Latest Experience with the 3F MicroStent in Complex BTK Procedures

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Disclosure

Speaker name:
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I have the following potential conflicts of interest to report:

- 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
Disclosures

Consultant/Medical Advisory Board

• Abbott
• BSCI
• Cardinal Health/Cordis
• Cook Medical
• CR BARD/Becton Dickinson
• CSI
• Endologix

• Inari
• Medtronic
• Micro Medical Solutions
• Philips/Volcano/Spectranetics
• Penumbra
• Terumo/Bolton
• WL Gore
Critical Limb Ischemia

- CLI is caused by multilevel and/or isolated infrapopliteal arterial disease
  - Primary goals of treatment include limb preservation, wound healing, and relief of ischemic rest pain
- Endovascular therapies well established above the knee (DCB, BMS, DES)
- Current options BTK are limited to PTA as the primary endovascular approach

1 Mustapha et al. PRIME Registry Interim Analysis Vasc Disease Mgmt 2017
2 Razavi J Vasc Interv Radiol 2014
## Challenges in Treating BTK Disease

### Increasingly complex lesions BTK
- Significant recoil post-PTA in up to 97% of cases\(^3\)
- PTA alone fails to attain $<30\%$ RS in up to 42% of cases\(^4\)
- Dissections occur in 20-30% of cases, often underreported due to small caliber of vessels\(^2,5,6\)

### Off-label use of BE coronary DES stents
- Limited to **short, proximal lesions**
- **Paclitaxel** in the news
- Limitations to stent design
  - Low flexibility
  - Limited stent lengths
  - Not able to use in areas of compression

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3 Baumann F J Endovasc Ther 2014
4 Scheinert J Am Coll Cardiol 2012
5 Fanelli J Cardiovasc Surg 2014
6 Zeller J Am Coll Cardiol 2014
• **Woven nitinol design**: Highly conformable, allows for complex placement BTK

• Proprietary **platinum core design**: - Exceptional visualization with both IVUS + DUS

• Effortlessly deploys from 3Fr MicroGuide™ catheter delivery system for accurate placement

• Broad size selection to tailor treatment:
  • Diameters: 3.0, 3.5, 4.0, 4.5
  • Lengths: 8, 15, 25, 40, 60 mm
  • Shaft: 40 cm, 120 cm lengths for optimal access
MicroStent™ and Imaging

- Platinum Core allows for exceptional visibility with IVUS
- IVUS allows physician to accurately assess stent wall apposition, ensures laminar flow
- BTK disease is different, stenting BTK is different
- MicroStent™ + IVUS = Better clinical outcomes
The visibility utilizing DUS, allows for non-invasive follow-up and assessment.

Platinum Core creates highly visible stent utilizing DUS
**US Feasibility Summary**

<table>
<thead>
<tr>
<th>Subject Characteristics</th>
<th>Ajudicated Core Lab Results</th>
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</thead>
<tbody>
<tr>
<td>▶ Broad Anatomic Distribution</td>
<td>➢ 100% delivery success</td>
</tr>
<tr>
<td>▶ High Percentage Diabetes Mellitus <em>(57.1%)</em></td>
<td>➢ 100% freedom from primary safety endpoint at 12 months <em>(POD + MALE)</em></td>
</tr>
<tr>
<td>▶ History of CAD +Peripheral Interventions <em>(35.7%, 64.3%)</em></td>
<td>➢ 82% Improved RCC ≥ 4 at 6 months, 72% RCC = 0 at 12 months</td>
</tr>
<tr>
<td>▶ Severe Stenosis</td>
<td>➢ 90.9% primary patency at 12 months <em>(Occlusion + CDTLR)</em></td>
</tr>
<tr>
<td>▶ Long lesions and CTO’s <em>(10-80mm)</em></td>
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</tbody>
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*Per Protocol Population – two subjects removed for violation of inclusion/exclusion criteria*
US IDE Pivotal Study
Prospective
Multi-Center: 27 Sites
Randomized: 2 Arms: 2:1 – MicroStent™ + PTA, PTA only
177 patients
6-month primary follow up
Enrollment to begin Q1

NOTE: The MicroStent™ is limited to Investigational use in the United States. The MicroStent™ has CE mark and is commercially available in select OUS markets.
OUS Registry - All comers, retrospective & prospective inclusion

Patients enrolling from 5 countries, 7 centers

Initial clinical data expected Q1-2020

International PI - Dr. Marco Manzi

MicroStent™ has CEMark approval OUS
MSMC Case: MicroStent® Delivery at Ostium of AT

Baseline Run-Off | Deployment | Final Run-Off

Excellent Results
Residual Stenosis 0%

Highly Visible
MSMC Case: MicroStent® Delivery at Mid PT
In Conclusion ...

- The MicroMedical Solutions MicroStent™ Feasibility Study demonstrated excellent safety and efficacy data.
- The 12-month 90.9% primary patency data shows excellent durability.
- Low profile, easy-to-use delivery system and flexible stent design enabled 100% delivery success.
- Enthusiastic about start of the pivotal STAND study and results, as well as, the forthcoming data from the HEAL study.
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