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:

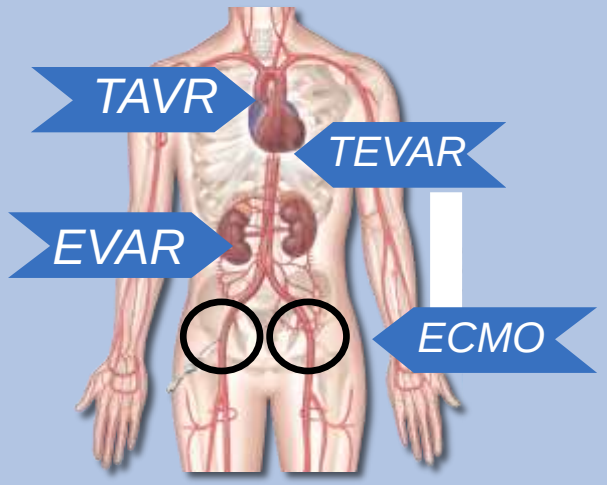
- [X] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest

Drivers of Clinical Need in Large Bore Vascular Closure

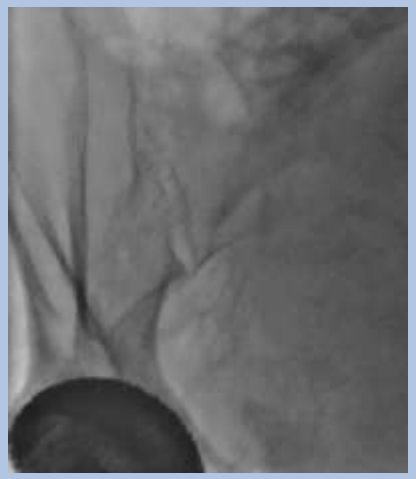
Desired Approach:

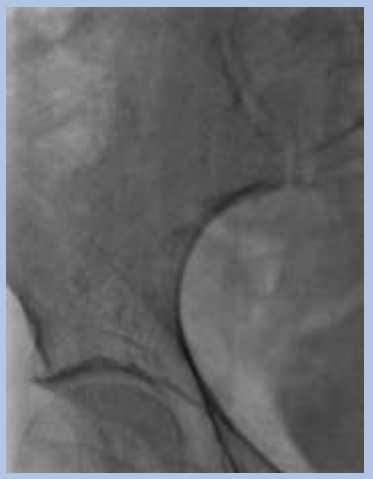
- Fully percutaneous
- Easy to use
- Safe and secure
- Fully absorbable



Challenge:

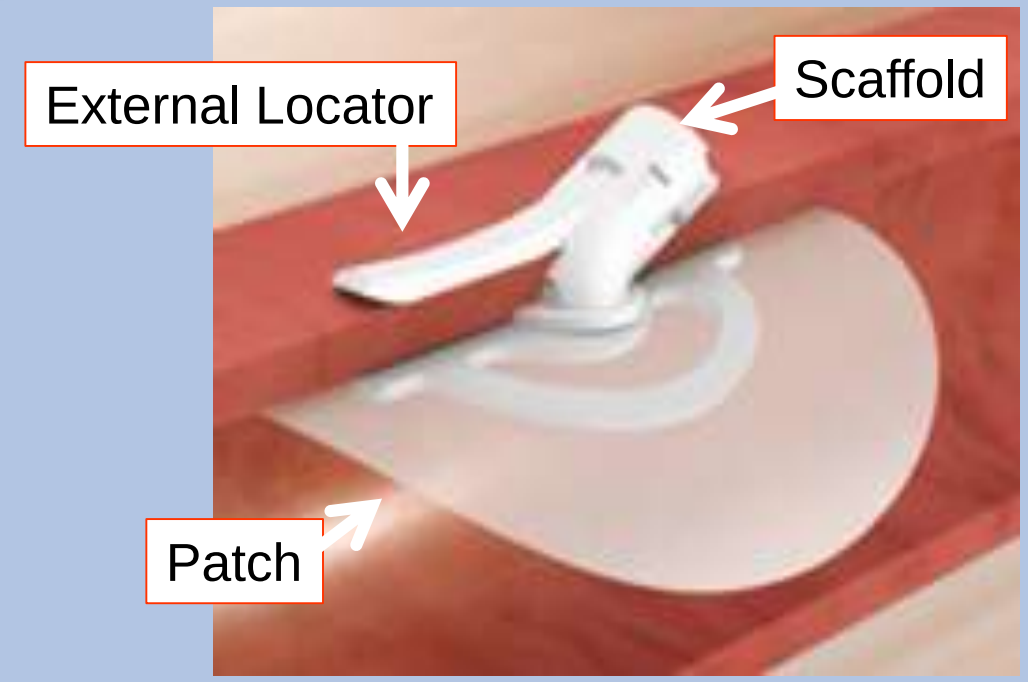
- 1-5% complications associated with currently available large hole closure

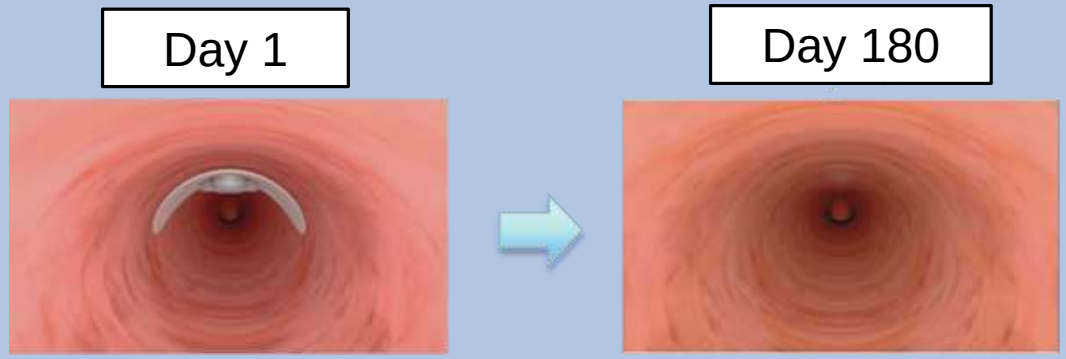




Fully Absorbable Patch-based Large Hole Closure Device

- 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

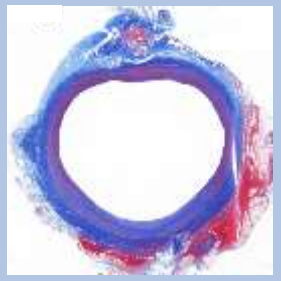
30-180 days post implantation

Implant Encapsulated

Cross-section @ 32 days

Implant absorbing and extra-arterial

Cross-section @ 91 days

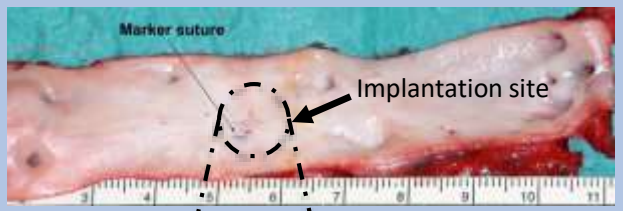


Implant Absorbed

Cross-section @ 180 days

162 days post implantation

Porcine abdominal aorta – luminal surface



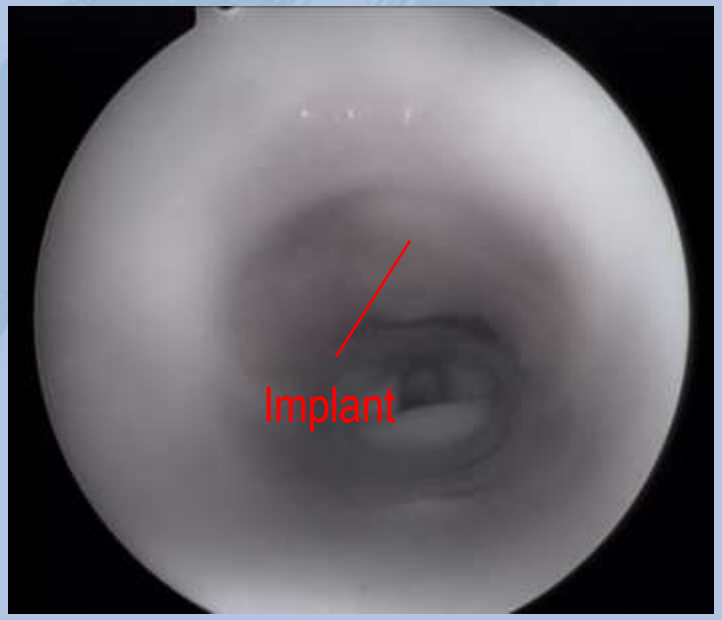
Longitudinal histology @ 162 days

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

Pre-Clinical Gross Pathology

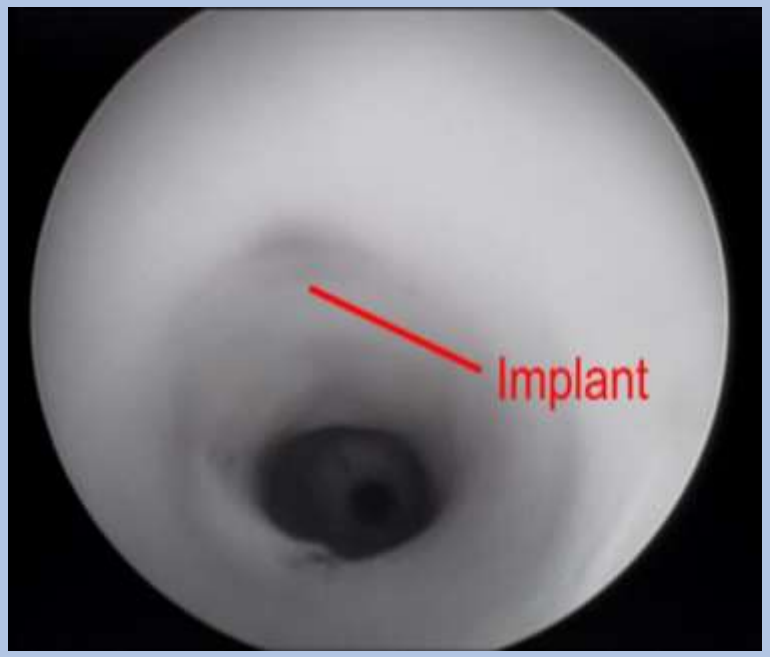
Porcine abdominal aorta

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[1]) is no worse than those associated with cut-down or suture based closure devices of 14.7%

1. Kappetein AP, Head SJ, Généreux P, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. European Journal of Cardio-Thoracic Surgery 42 (2012) S45–S60.

FRONTIER III – Procedural Information

CLOSURE PROCEDURES	
Patients (n / %)	62
TAVR	42 (68)
EVAR	16 (26)
TEVAR	4 (6)
Site Closures (n/ %)	70
TAVR	42 (60)
EVAR	24 (34)
TEVAR	4 (6)
Closure sheath size	
18F	89%
> 18F	11%

INDEX PROCEDURES			
Index Procedure Device	**Index Procedure Sheath**	**Hole OD for closing**	**(n=70)**
Sapien III	14F e-Sheath	23F	8
Sapien III	16F e-Sheath	~ 24F	13
Evolut™ R (w St Jude 18F)	14F	21F	15
Lotus™	18F	22F	5
SJM Portico	19F	22F	1
Nellix® (w/ Cook 18F)	14F	22F	2
Nellix® (w/ St Jude 18F)	14F	21F	3
Endurant® II	20F	20 F	13
Zenith® TX2®	22F	~ 24F	2
Zenith® TX2®	20F	22F	3
In-Craft® (w St Jude 18F)	14F	21F	5

FRONTIER III – Results

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

Follow-up	Patients
Discharge	62
3 Month	59
12 Month	54

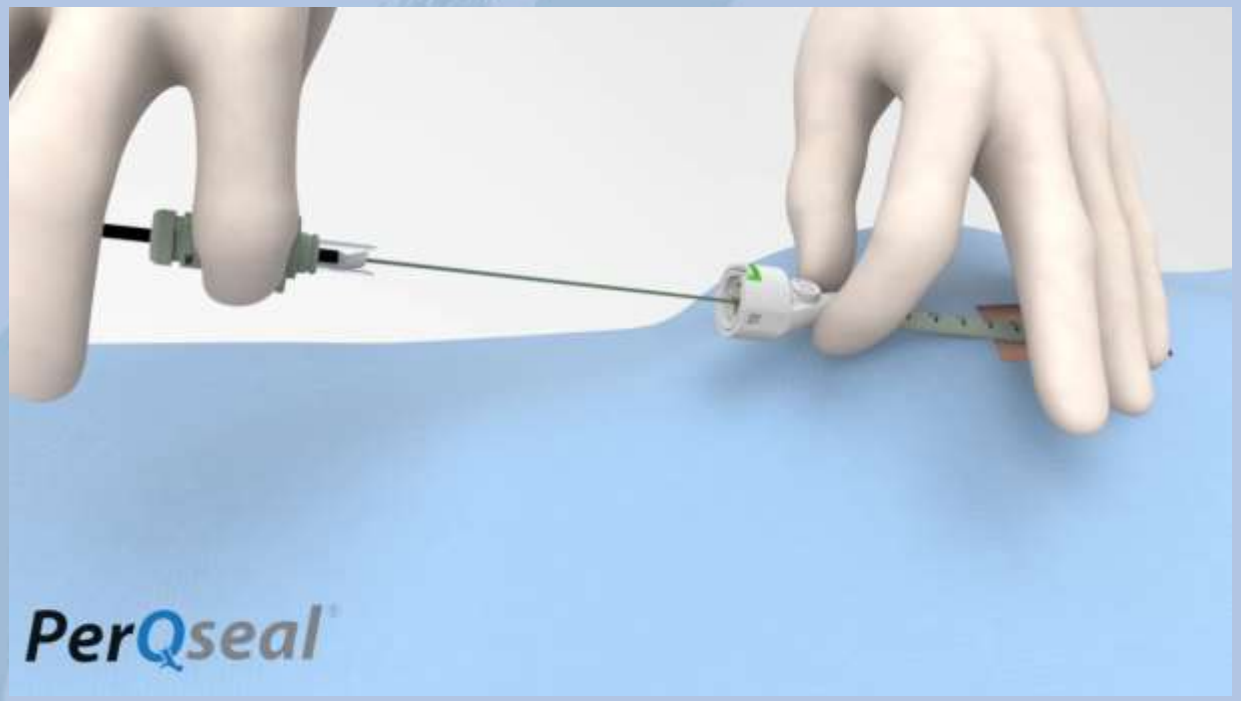
Procedures	No.
TAVR	42
EVAR	24
TEVAR	4

- 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 connect 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 secundary end points: incidence of major and minor vascular acces-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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