SIRONA

Head-to-Head Comparison of **SIROlimus** versus Paclitaxel Drug-Eluting Balloon **N A**ngioplasty in the Femoropopliteal Artery

Dierk Scheinert, MD
University of Leipzig Medical Center
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Disclosure

Advisory Board /Consultant:

Abbott, Alvimedica, Bayer, Boston Scientific, Cook Medical, Cardionovum, CR Bard, Gardia Medical/Allium, Medtronic, Philips, Upstream Peripheral Technologies
MAGICTOUCH PTA *VERSUS* STANDARD PTA

PLANNED CLINICAL TRIALS

Multicentre, double blinded, randomised controlled trials (SFA and BTK) of sirolimus DCB versus standard PTA

**SIRONA SFA**

**BTK-RCT (PI Prof. Zeller)**
Study Design

- **Study Objective:** investigate the safety and efficacy of a sirolimus DCB in comparison to the most used DCBs in Germany in patients with symptomatic femoropopliteal artery disease

- **Study Design:** prospective, multi-center, 1:1 randomized

- **Stratification according to lesion length into three groups:**
  - $\leq 10 \text{ cm} / > 10 \text{ cm}$
  - $\leq 20 \text{ cm} / > 20 \text{ cm}$
  - $\leq 30 \text{ cm}$

- **Study Population:** 478 patients (239 per study arm) suffering peripheral artery disease ranging from intermittent claudication to critical limb ischemia
### Planned Study Sites

**Germany:**

<table>
<thead>
<tr>
<th>Site</th>
<th>Contact Person</th>
<th>Institution</th>
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<tbody>
<tr>
<td>Jena</td>
<td>PD Dr. R. Aschenbach</td>
<td>University Hospital Jena</td>
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<tr>
<td>Leipzig</td>
<td>Prof. Dr. Dierk Scheinert</td>
<td>University Hospital Leipzig</td>
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<td>Altenburg</td>
<td>Albrecht Bormann</td>
<td>Hospital Altenburger Land</td>
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<td>Bad Krozingen</td>
<td>Prof. Dr. Thomas Zeller</td>
<td>University Heart Center Bad Krozingen</td>
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<td>Bautzen</td>
<td>Dr. Uwe Kersten Wahl</td>
<td>Oberlausitz Clinic</td>
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<td>Berlin</td>
<td>Dr. Ralf Langhoff</td>
<td>St. Gertrauden Clinic</td>
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<td>Berlin</td>
<td>PD Dr. M. DeBocourt</td>
<td>Charité Hospital</td>
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<td>Dresden</td>
<td>Prof. R.-T. Hoffmann</td>
<td>University Hospital Dresden</td>
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<td>Karlsbad</td>
<td>Prof. Dr. E. Blessing</td>
<td>SRH-Clinic</td>
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<tr>
<td>Frankfurt</td>
<td>Dr. Christina Kläffling</td>
<td>Goethe University Hospital Frankfurt</td>
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<td>Immenstadt</td>
<td>Dr. Wulf Ito</td>
<td>Cardiovascular Center Kempten</td>
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<td>Magdeburg</td>
<td>Prof. Dr. Maciej Pech</td>
<td>University Hospital Magdeburg</td>
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<td>Münster</td>
<td>Dr. Giovanni Torsello</td>
<td>St. Franziskus-Hospital</td>
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<td>Münster</td>
<td>PD Dr. Nasser Malyar</td>
<td>University Hospital Münster</td>
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<td>Radebeul</td>
<td>Dr. Torsten Fuss</td>
<td>Elbland Clinic</td>
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<td>Riesa</td>
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<td>Sonneberg</td>
<td>Dr. Markus Thieme</td>
<td>Medinos Clinic</td>
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<td>Torgau</td>
<td>Dr. Lars Maiwald</td>
<td>Hospital Torgau</td>
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**Austria:**

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<td>Graz</td>
<td>Prof. M. Brodmann</td>
<td>University Hospital Graz</td>
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<tr>
<td>Wien</td>
<td>PD Dr. Martin Werner</td>
<td>Hanusch Hospital</td>
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Study Endpoints

**Primary Endpoint**

**Efficacy**
- Patency rate

**Safety**
- Composite of:
  - freedom from all-cause death
  - freedom from target limb amputation
  - freedom from TVR through 12 months

**Secondary Endpoint**

**Efficacy**
- Freedom from TLR
- Rutherford improvement
- Walking capacity
- Binary restenosis (via DUS)
- EQ-5D-3L

**Safety**
- Composite of:
  - freedom from all-cause death
  - freedom from target limb amputation
  - freedom from TVR through 60 months
Key Eligibility Criteria

Inclusion

• Rutherford category 2-4

• **De-novo** stenotic / restenotic lesion with ≥ 70% stenosis

• Lesion length ≤ 30cm

• Reference vessel diameter (RVD) ≥ 4 mm and ≤ 6.5 mm

Exclusion

• Severe calcified lesions (PTA resistant)

• Major amputation

• Previous surgery

• SFA or PPA disease in the opposite leg that requires treatment at the index procedure
Follow-Up

- followed up through 60 months to assess the incidence of restenosis by DUS and major adverse events (MAE)
- at 1, 6, 12, 24, 36, 48 and 60 months after index procedure

On-site visits: at 6, 12 and 24 MF
Phone calls: at 1, 36, 48 and 60 MFU
## Trial Design and Endpoints

<table>
<thead>
<tr>
<th>Endpoints</th>
<th>Baseline</th>
<th>1 month</th>
<th>6 month</th>
<th>12 month</th>
<th>24 month</th>
<th>36 month</th>
<th>48 month</th>
<th>60 month</th>
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<td><strong>Primary</strong></td>
<td>Patency Rate*</td>
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<td>Composite of:</td>
<td>WIQ</td>
<td>• TLR rate</td>
<td>• Rutherford improvement</td>
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*defined as absence of clinically driven TLR (due to symptoms and drop of ABI of ≥ 20% or > 0.15 when compared to post-procedure) or restenosis with PVR > 2.4 evaluated by duplex ultrasound
Stratification

Randomization

1:1

478 subjects

239 subjects

≤ 10 cm/ > 10 cm
n = 80

≤ 20 cm/ > 20 cm
n = 80

≤ 30 cm
n = 79

≤ 10 cm/ > 10 cm
n = 80

≤ 20 cm/ > 20 cm
n = 80

≤ 30 cm
n = 79

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Be a part of the SIRONA study team!

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