



Medtronic

Valiant[®]

Thoracic Stent Graft with the Captivia[®] Delivery System

Instructions for Use

Explanation of symbols that may appear on product labeling

Refer to the device labeling to see which symbols apply to this product.

	Consult instructions for use at: www.medtronic.com/manuals
	Catalogue number
	CAUTION: Federal (USA) law restricts this device for sale by or on order of a physician.
	Contents: One Device
	Do not reuse
	Do not use if indicator turns black
	Do not use if package is damaged
	Manufactured In
	Manufacturer
	MR Conditional
	Non-pyrogenic
	Peel here
	Serial number
	Sterilized using irradiation
	Store at room temperature in a dark, dry place
	Use by
	FreeFlo Straight (Proximal Component)
	Closed Web Straight (Distal Component)
	Closed Web Tapered (Distal Component)
	Distal Bare Spring Straight (Distal Component)

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1. Device Description

The Valiant® Thoracic Stent Graft with the Captivia® Delivery System is designed for the endovascular repair of isolated lesions (excluding dissections) of the descending thoracic aorta (DTA). When placed within the target lesion, the stent graft provides an alternative conduit for blood flow within the patient's vasculature by excluding the lesion from blood flow and pressure.

The stent graft system is comprised of 2 main components: the implantable Valiant Thoracic Stent Graft and the disposable Captivia Delivery System. The stent graft is preloaded into the delivery system, which is inserted endoluminally via the femoral or iliac artery and tracked through the patient's vasculature to deliver the stent graft to the target site.

1.1. Stent Graft

A single, primary stent graft may be used alone if its size is sufficient to provide desired coverage, or it may be used in combination with additional stent graft sections, which increase the graft length either distal or proximal to the primary section.

All stent graft components are composed of a self-expanding, spring scaffold made from Nitinol wire sewn to a fabric graft with non-resorbable sutures. The metal scaffolding is composed of a series of serpentine springs stacked in a tubular configuration. Radiopaque markers are sewn onto each component of the stent graft to aid in visualization and to facilitate accurate placement. The Nitinol stents are also visible under fluoroscopy.

Stent graft components should be oversized to be larger than the measured nonaneurysmal vessel. The appropriate device oversizing is incorporated into the sizing guidelines. Section 10.2 contains detailed sizing information for all stent graft components. Table 1 contains a summary of the stent graft materials.

Table 1. Stent Graft Materials

Component	Material
Springs	Nitinol wire (55% Nickel, balance Titanium with trace elements)
Support Spring	Nitinol wire (55% Nickel, balance Titanium with trace elements)
Graft Fabric	High-density woven mono-filament polyester
Sutures	Braided polyester
Radiopaque Markers	Platinum-Iridium wire

The Valiant Thoracic Stent Graft System does not contain natural rubber latex; however, during the manufacturing process, it may have incidental contact with latex.

1.1.1. Stent Graft Configuration Options

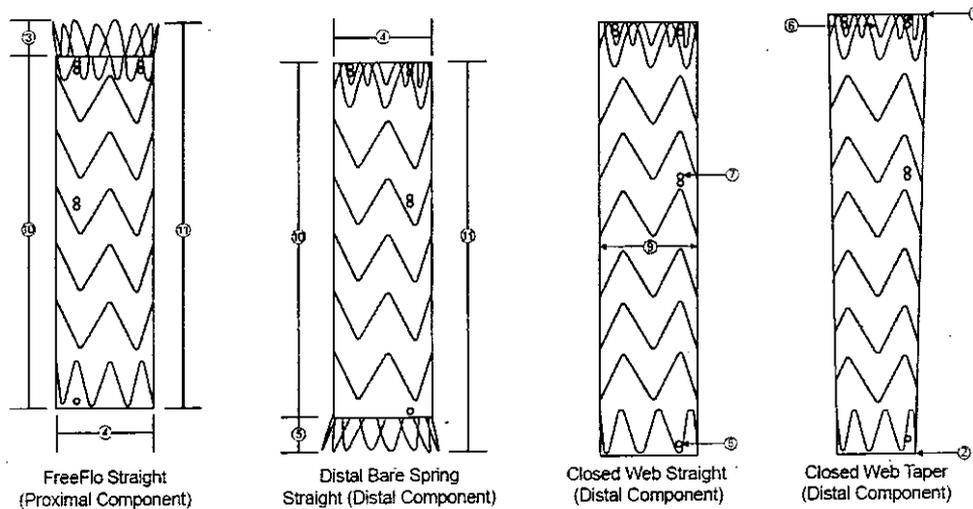


Figure 1. Stent Graft Configuration Components

- | | |
|------------------------|--------------------|
| 1. Proximal End | 7. Figur8 Marker |
| 2. Distal End | 8. Zero Marker |
| 3. FreeFlo | 9. Diameter |
| 4. Closed Web | 10. Covered Length |
| 5. Bare Spring | 11. Total Length |
| 6. Mini Support Spring | |

Note: This and all other product graphics appearing in this manual are not drawn to scale, are for graphical representation only, and may appear differently under fluoroscopy.

The Valiant Thoracic Stent Graft is available in 4 configuration options: FreeFlo Straight (proximal component), Closed Web Straight (distal component), Distal Bare Spring Straight (distal component), and Closed Web Taper (distal component). Each consists of an 8-peak fully covered stent and a mini support spring, which prevents the stent graft from infolding during and after deployment.

FreeFlo Straight Configuration (Proximal Component)

This configuration includes a FreeFlo proximal end and a Closed Web distal end. At the proximal end, an 8-peak bare stent extends past the covered stent graft to provide additional fixation while maintaining transvessel flow.

The FreeFlo Straight configuration stent grafts are available in diameters ranging from 22 mm to 46 mm and covered lengths of approximately 100 mm, 150 mm, and 200 mm. The proximal and distal end diameters of the FreeFlo Straight configuration are constant throughout the covered length of the device.

Caution: A FreeFlo end should never be placed inside the graft covered section of another stent graft.

Closed Web Straight Configuration (Distal Component)

This configuration includes Closed Web proximal and distal ends.

The Closed Web Straight configuration stent grafts are available in diameters ranging from 22 mm to 46 mm and covered lengths of approximately 100 mm, 150 mm, and 200 mm. The proximal and distal end diameters of the Closed Web Straight configuration are constant throughout the covered length of the device.

Caution: A Closed Web configuration should never be used as the most proximally implanted stent graft.

Caution: A Closed Web Straight configuration may be implanted as the primary section only when implanting multiple stent grafts in a nontortuous segment of the descending thoracic aorta with the distal-to-proximal implantation technique.

Distal Bare Spring Configuration (Distal Component)

This configuration includes a Closed Web proximal end and a Bare Spring distal end. At the distal end, an 8-peak bare stent extends past the covered stent graft to provide additional fixation while allowing for transvessel flow.

The Distal Bare Spring Straight configuration stent grafts are available in diameters ranging from 22 mm to 46 mm and a covered length of approximately 100 mm. The proximal and distal end diameters of the Distal Bare Spring Straight configuration are constant throughout the covered length of the device.

Caution: A Bare Spring end should never be placed inside the covered section of another stent graft.

Closed Web Taper Configuration (Distal Component)

This configuration includes Closed Web proximal and distal ends.

The Closed Web Taper configuration stent grafts are available in proximal end diameters ranging from 26 mm to 46 mm and distal end diameters ranging from 22 mm to 42 mm. The covered length is approximately 150 mm. The proximal end of the Closed Web Taper configuration is 4 mm larger in diameter than its distal end.

Caution: A Closed Web configuration should never be used as the most proximally implanted stent graft.

Caution: A Closed Web configuration may be implanted as the primary section only when implanting multiple stent grafts in a nontortuous segment of the descending thoracic aorta with the distal-to-proximal implantation technique.

1.2. Delivery System

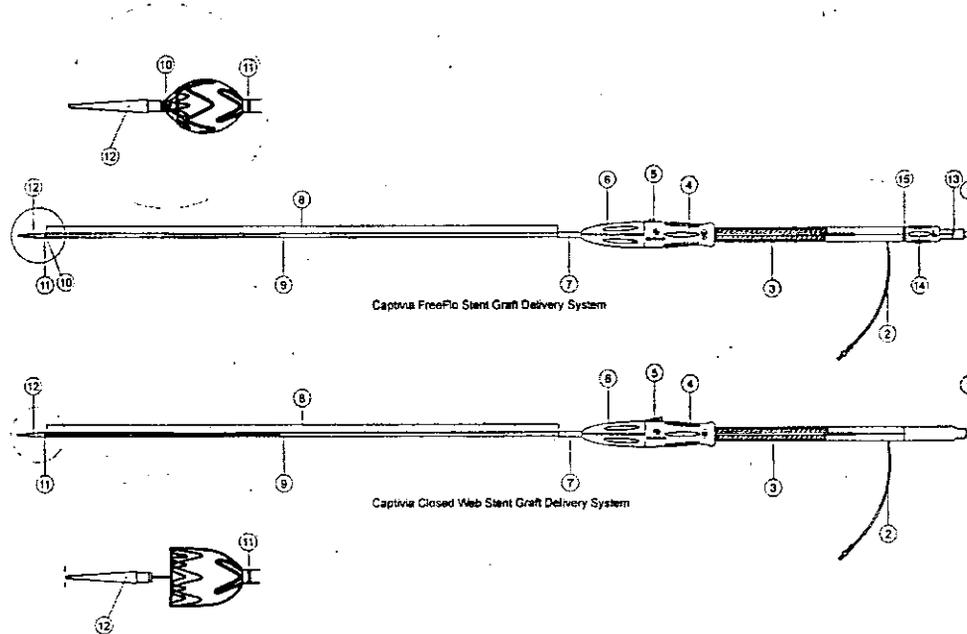


Figure 2. Captivia Stent Graft Delivery Systems

- | | |
|----------------------------------|--------------------------------|
| 1. Luer Connector | 9. Stent Stop |
| 2. Sideport Extension | 10. Tip Capture Mechanism |
| 3. Screw Gear | 11. RO Marker Band |
| 4. Slider/Handle | 12. Tapered Tip |
| 5. Trigger | 13. Back End Lock |
| 6. Front Grip | 14. Tip Capture Release Handle |
| 7. Strain Relief | 15. Clamping Ring |
| 8. Graft Cover/Introducer Sheath | |

The Captivia Delivery System consists of a single-use, disposable catheter with an integrated handle to provide controlled deployment. It is available in an outer diameter of 22, 24, and 25 French and a working length of approximately 83 cm. The catheter assembly is flexible and exclusively compatible with a 0.035 in (0.89 mm) guidewire. There are 2 types of Captivia delivery systems: the FreeFlo and Closed Web Stent Graft Delivery Systems. The FreeFlo system delivers the FreeFlo Straight configuration stent graft only. The Closed Web system delivers the Closed Web Straight, Distal Bare Spring Straight, and Closed Web Taper configuration stent grafts. The FreeFlo system features a tip capture mechanism, which is not present in the Closed Web system.

The Captivia Delivery System is a multilumen device. Each lumen serves one of the following distinct functions:

- The inner member provides a lumen to allow the system to track over a 0.035 in (0.89 mm) guidewire.
- The tip capture tube (**FreeFlo Stent Graft Delivery System only**) provides a lumen to actuate the tip capture mechanism.
- The flexible stent stop provides a lumen to aid in tracking the system through tortuous anatomy and maintains stent graft position during deployment.
- The graft cover with stainless steel braid provides a lumen to contain the stent graft during tracking and to release the stent graft during deployment.

A flexible tapered tip is attached to the end of the inner member and provides a smooth transition from the guidewire to the outer graft cover. The tapered tip and graft cover are coated with a lubricious hydrophilic coating. Once activated with a sterile gauze saturated in saline, this coating will facilitate vessel access and tracking through anatomy. A distal radiopaque marker indicates the graft cover edge under fluoroscopy. A hemostasis valve at the proximal end of the delivery system minimizes blood loss and leakage during the procedure. The stent graft is deployed by rotating or retracting the integrated slider handle. When using the FreeFlo Stent Graft Delivery System, the tip capture release handle at the rear of the delivery system is unlocked and retracted to release the bare stent.

Note: The Reliant® Stent Graft Balloon Catheter (packaged separately) can be used to assist in stent graft implantation.

2. Indications for Use

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

- iliac or femoral artery access vessel morphology that is compatible with vascular access techniques, devices, or accessories;
- nonaneurysmal aortic diameter in the range of 18 mm to 42 mm (fusiform and saccular aneurysms/penetrating ulcers) or 18 mm to 44 mm (blunt traumatic aortic injuries); and
- nonaneurysmal aortic proximal and distal neck lengths ≥ 20 mm.

3. Contraindications

The Valiant Thoracic Stent Graft System is contraindicated in the following patient populations:

- patients who have a condition that threatens to infect the graft
- patients with known sensitivities or allergies to the device materials (Table 1)

Also consider the information in Patient Selection (Section 4.2).

4. Warnings and Precautions

Caution: Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious consequences or injury to the patient.

4.1. General

- The Valiant Thoracic Stent Graft with the Captivia Delivery System should only be used by physicians and medical personnel trained in vascular interventional techniques, including training in the use of this device. Specific training expectations are described in Physician Training Requirements (Section 10.1).
- The safety and effectiveness of the Valiant Thoracic Stent Graft to treat traumatic aortic transections was determined based on 30 day follow-up data. Due to the short-term nature of this data, all patients should be advised that long-term, regular follow-up is necessary to assess patients' health status and stent graft performance.
- Always have a vascular surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.
- **Caution:** Federal (USA) law restricts this device for sale by or on the order of a physician.

4.2. Patient Selection

- 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 described in Section 10 through Section 13.
- The Valiant Thoracic Stent Graft System is not recommended in patients who cannot tolerate contrast agents necessary for intraoperative and postoperative follow-up imaging.
- The Valiant Thoracic Stent Graft System is not recommended in patients exceeding weight or size limits necessary to meet imaging requirements.
- Prior to the procedure, preoperative planning for access and placement should be performed. See Recommended Device Sizing (Section 10.2). Key anatomic elements that may affect successful exclusion of the lesion include tortuosity, short landing zone(s) [<20 mm], and thrombus or calcium formation at the implantation sites. In the presence of anatomical limitations, a longer landing zone and additional stent grafts may be required to obtain adequate sealing and fixation.
- If preoperative case planning measurements are not certain, an inventory of device lengths and diameters necessary to complete the procedure should be available to the physician. Use of the device outside the recommended anatomical sizing may result in serious device related events.
- The use of this device requires administration of radiographic agents. Patients with pre-existing renal insufficiency may have an increased risk of postoperative renal failure.
- Inappropriate patient selection may result in poor performance.
- The safety and effectiveness of the Valiant Thoracic Stent Graft with the Captivia Delivery System has not been evaluated in the following patient situations or populations:
 - The patient requires planned placement of the covered proximal end of the stent graft requires implant to occur in Zone 0 or Zone 1 (Figure 3).

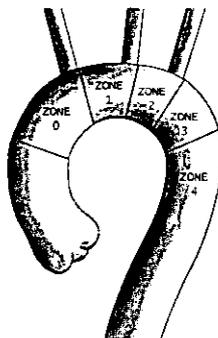


Figure 3. Covered Stent Graft Placement Zones

- The patient's access vessel, as determined by treating physician, precludes safe insertion of the delivery system.
Note: Iliac conduits may be used to ensure the safe insertion of the delivery system.
- The patient has a TAA with a contained rupture.
- The patient has connective tissue disease (for example, Marfan syndrome or medial degeneration).
- The patient has received a previous stent or stent graft or previous surgical repair in the descending thoracic aortic area.
- The patient has pseudoaneurysms resulting from previous graft placement.
- The patient will be undergoing a concomitant surgical or endovascular treatment of an infrarenal aortic aneurysm.
- The patient has a history of bleeding diathesis or coagulopathy, or refuses blood transfusions.
- The patient has had a cerebrovascular accident (CVA) within 3 months of the procedure.
- The patient has a known hypersensitivity or contraindication to anticoagulants or contrast media, which is not amenable to pretreatment.
- The patient has a significant or circumferential aortic mural thrombus, which could compromise fixation and seal of the implanted stent graft.
- The patient has active systemic infections.
- The patient has an aortic fistula.
- The patient has aortitis or an inflammatory aneurysm.
- The patient has an intramural hematoma.
- The patient has a mycotic aneurysm.
- The patient is a pregnant female.
- The patient is less than 18 years old.
- The patient has an aortic dissection of the thoracic aorta.
- The long-term safety and effectiveness of the Valiant Thoracic Stent Graft System has not been established. All patients should be advised that endovascular treatment requires lifelong, regular follow-up to assess the integrity and performance of the implanted endovascular stent graft. Patients with specific clinical findings (for example, enlarging aneurysm [>5 mm], endoleak, migration, or inadequate seal zone) should receive enhanced follow-up. Specific follow-up guidelines are described in Follow-up Imaging Recommendations (Section 13).
- Strict adherence to the Valiant Thoracic Stent Graft System sizing guidelines (Table 3 to Table 6) is expected when selecting the device size. The appropriate device oversizing is incorporated into the sizing guidelines. Sizing outside of this range can potentially result in endoleak, fracture, migration, infolding, or graft wear.
- Intervention or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aneurysms (>5 mm) or endoleak. An increase in aneurysm size or persistent endoleak may lead to rupture.

4.3. Implant Procedure

- A seal zone <20 mm could increase the risk of endoleak or migration of the stent graft. Migration may also be caused by deployment of the proximal stent into a thrombus-filled or severely angled vessel wall.
- Manipulation of wires, balloons, catheters, or endografts in the thoracic aorta may lead to vascular trauma, including aortic dissection and embolization.
- Do not bend, kink, or otherwise alter the Captivia Delivery System prior to implantation because it may cause deployment difficulties.
- Discontinue advancement of the guidewire or delivery system if resistance is felt. The cause of resistance must be assessed in order to avoid vessel or delivery catheter damage.
- Wire fractures are more likely to occur in conditions with an excessively oversized endoprosthesis, flexion, kinking, or bending during cardiac or respiratory cycles. Wire fractures may have clinical consequences, such as endoleak, endoprosthesis migration, or adjacent tissue damage.
- Oversize the aortic portion of the stent graft by 10 to 20% (3 to 5 mm), as appropriate for the patient. For additional sizing information, see Recommended Device Sizing (Section 10.2).

Caution: Oversizing of the stent graft to the vessel >10% may be unsafe in the presence of dissecting tissue or intramural hematoma.

- Wrinkling of stent graft material may promote thrombus formation. If this occurs, inflate a conformable balloon within the deployed stent graft lumen to reduce wrinkling of the material.
 - Note:** Medtronic recommends the Reliant Stent Graft Balloon Catheter for use with the Valiant Thoracic Stent Graft. Data is not available for remodeling the Valiant Thoracic Stent Graft with other balloon catheters.
 - Use the Reliant device according to the Instructions for Use (IFU) supplied with the product. Do not attempt to use the Reliant device before completely reading and understanding the IFU supplied with the product.
 - Do not use the Reliant device in patients with a history of aortic dissection disease. Do not over-inflate the balloon.
 - If the proximal and distal radiopaque markers of the Reliant device are not completely within the covered Valiant thoracic stent graft, there is an increased risk of vessel injury, rupture, or possible patient death.
 - Care should be taken when inflating the balloon, especially with calcified, tortuous, stenotic, or otherwise diseased vessels. Inflate slowly. It is recommended that a backup balloon be available.
 - Due to the increased risk of dislodging material during distal repositioning of the Valiant Thoracic Stent Graft, it is not recommended to position the device higher in the aorta in the presence of excessive calcification or thrombus formation. See Positioning the Captivia Delivery System (Section 11.5).
 - Do not advance the Valiant Thoracic Stent Graft System when it is partially deployed and is apposed to the vessel wall.
 - The proximal end of the covered Valiant Thoracic Stent Graft should not be placed beyond the origin of the left common carotid artery (ie, Zone 0 or Zone 1) (Figure 3).
 - FreeFlo and Bare Spring Straight ends should never be placed inside the fabric covered section of another stent graft. This may result in abrasion of the fabric by the bare spring and result in graft material holes or broken sutures.
 - Ensure that the Valiant devices are placed in a landing zone comprised of healthy tissue. Healthy tissue is defined as tissue without evidence of circumferential thrombus, intramural hematoma, dissection, ulceration, or aneurysmal involvement. Failure to do so may result in inadequate exclusion or vessel damage, including perforation.
 - Endoleak left untreated during the implantation procedure must be carefully monitored after the implantation procedure.
 - Avoid occluding arterial branches that do not have collateral or protected perfusion to end organs or body structures. If the left subclavian artery (LSA) is to be covered, check the blood flow of the vertebral or cerebral arteries and the retrograde flow of the LSA. If occlusion of the left subclavian artery ostium is required to obtain adequate neck length for fixation and sealing, transposition or bypass of the LSA should be considered.
- Caution:** Patients with a patent LIMA (left internal mammary artery)-LAD (left anterior descending artery) bypass should not be considered for coverage of the LSA unless additional bypasses are performed prior to the stent graft procedure.

4.4. Magnetic Resonance Imaging (MRI)

Nonclinical testing has demonstrated that the Valiant Thoracic Stent Graft is MR conditional. See MRI Information (Section 10.5) for more information.

Adverse Events

5.1. Potential Adverse Events

Adverse events or complications associated with the use of the Valiant Thoracic Stent Graft with the Captivia Delivery System that may occur or require intervention include, but are not limited to:

- Access failure
- Access site complications (eg, spasm, trauma, bleeding, rupture, dissection)
- Adynamic ileus
- Allergic reaction (to contrast, antiplatelet therapy, stent graft material)
- Amputation
- Anesthetic complications
- Aneurysm expansion
- 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
- Endoleaks
- Excessive or inappropriate radiation exposure
- Extrusion/erosion
- Failure to deliver the stent graft
- Femoral neuropathy
- Fistula (aortobronchia, aortoenteric, aortoesophageal, arteriovenous, lymph)
- Gastrointestinal bleeding/complications
- Genitourinary complications
- Hematoma
- Hemorrhage/bleeding
- Hypotension/hypertension
- Infection or fever
- Insertion or removal difficulty
- Intercostal pain
- Intramural hematoma
- Leg edema/foot edema
- Lymphocele
- Myocardial infarction
- Neuropathy
- Occlusion – Venous or Arterial
- Pain/Reaction at catheter insertion site
- Paralysis
- Paraparesis
- Paraplegia
- Paresthesia
- Peripheral ischemia
- Peripheral nerve injury
- Pneumonia
- Procedural bleeding
- Prosthesis dilatation
- Prosthesis infection
- Prosthesis rupture
- Prosthesis thrombosis
- Pseudoaneurysm
- Pulmonary edema
- Pulmonary embolism
- Reaction to anaesthesia
- Renal failure
- Renal insufficiency
- Reoperation
- Respiratory depression or failure
- Sepsis
- Seroma
- Shock
- Spinal neurological deficit
- Stent graft material failure (including breakage of metal portion of device)
- Stent graft migration
- Stent graft misplacement
- Stent graft occlusion
- Stent graft twisting or kinking
- Transient ischemic attack (TIA)
- Thrombosis
- Tissue necrosis
- Vascular ischemia
- Vascular trauma

- Dissection, perforation, or rupture of the aortic vessel & surrounding vasculature
- Embolism
- Post-implant syndrome
- Post-procedural bleeding
- Wound dehiscence
- Wound healing complications
- Wound infection

5.2. Adverse Event Reporting

Any adverse event or clinical incident involving the Valiant Thoracic Stent Graft with the Captivia Delivery System should be immediately reported to Medtronic Vascular. To report an incident in the US, call (800) 465-5533.

6. Summary of Clinical Studies

The clinical evidence supporting the safety and effectiveness of the Valiant Thoracic Stent Graft with the Captivia Delivery System is from a combination of 4 clinical studies:

Study	Objective
RESCUE US Clinical Study	to evaluate the Valiant Thoracic Stent Graft with the Captivia Delivery System in the treatment of severe blunt thoracic aortic injuries/transection (BTAI) in the descending thoracic aorta
Valiant Thoracic Stent Graft Clinical Study (VALOR II)	to demonstrate the safe and effective use of the Valiant Thoracic Stent Graft for the treatment of fusiform aneurysms and saccular aneurysms/penetrating ulcers of the descending thoracic aorta in subjects who were candidates for endovascular repair
Valiant Captivia OUS Registry	to provide confirmatory clinical information to support the engineering evaluation of the modified Captivia Delivery System
Talent® Captivia Study	to provide confirmatory clinical information to support the engineering evaluation of the modified Captivia Delivery System

Subsequent to the enrollment in VALOR II, the delivery system was updated from the Xcelerant to the Captivia Delivery System. The Captivia Delivery System is a design iteration of the Xcelerant Delivery System. The primary difference between the 2 delivery systems is the incorporation of a tip capture mechanism designed to constrain the proximal bare springs of the FreeFlo stent graft until proper positioning has been obtained.

6.1. RESCUE

The RESCUE study (G090201) was a prospective, non-randomized, multicenter study to evaluate the clinical performance of the Valiant Thoracic Stent Graft for treatment of blunt thoracic aortic injury (BTAI). The primary objective was to evaluate the safety and effectiveness of the Valiant Thoracic Stent Graft in the treatment of BTAI as determined by all-cause mortality within 30-days of the index procedure. CT images through 12 months will be evaluated by the sites and by an independent Core Lab. Site data will be used for reporting purposes at 2, 3, 4 and 5 years. Chest x-rays were evaluated by the sites and Core Lab at 1 year and will be evaluated by the sites at 3 and 5 years. All deaths were reviewed and adjudicated by an independent Clinical Events Committee (CEC), and will continued to be reviewed and adjudicated through 5 years. An independent Data Monitoring Committee (DMC) met to review trial conduct and study data after the first 20 subjects reached the 30-day follow-up time point and recommended that the clinical trial continue without modifications.

6.1.1. Clinical Endpoints

The primary safety endpoint was all-cause mortality within 30 days of the index procedure. Additional secondary objectives evaluated the acute and long term safety and effectiveness by reporting the following outcomes within 30 days: aortic related mortality, device, procedure and aortic related adverse event and successful delivery and deployment of the stent graft. The primary objective and set of secondary objectives were assessed descriptively and there was no formal hypothesis testing. The sample size of 50 subjects was planned without a formal statistical sample size calculation and selected based on precision around the estimated 30-day mortality.

6.1.2. Accountability of PMA Cohort

Fifty subjects (50) were enrolled in this study between April 2010 and January 2012 at 20 investigational sites. All enrolled subjects underwent endovascular repair with the Valiant Thoracic Stent Graft. Figure 4 summarizes the subject accountability and compliance by study interval.

Implant and Follow-up	Subject Follow-up % (m/n) ²			Subject Imaging % (m/n) ²			Patients with Adequate Imaging to Assess the Parameter % (m/n) ²			Subject Accountability N					
	Eligible ¹	Clinical Follow-up	Imaging Follow-up	CT/MR Imaging	Chest X-Ray	Additional Imaging Modalities	Endoleak	Migration from 1 Month	Integrity	Enrolled but not Implanted	Withdrawal	Conversion to Surgery	Death	Lost to Follow-up	Not Due for Next Visit
Implant	50														
Events Between Implant and 1-Month										0	0	0	4 ³	0	0
1-Month	47 ³	97.9% (46/47)	95.7% (45/47)	95.7% (45/47)		0.0% (0/47)	93.6% (44/47)		97.9% (46/47)						
Events Between 1-Month and 6-Month											0	0	1 ³	0	18
6-Month	27	85.2% (23/27)	81.5% (22/27)	81.5% (22/27)		0.0% (0/27)	81.5% (22/27)	81.5% (22/27)	81.5% (22/27)						
Events Between 6-Month and 12-Month											0	0	0	0	13
12-Month	14	85.7% (12/14)	85.7% (12/14)	85.7% (12/14)	85.7% (12/14)	0.0% (0/14)	85.7% (12/14)	85.7% (12/14)	85.7% (12/14)						
Events Between 12-Month and 2-Year											0	0	0	0	14
2-Year	0	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)		0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)						
Total										0	0	0	5	0	
Deaths Post Conversion to Surgery													0		
Total Deaths													5		

¹ Eligible at implant are all subjects enrolled by snapshot date. Eligible (E_t) for time intervals post implant is eligible from the previous interval (E_{t-1}) less the sum of enrolled but not implanted (ENI) plus withdrawal (W) plus conversion to surgery (CTS) plus death (D) plus lost to follow-up (LTF) plus not due for next visit (NDNV) subjects. $E_t = E_{t-1} - (ENI + W + CTS + D + LTF + NDNV)$.

² Percentages are based on number of all subjects enrolled by snapshot date and include subjects that have a completed clinical/imaging follow-up form for the time point, divided by number of eligible subjects. To be considered within window, a subject must have at a minimum, the clinical follow up or the imaging follow-up occurring within the follow-up window.

³ There were four (4) deaths within 30-days and 47 subjects were eligible at 1-month follow-up visit instead of 46 subjects since one subject that died had completed the 1-month follow-up visit prior to death. This subject is included under the eligible subjects at 1-month follow-up time point in the table
m = number of subjects in category, n = number of subjects with available data.

Site Reported Table.

Figure 4. RESCUE Trial Subject Follow-up, Imaging and Accountability

6.1.3. Subject Population Demographics and Baseline Parameters

Figure 5 through Figure 9 provide baseline parameters of the study subjects including demographics, medical history, associated injuries to the BTAI, pre-treatment risk using the injury severity score (ISS), and radiological aortic assessment.

Age (years)	
n	50
Mean ± SD	40.7 ± 17.4
Median	39.5
Min, Max	18, 76
Sex % (m/n)	
Male	76.0% (38/50)
Female	24.0% (12/50)
Weight (lbs)	
n	50
Mean ± SD	189.3 ± 39.3
Median	186.1
Min, Max	115, 324
Ethnicity % (m/n)	
Hispanic or Latino	20.0% (10/50)
Not Hispanic or Latino	72.0% (36/50)
Not Available	8.0% (4/50)
Race % (m/n)	
White	68.0% (34/50)
Black or African American	20.0% (10/50)
Asian	4.0% (2/50)
Native Hawaiian or Other Pacific Islander	0.0% (0/50)
American Indian or Alaska Native	0.0% (0/50)
Other	4.0% (2/50)
Not Available	4.0% (2/50)

m = number of subjects in category, n = number of subjects enrolled in this study.
 *Site Reported Table.

Figure 5. Subject Demographic

Subject Medical History	% (m/n)
Hypertension	
Yes	24.0% (12/50)
No	74.0% (37/50)
Unknown	2.0% (1/50)
COPD	
Yes	4.0% (2/50)
No	94.0% (47/50)
Unknown	2.0% (1/50)
Congestive Heart Failure	
Yes	2.0% (1/50)
No	96.0% (48/50)
Unknown	2.0% (1/50)
Paraplegia	
Yes	2.0% (1/50)
No	96.0% (48/50)
Unknown	2.0% (1/50)
Diabetes	
Yes	2.0% (1/50)
No	96.0% (48/50)
Unknown	2.0% (1/50)
GI Conditions	
Yes	2.0% (1/50)
No	94.0% (47/50)
Unknown	4.0% (2/50)
MI	
Yes	0.0% (0/50)
No	98.0% (49/50)
Unknown	2.0% (1/50)
Coronary Artery Bypass Grafting (CABG)	
Yes	0.0% (0/50)
No	98.0% (49/50)
Unknown	2.0% (1/50)
Renal Insufficiency	
Yes	0.0% (0/50)
No	98.0% (49/50)
Unknown	2.0% (1/50)
Stroke/Cerebrovascular Accident (CVA)	
Yes	0.0% (0/50)
No	98.0% (49/50)
Unknown	2.0% (1/50)
Paraparesis	
Yes	0.0% (0/50)
No	98.0% (49/50)
Unknown	2.0% (1/50)
Bleeding Disorder	
Yes	0.0% (0/50)
No	98.0% (49/50)
Unknown	2.0% (1/50)
Other important Medical Conditions	
Yes	46.0% (23/50)
No	54.0% (27/50)

m = number of subjects in category, n = number of intent to treat (ITT) subjects enrolled in this study.
Site Reported Table.

Figure 6. Subject Medical History

Subject Injury Characteristics	
Duration from Injury to Procedure (days)	
n	50
Mean ± SD	1.8 ± 4.0
Median	1.0
Min, Max	0, 23
Assigned ISS	
n	50
Mean ± SD	37.6 ± 14.3
Median	35.0
Min, Max	13, 75
Mechanism of Blunt Injury % (m/n)	
Motor Vehicle Accident	60.0% (30/50)
Motorcycle Accident	22.0% (11/50)
Pedestrian Hit by Motor Vehicle	10.0% (5/50)
Fall	4.0% (2/50)
Other	4.0% (2/50)
Associated Traumatic Injuries % (m/n)	
Head Injury	48.0% (24/50)
Long Bone Fracture	38.0% (19/50)
Pelvic Fracture	40.0% (20/50)
Scapula Fracture	8.0% (4/50)
Unstable C/T/L Spine Fractures	14.0% (7/50)
Abdominal Injury (solid organ, bowel, bladder, or diaphragm injury)	58.0% (29/50)
Lung Injury	70.0% (35/50)
Neurologic Deficits	12.0% (6/50)
Rib Fracture	64.0% (32/50)
Sternum Fracture	6.0% (3/50)
Other	50.0% (25/50)
Location of Aortic Injury % (m/n)	
Isthmus (just distal to the left subclavian artery to the third intercostals artery)	84.0% (42/50)
Distal Descending Thoracic Aorta	16.0% (8/50)
Extent of Aortic Injury % (m/n)¹	
Grade 1 - Intimal Tear	18.0% (9/50)
Grade 2 - Intramural Hematoma	12.0% (6/50)
Grade 3 - Aortic Pseudoaneurysm	68.0% (34/50)
Grade 4 - Free Rupture	2.0% (1/50)

m = number of subjects in category, n = number of subjects enrolled in this study.

Site Reported Table.

¹Azizzadeh A, Keyhani K, Miller CC, Coogan SM, Safi HJ, Estrera AL: Blunt traumatic aortic injury: Initial experience with endovascular repair. J Vasc Surg 2009; 49: 1403-8.

Figure 7. Subject Injury Characteristics

Thoracic Aortic Measurements: Diameters (mm)¹	
D1: Aortic Diameter at Left Common Carotid Artery	
n	50
Mean ± SD	24.2 ± 5.0
Median	24.0
Min, Max	10, 40
D2: Aorta Diameter (2 cm proximal to injury)	
n	50
Mean ± SD	24.3 ± 3.9
Median	23.5
Min, Max	18, 35
D3: Maximum Descending Thoracic Aorta Diameter	
n	50
Mean ± SD	26.5 ± 6.6
Median	25.5
Min, Max	18, 42
D4: Aorta Diameter (2 cm distal to the injury)	
n	50
Mean ± SD	22.5 ± 4.1
Median	21.0
Min, Max	18, 34
D5: Aortic Diameter at Celiac Axis	
n	49 ¹
Mean ± SD	20.5 ± 3.5
Median	20.0
Min, Max	14, 28
Right Common Iliac Diameter	
n	49 ¹
Mean ± SD	10.0 ± 1.7
Median	10.0
Min, Max	6, 13
Left Common Iliac Diameter	
n	49 ¹
Mean ± SD	10.0 ± 1.8
Median	10.0
Min, Max	6, 15
Right External Iliac Diameter	
n	49 ¹
Mean ± SD	8.1 ± 1.5
Median	8.0
Min, Max	3, 11
Left External Iliac Diameter	
n	49 ¹
Mean ± SD	8.1 ± 1.7
Median	8.0
Min, Max	3, 12
Right Femoral Diameter	
n	47 ²
Mean ± SD	8.2 ± 1.4
Median	8.0
Min, Max	5, 13
Left Femoral Diameter	
n	47 ²
Mean ± SD	8.0 ± 1.6
Median	8.0
Min, Max	4, 14

¹ The images taken for some subjects did not cover the celiac axis region.

² There were three cases in which the pre-implant image was insufficient and the access was assessed during the procedure. There were no access issues or any adverse events related to the procedure in these subjects.

Site Reported Table.

Figure 8. Site Reported Thoracic Aortic Measurements - Diameters

Thoracic Measurements: Lengths (mm)	
L1: Distance from LCC to Injury (pre-implant)	
n	50
Mean ± SD	30.0 ± 8.2
Median	29.5
Min, Max	20, 52
L2: Distance from LSA to Injury (pre-implant)	
n	50
Mean ± SD	15.0 ± 9.4
Median	13.5
Min, Max	0, 36
L3: Distance from Injury to Celiac Axis (pre-implant)	
n	42 ¹
Mean ± SD	175.1 ± 50.9
Median	182.5
Min, Max	17, 300

¹ The images taken for some subjects did not cover the celiac axis region.
Site Reported Table.

Figure 9. Thoracic Measurements - Lengths

6.1.4. Valiant Thoracic Stent Graft Usage

Information regarding numbers and sizes of devices are presented in Figure 10 through Figure 12.

Number of Devices Implanted ¹	Subjects % (m/n)
1	96.0% (48/50)
2	4.0% (2/50) ²

¹ Number of devices implanted includes devices implanted at initial procedure.
² One subject had one Talent Thoracic Stent Graft implanted distal to the Valiant Thoracic Stent Graft.
m = number of subjects in category, n = number of subjects enrolled in this study.
Site Reported Table.

Figure 10. Number of Devices Implanted

Valiant Device Diameter	Number of Devices Implanted
22	11
24	8
26	8
28	11
30	6
32	1
34	3
36	2
38	1
40	0
42	0
44	0
46	0

Site Reported Table.

Figure 11. Proximal Valiant Device Diameters Implanted at Initial Procedure

Length of Coverage (post-implant) (mm)	
n	45 ¹
Mean ± SD	130.4 ± 21.3
Median	136.2
Min, Max	90, 179

¹ This is core lab reported data. Core lab did not receive adequate imaging from all sites.
Core Lab Reported Table.

Figure 12. Length of Stent Graft Coverage

6.1.5. Acute Procedural Data

Vessel access was obtained in all subjects and the device was successfully delivered and deployed in all the subjects in this study population as shown in Figure 13.

Technical Success	% (m/n)
Vessel Access Success	100.0% (50/50)
Delivery Success	100.0% (50/50)
Deployment Success	100.0% (50/50)
m = number of subjects in category, n = number of subjects enrolled in this study. Site Reported Table.	

Figure 13. Technical Success

A summary of the acute measures at implant are summarized in Figure 14 through Figure 15.

Type of Anesthesia Used	% (m/n)
General	100.0% (50/50)
Spinal	0.0% (0/50)
Regional	0.0% (0/50)
Local	0.0% (0/50)
Systemic Heparinization	80.0% (40/50)
Spinal CSF Drainage Used	4.0% (2/50)
Any Other Spinal Protective Measure Used	6.0% (3/50)
LSA Coverage	
None	42.0% (21/50)
Partial	18.0% (9/50)
Complete	40.0% (20/50)
Subjects with LSA Coverage	58.0% (29/50)
LSA Covered subjects with pre-implant adjunctive procedure ¹	2.0% (1/50)

¹ Procedures involving LSA by-pass/LSA revascularization/LSA debranching/LSA transposition.
m = number of subjects in category, n = number of subjects enrolled in this study.
Site Reported Table.

Figure 14. Implant Procedure

Duration of Implant Procedure (min)	
n	50
Mean ± SD	102.2 ± 57.0
Median	90.5
Min, Max	35, 311
Contrast Volume (ml)	
n	47 ¹
Mean ± SD	120.8 ± 49.1
Median	110.0
Min, Max	31, 230
Total Fluoroscopic Time (mins)	
n	44 ¹
Mean ± SD	11.0 ± 10.1
Median	8.7
Min, Max	3, 66
Blood Loss During Procedure (ml)	
n	49 ²
Mean ± SD	123.4 ± 152.9
Median	50.0
Min, Max	10, 900
Subjects Requiring Blood Transfusion % (m/n)³	
18.0% (9/50)	
Hospital Survival % (m/n)	
94.0% (47/50)	
Overall Hospital Stay (days)	
n	49 ¹
Mean ± SD	14.7 ± 12.6
Median	11.0
Min, Max	1, 58
Time in Intensive Care Unit From Admission to Discharge (hours)	
n	49 ⁴
Mean ± SD	201.7 ± 194.3
Median	140.8
Min, Max	-3, 976

¹ Most of the subjects were treated emergently in the middle of the night; measurements like contrast volume, total fluoroscopic time, etc. may not be captured in the research coordinator's absence.

² Subject's blood loss information was not reported by the site but was reported that no blood transfusion was required.

³ Not limited to blood transfusion required as a result of blood loss during the procedure.

⁴ Subject was not discharged at the time of data snapshot date.

m = number of subjects in category, n = number of subjects with available data.
Site Reported Table.

Figure 15. Acute Measurement at Implant

6.1.6. Safety and Effectiveness Results

6.1.6.1. Safety Results: Primary and Secondary Endpoint Analysis

The primary endpoint for this study included all enrolled subjects and was measured by the all-cause mortality rate within 30 days. As shown in Figure 16, four (4) subjects died within 30 days of the index procedure. This result demonstrates a 30-day all-cause mortality rate of 8.0% for BTAI subjects treated with the Valiant Thoracic Stent Graft. Two of these deaths were adjudicated by the CEC to be aortic-related resulting in an aortic-related mortality of 4.0% (2/50). Neither of these deaths was reported by the sites to be aortic related (Figure 17).

Primary Endpoint	% (m/n)
30-day All-Cause Mortality	8.0% (4/50)

m = number of subjects in category, n = number of subjects enrolled in this study.
Site and clinical events committee (CEC) Adjudicated Reported Table.

Figure 16. Primary Endpoint

Subject ID	Procedure Date	Death Date	Time to Death (days)	Cause of Death Site Reported	Death Relatedness Site Reported	Death Relatedness CEC Adjudicated
00018-001	01/25/2011	01/26/2011	1	Hemothorax	Not Related	Aortic Related ¹
00182-001	10/06/2010	10/07/2010	1	Traumatic Brain Injury	Not Related	Not Related
00344-003	01/26/2011	01/31/2011	5	Arrhythmia	Not Related	Not Related
00059-002	08/26/2011	09/17/2011	22	Complications of Multiple Blunt Force Injuries	Device Relation Not Evaluable, Aortic Relation Not Evaluable, Not Related to Procedure	Device Related, Procedure Related, Aortic Related ²
00340-004	04/10/2011	09/26/2011	169	Infection	Not Related	Not Related

Site and CEC Adjudicated Reported Table.

¹A 22 year-old male, thrown from a horse into a tree, arrived with bilateral hemothoraces and a myocardial contusion (ISS=30, Grade III aortic injury). The patient underwent prompt and successful thoracic endovascular aneurysm repair (TEVAR), with the post-procedural aortogram demonstrating successful exclusion of BTAI and no extravasation or endoleak. While the left sided hemothorax subsided after TEVAR, the patient expired on the next day from continued right-sided massive hemothorax. An autopsy was performed on this patient and showed no evidence of an additional aortic injury. The CEC adjudicated this death to be related to the aortic injury and unrelated to the device or procedure.

²Sudden unexplained death day 22 in acute care facility, with limited information and no autopsy. Subject had a history of atrial fibrillation and recent pulmonary embolus on Coumadin. Imaging taken one week before death showed complete exclusion of pseudoaneurysm and good graft position. Due to unknown cause of death the CEC conservatively adjudicated the event to be related to the device, procedure, and aorta.

Figure 17. Deaths

6.1.6.2. Safety Results: Summary of All Adverse Events (AE)

As stated in the protocol, only those adverse/serious adverse events that are related to the device, to the implant procedure and/or to the aorta and serious adverse events (SAEs) that lead to death, regardless if they are related to the device, procedure or the aorta, were reported by the sites. SAEs are defined as any adverse event that:

- led to a death;
- led to a serious deterioration in the health of the subject that:
- resulted in life threatening illness or injury;
- resulted in a permanent impairment of a body structure or a body function;
- required in-patient hospitalization or prolongation of existing hospitalization; or
- resulted in medical or surgical intervention to prevent permanent impairment to a body structure or a body function; or
- led to fetal distress, fetal death or a congenital abnormality or birth defect.

The AEs reported during this study are identified in Figure 18. Of note is that no subject had a stroke/cerebrovascular accident, spinal cord ischemia, paraparesis or paraplegia.

Adverse events that occurred within 30-days of the procedure and were related to the procedure, aorta or device were reported by the study sites in six (6) subjects (12.0%). Of these adverse events, procedure related adverse events were reported in five (5) subjects (10.0%), and an aorta related adverse event was reported in one (1) subject (2.0%). The CEC, that adjudicated events associated with deaths, adjudicated one additional SAE as being related to the aorta. There were no adverse events reported to be related to the device by the sites, however the CEC adjudicated one death from unknown causes as related to the procedure, device and aorta, as described above. A listing of all AEs, including those SAEs that led to death, whether or not they were related to the device, procedure or the aorta, is shown in Figure 18.

Adverse Event	Relatedness Site Reported	Relatedness CEC Adjudicated
Any Procedure, Aorta or Device Related AE	12.0% (6/50)	N/A
Any Procedure Related AE	10.0% (5/50)	N/A
Any Aorta Related AE	2.0% (1/50)	N/A
Any Device Related AE	0% (0/50)	N/A
SAEs Leading to Death¹		
Hemothorax	Not Related	Aortic Related
Traumatic Brain Injury	Not Related	Not Related
Arrhythmia	Not Related	Not Related
Complications of Multiple Blunt Force Injuries	Not Evaluable Device Related, Not Evaluable Aortic Related; Not Related to Procedure	Device Related, Procedure Related, Aortic Related
SAEs Not Leading to Death		
Femoral Artery Dissection ²	Procedure Related	N/A
Anoxic Encephalopathy ³	Aortic Related	N/A
Left Arm Ischemia ^{4,5}	Procedure Related	N/A
Left Arm Claudication ⁶	Procedure Related	N/A
Additional AEs		
Hematoma ⁷	Procedure Related	N/A
Incision Site Erythema ⁸	Procedure Related	N/A
<p>¹Information on patients who died and had SAEs is provided in Figure 17. These are the only events adjudicated by the CEC, as the CEC is only responsible for adjudicating deaths and UADE's.</p> <p>²Subject had a right common femoral artery focal dissection during index procedure. Subject underwent a thrombectomy and patch angioplasty and the event recovered the same day.</p> <p>³Subject developed an anoxic brain injury related to the rupture on the day of the procedure. This subject's discharge summary notes mentioned that "the patient's course was complicated by hypoxicischemic encephalopathy secondary to significant hypotension and hypoxia after the accident as well as intra-operatively" prior to the deployment of the stent graft. Additionally this subject experienced another SAE: infection, on day 169 post procedure that led to death (refer to Figure 17).</p> <p>⁴Subject had peripheral ischemia on day seven (7), LSA was intentionally (partially) covered during initial procedure. Subject underwent a left carotid to subclavian bypass on day eight and the ischemia resolved the next day.</p> <p>⁵Subject experienced upper left limb ischemia on day 36 post procedure, related to the procedure. During the procedure, the physician intentionally completely covered the left subclavian artery (LSA). The subject eventually developed signs of upper left extremity ischemia. This subject underwent a left carotid to subclavian bypass on day 36 post procedure that led to resolution of the event on the day of the bypass.</p> <p>⁶Subject experienced left arm claudication on day 30, LSA was intentionally (completely) covered during initial procedure. Subject underwent left carotid to subclavian bypass on day 103 and the event has since resolved.</p> <p>⁷Subject developed a right groin hematoma on the day of the index procedure. The event resolved without treatment four days post procedure.</p> <p>⁸Subject developed erythema at right groin incision on day four (4) from the index procedure. The site reported this event to be related to the procedure. This event resolved the following day with medication.</p>		

Figure 18. All Adverse Events Within 30 Days

In addition to the events listed above, there was one subject that experienced peripheral arm ischemia on day 36 post-procedure. That same day a left carotid-to-subclavian by-pass procedure was performed and the peripheral arm ischemia was resolved on the day of the procedure. The site reported this as procedure related. There was also one subject that experienced no palpable radial pulse on day 39 post-procedure. The site reported this event to be related to the procedure and was 'unresolved, not treating' as of the data cut-off date for the data presented. There was also one death reported after 30-days as described in Figure 17. There were no additional adverse events reported during this study.

6.1.7. Effectiveness Results

To assess the effectiveness of the Valiant Thoracic Stent Graft, the RESCUE trial collected information on the success of device delivery and deployment. Information was also collected on technical observations including endoleaks, stent graft kinking, stent graft twisting, misaligned deployment, stent graft fracture, loss of stent graft integrity, loss of stent graft patency, migration and if the traumatic injury was covered by the stent. In addition, the following device assessments were collected by the sites and verified by the independent core laboratory:

- Loss of stent graft patency
- Total length of the stented segment
- Stent graft migration
- Presence and type of endoleaks

As shown in Figure 19, after gaining vessel access at procedure, the investigators reported that the device was delivered and deployed successfully in all 50 subjects. Successful delivery was defined as complete coverage of the traumatic injury with no misaligned deployment, with a patent graft at the conclusion of the procedure. There were no Type I or Type III endoleaks

reported in this study population. There were two (2) subjects reported to have a Type II endoleak at the end of procedure by the site, both of these endoleaks resolved without treatment by the 1-month visit. No technical observations were reported from the 1-month follow-up CTA/MRA images. The stent graft integrity was maintained in 100% of the cases. There were no reports of stent graft twisting, kinking, or fracture, and all stent grafts remained patent as reported by the sites and the core lab. There were no occurrences of Unanticipated Adverse Device Effects (UADEs) in this trial.

Secondary Efficacy Endpoint	% (m/n)
Successful Delivery and Deployment of the Stent Graft	100.0% (50/50)

m = number of subjects in category, n = number of subjects enrolled in this study.
Site and CEC Adjudicated Reported Table.

Figure 19. Secondary Efficacy Endpoint

There were no cases of endovascular re-intervention or conversion to open surgery reported. There was one (1) subject within 30-days and two (2) subjects between 31 and 365 days that required LSA bypass to correct left arm ischemia. These events are captured under the 'Other' category in Figure 20 below.

Secondary Procedure	0 to 30 Days % (m/n) ¹	31 to 365 Days % (m/n) ¹	366 to 731 Days % (m/n) ¹	732 to 1096 Days % (m/n) ¹	1097 to 1461 Days % (m/n) ¹	1462 to 1826 Days % (m/n) ¹
Conversion to Open Repair	0.0% (0/50)	0.0% (0/43)	0.0% (0/11)	N/A	N/A	N/A
Additional Endovascular Device Placed	0.0% (0/50)	0.0% (0/43)	0.0% (0/11)	N/A	N/A	N/A
Other ²	2.0% (1/50)	4.7% (2/43)	0.0% (0/11)	N/A	N/A	N/A

¹ m = number of subjects in category, n = number of subjects with study stent implanted who experienced an event or who were followed at least until the lower endpoint of the interval. For example, for column '0-30 Days', '31-365 Days', '366-731 Days', '732-1096 Days', '1097-1461 Days' and '1462-1826 Days', a subject had to be followed respectively for at least 0 day, 31 days, 366 days, 732 days, 1097 days and 1462 days in order to be included in the denominator, unless he/she experienced an event in the corresponding interval.

Site Reported Table.

² One subject had peripheral ischemia on day seven, LSA was intentionally (partially) covered during initial procedure. Subject underwent a left carotid to subclavian bypass on day eight and the ischemia resolved the next day. Another subject experienced left arm claudication on day 30, LSA was intentionally (completely) covered during initial procedure. Subject underwent left carotid to subclavian bypass on day 103 and the event has since resolved. A third subject experienced peripheral arm ischemia on day 36. On that same day a left carotid-to-subclavian by-pass procedure was performed and the peripheral arm ischemia was resolved on the day of the procedure.

Figure 20. Secondary Procedures (Implanted)

6.1.8. Overall Conclusions

Based on the data collected and presented, there is reasonable assurance of safety and effectiveness of the Valiant Thoracic Stent Graft in the treatment of BTAI of the DTA for subjects who have appropriate vascular anatomy and who are candidates for endovascular treatment.

6.2. VALOR II

The VALOR II clinical study (Valiant Test Group) was a prospective, multicenter, single-arm trial. The Valiant Test Group was compared on the primary safety endpoint to the Talent Control Group a study of the safety and effectiveness of the Talent Thoracic Stent Graft (PMA number P070007)¹. The Valiant Test Group, which enrolled 160 subjects, was conducted under the same indications and similar study requirements as the Talent Control Group, which enrolled 195 subjects.

The analysis included endpoints that were consistent with current literature and other thoracic endovascular aneurysm repair studies. Hypothesis testing included a comparison of the primary safety endpoint of all-cause mortality within 12 months between the Valiant Test Group and Talent Control Group. The primary effectiveness endpoint, Successful Aneurysm Treatment, which was compared to a fixed value, was defined as the absence of: a) aneurysm growth of more than 5 mm at the 12-month visit relative to the 1-month visit; and b) secondary procedure due to type I or III endoleak performed or recommended at or before the 12-month visit. Secondary endpoints were also presented. Follow-up evaluations were conducted at 1 month, 6 months, and 12 months, and will be conducted annually thereafter for a total of 5 years from the index procedure.

6.2.1. Suitability of the Control Group for the Primary Safety Objective

Although conducted over different periods of time, the Valiant Test and Talent Control Groups evaluated the same treatment indications and were conducted under similar study requirements. The design of both trials addressed sources of potential bias through the use of a physician screening committee to reduce potential selection bias and a core laboratory and clinical events committee (CEC) to reduce potential assessment bias. In addition, statistical testing was employed to control for differences in baseline risk factors. Nonetheless, there are several potential concerns associated with using a historical control. First, the control is non-concurrent so there is a temporal bias of unknown size that may affect the scientific validity of the study. Second, the historical control group may include a different subject population and/or outcomes than the contemporary study. There is no guarantee that the 2 groups are comparable, even with statistical techniques such as ANOVA or Cochran-Mantel-Haenszel analysis. In addition to the above concerns, protocol deviations occurred during this study and may have also introduced bias to the data.

6.2.2. Subject Accountability and Follow-up

Detailed subject accountability data, as well as imaging data available for analysis, is presented in Figure 21. Three of 160 subjects did not receive an implant due to access failures. No subjects withdrew or were lost to follow-up within 12 months. Subjects who expired after completing a physical exam were considered to have exited the study at the subsequent interval.

¹ The summary of Safety and Effectiveness Data and labeling is available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p070007>

Treatment / follow-up interval	Subject follow-up # (%)		Subjects with imaging (at each time interval) # (%)		Subjects with adequate imaging to assess the parameter # (%)				Subject events occurring before next visit #						
	Eligible	Treatment or clinical f/u	Imaging f/u	CTMR imaging	Chest X-ray	Max ANR diameter	Change in ANR diameter (from 1 month)	Endoleak	Migration (from 1 month)	Integrity	Intention to treat but not implanted	Conversion to surgery	Death	Withdrawal	Not due for next visit
Originally Enrolled	160	100% (160/160)													
Events between implant and 1 month follow-up visit															
1 month (0-122 days)	156	100.0% (156/156)	98.7% (154/156)	97.4% (152/156)	96.8% (151/156)	96.2% (150/156)	89.1% (139/156)	89.1% (139/156)	95.5% (149/156)	3	0	1 ³	0	0	0
Events between 1 month and 6 month follow-up visit															
6 month (123-336 days) ²	147	75.5% (111/147)	93.2% (137/147)	92.5% (136/147)	77.6% (114/147)	89.8% (132/147)	83.0% (122/147)	83.0% (122/147)	85.7% (126/147)		0	9	0	0	0
Events between 6 month and 12 months follow-up visit															
12 month (337-480 days)	133	87.2% (116/133)	91.0% (121/133)	87.2% (116/133)	84.2% (112/133)	86.5% (115/133)	85.7% (114/133)	75.2% (100/133)	78.9% (105/133)			7	0	0	7
Totals										3	0	17⁴	0	0	0
											Death post conversion to surgery		0		
											Total deaths		17		

Figure 21. Subject Accountability and Core Lab Imaging Compliance within 12 Months²: Vallant Test Group only

¹ The number of subjects eligible for each interval is determined by how many subjects completed a physical exam less those who converted to surgery, died, withdrew, or were lost to follow-up in the previous interval.
² Treatment or Clinical f/u at six months and "Events between 6 months 12 months follow-up visit" are based on the protocol-defined follow-up window. "Evaluable core lab imaging" is based on the analysis window of 123-366 days.
³ Four of 5 subjects who died within 30 days completed a physical exam at discharge and were therefore recorded as having completed the 1-month interval.
⁴ Two of 19 subjects who died within 365 days completed a physical exam prior to expiring and were therefore recorded as having completed the 12-month interval.

6.2.3. Study Demographics and Baseline Medical History

There were no statistically significant differences in demographic variables between Vallant Test Group and Talent Control Group populations. Figure 22 through Figure 25 provide the demographics, baseline medical history, and SVS risk classification of both groups.

² The number of subjects eligible for each interval is determined by how many subjects completed a physical exam less those who converted to surgery, died, withdrew, or were lost to follow-up in the previous interval.

	VALIANT TEST GROUP	TALENT CONTROL GROUP	p-value
Age (years)			
Total Population			
N	160	195	
Mean ± SD	72.2 ± 9.1	70.2 ± 11.1	0.459
Median	74	73	
Min, max	36, 85	27, 86	
Sex/Gender % (m/n)			
Male	59.4% (95/160)	59% (115/195)	0.769
Female	40.6% (65/160)	41% (80/195)	
Race % (m/n)			
American Indian or Alaska Native	0% (0/160)	0% (0/190)	0.787
Asian/Native Hawaiian/Pacific Islander	2.5% (4/160)	1.1% (2/190)	
Black	10% (16/160)	13.2% (25/190)	
White	86.3% (138/160)	85.3% (162/190)	
Subject refuses to answer	0% (0/160)	0% (0/190)	
Multi-racial / other	1.3% (2/160)	0.5% (1/190)	

Figure 22. Subject Demographics

There were several differences in baseline medical risk factors between the Valiant Test Group and Talent Control Group. Significant differences were found in a history of abdominal aortic aneurysm (AAA), prior AAA repair, carotid artery disease, angina, percutaneous coronary intervention, and hyperlipidemia. Additionally, the history of ascending thoracic aneurysms and the use of an abdominal aortic conduit for vascular access, both of which were exclusion criteria in the Talent Control Group, likely added to an increase in baseline risk factors for the Valiant Test Group.

Medical History	VALIANT TEST GROUP % (m/n) (N = 160)	TALENT CONTROL GROUP % (m/n) (N = 195)	p-value
Cardiovascular			
Abdominal aortic aneurysm (AAA)	38.8% (62/160)	19% (37/195)	<0.001
Previous AAA repair	20.6% (33/160)	2.1% (4/195)	<0.001
Ascending thoracic aneurysm ¹	8.1% (13/160)		
Angina	9.4% (15/160)	14.4% (28/195)	0.094
Arrhythmia	31.3% (50/160)	26.7% (52/195)	0.602
Carotid artery disease	28.1% (45/160)	5.6% (11/195)	<0.001
Congestive heart failure	11.9% (19/160)	8.7% (17/195)	0.546
Coronary artery disease	44.4% (71/160)	40.5% (79/195)	0.928
Coronary artery bypass grafting	13.8% (22/160)	10.3% (20/195)	0.466
Hypertension	93.8% (150/160)	87.2% (170/195)	0.186
Myocardial infarction	21.3% (34/160)	13.8% (27/195)	0.117
Percutaneous coronary intervention	16.9% (27/160)	5.6% (11/195)	0.002
Peripheral vascular disease	25% (40/160)	16.4% (32/195)	0.091
Pulmonary			
Chronic obstructive pulmonary disorder	35% (56/160)	36.9% (72/195)	0.426
Renal			
Renal insufficiency	16.3% (26/160)	17.4% (34/195)	0.479
Cerebrovascular / Neurological			
Transient ischemic attack	11.3% (18/160)	7.7% (15/195)	0.471
Cerebral vascular accident	10.6% (17/160)	9.7% (19/195)	0.958
Paraplegia	0% (0/160)	1% (2/195)	0.388
Paraparesis	0.6% (1/160)	0.5% (1/195)	0.984
Other Abnormal Body Systems			
Bleeding disorder	2.5% (4/160)	2.6% (5/195)	0.994
Diabetes	21.3% (34/160)	15.9% (31/195)	0.426
Gastrointestinal complications	40.6% (65/160)	53.8% (105/195)	0.006
Hyperlipidemia	73.8% (118/160)	43.6% (85/195)	<0.001
Tobacco use in last ten years ²	44.4% (71/160)	50.3% (98/195)	0.333

¹Data point was not collected in Talent Control Group.

²For Talent Control Group, subjects who answered 'Yes' to 'Tobacco Use' and whose resolution date was more than 10 years prior to implant were considered as 'No' to the question of 'Tobacco Use in the last 10 years'.

Figure 23. Baseline Medical History

Etiology	VALIANT TEST GROUP % (m/n) (N = 160)	TALENT CONTROL GROUP % (m/n) (N = 195)
Thoracic Aortic Aneurysm (Fusiform)	64.4% (103/160)	57.4% (112/195)
Thoracic Aortic Aneurysm (Saccular/Penetrating ulcer)	35.6% (57/160)	35.9% (70/195)
Both	0% (0/160)	6.7% (13/195)

Figure 24. Anatomic Lesion Type

More subjects in the Valiant Test Group had higher SVS scores as compared to Talent Control Group subjects.

SVS/AAVS Score ¹	VALIANT TEST GROUP	TALENT CONTROL GROUP	p-value ²
	% (m/n) (N = 160)	% (m/n) (N = 195)	
0	0.6% (1/160)	4.1% (8/195)	0.002
1	10.6% (17/160)	21% (41/195)	
2	87.5% (140/160)	72.8% (142/195)	
3	1.3% (2/160)	2.1% (4/195)	

¹ Modified SVS/AAVS Medical Comorbidity Grading System modified for age, hypertension, cardiac, pulmonary, and renal.

² p-value is calculated using one-way ANOVA with SVS score being the dependent variable.

Figure 25. Baseline Modified SVS/AAVS Classification

6.2.4. Baseline Aneurysm Data

Figure 26 and Figure 27 provide the baseline aneurysm and anatomical measurements of the Valiant Test Group and the Talent Control Group study populations.

Baseline Vessel Dimension	VALIANT TEST GROUP (N = 160)	TALENT CONTROL GROUP (N = 195)	P-value ¹
Proximal Neck Diameter (mm)			
n ²	157	187	
Mean ± SD	32.47±5.17	31.20±4.93	0.074
Median	32	31.50	
Min, Max	21, 51.5	18.5, 43.5	
Max Aneurysm Diameter (mm)			
n ²	160	187	
Mean ± SD	57±11.03	55.51±11.60	0.363
Median	56.1	56	
Min, Max	31.4, 97.7	26.2, 88.8	
Distal Neck Diameter (mm)			
n ²	157	184	
Mean ± SD	31.23±5.78	29.72±5	0.050
Median	30.5	29.5	
Min, Max	19, 51	17, 42.5	
Proximal Centerline Neck Length (mm)			
n ²	157	187	
Mean ± SD	83.03±51.05	80.02±52.09	0.882
Median	80	77.9	
Min, Max	14, 246.5	10, 234	
Aneurysm Length (mm)			
n ²	154	180	
Mean ± SD	123.25±73.02	121.38±72.69	0.861
Median	108.55	107.65	
Min, Max	17, 316.0	8, 297.5	
Distal Neck Length (mm)			
n ²	158	184	
Mean ± SD	90.62±58.52	90±62.9	0.711
Median	79.05	73.5	
Min, Max	0, 285	9, 255	
Right External Iliac Minimum Diameter (mm)			
n ²	120	122	
Mean ± SD	7.07±1.96	6.49±1.53	0.011
Median	7	6.5	
Min, Max	3.5, 13.5	2.9, 11	
Left External Iliac Minimum Diameter (mm)			
n ²	120	124	
Mean ± SD	7.04±1.93	6.59±1.55	0.046
Median	7	6.5	
Min, Max	3.5, 13	3.3, 10.9	

¹ Each variable will be assessed for balance between the treatment groups. This assessment is also adjusted for SVS score of (0, 1) versus (2, 3).

² n = number of known values.

Figure 26. Baseline Vessel Dimensions - Core Laboratory Reported

Diameter (mm)	VALIANT TEST GROUP		TALENT CONTROL GROUP	
		% (m/n) ¹		% (m/n) ¹
10-17		0% (0/160)		0% (0/187)
18-29		0% (0/160)		0.5% (1/187)
30-39		4.4% (7/160)		7.5% (14/187)
40-49		15.6% (25/160)		20.3% (38/187)
50-59		45% (72/160)		34.8% (65/187)
60-69		24.4% (39/160)		24.6% (46/187)
70-79		7.5% (12/160)		10.2% (19/187)
80-89		1.3% (2/160)		2.1% (4/187)
90-99		1.9% (3/160)		0% (0/187)
100-109		0% (0/160)		0% (0/187)
110-119		0% (0/160)		0% (0/187)
120+		0% (0/160)		0% (0/187)
Aneurysm diameter <50 mm (%m/n)		20% (32/160)		28.3% (53/187)
Aneurysm diameter >50 mm (% m/n)		80% (128/160)		71.7% (134/187)

¹m = numbers in category, n = number of known values.

Figure 27. Baseline Maximum Aneurysm Diameters – Core Laboratory Reported

6.2.5. Devices Implanted

A total of 288 stent grafts and an average of 1.8 stent grafts per subject were implanted in the Valiant Test Group. Figure 28 to Figure 30 provide a breakdown of the number of devices implanted in both the Valiant Test Group and the Talent Control Group.

Number of Devices Implanted	VALIANT TEST GROUP		TALENT CONTROL GROUP	
		% (m/n) ¹ N = 160		% (m/n) ¹ N = 195
0 ²		1.9% (3/160)		0.5% (1/195)
1		38.8% (62/160)		19.5% (38/195)
2		40% (64/160)		28.7% (56/195)
3		16.3% (26/160)		24.6% (48/195)
4		3.1% (5/160)		17.4% (34/195)
5		0% (0/160)		7.2% (14/195)
6		0% (0/160)		1.5% (3/195)
7+		0% (0/160)		0.5% (1/195)

¹N is the number of enrolled subjects.

²Three enrolled subjects did not receive a stent graft due to a failure to achieve access.

Figure 28. Number of Devices Implanted

Sizes of Devices Implanted

Proximal Diameter	Number of Devices	
		% (m/n) ¹
24		0.3% (1/288)
26		0.7% (2/288)
28		1.4% (4/288)
30		2.1% (6/288)
32		11.5% (33/288)
34		8.3% (24/288)
36		13.9% (40/288)
38		12.2% (35/288)
40		16.7% (48/288)
42		9% (26/288)
44		11.5% (33/288)
46		12.5% (36/288)

¹m is the number of devices of that proximal diameter implanted and n is the total number of devices implanted.

Figure 29. Devices Implanted by Proximal Diameter

Figure 30 tabulates the various configurations of the Valiant Thoracic Stent Grafts implanted per subject for the Valiant Test Group. One subject was implanted with a distal device in the proximal position which was a deviation from the protocol.

Device Configuration	% (m/n) ¹
Proximal FreeFlo Straight	99.4% (156/157) ²
Distal Closed Web Straight	29.3% (46/157)
Distal Closed Web Taper	24.2% (38/157)
Distal Bare Spring Straight	5.1% (8/157)

¹m = numbers in subjects who are implanted with the corresponding device, n = total number of implanted subjects.

²One subject was implanted with a Closed Web device in the proximal position due to an adjustment in size made at the time of procedure.

Figure 30. Type of Devices Implanted - Valiant Test Group only

6.2.6. Acute Procedural Data

Implant procedure data are presented in Figure 31.

Procedure Details	% (m/n) ¹
Left Subclavian Artery (LSA) Revascularization Pre-Implant or at Initial Procedure	13.8% (22/160)
Left subclavian transposition	1.3% (2/160)
Carotid to subclavian bypass	12.5% (20/160)
Arterial Access²	
Abdominal aortic conduit	1.9% (3/160)
Iliac conduit	13.1% (21/160)
Femoral/Iliac artery	85.6% (137/160)
Anesthesia²	
General	88.1% (141/160)
Epidural	0% (0/160)
Spinal	8.1% (13/160)
Local	5.6% (9/160)
Spinal Protection	
Spinal CSF drainage	53.8% (86/160)
Implantation Zone of Proximal Component	
Zone 0	0% (0/157)
Zone 1	0% (0/157)
Zone 2	31.2% (53/157)
Zone 3	46.5% (73/157)
Zone 4	22.3% (35/157)
LSA Coverage	
Complete	27.4% (43/157)
Partial	5.1% (8/157)
None	67.5% (106/157)

¹m = numbers in category, n = number of known values.
²Not mutually exclusive.

Figure 31. Acute Procedural Details : Valiant Test Group

6.2.7. Clinical Utility Data

Figure 32 presents the clinical utility measures in the Valiant Test Group and the Talent Control Group.

Parameter	VALIANT TEST GROUP N	VALIANT TEST GROUP	TALENT CONTROL GROUP N	TALENT CONTROL GROUP
Subjects requiring transfusion % ¹ (m/n)	160	10% (16/160)	194	22.7% (44/194)
Blood loss during procedure (cc) Mean±SD	153	277±468.8	189	371.2±514.4
Duration of procedure (min) Mean±SD	160	119.7±54.8	194	154.2±76
Time in ICU (hours) Mean±SD	160	66.5±112.3	193	46.8±114.3
Overall hospital stay (days) Mean±SD	160	8.1±8.9	195	6.4±11.5

¹m = numbers in category, n = number of known values.

Figure 32. Clinical Utility Data

6.2.8. Primary Safety Endpoint

The rate of all-cause mortality within 12 months in the Valiant Test Group was 12.6% (19/151) which compared to 16.1% (31/192) observed in the Talent Control Group. As shown in Figure 33, the upper endpoint of 1.18 of the adjusted odds ratio between the groups was below a predetermined noninferiority margin of 2.25, thereby demonstrating the primary safety

objective. All enrolled subjects were included in the analysis, including 3 subjects who were not implanted due to a failure to achieve vessel access (intent-to-treat, or ITT). A subject was considered officially enrolled when an access site incision was made. This group of subjects is referred to as the intent-to-treat (ITT) population. Five of 19 deaths occurred within 30 days. All 5 deaths were adjudicated as aneurysm-related by the CEC and per the Valiant Test Group clinical study protocol. There were no aneurysm-related deaths after 30 days and within 365 days.

Primary Safety Endpoint: All-Cause Mortality at 12-Months	% (m/n) ¹ (upper endpoint of 1-sided 95% CI)	Odds Ratio (upper endpoint of 1-sided 95% CI) ²	p-value for nonhomogeneity
Valiant Test Group	12.6% (19/151) (17.9%)	0.70 (1.18)	0.719
Talent Control Group	16.1% (31/192) (21.2%)		

¹ The numerator m is the number of ITT subjects who died within 365 days; the denominator n is the number of ITT subjects followed through at least 337 days. A subject was considered enrolled when an access site incision was made.
² The noninferiority test was performed using the Cochran-Mantel-Haenszel (CMH) test to adjust for SVS scores of (0, 1) versus (2, 3). The required assumption of homogeneity among the odds ratios defined by the SVS score strata was statistically tested using the Breslow-Day test.

Figure 33. Primary Safety Endpoint: VALOR II

A Kaplan-Meier analysis of freedom from all-cause mortality was performed and plotted in Figure 34.

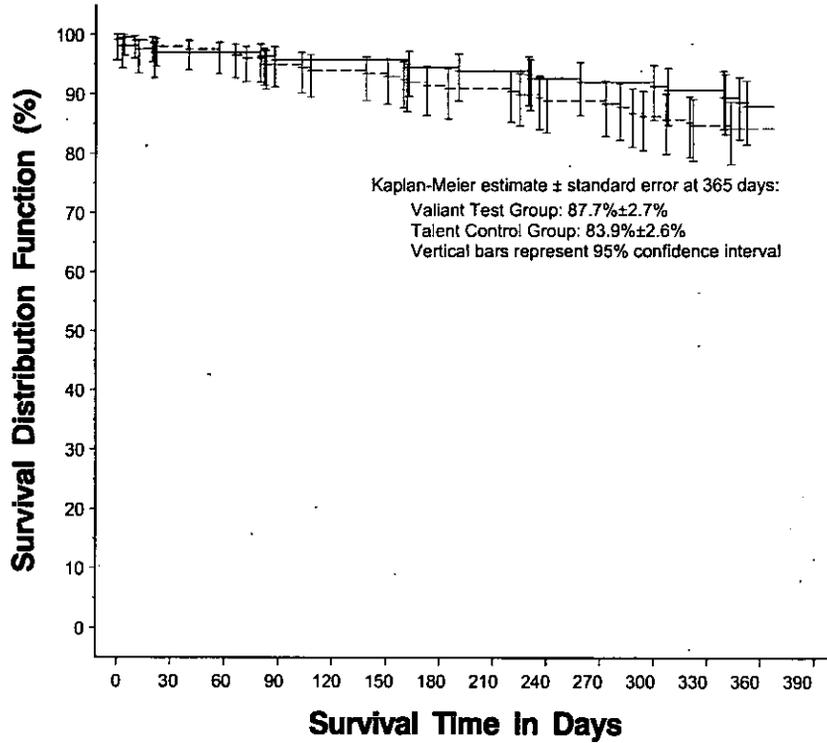


Figure 34. Kaplan-Meier Curve of Freedom from All-Cause Mortality within 12 Months

Days	Valiant Test Group			Talent Control Group		
	0 to 30	31 to 183	184 to 365	0 to 30	31 to 183	184 to 365
No. at Risk ¹	160	155	150	195	190	176
No. of Events	5	4	10	4	13	14
No. Censored ²	0	1	22	1	1	1
Kaplan-Meier Estimate ³	96.9%	94.4%	87.7%	97.9%	91.2%	83.9%
(2-sided 95% CI) ³	(92.7%, 98.7%)	(89.5%, 97%)	(81.3%, 92%)	(94.6%, 99.2%)	(86.3%, 94.5%)	(78%, 88.4%)
Standard Error ³	1.4%	1.8%	2.7%	1%	2%	2.6%

¹ Number of subjects at risk at the beginning of an interval.

² Subjects are censored because the last follow-up has not reached the end of the time interval. Censored subjects will include those who withdraw or are lost to follow-up.

³ Kaplan-Meier Estimate and Standard Error, and 95% CI were calculated at the end of a time interval.

Figure 35. Kaplan-Meier Estimates of Freedom from All-Cause Mortality within 12 Months

6.2.9. Secondary Safety Endpoints

A summary of secondary safety endpoints is presented in Figure 36.

Secondary Endpoints	Valiant Test Group(m/n)	Talent Test Group(m/n)
Within 30 days:		
Perioperative mortality ¹	3.1% (5/160)	2.1% (4/195)
Paraplegia ¹	0.6% (1/160)	1.5% (3/195)
Paraparesis ¹	1.9% (3/160)	7.2% (14/195)
One or more Major Adverse Events (MAE) ¹	38.1% (61/160)	41% (80/195)
Within 12 months:		
Aneurysm-related mortality ¹	3.3% (5/151)	3.1% (6/192)
Aneurysm rupture ¹	0% (0/154)	0.5% (1/192)
Conversion to open surgical repair ²	0% (0/154)	0.5% (1/192)
One or more Major Adverse Events (MAE) ¹	48.7% (75/154)	53.6% (103/192)
¹ CEC reported		
² Site reported		

Figure 36. Summary of Secondary Safety Endpoints

Perioperative Mortality

Five deaths occurred within 30 days in the VALOR II clinical study (3.1%). One subject died due to an aortic rupture at the time of procedure. The rupture occurred during advancement of the stent graft system in a subject with severe tortuosity of the thoracic aorta. One subject died following an acute dissection of the ascending aorta 3 days post procedure. An autopsy revealed a dissection extending from a point 1 to 2 cm proximal to the stent graft to the heart. Three other subjects expired due to pneumonia, respiratory failure, and multisystem organ failure.

Paraplegia and Paraparesis within 30 Days

One subject (1/160, 0.6%) experienced paraplegia 1 day following implant. The subject continues to be active in the trial albeit with permanent adverse sequelae. Three subjects (3/160, 1.9%) experienced paraparesis within 30 days of implant. Two of the 3 subjects continue to be active in the study, one with ongoing paraparesis and the other with paraparesis resolved 5 days post surgery. The third subject died 21 days post-procedure due to respiratory failure and had continuing paraparesis at time of death.

Aneurysm-Related Mortality

Five deaths within 365 days in the Valiant Test Group were adjudicated by the CEC to be aneurysm-related (5/151, 3.3%). Each death occurred within the first 30 days and was therefore classified as aneurysm related per protocol. A Kaplan-Meier analysis revealed freedom from ARM within 365 days was 96.9% with a standard error of 1.4%. This analysis is presented in Figure 37.

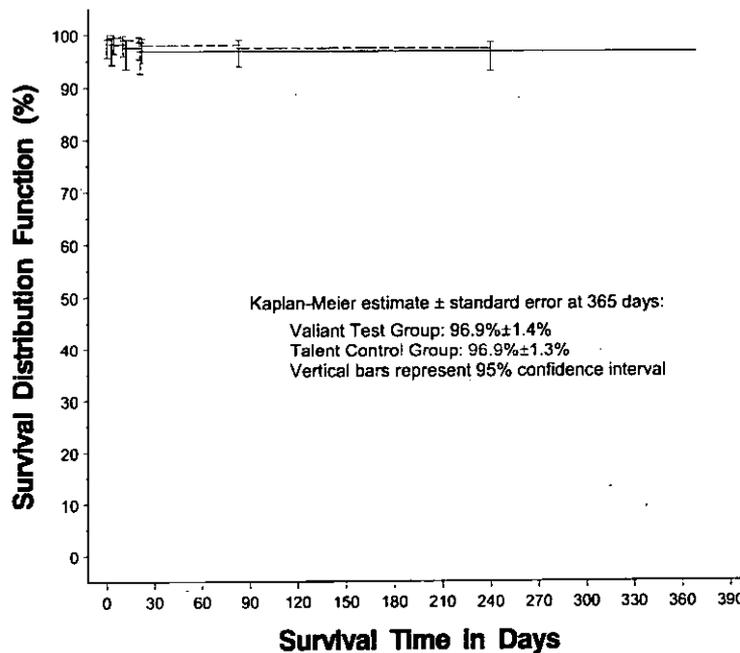


Figure 37. Kaplan-Meier Curve of Freedom from Aneurysm-Related Mortality within 12 Months: VALOR II

Days	Valiant Test Group			Talent Control Group		
	0 to 30	31 to 183	184 to 365	0 to 30	31 to 183	184 to 365
No. at Risk ¹	160	155	150	195	190	176
No. of Events	5	0	0	4	1	1
No. Censored ²	0	5	32	1	13	14
Kaplan-Meier Estimate ³ (2-sided 95% CI) ³	96.9% (92.7%, 98.7%)	96.9% (92.7%, 98.7%)	96.9% (92.7%, 98.7%)	97.9% (94.6%, 99.2%)	97.4% (93.9%, 98.9%)	96.8% (93.1%, 98.6%)
Standard Error ³	1.4%	1.4%	1.4%	1%	1.1%	1.3%

¹ Number of subjects at risk at the beginning of an interval.

² Subjects are censored because the last follow-up has not reached the end of the time interval. Censored subjects will include those who withdraw, are lost to follow-up, or die from causes adjudicated to be unrelated to the aneurysm.

³ Kaplan-Meier Estimate and Standard Error and 95% CI were calculated at the end of a time interval.

Figure 38. Kaplan-Meier Estimates of Freedom from Aneurysm-Related Mortality within 12 Months

Aneurysm Rupture and Conversion to Surgery

No subject experienced aneurysm rupture or conversion to open surgical repair within 12 months.

Major Adverse Events

Adverse events in the Valiant Test Group and the Talent Control Group were categorized by severity as Major Adverse Events (MAEs). MAEs were defined as the occurrence of any of the following:

- Death:
 - due to complications of the procedure, including bleeding, vascular repair, transfusion reaction, or conversion to open surgical TAA repair
 - within the relevant period (30 days or 12 months) of the baseline implant or surgical procedure
- Respiratory complications (atelectasis/pneumonia, pulmonary embolism, pulmonary edema, respiratory failure)
- Renal complications (renal failure, renal insufficiency)
- Cardiac: MI, unstable angina, new arrhythmia, exacerbation of congestive heart failure (CHF)
- Neurological: new CVA/embolic events, paraplegia/paraparesis
- Gastrointestinal: bowel ischemia
- Major bleeding complication
- Vascular complications

Figure 39 below presents a summary of the CEC reported MAEs through 12 months.

Category	0-30 days % (m/n) ¹		0-365 days % (m/n) ²	
	VALIANT TEST GROUP	TALENT CONTROL GROUP	VALIANT TEST GROUP	TALENT CONTROL GROUP
Mortality	3.1% (5/160)	2.1% (4/195)	12.6% (19/151)	16.1% (31/192)
Respiratory Complications	9.4% (15/160)	13.3% (26/195)	14.9% (23/154)	24% (46/192)
Renal Complications	5% (8/160)	6.2% (12/195)	8.4% (13/154)	10.4% (20/192)
Cardiac Complications	15% (24/160)	12.3% (24/195)	20.1% (31/154)	21.9% (42/192)
Neurological Complications	5% (8/160)	11.8% (23/195)	10.4% (16/154)	16.1% (31/192)
Gastrointestinal Complications	1.3% (2/160)	1% (2/195)	2.6% (4/154)	1.6% (3/192)
Major Bleeding Complications	6.9% (11/160)	15.4% (30/195)	7.8% (12/154)	16.7% (32/192)
Vascular Complications	20.6% (33/160)	21% (41/195)	24% (37/154)	24.5% (47/192)
Any MAE	38.1% (61/160)	41% (80/195)	48.7% (75/154)	53.6% (103/192)

¹ m is the number of subjects experiencing a certain event within 30 days, n is the number of ITT subjects.

² m is the number of subjects experiencing a certain event at the interval of 0-365 days, n is the number of subjects who either experienced at least 1 MAE or secondary procedure in the interval or are followed for at least 337 days.

Figure 39. Summary of MAEs within 12 Months - CEC Reported

6.2.10. Primary Effectiveness Endpoint

Successful Aneurysm Treatment at 12 months was 97.4%. Successful Aneurysm Treatment was a composite endpoint that included the absence of: a) aneurysm growth of more than 5 mm at the 12-month visit relative to the 1-month visit; and b) secondary procedure due to type I or III endoleak performed or recommended at or before the 12-month visit.

Primary Effectiveness Endpoint	Within Expanded Analysis Window % (m/n) ¹ (lower endpoint of 1-sided 95% CI)
Successful Aneurysm Treatment at 12 months	97.4% (112/115) (93.4%)

¹ m is the number of subjects confirmed with successful aneurysm treatment; n is the total implanted subjects.

Figure 40. Summary of Primary Effectiveness Endpoint : Valiant Test Group only

There were three subjects considered treatment failures in the Valiant Test Group. Two subjects were found to have aneurysm growth of more than 5 mm and had secondary procedures after 365 days (Figure 41). One subject had a distal type Ib endoleak for which a secondary procedure was recommended at the 12-month visit and subsequently performed after 15 days.

Change in maximum aneurysm diameter from one month ¹	VALIANT TEST GROUP % (m/n)	TALENT CONTROL GROUP % (m/n)
Increase more than 5 mm ²	1.7% (2/115)	8.5% (11/129)
Stable (within ±5 mm)	71.3% (82/115)	67.4% (87/129)
Decrease more than 5 mm	27% (31/115)	24% (31/129)

¹ Eligible subjects required CT/MR 1-month and 12-month images depicting location at the proximal and distal end of the stent graft.
² One subject had type II endoleak, had two additional endovascular procedures after 365 days, and was alive at the 24-month visit. The other subject had no endoleak per core laboratory at 12 months; a secondary endovascular procedure was performed to reline the graft when the investigational site reported continued aneurysm growth without radiographic evidence of endoleak at the 24-month visit.

Figure 41. Change in maximum aneurysm diameter from one month

Secondary Effectiveness Endpoints

A summary of secondary effectiveness endpoints is presented in Figure 42. In addition to these secondary endpoints, an evaluation of stent graft integrity was also performed. No subject had loss of stent graft integrity within 12 months.

Secondary Endpoints	VALIANT TEST GROUP % (m/n)	TALENT CONTROL GROUP % (m/n)
Successful deployment and delivery of the stent graft at implant ^{1,9}	96.3% (154/160)	99.5% (194/195)
Within 30 days:		
Secondary procedure due to endoleak after discharge ¹	0.6% (1/157)	0% (0/194)
Within 12 months:		
Endoleak at 12 months ^{2,3}	13% (13/100)	12.2% (15/123)
Type I	3% (3/100) ⁴	4.9% (6/123)
Type II	7% (7/100) ⁵	4.9% (6/123)
Type III	1% (1/100) ⁶	0% (0/123)
Type IV	0% (0/100)	0% (0/123)
Type V / unknown	2% (2/100) ⁷	2.4% (3/123)
Secondary endovascular procedure due to endoleak after 30 days and within 365 days ¹	0% (0/143)	6.5% (12/186)
Migration of the stent graft at 12 months relative to 1 month ^{2,3}	2.9% (3/105)	3.9% (4/103)
Proximal stent graft migration >10 mm proximally	0% (0/105)	0% (0/103)
Proximal stent graft migration >10 mm distally	0% (0/105)	1.9% (2/103)
Distal stent graft migration >10 mm proximally	2.8% (3/105) ⁸	1.9% (2/103)
Distal stent graft migration >10 mm distally	0% (0/105)	0% (0/103)
Loss of patency of the stent graft ^{2,3}	0% (0/100)	0% (0/107)

¹ Site reported.
² Core laboratory reported.
³ The follow-up windows for these endpoints are similar.
⁴ Three subjects had distal type Ib endoleak; 1 subject had a secondary procedure after 365 days, a second subject withdrew consent at day 609 post index procedure, and a third subject had no additional clinical sequelae related to endoleak. Of the 2 active subjects, both were alive at the most recent follow-up visit.
⁵ One subject had 2 additional endovascular procedures and was alive at the 24-month visit; 1 subject died of lung cancer at day 593 post index procedure; 1 subject died in a motor vehicle accident at day 679 post index procedure. The other 4 subjects had no clinical sequelae related to endoleak and were alive at the most recent study visit.
⁶ One subject had type III endoleak reported by the core laboratory at the 12-month interval. No endoleak was reported by the investigational site through the 24-month visit and the subject had no clinical sequelae related to endoleak. There was no separation of stent graft components. No loss of stent graft integrity was reported by core laboratory, though the 6- and 12-month x-ray images could not be evaluated for stent graft integrity. There was no site-reported loss of stent graft integrity through the 24-month visit.
⁷ One subject had endoleak of unknown type resolved at the 24-month visit following reduction of antiplatelet therapy; endoleak of unknown type again noted at the 36-month visit. Another subject had no clinical sequelae related to endoleak of unknown type.
⁸ None of these 3 subjects had clinical sequelae related to stent graft migration. Two of the 3 subjects had limited or no remaining stent graft coverage of the distal nonaneurysmal neck.
⁹ Defined as attaining vessel access, to insert the delivery catheter and deployment of the graft to the intended treatment site. If the thoracic treatment site cannot be accessed with the delivery catheter, it is considered a technical failure. Six subjects had unsuccessful deployment or delivery. Three of these six subjects did not receive a Valiant device due to access failure. Two other subjects had misaligned deployment, and one subject had an aortic rupture.

Figure 42. Summary of Secondary Endpoints

6.3. Valiant Captivia OUS Registry

The Valiant Captivia OUS Registry began when the Valiant Thoracic Stent Graft with the Captivia Delivery System received CE mark in September 2009. The objective of this ongoing registry is to gather pertinent post-approval clinical data to assess the Valiant Thoracic Stent Graft with the Captivia Delivery System ("Valiant Captivia") in the treatment of diseases of the descending thoracic aorta in both surgical and non-surgical candidates. Subjects diagnosed with a variety of thoracic aortic diseases were considered candidates for the registry. Subjects who enrolled in the study will be followed for up to 3 years post-implantation. A 30-day interim analysis was conducted on 50 subjects to assess acute performance of the Captivia Delivery System.

6.3.1. Study Population and Subject Accountability

These 50 subjects, hereafter referred to as the Registry Study Group, were enrolled in Europe and Turkey to participate in the Valiant Captivia OUS Registry. Only the 30-day analysis for the Registry Study Group was included. Of the 50 subjects who underwent repair using the Valiant Thoracic Stent Graft with the Captivia Delivery System, 25 (50%) were indicated for thoracic aortic aneurysm (TAA), 20 (40%) were indicated for Type B aortic dissection, and 8 (16%) were classified as "Other". Three of the subjects who are included in the "Other" category also had a concurrent thoracic aortic aneurysm or Type B aortic dissection, and are therefore included in more than 1 category. Since the acute deliverability of the delivery system is less dependent upon the type of aortic etiology, subjects with dissection and other etiologies were also considered relevant to the assessment.

Three subjects died and 1 subject was converted to open surgical repair within 30 days. No subjects were lost to follow-up or withdrew consent. Thirty-four of the 45 eligible subjects had a follow-up visit at 30 days post-implant. All of the remaining 11 eligible subjects were alive and underwent clinical evaluations at subsequent follow-up visits.

6.3.2. Successful Delivery and Deployment

Delivery and deployment of Valiant Captivia was evaluated at 30-days for the Valiant Captivia OUS Registry. Successful delivery and deployment was defined as deployment of the Valiant Thoracic Stent Graft in the planned location with no unintentional coverage of the left subclavian artery, left common carotid artery or brachiocephalic artery, and with the removal of the delivery system.

Successful delivery and deployment was achieved in all 50 enrolled subjects in the Registry Study Group, yielding a rate of 100% (95% CI 92.9%-100%).

	% (m/n) [95% CI]
Successful delivery and deployment at implant	100% (50/50) [92.9%-100%]

Figure 43. Successful Delivery and Deployment: Valiant Captivia OUS Registry

6.3.3. Secondary Study Endpoints

Secondary study endpoints evaluated in the 30-day analysis included both procedural complications and clinical outcomes. A summary of secondary endpoints is presented in Figure 44.

Three subjects died within 30 days of the index procedure. The CEC adjudicated 2 of the 3 deaths as due to causes other than cardiac or neurological. The first subject was treated for a symptomatic TAA and died from multi-organ failure. The second subject was treated for a TAA and subsequently died from a ruptured AAA. This subject, who had risk factors for neurologic complications, also experienced paraplegia that resolved 2 days later after placement of a lumbar drain. A third death occurred in a subject with a history of Marfan's syndrome and previous thoracic aortic dissection. The death was adjudicated as being related to the lesion in an acute complicated type B dissection.

One subject required a conversion to open surgery following aneurysm rupture at the index procedure. The subject became unstable after the first stent graft was successfully delivered and deployed. The subject underwent a thoracotomy and a second stent graft was placed, successfully sealing off the rupture site. The subject was alive at 30 days.

Two subjects, including the subject with Marfan's syndrome noted above, experienced aortic dissection within 30 days of the index procedure. Both events occurred in subjects treated for Type B aortic dissection.

Secondary Endpoints ¹	% (m/n)
Misaligned Deployment at Index Procedure (Site reported)	0% (0/50)
Aortic Perforation at Index Procedure	0% (0/50)
Death	
Mortality Within 30 Days	6% (3/50)
Paraplegia/Paraparesis	
Paraplegia Within 30 Days post-implantation	2% (1/50)
Paraparesis Within 30 Days post-implantation	0% (0/50)
Secondary Endovascular Procedure due to Endoleak within 30 days post-implantation	0% (0/50)
One or more Major Adverse Events (MAE)	
Any MAEs within 30 days post-implantation	24% (12/50)
One or more Serious Major Adverse Events ²	
Any Serious MAEs within 30 days post-implantation	22% (11/50)

¹ Death and rupture were adjudicated by CEC; all other categories were reported by the investigational sites.

² A serious MAE is defined as a MAE that was identified as a Serious Adverse Event (SAE) by the Investigator.

Figure 44. Secondary Endpoints: Valiant Captivia OUS Registry

6.4. Talent Captivia Study

In another study of the Captivia Delivery System, 10 subjects were enrolled in a modified open arm of the US IDE evaluation of the Talent Thoracic Stent Graft System in the treatment of patients with thoracic aortic disease. Disease etiologies included fusiform aneurysms and saccular aneurysms/penetrating ulcers of the descending thoracic aorta. A 30-day analysis was conducted on 10 subjects to assess the acute performance of the Captivia Delivery System. The data collected from this evaluation was considered relevant because the delivery systems for use with Talent and Valiant stent grafts are essentially identical in design and possess the same principles of operations.

6.4.1. Study Population and Subject Accountability

These 10 subjects with descending aortic aneurysms were enrolled at 4 sites in the United States to participate in the Talent Captivia Study. Of the 10 enrolled subjects, 1 subject died and another failed to receive a stent graft. No subject was lost to follow-up or withdrew consent.

6.4.2. Successful Delivery and Deployment

Delivery and deployment of the Talent Thoracic Stent Graft with the Captivia Delivery System was assessed. Implantation of the device was successful in 9 of 10 enrolled subjects, yielding a rate of 90% (95% CI 55.5%-99.7%). Successful delivery and deployment was defined as attaining vessel access to insert the delivery catheter and deployment of the graft to the intended treatment site. One enrolled subject did not receive a Talent Thoracic Stent Graft, as the Captivia Delivery System could not reach the targeted lesion due to severe angulation of the thoracic aortic arch. This subject was converted to an open surgical repair.

6.4.3. Secondary Study Endpoints

Secondary study endpoints evaluated in the 30-day analysis included both procedural complications and clinical outcomes. A summary of the results are provided in Figure 45.

One subject died within 30 days of the index procedure and was considered an aneurysm related death. The CEC adjudicated the death as due to cardiac causes. This subject and 1 other experienced paraplegia within 30 days. Both subjects who experienced paraplegia had significant risk factors for spinal cord ischemia.

Secondary Endpoints	% (m/n)
Misaligned Deployment at Index Procedure ²	0% (0/9)
Aortic Perforation at Index Procedure ²	0% (0/9)
Death	
Mortality within 30 Days ¹	10% (1/10)
Paraplegia/Paraparesis	
Paraplegia within 30 Days ¹	20% (2/10)
Paraparesis within 30 Days ¹	0% (0/10)
Secondary Endovascular Procedure due to Endoleak within 30 days post-implantation ²	0% (0/10)
One or more Major Adverse Events (MAE) within 30 days post-implantation ¹	40% (4/10)
One or more Serious Major Adverse Events (MAE) within 30 days post-implantation ¹	40% (4/10)

¹CEC reported

²Site reported

Figure 45. Secondary Endpoints: Talent Captivia Study

7. Patient Selection and Treatment

7.1. Individualization of Treatment

Each Valiant Stent Graft with the Captivia Delivery System must be ordered in a size appropriate to fit the patient's anatomy. Proper sizing of the device is the responsibility of the physician. The stent graft should be oversized no more than 3 to 5 mm. Refer to Recommended Device Sizing (Section 10.2).

Caution: Vessel damage such as dissection, perforation, or rupture may be caused by excessive oversizing of the stent graft in relation to the diameter of the blood vessel. Oversizing of the stent graft to the vessel more than the recommended device sizing as shown in Recommended Device Sizing (Section 10.2), may be unsafe, especially in the presence of dissecting tissue or intramural hematoma. Excess or insufficient oversizing may also result in Type 1 endoleak. Also, due to the nature of the design and the flexibility of the Valiant System, the overall length of each stent graft component may be shorter when deployed.

If preoperative case planning measurements are not certain, an inventory of system lengths and diameters necessary to complete the procedure should be available to the physician. This approach allows for greater intraoperative flexibility to achieve optimal procedural outcomes. Use of the device outside the recommended anatomical sizing may result in serious device related events.

Physicians may consult with a Medtronic representative to determine proper stent graft component dimensions based on the physician's assessment of the patient's anatomical measurements. The benefits and risks previously described should be carefully considered for each patient before using the Valiant System.

Patient selection factors to be assessed should include, but are not limited to:

- patient age and life expectancy
- comorbidities (eg, cardiac, pulmonary, or renal insufficiency prior to surgery, morbid obesity)
- patient's suitability for open surgical repair
- patient's anatomical suitability for endovascular repair
- the risk of lesion rupture compared to the risks of endovascular repair
- ability to tolerate general, regional, or local anesthesia
- iliac or femoral access vessel morphology, such as thrombus, calcium formation, or tortuosity, that is compatible with vascular access techniques, devices, or accessories
- nonaneurysmal aortic diameter in the range of 18 to 42 mm (TAA) or 18 to 44 mm (BTAI)
- nonaneurysmal aortic proximal and distal neck lengths ≥ 20 mm
- the final treatment decision is at the discretion of the physician and patient

8. Patient Counseling Information

The physician should review the following risks and benefits when counseling the patient about this endovascular device and procedure:

- Differences between endovascular repair and open surgical repair
 - Risks related to open surgical repair
 - Risks related to endovascular repair
- Pros and cons of open surgical repair and endovascular repair
- Endovascular repair is an option with potential advantages related to its minimally invasive approach
- It is possible that subsequent endovascular or open surgical repair of the aneurysm may be required
- The long-term effectiveness of endovascular repair has not been established
- Regular follow-up, including imaging of the device, should be performed at least every 6 to 12 months, or more frequently in subjects with enhanced surveillance needs. For more information, see Follow-up Imaging Recommendations (Section 13).
- Details contained in the patient information booklet regarding possible complication after implantation of the device, such as cardiac or neurological complications.
- Symptoms of aneurysm rupture.

Medtronic recommends that the physician disclose to the patient, in written form, all risks associated with treatment using the Valiant Stent Graft System. The list of potential risks occurring during and after implantation of the device are provided in Adverse Events (Section 5). Medtronic also recommends that detailed patient specific risks also be discussed. Additional counseling information can be found in the Patient Information Booklet.

9. How Supplied

9.1. Sterility

Each Valiant Thoracic Stent Graft is individually contained within a Captivia Delivery System. The Captivia Delivery System is sterilized using electron beam sterilization and is supplied sterile for single use only.

- Do not reuse or attempt to resterilize.
- If the device is damaged or the integrity of the sterilization barrier has been compromised, do not use the product and contact your Medtronic Vascular representative for return information.

9.2. Contents

- One Valiant Thoracic Stent Graft with the Captivia Delivery System
- One set Device Registration Packet

9.3. Storage

Store the system at room temperature in a dark, dry place.

10. Clinical Use Information

10.1. Physician Training Requirements

All physicians should complete in-service training prior to using the Valiant Thoracic Stent Graft System.

Caution: The Valiant Thoracic Stent Graft with the Captivia Delivery System should only be used by physicians and medical personnel trained in vascular interventional techniques and the use of this device.

The following are the knowledge and skill requirements for physicians using the Valiant Stent Graft with the Captivia Delivery System:

- natural history of thoracic lesions and comorbidities associated with repair
- radiographic, fluoroscopic, and angiographic image interpretation
- angioplasty
- appropriate use of radiographic contrast material
- embolization
- endovascular stent graft placement
- femoral cutdown, arteriotomy, and repair
- live fluoroscopic and angiographic image interpretation
- nonselective and selective guidewire and catheter techniques
- snare techniques
- techniques to minimize radiation exposure
- device selection and sizing
- percutaneous access and closure techniques

10.2. Recommended Device Sizing

Medtronic recommends that the Valiant Thoracic Stent Graft with the Captivia Delivery System be used according to the sizing guidelines in Table 3 through Table 7. If preoperative case planning measurements are not certain, an inventory of system lengths and diameters necessary to complete the procedure should be available to the physician. This approach allows for greater intraoperative flexibility to achieve optimal procedural outcomes. Use of the device outside the recommended anatomical sizing may result in serious device related adverse events or clinical incident.

The specific stent graft diameter used for treatment should be oversized relative to the nondiseased vessel using the sizing guidelines to ensure appropriate radial fixation. Strict adherence to the sizing guidelines is expected when selecting the appropriate device size. Table 3 to Table 6 describe the stent graft to vessel oversizing guidelines. Appropriate oversizing has already been incorporated into the recommended sizes. Additional oversizing should not be incorporated. Sizing outside of this range can result in endoleak, fracture, migration, infolding, or graft wear.

Caution: Oversizing of the stent graft to the vessel by more than 10% may be unsafe in the presence of dissecting tissue or intramural hematoma.

Caution: Proper sizing of the Valiant Thoracic Stent Graft is the responsibility of the physician. This stent graft sizing incorporates the recommended device oversizing for anatomical dimension and was based on in-vitro test data.

When multiple stent grafts are needed to exclude the target lesion, and the component junction or overlapping connection is not supported by the aorta (ie, in the TAA sac), the diameter of the inside component should be oversized by 4 mm relative to the outside component. If it is supported by the vessel, oversizing to the supporting native vessel should be used, as described in Table 3 to Table 6. In order to provide the appropriate oversizing at a component junction that is not supported by the vessel and at the distal landing zones, Closed Web Taper configurations may need to be used.

The order of deployment when using multiple stent graft configurations may vary, depending on the diameter of the aorta proximal to and distal to the lesion. Table 2 should be followed to determine the order of deployment when using multiple stent graft configurations.

Note: If the vessel diameter and condition require variable proximal and distal diameter configurations, the smallest diameter stent graft should be placed first, either at the proximal or distal end of the lesion. The most proximal component must be a FreeFlo Straight configuration.

Caution: A FreeFlo or Bare Spring Straight end should never be placed inside the covered section of another stent graft.

Table 2. Order of Deployment When Using Multiple Stent Graft Component Sections

	Proximal Aortic Diameter = Distal Aortic Diameter	Proximal Aortic Diameter > Distal Aortic Diameter ³	Proximal Aortic Diameter < Distal Aortic Diameter
First Section Implanted (Primary Section)	Proximal Main Section implanted at proximal end of lesion	Distal Main Section (or other configuration if more appropriate) implanted at distal end of lesion	Proximal Main Section implanted at proximal end of lesion
Second Section Implanted (Additional Section)	Distal Main Section implanted with correct junction oversizing. Due to tapered configuration of distal main section, this fits a straight aorta correctly.	Proximal Main Section implanted with correct oversizing at junction with Distal Main Section. Proximal telescoping of devices fits this shape of aorta.	Distal Main Section implanted with correct oversizing at junction.
Third Section Implanted (Additional Section)	[Optional] Additional Distal Main Sections or extensions implanted with correct oversizing at junction.	[Optional] Additional Proximal Main Sections or extensions to telescope to fit greater proximal diameter better.	Distal Extension (which is not tapered) to telescope to properly fit diameter of distal landing zone

Correct sizing of the aorta and iliac or femoral vessels must be determined before implantation of the Valiant Thoracic Stent Graft System. Medtronic recommends a Computed Tomography Angiogram (CTA) be performed within 3 months of the implantation. These images should be available for review during the procedure.

³ Use this option when implanting the proximal section first to avoid oversizing beyond the recommendations in Table 3 to Table 6

10.2.1. Fusiform and Saccular Aneurysms and Penetrating Ulcers Sizing Guidelines

Table 3. FreeFlo Straight Configuration (Proximal Component) Sizing Guidelines

OD (Fr)	Proximal x Distal Diameter (mm)	Covered Length (mm)	Native Vessel Inner Diameter (mm)	Suggested Sizing for Unsupported Junction with Graft Sizes from Column 2 (mm)
22	22x22	100, 150, 200	18, 19	26
	24x24		20, 21	28
	26x26		22, 23	30
	28x28		24, 25	32
	30x30		25, 26, 27	34
	32x32		27, 28, 29	36
24	34x34		29, 30, 31	38
	36x36		31, 32	40
	38x38		33, 34	42
	40x40		35, 36	44
25	42x42		37, 38	46
	44x44		39, 40	
	46x46		41, 42	

Table 4. Closed Web Straight Configuration (Distal Component) Sizing Guidelines

OD (Fr)	Proximal x Distal Diameter (mm)	Covered Length (mm)	Native Vessel Inner Diameter (mm)	Suggested Sizing for Unsupported Junction with Graft Sizes from Column 2 (mm)
22	22x22	100, 150, 200	18, 19	26
	24x24		20, 21	28
	26x26		22, 23	30
	28x28		24, 25	32
	30x30		25, 26, 27	34
	32x32		27, 28, 29	36
24	34x34		29, 30, 31	38
	36x36		31, 32	40
	38x38		33, 34	42
	40x40		35, 36	44
25	42x42		37, 38	46
	44x44		39, 40	
	46x46		41, 42	

Table 5. Distal Bare Spring Straight Configuration (Distal Component) Sizing Guidelines

OD (Fr)	Proximal x Distal Diameter (mm)	Covered Length (mm)	Native Vessel Inner Diameter (mm)	Suggested Sizing for Unsupported Junction with Graft Sizes from Column 2 (mm)
22	22x22	100	18, 19	26
	24x24		20, 21	28
	26x26		22, 23	30
	28x28		24, 25	32
	30x30		25, 26, 27	34
	32x32		27, 28, 29	36
24	34x34		29, 30, 31	38
	36x36		31, 32	40
	38x38		33, 34	42
	40x40		35, 36	44
25	42x42		37, 38	46
	44x44		39, 40	
	46x46		41, 42	

Table 6. Closed Web Taper Configuration (Distal Component) Sizing Guidelines

OD (Fr)	Proximal x Distal Diameter (mm)	Covered Length (mm)	Native Vessel Inner Diameter (mm)	Suggested Sizing for Unsupported Junction with Graft Sizes from Column 2 (mm)
22	26x22	150	18, 19	26
	28x24		20, 21	28
	30x26		22, 23	30
	32x28		24, 25	32
24	34x30		25, 26, 27	34
	36x32		27, 28, 29	36
	38x34		29, 30, 31	38
	40x36		31, 32	40
25	42x38		33, 34	42
	44x40		35, 36	44
	46x42		37, 38	46

10.2.2. BTAI Sizing Guideline

Table 7. Sizing Guidelines for Treatment of Blunt Traumatic Aortic Injury

Native Vessel (mm)	Suggested Graft (mm)	Oversizing (mm)
18	22	4
19	22	3

Native Vessel (mm)	Suggested Graft (mm)	Oversizing (mm)
20	22	2
21	22	1
22	24	2
23	24	1
24	26	2
25	26	1
26	28	2
27	28	1
28	30	2
29	32	3
30	32	2
31	34	3
32	34	2
33	36	3
34	36	2
35	38	3
36	38	2
37	40	3
38	40	2
39	42	3
40	42	2
40	44	4
41	44	3
42	44	2
42	46	4
43	46	3
44	46	2

10.3. Device Inspection

Inspect the device and packaging to verify that damage or defect does not exist. If the "Use by" date has elapsed, the device is damaged, or the sterilization barrier has been compromised, do not use the device and contact a Medtronic Vascular representative for return or replacement.

10.4. Additional Equipment Recommended

- an inventory of system lengths and diameters
- one additional Valiant Thoracic Stent Graft System with the size intended for implantation
- two additional Valiant Thoracic Stent Graft Systems sized one size smaller and one size larger than intended size for implantation
- assorted angiographic, angioplasty, and graduated pigtail catheters
- radiopaque contrast media
- fluoroscope with digital angiography capabilities and the ability to record and recall all imaging
- surgical suite in the event that emergency open conversion surgery is necessary
- heparin and heparinized saline solution
- transesophageal echocardiography (TEE)
- intravascular ultrasound catheter (IVUS)
- introducer sheaths
- power injector
- radiopaque ruler
- Reliant Stent Graft Balloon Catheter and other materials recommended in the Reliant Instructions for Use
- sterile lubricant
- an assortment of stiff 0.035 in (0.89 mm) diameter guidewires, ≥260 cm in length

10.5. MRI Information

Nonclinical testing has demonstrated that the Valiant Thoracic Stent Graft is MR Conditional. It can be scanned safely in both 1.5 tesla and 3.0 tesla MR systems under the following conditions:

- static magnetic field of 1.5 tesla and 3.0 tesla
- spatial gradient field of ≤1000 gauss/cm
- maximum whole-body-averaged specific absorption rate (SAR) of 4 W/kg for 15 minutes of scanning (or the maximum SAR allowed by the MR System, whichever is less).
- patients with a Valiant Stent Graft implanted in the thoracic aorta may safely undergo MRI for Normal Mode and First Level Controlled Operating Mode of the MR System, as defined in IEC Standard 60601-2-33.⁴

In nonclinical testing, the Valiant Stent Graft produced a temperature rise of less than 1°C when normalized to the local SAR for 15 minutes of MR scanning in both a 64 MHz whole-body-transmit coil (which corresponds to a static field of 1.5 tesla) and a 3.0 tesla MR scanner (TrioTim, Siemens AG).⁵

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant. During nonclinical testing in a 3.0 tesla MR scanner (TrioTim, Siemens AG) with a whole body coil, the image artifact extends approximately 5 mm (using spin echo sequence) and 13 mm (using gradient echo sequence) from the device, both inside and outside the device lumen.

⁴ IEC 60601-2-33 ED 3.0. MEDICAL ELECTRICAL EQUIPMENT –Part 2-33: Particular requirements for basic safety and essential performance of magnetic resonance equipment for medical diagnosis. Draft (August 10, 2007).

⁵ Siemens and Tim are registered trademarks of Siemens Aktiengesellschaft.

11. Implant Instructions

11.1. Vascular Access

1. Establish vascular access for the Captivia Delivery System introduction via a small oblique groin incision over the primary access artery. Iliac conduits may be used to ensure the safe insertion of the delivery system. A secondary access site should be used for diagnostic and imaging purposes. The secondary access site is determined at the discretion of the physician.
2. To reduce the risk of thromboembolism, it is recommended that patients be anticoagulated for the duration of the procedure to achieve an ACT of 250 to 300 seconds at the discretion of the physician. Antiplatelet therapy may also be administered at the discretion of the physician.
Caution: Never advance or retract equipment from the vasculature without visualization.

11.2. Initial Angiogram

1. Using continuous fluoroscopy, traverse a 0.035 in (0.89 mm) guidewire and graduated pigtail angiographic catheter (via the secondary access site) to confirm the target landing zones.
2. Using angiographic imaging, confirm preoperative CT measurements. See Valiant Thoracic Stent Graft Sizing Guidelines (Table 3 to Table 6) to confirm device diameter.
3. Leave the angiographic catheter in place during the procedure to aid in confirming the position of the graft.
Note: In order to enhance visualization of the thoracic aortic arch, an angulation of 45 to 60 degrees Left Anterior Oblique (LAO) should be chosen.

11.3. Preparation of the Valiant Thoracic Stent Graft System

1. Carefully inspect all product packaging for damage or defects prior to use. Do not use if the "Use by" date has elapsed, the device is damaged, or the sterilization barrier has been compromised.
2. While holding the Valiant Thoracic Stent Graft with the Captivia Delivery System upright, flush the graft cover using a syringe with heparinized saline solution via the sideport (tapping the sheath to aid in releasing air bubbles). If difficult to flush, continue to apply pressure to the syringe, allowing time for saline to infuse the stent graft.
3. Flush the guidewire lumen with heparinized saline solution via the luer connector.
Caution: Do not grip the tip capture release handle during flushing of the delivery system.
4. **(For the FreeFlo Stent Graft Delivery System only)** Verify that the tip capture release handle is in its locked position. In its locked position, as indicated in Figure 46, the handle should not be able to rotate clockwise.

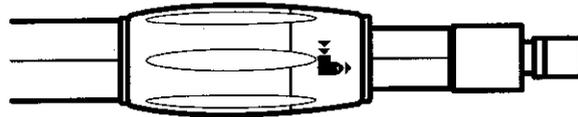


Figure 46. Tip Capture Release Handle in Locked Position

Caution: Initiating deployment of the stent graft with the tip capture release handle in its unlocked position (rotated counterclockwise) may result in premature release of the proximal bare stent of the FreeFlo Straight configuration.

11.4. Introducing the Captivia Delivery System

1. If necessary, open narrow entry vessels with standard PTA catheters or vessel dilators prior to Valiant Thoracic Stent Graft implantation according to standard endovascular procedures. If necessary, dilate vessel with tapered vessel dilator. A stepup approach is recommended for vessel dilation and is at the discretion of the physician.
2. Insert the Captivia Delivery System over the guidewire. Prior to insertion into the vessel, activate the hydrophilic coating by wiping the outer surface of the graft cover with a sterile gauze, saturated in saline, until the graft cover is slippery to touch.

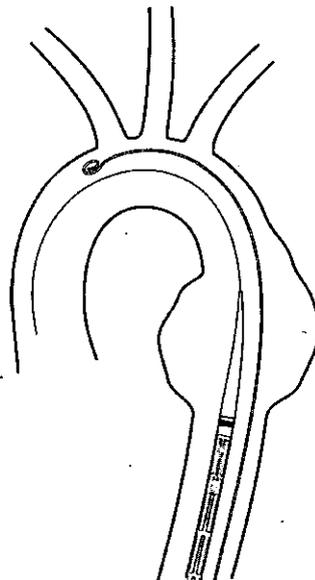


Figure 47. Introducing the Captivia Delivery System

Note: The Captivia Delivery System does not require a separate introducer sheath for the primary access site.

Caution: Manipulation of wires, balloons, catheters, and endografts in the thoracic aorta may lead to vascular trauma, including aortic dissection and embolization.

Caution: Do not bend, kink, or otherwise alter the Captivia Delivery System prior to implantation because it may cause deployment difficulties.

Caution: If an obstruction in the vessel, such as a tortuous bend, stenosis, or calcification formation, prevents advancement of the Captivia Delivery System, do not use excessive force to advance the delivery system. The cause of resistance must be assessed in order to avoid vessel or delivery catheter damage.

Caution: Do not grip the tip capture release handle during introduction of the delivery system.

11.5. Positioning the Captivia Delivery System

1. Slowly advance the Captivia Delivery System to the targeted landing zone. For patients who do not have excessive calcification or thrombus formation, it is suggested to position the device more proximal (a few millimeters higher in the vessel) to the targeted landing zone.
In patients with highly tortuous anatomy, it is suggested to position the device even more proximal to the targeted landing zone, as the stent graft may move distally when the graft cover is initially pulled back, then proximally when the first stent of the stent graft is released.

Caution: It is not recommended to position the device higher in the presence of excessive calcification or thrombus, due to the increased risk of dislodging material during distal repositioning of the stent graft.

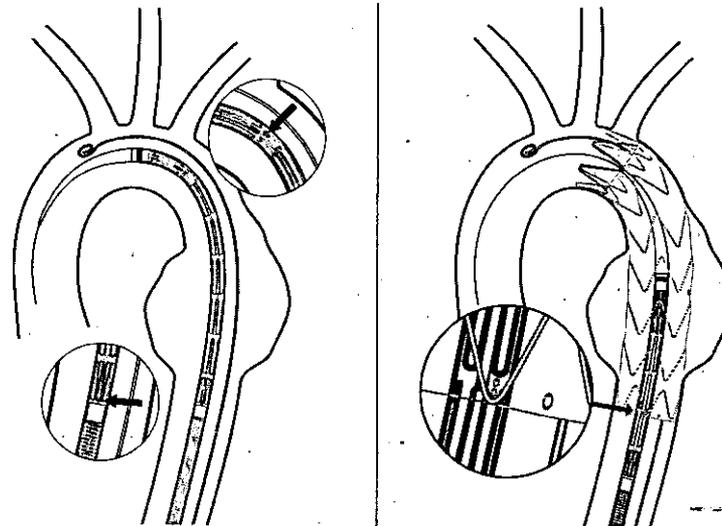
Caution: Be sure to avoid or compensate for parallax or other sources of visualization error.

Caution: Do not advance the Captivia Delivery System tip or guidewire across the aortic valve.

Caution: Do not grip the tip capture release handle during positioning of the delivery system.

11.6. Confirming Stent Graft Position

1. Before beginning deployment of the Valiant Thoracic Stent Graft, confirm proper position of the device using fluoroscope with digital angiography capabilities.
2. When placing the stent graft, verify that the proximal Figur8 markers are in the desired location (Figure 48). Placement of the distal end is verified by ensuring that the distal Zero markers are in the desired location. Additional stent grafts may be implanted to extend the length of coverage and exclude the lesion. For additional information, see Implanting Additional Configurations (Section 11.11).



Confirming position with Proximal Figur8 Markers and Distal Zero Markers

Confirming position of overlapping grafts with Figur8 Mid-Marker and Distal Zero Marker (An implanted FreeFlo configuration is shown in this image)

Figure 48. Confirm Stent Graft Position

Note: To confirm stent graft position when implanting 2 or more Valiant devices, the minimum overlap is achieved by aligning the distal Zero markers of the proximal graft with the single Figur8 Mid-Marker of the distal graft. See Implanting Additional Configurations (Section 11.11).

Caution: In the presence of excessive calcification or thrombus formation, it is not recommended to position the device higher and then reposition distally after partial stent graft deployment, due to increased risk of dislodging material.

Caution: Be sure to avoid or compensate for parallax or other sources of visualization error.

Caution: Do not grip the tip capture release handle while confirming the position of the delivery system.

11.7. Deploying the Valiant Thoracic Stent Graft

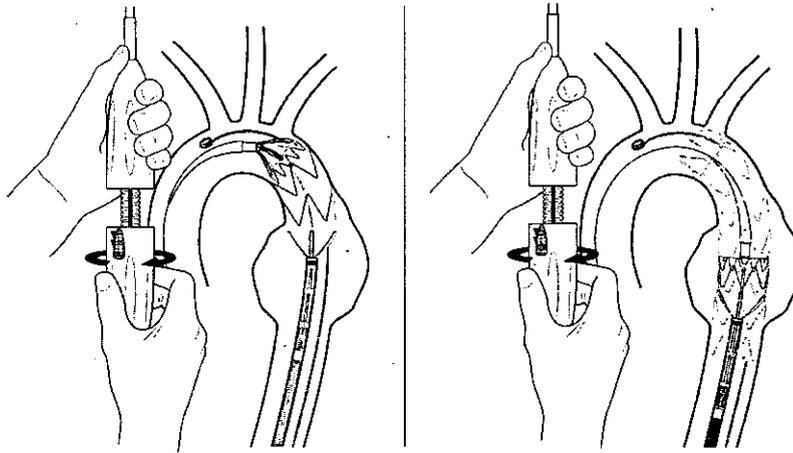
1. Decreasing Mean Arterial Blood Pressure (MAP) - Upon confirmation that the Captivia Delivery System is positioned properly, it may be appropriate to momentarily decrease the patient's MAP to approximately 80 mmHg (at the discretion of the physician) to avoid inadvertent displacement of the Valiant Thoracic Stent Graft upon withdrawal of the graft cover.
2. Deploying Proximal End - First hold the delivery system stationary with 1 hand on the grey front grip. Then, slowly withdraw the graft cover with the other hand by rotating the slider handle counter-clockwise. It may take multiple rotations before the graft cover separates from the tip, visualized by movement of the radiopaque marker band.

For the FreeFlo Stent Graft Delivery System: The proximal bare stent of the FreeFlo configuration will be constrained by the tip capture mechanism. Withdraw the graft cover until up to 2 covered stents are exposed.

For the Closed Web Stent Graft Delivery Systems: Withdraw the graft cover until up to 2 covered (body) stents are exposed.

In the unlikely event of delivery system failure and concomitant partial stent graft deployment due to graft cover severance, a "handle disassembly" technique will permit successful deployment of the stent graft. See Troubleshooting Techniques (Section 12).

Note: The Captivia Delivery System should be stabilized and remain stationary during stent graft deployment.



For the FreeFlo Stent Graft Delivery System, the proximal bare stent is constrained by the tip capture mechanism.

For the Closed Web Stent Graft Delivery Systems, the proximal end is not constrained.

Figure 49. Deploying the Proximal End of the Stent Graft

Caution: A Closed Web configuration should never be used as the most proximally implanted stent graft.

Caution: Do not place the proximal end of the covered stent graft beyond the distal edge of the left common carotid artery.

Caution: If the stent graft is deployed higher than the targeted landing zone, it is important to not deploy more than 2 covered stents prior to repositioning of the stent graft. Further deployment of the graft can impair the ability to move the graft to the desired landing zone.

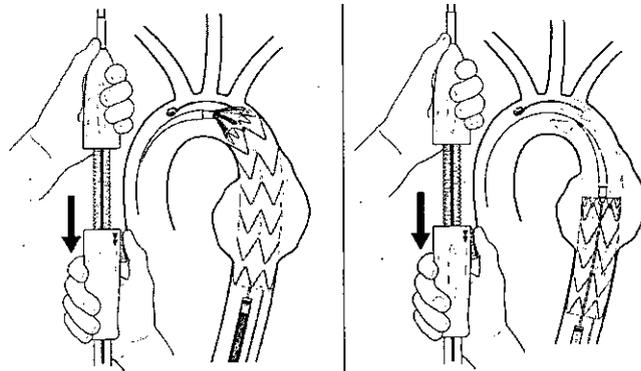
Caution: Do not release the proximal bare stent of the FreeFlo configuration before the entire stent graft has been deployed, as this may result in inaccurate deployment.

Caution: Ensure that the Valiant devices are placed in a landing zone comprised of healthy tissue. Healthy tissue is defined as tissue without evidence of circumferential thrombus, intramural hematoma, dissection, ulceration, or aneurysmal involvement. Failure to do so may result in inadequate exclusion or vessel damage, including perforation.

3. Verifying Position - Use angiography to verify the position of the stent graft in relation to the desired location. Use the proximal Figur8 markers to aid in visualizing the proximal end of the covered stent graft. If the stent graft was deployed higher than the targeted landing zone, maintain the position of the slider handle and pull down on the entire delivery system until the proximal Figur8 markers indicating the top edge of the fabric are at the desired position.
4. Deploying Remainder of Stent Graft - Continue withdrawing the graft cover. To more rapidly deploy the stent graft, place 1 hand firmly on the grey front grip and hold the system stationary. While maintaining support on the grey front grip, pull back the grey trigger to engage the quick-release function of the blue slider handle. Pull the blue slider handle away from the grey front grip until the RO Marker Band on the graft cover is beyond the distal spring. If excessive force is felt, release the grey trigger and rotate the blue slider handle to complete deployment of the stent graft.

For the FreeFlo Stent Graft Delivery System: At this point, the proximal bare stent is still constrained by the tip capture mechanism.

For the Closed Web Stent Graft Delivery Systems: At this point, the entire Closed Web stent graft has been deployed.



For the FreeFlo Stent Graft Delivery System, the proximal bare stent is constrained by the tip capture mechanism.

For the Closed Web Stent Graft Delivery Systems, the proximal end is deployed.

Figure 50. Deploying the Remainder of the Stent Graft

Note: If necessary, the stent graft can be repositioned distally to the desired location by retracting it, as long as no more than 2 of the proximal springs have been deployed.

Note: Deployment of the stent graft in the aortic arch can increase the deployment force. Deployment forces can be further increased by excessive tortuosity and a small radius aortic arch.

Note: In the unlikely event of delivery system failure and concomitant partial stent graft deployment due to graft cover severance, a "handle disassembly" technique may permit the successful deployment of the stent graft. For additional information, see Handle Disassembly Technique for Partial Stent Graft Deployment (Section 12.1).

Caution: When using the trigger to rapidly deploy the stent graft, assure the grey front grip remains stationary. Failure to do so will cause movement of the stent graft position and will result in inaccurate deployment.

Caution: Do not rotate the delivery system during deployment, as this may torque the delivery system and cause the stent graft to twist during deployment.

Caution: Once the entire covered portion of the stent graft has been deployed, do not attempt to adjust the position of the stent graft.

Caution: If the graft cover is inadvertently withdrawn, the stent graft will prematurely deploy and will be placed incorrectly.

11.8. Deploying Tip Capture Mechanism (on the FreeFlo System Only)

1. Continue to hold the delivery system stationary with 1 hand on the front grip.
2. With the other hand, rotate the tip capture release handle counter-clockwise to unlock the handle.

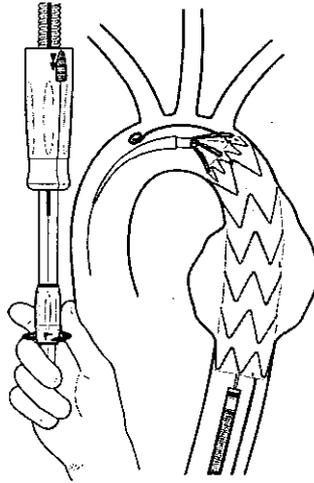


Figure 51. Unlocking the Tip Capture Release Handle

3. Pull the tip capture release handle back in a smooth motion until the tip capture mechanism is released, and the proximal bare stent of the FreeFlo configuration is completely open (Figure 52). Observe the opening of the bare stent under fluoroscopy and confirm that the proximal bare stent has been completely deployed.

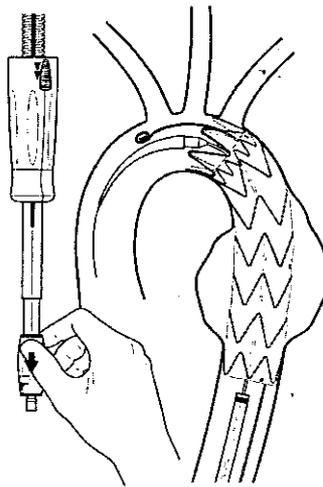


Figure 52. Deploying the Tip Capture Mechanism

Note: In the unlikely event that the proximal bare stent of the FreeFlo configuration cannot be deployed, refer to Troubleshooting Techniques (Section 12).

Caution: Keep the delivery system stationary while deploying the tip capture mechanism. Do not pull back on or push forward on the delivery system while deploying the tip capture mechanism, as it may cause the entire graft to move.

Caution: Do not push forward on the tip capture release handle or on the entire delivery system until the front grip has been pulled towards the slider handle. See Delivery System Removal (Section 11.9). Doing so may cause the tip capture mechanism to get caught on the proximal bare stent.

11.9. Delivery System Removal

1. Continue to hold the Captivia Delivery System with 1 hand on the front grip and the other hand on the slider.
2. Pull back the grey trigger and hold the slider handle stationary while bringing the grey front grip towards the slider handle as depicted in Figure 53. Use continual fluoroscopy and watch the proximal end of the Valiant Thoracic Stent Graft while slowly pulling back the tapered tip into the graft cover of the delivery system. It may be necessary to pull the entire delivery system back into a straight section of the aorta to aid in retraction of the tip.
3. **(FreeFlo Stent Graft Delivery System only)** After the front grip has been pulled back to rejoin the slider, push the tip capture release handle forward so that the tip capture component moves toward the RO marker band of the graft cover. Monitor the movement of the tip capture component using fluoroscopy.
(Closed Web Stent Graft Delivery System only) Proceed to Step 4.
4. Gently remove the delivery system, using fluoroscopy to ensure that the stent graft does not move during the withdrawal.

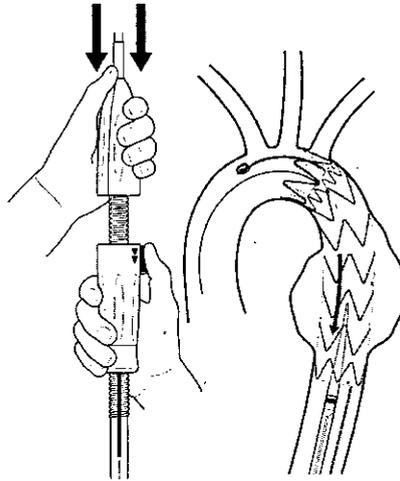


Figure 53. Delivery System Removal

Caution: Carefully monitor the retrieval of the tapered tip with fluoroscopy to ensure that the tip does not cause the Valiant Thoracic Stent Graft to be inadvertently pulled down.

11.10. Smoothing Stent Graft Fabric and Modeling the Stent Graft

Caution: Do not use a balloon catheter to treat aortic dissection.

The Reliant Stent Graft Balloon Catheter can be used to assist in stent graft implantation by modeling the covered springs and to remove wrinkles and folds from the graft material (Figure 54). Refer to the Instructions for Use supplied with the Reliant Stent Graft Balloon Catheter for more information.

Note: Care should be taken when inflating the balloon, especially with calcified, tortuous, stenotic, or otherwise diseased vessels. Inflate slowly. It is recommended that a backup balloon be available.

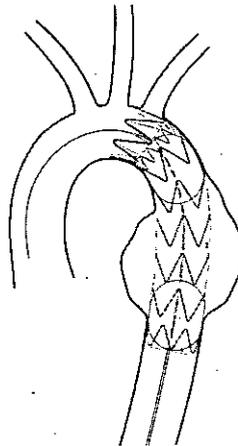


Figure 54. Balloon Modeling of the Stent Graft

Warning: Do not use the Reliant device in patients with a history of aortic dissection disease. Do not over-inflate the balloon.

Warning: When expanding a vascular prosthesis using the Reliant Balloon, there is an increased risk of vessel injury or rupture, and possible patient death, if the balloon's proximal and distal radiopaque markers are not completely within the covered (graft fabric) portion of the prosthesis.

11.11. Implanting Additional Configurations

If 2 or more Valiant Thoracic Stent Graft configurations are required to exclude the lesion, please follow the steps below.

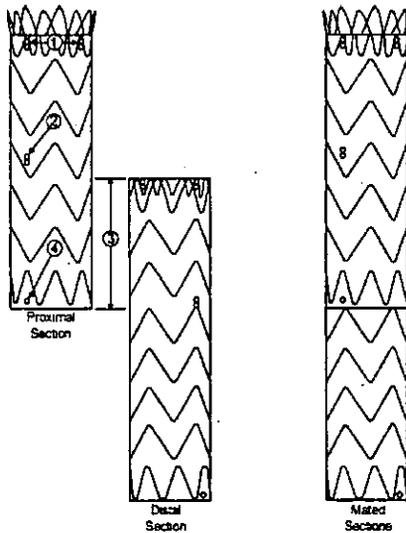
Caution: FreeFlo and Bare Spring Straight stent graft configurations should never be placed inside the graft covered section of another graft as doing so may result in abrasion of the fabric by the bare spring, resulting in graft material holes or broken sutures.

Caution: A Closed Web Taper or Straight configuration may be implanted as the primary section only when implanting multiple stent grafts in a nontortuous segment of the descending thoracic aorta with the distal-to-proximal implantation technique.

Caution: Failure to provide sufficient overlap may result in separation of stent graft components.

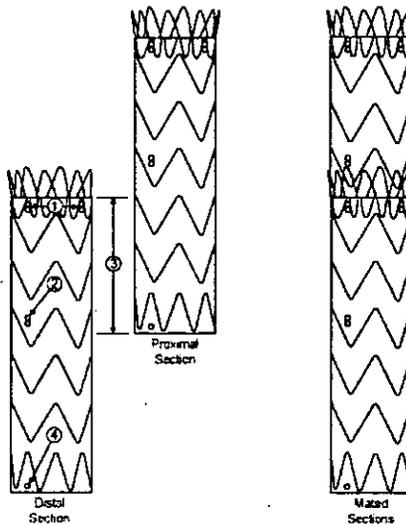
Note: *In vitro* durability (fatigue) testing may suggest that the long-term durability of the device may be compromised in conditions with excessive device oversizing or deformation associated with cardiac and respiratory cycles. Wire fractures may have unknown clinical consequences which may include, but are not limited to; device migration, vessel perforation, loss of aneurysm exclusion, or death.

1. Refer to Preparation of the Valiant Thoracic Stent Graft with the Captivia Delivery System (Section 11.3).
2. Refer to Introducing the Captivia Delivery System (Section 11.4). Advancement of the delivery system within the previously implanted stent graft must be carefully monitored under fluoroscopy to ensure that the implanted stent graft does not move.
3. Refer to Positioning the Captivia Delivery System (Section 11.5).
4. Refer to Confirming Stent Graft Position (Section 11.6). Radiographically verify that the Zero markers on the proximal graft align with the single Figur8 (between the third and fourth covered spring) on the distal graft to achieve the minimum overlap distance (Figure 48, Figure 55, and Figure 56). Also, verify that the markers on the additional stent graft indicate that the proximal and distal ends of the covered stent graft are at the desired locations.



Minimum overlap is achieved by aligning the Zero marker on the proximal section with the Figur8 Mid-Marker on the distal section.

Figure 55. Alignment of Additional Sections (First Graft Placed Proximally)



Minimum overlap is achieved by aligning the Zero marker on the proximal section with the Figur8 Mid-Marker on the distal section.

Figure 56: Alignment of Additional Sections (First Graft Placed Distally)

1. Proximal Figur8 Marker
2. Figur8 Mid-Marker
3. Minimum Required Overlap
4. Distal Zero Marker

5. Refer to Deploying the Valiant Thoracic Stent Graft (Section 11.7).
6. If the additional section is a FreeFlo Straight Configuration Stent Graft, refer to Deploying Tip Capture Mechanism (Section 11.8).
7. Refer to Delivery System Removal (Section 11.9).
8. Refer to Smoothing Stent Graft Fabric and Modeling the Stent Graft (Section 11.10).

11.12. Angiogram

Upon completion of the implant procedure, perform angiography to verify stent graft apposition and seals and any endoleaks at the proximal and distal ends of the stent graft. Assess the stent graft for mid-graft and graft junction endoleaks.

Perform adjunctive maneuvers as needed, such as ballooning or insertion of additional devices. The most reliable course of endoleak management (Type I or Type III) is by remodeling the stent graft with a balloon and, if needed, placing an additional stent graft (Section 11.11). A minor leak that does not seal after re-ballooning may seal spontaneously within several days. If any adjunctive maneuvers are conducted, perform a final angiogram to confirm successful exclusion of the lesion.

Caution: High pressure injections at the edges of the Valiant Thoracic Stent Graft immediately after implantation may cause acute endoleaks.

Caution: Any leak left untreated during the implantation procedure must be carefully monitored after implantation.

11.13. Entry Site Closure

Remove all remaining accessories (for example, guidewire, introducer sheath, or angiogram catheter). Close the arteriotomy site by standard surgical closure techniques.

12. Troubleshooting Techniques

12.1. Handle Disassembly Technique for Partial Stent Graft Deployment

In the unlikely event of delivery system failure and concomitant partial stent graft deployment due to graft cover severance, a "handle disassembly" technique may permit the successful deployment of the stent graft.

1. Pull back the trigger and fully retract the slider.
Note: Since the graft cover is severed, the slider can be retracted without further deploying the stent graft.
2. Stabilize the delivery system.
3. Insert the tips of a pair of hemostats into each of the handle disassembly ports on the front grip.
4. Disengage the front grip from the screw gear by pressing the tips of the hemostats into the handle disassembly ports and simultaneously advancing the front grip away from the screw gear.
5. Advance the front grip until it fully clears the screw gear.
6. Separate the screw gear halves in order to identify the location of graft cover severance.
7. Grip the graft cover manually or with hemostats and retract until the stent graft is fully deployed.
8. **(FreeFlo Stent Graft Delivery System only)** Deploy the tip capture mechanism (Section 11.8).
9. Remove the delivery system by gripping the screw gear and withdrawing from the patient.

12.2. Alternative Instruction for Deploying Tip Capture Mechanism

In the unlikely event of delivery system failure and non-release of the tip capture mechanism due to tip capture tube severance, an alternative technique may permit the successful release of the proximal bare stent.

1. Ensure the delivery system remains stationary and continue to monitor stent graft position.
2. Remove the back end lock by turning counter-clockwise and pulling off of the delivery system. It may be necessary to push the tip capture release handle forward to gain access to the back end lock.
3. Pull the tip capture release handle back as far as it can go.
4. Using a hemostat, separate the halves of the tip capture release handle and discard.
5. Remove the clamping ring by turning clockwise and pulling off of the delivery system.
6. Separate the screw gear halves at the back end in order to identify the location of tip capture tube severance. The tip capture tube is the brown tube from which the guidewire lumen emerges.
7. While holding the luer connector and guidewire lumen steady, grip the tip capture tube with hemostats and retract it until the proximal bare stent is fully released from the tip capture mechanism.
8. Hold the delivery system with one hand on the front grip and the other hand on the slider. Pull back the trigger and hold the slider stationary while bringing the front grip towards the slider as depicted in Figure 53.
9. Gently remove the delivery system while maintaining backwards tension on the guidewire lumen to keep the tapered tip seated within the graft cover. Use fluoroscopy to ensure that the stent graft does not move during the withdrawal.

13. Follow-up Imaging Recommendations

13.1. General

All patients should be advised that endovascular treatment requires lifelong, regular follow-up to assess their health and the performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms, or changes in the structure or position of the endovascular graft) should receive additional follow-up. Patients should be counseled on the importance of adhering to the follow-up schedule, both during the first year and at yearly intervals thereafter. Patients should be informed that regular and consistent follow-up is a critical part of ensuring the ongoing safety and effectiveness of endovascular treatment of thoracic aortic aneurysms, such as fusiform aneurysms, saccular aneurysms, and penetrating atherosclerotic ulcers. Physicians should evaluate patients on an individual basis and prescribe follow-up relative to the needs and circumstances of each individual patient.

Annual imaging follow-up may include chest X-ray and computed tomography angiogram (CTA), with and without contrast.

- The combination of contrast and non-contrast CT imaging provides information on aneurysm diameter change, endoleak, patency, tortuosity, progressive disease, fixation length and other morphological changes
- The chest X-rays provide information on device integrity (separation between components and stent fracture)

Figure 57 lists the recommended imaging follow-up for patients with the Valiant Thoracic Stent Graft. Ultimately, it is the physician's responsibility, based on previous clinical results and the overall clinical picture, to determine the appropriate imaging schedule for a particular patient.

Visit	Imaging Modality		
	Angiogram	CTA/MRA ^{2,3}	Chest X-ray ²
Pre-Procedure	X (optional)	X ¹	
Procedural	X		
1 Month		X ⁴	X
12 Month (annually thereafter)		X ⁴	X

¹ Pretreatment assessment should be done within 3 months prior to treatment.

² A six-month follow-up with CT Scan and Chest X-ray are recommended if an endoleak is reported at 1 month after the procedure.

³ Magnetic resonance angiogram (MRA) may be used in patients with impaired renal function or intolerance to contrast media at the discretion of the physician

⁴ If a Type I or III endoleak is present, prompt intervention and additional follow-up post-intervention is recommended.

Figure 57. Imaging Recommendations

13.2. Angiographic Imaging

Angiographic images are recommended at pre-treatment (within 3 months of implant) for centers without CTA 3-D reconstruction capabilities to assist in determining anatomic suitability. Angiographic images are also recommended during the treatment to evaluate anatomy and device placement.

13.3. CTA Images

CTA images are recommended pre-treatment to determine anatomic suitability for the Valiant Thoracic Stent Graft. CTA with 3-D reconstruction is recommended in order to accurately assess the patient's anatomy. The physician will determine the required pre-operative care for patients with allergies to contrast or who have impaired renal function.

CTA images are also recommended post-treatment for lesion and device assessment. The triphasic imaging protocol for follow-up CT should consist of an unenhanced, contrast enhanced, and 5 minute delay scan. Please refer to Table 8 for optimal CTA results. MRA may be used at the physician's discretion.

- Film sets should include all sequential images at the lowest possible slice thickness (<3 mm). Do not perform large slice thickness (>3 mm) or omit consecutive CT images or films sets, as this prevents precise anatomical and device comparisons over time.
- Both non-contrast and contrast runs are required, with matching or corresponding table positions.
- Pre-contrast and contrast run slice thicknesses and intervals must match.

- Do not change patient orientation or re-landmark the patient between non-contrast and contrast runs.

Non-contrast and contrast enhanced baseline and follow-up imaging are important for optimal patient surveillance. Table 8 lists examples of accepted imaging protocols.

Table 8. CTA Imaging Guidelines

Injection Volume (cc or mL)	100–150
Injection Rate (cc/sec or mL/sec)	3–4 via 20G IV or larger (4–5 for obese pts >220 lbs (99.8 kg))
Bolus Timing	SmartPrep, Carebolus, or equivalent
Scan Range	Thoracic inlet to aortic bifurcation
Scan Diameter (FOV)	Large
DFOV (cm)	24–30
Scan Type	Helical
Rotation Speed (sec)	0.8
Slice Thickness (mm)	≤2.5
Scan Mode	HS
Table Speed (mm/rot)	15
Interval (mm)	1
kVp	120
mA	120 for non-contrast/200 for contrast portion of study
Reconstruction (mm)	1 (normal body habitus) to 2 (>220 lbs (99.8 kg))

13.4. X-ray

Chest X-rays should be used to assess device integrity such as stent graft fracture or separation between components. Posterior/Anterior (PA) and lateral images are recommended for visualization of the stent graft. Ensure the entire device is captured on images for device assessment.

13.5. MRI/MRA Information

Patients with impaired renal function (i.e., renal insufficiency) may also be considered for magnetic resonance imaging (MRI) or angiography (MRA) at the discretion of the physician. Artifact may occur related to the stent, and care should be used to insure adequate imaging of the outer aneurysm wall to assess TAA size. Volume measurement may be helpful if the aneurysm is not clearly shrinking. If there are concerns regarding imaging of calcified areas, fixation sites, or the outer wall of the aneurysm sac, adjunctive CT without contrast may be needed. Additional MRI technical information can be obtained at <http://www.medtronic.com/mri/manuals>. Specific information on MRI can be found in MRI Information (Section 10.5).

13.6. Supplemental Imaging

Note: Additional radiological imaging may be necessary to further evaluate the stent graft in situ based on findings revealed by previous imaging assessments. The following recommendations may be considered.

- If there is evidence of poor or irregular position of the stent graft, severe angulation, kinking, or migration of the stent graft on chest X-rays, a spiral CT should be performed to assess aneurysm size and the presence or absence of an endoleak.
- If a new endoleak or increase in TAA size is observed by spiral CT, adjunctive studies such as 3-D reconstruction or angiographic assessment of the stent graft and native vasculature may be helpful in further evaluating any changes of the stent graft or aneurysm.
- Spiral CT without contrast, MRI or MRA may be considered in select patients who cannot tolerate contrast media or who have renal function impairment. For centers with appropriate expertise, gadolinium or CO₂ angiography may be considered in patients with renal function impairment requiring angiographic assessment.

14. Additional Surveillance and Treatment

Additional endovascular repair or open surgical aneurysm repair should be considered for patients with evidence of enlarged aneurysm (>5 mm), endoleak, migration, inadequate seal zone, or fracture.

Consideration for reintervention or conversion to open repair should include the attending physician's assessment of an individual patient's comorbidities, life expectancy, and the patient's personal choices. Patients should be counseled that subsequent reintervention may become necessary following an endograft procedure. This may include catheter-based or open surgical conversion.

15. Device Registration

The Valiant Thoracic Stent Graft System is packaged with additional specific information which includes:

- Temporary Device Identification Card** that includes both patient and stent graft information. Physicians should complete this card and instruct the patient to keep it in their possession at all times. The patients should refer to this card anytime they visit additional healthcare practitioners, particularly for an additional diagnostic procedure (e.g. MRI). This temporary identification card should only be discarded when the permanent identification card is received.
- Device Tracking Form** to be completed by the hospital staff and forwarded to Medtronic for the purposes of tracking all patients who received a Valiant Stent Graft (as required by Federal Regulation). The hospital's submission of the device tracking form to Medtronic is also required for a patient to receive the permanent identification card.

Upon receipt of the completed Device Tracking Form, Medtronic will mail the patient a **Permanent Device Identification Card**. This card includes important information regarding the implanted stent graft. Patients should refer to this card anytime they visit healthcare practitioners, particularly for any diagnostic procedures (eg, MRI). Patients should carry this card with them at all times. If a patient does not receive their permanent device identification card, or requires changes to the card, call 1-800-551-5544. In addition a patient information booklet (PIB) will be provided to the physicians during training and additional copies will be available upon request. The PIB will also be available online on the Medtronic website (www.medtronic.com). This booklet provides patients with basic information on thoracic aortic aneurysms and endovascular repair therapy.

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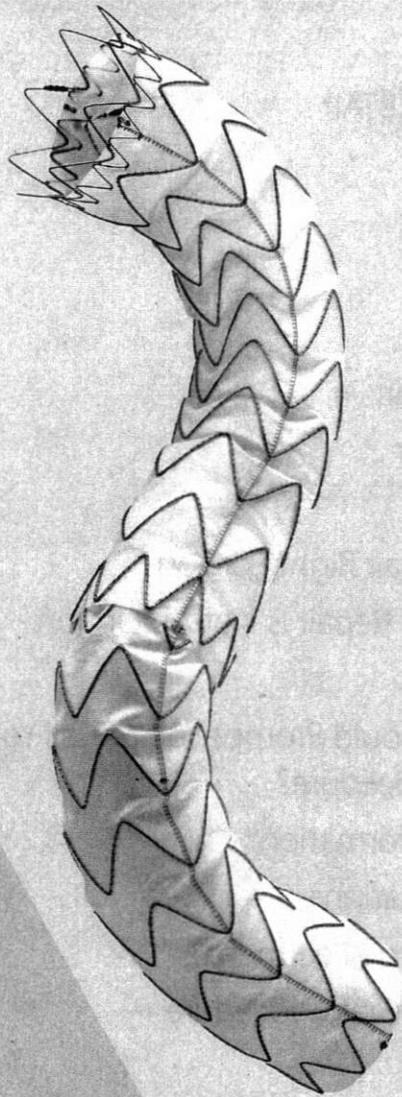


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Medtronic



PATIENT INFORMATION BOOKLET

**Thoracic Stent Grafts:
A Treatment for Blunt Thoracic Aortic
Injuries and other isolated lesions**

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*See pages 10, 11 and 12 for important safety information.

INTRODUCTION

An **endovascular repair** procedure is one option to treat a **blunt thoracic aortic injury (BTAI)** and other **isolated lesions** including but not limited to intramural hematomas and pseudoaneurysms. The doctor has given you this booklet to help you further understand the device and procedure. Only a doctor can determine if a patient is a good candidate for **endovascular repair**.

A glossary is in the next section to help you understand the medical terms used in this booklet. Words that are in bold text are defined in the glossary.

GLOSSARY

Anatomy: The study of parts of the body.

Aorta: The main vessel that carries blood from the heart to the rest of the body.

Blunt thoracic aortic injury (BTAI): An injured thoracic aorta due to traumatic force to the chest.

Congestive heart failure: A condition in which the heart can no longer pump enough blood to other organs of the body.

CT scan: A scan that takes X-rays or pictures of the aorta.

Endoleak: Blood flow between the stent graft and the aorta wall.

Endovascular: Inside or within a blood vessel.

Endovascular repair: A procedure in which a tube-shaped stent graft is placed inside an injured aorta without cutting open the chest or stomach.

Femoral artery: Blood vessels that carry blood to the thigh region of each leg. Doctors can use these as pathways to reach the aorta.

Fluoroscopy: A real-time X-ray image that allow doctors to see inside the patient.

Iliac artery: Blood vessels that carry blood to your pelvis. Doctors can use these as pathways to reach your aorta.

Imaging: The use of X-rays, CT scans, MRI scans or other techniques to get pictures of the inside of the body.

Intramural Hematoma: The abnormal collection of blood within the aortic walls. Over time, the collection of blood weakens the aorta and may lead to rupture.

Isolated Lesions: Isolated lesions include but are not limited to blunt thoracic aortic injuries, **intramural hematomas** and **pseudoaneurysms**.

Minimally invasive: Involving a small cut of the skin without exposing the organs.

Magnetic Resonance Imaging (MRI): A technique that uses magnetic fields to get pictures of the inside of the body.

Open surgery/Open surgical repair: A procedure in which a doctor makes a large cut in the chest to fix an injured aorta and then replaces it

with a fabric graft.

Paraplegia: The loss of the ability to move the legs and lower body.

Pneumonia: A breathing condition in which there is an infection of the lung.

Pseudoaneurysms: Bulges in the aorta, formed usually at areas in the aorta that have been damaged by previous surgery or trauma. Pseudoaneurysms can enlarge over time and could lead to rupture if left untreated.

Renal failure: A condition when the kidneys fail to adequately filter toxins and waste.

Rupture: A tear in the blood vessel wall near or in the diseased part of the vessel.

Spinal cord ischemia: A lack of blood flow to the vessels that carry blood to the spinal cord.

Stent graft/Thoracic stent graft: A fabric tube supported by a metal frame that a doctor puts inside the injured aorta.

Stroke: A loss of brain function due to the loss of blood supply to a part of the brain.

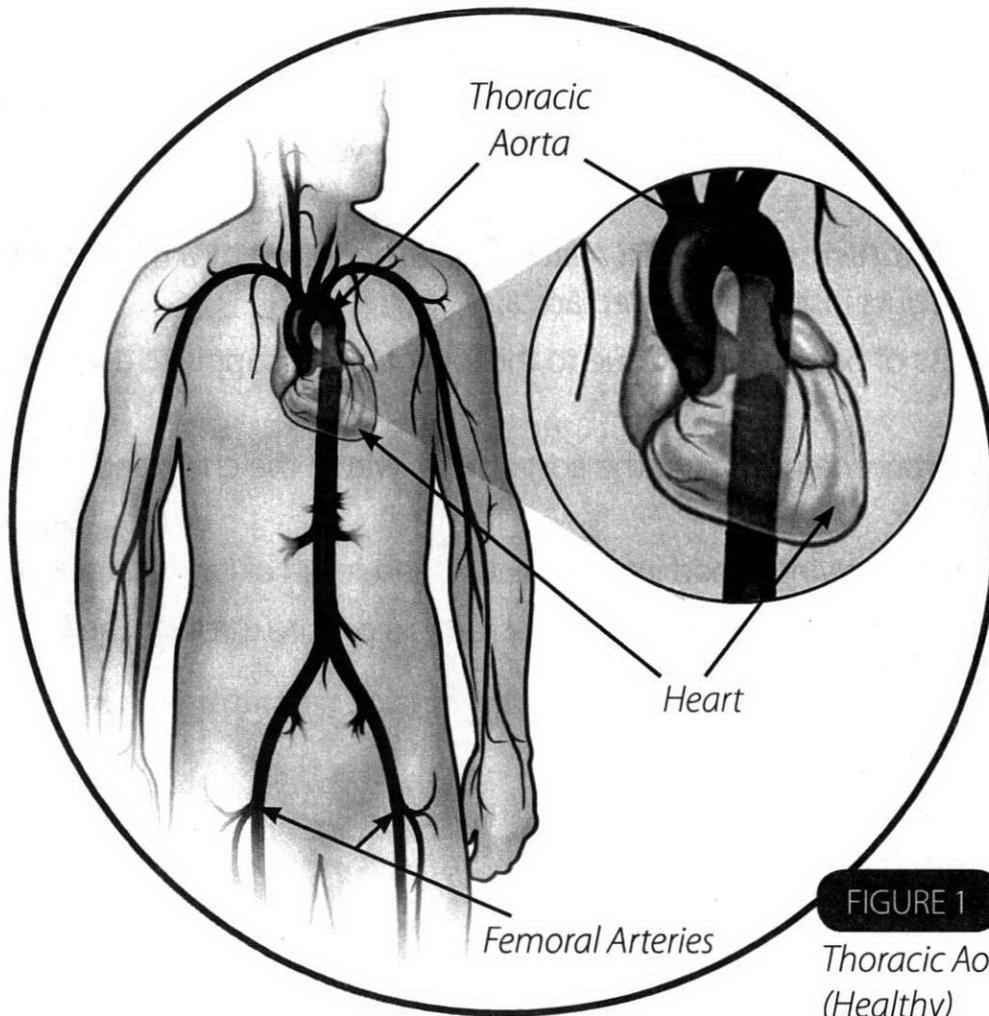
Thoracic Aorta: The portion of the aorta that is within the chest and close to the heart.

Transfusion: Receiving blood into circulation as a result of loss of blood.

Ultrasound: An imaging technique that creates a picture through the use of high frequency sound waves.

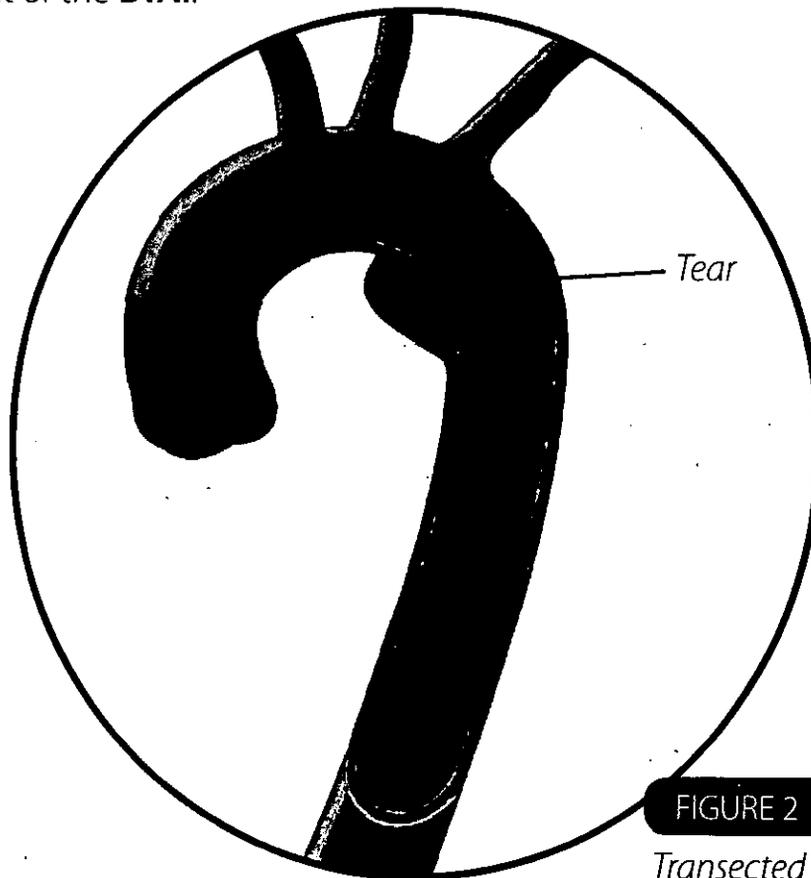
THORACIC AORTA

The **aorta** is the largest blood vessel in the body. It carries blood away from the heart to the rest of the body. The **thoracic aorta** is the part of the aorta located in the chest (Figure 1).



BLUNT THORACIC AORTIC INJURY (BTAI)

A **blunt thoracic aortic injury (BTAI)** is an injury to the **thoracic aorta** due to traumatic force to the chest. This injury can result in a complete tear in the wall of the **aorta** or a partial tear that weakens part of the **aorta** (Figure 2). **BTAI** is life-threatening due to the potential for the tear in the **aorta** to cause bleeding inside the body. **BTAI** has both **open surgical repair** and **endovascular repair** treatment options. Care of the patient will require immediate medical management and prompt diagnosis before a repair option is pursued by the doctor. Some patients who have other life-threatening injuries may need other surgical interventions prior to the treatment of the **BTAI**.



CAUSES

BTAI is commonly caused by motor vehicle accidents or falls and is often accompanied with additional injuries related to the accident.

SYMPTOMS

Most people do not have symptoms of **BTAI** and **imaging** is required to make a diagnosis.

OTHER ISOLATED LESIONS

In addition to **BTAI**, there are other **isolated lesions** of the thoracic **aorta**. These include but are not limited to **intramural hematomas** and **pseudoaneurysms**.

- **Intramural hematoma** is the abnormal collection of blood within the aortic walls. Overtime, the collection of blood weakens the **aorta** and may lead to **rupture**.
- **Pseudoaneurysms** of the **thoracic aorta** are bulges in the aorta, formed usually at areas in the **aorta** that have been damaged by previous surgery or trauma. Pseudoaneurysms can enlarge over time and could lead to **rupture** if left untreated.

TREATMENT OPTIONS

There are two primary treatment options available depending on your doctor's diagnosis:

- **open surgical repair**
- **endovascular repair**

Both treatment options have possible complications and benefits. When possible, patients should talk with their doctor about which option is best for them. See pages 10, 11, and 12 for important safety information about **endovascular repair**.

OPEN SURGICAL REPAIR¹:

Open surgical repair is the conventional medical procedure for **BTAI** and other **isolated lesions**. A doctor will cut open your chest (Figure 3), and repair the injury with suture or a fabric graft. This treatment aims to protect the injured **aorta** and prevent a **rupture**.

This procedure takes 4 to 6 hours. After this, you will likely spend 10 to 15 days in the intensive care unit and then 10 to 20 days in the hospital. Depending on the other injuries you have, you may have to stay in the intensive care unit or hospital longer due to treatment of injuries to other parts of your body. For the **open surgical repair** you will need 12 to 24 weeks to recover.

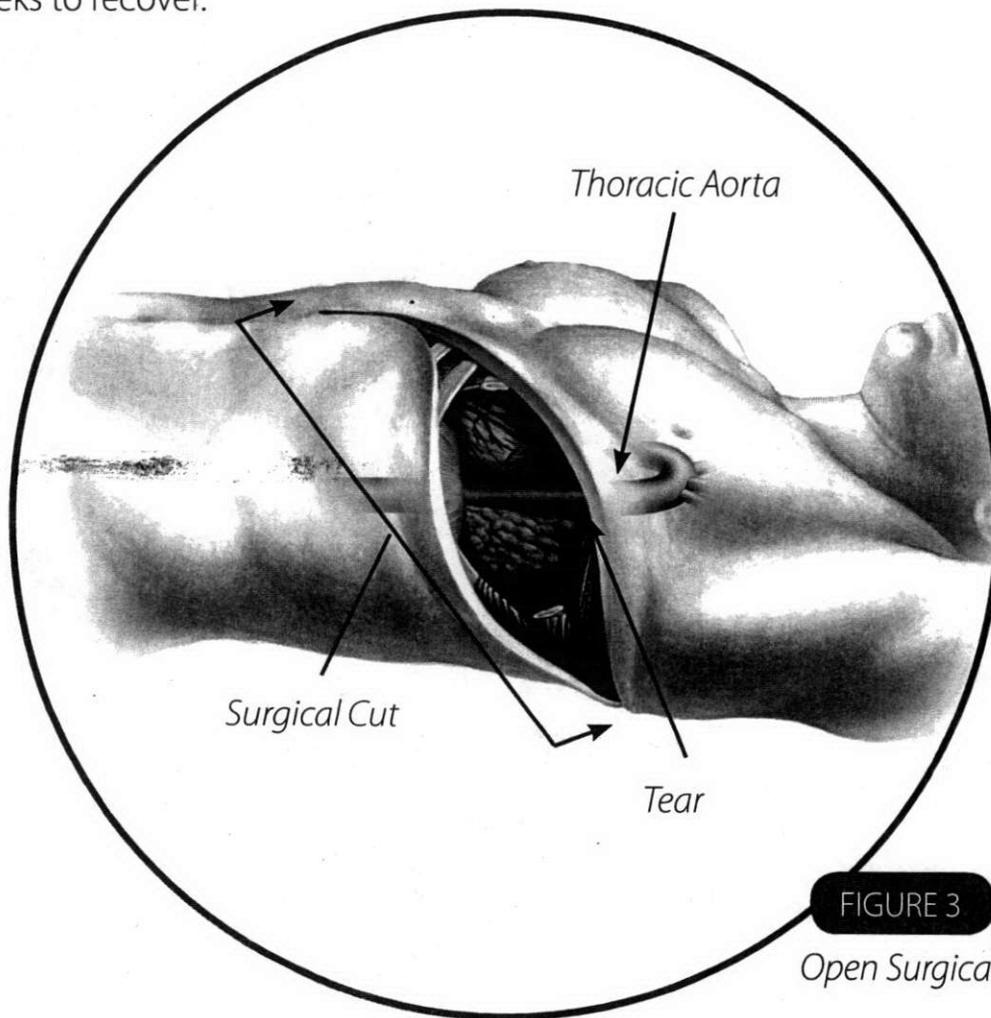


FIGURE 3

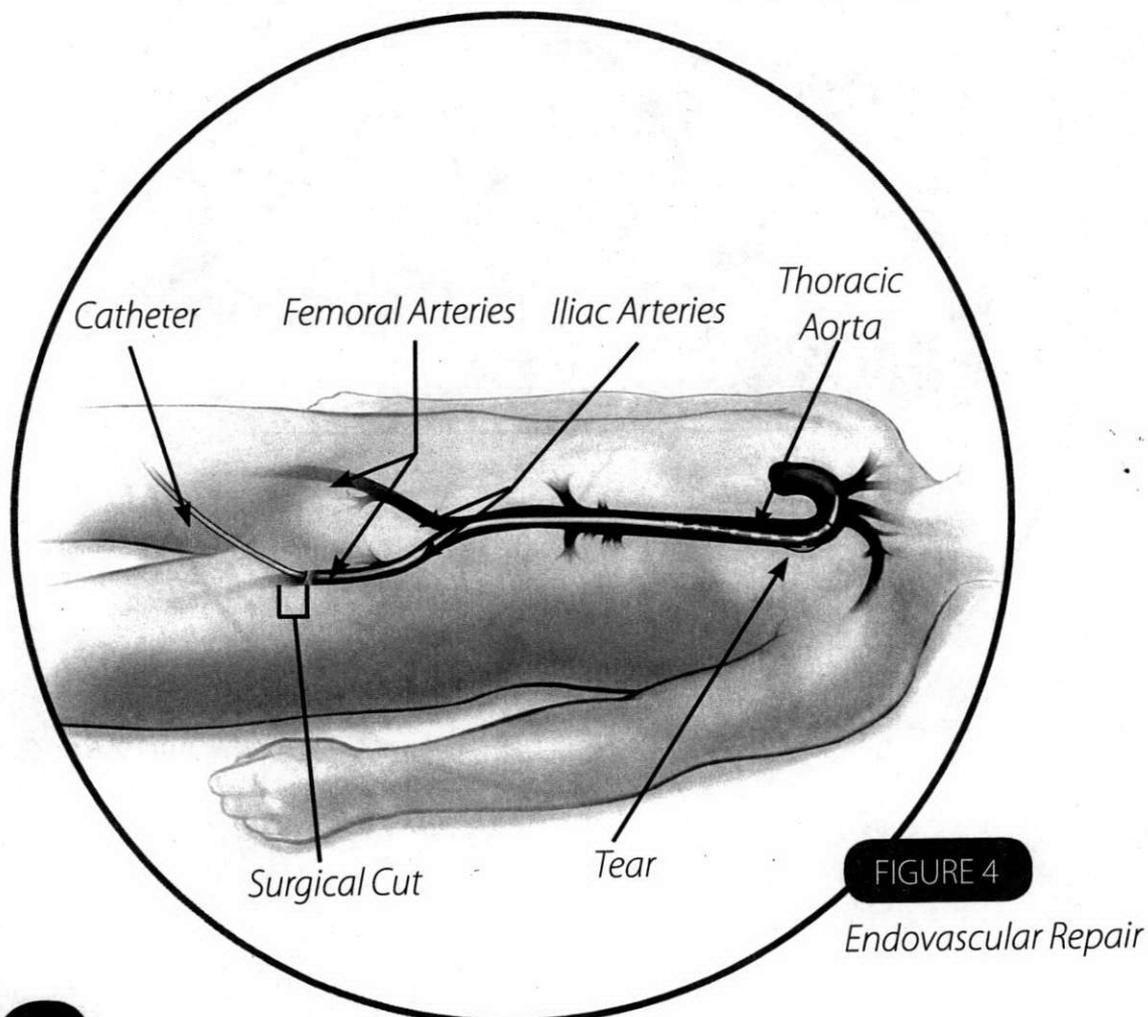
Open Surgical Repair

ENDOVASCULAR REPAIR²:

Endovascular repair is a newer **minimally invasive** medical procedure. The long-term results of **endovascular repair** with a **thoracic stent graft** have not been established. A doctor will make a small cut in your groin (Figure 4). A catheter holding a fabric and metal **stent graft** is inserted into the cut, guided to the location of the injury and then released into the **aorta**. This procedure protects the injured area of the **aorta**.

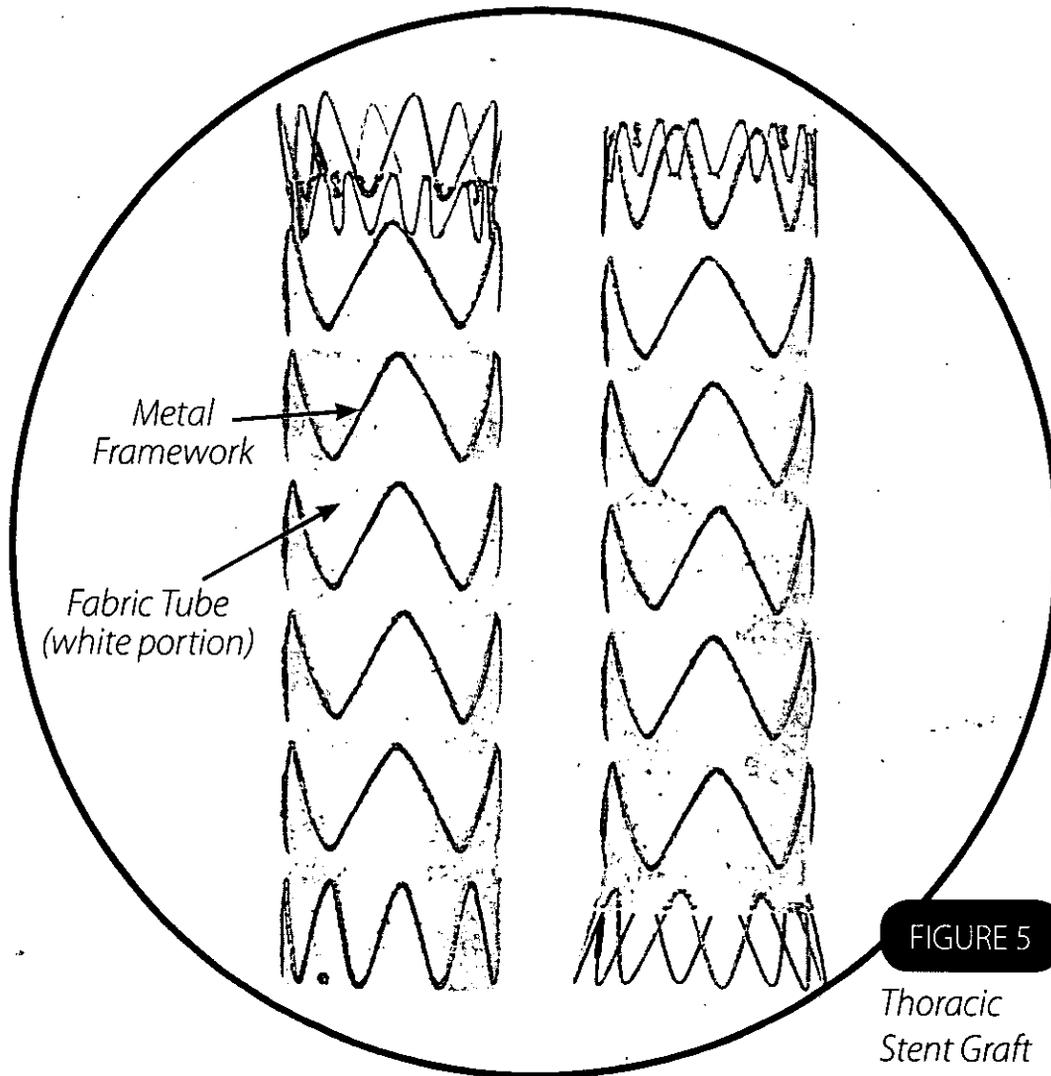
In some patients, the **iliac artery** and **femoral artery** are too narrow for this catheter. In these cases, your doctor will sew a fabric tube to your **iliac artery** and then put the catheter into the vessel.

This procedure takes 1 to 3 hours. After this, you will likely spend 2 to 9 days in the intensive care unit and 5 to 14 days in the hospital. Depending on your other injuries, you may have to stay in the intensive care unit or hospital longer due to treatment of injuries to other parts of your body. You will need 4 to 6 weeks to recover from the **endovascular repair**.



THORACIC STENT GRAFT

The **thoracic stent graft** is a fabric tube supported by a metal framework (Figure 5). A doctor puts it inside your **aorta** at the location of the injury using a catheter. It will help protect your **aorta** from **rupture**.



Note: The size of the stent graft in the figure above is not actual size. Medtronic devices are 80 mm (3.15 in) to 220 mm (8.66 in) long.

IS ENDOVASCULAR REPAIR RIGHT FOR YOU?

If you have the right **anatomy**, an **endovascular repair** procedure may be an option for your treatment.

WHEN ENDOVASCULAR REPAIR IS NOT AN OPTION

If you have a condition that can infect the **stent graft** or if you are allergic to the **stent graft** materials, an **endovascular repair** should not be performed because the graft could get infected or you could have an allergic reaction, both of which could be life-threatening.

Only the doctor can decide which treatment option is right for you.

WARNINGS

The use of **stent grafts** has not been studied in patients who:

- have received a previous **stent graft** in same area of their **aorta**
- have connective tissue disease
- refuse blood **transfusions**
- had a recent **stroke**
- are pregnant
- are less than 18 years old

The physician will need to help you decide whether it is appropriate for you to get a **thoracic stent graft** if any of these situations apply.

The **thoracic stent graft** may not be recommended by your physician if you:

- cannot complete regular follow-up visits and **imaging** examinations
- cannot tolerate **imaging** dyes
- have bleeding disorders
- have kidney disease
- cannot use blood thinners

WHAT SYMPTOMS SHOULD PROMPT YOU TO CALL YOUR DOCTOR AFTER THE PROCEDURE?

If you have any of these symptoms after your **endovascular repair**, call your doctor immediately to discuss these symptoms:

- pain in your back, chest, or groin
- dizziness
- fainting
- rapid heartbeat
- sudden weakness
- pain or numbness in left arm
- pain, numbness, coldness, or weakness in your legs or buttocks

IMPORTANT SAFETY INFORMATION

To better understand the complications and benefits of the **endovascular repair** of **blunt thoracic aortic injuries**, Medtronic conducted a clinical trial within the US and Canada with 50 patients. This trial enrolled patients between the ages of 18 and 74 years old. Most of these patients were involved in motor vehicle accidents and had multiple injuries, including the injury to their **aorta**³. During the trial, there were no issues with the stent graft during the endovascular procedure. There were two patients that had an endoleak during the procedure, but the endoleak went away within 30 days without an additional surgery. Three patients had to have an additional surgery to improve the blood flow to their arms after the endovascular procedure. The doctor can discuss how your situation differs from this patient population.

Many problems experienced after **endovascular repair** do not have symptoms associated with them. You will have to schedule regular follow-up visits with your doctor. This will allow the doctor to check on your progress.

POSSIBLE COMPLICATIONS

Complications associated with **endovascular repair** include, but are not limited to the following²:

The **endovascular stent graft** procedure is a surgical procedure; as such, there are possible complications associated with the procedure. Before deciding if the procedure is right for you, please review the list of possible procedural complications with your doctor:

- **Blood vessel** complications (for example, blood clot or injury to blood vessels)
- Neurological complications (for example, **stroke** or **paraplegia**)
- Cardiopulmonary complications (for example, heart attack)
- Gastrointestinal complications (for example, bowel obstruction)
- Pulmonary complications (for example, **pneumonia**)
- Wound healing complications
- Kidney failure
- Bleeding
- Conversion to **open surgery**
- Death

After your **endovascular repair**, there is a chance that an **endoleak** may occur. If this happens, your doctor may recommend a second **endovascular repair** procedure to treat the **endoleak**. If the **endoleak** is not repaired, the **aorta** could **rupture**.

Complications may be different for each patient. You should ask your doctor to help you understand and use this information.

POSSIBLE BENEFITS OF TREATMENT

Since **BTAI** and other **isolated lesions** can be life-threatening, the biggest benefit of treatment is protection of your **aorta**. Generally, when compared to a surgical procedure, patients who have been treated with **endovascular repair** need fewer hospital days to recover, have a lower risk of death and have a lower risk of complications like bleeding, blood **transfusion, pneumonia, paraplegia, spinal cord ischemia** and **renal failure**.^{1,2} Experts are still studying the long-term results of **endovascular stent graft repair**.³

ENDOVASCULAR STENT GRAFT PROCEDURE

Before the procedure:

Prior to the procedure, **imaging** tests are performed. These tests allow the doctor to assess your **aorta**.

During the procedure:

Typically, the **endovascular repair** procedure takes 1 to 3 hours to complete². You are asleep during the procedure and won't feel any pain.

1. A small cut is made on one side of your groin.
2. A catheter holding the **thoracic stent graft** is inserted into the cut and advanced through the **femoral artery** to reach the location of the **isolated lesion**.

*Note: **Fluoroscopy** is used to guide the catheter to the **isolated lesion**. This requires the use of dyes. If you have kidney problems, the doctor should be notified.*

3. Once the catheter is placed, the **stent graft** is released into your **aorta** (Figure 6).

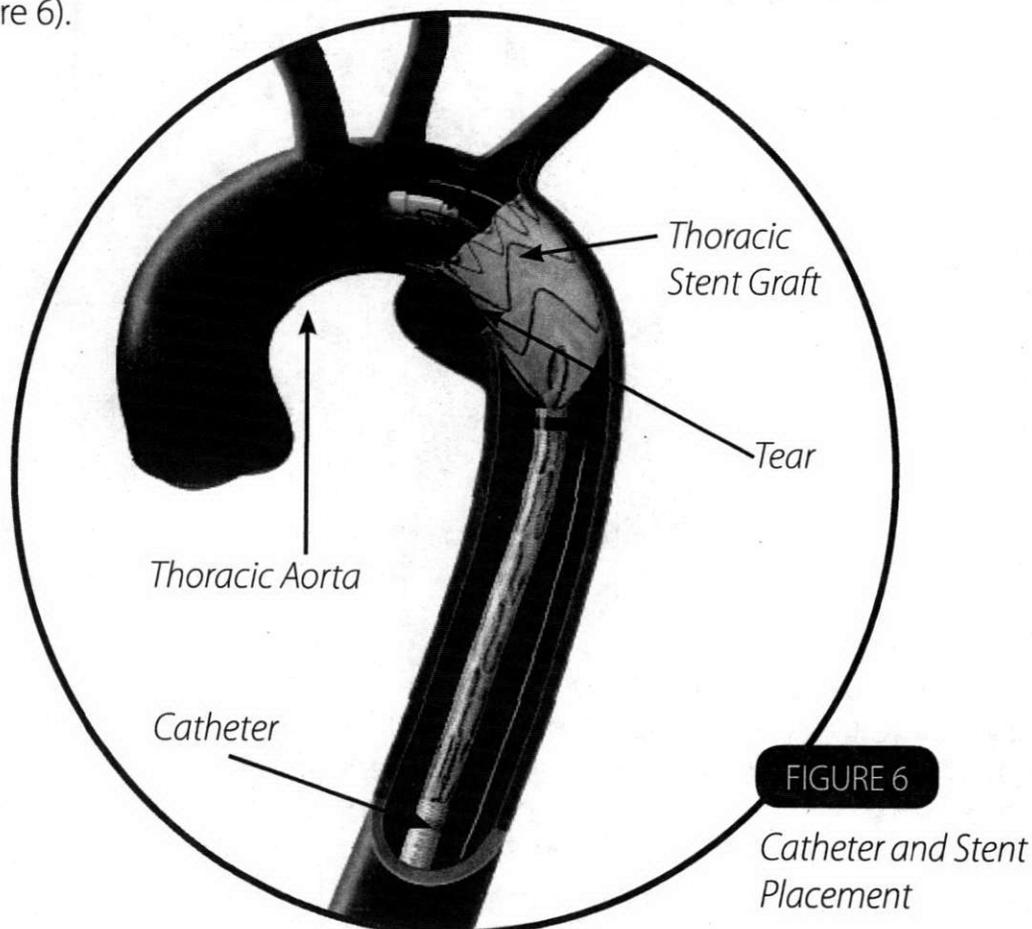


FIGURE 6

Catheter and Stent Placement

Note: Additional stent grafts may be required to completely protect the aorta.

4. When the **stent graft** is released, it expands to its proper size to fit in your **aorta**, at the site of the **isolated lesion** (Figure 7).
5. The catheter is removed and the doctor will test to make sure the stent graft is working properly.
6. The cut in your groin is closed and the procedure is complete.

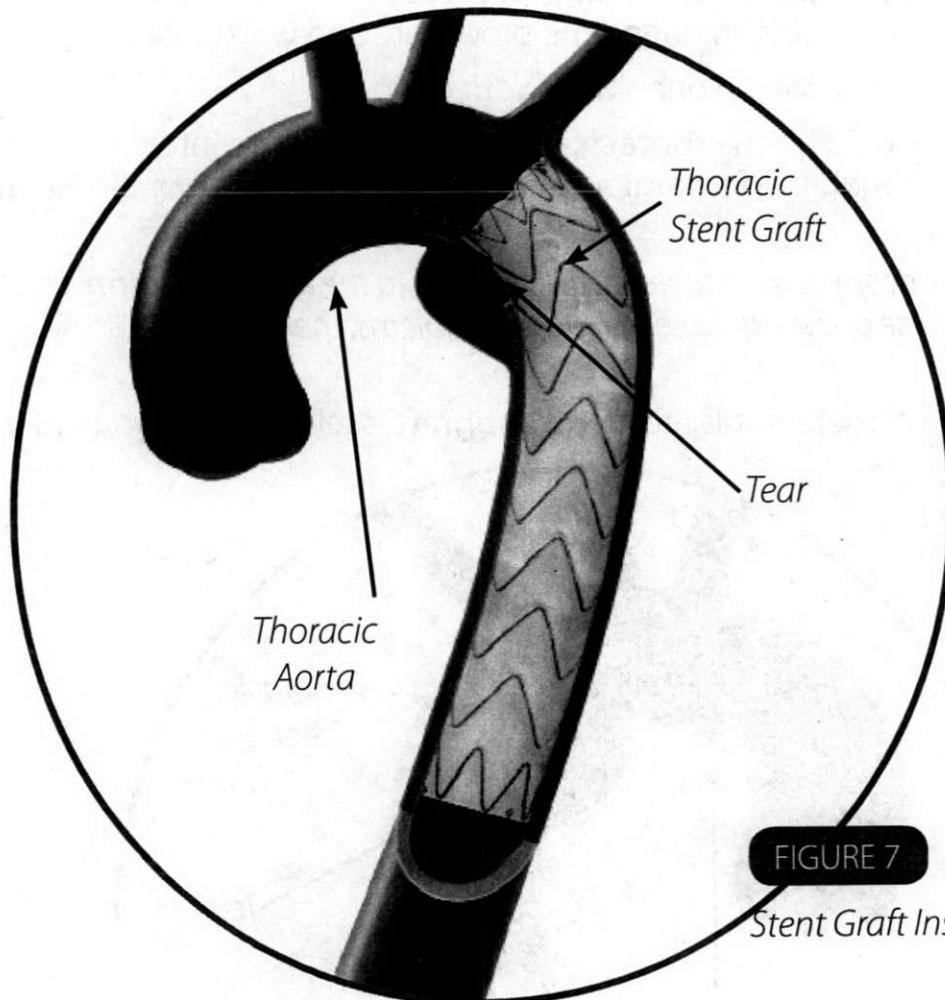


FIGURE 7

Stent Graft Inside Aorta

After the procedure:

After the **endovascular repair**, you will go to a recovery room where you will have to lay flat for up to six hours. This will allow the cut in the groin to start healing. You may feel some discomfort for up to two days. You will likely need to stay in the hospital 7 to 15 days and is dependent on treatment of your other injuries². The doctor will provide you or your caregiver with specific care instructions.

FOLLOW-UP

It is important to schedule regular follow-up visits with your doctor. Again, the long-term effects of **thoracic stent grafts** are not known and since most problems with **endovascular repair** also do not have symptoms, you will need to let your doctor check on your progress regularly. See pages 10, 11 and 12 for important safety information.

Your doctor will schedule follow-up visits depending on your condition. Most often these will occur at one month, one year and then each year thereafter. **Imaging** tests are required to monitor device performance.

IMPLANTED DEVICE IDENTIFICATION CARD

After your procedure, your doctor will give you a temporary implanted device identification (ID) card. This card will tell you the size and number of your **thoracic stent graft** implants.

Medtronic will mail you a permanent implanted device ID card to carry in your wallet. Your permanent ID card will list the following information:

- Type of device implanted
- Date of implant
- Your doctor's information
- **Magnetic Resonance Imaging (MRI)** information

Be sure to tell all of your healthcare providers that you have a **stent graft** and show them your implanted device ID card. You should keep your ID card with you at all times.

MAGNETIC RESONANCE IMAGING

Under certain conditions, after being implanted with a Medtronic thoracic stent graft, it is safe to have Magnetic Resonance Imaging (MRI) procedures.

MRI information is provided on your implanted device ID card. Show this ID card to your healthcare providers.

LIFESTYLE CHANGES

- You will need to go for regular follow-up visits to check your **stent graft**. Please consult your doctor to reschedule any follow-up visits if you are traveling.
- The **thoracic stent graft** is not expected to trigger any passenger screening devices such as airport security scanners.
- Please consult your doctor about your ability to perform strenuous physical activities.

QUESTIONS YOU MAY WANT TO DISCUSS WITH YOUR DOCTOR

- What are the other options for treating my aortic injury?
- Which **stent grafts** are approved for treatment of my aortic injury?
- What are all of the possible complications of an **endovascular repair procedure**?
- What are all of the possible complications of an **open surgical repair procedure**?
- Will my health insurance pay part or all of the cost associated with my **endovascular repair** procedure?
- After the **endovascular repair** procedure, how often must I follow-up with a doctor, and what tests will be done?
- Do I have to limit activities after treatment? If yes, for how long?
- How long can the **stent graft** remain implanted in my body?
- How many **endovascular repair** procedures has this facility performed?

This guide is not a substitute for detailed talks with your doctor. Only your doctor can decide if this procedure is right for you. This therapy is not for everyone. Please consult your doctor. A Prescription is required.

ADDITIONAL INFORMATION

Additional information regarding treatment of your aortic injury can be found at:

www.medlineplus.gov

www.fda.gov

www.vascularweb.org

CONTACTING MEDTRONIC:

If you have any questions concerning a Medtronic thoracic stent graft, you should contact your doctor. It is Medtronic's mission to alleviate pain, restore health and extend life. If there is anything that we as a company can do to assist you, please feel free to contact us at:

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ENDNOTES:

¹Open surgical repair procedure information is from a prospective, multicenter trial. The values for length of procedure, time in ICU, and total time in hospital are estimated from the results for this trial. Reference: "Operative Repair of Endovascular Stent Graft in Blunt Traumatic Thoracic Aortic Injuries: Results of an American Association for the Surgery of Trauma Multicenter Study." Demetriades D et al; J Trauma. 2008; 64; 561-571

²Benefits of endovascular repair in BTAI, including death and complications cited from the reference: "Endovascular repair of traumatic thoracic aortic injury: clinical practice guidelines of the Society for Vascular Surgery." Lee WA et al; J Vasc Surg. 2011; Jan;53(1):187-92.

³RESCUE Trial: Evaluation of Clinical Performance of the Valiant® Thoracic Stent Graft with the Captivia Delivery System for the Endovascular treatment of Blunt Thoracic Aortic Injuries. Values for length of procedure, time in ICU, and total time in hospital are restricted ranges as such that a quarter of patients will spend less time and a quarter will spend more time.

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