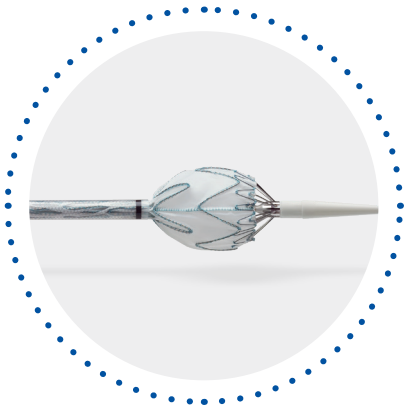
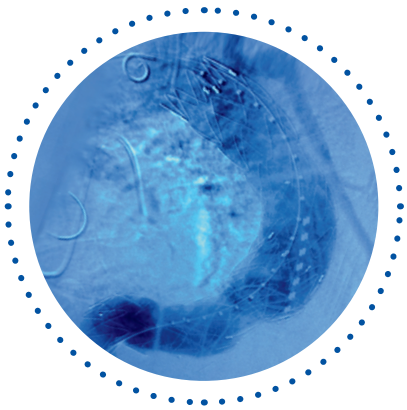
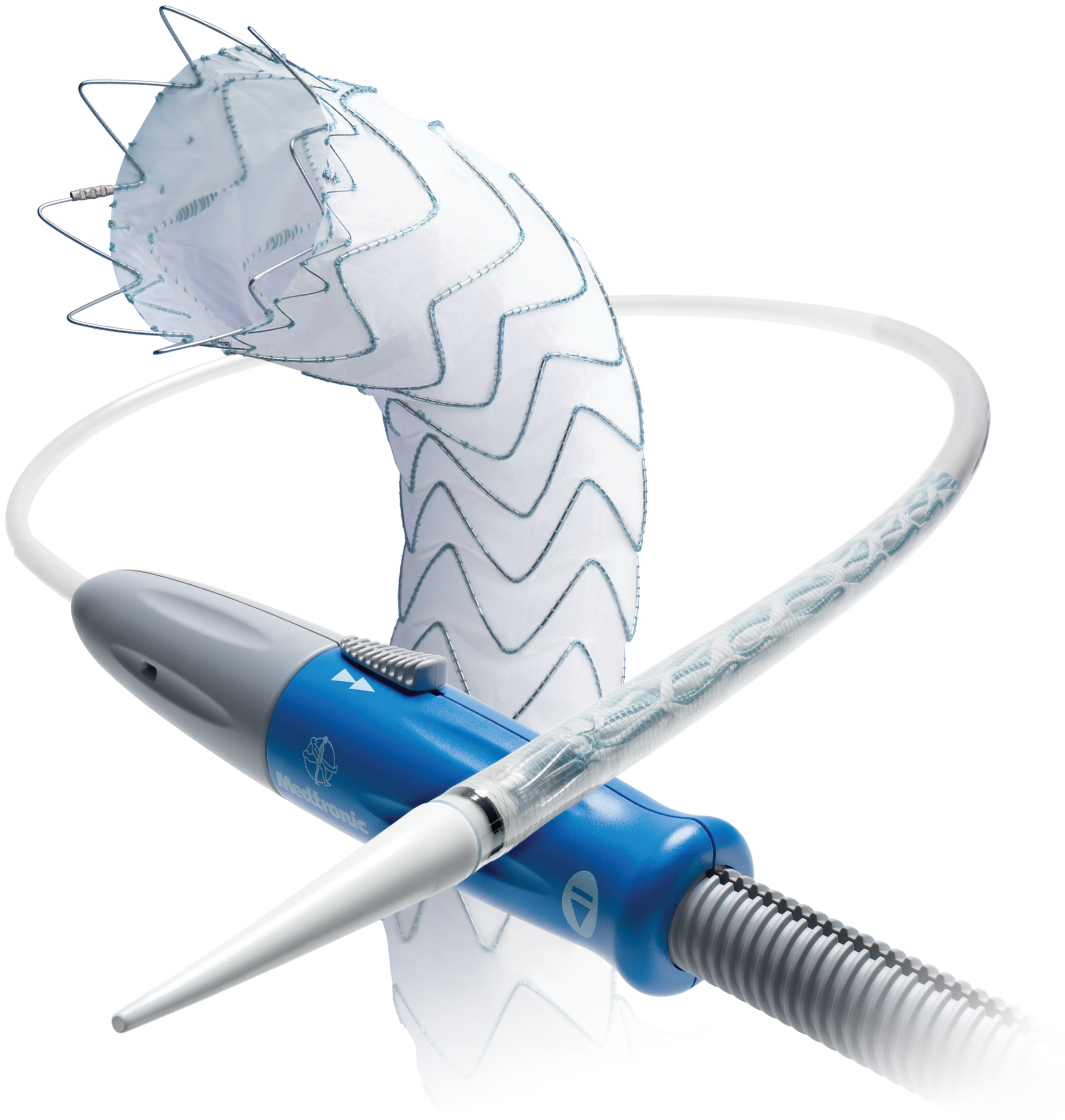
Medtronic

Valiant™ Captivia™
Thoracic Stent Graft System

Deploy durability





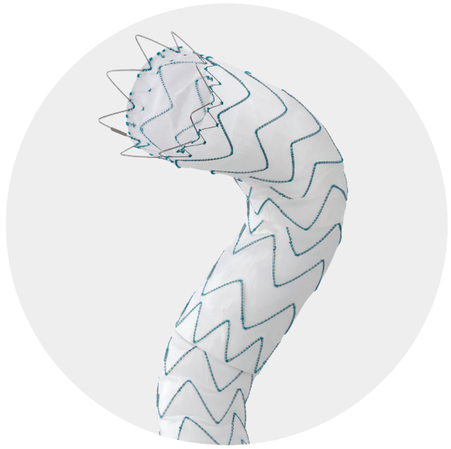


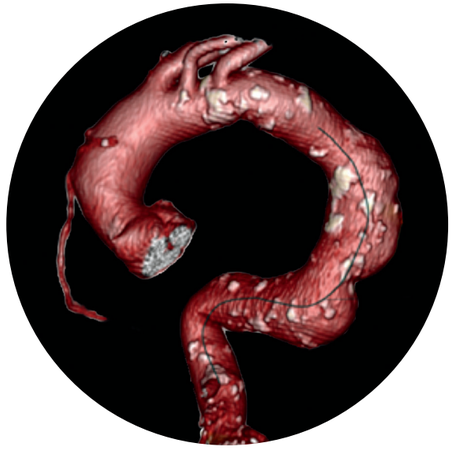
Risks associated with TEVAR procedures may include rupture, conversion to open repair, or secondary procedures.

Continuous seal

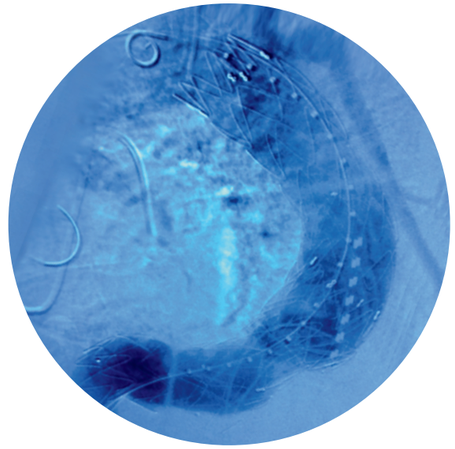
Achieving and maintaining seal is critical for TEVAR durability.

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





Pre –
3D reconstruction of patient anatomy†



Post –
Index procedure results†

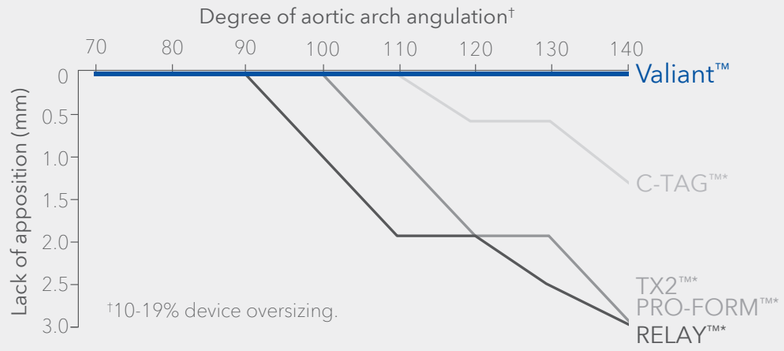
The Valiant™ stent graft is the only device that maintains complete apposition regardless of angulation and oversizing.[1]

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]



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.

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

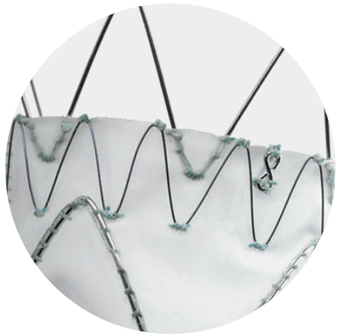
[1] Canaud L, Cathala P, Joyeux F, Branchereau P, Marty-Ané C, Alric P. Improvement in conformability of the latest generation of thoracic stent grafts. *J Vasc Surg*. April 2013;57(4):1084-1089.

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

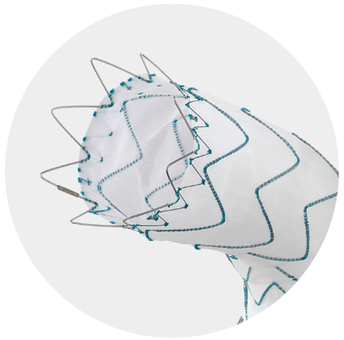
†Images courtesy of The Heart Hospital Baylor Plano.

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



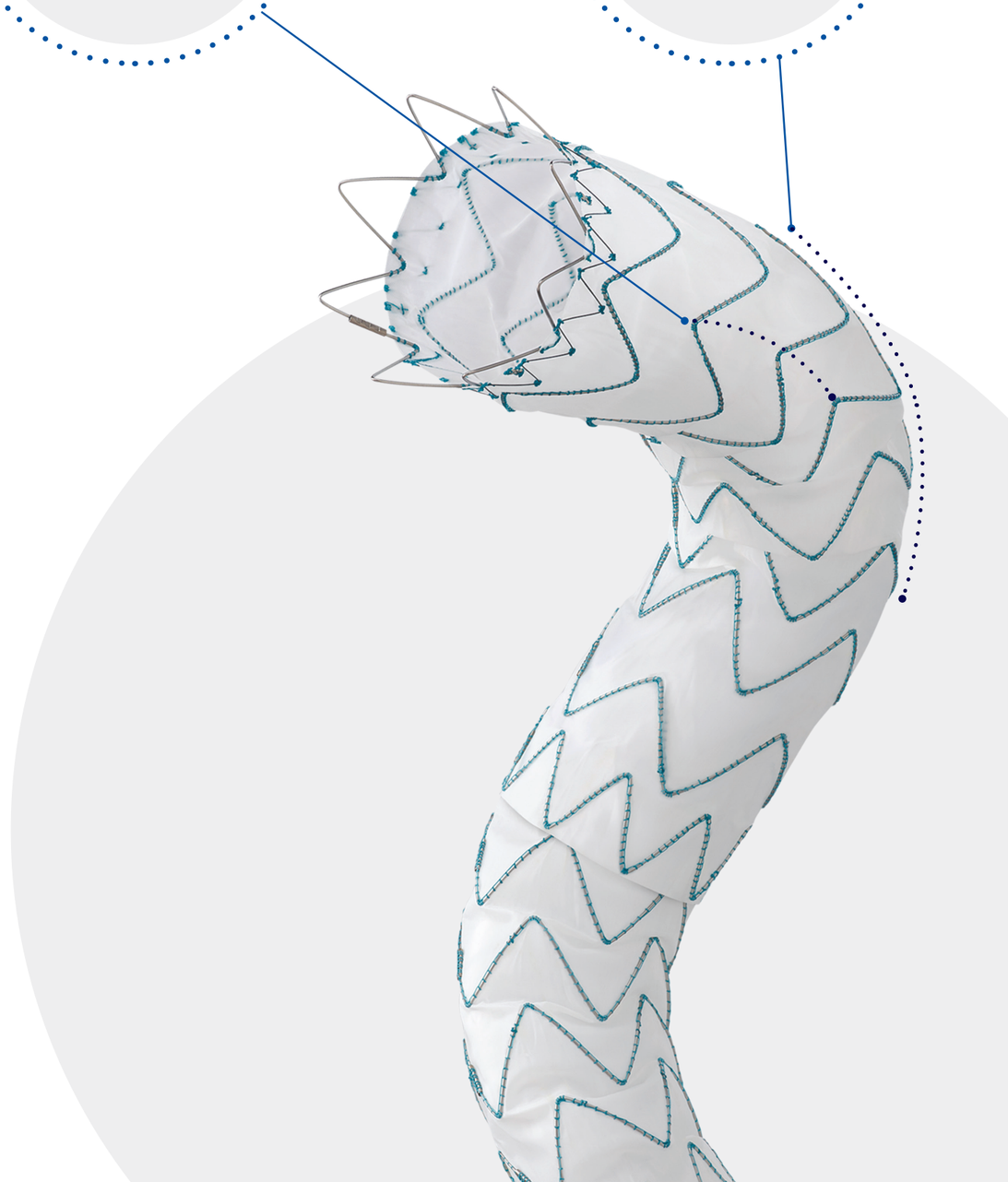
20 mm minimum neck length

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

5-year results
No migration[1]

Peak-to-valley design

Not constrained by a connecting bar



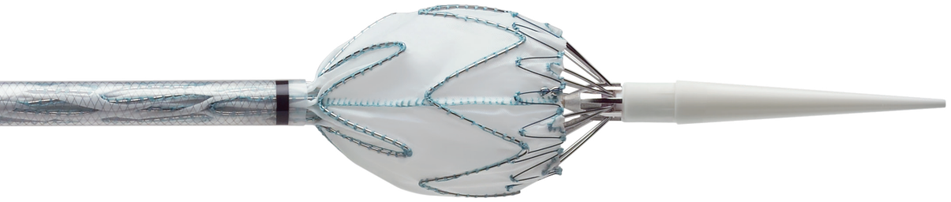
Risks associated with TEVAR procedures may include rupture, conversion to open repair, or secondary procedures.

[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.

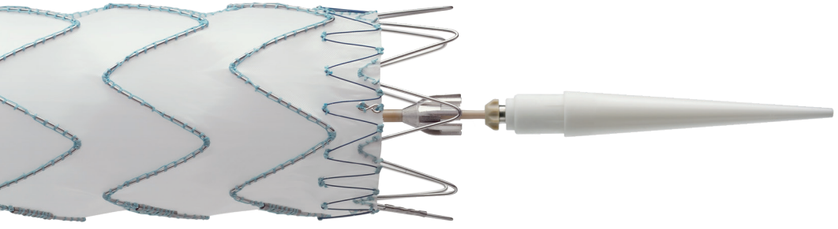
Precise deployment

Tip capture means control – critical for precise placement

Deployment



Captured

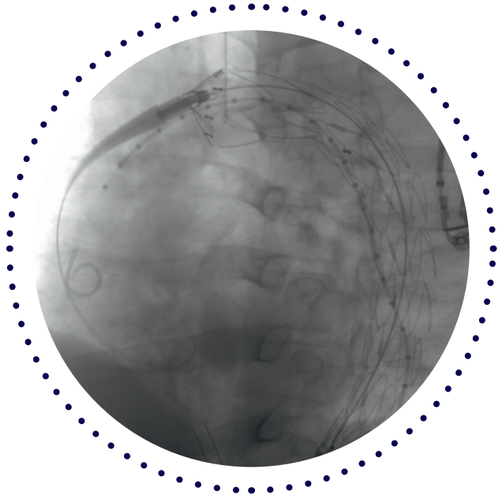


Released

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

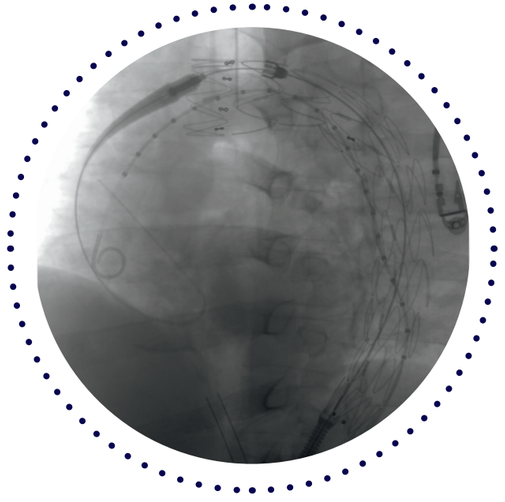
The Valiant™ Captivia™ system

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.

Precise deployment

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	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.

*™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

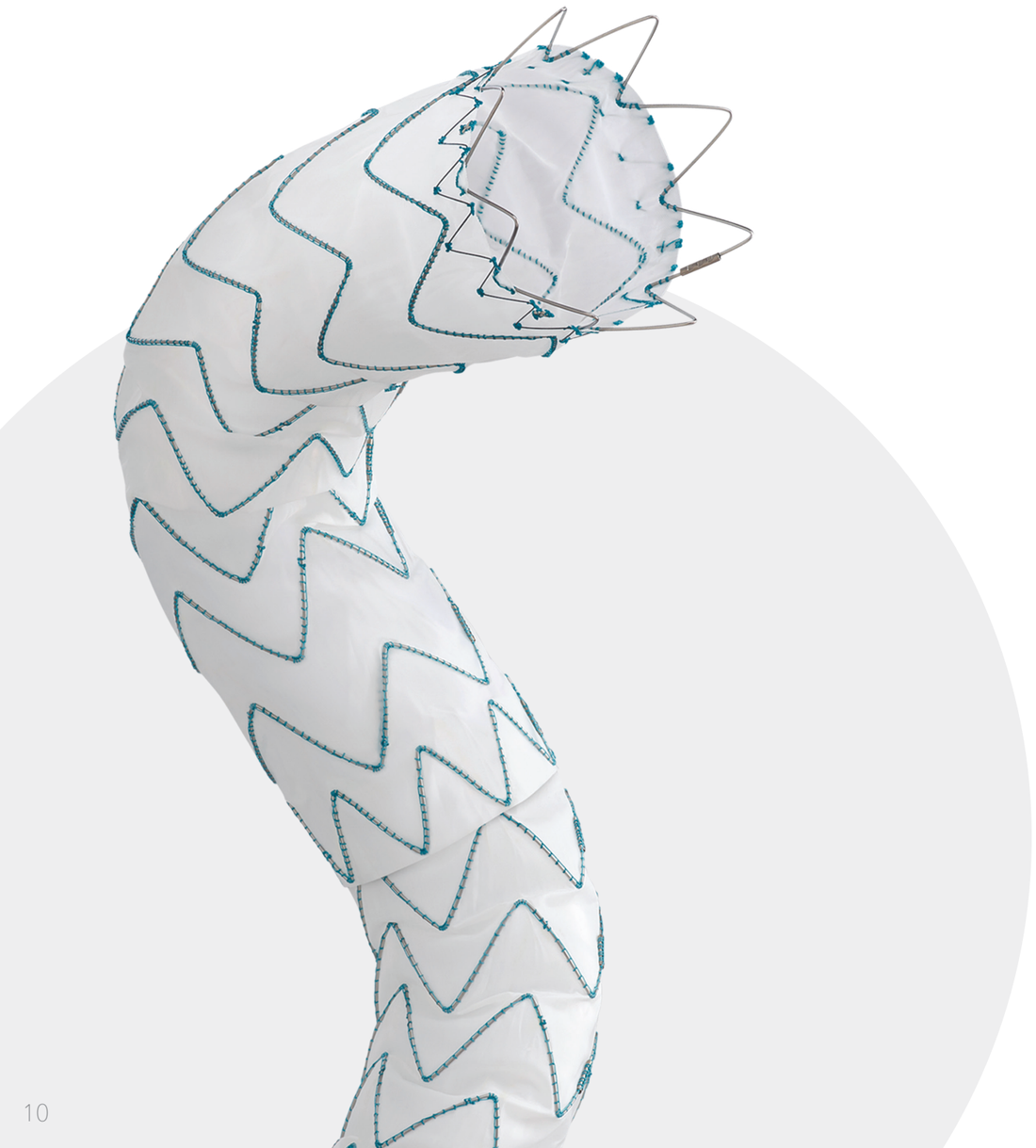
Step 1
Slow, controlled deployment for precise stent graft placement

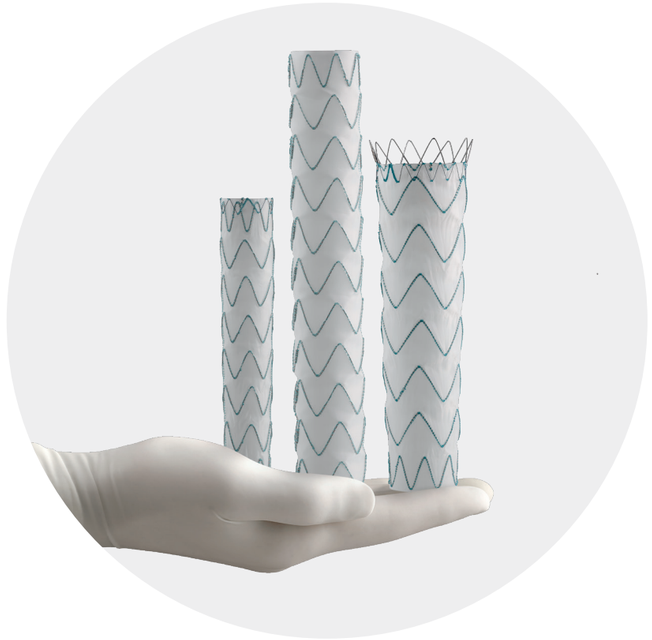
Step 2
Quick deployment option if desired

Step 3
Tip capture release

Hydrophilic coating
to facilitate stent graft delivery

100,000+ patients treated worldwide

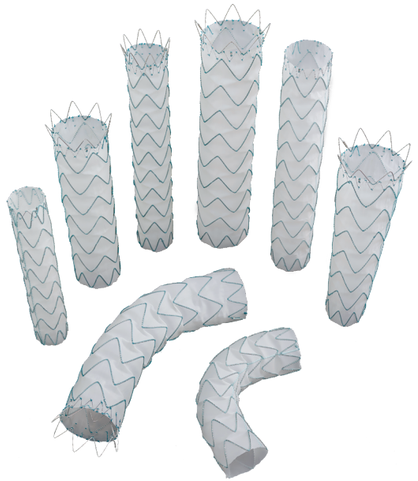




Broad sizing and tapering to tailor graft to patient anatomy.

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.

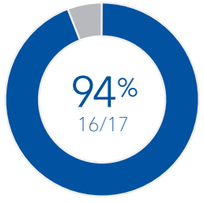
[1]Pantaleo A, Jafrancesco G, Buia F, et al. Distal Stent Graft-Induced New Entry: An Emerging Complication of Endovascular Treatment in Aortic Dissection. *Ann Thorac Surg*. August 2016;102(2):527-532.

Clinical track record

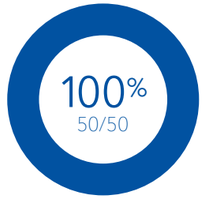
Acute complicated dissection outcomes[1]

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

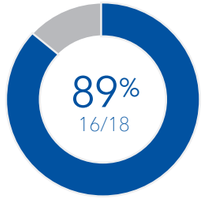
5-year evidence highlights



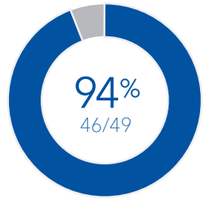
true lumen diameter increase/stable



proximal entry tears fully excluded[2]

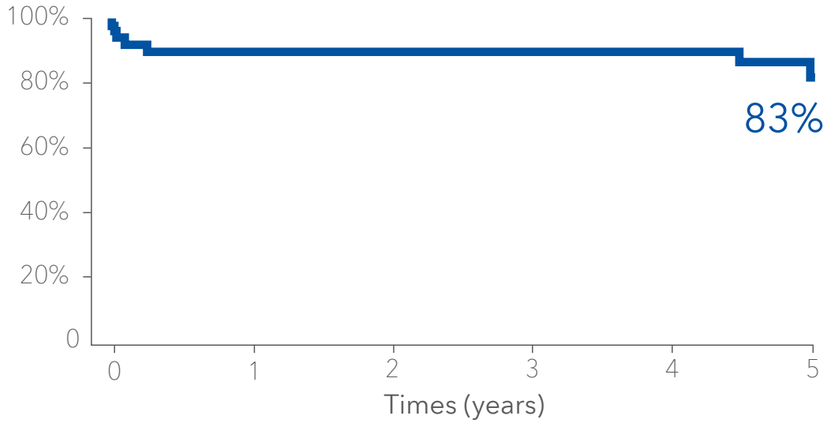


complete false lumen thrombosis



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.

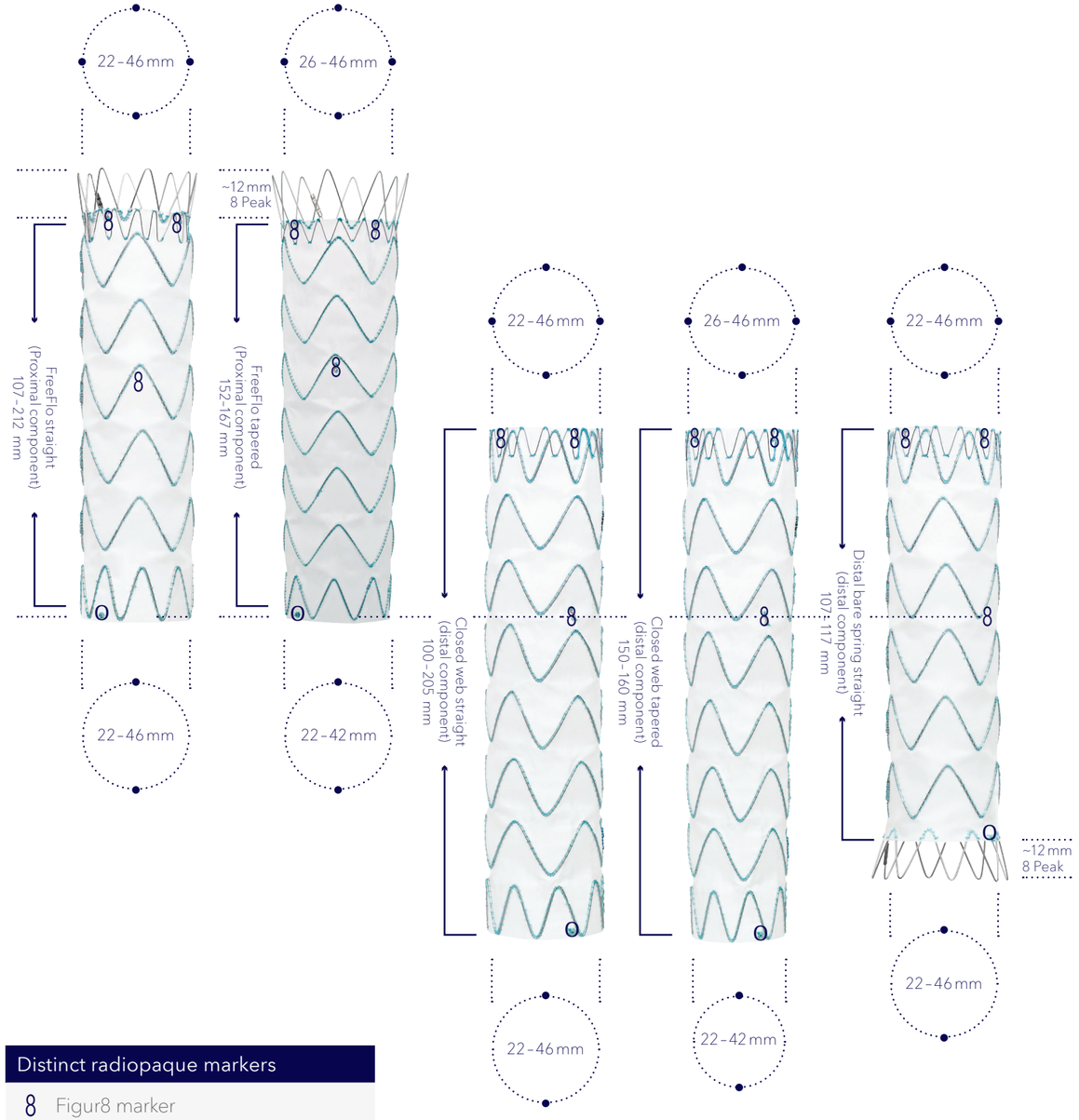
[2] Bavaria J, Brinkman WT, Hueghes GC, et al. Outcomes of Thoracic Endovascular Aortic Repair in Acute Type B Aortic Dissection: Results From the Valiant United States Investigational Device Exemption Study. *Ann Thorac Surg*. September 2015;100(3):802-808.

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



Distinct radiopaque markers

- 8 Figur8 marker
- O Zer0 marker

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	TU	22	112
VAMF	24	24	C	100	TU	22	112
VAMF	26	26	C	100	TU	22	112
VAMF	28	28	C	100	TU	22	117
VAMF	30	30	C	100	TU	22	117
VAMF	32	32	C	100	TU	22	117
VAMF	34	34	C	100	TU	24	107
VAMF	36	36	C	100	TU	24	107
VAMF	38	38	C	100	TU	24	107
VAMF	40	40	C	100	TU	24	107
VAMF	42	42	C	100	TU	25	112
VAMF	44	44	C	100	TU	25	112
VAMF	46	46	C	100	TU	25	112
VAMF	22	22	C	150	TU	22	152
VAMF	24	24	C	150	TU	22	152
VAMF	26	26	C	150	TU	22	152
VAMF	28	28	C	150	TU	22	157
VAMF	30	30	C	150	TU	22	157
VAMF	32	32	C	150	TU	22	157
VAMF	34	34	C	150	TU	24	167
VAMF	36	36	C	150	TU	24	167
VAMF	38	38	C	150	TU	24	167
VAMF	40	40	C	150	TU	24	167
VAMF	42	42	C	150	TU	25	157
VAMF	44	44	C	150	TU	25	157
VAMF	46	46	C	150	TU	25	162
VAMF	30	30	C	200	TU	22	192
VAMF	32	32	C	200	TU	22	192
VAMF	34	34	C	200	TU	24	212
VAMF	36	36	C	200	TU	24	207
VAMF	38	38	C	200	TU	24	207
VAMF	40	40	C	200	TU	24	212
VAMF	42	42	C	200	TU	25	207
VAMF	44	44	C	200	TU	25	212
VAMF	46	46	C	200	TU	25	212

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	TU	22	152
VAMF	28	24	C	150	TU	22	157
VAMF	30	26	C	150	TU	22	157
VAMF	32	28	C	150	TU	22	157
VAMF	34	30	C	150	TU	24	167
VAMF	36	32	C	150	TU	24	167
VAMF	38	34	C	150	TU	24	167
VAMF	40	36	C	150	TU	24	167
VAMF	42	38	C	150	TU	25	157
VAMF	44	40	C	150	TU	25	157
VAMF	46	42	C	150	TU	25	162

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	TU	22	150
VAMC	28	24	C	150	TU	22	150
VAMC	30	26	C	150	TU	22	150
VAMC	32	28	C	150	TU	22	150
VAMC	34	30	C	150	TU	24	160
VAMC	36	32	C	150	TU	24	160
VAMC	38	34	C	150	TU	24	160
VAMC	40	36	C	150	TU	24	160
VAMC	42	38	C	150	TU	25	150
VAMC	44	40	C	150	TU	25	150
VAMC	46	42	C	150	TU	25	155

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	TU	22	105
VAMC	24	24	C	100	TU	22	105
VAMC	26	26	C	100	TU	22	105
VAMC	28	28	C	100	TU	22	110
VAMC	30	30	C	100	TU	22	110
VAMC	32	32	C	100	TU	22	110
VAMC	34	34	C	100	TU	24	100
VAMC	36	36	C	100	TU	24	100
VAMC	38	38	C	100	TU	24	100
VAMC	40	40	C	100	TU	24	100
VAMC	42	42	C	100	TU	25	105
VAMC	44	44	C	100	TU	25	105
VAMC	46	46	C	100	TU	25	105
VAMC	22	22	C	150	TU	22	145
VAMC	24	24	C	150	TU	22	145
VAMC	26	26	C	150	TU	22	145
VAMC	28	28	C	150	TU	22	150
VAMC	30	30	C	150	TU	22	150
VAMC	32	32	C	150	TU	22	150
VAMC	34	34	C	150	TU	24	160
VAMC	36	36	C	150	TU	24	160
VAMC	38	38	C	150	TU	24	160
VAMC	40	40	C	150	TU	24	160
VAMC	42	42	C	150	TU	25	150
VAMC	44	44	C	150	TU	25	150
VAMC	46	46	C	150	TU	25	155
VAMC	30	30	C	200	TU	22	185
VAMC	32	32	C	200	TU	22	185
VAMC	34	34	C	200	TU	24	205
VAMC	36	36	C	200	TU	24	200
VAMC	38	38	C	200	TU	24	200
VAMC	40	40	C	200	TU	24	205
VAMC	42	42	C	200	TU	25	200
VAMC	44	44	C	200	TU	25	205
VAMC	46	46	C	200	TU	25	205

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	TU	22	112
VAMC	24	24	B	100	TU	22	112
VAMC	26	26	B	100	TU	22	112
VAMC	28	28	B	100	TU	22	117
VAMC	30	30	B	100	TU	22	117
VAMC	32	32	B	100	TU	22	117
VAMC	34	34	B	100	TU	24	107
VAMC	36	36	B	100	TU	24	107
VAMC	38	38	B	100	TU	24	107
VAMC	40	40	B	100	TU	24	107
VAMC	42	42	B	100	TU	25	112
VAMC	44	44	B	100	TU	25	112
VAMC	46	46	B	100	TU	25	112

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

Valiant™ Thoracic Stent Graft

Indications

The Valiant™ Thoracic Stent Graft with the Captivia™ Delivery System is indicated for the endovascular repair of all lesions of the descending thoracic aorta (DTA) in patients having appropriate anatomy, including:

- iliac/femoral artery access vessel morphology that is compatible with vascular access techniques, devices, or accessories;
- nonaneurysmal aortic diameter in the range of 18 mm to 42mm (fusiform and saccular aneurysms/penetrating ulcers), 18 mm to 44 mm (blunt traumatic aortic injuries), or 20 mm to 44 mm (dissections); and
- nonaneurysmal aortic proximal and distal neck lengths ≥ 20mm (fusiform and saccular aneurysms/penetrating ulcers), landing zone ≥20 mm proximal to the primary entry tear (blunt traumatic aortic injuries, dissections). The proximal extent of the landing zone must not be dissected.

Contraindications

The Valiant Thoracic Stent Graft with the Captivia Delivery System is contraindicated in:

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

Warnings and Precautions

The long-term safety and effectiveness of the Valiant Thoracic Stent Graft with the Captivia Delivery System has not been established. All patients should be advised that endovascular treatment requires lifelong, regular follow-up to assess the integrity and performance of the implanted endovascular stent graft. Patients with specific clinical findings (for example, enlarging aneurysm (>5mm), endoleaks, migration, inadequate seal zone, or continued flow into the false lumen in the case of a dissection) should receive enhanced follow-up. Specific follow-up guidelines are described in the Instructions for Use. The Valiant Thoracic Stent Graft with the Captivia Delivery System is not recommended in patients who cannot undergo, or who will not be compliant with, the necessary preoperative and postoperative imaging and implantation procedures as described in the Instructions for Use. Strict adherence to the Valiant Thoracic Stent Graft sizing guidelines as described in the Instructions for Use is expected when selecting the device size. Sizing outside of this range can potentially result in endoleak, fracture, migration, infolding, or graft wear. As cautioned in the Instructions for Use, a balloon should never be used when treating a dissection. The safety and effectiveness of the Valiant Thoracic Stent Graft with the Captivia Delivery System has not been evaluated in some patient populations. Please refer to the product Instructions for Use for details.

MRI Safety and Compatibility

Non-clinical testing has demonstrated that the Valiant Thoracic Stent Graft is MR Conditional. It can be scanned safely in both 1.5T and 3.0T MR systems under specific conditions as described in the product Instructions for Use. For additional information regarding MRI please refer to the product Instructions for Use.

Adverse Events

Potential adverse events include, but are not limited to access failure, access site complications (e.g. spasm, trauma, bleeding, rupture, dissection), adynamic ileus, allergic reaction (to contrast, antiplatelet therapy, stent graft material), amputation, anaesthetic complications, aortic expansion (e.g. aneurysm, false lumen), aneurysm rupture, angina, arrhythmia, arterial stenosis, atelectasis, blindness, bowel ischemia/ infarction, bowel necrosis, bowel obstruction, branch vessel occlusion, 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 aortobronchial, aortoenteric, aortoesophageal, arteriovenous, and lymph), gastrointestinal bleeding /complications, genitourinary complications, hematoma, hemorrhage / bleeding, hypotension / hypertension, infection or fever, insertion or 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, perfusion of the false lumen, peripheral ischemia, peripheral nerve injury, pneumonia, post-implant syndrome, procedural / post-procedural bleeding, prosthesis dilatation / infection / rupture / thrombosis, pseudoaneurysm, pulmonary edema, pulmonary embolism, reaction to anaesthesia, renal failure, renal insufficiency, reoperation, respiratory depression / failure, sepsis, seroma, shock, spinal neurological deficit, stent graft material failure (including breakage of metal portion of device) / migration / misplacement / occlusion / twisting / kinking, transient ischemic attack (TIA), thrombosis, tissue necrosis, vascular ischemia, vascular trauma, wound dehiscence, wound healing complications, 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.

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 visits to assess the patient's health status and endograft performance. The EndoAnchor™ implant does not reduce this requirement.
- The EndoAnchor™ implant and the Heli-FX™ 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™*, Medtronic AneuRx™, Medtronic Endurant™, Medtronic Talent™ AAA, Medtronic Talent™ TAA, Medtronic Valiant Xcelerant™, Medtronic Valiant™ Captivia™, and Medtronic Valiant Navion™ 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 together. 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 that are associated with the Heli-FX™ EndoAnchor™ system, include, but are not limited to: • Aneurysm rupture • Death n EndoAnchor™ implant embolization • Endoleaks (Type III) • Enteric fistula n Failure to correct/prevent Type I endoleak • Failure to prevent endograft migration • Infection n Renal complications (renal artery occlusion/dissection or contrast-induced acute kidney injury) • 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. Additional potential adverse events may be associated with endovascular aneurysm repair in general. Refer to the Instructions for Use provided with the endograft for additional potential 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 zones. 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 2 mm 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.

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