Medtronic

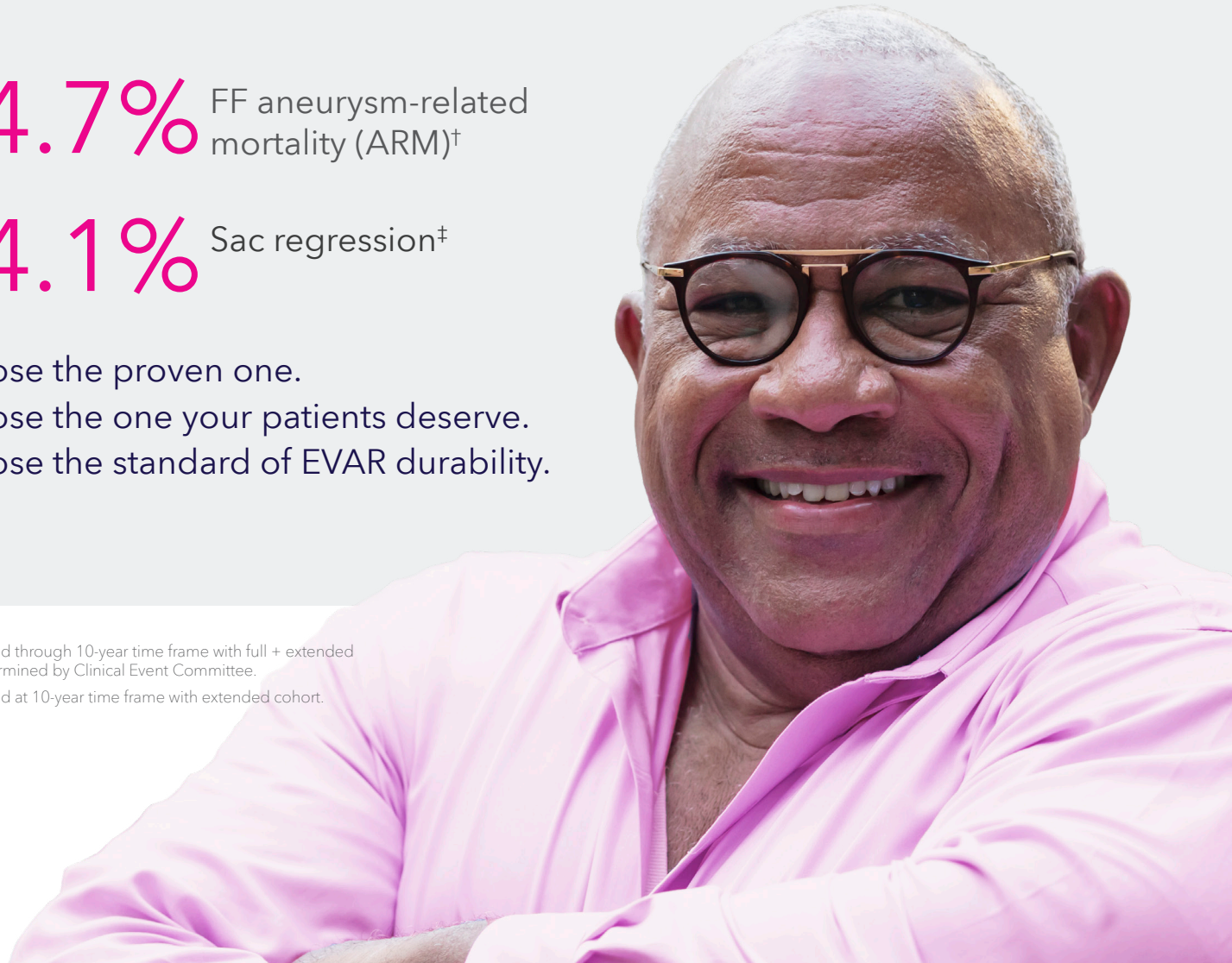
# The only one.[1]

**Endurant™ AAA stent graft system**
The first and only EVAR system with a decade of global registry outcomes.[1]

**94.7%** FF aneurysm-related mortality (ARM)†

**64.1%** Sac regression‡

Choose the proven one.
Choose the one your patients deserve.
Choose the standard of EVAR durability.



†Data reported through 10-year time frame with full + extended cohort, determined by Clinical Event Committee.

‡Data reported at 10-year time frame with extended cohort.

The Endurant system was designed with all the critical features to address sac regression and ensure durability. For that reason, Medtronic had the confidence to invest into a 10-year prospective global registry.

| 10-year global registry outcomes[1] | Medtronic | Gore | Cook | Terumo | Endologix |
|---|---|---|---|---|---|
| FF aneurysm-related mortality[†] | 94.7% | *Unavailable* | *Unavailable* | *Unavailable* | *Unavailable* |
| FF aneurysm-related reinterventions[‡§] | 70.3% | *Unavailable* | *Unavailable* | *Unavailable* | *Unavailable* |
| Sac regression[Ω] | 64.1% (107/167) | *Unavailable* | *Unavailable* | *Unavailable* | *Unavailable* |
| Type 1a endoleak[Ω] | 4.7% (8/172) | *Unavailable* | *Unavailable* | *Unavailable* | *Unavailable* |
| Migration[Ω] | 1.3% (1/77) | *Unavailable* | *Unavailable* | *Unavailable* | *Unavailable* |

## 21 countries, 49 centers, 390 patients[1,2]

[†]Data reported through 10-year time frame with full + extended cohort, determined by Clinical Event Committee.
[‡]Data reported through 10-year time frame with full + extended cohort.
[§]Aneurysm-related reinterventions are defined as all the secondary endovascular procedures (scheduled and unscheduled), secondary vascular procedures and conversions to open repair.
[Ω]Data reported at 10-year time frame with extended cohort.
[1] Verhagen, et al. The ENGAGE Registry: Ten-Year Outcomes with the Endurant Stent Graft for Endovascular Abdominal Aortic Aneurysm Repair. Presented at: Charing Cross 2023 International Symposium; April 26, 2023; London, UK.
[2] ENGAGE 10-year data. Data on file at Medtronic as of April 2023.

**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.

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