DEEPER OUS Trial: A Multicenter, single arm trial of the novel Temporary Spur Stent System used in conjunction with a commercially available, paclitaxel-coated balloon

CLINICAL CASE STUDY AT KLINIKUM HOCHSAUERLAND

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Complex technical world BTK
Temporary SPUR Stent System* (Reflow Medical)

- Self Expanding nitinol stent with integrated balloon
- Circumferential tines allow controlled penetration of plaque, calcification, artery wall
  - Channels facilitate deeper drug delivery when used with DCB
- Temporary (retrievable) stent → Stent-like results
  - Increase acute luminal gain
  - Decrease dissection
  - Nothing left behind

* For clinical investigational use only
Temporary Spur Stent System*: Clinical Trials

**DEEPER (completed 2019)**

- Prospective, single center, single arm feasibility study (Spur* + Lutonix DCB)
- Primary Patency 88.9% at 6 months
- 100% freedom from device and procedure related death, 94.1% freedom from target limb major amputation and CD-TLR through 6 months.

**DEEPER OUS (enrolling)**

**DEEPER LIMUS (enrolling)**

- Prospective, single center, single arm pilot study (Spur*+ limus-coated balloon)
- Primary endpoint: 6-month composite of All-Cause Mortality, Major Amputation and CD-TLR

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### DEEPER OUS Trial

#### DEEPER OUS (Goal N= 100)

Prospective, multicenter (Europe/New Zealand): Spur* + commercially available PTx-coated balloon

**Primary Efficacy:** Primary patency at 6 months (DUS)

**Primary Safety:** 30-day perioperative mortality

**Vessel Recoil Sub-study:** Minimal Lumen Diameter Measurement immediately post-Spur, then 15 minutes post-Spur (n=35)

#### DEEPER OUS Clinical Sites

<table>
<thead>
<tr>
<th>Germany</th>
<th>Germany</th>
<th>New Zealand</th>
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<tbody>
<tr>
<td>Prof. D. Scheinert (PI)</td>
<td>Dr. M. Piorkowski</td>
<td>Dr. A. Holden (PI)</td>
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<tr>
<td>Prof. Thomas Zeller</td>
<td>Dr. K. Hertting</td>
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<td>Dr. M. Lichtenberg</td>
<td>Prof. M. Thieme</td>
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<td>Prof. G. Tepe</td>
<td>Prof. M. Andrassy (pending)</td>
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<td>Switzerland</td>
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<td>Prof. J. van den Berg (PI)</td>
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Recoil Sub-Study

<table>
<thead>
<tr>
<th>Variable</th>
<th>Post SPUR (0 min)</th>
<th>Post SPUR (after 15 min)</th>
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<tbody>
<tr>
<td>Average MLD (mm)*</td>
<td>2.47</td>
<td>2.36</td>
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<td>*baseline MLD 0 (CTO)</td>
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<tr>
<td>Min. Luminal Diameter</td>
<td>2.61</td>
<td>2.44</td>
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<tr>
<td>Luminal Gain from baseline</td>
<td>2.61</td>
<td>2.44</td>
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<tr>
<td>Recoil</td>
<td>6.51%</td>
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Results (n = 17 patients)

- **Baseline** [avg (min, max)]: 1.27mm (0.18, 3.39)
- **Post Spur** [avg (min, max)]: 2.46mm (1.33, 3.45)

- Elastic Recoil*
  - Defined as lumen compromise ≥ 10% **Post 15 min of SPUR** usage
  - *corelab adjudicated: Syntropic
  - **consented patients who were candidates**

- 
  - *images courtesy of Prof. T. Zeller

- **11.8% (2/17)**
  - vs
  - Baumann study**: 97% (29/30)
    (Baumann F. J Endovasc Ther. 2014)

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Case Study: Patient History

Procedure: July, 2020

- 82 y old male, hx CAD, chronic kidney disease, hypertension, hyperlipidemia
- Rutherford class 5, wound left lateral malleolus
- Baseline ABI: .59; TBI: .52
- WIfI: Wound=1; Ischemia=1; Infection=0
Treatment preparation

• Antegrade access
• 6 French sheath
• **Inflow treatment**: Mid-distal SFA PTA + Stent
• **Target lesion**: proximal posterior tibial, lesion length 150 mm
Case: Treatment with Temporary Spur Stent System
Clinical Outcomes: Post procedure

Post Procedure

- Brisk flow post-treatment (acute luminal gain)
- No dissection observed post-Spur
- Type A dissection noted by core lab* post DCB
- Well-tolerated, patient discharged to home

* Syntropic, Columbus, OH
Clinical Outcomes: 3 month follow up

3 month follow up

- Wound debrided
- ABI .91; TBI .84
- WIfI: Wound=1; Ischemia=0; Infection=0
- Duplex ultrasound demonstrates flow through treated segment (max PSV 68 cm/sec)*
- 6 month follow up scheduled February

* Corelab adjudicated, Vascore, Boston, MA
Temporary SPUR Stent System*

- Provides **Localized** Drug Delivery (agnostic to drug choices)
  - Potential option for treatment algorithms for BTK disease
- Temporary stent may prevent acute vessel recoil and increase acute luminal gain
- Minimizes dissection through controlled penetration of vessel wall
- **LEAVES NOTHING BEHIND**: Preserves future treatment options

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Thank you for your kind attention