12-month results of a novel large access closure device: insights from the FRONTIER II Study

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- ❑ **I do not have any potential conflict of interest**

- ☑ **I have the following potential conflicts of interest to report:**

Honorarium:

Institutional grant/research support: ✓

Consultant: Avinger, Biotronik, Boston Scientific, Cordis, Johnson & Johnson, Terumo

Employment in industry:

Owner of a healthcare company:

Stockholder of a healthcare company:

Other(s):

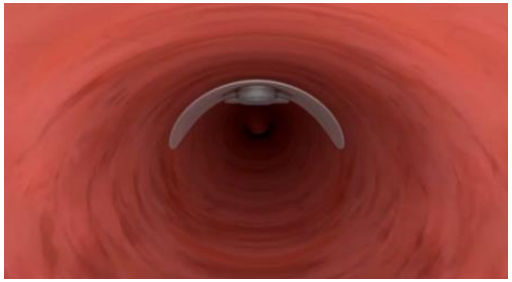
Frontier II CE-Mark Study

- Aim of the Studies: to evaluate the safety and performance of the
- VIVASURE CLOSURE DEVICE.
- 50+ patients undergoing large bore femoral percutaneous access for TAVI, EVAR and TEVAR, prospective, non-randomized in 7 European centres
- Assessment of puncture site with CCD at discharge, 30 days, 90 days and 1 year
- Primary endpoint:
  - Safety: 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. Standardized endpoint definitions for transcatheter aortic valve implantation clinical trials: a consensus report from the Valve Academic Research Consortium Leon et al. European Heart Journal 2011

VIVASURE CLOSURE DEVICE - Overview

- Designed for large arteriotomies (12 - 24F)
- Synthetic absorbable low-profile implant
- Over the wire delivery

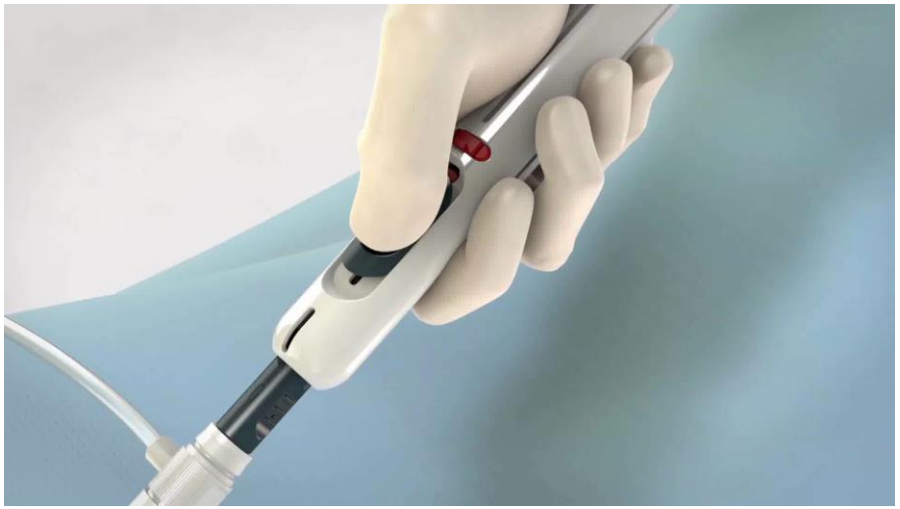


- Control of bleeding throughout delivery/deployment
- No sutures or collagen
- Used at conclusion of primary procedure (no pre-closure)

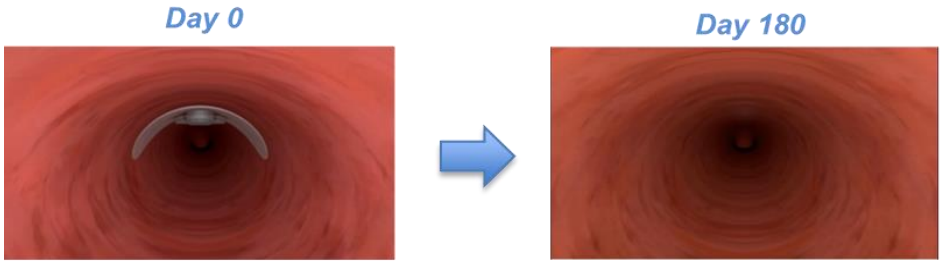
VIVASURE CLOSURE DEVICE - Overview

Features

PerQseal™ A NEW CLASS IN PERCUTANEOUS CLOSURE

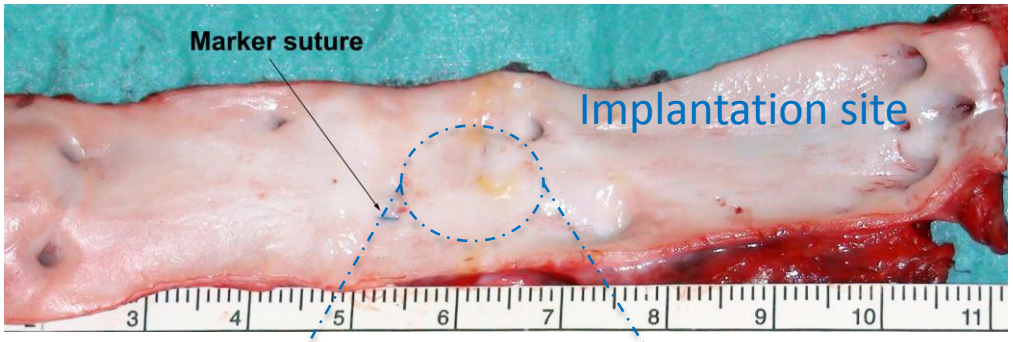


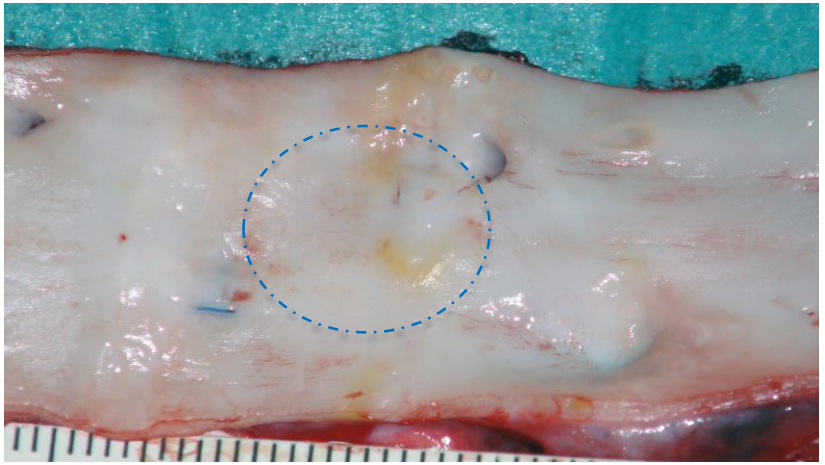
- Easy to use
  - ✓ 3 simple steps for deployment
  - ✓ No pre-placement
  - ✓ One device per arteriotomy
- Controls blood loss throughout procedure
- Maintains wire access
- Seals from inside
- Fully absorbable in 180 days

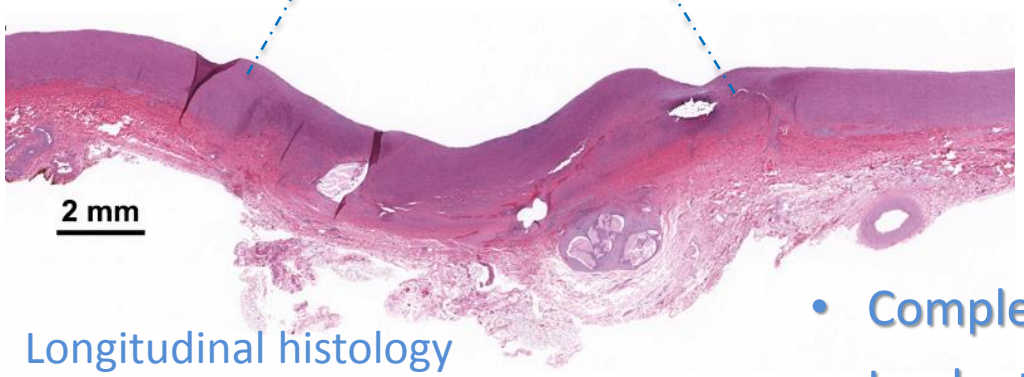


Pre-clinical Pathology – 162 days post-implant

Porcine abdominal aorta – luminal surface







Longitudinal histology

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

Multi-centred European Study - Results

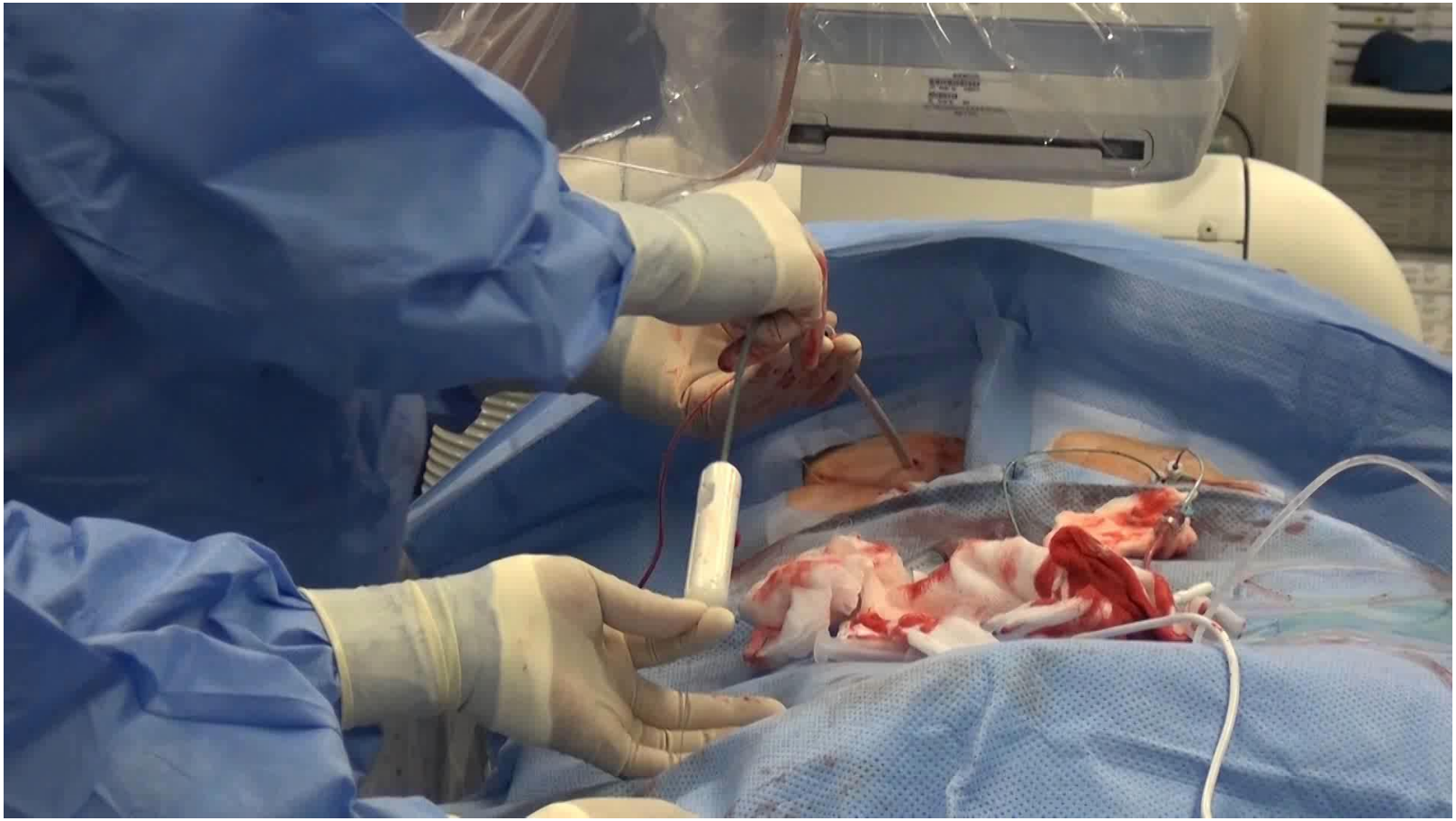
The FRONTIER II study was a non-inferior, prospective, multi-centered, non-randomized study to investigate the safety and performance of a new large hole closure device

- 58 subjects (66 closures) completed in 8 centers across Europe
  - 35 TAVI patients
  - 22 EVAR + 1 TEVAR patients

- No device related major vascular complications (VARC-2)
- 97% Technical success
- 55 subjects with 1 month follow-up; 51 with 3 Month follow-up and 42 with 12 month follow-up assessments completed – no late minor or major device related vascular complications
- No clinically significant changes on Ultrasound/CT

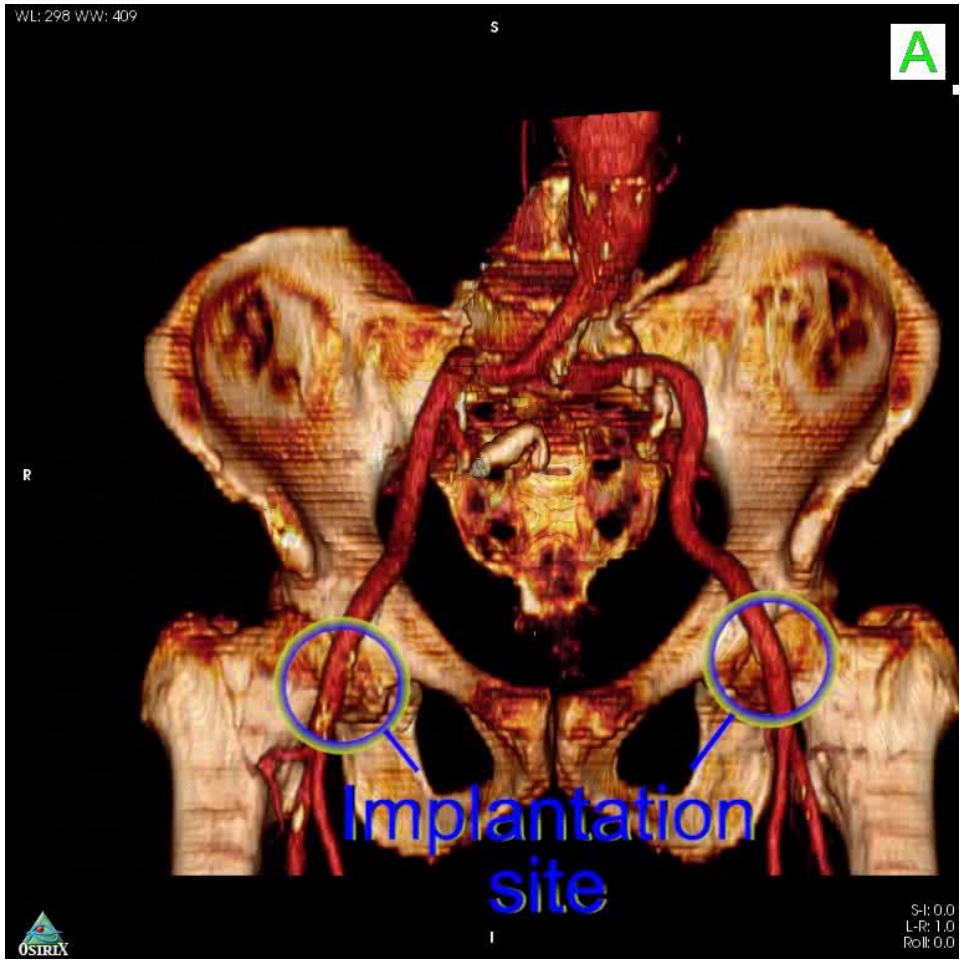
Clinical Case

- TAVR (Edwards 16F SAPIEN 3) - 77 year old Male, Height 175 cm, Weight 63.3 kg
- Right Access via 18 F sheath
- Med: 15 mg q.d. rivaroxaban

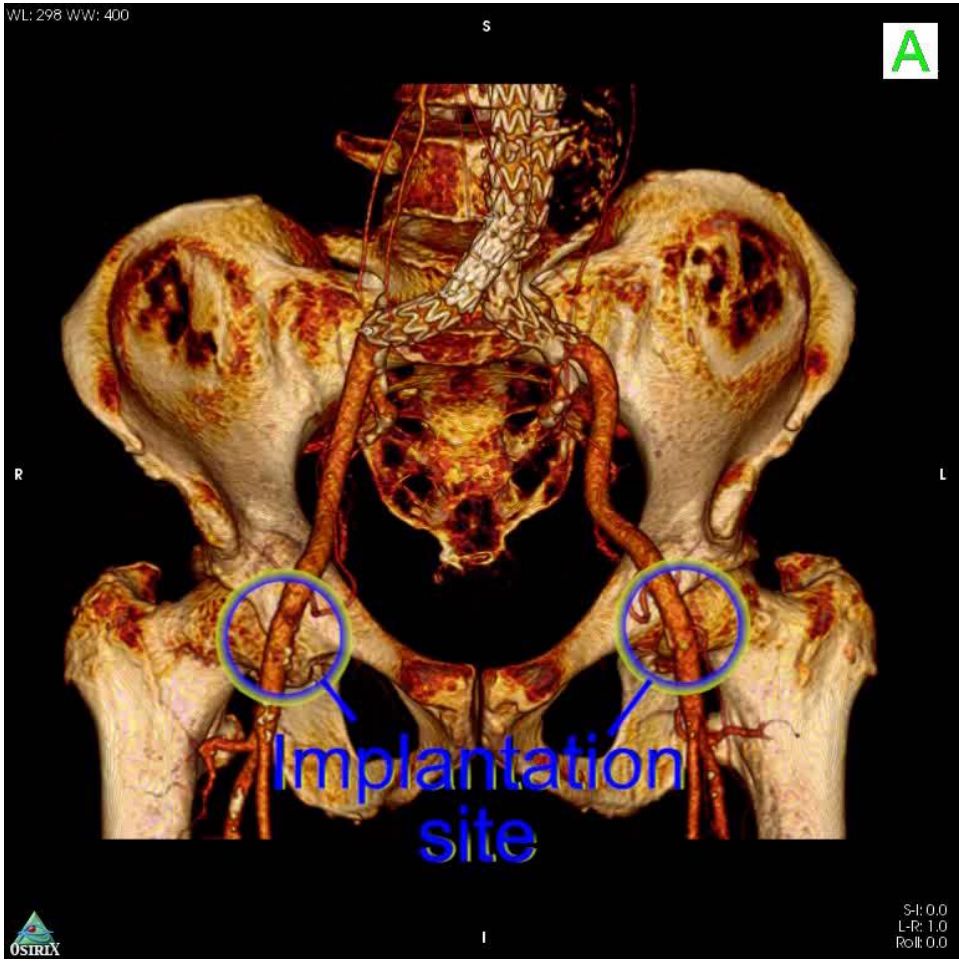


EVAR - bilateral arteriotomy closures

Pre-Implantation

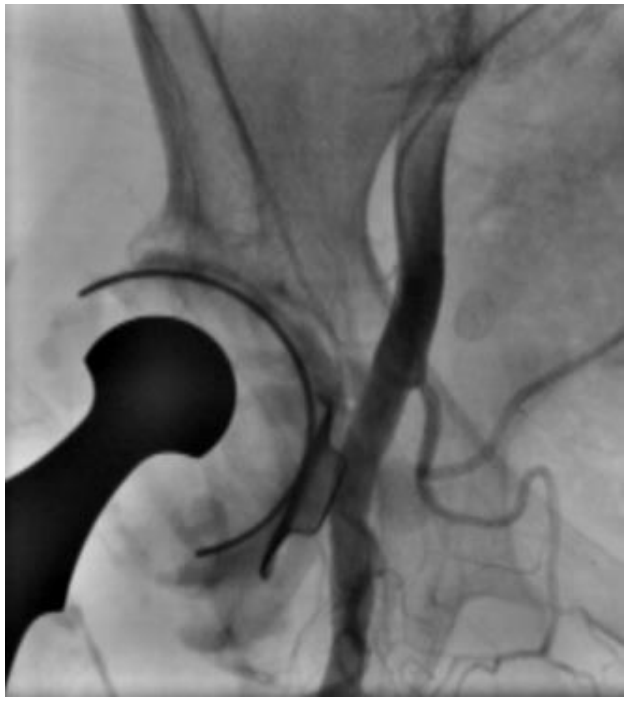


2 days Post Implantation

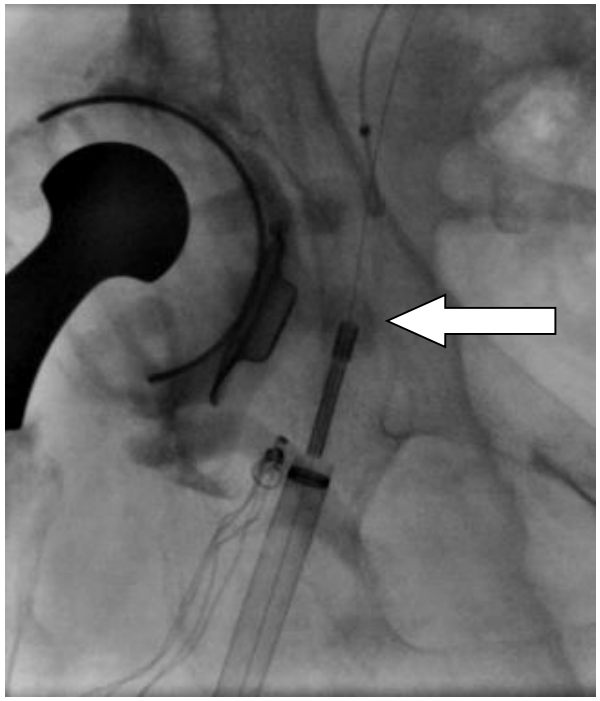


Angiograms – pre, peri and post procedure (Frontier II)

Pre-Implantation

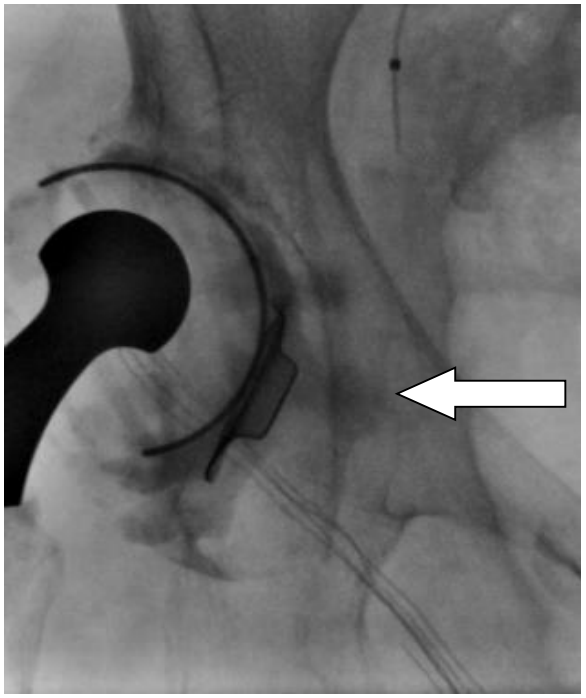


Tamponade peri-procedure



Control of bleeding during delivery

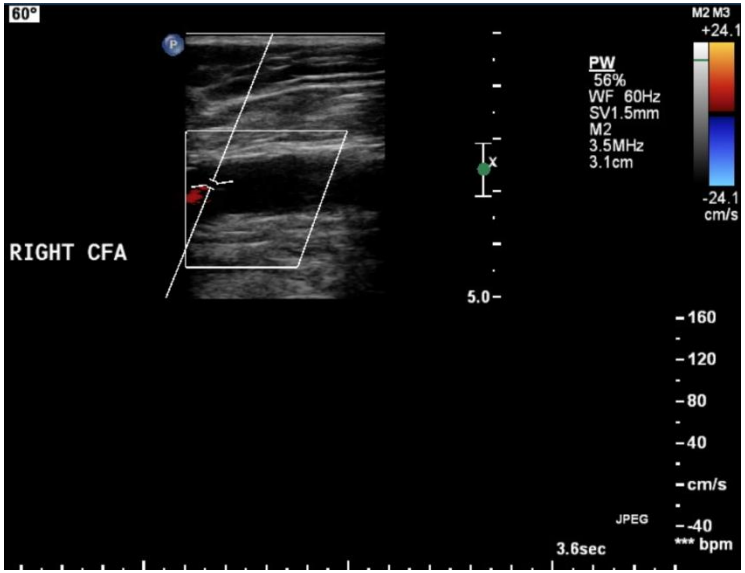
Post Implantation

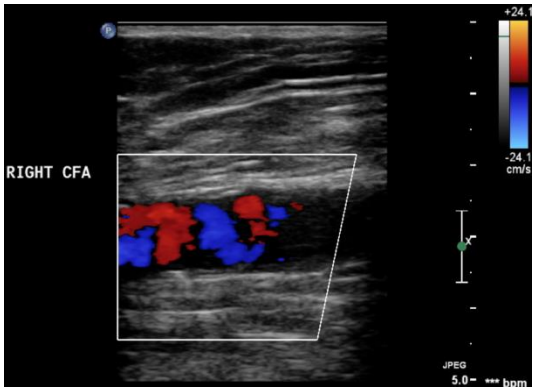


Complete haemostasis
No stenosis

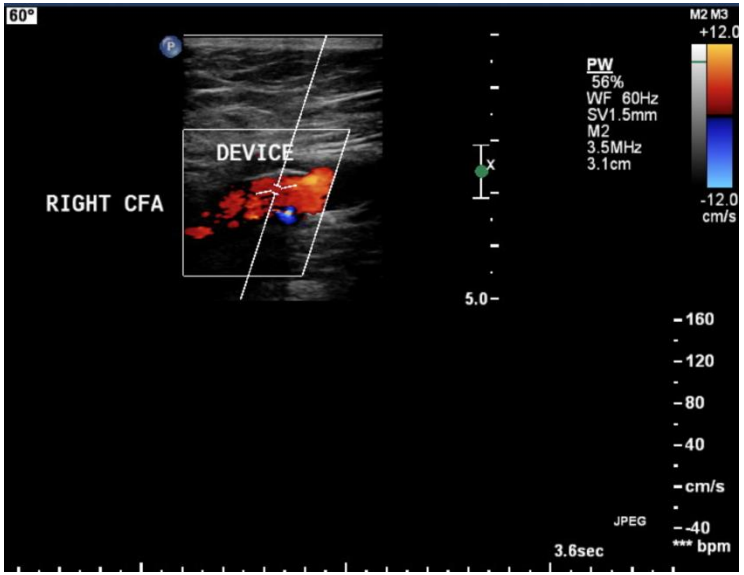
CE Mark Study Clinical Case Follow-up

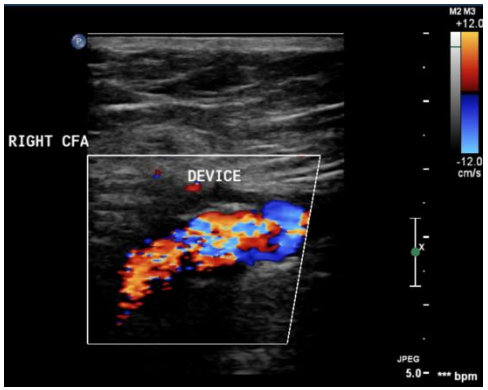
Pre-procedure





1 mo. post-procedure





Conclusions

- The new Vivasure closure device offers a safe and dependable alternative to open surgical closure, pre-close suture mediated or collagen plug devices for percutaneous closure of large hole femoral arteriotomies
- The device has demonstrated its safety and effectiveness with excellent outcomes from discharge through 1, 3 and 12 month follow-up
- The device performed reliably with a low learning curve (3 simple steps for deployment)
  - May be deployed in less than 1 minute with immediate haemostasis
  - No groin fibrosis or scaring observed to 12 months
- Uses an synthetic implant which is fully absorbable within 180 days
- Minimal haemodynamic impact observed
- Device provides a real option for fully percutaneous closure with reduced hospital costs and procedure times.