U.S. MEDTRONIC DISSECTION TRIAL
3 YEAR RESULTS
PROSPECTIVE, NON-RANDOMIZED, MULTI-CENTER TRIAL

TEVAR in Acute, Complicated Type B Aortic Dissection:
Results from the Valiant Captivia IDE Trial (n=50)

CLINICAL STATUS AT ONSET
Malperfusion: 86%
Rupture: 20%

The Valiant™ Captivia™ stent graft system demonstrates safety and effectiveness in the treatment of acute, complicated Type B aortic dissections

The Valiant™ Captivia™ stent graft system is stabilizing the aorta

RETROGRADE TYPE A AORTIC DISSECTION
POST-TEVAR FOR TYPE B AORTIC DISSECTION:

- Based on the published IDE data in the chart below, Retrograde Type A Dissections (RTADs) can occur with any device.

### RETROGRADE TYPE A AORTIC DISSECTION

#### POST-TEVAR FOR TYPE B AORTIC DISSECTION:

- According to the Systematic Review by Canaud et al., **pathology, landing zone, and oversizing are significantly associated with a risk of RTAD development regardless of device**, whereas proximal device configuration is not.

<table>
<thead>
<tr>
<th>STUDY</th>
<th>DEVICES STUDIED</th>
<th>PATIENTS</th>
<th>RETROGRADE TYPE A</th>
<th>1Y RTAD (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medtronic Dissection IDE¹</td>
<td>Medtronic Valiant™ Captivia™</td>
<td>50 acute</td>
<td>1 RTAD &lt;30d 1 RTAD &lt;1yr</td>
<td>4%</td>
</tr>
<tr>
<td>Gore Dissection IDE²</td>
<td>GORE cTAG™</td>
<td>50 acute</td>
<td>3 RTAD &lt;30d</td>
<td>6%</td>
</tr>
<tr>
<td>Cook STABLE IDE³</td>
<td>Cook Zenith™ TX2™</td>
<td>24 acute 16 sub acute</td>
<td>2 RTAD &lt;30d 1 RTAD &lt;1yr</td>
<td>7.5%</td>
</tr>
</tbody>
</table>

**NOTE:** These trials are not powered to be compared directly.

³ Dissection-related mortality
⁴ All-cause mortality
⁵ Valiant Captivia IFU
⁶ Gore cTAG IFU
OBJECTIVE
Evaluate the clinical performance of the Valiant™ thoracic stent graft with the Captivia™ delivery system for the treatment of acute, complicated Type B aortic dissections.

STUDY DESIGN
- 16 U.S. centers; enrollment 2010–2012
- N = 50 patients with acute, complicated (malperfusion, rupture) Type B aortic dissection
- 1° endpoint: all-cause mortality within 30 days of index procedure

MAIN CLINICAL FINDINGS THROUGH 3 YEARS
Treatment of trial patients resulted in:
- Primary endpoint achieved with 8% all-cause mortality at 30 days
- No conversions to open repair and three patients with dissection-related reinterventions
- No incidents of post-operative rupture
- 100% delivery and deployment success
- 100% coverage of primary entry tear
- 3 CVA / 1 CVI
- Favorable remodeling over stented segment

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Indications: The Valiant™ Thoracic Stent Graft with the Captivia™ Delivery System is intended for the endovascular repair of all lesions of the descending thoracic aorta (DTA) in patients having appropriate anatomy, including:
- iliac/femoral access vessel morphology that is compatible with vascular access techniques, devices, and/or accessories;
- nonaneurysmal aortic diameter in the range of 18 mm to 42 mm ( 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 ≥ 20 mm ( 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, 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 tear. 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, anesthetic 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, paralyses, paraparesis, paraplegia, paresthesia, perfusion of the false lumen, peripheral ischemia, peripheral nerve injury, pneumonia, post-mortem syndrome, procedural / post-procedural bleeding, prosthesis dilatation / infection / rupture / thrombosis, pseudoaneurysm, pulmonary edema, pulmonary embolism, reaction to anesthesia, 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.

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Medtronic
Aortic | Peripheral | endoVenous
3576 Unocal Place
Santa Rosa, CA 94403
USA
24-hour Technical Support
Toll free: +1.800.328.2518
Orders
Fax: +1.800.3103
CardioVascular LifeLine
Customer Support
Toll free: +1.877.526.7890
Fax: +1.877.526.7890
medtronic.com/aortic

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