Expanding EVAR indications with a next generation AAA endograft conforming to 90 degree neck angulations

Robert Y. Rhee, MD
Chief, Vascular and Endovascular Surgery
Director, Maimonides Aortic Center
Maimonides Medical Center
Brooklyn, New York

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Disclosures

- WL Gore: Consultant, PI clinical trial, Research Grants
- Medtronic: Research Grants
- Cook: Research Grants
- Boston Scientific: Consultant, MAB, Research Grants
- GE Healthcare: Consultant
Primary Predictor of EVAR FAILURE
The First EVAR Frontier...

Devices
• Medtronic AneuRx, Guidant Ancure, Gore Excluder, Cook Zenith

Design
• < 60° aortic necks
• 15mm neck length

Limitations
• Not intended for short or severely angulated proximal necks
  High incidence of Type 1A endoleaks
• Increased long term risk of rupture

DURABILITY of EVAR?

58% of EVAR procedures in USA do not meet IFU criteria!
Compensation for Procedural Control and Conformability

Tips and Trick including “off-label techniques”

- Bending guidewire
- Endoanchors
- Chimney/Snorkel
- Modifying device structure
- Endowedge

**Common Theme**

- Compensate for limitations in device *conformability* and/or *delivery system design*
Reality

Even in most large volume tertiary care centers….
~80% of all EVAR treated patients have *at least a 10 mm proximal neck*
Second generation...more conformable...but
How can we achieve better results in hostile necks?

Control and conformability must be built into the endovascular system

What would this achieve?

1. Entire use of landing zones
   every mm of neck used!
2. Stabilization of device and delivery system
during deployment
3. Conforming of the endovascular device to the
native proximal aortic anatomy
This is why we need a better device to handle angulated necks
A new conformable endovascular abdominal device
# GORE® EXCLUDER® Conformable AAA Endoprosthesis (CEXC)

<table>
<thead>
<tr>
<th>Current Treatment Limitations</th>
<th>EXCLUDER® Conformable AAA Endoprosthesis</th>
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<tbody>
<tr>
<td>Short infrarenal neck length</td>
<td>Designed to conform and seal in both straightforward and challenging patient anatomy:</td>
</tr>
<tr>
<td></td>
<td>• Up to 90° proximal aortic neck</td>
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<tr>
<td></td>
<td>• ≥ 10 mm seal zone in proximal aortic neck</td>
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<tr>
<td>High neck angulation</td>
<td></td>
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<tr>
<td>Adjunctive procedures to achieve proximal seal</td>
<td>ACTIVE CONTROL System</td>
</tr>
<tr>
<td></td>
<td>▪ Angulation control</td>
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<tr>
<td></td>
<td>▪ Enhanced repositionability (30% reduction inner sleeve)</td>
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<tr>
<td></td>
<td>▪ Conformable stent-graft</td>
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<tr>
<td>Small iliac access</td>
<td>Innovative delivery system combined with a conformable stent graft to achieve optimal seal.</td>
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<tr>
<td>Treatment diameter range</td>
<td>Delivery system at reduced profile (15-16 Fr)</td>
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<tr>
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<td>Broadest treatment range of patients: 16–32 mm proximal neck diameter</td>
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</tbody>
</table>

The Conformable Excluder
GORE® EXCLUDER® Conformable AAA Endoprosthesis*

- **Multi-component Design**
  - Trunk-Ipsilateral Leg
  - Aortic Extender
  - Contralateral Leg
  - Iliac Extender

- **Trunk and Aortic Extender Stent-graft Design**
  - Conformability
    - Leveraging GORE® Core Technology from the CTAG design
  - Reduced Profile
    - Leveraging ePTFE GORE® Core Technology

- **Same Ipsilateral Stent-graft Design**
  - Proven EXCLUDER® clinical performance
  - Proven EXCLUDER® durability

*Caution: Investigational Device. Limited by United States Law to Investigational Use Only.*
1303-199-001 - 30-day Follow-up
Prospective, non-randomized, study with 2 parallel substudies

- 50 U.S. sites
- First in Human in USA (19, December 2017)

**Substudy: Short Neck**
- Proximal neck angle: $\leq 60^\circ$
- Proximal seal length: $\geq 10$ mm
- 80 subjects

6 patients enrolled

**Substudy: High Neck Angulation**
- Proximal neck angle: $> 60^\circ$ and $\leq 90^\circ$
- Proximal seal length: $\geq 10$ mm
- 110 subjects

Begin recruitment
Expanding EVAR indication up to 90 degree angled necks

- **Conformability**
  Fit the anatomy within the natural aortic neck rather than alter it

- **Deliverability**
  Adjustable endograft system for more precise placement and *in situ* control

- **Durability**
  True long term durability is the goal based on proven Excluder design
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