What Are the Next Generation Large Sheath Closure Devices (MANTA, PerQSeal, InClosure and Next): How Do They Work and How Good Will They Be

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Emerging Large Vessel Closure Devices

<table>
<thead>
<tr>
<th>Device</th>
<th>Design</th>
<th>Company</th>
<th>Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>InClosure*</td>
<td>Bioabsorbable</td>
<td>InSeal Medical, Israel</td>
<td>EU (2016)</td>
</tr>
<tr>
<td>PerQseal*</td>
<td>Patch or Plug</td>
<td>Vivasure Medical Ireland</td>
<td>EU (2016)</td>
</tr>
<tr>
<td>MANTA*</td>
<td>Collagen and suture&amp; lock</td>
<td>Essential Medical, US</td>
<td>EU (2016)</td>
</tr>
<tr>
<td>(Xpro)</td>
<td>Cross Stitch</td>
<td>Medion Biodesign Taiwan&amp; Terumo, Japan</td>
<td>FIM (2015)</td>
</tr>
</tbody>
</table>

Disclosures

- On the speaker’s bureau for Endologix/TriVascular, Edwards, BARD, Abbott
- Principal co-investigator for the PEVAR Trial
- Principal co-investigator for the LIFE Trial
- Principal co-investigator for MANTA Trial

InClosure (InSeal Medical, Israel)

- 23 subjects (20 TAVI, 1 AAA)
- Pts. with calcified CFA were included
- Successful delivery: 20/23 (87%)
- Successful hemostasis 19/23 (83%)
- Mean time to hemostasis: 1.1 ± 2.6 min.
- One month follow-up: no complications
- CE Mark approval (August 2016)

PerQseal (Vivasure Medical)

- For arteriotomies 12-24F
- OTW post intervention (3 steps)
- Synthetic absorbable patch graft seals from inside, absorbs in 180 days

CLINICAL EXPERIENCE

- > 120 patients post TAVR
- MAE 1%
- CE Mark approved in 2016
- Frontier III clinical trial of 70 closures 97% technical success and no major adverse events by 90 days
- Frontier IV clinical trial is enrolling now

MANTA (Essential Medical, US)

- Over-the wire design
- Achieves hemostasis by “sandwiching” arteriotomy
- Poly-lactic-co-glycolic acid intra-arterial toggle
- Extra-vascular bovine collagen plug
- 2-0 Polyester Suture
- 316L Stainless Steel Suture Lock
- 14 F MANTA (closes up to 18F)
- 18F MANTA (closes up to 25F)
**MANTA Completed and Future Studies**

- CE Mark Study, 50 patients, Jul 2015-Feb 2016
- US IDE Pivotal Study, 263 patients, Nov 2016-Dec 2017
- EU Post-Market Registry, 719 pts., Dec 2016-Nov 2017
- Finland Registry Study (Ongoing)
- MARVEL Registry (20 EU & Canada), Feb. 2018 -Fall 2018

**MANTA EU Clinical Trial (50 pts. Jul 2015-Feb 2016)**

<table>
<thead>
<tr>
<th>Hemostasis Measure</th>
<th>MANTA</th>
</tr>
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<tbody>
<tr>
<td>Deployment time</td>
<td>1-2 min</td>
</tr>
<tr>
<td>Success (% &lt; 10 min)</td>
<td>94%</td>
</tr>
<tr>
<td>Major Vascular Complications</td>
<td>2%</td>
</tr>
</tbody>
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<tr>
<th>Procedure Type</th>
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<tr>
<td>TAVR 48 (96%)</td>
</tr>
<tr>
<td>BAV 2 (4%)</td>
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<th>Device Size</th>
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<tr>
<td>14F = 16 (32%)</td>
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<tr>
<td>18F = 34 (68%)</td>
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**MANTA Post-Market Surveillance**

From DEC 2016-NOV 2017

Results from 719 commercial cases in Netherlands /Nordic Centers

<table>
<thead>
<tr>
<th>Anticoagulation Level (ACT, mean)</th>
<th>212 sec</th>
</tr>
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<tbody>
<tr>
<td>Time to Hemostasis (TTH, mean)</td>
<td>84 sec</td>
</tr>
<tr>
<td>Time to Hemostasis (TTH, median)</td>
<td>10 sec</td>
</tr>
<tr>
<td>MAJOR VARC-2 Vascular Complications</td>
<td>1.9%</td>
</tr>
<tr>
<td>Minor VARC-2 Vascular Complications</td>
<td>2.4%</td>
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**MANTA US IDE Pivotal Trial: Effectiveness Outcomes**

- **Time to Hemostasis**
  - Median: 24 sec
  - Hemostasis in under 1 minute was achieved in 86% of patients
  - Hemostasis in under 5 minutes was achieved in 94% of patients

- **Secondary Endpoint: Technical Success 97.7%**

**Conclusions**

- Several (post-intervention) LB VCD are emerging
  - MANTA EU Trial
    - Technical success 94%, (VARC-2) MVC 2%
  - Manta Pivotal Trial (US & Canada)
    - Technical success 97.7%, (VARC-2) MVC 4.2%
  - PerQseal EU trial
    - Technical success 97%, (VARC-2) MVC 0%
  - InClosure EU trial
    - Technical success 83%

**Thank you**