VEITH SYMPOSIUM
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Greenwood Leflore Hospital

Xeltis Vascular aXess Graft:

Update on the US IDE Pivotal Study

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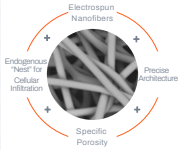
Disclosure statement

National PI of the aXess IDE trial

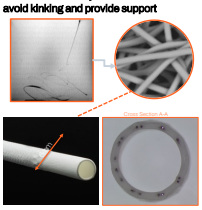
Xeltis' vascular access conduit for hemodialysis driven by a revolutionary advancement in novel polymer technology

Precise electrospinning

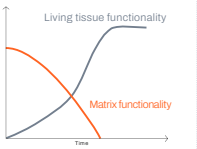


Porous conduit design allows for patient's cells to infiltrate and generate healthy response

The polymer is extruded around a laser cut strain release system of Nitinol to avoid kinking and provide support



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



Polymer degradation and new tissue creation go hand in hand

Exclusively to Xeltis

The aXess AV dialysis access conduit

Enabling the body to create its own vessel

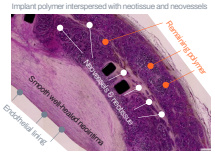
From an arteriovenous implant...

Endogenous Tissue Restoration (ETR)

... to a living natural conduit

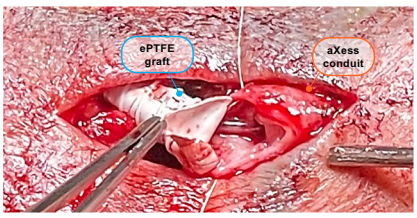
14 months follow-up in human

Implant polymer interspersed with neotissue and neovessels



Breakthrough device designation granted in November 2024

Over time aXess becomes like a native vessel



"At 6 months, the aXess conduit is soft and flexible, very similar to a native vessel."

Dr. Jan de Letter
Vascular Surgeon, AZ Sint Jan, Brugge, Belgium

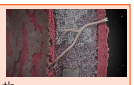
ePTFE grafts vs

The aXess conduit

ePTFE grafts

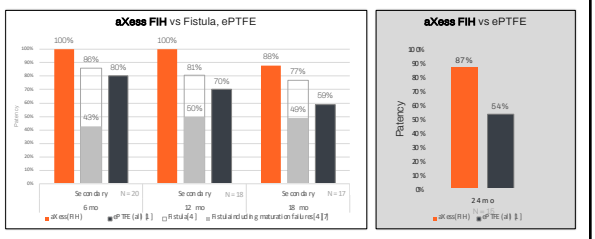
- Small pores
- Limited cell ingrowth
- Biofilm formation
- No remodeling
- No neointima / endothelization

aXess conduit



- Large pores
- Significant cell ingrowth
- No biofilm formation
- Positive remodeling with neotissue and neovessels development
- Neointima formation and evidence of endothelization

aXess EU FIH trial
24-month results *vs* current alternatives



[2] R.J. Hallett et al, "Patency of ePTFE Arteriovenous Graft Placements in Hemodialysis Patients" Kidney360 1(12):p 1437-1446, Dec 2020
[3] T.S. Huber et al, "Patency of autogenous and polytetrafluoroethylene upper extremity arteriovenous hemodialysis accesses: A systematic review" JVS, vol 38, pg 1005-1018, Nov 2003
[7] H.J. Woodside et al, "Arteriovenous Fistula Maturation in Prevalent Hemodialysis Patients in the United States" A.J.KD, Vol 71, iss 6, pg 793-803 Feb 2018

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Global Clinical Experience
aXess conduit

aXess FIH trial
20 patients enrolled
4 EU countries, 6 sites
24 months FU completed; extended FU ongoing

aXess EU pivotal trial
9 EU countries; 20 sites; 120 patients
Enrollment nearly completed
Primary endpoint -> primary patency @ 6months

aXess US pivotal trial
140 patients, up to 20 sites
Enrollment started!

Total clinical experience:
130+ implanted patients with the aXess conduit
12000+ dialysis sessions
<1% cannulation related infections

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aXess US Pivotal trial
Study overview

Study scope

- Subjects aged 18 and above
- end-stage kidney disease
  (or starting HD within 6 months)
- unsuitable for fistula creation
  (in target extremity)

Stage 1: up to 20 subjects and 5 sites
Results of the first 10 subjects will be assessed at M6 by the DSMB. If there are no safety concerns,
Stage 2: up to 120 subjects and 20 sites

Assessed at baseline, day of procedure
1, 3, 6, 12, 18, 24, 36, 48, and 60 months

Primary endpoints

Rate of device related infections and bleeding at 12 months

Secondary patency rate at 12 months in survivors

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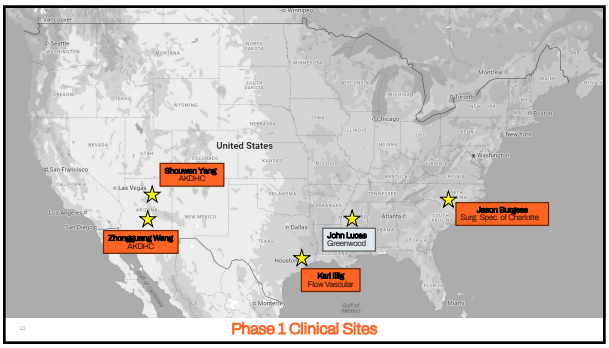
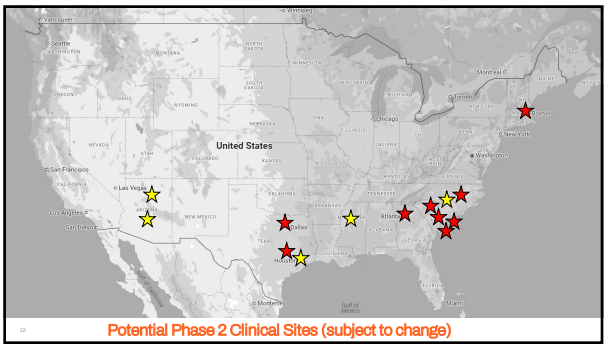
aXess US Pivotal trial
Study design

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

XELTIS



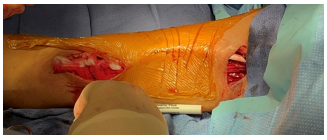
11 Phase 1 Clinical Sites



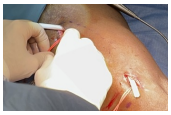
10 Potential Phase 2 Clinical Sites (subject to change)

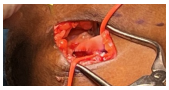
aXess US Pivotal trial
First patient enrolled on Nov 11th 2024

FLOW VASCULAR INSTITUTE



aXess US Pivotal trial
Second patient enrolled on Nov 18th 2024





XELTIS

aXess US Pivotal trial
Conclusion

- **The aXess conduit has the potential to combine**
  short term benefits of an AVG with
  long term benefits of an AVF.
- **Significant clinical experience in Europe**,
  130+ patients implanted.
- **aXess US Pivotal trial stage 1 has started enrolling**,
  expecting completion in Q1 2025.
- **US experience will be added to the EU study**
  add further evidence and strengthen results.

XELTIS