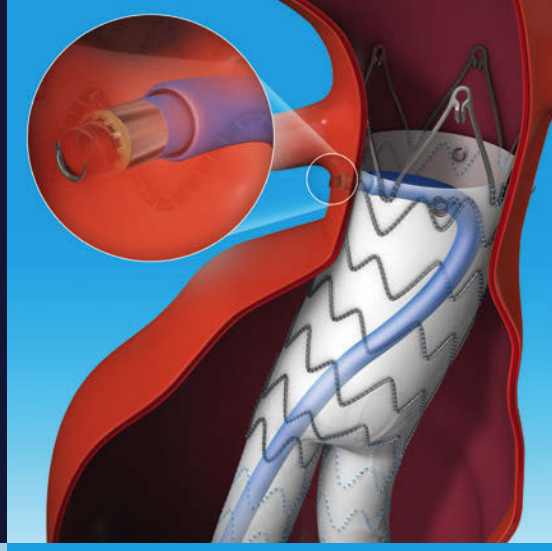
EXPANDING PATIENT CARE OPTIONS

ESAR (ENDOSUTURE ANEURYSM REPAIR) WITH ENDOANCHOR™ FIXATION FOR SHORT AORTIC NECKS†



ANCHOR REGISTRY SHORT NECK COHORT SHOWS FAVORABLE OUTCOMES OF HELI-FX™ ENDOANCHOR™ SYSTEM + ENDURANT™ STENT GRAFTS

Endurant™ II/IIs
AAA Stent Graft System
and
Heli-FX™
EndoAnchor™ System

SUCCESSFUL INITIAL IMPLANT PROCEDURES

97.1% (68/70)	Overall procedural success‡
92.9% (65/70)	Successful and accurate deployment of EndoAnchor™ implants§
88.6% (62/70)	Technical success¹

FAVORABLE 1-YEAR AND 2-YEAR OUTCOMES

1-year	2-year	
2.0% (1/49)	**0.0%** (0/32)	Type Ia Endoleak
1.4% (1/70)	**1.6%** (1/63)	Type Ia-related Secondary Endovascular Procedures²
0% (0/70)	**0%** (0/63)	Conversion to Open Surgical Repair
0% (0/70)	**0%** (0/63)	AAA Rupture

HELI-FX™ ENDOANCHOR™ IMPLANTS USED WITH ENDURANT™ STENT GRAFT PROMOTE AAA SAC REGRESSION

AAA Sac Diameter Changes – Core Lab

†Indicated for necks < 10 mm down to 4 mm; please consult product IFU for further details.
‡2 investigator-reported cases of unsuccessful procedures: 1) failure to deliver the main body endograft to intended landing zone, 2) persistent Type Ia endoleak
§There were 4 cases where the investigator assessed that one EndoAnchor™ implant did not penetrated the aortic wall and 1 case of unsuccessful implantation of EndoAnchor™ implants.
¹At least 1 EndoAnchor™ implant didn't adequately penetrate aortic wall (N=4, All 4 procedures determined to be successful by the investigator). Unsuccessful delivery of main body to intended landing zone (N=3, Endografts delivered slightly distal to intended target; 1 cuff covered renal). One subject with combination of low endograft landing, unintentional coverage of a renal artery with cuff, and unsuccessful implant of EndoAnchor™ implants).
²One patient received an additional graft extension and sac embolization to treat a type Ia endoleak on day 9, which resolved.

Medtronic
Further, Together

ANCHOR REGISTRY

Design: Post-market, prospective, multi-arm registry with Core Lab analysis

Enrollment: 70 Subjects in the Short Neck Cohort were analyzed at 22 EU and US sites[†]

Eligibility: Proximal neck length <10mm and ≥4mm, as measured by the Core Lab. Neck length defined as the length over which the aortic diameter remains within 10% of the infrarenal diameter.[1]

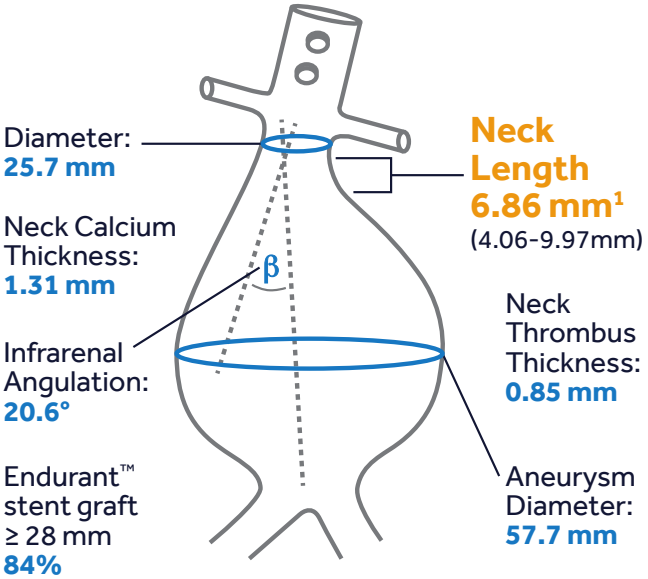
Primary Outcomes:

- Type Ia endoleak rate at 1 month (core laboratory assessed)
- Type Ia endoleak rate at 12 months (core laboratory assessed)
- Re-intervention rate through 12 months[‡]
- Technical success rate[§]

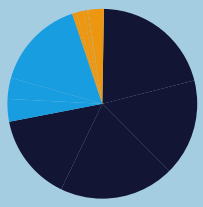
Secondary Outcomes: Index procedure outcomes, device-related events, safety and effectiveness related measures

BASELINE ANATOMICAL CHARACTERISTICS – CORE LAB

Mean measurements

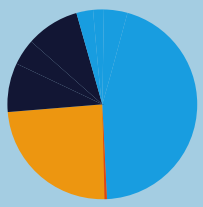


Aneurysm Status



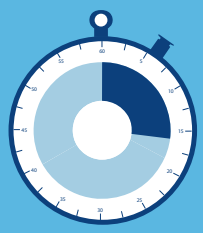
- **69%** Elective
- **22%** Urgent
- **8%** Emergent

Reason for EndoAnchor™ Implant Placement — site-reported



- **56%** Concern for Late Failure
- **23%** Prevention of Neck Dilatation
- **20%** Treatment of Type Ia Endoleak
- **1%** concern for Type Ia Endoleak

Minimal time added



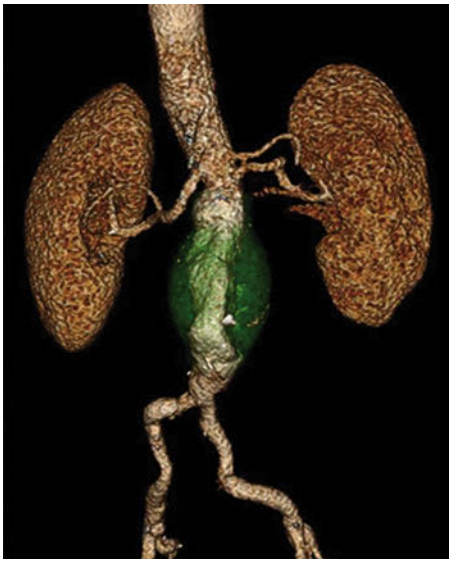
17 min. (avg)

Average 5.5 EndoAnchor™ implants (range 2-12)

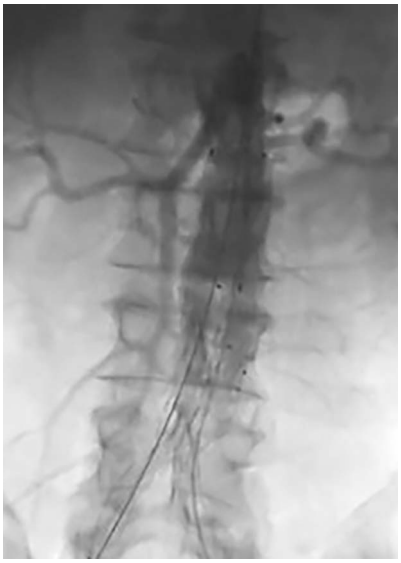
[†]Data on file. As of April 2019
[‡]Re-interventions are defined as any endovascular or surgical procedure performed following the completion of the operative initial implantation procedure (thus on subsequent occasion after final closure of the last artery access site) which involves the targeted vascular segment treated by the Endurant™ stent graft system, including access sites and bypasses of the targeted vascular segment in which there is either manipulation of the implanted Endurant™ stent graft, or implantation or usage of additional devices.
[§]Technical success defined as: successful delivery and deployment of the endograft and EndoAnchor™ implants without unintentional coverage of the renal arteries
[1]Neck length measured as: Proximal neck length. Proximal neck length is defined as the non-aneurysmal aortic neck length measured from the lowest main renal artery to where the dilatation of the aneurysm begins (i.e., less than 10% increase from the diameter at the lowest renal artery).

CASE EXAMPLE:

- 5cm AAA
- Infrarenal neck diameter (@ renals): 25.7mm
- Infrarenal neck length: 7.6mm
- Infrarenal angulation: 11˚
- No infrarenal neck calcium & minimal mural thrombus



Pre-case CT



No endoleak at 1-year post op

"Current endovascular treatment options for AAA patients with short proximal neck are often limited to complex procedures with higher failure risk. Heli-FX™ EndoAnchor™ implants used with the Endurant™ II/IIs system offer a safer, simpler, off-the-shelf durable solution for patients and physicians."

- Apostolos K. Tassiopoulos, MD

Professor of Surgery and Vice Chair for Quality and Outcomes
Chief, Vascular and Endovascular Surgery Division
Co-Director of Aortic Center and Director of Surgical Skills Center
Stony Brook School of Medicine, New York

CONCLUSIONS

- Medtronic provides the first ESAR indicated for patients with short necks
- ANCHOR short neck one year and two year clinical results support the use of Endurant™ II/IIs system + Heli-FX™ EndoAnchor™ system in short aortic necks†
- 0% of ANCHOR Endurant II/IIs + Heli-FX short neck patients experienced increasing AAA sacs at 1 and 2 years and 44% had sac regression at 1 year and 65% had sac regression at 2 years
- Long-term safety and effectiveness data will continue to be collected up to 5 years

†Neck length ≥4 and < 10mm

Endurant™ II / IIs

AAA Stent Graft System

Indications

The Endurant™ II/Endurant™ IIs bifurcated stent grafts are indicated for the endovascular treatment of infrarenal abdominal aortic or aortoiliac aneurysms. They may be utilized in conjunction with the Heli-FX EndoAnchor System when augmented radial fixation and/or sealing is required; in particular, in the treatment of abdominal aortic aneurysms with short (≥ 4 mm and < 10 mm) infrarenal necks. The Endurant II Stent Graft System aorto-uni-iliac (AUI) stent graft is indicated for the endovascular treatment of infrarenal abdominal aortic or aortoiliac aneurysms in patients whose anatomy does not allow the use of a bifurcated stent graft. The Endurant II/IIs Stent Graft System is indicated for use in patients with the following characteristics:

- Adequate iliac or femoral access that is compatible with vascular access techniques, devices, or accessories
- Proximal neck length of
  - ≥ 10 mm; or
  - ≥ 4 mm and < 10 mm when used in conjunction with the Heli-FX EndoAnchor System (bifurcated stent graft only)

  Note: Neck length is defined as the length over which the aortic diameter remains within 10% of the infrarenal diameter.
- Infrarenal neck angulation of ≤ 60°
- Aortic neck diameters with a range of 19 to 32 mm
- Distal fixation length(s) of ≥ 15 mm
- Iliac diameters with a range of 8 to 25 mm
- Morphology suitable for aneurysm repair

Contraindications

The Endurant II/Endurant IIs Stent Graft System is contraindicated in:

- Patients who have a condition that threatens to infect the graft.
- Patients with known sensitivities or allergies to the device materials.

Warnings and Precautions

- The long-term safety and effectiveness of the Endurant II/Endurant IIs Stent Graft System has not been established. All patients should be advised that endovascular treatment requires lifelong, regular follow-up to assess the health and the performance of the implanted endovascular stent graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms, changes in the structure or position of the endovascular graft, or less than the recommended number of EndoAnchors when used in short (≥ 4 mm and < 10 mm) proximal necks) should receive enhanced follow-up. Specific follow-up guidelines are described in the *Instructions for Use*.
- Patients experiencing reduced blood flow through the graft limb, aneurysm expansion, and persistent endoleaks may be required to undergo secondary interventions or surgical procedures.
- The Endurant II/Endurant IIs Stent Graft System is not recommended in patients unable to undergo or who will not be compliant with the necessary preoperative and postoperative imaging and implantation studies as described in the *Instructions for Use*.
- Renal complications may occur: 1) From an excess use of contrast agents. 2) As a result of emboli or a misplaced stent graft. The radiopaque marker along the edge of the stent graft should be aligned immediately below the lower-most renal arterial origin.
- Studies indicate that the danger of micro-embolization increases with increased duration of the procedure.
- The safety and effectiveness of the Endurant II/Endurant IIs Stent Graft System has not been evaluated in some patient populations. Please refer to the product *Instructions for Use* for details.

MRI Safety and Compatibility

Non-clinical testing has demonstrated that the Endurant II/Endurant IIs Stent Graft is MR Conditional. It can be scanned safely in both 1.5T & 3.0T MR systems under certain conditions as described in the product *Instructions for Use*. For additional information regarding MRI please refer to the product *Instructions for Use*.

Adverse Events

Potential adverse events include (arranged in alphabetical order): amputation; anesthetic complications and subsequent attendant problems (e.g., aspiration), aneurysm enlargement; aneurysm rupture and death; aortic damage, including perforation, dissection, bleeding, rupture and death; arterial or venous thrombosis and/or pseudoaneurysm; arteriovenous fistula; bleeding, hematoma or coagulopathy; bowel complications (e.g., ileus, transient ischemia, infarction, necrosis); cardiac complications and subsequent attendant problems (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension, hypertension); claudication (e.g., buttock, lower limb); death; edema; EndoAnchor (for infrarenal EVAR procedures using the Heli-FX EndoAnchor system): partial deployment, inaccurate deployment, fracture, dislodgement, embolization, stent graft damage, modelling balloon damage); embolization (micro and macro) with transient or permanent ischemia or infarction; endoleak; fever and localized inflammation; genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, femoral-femoral artery thrombosis, fistula, incontinence, hematuria, infection); hepatic failure; impotence; infection of the aneurysm, device access site, including abscess formation, transient fever and pain; lymphatic complications and subsequent attendant problems (e.g., lymph fistula); neurologic local or systemic complications and subsequent attendant problems (e.g., confusion, stroke, transient ischemic attack, paraplegia, paraparesis, paralysis); occlusion of device or native vessel; pulmonary complications and subsequent attendant problems; renal complications and subsequent attendant problems (e.g., artery occlusion, contrast toxicity, insufficiency, failure); stent graft: improper component placement; incomplete component deployment; component migration; suture break; occlusion; infection; stent fracture; graft twisting and/or kinking; insertion and removal difficulties; graft material wear; dilatation; erosion; puncture and perigraft flow; surgical conversion to open repair; vascular access site complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula, dissection; vascular spasm or vascular trauma (e.g., iliofemoral vessel dissection, bleeding, rupture, death); vessel damage; wound complications and subsequent attendant problems (e.g., dehiscence, infection, hematoma, seroma, cellulitis)

Please reference product *Instructions for Use* for more information regarding indications, warnings, precautions, contraindications and adverse events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Heli-FX™

EndoAnchor™ System

Indications for Use: The Heli-FX™ EndoAnchor™ system is intended to provide fixation and sealing between endovascular aortic grafts and the native artery. The 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™ implant may be implanted at the time of the initial endograft placement, or during a secondary (i.e. repair) procedure.

Contraindications: Treatment with the 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 EndoAnchor™ implant has not been established. All patients should be advised endovascular aneurysm treatment requires long-term, regular follow-up visits to assess the patient's health status and endograft performance. The EndoAnchor™ implant does not reduce this requirement.

- The EndoAnchor™ implant and the Heli-FX™ 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™*, Medtronic AneuRx™, Medtronic Endurant™, Medtronic Talent™ AAA, Medtronic Talent™ TAA, Medtronic Valiant Xcelerant™, Medtronic Valiant™ Captivia™, and Medtronic Valiant Navion™ endografts. Use with endografts other than those listed above has not been evaluated.
- The performance of the EndoAnchor™ implant has not been evaluated for securing multiple endograft components together. Not securing EndoAnchor™ implants into aortic tissue could result in graft fabric damage, component separation, and resultant Type III endoleaks.
- The performance of the EndoAnchor™ implant has not been evaluated in vessels other than the aorta. Use of the EndoAnchor™ implant 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 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™ 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 • 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.

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 zones. 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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