Percutaneous Treatment of Abdominal Aortic Aneurysms

Richard R. Heuser, M.D., F.A.C.C., F.A.C.P.
Director of Cardiovascular Research
St. Joseph’s Hospital and Medical Center Phoenix, AZ
Clinical Professor of Medicine
University of Arizona College of Medicine
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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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
Extensive mechanical testing
- Implant
- Delivery System
Challenging conditions
Confirmed simulated design performance
Successful 400M cycle fatigue tests

Analyze → Design → Test
TRIVASCULAR™ Stent Graft
Unique Design with Proven Materials

- Nitinol stents
- ePTFE graft
- Biopolymer fill
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

Deploy & Refine Position

Staged Stent

Orthogonal

Confirm Renal 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

Lumen

Sealing Cuff

Stent
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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- Familiar techniques
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TRIVASCULAR Approach

3 Ph.D. Engineers

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Novel Tools & Methodologies

Unmet Clinical Need

2 M.D. Radiologists

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.