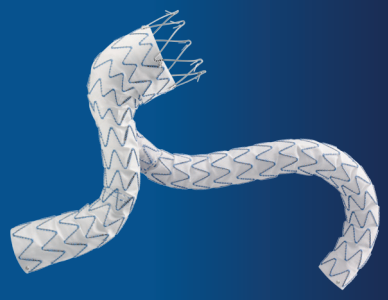
THE ENDURANT™ STENT GRAFT SYSTEM: A LEGACY OF CLINICAL SUCCESS

Endurant™ II /IIs
AAA Stent Graft System



The ENGAGE Registry achieves a significant milestone of **5 years** of clinical excellence.[1]

- The most validated EVAR registry with single manufacturer's stent graft.
- International multicenter registry enrolled 1263 patients across 79 centers in 30 countries on 6 different continents. This diverse physician and patient population resulted in consistent clinical performance comparable to the more straightforward Endurant US IDE trial.[2,3]
- Extensive ongoing monitoring: 100% data management review, independent data monitoring (100% endpoints), and independent Clinical Event Committee (adjudicates all 30-day MAE and all deaths).
- Demonstrated commitment to long-term clinical excellence and follow-up planned to 10 years.

Medtronic's commitment to advancing aortic care

- The ENGAGE Registry was initiated less than 1 year post CE mark approval to gather clinical insight and not just further market presence.
- The goal of the registry was to gather evidence in a real-world patient population.

The Endurant™ stent graft system sets a new benchmark for EVAR device performance.[4]

5 years of real-world clinical excellence

Aneurysm Related Mortality[5]	FF 97.8%
Secondary Endovascular Procedure[5] (overall)	FF 84.3%
AAA sac Diameter Stable or Decrease[6]	89.4%
Type Ia Endoleaks[6]	1.6%
Main Body Migration[6]	0.3%

The robust follow-up of the ENGAGE Registry ensures accurate reporting of data:
- >90% clinical follow up at 5 years
- >75% imaging follow up at 5 years

There is no need to compromise on clinical results

- The Endurant™ system has unparalleled clinical experience: A combination of more than 275,000 patients treated worldwide and favorable clinical outcomes.[7]
- The Endurant™ system is the device of choice designed to treat both challenging and straightforward anatomies.[8]
- Demand results. Trust the Endurant™ system.

Medtronic
Further, Together

1 ENGAGE 5-year data, Data on file at Medtronic
2 ENDURANT US IDE trial: Singh, et al. *J Vasc Surg* 2016;64:55-62
3 ENGAGE Registry: R.A. Stokmans, et al. *European Journal of Vascular and Endovascular Surgery* 44 (2012) 369-375
4 Dittmar Böckler, MD, "Latest Generation Device. Aneurysm – Related Mortality versus Benchmark EVAR 1 Trial at 4 years" Charing Cross, 2016
5 Data reported through 5-year timeframe
6 Data reported at 5-year timeframe
7 Data on file at Medtronic
8 Hence Verhagen, MD. PhD, "How clinical evidence supports my daily clinical practice – standard EVAR in patients with short proximal necks ≥10 mm", VEITH 2015

Indications: The Endurant™ II/Endurant™ IIs bifurcated stent graft is indicated for the endovascular treatment of infrarenal abdominal aortic or aorto-iliac aneurysms. 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/Endurant IIs stent graft system is indicated for use in patients with the following characteristics:
- Adequate iliac/femoral access that is compatible with vascular access techniques, devices and/or accessories
- Proximal neck length of ≥10 mm
- Infrarenal neck angulation of ≤60°
- Aortic neck diameters with a range of 19 to 32 mm
- Distal fixation length(s) of ≥15 mm
- Iliac diameters with a range of 8 to 25 mm
- Morphology suitable for aneurysm repair

Contraindications: The Endurant II/Endurant IIs Stent Graft System is contraindicated in:
- Patients who have a condition that threatens to infect the graft.
- Patients with known sensitivities or allergies to the device materials.

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

MRI Safety and Compatibility: Non-clinical testing has demonstrated that the Endurant II/Endurant IIs Stent Graft is MR Conditional. It can be scanned safely in both 1.5T & 3.0T MR systems under certain conditions as described in the product *Instructions for Use*. For additional information regarding MRI please refer to the product *Instructions for Use*.
Adverse Events: Potential adverse events include (arranged in alphabetical order): amputation; anesthetic complications and subsequent attendant problems (e.g., aspiration), aneurysm enlargement; aneurysm rupture and death; aortic damage, including perforation, dissection, bleeding, rupture and death; arterial or venous thrombosis and/or pseudoaneurysm; arteriovenous fistula; bleeding, hematoma or coagulopathy; bowel complications (e.g., ileus, transient ischemia, infarction, necrosis); cardiac complications and subsequent attendant problems (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension, hypertension); claudication (e.g., buttock, lower limb); death; edema; 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.
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