

SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Endovascular Graft

Device Trade Name: Endurant™ II/Endurant™ IIs Stent Graft System

Device Procode: MIH

Applicant's Name and Address: Medtronic Vascular
3576 Unocal Place
Santa Rosa, CA 95403

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P100021/S063

Date of FDA Notice of Approval: September 29, 2017

The Endurant Stent Graft System original PMA (P100021) was approved for the treatment of infrarenal abdominal aortic aneurysms on December 16, 2010. The Endurant™ II/Endurant™ IIs Stent Graft Systems (hereinafter referred to as Endurant II/IIs Stent Graft System) are next-generation stent graft systems based on Endurant. The Endurant II Stent Graft System received FDA approval on April 27, 2012 (P100021/S011). The Endurant IIs Stent Graft System received FDA approval on October 23, 2015 (P100021/S039).

The Summary of Safety and Effectiveness Data (SSED) to support the original approval is available on the CDRH website (https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100021b.pdf) and is incorporated by reference here. The current supplement was submitted to expand the indication for the Endurant II/IIs Stent Graft System to include treatment of infrarenal abdominal aortic aneurysms having neck lengths ≥ 4 mm and < 10 mm (“short necks”), when used in conjunction with the Heli-FX EndoAnchor System (K102333).

II. INDICATIONS FOR USE

The Endurant II/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 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 $\leq 60^\circ$
- 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

III. CONTRAINDICATIONS

The Endurant II/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

When used with the Heli-FX EndoAnchor system, the Endurant II/IIs Stent Graft System is also contraindicated in:

- patients with known sensitivities to the EndoAnchor implant materials

For contraindications regarding ancillary devices used with the Endurant II/IIs stent graft system, refer to the instructions for use provided with each device.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions specific to the use of the Endurant II/IIs and to the use of this device in conjunction with the Heli-FX EndoAnchor System are included in the Endurant II/IIs Stent Graft System instructions for use. The warnings and precautions for the Heli-FX EndoAnchor System are also applicable for the expanded indication and can be found in the instructions for use for that device.

V. DEVICE DESCRIPTION

Endurant II/IIs Stent Graft System

The Endurant II/IIs Stent Graft System is intended for the treatment of abdominal aortic aneurysms (AAA) using an endovascular approach. When placed within the target lesion,

the stent graft (implant) self-expands to provide a permanent, alternative conduit for blood flow within the vasculature by excluding the aneurysmal sac from blood flow and pressure.

The Endurant II/IIIs Stent Graft System is comprised of two main components: an implantable stent graft and a disposable delivery system. The stent graft, preloaded into the delivery system, is advanced to the aneurysm location over a guidewire. Upon retraction of the graft cover, the stent graft self-expands to the indicated vessel diameter. During deployment and expansion, the stent graft is intended to form proximal and distal seal zones surrounding the aneurysm location.

The Endurant II/IIIs Stent Graft System stent graft is based on the Endurant stent graft. The Endurant II/IIIs Stent Graft System comprises a product line extension. The differences in these devices are described in the Annual Physician Clinical Update for the Endurant/Endurant II/Endurant IIIs Stent Graft Systems. All Endurant family aortic stent grafts (Endurant/Endurant II/Endurant IIIs) are identical with respect to the design of the proximal end, including the suprarenal stent, anchor pins and sealing zone.

There have been no changes in the stent graft system associated with the change in labeling to allow for the treatment of short necks when used with the Heli-FX EndoAnchor System.

Stent Grafts

The Endurant II/IIIs Stent Graft System is modular. The component configurations affected by the change in indications for use include the following:

- Bifurcated component (Endurant II and Endurant IIIs)
- Limb component
- Aortic extensions
- Iliac extensions

Each component is introduced separately into the patient's vascular system. After the placement of the bifurcated and contralateral limb components, aortic and limb extension components may be introduced separately into the vessel and are mated *in vivo* to the components already *in situ*. All components are composed of nitinol metal stents sewn to a polyester fabric graft. The suprarenal stents with anchoring pins on the proximal end are laser cut from a nitinol tube. The remaining stents are formed in a ring with opposing ends being terminated together in crimp sleeves. These are called wire formed stents. The wire formed stents are sewn to the polyester graft fabric using a polyester suture, whereas the suprarenal stents are sewn to the graft fabric using an ultra-high molecular weight polyethylene suture. This suture is designed to aid in better stent to graft attachment strength, thus providing a more durable proximal attachment. Radiopaque markers, constructed of platinum, are sewn onto the stent graft to aid in visualization of the stent graft under fluoroscopy and to facilitate accurate placement of the device. Refer to **Figure 1** for an overview of stent graft components.

The stent graft is designed to be placed in the native vessel such that the unconstrained stent graft diameter is larger than the diameter of the native vessel into which it is to be placed. This “oversizing” helps to exclude the aneurysm from aortic blood flow and to ensure the stent graft is held in place. The amount of oversizing required is dependent on the diameter of the native vessel.



Endurant II
Bifurcated Stent
Graft



Endurant IIs
Bifurcated
Stent Graft



Aortic Extension
Stent Graft



Limb Stent
Graft



Iliac Extension
Stent Graft

Figure 1. Relevant Endurant II and Endurant IIs Stent Graft Configurations

Delivery Systems

There are two types of delivery systems for the Endurant II/IIIs Stent Graft System, the Aortic Delivery System and the Iliac Delivery System. The Aortic Delivery System is used to deliver the aortic extension, bifurcated, and AUI stent grafts. The Iliac Delivery System is used to deliver contraateral limbs and iliac extensions. See **Figure 2** and **Figure 3** below for an overview of the Aortic and Iliac Delivery Systems, respectively.

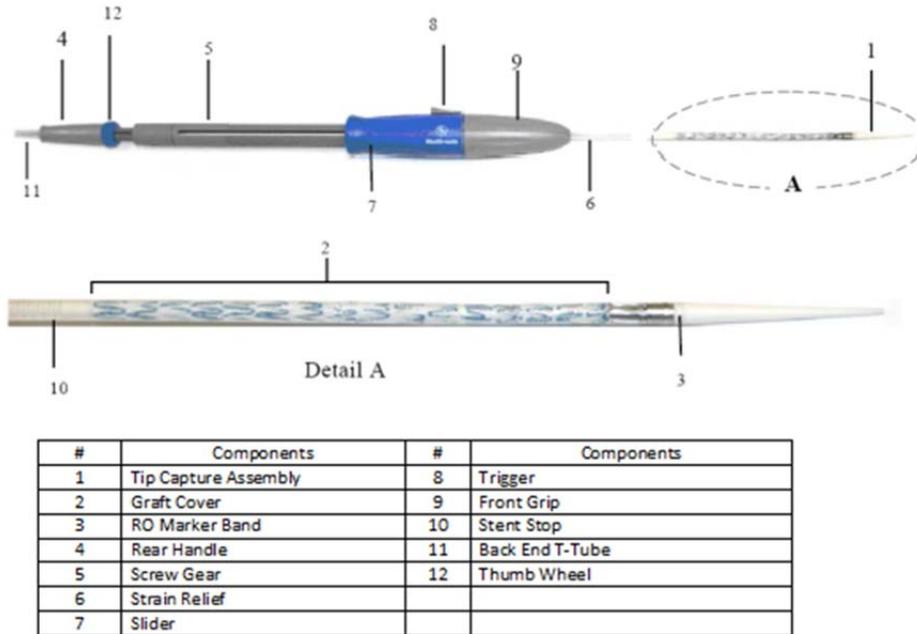


Figure 2. Endurant II/IIIs Aortic Delivery System

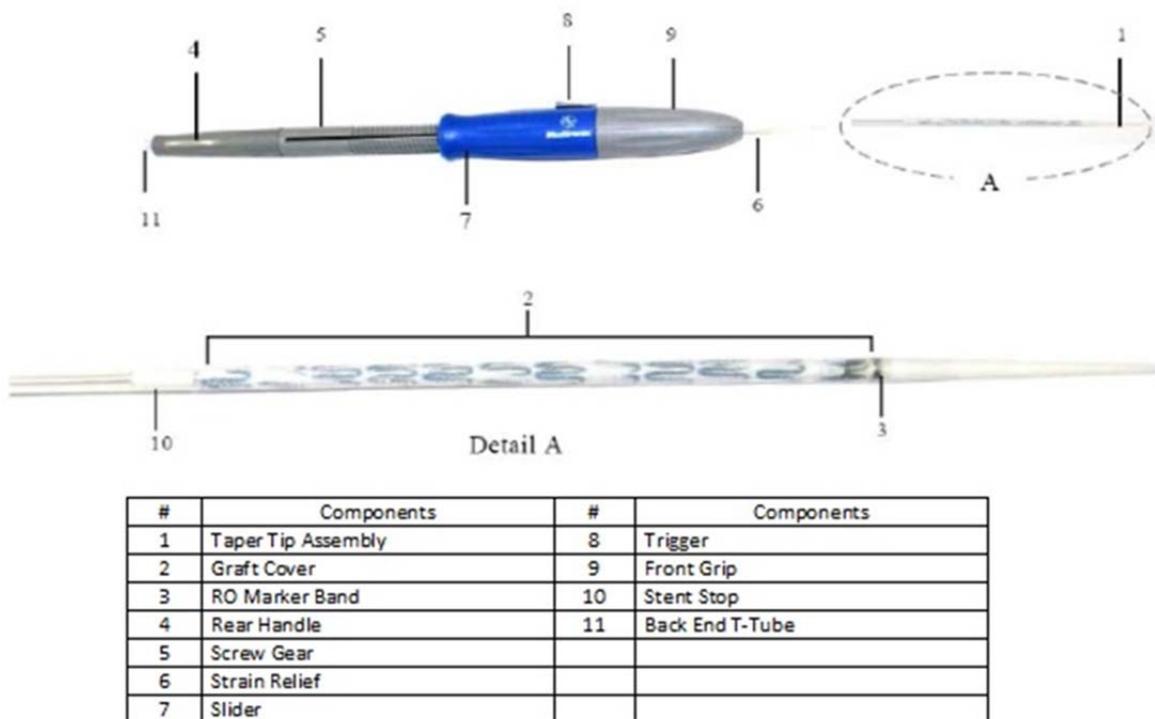


Figure 3. Endurant II Iliac Delivery System

Please refer to the Physician Instructions for Use for additional details.

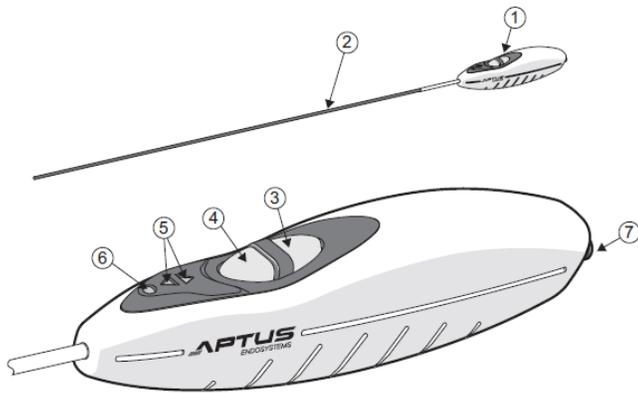
Heli-FX EndoAnchor System

The Heli-FX EndoAnchor System is a class II device cleared through the Premarket Notification [510(k)] process and is not part of this PMA. However, the expanded indications for use in this submission require the use of the Heli-FX EndoAnchor System in conjunction with the Endurant II/IIs Stent Graft System.

The Heli-FX EndoAnchor System is intended to provide fixation and sealing between endovascular aortic grafts and the native artery. It is comprised of the EndoAnchor implant (an intravascularly-applied suture constructed of medical-grade nickel-cobalt wire, supplied in a cassette containing 10 EndoAnchors), the Heli-FX Applier (a catheter-based device for placement of the EndoAnchor), and the Heli-FX Guide (a deflectable sheath to position the Applier). Please see **Figure 4**, **Figure 5** and **Figure 6**.

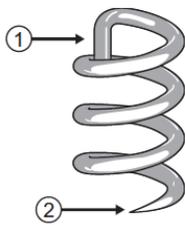
It is recommended that the EndoAnchor implantation be done after the aortic endograft has been placed and any balloon remodeling of the infrarenal seal zone of the stent graft system has been completed. The recommended Heli-FX Guide tip configuration is based on native vessel diameter. The recommended number of EndoAnchor implants is based on endograft type, graft angulation and native vessel diameter.

Further detail is available in the physician instructions for use for the Heli-FX EndoAnchor System and the Endurant II/IIs instructions for use.



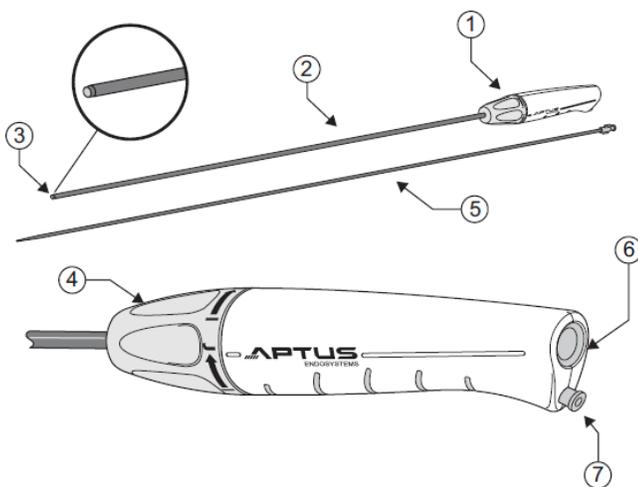
1. Control handle
2. Catheter
3. Reverse control button
4. Forward control button
5. Green forward and reverse indicators
6. Error indicator
7. Flush port

Figure 4. Diagram of the Heli-FX Applier



1. Crossbar
2. Leading end

Figure 5. Heli-FX EndoAnchor



1. Control handle
2. Guide catheter
3. Radiopaque markers
4. Deflector knob
5. Obturator
6. Hemostatic seal
7. Flush port

Figure 6. Components of the Heli-FX Guide

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several alternatives for the treatment of abdominal aortic aneurysms with short infrarenal necks including fenestrated endografts, another endovascular graft indicated for treatment of shorter necks, medical management, and open surgical repair. Each alternative has its own advantages and disadvantages. The physician should fully discuss these alternatives with his/her patient to select the method that best meets expectations and lifestyle.

VII. MARKETING HISTORY

Endurant II/IIs Stent Graft System is commercially available in the following countries:

Argentina	Guatemala	Philippines
Australia	Hong Kong	Poland
Austria	Hungary	Portugal
Belarus	Iceland	Romania
Belgium	India	Russia
Bolivia	Indonesia	Saudi Arabia
Bosnia and Herzegovina	Ireland	Serbia
Brazil	Israel	Singapore
Bulgaria	Italy	Slovakia
Canada	Japan	Slovenia
Chile	Jordan	South Africa
Colombia	Kuwait	South Korea
Costa Rica	Latvia	Spain
Croatia	Liechtenstein	Sweden
Cyprus	Lithuania	Switzerland
Czech Republic	Luxembourg	Taiwan
Denmark	Macedonia	Thailand
Ecuador	Malaysia	Turkey
El Salvador	Malta	UK/Northern Ireland
Estonia	Mexico	Ukraine
Finland	Netherlands	United States/PR
France	New Zealand	Uruguay
Germany	Norway	Venezuela
Greece	Peru	Vietnam

A global voluntary recall of a limited number of Endurant and Endurant II stent grafts was initiated on March 2, 2017, due to varying fabric permeability in specific lots. To date, there have been no other market withdrawals of the Endurant, Endurant II and Endurant IIs Stent Graft Systems for reasons related to safety or effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) that may be associated with the use of the Endurant II/II_s Stent Graft System or with the use of Endurant II/II_s Stent Graft System in conjunction with the Heli-FX EndoAnchor System, with those uniquely associated with the use of EndoAnchors listed under “EndoAnchor.”

- Amputation
- Anesthetic complications and subsequent attendant problems (eg, 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 (eg, arrhythmia, myocardial infarction, congestive heart failure, hypotension, hypertension)
- Claudication (e.g., buttock, lower limb)
- Death
- Edema
- Embolization (micro and macro) with transient or permanent ischemia or infarction
- EndoAnchor (for infrarenal endovascular aneurysm repair (EVAR) procedures using the Heli-FX EndoAnchor system): partial deployment, inaccurate deployment, fracture, dislodgement, embolization, stent graft damage, modelling balloon damage
- Endoleak
- Femoral-femoral artery bypass thrombosis
- Fever and localized inflammation
- Genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, 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 (eg, 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 (eg, artery occlusion, contrast toxicity, insufficiency, failure)
- Stent graft: improper component placement; incomplete component deployment; component migration; suture break; occlusion; thrombus; 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 (eg, dehiscence, infection, hematoma, seroma, cellulitis)

For the specific adverse events that occurred in the clinical studies, please see Section X (Summary of Primary Clinical Evidence) below.

IX. SUMMARY OF NONCLINICAL STUDIES

Medtronic performed a risk assessment to identify the device attributes that could potentially be impacted by the proposed indication expansion and presented the rationale for the information needed to evaluate each of the attributes (i.e., existing test data or new testing). Nonclinical studies previously conducted continue to be applicable to and supportive of the use of the Endurant II/IIs Stent Graft System and the Heli-FX EndoAnchor System. Medtronic also conducted additional laboratory studies, summarized below, to confirm continued performance of the Endurant II/IIs Stent Graft System in conjunction with Heli-FX in the short neck application.

A. Laboratory Studies

In Vitro Bench Studies

Medtronic performed the *in vitro* tests shown in the table below to confirm that Endurant II/IIs Stent Graft System continues to perform as expected when utilized in conjunction with Heli-FX EndoAnchors in the short neck application.

Table 1. In Vitro Bench Studies

Test	Purpose	Acceptance Criteria	Result
Simulated Use	<p>The purpose of the simulated use testing was to demonstrate that the Endurant II/IIs Stent Graft System and the Heli-FX system can be appropriately used in the proposed short neck anatomies following the currently approved implant procedures.</p> <p>Endurant II/IIs stent grafts and Heli-FX EndoAnchors were deployed in a test environment designed to simulate physiological conditions, utilizing fluoroscopic visualization only. A worst-case anatomical model that included the most challenging proximal neck anatomy coupled with the angulation that covers the limits of the indication was utilized.</p> <p>For Endurant II/IIs Stent Graft System, the following performance requirements were evaluated: deployment accuracy, ability to withdraw, migration resistance.</p> <p>For Heli-FX, the following performance requirements were evaluated: trackability, pushability, torqueability, flex/kink, deployment accuracy, ability to withdraw, EndoAnchor penetration.</p>	<p>The radiopaque marker on the guide can be tracked within the proximal seal zone of the Endurant II/IIs stent graft (proximal most stent).</p> <p>The system must be able to be pushed through simulated tortuous anatomies such that the radiopaque marker on the guide can reach the proximal seal zone of the Endurant II/IIs stent graft (proximal most stent).</p> <p>The tip of the system must be able to be rotated a full 360° while located at the proximal seal zone of the Endurant II/IIs stent graft (proximal most stent).</p> <p>The EndoAnchors must be successfully deployed at the deployment target.</p> <p>The operator must recapture the spindle and tapered tip, and the delivery system must be withdrawn, intact, from the simulated use model after stent graft deployment.</p> <p>The operator must be able to withdraw the Heli-FX applicator and</p>	All acceptance criteria were met.

Test	Purpose	Acceptance Criteria	Result
		<p>guide from the simulated use model after deployment without dislodging the stent graft.</p> <p>EndoAnchor must penetrate through the stent graft, into the mock vessel, and remain attached to the mock vessel following removal of all delivery systems from the mock vessel.</p> <p>The stent graft shall not migrate more than 4mm during the full Simulated Use procedure.</p>	
Seal Testing	The purpose of this testing was to determine the seal performance of the Endurant II/II's Stent Graft System in conjunction with the Heli-FX EndoAnchor system in the proposed indication expansion, under worst case conditions. Relative performance of Endurant II/II's stent graft without EndoAnchor implants was also evaluated and lastly, a comparison to historical seal performance of Endurant II and Talent stent grafts was made.	Endurant II/II's stent graft 4 mm Seal Performance with EndoAnchors is better than 35.93 g/sec.	Acceptance criteria were met.

Modeling Studies

Medtronic performed the modeling studies described below to evaluate the fatigue strains occurring under the new use conditions.

Table 2. Modeling Studies

Test	Purpose	Acceptance Criteria	Result
Finite Element Analysis (FEA)	<p>The purpose of the analysis was to quantify the fatigue strains occurring in the Endurant II/II's suprarenal and seal stents under the <i>in-vivo</i> loading conditions represented by the expanded indication. These strains are used to calculate estimates of fatigue safety factors.</p> <p>The modeling included the impact of other anatomical and use conditions (i.e. vessel wall conicality and stent oversizing) on the endurance limit of the system to confirm worst case configurations were utilized in the analysis.</p>	Safety factors based on the endurance limits must be > 1.6.	All safety factors based on the endurance limit satisfied the acceptance criteria.

X. SUMMARY OF PRIMARY CLINICAL EVIDENCE

Medtronic utilized real-world evidence to establish the safety and effectiveness of Endurant II/IIIs Stent Graft System in conjunction with Heli-FX in abdominal aortic aneurysms (AAAs) for the treatment of short infrarenal necks. Information available from the ANCHOR Registry (Aneurysm Treatment using the Heli-FX EndoAnchor System Global Registry (clinicaltrials.gov identifier NCT01534819)) was used. Although this is a prospectively enrolling registry, patient selection was retrospective for this analysis.

The ANCHOR Registry enrolls subjects into either the Primary Group (utilization of Heli-FX EndoAnchor implants during initial endovascular treatment) or the Revision Group (utilization of Heli-FX EndoAnchors during a reintervention). Subjects are treated with endovascular grafts made by several manufacturers.

Subjects enrolled in the Primary Group with neck lengths of ≥ 4 mm and < 10 mm and treated with Endurant or Endurant II/IIIs Stent Graft Systems comprised the study cohort, referred to as the “Short Neck Cohort”. Information on subjects in the Primary Group with neck lengths < 4 mm and treated with any endovascular graft, and those with neck lengths of ≥ 10 mm and treated with Endurant or Endurant II/IIIs Stent Graft Systems is presented to provide context for the study cohort outcomes. Data from previous Endurant studies and a literature review are presented to further allow for interpretation of the study results.

Data from this analysis were the basis for the PMA approval decision. A summary of the data are presented below.

A. Study Design

The ANCHOR Registry is a prospective, observational, international, multi-center, post-market registry. The study consists of a prospectively defined retrospective analysis.

The Registry enrollment began in 2012 and is ongoing. As of June 15, 2016, 604 subjects were enrolled. Of these, a total of 70 subjects with a core lab-verified infrarenal neck length of ≥ 4 mm and < 10 mm (defined as the length over which the aortic diameter remains within 10% of the infrarenal diameter) were enrolled into the Primary Group and were treated with Endurant or Endurant II/IIIs Stent Graft Systems. This group of subjects is referred to as the “Short Neck Cohort”. The first Short Neck Cohort subject was enrolled on May 19, 2012. The 70th subject was enrolled on December 31, 2015. A total of 22 sites contributed subjects to the Short Neck Cohort; 19 of these were in the US and 3 were located in Europe.

In order to obtain independent verification of imaging findings, standard of care imaging studies for the subjects in the Short Neck Cohort were sent by the investigational sites to Syntactx, the independent Imaging Core Laboratory for the ANCHOR registry.

An independent Medical Monitor acted in an advisory capacity to monitor participant safety and data quality. The Medical Monitor may review imaging films, and/or the electronic data capture (EDC) entry and source documentation for site reported unanticipated adverse events (UADEs), serious adverse events (SAEs), and adverse

events (AEs). The ANCHOR Registry does not use a clinical events committee (CEC) or data monitoring committee (DMC).

This clinical study was not designed to measure a treatment effect against a control group or performance goal. Rather, it was designed to evaluate whether the Endurant II/IIIs Stent Graft System with Heli-FX in the “short neck” use condition is clinically safe and performs as expected when compared to alternative short neck treatments reported in the literature or when compared to treatment with the Endurant II/IIIs Stent Graft System in other use conditions. All endpoints were analyzed descriptively. No formal hypothesis test was planned for this study.

To support the indication expansion and to provide additional context for discussion, data from supportive and reference cohorts were presented. Supportive cohorts included other cohorts from the ANCHOR Registry. The “Very Short Neck Cohort” is comprised of subjects in the primary treatment arm that were treated with any manufacturer’s stent graft system in an infrarenal neck of < 4 mm. The “On-Label Neck Length Cohort” is comprised of subjects in the primary treatment arm, treated with an Endurant or Endurant II/IIIs Stent Graft System and Heli-FX and having an infrarenal neck ≥ 10 mm. In addition, ENGAGE¹ and Endurant IDE² results were presented as supportive cohorts to provide context of clinical results within patients that typically had infrarenal neck lengths that aligned with the current Endurant II/IIIs Stent Graft System indications for use. Finally, a literature review was performed to assess the clinical results from short neck EVAR (snEVAR), fenestrated stent grafts (fEVAR), and chimney/snorkel procedures (chEVAR). These reference groups were selected as they comprise the most commonly used endovascular treatment modalities for the repair of short infrarenal neck aortic aneurysms, although the devices used in chEVAR are used off-label.

1. Clinical Inclusion and Exclusion Criteria

All subjects in the Short Neck Cohort met the selection criteria for the Primary Group of the ANCHOR Registry. Additionally, subjects in the Short Neck Cohort were required to be treated with an Endurant or Endurant II/IIIs Stent Graft System and have an AAA with an infrarenal neck length measured as ≥ 4 to < 10 mm by the core laboratory.

Enrollment in the Primary Group of the ANCHOR Registry was limited to patients who met the following inclusion criteria:

- Subject with asymptomatic, symptomatic or ruptured abdominal aortic aneurysm,
- Subject ≥ 18 years old,
- Subject has provided written informed consent either before or less than or equal to 30 days after the index procedure,
- Subject is willing to comply with standard of care follow- up evaluations,

¹ The ENGAGE Global Registry is a prospective, single-arm, multi-center, non-randomized, non-interventional, global clinical registry. A total of 1263 subjects were enrolled from 2009 to 2011 at 79 centers globally.

² The Endurant Stent Graft System US Clinical Study (referred to as Endurant IDE Clinical Study) is a two-arm (Bifurcated and AUI), prospective, non-randomized, multicenter study designed to evaluate the safety and effectiveness of the Endurant Stent Graft System in the treatment of infrarenal abdominal aortic and aortoiliac aneurysms. The bifurcated arm completed first with 150 subjects enrolled across 26 sites in the United States.

- Subject's iliac/femoral access is compatible with a 16 French sheath,
- Subject has a previously implanted AAA endograft (Revision Group), or will be undergoing repair (Primary Group),
- Subject has a previously implanted Endograft that has migrated or has a Type Ia Endoleak (Revision Group), or
- Subject has/will undergo implantation of EndoAnchor implants during initial endograft implantation due to, in the opinion of the investigator, an increased risk of Type Ia endoleak or migration (Primary Group)

Patients were not permitted to enroll in the Primary Group of the ANCHOR Registry if they met any of the following exclusion criteria:

- Subject has known allergy to the EndoAnchor implant material (nickel, chromium, molybdenum, or cobalt),
- Subject has a life expectancy of less than 1 year,
- Subject is participating in a clinical study or registry that, in the Investigator's opinion, may conflict or may have a negative impact on the subject's safety,
- Subject has already been implanted with an EndoAnchor device in a procedure performed prior to the index procedure,
- Subject has an active or known history of bleeding diathesis,
- Subject has a condition that threatens to infect the endograft (active bacteremia, or infections that carry increased risk of endograft infection),
- Infrarenal aortic neck with significant thrombus or calcium that precludes adequate EndoAnchor penetration of the aortic wall, or
- Use of EndoAnchor implants to secure one endograft component to another, without placing each EndoAnchor into the aortic wall.

2. Follow-up Schedule

ANCHOR Registry follow-up evaluations, including imaging, were scheduled per the Investigator's discretion and local standard of care. Data was collected for each subject enrolled from baseline and up to 5 years after the index procedure. Follow-ups at 30 days and 12 months were included in the outcomes analyses to support the short neck indication.

Due to the nature of the ANCHOR Registry as a collection tool for real-world data completed as standard of care, time windows for visits were not defined or required in the protocol. For the purposes of the Short Neck Cohort evaluation, statistical analysis windows were defined broadly in order to include as many subjects as possible and present more complete follow-up information. For image-based assessments, such as stent-graft endoleak, migration and other imaging findings, the following time windows were applied: Implant: Day 0; Day 30: 1 – 183 days; Day 365: 184 – 913 days.

The ANCHOR Registry allows for the capture of the following preoperative information: demographics, medical history/risk factors, ASA classification, aneurysm symptomology, reason for EndoAnchor use, and various anatomical and aneurysm measurements.

The ANCHOR Registry allows for the capture of the following postoperative information: procedural data, device components utilized, device delivery and deployment, endoleaks, device integrity (e.g., fracture, penetration) and reinterventions. Additionally, post-operative data on safety-related data including adverse events, device migration, mortality and aneurysm expansion are also collected. Imaging data is collected per standard of care and is evaluated per protocol by an imaging core lab.

3. Clinical Endpoints

With regards to safety, the data from each device submitted in their respective marketing applications were extrapolated to the combination of the devices to treat short neck AAA. There was no primary safety outcome; however, morbidity and mortality were presented as safety supportive outcomes.

With regards to effectiveness, outcomes of particular importance in evaluating the treatment success for short neck abdominal aortic aneurysms were selected for the analysis. The primary outcomes addressed the ability to accurately deliver and deploy the endovascular graft, achieve adequate sealing of the graft to the aorta, and maintain effectiveness without the need for additional interventions.

The primary and supportive outcomes are listed below. Key additional outcomes that were reported in relation to AAA studies were also included in order to provide a broader view of the clinical results.

All outcomes were analyzed descriptively. Success/failure criteria were not applied. Distribution frequencies described the qualitative parameters. Quantitative parameters were described by the mean, standard deviation, minimum, maximum, median, and number of subjects with assessable data. No available data were excluded from the analysis.

Procedure-Related Supportive Outcomes

Index procedure-related measures

- Procedure time
- Fluoroscopy time
- Procedure success
- Accessory devices used, and relation to any device- or procedure-related event

Safety

Supportive Outcomes

Safety-related measures

- Aneurysm-related mortality through 30 days and 12 months
- Aneurysm rupture through 30 days and 12 months
- Major adverse events through 30 days
- Renal insufficiency through 30 days
- Renal failure through 30 days

Additional outcomes

- All-cause mortality through 12 months
- Major adverse events through 12 months
- Serious adverse events through 12 months

Effectiveness

Primary Outcomes

- Technical success rate
- 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

Supportive Outcomes

Device-related measures

- Evidence of endograft or EndoAnchor loss of integrity through 12 months
- Impact of number of EndoAnchor implants used on the primary outcomes
- Adequate maintenance of EndoAnchor implants into the aortic wall at 30 days and at 12 months

Effectiveness-related measures

- Aneurysm expansion at 12 months
- Migration at 12 months
- Re-interventions through 30 days
- Conversion to open surgical repair through 30 days
- Type III endoleaks at 30 days and 12 months

B. Accountability of Short Neck Cohort

The ANCHOR Registry protocol collected data from standard of care follow-up visits and imaging. Visit windows were not prospectively defined. For the purposes of the Short Neck Cohort evaluation, statistical analysis windows were defined broadly in order to include as many subjects as possible and present more complete follow-up information.

A core laboratory evaluated images from the sites to provide independent verification of findings. Since the method of image collection was completed per institutional standard of care, some imaging studies were inadequate for the core lab to assess specific parameters. A total of 88% (58/66) of subjects had 12-month imaging follow-up; however, only 54/66 (82%), 53/66 (80%), and 41/66 (62%) subjects had adequate imaging to assess aneurysm size increase, Type Ia endoleaks, and migration, respectively.

To allow for an alternate evaluation of migration, imaging assessments were supplemented by review of adverse event reports and reasons for re-intervention. Among the 25 subjects lacking adequate imaging to assess migration, there was one core lab-reported Type Ia endoleak, which required a secondary endovascular repair. The absence of interventions that could be associated with a migration supports the likelihood that the other 24 patients did not experience migration within 12 months; however, migration assessments for 16 subjects were not available due to a lack of adequate 30-day imaging in 7 subjects and study exit in 9 subjects.

Clinical follow up of the Short Neck Cohort was greater than 90% at both the 1-month and 12-month time points.

Considering the levels of evaluable imaging that were achieved, from a statistical perspective, 10% estimation precision was still reached in every 95% confidence interval of the primary outcomes, as planned.

Table 3. Subject and Imaging Accountability

Interval (Analysis Window)	Subject follow-up				Subjects with imaging performed			Subjects with adequate imaging to assess the parameter ¹			Subject events occurring before next visit			
	Eligible ²	Clinical Follow-up	Imaging Follow-up	Subjects with follow-up pending ³	CT Imaging ⁴	KUB Imaging	Duplex Ultrasound	Aneurysm size increase	Endoleak	Migration	No Implant	Death	Withdrawal/Early Termination	Lost to Follow-up
Originally Enrolled	70										0	0	0	
1 Month (Day 1-183)	70	64 (91%)	62 (89%)	0 (0%)	60 (86%)	12 (17%)	19 (27%)		59 (84%)			4	0	0
12 Months (Day 184-913)	66	61 (92%)	58 (88%)	0 (0%)	43 (65%)	13 (20%)	32 (48%)	54 (82%)	53 (80%)	41 (62%)		8	3	1

Based on number of all enrolled subjects within the Short Neck Cohort with available data.
¹ Not the number of subjects with these reported events, but rather, the number with adequate imaging, such as a paired size data to evaluate aneurysm growth
² Eligible for follow-up = eligible for follow-up from the previous interval – (death + withdrawn + lost to follow-up) from the previous interval. All subjects that had an endovascular graft implanted are eligible for follow-up for the operative row.
³ Subjects still within the follow-up window, but data not yet available
⁴ Computerized tomography (CT) count includes CT and magnetic resonance angiogram (MRA)

C. Study Population Demographics and Baseline Parameters

Demographics and Medical History

The demographics of the study population are atypical for an AAA endovascular graft study performed in the US due to their relatively poor health status. However, the results apply to all patients who would be eligible for treatment with the devices, including patients with less advanced disease who would be expected to have as good or better outcomes.

Table 3 below provides the demographics and medical history of subjects in the Short Neck cohort, the Very Short Neck Cohort and the On-Label Neck Length Cohort from the ANCHOR Registry. The medical history and the risk factors were noted to be similar across the cohorts. Specifically, in the Short Neck Cohort, the median age of the cohort was 72 years (range: 49 to 95); 72.9% (51/70) of subjects were male and 27.1% (19/70) of subjects were female. The baseline medical history revealed cardiovascular risk factors frequently occurring in the population, including hypertension (84.3% (59/70) of subjects), past or current tobacco use (80.0% (56/70) of subjects), and hyperlipidemia (74.3% (52/70) of subjects); 62.9% (44/70) of subjects were diagnosed with cardiac disease.

Table 4. Baseline Characteristics and Risk Factors

	ANCHOR Short Neck (N = 70) % (m/n)¹	ANCHOR supportive cohort: Very Short Neck < 4 mm (all stent grafts) (N = 32) % (m/n)¹	ANCHOR supportive cohort: On-Label Neck ≥ 10 mm (Endurant) (N = 100) % (m/n)¹
Age (year)			
n	70	32	100
Mean ± SD	71.31 ± 8.13	75.66 ± 8.37	71.95 ± 8.41
Gender %(m/n)			
Male	72.9% (51/70)	53.1% (17/32)	79.0% (79/100)
Female	27.1% (19/70)	46.9% (15/32)	21.0% (21/100)
Tobacco Use (past or current)	80.0% (56/70)	87.5% (28/32)	78.0% (78/100)
Hypertension	84.3% (59/70)	87.5% (28/32)	78.0% (78/100)
Hyperlipidemia	74.3% (52/70)	68.8% (22/32)	71.0% (71/100)
Diabetes	22.9% (16/70)	12.5% (4/32)	19.0% (19/100)
Cardiac disease			
Coronary Artery Disease	8.6% (6/70)	12.5% (4/32)	8.0% (8/100)
CHF	7.1% (5/70)	15.6% (5/32)	4.0% (4/100)
Prior MI	34.3% (24/70)	28.1% (9/32)	14.0% (14/100)
Chronic Obstructive Pulmonary Disease (COPD)	44.3% (31/70)	43.8% (14/32)	27.0% (27/100)
Renal Disease			
Renal Insufficiency	11.4% (8/70)	15.6% (5/32)	14.0% (14/100)
Dialysis-Dependent Renal Failure (End-stage renal disease)	0.0% (0/70)	0.0% (0/32)	0.0% (0/100)
Stroke/Cerebral Vascular Accident	10.0% (7/70)	6.3% (2/32)	9.0% (9/100)
Bleeding Disorder	2.9% (2/70)	6.3% (2/32)	1.0% (1/100)
Gastrointestinal Disease	34.3% (24/70)	37.5% (12/32)	39.0% (39/100)
Peripheral Artery Disease (PAD)	18.6% (13/70)	12.5% (4/32)	11.0% (11/100)
Thoracic Aneurysm	2.9% (2/70)	0.0% (0/32)	5.0% (5/100)

¹m = number of subjects in category, n = number of all enrolled subjects with non-missing values.

ASA Classification

Table 5 below provides the baseline ASA classification of subjects in the Short Neck cohort, the Very Short Neck Cohort and the On-Label Neck Length Cohort from the ANCHOR Registry. Most subjects enrolled in the Short Neck Cohort were reported to be ASA Class III (67.1%), with severe systemic disease, and a large proportion of the subjects were at high risk of death, with 25.7% (18/70) subjects in ASA Class IV.

Table 5. Baseline ASA Classification

	ANCHOR Short Neck (N = 70) % (m/n)¹	ANCHOR supportive cohort: Very Short Neck < 4 mm (all stent grafts) (N = 32) % (m/n)¹	ANCHOR supportive cohort: On-Label Neck ≥ 10 mm (Endurant) (N = 100) % (m/n)¹
ASA Classification			
Class I	2.9% (2/70)	0.0% (0/32)	1.0% (1/100)
Class II	4.3% (3/70)	0.0% (0/32)	13.0% (13/100)
Class III	67.1% (47/70)	65.6% (21/32)	67.0% (67/100)
Class IV	25.7% (18/70)	34.4% (11/32)	19.0% (19/100)

¹m = number of subjects in category, n = number of all enrolled subjects with non-missing values.

Baseline Parameters

The mean core lab-reported neck length (defined as that length over which the aortic diameter remains within 10% of the infrarenal diameter) was 6.86 ± 1.59 mm (range: 4.1 mm to 10.0 mm) for the Short Neck Cohort. Mean site-reported neck length (typically measured from the lowest main renal artery to where the neck visually dilates) was 12.07 ± 5.58 mm (range: 4.0 mm to 33.0 mm). The differences in the core lab vs site-reported neck lengths were likely related to differences in the method of measuring the neck. For the new indication, the core lab methodology should be applied when determining whether EndoAnchors should be used with the endograft. Please see the Physician Instructions for Use for more information.

The mean core lab-reported proximal neck diameter was 25.74 ± 4.04 mm (range: 19.0 mm to 36.5 mm) for the Short Neck Cohort. The core lab reported the mean maximum aneurysm diameter as 57.70 ± 12.74 mm (range: 34.1 mm to 112.0 mm). Information regarding the type of lesion treated and the decision to treat (e.g., rapidly growing, twice the normal aortic diameter, >5.5mm) were not captured in the registry.

The core lab reported infrarenal angle and suprarenal angle mean as $20.59^\circ (\pm 14.44)$ and $14.07^\circ (\pm 8.28)$, respectively.

Table 6. Anatomical and Other Measurements (Core Laboratory-Reported)

Measurement	ANCHOR Short Neck (Core laboratory reported) (N = 70)	ANCHOR	ANCHOR
		supportive cohort: Very Short Neck < 4 mm (all stent grafts) (Core laboratory reported) (N = 32)	supportive cohort: On-Label Neck ≥ 10 mm (Endurant) (Core laboratory reported) (N = 100)
Proximal neck diameter at renal arteries			
n	70	32	100
Mean ± SD	25.74 ± 4.04	25.55 ± 5.20	25.69 ± 4.13
Median	25.90	24.85	24.75
Min, Max	19.0, 36.5	16.9, 35.7	17.4, 39.8
Proximal Neck Length			
n	70	32	100
Mean ± SD	6.86 ± 1.59	2.95 ± 0.82	22.37 ± 11.82
Median	6.69	3.03	18.20
Min, Max	4.1, 10.0	1.1, 4.0	10.0, 62.0
Distal Aortic Diameter			
n	70	32	100
Mean ± SD	28.80 ± 4.79	28.34 ± 5.82	27.84 ± 4.53
Median	28.40	26.35	27.50
Min, Max	19.3, 40.5	19.1, 49.3	18.4, 43.2
Maximum aortic diameter			
n	69	32	100
Mean ± SD	57.70 ± 12.74	56.46 ± 10.33	55.91 ± 11.06
Median	55.00	53.70	53.05
Min, Max	34.1, 112.0	41.7, 92.5	28.5, 101.0
Suprarenal Angulation			
n	70	32	100
Mean ± SD	14.07 ± 8.28	13.31 ± 8.71	15.70 ± 10.34
Median	12.00	13.50	14.00
Min, Max	1.0, 38.0	2.0, 39.0	2.0, 49.0
Infrarenal Angulation			
n	69	32	100
Mean ± SD	20.59 ± 14.44	23.16 ± 15.98	26.14 ± 18.55
Median	18.00	18.50	22.00
Min, Max	2.0, 69.0	1.0, 68.0	1.0, 80.9

Measurement	ANCHOR Short Neck (Core laboratory reported) (N = 70)	ANCHOR supportive cohort: Very Short Neck < 4 mm (all stent grafts) (Core laboratory reported) (N = 32)	ANCHOR supportive cohort: On-Label Neck ≥ 10 mm (Endurant) (Core laboratory reported) (N = 100)
	Neck Thrombus Average Thickness		
n	64	29	94
Mean ± SD	0.85 ± 1.06	1.23 ± 1.42	0.89 ± 1.48
Median	0.00	1.30	0.00
Min, Max	0.0, 3.5	0.0, 5.3	0.0, 8.9
Neck Thrombus Circumference > 1 mm			
n	64	29	94
Mean ± SD	61.41 ± 86.33	62.94 ± 80.45	46.63 ± 72.63
Median	0.00	19.60	0.00
Min, Max	0.0, 320.0	0.0, 298.0	0.0, 320.0
Neck Calcium Average Thickness			
n	70	32	100
Mean ± SD	1.31 ± 1.23	1.77 ± 1.28	1.03 ± 1.11
Median	1.30	1.94	1.00
Min, Max	0.0, 4.0	0.0, 4.3	0.0, 4.6
Neck Calcium Circumference > 1 mm			
n	70	32	100
Mean ± SD	23.39 ± 29.83	38.50 ± 43.62	18.26 ± 24.91
Median	16.25	20.40	10.00
Min, Max	0.0, 155.0	0.0, 180.0	0.0, 114.0

Device Usage

Endurant stent grafts were utilized in 47.1% (33/70) of subjects in the Short Neck Cohort and Endurant II/IIs stent grafts were utilized in 52.9% (37/70) of the subjects. The most frequently used proximal stent graft size in the Short Neck Cohort was 36 mm, which was used in 34.3% (24/70) of subjects. Most subjects were implanted with an Endurant or Endurant II/IIs stent graft with a proximal diameter of 28 mm or larger.

The differences in the Endurant, Endurant II and Endurant IIs stent grafts are described in the Annual Physician Clinical Update. All Endurant family aortic stent grafts (Endurant, Endurant II, Endurant IIs) are identical with respect to the design of the proximal end, including the suprarenal stent, anchor pins and sealing zone.

The average number of Heli-FX EndoAnchor implants per subject was 5.49 ± 2.08 . The median was 5.0, the minimum was 2.0, and the maximum was 12.0.

Table 7 provides detail on stent graft sizing and EndoAnchor usage.

Table 7. Endurant Stent Graft Sizing (Proximal Diameter) and Heli-FX EndoAnchor Use

Proximal Size of the Endurant Stent Graft	23 mm (m/n)%	25 mm (m/n)%	28 mm (m/n)%	32 mm (m/n)%	36 mm (m/n)%
Recommended Number of EndoAnchor Implants ¹	4	4	4	4	6
Number of EndoAnchor Implants Used					
2	0.0% (0/5)	0.0% (0/6)	5.6% (1/18)	5.9% (1/17)	0.0% (0/24)
3	20.0% (1/5)	16.7% (1/6)	0.0% (0/18)	0.0% (0/17)	8.3% (2/24)
4	40.0% (2/5)	16.7% (1/6)	44.4% (8/18)	41.2% (7/17)	33.3% (8/24)
5	20.0% (1/5)	16.7% (1/6)	11.1% (2/18)	5.9% (1/17)	0.0% (0/24)
6	20.0% (1/5)	33.3% (2/6)	27.8% (5/18)	17.6% (3/17)	29.2% (7/24)
> 6	0.0% (0/5)	16.7% (1/6)	11.1% (2/18)	29.4% (5/17)	29.2% (7/24)

Based on number of all enrolled subjects within the Short Neck Cohort with available data.

m = number of subjects in category, n = number of all enrolled subjects within the Short Neck Cohort with non-missing values.

¹The Heli-FX EndoAnchor System IFU provides a minimum recommended number of EndoAnchor implants based on aortic neck diameter, not device size. The recommended number of EndoAnchor implants used in an aortic neck of ≤ 29 mm is 4, and a minimum of 6 EndoAnchor implants are recommended in an aortic neck >29 . The numbers provided in this table are based on the most likely aortic neck diameter for a given device size, based on the Endurant II/IIIs Stent Graft System IFU recommended device sizing relative to the aortic vessel inner diameter.

In most subjects, a single applier was used, with two SA-85 Heli-FX Appliers used in one subject. The most common Heli-FX guide used was the 22 mm model, which was used in 73.5% (36/49) of the subjects, followed by the 28 mm model, which was used in 26.5% (13/49) of the subjects. See Table 8.

Table 4. Heli-FX EndoAnchor System Usage

	Short Neck Cohort (N = 70)
Number of Heli-FX Appliers Used	
n	49
Mean ± SD	1.02 ± 0.14
Median	1.00
Min, Max	1.0, 2.0
Size of Heli-FX Applier(s) Used (m/n)%	
SA-85 Heli-FX Applier	98.0% (48/49)
HA-18-114 Heli-FX Applier	2.0% (1/49)
Number of Heli-FX Guides Used	
n	49
Mean ± SD	1.04 ± 0.20
Median	1.00
Min, Max	1.0, 2.0
Size of Heli-FX Guide(s) Used (m/n)%	
Heli-FX Guide 22 mm – SG-64	73.5% (36/49)
Heli-FX Guide 22 mm – HG-18-90-22	0.0% (0/49)
Heli-FX Guide 42 mm – HG-18-90-42	0.0% (0/49)
Heli-FX Guide 28 mm – HG-16-62-28	26.5% (13/49)
Heli-FX Guide 32 mm – HG-18-90-32	2.0% (1/49)
Min, Max	2.0, 12.0

Based on number of all enrolled subjects within the Short Neck Cohort with available data.

m = number of subjects in category, n = number of all enrolled subjects within the Short Neck Cohort with non-missing values.

Accessory Device Usage

Twenty-five of 70 subjects in the Short Neck Cohort received at least one accessory device during the index procedure. The type of accessory device used and number of subjects is as follows: Stent (11 subjects), balloon (10 subjects), coil (4 subjects), cuff (3 subjects), vascular plug (2 subjects), and vascular graft (1 subject). Note that subjects may have received more than one accessory device.

Initial Procedural Data

All Short Neck Cohort subjects had EndoAnchors implanted. The mean duration of the procedure was 148.00 ± 80.03 minutes, with average time of EndoAnchor implant of 17.12 ± 11.54 minutes. Mean fluoroscopy time was 35.34 ± 21.98 minutes. See **Table 9** for additional information. The mean overall intensive care unit (ICU) stay was 0.84 ± 1.63 days, and the mean overall hospital stay was 3.73 ± 4.31 days.

All Short Neck and on On-Label Neck Cohort subjects had Endurant or Endurant II/IIIs stent grafts implanted. In the Very Short Neck Cohort the following stent grafts were used: Cook Zenith 6.3% (2/32), Gore Excluder 25.0% (8/32), Jotec e-Vita 0% (0/32),

Medtronic AneuRx 0% (0/32), Medtronic Endurant 68.8% (22/32), Medtronic Talent 0% (0/32)³.

Table 9. Initial Procedural Data

Measurement	Short Neck Cohort (N = 70)
Type of Procedure (m/n)%	
Elective	69.4% (34/49)
Urgent (investigator assessed)	22.4% (11/49)
Emergent (investigator assessed)	8.2% (4/49)
Procedure Entry Site ¹ (m/n)%	
Left Femoral Artery	82.9% (58/70)
Right Femoral Artery	91.4% (64/70)
Left Iliac Artery	0.0% (0/70)
Right Iliac Artery	0.0% (0/70)
Left: Other - Brachial percutaneous	1.4% (1/70)
Right: Other - Brachial	1.4% (1/70)
Type of Access (m/n)%	
Open	62.9% (44/70)
Percutaneous	37.1% (26/70)
Duration of implant procedure (min)	
N	70
Mean ± SD	148.00 ± 80.03
Median	127.50
Min, Max	38.0, 423.0
Type of anesthesia used (m/n)%	
General	84.3% (59/70)
Spinal	2.9% (2/70)
Epidural	1.4% (1/70)
Local	11.4% (8/70)
Volume of contrast (cc)	
N	26
Mean ± SD	126.12 ± 80.76
Median	102.50
Min, Max	30.0, 399.0
Total fluoroscopic time (mins)	
N	44
Mean ± SD	35.34 ± 21.98
Median	30.00
Min, Max	7.0, 123.0

³Devices reported as “other” in the Short Neck, On-Label Neck, and Very Short Neck Cohorts were confirmed to be Endurant devices.

Measurement	Short Neck Cohort (N = 70)
Subjects Receiving EndoAnchor implants (m/n)%	100.0% (70/70)
Time to Implant EndoAnchor implants (mins) ⁵	
N	68
Mean ± SD	17.12 ± 11.54
Median	13.50
Min, Max	4.0, 60.0
Hospital stay (Days) ²	
N	70
Mean ± SD	3.73 ± 4.31
Median	2.00
Min, Max	1.0, 24.0
Procedure stay (Days) ³	
N	70
Mean ± SD	3.03 ± 3.17
Median	2.00
Min, Max	1.0, 23.0
Duration of ICU stay (Days) ⁴	
N	69
Mean ± SD	0.84 ± 1.63
Median	0.00
Min, Max	0.0, 11.0

Based on number of all enrolled subjects within the Short Neck Cohort with available data.

m = number of subjects in category, n = number of all enrolled subjects within the Short Neck Cohort with non-missing values.

¹Note that more than one procedure entry site per subject may be reported if multiple entry sites were used.

²Overall hospital stay (days) = Date of Hospital Discharge – Date of Hospital Admission. In the case where Date of Hospital Discharge = Date of Hospital Admission, Overall hospital stay will be considered to be 0.5 day

³Procedural hospital stay (days) = Date of Hospital Discharge – Date of Initial Procedure. In the case where Date of Hospital Discharge = Date of Initial Procedure, procedural hospital stay will be considered to be 0.5 day

⁴ICU stay: days collected as 0, 1, 2...10 days or 10+days. 10+days set to 11 days for summary statistics

⁵ EndoAnchor total implant time includes all EndoAnchor implants for one subject

Procedure-Related Supportive Outcomes

Index Procedure-Related Measures for the Short Neck Cohort

Index procedure-related measures include procedure time, fluoroscopy time, procedure success and accessory devices used (and relation, if any, to device or procedure-related events).

Procedure Success

Procedure success was reported by investigators and was not prospectively defined. Investigators reported an overall procedure success of 97.1% (68/70); unsuccessful procedures were reported in one subject due to failure to deliver the main body endograft to the intended landing zone and in another subject due to a persistent Type Ia endoleak. There were no main body endograft components that were misdeployed proximally to the intended landing zone. Type Ia endoleak was reported as present at the end of the procedure in 12.9% (9/70) of subjects. There were no Type III endoleaks reported as present at the end of the procedure. See the **Primary Outcomes** section below for further information.

Accessory Devices

Twenty-five of 70 subjects in the Short Neck Cohort received at least one accessory device during the index procedure. A majority of accessory devices were placed in subjects without reported AEs on the day of index procedure. Reasons for accessory device usage were not documented. See Device Usage section (above) for additional detail.

D. Safety and Effectiveness Results

1. Safety Results

There was not a Primary Outcome analysis for safety. It should be noted that the safety of the Endurant II/II_s Stent Graft System for the treatment of infrarenal abdominal aortic aneurysms having neck lengths ≥ 4 mm and < 10 mm (“short necks”), when used in conjunction with the Heli-FX EndoAnchor System was not based on this study alone, but rather on data from the entire ANCHOR Registry (summarized below), the prior EndoAnchor study (summarized in the Instructions for Use of the Heli-FX EndoAnchor System), and the prior Endurant studies (summarized in the Annual Physician Clinical Update for the Endurant/Endurant II/Endurant II_s Stent Graft Systems).

Supportive Outcomes

The analysis of safety was based on the Short Neck Cohort of 70 patients available for the 1-month evaluation and 66 patients available for the 12-month evaluation. The key safety outcomes for this study are presented below in **Table 10** through **Table 5**. Adverse effects are reported in **Table 6** through **Table 7**.

Safety-related measures

Safety-related measures presented here include aneurysm-related mortality through 30 days and 12 months, aneurysm rupture through 30 days and 12 months, major adverse events through 30 days, renal insufficiency through 30 days, and renal failure through 30 days. Results for the Very Short Neck Cohort and the On-Label Neck Cohort are included to provide context for the Short Neck Cohort results.

Aneurysm-related mortality is defined as any death within 30 days of the index procedure or secondary procedure to address aneurysm, or death from any rupture. Four of 70 subjects (5.7%) died within 30 days of the index procedure. It is important to note that the adverse events leading to death were assessed by the investigator, and no events were noted as related to the aneurysm.

Table 8. Summary of Aneurysm-related Deaths through 12 Months

Subject Number	Days to Death	Death within 30 days of the initial procedure	Death within 30 days of a re-intervention	Cause of Death (Investigator Determined)
172-014	6	Yes	No	Cardiac arrest, congestive heart failure
109-009	9	Yes	No	Cardiac and Respiratory Arrest
172-026	5	Yes	No	Cardiac Arrest
109-031	13	Yes	No	Acute Alcoholic Hepatitis, Acute Renal Failure, Acute Pancreatitis

Based on number of all enrolled subjects within the Short Neck Cohort with available data.

Table 9 Error! Reference source not found. summarizes a number of safety-related measures that were identified as Supportive Outcomes in the analysis of the Short Neck Cohort. Of note, 5.7% (4/70) of Short Neck Cohort subjects died within one month of the index procedure, which by definition classifies them as aneurysm-related regardless of the cause of death determined by the investigator. See **Table 10** above for further detail. No subjects experienced aneurysm rupture through one year. As will be discussed below, 15.7% (11/70) of Short Neck Cohort subjects experienced at least one major adverse event through one month. One subject experienced renal insufficiency within 30 days of the index procedure. No renal failure was reported by sites through one month; however, one subject with a history of renal insufficiency died on Day 13, and the investigator-determined cause of death included renal failure.

Table 10. Summary of Safety-Related Measures

Safety-related measures	ANCHOR Short Neck (N = 70)	ANCHOR supportive cohort: Very Short Neck < 4 mm (all stent grafts) (N = 32)	ANCHOR supportive cohort: On-Label Neck ≥ 10 mm (Endurant) (N = 100)
Aneurysm-related mortality through 30 days ¹	5.7% (4/70)	6.3% (2/32)	0.0% (0/100)
Aneurysm-related mortality through 12 months ¹	5.9% (4/68)	7.1% (2/28)	0.0% (0/91)
Aneurysm rupture through 30 days	0.0% (0/70)	0.0% (0/32)	0.0% (0/100)
Aneurysm rupture through 12 months	0.0% (0/64)	0.0% (0/26)	0.0% (0/91)
Major adverse events through 30 days	15.7% (11/70)	9.4% (3/32)	4.0% (4/100)
Renal insufficiency through 30 days ²	0.0% (0/70) ⁵	6.3% (2/32)	0.0% (0/100)
Renal failure through 30 days ³	0.0% (0/70) ⁴	0.0% (0/32)	0.0% (0/100)

m = number of subjects in category, n = number of subjects with available imaging assessments for aneurysm expansion and migration and endoleak at 12 months, and number of subjects who had an event in question or reached the lower time window of the time period for site-reported events.

¹Aneurysm-related mortality is defined as death within 30 days of the index procedure, death within 30 days of any secondary procedure to address the aneurysm, or death from rupture.

²A rise in creatinine greater than 50% above the pre-procedure level resulting in a creatinine level above the upper limit of normal (site reported)

³Defined as when the need for dialysis is required, an increase in serum creatinine of 2x the baseline value or new need for hemodialysis (site reported)

⁴Subject 109-031 died on Day 13 post-index procedure and the investigator-determined cause of death included acute renal failure. Acute renal failure was captured under multi-system organ failure in **Table 14**.

⁵Subject 138-012 experienced renal insufficiency through 30 days from the index procedure. The site entered the start date of this event as a partial date of March 2014 in the database. Due to the partial date entry, the days from index for this event was imputed per the statistical analysis plan. The imputation of this event resulted in the event populating at -2 days from index procedure. Although the exact start date is unknown, it is known that the event occurred within the same month of the index procedure. The renal insufficiency category in this table captures events between Day 0-30. Due to this, the renal insufficiency event for this subject at -2 days is not populating in this table.

Additional Outcomes

Key additional safety outcomes that are reported in relation to AAA studies were included to provide a broader view of the clinical results. The additional outcomes presented here include all-cause mortality, major adverse events through 12 months and serious adverse events through 12 months.

All-Cause Mortality: Of the 70 subjects in the Short Neck Cohort, five died within the first 12 months of the index procedure. No subjects died on the day of the index procedure. Four of 70 subjects (5.7%) died within the 30 days of the index procedure and these deaths were therefore determined to be aneurysm-related. One additional subject died on Day 353 post-index procedure due to septic shock secondary to pneumonia/

septicemia. This event was not determined to be related to the aneurysm, device, or index procedure.

Kaplan-Meier survival estimates for all-cause mortality (ACM) were made through 365 days post-implant as shown in **Table 11** and Figure 7. The Kaplan-Meier one-year survival estimate for ACM was 92.6%.

Table 12. Kaplan-Meier Estimates for All-Cause Mortality – Short Neck Cohort Subjects

	Day 0	Day 30	Day 182	Day 365
No. at Risk ¹	70	66	61	53
No. of Events	0	4	4	5
No. Censored ²	0	0	5	12
Kaplan-Meier Estimate ³	1.000	0.943	0.943	0.926
Peto Standard Error	0.000	0.028	0.028	0.034

¹Number of subjects at risk at each timepoint. Based on number of all enrolled subjects within the Short Neck Cohort with available data.

²Subjects are censored because no event was observed by the time point, including those not yet reached the correspondent time point or lost to follow-up.

³Estimate made at each timepoint.

Note: All numbers except standard errors are cumulative.

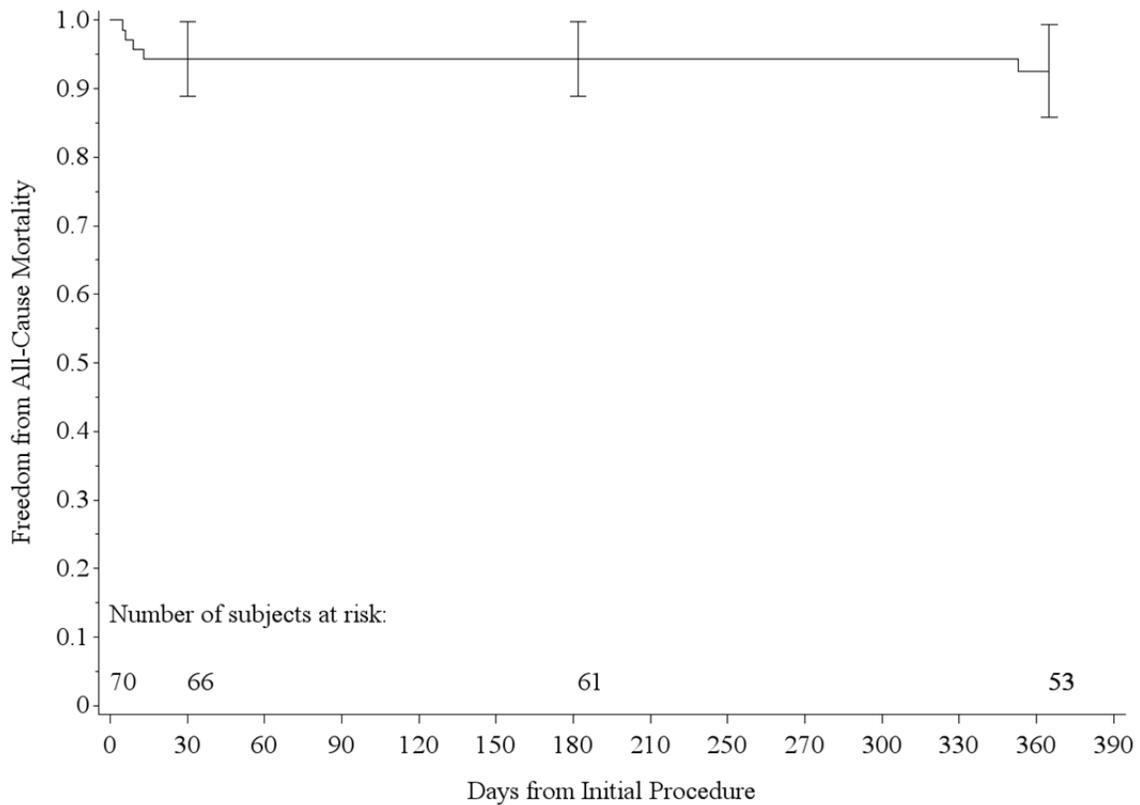


Figure 7. Freedom from All-Cause Mortality

Major Adverse Events through 12 Months: A total of 18 MAEs were reported among 15 subjects between 0 and 365 days. Among those, 13 MAEs were reported in 11 subjects between 0 and 30 days, and five MAEs were reported in five subjects between 31 and 365 days. Three subjects had more than one MAE within the first year.

There were no reports of paraplegia, or renal failure through 12 months. However, as mentioned previously, one subject with a history of renal insufficiency died on Day 13 post-index procedure and the investigator-determined cause of death included acute renal failure. **Table 13** summarizes the major adverse events through 12 months.

Table 14. Major Adverse Events (MAEs) through 12 months

Event	0-30 Days % (m/n)	31-365 Days % (m/n)	0-365 Days % (m/n)
One or more major adverse events (MAE)	15.7% (11/70)	7.6% (5/66)	21.4% (15/70)
Total Number of MAEs	13	5	18
All-Cause Mortality	5.7% (4/70)	1.5% (1/66)	7.1% (5/70)
Bowel ischemia	1.4% (1/70)	0.0% (0/66)	1.4% (1/70)
Myocardial infarction	2.9% (2/70)	1.5% (1/66)	2.9% (2/70)
Paraplegia	0.0% (0/70)	0.0% (0/66)	0.0% (0/70)
Procedural blood loss ¹	7.1% (5/70)	0.0% (0/66)	7.1% (5/70)
Renal failure	0.0% (0/70) ²	0.0% (0/66)	0.0% (0/70) ²
Respiratory failure	1.4% (1/70)	3.0% (2/66)	4.3% (3/70)
Stroke	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)

Based on number of all enrolled subjects within the Short Neck Cohort with available data.

m = number of subjects in category, n = number of subjects are at risk at the beginning of the time period.

¹Volume of blood loss was not collected, therefore, procedural blood loss/hemorrhage reported as an SAE at the time of the index procedure or secondary procedure has been reported as an MAE

² Subject 109-031 died on Day 13 post-index procedure and the investigator-determined cause of death included acute renal failure. Acute renal failure was captured under multi-system organ failure in **Table 15**.

Serious Adverse Events through 12 Months: Thirty of 70 subjects (42.9%) experienced one or more serious adverse event between 0 and 365 days. Sixteen (16) of 70 subjects (22.9%) experienced one or more serious adverse event between 0 and 30 days, and 19 out of 66 subjects (28.8%) experienced one or more serious adverse event between 31 and 365 days.

The most common type of SAEs were cardiac disorders, reported in 9 out of 70 subjects (12.9%). The second most common type of SAEs were vascular disorders and gastrointestinal disorders, reported in 7 out of 70 subjects (10.0%). Error! Reference source not found. summarizes the subjects with serious adverse events by date of onset.

Table 14. Serious Adverse Events (SAEs) through 12 months

Category	0 to 30 Days % (m/n)	31 to 365 Days % (m/n)	0 to 365 Days % (m/n)
Number of Subjects Eligible for each follow-up window	70	66	70
Subjects Experiencing One or More SAEs¹	22.9% (16/70)	28.8% (19/66)	42.9% (30/70)
Blood and lymphatic system disorders	2.9% (2/70)	1.5% (1/66)	4.3% (3/70)
Anemia	1.4% (1/70)	0.0% (0/66)	1.4% (1/70)
Anemia postoperative	1.4% (1/70)	0.0% (0/66)	1.4% (1/70)
Neutropenic fever	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
Cardiac disorders	7.1% (5/70)	7.6% (5/66)	12.9% (9/70)
Arrhythmia	1.4% (1/70)	0.0% (0/66)	1.4% (1/70)
Cardiac arrest	2.9% (2/70)	0.0% (0/66)	2.9% (2/70)
Congestive cardiac failure aggravated	1.4% (1/70)	0.0% (0/66)	1.4% (1/70)
Congestive heart failure	0.0% (0/70)	4.5% (3/66)	4.3% (3/70)
Coronary artery disease aggravated	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
Myocardial infarction	2.9% (2/70)	1.5% (1/66)	2.9% (2/70)
Ventricular tachycardia	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
Gastrointestinal disorders	2.9% (2/70)	7.6% (5/66)	10.0% (7/70)
Diverticulitis	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
GI bleed	1.4% (1/70)	0.0% (0/66)	1.4% (1/70)
Hernia inguinal	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
Ischemic colitis	1.4% (1/70)	0.0% (0/66)	1.4% (1/70)
Pancreatic cancer	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
Retroperitoneal hematoma	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
Retroperitoneal mass	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
General disorders and administration site conditions	4.3% (3/70)	0.0% (0/66)	4.3% (3/70)
Device occlusion	1.4% (1/70)	0.0% (0/66)	1.4% (1/70)
Multi organ failure	1.4% (1/70)	0.0% (0/66)	1.4% (1/70)
Stent-graft endoleak	1.4% (1/70)	0.0% (0/66)	1.4% (1/70)
Infections and infestations	1.4% (1/70)	6.1% (4/66)	7.1% (5/70)
Bronchitis	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
Pneumonia	0.0% (0/70)	3.0% (2/66)	2.9% (2/70)
Sepsis	1.4% (1/70)	0.0% (0/66)	1.4% (1/70)
Septicaemia	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
Urinary tract infection	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
Injury, poisoning and procedural complications	4.3% (3/70)	1.5% (1/66)	5.7% (4/70)
Femoral artery injury	1.4% (1/70)	0.0% (0/66)	1.4% (1/70)
Post procedural bleeding	2.9% (2/70)	0.0% (0/66)	2.9% (2/70)
Procedural bleeding	2.9% (2/70)	0.0% (0/66)	2.9% (2/70)
Scalp laceration	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
Vascular access site bleeding	1.4% (1/70)	0.0% (0/66)	1.4% (1/70)
Metabolism and nutrition disorders	1.4% (1/70)	3.0% (2/66)	4.3% (3/70)
Respiratory failure	1.4% (1/70)	3.0% (2/66)	4.3% (3/70)

Category	0 to 30 Days % (m/n)	31 to 365 Days % (m/n)	0 to 365 Days % (m/n)
Neoplasms benign, malignant and unspecified (including cysts and polyps)	0.0% (0/70)	3.0% (2/66)	2.9% (2/70)
Bladder cancer recurrent	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
Hepatic cancer	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
Nervous system disorders	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
Subarachnoid hemorrhage	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
Psychiatric disorders	1.4% (1/70)	0.0% (0/66)	1.4% (1/70)
Mental status changes	1.4% (1/70)	0.0% (0/66)	1.4% (1/70)
Renal and urinary disorders	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
Renal insufficiency	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
Respiratory, thoracic and mediastinal disorders	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
COPD exacerbation	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
Skin and subcutaneous tissue disorders	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
Lower extremities ulcers of	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
Vascular disorders	5.7% (4/70)	6.1% (4/66)	10.0% (7/70)
Aneurysm	1.4% (1/70)	1.5% (1/66)	2.9% (2/70)
Deep vein thrombosis	1.4% (1/70)	0.0% (0/66)	1.4% (1/70)
Hypertension	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
Peripheral artery dissection	0.0% (0/70)	1.5% (1/66)	1.4% (1/70)
Peripheral ischemia	1.4% (1/70)	1.5% (1/66)	2.9% (2/70)
Thrombosis	1.4% (1/70)	1.5% (1/66)	2.9% (2/70)

Based on number of all enrolled subjects within the Short Neck Cohort with available data.

m = number of subjects experiencing one or more serious adverse events in a category, n = number of subjects at risk at the beginning of the time period.

¹A subject may report multiple adverse events and in different subcategories; hence, number of subjects in each category may not be the sum of those in each subcategory. Each subject was only counted once in each subcategory and category.

Investigators were asked to assess relatedness of reported SAEs to device, index or re-intervention procedure, or AAA disease, the results of which are shown in **Table 16**. All events determined to be related to device, procedure, or AAA occurred within 30 days of the index procedure, many of which occurred on the day of the index procedure. There were no re-intervention-related SAEs or unanticipated adverse device effects (UADEs) reported through 365 days.

Of the events determined to be related to device, index or re-intervention procedure or AAA disease, SAEs were most commonly reported to be index procedure-related. Nine out of 70 subjects (12.9%) were reported to have an index procedure-related SAE between 0 and 30 days; three subjects experienced these on the day of the index procedure. The most common reasons for index procedure-related SAEs were procedural bleed and anemia.

Two out of 70 subjects (2.9%) were reported to have an AAA-related SAE between 0 and 30 days, both occurred on Day 0. One subject experienced a femoral artery injury and bleeding at the vascular access site. The other subject experienced post-procedural bleeding.

There were two device-related adverse events through 12 months. Subject 178-013 was hospitalized for device occlusion on Day 18 post-index procedure. The subject underwent an emergent, endovascular thrombectomy entirely within the endograft. Subject 162-002 experienced peripheral ischemia with bilateral claudication on Day 59 post-index procedure. The subject was treated with medication and the AE remained continuing with treatment as of the date of this summary.

Table 175. Device-Related Adverse Events through 12 months

Subject Number	Event Type (AE/SAE)	Related to Endograft, Heli-FX, or Both	Study Day	AE Term ¹
178-013	SAE	Related to Endograft	18	Device occlusion
162-002	AE	Related to Endograft	59	Peripheral ischemia

Based on number of all enrolled subjects within the Short Neck Cohort with available data.

¹Subjects may appear on this table more than one time if they experienced more than one device related event.

Table 18: Relatedness of Serious Adverse Events through 12 Months

	0-30 Days % (m/n)	31-365 Days % (m/n)	0-365 Days % (m/n)
Index procedure related SAEs	12.9% (9/70)	0.0% (0/66)	12.9% (9/70)
Re-intervention related SAEs	0.0% (0/70)	0.0% (0/66)	0.0% (0/70)
AAA-related SAEs	2.9% (2/70)	0.0% (0/66)	2.9% (2/70)
Device related SAE	1.4% (1/70)	0.0% (0/66)	1.4% (1/70)
Related to Endograft	1.4% (1/70)	0.0% (0/66)	1.4% (1/70)
Related to Heli-FX	0.0% (0/70)	0.0% (0/66)	0.0% (0/70)
Related to both	0.0% (0/70)	0.0% (0/66)	0.0% (0/70)
UADEs	0.0% (0/70)	0.0% (0/66)	0.0% (0/70)

Based on number of all enrolled subjects within the Short Neck Cohort with available data.

m = number of subjects in category, n = number of subjects who are at risk at beginning of the time period.

2. Effectiveness Results

The analysis of effectiveness was based on the Short Neck Cohort of 70 patients available for the 1-month evaluation and 66 patients available for the 12-month evaluation. Key effectiveness outcomes are presented in **Table 19** through **Table 21**.

Primary Outcomes

The primary effectiveness outcomes were technical success rate, Type Ia endoleak rate at 1 month and 12 months and reintervention rate through 12 months. A summary of primary outcomes for the ANCHOR Short Neck Cohort, ANCHOR Very Short Neck Cohort and ANCHOR On-Label Neck Cohort is provided in **Table 20**, below.

The impact of the number of EndoAnchors used on primary outcomes is discussed below and is summarized in the **Supportive Outcomes** section, **Table 19**.

Table 21. Summary of Primary Outcomes

Event	ANCHOR Short Neck (N = 70)	95% Confidence Interval	ANCHOR supportive cohort: Very Short Neck < 4 mm (all stent grafts) (N = 32)	ANCHOR supportive cohort: On-Label Neck ≥ 10 mm (Endurant) (N = 100)
Type Ia Endoleak at 1-month ¹	6.8% (4/59)	[1.9%, 16.5%]	16.0% (4/25)	0.0% (0/91)
Type Ia Endoleak at 1-year ¹	1.9% (1/53)	[0.0%, 10.1%]	0.0% (0/20)	0.0% (0/73)
Secondary Procedures through 1 year	4.7% (3/64)	[1.0%, 13.1%]	7.7% (2/26)	2.2% (2/91)
Secondary Endovascular Procedures through 1 year	4.7% (3/64)	[1.0%, 13.1%]	7.7% (2/26)	2.2% (2/91)
Conversion to Open Surgical Repair through 1 year	0.0% (0/64)	[0.0%, 5.6%]	0.0% (0/26)	0.0% (0/91)
Other Secondary Open Surgical Procedures through 1 year	1.6% (1/64)	[0.0%, 8.4%]	0.0% (0/26)	0.0% (0/91)
Technical Success Rate at Index Procedure ² :	88.6% (62/70)	[78.7%, 94.9%]	84.4% (27/32)	94.9% (94/99)
Successful delivery:				
Access to the targeted aortic site was achieved by the EndoAnchor system	100.0% (70/70)	[94.9%, 100.0%]	100.0% (32/32)	100.0% (100/100)
Successful delivery of the main body to the intended landing zone	94.3% (66/70)	[86.0%, 98.4%]	96.9% (31/32)	99.0% (99/100)
Successful and accurate deployment of the Endurant II/IIs stent graft and the Aptus Heli-FX EndoAnchor System				
Successful deployment of the endovascular stent graft at the intended implantation site ³	100.0% (70/70)	[94.9%, 100.0%]	100.0% (32/32)	98.0% (97/99)
Successful and accurate deployment of EndoAnchor implants was achieved ⁴	92.9% (65/70)	[84.1%, 97.6%]	87.5% (28/32)	96.0% (96/100)
Absence of unintentional coverage of the renal arteries	97.1% (68/70)	[90.1%, 99.7%]	96.9% (31/32)	100.0% (100/100)

Based on number of all enrolled subjects within the Short Neck Cohort with available data.

m = number of subjects in category, n = number of subjects with available values. For secondary procedures through 1 year, the denominator includes subjects who had an event or had been followed for at least 184 days.

¹Core laboratory reported

²Technical success was defined as: successful delivery and deployment of the stent graft, without unintentional coverage of the renal arteries, and successful implantation of the EndoAnchor implants at the target aortic site.

³Absence of misdeployment of the main body proximal to the intended landing zone

⁴Each EndoAnchor adequately penetrated the aortic wall (investigator's assessment) and, in the investigator's opinion, the implantation of the EndoAnchor implants was successful.

Technical Success

Technical success was defined as:

- Successful delivery, defined as:
 - Access to the targeted aortic site was achieved
 - Successful delivery of the main body to the intended landing zone was achieved
- Successful and accurate deployment of the stent graft, defined as:
 - successful deployment of the endovascular stent-graft at the intended implantation site was achieved
 - successful and accurate deployment of EndoAnchor implants was achieved
 - absence of unintentional covering of the renal arteries was achieved

The overall technical success rate for both endograft and EndoAnchor implants was 88.6% (62/70). Delivery and deployment of the main body stent graft at the intended landing zone was achieved in 94.3% (66/70) and 100% (70/70), respectively, with absence of unintentional coverage of the renal arteries achieved in 97.1% (68/70) of subjects. Delivery and deployment of the EndoAnchors at the target aortic site was achieved in 100% (70/70) and 92.9% (65/70), respectively.

Technical success was not achieved in four subjects due to inadequate penetration of at least one EndoAnchor into the aortic wall. In all cases, the procedures were determined by the investigator to be successful.

Three subjects did not achieve technical success due to unsuccessful delivery of the endograft main body into the intended landing zone; specifically, endografts were delivered slightly distal to the intended landing zone. There was an unintentional coverage of the renal artery in one subject due to cuff placement, but the investigator placed bilateral renal stents to maintain renal perfusion. In all cases, the procedures were determined by the investigator to be successful.

One subject did not achieve technical success due to factors related to both the Endograft and EndoAnchor implants. The endograft main body was not delivered successfully to the intended landing zone and required additional proximal stent graft extension, resulting in unintentional coverage of the left accessory renal artery. Seven EndoAnchor implants were deployed due to an observed Type Ia endoleak, each of which adequately penetrated the aortic wall. The investigator felt that the implantation of the EndoAnchor implants was unsuccessful because a Type II endoleak was observed at the proximal neck; the investigator determined that the procedure was unsuccessful for the same reason.

As summarized in **Table 19** in the **Supportive Outcomes** section, 15 of the 18 subjects without the recommended number of EndoAnchor devices implanted achieved technical success, that is, successful delivery and deployment of the endograft and EndoAnchors without unintentional coverage of the renal arteries. Three subjects did not achieve technical success due to inadequate penetration of at least one EndoAnchor into the aortic wall.

While technical success, which was dependent on successful delivery and deployment of the endograft and each EndoAnchor used, was determined to be 88.6% (62/70), it should be noted that overall procedural success, as noted by investigators, was determined to be 97.1% (68/70). Please see **Table 22**.

Type Ia Endoleak

As per the core lab, Type Ia endoleak was reported in 6.8% (4/59) of subjects at the 1-month follow-up visit and 1.9% (1/53) of subjects at the 12-month follow-up visit. Only one subject required re-intervention to treat a Type Ia endoleak. Three of the four subjects with Type Ia endoleak reported at 1-month had adequate imaging to assess endoleak at 12 months. Of these three subjects, only one subject had a reported persistent Type Ia endoleak. The remaining one subject did not have adequate imaging to assess endoleak at 12 months. No additional events have been reported in this subject. All Type Ia endoleak occurrences, regardless of re-intervention and subsequent resolution, have been captured in the 1-month and 12-month information presented here. Additionally, all interventions for Type Ia endoleaks are captured in this section as well.

Three of the four subjects who reported Type Ia endoleak at 1-month follow-up had less than the recommended number of EndoAnchors implanted. Please see **Table 19** in the **Supportive Outcomes** section, below. One of these was reported by the core lab to have a Type Ia endoleak at 12-month follow-up as well, as mentioned above. The second subject underwent a re-intervention for Type Ia endoleak on Day 9 post-index procedure. In the third subject, the core lab was unable to assess presence or absence of a Type Ia endoleak at the 12-month follow-up, also mentioned above.

Secondary Procedures

Three of 64 subjects (4.7%) had one or more re-interventions through 12 months. Thrombosis, occlusion, and Type Ia endoleak (mentioned above) were the reasons for reintervention. There were no conversions to open surgical repair through 12 months.

Two of the three Short Neck Cohort subjects who underwent secondary procedures through 12 months were implanted with less than the recommended number of EndoAnchor implants, however, one of the two subjects had an intervention that was entirely unrelated to the quantity of EndoAnchor implants. (This subject underwent three secondary procedures within 12 months post-index procedure to treat a pseudoaneurysm with deep vein thrombosis and endograft thrombosis.) The other subject underwent a re-intervention on Day 9 to treat a Type Ia endoleak, as previously mentioned.

Initial Implantation Outcomes

Procedure success was not prospectively defined and is not a primary outcome, but is relevant to the evaluation of technical success. Investigators reported an overall procedure success of 97.1% (68/70); unsuccessful procedures were reported in one subject due to a Type II endoleak observed at the proximal neck and in a second subject due to a persistent Type Ia endoleak. There were no main body endograft components that were misdeployed proximally to the intended landing zone. Type Ia endoleak was reported by investigators as present at end of procedure in 12.9% (9/70) of subjects. There were no Type III endoleaks reported as present at the end of the procedure. **Error! Reference source not found.** provides investigator-reported details on the initial implant outcomes of the index procedure.

Table 23. Initial Implantation Outcomes

Event	Short Neck Cohort (N = 70) (m/n)%
Overall Procedure was successful (Investigator assessed)	97.1% (68/70)
Endograft Components Misdeployed Proximally to Intended Landing Zone	
Stent Graft Main Body ¹	0.0% (0/70)
Left Iliac Extension	0.0% (0/70)
Right Iliac Extension	0.0% (0/70)
Aortic Cuff	1.4% (1/70)
Endoleak present at end of procedure	
Type Ia	12.9% (9/70)
Type Ib	1.4% (1/70)
Type II	20.0% (14/70)
Type III	0.0% (0/70)
Type IV	7.1% (5/70)

Based on number of all enrolled subjects within the Short Neck Cohort with available data.

m = number of subjects in category, n = number of subjects with available values

¹Misdeployment of the main body component proximally to the intended landing zone is a component of technical success

Discussion of Primary Outcomes

Overall, primary outcomes across the Registry cohorts were noted to be similar with the exception of technical success and Type Ia endoleak at one month. Specifically, technical success was less favorable in the ANCHOR Short Neck Cohort (88.6%) and Very Short Neck Cohort (84.4%) as compared to the ANCHOR On-Label Neck Cohort (94.9%), Endurant IDE Clinical Study (99.3%), and ENGAGE Registry (99.0%). Furthermore, technical success in deployment of the stent graft at the intended implantation site is higher across the ANCHOR cohorts than deployment of the EndoAnchor implants. There was a higher rate of Type Ia endoleak reported in the Short Neck Cohort (6.8%) and Very Short Neck Cohort (16.0%) compared to the On-Label Neck Cohort (0.0%), Endurant IDE Clinical Study (0.0%) and ENGAGE Registry (0.7%) at one month. In all groups, reported rates of Type Ia endoleak at 12 months were similar and very low with one endoleak at 12 months reported in the ANCHOR Short Neck Cohort. The rate of secondary procedures within the Short Neck Cohort was similar to rates observed in the Very Short Neck Cohort as well as the Endurant on-label neck length cohorts (both with and without EndoAnchors).

A literature review was performed to assess the clinical results from snEVAR, fEVAR, and chEVAR. The literature search yielded data from 21 publications with 526 patients who underwent snEVAR, 51 publications with 3,029 patients who underwent fEVAR, and 27 publications with 465 patients who underwent chEVAR. Type Ia endoleak at one month was reported in 6.8% (4/58) of Short Neck Cohort Subjects. This rate was similar to those reported for snEVAR (9.1%), fEVAR (3.1%), and chEVAR (6.9%) literature reference groups. Endoleak rates at 1 year were also similar with rates for snEVAR,

fEVAR and chEVAR reported as 1.6%, 1.4%, and 1.0% respectively. In addition, secondary procedure rates through 1-year in the Short Neck Cohort compared favorably to the all literature-referenced alternative therapies for short neck AAAs with the following rates being reported chEVAR (10.0%) fEVAR (15.7%), and snEVAR (10.0%).

Supportive Outcomes

Supportive effectiveness outcomes were provided in two categories: device-related and effectiveness-related measures.

Device-Related Measures

Device-related measures included endograft or EndoAnchor loss of integrity, impact of the number of EndoAnchors used on the primary outcomes and adequate maintenance of EndoAnchor implants into the aortic wall.

Endograft or EndoAnchor loss of integrity: There was no loss of device integrity reported within the 1-month or 12-month follow-up window for either endografts or EndoAnchor implants for the Short Neck Cohort.

Impact of the Number of EndoAnchors Used on Primary Outcomes: The Heli-FX EndoAnchor Instructions for Use (IFU) contains a recommendation for the minimum number of EndoAnchor implants based on the aortic neck diameter. The use of “real world” Short Neck Cohort data from the ANCHOR Registry allowed for an examination of cases in which the recommended number of EndoAnchor implants was not used.

Table 19 summarizes primary outcomes for the 18 of 70 Short Neck Cohort subjects in whom the recommended number of EndoAnchor implants was not used.

Table 24. Outcomes in Subjects where the Recommended Number of EndoAnchor Implants were Not Used

Subject Number	Recommended Number of EndoAnchor Implants ¹	Number of EndoAnchor Implants Used	Technical Success (Yes/No/UNK)	Type Ia Endoleak at 30 days ² (Yes/No/UNK)	Type Ia Endoleak at 12 months ² (Yes/No/UNK)	Re-intervention through 365 days (Yes/No/UNK)
100-052	4	3	No	No	UNK	UNK
109-041	6	2	Yes	No	No	No
109-002	6	4	Yes	Yes	Yes	Yes
109-048	6	3	Yes	Yes	No	Yes
109-057	6	4	Yes	No	No	No
109-016	6	4	Yes	No	No	No
109-042	4	2	Yes	No	No	No
109-039	6	4	Yes	No	UNK	No
135-004	6	4	Yes	No	No	No
135-006	6	4	No	No	No	No
155-002	6	4	Yes	UNK	UNK	No
168-010	6	4	Yes	No	No	No
172-005	6	4	Yes	No	No	No

Subject Number	Recommended Number of EndoAnchor Implants ¹	Number of EndoAnchor Implants Used	Technical Success (Yes/No/UNK)	Type Ia Endoleak at 30 days ² (Yes/No/UNK)	Type Ia Endoleak at 12 months ² (Yes/No/UNK)	Re-intervention through 365 days (Yes/No/UNK)
172-024	6	4	Yes	No	No	No
178-009	6	4	Yes	No	No	No
178-011	6	4	No	Yes	UNK	No
178-005	6	4	Yes	No	No	No
189-003	6	3	Yes	No	No	No

Based on number of all enrolled subjects within the Short Neck Cohort with available data.

¹Based on the IFU, the minimum recommended number of EndoAnchor implants used in an aortic neck of ≤ 29 mm is 4, and a minimum of 6 EndoAnchor implants are recommended in an aortic neck > 29 mm

²Core laboratory reported

Please see **Primary Outcomes** section, above, for a discussion of the impact of the number of EndoAnchors used on primary outcomes.

Adequate Maintenance of EndoAnchor Implants into the Aortic Wall: EndoAnchor implants maintained adequate penetration through the aortic wall in 98% (50/51) of the subjects at 30 days and in 94.9% (37/39) of subjects at 12 months. In one subject, inadequate penetration of one EndoAnchor was attributed to thick thrombus in the posterior wall of the aorta. This subject was noted to have inadequate penetration of the same EndoAnchor at 1-month and 12-month follow-up. As of the cut-off date of this summary, no re-interventions have been reported in this subject. In the other subject, one of the Endo Anchor implants had lost adequate penetration through the aortic wall at 12 months. As of the date of data cut off, there have been no reports of endoleaks or re-interventions in this subject.

Table 25 summarizes the maintenance of adequate penetration by EndoAnchor implants.

Table 26. Maintenance of Adequate Penetration by EndoAnchor Implants

	% (m/n)
Did EndoAnchor implants maintain adequate penetration into aortic wall	
30 days	98.0% (50/51)
12 months	94.9% (37/39)

Based on number of all enrolled subjects within the Short Neck Cohort with available data.

m = number of subjects in category, n = number of subjects with available values

Effectiveness-Related Measures

Table 27 Error! Reference source not found. summarizes a number of effectiveness-related measures that were identified as Supportive Outcomes in the analysis of the Short Neck Cohort. Results for the Very Short Neck Cohort and the On-Label Neck Cohort are included to provide context for the Short Neck Cohort results. Three of 70 Short Neck Cohort subjects underwent secondary procedures through 1 month (also discussed under **Primary Outcomes**). No subjects underwent conversion to open surgical repair through 12 months. Type III endoleaks were reported by core lab in 1.7% (1/59) of subjects at 1-month follow-up and 1.9% (1/53) of subjects at 12-month follow-up. No subjects experienced endograft migration at one year.

Table 21. Summary of Effectiveness-Related Measures

Effectiveness-related measures	ANCHOR Short Neck (N = 70)	ANCHOR	ANCHOR
		supportive cohort: Very Short Neck < 4 mm (all stent grafts) (N = 32)	supportive cohort: On-Label Neck ≥ 10 mm (Endurant) (N = 100)
Aneurysm expansion at 12 months ^{1,2}	0.0% (0/54)	5.3% (1/19)	0.0% (0/73)
Migration at 12 months ^{1,3}	0.0% (0/41)	0.0% (0/16)	0.0% (0/58)
Secondary procedures through 30 days	4.3% (3/70)	0.0% (0/32)	1.0% (1/100)
Conversion to open surgical repair through 12 months	0.0% (0/64)	--	--
Type III endoleaks at 30 days ¹	1.7% (1/59)	--	--
Type III endoleaks at 12 months ¹	1.9% (1/53)	--	--

m = number of subjects in category, n = number of subjects with available imaging assessments for aneurysm expansion and migration and endoleak at 12 months, and number of subjects who had an event in question or reached the lower time window of the time period for site-reported events.

¹Based on core laboratory related data.

²Aneurysm expansion (alternatively noted as AAA diameter increase) is defined as a > 5 mm increase in maximum diameter as compared to 1 month post-implantation measurement.

³Migration is defined as a > 10mm movement of the aortic endograft from its position at the 1 month post-implantation measurement.

Data Post-12 Months

Following is a summary of the data post-12 months that had been reported as of the April 06, 2017 data cut-off date: One core lab-reported Type Ia endoleak was identified on Day 1271. The subject did not undergo re-intervention to treat it. One subject underwent a secondary endovascular procedure along with a conversion to open surgical repair on Day 900 post-index procedure to treat a Type II endoleak and aneurysm enlargement. In addition, one subject underwent a secondary endovascular procedure on Day 758 to treat a Type Ib endoleak and aneurysm enlargement. No aneurysm ruptures have occurred beyond the 12-month time point. One subject experienced renal failure on Day 888, which was assessed by the investigator as not aneurysm, procedure or device related and the event has been reported as resolved. Seven subjects have experienced MAEs beyond the 12-month time point. A total of nine deaths have occurred after Day 365, none of these deaths were determined to be aneurysm-related.

3. Subgroup Analyses

While the number of women in the Short Neck Cohort (27.1% (19/70)) was relatively high compared to other AAA studies, the data were insufficient to conduct a subgroup analysis. No other subgroup analyses were conducted.

4. Pediatric Extrapolation

In this premarket application, existing clinical data was not leveraged to support approval of a pediatric patient population.

E. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The ANCHOR Registry Short Neck Cohort included investigators at 22 active sites, none of whom were full-time or part-time employees of Medtronic. Six investigators disclosed financial interests/arrangements with Aptus Endosystems and/or Medtronic. Two of these disclosed payments show they received under \$25,000 and are hence not included here. The types of compensation defined in 21 CFR 54.2 (a), (b), (c) and (f) are summarized below, along with the number of investigators reporting that type of compensation:

- Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: 0
- Significant equity interest held by investigator in Sponsor of covered study: 0
- Proprietary interest in the product tested held by the investigator: 0
- Significant payment of other sorts (having a monetary value over \$25,000): 4

The applicant has adequately disclosed the financial interest/arrangements with clinical investigators. The information provided does not raise any questions about the reliability of the data.

XI. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

Medtronic has not conducted any clinical evaluation of the Endurant II/II_s Stent Graft System utilized in conjunction with Heli-FX in the treatment of short neck infrarenal abdominal aortic aneurysms, beyond the analysis of the Short Neck Cohort in the ANCHOR Registry. To evaluate any supplemental clinical information that may be available, an independent literature review was conducted for Medtronic by Galen Press.

Nine articles were found in which the Endurant or Endurant II/II_s Stent Graft System was used with Heli-FX EndoAnchors for the period of January 2009 through December 31, 2016. The most substantial evidence supporting the use of the Endurant or Endurant II/II_s Stent Graft System with EndoAnchor implants was derived from five articles that have reported results from the ANCHOR Registry. While results for “short neck” patients were not separately reported, many of the patients in whom EndoAnchors were used presented with hostile neck anatomy, i.e., short and/or angulated neck, large diameter neck or extensively calcified neck. Of the five articles reporting results from the ANCHOR Registry, that by Jordan et al in 2014 is the most substantial in terms of the number of

patients reported (n = 319)⁴ and the inclusion of short-term and mid-term results. Rates of technical success, procedural success, endoleak, secondary procedures, surgical conversions, aneurysm-related deaths and aneurysm ruptures were reported. Investigators in this article concluded that EndoAnchors offered a useful adjunct to EVAR for prophylaxis against aortic neck complications in patients with hostile neck anatomy and for treatment of Type Ia endoleak and/or migration when they develop.

In addition to the five ANCHOR registry articles, there have been two other studies about EndoAnchors in which the Endurant or Endurant II/IIIs Stent Graft System has been mentioned. Perdikides et al⁵ retrospectively analyzed data from a small registry to evaluate the use of EndoAnchors as prophylaxis against Type Ia endoleaks and stent graft migration at the time of initial EVAR in patients with unfavorable neck anatomy. The investigators enrolled 13 consecutive patients. Of these, four patients received the Endurant stent graft and nine patients received the Zenith stent graft. The investigators concluded that the prophylactic use of EndoAnchors was safe and feasible, with favorable short-term results.

Melas et al⁶ used human cadaveric aortas to evaluate improvement of proximal fixation of the stent graft with EndoAnchors.

Lastly, two articles have reported the use of EndoAnchors as an adjunctive EVAR procedure. Donas et al⁷ retrospectively analyzed their single-institution experience with the Endurant stent graft in 712 consecutive all-comer high-risk AAA patients who underwent elective or urgent EVAR. A total of 15 patients (2.1%) had evidence of a persistent Type Ia or Ib endoleak; 1 of these 15 patients was treated successfully with an EndoAnchor.

Troisi et al⁸ retrospectively reviewed data from 817 AAA patients treated with the Endurant stent graft to compare early and midterm outcomes in patients with narrow aortic bifurcation (NA group) versus those in patients with standard aortic bifurcation (SA group). In one patient in the NA group, there was a Type I endoleak that was unresponsive to fixation with EndoAnchors.

4 Jordan WD Jr, Mehta M, Varnagy D, Moore WM Jr, Arko FR, Joye J, Ouriel K, de Vries JP; Aneurysm Treatment using the Heli-FX Aortic Securement System Global Registry (ANCHOR) Workgroup Members. Results of the ANCHOR prospective, multicenter registry of EndoAnchors for type Ia endoleaks and endograft migration in patients with challenging anatomy. *J Vasc Surg.* 2014;60(4):885-92.e2.

5 Perdikides T, Melas N, Lagios K, Saratzis A, Siafakas A, Bountouris I, Kouris N, Avci M, Van den Heuvel DA, de Vries JP. Primary endoanchoring in the endovascular repair of abdominal aortic aneurysms with an unfavorable neck. *J Endovasc Ther.* 2012;19(6):707-15.

6 Melas N, Perdikides T, Saratzis A, Saratzis N, Kiskinis D, Deaton DH. Helical EndoStaples enhance endograft fixation in an experimental model using human cadaveric aortas. *J Vasc Surg.* 2012;55(6):1726-33.

7 Donas KP, Torsello G, Weiss K, Bisdas T, Eisenack M, Austermann M. Performance of the Endurant stent graft in patients with abdominal aortic aneurysms independent of their morphologic suitability for endovascular aneurysm repair based on instructions for use. *J Vasc Surg.* 2015;62(4):848-54.

8 Troisi N, Donas KP, Weiss K, Michelagnoli S, Torsello G, Bisdas T. Outcomes of Endurant stent graft in narrow aortic bifurcation. *J Vasc Surg.* 2016;63(5):1135-40.

XII. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

The safety and effectiveness of the Endurant II/II_s Stent Graft System used in conjunction with Heli-FX EndoAnchor System in the treatment of abdominal aortic aneurysms with infrarenal neck length ≥ 4 mm and < 10 mm is based on the ANCHOR Registry along with a combination of previous nonclinical, pre-clinical and clinical testing (P100021, P100021/S011, P100021/S21, P10021/S39 and K102333) and on additional nonclinical testing to establish that the device combination performs as expected in the use condition.

A. Effectiveness Conclusions

Key effectiveness parameters evaluated for the short neck indication included rate of technical success at the index procedure, rate of Type Ia endoleak at 1 month and at 1 year, and rate of re-intervention through 1 year.

Technical success included elements of successful delivery and deployment of the stent graft and EndoAnchor implants, in absence of unintentional coverage of the renal arteries. The overall technical success rate for both endograft and EndoAnchor implants was 88.6% (62/70). As expected, the technical success rate was lower than what is typically observed for Endurant alone due to the requirement for successful delivery and deployment of the endograft and each EndoAnchor used. Unsuccessful delivery of the endograft main body to the intended landing zone and inadequate EndoAnchor penetration were primary reasons for not achieving technical success. As per the core lab, Type Ia endoleak was reported in 6.8% (4/59) of subjects at the 1-month follow-up visit and 1.9% (1/53) of subjects at the 12-month follow-up visit. Three of 64 subjects (4.7%) had one or more re-interventions through 12 months.

While the rate of Type Ia endoleak at 1 month was high, it had dropped considerably at 1 year. The re-intervention rate through 1 year corresponded to that seen in previous reports. The rate of technical success at implantation must take into account the delivery and deployment of the stent graft and each EndoAnchor. The rate of overall procedure success recorded by the investigators was 97.1% (68/70).

EndoAnchor implants maintained adequate penetration through the aortic wall in 98% (50/51) of subjects at 30 days and in 94.9% (37/39) of subjects at 12 months. No migration, aneurysm expansion, aneurysm rupture or conversion to open surgical repair through 12 months were reported. Overall, the combination of Endurant II/II_s Stent Graft System and Heli-FX EndoAnchor System allowed for effective treatment of abdominal aortic aneurysms in subjects exhibiting short infrarenal necks.

B. Safety Conclusions

The majority of subjects in the ANCHOR Registry Short Neck Cohort were reported to be ASA Class III (67.1%), with severe systemic disease, and a large proportion were at high risk of death with 25.7% in ASA Class IV. This reflects a population with overall poorer health than that reported in previous Endurant studies. Four subjects in the Short Neck Cohort died within 30 days of the index procedure, contributing to a relatively high rate of aneurysm-related mortality. However, it should be noted that the adverse events leading to the deaths were assessed by the investigators and no events were noted as related to the aneurysm.

One device-related serious adverse event (endograft occlusion) occurred in one subject (1.4% (1/70)). Index procedure-related serious adverse events occurred in 12.9% (9/70) subjects. A total of 18 MAEs were reported among 15 subjects between 0 and 365 days. Among those, 13 MAEs in 11 subjects were reported between 0 and 30 days. No subjects experienced paraplegia, renal failure or conversion to open surgical repair through 12 months. One subject with a history of renal insufficiency died within 30 days of the index procedure; the investigator-determined cause of death included renal failure.

C. Benefit-Risk Determination

Analysis of outcomes for the ANCHOR Registry Short Neck Cohort has shown acceptable safety and effectiveness for this high risk population. No aneurysm expansion or rupture were reported. The rate of Type Ia endoleak at 1 year was acceptable, as was the rate of re-intervention. These patients received protection against aneurysm rupture without undergoing major surgery. Renal failure was reported as a cause of death in one subject with a history of renal insufficiency. There were no other reports of renal failure nor were there any reports of paraplegia. Only one report of stroke (at Day 320) and one report of bowel ischemia were received.

Short neck anatomies such as those seen in the ANCHOR Registry Short Neck Cohort may be indicative of a more advanced state of aortic disease. In addition, the overall health status of the cohort, as measured by ASA Classification, was low; 92.8% (65/70) fell into ASA Class III or Class IV. Treatment of abdominal aortic aneurysm via open surgical repair is not a viable option for many of these patients due to the prolonged recovery time and the higher rate of associated serious adverse events. Furthermore, endovascular repair options are limited due to the short infrarenal neck, which may preclude standard EVAR treatments.

Given the available information above, the data support that for patients with abdominal aortic aneurysms with infrarenal neck lengths of ≥ 4 mm and < 10 mm undergoing EVAR with the Endurant II/II_s Stent Graft System with Heli-FX EndoAnchors, the probable benefits outweigh the probable risks

1. Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

D. Overall Conclusions

The data in this application support a reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use.

The safety and effectiveness of the treatment of abdominal aortic aneurysms with infrarenal neck lengths of ≥ 4 mm and < 10 mm with the Endurant II/II_s Stent Graft System used in conjunction with Heli-FX EndoAnchors has been established based on the outcomes derived from a real-world evidence dataset via the ANCHOR Registry Short Neck Cohort and the nonclinical testing described herein, in addition to previous nonclinical, pre-clinical and clinical testing of both Endurant and Heli-FX.

XIV. CDRH DECISION

CDRH issued an approval order on September 29, 2017. The final conditions of approval cited in the approval order are described below.

1. In addition to the post approval study requirements listed below, you have agreed to include as part of the Annual Report, a copy of the Annual Clinical Update that you will provide to physician users at least annually. This update will include information regarding the treatment of short neck infrarenal abdominal aortic aneurysms using the Endurant II/Endurant II_s Stent Graft System in conjunction with the Heli-FX EndoAnchor System in addition to the information required per previous approval orders for this PMA.
2. *ODE Lead PMA Post-Approval Study – Continued Follow-Up ANCHOR Registry Short Neck Cohort:* The Office of Device Evaluation (ODE) will have the lead for this clinical study, which was initiated prior to device approval. The Continued Follow-Up ANCHOR Registry Short Neck Cohort is a prospective, observational, international, multi-center, post-market registry.

The purpose of the Continued Follow-Up ANCHOR Registry Short Neck Cohort is to obtain longer-term follow-up on the use of the Endurant II/Endurant II_s Stent Graft System to treat short neck infrarenal abdominal aortic aneurysms when used in conjunction with the Heli-FX EndoAnchor System. Five-year follow-up on the surviving patients from the Short Neck Cohort, in accordance with the ANCHOR Registry protocol, will be reported. Clinical outcomes will include aneurysm-related mortality, aneurysm rupture, aneurysm expansion, Type Ia endoleak, migration, Type III endoleak, re-intervention, device-related adverse events, and device integrity. These endpoints will be analyzed descriptively on a yearly basis.

XV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.

XVI. REFERENCES

Donas KP, Torsello G, Weiss K, Bisdas T, Eisenack M, Austermann M. Performance of the Endurant stent graft in patients with abdominal aortic aneurysms independent of their morphologic suitability for endovascular aneurysm repair based on instructions for use. *J Vasc Surg.* 2015;62(4):848-54.

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