WELCOME *To the*

2026 SYMPOSIUM

# Xeltis aXess: Transforming Polymer into Living Tissue

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VASCULAR ACCESS SOCIETY OF THE AMERICAS VASA Access Excellence.

# Disclosures:

Merit Medical – Investigator, Educator

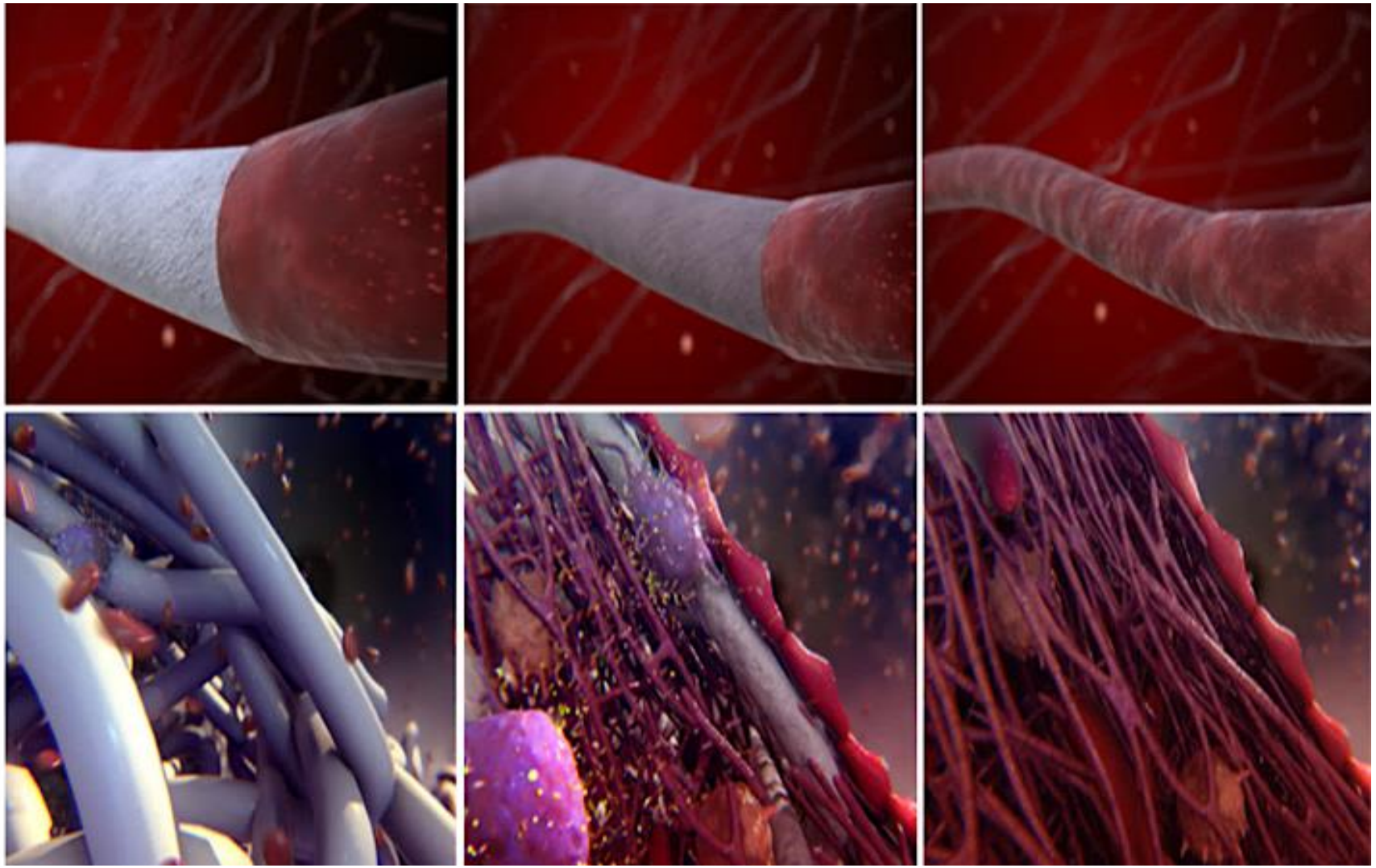
Boston Scientific – Investigator

Gore Medical – Investigator

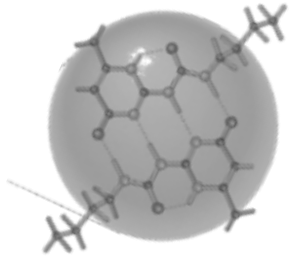
Laminate Medical – Investigator

Xeltis – Investigator

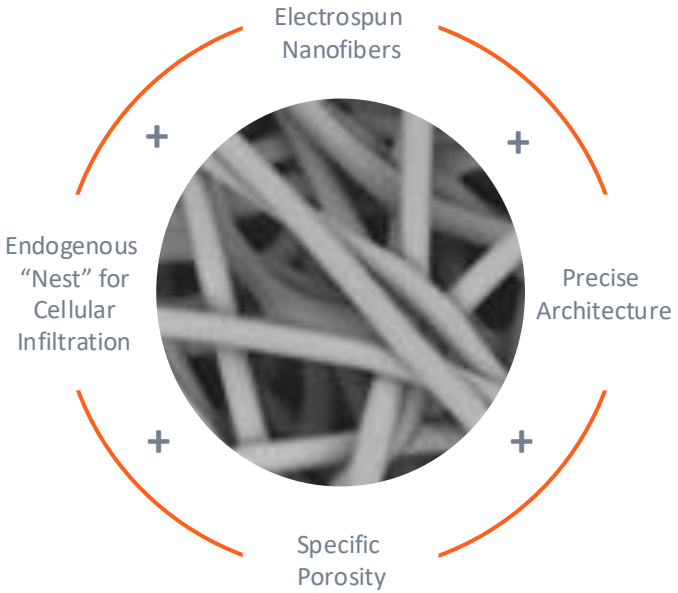
# Xeltis Restorative conduits enabling the natural creation of living and long-lasting vessels



# Xeltis' vascular aXess conduit for hemodialysis: A revolutionary advancement in novel polymer technology

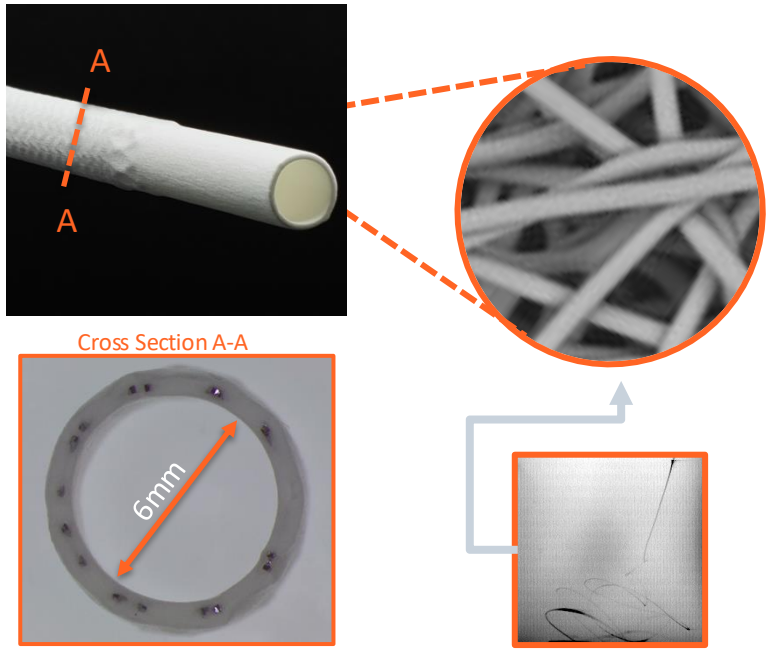


**Precise electrospinning**

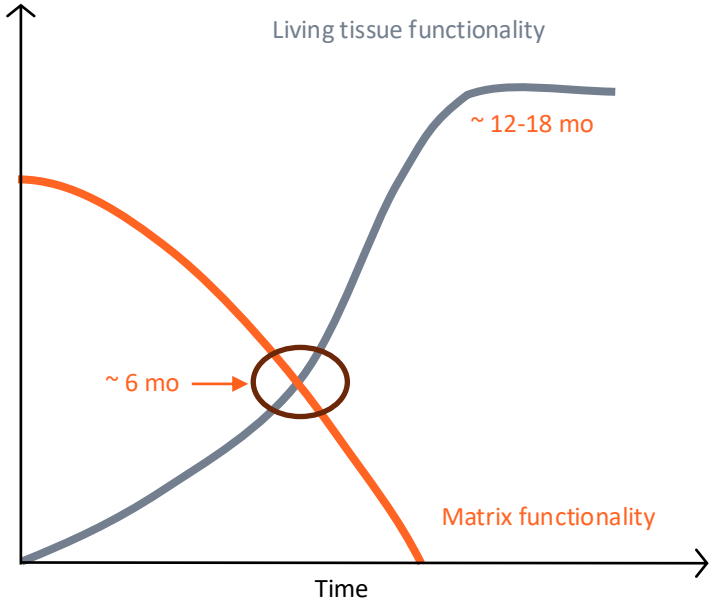



**Porous conduit design allows for patient's immune system to infiltrate and generate healthy response**

**Laser cut strain relief system (SRS) – Provides radial and kink support**




***Supramolecular chemistry creating novel class of Polymers**
**- Nobel Prize winning science -**




Polymer degradation and new tissue creation go hand in hand

*Exclusive to Xeltis

# Cross-section of supramolecular vessel transforming into natural tissue (ETR)

## Proposed paradigm based on currently available preclinical and clinical data

### 1. Early Phase (0-3 mo)

- Hemostasis within minutes after implant by fibrin and other blood components
- Diffuse macrophage infiltration with onset of polymer absorption at ablumen
- Abluminal early physiological healing and tissue growth

### 2. Intermediary phase (3-12 mo)

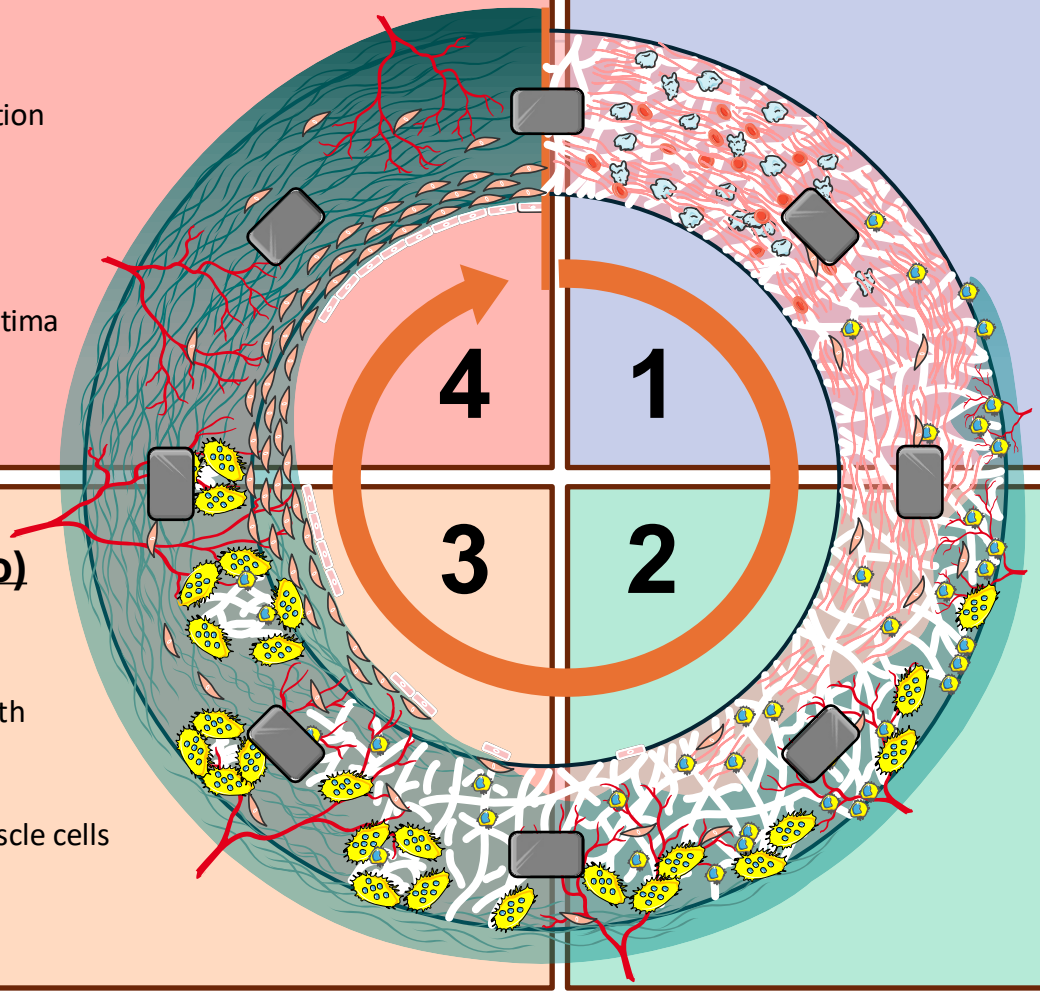
- Continued polymer absorption with abluminal giant cell formation
- Early formation of capillaries originating from abluminal tissue
- Onset of new connective tissue formation (via myofibroblasts)

### 3. Advanced phase (6-24 mo)

- Formation of giant cell-rimmed, actively absorbing, polymer islands
- Locally complete polymer absorption with resolution of inflammation
- Transmural capillary formation
- Neointima formation rich in smooth muscle cells with focal endothelial cells

### 4. Final stage (>24 mo)

- Uniform & complete polymer absorption
- Collagenized wall with inflammation resolution (neomedia)
- Reduction in transmural vascularity (quiescence)
- Mature, endothelialized, stable neointima




Supramolecular polymer implant

Microskeleton nitinol strut (SRS)

Fibrin, platelets & red blood cells

Macrophage

Foreign Body Giant cell

Smooth muscle cell /myofibroblast

Endothelial cell

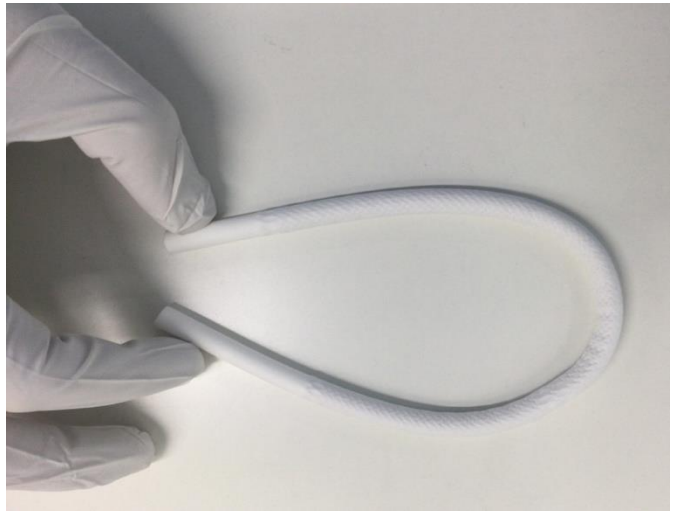
(transmural) blood vessels

Collagen

The aXess AV dialysis access conduit

# Enabling the body to create its own vessel

**From an arteriovenous implant…**

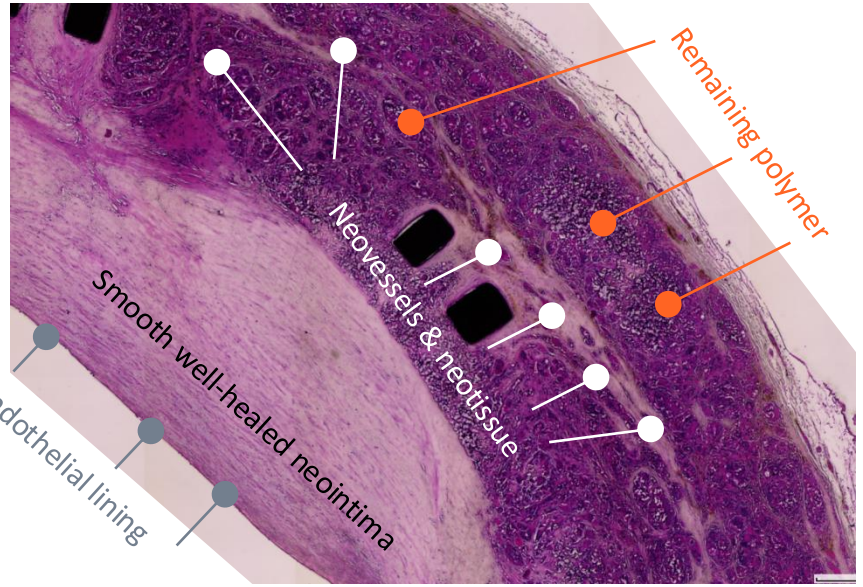


Endogenous Tissue Restoration (ETR)

**… to a living natural conduit**

14 months follow-up in human

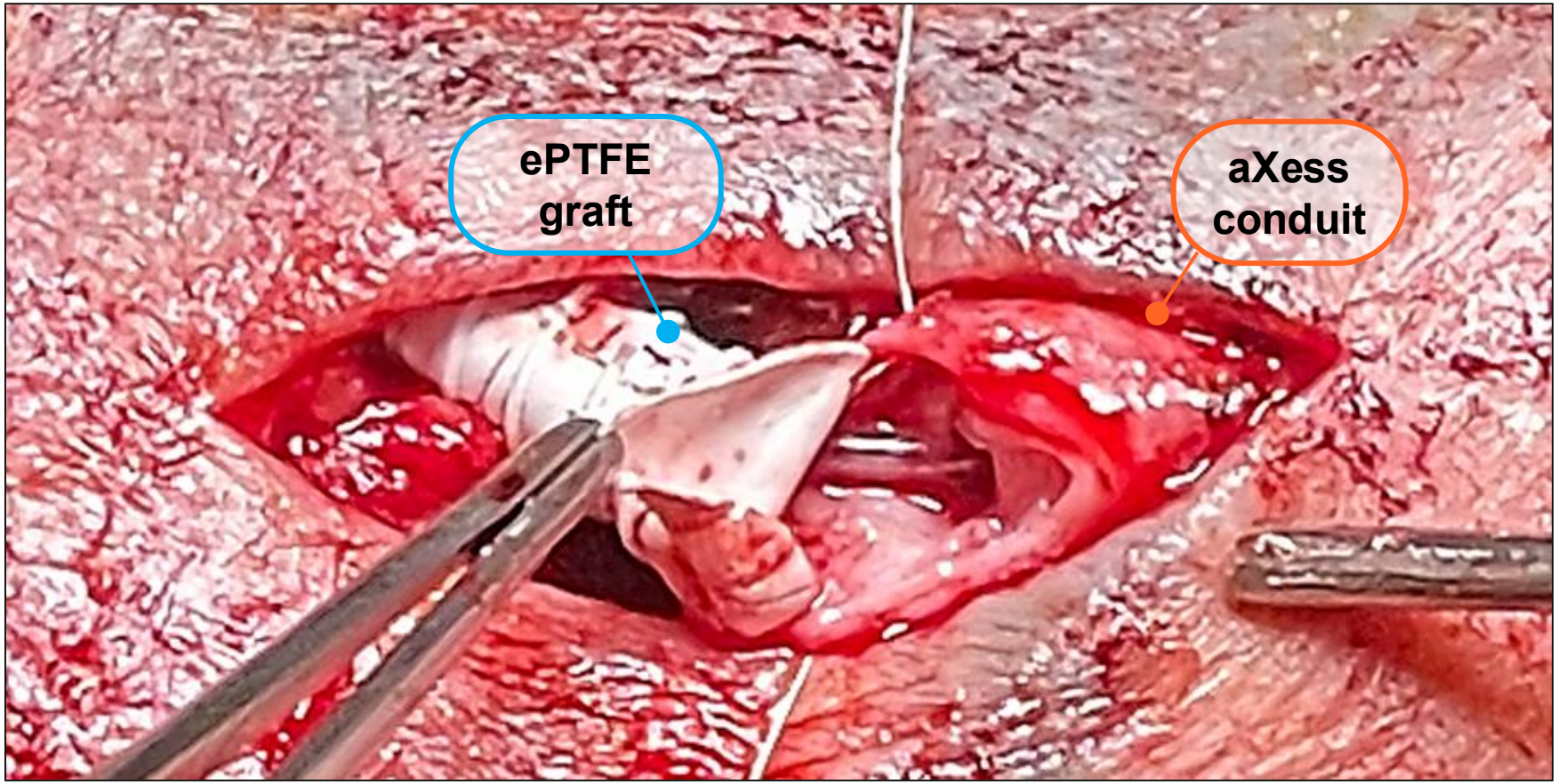
Implant polymer interspersed with neotissue and neovessels




The aXess conduit harnesses the body's natural healing systems:

as ETR occurs, Xeltis' implants (AVG) are gradually absorbed by the body, leaving a living natural conduit (AVF).

# Clinical Evidence of aXess Biotransformation




6 months post implant

- RC AVF inflow to new aXess
- Inflow issue at 6mo
- Revised with ePTFE cuff

# aXess vs ePTFE

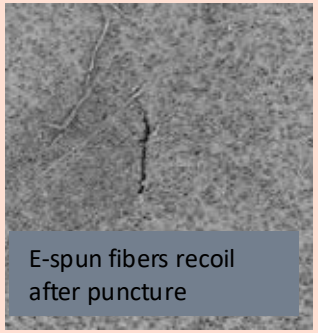
## aXess structure provides recoil and healing in response to cannulation

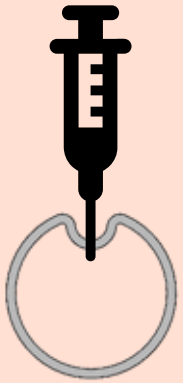
### aXess

- Electrospun microstructure recoils after puncture
- Nitinol support cannulation recoil prevents back-wall puncture
- Supramolecul polymer & microstructure enable healing after cannulation in vivo

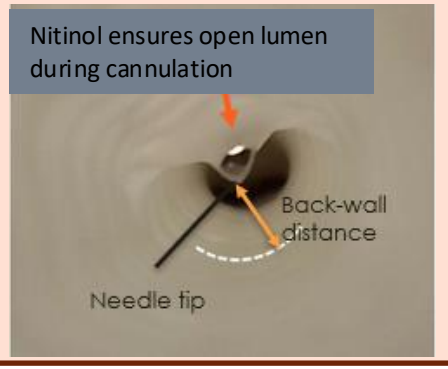
**Bench**

No puncture hole



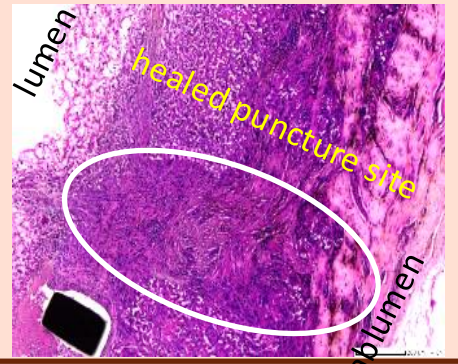



No back-wall puncture




**In vivo**

Healing & tissue integration




4 months post implant

### ePTFE

- No recoil after puncture – leaving hole
- Near-collapse of lumen during cannulation – back-wall puncture risk
- No healing after puncture – only plugging holes

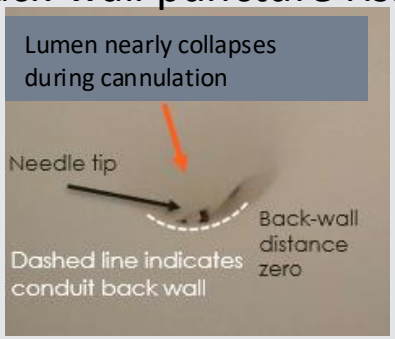
**Bench**

Puncture hole



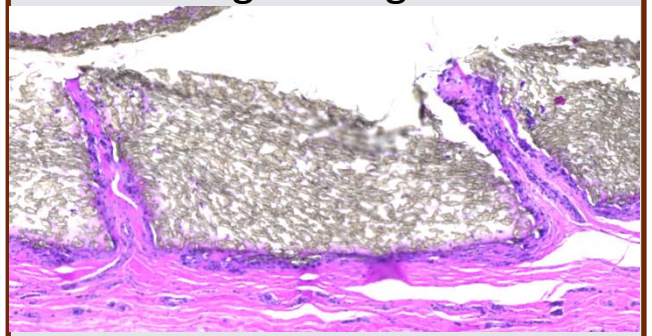



Back-wall puncture risk




**In vivo**

No healing & integration



11 months post implant

XELTIS

# aXess Moves like a Vessel

Ultrasound indicates that **graft compliance** may develop over time

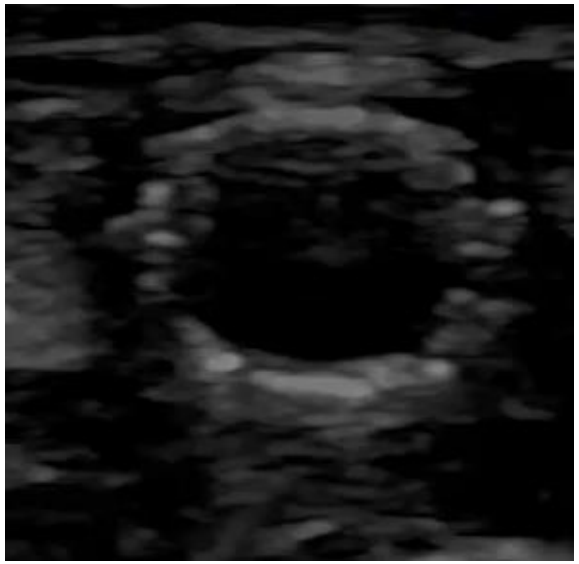
**Evidence of compliance in remodelled tissue → improving over time**



12 months



18 months



24 months

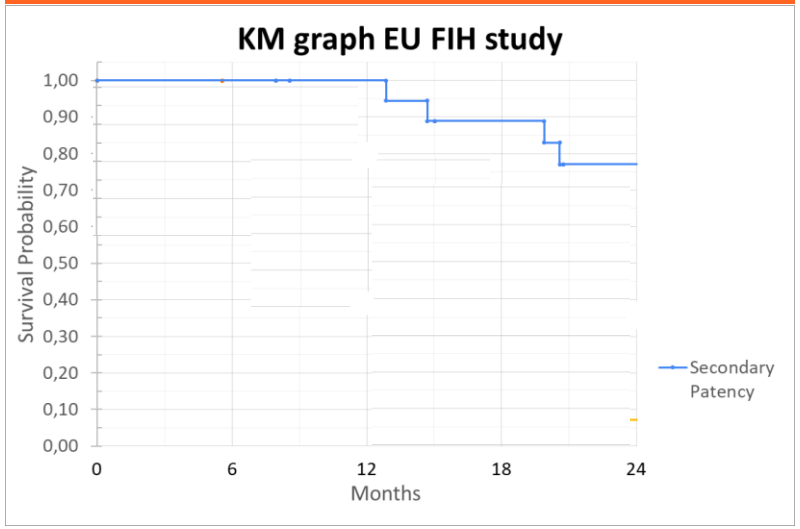
# What's the Clinical Value?

## Resistance to Infection

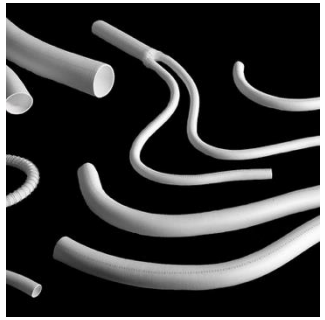


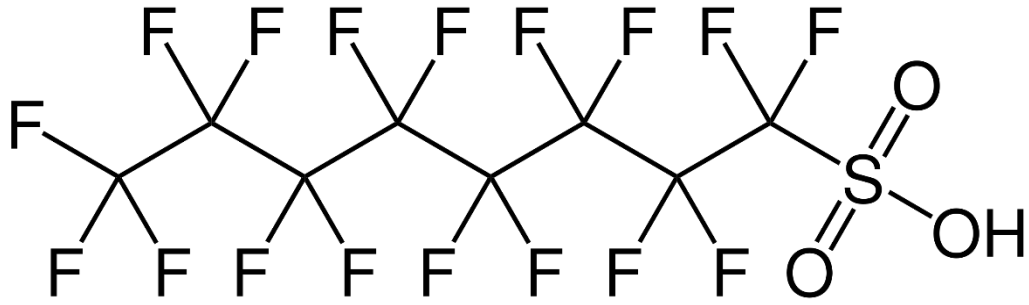
Reduced Interventions

## Improved Patency

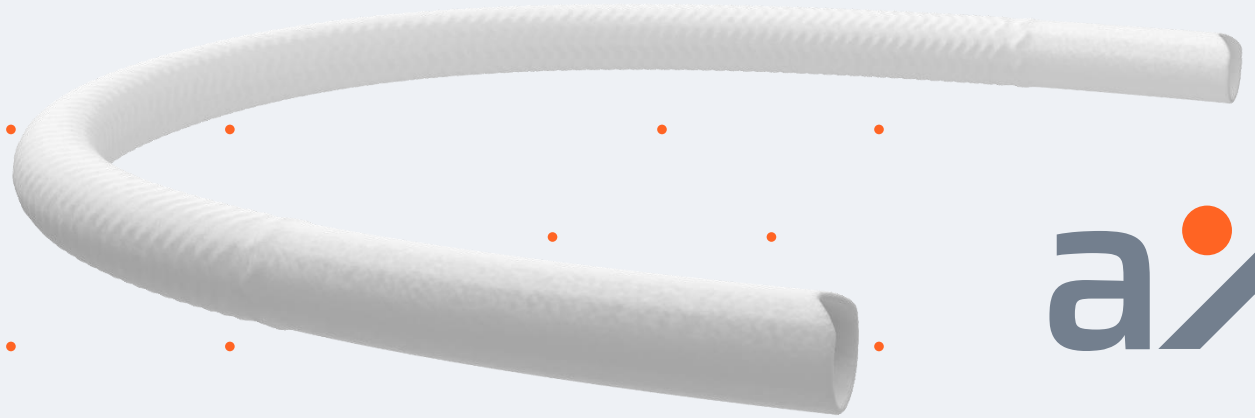



## PFAS Free






Majority of dialysis and vascular grafts



aXess PIVOTAL

# EU Pivotal Study

## Mid-term results summary

XELTIS

# aXess Pivotal EU trial

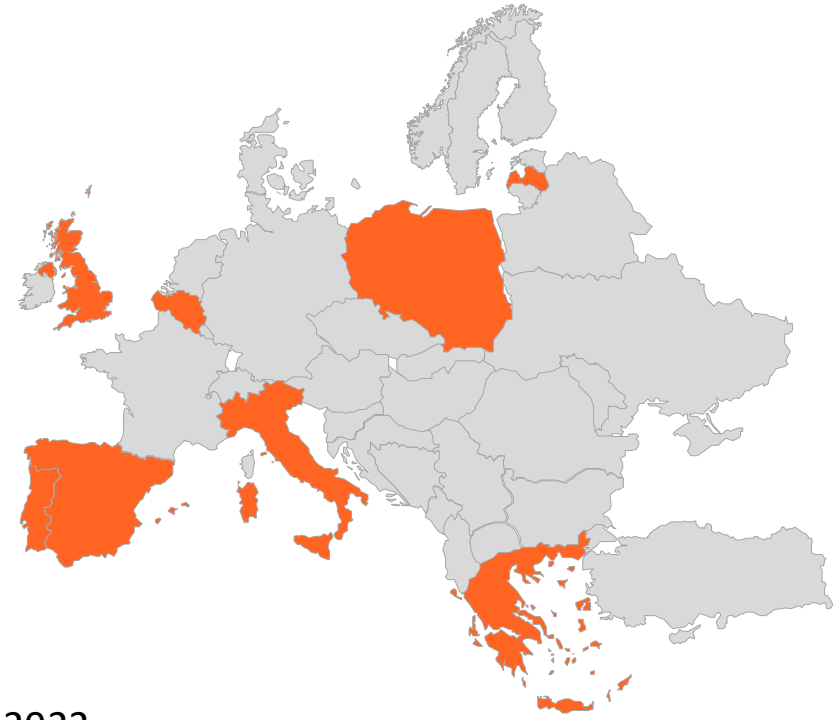
## Study design

1. European Pivotal Study
2. Multi-center, prospective, single-arm
3. Up to 22 centers
4. 120 subjects implanted
5. Full study follow-up 5 years

## Primary endpoints

- Freedom from device related serious adverse events at 6 months
- Primary patency at 6 months

**120 Patients** enrolled at **18 sites** in **8 countries**



**First patient enrolled:** 08-Nov-2022

**Last patient enrolled:** 19-Dec-2024

**Primary endpoint reached:** 23-Jun-2025

**Current status:** long term follow-up ongoing post 12M

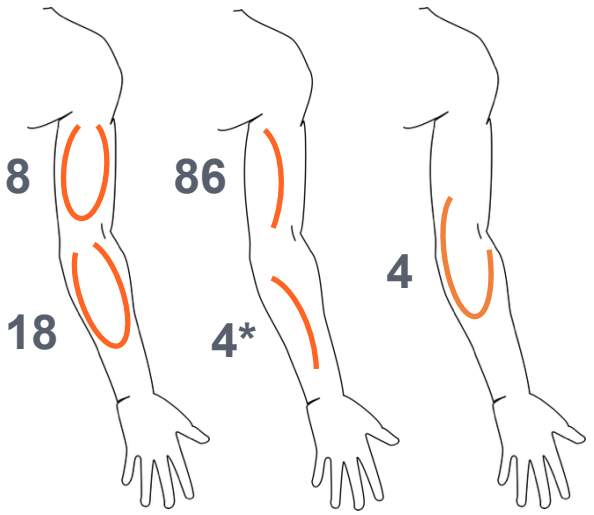
# aXess EU Pivotal trial

## Baseline characteristics

| Baseline patient characteristics | |
|---|---|
| Number of patients enrolled | 120 |
| Men (N; %) | 63 ; 53% |
| Mean age (years ± SD) | 64 ± 15 |
| Previous CVC (N; %) | 79; 66% |
| Failed fistula (N; %) | 41; 34% |
| Multiple previous fistulas (N; %) | 20; 17% |
| Failed AVG (N; %) | 7; 6% |
| Comorbidities (N; %) | |
| Diabetes (all) | 46/119; 39% |
| Cardiovascular disease | 25/119; 21% |
| Nicotine Usage (n/N; %) | |
| Current | 16; 13% |
| Previous | 29; 24% |

| Operative data | |
|---|---|
| Mean operative time (minutes ± SD) | 99 ± 37 |
| Implantation Success rate (N, %) | 119, 99% |
| Implant configuration<br>• Straight<br>• Loop | <br>90 ; 75%<br>30 ; 25% |
| Post operative Aspirin use (N; %) | 57; 48% |

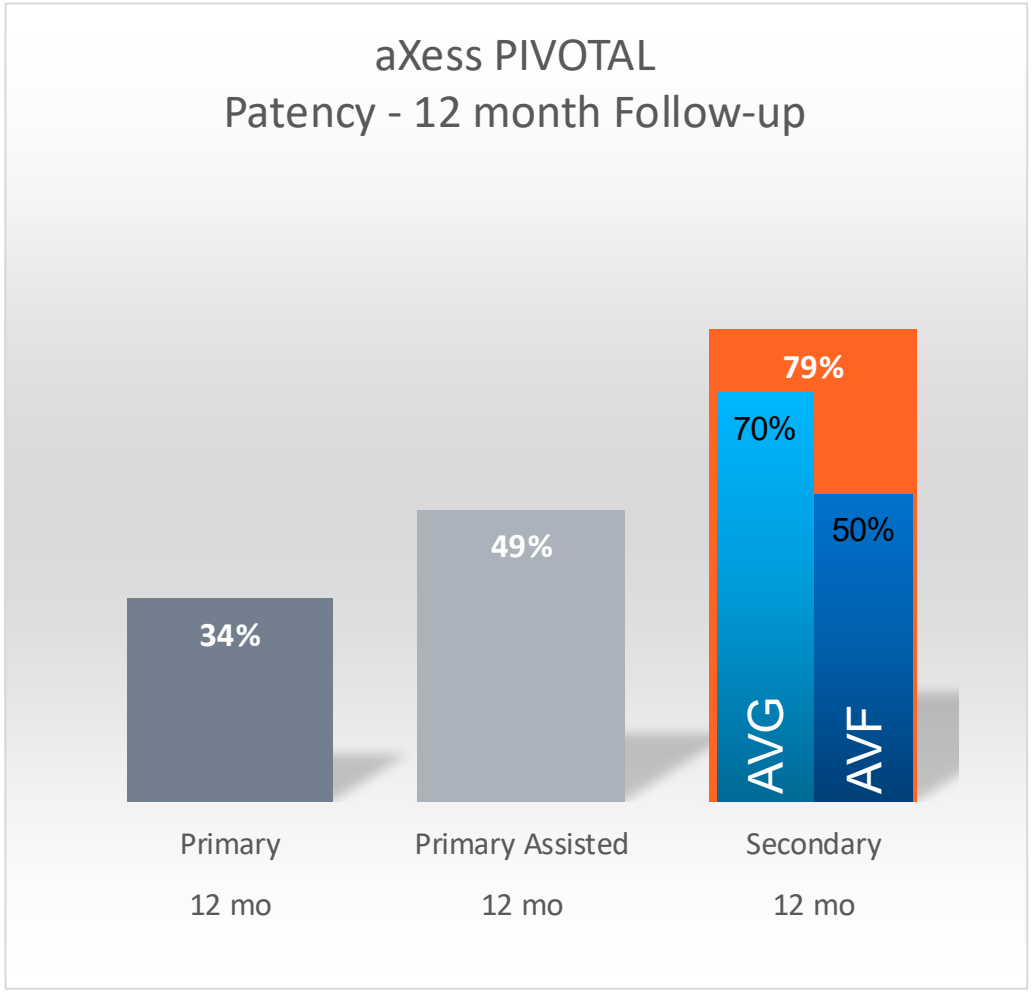
***Implant Configuration:***

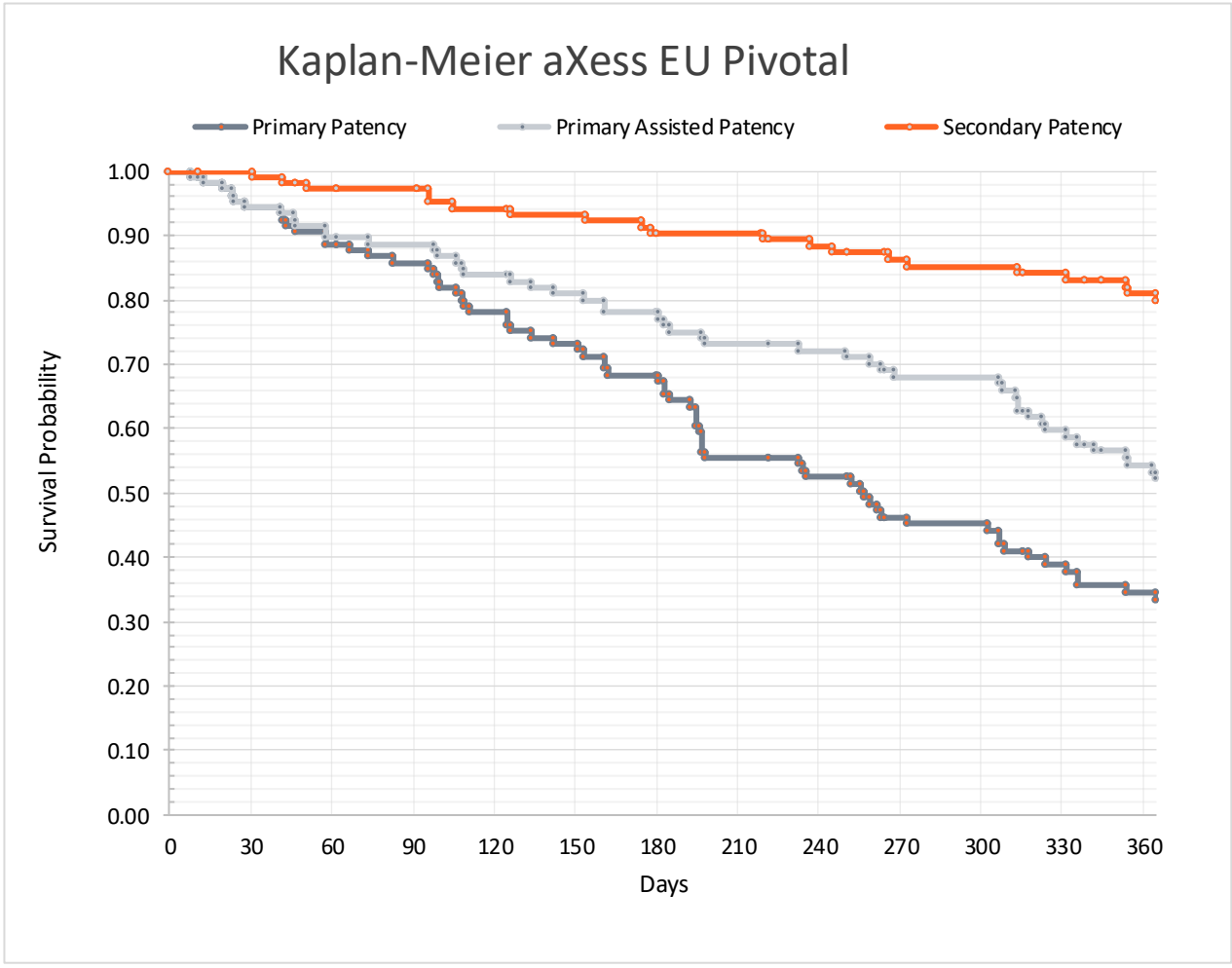



** 1 patient with lower arm straight crossing the elbow*

# aXess EU Pivotal trial

## 12 month results



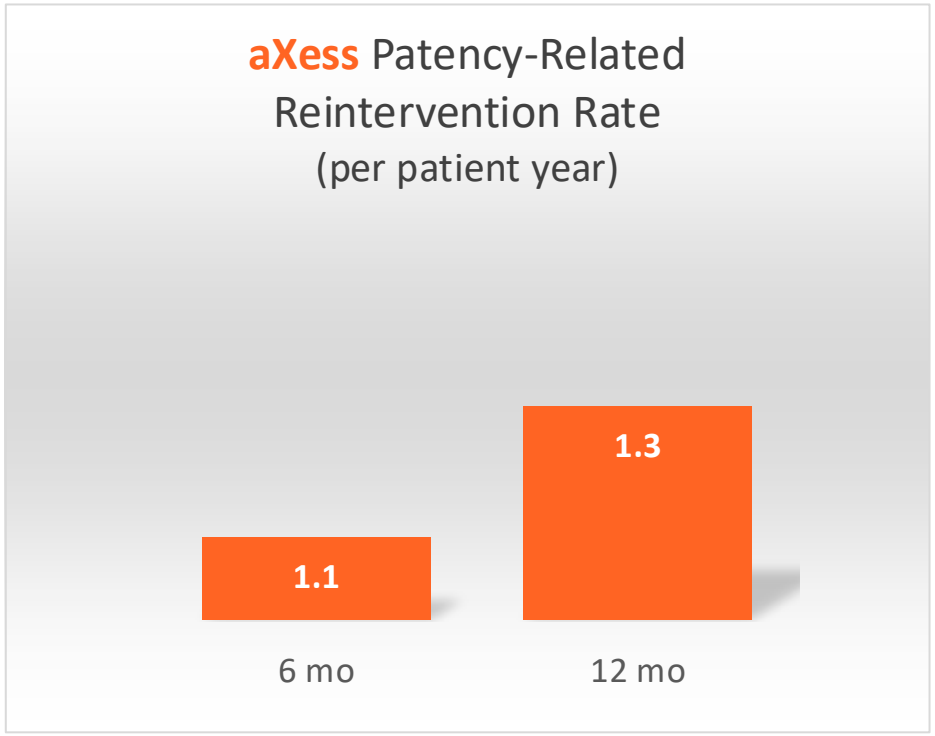



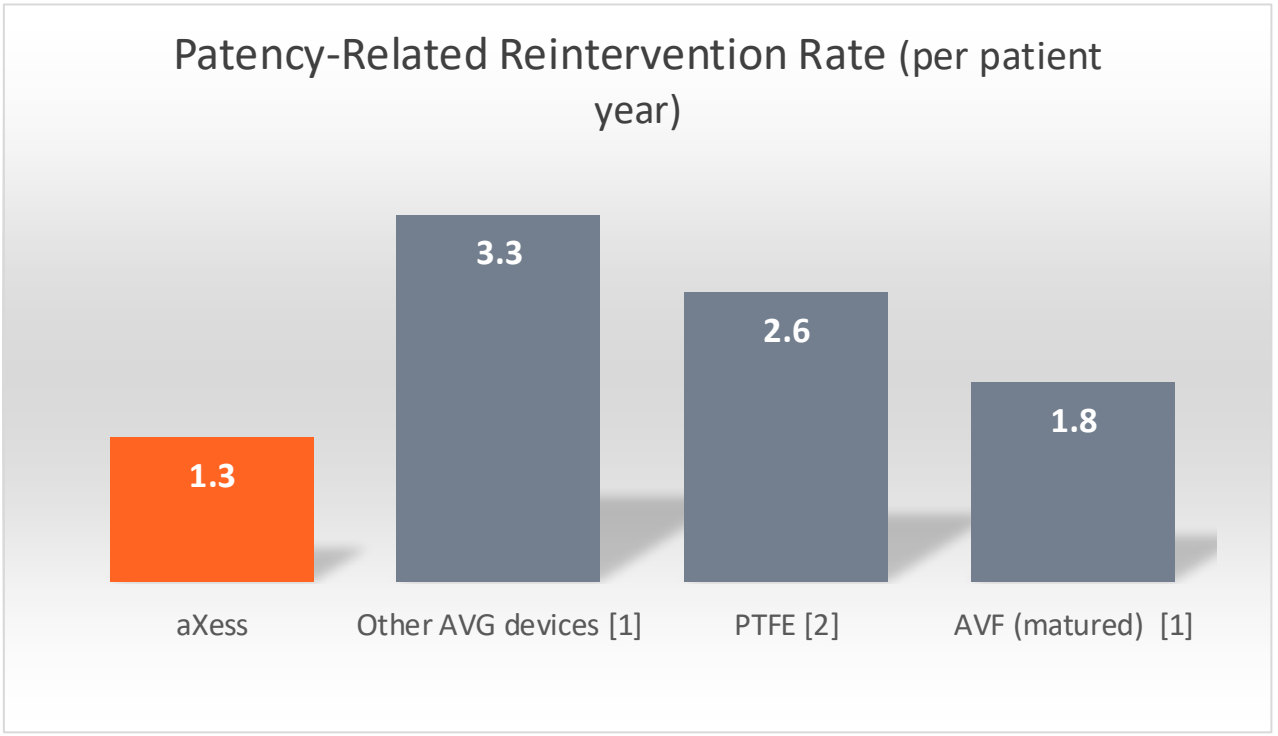


[1] R.J. Halbert et al, "Patency of ePTFE Arteriovenous Graft Placements in Hemodialysis Patients" 2020.
[2] T. S. Huber et al, "Patency of autogenous and polytetrafluoroethylene upper extremity arteriovenous hemodialysis accesses: A systematic review" 2003.
[3] K.J. Woodside et al, "Arteriovenous Fistula Maturation in Prevalent Hemodialysis Patients in the United States" 2018, AJKD, Vol 71, Iss 6, pg 793-801.

# aXess EU Pivotal trial

## 12 month results – **reintervention rates**

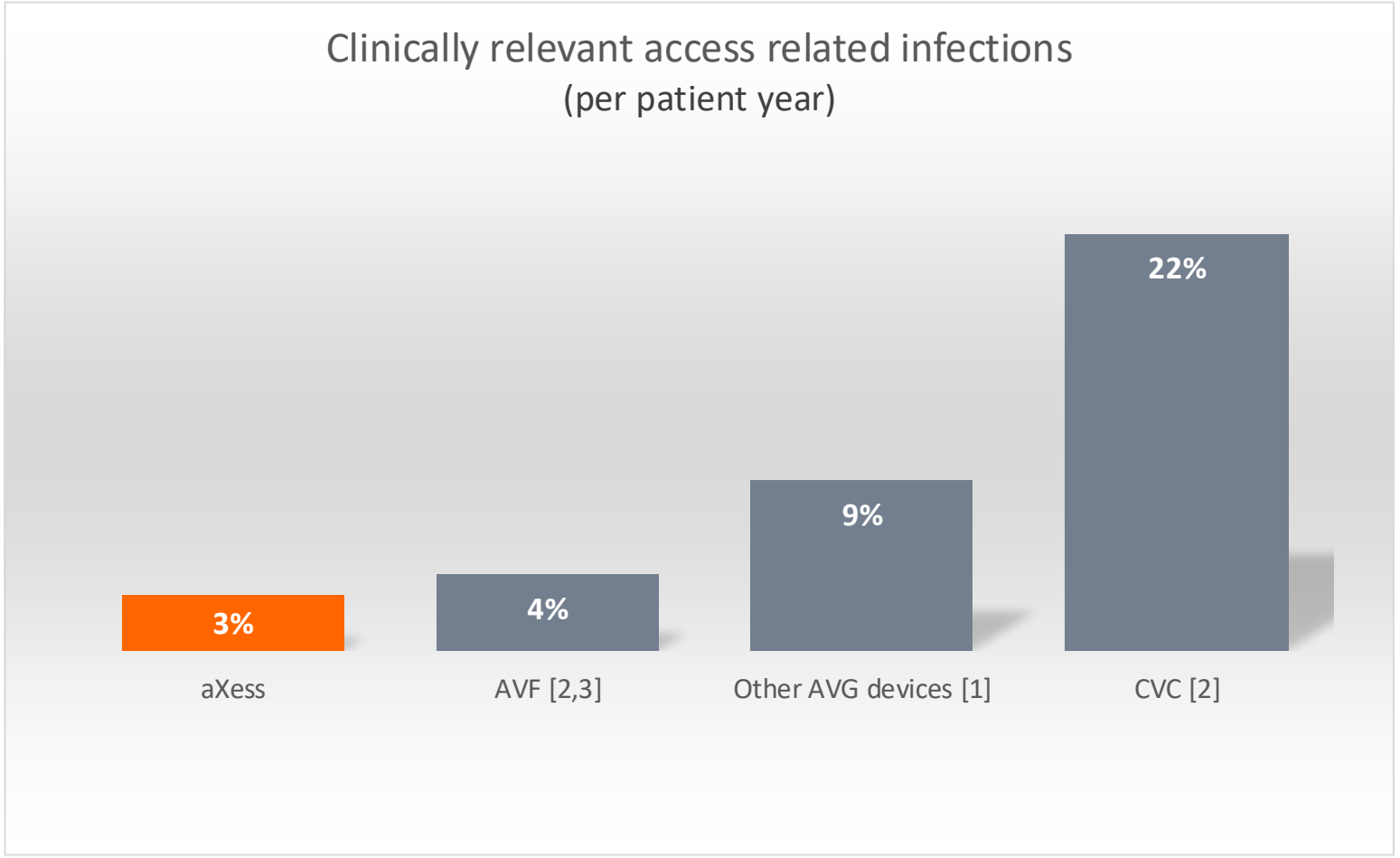



[1] Voorzaat BM, Janmaat CJ, van der Bogt KEA, Dekker FW, Rotmans JI. Patency Outcomes of Arteriovenous Fistulas and Grafts for Hemodialysis Access: A Trade-Off between Nonmaturation and Long-Term Complications. Kidney360. 2020 Jul 23;1(9):916-924.
[2] P. Marcus, A. Echeverria, M. Cheung, E. Kfoury, K. Shim, and P. H. Lin, "Early Cannulation of Bovine Carotid Artery Graft Reduces Tunneled Dialysis Catheter-Related Complications: A Comparison of Bovine Carotid Artery Graft Versus Expanded Polytetrafluoroethylene Grafts in Hemodialysis Access," Vasc Endovascular Surg, vol. 53, no. 2, pp. 104–111, Feb. 2019

# aXess EU Pivotal trial

## 12 month results – **infection rates**




1 R.J. Halbert et al, "Patency of ePTFE Arteriovenous Graft Placements in Hemodialysis Patients" 2020

2 A. A. Al-Jaish et al, "Complications of the Arteriovenous Fistula: A Systematic Review", Am Soc Nephrol 28: 1839–1850, 2017

3 D.B Nguyen et al, "National Healthcare Safety Network (NHSN) Dialysis Event Surveillance Report for 2014", Clin J Am Soc Nephrol, vol 12, July 2017

# aXess EU Pivotal trial

## 12 month results – **Dialysis data**

### Proven success in the dialysis clinics

- First cannulation as early as 14 days
- 27% of patients cannulated within 14-30 days
- Low bleeding complications due to cannulation 0.02%
- Post-cannulation Time To Hemostasis (TTH) was between 5 – 10 min. (mean 7.4 min.) in >95% of patients

| Dialysis data of 120 pts at 12mo follow-up | |
|---|---|
| Number of patients cannulated (N; %) | 101; 84% |
| Days to first cannulation (median; range) | 38; 14 – 217 |
| Estimated number of dialysis sessions | 10792 |
| Cannulation related bleeding (events, % of dialysis sessions) | 2, 0.02% |
| Average (spKt/V) | 1.51 |
| Median URR | 72% |



# aXess EU Pivotal trial
## Conclusions from EU Pivotal

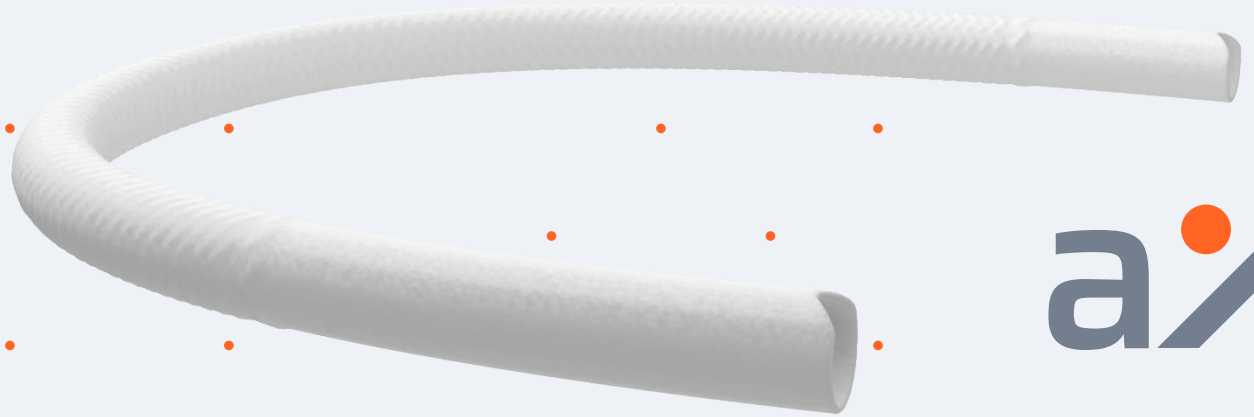
Demonstrated safe and easy implantation

Low reintervention and infection rates compared to ePTFE

Reintervention and infection rates similar to autologous AVF

Cannulation as early as 14 days

aXess becomes a pulsating vascular tissue conduit by 12 months



aXess PIVOTAL

# US Pivotal Study

XEL-CR-12

XELTIS

# aXess Pivotal US trial

## Study design

1. US IDE, staged-Pivotal trial
2. Multi-center, prospective, single-arm, non-randomized
3. Up to 20 centers
4. Approximately 140 subjects in total
5. Full study follow-up 5 years

## Primary endpoints

- Rate of device related infections and bleeding at 12 months
- Secondary patency rate at 12 months in survivors

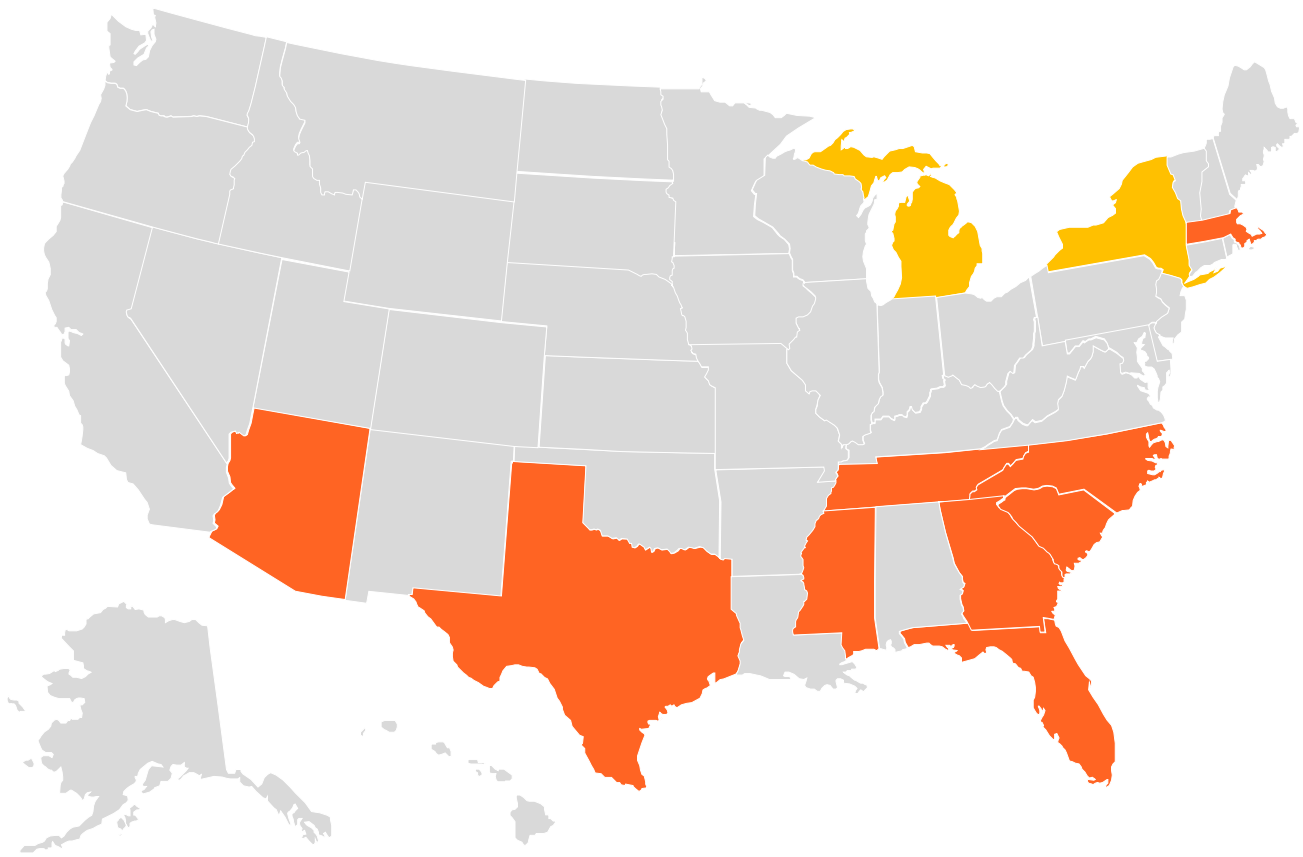
## Secondary endpoints

- Freedom from device-related SAE (assessed at discharge, 1, 3, 6, 12, 18, 24, and 60 months).
- Implantation success rate.
- Patency (primary, primary assisted, secondary, and functional) rates at 6, 12, 18, 24, and 60 months.
- Time to first intervention and to access abandonment
- Rate of access-related interventions required to achieve/maintain patency at 6, 12, 18, 24, 60 months.
- Incidence rate of access site infections at 6, 12, 18, 24, and 60 months.
- Time to the first cannulation.

# aXess **Pivotal US trial**

## Site Distribution

Currently **50+ Patients** enrolled at **17 active sites** in **9 states**

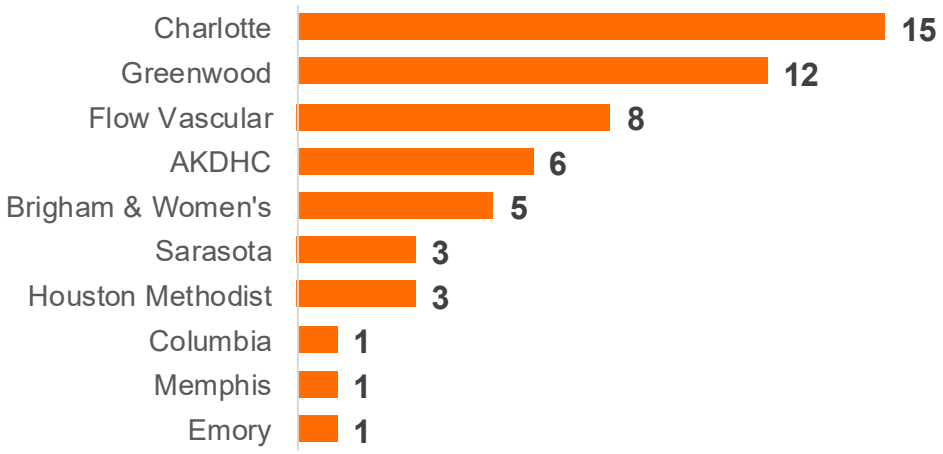


| State | | Sites | PIs |
|---|---|---|---|
| | **MS** | Greenwood Leflore | Dr. Lucas |
| | **NC** | Surgical Specialists of Charlotte<br>Duke<br>Raleigh Access | Dr. Burgess<br>Dr. Chun<br>Dr. Patel |
| | **TX** | Flow Vascular Houston<br>Houston Methodist Hospital<br>Baylor | Dr. Illig<br>Dr. Peden<br>Dr. Hohmann |
| | **AZ** | Arizona Kidney Disease & Hypertension Centers (Phoenix) | Dr. Wang |
| | **MA** | Brigham & Women's | Dr. Selim |
| | **FL** | Sarasota Memorial<br>AAC Miami | Dr. Wagner<br>Dr. Ramirez |
| | **TN** | Memphis Access | Dr. Gardner |
| | **SC** | Columbia<br>MUSC<br>Spartanburg | Dr. Franga<br>Dr. London<br>Dr. Tanious<br>Dr. Kramer |
| | **GA** | Emory | Dr. Mahajan |

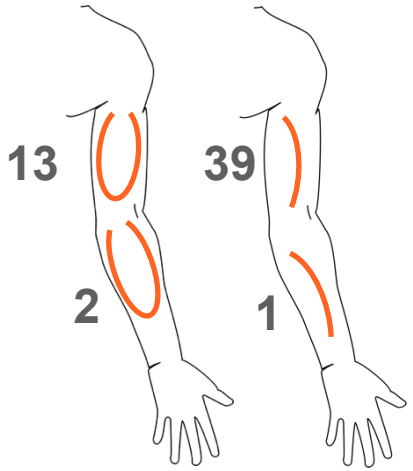
# aXess US Pivotal – Outcome Dashboard

| Patients Treated | Implantation Success Rate | Estimated Hemodialysis Session | Median Follow-Up | Longest Ongoing Follow up |
|---|---|---|---|---|
| **55** | **100%** | **>3500** | **221 d** | **>18 M** |
| *Female: 22 Male: 33*<br>*Age: Ø58 (23-82) yrs* | *55 / 55* | *Assumes 2.8 sessions per week* | *Cumulative: 11513 days* | |

## *Site Distribution:*




## *Procedure / Device Details:*




**0** Severe Bleeding Complications

**1** Cannulation-related complication

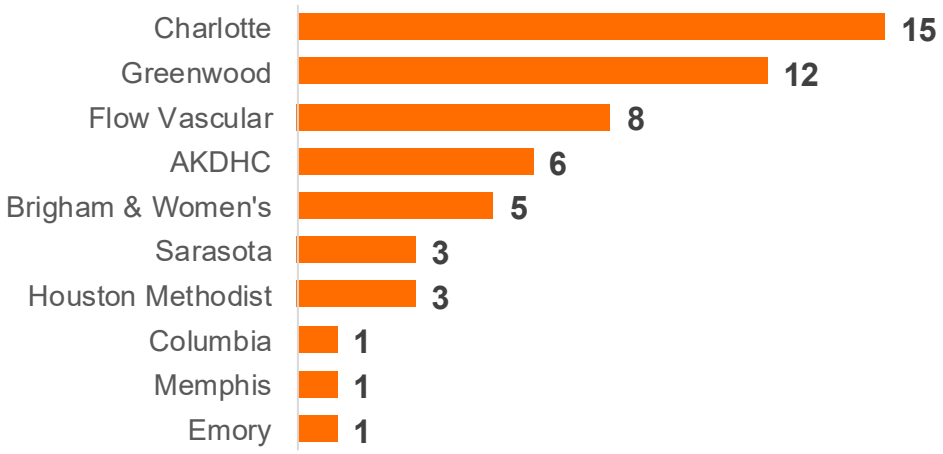
**1** Cannulation site infection

# aXess US Pivotal – Outcome Dashboard

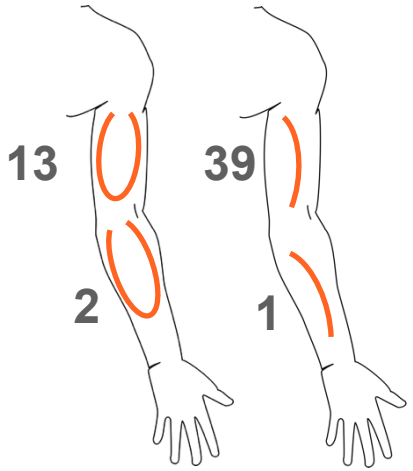
aXess PIVOTAL

# L configuration now approved for straight configuration implantation!

***Site Distribution:***




***Procedure / Device Details:***




**0**
Severe Bleeding Complications

**1**
Cannulation-related complication

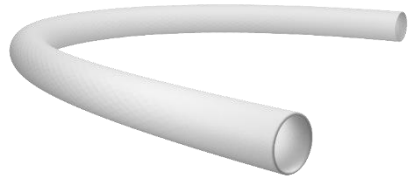
**1**
Cannulation site infection

XELTIS

# aXess

## Current Conclusions

- aXess transforms into native tissue over time
- It's a self-healing, PFAS free vascular conduit
- Performance of aXess to date, in the EU and US studies continue to suggest a potential for:
  - reduced infection and
  - intervention rates, and
  - improved patency.



# Mounting Patient Experience

Approved in EU!!



**>200** patients have received a Xeltis implant

**>10** clinical trials

**>250** patient-years

**>25k** dialysis-sessions

# Thank You!