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.

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.

<table>
<thead>
<tr>
<th>Product tested</th>
<th>Proximal apposition at different landing zone angulation</th>
<th>Body apposition at different landing zone angulation</th>
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</thead>
<tbody>
<tr>
<td>Medtronic Valiant™</td>
<td>No lack of apposition (remained apposed)</td>
<td>No lack of apposition (remained apposed)</td>
</tr>
<tr>
<td>Gore™ C-TAG™</td>
<td>Lack of apposition above 120°</td>
<td>No lack of apposition (remained apposed)</td>
</tr>
<tr>
<td>Bolton Relay™</td>
<td>Lack of apposition above 110°</td>
<td>No lack of apposition (remained apposed)</td>
</tr>
<tr>
<td>Cook Zenith™ TX2™ Pro-Form™</td>
<td>No lack of apposition (remained apposed)</td>
<td>Lack of apposition above 110°</td>
</tr>
</tbody>
</table>

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

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

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

Continuous seal

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

Precise deployment

Tip capture means control – critical for precise placement

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

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

<table>
<thead>
<tr>
<th></th>
<th>Medtronic Valiant™</th>
<th>Bolton Relay™ Plus</th>
<th>Bolton Relay™ Pro</th>
<th>Cook Zenith™ TX2™ Pro-Form™</th>
<th>Gore™ C-TAG™ TX2™</th>
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<tbody>
<tr>
<td>Crossing profile (OD)</td>
<td>24 F</td>
<td>24 F</td>
<td>23 F</td>
<td>26 F</td>
<td>27 F</td>
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<tr>
<td>Hydrophilic coating</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Sheath required</td>
<td>No</td>
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</tbody>
</table>

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
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.⁴

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


### Acute complicated dissection outcomes
Positive aortic remodeling through five years in type B aortic dissections.

### 5-year evidence highlights
- **94%** 16/17 true lumen diameter increase/stable
- **100%** 50/50 proximal entry tears fully excluded
- **89%** 16/18 complete false lumen thrombosis
- **94%** 46/49 presented with DeBakey class IIIb dissections

### Freedom from dissection-related mortality
- **100%**
- **80%**
- **60%**
- **40%**
- **20%**
- **0%**

### Medtronic clinical data supports the use of TEVAR across multiple pathologies

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

### Distinct radiopaque markers
- **8** Figur8 marker
- **0** Zer0 marker

### Proximal FreeFlo tapered

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### Distal bare spring straight

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### Proximal FreeFlo straight

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### Heli-FX® thoracic recommended number of EndoAnchor™ implants

<table>
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<th>Product code</th>
<th>Diameter (mm)</th>
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### Remarks
- The following indications are based on clinical experience.
- Implanted EndoAnchor™ may be placed at physician discretion.

**Additional information:**
- **VAMC** denotes the vessel of interest.
- **Catheter diameter** and **stent graft diameter** are specified in millimeters.
- **Design** indicates the type of component used.
- **Length** specifies the length of the component in millimeters.

### Designation
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- **Catheter diameter** and **stent graft diameter** are specified in millimeters.
- **Design** indicates the type of component used.
- **Length** specifies the length of the component in millimeters.

**Sprig of the anatomy and EndoAnchor™ decisions are the responsibility of the physician.**

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**Images:**
- Distinct radiopaque markers
- Proximal FreeFlo tapered
- Closed web tapered
- Closed web straight
- Distal bare spring straight
- Proximal FreeFlo straight
- Heli-FX® thoracic recommended number of EndoAnchor™ implants
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;
- noneuamyoma arterial 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
- noneuamyoma 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 MRI 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), adynamie ileus, allergic reaction (to contrast, antiplatelet therapy, stent graft material), amputation, anesthetic complications, aortic expansion (e.g. aneurysm, false lumen), aneurysm rupture, aortic, angina, artheral stenosis, atelectasis, blindness, bowel ischemia/ infection, bowel necrosis, bowel obstruction, branch vessel occlusion, buttlock claudication, cardiac tamponade, catherter 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, hemotoma, 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, paralyis, paraparesis, paraplegia, paresis, perfusion of the false lumen, peripheral ischemia, periphery, renal insufficiency, restenosis, stenosis, post-implantation procedure / post-procedural bleeding, prosthesis dilatation / infection / rupture / thrombosis, pseudoaneurysm, pulmonary edema, pulmonary embolism, reaction to anasthesia, renal failure, renal insufficiency, reoperation, respiratory depression / failure, sepsis, sevoma, shock, spinal neurological deficit, stent graft material failure (including breakage of metal portion of dilating ulcers), treatment failure / 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 these devices 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 (MF35N-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™ TX™, Core Excluder™, Gore TAG™, Medtronic AneuRx™, Medtronic Endurant™, Medtronic Talent™ AAA, Medtronic Talent™ TAA, Medtronic Valiant Xcelerator™, 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, bleedling, 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
- 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/diseastion 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.