

An aerial photograph of a city, likely Phoenix, Arizona, showing a dense urban landscape with numerous skyscrapers and buildings. In the background, there are mountains under a clear sky. The title text is overlaid on the top half of the image.

Percutaneous Treatment of **Abdominal Aortic Aneurysms**

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TRIVASCULAR™
Stent Graft

CAUTION: Investigational Device. Limited by Federal law to investigational use.

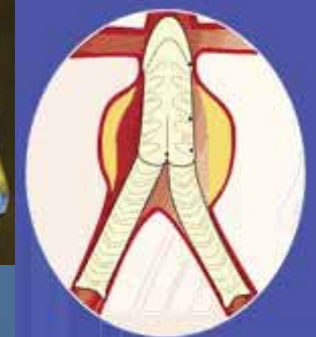
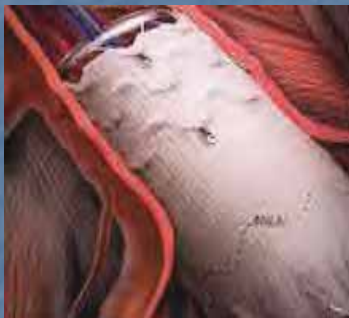
AAA Stent Grafts

Exciting alternative to open surgery

Continued interest despite product setbacks

Industry responding with design changes

Various design approaches



Device Failure Modes

- **Metal fatigue**
- **Metal / fabric erosion**
- **Migration**
- **Component separation**
- **Sealing**
- **Flow lumen integrity: acute & chronic**

CONCEPT:

True Percutaneous &
Durable

Distinct stent and
graft zones

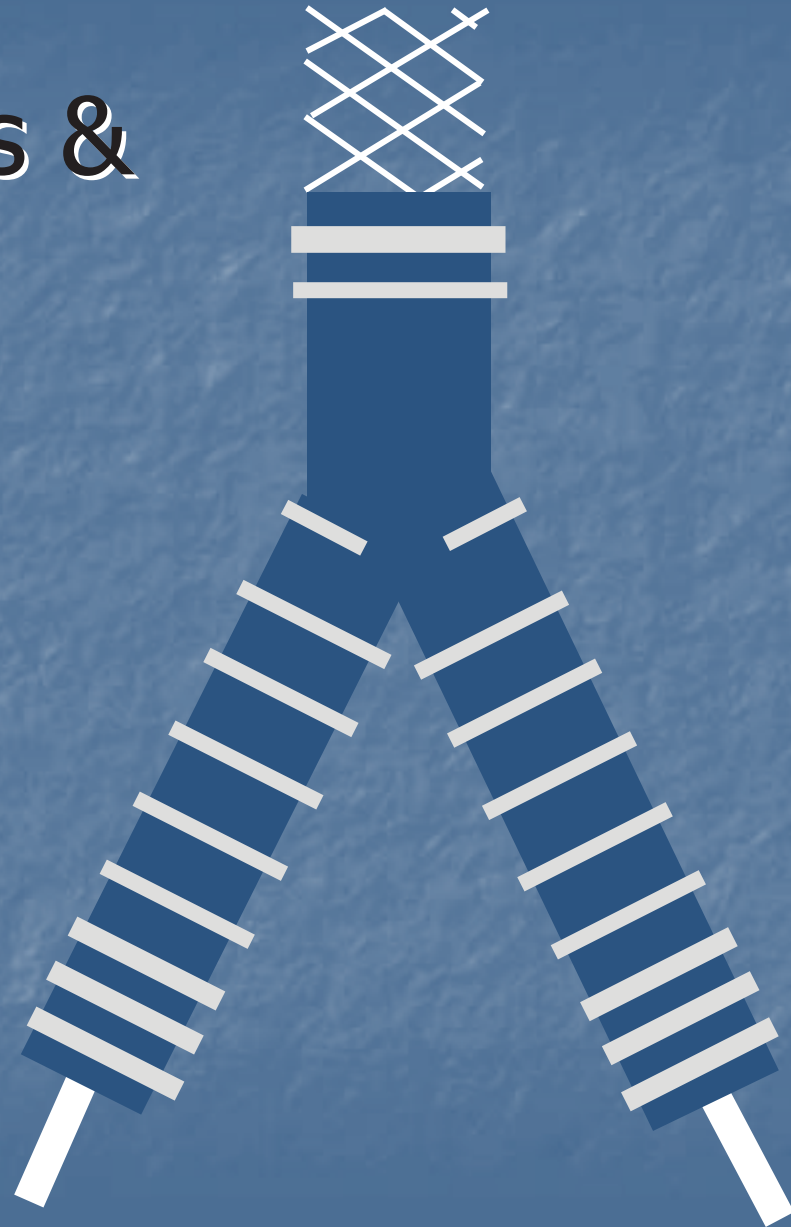


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**Independent seal and
fixation mechanisms**

**Staged material
delivery**

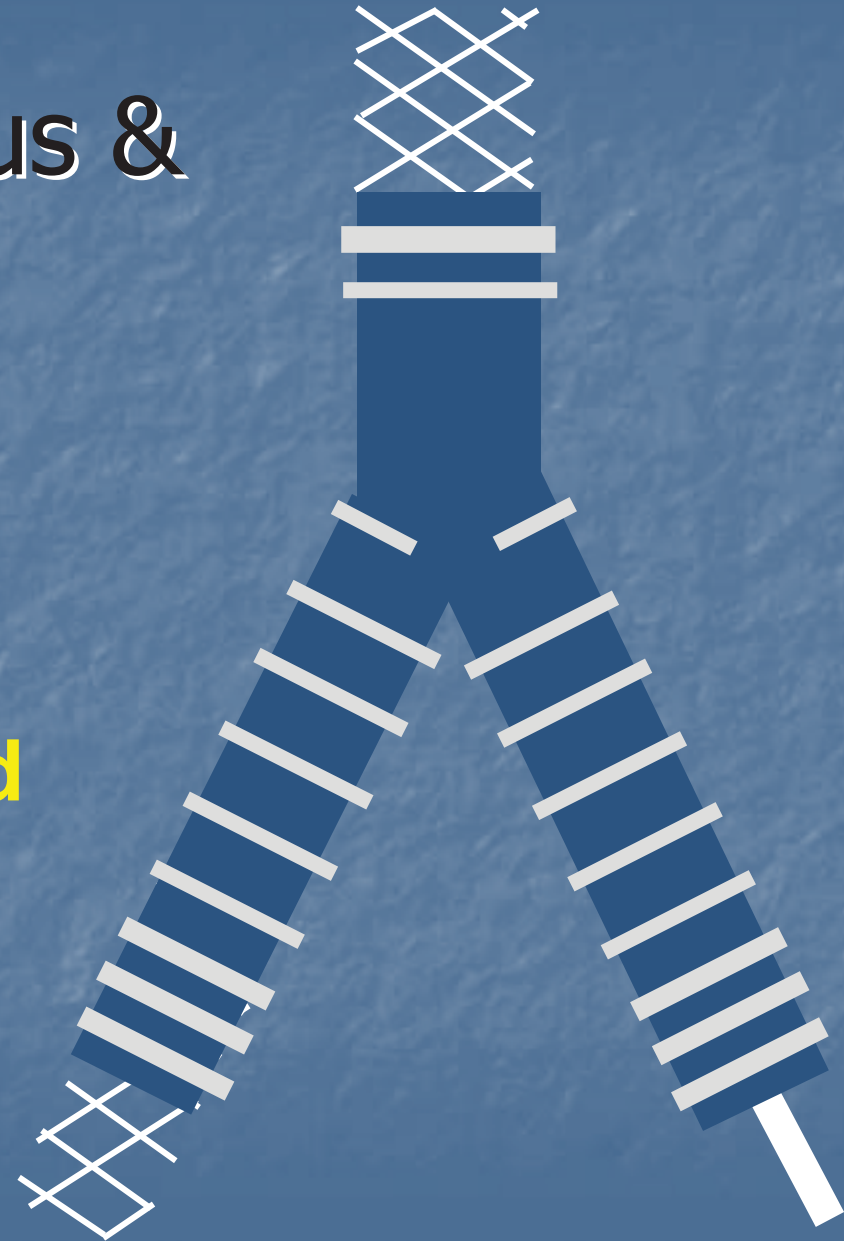


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Analyze

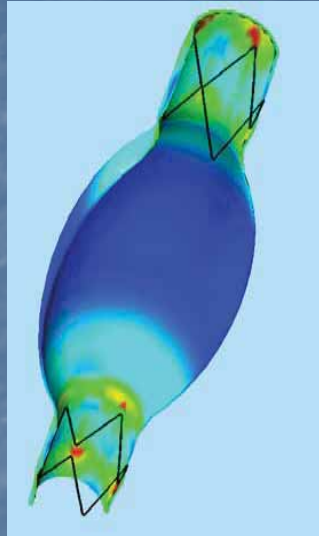
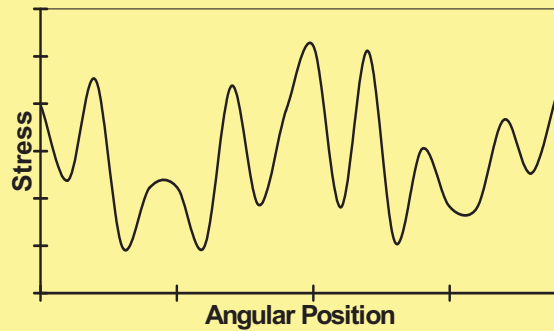


Design

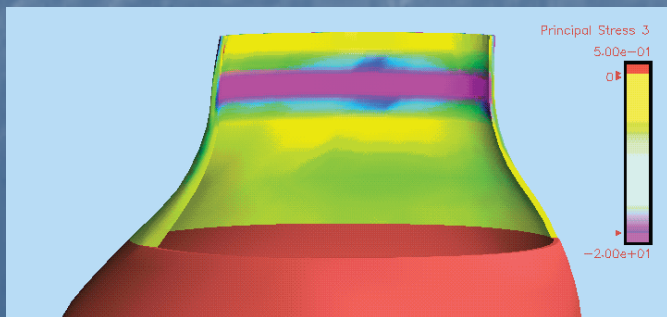
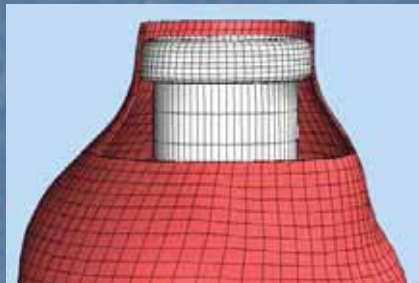


Test

Circumferential Stress Variation
in Artery Wall



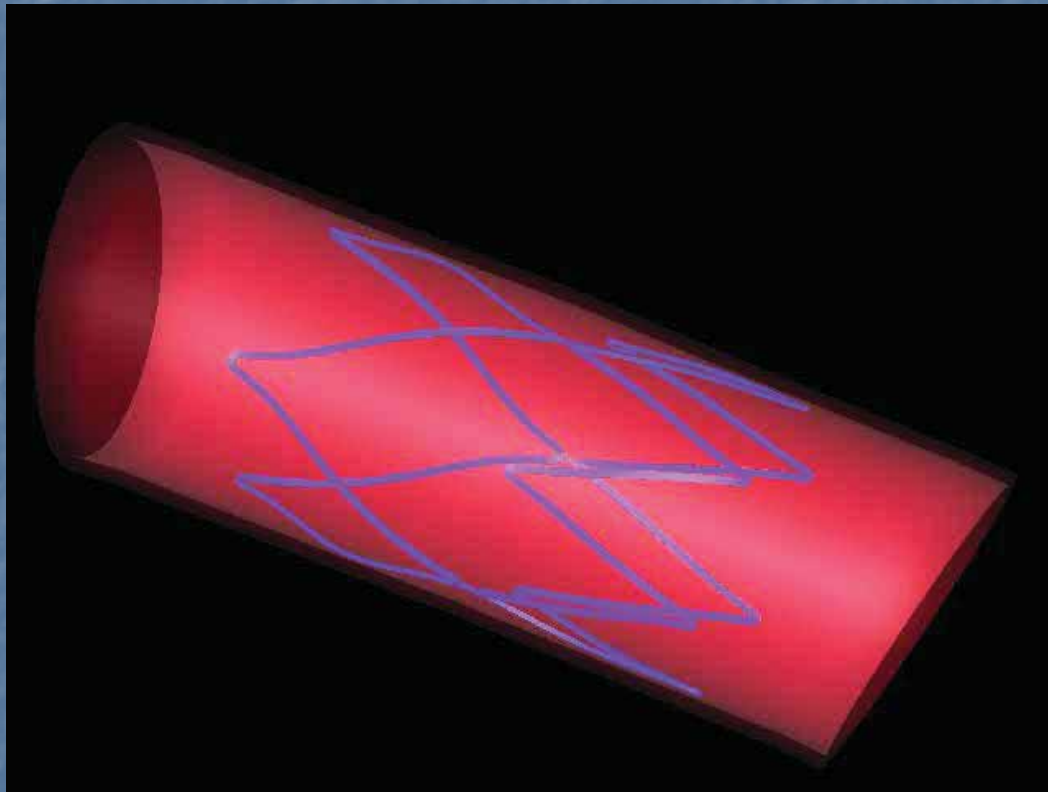
Irregular stent-fabric seal
in idealized setting



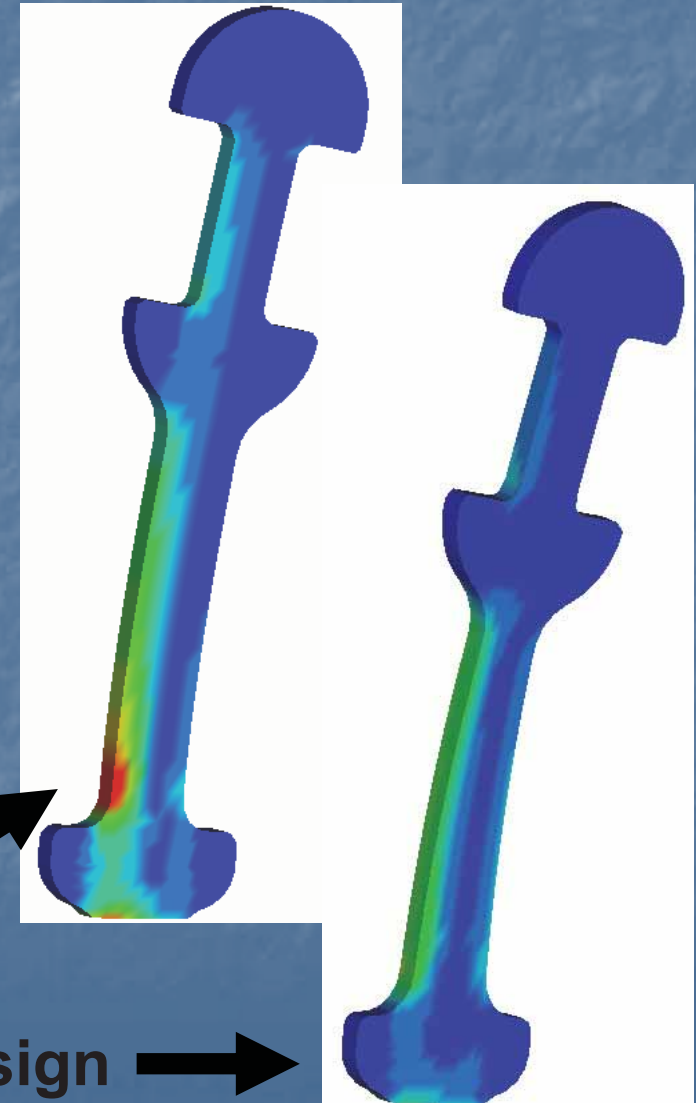
Uniform pressure of
sealing cuff in modeled
human aneurysm

Analyze → **Design** → Test

Utilize proprietary,
advanced design tools



High stress



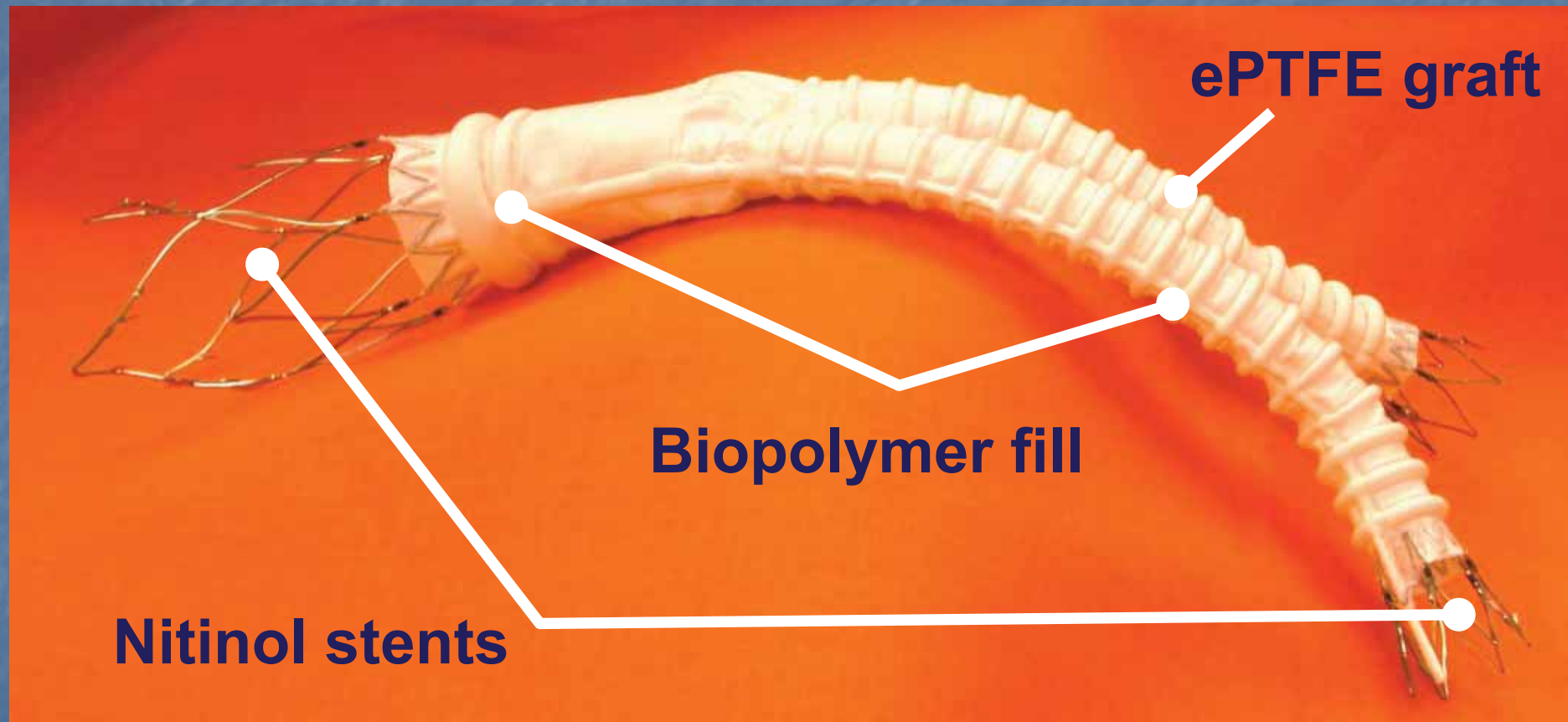
Preferred design

Analyze → Design → **Test**

- **Extensive mechanical testing**
 - **Implant**
 - **Delivery System**
- **Challenging conditions**
- **Confirmed simulated design performance**
- **Successful 400M cycle fatigue tests**

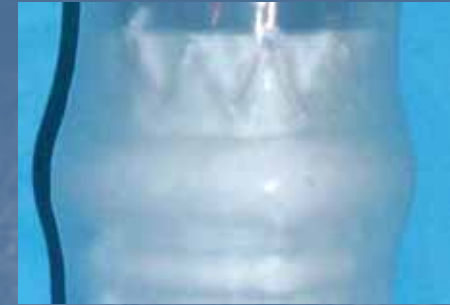
TRIVASCULAR™ Stent Graft

Unique Design with Proven Materials





Stent Graft



Inflatable sealing cuffs

Suprarenal positive fixation

Distal positive fixation

Unibody graft designed for:

Kink resistance

Conformance to anatomy

Durability



No welded metals



No sutures



**No “metal- fabric” interface
in seal zone**

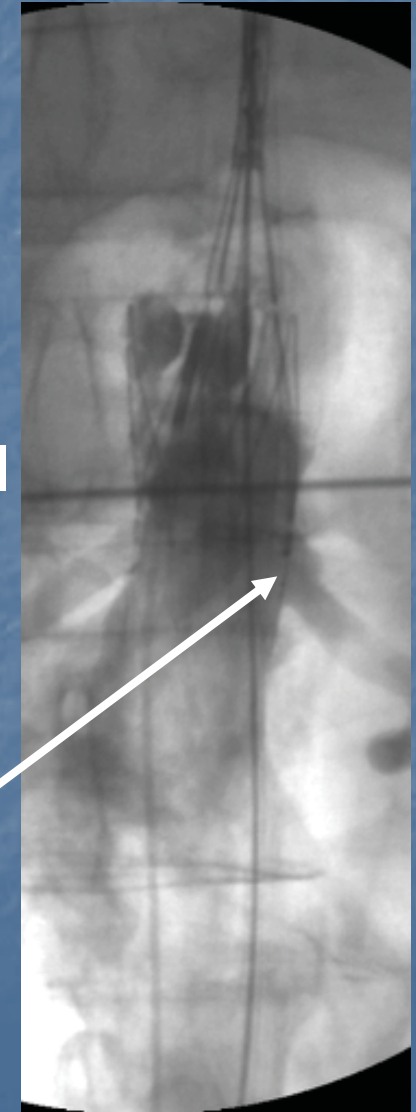
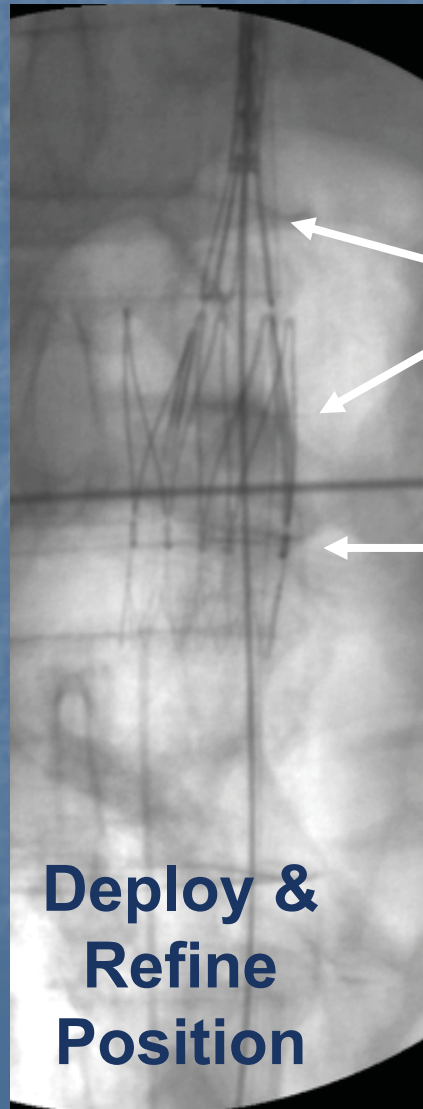
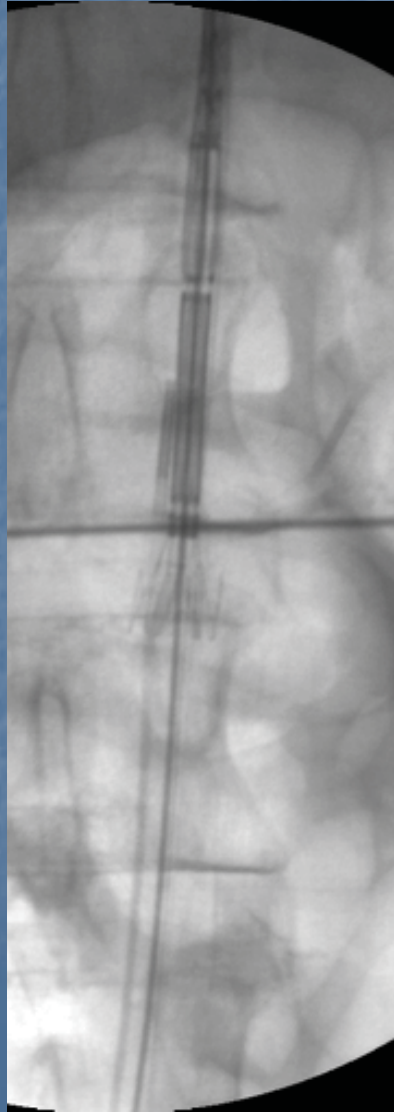
Delivery System



- **Integral 14F introducer**
- **Familiar techniques**
 - "Pull back" outer
 - Stent release lines
 - Inflation
- **Staged stent deployment**
- **Biopolymer injection channel**

Constrained Stent

C – Arm Orientation



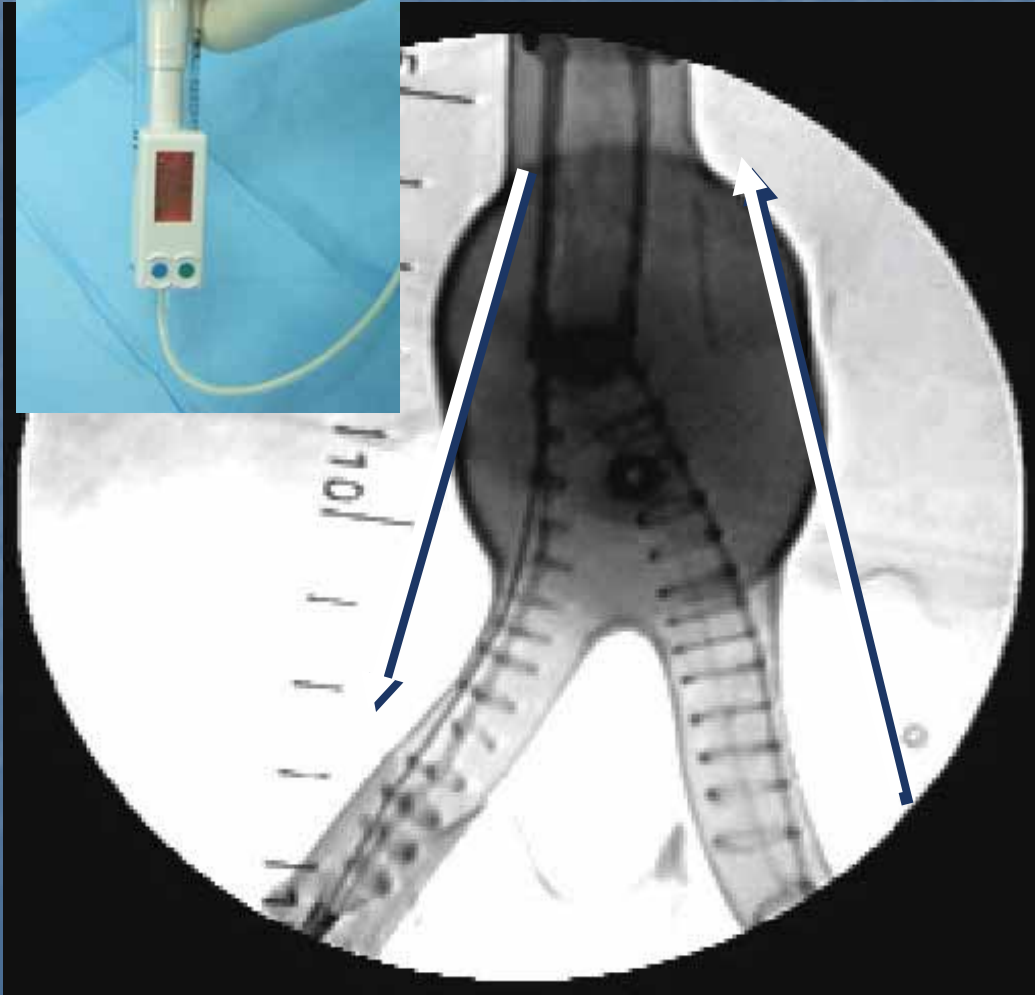
Staged Stent

Orthogonal

Confirm Renal Position

Deploy & Refine Position

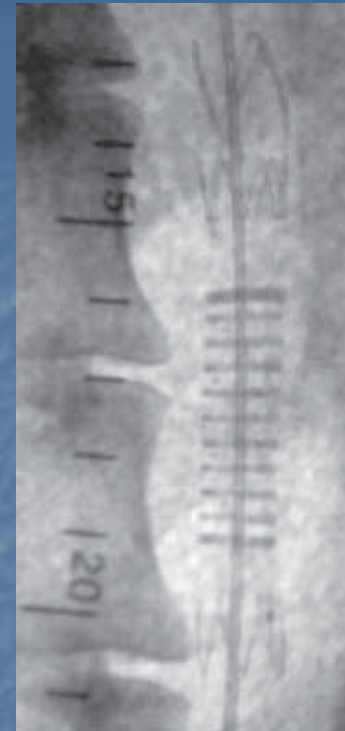
Biopolymer Fill



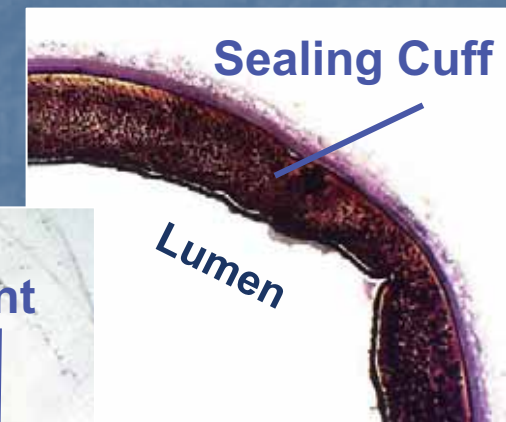
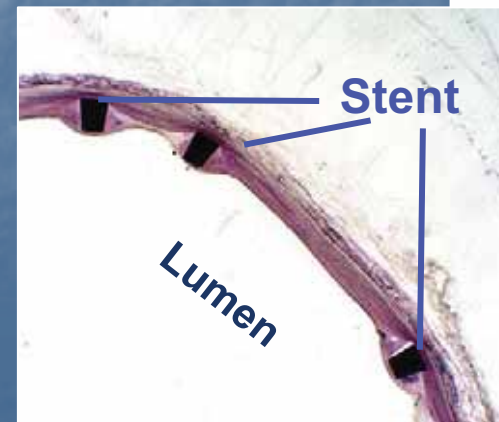
- Radiopaque
- Low pressure delivery
- Cures *in situ*

Animal Studies

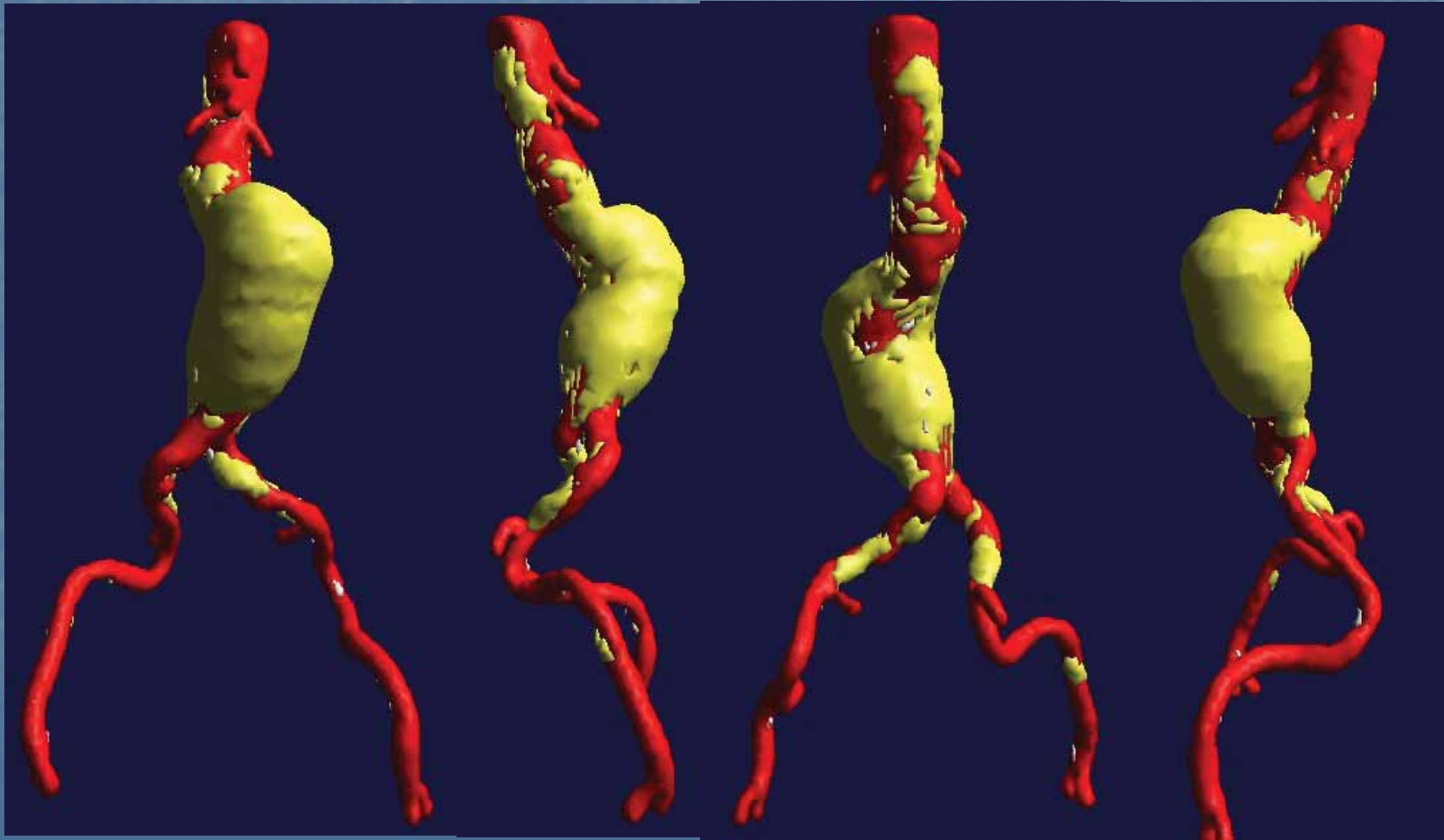
- 60+ animal implants
 - Canine
 - Ovine
 - Bovine
- Acute and chronic studies
 - Up to 1 year follow-up
- Completed GLP evaluation to support IDE
- Successful outcomes & pathology



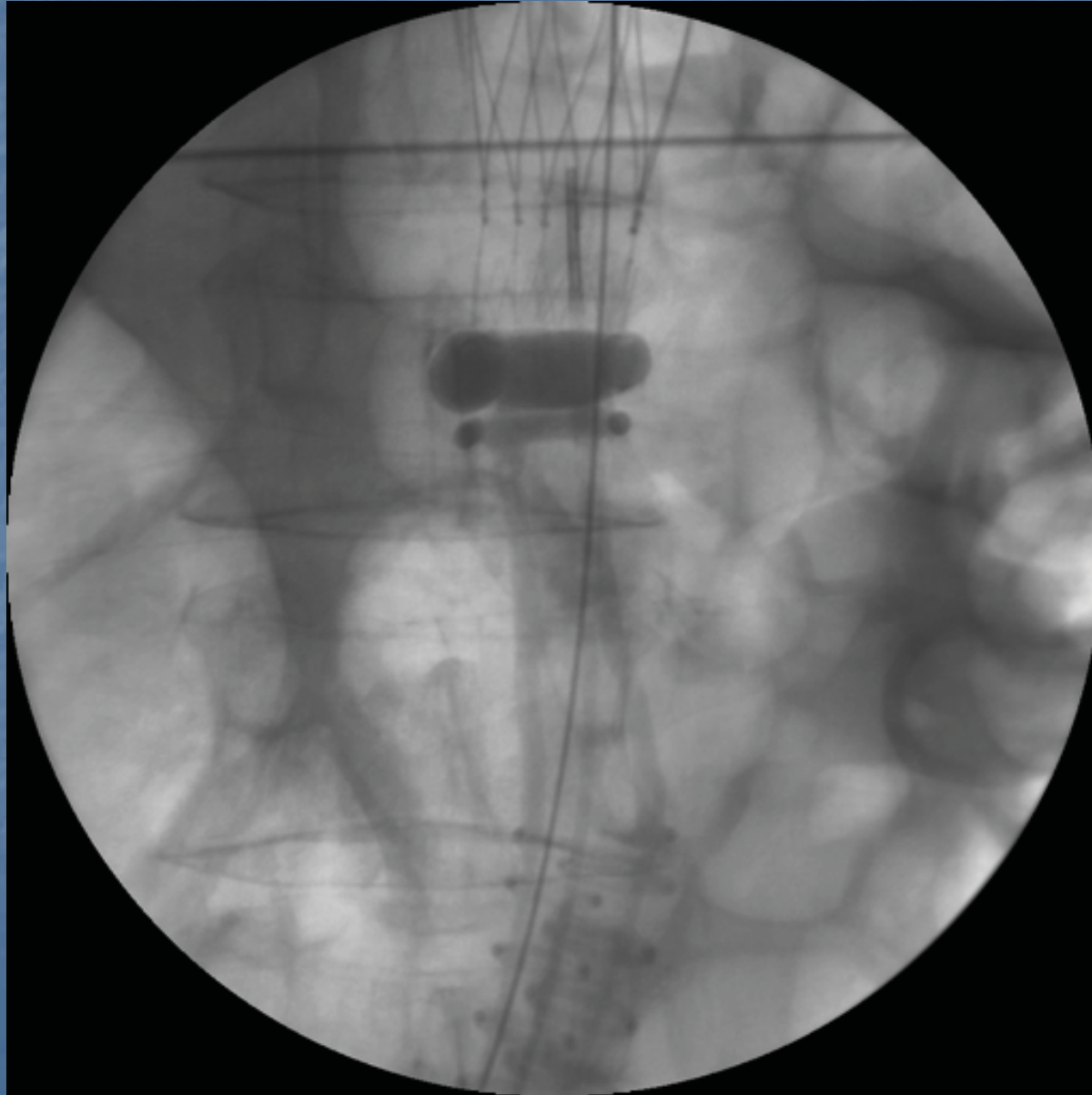
3 months



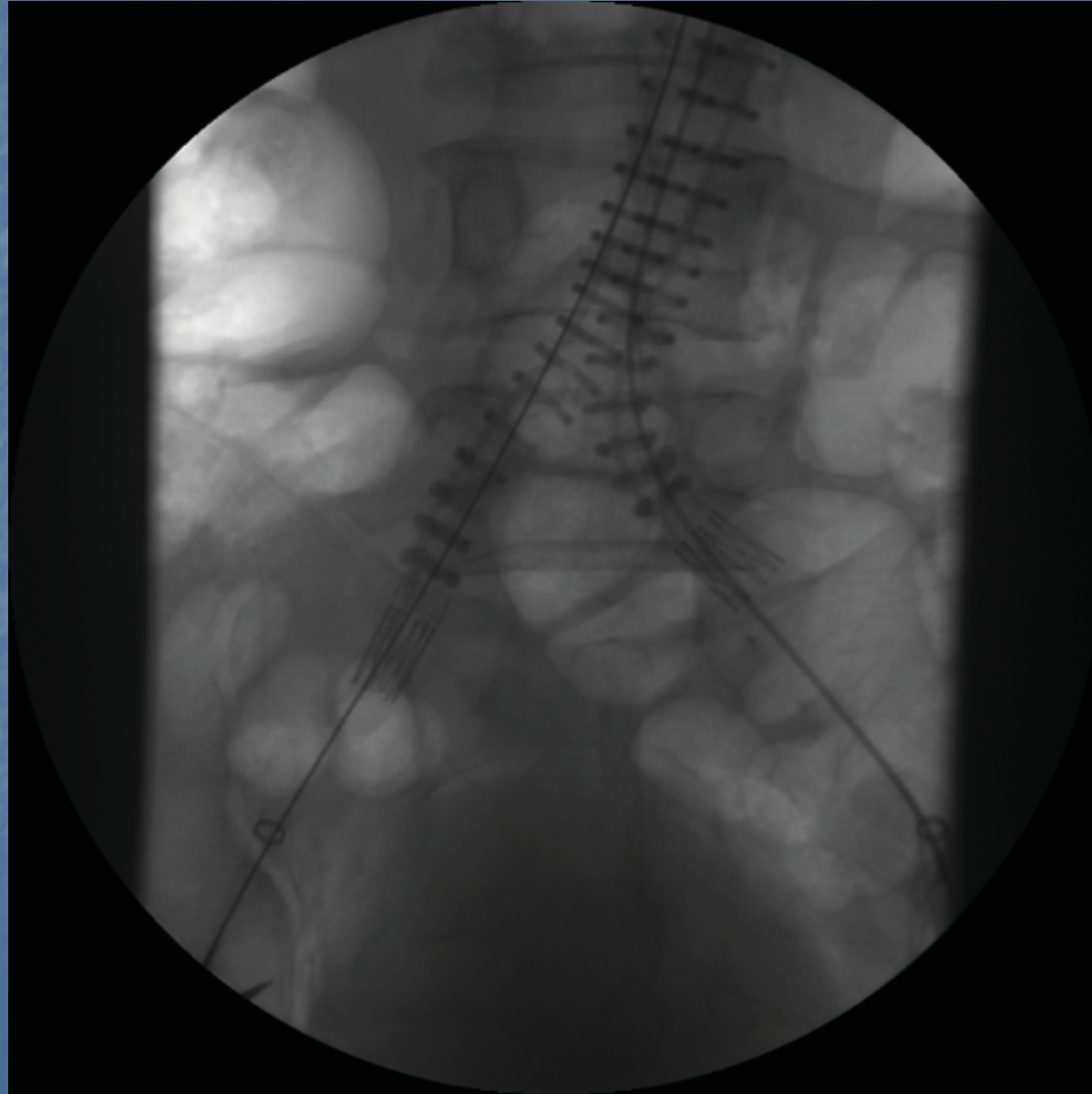
Early Clinical Evaluation



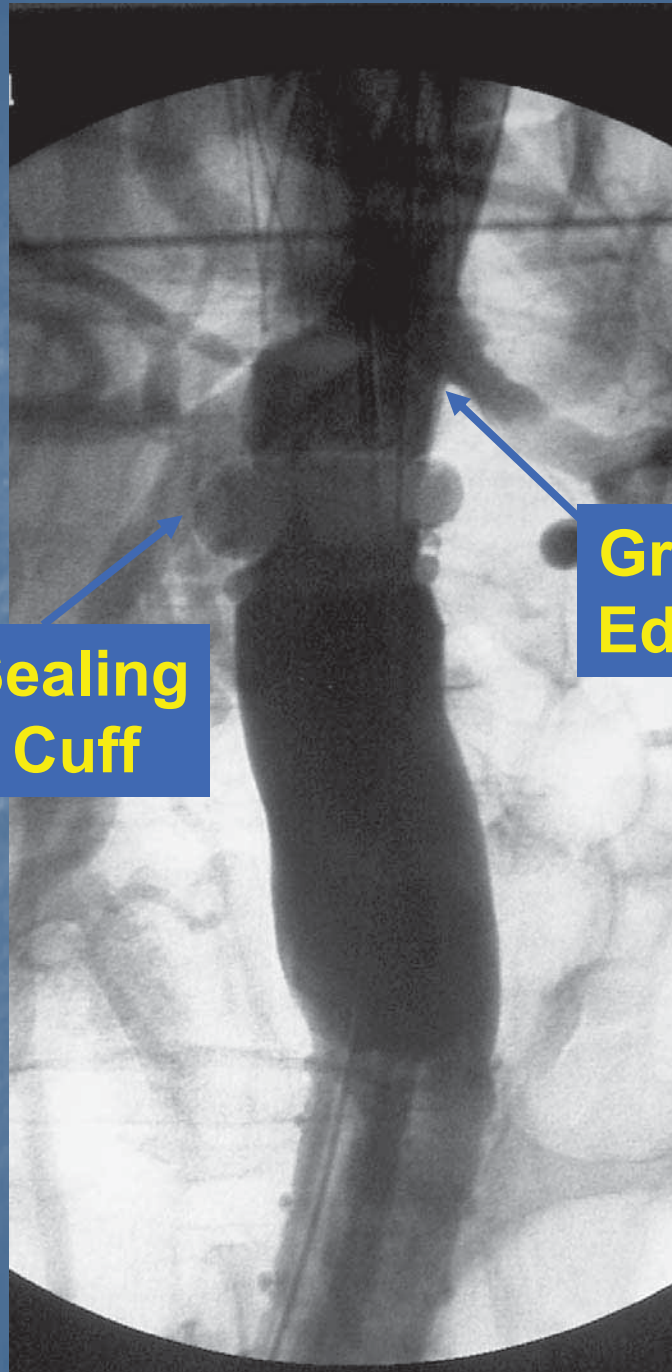
Completion Angiography



Completion Angiography

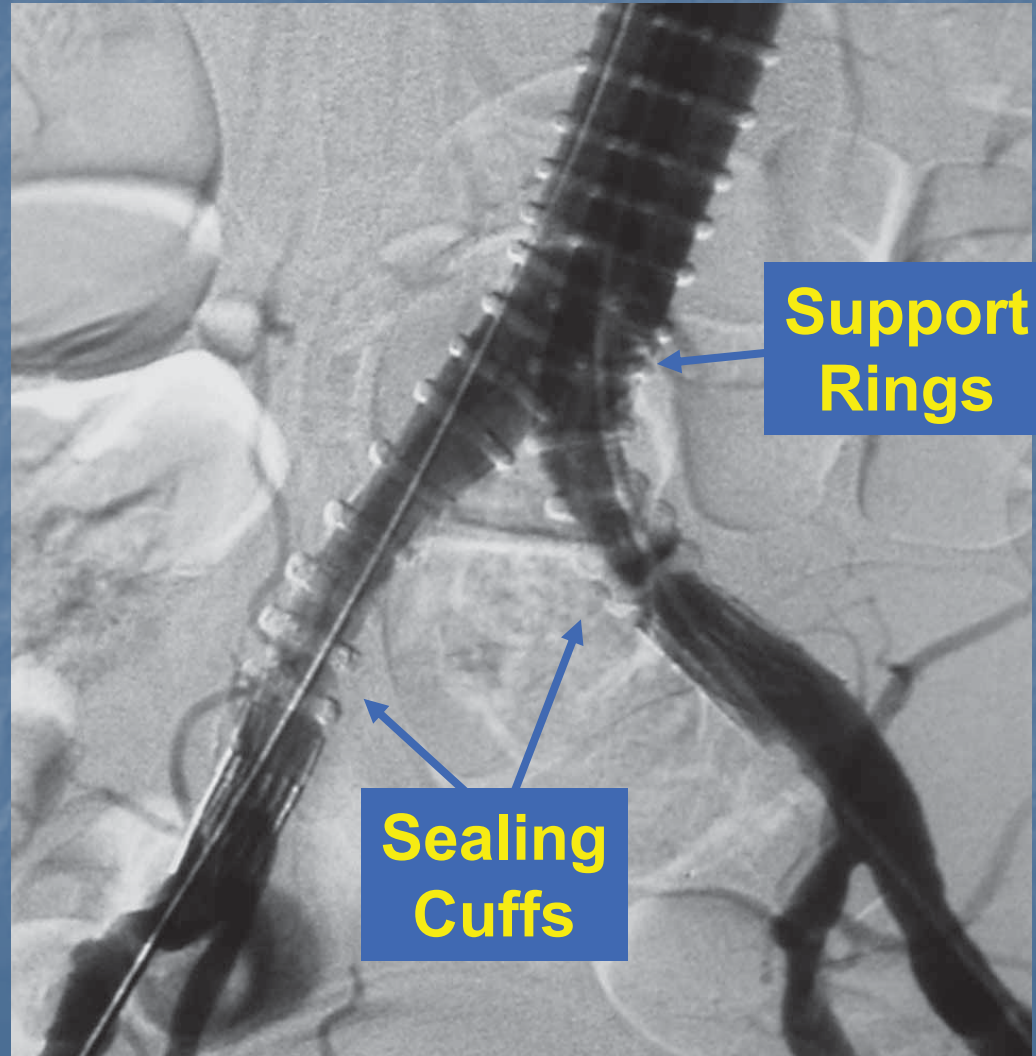


Aneurysm Exclusion



**Sealing
Cuff**

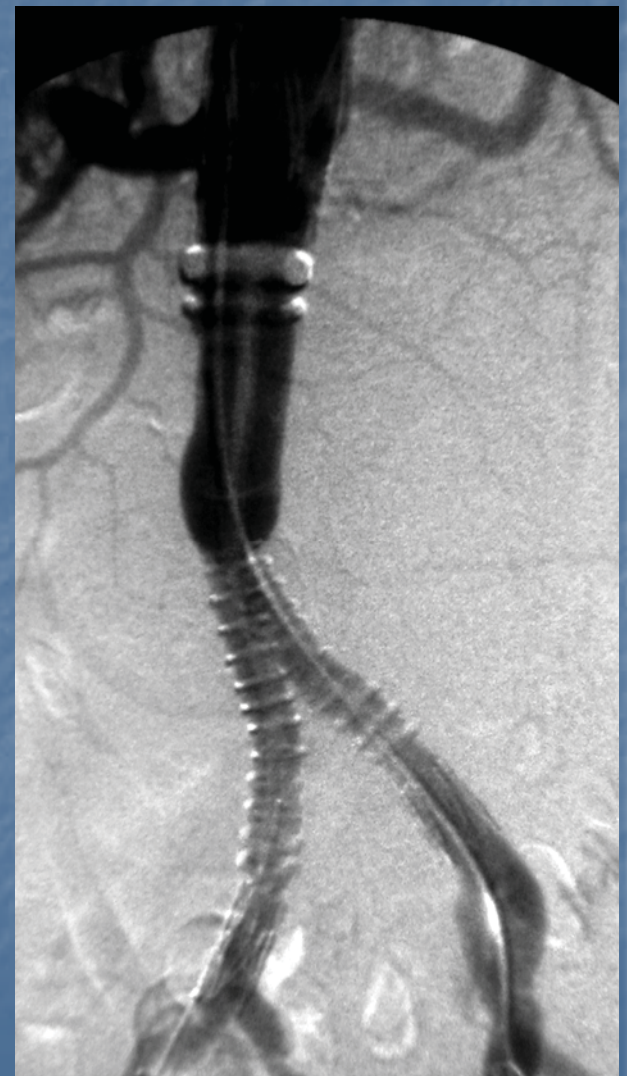
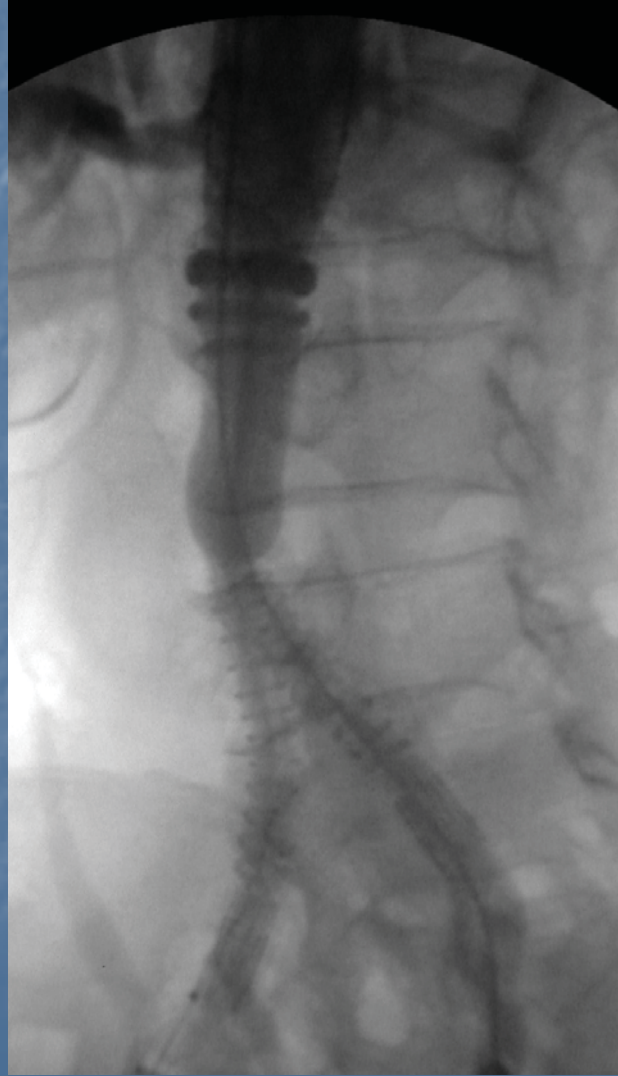
**Graft
Edge**



**Support
Rings**

**Sealing
Cuffs**

Completion Angiography



DESIGN GOAL

The first *percutaneous*,
durable AAA stent-graft

Delivery System

- **Integral 14F introducer → 12F**
- **Familiar techniques**
 - **“Pull back” outer**
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- **Biopolymer injection channel**

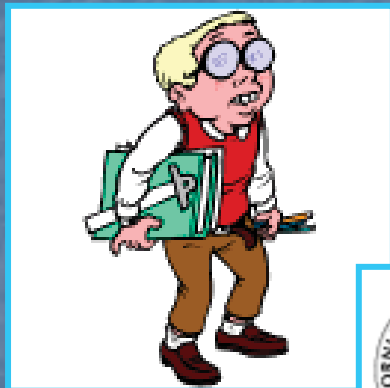
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TRIVASCULAR Approach

3 Ph.D. Engineers



Novel Tools & Methodologies

2 M.D. Radiologists



Unmet Clinical Need

12F Durable AAA Stent Graft

Prediction

The Abdominal Aortic Aneurysms can and will be able to be treated percutaneously in the Cath Lab in the near future and will no longer be exclusively the domain of the Vascular Surgeon.

