

Medtronic

Suprarenal fixation without compromise



The Endurant™ Stent Graft system design with suprarenal stents optimizes EVAR outcomes by:

- Separating fixation from seal to engage with healthy aorta tissue
- Enhancing graft conformability in angulated anatomy
- Reducing migration risk and device movement
 - Endurant IDE Bifur Study: 0% main body migration at 5 years¹ (N = 0/83)
 - ENGAGE OUS Registry: 0.8% main body migration at 8 years² (N = 1/127)

Not all suprarenal stents are created equal when it comes to renal access. What makes the Endurant stent graft unique?

Endurant II/IIIs stent graft has a large open cell configuration to minimize the number of struts that could cross the renals, maximizing future renal access.

Suprarenal stent measurements:[†]



○ Represents average renal artery measurement³

Suprarenal stent	Endurant II/IIIs	Cook™ Zenith Flex™	Endologix™ Ovation iX™
Height <i>in vitro</i>	15 mm	23 mm	48 mm
Strut quantity	10	24	16

Do suprarenal stents impact renal function?

A meta-analysis demonstrated no statistical difference in renal complications.⁴ In fact, SVS guidelines state that renal dysfunction between supra and infrarenal grafts is “not significantly different.”⁵

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[†]Based on comparative marketing models of EndurantTM IIs, Zenith FlexTM, and Ovation iXTM with 24 mm inner diameter glass tube created for illustrative purposes only, per the IFU and not indicative of clinical performance. Performance may vary depending on use. Medtronic data on file.

References

- 1 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.
- 2 Tejjink J, Power A, van Sterkenburg S, et al. 8-Year Data from the ENGAGE Registry Extension: Insights about the Long-term Performance of a Contemporary EVAR Device. Presented online at ESVS 35th Annual Meeting. September 20, 2021.
- 3 Mohiuddin M, Manzoor A, Ali M, Hassan N. Analysis of renal artery morphometry in adults: A study conducted by using Multidetector computed Tomography Angiography. *Pak J Med Sci.* July-August 2017; 33(4): 943-947.
- 4 Miller LE, Razavi MK, Lal BK. Suprarenal versus infrarenal stent graft fixation on renal complications after endovascular aneurysm repair. *J Vasc Surg.* May 2015;61(5):1340-9.e1.
- 5 Chaikof E, Dalman R, Eskandari M, et al. The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm. *J Vasc Surg.* Jan. 2018;67(1)2-77.

Indications

The EndurantTM II/EndurantTM 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-FXTM EndoAnchorTM 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 $\leq 60^\circ$
 - 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

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.

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