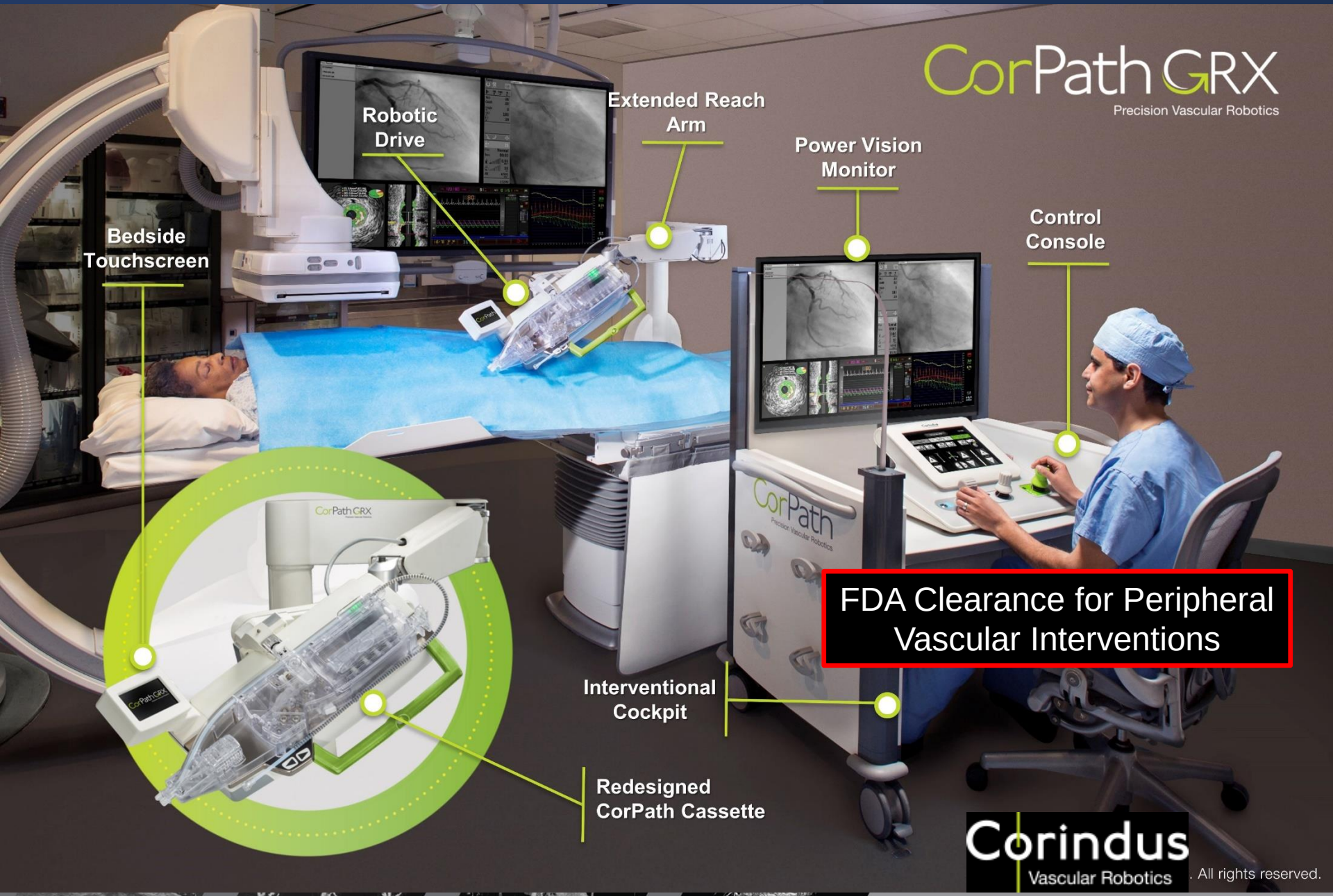
Pepper

# Robotics in the Hospital

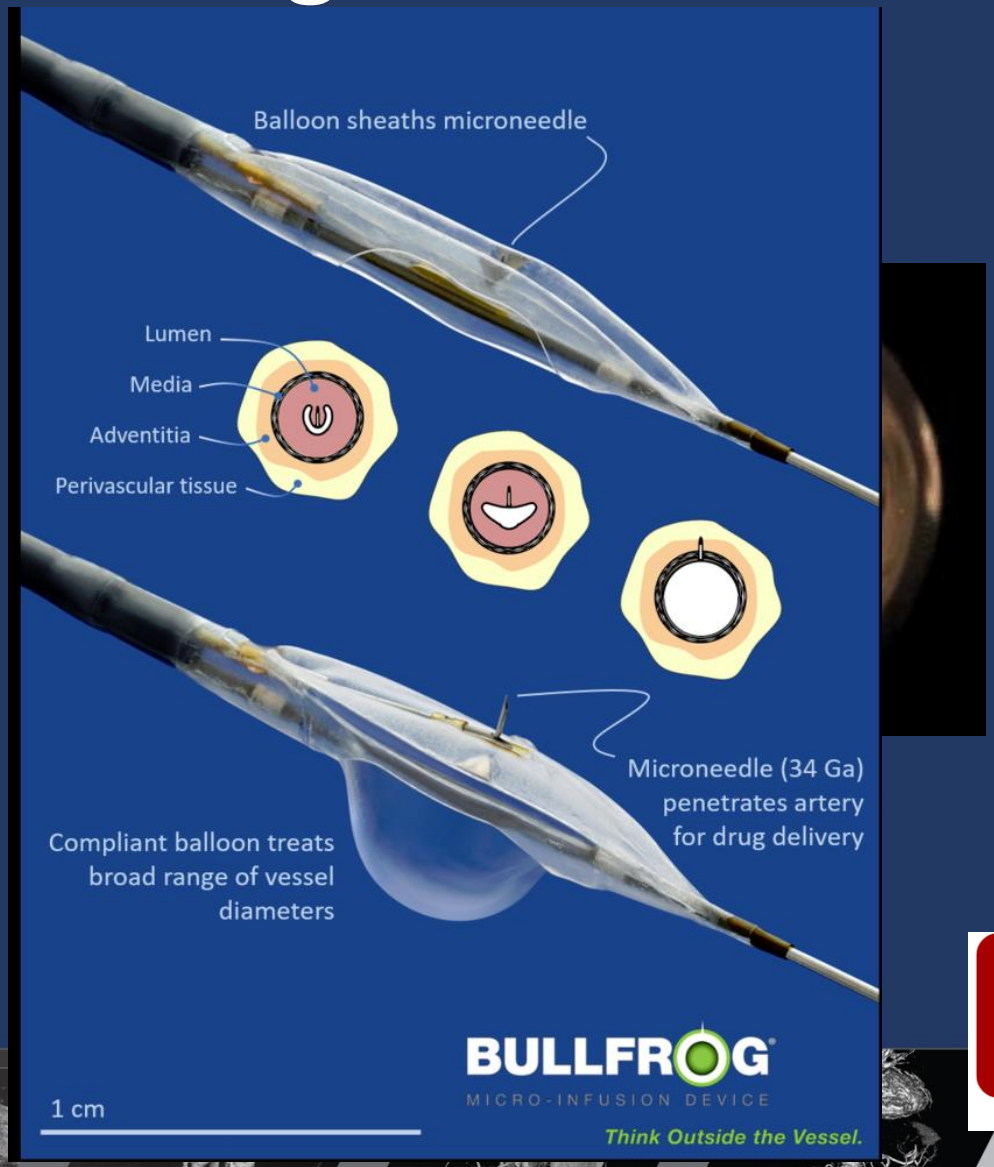
# Magellan Robotic System

hansen® MEDICAL
The Global Leader in Intravascular Robotics

- Provides precise steering of guide wires and robotic catheters in complex anatomy
- Physicians perform Magellan procedures while seated at a remote physician console, away from radiation



# Bullfrog® Micro-Infusion Device




Mercator MedSystems

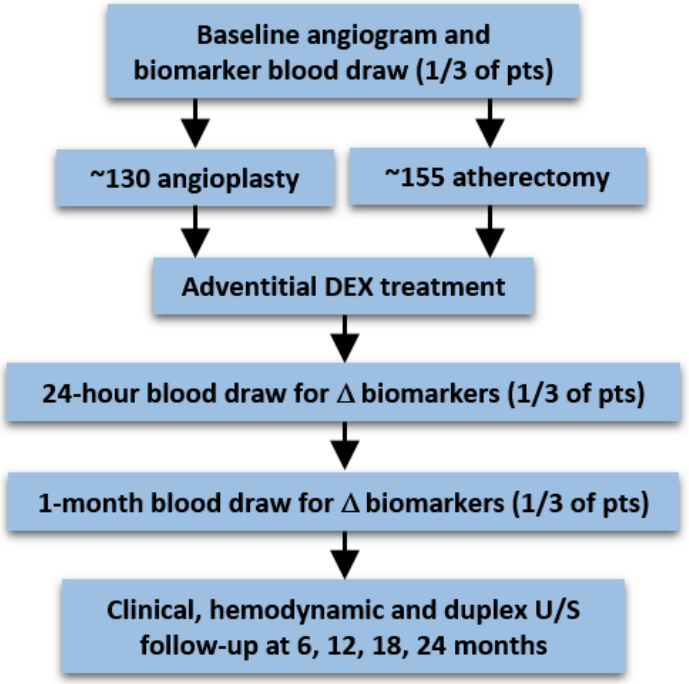
# DANCE

## Delivery of **D**examethasone to the **A**dventitia to e**N**hance **C**linical **E**fficacy after Femoropopliteal Revascularization

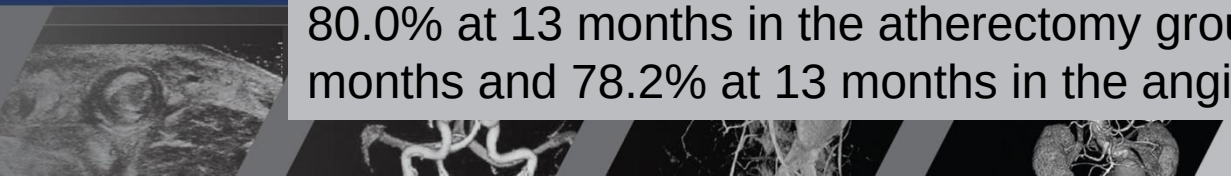
The DANCE trial (NCT01983449) will examine the ability for adventitial dexamethasone to safely delay restenosis in patients at least 18 years of age, who have peripheral atherosclerotic lesions involving the superficial femoral and/or popliteal arteries. These patients have no current therapeutic alternatives beyond the procedure used to open, or revascularize, their superficial femoral and/or popliteal arteries. Metal stents have the potential to fracture when implanted in this artery segment due to continual flexion and bending of the knee. It is desirable to improve the patency of this artery after percutaneous transluminal angioplasty (PTA) and/or atherectomy-based revascularization.

For more information, please contact clinicaltrials@mercatormed.com.

BULLFROG®
MICRO-INFUSION DEVICE
*Think Outside the Vessel.*




The primary patency was similar, with 83.6% at 12 months and 80.0% at 13 months in the atherectomy group and 80.2% at 12 months and 78.2% at 13 months in the angioplasty group.



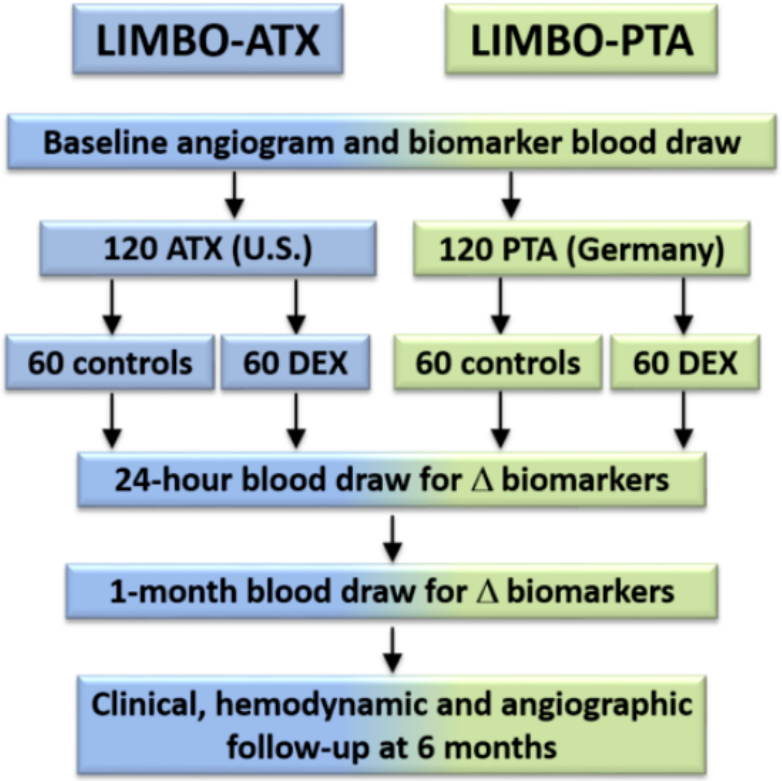
# LIMBO

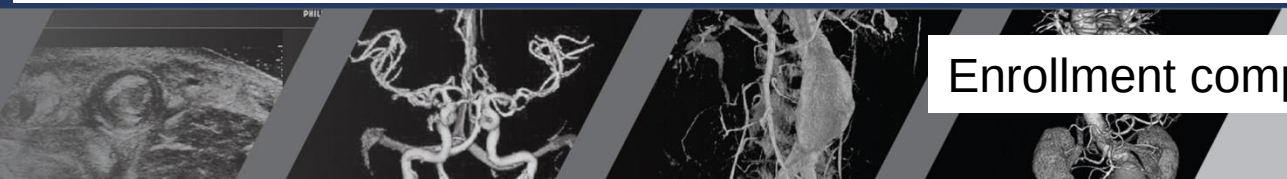
## **L**ower-Limb Adventitial **I**nfusion of Dexa**M**ethasone Via **B**ullfrog to Reduce **O**ccurrence of Restenosis

The LIMBO trials are two prospective, multi-center, randomized pilot studies to document the effects of adventitial delivery of dexamethasone sodium phosphate injection (4 mg/mL) after balloon angioplasty or atherectomy of lesions below the knee in symptomatic patients with critical limb ischemia (CLI). Up to 120 patients (60 treatment and 60 control), including up to 20 Rutherford 6 patients (10 treatment and 10 control) in Europe (LIMBO-PTA, NCT02479555) and up to 120 patients (60 treatment and 60 control), including up to 20 Rutherford 6 patients (10 treatment and 10 control) in the United States (LIMBO-ATX, NCT02479620) will be enrolled in the trials. This study will assess the safety and effectiveness of Bullfrog Micro-Infusion Device adventitial deposition of dexamethasone in reducing inflammation and restenosis in patients with clinical evidence of chronic critical limb ischemia with an angiographically significant lesion in the infrapopliteal crural vessels.

For more information, please contact clinicaltrials@mercatormed.com.

BULLFROG
MICRO-INFUSION DEVICE
*Think Outside the Vessel.*



Enrollment completed: October 30, 2017

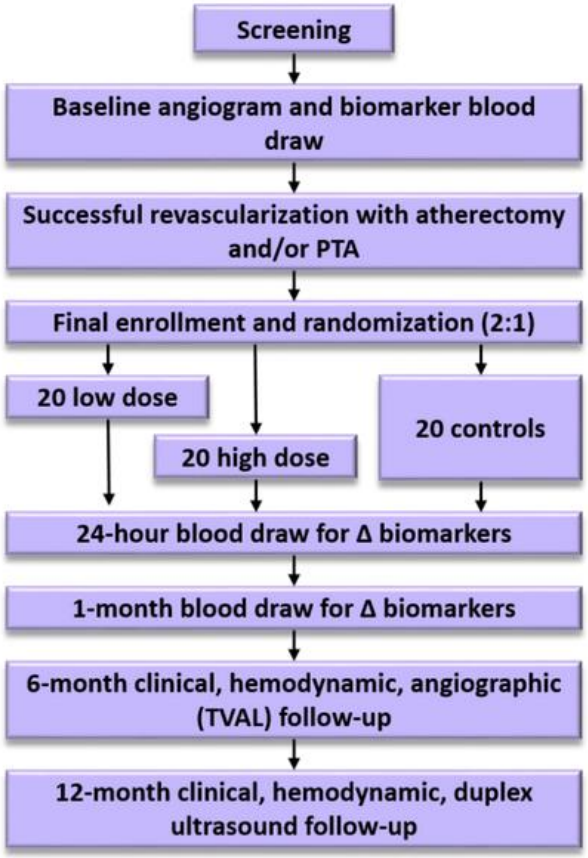
# TANGO

## **T**emsirolimus Adventitial Delivery to Improve **Ang**iographic **O**utcomes Below the Knee

The TANGO trial is a prospective, multi-center, randomized, dose escalation study to document the effects of adventitial delivery of TORISEL® (temsirolimus) after revascularization of lesions below the knee in symptomatic patients with critical limb ischemia (CLI). Up to 60 patients (20 low-dose, 20 high-dose and 20 control) will be enrolled at up to 15 sites in the United States. This study will assess the safety and effectiveness of Bullfrog® Micro-Infusion Device adventitial deposition of temsirolimus in reducing intimal hyperplasia, inflammatory markers and composite safety endpoints in patients with clinical evidence of chronic critical limb ischemia after revascularization of one or more angiographically significant lesion(s) in below-knee popliteal or tibial vessels.

For more information, please contact clinicaltrials@mercatormed.com.

BULLFROG®
MICRO-INFUSION DEVICE
*Think Outside the Vessel.*




# Percutaneous Deep Vein Arterialization

## The History

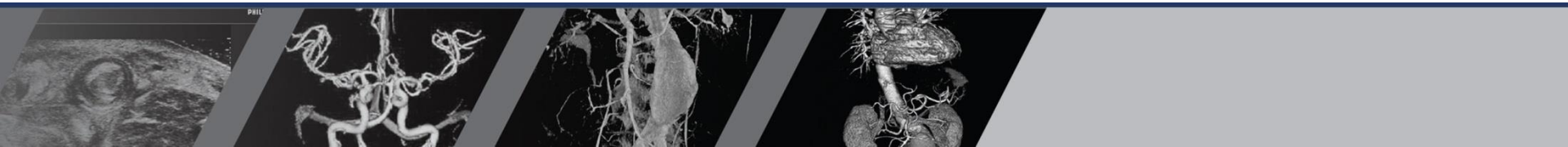
European Journal of Vascular & Endovascular Surgery
esvs Journal
Vol 31, May 2006

# Meta-analysis of the Clinical Effectiveness of Venous Arterialization for Salvage of Critically Ischaemic Limbs

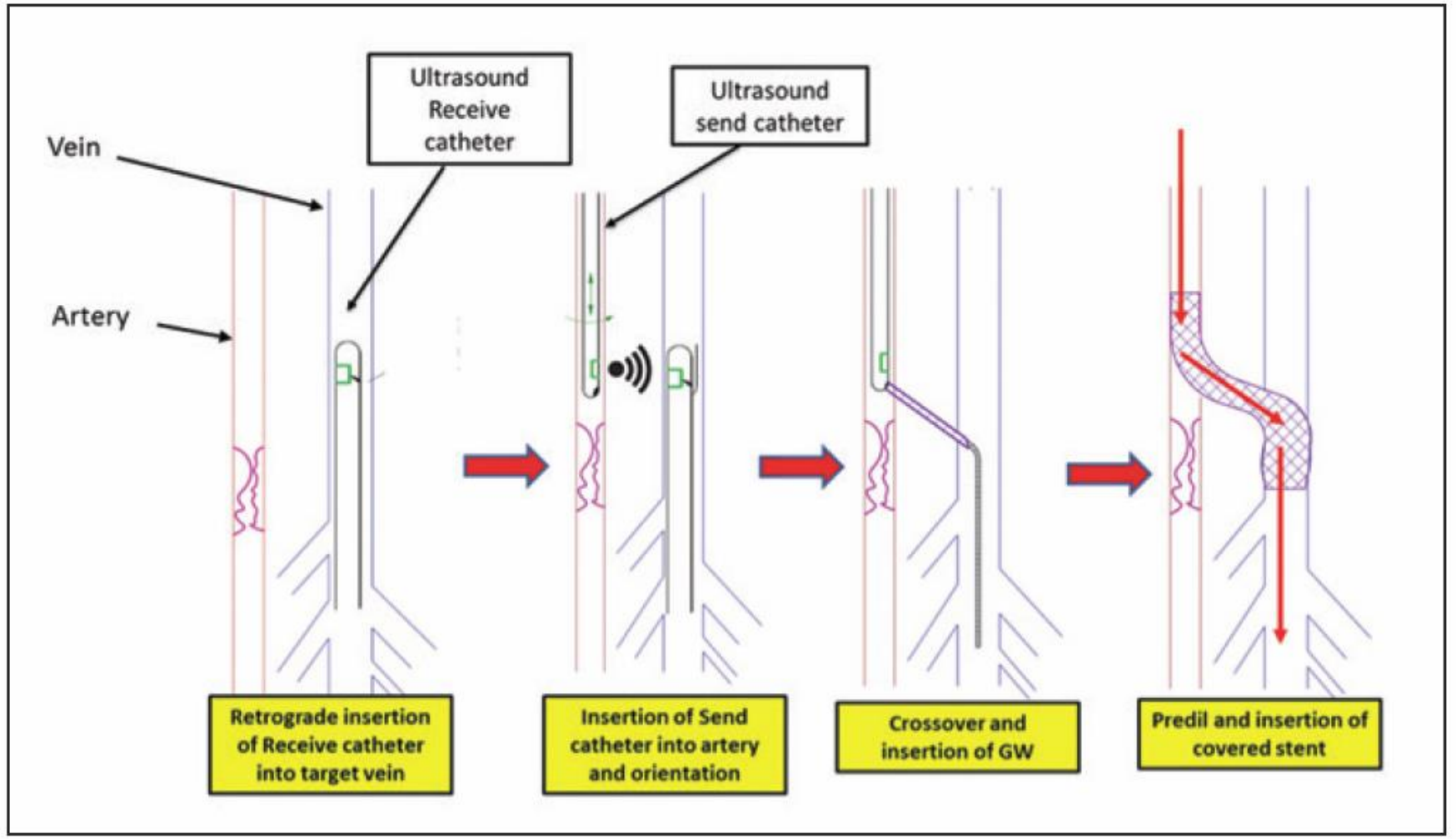
**X.W. Lu,[1] M.M. Idu,[1] D.T. Ubbink[1,2] and D.A. Legemate[1*]**

*Departments of [1]Surgery, and [2]Clinical Epidemiology and Biostatistics, Academic Medical Center, Amsterdam, The Netherlands*

***Objective***. *The aim of this study is to assess the clinical effectiveness of venous arterialization in patients with critical limb ischaemia not reconstructable by conventional bypass.*
***Design***. *Meta-analysis of observational studies.*
***Materials***. *Eligible studies concerning treatment by venous arterialization for chronic critical leg ischaemia were identified from electronic database, cross-reference search and pertinent articles. There was no language restriction.*
***Methods***. *All relevant studies were systematically reviewed and data extracted by two independent reviewers. Study endpoints were foot preservation, secondary graft patency, postoperative clinical improvement and complications.*
***Results***. *A total of 56 studies were selected for comprehensive review. No RCTs were identified. Seven patient series, comprising 228 patients, matched the selection criteria. Overall 1-year foot preservation was 71% (95% CI: 64–77%) and 1-year secondary patency was 46% (95% CI: 39–53%). The large majority of patients in whom major amputation was avoided experienced successful wound healing, disappearance of rest pain and absence of serious complications.*
***Conclusion***. *On the basis of limited evidence, venous arterialization may be considered as a viable alternative before major amputation is undertaken in patients with 'inoperable' chronic critical leg ischaemia.*



LimFlow
Transforming CLI




LimFlow

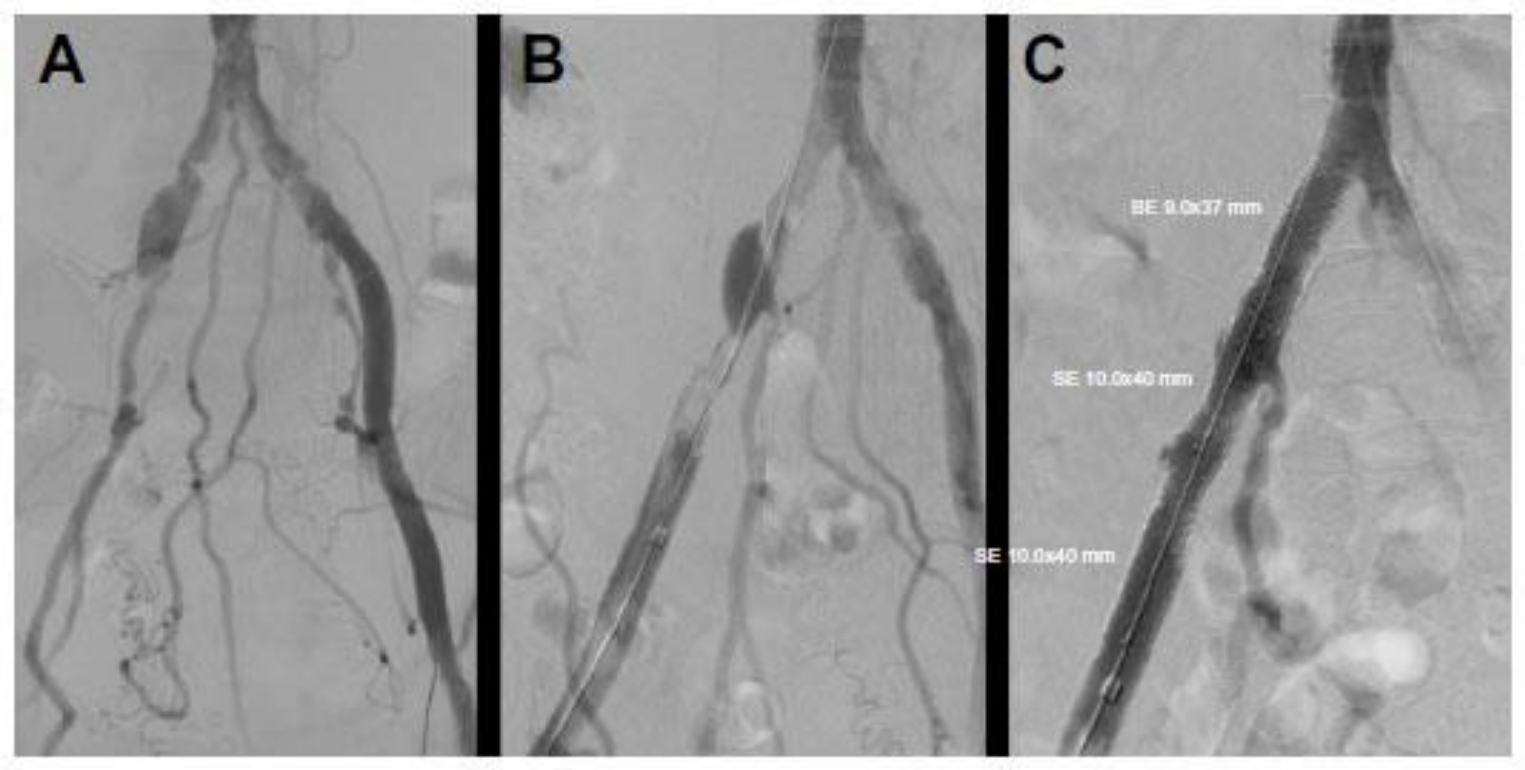
Transforming CLI

LimFlow

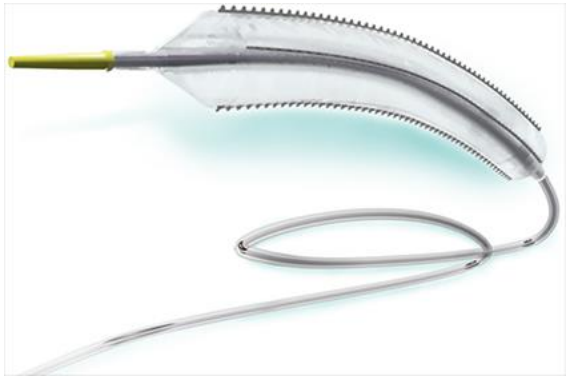
Transforming CLI

LimFlow
Transforming CLI

- PROMISE I - US feasibility study
  - multicenter, prospective, single-arm study that will enroll 10 patients with end-stage critical limb ischemia (CLI) at three centers in the US
- PROMISE International - international postmarket study

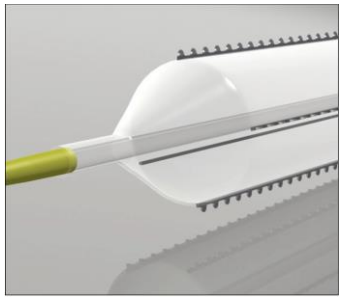



# The Next Problem: Arterial Dissection



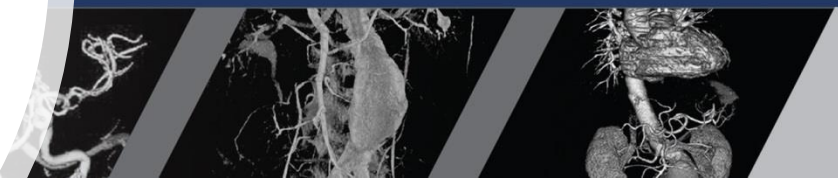
# Serranator

PTA Serration Balloon Catheter



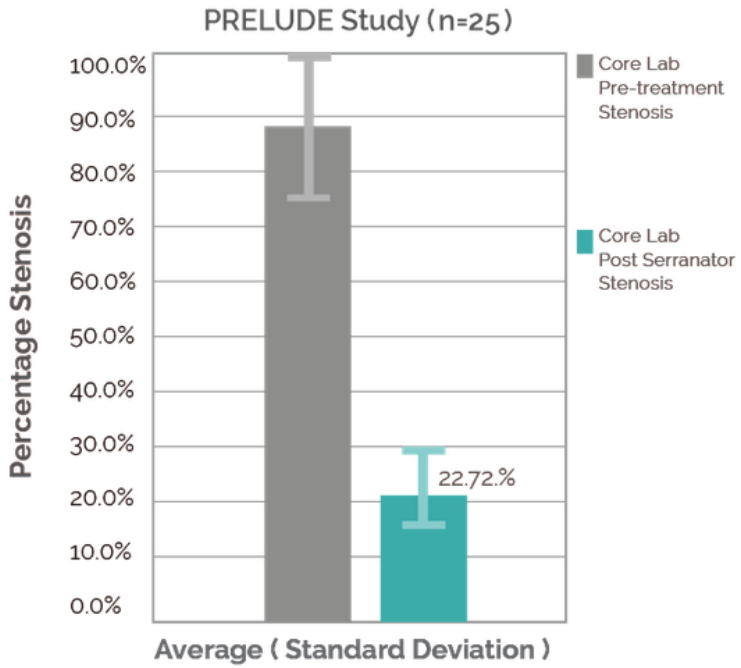
- Serrated balloon
- Designed to create linear interrupted lines of serration

CAGENT® VASCULAR



Serranator

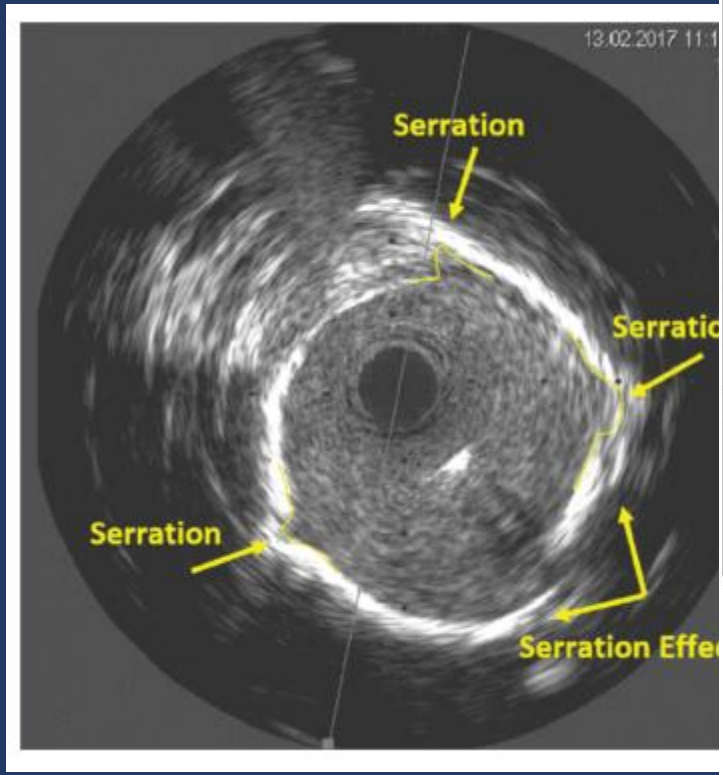
PTA Serration Balloon Catheter

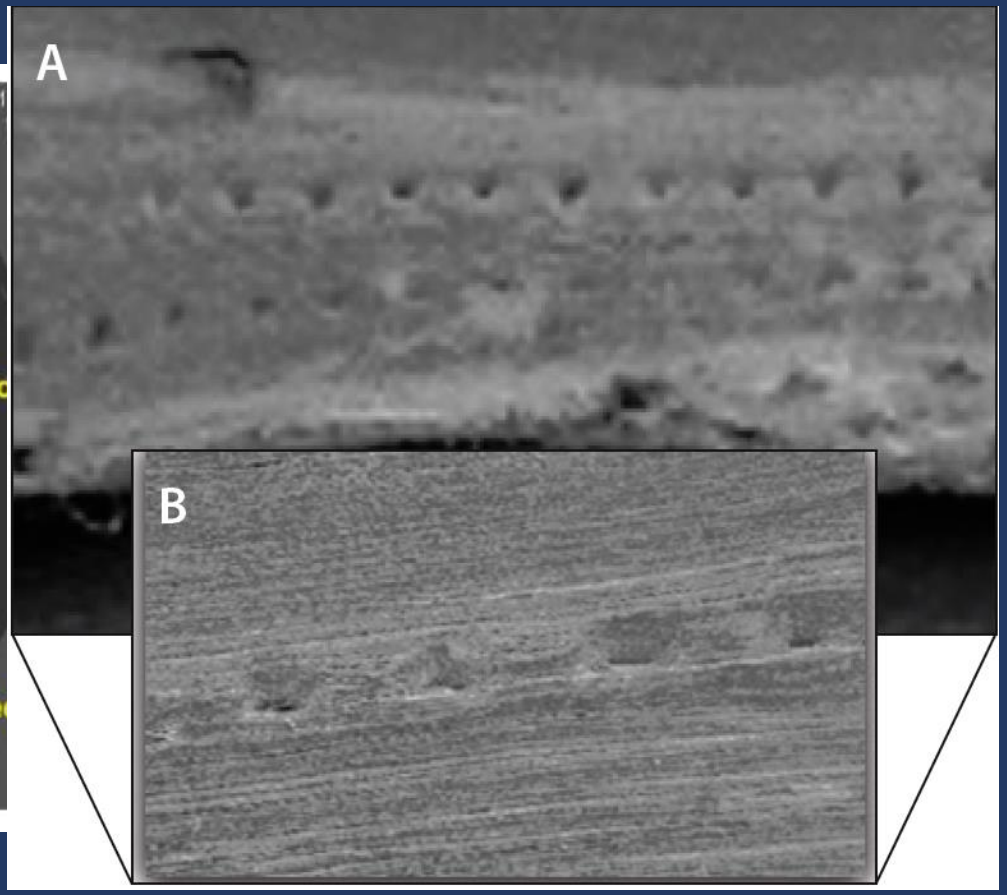



- PRELUDE Study – evaluate safety and efficiacy
- 25 patients in NZ and EU
- No dissections or bail-out stents
- 30 day patency – 100%

# Serranator

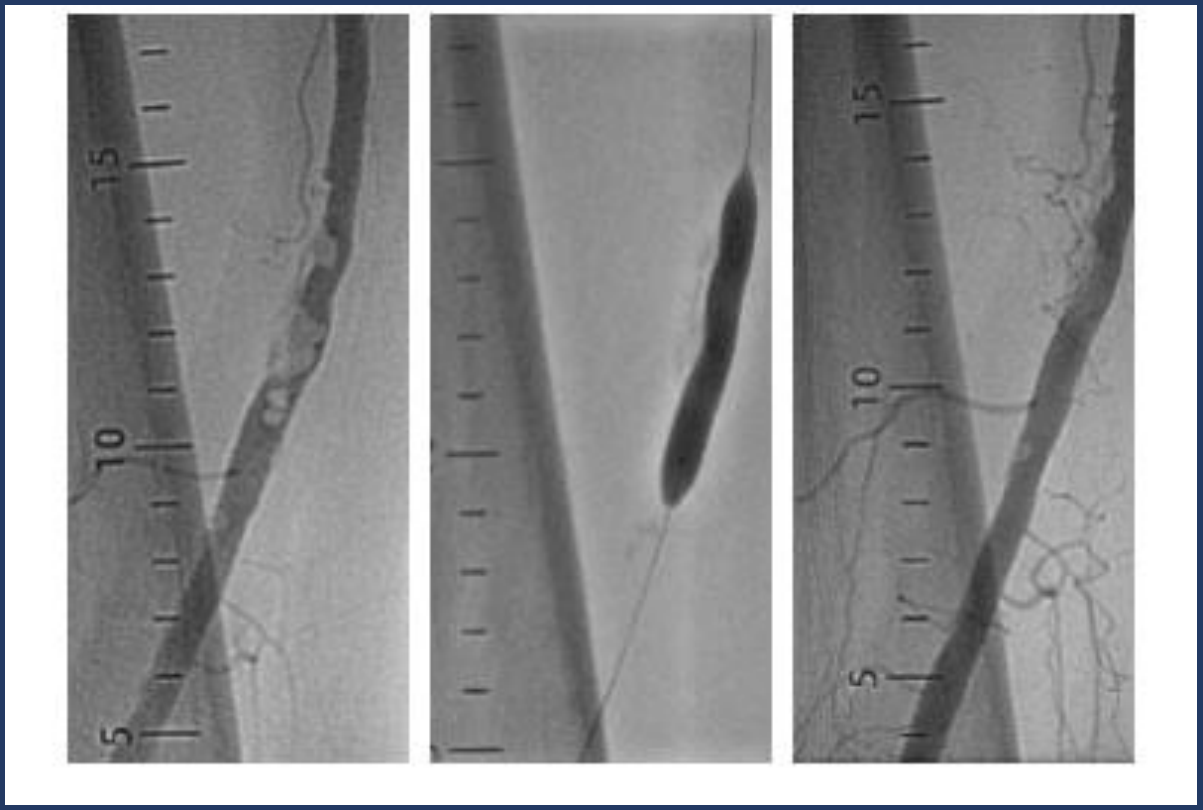
PTA Serration Balloon Catheter




Serranator

PTA Serration Balloon Catheter




- PRELUDE – BTK
  - Expected in 2018

# Conclusion


IF LANDING AN SUV ON MARS WASN'T COOL ENOUGH, HERE ARE
9 THINGS NASA
HAS HELPED BRING US
SATELLITE T.V.
CLEAR BRACES
WATER FILTERS
U.V. SUNGLASSES
HANG GLIDERS
ELECTRIC CAR BATTERIES
MEMORY FOAM
ATHLETIC SHOES
MODERN TIRES