The DETOUR Percutaneous Bypass Procedure for Patients with Long, Complex SFA Lesion

Patient Screening & Selection

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DETOUR 2 Trial National Co-Principal Investigator
Disclosure

Speaker name: Sean P. Lyden, MD

I have the following potential conflicts of interest to report:

- Consulting: PQ Bypass, Intact Vascular, Philips Medtronic, Boston Scientific, Endologix, Shockwave, VIVA Physicians

- Employment in industry

- Stockholder of a healthcare company

- Owner of a healthcare company

- Other(s)

- I do not have any potential conflict of interest
Existing Devices Designed for Shorter SFA Lesions, Deliver Sub-Optimal Results in Long SFA Lesions

Further confounded by complex morphologies: CTO, Ca++, ISR

LIMITED TREATMENT OPTIONS

~50% Patency at 12M
Percutaneous Femoropopliteal Bypass

Surgical principles using an endovascular approach

Originates in SFA, travels within the femoral vein, and returns to the popliteal artery

Femoral vein becomes pathway for stent graft bypass

Torus Stent Graft

PQ Snare

PQ Crossing
“Long” Lesion vs. a “DETOUR” Lesion
DETOUR I Lesion Distribution by Length
Independently adjudicated by Cleveland Clinic Core Laboratory

Lesion Distribution

97.5% > 25 cm
86.4% > 30 cm
71.6% > 35 cm
33.1% > 40 cm
DETOUR: Before
DETOUR: After
**DESIGN:** Prospective, single-arm, multi-center clinical evaluation of the DETOUR™ System and Procedure for Percutaneous Bypass

**INCLUSION CRITERIA:** De novo, CTO, or ISR femoropopliteal lesion

**INDEPENDENT REVIEW:** Core Lab (DUS, CT, Angio) by Cleveland Clinic; Clinical Events Committee by Syntactx

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202 evaluable subjects across 40 centers in US and Europe

Follow up at 30D, 6M, 12M, 24M, 36M

Primary Safety: MAE at 30D (Death, TLR, Amputation, DVT)

Primary Efficacy: Primary Patency at 12M (PSVR \( \leq 2.5 \)) with no TLR

STATUS: Ongoing U.S. IDE Clinical Trial (ClinicalTrials.gov identifier: NCT03119233)
Key Inclusion Criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Requirements</th>
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<tbody>
<tr>
<td>Rutherford Classification</td>
<td>3 - 5</td>
</tr>
<tr>
<td>Venous Clinical Severity Score</td>
<td>&lt; 3</td>
</tr>
<tr>
<td>Femoral Vein Diameter</td>
<td>&gt; 1cm or duplicate</td>
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<tr>
<td>TASC Classification</td>
<td>TASC D and Complex C</td>
</tr>
<tr>
<td>Lesion Length</td>
<td>&gt;20 cm</td>
</tr>
<tr>
<td>Lesion Diameter</td>
<td>4.5mm - 6.7 mm</td>
</tr>
<tr>
<td>Vessel runoff</td>
<td>≥ 1</td>
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Key exclusion criteria: history of DVT, Stent within 3cm of SFA ostium, Known hypersensitivity/allergy to the investigational devices and/or required pharmacotherapy
Anatomic Criteria

- Access
  - Inflow – Assess or Treat
  - CFA
- Arterial Diameter
- Lesion Length
- Landing Zone - Popliteal Diameter
- Outflow
- Runoff
- Venous Verification

- Inflow lesions (treated if >50%)
- Patent iliac and femoral arteries of sufficient size and morphology for 8F sheath
- Visible stump
- Lesion length
- Popliteal diameter/disease
- ≥1 Run-off vessel

- FV ≥ 10 mm or Duplicate Vein
CASE STUDY

Female, 68 yo, Right Leg
Rutherford 3 at Baseline
TASC II D lesion
Lesion length 35.6 cm
CTO length of 21.0 cm
Inflow Lesion - Right

**Lesion Length**: 32.1 CM

**PFA Origin**:  

**CFA**:  

![Lesion Image](image1.jpg)

![PFA Origin Image](image2.jpg)

![CFA Image](image3.jpg)
Right (Target Lesion) Inflow
Right Inflow Disease
Landing Zone - Right

Largest Dia 4.4 mm

3 cm between lines

4.1 mm

3.5 mm

Po Kylie diameters

2.8 mm
Right Runoff = 2
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