NOVEL ENDOVASCULAR DEVICE, A GUIDEWIRE FIXATOR

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Disclosure

Speaker name: Dr Krister Liungman

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

☐
Guidewire fixator

- Novel device – Guidewire fixator 0.035”
- Provide distal fixation while maintaining blood flow
Does it work?
# Safety and Functionality Study

Porcine Model, N 11, n=44 (CT, SMA, RR, LR)

<table>
<thead>
<tr>
<th>Test</th>
<th>Endpoint</th>
<th>RESULTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delivery</td>
<td>Success/Failure</td>
<td>- Uneventful 44</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- 1 failure – bail out used</td>
</tr>
<tr>
<td>Retrieval</td>
<td>Success/Failure</td>
<td>- Uneventful 43</td>
</tr>
<tr>
<td>Deposition</td>
<td>Occlusion, Thrombosis</td>
<td>- No arterial occlusion</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Two clots &lt;1 mm</td>
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<tr>
<td>Fixation</td>
<td>Dissection, Rupture, dislocation force</td>
<td>- Force of dislocation 7.6N</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- No dissection/rupture</td>
</tr>
</tbody>
</table>
What can it do?

Distal fixation allows:
• secure guidewire position,
• parallel work,
• stiffness through tension,

• and proximal repositioning that allows completely new guidewire techniques
Example 1.
Re-routing for branch or fenestration connection

Pre-loaded guidewire through fenestration

Guidewire fixated in target artery

Pre-loaded guidewire positioned cross-over
Rerouting of proximal end
Rerouting of proximal end
Rerouting of proximal end
Rerouting of proximal end
Example 2. Facilitated f/b-EVAR

- Pre-lined catheters through fenestrations
- Guidewires fixated in the target arteries
The three wires are lined through the graft delivery system.
Pre-cannulated f-EVAR using Guidewire Fixators

Pig Model
Possible benefits to facilitated f-EVAR

- Stepwise, predictable
  - Shorter procedure
  - Reduced radiation
  - Less contrast
- Tension adds to stiffness
- Opportunity for standardized grafts
Summary

A guidewire fixator enables new techniques and methods

Clinical study ongoing
CE-certification pending
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