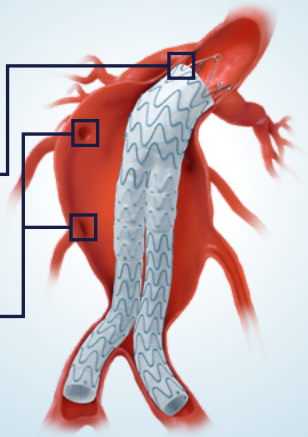
YOU CAN ADDRESS SAC REGRESSION BECAUSE WE'RE HERE

Design Benefits of Endurant™ II/IIs AAA Stent Graft Address Sac Regression

? What are the critical factors for sac regression?

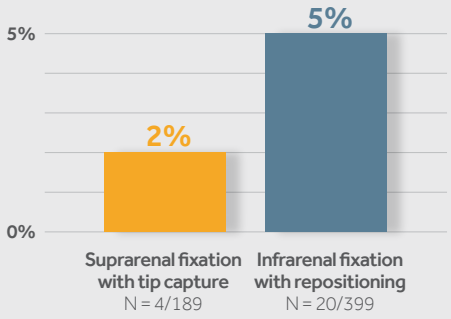
Proximal Seal 1 2
Critical for depressurizing the aneurysm, as type Ia endoleak transmits the highest pressures into the sac, compared to other types of endoleak[1]

Non-patent Branches 3
Critical for maintaining aneurysm regression, as type II endoleak is the most common type of endoleak[2] with significant impact on long-term sac dynamics[3]



1 Accurate placement and controlled delivery

Perioperative Cuff Usage Rates†4,5

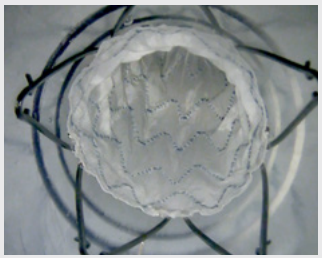


Infrarenal mean neck length	2.0 cm	2.8 cm
Infrarenal mean neck angulation	40°	33°

2 Continuous seal, fixation, and graft conformability

Visual Illustrations of Seal

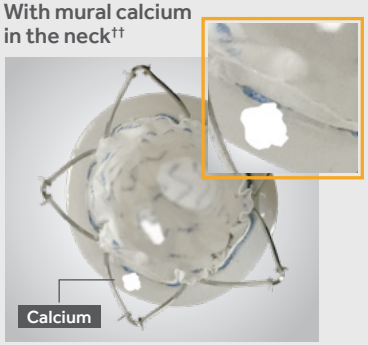
With 60° neck angulation**



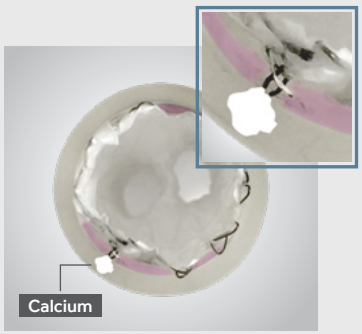
With suprarenal & m-stent

Without suprarenal & m-stent

With mural calcium in the neck††



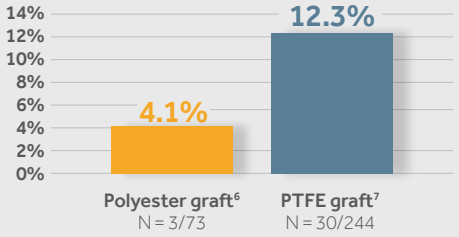
Fixation outside seal zone



Fixation within seal zone

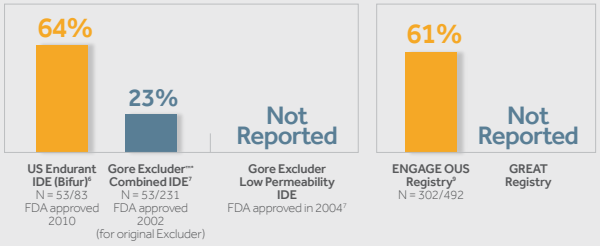
3 Resistance against type II endoleak

Type II Endoleak at 5 Years†



THERAPY GOAL Sac regression[8]

5-year Sac Regression Rate†
in Prospective Studies



Medtronic

™*** Third party brands are trademarks of their respective owners.

† Results are taken from independent clinical studies for illustration purposes only and are not based on statistical analysis. Results may differ in a head-to-head comparison; multiple factors contribute to clinical study outcomes and need to be considered in making assessments across different studies.

** Based on internal assessment of Endurant IIs vs. C3 Excluder under equal physiological and anatomical conditions, with 60-degree neck angulation. Bench top models shown not indicative of clinical performance. The images shown are for illustrative purposes only. Performance may vary depending on use. Medtronic data on file.

†† Based on comparative marketing models created for illustrative purposes only, per the IFU and not indicative of clinical performance. Performance may vary depending on use.

REFERENCES

[1] Li J, Tian X, Wang Z, et al. Influence of endoleak positions on the pressure shielding ability of stent-graft after endovascular aneurysm repair (EVAR) of abdominal aortic aneurysm (AAA). *Biomed Eng Online.* December 28, 2016;15(Suppl 2):135.

[2] Bryce Y, Schiro B, Cooper K, et al. Type II endoleaks: diagnosis and treatment algorithm. *Cardiovasc Diagn Ther.* April 2018;8(Suppl 1):S131-S137.

[3] Dijkstra M, Clark Z, Verhagen H, et al. Incidence, natural course, and outcome of type II endoleaks in infrarenal endovascular aneurysm repair based on the ENGAGE registry data. *J Vasc Surg.* March 2020;71(3):780-789.

[4] Sayed T, EL Basty A, Hildebrand, D, et al. Mid-term outcomes of endovascular aneurysm repair in challenging aortic neck anatomy based on experience from the GREAT C3 registry. *J Cardiovasc Surg (Torino).* Published online March 21, 2019.

[5] Broos PP, Stokmans RA, van Sterkenburg SM, et al. Performance of the Endurant stent graft in challenging anatomy. *J Vasc Surg.* 2015;62(2):312-318.

[6] Singh MJ, Fairman R, Anain P, et al. Final Results of the Endurant Stent Graft System in the United States Regulatory Trial. *J Vasc Surg.* July 2016;64(1):55-62.

[7] Gore Excluder Instructions for Use.

[8] O'Donnell TFX, Deery SE, Boitano LT, et al. Aneurysm sac failure to regress after endovascular aneurysm repair is associated with lower long-term survival. *J Vasc Surg.* 2019;69(2):414-422.

[9] Teijink JAW, Power AH, Böckler D, et al. Editor's Choice - Five Year Outcomes of the Endurant Stent Graft for Endovascular Abdominal Aortic Aneurysm Repair in the ENGAGE Registry. *Eur J Vasc Endovasc Surg.* August 2019;58(2):175-181.

INDICATIONS

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

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

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

CONTRAINDICATIONS

The Endurant II/Endurant IIs stent graft system is contraindicated in:

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

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/Endurant IIs stent graft system, refer to the *Instructions for Use* provided with the device.

WARNINGS AND PRECAUTIONS

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

MRI Safety and Compatibility: Nonclinical testing has demonstrated that the Endurant II/Endurant IIs stent graft is MR Conditional. It can be scanned safely in both 1.5T and 3.0T MR systems under certain conditions as described in the product *Instructions for Use.* For additional MRI safety information, please refer to the product *Instructions for Use.*

ADVERSE EVENTS

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

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

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

Medtronic