ANCHOR REGISTRY

**Design:** Post-market, prospective, multi-arm registry

**Enrollment:** Up to 2000 patients followed for 5-years

**Devices Include:** Medtronic Endurant™, Talent™ and AneuRx™ grafts; Gore Excluder™ grafts, Cook Zenith™ grafts and Jotec E™-vita grafts

**Principal Investigators:**
- United States: Dr. William Jordan – Chief of Vascular Surgery/Endovascular Therapy, Emory University School of Medicine, Atlanta, Georgia
- Europe: Dr. Jean-Paul de Vries – Chair of Department of Surgery, University Medical Center Groningen, the Netherlands

ANCHOR ENROLLMENT (ABDOMINAL ARM)

<table>
<thead>
<tr>
<th>ENROLLMENT STATUS†</th>
<th>ANCHOR REGISTRY†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients since 2012</td>
<td>&gt;800</td>
</tr>
<tr>
<td>Countries</td>
<td>10</td>
</tr>
<tr>
<td>Sites</td>
<td>72</td>
</tr>
</tbody>
</table>

**Stent Grafts - Primary Arm**
- 57% Medtronic Endurant™
- 30% Gore Excluder™
- 12% Cook Zenith™
- 1% Jotec E™-vita abdominal
- 2% Other

**Stent Grafts - Revision Arm**
- 22% Medtronic Endurant™
- 13% Medtronic Talent™
- 17% Medtronic AneuRx™
- 20% Gore Excluder™
- 13% Cook Zenith™
- 1% Jotec E™-vita abdominal
- 14% Other/unknown

CONCLUSIONS

- ANCHOR captures post-clearance use of the Heli-FX™ system with primarily Medtronic grafts, Gore Excluder™ grafts, Cook Zenith™ grafts and Jotec E™-vita grafts
- Majority of patients enrolled have met the Society for Vascular Surgery analysis criteria for hostile neck
- By recreating the durability of a sutured anastomosis, ESAR protects against neck dilatation and promotes sac regression, which has shown to predict better long-term survival
A more competent proximal seal potentially induces AAA remodeling, which could benefit long-term survival

- **Sacc regression predicts improved long-term survival.** Analysis of 1,802 EVARs demonstrated that patients with sacc regression experienced significantly higher long-term survival than patients with AAA sac diameters that remained stable or expanded. 6

- **ESAR (EndoAnchor Aneurysm Repair) had significantly greater sac regression as compared to EVAR alone at 2 year post-op (81% vs. 49% without EndoAnchor® fixation, p=.01).**

- **Heli-FX® EndoAnchor™ implants promote sac regression in ANCHOR primary prophylactic cohort at 3 years.** The rate for subjects exhibiting decreasing sac size at 1 year was 37.2% (N=293), 49.1% (N=175) at 2-years and 50.4% (N=115) at 3 years.1

85.5% of prophylactic ANCHOR patients1 have “hostile” neck characteristics as defined by Society for Vascular Surgery guidelines (N=456)

### Sac Behavior and Survival

<table>
<thead>
<tr>
<th>Years</th>
<th>Proportion/Surviving</th>
<th>Long-Term Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0.75</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>0.50</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>0.25</td>
<td></td>
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<tr>
<td>4</td>
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</tr>
</tbody>
</table>

P < .01 for all comparisons. SE = 0.1

### Cumulative Sac Regression

<table>
<thead>
<tr>
<th>Days Postoperative</th>
<th>Cumulative Sac Regression</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>120</td>
<td>0.05</td>
</tr>
<tr>
<td>240</td>
<td>0.10</td>
</tr>
<tr>
<td>360</td>
<td>0.15</td>
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<tr>
<td>480</td>
<td>0.20</td>
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<tr>
<td>600</td>
<td>0.25</td>
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<tr>
<td>720</td>
<td>0.30</td>
</tr>
<tr>
<td>840</td>
<td>0.35</td>
</tr>
</tbody>
</table>

P value = 0.01 at 2 years

### 3 Year Primary Prophylactic SAC Behavior in Anchor

- The performance of the EndoAnchor® implant has not been evaluated for securing multiple anatomical structures together. Such use could result in adverse patient consequences such as vascular perforation, bleeding, or embolic events.
- MRI Safety and Compatibility

  - The EndoAnchor® implant has been determined to be MR Conditional at 3T or less when the scanner is in normal Operating Mode with whole body averaged SAR of 2 W/kg, or in First Level Controlled Mode with a maximum whole body averaged SAR of 4 W/kg.
  - Please refer to documentation provided by the endograft system manufacturer for MRI safety status of the endograft system with which the EndoAnchor® implants are being used.

### Potential Adverse Events

Possible adverse events associated with the Heli-FX® EndoAnchor™ system include, but are not limited to: Aneurysm rupture; Death; EndoAnchor™ implant embolization; EndoAnchor™ devices (Type III), EndoAnchor™ devices failure to correct/prevent Type I endoleak; Failure to prevent endograft migration; Infection; Renal complications (renal artery occlusion/budding or contrast-induced injury). Stroke; Surgical conversion to open repair; Vascular access complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula; Vessel injury, including dissection, perforation, and spasm.

Please reference product instructions for use for more information regarding indications, warnings, precautions, contraindications and adverse events.

**CAUTION:** Federal (USA) law restricts these devices to sale by or on the order of a licensed healthcare practitioner. See package inserts for full product information.

**CAUTION:** EndoAnchor™ implant locations should be based upon a detailed examination of the preoperative CT (including cases involving irregular or eccentric plaque in the intended sealing zone(s)). EndoAnchor™ implants should be implanted only into areas of aortic tissue free of calcified plaque or thrombus, or where such pathology is diffuse and less than 2mm in thickness. Attempting to place EndoAnchor™ implants into more severe plaque or thrombus may be associated with implantation difficulty and suboptimal endograft fixation and/or sealing.

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**Not to be removed from implant container prior to final deployment of endografting system.**

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**Medtronic**

Aortic | Peripheral | Venous
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