Medtronic

ADVANCE Trial

Endur**A**nt stent graft system vs. Exclu**D**er endoprosthesis – a global, prospecti**V**e, r**AN**domized **C**linical trial in sac r**E**gression

You're invested.
So are we.

Strength in evidence

ADVANCE is designed to empower your decisions as the first head-to-head EVAR randomized controlled trial advancing sac regression evidence to improve patient outcomes.

ADVANCE Trial rationale

- The ENGAGE OUS Registry and other large registries demonstrated that one-year sac regression is a robust indicator of EVAR durability and is linked to long-term outcomes, including mortality and secondary reinterventions.[1-5]

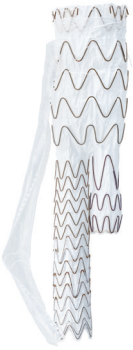
- The ADVANCE Trial is a head-to-head randomized controlled trial (RCT) designed to shed further light on:
  1. The underlying factors of sac regression
  2. Specific key outcomes between the Endurant™ II/IIs stent graft and Excluder™*/Excluder™* Conformable

- The study will further EVAR evidence, demonstrate contemporary outcomes, and empower physicians to make precise, evidence-based clinical decisions that improve patient outcomes.

Devices include

Endurant™ II/IIs stent graft

VS

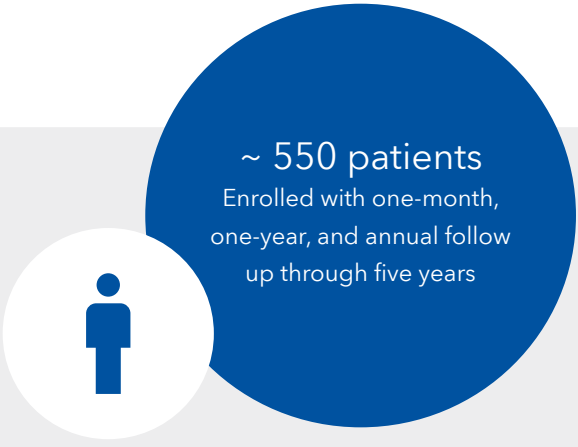


Excluder™*/Excluder™* Conformable AAA Endoprosthesis

ADVANCE Trial design

A global, prospective, multicenter, randomized (1:1) trial to evaluate the Endurant II/IIs stent graft and GORE™* Excluder™*/Excluder™* Conformable with regards to sac regression in standard EVAR subjects.

All imaging-based endpoints will be based on computed tomography angiography (CTA) and analyzed by a core lab. Imaging will be collected for all follow-up time points.



Primary endpoint‡

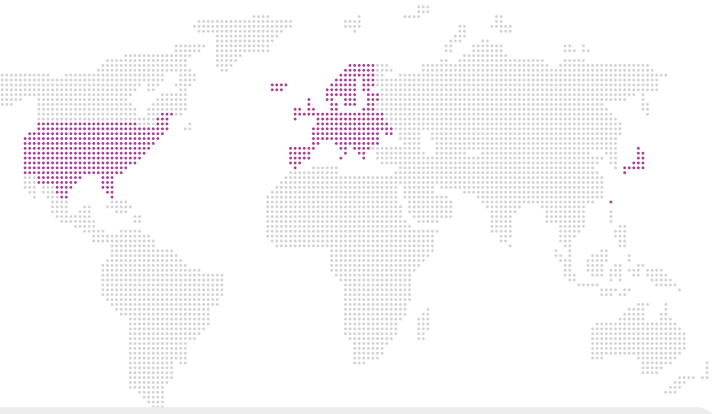
- Evaluate sac regression outcomes of the Endurant™ II/IIs stent graft and GORE™* Excluder™*/Excluder™* Conformable at one year post EVAR procedure

Secondary endpoints

- Sac regression (diameter/volume) through five years
- All-cause mortality
- Secondary interventions
- Type I/II endoleaks

50+ centers worldwide

United States, European Union, Japan, and Taiwan



Ancillary objectives

Procedure

- Sustained treatment success = technical success + freedom from key clinical outcomes, including secondary interventions
- Adjunctive procedures comparison (cuff usage) and deployment accuracy comparison

Safety

- MAE, ARM
- Renal complications and decline
- Systemic inflammation markers

Imaging

- Type III endoleaks
- Migration
- Aortic neck dilatation
- Limb occlusion

References

1 Böckler D, Li C, Dansey K, et al. Sac regression is associated with lower all-cause mortality after contemporary endovascular aneurysm repair – a new paradigm for success. Presented at ESVS 34th Annual Meeting, October 6, 2020.

2 ENGAGE five-year data. Data on file at Medtronic.

3 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.

4 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.

5 Rouwet EV, Torsello G, de Vries JP, et al. Final results of the prospective European trial of the Endurant stent graft for endovascular abdominal aortic aneurysm repair. *Eur J Vasc Endovasc Surg*. October 2011;42(4):489-497.

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 (see Neck length definition below). 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 lower-most 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: Non-clinical testing has demonstrated that the Endurant II/Endurant IIs stent graft is MR Conditional. It can be scanned safely in both 1.5T & 3.0T MR systems under certain conditions as described in the product *Instructions for Use*. For additional 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.

The use of Heli-FX™ EndoAnchors™ is not included as part of the ADVANCE Trial.

Not for distribution to patients.

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