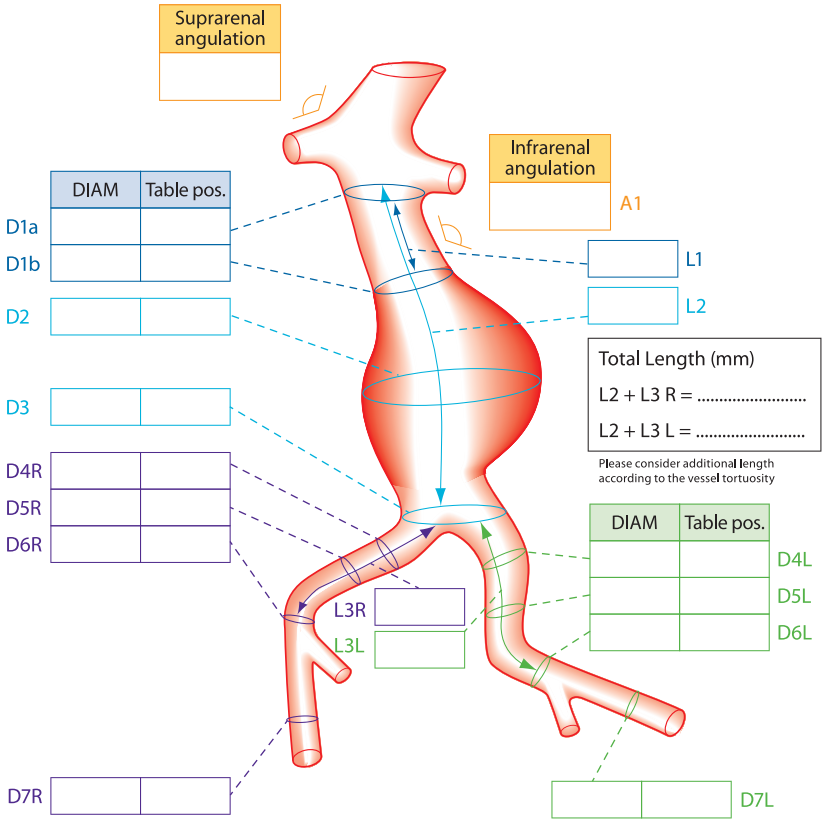
Endurant™ II/IIs
AAA Stent Graft System

FOR USE BY PHYSICIAN ONLY

Date of CT Study:	Patient ID:	Patient DOB: / /
CT Slice Thickness:	Implanting Physician:	Hospital Name:
	Evaluation Date:	Procedure Date:



SMA patent?
☐ Yes ☐ No

Lowest renal artery
☐ Right ☐ Left

Disease Progression Risk
Proximal neck:
☐ **S**hort (L1)
☐ **W**ide (D1a)
☐ **A**ngled (A1)
☐ **C**onical (% change D1/L1)

Proximal neck thrombus
☐ Nil ☐ Mild
☐ Moderate ☐ Severe

Proximal neck calcification
☐ Nil ☐ Mild
☐ Moderate ☐ Severe

Consider EndoAnchors?
☐ Yes ☐ No

Lumbar patent?
☐ Yes ☐ No

IMA patent?
☐ Yes ☐ No

Right iliac calcification
☐ Nil ☐ Mild
☐ Moderate ☐ Severe

Left iliac calcification
☐ Nil ☐ Mild
☐ Moderate ☐ Severe

Coil hypo
☐ Right ☐ Left
☐ No

Proposed bifur side
☐ Right ☐ Left

QTY	Product Code	QTY	Product Code

Please reference appropriate product *Instructions for Use* for a more detailed list of indications, warnings, precautions and potential adverse events and sizing guidelines.

Drawing

Comments

Physician Signature: _____

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PRODUCT CODES

ENDURANT II BIFURCATIONS

Product Code	Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	Catheter Outer Diameter (Fr)
ETBF	23	13	C	124	E	18
ETBF	23	13	C	145	E	18
ETBF	23	13	C	166	E	18
ETBF	23	16	C	124	E	18
ETBF	23	16	C	145	E	18
ETBF	23	16	C	166	E	18
ETBF	25	13	C	124	E	18
ETBF	25	13	C	145	E	18
ETBF	25	13	C	166	E	18
ETBF	25	16	C	124	E	18
ETBF	25	16	C	145	E	18
ETBF	25	16	C	166	E	18
ETBF	28	13	C	124	E	18
ETBF	28	13	C	145	E	18
ETBF	28	13	C	166	E	18
ETBF	28	16	C	124	E	18
ETBF	28	16	C	145	E	18
ETBF	28	16	C	166	E	18
ETBF	28	20	C	124	E	18
ETBF	28	20	C	145	E	18
ETBF	28	20	C	166	E	18
ETBF	32	16	C	124	E	20
ETBF	32	16	C	145	E	20
ETBF	32	16	C	166	E	20
ETBF	32	20	C	124	E	20
ETBF	32	20	C	145	E	20
ETBF	32	20	C	166	E	20
ETBF	36	16	C	145	E	20
ETBF	36	16	C	166	E	20
ETBF	36	20	C	145	E	20
ETBF	36	20	C	166	E	20

ENDURANT IIs BIFURCATIONS

Product Code	Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	Catheter Outer Diameter (Fr)
ESBF	23	14	C	103	E	18
ESBF	25	14	C	103	E	18
ESBF	28	14	C	103	E	18
ESBF	32	14	C	103	E	20
ESBF	36	14	C	103	E	20

LIMBS*

Product Code	Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	Catheter Outer Diameter (Fr)	Total Contralateral Covered Length with EII/EIIs Bifurcated†	Total Ipsilateral Covered Length with EIIs Bifurcated**
ETLW	16	10	C	82	E	14	136	155
ETLW	16	10	C	93	E	14	147	166
ETLW	16	10	C	124	E	14	178	177–197
ETLW	16	10	C	156	E	16	210	209–229
ETLW	16	10	C	199	E	16	253	252–272
ETLW	16	13	C	82	E	14	136	155
ETLW	16	13	C	93	E	14	147	166
ETLW	16	13	C	124	E	14	178	177–197
ETLW	16	13	C	156	E	16	210	209–229
ETLW	16	13	C	199	E	16	253	252–272
ETLW	16	16	C	82	E	14	136	135–155
ETLW	16	16	C	93	E	14	147	146–166
ETLW	16	16	C	124	E	14	178	177–197
ETLW	16	16	C	156	E	16	210	209–229
ETLW	16	16	C	199	E	16	253	252–272
ETLW	16	20	C	82	E	16	136	155
ETLW	16	20	C	93	E	16	147	166
ETLW	16	20	C	124	E	16	178	177–197
ETLW	16	20	C	156	E	16	210	209–229
ETLW	16	20	C	199	E	16	253	252–272
ETLW	16	24	C	82	E	16	136	155
ETLW	16	24	C	93	E	16	147	166
ETLW	16	24	C	124	E	16	178	177–197
ETLW	16	24	C	156	E	16	210	209–229
ETLW	16	24	C	199	E	16	253	252–272
ETLW	16	28	C	82	E	16	136	155
ETLW	16	28	C	93	E	16	147	166
ETLW	16	28	C	124	E	16	178	177–197
ETLW	16	28	C	156	E	16	210	209–229
ETLW	16	28	C	199	E	16	253	252–272

*The limb mates with the AUI stent graft on the ipsilateral side.

†These calculations assume the minimum 30 mm overlap between the bifurcated stent graft and the contralateral iliac limb per the Endurant II Stent Graft System Instructions For Use. When using the 124 mm length bifurcated stent graft, subtract 10 mm from Total Contralateral Covered Length with Bifurcated.

**The 3-5 stent overlap is available only with select limbs. Please refer to the Instructions For Use for more information.

AORTIC EXTENSIONS

Product Code	Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	Catheter Outer Diameter (Fr)
ETCF	23	23	C	49	E	18
ETCF	25	25	C	49	E	18
ETCF	28	28	C	49	E	18
ETCF	32	32	C	49	E	20
ETCF	36	36	C	49	E	20
ETTF	23	23	C	70	E	18
ETTF	25	25	C	70	E	18
ETTF	28	28	C	70	E	18
ETTF	32	32	C	70	E	20
ETTF	36	36	C	70	E	20

ILIAC EXTENSIONS

Product Code	Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	Catheter Outer Diameter (Fr)
ETEW	10	10	C	82	E	14
ETEW	13	13	C	82	E	14
ETEW	20	20	C	82	E	16
ETEW	24	24	C	82	E	16
ETEW	28	28	C	82	E	18

AUI

Product Code	Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	Catheter Outer Diameter (Fr)
ETUF	23	14	C	102	E	18
ETUF	25	14	C	102	E	18
ETUF	28	14	C	102	E	18
ETUF	32	14	C	102	E	20
ETUF	36	14	C	102	E	20

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 system when used in short (≥ 4 mm and < 10 mm) proximal necks) 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; 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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