2-Year Results of Paclitaxel-Coated Balloons for Long Femoropopliteal Artery Disease:

Evidence From the SFA-Long Study

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Disclosure

Speaker name:
Antonio Micari

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
Hypothesis

Drug-Eluting Balloons reduce femoro-popliteal restenosis as alternative to Stenting for the treatment of long femoro-popliteal arterial disease in patients with claudication and rest pain.

**IN.PACT™ ADMIRAL™ - Medtronic**

- OTW / 0.035” gw compatible
- 4.0 – 7.0 mm balloon diameter range
- 40, 60, 80, 120, 150 mm balloon lengths

**Freepac™**

- Proprietary hydrophilic drug coating formulation
Key Patient Selection Criteria

**Inclusions**
- RC 2-3-4
- Reference vessel diameter 4 - 7 mm
- Lesions and/or occlusions > 15 cm
- ≥ 1 crural vessel run-off either pre-existing or successfully established
- Adequate in-flow

**Exclusions**
- In Stent restenosis
- Aneurism in the target vessel
- Acute thrombus in the target limb
- Failure to cross the Target Lesion with a guide wire
- Use of alternative therapies (e.g. atherectomy, cutting balloon, laser, radiation therapy, cryoplasty,...)
Independent adjudication by
Angiographic and Duplex Core Labs
Clinical Event Committee

Data Monitoring with 100% source data verification
Endpoints

Primary Endpoint:
The rate of primary patency within 12 months post-index procedure

Primary patency is defined as freedom from the combined endpoints of clinically-driven target lesion revascularization (TLR) and >50% restenosis in the treated lesion.

Clinically-driven TLR is defined as any re-intervention within the target lesion due to symptoms or drop of ABI of ≥20% or >0.15 when compared to post-procedure.

Restenosis > 50% is defined by a peak systolic velocity ratio (PSVR) > 2.4

Secondary Endpoints:
- Composite of all Major Adverse Events (MAE) through 24 months (i.e. first occurrence of any of the following):
  - Death from any cause
  - Major target limb amputation
  - Thrombosis at the target lesion site
  - Non-target lesion target vessel revascularization
- Incidence of MAE individual components through 24 months
- Clinical improvement as assessed by Rutherford Class changes at 6, 12, and 24 months with respect to baseline
# Baseline Characteristics

## Clinical Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N = 105</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, Y ± SD</td>
<td>68.03 ± 9.26</td>
</tr>
<tr>
<td>Male, % (n)</td>
<td>81.9% (86)</td>
</tr>
<tr>
<td>Hypertension, % (n)</td>
<td>88.6% (93)</td>
</tr>
<tr>
<td>Hyperlipidemia, % (n)</td>
<td>78.1% (82)</td>
</tr>
<tr>
<td>Diabetes, % (n)</td>
<td>57.2% (60)</td>
</tr>
<tr>
<td>Current smoker, % (n)</td>
<td>68.6% (72)</td>
</tr>
<tr>
<td>Renal failure, % (n)</td>
<td>16.2% (17)</td>
</tr>
<tr>
<td>Coronary artery disease, % (n)</td>
<td>55.2% (58)</td>
</tr>
<tr>
<td>Previous peripheral revascularization, % (n)</td>
<td>47.6% (50)</td>
</tr>
<tr>
<td>Previous SFA revascularization, % (n)</td>
<td>38.1% (40)</td>
</tr>
</tbody>
</table>

## Rutherford class, % (n)

<table>
<thead>
<tr>
<th>Class</th>
<th>% (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 or 1</td>
<td>0% (0)</td>
</tr>
<tr>
<td>2</td>
<td>27.6% (29)</td>
</tr>
<tr>
<td>3</td>
<td>61.9% (65)</td>
</tr>
<tr>
<td>4</td>
<td>8.6% (9)</td>
</tr>
<tr>
<td>5*</td>
<td>1.9% (2)</td>
</tr>
<tr>
<td>6</td>
<td>0% (0)</td>
</tr>
</tbody>
</table>

* Protocol Deviations

## Lesion Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N = 105</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion Type</td>
<td></td>
</tr>
<tr>
<td>De novo</td>
<td>91.4%</td>
</tr>
<tr>
<td>Restenotic</td>
<td>8.6%</td>
</tr>
<tr>
<td>Calcification</td>
<td></td>
</tr>
<tr>
<td>None or slight</td>
<td>37.1% (39)</td>
</tr>
<tr>
<td>Moderate</td>
<td>37.1% (39)</td>
</tr>
<tr>
<td>Severe</td>
<td>13.3% (14)</td>
</tr>
<tr>
<td>Lesion Length (mm)</td>
<td>251.71 ± 78.9</td>
</tr>
<tr>
<td>Reference Vessel Diameter</td>
<td>5.1 ± 0.5</td>
</tr>
<tr>
<td>Diameter Stenosis, %</td>
<td>93.7 ± 8.4</td>
</tr>
<tr>
<td>Total Occlusion</td>
<td>49.5% (52)</td>
</tr>
<tr>
<td>Inflow disease</td>
<td>13.3% (14)</td>
</tr>
<tr>
<td>Outflow disease</td>
<td>40% (42)</td>
</tr>
</tbody>
</table>

* Protocol Deviations
Freedom from Composite Endpoint (TLR or >50% Restenosis)
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Occlusive vs. Stenotic Lesions

Log-Rank $P = .42$

Days to Primary Patency
Freedom from Composite Endpoint (TLR or >50% Restenosis)

Long vs. Very Long (>25 cm) Lesions

Log-Rank $P = .25$

Days to Primary Patency

% freedom from composite endpoint ± SE

Long lesions (<25 cm)

Very long lesions (≥25 cm)
Rutherford Clinical Category Through 24 Months

- Rutherford 0: 59 (Pre-procedure), 51 (12-month FU), 28 (24-month FU)
- Rutherford 1: 0 (Pre-procedure), 18 (12-month FU), 12 (24-month FU)
- Rutherford 2: 0 (Pre-procedure), 12 (12-month FU), 28 (24-month FU)
- Rutherford 3: 62 (Pre-procedure), 11 (12-month FU), 10 (24-month FU)
- Rutherford 4: 3 (Pre-procedure), 13 (12-month FU), 9 (24-month FU)
- Rutherford 5: 0 (Pre-procedure), 0 (12-month FU), 2 (24-month FU)
Conclusions

- To our knowledge, this is the first study focused on the use of DEB in very long SFA lesions with outcome data through 24 months.

- Strong 2-year results support the safety and usefulness of the IN.PACT Admiral PCB technology in achieving a good primary patency rate and in limiting the need for clinically-driven revascularizations.

- Instrumental results are corroborated by good maintenance of clinical benefit.
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