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

ANCHOR Objective:
Capture post-commercial availability usage and long term outcomes of ESAR (EndoSuture Aneurysm Repair) with Heli-FX™ EndoAnchor™ System
Design: Post-market, prospective, multi-arm registry

Enrollment: Up to 1200 patients followed for 5-years

Devices Include: Medtronic Endurant™, Talent™ and AneuRx™ grafts; Gore Excluder™ grafts and Cook Zenith™ 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 STATUS¹</th>
<th>ANCHOR REGISTRY¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients since 2012</td>
<td>&gt;950</td>
</tr>
<tr>
<td>Countries</td>
<td>ANZ, US and EU</td>
</tr>
<tr>
<td>Sites</td>
<td>95</td>
</tr>
</tbody>
</table>

Stent Grafts - Primary Arm
- 61% Medtronic Endurant™
- 27% Gore Excluder™
- 10% Cook Zenith™
- 2% Other

Reasons for ESAR
- 57.3% Concern for Late Failure
- 21.9% Prevention of Neck Dilatation
- 20.1% Treatment of Type Ia at Index
- 87.9% ASA Class III/IV
- 18.2% Urgent/Emergent Cases

We are observing that patients treated prophylactically with ESAR are seeing the most therapeutic benefit, which tells us that EndoAnchor™ implants are an opportunity for EVAR improvement in patients at risk for disease progression.

- Dr. William Jordan
ANCHOR Co-Principal Investigator

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¹June 2019
CONCLUSIONS

ANCHOR captures post-commercial availability use of the Heli-FX™ system with primarily Medtronic grafts, Gore Excluder™ grafts and Cook Zenith™ 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.\(^5\,^7\)

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<table>
<thead>
<tr>
<th>Patients with decreasing aneurysm sac (64/103)</th>
<th>62.1%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type Ia Endoleak (4/117)(^3)</td>
<td>3.4%</td>
</tr>
<tr>
<td>Migration (0/57)</td>
<td>0%</td>
</tr>
<tr>
<td>EndoAnchor™ Implants Adequately Penetrated Aorta (683/712)</td>
<td>95.9%</td>
</tr>
</tbody>
</table>

88.6% of prophylactic ANCHOR patients\(^4\) have “hostile” neck characteristics as defined by Society for Vascular Surgery guidelines (N=530 out of 598).

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\(^1\)Based on June 2019 data cut.

\(^2\) 2 patients with 4mm infrarenal thrombus (outside Heli-FX™ EndoAnchor™ implant IFU recommendation). One patient with graft misdeployment and persistent type Ia endoleak.

\(^3\) Baseline characteristics and aneurysm measurements are mean (or unless otherwise indicated) based on 598 patients with baseline CT.


\(^6\) Muhs BE. In Patients With Hostile Neck Anatomy EndoAnchors Prevent Endoleaks And Migration: A Propensity Matched Comparison Of EVAR In Hostile Neck Patients w/ and w/o EndoAnchors Presented at Veith; November 2016; New York, NY.
Sac regression predicts improved long-term survival. Analysis of 1,802 EVARs demonstrated that patients with sac regression experienced significantly higher long-term survival than patients with AAA sac diameters that remained stable or expanded.1

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)2

Heli-FX™ EndoAnchor™ implants promote sac regression in ANCHOR primary prophylactic cohort. Through 4 years, ANCHOR patients show positive sac regression despite hostile anatomy characteristics.

SAC BEHAVIOR AND SURVIVAL1

<table>
<thead>
<tr>
<th>Proportion Surviving</th>
<th>Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion Surviving</td>
<td>0.00</td>
</tr>
<tr>
<td>Proportion Surviving</td>
<td>0.25</td>
</tr>
<tr>
<td>Proportion Surviving</td>
<td>0.50</td>
</tr>
<tr>
<td>Proportion Surviving</td>
<td>0.75</td>
</tr>
<tr>
<td>Proportion Surviving</td>
<td>1.00</td>
</tr>
</tbody>
</table>

P < .01 for all comparisons. SE < 0.1

PRIMARY PROPHYLACTIC SAC BEHAVIOR IN ANCHOR

<table>
<thead>
<tr>
<th>Years</th>
<th>1-Year</th>
<th>2-Year</th>
<th>3-Year</th>
<th>4-Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>443</td>
<td>266</td>
<td>182</td>
<td>103</td>
</tr>
<tr>
<td>Enlargement (%)</td>
<td>38%</td>
<td>42%</td>
<td>51%</td>
<td>55%</td>
</tr>
<tr>
<td>Stable (%)</td>
<td>52%</td>
<td>48%</td>
<td>49%</td>
<td>44%</td>
</tr>
<tr>
<td>Regression (%)</td>
<td>10%</td>
<td>10%</td>
<td>12%</td>
<td>10%</td>
</tr>
</tbody>
</table>

CUMULATIVE SAC REGRESSION2

- EndoAnchor™ fixation 81.1% ± 9.5%
- Control 48.7% ± 5.9%

P value = 0.01 at 2 years

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.

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 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 MR safety status of the endograft system with which the EndoAnchor™ implants are being used.

Potential Adverse Events: Possible adverse events that are associated with the Heli-FX™ EndoAnchor™ system, include, but are not limited to: • Aneurysm rupture • Death • EndoAnchor™ implant embolization • EndoBridge-like • 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 acute kidney injury) • Stroke • Surgical conversion to open repair • Vascular access complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula • Vessel damage, including dissection, perforation, and spasm Please reference product instructions for use for more information regarding indications, warnings, precautions, contraindications and adverse events. Additional potential adverse events may be associated with endovascular aneurysm repair in general. Refer to the instructions for use provided with the endograft for additional potential adverse events.

References:

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.