New Fully Absorbable Patch Based Large Hole Vascular Closure Device

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Disclosure

Speaker name: Arne Schwindt, 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
Drivers of Clinical Need in Large Bore Vascular Closure

Desired Approach:
- Fully percutaneous
- Easy to use
- Safe and secure
- Fully absorbable

Challenge:
- 1-5% complications associated with currently available large hole closure
Fully Absorbable Patch-based Large Hole Closure Device

- Designed for large arteriotomies up to 24F
- Simple OTW operation
- All components fully absorbable from same synthetic polymer
- Seals from inside
- No suture, collagen or metal components
Pre-Clinical Histology

30-180 days post implantation

- 22F Arteriotomy
- Complete absorption
- Implantation site undifferentiated from native arterial wall
- No granuloma/scarring
- No perivascular fibrosis
Pre-Clinical Gross Pathology

Porcine abdominal aorta

32 Day post implantation

Endoluminal coverage of the implant by mature, stable and generally endothelialized neointima

91 Day post implantation

Implant patch absorbed, foot section migrated extra-arterial and absorbing
FRONTIER III Clinical Case

77 year old Male,
Ht. 175 cm, Wt. 63 kg
Med: 15 mg q.d.
rivaroxaban
TAVR
Edwards 16F
SAPIEN 3
29mm valve
Closure
Vivasure PerQseal

Dr Peter Crean, St. James Hospital, Dublin, Ireland
FRONTIER III Study

Aim
Assess the safety and clinical performance of a new fully percutaneous patch based synthetic absorbable Large Hole Closure Device (18-24F)

Methods
- 50+ patients undergoing large bore femoral percutaneous access for TAVI, EVAR and TEVAR, prospective, non-randomized in 6 European centres
- Assessment of puncture site with DUS/CT at discharge, 30 days, 90 days and 1 year
- Primary endpoint: Incidence and severity of major complication rates directly related to the VIVASURE CLOSURE DEVICE™ up to 3 months from implantation (as defined by VARC-2) is no worse than those associated with cut-down or suture based closure devices of 14.7%

# FRONTIER III – Procedural Information

## Closure Procedures

<table>
<thead>
<tr>
<th>Patients (n / %)</th>
<th>62</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAVR</td>
<td>42 (68)</td>
</tr>
<tr>
<td>EVAR</td>
<td>16 (26)</td>
</tr>
<tr>
<td>TEVAR</td>
<td>4 (6)</td>
</tr>
<tr>
<td>Site Closures (n / %)</td>
<td>70</td>
</tr>
<tr>
<td>TAVR</td>
<td>42 (60)</td>
</tr>
<tr>
<td>EVAR</td>
<td>24 (34)</td>
</tr>
<tr>
<td>TEVAR</td>
<td>4 (6)</td>
</tr>
<tr>
<td>Closure sheath size</td>
<td></td>
</tr>
<tr>
<td>18F</td>
<td>89%</td>
</tr>
<tr>
<td>&gt; 18F</td>
<td>11%</td>
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</table>

## Index Procedures

<table>
<thead>
<tr>
<th>Index Procedure Device</th>
<th>Index Procedure Sheath</th>
<th>Hole OD for closing</th>
<th>(n=70)</th>
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<tbody>
<tr>
<td>Sapien III</td>
<td>14F e-Sheath</td>
<td>23F</td>
<td>8</td>
</tr>
<tr>
<td>Sapien III</td>
<td>16F e-Sheath</td>
<td>~ 24F</td>
<td>13</td>
</tr>
<tr>
<td>Evolut™ R (w St Jude 18F)</td>
<td>14F</td>
<td>21F</td>
<td>15</td>
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<tr>
<td>Lotus™</td>
<td>18F</td>
<td>22F</td>
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<td>SJM Portico</td>
<td>19F</td>
<td>22F</td>
<td>1</td>
</tr>
<tr>
<td>Nellix® (w/ Cook 18F)</td>
<td>14F</td>
<td>22F</td>
<td>2</td>
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<tr>
<td>Nellix® (w/ St Jude 18F)</td>
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<tr>
<td>Zenith® TX2®</td>
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<td>~ 24F</td>
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<tr>
<td>Zenith® TX2®</td>
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<tr>
<td>In-Craft® (w St Jude 18F)</td>
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</table>
FRONTIER III – Results

- 62 Patients (with 70 closures) completed across 6 European centers

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>Patients</th>
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<tbody>
<tr>
<td>Discharge</td>
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<tr>
<td>3 Month</td>
<td>59</td>
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<td>12 Month</td>
<td>54</td>
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- No device related major vascular complications (VARC-2)
- 97% Technical success
- 3 minor device related complications (haematoma, asymptomatic stenosis, and pseudoaneurysm)
- No late minor or major device related vascular complications
- No clinically significant changes on ultrasound or CT-angiogram
- CE Mark approved
FRONTIER III - Conclusions

- Easy to use device
- Requires no pre-procedure steps
- Has clinically demonstrated its safety with excellent outcomes from discharge through 1, 3 and 12 month follow-ups
- The device has performed reliably with a low learning curve (3 simple steps for deployment)
- Provides a real option for fully percutaneous closure with reduced hospital costs and procedure times
PerQseal® VCD – Next Generation

- Loading cannula connects to the introducer hub
- Device handle connects with the introducer hub forming an integrated unit
- Sheath actuator is rotated 180 degree clockwise releasing the outer sheath and exposing the implant patch
- Delivery system is retracted until the patch contacts the arterial wall
- Guidewire removed
- Release actuator rotated 180 degree clockwise
- External locator secures implant
FRONTIER IV Study

- **Study purpose:** to confirm safety and performance of PerQseal® and to expand indications of use to a wider range of arteriotomy sizes

- **Primary and secondary end points:** incidence of major and minor vascular access-site complications at 1 month from implantation compared to cut-down and sutured closure

- **Scope:** 13 sites in Germany and Ireland

- **Status:** enrolling
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