

**PAGINA 0**

**CREATA PENTRU A  
PUTEA SEMNA  
ELECTRONIC  
DOCUMENTUL**



REQUEST MORE INFORMATION  
CONTACT US

RELATED PAGES

- Clinical Outcomes
- Use in EVAR Procedures
- Short Neck Indication with the Helix FX System
- Aneurysm Sac Regression

RELATED PRODUCTS

- Aortic Stent Graft Products
- Cardiovascular Products

AORTIC CATALOGUE

Choose from a complete portfolio of market-leading aortic vascular therapies to treat aneurysm disease.

OVERVIEW

Choose the AAA proven solution as varied as your patients. The Endurant™ II system family of products provides the standard of care with a legacy of clinical success for the treatment of abdominal aortic aneurysm (AAA). For the past 5 years, the Endurant II stent graft system has been used in 1 out of 2 EVAR cases\*. The Endurant II stent graft has deep clinical experience and favorable clinical outcomes designed to treat both straightforward and challenging anatomy.

INDICATIONS

All indications related to Endurant II/IIIS Stent Graft System are not approved globally. Please check your local regulatory approval status. Refer to the complete instructions for use manual of the Endurant II/IIIS stent graft system for the indications approved in your geography.

- See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential
- iliac distal fixation length of 15 mm
  - iliac diameters with a range of 8 to 25 mm
  - morphology suitable for aneurysm repair
  - one of the following:
    - aneurysm diameter >5 cm
    - aneurysm diameter of 4 to 5 cm, which has also increased in size by 0.5 cm in the last 6 months
    - aneurysm that is at least 1.5 times the diameter of the normal infrarenal aorta

In addition, for treatment of infrarenal abdominal aortic or aortoiliac aneurysms, the following patient characteristics apply:

- aortic neck diameters with a range of 19 to 32 mm
- proximal neck length of ≥10 mm or 24 mm and <10 mm when used in conjunction with the Helix FX EndoAnchor system, with insignificant calcification, or insignificant thrombus with ≤60° infrarenal and ≤45° suprarenal angulation and a vessel diameter approximately 10% to 20% smaller than the labelled Endurant II/Endurant IIIS stent graft diameter
- proximal neck length of ≥15 mm with insignificant calcification, or insignificant thrombus with ≤75° infrarenal and ≤60° suprarenal angulation and a vessel diameter approximately 10% to 20% smaller than the labelled Endurant II/Endurant IIIS stent graft diameter

In addition, for treatment of juxtarenal abdominal aortic or aortoiliac aneurysms with the parallel graft technique, the following patient characteristics apply:

- aortic neck diameters with a range of 19 mm to 30 mm
- infrarenal proximal neck length of 82 mm and total available proximal seal length ≥15 mm with a balloon expandable covered stent deployed in a parallel graft technique in one or two renal arteries and with insignificant calcification, or insignificant thrombus with ≤60° infrarenal, ≤45° suprarenal, and ≤45° suprasuprarenal mesenteric artery angulation (supraSMA angulation) and an aortic diameter approximately 20% to 30% smaller than the labelled Endurant II/Endurant IIIS stent graft diameter
- adequate brachial or axillary access that is compatible with vascular access techniques, devices, or accessories
- sufficient renal fixation length
- renal take off angulation <90° relative to the aortic centerline

Note: The angle between the aortic and renal artery blood lumen centerlines is the renal take off angulation. An angle of <90° is associated with a downward pointed renal artery relative to the trajectory of the aortic centerline.

ENDURANT II/IIIS STENT GRAFT PRODUCT FEATURES

ENDURANT II FAMILY OF PRODUCTS

- The Endurant II family:
- Includes Endurant II, Endurant II AII and Endurant IIIS stent grafts
  - Designed to meet a wide range of patient anatomies
  - Utilizes the Endurant II delivery system, which allows for accurate placement and controlled deployment



- Endurant IIIS stent graft is a three piece system that:
- Leverages the proven design of the leading Endurant II abdominal stent graft
  - Expands anatomical customization options
  - Offers a shorter ipsilateral leg for more flexible, targeted limb placement
  - Features equal leg diameters to allow limbs to be used on either side
  - Utilizes the existing delivery system allowing accurate placement and controlled deployment

- The Endurant IIIS stent graft:
- Provides up to a 20% reduction in distal diameter compared to select Endurant II bifurcations
  - Enables in situ sizing with select ipsilateral limbs, allowing a 3-5 stent overlap for adjustment during case
  - Allows easier pre case planning to simplify sizing

ENDURANT II STENT GRAFT FEATURES\*

- Flexibility and conformability** Designed to conform to the natural tortuosity of the vessel. Low profile, hydrophilic delivery coating enhances access and trackability.
- Accurate placement and controlled deployment** Flexible, link resistant delivery system facilitates stent graft delivery. Tip captures for precise positioning adjustments, including adjustment of placement proximally or distally.
- Optimal seal and fixation** M shaped proximal stents provide seal apposition and minimize in folding. Suprarenal stent anchor pins provide secure fixation.
- Durability and strength** High density, multifilament polyester graft material provides lower porosity for resistance against aneurysm sac growth.



DELIVERY AND DEPLOYMENT

The Endurant II delivery system helps ensure precise control and accurate placement at every stage of deployment:

- 100% PEVAR delivery and deployment success†
- 99.3% delivery and deployment success‡

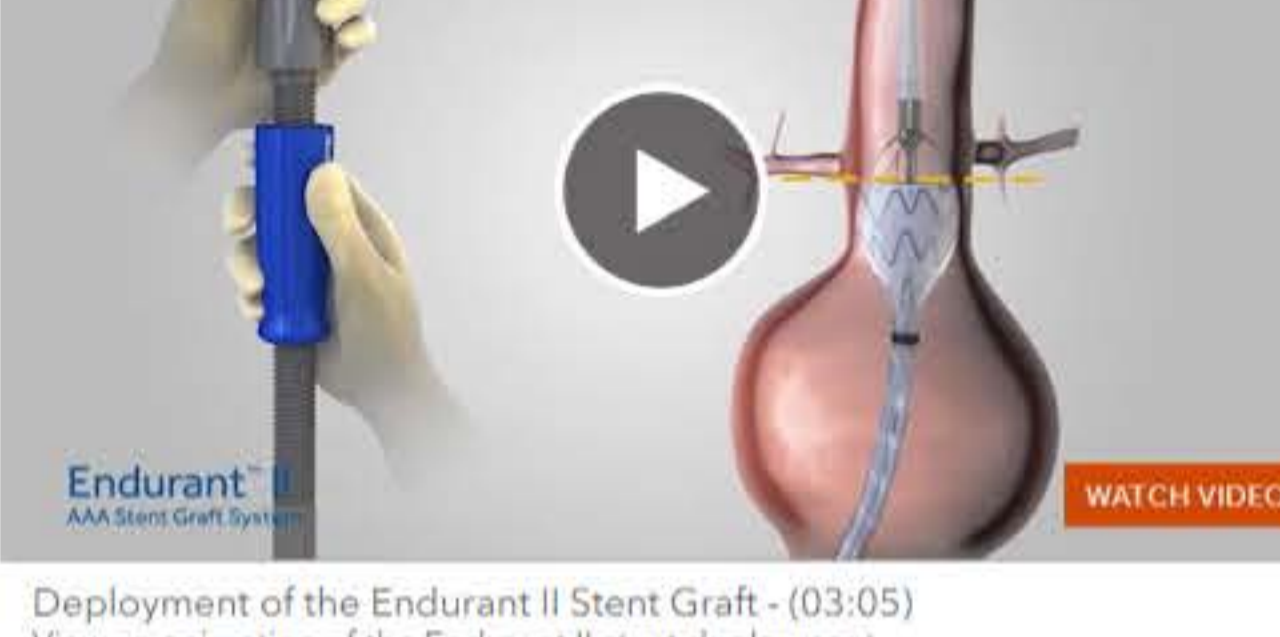
Tip capture delivery allows precise adjustment of position, proximally or distally, even after deployment of three stent legs. Control the release of the suprarenal stent and anchor pins with the back-end thumb wheel.

Endurant II Delivery System Controlled Deployment

Deployment, capture, and release of the Endurant II stent.



Deployment of the Endurant II Stent Graft - (06:34)  
View an animation of the Endurant II stent graft deployment.



Deployment of the Endurant II Stent Graft - (03:05)  
View an animation of the Endurant II stent deployment.

\*Data on file at Medtronic.  
†Based on data on file at Medtronic. Bench test data may not be indicative of clinical performance.  
‡Data on file from the 178-day non-patients from the ENGAGE Post-Approval Study (PAS).  
§Delivery access = successful vascular access and delivery of the device to the intended anatomical treatment site. Deployment success = successful deployment of the device in the intended site and the successful removal of the delivery system. Endurant™ US Case Study: Mid-term outcomes of the 50 regulatory trial of the Endurant™ stent graft system. J Vasc Med Biol. 2011; 23(4):408.

MANUALS AND TECHNICAL GUIDES

Instructions for Use  
Find this technical manual in the Medtronic Manual Library or in the product labeling supplied with each device.

MODEL SPECIFICATIONS

Endurant II/IIIS System Sizing Sheet (01) (U)  
Use this tool to plan case specifics such as sizing and placement. 2954B

ORDERING INFORMATION: ENDURANT II BIFURCATED DEVICES

Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	
ETBF	23	13	C	124	EE
ETBF	23	13	C	145	EE
ETBF	23	13	C	166	EE
ETBF	23	16	C	124	EE
ETBF	23	16	C	145	EE
ETBF	23	16	C	166	EE
ETBF	25	13	C	124	EE
ETBF	25	13	C	145	EE
ETBF	25	13	C	166	EE
ETBF	25	16	C	124	EE
ETBF	25	16	C	145	EE
ETBF	25	16	C	166	EE
ETBF	28	13	C	124	EE
ETBF	28	13	C	145	EE
ETBF	28	13	C	166	EE
ETBF	28	16	C	124	EE
ETBF	28	16	C	145	EE
ETBF	28	16	C	166	EE
ETBF	28	20	C	124	EE
ETBF	28	20	C	145	EE
ETBF	28	20	C	166	EE
ETBF	32	16	C	124	EE
ETBF	32	16	C	145	EE
ETBF	32	16	C	166	EE
ETBF	32	20	C	124	EE
ETBF	32	20	C	145	EE
ETBF	32	20	C	166	EE
ETBF	36	16	C	145	EE
ETBF	36	16	C	166	EE
ETBF	36	20	C	145	EE
ETBF	36	20	C	166	EE

ORDERING INFORMATION: ENDURANT IIIS BIFURCATED DEVICES

Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	
ESBF	23	14	C	103	EE
ESBF	25	14	C	103	EE
ESBF	28	14	C	103	EE
ESBF	32	14	C	103	EE
ESBF	36	14	C	103	EE

ORDERING INFORMATION: LIMBS\*

Distal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	
ETLW	16	10	C	82	EE
ETLW	16	10	C	93	EE
ETLW	16	10	C	124	EE
ETLW	16	10	C	156	EE
ETLW	16	10	C	199	EE
ETLW	16	13	C	82	EE
ETLW	16	13	C	93	EE
ETLW	16	13	C	124	EE
ETLW	16	13	C	156	EE
ETLW	16	13	C	199	EE
ETLW	16	16	C	82	EE
ETLW	16	16	C	93	EE
ETLW	16	16	C	124	EE
ETLW	16	16	C	156	EE
ETLW	16	16	C	199	EE
ETLW	16	20	C	82	EE
ETLW	16	20	C	93	EE
ETLW	16	20	C	124	EE
ETLW	16	20	C	156	EE
ETLW	16	20	C	199	EE
ETLW	16	24	C	82	EE
ETLW	16	24	C	93	EE
ETLW	16	24	C	124	EE
ETLW	16	24	C	156	EE
ETLW	16	24	C	199	EE
ETLW	16	28	C	82	EE
ETLW	16	28	C	93	EE
ETLW	16	28	C	124	EE
ETLW	16	28	C	156	EE
ETLW	16	28	C	199	EE

\* The limb sides with the AII stent graft on the labeled side.  
† These calculations assume the minimum 20 mm overlap between the bifurcated stent graft and the contralateral iliac limb per the Endurant IIIS Stent Graft System Instructions For Use. When using the 124 mm length bifurcated stent grafts, add a 15 mm from Total Contralateral Covered Length with bifurcated.  
‡ The 15.6 cm overlap is available only with select limbs. Please refer to the instructions for use for more information.

ORDERING INFORMATION: AORTIC EXTENSIONS

Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	
ETCF	23	23	C	49	EE
ETCF	25	25	C	49	EE
ETCF	28	28	C	49	EE
ETCF	32	32	C	49	EE
ETCF	36	36	C	49	EE

ORDERING INFORMATION: ABDOMINAL TUBES

Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	
ETTF	23	23	C	70	EE
ETTF	25	25	C	70	EE
ETTF	28	28	C	70	EE
ETTF	32	32	C	70	EE
ETTF	36	36	C	70	EE

ORDERING INFORMATION: ENDURANT II AII

Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	
ETUF	23	14	C	102	EE
ETUF	25	14	C	102	EE
ETUF	28	14	C	102	EE
ETUF	32	14	C	102	EE
ETUF	36	14	C	102	EE

ORDERING INFORMATION: ILIAC EXTENSIONS

Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	
ETEW	10	10	C	82	EE
ETEW	13	13	C	82	EE
ETEW	20	20	C	82	EE
ETEW	24	24	C	82	EE
ETEW	28	28	C	82	EE



REQUEST MORE INFORMATION  
CONTACT US OR

- RELATED PAGES
- Clinical Outcomes
  - Use in ENEVAR Procedures
  - Short Neck Indication with the Helix FX System
  - Aneurysm Sac Regression

- RELATED PRODUCTS
- Aortic Stent Graft Products
  - Cardiovascular Products

### OVERVIEW

Choose the AAA proven solution as varied as your patients. The Endurant™ II system family of products provides the standard of care with a legacy of clinical success for the treatment of abdominal aortic aneurysm (AAA). For the past 5 years, the Endurant II stent graft system has been used in 1 out of 2 EVAR cases.\* The Endurant II stent graft has deep clinical experience and favorable clinical outcomes designed to treat both straightforward and challenging anatomy.

**Indications, Safety, and Warnings**

**INDICATIONS**

All indications related to Endurant II/IIIS Stent Graft System are not approved globally. Please check your local regulatory approval status. Refer to the complete instructions for use manual of the Endurant II/IIIS stent graft system for the indications approved in your geography.

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential

- iliac distal fixation length of ≥ 15 mm
- iliac diameters with a range of 8 to 25 mm
- morphology suitable for aneurysm repair
- one of the following:
  - aneurysm diameter > 5 cm
  - aneurysm diameter of 4 to 5 cm, which has also increased in size by 0.5 cm in the last 6 months
  - aneurysm that is at least 1.5 times the diameter of the normal infrarenal aorta

In addition, for treatment of infrarenal abdominal aortic or aortiliac aneurysms, the following patient characteristics apply:

- aortic neck diameters with a range of 17 to 32 mm
- proximal neck length of ≥ 10 mm or 24 mm and < 10 mm when used in conjunction with the Helix FX EndoAnchor system, with insignificant calcification, or insignificant thrombus with ≤ 60° infrarenal, ≤ 45° suprarenal, and ≤ 45° suprarenal mesenteric artery angulation (supraSMA, angulation) and a vessel diameter approximately 10% to 20% smaller than the labelled Endurant II/Endurant IIIS stent graft diameter
- proximal neck length of ≥ 15 mm with insignificant calcification, or insignificant thrombus with ≤ 75° infrarenal and ≤ 60° suprarenal angulation and a vessel diameter approximately 10% to 20% smaller than the labelled Endurant II/Endurant IIIS stent graft diameter

In addition, for treatment of juxtarenal abdominal aortic or aortiliac aneurysms with the parallel graft technique, the following patient characteristics apply:

- aortic neck diameters with a range of 19 mm to 30 mm
- infrarenal proximal neck length of ≥ 2 mm and total available proximal seal length ≥ 5 mm with a balloon expandable covered stent deployed in a parallel graft technique in one or two renal arteries and with insignificant calcification, or insignificant thrombus with ≤ 60° infrarenal, ≤ 45° suprarenal, and ≤ 45° suprarenal mesenteric artery angulation (supraSMA, angulation) and an aortic diameter approximately 20% to 30% smaller than the labelled Endurant II/Endurant IIIS stent graft diameter
- adequate brachial or axillary access that is compatible with vascular access techniques, devices, or accessories
- sufficient renal fixation length
- renal take off angulation < 90° relative to the aortic centerline

**Notes:** The angle between the aortic and renal artery blood lumen centerlines is the renal take off angulation. An angle of < 90° is associated with a downward pointed renal artery relative to the trajectory of the aortic centerline.

### AORTIC CATALOGUE

Choose from a complete portfolio of market-leading aortic vascular therapies to treat aneurysm disease.

### ENDURANT II/IIIS STENT GRAFT PRODUCT FEATURES

#### ENDURANT II FAMILY OF PRODUCTS

The Endurant II family:

- Includes Endurant II, Endurant II ALI, and Endurant IIIS stent grafts
- Designed to meet a wide range of patient anatomies
- Utilizes the Endurant II delivery system, which allows for accurate placement and controlled deployment



Endurant IIIS stent graft is a three-piece system that:

- Leverages the proven design of the leading Endurant II abdominal stent graft
- Expands anatomical customization options
- Offers a shorter ipsilateral leg for more flexible, targeted limb placement
- Features equal leg diameters to allow limbs to be used on either side
- Utilizes the existing delivery system allowing accurate placement and controlled deployment

The Endurant IIIS stent graft:

- Provides up to a 20% reduction in distal diameter compared to select Endurant IIIs stent grafts
- Enables in situ sizing with select ipsilateral limbs, allowing a 3-5 stent overlap for adjustment during case
- Allows easier pre-case planning to simplify sizing

#### ENDURANT II STENT GRAFT FEATURES<sup>1</sup>

- Flexibility and conformability.** Designed to conform to the natural tortuosity of the vessel. Low profile, hydrophilic delivery coating enhances access and trackability.
- Accurate placement and controlled deployment.** Flexible, link-resistant delivery system facilitates stent graft delivery. Tip capture for precise positioning adjustments, including adjustment of placement proximally or distally.
- Optimal seal and fixation.** M shaped proximal stents provide wall apposition and minimize in-folding. Suprarenal stent anchor pins provide secure fixation.
- Durability and strength.** High density, multifilament polyester graft material provides lower porosity for resistance against aneurysm sac growth.



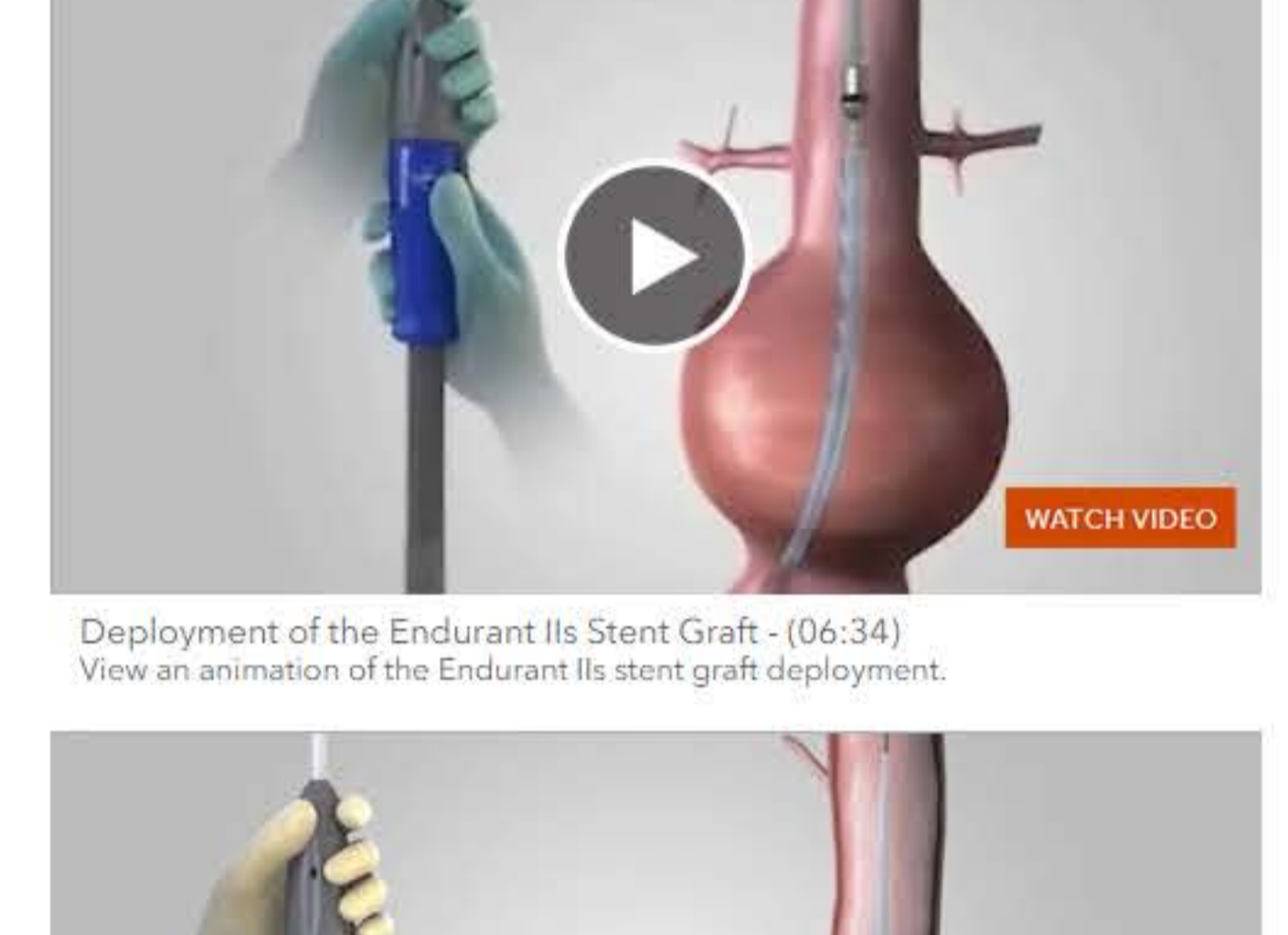
#### DELIVERY AND DEPLOYMENT

The Endurant II delivery system helps ensure precise control and accurate placement at every stage of deployment.

- 100% PEVAR delivery and deployment success<sup>2</sup>
- 93.3% delivery and deployment success<sup>3</sup>

Tip capture delivery allows precise adjustment of position, proximally or distally, even after deployment of three stent rings. Control the release of the suprarenal stent and anchor pins with the back and thumb wheel.

**Endurant II Delivery System Controlled Deployment**  
Deployment, capture, and release of the Endurant II stent.



Deployment of the Endurant IIIS Stent Graft - (06:34)  
View an animation of the Endurant IIIS stent graft deployment.



Deployment of the Endurant II Stent Graft - (03:05)  
View an animation of the Endurant II stent deployment.

<sup>1</sup>Data on file at Medtronic.  
<sup>2</sup>Bench test data on file at Medtronic. Bench test data may not be indicative of clinical performance.  
<sup>3</sup>Data on file from the 178-de novo patients from the ENGAGE Post-Approval Study (PAS).

<sup>4</sup>Delivery success = successful vascular access and delivery of the device to the intended anatomical location; Deployment success = successful deployment of the device in the intended site and the successful removal of the delivery system. Endurant™ US CE trial; Makarum M. One-year outcomes of the US regulatory trial of the Endurant™ stent graft system. J Vasc Surg. 2011;54:601-608.

### MANUALS AND TECHNICAL GUIDES

**Instructions for Use**  
Find this technical manual in the Medtronic Manual Library or in the product labeling supplied with each device.

### MODEL SPECIFICATIONS

Endurant II/IIIS System Sizing Sheet [Use this tool to plan case specifics such as sizing and placement.](#)  
39593

#### ORDERING INFORMATION: ENDURANT II BIFURCATED DEVICES

Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	Catheter Outer Diameter (F)
23	13	C	124	EE	18
23	13	C	145	EE	18
23	13	C	166	EE	18
23	16	C	124	EE	18
23	16	C	145	EE	18
23	16	C	166	EE	18
25	13	C	124	EE	18
25	13	C	145	EE	18
25	13	C	166	EE	18
25	16	C	124	EE	18
25	16	C	145	EE	18
25	16	C	166	EE	18
28	13	C	124	EE	18
28	13	C	145	EE	18
28	13	C	166	EE	18
28	16	C	124	EE	18
28	16	C	145	EE	18
28	16	C	166	EE	18
28	20	C	124	EE	18
28	20	C	145	EE	18
28	20	C	166	EE	18
32	16	C	124	EE	20
32	16	G	145	EE	20
32	16	C	166	EE	20
32	20	C	124	EE	20
32	20	C	145	EE	20
32	20	G	166	EE	20
36	16	C	145	EE	20
36	16	C	166	EE	20
36	20	C	145	EE	20
36	20	C	166	EE	20

#### ORDERING INFORMATION: ENDURANT IIIS BIFURCATED DEVICES

Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	Catheter Outer Diameter (F)
23	14	C	103	EE	18
25	14	C	103	EE	18
28	14	C	103	EE	18
32	14	C	103	EE	20
36	14	C	103	EE	20

#### ORDERING INFORMATION: LIMBS\*

Distal Design	Total Covered Length (mm)	Delivery System	Catheter Outer Diameter (F)	Total Contralateral Covered Length with Ells/Bifurcated†	Total Ipsilateral Covered Length with Ells/Bifurcated†
C	82	EE	14	136	155
C	93	EE	14	147	166
C	124	EE	14	178	177-197
C	156	EE	16	210	209-229
C	199	EE	16	253	252-272
C	82	EE	14	136	155
C	93	EE	14	147	166
C	124	EE	14	178	177-197
C	156	EE	16	210	209-229
C	199	EE	16	253	252-272
C	82	EE	14	136	155
C	93	EE	14	147	166
C	124	EE	14	178	177-197
C	156	EE	16	210	209-229
C	199	EE	16	253	252-272
C	82	EE	16	136	155
C	93	EE	16	147	166
C	124	EE	16	178	177-197
C	156	EE	16	210	209-229
C	199	EE	16	253	252-272
C	82	EE	16	136	155
C	93	EE	16	147	166
C	124	EE	16	178	177-197
C	156	EE	16	210	209-229
C	199	EE	16	253	252-272

\* The limb sizes with the ALI stent graft on the ipsilateral side.

† These calculations assume the minimum 30 mm overlap between the bifurcated stent graft and the contralateral (see 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 and Ipsilateral Covered Length.

‡ The 3-5 stent overlap is available only with select limbs. Please refer to the instructions for use for more information.

#### ORDERING INFORMATION: AORTIC EXTENSIONS

Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	Catheter Outer Diameter (F)
23	23	C	49	EE	18
25	25	C	49	EE	18
28	28	C	49	EE	18
32	32	C	49	EE	20
36	36	C	49	EE	20

#### ORDERING INFORMATION: ABDOMINAL TUBES

Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	Catheter Outer Diameter (F)
23	23	C	70	EE	18
25	25	C	70	EE	18
28	28	C	70	EE	18
32	32	C	70	EE	20
36	36	C	70	EE	20

#### ORDERING INFORMATION: ENDURANT II ALI

Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	Catheter Outer Diameter (F)
23	14	C	102	EE	18
25	14	C	102	EE	18
28	14	C	102	EE	18
32	14	C	102	EE	20
36	14	C	102	EE	20

#### ORDERING INFORMATION: ILIAC EXTENSIONS

Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	Catheter Outer Diameter (F)
10	10	C	82	EE	14
13	13	C	82	EE	14
20	20	C	82	EE	16
24	24	C	82	EE	16
28	28	C	82	EE	18