Medtronic

The Valiant® Thoracic Stent Graft with the Captivia® Delivery System

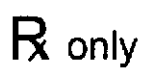
STERILE R

Instructions for Use (IFU)

IMPORTANT!

- Do not attempt to use the **Valiant Thoracic Stent Graft with the Captivia Delivery System** before completely reading and understanding the information contained in the Instructions for Use.
- Carefully inspect all product packaging for damage or defects prior to use. Do not use product if any sign of damage or breach of the sterile barrier is observed.
- These devices are supplied STERILE for single use only. After use, dispose of the delivery system in accordance with hospital, administrative, or government policies. Do not resterilize.
- **Caution:** Federal law (USA) restricts this device for sale by or on the order of a physician.

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)

Distal Bare Spring Straight (Distal Component)

Closed Web Tapered (Distal Component)

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1.0 DEVICE DESCRIPTION

The Valiant® Thoracic Stent Graft with the Captivia® Delivery System is designed for the endovascular repair of fusiform aneurysms and saccular aneurysms/penetrating ulcers of the descending thoracic aorta. 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 9.2 contains detailed sizing information for all stent graft components. Table 1 contains a summary of the 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

Table 1. Stent Graft Materials

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

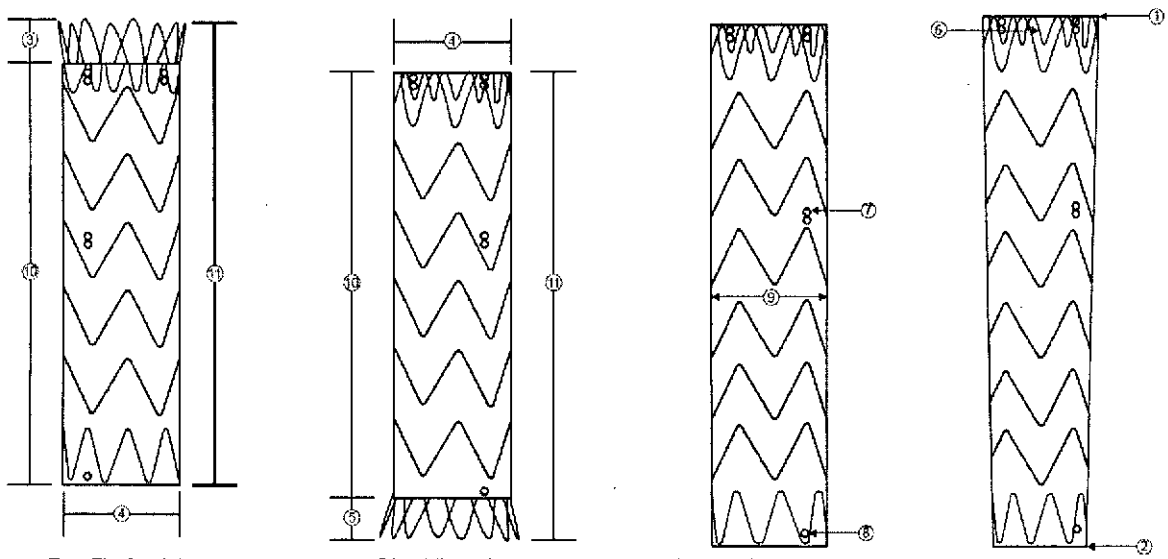

Figure 1. Stent Graft Configuration Components

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.

1. Proximal End
2. Distal End
3. FreeFlo
4. Closed Web
5. Bare Spring
6. Mini Support Spring
7. Figur8 Marker
8. Zer0 Marker
9. Diameter
10. Covered Length
11. Total Length

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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.

1.1.1.1 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.

1.1.1.2 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.

1.1.1.3 Distal Bare Spring Straight 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.

1.1.1.4 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 Taper 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

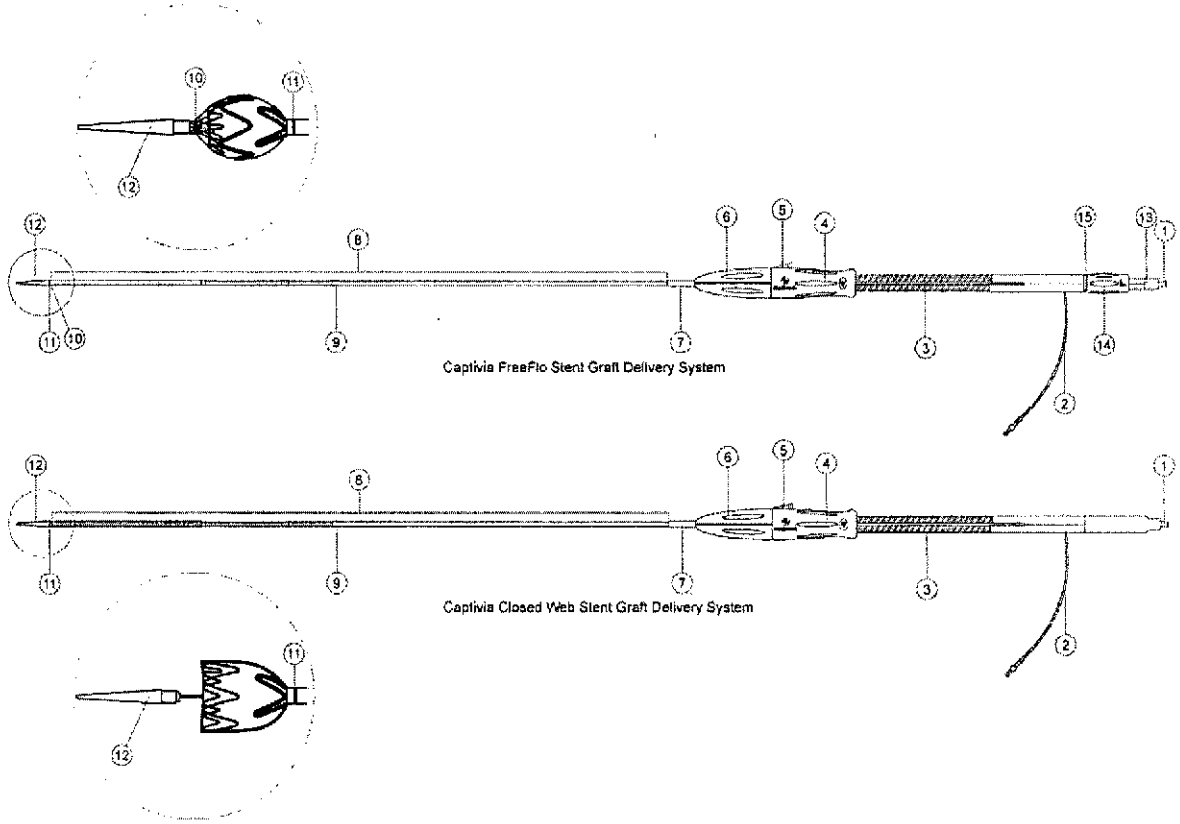

Figure 2 Captivia Stent Graft Delivery Systems

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

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.

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2.0 INDICATIONS FOR USE

The Valiant Thoracic Stent Graft with the Captivia Delivery System is indicated for the endovascular repair of fusiform aneurysms and saccular aneurysms/penetrating ulcers of the descending thoracic aorta in patients having 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
- nonaneurysmal aortic proximal and distal neck lengths ≥20 mm

3.0 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 who are sensitive to or have allergies to the device materials listed in **Table 1**

Also consider the information in Section 4.2, Patient Selection.

4.0 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 teams trained in vascular interventional techniques, including training in the use of this device. Specific training expectations are described in Section 9.1, Physician Training Requirements.
- Always have a vascular surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

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 Sections 9-12.
- 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 Section 9.2, Recommended Device Sizing. Key anatomic elements that may affect successful exclusion of the aneurysm 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 of the Valiant Thoracic Stent Graft with the Captivia Delivery System.
- 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. See Figure 3.

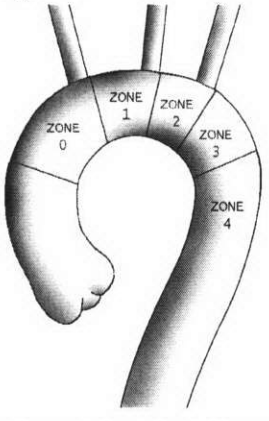

Figure 3: Covered Stent Graft Placement Zones

  - 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 thoracic aneurysm 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 will be undergoing a concommitant 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 is a pregnant female.
- The patient is less than 18 years old.
- The patient has a dissection or transection 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 Section 12, Follow-up Imaging Recommendations.
- Strict adherence to the Valiant Thoracic Stent Graft System sizing guidelines (Tables 22 to 25) 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 aneurysm 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 of 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 Section 9.2, Recommended Device Sizing.
- 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 aortic vessel in the presence of excessive calcification or thrombus formation. See Section 10.5, Positioning the Captivia Delivery System.
- 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 (i.e., Zone 0 or Zone 1) See 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. It is the discretion of the physician to cover the left subclavian artery (LSA) and to check the blood flow at the level of the vertebral or cerebral arteries and the retrograde blood flow at the LSA.

  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 Section 9.5 for more information.

5.0 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	• Endoleaks	• Procedural bleeding
• Adynamic Ileus	• Excessive or inappropriate radiation exposure	• Prosthesis dilatation
• Allergic reaction (to contrast, anti-platelet therapy, stent graft material)	• Extrusion/erosion	• Prosthesis infection
• Amputation	• Failure to deliver the stent graft	• Prosthesis rupture
• Anesthetic complications	• Femoral neuropathy	• Prosthesis thrombosis
• Aneurysm expansion	• Fistula (including aortoenteric, arteriovenous, and lymph)	• Pseudoaneurysm
• Aneurysm rupture	• Gastrointestinal bleeding/complications	• Pulmonary edema
• Angina	• Genitourinary complications	• Pulmonary embolism
• Arrhythmia	• Hematoma	• Reaction to anaesthesia
• Arterial stenosis	• Hemorrhage/bleeding	• Renal failure
• Atelectasis	• Hypotension/hypertension	• Renal insufficiency
• Blindness	• Infection or fever	• Reoperation
• Bowel ischemia	• Insertion or removal difficulty	• Respiratory depression or failure
• Bowel necrosis	• Intercostal pain	• Sepsis
• Bowel obstruction	• Intramural hematoma	• Seroma
• Branch vessel occlusion	• Leg edema/foot edema	• Shock
• Breakage of the metal portion of the device	• Lymphocele	• Spinal neurological deficit
• Buttock claudication	• Myocardial infarction	• Stent graft migration
• Cardiac tamponade	• Neuropathy	• Stent graft misplacement
• Catheter breakage	• Occlusion – Venous or Arterial	• Stent graft occlusion
• Cerebrovascular accident (CVA)/Stroke	• Pain/Reaction at catheter insertion site	• Stent graft twisting or kinking
• Change in mental status	• Paralysis	• Transient ischemic attack (TIA)
• Coagulopathy	• Paraparesis	• Thrombosis
• Congestive heart failure	• Paraplegia	• Tissue necrosis
• Contrast toxicity	• Paresthesia	
• Conversion to surgical repair	• Peripheral ischemia	• Vascular ischemia
• Death	• Peripheral nerve injury	• Vascular trauma
• Deployment difficulties/ failures	• Pneumonia	• Wound dehiscence
• Dissection, perforation, or rupture of the aortic vessel & surrounding vasculature	• Post-implant syndrome	• Wound healing complications
• Embolism	• Post-procedural bleeding	• 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.

6.0 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 3 clinical studies: the Valiant Thoracic Stent Graft Clinical Study (VALOR II), the Valiant Captivia OUS Registry, and the Talent Captivia Study. The purpose of the VALOR II clinical study was 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. The 2 latter studies supplied clinical data on the Captivia Delivery System. Summaries of the studies are provided below.

6.1 VALOR II: VALIANT THORACIC STENT GRAFT PIVOTAL STUDY

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.

6.1.1 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.

6.1.2 Subject Accountability and Follow-up

Detailed subject accountability data, as well as imaging data available for analysis, is presented in Table 2. 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

Table 2: Subject Accountability and Core Lab Imaging Compliance within 12 Months[1]: Valiant Test Group only

	Subject follow-up # (%)			Subjects with imaging (at each time interval) # (%)		Subjects with adequate imaging to assess the parameter # (%)					Subject events occurring before next visit #					
Treatment / follow-up interval	Eligible[1]	Treatment or clinical f/u	Imaging f/u	CT/MR imaging	Chest X-ray	Max ANR diameter	Change in ANR diameter (from 1 month)	Endoleak	Migration (from 1 month)	Integrity	Intent to treat but not implanted	Con-version to surgery	Death	Withdrawal	LTF	Not due for next visit
Originally Enrolled	160	100% (160/160)														
Events between implant and 1 month follow-up visit											3	0	1[3]	0	0	0
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)		95.5% (149/156)						
Events between 1 month and 6 month follow-up visit												0	9	0	0	0
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)	85.7% (126/147)	76.9% (113/147)						
Events between 6 month and 12 months follow-up visit												0	7	0	0	7
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)	82.7% (110/133)						
										Totals	3	0	17[4]	0	0	
										Death post conversion to surgery			0			
										Total deaths			17			

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.

6.1.3 Study Demographics and Baseline Medical History

There were no statistically significant differences in demographic variables between Valiant Test Group and Talent Control Group populations. **Tables 3 through 5** provide the demographics, baseline medical history, and SVS risk classification of both groups.

Table 3: Subject Demographics

	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)	

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.

Table 4: Baseline Medical History

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

[1] Data point was not collected in Talent Control Group.
[2] For 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'.

Table 4b: Anatomic Lesion Type

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)

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

Table 5: Baseline Modified SVS/AAVS Classification

SVS/AAVS Score[1]	VALIANT TEST GROUP % (m/n) (N = 160)	TALENT CONTROL GROUP % (m/n) (N = 195)	p-value[2]
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.

6.1.4 Baseline Aneurysm Data

Tables 6 and 7 provide the baseline aneurysm and anatomical measurements of the Valiant Test Group and the Talent Control Group study populations.

Table 6: Baseline Vessel Dimensions - Core Laboratory Reported

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	

Table 6: Baseline Vessel Dimensions - Core Laboratory Reported

Baseline Vessel Dimension	VALIANT TEST GROUP (N = 160)	TALENT CONTROL GROUP (N = 195)	P-value[1]
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.

Table 7: Baseline Maximum Aneurysm Diameters – Core Laboratory Reported

Diameter (mm)	VALIANT TEST GROUP % (m/n)[1]	TALENT CONTROL GROUP % (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)

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

6.1.5 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. **Tables 8** to **8b** provide a breakdown of the number of devices implanted in both the Valiant Test Group and the Talent Control Group.

Table 8: Number of Devices Implanted

Number of Devices Implanted	VALIANT TEST GROUP % (m/n)[1] N = 160	TALENT CONTROL GROUP % (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)

[1] N is the number of enrolled subjects.
[2] Three enrolled subjects did not receive a stent graft due to a failure to achieve access.

Sizes of Devices Implanted

Table 8a: Devices Implanted by Proximal Diameter

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)

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

Table 8b 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.

Table 8b: Type of Devices Implanted - Valiant Test Group only

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)

[1] m = numbers in subjects who are implanted with the corresponding device, n = total number of implanted subjects.
[2] One subject was implanted with a Closed Web device in the proximal position due to an adjustment in size made at the time of procedure.

6.1.6 Acute Procedural Data

Implant procedure data are presented in **Table 9**.

Table 9: Acute Procedural Details : Valiant Test Group	
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 Access[2]	
Abdominal aortic conduit	1.9% (3/160)
Iliac conduit	13.1% (21/160)
Femoral/Iliac artery	85.6% (137/160)
Anesthesia[2]	
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)

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

6.1.7 Clinical Utility Data

Table 10 presents the clinical utility measures in the Valiant Test Group and the Talent Control Group.

Table 10: Clinical Utility Data

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	6.1±8.9	195	6.4±11.5

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

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6.1.8 Safety Data

6.1.8.1 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 **Table 11**, 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.

Table 11: Primary Safety Endpoint: VALOR II

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.

A Kaplan-Meier analysis of freedom from all-cause mortality was performed and plotted in **Figure 4**.

Figure 4: Kaplan-Meier Curve of Freedom from All-Cause Mortality within 12 Months

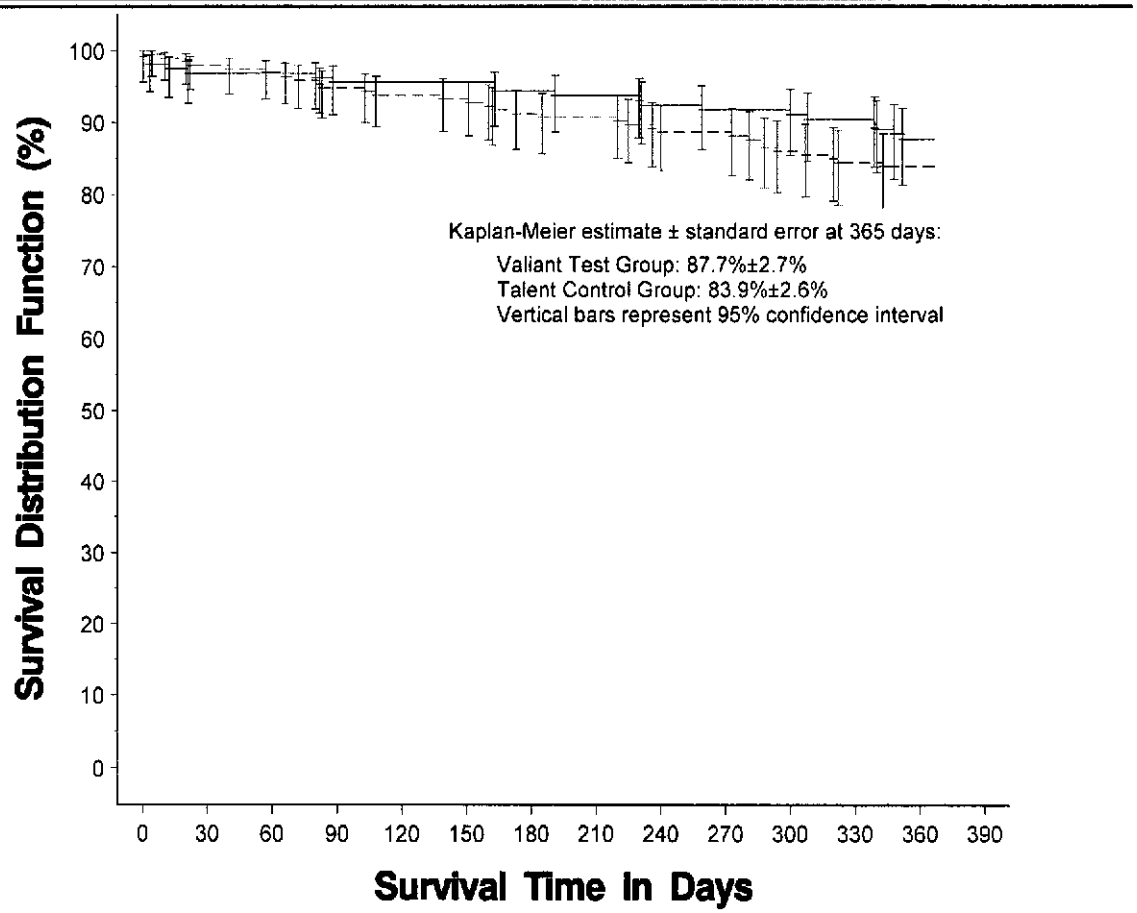

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Table 12: Kaplan-Meier Estimates of Freedom from All-Cause Mortality within 12 Months

	Valiant Test Group			Talent Control Group		
Days	**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.

6.1.8.2 Secondary Safety Endpoints

A summary of secondary safety endpoints is presented in **Table 13**.

Table 13: Summary of Secondary Safety Endpoints

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

6.1.8.2.1 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 1-2 cm proximal to the stent graft to the heart. Three other subjects expired due to pneumonia, respiratory failure, and multisystem organ failure.

6.1.8.2.2 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.

6.1.8.2.3 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 5**.

Figure 5: Kaplan-Meier Curve of Freedom from Aneurysm-Related Mortality within 12 Months: VALOR II

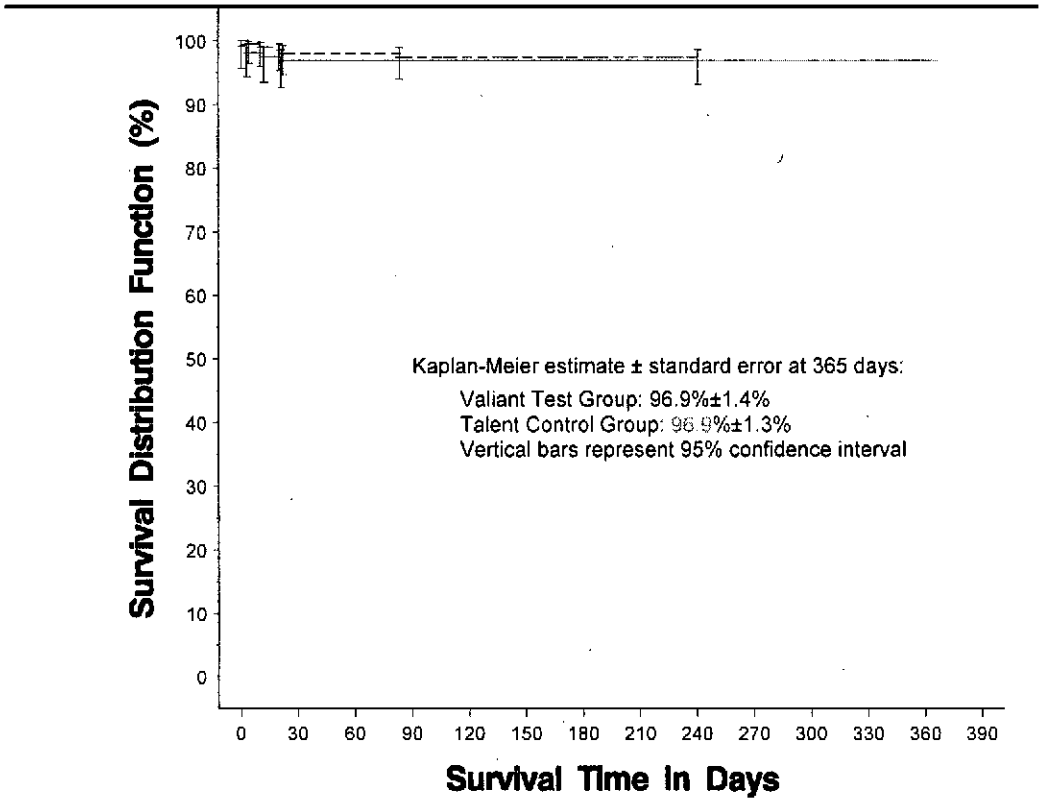


Table 14 : Kaplan-Meier Estimates of Freedom from Aneurysm-Related Mortality within 12 Months

	Valiant Test Group			Talent Control Group		
Days	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]	96.9%	96.9%	96.9%	97.9%	97.4%	96.8%
(2-sided 95% CI)[3]	(92.7%, 98.7%)	(92.7%, 98.7%)	(92.7%, 98.7%)	(94.6%, 99.2%)	(93.9%, 98.9%)	(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.

6.1.8.2.4 Aneurysm Rupture and Conversion to Surgery

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

6.1.8.2.5 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

Table 15 below presents a summary of the CEC reported MAEs through 12 months.

Table 15: Summary of MAEs within 12 Months - CEC Reported

	0-30 days % (m/n)[1]		0-365 days % (m/n)[2]	
Category	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.

6.1.9 Effectiveness Data

6.1.9.1 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.

Table 16: Summary of Primary Effectiveness Endpoint : Valiant Test Group only

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.

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 (**Table 17**). One subject had a distal type Ib endoleak for which a secondary procedure was recommended at the 12-month visit and subsequently performed after 365 days.

Table 17: Change in maximum aneurysm diameter from one month

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.

6.1.9.1.1 Secondary Effectiveness Endpoints

A summary of secondary effectiveness endpoints is presented in **Table 18**. 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.

Table 18: Summary of Secondary Endpoints

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 though 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.

6.2 SUMMARY OF CAPTIVIA DELIVERY SYSTEM CLINICAL STUDIES

Subsequent to the enrollment in the pivotal stent graft study presented above, 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. The following 2 studies were conducted to provide confirmatory clinical information to support the engineering evaluation of the modified delivery system.

6.2.1 Valiant Captivia OUS Registry Summary

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.

6.2.1.1 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.

6.2.1.2 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%).

Table 19: Successful Delivery and Deployment: Valiant Captivia OUS Registry

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

6.2.1.3 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 **Table 20.**

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.

Table 20: Secondary Endpoints: Valiant Captivia OUS Registry

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.

6.2.2 TALENT CAPTIVIA STUDY SUMMARY

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.

6.2.2.1 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.

6.2.2.2 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.

6.2.2.3 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 **Table 21**.

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.

Table 21: Secondary Endpoints: Talent Captivia Study

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] Paraparesis within 30 Days[1]	20% (2/10) 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)

[1]CEC reported
[2]Site reported

7.0 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 Section 9.2, Recommended Device Sizing.

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 Section 9.2, 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 (e.g., cardiac pulmonary or renal insufficiency prior to surgery, morbid obesity, etc.)
- Patient's suitability for open surgical repair
- Patient's anatomical suitability for endovascular repair
- The risk of aneurysm 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
- Nonaneurysmal aortic proximal and distal neck lengths ≥20 mm
- The final treatment decision is at the discretion of the physician and patient

7.2 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 Section 12.
- 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 Section 5, Adverse Events. Medtronic also recommends that detailed patient specific risks also be discussed. Additional counseling information can be found in the Patient Information Booklet.

8.0 HOW SUPPLIED

8.1 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.

8.2 CONTENTS

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

8.3 STORAGE

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

9.0 CLINICAL USE INFORMATION

9.1 PHYSICIAN TRAINING REQUIREMENTS

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

Caution: The Valiant Thoracic Stent Graft with the Captivia Delivery System should only be used by physicians and teams trained in vascular interventional techniques and in 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 aortic aneurysms (TAA), fusiform and saccular aneurysms or penetrating ulcers, and comorbidities associated with TAA
- radiographic, fluoroscopic, and angiographic image interpretation
- angioplasty
- appropriate use of radiographic contrast material
- embolization
- endovascular stent graft placement
- femoral cutdown, arteriotomy, and repair
- nonselective and selective guidewire and catheter techniques
- snare techniques
- techniques to minimize radiation exposure
- device selection and sizing
- percutaneous access and closure techniques

9.2 RECOMMENDED DEVICE SIZING

Medtronic recommends that the Valiant Thoracic Stent Graft with the Captivia Delivery System be used according to the sizing guidelines in Tables 22 through 25. 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 nonaneurysmal vessel using the sizing guidelines to ensure appropriate radial fixation. Strict adherence to the sizing guidelines is expected when selecting the appropriate device size. Tables 22 to 25 describes 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 potentially result in endoleak, fracture, migration, infolding, or graft wear.

OD (Fr)	Proximal x Distal Diameter (mm)	Covered Length (mm)	Native Vessel Inner Diameter (mm)	Suggested Oversizing 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 22: FreeFlo Straight Configuration (Proximal Component) Sizing Guidelines

OD (Fr)	Proximal x Distal Diameter (mm)	Covered Length (mm)	Native Vessel Inner Diameter (mm)	Suggested Oversizing 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 23: Closed Web Straight Configuration (Distal Component) Sizing Guidelines

OD (Fr)	Proximal x Distal Diameter (mm)	Covered Length (mm)	Native Vessel Inner Diameter (mm)	Suggested Oversizing 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 24: 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 Oversizing 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

Table 25: Closed Web Taper Configuration (Distal Component) Sizing Guidelines

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 nondiseased vessel (i.e. in the aneurysm 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 Tables 22 to 25. 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 component sections may vary, depending on the diameter of the aorta proximal to and distal to the lesion. Table 26 should be followed to determine the order of deployment when using multiple stent graft component sections.

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.

	Proximal Aortic Diameter = Distal Aortic Diameter	Proximal Aortic Diameter > Distal Aortic Diameter*	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

** Use this option when implanting the proximal section first to avoid oversizing beyond the recommendations in Tables 22 to 25*

Table 26: Order of Deployment When Using Multiple Stent Graft Component Sections

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.

9.3 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.

9.4 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

9.5 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.[1*]

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 Siemens TrioTim (GE Signa HDx) MR scanner.*

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 non-clinical testing in a 3.0 tesla Siemens TrioTim (GE Signa HDx) MR system 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.

10.0 IMPLANT INSTRUCTIONS

10.1 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 – 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.

10.2 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 Tables 22 to 25, Valiant Thoracic Stent Graft Sizing Guidelines 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 45-60 degrees Left Anterior Oblique (LAO) should be chosen.

[1*] 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).

* Siemens and Tim are registered trademarks of Siemens Aktiengesellschaft.

10.3 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 6, the handle should not be able to rotate clockwise.

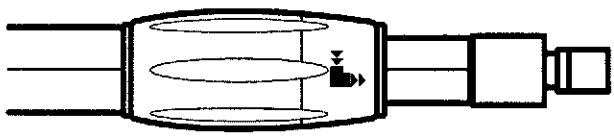


Figure 6: Tip Capture Release Handle in Locked Position

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.

10.4 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.

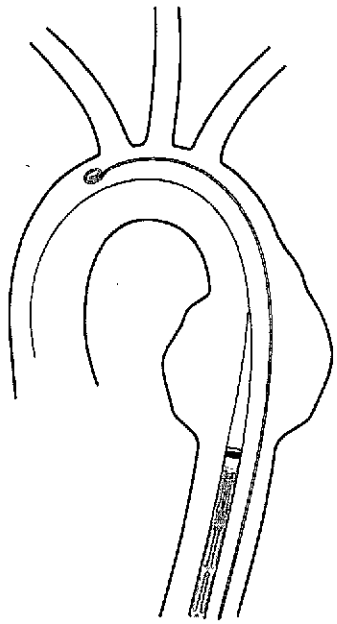


Figure 7: Introducing the Captivia Delivery System

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.

10.5 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.
2. 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.

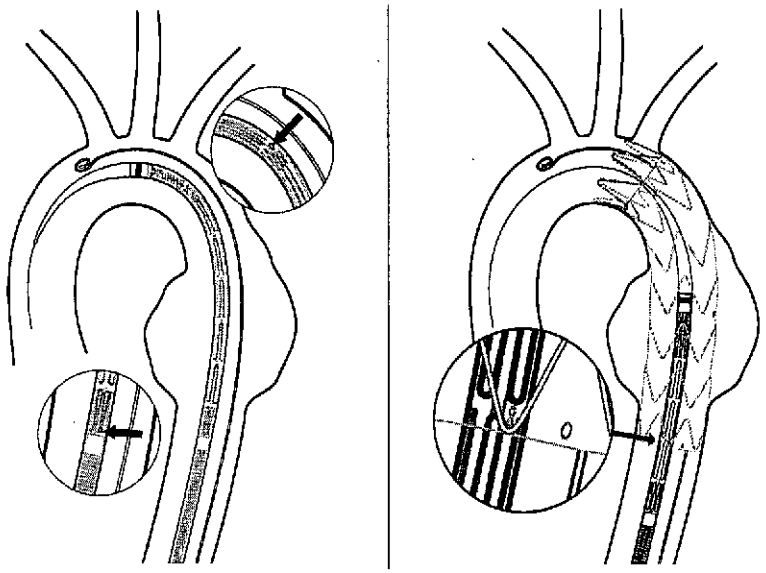
Caution: Be sure to avoid or compensate for parallax or other sources of visualization error.

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.

10.6 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 8). Placement of the distal end is verified by ensuring that the distal Zer0 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 Section 10.11.



Confirming position with Proximal Figur8 Markers and Distal Zer0 Markers

Confirming position of overlapping grafts with Figur8 Mid-Marker and Distal Zer0 Marker (An implanted FreeFlo configuration is shown in this image)

Figure 8: 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 Zer0 markers of the proximal graft with the single Figur8 Mid-Marker of the distal graft. See Section 10.11, Implanting Additional Sections.

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.

10.7 DEPLOYING THE VALIANT THORACIC STENT GRAFT

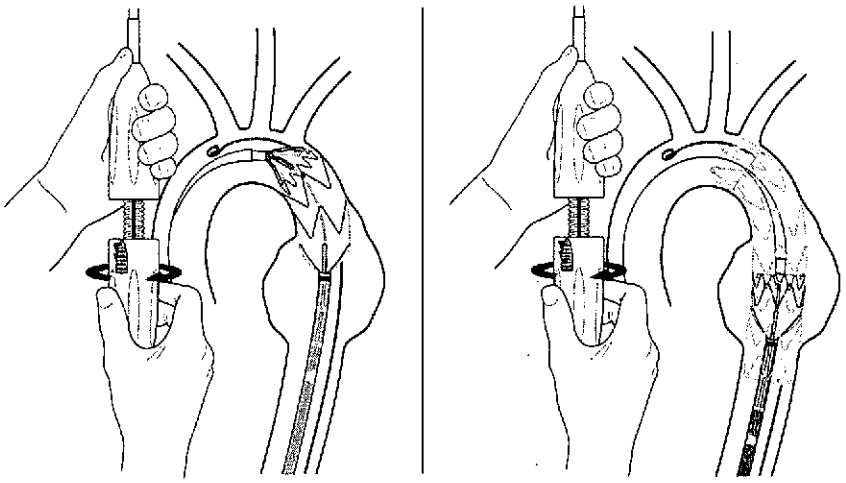
1. Decreasing Mean Arterial Blood Pressure (MAP) - Upon confirmation that the Captivia Delivery System is positioned properly, it may be appropriate to momentarily decrease the patient's MAP to approximately 80 mmHg (at the discretion of the physician) to avoid inadvertent displacement of the Valiant Thoracic Stent Graft upon withdrawal of the graft cover.

2. Deploying Proximal End - First hold the delivery system stationary with one 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.[1*]

   For the Closed Web Stent Graft Delivery Systems: Withdraw the graft cover until up to 2 covered (body) stents are exposed.[1*]

   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 9: 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.

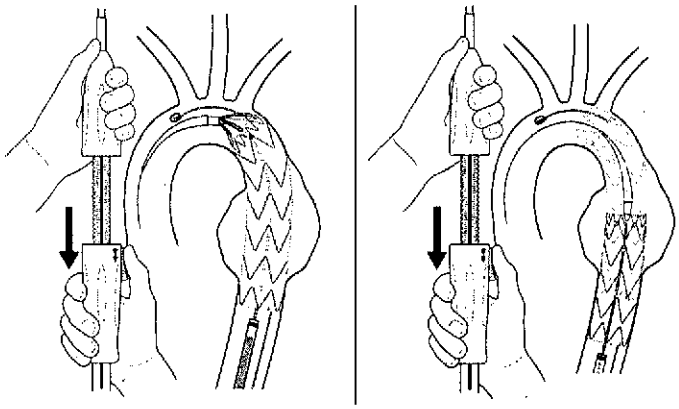
Caution: Ensure that the Valiant devices are placed in a landing zone comprised of healthy tissue. Healthy tissue is defined as tissue without evidence of circumferential thrombus, intramural hematoma, dissection, ulceration, or aneurysmal involvement. Failure to do so may result in inadequate exclusion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

[1*] 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 Section 11, Bail-Out Techniques.



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 10: 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 Section 11.1.

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.

10.8 DEPLOYING TIP CAPTURE MECHANISM (ON THE FREEFLO SYSTEM ONLY)

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

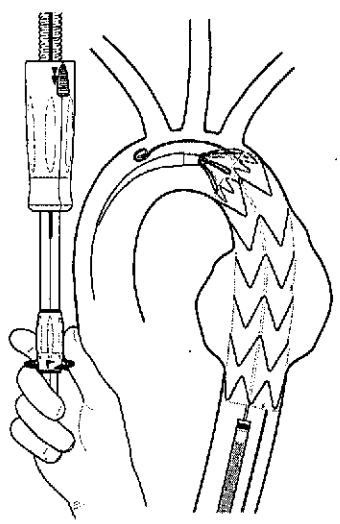


Figure 11: Unlocking the Tip Capture Release Handle

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 (see Figure 12). Observe the opening of the bare stent under fluoroscopy and confirm that the proximal bare stent has been completely deployed.

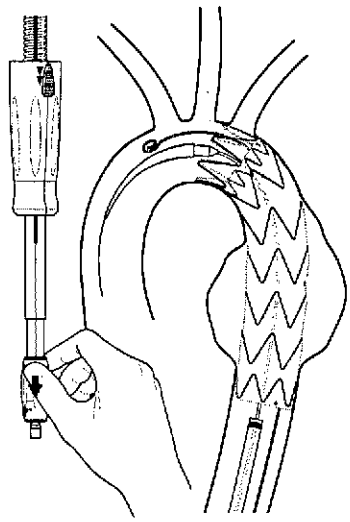


Figure 12: Deploying the Tip Capture Mechanism

Note: In the unlikely event that the proximal bare stent of the FreeFlo configuration cannot be deployed, refer to section 11, Bail-Out Techniques.

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 Section 10.9, Delivery System Removal. Doing so may cause the tip capture mechanism to get caught on the proximal bare stent.

10.9 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 13. 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.

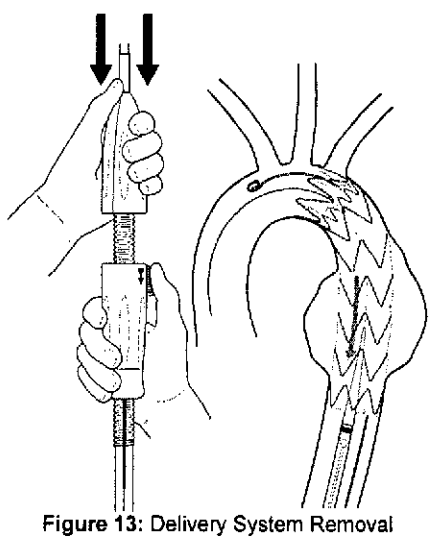


Figure 13: Delivery System Removal

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.

10.10 SMOOTHING STENT GRAFT FABRIC AND MODELING THE STENT GRAFT

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. See Figure 14. 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.

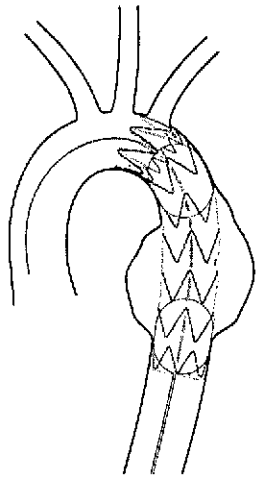


Figure 14: Balloon Modeling of the Stent Graft

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 and/or rupture, and possible patient death, if the balloon's proximal and distal radiopaque markers are not completely within the coveted (graft fabric) portion of the prosthesis.

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.

10.11 IMPLANTING ADDITIONAL SECTIONS

If 2 or more Valiant Thoracic Stent Graft sections 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.

1. Refer to Section 10.3, Preparation of the Valiant Thoracic Stent Graft with the Captivia Delivery System.
2. Refer to Section 10.4, Introducing the Captivia Delivery System. 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 Section 10.5, Positioning the Captivia Delivery System.
4. Refer to Section 10.6, Confirming Stent Graft Position. Radiographically verify that the Zer0 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. See Figure 8, Figure 15, and Figure 16. 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.

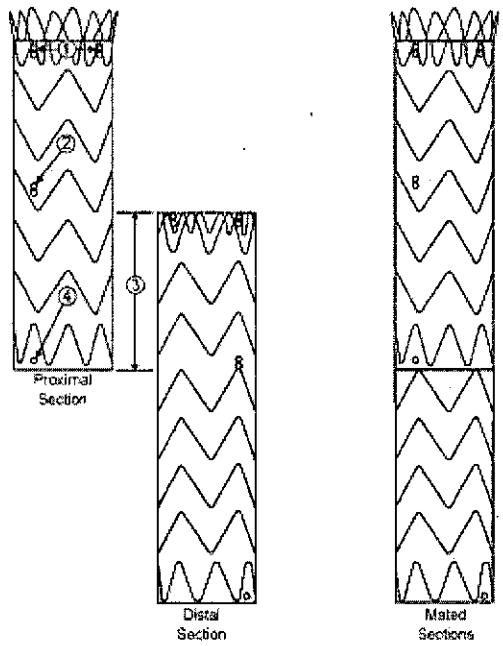


Figure 15: Alignment of Additional Sections (First Graft Placed Proximally)
Minimum overlap is achieved by aligning the Zer0 marker on the proximal section with the Figur8 Mid-Marker on the distal section.

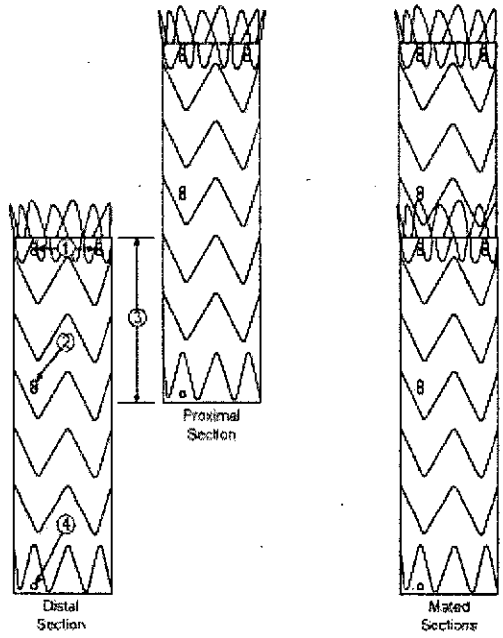


Figure 16: Alignment of Additional Sections (First Graft Placed Distally)
Minimum overlap is achieved by aligning the Zer0 marker on the proximal section with the Figur8 Mid-Marker on the distal section.

1. Proximal Figur8 Marker
2. Figur8 Mid-Marker
3. Minimum Required Overlap
4. Distal Zer0 Marker

5. Refer to Section 10.7, Deploying the Valiant Thoracic Stent Graft.
6. If the additional section is a FreeFlo Straight Configuration Stent Graft, refer to Section 10.8, Deploying Tip Capture Mechanism.
7. Refer to Section 10.9, Delivery System Removal.
8. Refer to Section 10.10, Smoothing Stent Graft Fabric and Modeling the Stent Graft.

10.12 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 (See Section 10.11). 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 aneurysm.

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.

10.13 ENTRY SITE CLOSURE

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

11.0 BAIL-OUT TECHNIQUES

11.1 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 per Section 10.8.
9. Remove the delivery system by gripping the screw gear and withdrawing from the patient.

11.2 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 13.
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.

12.0 FOLLOW-UP IMAGING RECOMMENDATIONS

12.1 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)

Table 27 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.

Table 27: Imaging Recommendations

12.2 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.

12.3 CTA IMAGES

CTA images are recommended pre-treatment (within 3 months of implant) 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 28 for optimal CTA results.

- 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 relandmark 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 28** lists examples of accepted imaging protocols.

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))

Table 28: CTA Imaging Guidelines

12.4 X-RAY

Chest X-rays should be used to assess the presence of stent graft fracture. 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.

12.5 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/mrimanuals. Specific information on MRI can be found in Section 9.5, MRI Information.

12.6 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.

13.0 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.

14.0 DISCLAIMER OF WARRANTY

ALTHOUGH THE MEDTRONIC VASCULAR VALIANT THORACIC STENT GRAFT WITH THE CAPTIVIA DELIVERY SYSTEM HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, MEDTRONIC, INC., MEDTRONIC VASCULAR, INC. AND THEIR RESPECTIVE AFFILIATES (COLLECTIVELY "MEDTRONIC") HAVE NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS PRODUCT IS USED. MEDTRONIC, THEREFORE, DISCLAIMS ALL WARRANTIES, BOTH EXPRESSED AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. MEDTRONIC SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE, OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT, OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND MEDTRONIC TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

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15.0 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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