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OffRoad Re-entry Catheter System for Subintimal Recanalization of Chronic Total Occlusions in Femoropopliteal Arteries

Primary Safety and Efficacy Results of the Re-ROUTE Trial

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Disclosure slide

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☐ I have the following potential conflicts of interest to report:
   - ☐ Consulting
   - ☐ Employment in industry
   - ☐ Stockholder of a healthcare company
   - ☐ Owner of a healthcare company
   - ☐ Other(s)

☐ I do not have any potential conflict of interest
Subintimal Approach to Chronic Total Occlusions

- Chronic total occlusions (CTOs) are common in peripheral vascular disease.
- Subintimal angioplasty is an option for CTOs that cannot be crossed with conventional intraluminal approaches.
- Failure to advance a guidewire into the true lumen is the main cause of subintimal procedure failure\(^1\)-\(^3\).
- Re-entry devices are intended to access the true lumen and contribute to procedure technical success.

OffRoad Re-Entry Catheter System

• Positioning Balloon Catheter
  – Over-the-wire
  – Tipless shape and flexible neck for natural movement into the true lumen

• Microcatheter Lancet
  – Single-lumen hypotube catheter with a lancet tip
  – Advanced coaxially in the inner lumen of the Positioning Balloon Catheter

**OffRoad System Components**

<table>
<thead>
<tr>
<th>Component</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nominal balloon diameter</td>
<td>5.4 mm</td>
</tr>
<tr>
<td>Nominal inflation pressure</td>
<td>2 atm</td>
</tr>
<tr>
<td>Radiopaque marker</td>
<td>Within balloon body</td>
</tr>
<tr>
<td>Guide sheath diameter</td>
<td>6F</td>
</tr>
<tr>
<td>Recommended guidewire</td>
<td>≤0.035 in (balloon)</td>
</tr>
<tr>
<td></td>
<td>≤0.014 in (lancet)</td>
</tr>
</tbody>
</table>

• Intended to facilitate the placement and positioning of guidewires within the peripheral vasculature

• Available for commercial use in Europe and Canada
The Re-ROUTE Trial

- Prospective, single-arm, non-randomized, multicenter (Europe and Canada), post-market study
- Assess safety rates and device technical success of the OffRoad Re-entry Catheter System for subintimal recanalization of *de novo* or re-occluded CTOs in native femoropopliteal arteries
Re-ROUTE Trial

Eligibility Screening

• Claudication or critical limb ischemia (Rutherford Category 2-5)
• Age ≥18 years
• Informed consent

Index Procedure

Clinically successful treatment of non-target lesion, if applicable

Target Vessel Angiogram

Angiographic inclusion criteria:
• De novo or re-occluded CTO in native femoropopliteal artery
• Occlusion length 1-30 cm
• Vessel diameter ≥4 mm
• Distal vessel visualization
• (collateral supply)

Angiographic exclusion criteria:
• Thrombus or intraluminal filling defects
• Occlusion in a stent
• Target lesion within/near an aneurysm
• Perforated vessel
• Heavily calcified lesion

OffRoad introduced to treat the target lesion (enrollment)

30-Day Follow-up

• Rutherford Category assessment
• Duplex ultrasound, if applicable
**Re-ROUTE Trial Endpoints**

**Primary Safety**
- Device-related MAEs through 30 days following the index procedure
  - Death
  - Perforation requiring intervention
  - Clinically significant peripheral embolism
  - Major amputation
- Adjudicated by clinical events committee
- Performance goal of 15% MAE rate

**Primary Effectiveness**
- Device technical success
  - Placement of a guidewire in the true lumen distal to the CTO
- Performance goal of 76% technical success rate

*MAE = major adverse event*
Re-ROUTE Subject Disposition

Eligibility Screening (N = 108)
- Inclusion criteria not met (n = 5)
- Exclusion criteria met (n = 5)
- Other treatment chosen (n = 4)
- Other (n = 2)

Index Procedure/Enrolled (N= 92)
- Died (n = 1)*
- Withdrew (n = 4)

30-Day Follow-up Visit (N = 87)
Evaluable for 30- day MAE** (N = 90)

* Subject died 15 days after the procedure due to cholecystitis. The Clinical Events Committee determined that this death was not related to the study device.

** Follow-up ≥23 days or had an event within 30 days.

MAE = major adverse event
## Baseline Patient Characteristics

### Demographic Characteristics (N = 92)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean ± SD</td>
<td>70.29 ± 10.56</td>
</tr>
<tr>
<td>Male gender</td>
<td>69.6%</td>
</tr>
<tr>
<td>Caucasian race</td>
<td>98.9%</td>
</tr>
</tbody>
</table>

### General Medical History (N = 92)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of smoking</td>
<td>77.2%</td>
</tr>
<tr>
<td>Current diabetes mellitus</td>
<td>51.1%</td>
</tr>
<tr>
<td>History of hyperlipidemia requiring medication</td>
<td>66.3%</td>
</tr>
<tr>
<td>History of hypertension requiring medication</td>
<td>81.5%</td>
</tr>
<tr>
<td>History of chronic obstructive pulmonary disease (COPD)</td>
<td>9.8%</td>
</tr>
<tr>
<td>History of renal insufficiency</td>
<td>19.6%</td>
</tr>
</tbody>
</table>
## Cardiovascular History

<table>
<thead>
<tr>
<th>Cardiovascular History (N = 92)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>History of coronary artery disease (CAD)</td>
<td>32.6%</td>
</tr>
<tr>
<td>History of myocardial infarction</td>
<td>17.4%</td>
</tr>
<tr>
<td>History of chronic heart failure (CHF)</td>
<td>6.5%</td>
</tr>
<tr>
<td>History of percutaneous coronary intervention (PCI)</td>
<td>17.4%</td>
</tr>
<tr>
<td>History of coronary artery bypass graft (CABG)</td>
<td>5.4%</td>
</tr>
<tr>
<td>History of cerebrovascular accident</td>
<td>12.0%</td>
</tr>
<tr>
<td>History of other peripheral interventions</td>
<td>43.5%</td>
</tr>
<tr>
<td>History of claudication</td>
<td>89.1%</td>
</tr>
</tbody>
</table>
## Lesion Characteristics

<table>
<thead>
<tr>
<th>Baseline Lesion Characteristics (N = 92)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference vessel diameter (mm)</td>
<td>5.18 ± 0.62</td>
</tr>
<tr>
<td>% Occluded</td>
<td>100.00 ± 0.00</td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td>175.12 ± 85.42</td>
</tr>
<tr>
<td>Calcification</td>
<td></td>
</tr>
<tr>
<td>None/mild</td>
<td>46.7%</td>
</tr>
<tr>
<td>Moderate</td>
<td>47.8%</td>
</tr>
<tr>
<td>Severe</td>
<td>5.4%</td>
</tr>
<tr>
<td>Primary diagnosis</td>
<td></td>
</tr>
<tr>
<td>Claudication</td>
<td>84.8%</td>
</tr>
<tr>
<td>Critical limb ischemia</td>
<td>15.2%</td>
</tr>
</tbody>
</table>
Case 2046-07 presentation

- 71 year-old female
- Vascular risk factor: nicotine abuse
- Current status:
  R2 bilateral
  Pulsations only femoral, no distal
  ABI 0.7
  CFDU: ostial-SFA occlusion
  MRI

Ostial 180mm occlusion right SFA

Abnormal origin ant. tibial artery

Normal inflow

10/2012
Case 2046-07: Ostial 180mm CTO of SFA (mild calicification, RVD 4.5 mm)
Subintimal recanalization until intended re-entry

Placement Offroad balloon catheter

Positioning Offroad and advancing microcatheter lance and GW
PTA 4 x 60

Final angiogram after PTA
Re-ROUTE Primary Endpoint Results

- **Primary Safety Endpoint Met**
  - 3.3% composite rate of device-related MAEs at 30 days
  - The 3 events were clinically significant peripheral emboli
  - Upper confidence bound MAE rate (6.5%) less than the performance goal of 15%

- **Primary Effectiveness Endpoint Met**
  - Site-reported technical success (lumen re-entry) 84.8% (78/92)
  - Lower confidence bound for site-reported technical success (78.6%) exceeded the performance goal of 76%
Re-ROUTE Symptom Outcomes

- Rutherford Assessments
  - 75% of subjects decreased ≥1 category at 30 days post-procedure
  - Range shifted from categories 2-5 at baseline to 0-5 at 30 days
CONCLUSION

The Re-ROUTE results demonstrate that the OffRoad System is a safe and effective treatment option for recanalization of femoropopliteal CTOs