RANGER SFA REGISTRY
Interim Analysis

Bernd Gehringhoff, MD
On behalf the Ranger SFA Registry Investigators
## Conflict of Interest - Disclosure

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<table>
<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Honoraria for lectures: CR Bard, Veniti, AB Medica, Volcano, Optimed GmbH, Straub Medical, Terumo, Biotronik, Veryan</td>
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<tr>
<td>2. Honoraria for advisory board activities: Veniti, Optimed GmbH, Straub Medical, Biotronik, Veryan, Boston Scientific</td>
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<tr>
<td>3. Participation in clinical trials: Biotronik, CR Bard, Veryan, Straub Medical, Veniti, TVA Medical, Boston Scientific, LimFlow</td>
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<tr>
<td>4. Research funding: Biotronik, Boston Scientific, Veryan, Veniti, AB medica</td>
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</table>
Next Generation DCB: Boston Scientific Ranger™

- Sterling balloon platform
- TransPax™ coating technology
  Paclitaxel
- Ranger™ DCB Loading Tool
  Designed to protect the drug coating
- Size matrix:
  SFA: 4-8 mm; 30-100 mm
  BTK: 2-4 mm; up to 150 mm
Investigator Sponsored Research
Ranger Drug Coated Balloon

**Indication**
- **Expansion**
  - Haemodialysis AVF Rescue
    - Prospective, multicentre, RCT 1:1
    - N = 200

**Confirmatory**
- SFA RCT
  - Prospective, RCT 1:1 (Head to Head)
  - N = 150
- SFA Registry
  - Prospective, multicentre, registry
  - N = ~180

**Exploratory**
- BTK Angiographic
  - Feasibility, observational, angio F/U
  - N = 30
- BTK Clinical
  - Prospective, RCT 1:1 (Ranger vs PTA)
  - N = 70

These investigator-sponsored studies are supported by grant funding from Boston Scientific. Boston Scientific is not responsible for the collection, analysis or reporting of these studies which remain the sole responsibility of the investigators. Information for the use in countries with applicable product registrations.
### Ranger SFA Registry

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

<table>
<thead>
<tr>
<th><strong>PI</strong></th>
<th>Michael Lichtenberg</th>
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<tbody>
<tr>
<td><strong>Design</strong></td>
<td>Multicentre, prospective all comer registry</td>
</tr>
<tr>
<td><strong>Centres</strong></td>
<td>Germany (Dr. von Bilderling (Munich), Dr. Ranft, Dr. Niemöller (Bottrop), Dr. Grell (Trier), Dr. Lichtenberg (Arnsberg) and Switzerland (Dr. Saucy, Lausanne))</td>
</tr>
<tr>
<td><strong>Population</strong></td>
<td>Planned 180 patients</td>
</tr>
<tr>
<td><strong>Primary Safety Endpoint</strong></td>
<td>Major Adverse Events (MAE): composite of device or procedure related mortality and major target limb amputation at 6 months</td>
</tr>
<tr>
<td><strong>Primary Efficacy Endpoint</strong></td>
<td>Primary patency at 12 and 24 months, defined as freedom from $\geq 50%$ restenosis as indicated by duplex ultrasound peak systolic velocity ratio (PSVR) $\geq 2.4$ in the target lesion with no re-intervention</td>
</tr>
<tr>
<td><strong>Key Inclusion Criteria</strong></td>
<td>PAOD SFA – PIII, Rutherford II - V</td>
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Study is sponsored by Klinikum Arnsberg
Standard of practice

– **DCB transit time:** $< 30$ sec.
– **DCB inflation time:** $> 90$ sec., optimal $180$ sec.
– **DCB / angiographic vessel diameter:** $\geq 1$
Ranger SFA Registry – Interim

**Patient Demographics**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>149</td>
</tr>
<tr>
<td>Mean Age (years)</td>
<td>70</td>
</tr>
<tr>
<td>Male</td>
<td>63 %</td>
</tr>
<tr>
<td>ABI</td>
<td>0.60 (0.01-1.43)</td>
</tr>
</tbody>
</table>

**General Medical History**

- Diabetes mellitus: 34%
- Hyperlipidemia: 94%
- Hypertension: 93%
- Smoking: Current 34%, Previous 44%

**Renal History**

- Renal disease: 19%

**Rutherford stage**

- I: 3%
- II: 17%
- III: 66%
- IV: 7%
- V: 6%
- VI: 1%

Study is sponsored by Klinikum Arnsberg
<table>
<thead>
<tr>
<th>Lesion Characteristics</th>
<th>Ranger DCB</th>
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<tbody>
<tr>
<td>Lesion (N)</td>
<td>210</td>
</tr>
<tr>
<td>SFA Prox</td>
<td>68</td>
</tr>
<tr>
<td>SFA Mid</td>
<td>103</td>
</tr>
<tr>
<td>SFA Distal</td>
<td>99</td>
</tr>
<tr>
<td>POP Prox</td>
<td>61</td>
</tr>
<tr>
<td>POP Mid</td>
<td>43</td>
</tr>
<tr>
<td>POP Distal</td>
<td>12</td>
</tr>
<tr>
<td><strong>Lesion length (mm)</strong></td>
<td><strong>135 mm (50 –400 mm)</strong></td>
</tr>
<tr>
<td>Calcification</td>
<td></td>
</tr>
<tr>
<td>low</td>
<td>74%</td>
</tr>
<tr>
<td>moderate</td>
<td>23%</td>
</tr>
<tr>
<td>severe</td>
<td>3%</td>
</tr>
<tr>
<td><strong>Percent diameter stenosis</strong></td>
<td><strong>91 % ± 10 %</strong></td>
</tr>
<tr>
<td><strong>TASCII</strong></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>20%</td>
</tr>
<tr>
<td>B</td>
<td>21%</td>
</tr>
<tr>
<td>C</td>
<td>21%</td>
</tr>
<tr>
<td>D</td>
<td>38%</td>
</tr>
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Study is sponsored by Klinikum Arnsberg
<table>
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<tr>
<th>Procedure</th>
<th>TLD Number</th>
</tr>
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<tbody>
<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>2.5%</td>
</tr>
<tr>
<td>5</td>
<td>0.5%</td>
</tr>
<tr>
<td>Predilatation before DCB</td>
<td>80.2%</td>
</tr>
<tr>
<td>Ranger DCB avg. inflation time (sec)</td>
<td>114</td>
</tr>
<tr>
<td>Bail out stent rate</td>
<td>27%</td>
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**Procedure Outcomes**

- Technical success for DCB only (no flow limiting dissection): 73%
- Procedural success DCB plus adjunctive therapy (stent): 100%
- Residual angiographic stenosis: 12%

Study is sponsored by Klinikum Arnsberg
Stents used in DCB studies

Longer mean lesion length in DCB studies is correlated with higher provisional stenting rate.

Provisional Stenting in Randomized Controlled Trials may not be representative of actual stenting in studies due to study design.

Results from different trials are not directly comparable.

Information provided for educational purposes.

Ranger SFA Registry - Interim

Primary Patency – 6M

Primary Patency of 91% at 6M

PP 91% at 6M
92% freedom from TLR at 6M by Kaplan Meier Estimate

fTLR 92% at 6M
Patient Outcomes

- 91% of patients moved up at least 1 Rutherford category at 6M
- 80% of patients moved up ≥2 Rutherford categories at 6M
Patient Outcomes

Statistically significant difference for the affected limb from baseline to 6M

Study is sponsored by Klinikum Arnsberg
Conclusions

The Ranger DCB shows promising results in the real world setting. Interim data from the Ranger All Comer Registry showed:

- 92% freedom from TLR at 6 months
- 91% primary patency at 6 months

DCB 12 M Primary Patency may be positively influenced by procedural variables - Balloon Transit time, Inflation Pressure, Inflation Time and Final % Diameter Stenosis
THANK YOU FOR YOUR ATTENTION
RANGER SFA REGISTRY
Interim Analysis

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