ENDURANT™/ENDURANT-II™ STENT GRAFT

Indications: The Endurant™/Endurant-II™ stent grafts are indicated for the endovascular treatment of infrarenal abdominal aortic or aortic aneurysms. They may be utilized in concert with the Heli-FX EndoAnchor System when augmented radial fixation and/or sealing is required in the treatment of infrarenal aortic aneurysms with short (3 cm or less) juxtarenal necks. The Endurant/Stent Graft System aorta-to-side (ASA) stent grafts are indicated for the endovascular treatment of infrarenal abdominal aortic or aortic aneurysms whose necks have a juxtarenal length of 10 mm or less. The Heli-FX EndoAnchor System is indicated for use with the Endurant™/Endurant-II™ Stent Graft System for use in patients with the following characteristics:

- Adequate aortic or renal access that is compatible with vascular access device, devices, or accessories
- Physical access length:
  • ≥ 20 cm or
  • ≥ 4 mm and ≥ 10 cm when used in conjunction with the Heli-FX EndoAnchor System (flexed 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 length of 10 cm or less
- Dual diameters with a range of 10 mm
- Morphology suitable for aneurysm repair

Contraindications: The Endurant Stent Graft System is contraindicated in patients who have a condition that threatens to infect the graft. Patients with lesions sensitive or allergic to the device materials.

Warnings and Precautions: The Endurant I/Endurant II 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 performance of the implanted endovascular stent graft. Patients with specific clinical findings, (e.g., endoleaks, enlarging aneurysmal changes in the structure or position of the endovascular graft, or less than the recommended number of EndoAnchors when used short ≤ 3 cm; and ≥ 4 mm and ≥ 10 cm. Please refer to the overall follow-up procedures in the first reference. Specific patient issues and patient follow-up guidelines are discussed in the product Instructions for Use.
- Patients experiencing reduced blood flow through the graft limb, aneurysm expansion, and persistent endoleak may be required to undergo secondary interventions or surgical procedures.
- The Endurant I/Endurant II Stent Graft System is not recommended for use in patients unable to undergo or who will not comply with the necessary preoperative and postoperative imaging and evaluation studies as described in the Instructions for Use.
- Renal complications may occur. It is possible that a decrease in renal blood flow and kidney function or failure may result. Use of endo-implanted stent graft. The risk of aneurysm rupture along the edge of the stent graft should be identified immediately below the most proximal renal or ureteral arteriovenous fistula.
- Studies indicate that the danger of micro-embolization increases with increased duration of stent deployment.
- The safety and effectiveness of the Endurant I/Endurant II Stent Graft System has not been evaluated in patients with renal insufficiency or kidney failure.

MRI Safety and Compatibility: From time-to-time it has been determined that the Endurant™/Endurant-II™ Stent Graft System is MR Conditional. It can be scanned safely in 1.5T and 3T MRI 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):

- Aneurysm expansion
- Endoleak 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., depression, dementia, seizure, incontinence, injury, hematoma, infection, venom, cellulitis)
- Renal complications and subsequent attendant problems (e.g., lymph fistula);
- Impotence;
- Infection of the aneurysm, device access site, including abscess;
- Femoral-femoral artery thrombosis, fistula, incontinence, hematuria, infection);
- Hepatic genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, transient or permanent ischemia or infarction; endoleak; fever and localized inflammation;
- Stent graft damage, modelling balloon damage);
- Embolization (micro and macro) with subsequent attendant problems (e.g., ileus, transient ischemia, infarction, necrosis);
- Cardiac complications (e.g., myocardial infarction, coronary artery thrombosis, pericardial effusion, tamponade, myocardial rupture and death; arterial or venous thrombosis and/or embolization, myocardial infarction, coronary artery thrombosis, pericardial effusion, tamponade, myocardial rupture and death; atrial fibrillation, ventricular fibrillation, ventricular tachycardia, cardiogenic shock);
- Stroke;
- Peripheral ischemia or infarction;
- Systemic complications (e.g., fever, systemic inflammation, disseminated intravascular coagulation);
- Wound complications and subsequent attendant problems (e.g., dehiscence, necrosis, cellulitis, infection, abscess, hematoma;
- Renal impairment;
- Venous thrombosis and/or embolization;
- Pulmonary complications (e.g., pulmonary embolism, pneumothorax, pneumonia);
- Hypoxemia, respiratory failure;
- Sepsis, septic shock;
- Shock;
- Death;
TAILOR SEAL AND FIXATION IN EVAR†

- The Heli-FX™ EndoAnchor™ system designed to enhance the outcomes and durability of EVAR
- Helical EndoAnchor™ implants designed to provide independent transmural fixation and the stability of a surgical anastomosis‡
- Enhances the inherent sealing and fixation mechanisms of approved endografts
- Steerable guide for precise and accurate EndoAnchor™ implant placement

Motorized, intuitive controls for precise placement of EndoAnchor™ implants
- Excellent system and EndoAnchor™ implant radiopacity
- Compatible with the Cook Zenith™, Gore Excluder™*, Jotec E-vita abdominal, Medtronic AneuRx™, Medtronic Endurant™, and Medtronic Talent™ endografts

Recommended Heli-FX™ Guide Selection

<table>
<thead>
<tr>
<th>Aortic Inner Diameter</th>
<th>Deflected Tip Reach</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-28mm</td>
<td>22mm</td>
</tr>
<tr>
<td>28-32mm</td>
<td>28mm</td>
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</tbody>
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Ordering Information

<table>
<thead>
<tr>
<th>AAA Components</th>
<th>Catalog Number</th>
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</thead>
<tbody>
<tr>
<td>Heli-FX™ Guide, 22mm</td>
<td>SG-64</td>
</tr>
<tr>
<td>Heli-FX™ Guide, 28mm</td>
<td>HG-16-62-28</td>
</tr>
<tr>
<td>Heli-FX™ Applier and EndoAnchor™ Cassette (contains 10 EndoAnchor™ implants)</td>
<td>SA-85</td>
</tr>
<tr>
<td>Ancillary EndoAnchor™ Cassette (contains 4 EndoAnchor™ implants)</td>
<td>EC-05</td>
</tr>
</tbody>
</table>

All products may not be available in all geographic regions. Contact your local Medtronic representative for more information.

EXPANDING PATIENT CARE OPTIONS

THE FIRST APPROVED OFF-THE-SHELF SHORT NECK EVAR SOLUTION

Indicated for patients with necks <10mm length and ≥4mm and ≤60° infrarenal angle

Case example:
- Prophylactic use of Heli-FX™ EndoAnchor™ system with Endurant™ AAA stent graft in complex proximal neck anatomy
- No type Ia endoleak at 1-year post op†

Technical Specifications

EndoAnchor™ Implant‡
- 3.0mm diameter x 4.5m length
- 0.5mm diameter MP35N-LT wire thickness
- Atraumatic conical tip (similar to SH1 needle)
- Crossbar feature prevents over-penetration

Heli-FX™ Guide
- Two available tip deflection lengths
- Unique radiopaque tip markers for 3D orientation
- 16F OD
- 62cm working length
- 0.035" guidewire compatible

Heli-FX™ Applier
- Battery-operated delivery device with visual and audio feedback
- One-touch auto loading of EndoAnchor™ implants
- Two-stage EndoAnchor™ implant deployment allows placement confirmation and repositioning
- 86cm working length

†Bench Test Data on file at Medtronic. Data not indicative of clinical performance.