ANCHOR ANEURYSM TREATMENT USING THE HELI-FX™ AORTIC SECUREMENT SYSTEM GLOBAL REGISTRY

ANCHOR Objective: Capture real-world usage and long term outcomes of EndoAnchor fixation in endovascular aneurysm repair

REAL WORLD REGISTRY
- Design: Prospective, observational, global, multicenter, dual-arm registry with Core Lab Analysis
- Enrollment: Up to 2000 patients
- Follow-up: 5 years

TREATMENT ARMS
- “Primary” – EndoAnchor implant deployment in the primary EVAR setting as a prophylactic adjunct or for the treatment of intraoperative Type Ia endoleak
- “Revision” – EndoAnchor implant deployment in the revision EVAR setting for the treatment of late Type Ia endoleak and/or endograft migration

ANCHOR ENROLLMENT

<table>
<thead>
<tr>
<th>ENROLLMENT STATUS</th>
<th>PRIMARY ARM</th>
<th>REVISION ARM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients since 2012</td>
<td>&gt;600</td>
<td></td>
</tr>
<tr>
<td>Countries</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Sites</td>
<td>57</td>
<td></td>
</tr>
</tbody>
</table>

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 – Chief of Vascular Surgery, St. Antonious Hospital, Nieuwegein, the Netherlands

“In patients with complex anatomies who have been traditionally problematic for EVAR, we are finding relative ease in treating these patients with EndoAnchor fixation and also maintaining strong outcomes in follow-up.”

- Dr. Jean-Paul de Vries, ANCHOR Co-Principal Investigator

CONCLUSIONS
- ANCHOR is capturing real world usage and outcomes
- Majority of patients enrolled have met the analysis criteria for hostile neck
- With minimal time added to EVAR, ANCHOR confirms EndoAnchor fixation enhances outcomes and durability
**TRENDS FROM REAL-WORLD UTILIZATION**

Majority of patients met criteria for hostile neck:
- 77.6% of prophylactic subjects in the primary arm
- 74.5% of therapeutic subjects in the primary and revision arms

Minimal time added to EVAR

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Time (min.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prophylactic EndoAnchor implantation</td>
<td>16</td>
</tr>
<tr>
<td>Treatment of late Type Ia endoleaks</td>
<td>23</td>
</tr>
</tbody>
</table>

**REAL-WORLD OUTCOMES**

**Prophylactic EndoAnchor™ Fixation**

- 98.3% freedom from Type Ia endoleak
  - (173/177) in CT follow-up
  - (mean 8.2 months, range 0-27 months)
  - per Core Lab

- Zero (0/269) “EndoAnchor implant-related” serious adverse events in clinical follow-up
  - (mean 21.3 months, range 0-39 months)

- 64.1% subjects with sac regression (25/39) at 1-year CT follow-up
  - Zero (0/39) subjects with sac expansion

**Therapeutic EndoAnchor™ Fixation**

- 97.7% freedom from re-intervention for Type Ia endoleak
  - (257/263) in clinical follow-up

- 85.1% (120/141) and 82.8% (101/122) success in sealing persistent acute and late Type Ia endoleaks after final angio, respectively

- 0.7% (2/263) EndoAnchor implant-related serious adverse events in clinical follow-up

- 99.6% freedom from rupture (262/263) in clinical follow-up

**Indications for Use:** The Aptus™ Heli-FX™ EndoAnchor System is indicated for use in patients whose endovascular grafts have exhibited migration or endoleak, or are at risk of such complications, in whom augmented radial fixation and/or sealing is required to regain or maintain adequate aneurysm exclusion. The EndoAnchor may be implanted at the time of the initial endograft placement, or during a secondary (i.e., repair) procedure.

**Contraindications:** Treatment with the Aptus Heli-FX EndoAnchor system is contraindicated for use in the following circumstances:
- In patients with known allergies to the EndoAnchor implant material
- In conjunction with the Endologix Powerlink™ system

**Warnings:**
- The long-term performance of the Aptus EndoAnchor has not been established. All patients should be advised endovascular aneurysm treatment requires long-term, regular follow-up to assess the patient’s health status and endograft performance, and the EndoAnchor does not reduce this requirement.
- The EndoAnchor Heli-FX™ EndoAnchor System and Heli-FX Thoracic EndoAnchor System have been evaluated via in vitro testing and determined to be compatible with the Cook Zenith™, Cook Zenith TX²™, Gore Excluder™, Gore TAG™, Jotec E-vita abdominal, Jotec E-vita thoracic, Medtronic AneuRx™, Medtronic Endurant™, Medtronic Talent™, and Medtronic Valiant™ endografts. Use with endografts other than those listed above has not been evaluated.

**Potential Adverse Events:**
- Possible adverse events associated with the Heli-FX EndoAnchor include, but are not limited to: aneurysm rupture; death; EndoAnchor embolization; Endoleaks (Type III); enteric fistula; failure to correct/prevent Type I endoleak; failure to prevent endograft migration; infection; renal complications (renal artery occlusion/dissection or contrast-induced AKI); stroke; surgical conversion to open repair; vascular access complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula; vessel damage, including dissection, perforation, and spasm.

**MRI Safety and Compatibility:**
- The EndoAnchor implants have been determined to be MR Conditional at 3T or less when the scanner is in Normal Operating Mode with 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.

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**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 imaging in cases involving irregular or eccentric plaque in the intended sealing zone(s).

This therapy is not for everyone. Please consult your physician. A prescription is required.

For further information, please call Medtronic at +1.888.283.7868.

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