WELCOME *To the*

2026 SYMPOSIUM

From clinical provider to industry: *Device idea to clinical trials and beyond*

Shawn Gage, PA-C
VP of US Clinical Affairs
Xeltis, BV

Disclosures

- Co-Inventor of InnAVasc graft
- Previous owner, shareholder, and employee at InnAVasc (acquired by W.L. Gore & Associates)
- Former investigator for Humacyte study
- Former employee at Humacyte
- Current employee at Xeltis, BV

the beginning

A little background

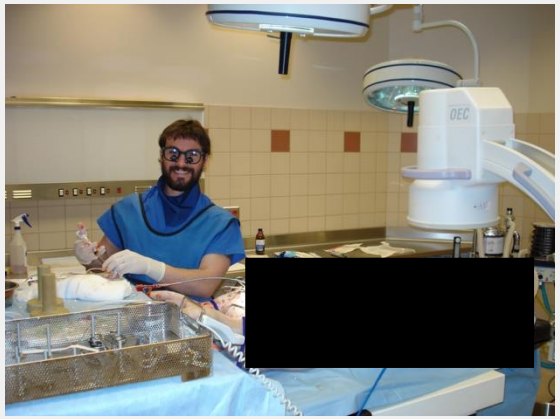


Training at Duke





Busy Vascular practice



Venture into pre-clinical research

2004 Duke → 2010

Joined the team



Venture into clinical research



the idea





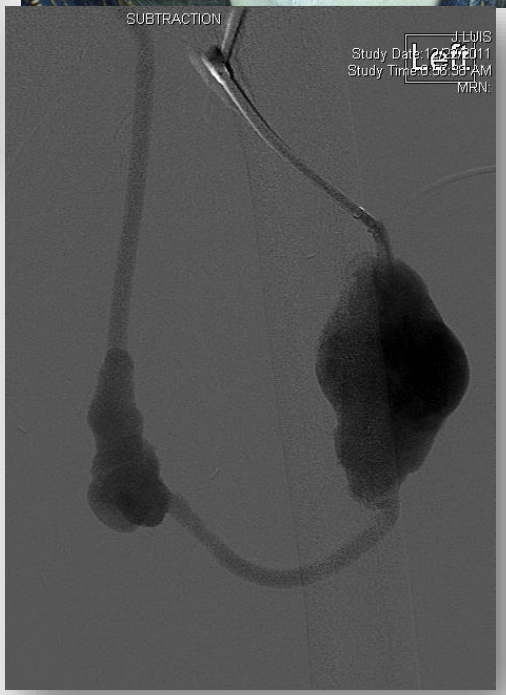






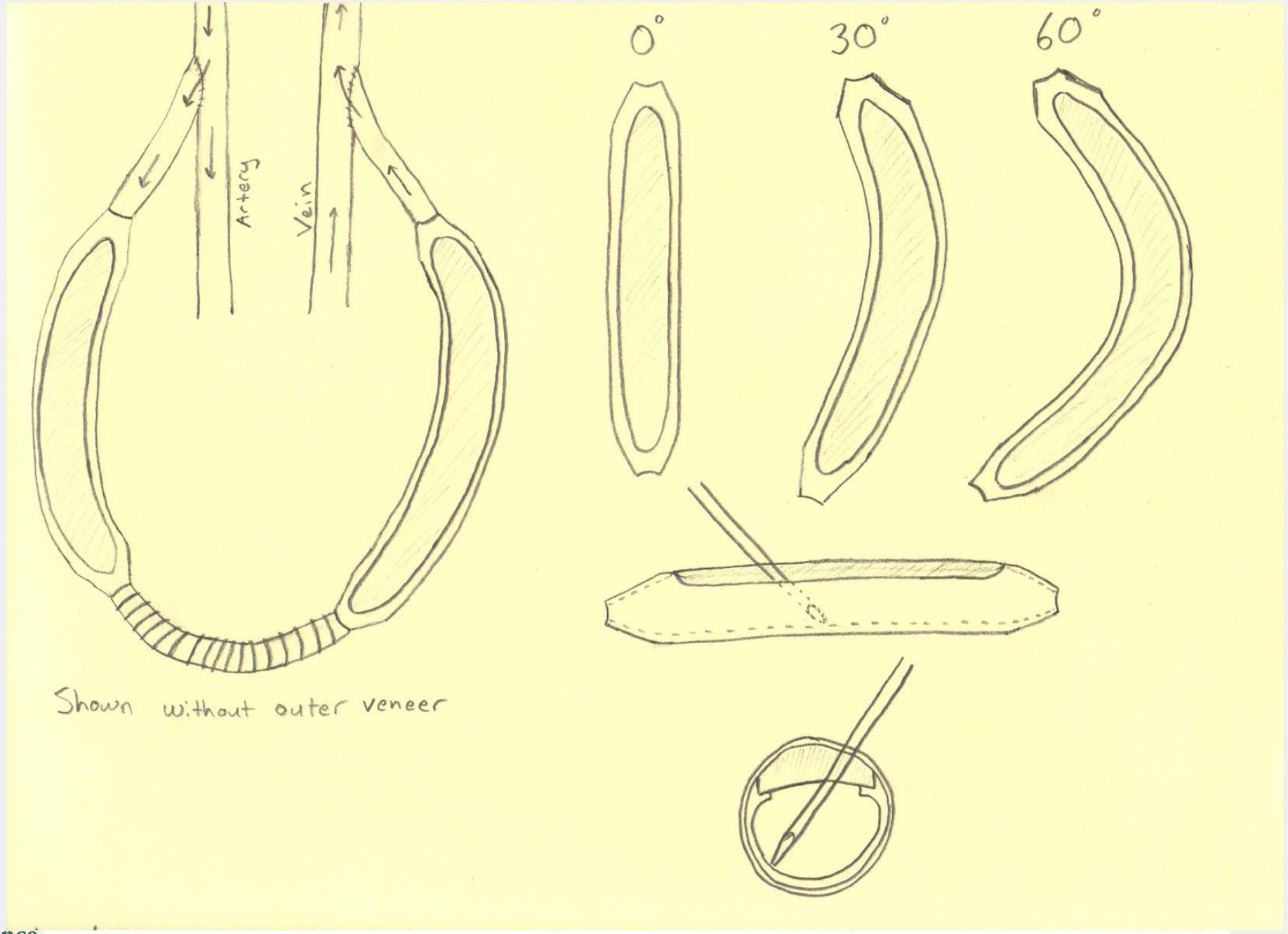




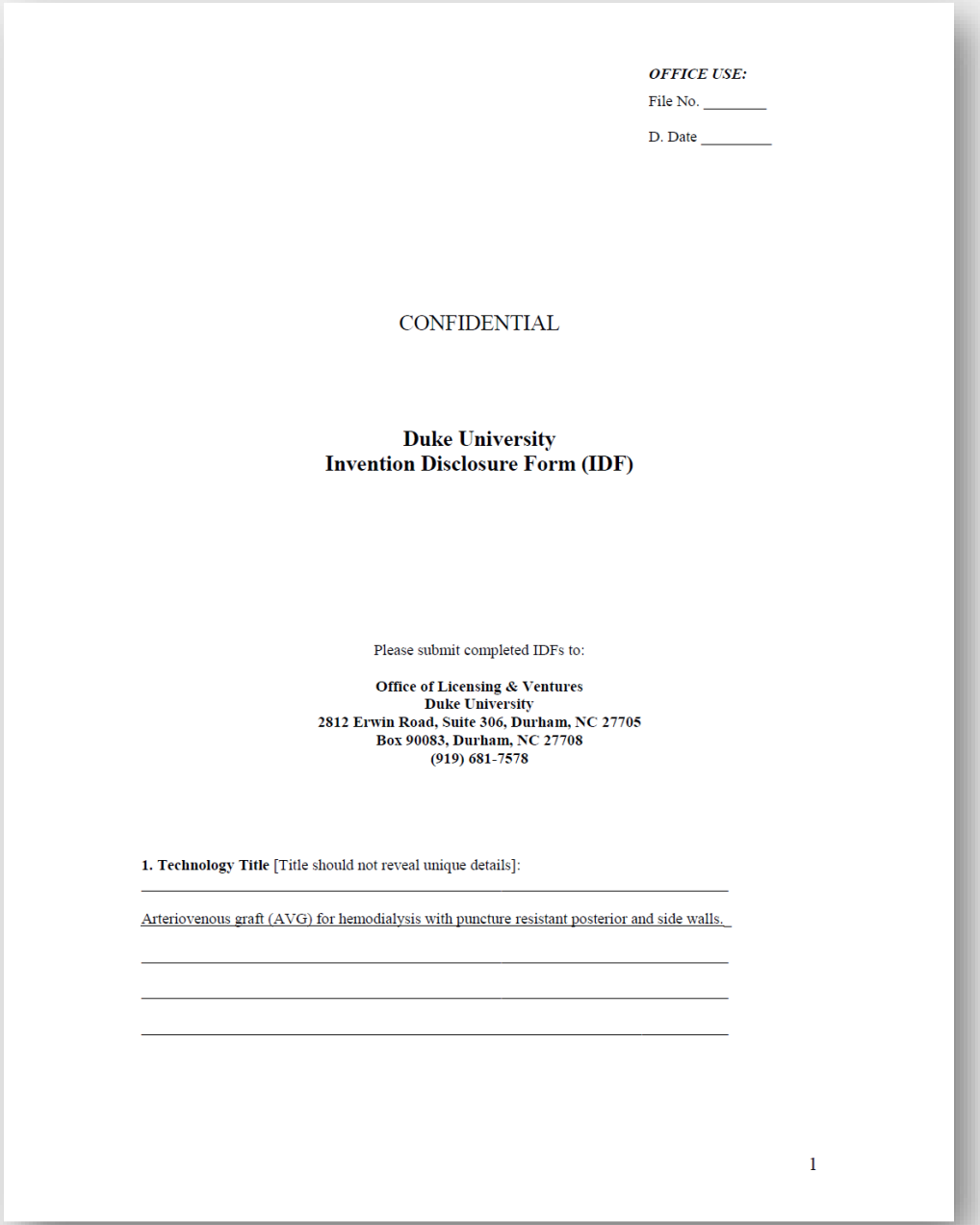


Access Excellence.


10:14
3
9
22
0.71
10
7.0
38.3
NARKOMED
VAPOR 19.1
ISOFLURANE


Artery
Vein
0°
30°
60°
Shown without outer veneer

inspiration



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Invention Disclosure Form (IDF)

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Office of Licensing & Ventures
Duke University
2812 Erwin Road, Suite 306, Durham, NC 27705
Box 90083, Durham, NC 27708
(919) 681-7578

1. Technology Title [Title should not reveal unique details]:

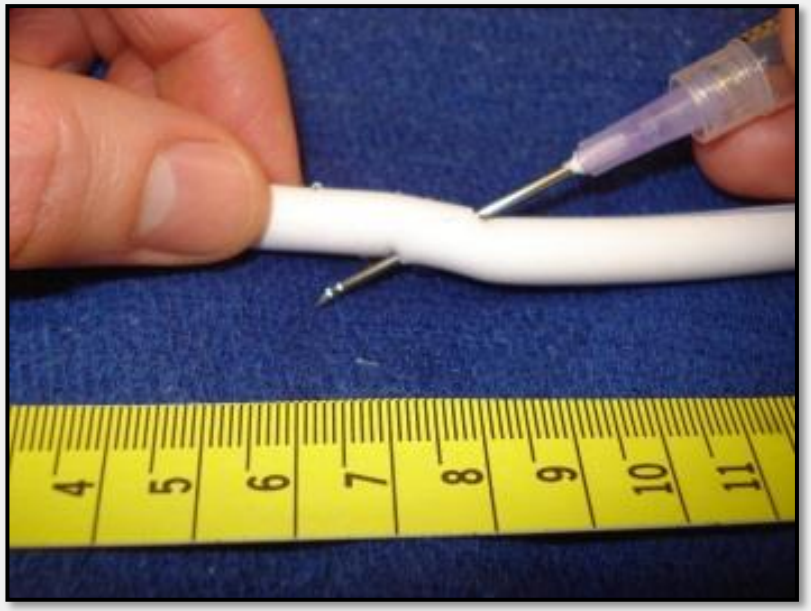
Arteriovenous graft (AVG) for hemodialysis with puncture resistant posterior and side walls.

1

- Office of License and Venture
- IP protection and potential source of revenue
- Limited resources from the institution to help
- How to articulate the need?
- How to best demonstrate the solution?



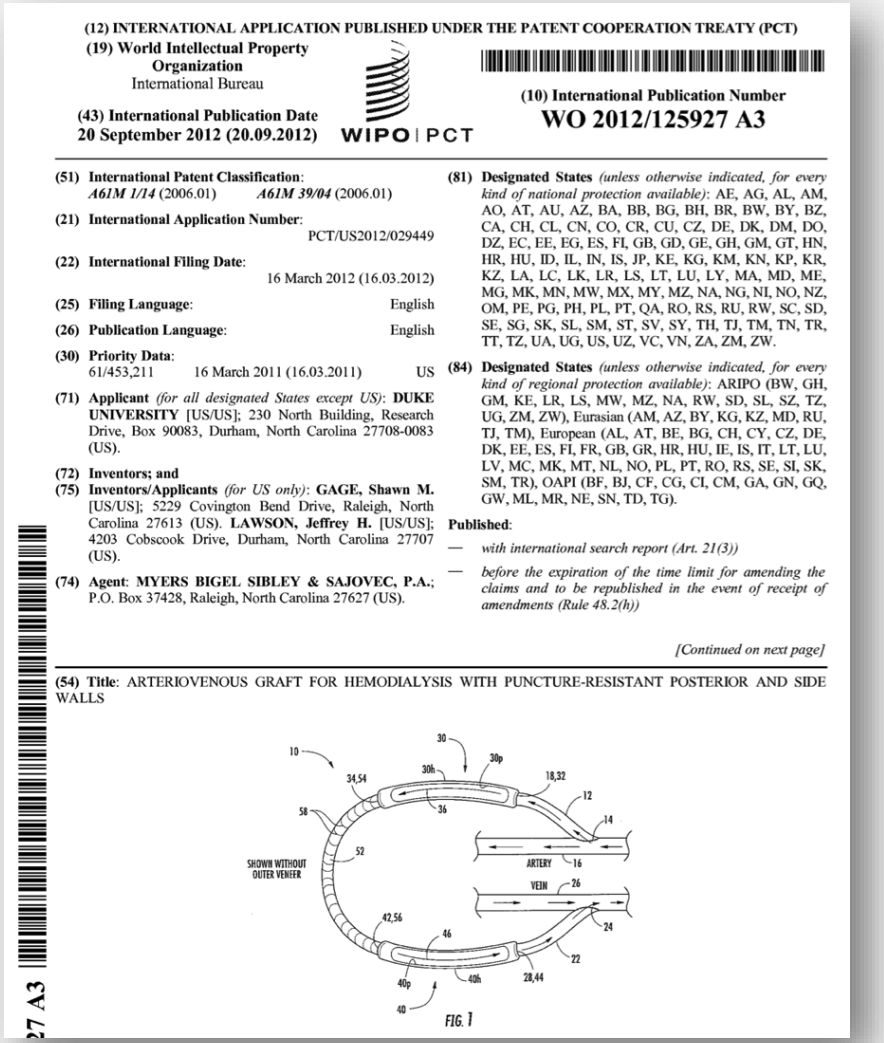
To the Garage







Duke agrees to support



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[Continued on next page]

(54) Title: ARTERIOVENOUS GRAFT FOR HEMODIALYSIS WITH PUNCTURE-RESISTANT POSTERIOR AND SIDE WALLS

Protect the Invention

- Patent attorney
- Duke held initial license
- Initial financial support for patent attorney and patent fees
- Filed provisional patent

Need?

OLV

Patent

Business model?

prototyping

Engineering?

Funding?

Licensing?

FDA

Inc ?

technology



A Decade of…..



Bench testing

Animal work



MedBlue

First Investment

CEO



Engineer



1st Clinical study



NSF

NIH National Institutes of Health

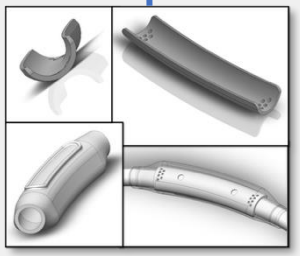
$4M

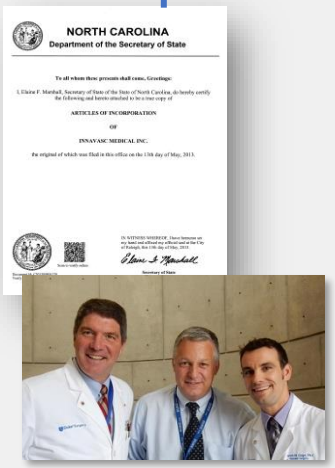
2011

Duke

2016

2022



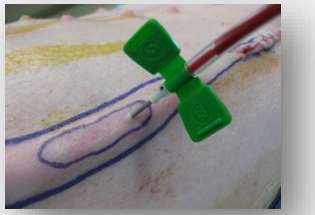


1st FDA interactions



NIH National Institutes of Health

$2M



2nd Clinical study



Duke ANGEL NETWORK

A new journey



Bench testing

Animal work



MedBlue

First Investment

CEO



HUMACYTE

Engineer



1st Clinical study



NSF

NIH National Institutes of Health

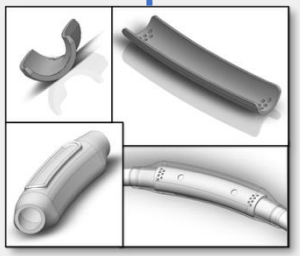
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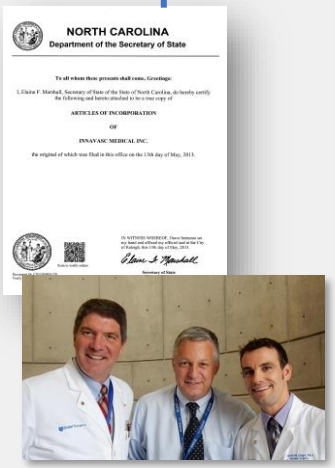
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Duke

2016

2022



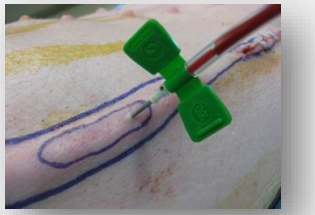


1st FDA interactions



NIH National Institutes of Health

$2M



2nd Clinical study



Duke ANGEL NETWORK



Going to the dark side

A new Gig

- Left clinical practice
- focus on development of technology and run clinical study
  - Humacyte first,
  - then InnAVasc
- Steep learning curve on the industry side “Clinical Development”
- Better life/family balance
- Less financial stability
- More stress (InnAVasc)





A New Team

- Clinical development project managers
- Regulatory Affairs
- Safety Monitors
- CRO team
- Biomedical engineers
- Process engineers
- Finance
- Grants





Clinical Trial Development

- Development of clinical protocol
- Study management
- Regulatory interactions
- Clinical sites selected
- Clinical site contracting/budget
- Study start up process
- Study Enrollment
- Study/surgery logistics
- Subject follow up
- Safety Monitoring

Clinical Ops and surgical/clinical knowledge

CRO manages



Singular focus



Bench testing

Animal work



MedBlue

First Investment

CEO



INNAVASC

Engineer



1st Clinical study



NSF

NIH National Institutes of Health

$4M

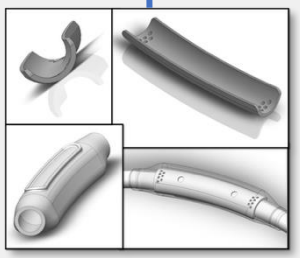
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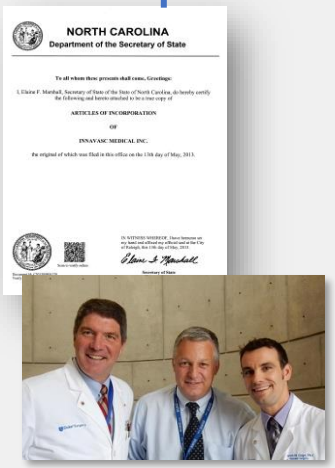
Duke

2016

2018

2022



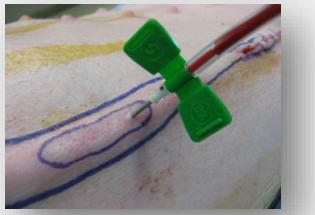


1st FDA interactions



NIH National Institutes of Health

$2M



Duke ANGEL NETWORK

2nd Clinical study



Clinical Trial Development

- Development of clinical protocol
- Study management (assembled team)
- Regulatory interactions
- Clinical sites selected
- Clinical site contracting/budget
- Study start up process
- Study Enrollment
- Study/surgery logistics
- Subject follow up
- Safety Monitoring



Final Mission for InnAVasc

- One last shot
- Study team together
- Friends and colleagues together
- Devices on hand
- Logistics and execution strategy
- Shoestring budget
- Limited time
- Burning money every day









the exit



Acquisition



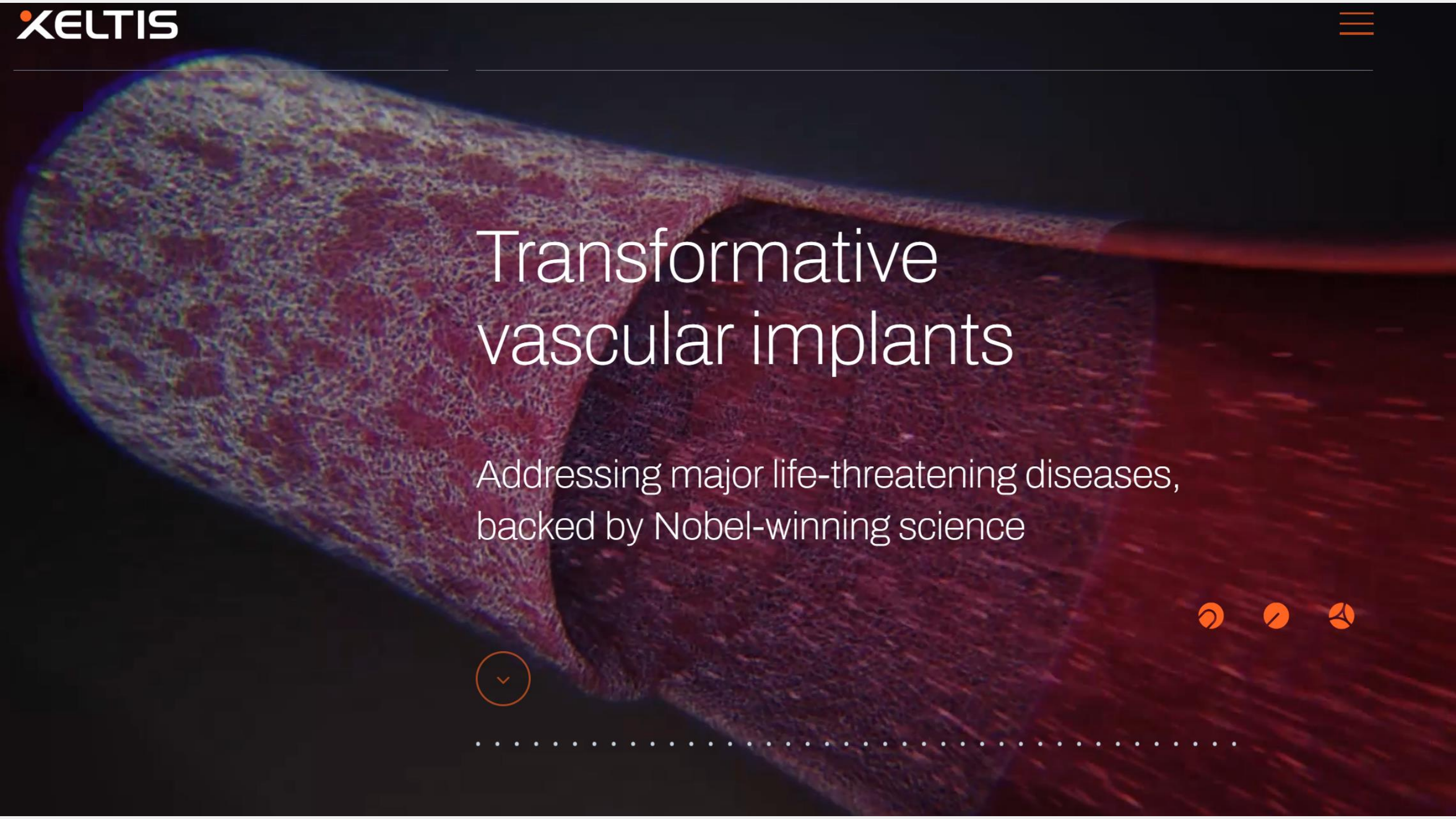
industry

Transition everything

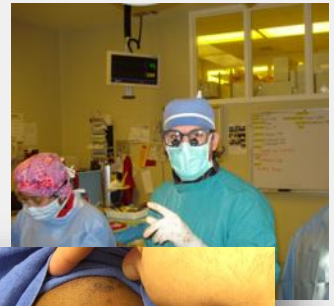
- Transition everything over to clinical team
- Entire history
- Need / solution
- Engineering / prototyping / IP
- Clinical trial activities
- Close out grants
- Started a few new initiatives



present


XELTIS
Transformative vascular implants
Addressing major life-threatening diseases, backed by Nobel-winning science







HUMACYTE

INNOVASC





XELTIS

GORE

