Indications
The Valiant® Thoracic Stent Graft with the Captivia® Delivery System is intended for the endovascular repair of fusiform aneurysms and saccular aneurysms/penetrating ulcers of the descending thoracic aorta in patients having appropriate anatomy, including:

- Iliac/femoral access vessel morphology that is compatible with vascular access techniques, devices, and/or accessories;
- Non-aneurysmal aortic diameter in the range of 18 – 42 mm; and
- Non-aneurysmal aortic proximal and distal neck lengths ≥ 20 mm

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 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 endovasculartreatment 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, endoleaks, migration, or inadequate seal zone) 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. Sizing outside of this range can potentially result in endoleak, fracture, migration, infolding, or graft wear. 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 1.5 T & 3.0 T 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, but are not limited to access failure, adynamic ileus, allergic reaction (to contrast, antiplatelet therapy, stent graft material), amputation, anaesthetic complications, aneurysm expansion, aneurysm rupture, angina, arrhythmia, arterial stenosis, atelectasis, 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, death, deployment difficulties/failures, dissection/perforation/rupture of the aortic vessel and/or surrounding vasculature, embolism, endoleak(s), excessive or inappropriate radiation exposure, extrusion/erosion, failure to deliver stent graft, femoral neuropathy, fistula (including aortoenteric,arteriovenous, and lymph), Gastrointestinal bleeding/complications, genitourinary complications, hematoma, hemorrhage/bleeding, hypotension/hypertension, infection and/or fever, insertion and removal difficulties, intercostal pain, intramural hematoma, leg/foot edema, lymphocele, myocardial infarction, neuropathy, occlusion – venous or arterial, pain/reaction at catheter insertion site, paralysis, paraparesis, paraplegia, paresthesia, peripheral ischemia, peripheral nerve injury, pneumonia, post-implant syndrome, procedural/post-procedural bleeding, prosthesis dilatation/infection/rupture/thrombosis, pseudoaneurysms, pulmonary edema, pulmonary embolism, reaction to anaesthesia, renal failure, renal insufficiency, reoperation, respiratory depression/failure, sepsis, seroma, shock, spinal neurological deficit, stent graft migration/misplacement/occlusion/twisting/kinking, transient ischemic attack (TIA), thrombosis, tissue necrosis, vascular ischemia, vascular trauma, wound dehiscence, wound healing complications, and/or wound infection.

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.

Medtronic

Valiant® Captivia®

THORACIC STENT GRAFT DELIVERY SYSTEM

Innovating for life.

www.medtronic.com
www.medtronicendovascular.com

Medtronic Vascular, Inc.
3576 Unocal Place
Santa Rosa, CA 95403
USA

Product Services Support Center
Tel: 888.283.7868
Fax: 800.838.3103

CardioVascular LifeLine Customer Support
Tel: 877.526.7890
Tel: 763.526.7890

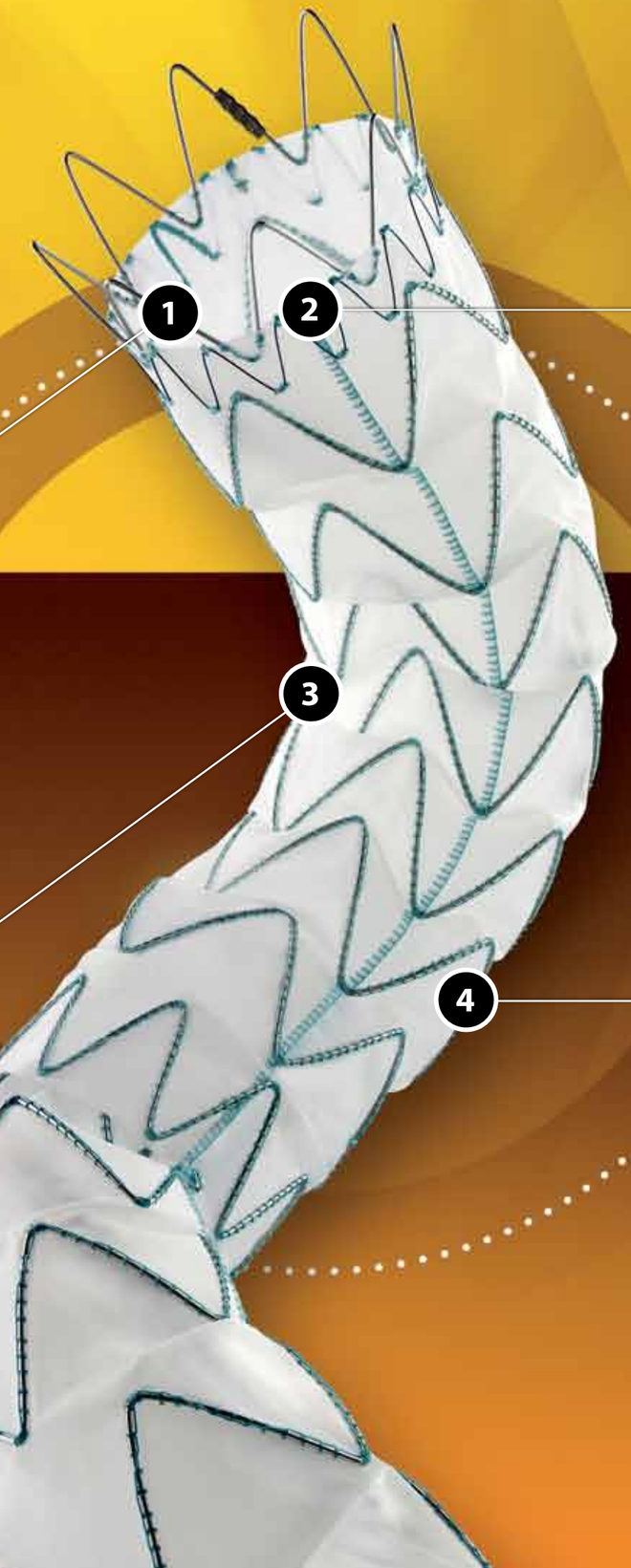
Medtronic

ADVANCED DESIGN

The **Valiant Captivia** system leverages Medtronic's 13 years of thoracic stent graft experience and innovation. Our advanced design enhances confidence—and is proven in more than 40,000 implants.*

1. Proximal 8-Peak FreeFlo Configuration
Evenly distributes radial force over multiple apices

3. Enhanced Conformability
Absence of longitudinal bar allows for enhanced flexibility and kink resistance



2. Figur8 Markers
Platinum iridium markers provide high visibility

4. Broad Selection of Pieces
Broad selection of proximal and distal components leads to many combinations to customize for a variety of patients

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

CONFIDENCE IN CONTROL

The **Valiant Captivia** system features tip capture of the proximal stent. Tip capture provides controlled deployment and placement when navigating the thoracic aorta.

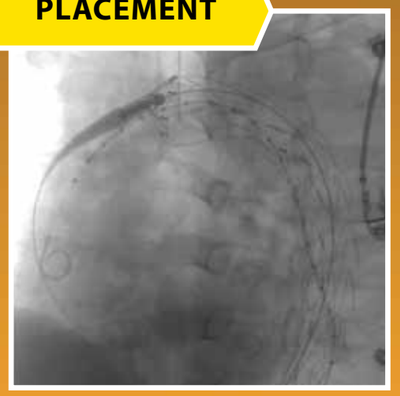
CONTROLLED DEPLOYMENT WITH TIP CAPTURE

1. Tip Deployment

2. Tip Capture

3. Tip Release

PLACEMENT



Tip capture provides accurate stent graft placement

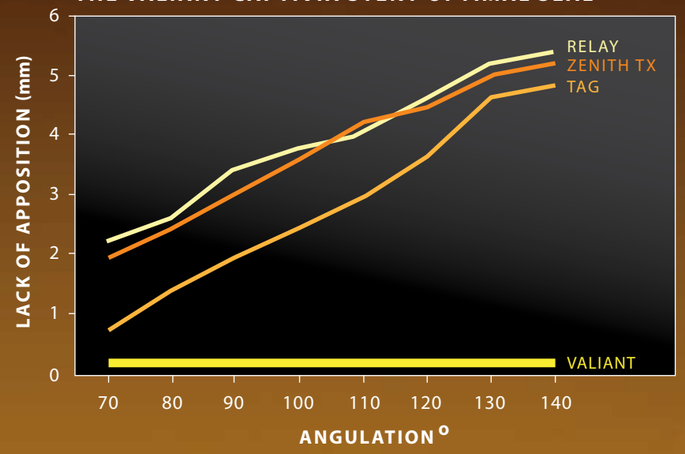
RELASE

After tip capture is released, Valiant conforms to the patient's anatomy

CONFORMABILITY DELIVERED

The **Valiant Captivia** system is designed to conform to the thoracic aorta. The sinusoidal shape and placement of the nitinol springs provide flexibility and conformability to the anatomy. Super-elastic nitinol springs exert active radial force—enhancing seal and conformability.

ANGULAR FLEXIBILITY & RADIAL STRENGTH GIVE THE VALIANT CAPTIVIA STENT OPTIMAL SEAL

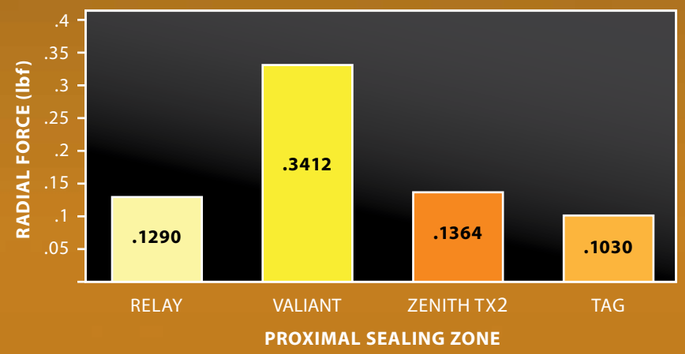


Results: The Valiant stent graft remained apposed to the aortic wall at each increment of neck angulation and degree of oversizing in simulated environment.

For the other stent grafts tested, lack of device wall apposition was observed between the proximal anchorage segment and the inferior aortic wall.

Ludovic Canaud, Pierre Alric, Martrille Laurent, Thierry-Pascal Baum, Pascal Branchereau, Charles Henri Marty-Ané, and Jean-Phillipe Berthet (2008) Proximal Fixation of Thoracic Stent-Grafts as a Function of Oversizing and Increasing Aortic Arch Angulation in Human Cadaveric Aortas. Journal of Endovascular Therapy: June 2008, Vol. 15, No. 3, pp. 326-334.

STENT GRAFT RADIAL FORCE



Test data on file at Medtronic, Inc.; 2007; bench test results may not be indicative of clinical performance.

Preprocedure CT image of patient in VALOR II US PMA trial

Postprocedure image of one-year patient follow-up in VALOR II US PMA trial

OPTIMIZED ACCESS

The **Valiant Captivia** system features a crossing profile similar to or lower than other thoracic stent grafts. Ease of access means control at every step, across a broad range of anatomies.

Hydrophilic coating to facilitate stent graft delivery

Tip Capture Release Handle

Simple turn-and-pull motion for tip release

Fiksavimo atleidimo rankena
Paprastas posūkio ir traukimo judesys, leidžiantis atleisti antgalį

AVAILABLE PROXIMAL GRAFT DIAMETERS (mm)*

Diametras nuo 22 iki 46 mm

Medtronic Valiant® Captivia®	22	24	26	28	30	32	34	36	38	40	42	44	46
Gore TAG®			26	28		31	34		37	40			45
Cook Zenith® TX2®				28	30	32	34	36	38	40	42		

*Per device *IFU*

EASY THREE–STEP DEPLOYMENT PROCESS

Step 1. Slow, controlled deployment for precise stent graft placement

Lėtas, kontroliuojamas diegimas tiksliam stentgrafto išdėstymas

Step 2. Quick deployment option if desired

Greitas diegimas, jei pageidaujama

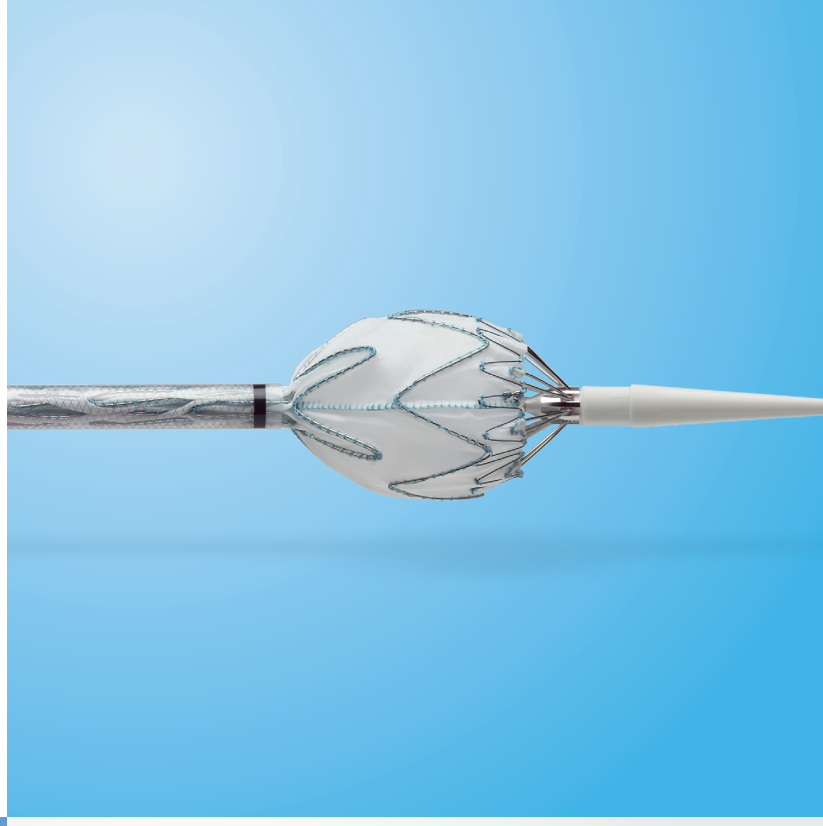
Step 3. Tip capture release

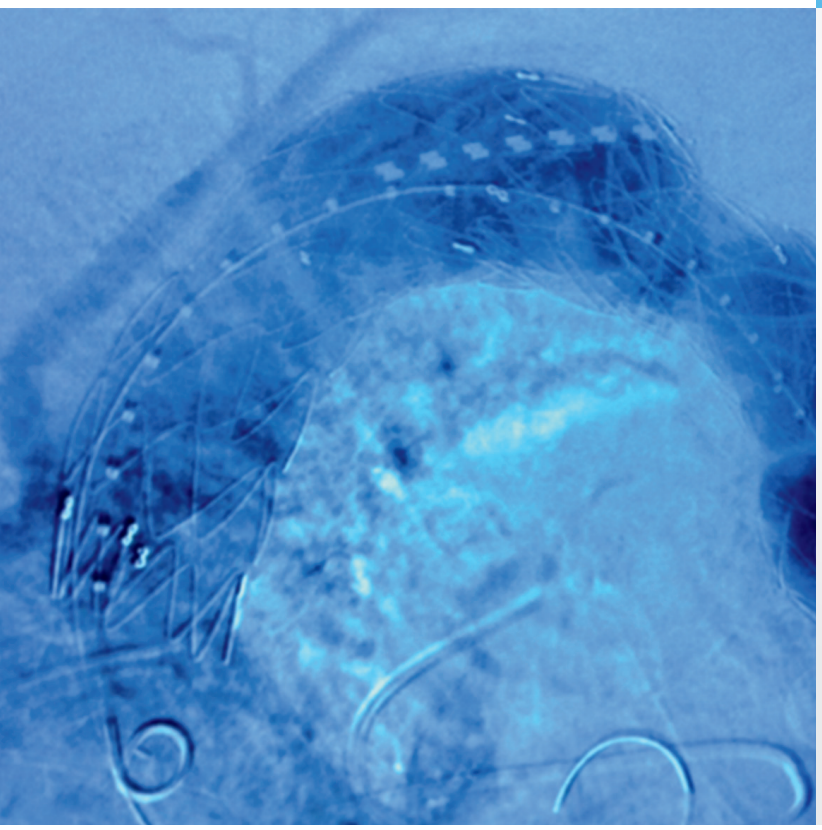
Fiksavimas

Įvedimo sistema užtikrina tikslią lokalizaciją išskleidžiant stentgraftą dviem būdais – laipsniškai arba staigiai

Valiant™ Captivia™

Thoracic Stent Graft System

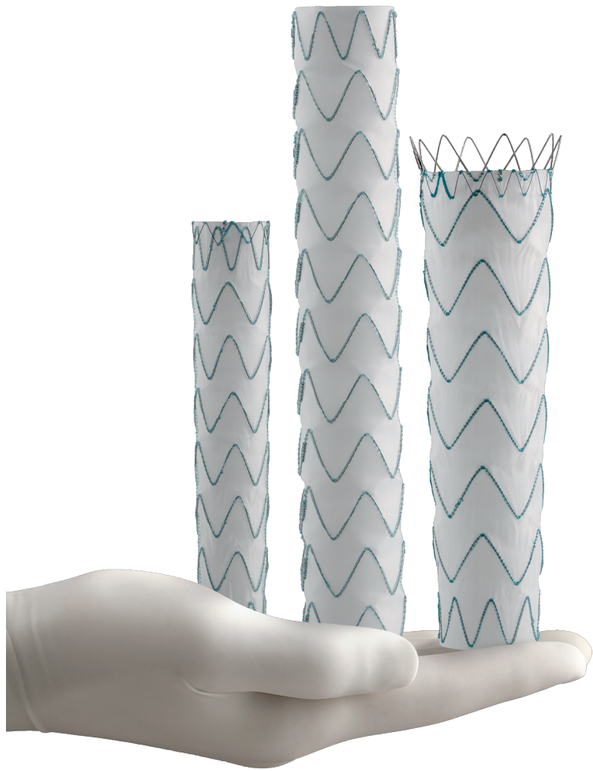




Medtronic

PROVEN DESIGN

The proven design and performance of the **Valiant Captivia system** offers a broad set of options to treat a wide range of patient anatomies.

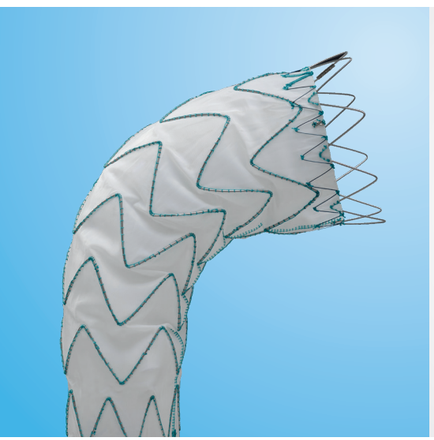


The Valiant Captivia system with proximal FreeFlo tapers continues to deliver proven performance with additional components for broad patient suitability.

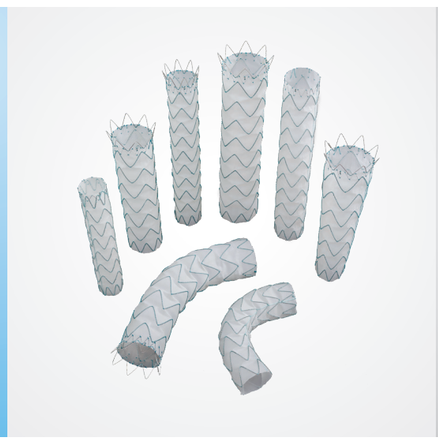
A tapered stent graft should be preferred for the majority of patients with dissection.[1]

The Valiant Captivia system with proximal FreeFlo tapers helps you treat more anatomies with confidence.

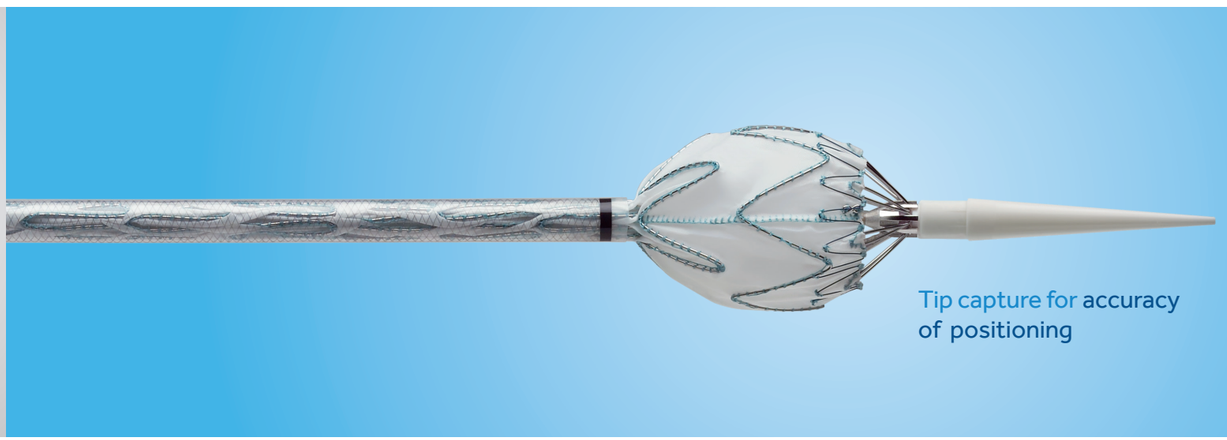
Proven design with **enhanced conformability and kink resistance**



Additional components to **treat a wide range of anatomies**



Consistent clinical performance across a variety of **pathologies**

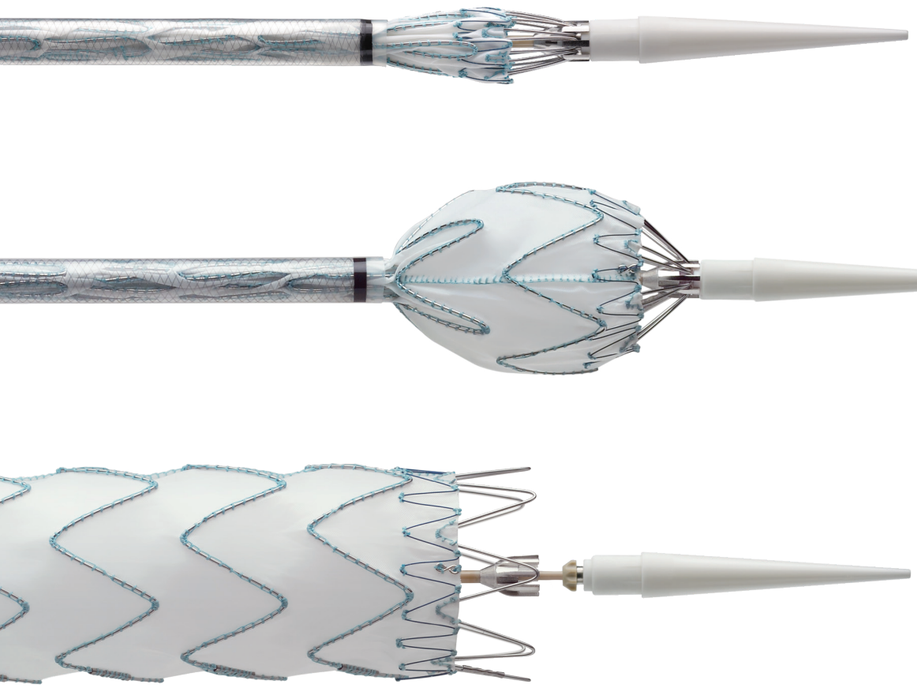


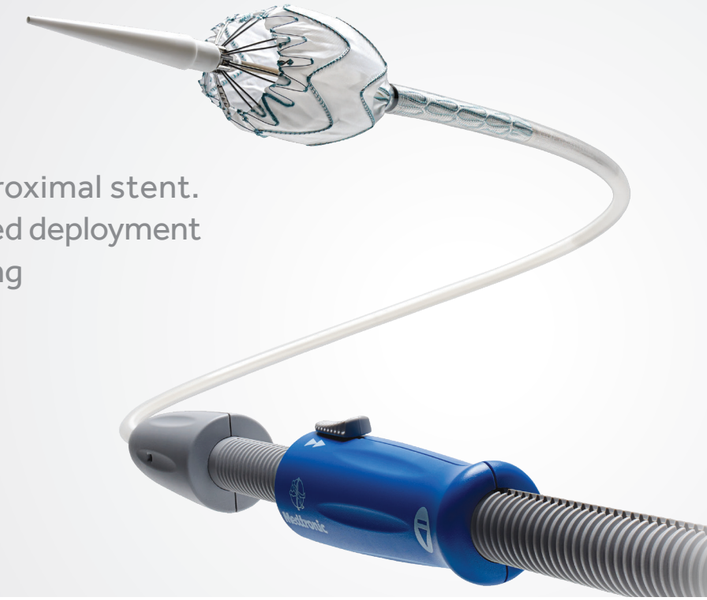
Tip capture for **accuracy of positioning**

[1]Pantaleo A, Jafrancesco G, Buia F, et al. Distal Stent Graft-Induced New Entry: An Emerging Complication of Endovascular Treatment in Aortic Dissection. *Ann Thorac Surg*. 2016;102(2):527-532.

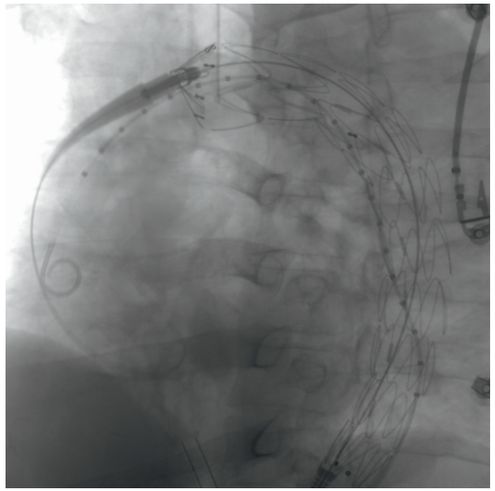
PRECISE DEPLOYMENT

Controlled Deployment with Tip Capture



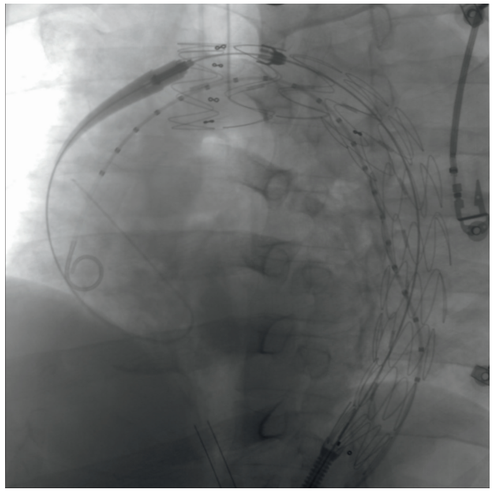


The Valiant Captivia system features tip capture of the proximal stent. Tip capture provides controlled deployment and placement when navigating the thoracic aorta.



PLACEMENT

Tip capture provides accurate stent graft placement

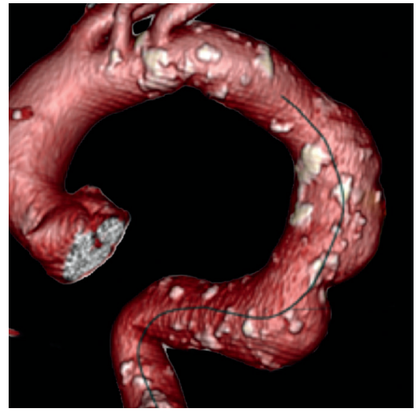


RELEASE

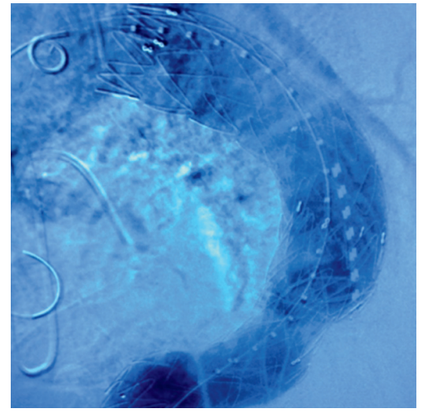
After tip capture is released, the Valiant Captivia system conforms to the patient's anatomy

OPTIMAL SEAL

The Valiant Captivia system is designed to conform to the thoracic aorta. The sinusoidal shape and placement of nitinol springs provide flexibility and conformability to the anatomy. The Valiant stent graft is the only device that maintains complete apposition regardless of angulation and oversizing.[2]



PRE — 3-D reconstruction of patient anatomy†



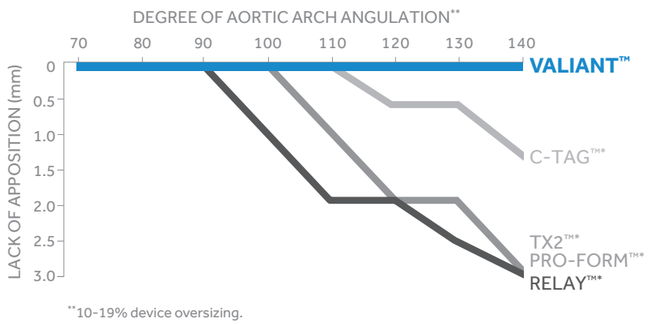
POST-index procedure result†

RESULTS

The Valiant stent graft remained apposed to the aortic wall at each increment of neck angulation and degree of oversizing in a simulated environment.

For the other stent grafts tested, lack of device wall apposition was observed between the proximal anchorage segment and the inferior aortic wall.

Angular Flexibility and Radial Strength Give the Valiant Captivia Stent Graft Conformability and Optimal Seal[2]



**10-19% device oversizing.

PRODUCT TESTED	Proximal Apposition at Different Landing Zone Angulation	Body Apposition at Different Landing Zone Angulation
Medtronic Valiant™	No lack of apposition (remained apposed)	No lack of apposition (remained apposed)
Gore™* C-TAG™*	Lack of apposition above 120°	No lack of apposition (remained apposed)
Bolton Relay™*	Lack of apposition above 110°	No lack of apposition (remained apposed)
Cook Zenith™* TX2™* Pro-Form™*	No lack of apposition (remained apposed)	Lack of apposition above 110°

Test data not indicative of clinical performance.

*™Third party brands are trademarks of their respective owners.
[2]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.

*™Third party brands are trademarks of their respective owners.
†Images courtesy of The Heart Hospital Baylor Plano.

EASE OF ACCESS

Patogus valdymas ir fiksavimas, priklausomai nuo patologijos. Įvedimo sistema užtikrina tikslią lokalizaciją išskleidžiant stentgraftą dviem būdais – laipsniškai arba staigiai.

The Valiant Captivia system features a crossing profile similar to or lower than other thoracic stent grafts for ease of access. Tip capture release means control across a broad range of pathologies.

TIP CAPTURE RELEASE HANDLE

Simple turn-and-pull motion for tip release

DEVICE OUTER DIAMETER PROFILES

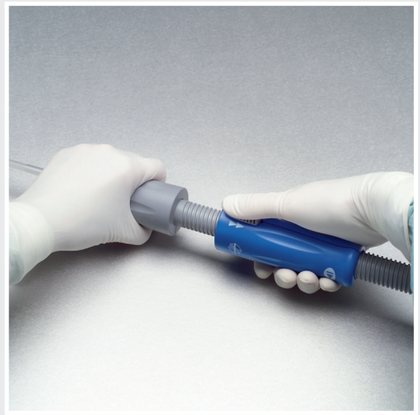
	Medtronic Valiant™	Bolton Relay™* Plus	Cook Zenith™* TX2™* Pro-Form™*	Gore™* C-TAG™*
Crossing Profile (OD)†	24 F	24 F	26 F	27 F
Hydrophilic Coating	**Yes**	Yes	No	No
Sheath Required	**No**	No	Yes	Yes

System OD for Gore C-TAG and Cook Zenith list the OD of sheath as their IFUs recommend the use of a sheath. The System OD for Medtronic Valiant and Bolton Relay list the OD of the delivery catheter as the use of a sheath is not required per the respective IFUs.

*™Third party brands are trademarks of their respective owners.
†36 mm diameter graft used for comparison for all manufacturers except Gore. A 37 mm diameter graft used for Gore since no 36 mm diameter graft exists.

EASY THREE–STEP DEPLOYMENT PROCESS

Step 1
Slow, controlled deployment for precise stent graft placement

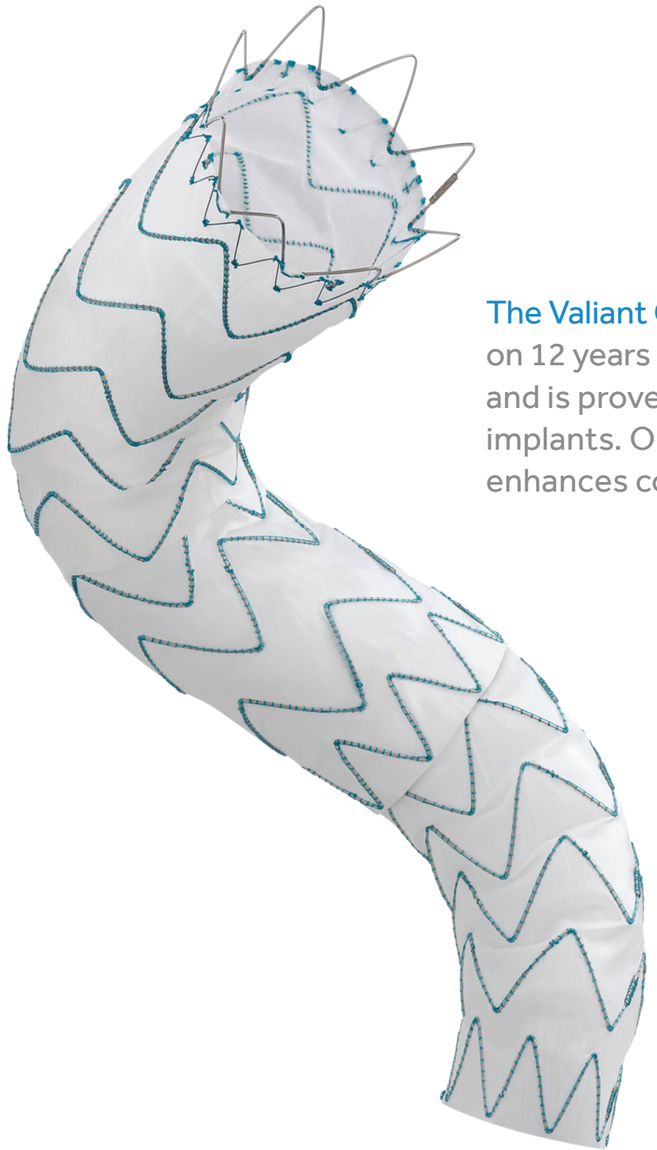


Step 2
Quick deployment option if desired

Step 3
Tip capture release

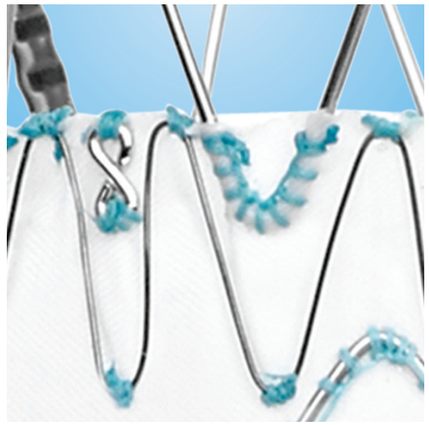
HYDROPHILIC COATING
to facilitate stent graft delivery

PROVEN DESIGN

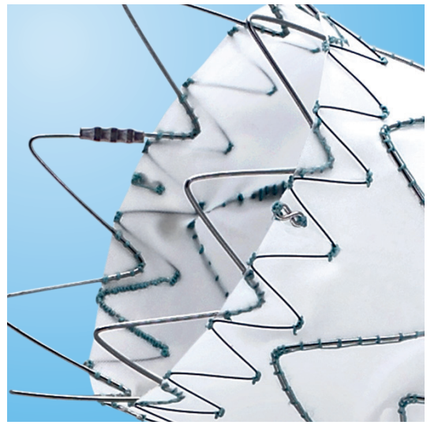


The Valiant Captivia system is built on 12 years of worldwide experience and is proven in more than 100,000 implants. Our advanced design enhances confidence.†

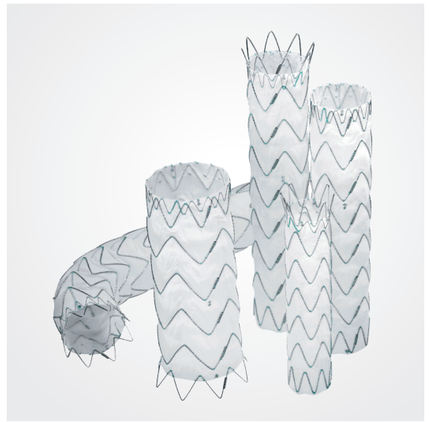
Turi graftu nedengtą proksimalaus tvirtinimo žiedą (ar stentą), leidžiantį fiksuoti stentgraftą aortos lanke proksimaliau a. subclavia



Figur8 Markers for Accurate Placement. Platinum-iridium markers provide high visibility.



Proximal 8-peak FreeFlo Configuration. Evenly distributes radial force over multiple apices.



Broad Selection of Pieces. Broad selection of proximal and distal components leads to many combinations to customize for a variety of patients.

Enhanced Conformability. Absence of longitudinal bar allows for enhanced flexibility and kink resistance.

Prailgintojai tiek cilindriniai, tiek konizuoti (distaliai siaurėjantys);

†Bench test results may not be indicative of clinical performance.

PROVEN CLINICAL TRACK RECORD

Proven performance across a variety of thoracic pathologies

U.S. Medtronic Dissection Trial[3]

Prospective, nonrandomized, multicenter

Long-term Outcomes of TEVAR in Acute Type B Aortic Dissection: Results from the Valiant™ U.S. IDE Trial

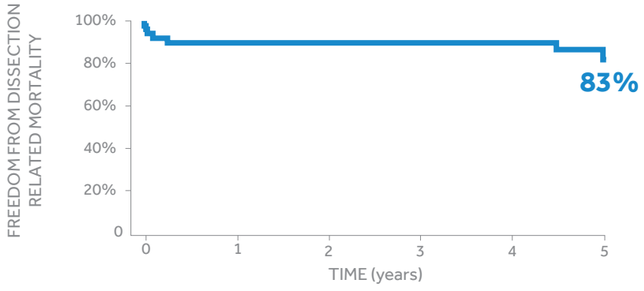
FIVE-YEAR RESULTS

The Valiant Captivia system effectively treated acute complicated Type B aortic dissections with positive aortic remodeling through five years

FIVE-YEAR EVIDENCE HIGHLIGHTS

- **94%** (16/17) true lumen diameter increase/stable
- **100%** (50/50) proximal entry tears fully excluded[4]
- **89%** (16/18) complete false lumen thrombosis
- **94%** (46/49) presented with DeBakey class IIIB dissections

FREEDOM FROM DISSECTION-RELATED MORTALITY



"The majority of patients with acute Type B dissection will fail medical therapy over time... Patients who underwent any aortic intervention had a significant survival advantage over those who were treated with medical management alone."[5]

[3] Bavaria JE, Brinkman WT, Hughes GC, et al. Five-year outcomes of endovascular repair of complicated acute type B aortic dissections. *J Thorac Cardiovasc Surg*. Published online May 13, 2020.

[4] Bavaria J, Brinkman W, Hughes C, 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.

[5] Any aortic intervention compared to medical management alone (76.4% +/- 4.7% vs 59.3% +/- 3.8%; p<0.05). Further study is necessary to determine who will benefit most from early intervention. Durham CA, Cambria RP, Wang LJ, et al. The natural history of medically managed acute type B aortic dissection. *J Vasc Surg*. May 2015;61(5):1192-1198.

The Valiant Captivia System Successfully Treats

Broad Range of Pathologies and Anatomies

Comprehensive clinical studies and registries support the use of TEVAR with Valiant Captivia in patients with aortic dissections

MEDTRONIC CLINICAL DATA SUPPORTS THE USE OF TEVAR ACROSS MULTIPLE PATHOLOGIES

CLINICAL TRIAL/STUDY	# PATIENTS ENROLLED	TRIAL STUDY DESIGN
VALOR II (Valiant stent graft)	160	Prospective, nonrandomized, multicenter U.S. IDE study conducted to evaluate the safety and effectiveness of the Valiant stent graft system in patients with descending thoracic aneurysms
VIRTUE (Valiant stent graft)	100	Prospective, nonrandomized, multicenter European registry evaluating Valiant in Type B aortic dissections
VALIANT CAPTIVIA REGISTRY (Valiant Captivia system)	100	Multicenter, noninterventional, single arm registry, mid- to high-risk all comer cohort
RESCUE (Valiant Captivia system)	50	Prospective, nonrandomized, multicenter U.S. IDE trial to evaluate device performance in blunt thoracic aortic injury
Medtronic U.S. DISSECTION Trial (Valiant Captivia system)	50	Prospective, nonrandomized, multicenter U.S. IDE trial to evaluate device performance in acute, complicated Type B aortic dissections

Valiant™ Captivia™

Thoracic Stent Graft Delivery System

Torokalinės aortos dalies stentgraftas

FEATURES

Precise Deployment†

- Platinum iridium Figur8 markers provide high visibility and assist deployment
- 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 8-Peak FreeFlo configuration evenly distributes radial force over multiple apices
- Sinusoidal shape and placement of nitinol springs for high flexibility
- Super-elastic nitinol springs exert active radial force to enhance seal and apposition

Ease of Access

- Hydrophilic coating facilitates stent graft delivery†
- Easy three-step deployment process†
- Broad selection of proximal and distal components treats a variety of patients

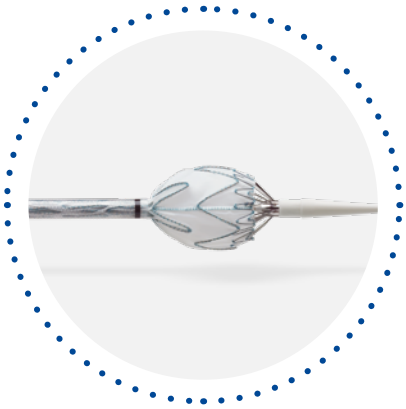
Turi galimybę prijungti distalinį prailgintoją (-us);

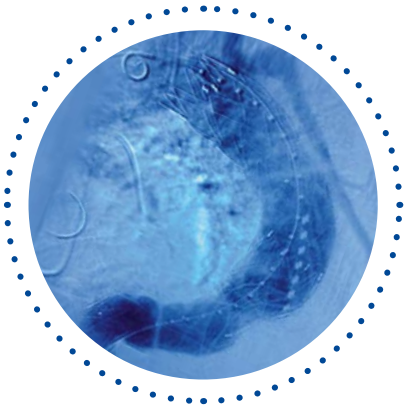
† Test data on file at Medtronic. Bench test results may not be indicative of clinical performance.

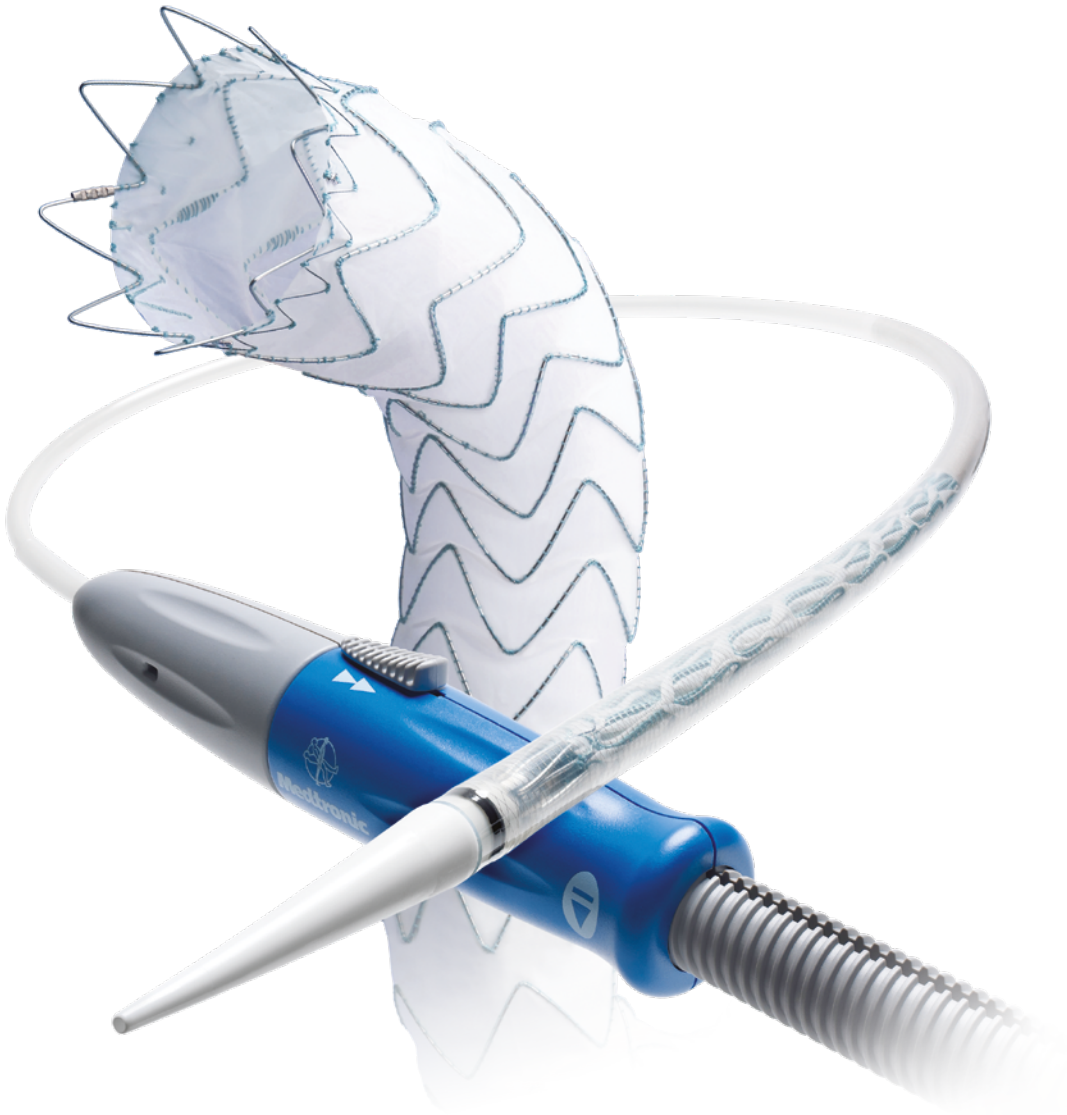
Medtronic

Valiant™ Thoracic Stent Graft with the
Captivia™ Delivery System

Deploy durability







Continuous seal

Achieving and maintaining seal is critical for TEVAR durability.

The Valiant™ Captivia™ system establishes and maintains a continuous seal and optimizes apposition in a dynamic environment.

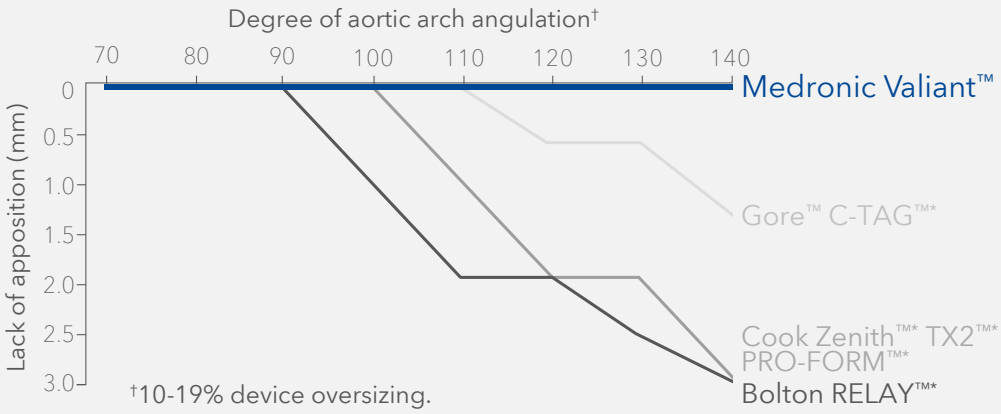
The Valiant™ stent graft is the only device that maintains complete apposition regardless of angulation and oversizing.[1]

Results

The Valiant™ stent graft remained apposed to the aortic wall at each increment of neck angulation and degree of oversizing in a simulated environment.

For the other stent grafts tested, lack of device wall apposition was observed between the proximal anchorage segment and the inferior aortic wall.

Angular Flexibility and Radial Strength Give the Valiant Captivia Stent Graft Conformability and Optimal Seal[1]

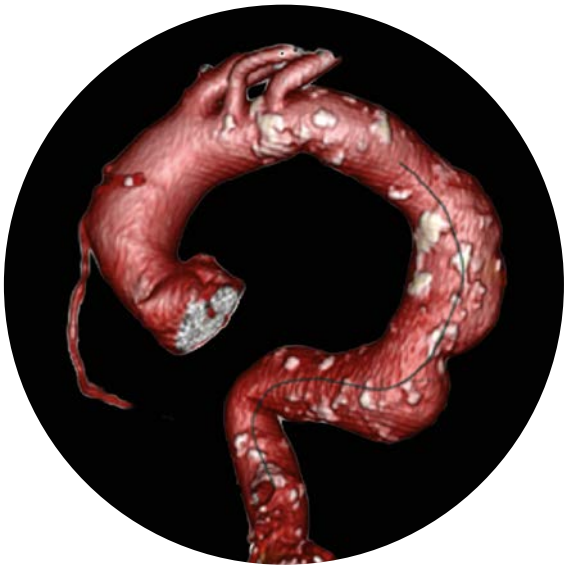


†10-19% device oversizing.

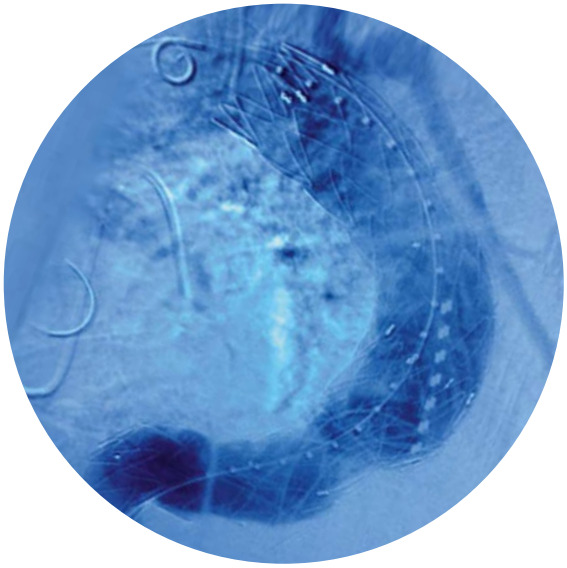
Risks associated with TEVAR procedures may include rupture, conversion to open repair, or secondary procedures.

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

[1] 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.



Pre –
3D reconstruction of patient anatomy†



Post –
Index procedure results†

Product tested	Proximal apposition at different landing zone angulation	Body apposition at different landing zone angulation
Medtronic Valiant™	No lack of apposition (remained apposed)	No lack of apposition (remained apposed)
Gore™* C-TAG™*	Lack of apposition above 120°	No lack of apposition (remained apposed)
Bolton Relay™*	Lack of apposition above 110°	No lack of apposition (remained apposed)
Cook Zenith™* TX2™* Pro-Form™*	No lack of apposition (remained apposed)	Lack of apposition above 110°

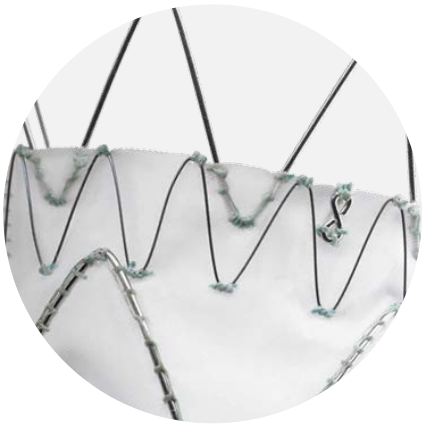
Test data not indicative of clinical performance.

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

† Images courtesy of The Heart Hospital Baylor Plano.

Continuous seal

0%
type I endoleak (EL) at 5 years[1]



8 mm mini support spring
enhances proximal apposition which leads to low type I EL rates

20 mm minimum neck length

Proximal design
ensures even distribution of radial force for complete vessel wall apposition and fixation

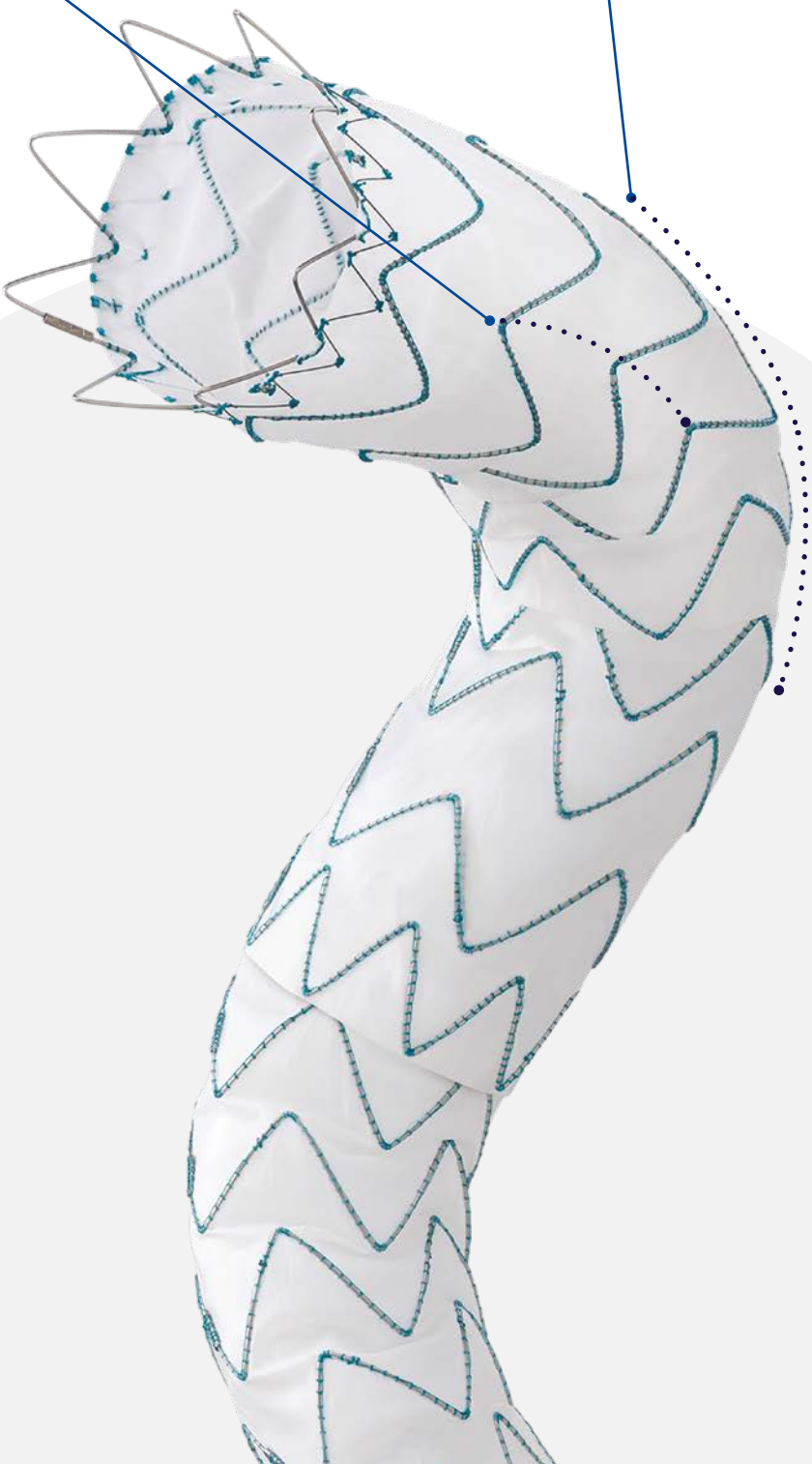
5-year results
No migration[1]

Risks associated with TEVAR procedures may include rupture, conversion to open repair, or secondary procedures.

[1] Conrad MF, Tuchek J, Freezor R, et al. Results of the VALOR II trial of the Medtronic Valiant Thoracic Stent Graft. *J Vasc Surg*. August 2017;66(2):335-342.

Peak-to-valley design

Not constrained by a connecting bar

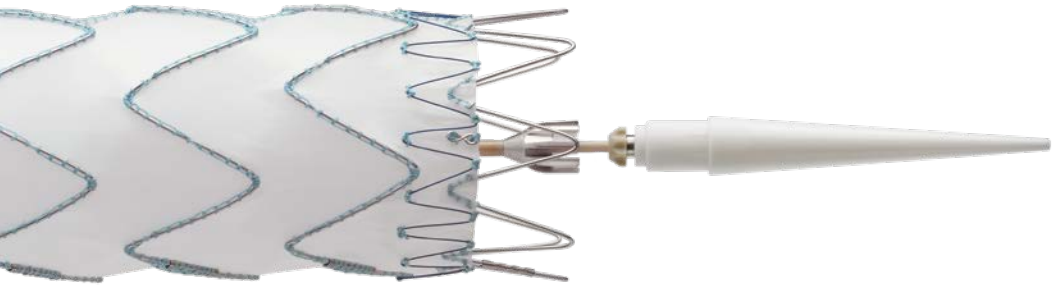


Precise deployment

Tip capture means control – critical for precise placement

Deployment

Captured

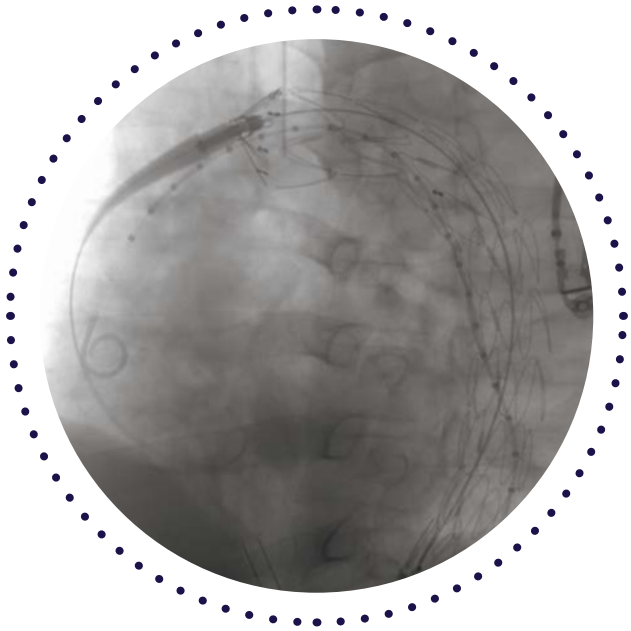


Released

Risks associated with TEVAR procedures may include rupture, conversion to open repair, or secondary procedures.

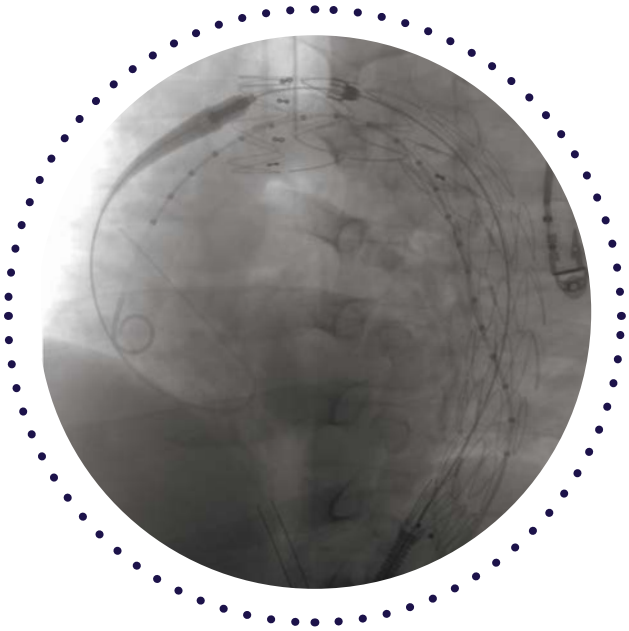
Valiant™ Thoracic Stent Graft with the Captivia™ Delivery System

features tip capture of the proximal stent.
Tip capture provides controlled deployment
and placement when navigating the thoracic aorta.



Placement

Tip capture provides accurate
stent graft placement.



Release

After tip capture is released,
the Valiant™ Captivia™ system conforms
to the patient's anatomy.

Precise deployment

Valiant™ Thoracic Stent Graft with the Captivia™ Delivery System

features a crossing profile similar to or lower than other thoracic stent grafts for ease of access.
Tip capture release means control across a broad range of pathologies.

Tip capture release handle

Simple turn-and-pull motion for tip release

Device outer diameter profiles

	Medtronic Valiant™	Bolton Relay™* Plus	Bolton Relay™* Pro	Cook Zenith™* TX2™* Pro-Form™*	Gore™* C-TAG™*
Crossing profile (OD)†	24 F	24 F	23 F	26 F	27 F
Hydrophilic coating	Yes	Yes	Yes	No	No
Sheath required	No	No	No	Yes	Yes

1F = 0.33 mm

Risks associated with TEVAR procedures may include rupture, conversion to open repair, or secondary procedures.
System OD for Gore C-TAG and Cook Zenith list the OD of sheath as their IFUs recommend the use of a sheath. The System OD for Medtronic Valiant and Bolton Relay list the OD of the delivery catheter as the use of a sheath is not required per the respective IFUs.

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† 36 mm diameter graft used for comparison for all manufacturers except Gore. A 37 mm diameter graft used for Gore since no 36 mm diameter graft exists.

Easy three-step deployment process

Step 1

Slow, controlled deployment for precise stent graft placement

Step 2

Quick deployment option if desired

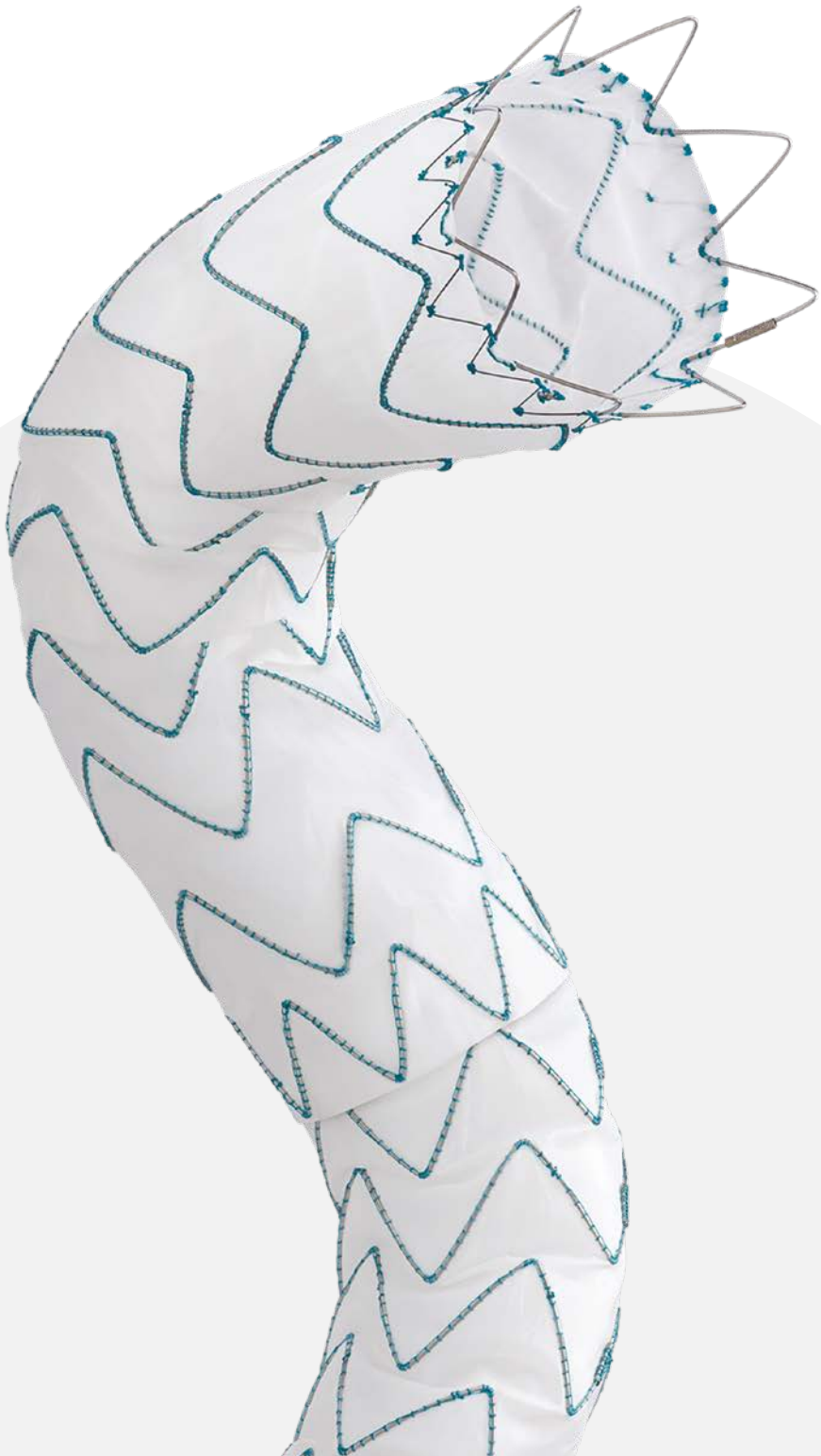
Step 3

Tip capture release

Hydrophilic coating

to facilitate stent graft delivery

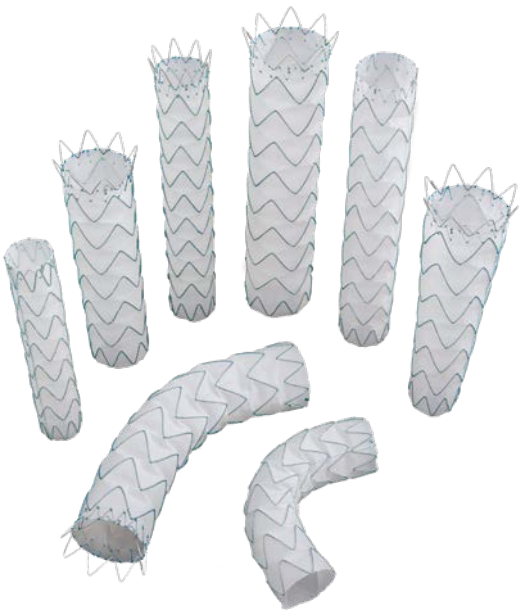
100,000+ patients treated worldwide



Broad sizing and tapering to tailor graft to patient anatomy.

A tapered stent graft should be preferred for the majority of patients with dissection.[1]

The Valiant™ Captivia™ system with proximal FreeFlo tapers helps you treat more anatomies with confidence.



Broad selection of pieces

Broad selection of proximal and distal components leads to many combinations to customize for a variety of patients.

Enhanced conformability.

Absence of longitudinal bar allows for enhanced flexibility and kink resistance.

Risks associated with TEVAR procedures may include rupture, conversion to open repair, or secondary procedures.

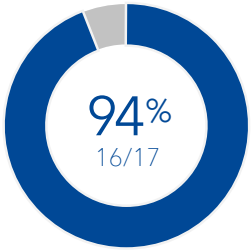
[1] Pantaleo A, Jafrancesco G, Buia F, et al. Distal Stent Graft-Induced New Entry: An Emerging Complication of Endovascular Treatment in Aortic Dissection. *Ann Thorac Surg*. August 2016;102(2):527-532.

Clinical track record

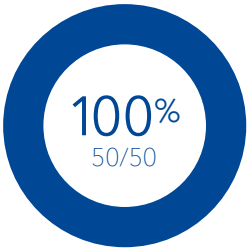
Acute complicated dissection outcomes[1]

Positive aortic remodeling through five years in type B aortic dissections.

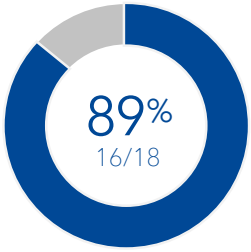
5-year evidence highlights



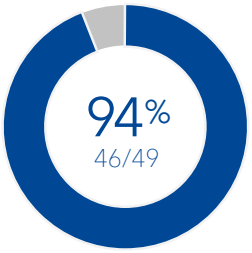
true lumen diameter increase/stable



proximal entry tears fully excluded[2]

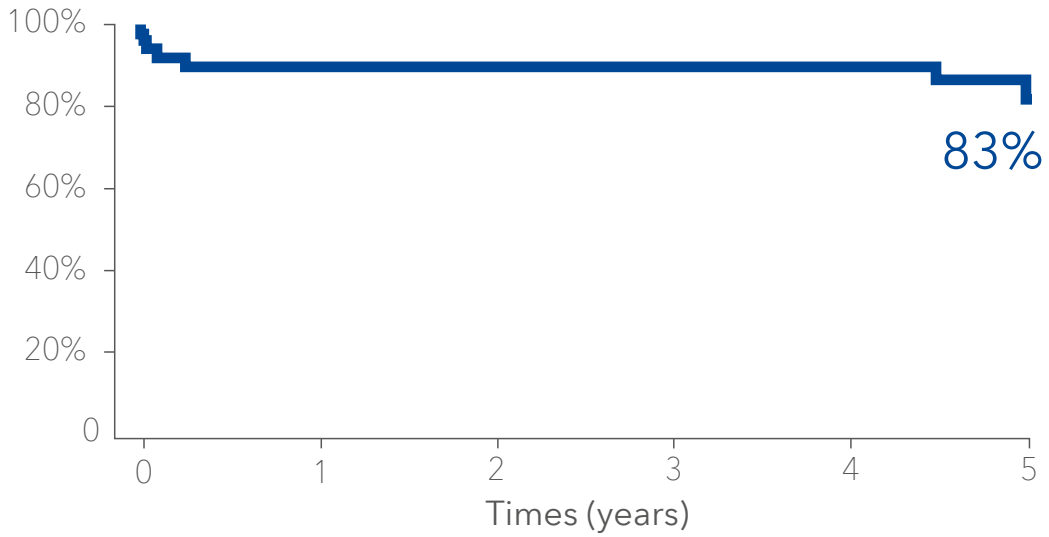


complete false lumen thrombosis



presented with DeBakey class IIIB dissections

Freedom from dissection-related mortality



Risks associated with TEVAR procedures may include rupture, conversion to open repair, or secondary procedures.

[1] 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.

[2] 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.

5-year outcomes in all descending thoracic aortic pathologies

Medtronic clinical data supports the use of TEVAR across multiple pathologies

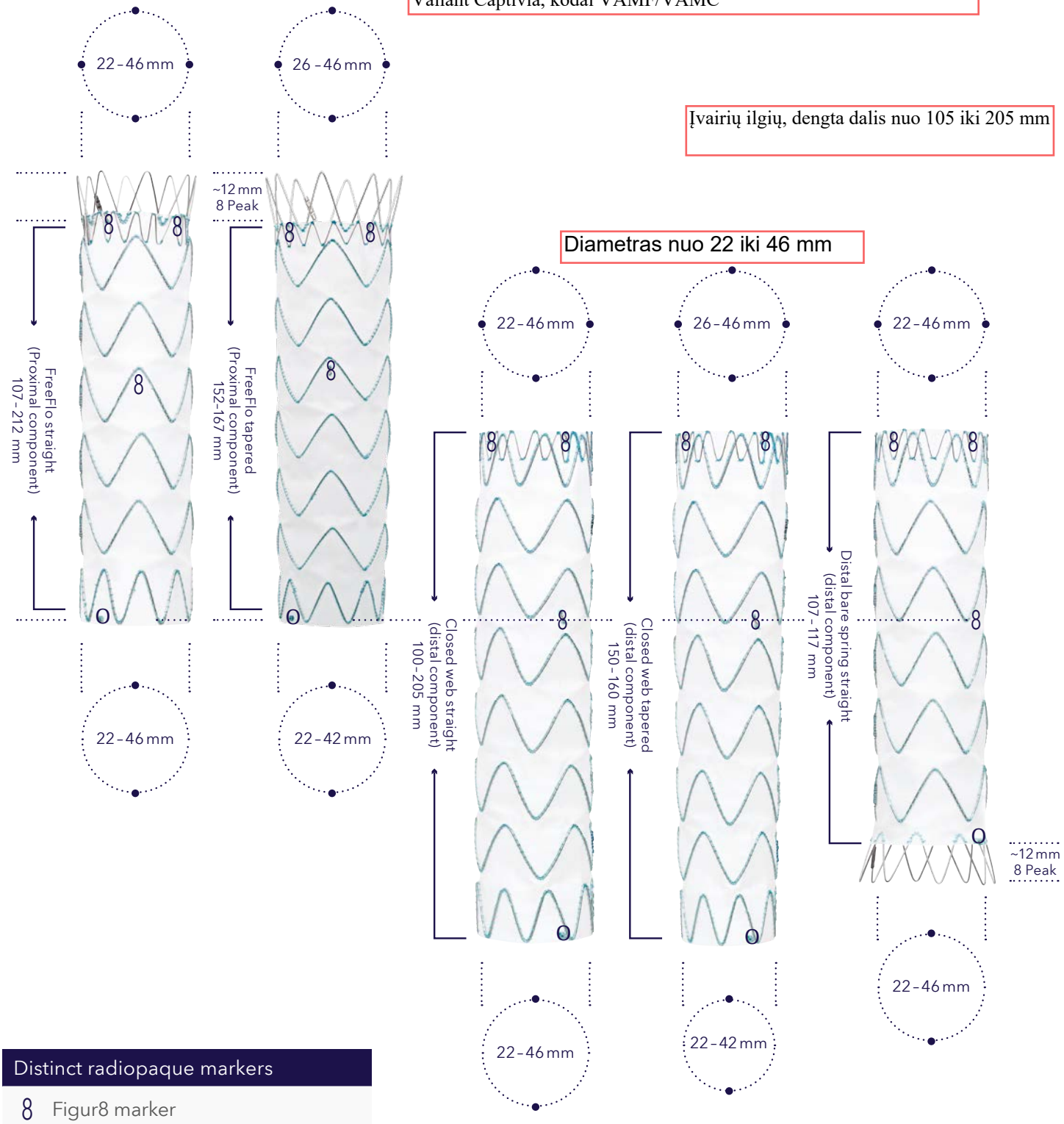
Clinical trial/study	# patients enrolled	Trial study design
VALOR II (Valiant stent graft)	160	Prospective, nonrandomized, multicenter U.S. IDE study conducted to evaluate the safety and effectiveness of the Valiant stent graft system in patients with descending thoracic aneurysms
VIRTUE (Valiant stent graft)	100	Prospective, nonrandomized, multicenter European registry evaluating Valiant in type B aortic dissections
Valiant Captivia Registry (Valiant Captivia system)	100	Multicenter, noninterventional, single arm registry, mid- to high-risk all comer cohort
RESCUE (Valiant Captivia system)	50	Prospective, nonrandomized, multicenter U.S. IDE trial to evaluate device performance in blunt thoracic aortic injury
Medtronic U.S. Dissection Trial (Valiant Captivia system)	50	Prospective, nonrandomized, multicenter U.S. IDE trial to evaluate device performance in acute, complicated type B aortic dissections
Valiant Captivia France (Valiant Captivia system)	160	Prospective, noninterventional, consecutive, multicenter, nonrandomized post-market trial to assess the safety and effectiveness benefits of endovascular repair of descending thoracic aortic diseases

Component placement guide and product codes

Torokalinės aortos dalies stentgrafto distalinis prailgintojas:
Valiant Captivia, kodai VAMF/VAMC

Įvairių ilgių, dengta dalis nuo 105 iki 205 mm

Diametras nuo 22 iki 46 mm



Distinct radiopaque markers
8 Figur8 marker
O Zer0 marker

Prailgintojai tiek cilindriniai, tiek konizuoti (distaliai siaurėjantys);

Įvairių ilgių dengta dalis

Įvedimo sistemos išorinis diametras nuo 22-25F

Proximal FreeFlo straight

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

Proximal FreeFlo tapered

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

Closed web tapered

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

Closed web straight

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

Distal bare spring straight

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

Heli-FX™ thoracic recommended number of EndoAnchor™ implants

- The following is recommended based on internal testing
- Additional or fewer EndoAnchor implants may be placed at physician discretion

	Recommended minimum number of EndoAnchor implants Graft angulation		
Aortic neck diameter (proximal or distal)	≤ 60°	> 60°–75°	> 75°–90°
≤ 29 mm	4	4	4
30–32 mm	4	4	5
33–36 mm	4	5	7
37–40 mm	5	6	8
> 40 mm	5	7	9

Sizing of the anatomy and EndoAnchor decisions are the responsibility of the physician

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.

For applicable products, consult instructions for use on www.medtronic.com/manuals. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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