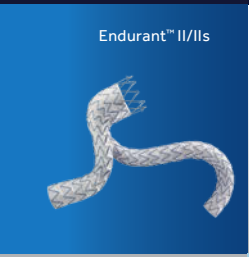
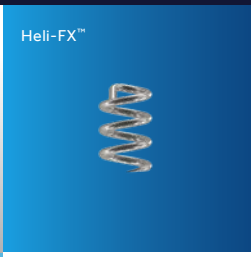
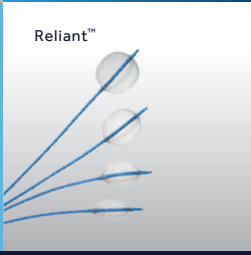
U.S. AORTIC PRODUCT CATALOG







Medtronic
Further, Together

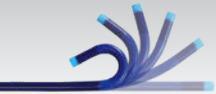
Endurant™ II/IIs

Endurant™ II AUI

Talent™
Occluder

Valiant
Navion™

Heli-FX™



TourGuide™

Sentrant™

Reliant™

TABLE OF CONTENTS

Endurant™ II/IIs

AAA Stent Graft System

FEATURES†

Endurant™ IIs System Expands Anatomical Customization Options

- A three-piece system that leverages the proven design of the Endurant™ II abdominal stent graft
- 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

Low Profile and Easy Access

- Low profile and hydrophilic coating enhances access and trackability
- Flexible, kink-resistant delivery system facilitates stent graft delivery

Complete Conformability, Optimal Seal

- M-shaped proximal stents provide wall apposition and minimize infolding for a short sealing zone in the infrarenal aorta
- Laser cut suprarenal stent anchor pins provides secure fixation to mitigate migration
- Spacing between limb stents optimized to conform to anatomy to reduce kinking

Total Control Provides Consistent Precision

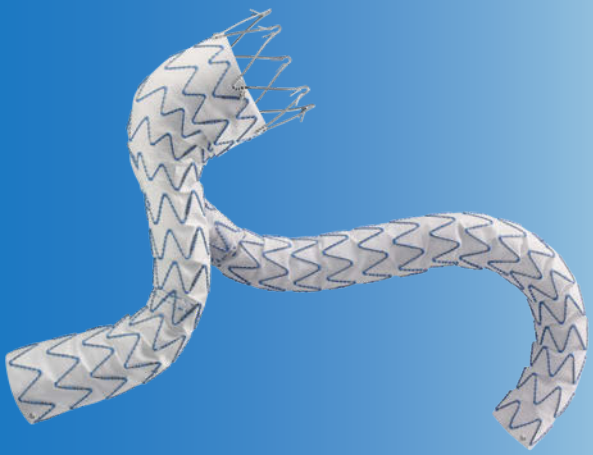
- Tip capture mechanism allows for precise positioning and intraoperative adjustments
- Backend thumb wheel provides controlled release of the suprarenal stent and anchor pins
- Improved radiopacity provides increased visibility‡
- Four proximal markers assist in accurate deployment
- e-shaped marker assists with A/P orientation

Durable Design, Dependable Performance

- Ultra-high molecular weight polyethylene sutures are three times stronger than surgical sutures
- High-density multifilament polyester graft material provides low porosity
- Electropolished nitinol stents improve fatigue resistance

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

‡ Contralateral gate marker.



PROVEN SOLUTIONS AS VARIED AS YOUR PATIENTS

Endurant™ II/IIs

AAA Stent Graft System

ENDURANT™ II/IIs SYSTEM PRODUCT CODE DESCRIPTION

ET	B	F	23	13	C	124	E	18

Catheter Outer Diameter

Delivery System
E - Endurant™ II System

Total Covered Length

Distal Design
C - Closed Web

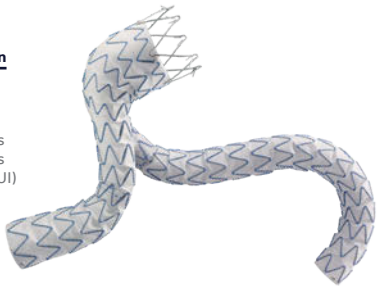
Distal Graft Diameter

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	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

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	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™ II/IIs

AAA Stent Graft System

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.

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

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

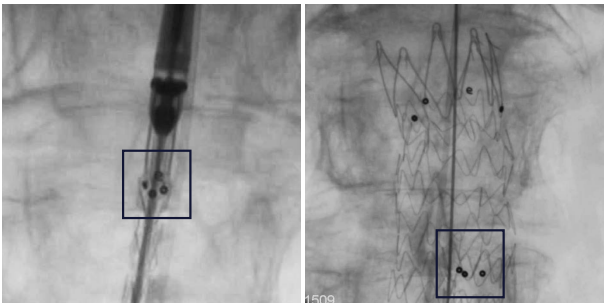
AUI

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

PLACEMENT AND SIZING GUIDELINES

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

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™ IIs 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™ IIs 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

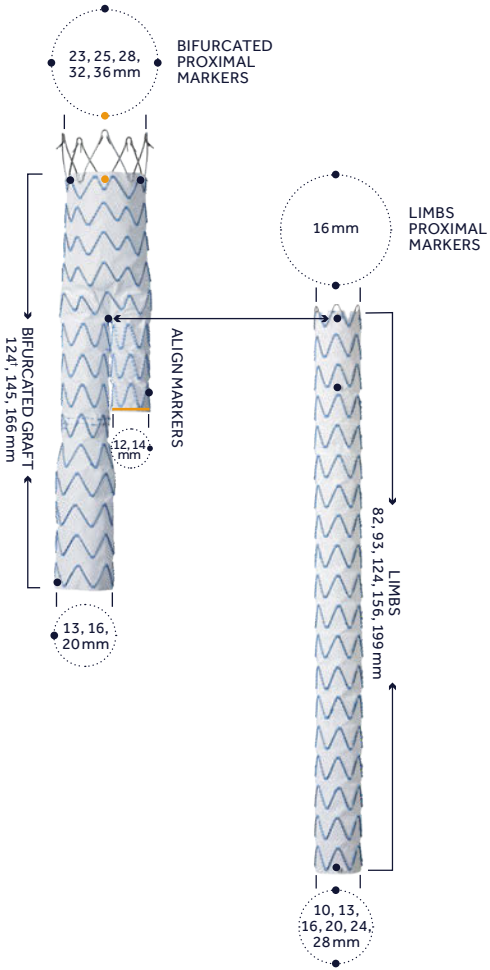
Native Vessel (mm)	Recommended Endurant™ II System Diameter (mm)
8–9	10
10–11	13
15–18	20
19–22	24
23–25	28

LIMBS

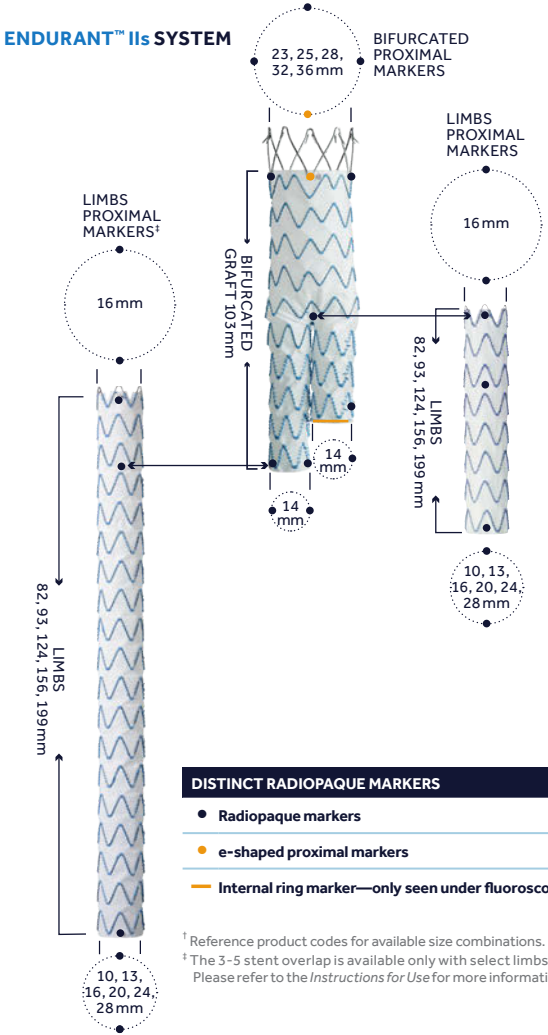
Native Vessel (mm)	Recommended Endurant™ II System Diameter (mm)
8–9	10
10–11	13
12–14	16
15–18	20
19–22	24
23–25	28

COMPONENT PLACEMENT GUIDE†

ENDURANT™ II SYSTEM



ENDURANT™ IIs SYSTEM



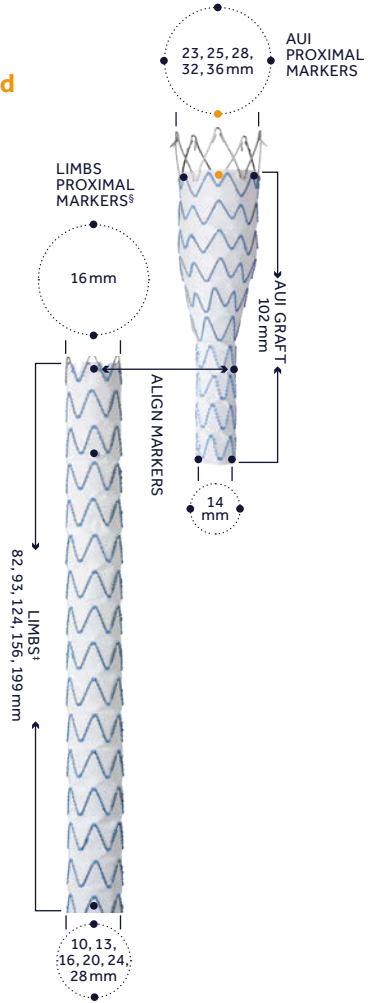
DISTINCT RADIOPAQUE MARKERS

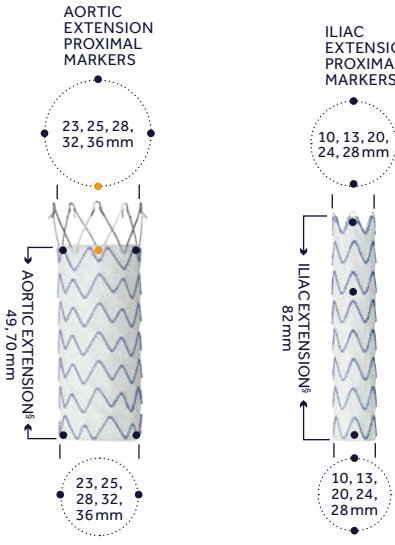
- **Radiopaque markers**
- **e-shaped proximal markers**
- **Internal ring marker—only seen under fluoroscopy**

† 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.

COMPONENT PLACEMENT GUIDE

The only device with an FDA-approved AUI Indication†

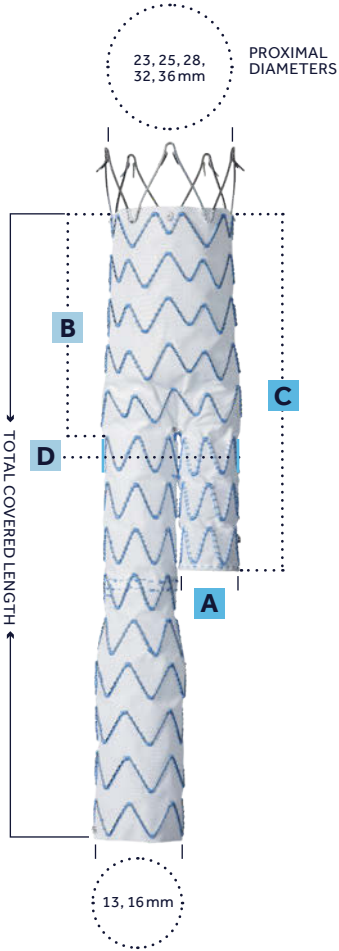




DISTINCT RADIOPAQUE MARKERS

- **Radiopaque markers**
- **e-shaped proximal markers**

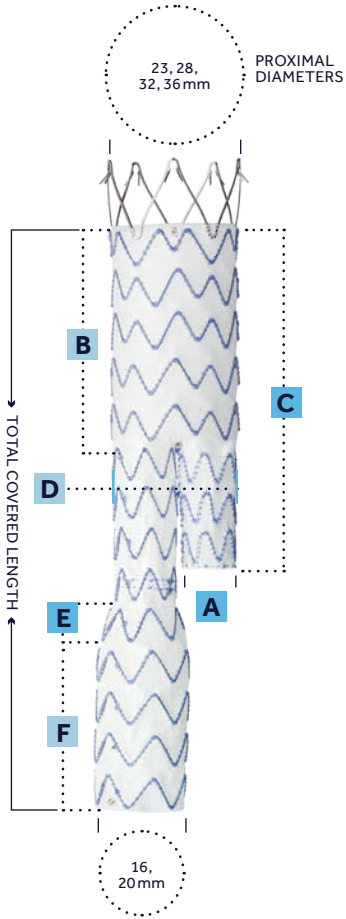
† As of October 2018.
‡ The limb mates with the Endurant™ II AUI stent graft on the ipsilateral side.
§ Requires minimum 3 stent overlap. See *Instructions for Use* for more information.



ENDURANT™ II SYSTEM BIFURCATIONS–STRAIGHT LIMBS

ENDURANT™ II SYSTEM BIFURCATIONS–STRAIGHT LIMBS

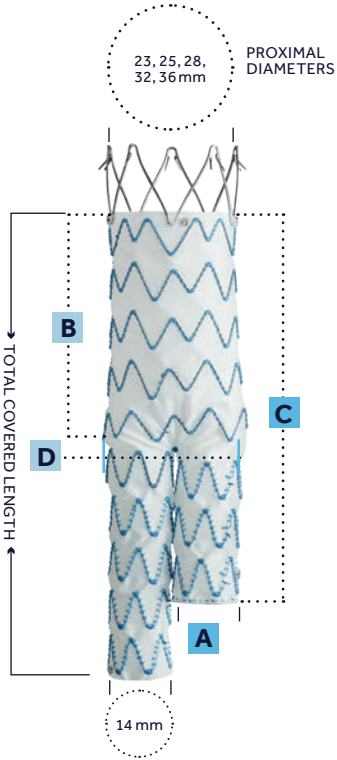
Product Code	Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	Graft Dimensions (mm) A	B	C	D
ETBF	23	13	C	124	E	12	40	74	25
ETBF	23	13	C	145	E	12	50	84	25
ETBF	23	13	C	166	E	12	50	84	25
ETBF	25	13	C	124	E	14	40	74	27
ETBF	25	13	C	145	E	14	50	84	27
ETBF	25	13	C	166	E	14	50	84	27
ETBF	25	16	C	124	E	14	40	74	30
ETBF	25	16	C	145	E	14	50	84	30
ETBF	25	16	C	166	E	14	50	84	30
ETBF	28	13	C	124	E	14	40	74	27
ETBF	28	13	C	145	E	14	50	84	27
ETBF	28	13	C	166	E	14	50	84	27
ETBF	28	16	C	124	E	14	40	74	30
ETBF	28	16	C	145	E	14	50	84	30
ETBF	28	16	C	166	E	14	50	84	30
ETBF	32	16	C	124	E	14	40	74	30
ETBF	32	16	C	145	E	14	50	84	30
ETBF	32	16	C	166	E	14	50	84	30
ETBF	36	16	C	145	E	14	50	84	30
ETBF	36	16	C	166	E	14	50	84	30



ENDURANT™ II SYSTEM BIFURCATIONS-FLARED LIMBS

ENDURANT™ II SYSTEM BIFURCATIONS–FLARED LIMBS

Product Code	Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	Graft Dimensions (mm) A	B	C	D	E	F
ETBF	23	16	C	124	E	12	40	74	25	10	30
ETBF	23	16	C	145	E	12	50	84	25	10	40
ETBF	23	16	C	166	E	12	50	84	25	10	60
ETBF	28	20	C	124	E	14	40	74	30	10	30
ETBF	28	20	C	145	E	14	50	84	30	10	40
ETBF	28	20	C	166	E	14	50	84	30	10	60
ETBF	32	20	C	124	E	14	40	74	30	10	30
ETBF	32	20	C	145	E	14	50	84	30	10	40
ETBF	32	20	C	166	E	14	50	84	30	10	60
ETBF	36	20	C	145	E	14	50	84	30	10	40
ETBF	36	20	C	166	E	14	50	84	30	10	60



ENDURANT™ IIs SYSTEM BIFURCATIONS

ENDURANT™ IIs SYSTEM BIFURCATIONS

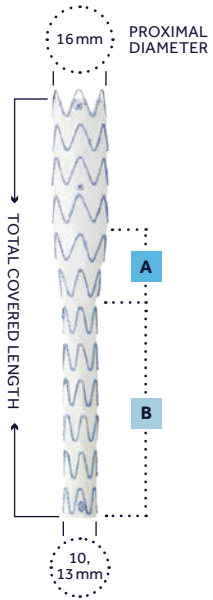
Product Code	Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	Graft Dimensions (mm) A	B	C	D
ESBF	23	14	C	103	E	14	50	84	28
ESBF	25	14	C	103	E	14	50	84	28
ESBF	28	14	C	103	E	14	50	84	28
ESBF	32	14	C	103	E	14	50	84	28
ESBF	36	14	C	103	E	14	50	84	28

Endurant™ II/IIs

AAA Stent Graft System

TAPERED LIMBS

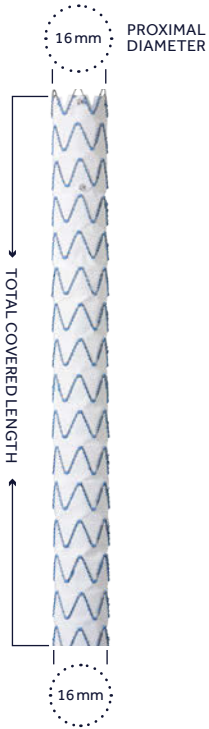
Product Code							
	Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	Graft Dimensions (mm) A	B
ETLW	16	10	C	82	E	20	30
ETLW	16	10	C	93	E	20	40
ETLW	16	10	C	124	E	20	40
ETLW	16	10	C	156	E	20	72
ETLW	16	10	C	199	E	20	115
ETLW	16	13	C	82	E	10	30
ETLW	16	13	C	93	E	10	40
ETLW	16	13	C	124	E	10	40
ETLW	16	13	C	156	E	10	72
ETLW	16	13	C	199	E	10	115



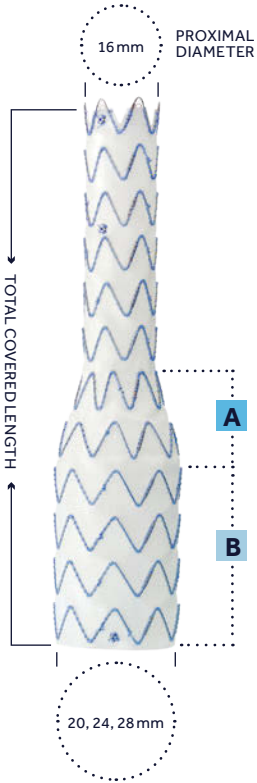
TAPERED LIMBS

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	E
ETLW	16	16	C	93	E
ETLW	16	16	C	124	E
ETLW	16	16	C	156	E
ETLW	16	16	C	199	E



STRAIGHT LIMBS



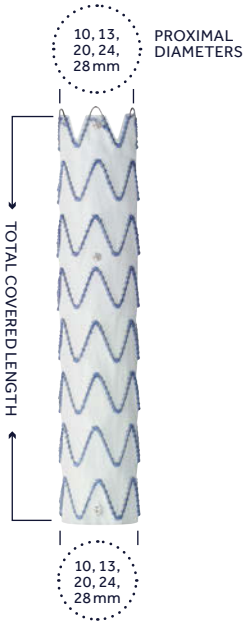
FLARED LIMBS

FLARED LIMBS

Product Code							
	Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	Graft Dimensions (mm) A	B
ETLW	16	20	C	82	E	10	30
ETLW	16	20	C	93	E	10	40
ETLW	16	20	C	124	E	10	40
ETLW	16	20	C	156	E	10	40
ETLW	16	20	C	199	E	10	40
ETLW	16	24	C	82	E	20	30
ETLW	16	24	C	93	E	20	40
ETLW	16	24	C	124	E	20	40
ETLW	16	24	C	156	E	20	40
ETLW	16	24	C	199	E	20	40
ETLW	16	28	C	82	E	20	30
ETLW	16	28	C	93	E	20	40
ETLW	16	28	C	124	E	20	40
ETLW	16	28	C	156	E	20	40
ETLW	16	28	C	199	E	20	40

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	E
ETEW	13	13	C	82	E
ETEW	20	20	C	82	E
ETEW	24	24	C	82	E
ETEW	28	28	C	82	E

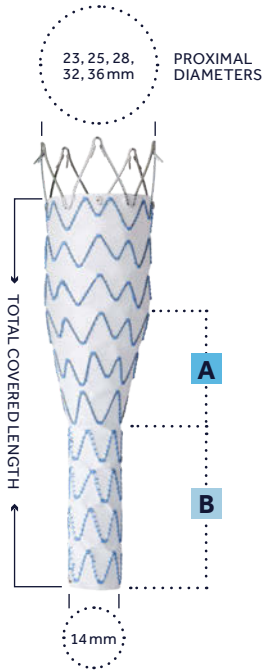


ILIAC EXTENSIONS

AUI

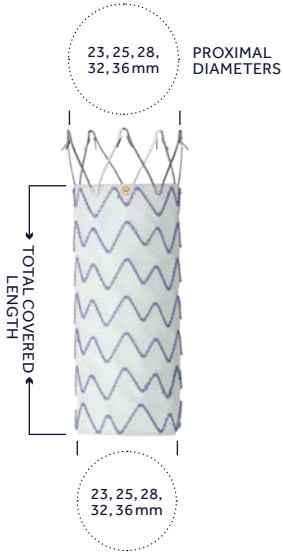
Product Code							
	Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design	Total Covered Length (mm)	Delivery System	Graft Dimensions (mm) A	B
ETUF	23	14	C	102	E	30	40
ETUF	25	14	C	102	E	30	40
ETUF	28	14	C	102	E	30	40
ETUF	32	14	C	102	E	30	40
ETUF	36	14	C	102	E	30	40

The only device with an FDA-approved AUI Indication†



† As of October 2018

ENDURANT™ II AUI



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	E
ETCF	25	25	C	49	E
ETCF	28	28	C	49	E
ETCF	32	32	C	49	E
ETCF	36	36	C	49	E
ETTF	23	23	C	70	E
ETTF	25	25	C	70	E
ETTF	28	28	C	70	E
ETTF	32	32	C	70	E
ETTF	36	36	C	70	E

Talent™ Occluder

with Occluder Delivery System

FEATURES

Double spring configuration securely anchors in the iliac artery to seal the lumen and to prevent retrograde blood flow.

COMPONENT PLACEMENT GUIDE

PRODUCT CODE DESCRIPTION

OCL	8	US	31	17.5

Catheter Diameter

Total Length

Proximal / Distal Diameter

Device Configuration

OCL- Occluder

TALENT™ OCCLUDER
31–35mm

8–24mm

● Radiopaque markers

TALENT™ OCCLUDER

Product Code	Proximal Distal Diameter (mm)		Total Length (mm)	Catheter Diameter (Fr)
OCL	8	US	31	17.5
OCL	10	US	31	17.5
OCL	12	US	31	17.5
OCL	14	US	33	17.5
OCL	16	US	33	17.5
OCL	18	US	33	17.5
OCL	20	US	35	17.5
OCL	22	US	35	17.5
OCL	24	US	35	17.5

Valiant Navion™

Thoracic Stent Graft System

Freedom to Do More

Low profile, easy-to-use delivery system designed for expanded access with smooth navigation

FEATURES

Delivery System

- Tip Capture: for controlled delivery and deployment on both FreeFlo and CoveredSeal configurations
- Designed for simplified navigation: flexible, kink-resistant hydrophilic-coated catheter
- Shorter tapered tip designed to decrease vessel impact

Stent Graft

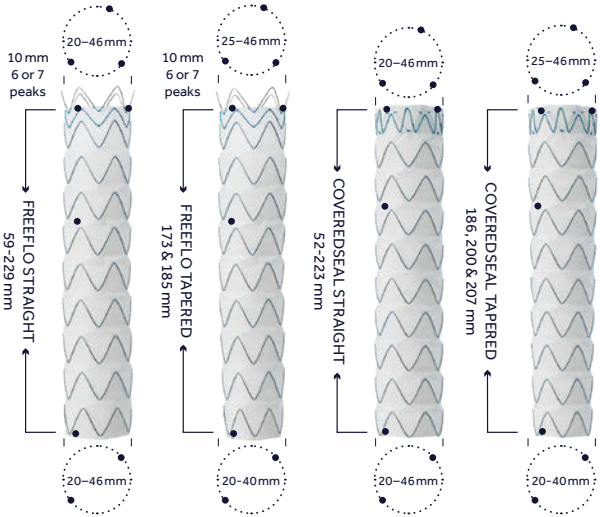
- Multi-filament thoracic graft material based on Endurant™ stent graft yarn designed for flexibility and superior permeability resistance
- Aligned stent peaks and valleys designed for increased flexibility throughout the stent graft
- Increased distance between stents designed to optimize migration resistance and conformability

Proven Platforms

- Leverages proven design of the Valiant™ and Endurant™ stent graft system platforms
- 100K+ thoracic and 300K abdominal patients treated[†]
- Over 20 years of endovascular experience with deep clinical history

[†] Data on file at Medtronic.

COMPONENT GUIDE



DISTINCT RADIOPAQUE MARKER

- Spherical RO Marker

Each Valiant Navion™ thoracic stent graft device must be ordered in a size appropriate to fit the patient's anatomy. Proper sizing of the Valiant Navion™ thoracic stent graft is the responsibility of the physician.

Aneurysms, Penetrating Ulcers (PAU):
Oversize the aortic portion of the stent graft by 3 to 7 mm, as appropriate for the patient. The following table is provided as a guideline.

Dissection:
Do not oversize the stent graft more than 10% of the healthy aorta nominal diameter. The following table is provided as a guideline.

For Additional Sections:
When the stent graft junction is located within the aneurysmal sac or is not supported by tissue, 6 mm oversizing between the primary component and additional section is recommended. In the case when a 20 mm stent graft is used as an outside component, the diameter of the inside component should be oversized by 5 mm relative to the outside component.
When the stent graft junction is supported by tissue (e.g., dissections), the stent graft should be oversized relative to the supporting native vessel.

Aneurysms or PAU

Native Vessel (mm)	Recommended Stent Graft Diameter (mm)	Oversizing (mm)
16	20	4
17	20	3
18	22	4
19	22	3
20	25	5
21	25	4
22	25	3
23	28	5
24	28	4
25	28	3
26	31	5
27	31	4
28	31	3
28	34	6
29	34	5
30	34	4
31	34	3
30	37	7
31	37	6
32	37	5
33	37	4
33	40	7
34	40	6
35	40	5
36	40	4
36	43	7
37	43	6
38	43	5
39	43	4
39	46	7
40	46	6
41	46	5
42	46	4

Dissection

Native Vessel (mm)	Recommended Stent Graft Diameter (mm)	Oversizing (mm)
19	20	1
20	22	2
21	22	1
22	22	0
23	25	2
24	25	1
25	25	0
26	28	2
27	28	1
28	28	0
29	31	2
30	31	1
31	34	3
32	34	2
33	34	1
34	37	3
35	37	2
36	37	1
37	40	3
38	40	2
39	40	1
39	43	4
40	43	3
41	43	2
42	43	1
42	46	4
43	46	3
44	46	2
45	46	1

Blunt Thoracic Aortic Injury

Native Vessel (mm)	Recommended Stent Graft Diameter (mm)	Oversizing (mm)
16	20	4
17	20	3
18	22	4
19	22	3
20	22	2
20	25	5
21	25	4
22	25	3
23	25	2
23	28	5
24	28	4
25	28	3
26	28	2
26	31	5
27	31	4
28	31	3
29	31	2
28	34	6
29	34	5
30	34	4
31	34	3
32	34	2
30	37	7
31	37	6
32	37	5
33	37	4
34	37	3
35	37	2
33	40	7
34	40	6
35	40	5
36	40	4
37	40	3
38	40	2
36	43	7
37	43	6
38	43	5
39	43	4
40	43	3
41	43	2
39	46	7
40	46	6
41	46	5
42	46	4
43	46	3
44	46	2

VALIANT NAVION™ SYSTEM PRODUCT CODE DESCRIPTION

VN	M	C	22	22	C	100	TU	22

Product Name
VN - Valiant Navion™ System

Device Configuration
M - Main Stent Graft

Proximal Design
C - CoveredSeal
F - FreeFlo

Proximal Diameter

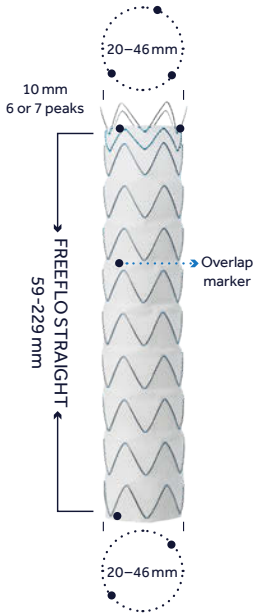
Distal Diameter

Distal Design

Nominal Stent Graft Covered Length

Delivery System
TU - Thoracic

Catheter Outer Diameter



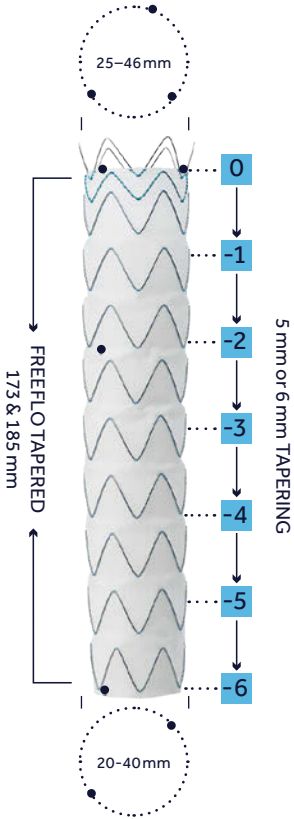
FREEFLO STRAIGHT

FREEFLO STRAIGHT

Product Code							
	Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)		Stent Graft Covered Length (mm)		Catheter Outer Diameter (Fr)
VNMF	20	20	C	96	TU	18
VNMF	22	22	C	96	TU	18
VNMF	22	22	C	185	TU	18
VNMF	25	25	C	96	TU	18
VNMF	25	25	C	185	TU	18
VNMF	28	28	C	97	TU	20
VNMF	28	28	C	174	TU	20
VNMF	31	31	C	97	TU	20
VNMF	31	31	C	174	TU	20
VNMF	31	31	C	229	TU	20
VNMF	34	34	C	59	TU	20
VNMF	34	34	C	97	TU	20
VNMF	34	34	C	174	TU	20
VNMF	34	34	C	229	TU	20
VNMF	37	37	C	59	TU	20
VNMF	37	37	C	97	TU	20
VNMF	37	37	C	174	TU	20
VNMF	37	37	C	229	TU	20
VNMF	40	40	C	62	TU	22
VNMF	40	40	C	103	TU	22
VNMF	40	40	C	183	TU	22
VNMF	40	40	C	223	TU	22
VNMF	43	43	C	62	TU	22
VNMF	43	43	C	103	TU	22
VNMF	43	43	C	183	TU	22
VNMF	43	43	C	223	TU	22
VNMF	46	46	C	62	TU	22
VNMF	46	46	C	103	TU	22
VNMF	46	46	C	183	TU	22
VNMF	46	46	C	223	TU	22

LOCATION OF OVERLAP MARKER

Proximal Diameter (mm)	Overlap Marker positioning (distance from fabric edge) FreeFlo straight configuration (mm)
20	48.0
22	48.0
25	48.0
28	56.5
31	56.5
34	56.5
37	56.5
40	59.0
43	59.0
46	59.0



FREEFLO TAPERED

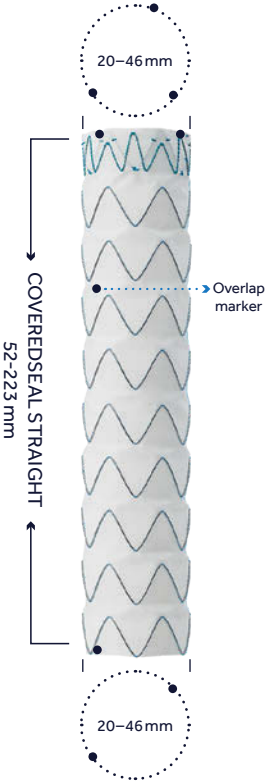
FREEFLO TAPERED

Product Code							
	Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)		Stent Graft Covered Length (mm)			Catheter Outer Diameter (Fr)
VNMF	25	20	C	185	TU		18
VNMF	28	22	C	173	TU		20
VNMF	31	25	C	173	TU		20
VNMF	34	28	C	173	TU		20
VNMF	37	31	C	173	TU		20
VNMF	40	34	C	185	TU		22
VNMF	43	37	C	185	TU		22
VNMF	46	40	C	185	TU		22

GRADUATED TAPERING SPECIFICATIONS

FREEFLO TAPERED CONFIGURATION (5mm taper)		FREEFLO TAPERED CONFIGURATION (6mm taper)		FREEFLO TAPERED CONFIGURATION (6mm taper)	
25mm x 20mm x 185mm		28mm x 22mm x 173mm 31mm x 25mm x 173mm 34mm x 28mm x 173mm 37mm x 31mm x 173mm		40mm x 34mm x 185mm 43mm x 37mm x 185mm 46mm x 40mm x 185mm	
Distance from proximal edge (mm)	1mm Taper Increments	Distance from proximal edge (mm)	1mm Taper Increments	Distance from proximal edge (mm)	1mm Taper Increments
0	0	0	0	0	0
37	-1	29	-1	31	-1
74	-2	58	-2	62	-2
111	-3	87	-3	93	-3
148	-4	115	-4	123	-4
185	-5	144	-5	154	-5
		173	-6	185	-6

Available in nominal length of ~175mm length



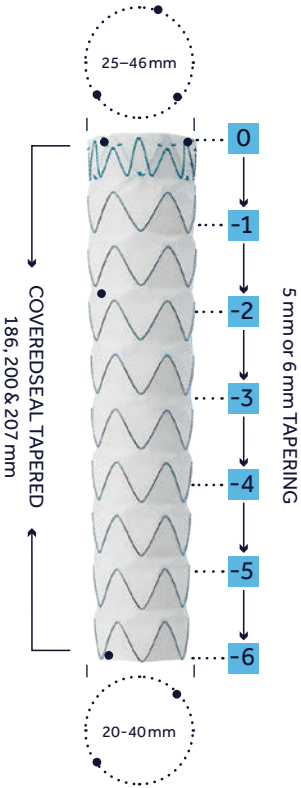
COVEREDSEAL STRAIGHT

COVEREDSEAL STRAIGHT

Product Code						
	Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)		Stent Graft Covered Length (mm)		Catheter Outer Diameter (Fr)
VNMC	20	20	C	94	TU	18
VNMC	22	22	C	94	TU	18
VNMC	22	22	C	180	TU	18
VNMC	25	25	C	94	TU	18
VNMC	25	25	C	180	TU	18
VNMC	28	28	C	90	TU	20
VNMC	28	28	C	182	TU	20
VNMC	31	31	C	90	TU	20
VNMC	31	31	C	182	TU	20
VNMC	31	31	C	223	TU	20
VNMC	34	34	C	52	TU	20
VNMC	34	34	C	90	TU	20
VNMC	34	34	C	182	TU	20
VNMC	34	34	C	223	TU	20
VNMC	37	37	C	52	TU	20
VNMC	37	37	C	90	TU	20
VNMC	37	37	C	182	TU	20
VNMC	37	37	C	223	TU	20
VNMC	40	40	C	55	TU	22
VNMC	40	40	C	95	TU	22
VNMC	40	40	C	175	TU	22
VNMC	40	40	C	218	TU	22
VNMC	43	43	C	55	TU	22
VNMC	43	43	C	95	TU	22
VNMC	43	43	C	175	TU	22
VNMC	43	43	C	218	TU	22
VNMC	46	46	C	55	TU	22
VNMC	46	46	C	95	TU	22
VNMC	46	46	C	175	TU	22
VNMC	46	46	C	218	TU	22

LOCATION OF OVERLAP MARKER

Proximal Diameter (mm)	Overlap Marker positioning (distance from fabric edge) CoveredSeal straight configuration (mm)
20	46.5
22	46.5
25	46.5
28	52.5
31	52.5
34	52.5
37	52.5
40	55.5
43	55.5
46	55.5



COVEREDSEAL TAPERED

COVEREDSEAL TAPERED

Product Code							
	Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)		Stent Graft Covered Length (mm)		Catheter Outer Diameter (Fr)
VNMC	25	20	C	186	TU	18
VNMC	28	22	C	207	TU	20
VNMC	31	25	C	207	TU	20
VNMC	34	28	C	207	TU	20
VNMC	37	31	C	207	TU	20
VNMC	40	34	C	200	TU	22
VNMC	43	37	C	200	TU	22
VNMC	46	40	C	200	TU	22

GRADUATED TAPERING SPECIFICATIONS

COVEREDSEAL TAPERED CONFIGURATION (5mm taper)	
25mm x 20mm x 186mm	
Distance from proximal edge (mm)	1mm Taper Increments
0	0
37	-1
74	-2
112	-3
149	-4
186	-5

COVEREDSEAL TAPERED CONFIGURATION (6mm taper)	
28mm x 22mm x 207mm 31mm x 25mm x 207mm 34mm x 28mm x 207mm 37mm x 31mm x 207mm	
Distance from proximal edge (mm)	1mm Taper Increments
0	0
35	-1
69	-2
104	-3
138	-4
173	-5
207	-6

COVEREDSEAL TAPERED CONFIGURATION (6mm taper)	
40mm x 34mm x 200mm 43mm x 37mm x 200mm 46mm x 40mm x 200mm	
Distance from proximal edge (mm)	1mm Taper Increments
0	0
33	-1
67	-2
100	-3
133	-4
167	-5
200	-6

Available in ~ 175mm nominal length only for the smallest device
Devices from 28mm to 46mm available in ~200mm nominal length

Heli-FX™

EndoAnchor™ System

FEATURES

Tailor seal and fixation in EVAR and TEVAR

- The Heli-FX™ EndoAnchor™ system is designed to enhance the outcomes and durability of EVAR and TEVAR
- Helical EndoAnchor™ implants are designed to provide independent transmural fixation and the stability of a surgical anastomosis†
- Enhances the inherent sealing and fixation mechanisms of approved endografts
  - Cook Zenith™*, Cook Zenith TX2™*, Gore Excluder™*, Gore TAG™*, Medtronic AneuRx™, Medtronic Endurant™, Medtronic Talent™ AAA, Medtronic Talent™ TAA, and Medtronic Valiant™ endografts
- The Heli-FX™ EndoAnchor™ implant is contraindicated with Endologix AFX™* stent grafts
- Motorized, intuitive controls for precise placement of EndoAnchor™ implants

Expanding Patient Care Options

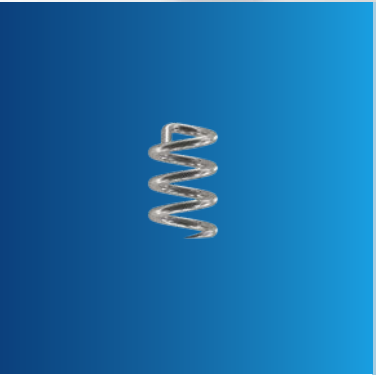
- Endurant™ II/IIs AAA stent graft system and Heli-FX™ EndoAnchor™ system
- The first off-the-shelf short neck EVAR solution
- Indicated for patients with neck lengths ≥10mm; or ≥4mm and <10mm and ≤60° infrarenal angle

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

† Melas N, et al. Helical EndoAnchor Implants Provide the Stability of a Surgical Anastomosis. J Vasc Surg. 2012;55(6):1726-1733.



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™ Applier 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

TourGuide™

Steerable Sheath

FEATURES

Precisely Guide Your Next Intervention†

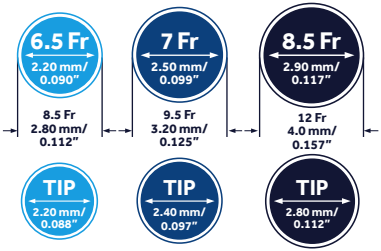
Quickly Access Indicated Anatomy with the TourGuide™ Steerable Sheath.

- **Conformability**
  Steerable sheath improves access to hard-to-reach sites and eliminates need to change sheaths to reach desired position
- **Versatility**
  The TourGuide™ sheath has a wide variety of applications within the human vasculature, from the periphery to the intracardiac
- **Control**
  Precise deflection using the self-locking rotating knob allows you to maintain control of the full procedure

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

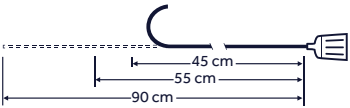
Inner Diameter Compatibility

For use with aortic and peripheral interventional devices



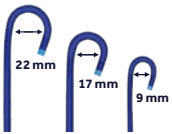
Three Working Lengths

Can access challenging anatomy in order to perform aortic and peripheral interventions



Adjustable Tip Deflection

May reduce overall procedure time by minimizing multiple exchanges associated with different catheter selections



ORDERING INFORMATION

Catalog Number	Inner Diameter Size (Fr)	Usable Length (cm)	Deflection Length @ 180° (mm)
TG0654509	6.5	45	9
TG0654517	6.5	45	17
TG0655509	6.5	55	9
TG0655517	6.5	55	17
TG0659009	6.5	90	9
TG0704509	7.0	45	9
TG0704517	7.0	45	17
TG0705509	7.0	55	9
TG0705517	7.0	55	17
TG0709009	7.0	90	9
TG0854517	8.5	45	17
TG0854522	8.5	45	22
TG0855517	8.5	55	17
TG0855522	8.5	55	22
TG0859017	8.5	90	17

Sentrant™

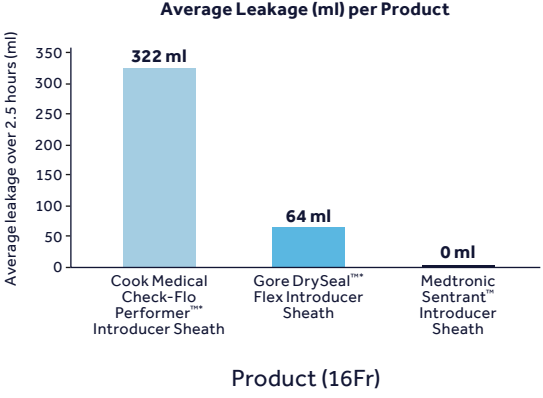
Introducer Sheath with Hydrophilic Coating

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

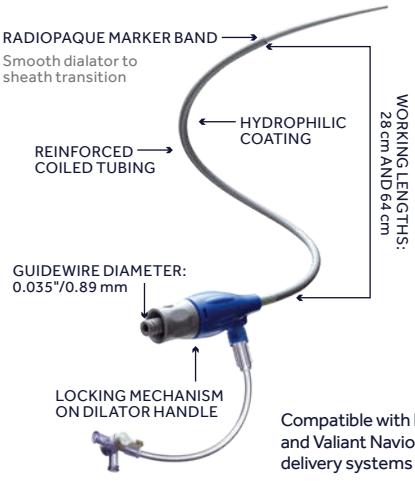
Superior leak resistance versus Cook Check-Flo Performer™* introducer sheath and Gore DrySeal™* Flex introducer sheath†



* 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 SUPERIOR HEMOSTASIS†



Compatible with Endurant™ and Valiant Navion™ stent graft delivery systems

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

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†	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.

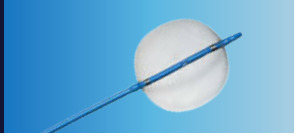
PRODUCT INFORMATION

RELIANT™ STENT GRAFT BALLOON CATHETER‡

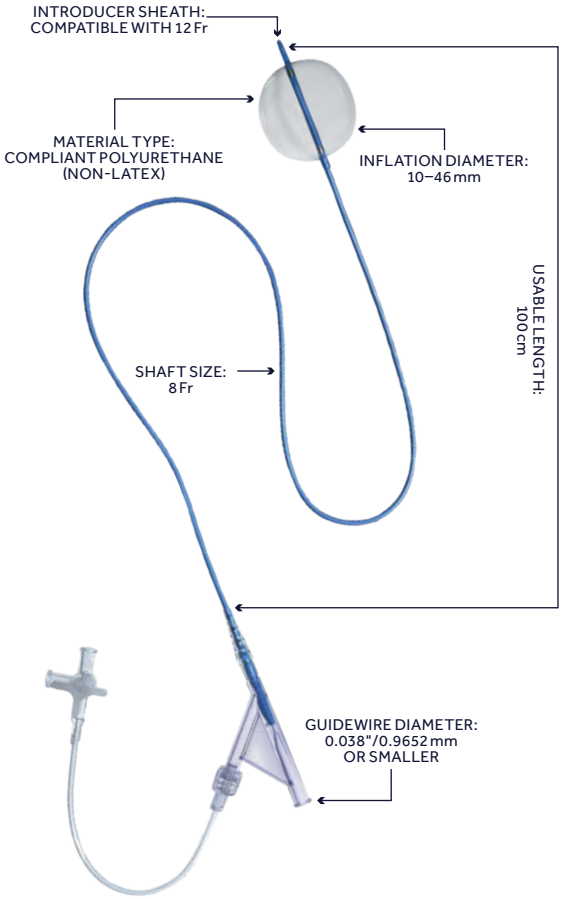
Product Code	Inflation Diameter (mm)	Shaft Size (Fr)	Usable Length (cm)	Sheath Compatibility (Fr)
REL46	10–46	8	100	12

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

†Maximum inflation diameter.
‡Does not contain latex.



MULTIPLE PURPOSES, SINGLE SOLUTION



Endurant™ II / IIs

AAA Stent Graft System

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. 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.

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 EndoAnchors 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 (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.

Talent™ Occluder

with Occluder Delivery System

Indications

The Talent™ Occluder with Occluder Delivery system is intended for endoluminal occlusion of the common iliac artery in order to prevent retrograde blood into the aneurysm sac when used in conjunction with a fem-fem bypass (for example, the Talent Occluder can be used in combination with the Talent Converter Stent Graft).

The anatomical considerations are as follows:

- Iliac/femoral access vessel morphology that is compatible with vascular access techniques and a delivery system profile of 17.5 French
- Common iliac vessel diameters between 6 mm and 20 mm

Contraindications

The Talent Occluder is contraindicated in:

- Patients who have a condition that threatens to infect the graft
- Patients with sensitivities or allergies to the device materials

Warnings and Precautions

- The long-term performance of the Talent Occluder has not yet been established. All patients receiving the Talent Occluder should receive enhanced follow-up. Specific follow-up guidelines are described in the *Instructions for Use*.
- Renal complications may occur: 1) From an excess use of contrast agents 2) As a result of emboli.
- Studies indicate that the danger of micro-embolization increases with increased duration of the procedure.
- The safety and effectiveness of the Talent Occluder 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 Talent Occluder 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*.

Potential Adverse Events

Potential adverse events include (not arranged in any particular order): Aneurysm enlargement; aneurysm rupture and death; aortic damage (including perforation, dissection, bleeding, rupture and death); arterial or venous thrombosis and/or pseudoaneurysm; bleeding, hematoma or coagulopathy; cardiac complications and subsequent attendant problems; claudication; dislodgement of pre-existing graft (for example, a Talent Converter); death; embolization (micro and macro) with transient or permanent ischemia or infarction; endoleak; fever and localized inflammation; pulmonary/respiratory complications; renal complications; surgical conversion to open repair; vascular access site complications ;vascular spasm or vascular trauma; vessel damage; wound complications and subsequent attendant problems; stent graft complications: 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.

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.

Valiant Navion™

Thoracic Stent Graft System

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

- iliac or femoral artery access vessel morphology that is compatible with vascular access techniques, devices, or accessories;
- nonaneurysmal aortic diameter in the range of:
  - 16 mm to 42 mm for fusiform and saccular aneurysms/penetrating ulcers
  - 16 mm to 44 mm for blunt traumatic aortic injuries
  - 19 mm to 45 mm for dissections;
- proximal landing zone (nonaneurysmal aortic proximal neck length for fusiform and saccular aneurysms/penetrating ulcers *or* nondissected length of aorta proximal to the primary entry tear for blunt traumatic aortic injuries and dissections) of:
  - ≥ 20 mm for FreeFlo configuration
  - ≥ 25 mm for CoveredSeal configuration; and
- nonaneurysmal aortic distal neck length ≥ 20 mm for FreeFlo and CoveredSeal configurations for fusiform and saccular aneurysms/penetrating ulcers.

Contraindications
The Valiant Navion thoracic stent graft system is contraindicated in the following patient populations:

- Patients who have a condition that threatens to infect the graft
- Patients who are sensitive to or have allergies to the device materials

Warnings and Precautions

- The long-term safety and effectiveness of the Valiant Navion thoracic stent graft 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. Specific follow-up guidelines are described in the *Instructions for Use*. Of note, patients with specific clinical findings should receive enhanced follow-up.
- The Valiant Navion thoracic stent graft 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 described in the *Instructions for Use*.
- The safety and effectiveness of Valiant Navion thoracic stent graft system has not been evaluated in certain patient situations and/or populations. Please refer to product *Instructions for Use* for details.
- Strictly adhere to the Valiant Navion thoracic stent graft system sizing configurations and guidelines as described in the *Instructions for Use* when selecting the device size. The appropriate device oversizing is incorporated into the sizing guidelines. Sizing outside of this range can potentially result in endoleak, fracture, migration, infolding, or graft wear.
- Never use a balloon when treating a dissection.

Please refer to the product *Instructions for Use* for details.

MRI Safety and Compatibility
MRI may be used on the Valiant Navion thoracic stent graft only under specific conditions. 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
Adverse events or complications associated with the use of the Valiant Navion thoracic stent graft system that may occur or require intervention include, but are not limited to: Access failure; Access site complications (for example: spasm, trauma, bleeding, rupture, dissection); Adynamic Ileus; Allergic reaction (to contrast, antiplatelet therapy, stent graft material); Amputation; Anaphylaxis; Anesthetic complications; Aneurysm rupture; Angina; Aortic expansion (for example: aneurysm, false

lumen); Aortic valve damage; Aortic vessel rupture; Arrhythmia; Arterial stenosis; Atelectasis; Balloon rupture; Blindness; Bowel ischemia; Bowel necrosis; Bowel obstruction; Branch vessel occlusion; Breakage of the metal portion of the device; Buttock claudication; Cardiac tamponade; Catheter breakage; Cerebrovascular accident (CVA)/Stroke; Change in mental status; Coagulopathy; Congestive heart failure; Contrast toxicity; Conversion to surgical repair; Damage to the vessel; Death; Deployment difficulties/failures; Dissection, perforation, or rupture of the aortic vessel & surrounding vasculature; Embolism; Endoleaks; Excessive or inappropriate radiation exposure; Extrusion/erosion; Failure to deliver the stent graft; Femoral neuropathy; Fistula (including aortobronchia, aortoenteric, aortoesophogeal, arteriovenous, and lymph); Gastrointestinal bleeding/complications; Genitourinary complications; Hematoma; Hemorrhage/bleeding; Hypotension/hypertension; Infection or fever; Insertion or removal difficulty; Intercostal pain; Intramural hematoma; Leg edema/foot edema; Loss of patency; Lymphocele; Myocardial infarction; Neck enlargement; Nerve injury; Neuropathy; Occlusion - Venous or Arterial; Pain/reaction at catheter insertion site; Paralysis; Paraparesis; Paraplegia; Paresthesia; Perfusion of the false lumen; Peripheral ischemia; Peripheral nerve injury; Pneumonia; Postimplant syndrome; Post-procedural bleeding; Procedural bleeding; Prosthesis dilatation; Prosthesis infection; Prosthesis rupture; Prosthesis thrombosis; Pseudoaneurysm; Pulmonary edema; Pulmonary embolism; Reaction to anesthesia; Renal failure; Renal insufficiency; Reoperation; Respiratory depression or failure; Retrograde type A dissection; Sepsis; Seroma; Sexual dysfunction; Shock; Spinal neurological deficit; Stenosis; Stent graft migration; Stent graft misplacement; Stent graft occlusion; Stent graft rupture (for example: holes, tears); Stent graft twisting or kinking; Transient ischemic attack (TIA); Thrombosis; Tissue necrosis; Vascular ischemia; Vascular trauma; Wound dehiscence; Wound healing complications and Wound infection.

Please reference the 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.

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 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 and determined to be compatible with the Cook Zenith™*, Cook Zenith™* TX2™*, Gore Excluder™*, Gore TAG™*, Jotec E™*-vita abdominal, Jotec E™*-vita thoracic, Medtronic AneuRx™, Medtronic Endurant™, Medtronic Talent™, and Medtronic Valiant™ endografts. 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
- EndoAnchor™ implant 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.

TourGuide™

Steerable Sheath

The following disclosures must be on all promotional/advertising materials.

CAUTION: Federal Law restricts this device to sale by or on the order of a physician (U.S.A.). Please refer to the Instructions for Use for a complete listing of the indications, contraindications, precautions and warnings, where applicable.

Important Information: Prior to use, refer to the *Instructions for Use* supplied with these devices for indications, contraindications, suggested procedure, warnings and precautions. Failure to properly follow the *instructions for use*, warnings, and precautions may lead to serious consequences or injury to the patient.

If the indications for use of the device are discussed, the following statement must appear:

Indications for Use: The steerable sheath, model TourGuide™ is intended for the introduction of diagnostic and therapeutic devices into the human vasculature, including but not limited to intracardiac, renal or other peripheral placements. Do not use this device for neural placements.

Contraindications:
- Known active or systemic local infection
- Known inability to obtain vascular access
- Patients with atrial thrombosis or myxoma, or interatrial baffle or patch
- Use of a steerable sheath is contraindicated in patients with obstructive or inadequate vasculature

Potential Adverse Events: Possible adverse events associated with the use of TourGuide™ Steerable Sheath include, but are not limited to:
- Air Embolism
- Allergic reaction to contrast media
- Aortic puncture
- Arrhythmias
- Arteriovenous fistula formation
- Atrial septal defect
- Bleeding plexus injury
- Catheter entrapment
- Cardiac tamponade
- Coronary artery spasm and/or damage

- Dislodgement
- Dissection
- Endocarditis
- Heart Block
- Hematoma formation
- Hemorrhage
- Hemothorax
- Infection
- Intimal tear
- Irregular heart beat
- Local nerve damage
- Mediastinal widening
- Myocardial infarction
- Pacemaker/defibrillator lead displacement
- Perforation
- Pericardial/pleural effusion
- Pneumothorax
- Pseudoaneurysm formation
- Pulmonary edema
- Stroke
- Subclavian artery puncture
- Thromboembolic events
- Thrombophlebitis
- Valve damage
- Vascular occlusion
- Vasovagal reaction
- Vessel damage/Vessel trauma
- Vessel spasm

PRECAUTION: Transvenous device compatibility: Use the steerable sheath only with compatible transvenous devices. Use the appropriate size sheath for the size of the transvenous device being utilized. Consequences of using the steerable sheath with incompatible devices may include the inability to deliver the transvenous device or damage to the transvenous device during delivery.

WARNING: If the patient has left bundle branch block, back up pacing should be readily available during insertion of the steerable sheath assembly. Use of the steerable sheath assembly may cause heart block.

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.

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a licensed healthcare practitioner.

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.

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a licensed healthcare practitioner.

NOTES

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