

FREEDOM TO **DO MORE**

Valiant Navion™
Thoracic Stent Graft System

Low Profile: 18 Fr O.D.



The only low-profile
system with both a bare
stent and covered stent
configuration

**ALL WITH
TIP CAPTURE**

Medtronic
Further. Together

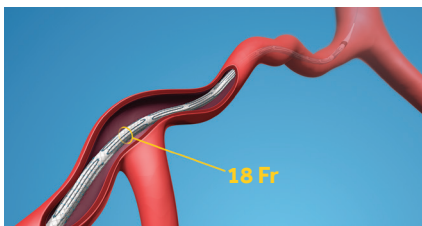
DO MORE: REIMAGINED DESIGN

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

ACCESS MORE

Low-profile delivery system

18-22Fr designed for expanded access



Designed for smooth navigation

Highly flexible, kink resistant, hydrophilic-coated catheter smoothly navigates through tortuous, diseased, and heavily calcified vessels

Shorter tapered tip

Designed to minimize vessel impact and ensure trackability without the need of a sheath

CONTROL MORE

Tip capture

For controlled delivery and accurate deployment on both FreeFlo and CoveredSeal configurations

Easy to use screwgear

Provides a mechanical advantage for consistent, smooth deployment

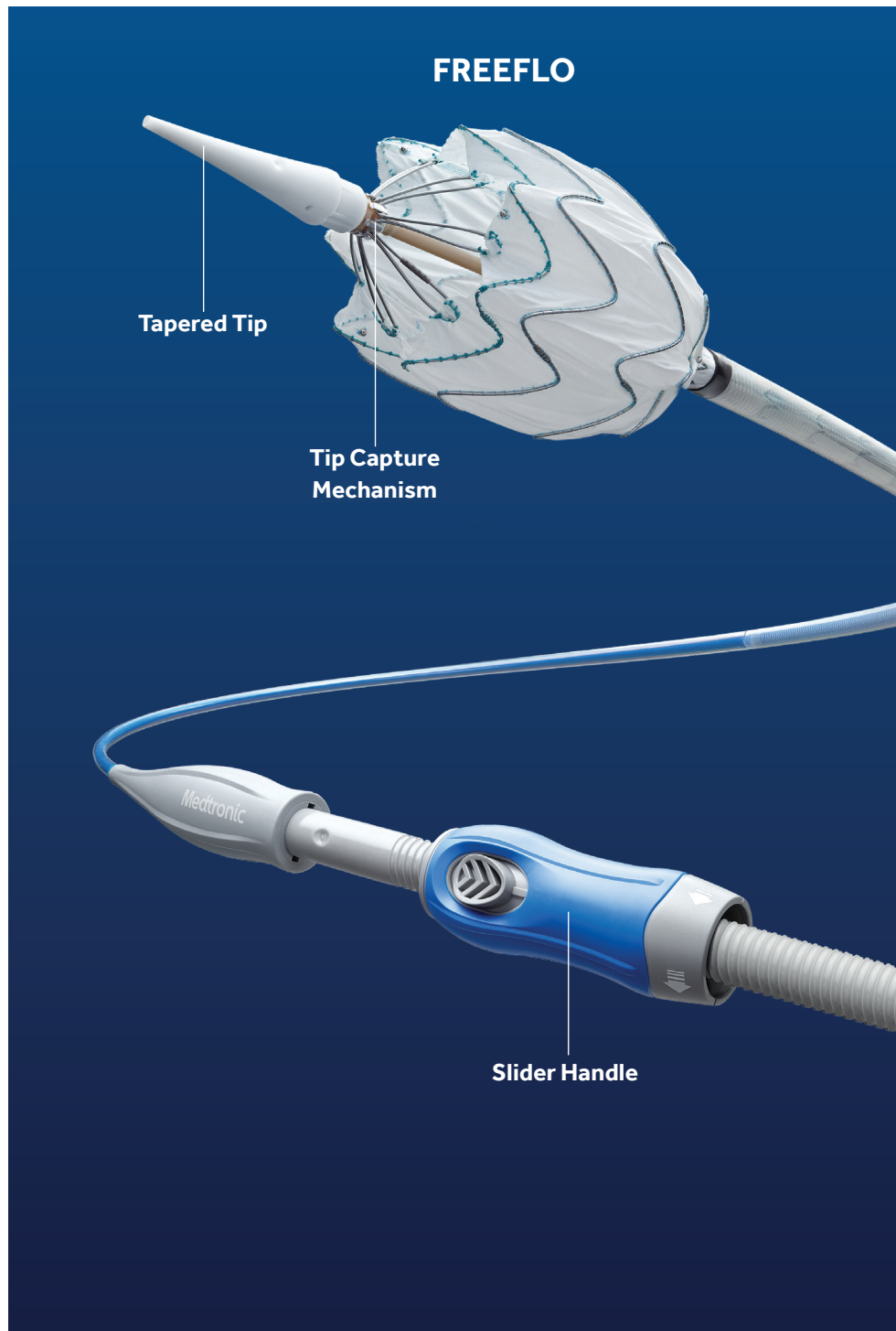
Ergonomic design

Versaflex material engineered for enhanced feel

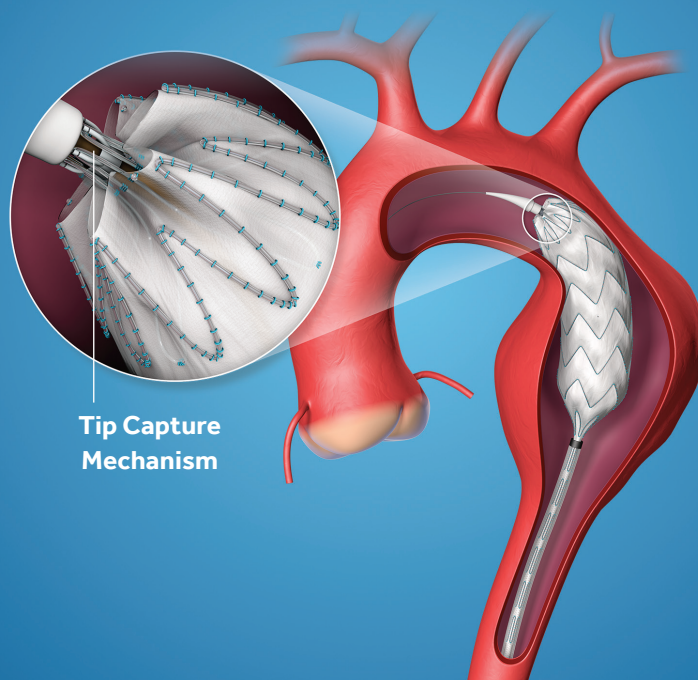
Integrated flush port

Allows for easy flushing of the device prior to vessel access

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



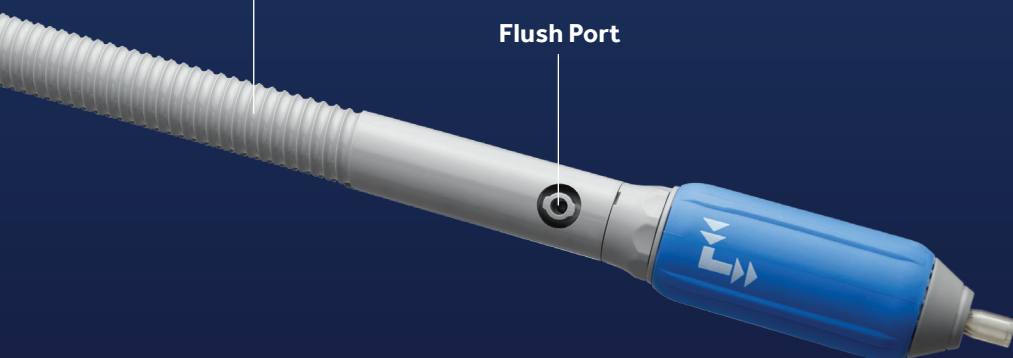
COVEREDSEAL



A true covered stent option with
the control and accuracy you
have come to expect

Screwgear

Flush Port



DO MORE: REIMAGINED DESIGN

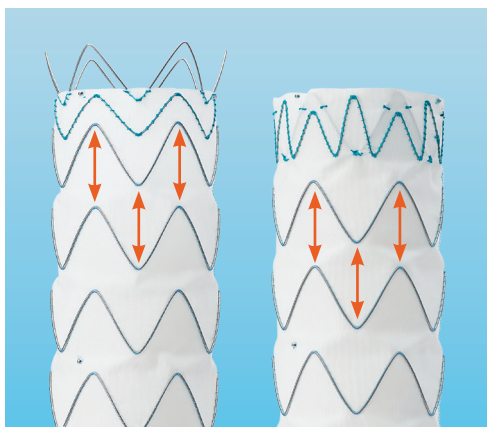
Versatile, durable design with the control, accuracy and conformability you have come to expect

CONFORM TO MORE

Stent Design

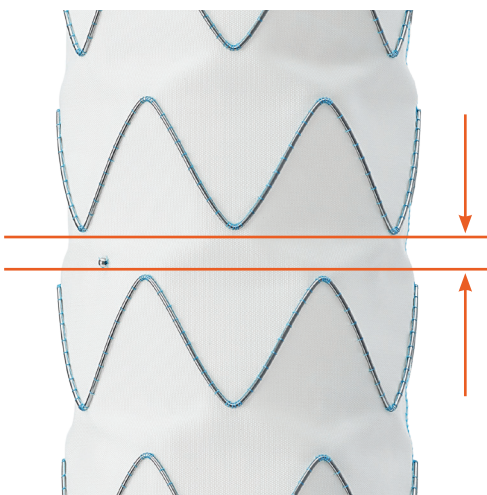
Aligned stent peaks and valleys

Designed for increased flexibility throughout the stent graft



Increased distance between stents

Designed to optimize migration resistance & conformability

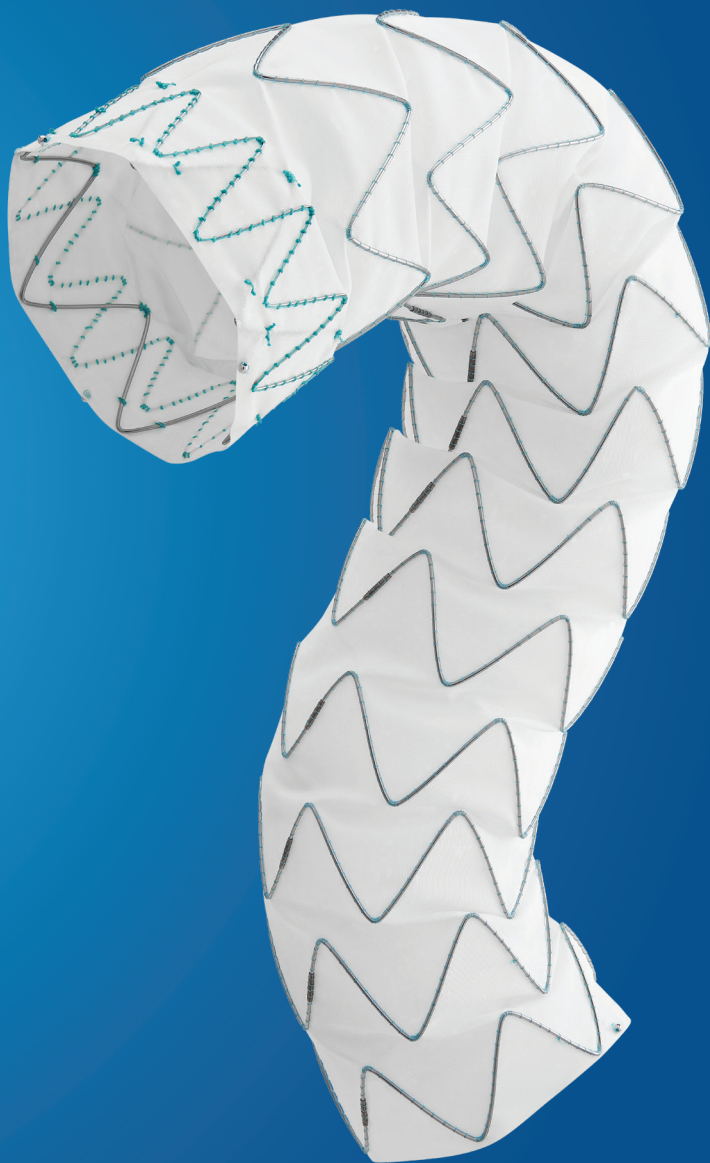


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Data not indicative of clinical performance.

FREEFLO



COVEREDSEAL

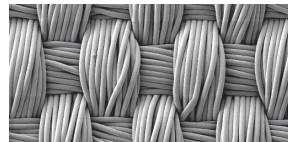


SEAL MORE

Improved Seal - leveraging our experience in the abdominal space to optimize the graft material

Thoracic graft material

Multi-filament thoracic graft material, based on Endurant™ stent graft yarn, designed for flexibility and superior permeability resistance



FreeFlo support stent & CoveredSeal W-stent

Designed to support the proximal fabric and prevent in-folding

CUSTOMIZE MORE

Better treat the pathology at hand

CoveredSeal with tip capture

Offers reduced focal interaction & consistent distribution of radial force in the seal zone



Broad size matrix

Shorter and longer lengths, smaller diameter and greater tapering offer more sizing options to tailor fit varied pathologies

DO MORE: PROVEN PLATFORMS

Leveraging the proven design of Endurant™
and Valiant™ stent graft systems

BUILT ON PROVEN PLATFORMS

100K+

thoracic patients treated with
Valiant™ graft worldwide



300K+

abdominal patients treated with
Endurant™ graft worldwide

OVER 20 YEARS

of endovascular experience with
deep clinical history

Versatile with Low Profile

18Fr - 22Fr O.D.

with multiple options for
proximal configuration

74.7% proximal
FreeFlo usage
(65/87)†

25.3% proximal
CoveredSeal
usage (22/87)†

NO access vessel
failures (0/87)†

50.6% percutaneous
access (44/87)†

Challenging patients: Challenging anatomy

71.2% of patients with
ASA III/IV (62/87)†

85.7% of patients with
high thoracic aorta
tortuosity (66/87)†

NO conversion to open
surgery (0/87)†

NO deployment
failures (0/87)†

1.2% Type I EL at
30-days (1/81)†

†Data on file at Medtronic

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EASY THREE-STEP DEPLOYMENT PROCESS



Step 1

Slow, controlled deployment for precise stent graft placement



Step 2

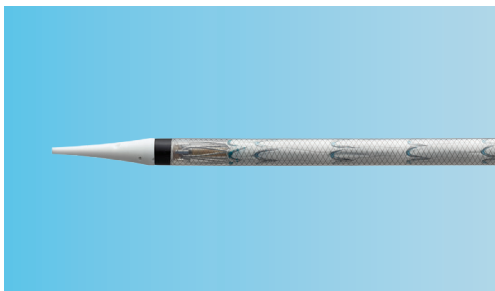
Quick deployment option, if desired



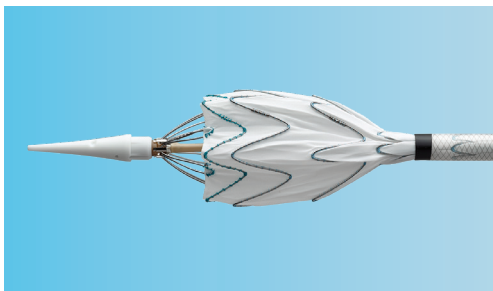
Step 3

Tip capture release

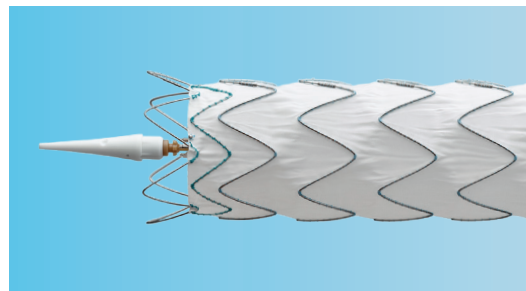
FREEFLO



Deployment



Captured

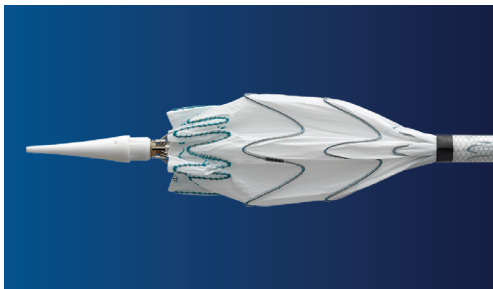


Released

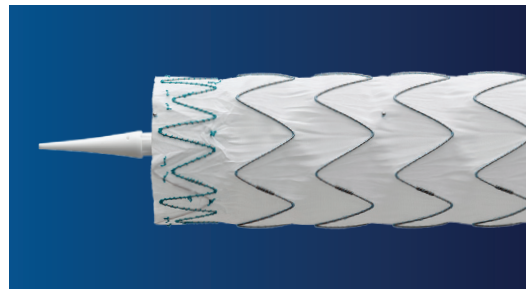
COVEREDSEAL



Deployment



Captured

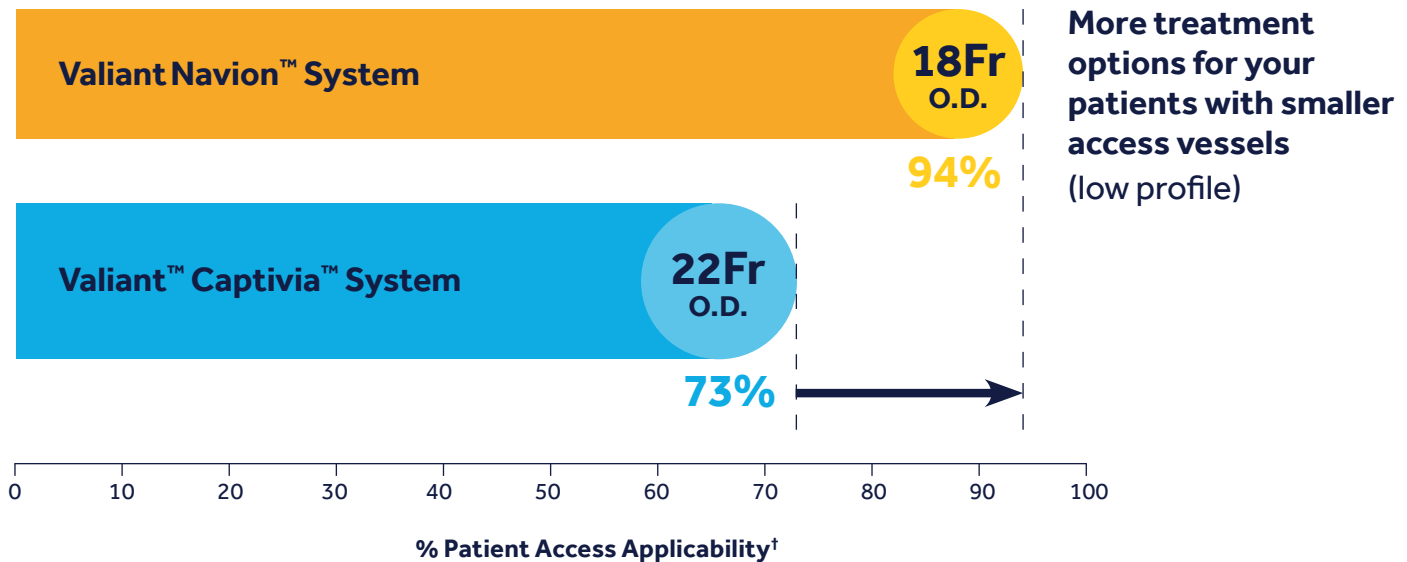


Released

DO MORE: REACH FURTHER

The Valiant Navion™ system offers an easy-to-use endovascular solution to treat more patients

PATIENT APPLICABILITY



	Medtronic Valiant Navion™‡	Gore C-TAG™§	Cook Zenith™* Alpha™ Thoracic¹	Bolton Relay™* Plus²
Profile	✓ 18Fr-22Fr O.D.	20Fr-27Fr O.D. (18Fr-24Fr ID Sheaths)	18Fr-23Fr O.D.	22Fr-26Fr O.D.
Sheath Required	✓ No	Yes	No	No
Aneurysm, Dissection, PAU, BTAI, IMH	✓ Yes	Yes	No	No
Tip Capture	✓ Yes	No	Yes Exposed barbs	Yes
Proximal Design	✓ FreeFlo CoveredSeal	Mini-bare stents	Bare stents with barbs	Bare stent
Distal Taper	✓ 5-6mm	4mm	4mm	4mm

™*Third party brands are trademarks of their respective owners.

†Based on M2S anatomical data for 45K subjects

‡Data on file at Medtronic

§Gore C-TAG™ thoracic stent graft IFU

¹Cook Zenith™ Alpha™ thoracic stent graft IFU

²Bolton Relay™ Plus thoracic stent graft IFU

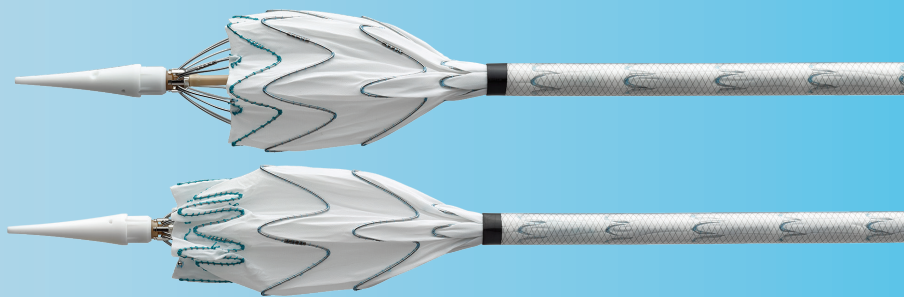
FREEDOM TO DO MORE

REIMAGINED DESIGN

For expanded treatment with the control and accuracy you have come to expect, now with FreeFlo and CoveredSeal options

FreeFlo & CoveredSeal
with tip capture

Optimized graft
material & stent design



BUILT ON PROVEN PLATFORMS

Leveraging the proven design of Endurant™ and Valiant™ stent graft systems

OVER **20** YEARS
of endovascular
experience with deep
clinical history

100K+
thoracic patients
treated with Valiant™
graft worldwide

300K+
abdominal patients
treated with Endurant™
graft worldwide

REACH FURTHER

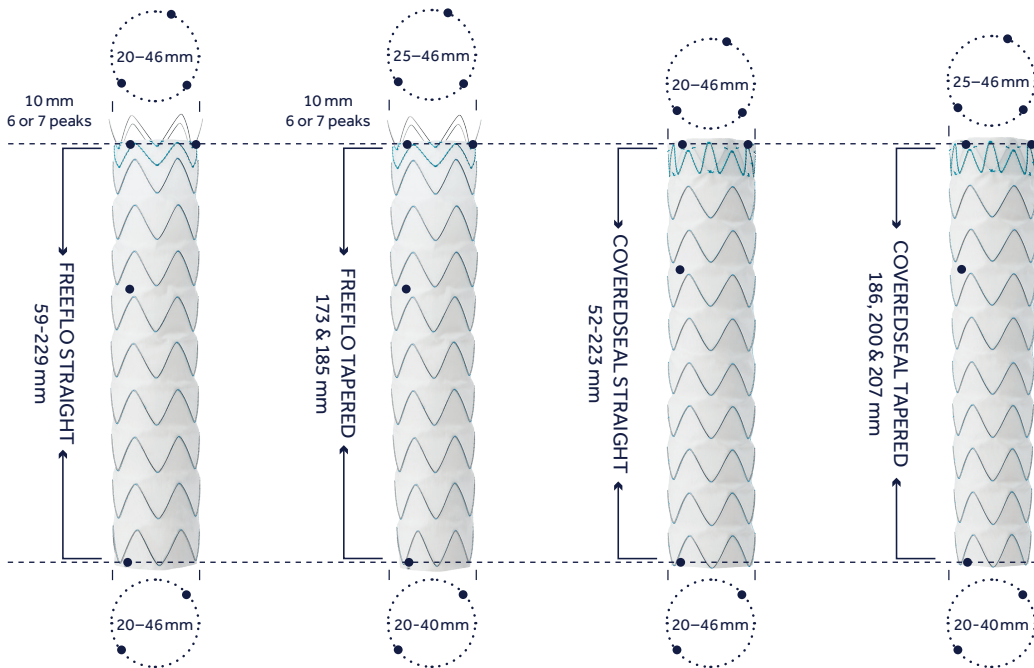
The Valiant Navion™ system offers an easy-to-use endovascular solution to treat more patients



- Low profile 18 Fr - 22 Fr O.D.
- Broader patient applicability
- Enhanced customization:
Expanded size matrix and configurations

Bench test data on file at Medtronic.
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COMPONENT PLACEMENT GUIDE AND PRODUCT CODES



DISTINCT RADIOPAQUE MARKER

- Spherical RO Marker

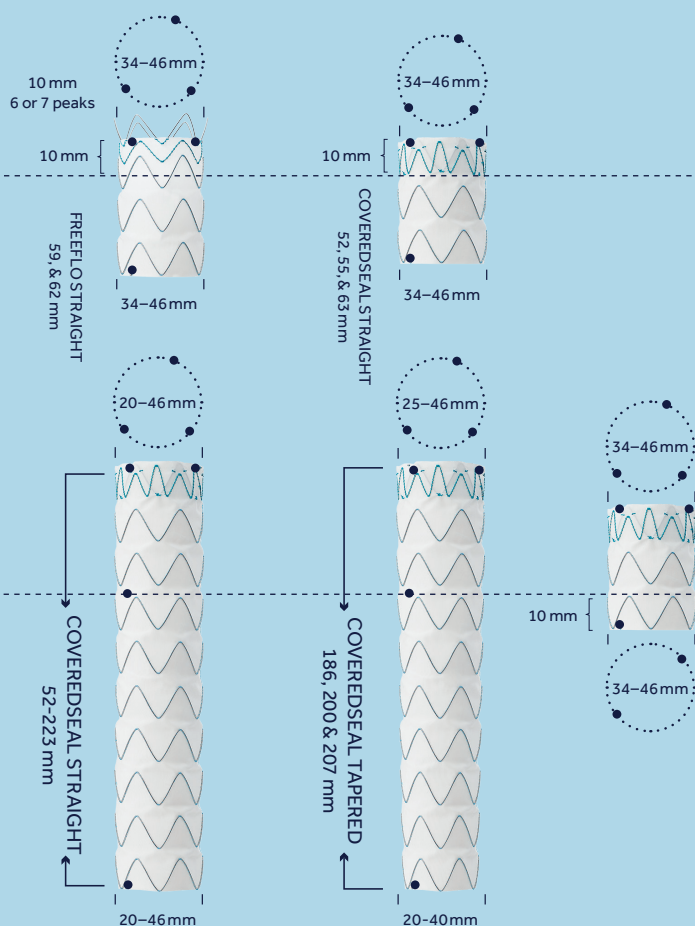
FREEFLO STRAIGHT

Product Code									
	Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Stent Graft Covered Length (mm)			Vessel Diameter: TAA, PAU (mm)	Vessel Diameter: Dissection (mm)	Vessel Diameter: BTAI (mm)	Catheter Outer Diameter (Fr)
VNMF	20	20	C 96	TU		16-17	19	16-17	18
VNMF	22	22	C 96	TU		18-19	20-22	18-20	18
VNMF	22	22	C 185	TU		18-19	20-22	18-20	18
VNMF	25	25	C 96	TU		20-22	23-25	20-23	18
VNMF	25	25	C 185	TU		20-22	23-25	20-23	18
VNMF	28	28	C 97	TU		23-25	26-28	23-26	20
VNMF	28	28	C 174	TU		23-25	26-28	23-26	20
VNMF	31	31	C 97	TU		26-28	29-30	26-29	20
VNMF	31	31	C 174	TU		26-28	29-30	26-29	20
VNMF	31	31	C 229	TU		26-28	29-30	26-29	20
VNMF	34	34	C 59	TU		28-31	31-33	28-32	20
VNMF	34	34	C 97	TU		28-31	31-33	28-32	20
VNMF	34	34	C 174	TU		28-31	31-33	28-32	20
VNMF	34	34	C 229	TU		28-31	31-33	28-32	20
VNMF	37	37	C 59	TU		30-33	34-36	30-35	20
VNMF	37	37	C 97	TU		30-33	34-36	30-35	20
VNMF	37	37	C 174	TU		30-33	34-36	30-35	20
VNMF	37	37	C 229	TU		30-33	34-36	30-35	20
VNMF	40	40	C 62	TU		33-36	37-39	33-38	22
VNMF	40	40	C 103	TU		33-36	37-39	33-38	22
VNMF	40	40	C 183	TU		33-36	37-39	33-38	22
VNMF	40	40	C 223	TU		33-36	37-39	33-38	22
VNMF	43	43	C 62	TU		36-39	39-42	36-41	22
VNMF	43	43	C 103	TU		36-39	39-42	36-41	22
VNMF	43	43	C 183	TU		36-39	39-42	36-41	22
VNMF	43	43	C 223	TU		36-39	39-42	36-41	22
VNMF	46	46	C 62	TU		39-42	42-45	39-44	22
VNMF	46	46	C 103	TU		39-42	42-45	39-44	22
VNMF	46	46	C 183	TU		39-42	42-45	39-44	22
VNMF	46	46	C 223	TU		39-42	42-45	39-44	22

FREEFLO TAPERED

Product Code									
	Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Stent Graft Covered Length (mm)			Vessel Diameter: TAA, PAU (mm)	Vessel Diameter: Dissection (mm)	Vessel Diameter: BTAI (mm)	Catheter Outer Diameter (Fr)
VNMF	25	20	C 185	TU		16-17	19	16-17	18
VNMF	28	22	C 173	TU		18-19	20-22	18-20	18
VNMF	31	25	C 173	TU		18-19	20-22	18-20	18
VNMF	34	28	C 173	TU		20-22	23-25	20-23	18
VNMF	37	31	C 173	TU		20-22	23-25	20-23	18
VNMF	40	34	C 185	TU		23-25	26-28	23-26	20
VNMF	43	37	C 185	TU		23-25	26-28	23-26	20
VNMF	46	40	C 185	TU		26-28	29-30	26-29	20

Additional Components



COVEREDSEAL STRAIGHT

Product Code									
	Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)		Stent Graft Covered Length (mm)		Vessel Diameter: TAA, PAU (mm)	Vessel Diameter: Dissection (mm)	Vessel Diameter: BTAI (mm)	Catheter Outer Diameter (Fr)
VNMC	20	20	C	94	TU	16-17	19	16-17	18
VNMC	22	22	C	94	TU	18-19	20-22	18-20	18
VNMC	22	22	C	180	TU	18-19	20-22	18-20	18
VNMC	25	25	C	94	TU	20-22	23-25	20-23	18
VNMC	25	25	C	180	TU	20-22	23-25	20-23	18
VNMC	28	28	C	90	TU	23-25	26-28	23-26	20
VNMC	28	28	C	182	TU	23-25	26-28	23-26	20
VNMC	31	31	C	90	TU	26-28	29-30	26-29	20
VNMC	31	31	C	182	TU	26-28	29-30	26-29	20
VNMC	31	31	C	223	TU	26-28	29-30	26-29	20
VNMC	34	34	C	52	TU	28-31	31-33	28-32	20
VNMC	34	34	C	90	TU	28-31	31-33	28-32	20
VNMC	34	34	C	182	TU	28-31	31-33	28-32	20
VNMC	34	34	C	223	TU	28-31	31-33	28-32	20
VNMC	37	37	C	52	TU	30-33	34-36	30-35	20
VNMC	37	37	C	90	TU	30-33	34-36	30-35	20
VNMC	37	37	C	182	TU	30-33	34-36	30-35	20
VNMC	37	37	C	223	TU	30-33	34-36	30-35	20
VNMC	40	40	C	55	TU	33-36	37-39	33-38	22
VNMC	40	40	C	95	TU	33-36	37-39	33-38	22
VNMC	40	40	C	175	TU	33-36	37-39	33-38	22
VNMC	40	40	C	218	TU	33-36	37-39	33-38	22
VNMC	43	43	C	55	TU	36-39	39-42	36-41	22
VNMC	43	43	C	95	TU	36-39	39-42	36-41	22
VNMC	43	43	C	175	TU	36-39	39-42	36-41	22
VNMC	43	43	C	218	TU	36-39	39-42	36-41	22
VNMC	46	46	C	55	TU	39-42	42-45	39-44	22
VNMC	46	46	C	95	TU	39-42	42-45	39-44	22
VNMC	46	46	C	175	TU	39-42	42-45	39-44	22
VNMC	46	46	C	218	TU	39-42	42-45	39-44	22

COVEREDSEAL TAPERED

Product Code					Catheter Outer Diameter (Fr)	
	Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)		Stent Graft Covered Length (mm)		
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

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, aortoesophageal, 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.

Medtronic

Aortic | Peripheral | Venous

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