

**Medtronic**

Engineering the extraordinary

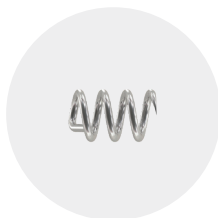
# Aortic product catalog



Endurant™ II/IIIs Stent Graft System



Valiant™ Stent Graft with Captivia™ Delivery System



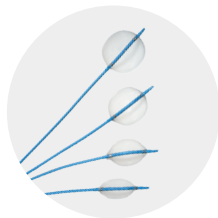
Heli-FX™ EndoAnchor™ System



Steerant™ Super Stiff Guidewire



Sentrant™ Introducer Sheath with Hydrophilic Coating



Reliant™ Stent-Graft Balloon Catheter

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Stent-Graft Balloon Catheter

# Endurant™ II/IIs

## Stent Graft System

### Features†

You can be confident in your outcomes with a design that addresses sac regression.

### Accurate placement & controlled deployment

- Intuitive graft deployment system provides controlled release of the suprarenal stent & anchor pins and offers controlled delivery at the intended target zone with 99.1% delivery and deployment success (ENGAGE PAS<sup>1</sup>)
- Tip capture deployment mechanism allows precise positioning – even after deployment of 3 stent rings– and allows greater control of deployment and landing accuracy

### Continuous seal, fixation & graft comfortability

- M-shaped proximal stents maximize wall apposition & circumferential conformability and minimize in-folding resulting in low Type Ia endoleak rates
- 45° suprarenal stent anchor pins provide secure fixation over time and reduce main migration risk and device movement
- Electropolished nitinol stent maximize circumferential conformability with dynamic continuous seal

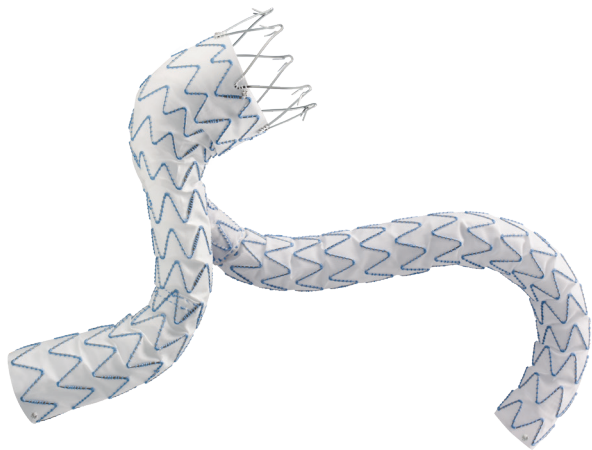
### Durable hemostatic barrier & resistance against type II ELs

- Graft material addresses sac regression provides durable hemostatic barrier and reduced Type II endoleaks
- Multifilament polyester material provides low permeability

† Test data on file at Medtronic. Bench test results may not be indicative of clinical performance.

<sup>1</sup> Endurant Stent Graft System Post Approval Study (ENGAGE PAS), Duke Clinical Research Institute, Last update posted October 29, 2021, <https://classic.clinicaltrials.gov/ct2/show/NCT01379222>

Optimize  
outcomes for  
the broadest  
patient base

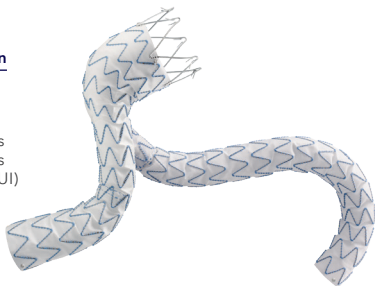


# Endurant™ II/IIs

Stent Graft System

## Endurant™ II/IIs system product code description

<b>ET</b>	<b>B</b>	<b>F</b>	<b>23</b>	<b>13</b>	<b>C</b>	<b>124</b>	<b>EE</b>	<b>18</b>
								Catheter outer diameter
							Delivery system	EE - Endurant™ II system
						Total covered length		
					Distal design	C - Closed web		
				Distal graft diameter				
			Proximal graft diameter					
		Proximal design	F - FreeFlo W - Open web					
		Device configuration	B - Bifurcations L - Limbs E - Iliac extension C - Extensions & cuffs T - Extensions & cuffs U - Aorto-uni-iliac (AUI)					
		Product name	ET - Endurant™ II system ES - Endurant™ IIs system					



## Endurant™ IIs system 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	EE	18
ESBF	25	14	C	103	EE	18
ESBF	28	14	C	103	EE	18
ESBF	32	14	C	103	EE	20
ESBF	36	14	C	103	EE	20



## Endurant™ II system 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	EE	18
ETBF	23	13	C	145	EE	18
ETBF	23	13	C	166	EE	18
ETBF	23	16	C	124	EE	18
ETBF	23	16	C	145	EE	18
ETBF	23	16	C	166	EE	18
ETBF	25	13	C	124	EE	18
ETBF	25	13	C	145	EE	18
ETBF	25	13	C	166	EE	18
ETBF	25	16	C	124	EE	18
ETBF	25	16	C	145	EE	18
ETBF	25	16	C	166	EE	18
ETBF	28	13	C	124	EE	18
ETBF	28	13	C	145	EE	18
ETBF	28	13	C	166	EE	18
ETBF	28	16	C	124	EE	18
ETBF	28	16	C	145	EE	18
ETBF	28	16	C	166	EE	18
ETBF	28	20	C	124	EE	18
ETBF	28	20	C	145	EE	18
ETBF	28	20	C	166	EE	18
ETBF	32	16	C	124	EE	20
ETBF	32	16	C	145	EE	20
ETBF	32	16	C	166	EE	20
ETBF	32	20	C	124	EE	20
ETBF	32	20	C	145	EE	20
ETBF	32	20	C	166	EE	20
ETBF	36	16	C	145	EE	20
ETBF	36	16	C	166	EE	20
ETBF	36	20	C	145	EE	20
ETBF	36	20	C	166	EE	20

# Endurant™ II/IIs

## Stent Graft System

### Limbs†

	Product code					Catheter outer diameter (Fr)	Total contralateral covered length with EII/EIIs bifurcated**	Total ipsilateral covered length with EIIs bifurcated††
	Proximal graft diameter (mm)	Distal graft diameter (mm)	Distal design	Total covered length (mm)	Delivery system			
ETLW	16	10	C	82	EE	14	132	152
ETLW	16	10	C	93	EE	14	143	163
ETLW	16	10	C	124	EE	14	174	174 - 194
ETLW	16	10	C	146	EE	16	196	196 - 216
ETLW	16	10	C	156	EE	16	206	206 - 226
ETLW	16	10	C	199	EE	16	249	249 - 269
ETLW	16	13	C	82	EE	14	132	152
ETLW	16	13	C	93	EE	14	143	163
ETLW	16	13	C	124	EE	14	174	174 - 194
ETLW	16	13	C	146	EE	16	196	196 - 216
ETLW	16	13	C	156	EE	16	206	206 - 226
ETLW	16	13	C	199	EE	16	249	249 - 269
ETLW	16	16	C	82	EE	14	132	132 - 152
ETLW	16	16	C	93	EE	14	143	143 - 163
ETLW	16	16	C	124	EE	14	174	174 - 194
ETLW	16	16	C	146	EE	16	196	196 - 216
ETLW	16	16	C	156	EE	16	206	206 - 226
ETLW	16	16	C	199	EE	16	249	249 - 269
ETLW	16	20	C	82	EE	16	132	152
ETLW	16	20	C	93	EE	16	143	163
ETLW	16	20	C	124	EE	16	174	174 - 194
ETLW	16	20	C	146	EE	16	196	196 - 216
ETLW	16	20	C	156	EE	16	206	206 - 226
ETLW	16	20	C	199	EE	16	249	249 - 269
ETLW	16	24	C	82	EE	16	132	152
ETLW	16	24	C	93	EE	16	143	163
ETLW	16	24	C	124	EE	16	174	174 - 194
ETLW	16	24	C	146	EE	16	196	196 - 216
ETLW	16	24	C	156	EE	16	206	206 - 226
ETLW	16	24	C	199	EE	16	249	249 - 269
ETLW	16	28	C	82	EE	16	132	152
ETLW	16	28	C	93	EE	16	143	163
ETLW	16	28	C	124	EE	16	174	174 - 194
ETLW	16	28	C	146	EE	16	196	196 - 216
ETLW	16	28	C	156	EE	16	206	206 - 226
ETLW	16	28	C	199	EE	16	249	249 - 269

† 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.

Some products, /indications/therapy areas may not be licensed in accordance with Canadian Law.



## 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	EE	14
ETEW	13	13	C	82	EE	14
ETEW	20	20	C	82	EE	16
ETEW	24	24	C	82	EE	16
ETEW	28	28	C	82	EE	18

## 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	EE	18
ETCF	25	25	C	49	EE	18
ETCF	28	28	C	49	EE	18
ETCF	32	32	C	49	EE	20
ETCF	36	36	C	49	EE	20
ETTF	23	23	C	70	EE	18
ETTF	25	25	C	70	EE	18
ETTF	28	28	C	70	EE	18
ETTF	32	32	C	70	EE	20
ETTF	36	36	C	70	EE	20

## 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	EE	18
ETUF	25	14	C	102	EE	18
ETUF	28	14	C	102	EE	18
ETUF	32	14	C	102	EE	20
ETUF	36	14	C	102	EE	20



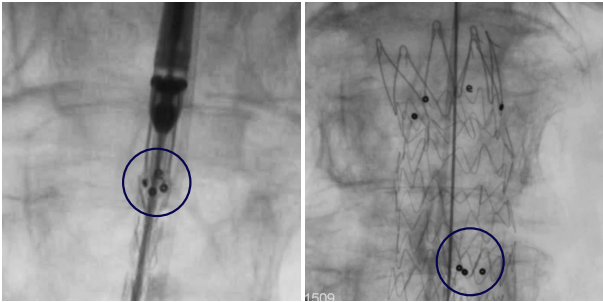
# Endurant™ II/IIs

## Stent Graft System

### Placement and sizing guidelines

Use the proximal radiopaque markers to position the top edge of the graft material.

**e** e-shaped marker assists with A/P orientation



Radiopaque markers

**For the contralateral side:** The radiopaque markers at the proximal limb should be aligned with the radiopaque markers at the flow divider of the Endurant™ II system or Endurant™ II's system bifurs.

**For the ipsilateral side:** Depending on the limb configuration used, the radiopaque markers at the proximal end of the limb should be aligned to the distal radiopaque marker on the ipsilateral leg or the flow divider marker of the Endurant™ II's system bifur. Select limbs will allow a 3-5 stent overlap adjustment during the case. Please refer to the *Instructions for Use* for more information as needed.



Each Endurant™ II/Endurant™ IIs AAA stent graft must be ordered in a size that is appropriate to fit the patient's anatomy. Proper sizing of the Endurant™ II/Endurant™ IIs AAA stent graft is the responsibility of the physician. The following suggestions for stent graft diameters are based on vessel **inner wall** measurements.

## Bifurcations, AUI and aortic extensions

Native vessel (mm)	Recommended Endurant™ II system diameter (mm)
19-20	23
21-22	25
23-25	28
26-28	32
29-32	36

## Iliac extensions

Native vessel (mm)	Recommended Endurant™ II system diameter (mm)
8-9	10
10-11	13
15-18	20
19-22	24
23-25	28

## Limbs

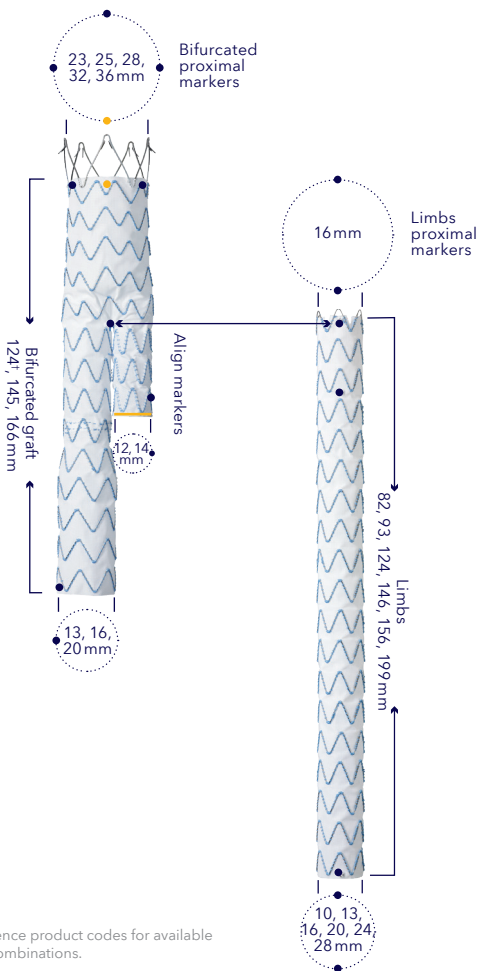
Native vessel (mm)	Recommended Endurant™ II system diameter (mm)
8-9	10
10-11	13
12-14	16
15-18	20
19-22	24
23-25	28

# Endurant™ II/IIs

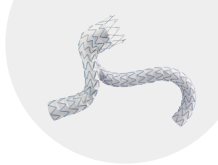
Stent Graft System

## Component placement guide†

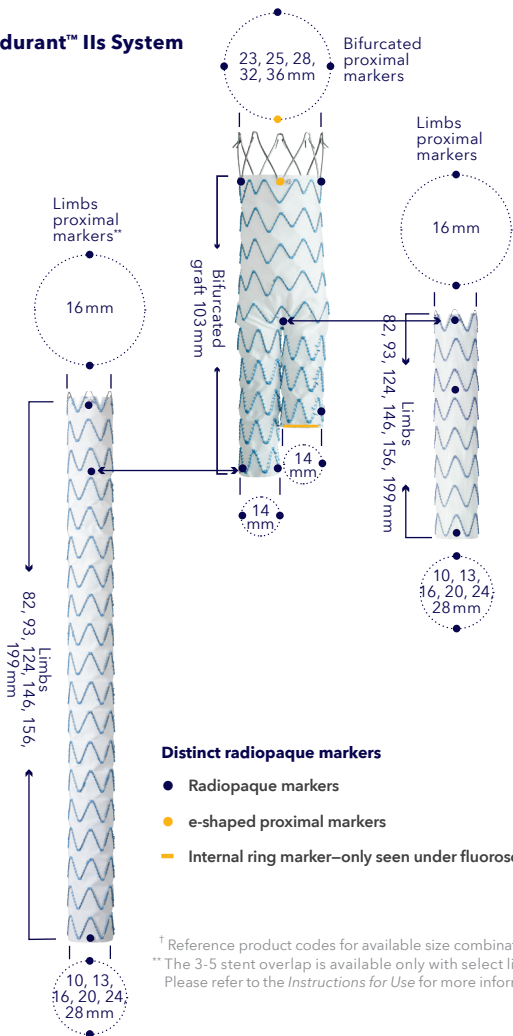
### Endurant™ II system



† Reference product codes for available size combinations.



## Endurant™ II System



### Distinct radiopaque markers

- Radiopaque markers
- e-shaped proximal markers
- Internal ring marker—only seen under fluoroscopy

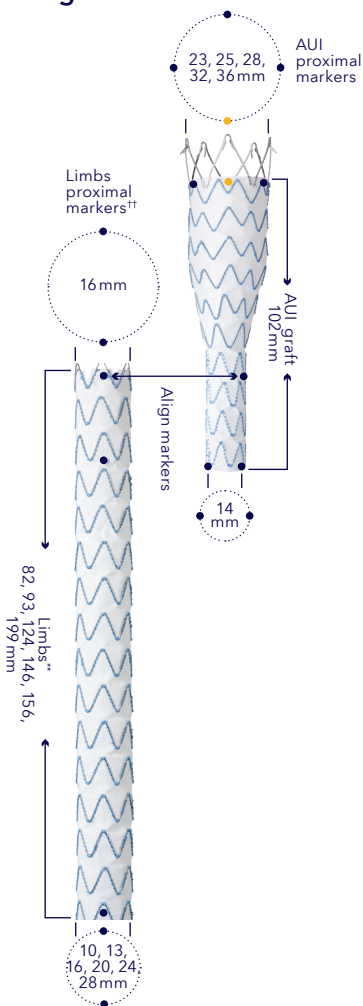
† Reference product codes for available size combinations.

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

# Endurant™ II/IIs

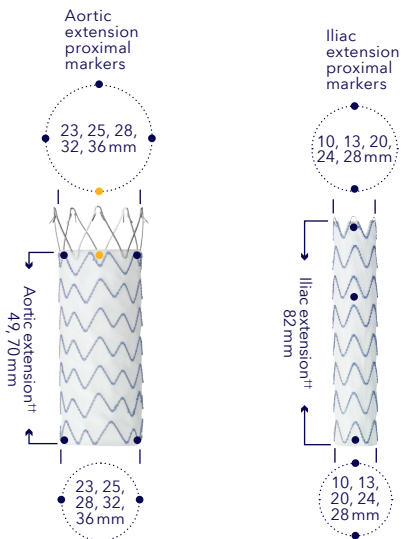
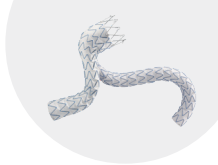
Stent Graft System

## Component placement guide



<sup>\*\*</sup> The limb mates with the Endurant™ II AUI stent graft on the ipsilateral side.

<sup>††</sup> Requires minimum 3 stent overlap. See *Instructions for Use* for more information.



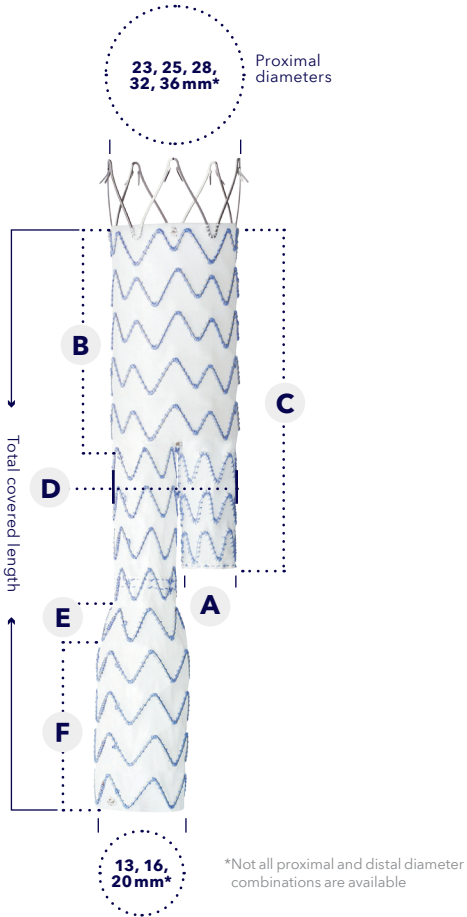
### Distinct radiopaque markers

- Radiopaque markers
- e-shaped proximal markers

†† Requires minimum 3 stent overlap. See *Instructions for Use* for more information.

# Endurant™ II/IIs

Stent Graft System



## Endurant™ II system bifurcations



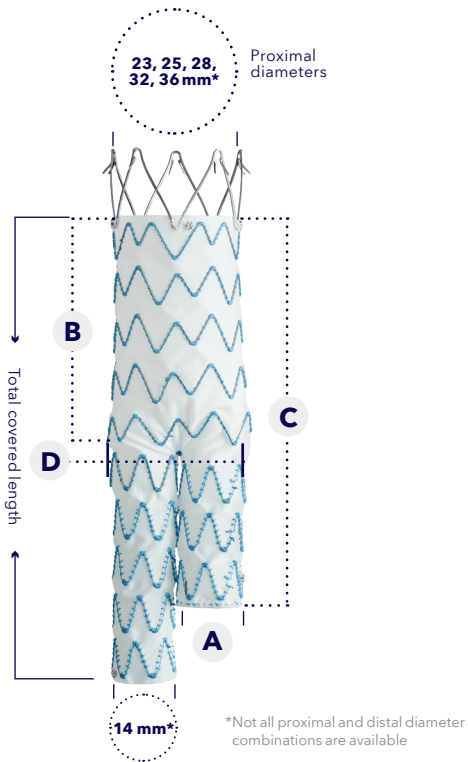
## Endurant™ II system bifurcations

	Product code					Graft dimensions (mm)					
	Proximal graft diameter (mm)	Distal graft diameter (mm)	Distal design	Total covered length (mm)	Delivery system	A	B	C	D	E	F
ETBF	23	13	C	124	EE	12	40	74	25	-	-
ETBF	23	13	C	145	EE	12	50	84	25	-	-
ETBF	23	13	C	166	EE	12	50	84	25	-	-
ETBF	23	16	C	124	EE	12	40	74	25	10	30
ETBF	23	16	C	145	EE	12	50	84	25	10	40
ETBF	23	16	C	166	EE	12	50	84	25	10	60
ETBF	25	13	C	124	EE	14	40	74	27	-	-
ETBF	25	13	C	145	EE	14	50	84	27	-	-
ETBF	25	13	C	166	EE	14	50	84	27	-	-
ETBF	25	16	C	124	EE	14	40	74	30	-	-
ETBF	25	16	C	145	EE	14	50	84	30	-	-
ETBF	25	16	C	166	EE	14	50	84	30	-	-
ETBF	28	13	C	124	EE	14	40	74	27	-	-
ETBF	28	13	C	145	EE	14	50	84	27	-	-
ETBF	28	13	C	166	EE	14	50	84	27	-	-
ETBF	28	16	C	124	EE	14	40	74	30	-	-
ETBF	28	16	C	145	EE	14	50	84	30	-	-
ETBF	28	16	C	166	EE	14	50	84	30	-	-
ETBF	28	20	C	124	EE	14	40	74	30	10	30
ETBF	28	20	C	145	EE	14	50	84	30	10	40
ETBF	28	20	C	166	EE	14	50	84	30	10	60
ETBF	32	16	C	124	EE	14	40	74	30	-	-
ETBF	32	16	C	145	EE	14	50	84	30	-	-
ETBF	32	16	C	166	EE	14	50	84	30	-	-
ETBF	32	20	C	124	EE	14	40	74	30	10	30
ETBF	32	20	C	145	EE	14	50	84	30	10	40
ETBF	32	20	C	166	EE	14	50	84	30	10	60
ETBF	36	16	C	145	EE	14	50	84	30	-	-
ETBF	36	16	C	166	EE	14	50	84	30	-	-
ETBF	36	20	C	145	EE	14	50	84	30	10	40
ETBF	36	20	C	166	EE	14	50	84	30	10	60

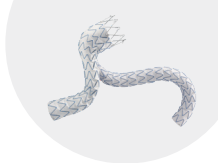


# Endurant™ II/IIs

Stent Graft System



Endurant™ IIs system bifurcations



## Endurant™ IIs system bifurcations

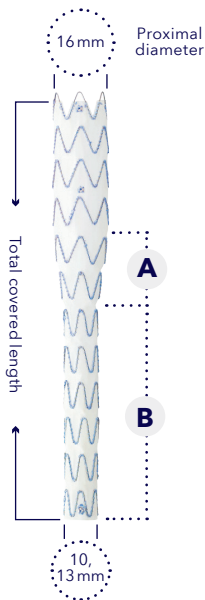
Product code						Graft dimensions (mm)			
	Proximal graft diameter (mm)	Distal graft diameter (mm)	Distal design	Total covered length (mm)	Delivery system	A	B	C	D
ESBF	23	14	C	103	EE	14	50	84	28
ESBF	25	14	C	103	EE	14	50	84	28
ESBF	28	14	C	103	EE	14	50	84	28
ESBF	32	14	C	103	EE	14	50	84	28
ESBF	36	14	C	103	EE	14	50	84	28

# Endurant™ II/IIIs

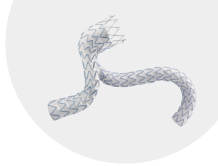
## Stent Graft System

### Tapered limbs

	Product code					Graft dimensions (mm)	
	Proximal graft diameter (mm)	Distal graft diameter (mm)	Distal design	Total covered length (mm)	Delivery system	A	B
	ETLW	16	10	C	82	EE	20
ETLW	16	10	C	93	EE	20	40
ETLW	16	10	C	124	EE	20	40
ETLW	16	10	C	156	EE	20	72
ETLW	16	10	C	199	EE	20	115
ETLW	16	13	C	82	EE	10	30
ETLW	16	13	C	93	EE	10	40
ETLW	16	13	C	124	EE	10	40
ETLW	16	13	C	156	EE	10	72
ETLW	16	13	C	199	EE	10	115

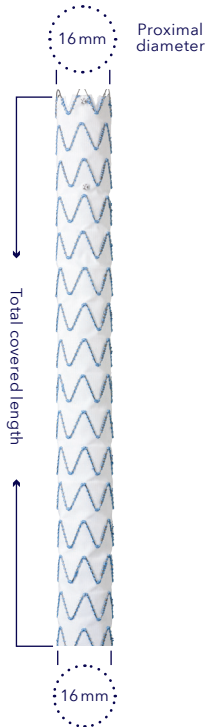


**Tapered limbs**



## Straight limbs

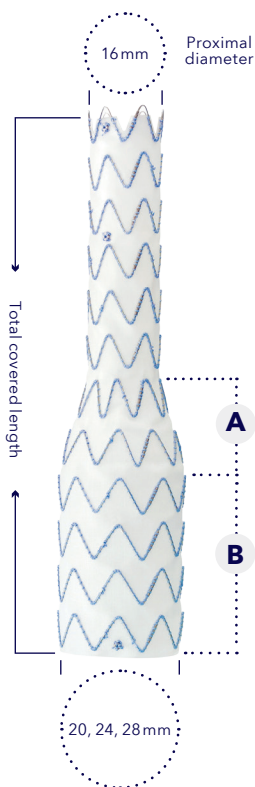
Product code					
	Proximal graft diameter (mm)	Distal graft diameter (mm)	Distal design	Total covered length (mm)	Delivery system
ETLW	16	16	C	82	EE
ETLW	16	16	C	93	EE
ETLW	16	16	C	124	EE
ETLW	16	16	C	156	EE
ETLW	16	16	C	199	EE



**Straight limbs**

# Endurant™ II/IIs

Stent Graft System



**Flared limbs**



## Flared limbs

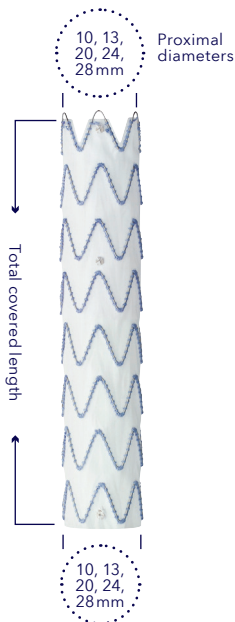
	Product code					Graft dimensions (mm)	
	Proximal graft diameter (mm)	Distal graft diameter (mm)	Distal design	Total covered length (mm)	Delivery system	A	B
ETLW	16	20	C	82	EE	10	40
ETLW	16	20	C	93	EE	10	40
ETLW	16	20	C	124	EE	10	40
ETLW	16	20	C	156	EE	10	40
ETLW	16	20	C	199	EE	10	40
ETLW	16	24	C	82	EE	20	30
ETLW	16	24	C	93	EE	20	40
ETLW	16	24	C	124	EE	20	40
ETLW	16	24	C	156	EE	20	40
ETLW	16	24	C	199	EE	20	40
ETLW	16	28	C	82	EE	20	30
ETLW	16	28	C	93	EE	20	40
ETLW	16	28	C	124	EE	20	40
ETLW	16	28	C	156	EE	20	40
ETLW	16	28	C	199	EE	20	40

# Endurant™ II/IIIs

Stent Graft System

## Iliac extensions

Product code					
	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

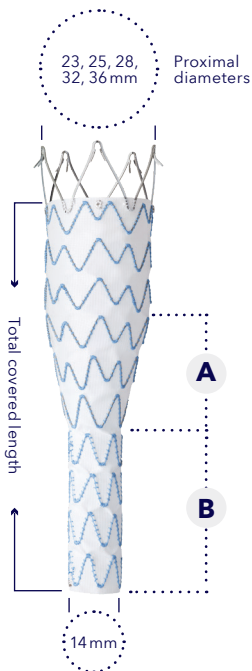


**Iliac extensions**



## AUI

	Product code						Graft dimensions (mm)	
	Proximal graft diameter (mm)	Distal graft diameter (mm)	Distal design	Total covered length (mm)	Delivery system	Graft dimensions (mm)		
						A	B	
ETUF	23	14	C	102	EE	30	40	
ETUF	25	14	C	102	EE	30	40	
ETUF	28	14	C	102	EE	30	40	
ETUF	32	14	C	102	EE	30	40	
ETUF	36	14	C	102	EE	30	40	

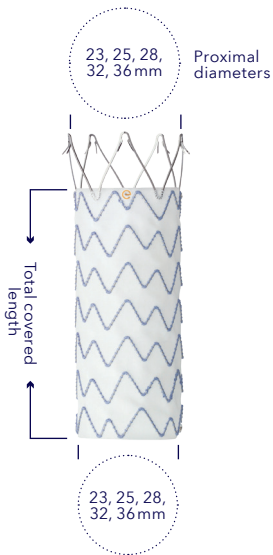


**Endurant™ II AUI**



# Endurant™ II/IIs

Stent Graft System



**Aortic extensions**



## Aortic extensions

	Product code				
	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
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

# Valiant™ Stent Graft

with Captivia™ Delivery System

## Deploy durability

### Precise deployment†

- Easy three step deployment process†
- Tip capture provides controlled deployment and precise placement in the thoracic aorta
- Tip capture release handle provides simple turn-and-pull motion to release proximal stents

### Optimal seal†

- Proximal FreeFlo configuration evenly distributes radial force over multiple apices
- Mini support spring optimizes proximal apposition with the vessel wall
- Only device that maintains complete apposition regardless of angulation and oversizing<sup>1</sup>

## Clinical track record in all descending thoracic aortic pathologies<sup>2,3</sup>

- 5-year outcomes in TAA, PAU, BTAI and Dissection<sup>2,3</sup>
- Positive aortic remodeling through 5 years in acute complicated Type B aortic dissection<sup>2,3</sup>
- Broad selection of proximal and distal components and tapered sizes treats a variety of patients<sup>2,3</sup>

† Test data on file at Medtronic. Bench test results may not be indicative of clinical performance.

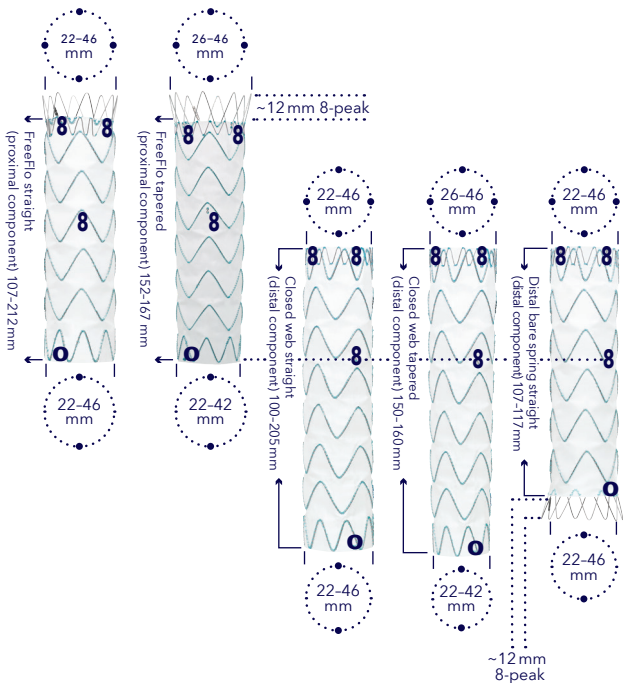
<sup>1</sup> Canaud L, Cathala P, Joyeux F, Branchereau P, Marty-Ané C, Alric P. Improvement in conformability of the latest generation of thoracic stent grafts. *J Vasc Surg.* April 2013;57(4):1084-1089.

<sup>2</sup> Bavaria J, Brinkman W, Hughes C, et al. Five-year outcomes of endovascular repair of complicated acute type B aortic dissections. *J Thorac Cardiovasc Surg.* 2020; S0022-5223(20)31092-31098.

<sup>3</sup> Bavaria J, Brinkman WT, Hueghes GC, et al. Outcomes of Thoracic Endovascular Aortic Repair in Acute Type B Aortic Dissection: Results From the Valiant United States Investigational Device Exemption Study. *Ann Thorac Surg.* September 2015;100(3):802-808.



## Component placement guide



### Distinct radiopaque markers

- 8** Figur8 marker
- 0** Zer0 marker

# Valiant™ Stent Graft

with Captivia™ Delivery System

Medtronic recommends that the Valiant™ Stent Graft with Captivia™ Delivery System be used according to the sizing guidelines contained in the IFU. Proper sizing of the Valiant™ Stent Graft is the responsibility of the physician.

## **Aneurysms, penetrating ulcers and traumatic ruptures:**

Full sizing guidelines are detailed in the *Instructions for Use* (IFU). Additional oversizing should not be incorporated. Please visit [manuals.medtronic.com](http://manuals.medtronic.com) for more detailed sizing information.

## **Dissection:**

For Dissections, appropriate oversizing has already been incorporated into the recommended sizes. Additional oversizing should not be incorporated. Oversizing of the stent graft to the vessel >10% may be unsafe in the presence of dissecting tissue or intramural hematoma.

## **For additional sections:**

When multiple stent grafts are needed to exclude the target lesion, and the component junction or overlapping connection is not supported by the aorta, the diameter of the inside component should be oversized by 4 mm relative to the outside component. If it is supported by the vessel, oversizing to the supporting native vessel should be used.

## **Fusiform & saccular aneurysms and penetrating ulcers sizing guidelines**

Native vessel (mm)	Suggested FreeFlo straight stent graft diameter (mm)
18, 19	22
20, 21	24
22, 23	26
24, 25	28
25, 26, 27	30
27, 28, 29	32
29, 30, 31	34
31, 32	36
33, 34	38
35, 36	40
37, 38	42
39, 40	44
41, 42	46



## Blunt traumatic aortic injury sizing guidelines

Native vessel (mm)	Suggested stent graft diameter (mm)
18	22
19	22
20	22
21	22
22	24
23	24
24	26
25	26
26	28
27	28
28	30
29	32
30	32
31	34
32	34
33	36
34	36
35	38
36	38
37	40
38	40
39	42
40	42
40	44
41	44
42	44
42	46
43	46
44	46

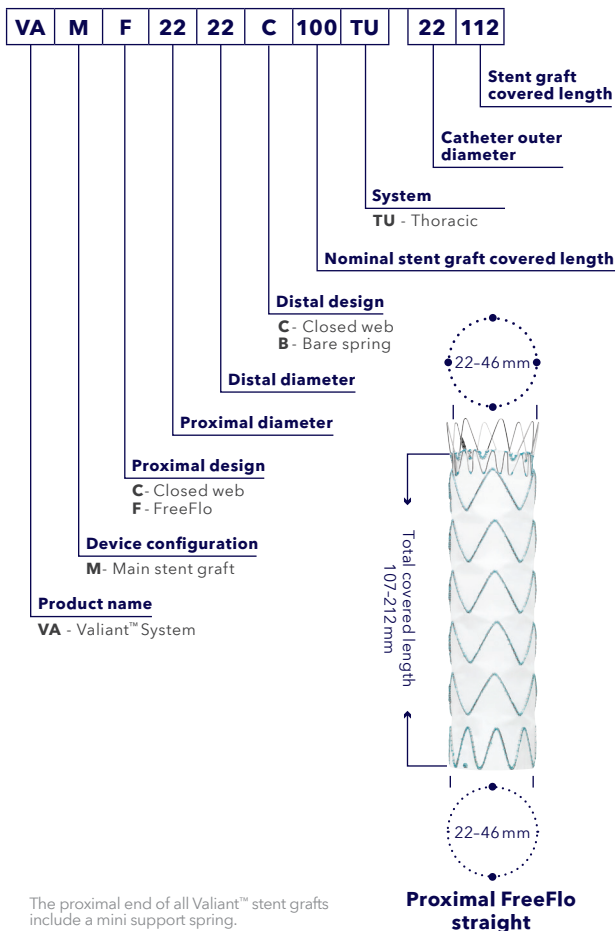
## Dissection sizing guidelines

Native vessel (mm)	Suggested stent graft diameter (mm)
20	22
21	22
22	24
23	24
24	26
25	26
26	28
27	28
28	30
29	32
30	32
31	34
32	34
33	36
34	36
35	38
36	38
37	40
38	40
39	42
40	42
40	44
41	44
42	44
42	46
43	46
44	46

# Valiant™ Stent Graft

with Captivia™ Delivery System

## Valiant™ Captivia™ thoracic stent graft system product code description



The proximal end of all Valiant™ stent grafts include a mini support spring.



## Proximal FreeFlo straight

Product code						Catheter outer diameter (Fr)	Stent graft covered length (mm)
	Proximal graft diameter (mm)	Distal graft diameter (mm)	Distal design				
VAMF	22	22	C	100	TU	22	112
VAMF	24	24	C	100	TU	22	112
VAMF	26	26	C	100	TU	22	112
VAMF	28	28	C	100	TU	22	117
VAMF	30	30	C	100	TU	22	117
VAMF	32	32	C	100	TU	22	117
VAMF	34	34	C	100	TU	24	107
VAMF	36	36	C	100	TU	24	107
VAMF	38	38	C	100	TU	24	107
VAMF	40	40	C	100	TU	24	107
VAMF	42	42	C	100	TU	25	112
VAMF	44	44	C	100	TU	25	112
VAMF	46	46	C	100	TU	25	112
VAMF	22	22	C	150	TU	22	152
VAMF	24	24	C	150	TU	22	152
VAMF	26	26	C	150	TU	22	152
VAMF	28	28	C	150	TU	22	157
VAMF	30	30	C	150	TU	22	157
VAMF	32	32	C	150	TU	22	157
VAMF	34	34	C	150	TU	24	167
VAMF	36	36	C	150	TU	24	167
VAMF	38	38	C	150	TU	24	167
VAMF	40	40	C	150	TU	24	167
VAMF	42	42	C	150	TU	25	157
VAMF	44	44	C	150	TU	25	157
VAMF	46	46	C	150	TU	25	162
VAMF	30	30	C	200	TU	22	192
VAMF	32	32	C	200	TU	22	192
VAMF	34	34	C	200	TU	24	212
VAMF	36	36	C	200	TU	24	207
VAMF	38	38	C	200	TU	24	207
VAMF	40	40	C	200	TU	24	212
VAMF	42	42	C	200	TU	25	207
VAMF	44	44	C	200	TU	25	212
VAMF	46	46	C	200	TU	25	212



# Valiant™ Stent Graft

with Captivia™ Delivery System



**Proximal FreeFlo  
tapered**



## Proximal FreeFlo tapered

Product code							
	Proximal graft diameter (mm)	Distal graft diameter (mm)	Distal design	Nominal stent graft covered length (mm)		Catheter outer diameter (Fr)	Stent graft covered length (mm)
VAMF	26	22	C	150	TU	22	152
VAMF	28	24	C	150	TU	22	157
VAMF	30	26	C	150	TU	22	157
VAMF	32	28	C	150	TU	22	157
VAMF	34	30	C	150	TU	24	167
VAMF	36	32	C	150	TU	24	167
VAMF	38	34	C	150	TU	24	167
VAMF	40	36	C	150	TU	24	167
VAMF	42	38	C	150	TU	25	157
VAMF	44	40	C	150	TU	25	157
VAMF	46	42	C	150	TU	25	162

# Valiant™ Stent Graft

with Captivia™ Delivery System



**Closed web straight**



## Closed web straight

Product code						Catheter outer diameter (Fr)	Stent graft covered length (mm)
	Proximal graft diameter (mm)	Distal graft diameter (mm)	Distal design				
VAMC	22	22	C	100	TU	22	105
VAMC	24	24	C	100	TU	22	105
VAMC	26	26	C	100	TU	22	105
VAMC	28	28	C	100	TU	22	110
VAMC	30	30	C	100	TU	22	110
VAMC	32	32	C	100	TU	22	110
VAMC	34	34	C	100	TU	24	100
VAMC	36	36	C	100	TU	24	100
VAMC	38	38	C	100	TU	24	100
VAMC	40	40	C	100	TU	24	100
VAMC	42	42	C	100	TU	25	105
VAMC	44	44	C	100	TU	25	105
VAMC	46	46	C	100	TU	25	105
VAMC	22	22	C	150	TU	22	145
VAMC	24	24	C	150	TU	22	145
VAMC	26	26	C	150	TU	22	145
VAMC	28	28	C	150	TU	22	150
VAMC	30	30	C	150	TU	22	150
VAMC	32	32	C	150	TU	22	150
VAMC	34	34	C	150	TU	24	160
VAMC	36	36	C	150	TU	24	160
VAMC	38	38	C	150	TU	24	160
VAMC	40	40	C	150	TU	24	160
VAMC	42	42	C	150	TU	25	150
VAMC	44	44	C	150	TU	25	150
VAMC	46	46	C	150	TU	25	155
VAMC	30	30	C	200	TU	22	185
VAMC	32	32	C	200	TU	22	185
VAMC	34	34	C	200	TU	24	205
VAMC	36	36	C	200	TU	24	200
VAMC	38	38	C	200	TU	24	200
VAMC	40	40	C	200	TU	24	205
VAMC	42	42	C	200	TU	25	200
VAMC	44	44	C	200	TU	25	205
VAMC	46	46	C	200	TU	25	205

# Valiant™ Stent Graft

with Captivia™ Delivery System



**Closed web tapered**



## Closed web tapered

Product code							
	Proximal graft diameter (mm)	Distal graft diameter (mm)	Distal design	Nominal stent graft covered length (mm)		Catheter outer diameter (Fr)	Stent graft covered length (mm)
VAMC	26	22	C	150	TU	22	150
VAMC	28	24	C	150	TU	22	150
VAMC	30	26	C	150	TU	22	150
VAMC	32	28	C	150	TU	22	150
VAMC	34	30	C	150	TU	24	160
VAMC	36	32	C	150	TU	24	160
VAMC	38	34	C	150	TU	24	160
VAMC	40	36	C	150	TU	24	160
VAMC	42	38	C	150	TU	25	150
VAMC	44	40	C	150	TU	25	150
VAMC	46	42	C	150	TU	25	155

# Valiant™ Stent Graft

with Captivia™ Delivery System



**Distal bare spring straight**



## Distal bare spring straight

Product code							
	Proximal graft diameter (mm)	Distal graft diameter (mm)	Distal design	Nominal stent graft covered length (mm)		Catheter outer diameter (Fr)	Stent graft covered length (mm)
VAMC	22	22	B	100	TU	22	112
VAMC	24	24	B	100	TU	22	112
VAMC	26	26	B	100	TU	22	112
VAMC	28	28	B	100	TU	22	117
VAMC	30	30	B	100	TU	22	117
VAMC	32	32	B	100	TU	22	117
VAMC	34	34	B	100	TU	24	107
VAMC	36	36	B	100	TU	24	107
VAMC	38	38	B	100	TU	24	107
VAMC	40	40	B	100	TU	24	107
VAMC	42	42	B	100	TU	25	112
VAMC	44	44	B	100	TU	25	112
VAMC	46	46	B	100	TU	25	112



### Features

#### Reinforced seal, durable outcomes

- EndoSuture Aneurysm Repair (ESAR) with the Heli-FX™ EndoAnchor™ system enhances the durability of EVAR and TEVAR endografts and protects against neck dilatation.<sup>1</sup>
- EndoAnchor™ implants are designed to provide radial support via transmural fixation, offering the strength and stability of a surgical anastomosis in an endovascular fashion<sup>2</sup>
- The EndoAnchor™ implant and Heli-FX™ EndoAnchor™ system have been evaluated via in vitro testing.

#### Expanding patient care options

- Endurant™ II/IIIs stent graft system and Heli-FX™ EndoAnchor™ system
- The first off-the-shelf short neck EVAR solution
- Endurant II/IIIs stent graft system is indicated for proximal neck length of  $\geq 4$  mm and  $< 10$  mm when used in conjunction with the Heli-FX EndoAnchor system.

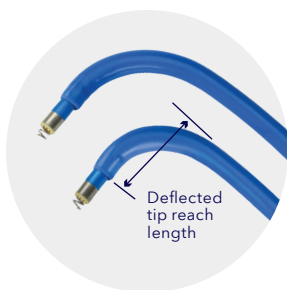
### EVAR ordering information

AAA components (mm)	Deflected tip reach (mm)	Recommended neck diameter (mm)	Working length (cm)	O.D. (Fr)	Catalog number
Heli-FX™ system guide, 22	22	18-28	62	16	SG-64
Heli-FX™ system guide, 28	28	28-32	62	16	HG-16-62-28
Heli-FX™ applier and EndoAnchor™ cassette (w/10 EndoAnchor™ implants)	NA	NA	86	12	SA-85
Ancillary EndoAnchor™ cassette (w/5 EndoAnchor™ implants)	NA	NA	NA	NA	EC-05

\* Third party brands are trademarks of their respective owners

<sup>1</sup> Tassiopoulos AK, Monastiriotes S, Jordan WD, Muhs BE, Ouriel K, De Vries JP. Predictors of early aortic neck dilatation after endovascular aneurysm repair with EndoAnchors. *J Vasc Surg.* July 2017;66(1):45-52.

<sup>2</sup> Melas N, Perdikides T, Saratzis A, et al. Helical EndoStaples enhance endograft fixation in an experimental model using human cadaveric aortas. *J Vasc Surg.* 2012 Jun;55(6):1726-33.



## TEVAR ordering information

TAA components (mm)	Deflected tip reach (mm)	Recommended neck diameter (mm)	Working length (cm)	O.D. (Fr)	Catalog number
Heli-FX™ system guide, 22	22	18-28	90	18	HG-18-90-22
Heli-FX™ system guide, 32	32	28-38	90	18	HG-18-90-32
Heli-FX™ system guide, 42	42	38-42	90	18	HG-18-90-42
Heli-FX™ applicator and EndoAnchor™ cassette (w/10 EndoAnchor™ implants)	NA	NA	114cm	12	HA-18-114
Ancillary EndoAnchor™ cassette (w/5 EndoAnchor™ implants)	NA	NA	NA	NA	EC-05

# Steerant™

Super Stiff Guidewire

## Advance your control

Meet Steerant™, the super stiff guidewire designed to advance your control throughout the aortic procedure.

The guidewire's soft, atraumatic tip gradually transitions to a stiff main body, providing protection for fragile aortic anatomy along with the support needed for device deployment.

Steerant guidewire is offered in lengths tailored for EVAR and TEVAR procedures.

## Tailored for aortic procedures

- Lengths and tip curves designed for EVAR and TEVAR
- The 8 cm radiopaque tip facilitates clear guidewire navigation and target visualization

## Protects fragile aortic anatomy

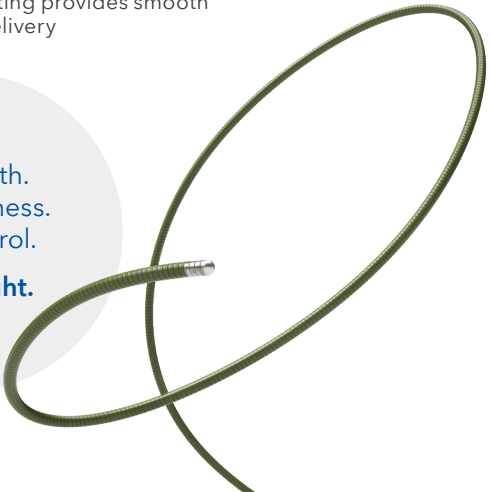
- Flexible, soft tip provides an atraumatic interface
- 15 cm flexible tip to protect anatomy

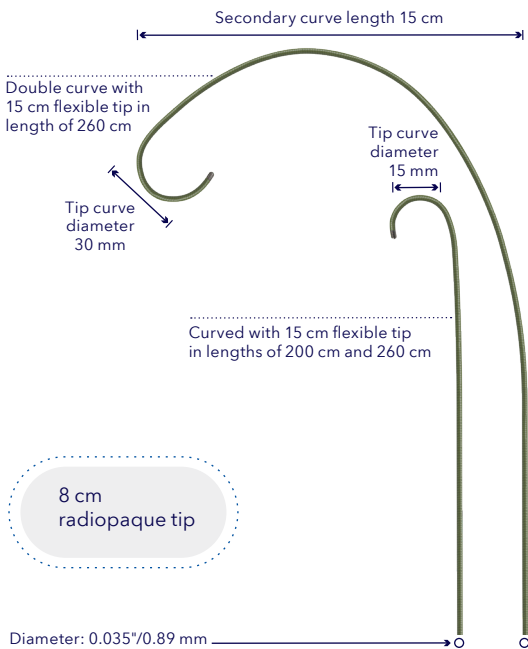
## Controlled wire delivery

- Gradual stiffness transition provides balanced control in straightforward and challenging anatomy
- PTFE coating provides smooth device delivery

Right length.  
Right stiffness.  
Right control.

**It's just right.**





## Ordering information

Catalog number	Length (cm)	Tip shape	Transition length (cm)	Tip curve diameter (mm)	Secondary curve length (cm)	Wire diameter (in/mm)	RO length (cm)
AGWSJ200	200	Curved	15	15	N/A	0.035/0.89	8
AGWSJ260	260	Curved	15	15	N/A	0.035/0.89	8
AGWDJ260	260	Double curve	15	30	15	0.035/0.89	8

# Sentrant™

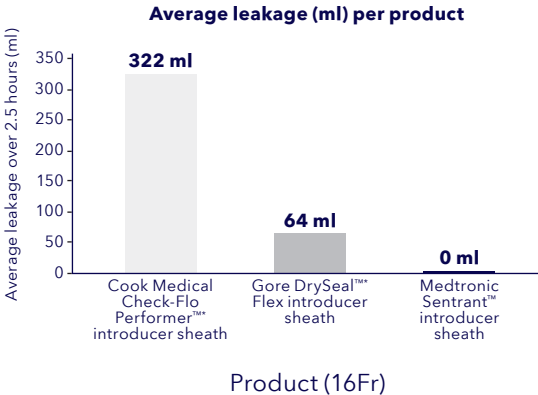
Introducer Sheath with Hydrophilic Coating

## Features

### Engineered to deliver procedural confidence

- EnsureSeal technology delivers superior leak resistance versus competitors†
- Coil-reinforced tubing for added stability and kink resistance
- Maintains lubricity after multiple insertions
- Radiopaque dilator shaft and sheath tip for accurate visualization and guidance
- 64 cm configuration launched to service a broader range of anatomies and procedures
- Compatible with a wide range of endovascular portfolios

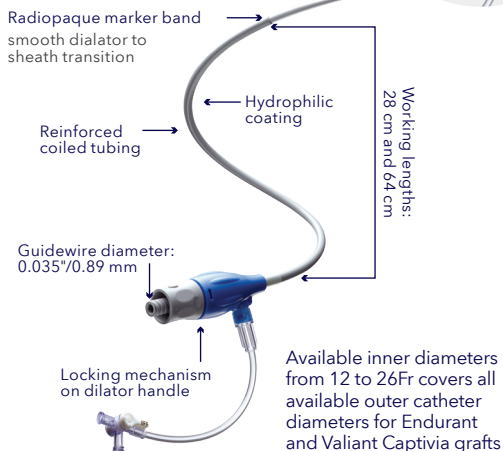
### Leak resistance versus Cook Check-Flo Performer™\* introducer sheath and Gore DrySeal™\* Flex introducer sheath†



\* Third party brands are trademarks of their respective owners

† Leak Resistance Bench Test Data on file at Medtronic. Test data not indicative of clinical performance. Bench Test compared Cook Check-Flo Performer™\* 16 Fr and Gore DrySeal™\* Flex 16 Fr to Sentrant™ 16 Fr. Graph shows average leakage over an extrapolated 2.5 hour procedure.

## The choice for hemostasis†



### Ordering information

Catalog number	Inner diameter (Fr)	Usable length (cm)
SENSH1228W	12	28
SENSH1428W	14	28
SENSH1628W	16	28
SENSH1828W	18	28
SENSH2028W	20	28
SENSH2228W	22	28
SENSH2428W	24	28
SENSH2628W	26	28
SENSH1264W	12	64
SENSH1464W	14	64
SENSH1664W	16	64
SENSH1864W	18	64
SENSH2064W	20	64
SENSH2264W	22	64
SENSH2464W	24	64
SENSH2664W	26	64

† Leak Resistance Bench Test Data on file at Medtronic. Test data not indicative of clinical performance. Bench Test compared Cook Check-Flo Performer™ 16 Fr and Gore DrySeal™ Flex 16 Fr to Sentrant™ 16 Fr. Graph shows average leakage over an extrapolated 2.5 hour procedure.

# Reliant™

## Stent-Graft Balloon Catheter

### Features

#### Expand possibilities

A single-solution balloon catheter for your stent graft procedure needs

*Clinical uses include:*

- Abdominal and thoracic use
- Endograft modeling
- Endoleak sealing support

#### Wide range of balloon inflation diameters

##### Balloon inflation table

46 mm balloon	
Diameter (mm)	MI (cc)
10	3
20	9
30	19
40	41
46 <sup>†</sup>	60

Caution: This table is only a guide. Balloon expansion should be carefully monitored under fluoroscopy. Do not exceed maximum inflation diameter (46 mm). Rupture of balloon may occur.

### Product information

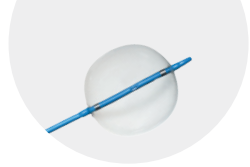
#### Reliant™ stent graft balloon catheter\*\*

Product code	Inflation diameter (mm)	Shaft size (Fr)	Usable length (cm)	Sheath compatibility (Fr)
AB46	10-46	8	100	12

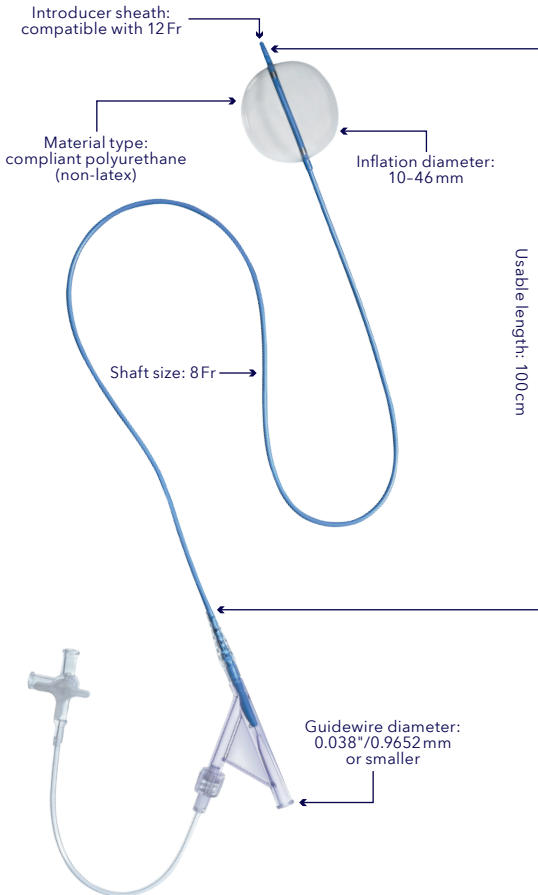
Please reference appropriate product *Instructions for Use* for a more detailed list of indications, warnings, precautions and potential adverse events.

<sup>†</sup>Maximum inflation diameter.

\*\*Does not contain latex.



## Multiple purposes, single solution





# Endurant™ II/IIs

## Stent Graft System

The Endurant II/IIs stent graft system is indicated for the endovascular treatment of infrarenal abdominal aortic or aortoiliac aneurysms in patients with the following characteristics:

- adequate iliac or femoral access vessel morphology that is compatible with vascular access techniques, devices, or accessories
- iliac distal fixation length of  $\geq 15$  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  $\geq 10$  mm, or  $\geq 4$  mm and  $< 10$  mm when used in conjunction with the Heli-FX EndoAnchor system, with insignificant calcification, or insignificant thrombus with  $\leq 60^\circ$  infrarenal and  $\leq 45^\circ$  suprarenal angulation and a vessel diameter approximately 10% to 20% smaller than the labeled Endurant II/IIs stent graft diameter
- proximal neck length of  $\geq 15$  mm with insignificant calcification, or insignificant thrombus with  $\leq 75^\circ$  infrarenal and  $\leq 60^\circ$  suprarenal angulation and a vessel diameter approximately 10% to 20% smaller than the labeled Endurant II/IIs stent graft diameter

### 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 ( $\geq 4$  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.
- 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, 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.

## **Valiant™ Stent Graft**

with Captivia™ Delivery System

### **Indications**

The Valiant™ thoracic stent graft with the Captivia™ delivery system is indicated for the endovascular repair of all lesions of the descending thoracic aorta (DTA) in patients having appropriate anatomy, including:

- iliac/femoral artery access vessel morphology that is compatible with vascular access techniques, devices, or accessories;
- nonaneurysmal aortic diameter in the range of 18 mm to 42mm (fusiform and saccular aneurysms/penetrating ulcers), 18 mm to 44 mm (blunt traumatic aortic injuries), or 20 mm to 44 mm (dissections); and
- nonaneurysmal aortic proximal and distal neck lengths  $\geq$  20mm (fusiform and saccular aneurysms/ penetrating ulcers), landing zone  $\geq$  20 mm proximal to the primary entry tear

(blunt traumatic aortic injuries).

### **Contraindications**

The Valiant thoracic stent graft with the Captivia delivery 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.

### **Warnings and Precautions**

The long-term safety and effectiveness of the Valiant thoracic stent graft with the Captivia delivery system has not been established. All patients should be advised that endovascular treatment requires lifelong, regular follow-up to assess the integrity and performance of the implanted endovascular stent graft. Patients with specific clinical findings (for example, enlarging aneurysm (>5mm), endoleaks, migration, inadequate seal zone, or continued flow into the false lumen in the case of a dissection) should receive enhanced follow-up. Specific follow-up guidelines are described in the *Instructions for Use*. The Valiant thoracic stent graft with the Captivia delivery system is not recommended in patients who cannot undergo, or who will not be compliant with, the necessary preoperative and postoperative imaging and implantation procedures as described in the *Instructions for Use*. Strict adherence to the Valiant thoracic stent graft sizing guidelines as described in the *Instructions for Use* is expected when selecting the device size. Use of the device outside the recommended anatomical sizing may result in potential serious device-related events. As cautioned in the *Instructions for Use*, a balloon should never be used when treating a dissection. The safety and effectiveness of the Valiant thoracic stent graft with the Captivia delivery 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 Valiant thoracic stent graft is MR Conditional. It can be scanned

safely in both 1.5T and 3.0T MR systems under specific conditions as described in the product *Instructions for Use*. For additional information regarding MRI please refer to the product *Instructions for Use*.

### **Adverse Events**

Complications associated with use of the Valiant thoracic stent graft with the Captivia delivery system include, but are not limited to the following:

- Access failure
- Adynamic Ileus
- Dissection, perforation, or rupture of the aortic vessel & surrounding vasculature
- Post-implant syndrome
- Post-procedural bleeding
- Allergic reaction (to contrast, anti-platelet therapy, stent graft material)
- Amputation
- Anastomotic false aneurysm
- Anesthetic complications
- Embolism
- Endoleaks
- Excessive or inappropriate radiation exposure
- Extrusion/erosion
- Procedural bleeding
- Prosthesis dilatation
- Prosthesis infection
- Prosthesis rupture
- Aneurysm expansion
- Aneurysm rupture
- Failure to deliver the stent graft
- Femoral neuropathy
- Prosthesis thrombosis
- Pseudoaneurysm
- Angina
- Gastrointestinal bleeding/complications
- Pulmonary edema
- Aortic vessel rupture
- Genitourinary complications
- Pulmonary embolism
- Aortoenteric fistula
- Arrhythmia
- Hemorrhage/bleeding
- Hematoma
- Reaction to anaesthesia
- Renal failure
- Arteriovenous fistula
- Atelectasis
- Hypotension/hypertension
- Infection or fever
- Renal insufficiency
- Re-operation
- Balloon rupture
- Insertion or removal difficulty
- Respiratory depression or failure
- Blindness
- Intercostal pain
- Sepsis
- Bowel ischemia
- Intramural hematoma
- Seroma
- Bowel necrosis
- Leg edema/foot edema
- Sexual dysfunction
- Bowel obstruction
- Branch vessel occlusion
- Loss of patency
- Lymphocele/lymph fistula
- Shock/pulmonary edema
- Spinal neurological deficit
- Breakage of the metal portion of the device
- Buttock claudication
- Myocardial infarction

- Neck enlargement • Stenosis • Stent graft migration • Cardiac tamponade • Neoplasm • Stent graft misplacement • Catheter breakage • Nerve injury • Stent graft rupture • Cerebrovascular accident (CVA) • Neuropathy • Thrombosis • Change in mental status • Occlusion - Venous or Arterial • Stent graft twisting or kinking • Coagulopathy • Pain/reaction at catheter insertion site • Stroke/Transient-ischemic attack (TIA) • Congestive heart failure • Contrast toxicity • Paralysis • Paraparesis • Tissue necrosis • Vascular ischemia • Conversion to surgical repair • Damage to the vessel which may require a conversion to open repair • Paraplegia • Paresthesia • Vascular trauma • Vessel occlusion • Death • Peripheral ischemia • Wound healing complications • Dehiscence • Peripheral nerve injury • Wound infection • Deployment difficulties/ failures • Pneumonia

Please reference product *Instructions for Use* for more information regarding indications, warnings, precautions, contraindications and adverse events.

## Heli-FX™ EndoAnchor™ system

### Indications for Use

The Heli-FX™ EndoAnchor™ system is intended to provide fixation and sealing between endovascular aortic grafts and the native artery. The Heli-FX™ EndoAnchor™ system is indicated for use in patients whose endovascular grafts have exhibited migration or endoleak, or are at risk of such complications, in whom augmented radial fixation and/or sealing is required to regain or maintain adequate aneurysm exclusion. The EndoAnchor™ implant may be implanted at the time of the initial endograft placement, or during a secondary (i.e. repair) procedure.

### Contraindications

Treatment with the Heli-FX EndoAnchor system is contraindicated for use in the following circumstances:

- In patients with a condition that

threatens to infect the endograft

- In patients with a bleeding diathesis
- In patients with known allergies to the EndoAnchor implant material (MP35N-LT)
- In conjunction with the Endologix Powerlink™\* endograft

### Warnings

- The long-term performance of the EndoAnchor™ implant has not been established. All patients should be advised endovascular aneurysm treatment requires long-term, regular follow-up to assess the patient's health status and endograft performance, and the EndoAnchor™ implant does not reduce this requirement.
- The EndoAnchor™ implant and the Heli-FX™ EndoAnchor™ system and Heli-FX™ thoracic EndoAnchor™ system have been evaluated via in vitro testing. Use with endografts other than those listed above has not been evaluated.
- The performance of the EndoAnchor™ implant has not been evaluated for securing multiple endograft components to one another. Not securing EndoAnchor™ implants into aortic tissue could result in graft fabric damage, component separation, and resultant Type III endoleaks.
- The performance of the EndoAnchor™ implant has not been evaluated in vessels other than the aorta. Use of the EndoAnchor™ implant to secure endografts to other vessels may result in adverse patient consequences such as vascular perforation, bleeding, or damage to adjacent structures.
- The performance of the EndoAnchor™ implant has not been evaluated for securing multiple anatomical structures together. Such use could result in adverse patient consequences such as vascular perforation, bleeding, or embolic events.

### MRI Safety and Compatibility

- The EndoAnchor™ implants have been determined to be MR Conditional at 3T or less when the scanner is in Normal Operating Mode with whole body averaged SAR of 2 W/kg, or in First Level Controlled Mode with a

maximum whole body averaged SAR of 4 W/kg.

- Please refer to documentation provided by the endograft system manufacturer for MR safety status of the endograft system with which the EndoAnchor™ implants are being used.

#### Potential Adverse Events

Possible adverse events associated with the Heli-FX™ EndoAnchor™ system include, but are not limited to:

- Aneurysm rupture
- Death
- Embolization
- Endoleaks (Type III)
- Enteric fistula
- Failure to correct/prevent Type I endoleak
- Failure to prevent endograft migration
- Infection
- Renal complications (renal artery occlusion/dissection or contrast-induced AKI)
- Stroke
- Surgical conversion to open repair
- Vascular access complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula
- Vessel damage, including dissection, perforation, and spasm.

Please reference product *Instructions for Use* for more information regarding indications, warnings, precautions, contraindications and adverse events.

**Caution:** Federal (USA) law restricts these devices to sale by or on the order of a licensed healthcare practitioner. See package inserts for full product information.

**Caution:** EndoAnchor™ implant locations should be based upon a detailed examination of the preoperative CT imaging in cases involving irregular or eccentric plaque in the intended sealing zone(s). EndoAnchor™ implants should be implanted only into areas of aortic tissue free of calcified plaque or thrombus, or where such pathology is diffuse and less than 2mm in thickness. Attempting to place EndoAnchor™ implants into more severe plaque or thrombus may be associated with implantation difficulty and suboptimal endograft fixation and/or sealing.

## Steerant™

Super Stiff Guidewire

**Important Information:** Prior to use, refer to the *Instructions for Use* for indications, contraindications, suggested procedure, warnings and precautions.

## Sentrant™

Introducer Sheath with Hydrophilic Coating

**Important Information:** Prior to use, refer to the *Instructions for Use* for indications, contraindications, suggested procedure, warnings and precautions.

**Indications for Use:** The Medtronic Sentrant™ Introducer Sheaths with Hydrophilic Coating are intended to provide a conduit for the insertion of diagnostic or endovascular devices into the vasculature and to minimize blood loss associated with such insertions.

## Reliant™

Stent-Graft Balloon Catheter

**Important Information:** Prior to use, refer to the *Instructions for Use* for indications, contraindications, suggested procedure, warnings and precautions.

**Indications for Use:** The Reliant™ stent graft balloon catheter is intended for temporary occlusion of large vessels or to expand vascular prostheses. The device is intended to assist in the expansion of self-expanding stent grafts.



# Medtronic

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