**Objective**
To prove the superior performance of the Ranger™ paclitaxel-coated PTA balloon catheter (Boston Scientific) for angioplasty for femoropopliteal artery lesions when compared to non-coated balloons.

**Trial Design**
Prospective, multicenter, randomized, controlled trial (2:1 Ranger DCB vs. non-drug-coated balloon). Follow up through 3 years.

**Key Enrollment Criteria**
- Rutherford 2, 3 or 4
- Stenotic, restenotic or occlusive lesions (≥70% stenosis) in the native non-stented SFA/PPA
- No prior treatment with drug coated balloons or drug-eluting stents in the treated limb
- Lesion length ≥20 mm and ≤150 mm

**Key Baseline Lesion Characteristics**
<table>
<thead>
<tr>
<th></th>
<th>PTA (34)</th>
<th>Ranger DCB (71)</th>
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</thead>
<tbody>
<tr>
<td>Target Lesion Length (mm)</td>
<td>60 ± 48</td>
<td>68 ± 46</td>
</tr>
<tr>
<td>Reference Vessel Diameter (mm)</td>
<td>4.5 ± 0.83</td>
<td>5 ± 0.89</td>
</tr>
<tr>
<td>Percent Diameter Stenosis (%)</td>
<td>82 ± 18</td>
<td>85 ± 15</td>
</tr>
<tr>
<td>Total Occlusions (%)</td>
<td>34</td>
<td>34</td>
</tr>
</tbody>
</table>

**12 Month Outcome**

**Patency**
- Ranger achieved an 86% primary patency at 12 months (patent by DUS and without reintervention)
- Ranger demonstrated primary patency superior* to PTA

**Freedom from TLR**
- Ranger achieved a 91% Freedom from TLR at 12 months
- Ranger demonstrated Freedom from TLR superior* to PTA

* p<0.001 log rank test, Kaplan-Meier Analysis

Presented by Prof. Scheinert, Charing Cross - 2017
Conclusions

- Greater patency rate at 12 months for Ranger DCB than Control (86% vs 56%)
- Freedom from TLR greater for Ranger DCB than Control at 12 months (91% vs 70%)
- Patients treated with Ranger DCB demonstrated significant improvements in symptoms and hemodynamics at 12 months
  - Symptomatic improvement generally similar to Control but with ~1/3 as many revascularizations

**Patient Outcomes**

Rutherford score

- 84% of Ranger subjects had no or mild symptoms - Rutherford category 0 or 1
- Compared to baseline, Ranger and PTA groups both showed improvement in Rutherford score and ABI

**Primary Patency at 12 months from DCB trials of the SFA**

- **ILLUMENATE**
  - 89.5% ±
- **RANGER SFA**
  - 86.0% ±
- **IN.PACT SFA**
  - 56.0% ±
- **LEVANT 2**
  - 52.4% ±
- **LEVANT 1**
  - 56.8% ±
- **DCB**: 67.0% ±
- **Control**: 55.0% ±

**TLR at 12 months from DCB trials of the SFA**

- **IN.PACT SFA**
  - 2% ±
- **PACIFIER**
  - 21% ±
- **RANGER SFA**
  - 7% ±
- **ILLUMENATE**
  - 28% ±
- **LEVANT 2**
  - 26% ±
- **LEVANT 1**
  - 12% ±
- **DCB**: 42% ±
- **Control**: 29% ±

**References**


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Ranger™ Paclitaxel Coated PTA Balloon Catheter is manufactured by Hemotec AG and distributed by Boston Scientific Corporation.

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