CASE BOOK: ENDOANCHOR™ FIXATION

UC201700368 EN
PURPOSE OF THIS MATERIAL

The Aptus™ Heli-FX™ EndoAnchor™ systems have been used in over 5,000 patients worldwide, with over 30,000 EndoAnchor implants deployed to-date. Over 800 patients have been enrolled in IDE and post-market registry studies.

Medtronic is providing this case book to help physicians with making stronger informed decisions for their patients with abdominal aortic aneurysms (AAA) or thoracic aortic aneurysms (TAA), for whom they have or may be considering the Aptus™ Heli-FX™ EndoAnchor™ systems.

Medtronic's Mission is to contribute to human welfare by application of biomedical engineering in the research, design, manufacture, and sale of instruments or appliances that alleviate pain, restore health, and extend life. This technology reflects our commitment to our Mission and improving patient outcomes.

Questions or comments should be directed to Randy Bassett, PhD, Medical Science Advisor, Tel +1.707.543.2259, Fax +1.651.367.7050, g.randy.bassett@medtronic.com
The Aptus™ Heli-FX™ EndoAnchor™ Systems are intended to provide fixation and sealing between endovascular aortic grafts and the native artery.

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.

Evaluated and determined to be compatible with¹,²
- Medtronic Endurant™, Valiant™, Talent™, AneuRx™
- Gore Excluder™* and Gore TAG™*
- Cook Zenith™* and Zenith TX2™*

¹Per data on file at Medtronic
²Per Instructions for Use, the EndoAnchor should be used with caution in Talent and Valiant endografts.
OFF LABEL PROMOTION PROHIBITED

- Off label promotion of any endograft is strictly prohibited by Medtronic

<table>
<thead>
<tr>
<th>Stent Graft</th>
<th>Neck Length</th>
<th>Neck Angle</th>
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</thead>
<tbody>
<tr>
<td>Endurant™</td>
<td>≥10mm</td>
<td>≤60°</td>
</tr>
<tr>
<td>Zenith™* Fenestrated</td>
<td>≥4mm</td>
<td>≤45°</td>
</tr>
<tr>
<td>Zenith™* Flex</td>
<td>≥15mm</td>
<td>≤60°</td>
</tr>
<tr>
<td>Excluder™*</td>
<td>≥15mm</td>
<td>≤60°</td>
</tr>
<tr>
<td>Ovation™*</td>
<td>Not tested with EndoAnchor implants</td>
<td></td>
</tr>
<tr>
<td>Aorfix™*</td>
<td>Not tested with EndoAnchor implants</td>
<td></td>
</tr>
<tr>
<td>Endologix Powerlink™*</td>
<td>Contraindicated with EndoAnchor fixation²</td>
<td></td>
</tr>
</tbody>
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¹Per manufacturers' IFU as of May 2016
²Other contraindication for EndoAnchor fixation is in patients with known allergies to the EndoAnchor implant material (MP35N-LT)
CASE BOOK MAP
HOW LEADING PHYSICIANS USE ENDOANCHOR FIXATION TO ENHANCE OUTCOMES AND DURABILITY

Prophylactic Applications
- Conical necks
- Short necks
- Multiple variables
- Angulated necks
- Wide necks

Therapeutic Applications
- Intra-op type I endoleak
- Late type I endoleak
- Graft migration

Specialty Applications
- Ruptures
- FEVAR
CONICAL NECKS
PRIMARY EVAR – CONICAL NECK
SHEPPARD MONDY III, MD, SAVANNAH, GA
PRIMARY EVAR – CONICAL NECK
PETER SCHNEIDER, MD, HONOLULU, HAWAII
PRIMARY TEVAR – CONICAL NECK
ALAN LUMSDEN, MD, HOUSTON, TX
PRIMARY TEVAR – CONICAL NECK
GRAYSON WHEATLEY, MD, TEMPLE UNIVERSITY, PENNSYLVANIA
SHORT NECKS
PRIMARY EVAR – SHORT, CONICAL NECK
PETER SCHNEIDER, MD, HONOLULU, HAWAII
Type 1a leak after graft implantation

Initial angio

4 EndoAnchor implants deployed

Final Angio, leak resolved
PRIMARY TEVAR – SHORT PROXIMAL/DISTAL NECKS
JEAN M. PANNETON, MD, EASTERN VIRGINIA MEDICAL
WIDE NECKS
ANGULATED NECKS
PRIMARY EVAR – ANGULATION, INTRA-OP TYPE I ENDOLEAK
COLIN D. BICKNELL, MD, IMPERIAL COLLEGE, LONDON, UK

Type 1a endoleak in angulated aortic neck

EndoAnchor implants resolve endoleak

1 year post-op follow-up shows no complications
REVISION EVAR – ANGULATION, LATE TYPE I ENDOLEAK
KRASSI IVANCEV, MD, LONDON, UK
PRIMARY EVAR – SHORT / CONICAL / ANGULATED
CLIFF LYND, MD
INTRA-OP TYPE I ENDOLEAKS
PRIMARY EVAR – INTRA-OP TYPE IA ENDOLEAK
ELIE SEMAAN, MD & MARCUS D’AYALA, MD, BROOKLYN, NY

Post balloon Type 1
PRIMARY EVAR – INTRA-OP TYPE IA ENDOLEAK
RIPAL GANDHI, MD, BARRY KATZEN, MD, MIAMI, FL

Pre-op

Persisting type 1 after repeat ballooning

6 EndoAnchor implants

2 months post op
PRIMARY EVAR – INTRA-OP TYPE IA ENDOLEAK

COLIN D. BICKNELL, MD, LONDON, UK

Type 1a endoleak in angulated aortic neck

EndoAnchor fixation resolves endoleak

1 year post-op follow-up shows no complications
PRIMARY EVAR – INTRA-OP TYPE IA ENDOLEAK
JAMES JOYE, DO, MOUNTAIN VIEW, CA
PRIMARY EVAR – INTRA-OP TYPE IA ENDOLEAK
MANISH MEHTA, MD, PHILIP PATY, MD, NEW YORK
PRIMARY EVAR – INTRA-OP TYPE IA ENDOLEAK
MANISH MEHTA, MD, PHILIP PATY, MD, NEW YORK
PRIMARY TEVAR – SHORT PROXIMAL/DISTAL NECKS
PIOTR KASPRZAK MD, REGENSBURG, GERMANY

Type 1a leak after graft implantation

4 EndoAnchor implants deployed

Final Angio, leak resolved
PRIMARY TEVAR – INTRA-OP TYPE IA ENDOLEAK
FIRAS MUSSA, MD, NYU LANGONE, NEW YORK, NEW YORK
LATE TYPE I ENDOLEAKS
Type 1a Endoleak

Endoleak persists after cuff and 4 EndoAnchor implants

2 more EndoAnchor implants and endoleak is resolved

Post op CT
REVISION EVAR – LATE TYPE IA ENDOLEAK
FRED BEAVERS, MD, CLINTON, MARYLAND
REVISIÓN EVAR – LATE TYPE IA ENDOLEAK
KRASSI IVANCEV, MD, LONDON, UK
Late type I endoleak

EndoAnchor fixation after cuff implantation

Endoleak resolved
REVISION TEVAR – LATE TYPE IA/IB ENDOLEAKS
NEIL HALIN, DO, TUFTS UNIVERSITY
REVISION TEVAR – LATE TYPE IB ENDOLEAK
JOSH BERNHEIM, MD, DANIEL CHAR, MD, RIDGEWOOD, NJ
ENDOGRAFT MIGRATION
REVISION EVAR – ENDOGRAFT MIGRATION
ERIC VERHOEVEN, MD, PHD, NUREMBERG, GERMANY
Late endograft migration with Type Ia endoleak

Cuff and EndoAnchor implants deployed

Endoleak resolved
REVISION TEVAR – ENDOGRAFT MIGRATION
COLIN BICKNELL, MD, MOHAMAD HAMADY, MD,
IMPERIAL COLLEGE, LONDON, UK

Initial Angio

Post graft deployment

Post deployment of 4 EndoAnchor implants
RUPTURES
REVISION EVAR – TYPE I ENDOLEAK IN RUPTURED AAA
BART MUHS, MD, PHD, NEW HAVEN, CONNECTICUT

Persisting type Ia endoleak post rEVAR

9 EndoAnchor implants deployed in proximal neck

Endoleak resolved
FEVAR
**Indications for Use:** The Aptus™ Heli-FX™ EndoAnchor™ System is intended to provide fixation and sealing between endovascular aortic grafts and the native artery. 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 (MP35N-LT)
- In conjunction with the Endologix Powerlink™* endograft

**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.
- The performance of the Aptus EndoAnchor has not been evaluated for securing multiple endograft components to one another. Not securing EndoAnchor implants into aortic tissue could result in graft fabric damage, component separation, and resultant Type III endoleaks.
- The performance of the Aptus EndoAnchor has not been evaluated in vessels other than the aorta. Use of the EndoAnchor to secure endografts to other vessels may result in adverse patient consequences such as vascular perforation, bleeding, or damage to adjacent structures.
- The performance of the Aptus EndoAnchor 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 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 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
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 imaging in 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.

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.