A Pilot Study Examining the Performance and Safety of the Temporary Spur Stent System* In Infrapopliteal Arteries:

First-Time Use with a Limus-Coated Balloon (DEEPER LIMUS)

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* For clinical investigational use only
Disclosure

Speaker name: Brodmann Marianne, MD

I have the following potential conflicts of interest to report:

- [x] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest
Challenges to treatment of BTK arteries

- Infrapopliteal disease
  - Vessel Recoil
  - Calcification
  - Lesion length/tortuosity
  - Dissection

- Drug Coated Technology
  - Drug uptake
    - Diameter mismatch
    - Luminal surface contact
    - Uptake
    - Penetration
    - Lesion length/tortuosity
Temporary SPUR Stent System*
Reflow Medical

- Self-expanding nitinol stent with radial spikes mounted on an integrated balloon system
- Controlled penetration of plaque, calcium, and artery wall
  - Channels facilitate deeper drug delivery when used with DCB
- Minimize vessel recoil and dissection
- Acute Luminal Gain
- Follow treatment with commercially available drug coated balloon
- Nothing left behind

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Temporary SPUR Stent System*

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Controversies in Drug-coating

- Concerns for long-term impact of Paclitaxel (Katsanos, et. al., 2018, 2020)
- Limus-based drug coating historically challenging to deliver in absence of stent
- Temporary Spur Stent System ➔ Ideal platform for DRUG DELIVERY into diseased artery, may improve tissue absorption and elution

Gaines: Presentation from CRR2019
# DEEPER LIMUS Pilot Study

**DEEPER LIMUS** (Goal N=30, current n=12)

**Prospective, single-center Spur* + LIMUS-coated DCB**

**PI:** Prof. M. Brodmann, Univ. Graz, Austria

### Primary Safety Endpoint:
6-month composite of All-Cause Mortality, Major Amputation and Clinically Driven Target Lesion Revascularization (CD-TLR)

### Secondary Endpoints:
1. LLL at 6 months by QVA
2. Primary patency at 6 months by QVA
3. Freedom from MALE and POD at 30 days
4. Freedom from MALE at 6 and 12 months
5. Improvement in Rutherford at 3, 6, 12 months
6. Wound healing/WIfI at 6 and 12 months

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73 year-old female, **Rutherford class 5**

- Pertinent history:
  - Type II Diabetes;
  - Chronic kidney disease
  - Heel and toe wounds

- Baseline ABI/TBI: .66; .3

- **WIfI**:
  - Wound: 3
  - Ischemia: 1
  - Infection: 0
DEEPER LIMUS Case Presentation

Image of 3.0x60 mm Spur* inflated

Post-Spur*

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DEEPER LIMUS Case Presentation: 6-month angiogram

Baseline avg. subsegmental lumen $\Phi = 1.39$ mm

Index avg. subsegmental lumen $\Phi = 2.34$ mm

6 Month avg. subsegmental lumen $\Phi = 2.02$ mm

*Corelab adjudicated (Syntropic)

- Difference post-procedure $\rightarrow$ 6 months $= 0.32$ mm*
- Percent difference $= 13\%$
DEEPER LIMUS Case Presentation: 6 month Clinical follow up

<table>
<thead>
<tr>
<th>Baseline ABI/TBI</th>
<th>6 Month ABI/TBI</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABI: .66/ TBI: .3</td>
<td>ABI: 1.41/ TBI: .75</td>
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<table>
<thead>
<tr>
<th>Baseline WIfI</th>
<th>6 Month WIfI</th>
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<tbody>
<tr>
<td>Wound: 3</td>
<td>Wound: 0</td>
</tr>
<tr>
<td>Ischemia: 1</td>
<td>Ischemia: 0</td>
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<tr>
<td>Infection: 0</td>
<td>Infection: 0</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Baseline Wound</th>
<th>6 Month Wound</th>
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<tbody>
<tr>
<td>[Image of baseline wound]</td>
<td>[Image of 6 month wound]</td>
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## DEEPER LIMUS: Clinical Data

<table>
<thead>
<tr>
<th>Primary Endpoint</th>
<th>One Month</th>
<th>3 Months</th>
<th>6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-month composite of All-Cause Mortality, Major Amputation and Clinically Driven Target Lesion Revascularization (CD-TLR)</td>
<td>0/11</td>
<td>0/9</td>
<td>0/4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Important Secondary Endpoint</th>
<th>One Month</th>
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</thead>
<tbody>
<tr>
<td>Freedom from MALE and POD at 30 days</td>
<td>0/11</td>
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</table>
Temporary SPUR Stent System*

• Provides **Localized** Drug Delivery (agnostic to drug choices)
• Temporary stent may prevent acute vessel recoil and increase luminal gain
• Reduces dissection risk through controlled penetration of vessel wall
• Leaves nothing behind, preserving natural function of the vessel and allowing future treatment options.
• Promising clinical data (DEEPER LIMUS, DEEPER OUS, DEEPER)

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Thank you for your kind attention.