1-Year Results With The Ranger DCB (Boston Scientific) For The Treatment Of Fem-Pop Lesions: Equivalent Benefits In Diabetic Patients And 12-Month All Comer Registry Data

(on behalf of Dr M. Lichtenberg)

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Department of Angiology
University-Hospital Leipzig, Germany

Next Generation DCB:
Boston Scientific Ranger™

- Sterling balloon Ranger™
- TransPax™ coating technology
  - Paclitaxel 2 µg/mm²
- Ranger™ DCB Loading Tool
  - Designed to protect the drug coating
- Size matrix:
  - SFA: 4-8 mm; 30-200 mm
  - BTK: 2-4 mm; up to 150 mm

Ranger-SFA Study

Clinical Study Overview: Ranger

<table>
<thead>
<tr>
<th>Name</th>
<th>Ranger SFA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Investigator</td>
<td>Dierk Scheinert, MD</td>
</tr>
<tr>
<td>Study Sponsor</td>
<td>Hemoteq AG (Würselen, Germany)</td>
</tr>
<tr>
<td>Study Device</td>
<td>Ranger™ Paclitaxel-Coated PTA Balloon Catheter</td>
</tr>
<tr>
<td>Sizes available for the RANGER SFA study</td>
<td>4-7 mm diameter; 40-100 mm length</td>
</tr>
<tr>
<td>Study Design</td>
<td>Prospective, randomized, multicenter, controlled trial (2:1 Ranger DCB vs. uncoated balloon)</td>
</tr>
<tr>
<td>Subjects</td>
<td>105 patients with femoropopliteal artery lesions (Rutherford 2-4, lesion length 20 mm – 150 mm)</td>
</tr>
<tr>
<td>Investigational Centers</td>
<td>10 sites (Germany, France, and Austria)</td>
</tr>
</tbody>
</table>

Endpoints

- Primary endpoint:
  - In-segment late lumen loss of the treated segment, as observed by angiography at six months post-procedure
- Secondary Endpoints:
  - Restenosis and patency rates
  - Rutherford classification / clinical success
  - Ankle-brachial index / hemodynamic success
  - Quality of life (WIQ, EQ5D, SF12)

Study follow-up complete through 12M

Ranger-SFA Study

Patient Enrollment & Follow-up

<table>
<thead>
<tr>
<th>105 patients treated at 10 study centers</th>
</tr>
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Ranger-SFA Study

Patient Characteristics

Baseline clinical characteristics similar between Ranger and control groups

DISCLOSURE STATEMENT OF FINANCIAL INTEREST

Speaker’s name: Dierk Scheinert

I have the following potential conflicts of interest to report:

Advisory Board /Consultant:
- Abbott, Biotronik, Boston Scientific, Cook
- Medical, Cordis, CR Bard, Gardia
- Medical/Allium, Medtronic, TriReme Medical, Trivascular, Upstream Peripheral Technologies

Disclosure: Speaker’s name: Dierk Scheinert
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### Ranger-SFA Study: Lesion (Core Lab) and Procedure Characteristics

**Similar lesion characteristics between Ranger and control groups**

<table>
<thead>
<tr>
<th>Lesion Characteristic</th>
<th>Ranger</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location</td>
<td>Proximal popliteal</td>
<td>Distal SFA</td>
</tr>
<tr>
<td>Diameter</td>
<td>4.5 ± 0.83</td>
<td>5 ± 0.89</td>
</tr>
<tr>
<td>Calcification</td>
<td>Severe</td>
<td>Moderate</td>
</tr>
<tr>
<td>Total occlusion</td>
<td>3.3</td>
<td>3.5</td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td>1.1 ± 0.26</td>
<td>1.2 ± 0.25</td>
</tr>
<tr>
<td>MLD (mm)</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>LLL (%)</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Change from post-op</td>
<td>1.0000</td>
<td>1.0000</td>
</tr>
</tbody>
</table>

**Freedom from TLR – 12 Months**

- **Primary Patency of lesion**
- **Technical success** without MAE within 24 hours
- **Post-op % diameter stenosis**

### Ranger-SFA Study: Primary Efficacy Endpoint – 6 Months

- **Primary endpoint was met**
- Kaplan Meier estimate of primary patency rate at 12 months:
  - 100% Ranger DCB vs 56% Control

### Ranger-SFA Study: Diabetic Patients – 12 Months

- **No target limb amputations**
- 1 death by 1 year of follow up among patients with diabetes (Ranger group); not related to the device or procedure

### Boston Scientific Global Pivotal Study: RANGER II SFA

- **Study Objective**: Balloon Angioplasty for the Treatment of Superficial Femoral Arteries (SFA) and Proximal Popliteal Arteries (PFA)
- **Study Design**: Prospective, multicenter, single-blind, superiority, RCT 3:1 (RANGER DCB : Standard PTA)
- **Subjects**: Up to 1150 patients in centers in Canada, Europe (Great Britain, Germany, Norway), Japan, New Zealand, and the USA
- **Duration**: Up to 5.5 years

**Primary Endpoints**
- **Freedom from TLR**
- **Primary Patency of lesion**
- **Technical success** without MAE within 24 hours
- **Post-op % diameter stenosis**

**Secondary Endpoints**
- **Primary efficacy endpoint (6 months)**
- **Late lumen loss**
- **Post-op % diameter stenosis**
- **Technical success** without MAE
RANGER II SFA

Study Flow

- Guidewire crosses target lesion
- Successful pre-dilation
- Obtain randomization code (3:1)
- Post-dilation per discretion
- Post-procedure & Pre-discharge Assessments

Signed ICF & Baseline Testing

Eligibility criteria met

Follow-up Evaluations
- Office: 1, 6, 12, 24, 36 Month FU
- Office / Phone: 48, 60 Month FU

Ranger SFA All Comer Registry

Clinical Study Overview: ARMED II-FA registry (Confirmatory)

Title
Ranger All-Comer Registry  Treatment of femoro-popliteal atherosclerotic lesions using the Drug eluting Balloon Ranger: An All Comers Registry

Primary Investigator / Sponsor
Michael Lichtenberg, MD – Germany
Klinikum Arnsberg - Germany

Centres
Germany (Dr. von Bilderling (Munich), Dr. Ranft, Dr. Niemöller (Bottrop), Dr. Grell (Trier) and Switzerland (Dr. Saucy, Lausanne)

Study Design
Multicentre, all comer registry

Subjects
Planned 180 patients

Key Inclusion Criteria
PAOD SFA – PIII, Rutherford II - V

Primary Safety Endpoint
Major Adverse Events (MAE): composite of device or procedure related mortality and major target limb amputation at 6 months

Primary Efficacy Endpoint
Primary patency at 12 and 24 months, defined as freedom from ≥ 50% restenosis as indicated by duplex ultrasound peak systolic velocity ratio (PSVR) ≥2.4 in the target lesion with no re-intervention

Patient Characteristics (N=172)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>172</td>
</tr>
<tr>
<td>Mean Age (years)</td>
<td>71</td>
</tr>
<tr>
<td>Male</td>
<td>62 %</td>
</tr>
<tr>
<td>ABI</td>
<td>0.40 (0.05 - 1.67)</td>
</tr>
</tbody>
</table>

General Medical History
- Diabetes mellitus 35 %
- Hyperlipidemia 94 %
- Hypertension 92 %
- Smoking
  - Current 34 %
  - Previous 43 %

Renal History
- Renal disease 19 %

Rutherford stage
- I 2 %
- II 18 %
- III 64 %
- IV 9 %
- V 5 %
- VI 1 %

Lesion Characteristics (N=226)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion (N)</td>
<td>226</td>
</tr>
<tr>
<td>SFA prox.</td>
<td>76 (34%)</td>
</tr>
<tr>
<td>SFA mid</td>
<td>112 (50%)</td>
</tr>
<tr>
<td>SFA distal</td>
<td>38 (17%)</td>
</tr>
<tr>
<td>SFA total</td>
<td>166 (73%)</td>
</tr>
</tbody>
</table>

Lesion length (mm)
129 mm (5 - 400 mm)

Calcification
- None 78 %
- Moderate 21 %
- Severe 1 %

Percent diameter stenosis
- 95 % ± 30 %

TASCII
- A 24 %
- B 21 %
- C 28 %
- D 30 %
- unclassified 7 %

Ranger SFA Registry

Baseline Information

Procedure Characteristics

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of lesion segments per patient</td>
<td>69%</td>
</tr>
<tr>
<td>1</td>
<td>69%</td>
</tr>
<tr>
<td>2</td>
<td>20%</td>
</tr>
<tr>
<td>3</td>
<td>6%</td>
</tr>
<tr>
<td>4</td>
<td>2%</td>
</tr>
<tr>
<td>5</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

Pre-dilatation before DCB
- 76.1 %

Ranger DCB avg. Inflation time (sec)
- 115

Bail out stent rate
- 22 %

Procedural Outcomes
- Technical success for DCB only (no flow limiting dissection)
- 100 %

Procedural success: DCB plus adjunctive therapy (stent)
- 100 %

Residual angiographic stenosis
- 12 %

Ranger SFA Registry

Efficacy and Safety - 12 Months

- The Ranger clinical program is a robust series of studies aimed to assess the safety and efficacy of the Ranger DCB in various anatomies and diseases
- Consistent results between the Ranger DCB Registry and FIM RCT at 12 months
- Results from the Ranger SFA All-Comer Registry showed:
  - Baseline mean lesion length 129mm & 48% TASC II C/D
  - 84% primary patency at 12 months
  - 89% freedom from TLR at 12 months

Kaplan-Meier Estimates

Primary Patency
- Freedom from TLR
- 91 % & 92 %