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New Fully Absorbable Patch Based Large Hole Vascular Closure Device

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EAPCI European Society of Cardiology PCR

Potential conflicts of interest

Speaker's name : Thomas, Schmitz, Essen

☑ I do not have any potential conflict of interest

Drivers of Clinical Need in Large Bore Vascular Closure

Desired Approach:

Fully percutaneous

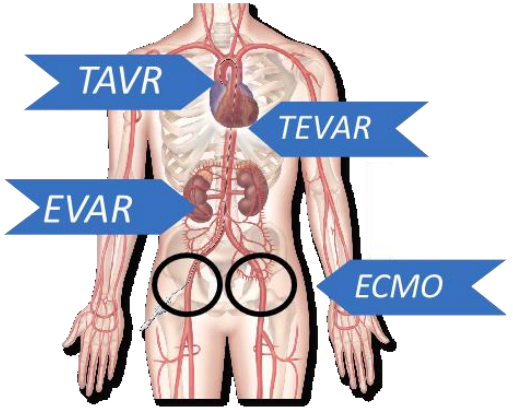
Easy to use

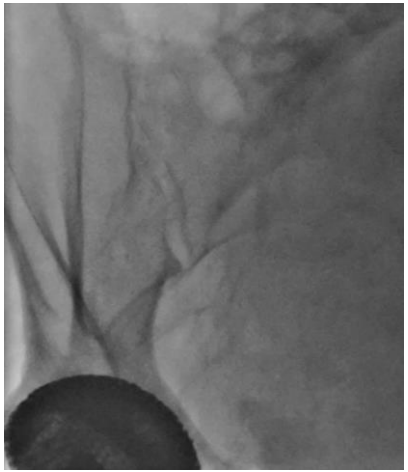
Safe and secure

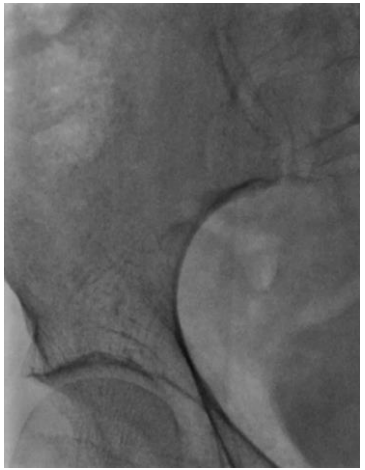
Fully absorbable

Challenge:

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







PerQseal® – Vivasure Medical Ltd

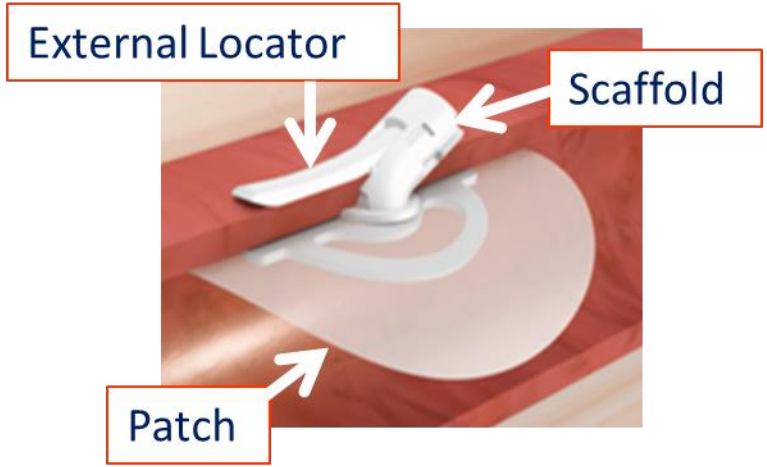
Designed for large arteriotomies up to 24F

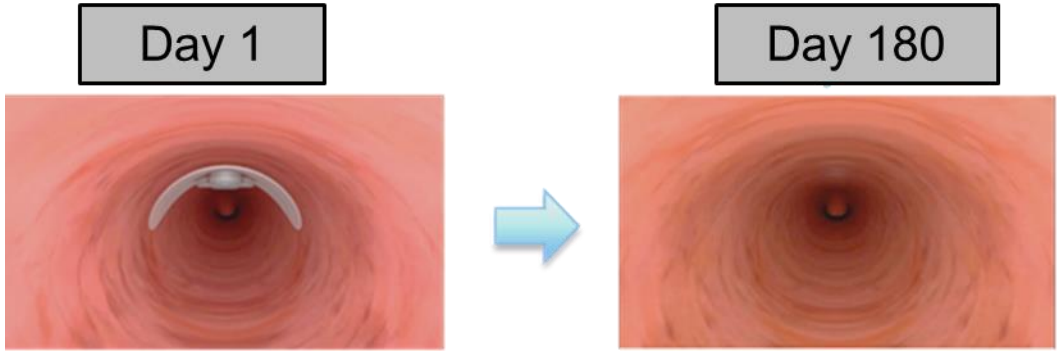
Simple OTW operation

All components fully absorbable from same synthetic polymer

Seals from inside

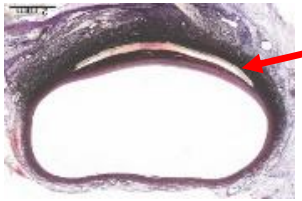
No suture, collagen or metal components





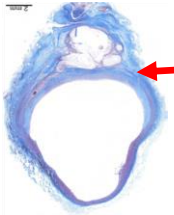
Pre-Clinical Histology

30-180 days post implantation



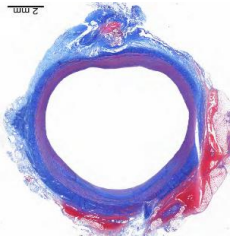
Implant Encapsulated

Cross-section @ 32 days



Implant absorbing and extra-arterial

Cross-section @ 91 days

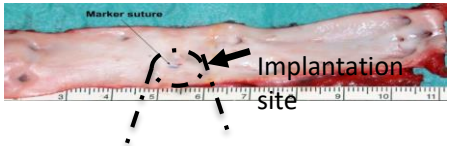


Implant Absorbed

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

Clinical Program

Study	Type	# sites	# Patients	TAVR: EVAR:TEVAR
Frontier I*	FIM	2	12	10:2:0
Frontier II*	CE Mark	8	46	25:20:1
Frontier III*	CE Mark	6	62	42:16:4
Enrolling				
Frontier IV	Indication Expansion	12	75	On-going
Planned				
Registry	Post market	15+	300+	

* No acute major device related vascular complications
* No late major or minor device related vascular complications

FRONTIER III Clinical Study

Aim

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

Methods

50+ patients undergoing large bore femoral percutaneous access for TAVI, EVAR and TEVAR, prospective, non-randomized in 6 European centre

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

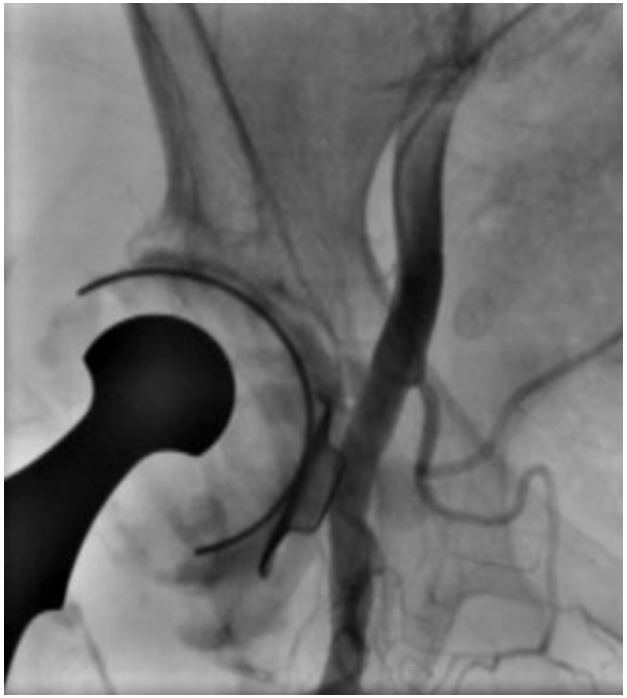
FRONTIER III – Procedural Information

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%

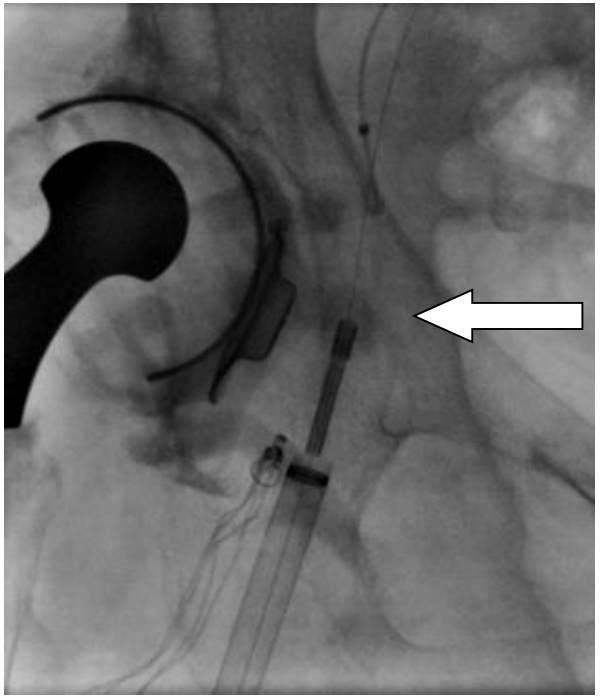
INDEX PROCEDURES			
Index Procedure Device	**Index Procedure Sheath**	**Hole OD for closing**	**(n=70)**
Sapien III	14F e-Sheath	23F	8
Sapien III	16F e-Sheath	~ 24F	13
Evolut™ R (w St Jude 18F)	14F	21F	15
Lotus™	18F	22F	5
SJM Portico	19F	22F	1
Nellix® (w/ Cook 18F)	14F	22F	2
Nellix® (w/ St Jude 18F)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

Pre-, peri- and post procedure angiograms

Pre-Implantation

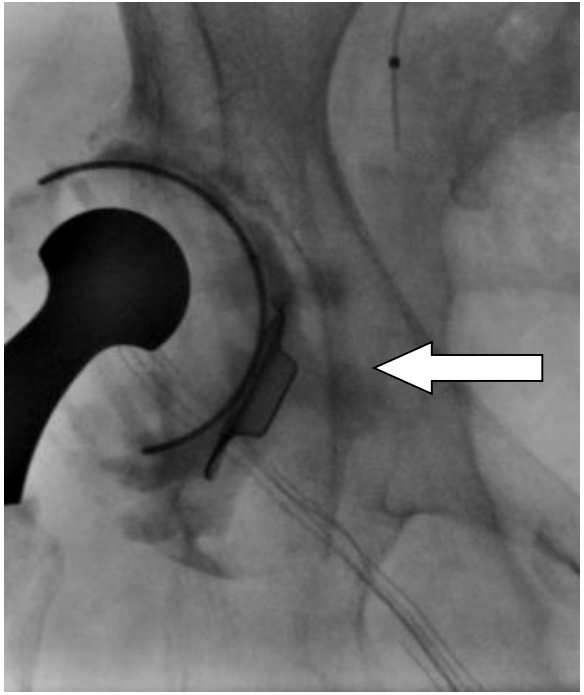


Tamponade peri-procedure



Control of bleeding during delivery

Post Implantation



Complete haemostasis
No stenosis

Frontier III – Results

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

Procedures	Patients	Closures	Related Complications (Minor)			
			Pre-Discharge	1 month	3 months	12 months
n	62	70	62	55	59	54
TAVR	42	42	0	0	0	0
EVAR	16	24	3 (5%)	0	0	0
TEVAR	4	4	0	0	0	0

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

Overall Clinical Experience
Frontier I, II & III

Over 120 patents implanted (9 centres across EU)

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

FRONTIER IV Clinical Study - active

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

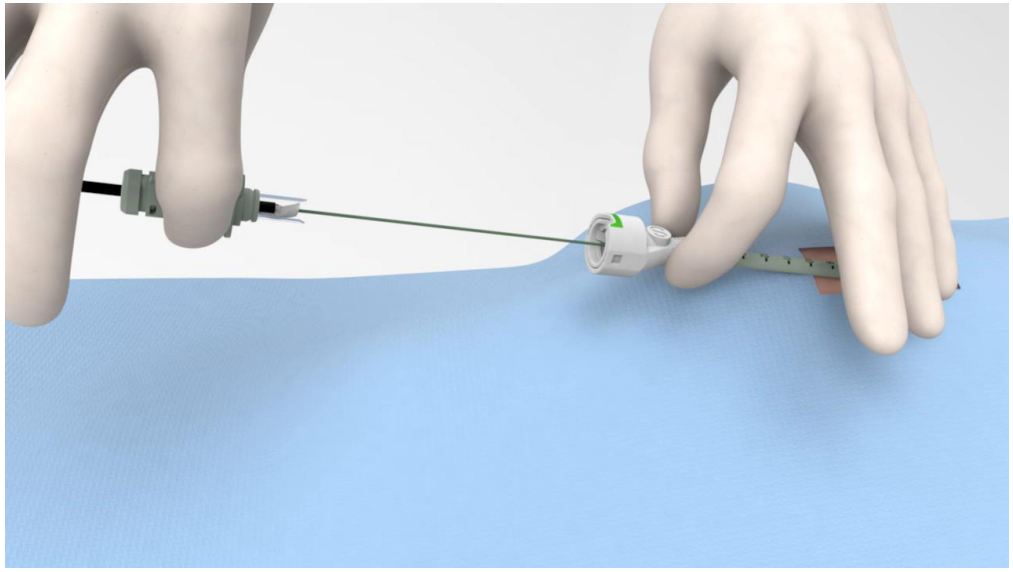
Scope

11 sites in Germany and Ireland

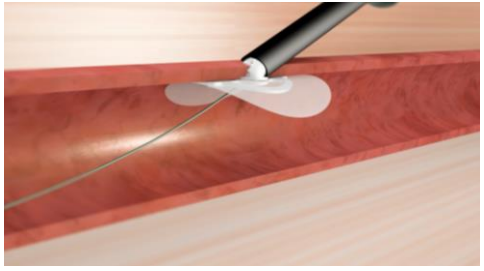
Status

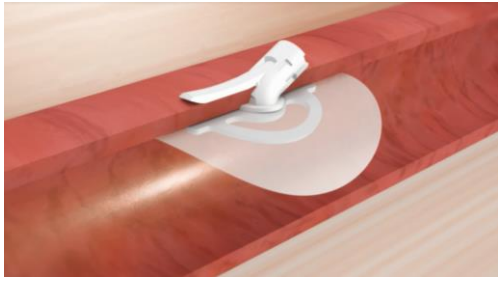
Enrolling

FRONTIER IV Clinical Study



- Dedicated introducer
- 0.014’ safety wire
- Simple 3-step delivery and deployment
- Immediate tamponade response





PerQseal® – Take aways

Designed for large arteriotomies

Fully synthetic, fully absorbable low profile implant

Simple over the wire delivery with safety wire in position

Full hemostasis control throughout delivery and deployment

No pre-closure

No metal, no sutures, no collagen

Safe