New Fully Absorbable Patch Based Large Hole Vascular Closure Device

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Disclosure Statement of Financial Interest

Over the past year, I have received the following:

Institutional Grants: Medtronic, Boston Scientific, Abbott Vascular, Edwards, Cook

Medical Advisory Board: Boston Scientific

Consultant: Cordis, Edwards
Drivers of Clinical Need in Large Bore Vascular Closure

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

Challenge:
- 1-5% complications associated with currently available large hole closure
PerQseal

- Designed for large arteriotomies
- Simple OTW operation
- All components fully absorbable from same synthetic polymer
- Seals from inside
- Up to 24F holes
- No suture, collagen or metal components
PerQseal Three Step Device Deployment

- 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
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
Pre-Clinical Histology

30-180 days post implantation

- 22F Arteriotomy
- Complete absorption
- Implantation site undifferentiated from native arterial wall
- No granuloma/scaring
- No perivascular fibrosis
Clinical Experience

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
# Clinical Program

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<th>Type</th>
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<th># Cases</th>
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**Enrolling**

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**Planned**

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* No acute major device related vascular complications
* No late major or minor device related vascular complications
Overall Clinical Experience

- Over 120 patents implanted (9 centres across EU)
  - TAVR
  - EVAR
  - TEVAR
- No major VARC-II vascular complications (no roll ins)
- Follow up assessments completed (30d, 90d, 1yr)
- No late major or minor device related vascular complications
- No clinically significant stenosis, turbulence, aneurysm formation on follow-up Ultrasound scans
- CE Mark
Clinical Experience

Vessel patency post-implantation

Pre-implantation

Peri-procedure tamponade

< 15 min. Post-implantation

Low profile, non-stenosing absorbable implant
Clinical Experience

Pre-procedure

1 mo. Post-procedure
Clinical Experience

EVAR - bilateral arteriotomy closures

Pre-Implantation

2 days Post Implantation
Technology Development

PerQseal

A new class in percutaneous closure
PerQseal Summary

- Easy to use device with low learning curve
- Patch-based, fully absorbable implant
- Requires no pre-procedure steps
- Has clinically demonstrated its safety and effectiveness with excellent outcomes from discharge through 12 month follow-up (>120 patients in Frontier studies)
- Device provides a real option for fully percutaneous closure with the potential to reduce hospital costs and procedure times
- Proprietary polymer technology promising in expanded vascular indications