Medtronic

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TALENT™ THORACIC STENT GRAFT SYSTEM

INSTRUCTIONS FOR USE

STERILE EO

IMPORTANT!

- Do not attempt to use the Talent Thoracic Stent Graft System before completely reading and understanding the information contained in this booklet.
- 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 and/or government policies. Do not resterilize.
- Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.

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1.0 Introduction

The Talent™ Thoracic Stent Graft System is intended 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.

2.0 Device Description

2.1 Talent Thoracic Stent Graft System

The Talent Thoracic Stent Graft System includes:

- The Talent Thoracic Stent Graft
- The CoilTrac Delivery System

The Talent Thoracic Stent Graft is pre-loaded into the CoilTrac Delivery System. The loaded delivery system 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.

2.2 Talent Thoracic Stent Graft

The Talent Thoracic Stent Graft is composed of a series of shaped, sinusoidal, self-expanding nitinol wire rings which act as springs that are stacked in a tubular arrangement to form a self expanding nitinol structure. Proximal and distal springs of the stent graft are connected by a full-length connecting bar. The self-expanding nitinol structure is covered by a mono-filament polyester woven graft. The graft material is sewn to the nitinol structure, which securely incorporates the springs into the graft. Radiopaque markers, made out of platinum-iridium in shape of a figure eight (known as Figur8™), are sewn to the graft to help visualize and identify: the edge of the graft material, the location of the connecting bar, and the minimum overlap required when multiple stent grafts are used. A support spring surrounding the proximal edge of the graft material is also used in some configurations. Table 1 lists the materials comprising the stent graft.

Table 1 – Stent Graft Materials

Stent Graft Component	Material
Springs	Nitinol wire (55% Nickel, balance Titanium with trace elements)
Connecting Bar	Nitinol wire (55% Nickel, balance Titanium with trace elements)
Support Spring (FreeFlo™ only)	Nitinol wire (55% Nickel, balance Titanium with trace elements)
Stent Fabric	High-density woven mono-filament polyester
Sutures	Braided polyester suture
Radiopaque Markers	Figur 8 Platinum Iridium wire

The Talent Thoracic Stent Graft System is a modular device system that accommodates the use of multiple stent graft sections. Depending on the patient's anatomy, single or multiple stent grafts may be required to achieve sufficient coverage and exclude the target lesion. Table 2 summarizes the features of various modular stent graft component sections. Each component section is described in detail below.

Table 2 - Talent Thoracic Stent Graft Summary

Component	Proximal End Configuration	Distal End Configuration	Total Length	Covered Length	Available Diameters	Straight or Tapered Tube
Proximal Main Section	FreeFlo (>22mm) Bare Spring (22mm)	Closed Web	130mm	112-116mm	22mm – 46mm	Straight Tube
Distal Main Section	Open Web	Closed Web	130mm	110-114mm	26mm – 46mm	Tapered Tube
Proximal Extension	FreeFlo (Bare Spring with Support Spring)	Open Web	80-90mm	46-54mm	26mm – 46mm	Straight Tube
Distal Extension	Open Web	Bare Spring	80-90mm	46-54mm	26mm – 46mm	Straight Tube

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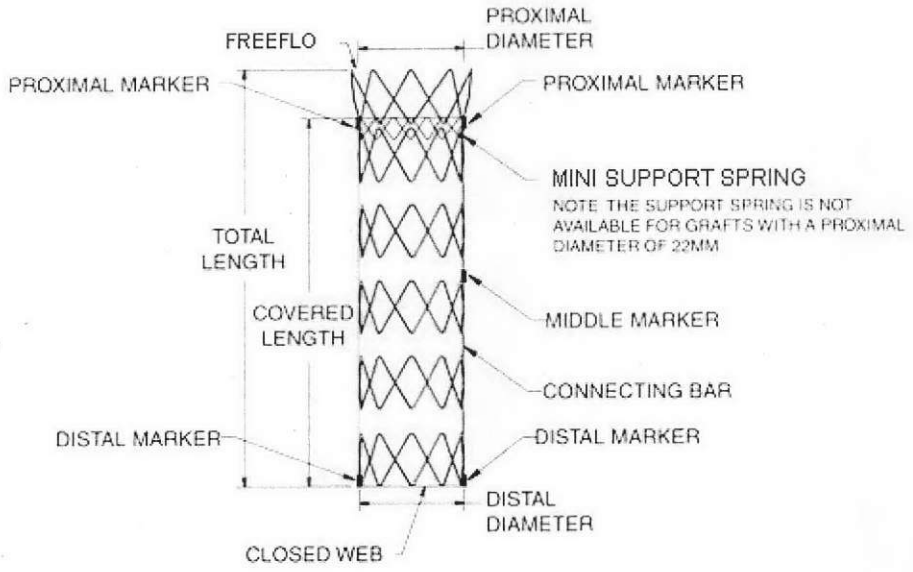
2.2.1 Proximal Main Section

The proximal main section has an uncovered nitinol spring as the proximal end configuration, which allows for trans-vessel flow. Proximal main stent grafts with a proximal diameter greater than 22mm have a mini-support spring to aid in sealing. The proximal end configuration in which an uncovered nitinol spring and mini-support spring are present is called the 'FreeFlo' configuration. The proximal end configuration in which an uncovered nitinol spring is present without a mini-support spring is called a 'Bare Spring' configuration. The distal end of the stent graft has a Closed Web configuration. The two proximal markers and two distal markers indicate the ends of the covered portion of the stent graft. The middle marker indicates the rotational position of the connecting bar. See Figure 1.

Figure 1 - Thoracic Stent Graft - Main Section



[GRAPHICAL REPRESENTATION ONLY. MAY APPEAR DIFFERENTLY UNDER FLUOROSCOPY]

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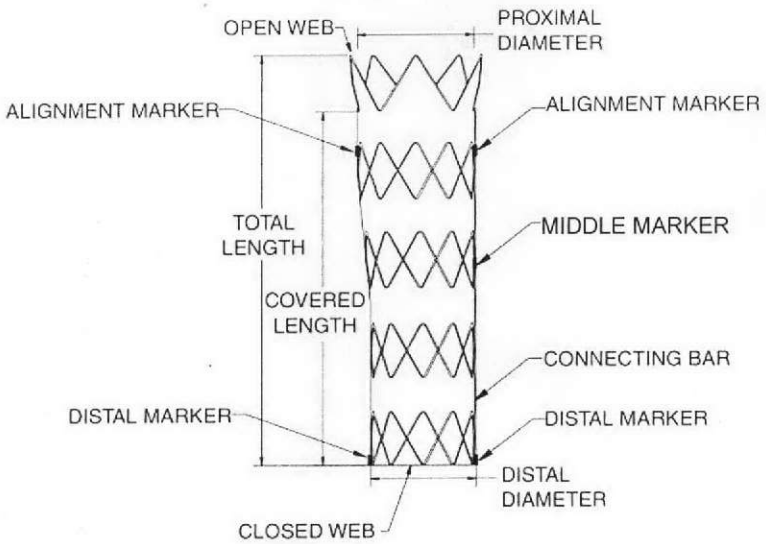
2.2.2 Distal Main Section

Distal main sections are used to increase the length of coverage of the treated vessel when the proximal main section is inadequate in length to exclude the aneurysm. The proximal end of the distal main section utilizes a configuration in which the outline of the most proximal spring is covered with fabric leaving a "tulip" effect, called Open Web. The distal end of the distal main section is a Closed Web configuration. Two alignment markers are used to indicate the 30mm minimum overlap with the mating graft. The two distal markers indicate the bottom edge of the covered portion of the stent graft. The middle marker indicates the rotational position of the connecting bar. See Figure 2.

Figure 2 - Thoracic Stent Graft - Additional Distal Main Section

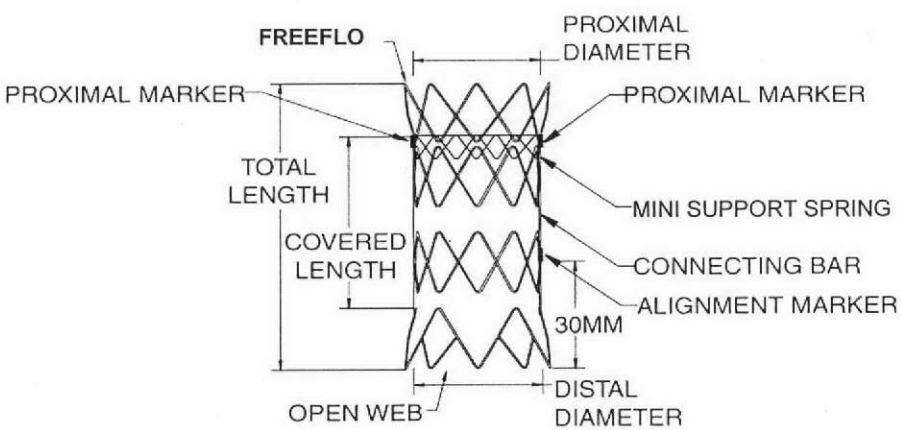


[GRAPHICAL REPRESENTATION ONLY. MAY APPEAR DIFFERENTLY UNDER FLUOROSCOPY]

2.2.3 Proximal Extension

Proximal extensions are intended to be used when the proximal end of the stent graft requires extension to fully exclude the target lesion, or to treat proximal Type I endoleaks. The proximal extension is deployed within the proximal end of the proximal main section. The proximal end of the proximal extension section has a FreeFlo configuration, which allows for trans-vessel flow. The distal end of the proximal extension section has an Open Web configuration. The two proximal markers indicate the top edge of the covered stent graft. The single alignment marker is used to indicate the 30mm minimum overlap with the mating graft, as well as the rotational location of the connecting bar. See Figure 3.

Figure 3 - Thoracic Stent Graft - Proximal Extension

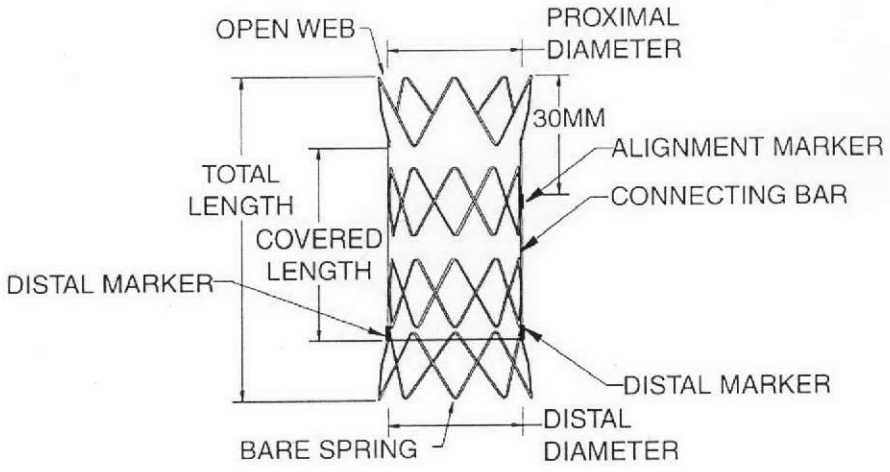


[GRAPHICAL REPRESENTATION ONLY. MAY APPEAR DIFFERENTLY UNDER FLUOROSCOPY]

2.2.4 Distal Extension

Distal extensions are intended to be used when the distal end of the stent graft requires extension to fully exclude the target lesion, or to treat distal Type I endoleaks. The distal extension is deployed in the distal end of the proximal main or distal main section and extends distally. The proximal end has an Open Web configuration. The distal end has a bare spring extending beyond the edge of the fabric, which allows for trans-vessel flow. The single "alignment marker" indicates the 30mm minimum overlap with the mating graft, as well as the rotational position of the connecting bar. The two distal markers indicate the bottom edge of the covered portion of the stent graft. See Figure 4.

Figure 4 - Thoracic Stent Graft - Distal Extension



[GRAPHICAL REPRESENTATION ONLY. MAY APPEAR DIFFERENTLY UNDER FLUOROSCOPY]

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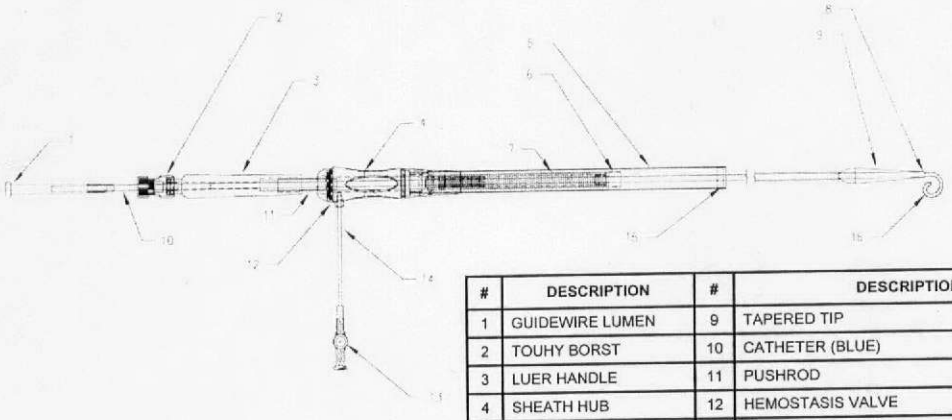
2.3 CoilTrac Delivery System

The CoilTrac Delivery System is composed of an inner (blue) catheter with a tapered tip, a luer handle connected to a push rod shaft with spring and cup plunger, and a sheath hub connected to the graft cover. The inner (blue) catheter allows tracking of the system over an 0.035" guidewire. The luer handle and push rod shaft with spring and cup plunger is the deployment platform. The graft cover is for graft containment and deployment. The nose of the system is a flexible tapered tip. The graft cover has a hemostasis valve at its proximal section and a radiopaque marker band at its distal end. The hemostasis valve function is to minimize leaking and blood loss during the procedure. The radiopaque marker indicates the distal end of the sheath under fluoroscopy. See Figure 5.

Figure 5 - CoilTrac Delivery System



#	DESCRIPTION	#	DESCRIPTION
1	GUIDEWIRE LUMEN	9	TAPERED TIP
2	TOUHY BORST	10	CATHETER (BLUE)
3	LUER HANDLE	11	PUSHROD
4	SHEATH HUB	12	HEMOSTASIS VALVE
5	GRAFT COVER	13	STOPCOCK
6	CUP PLUNGER	14	SIDE PORT EXTENSION
7	PUSHROD SPING COIL	15	RADIOPAQUE MARKER
8	DISTAL PORT	16	TRANSPORT WIRE (REMOVE BEFORE USE)

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3.0 Indications for Use

The Talent Thoracic Stent Graft System is intended for the endovascular repair of fusiform aneurysms and saccular aneurysms/penetrating ulcers of the descending thoracic aorta in patients having appropriate anatomy, including:

- iliac/femoral access vessel morphology that is compatible with vascular access techniques, devices, and/or accessories;
- non-aneurysmal aortic diameter in the range of 18 – 42mm; and
- non-aneurysmal aortic proximal and distal neck lengths ≥ 20mm

4.0 Contraindications

The Talent Thoracic Stent Graft is contraindicated in:

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

5.0 Warnings and Precautions

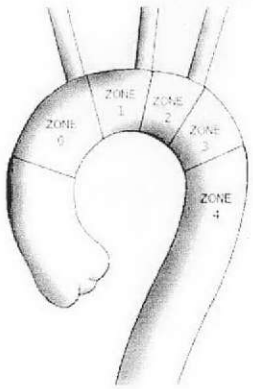
5.1 General

- Read all instructions carefully. Failure to properly follow the instructions, warnings and precautions may lead to serious consequences or injury to the patient
- The Talent Thoracic Stent Graft 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 11.1
- Always have a vascular surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary

5.2 Patient Selection, Treatment and Follow-Up

- Do not attempt to use the Talent Thoracic Stent Graft with the CoilTrac Delivery System in patients unable to undergo the necessary preoperative and postoperative imaging and implantation studies as described in Section 13.0.
- The Talent Thoracic Stent Graft System is not recommended in patients who cannot tolerate contrast agents necessary for intra-operative and post-operative follow-up imaging.
- The Talent Thoracic Stent Graft System is not recommended in patients exceeding weight and/or size limits which compromise or prevent the necessary imaging requirements
- Prior to the procedure, pre-operative planning for access and placement should be performed. See Section 11.3. Key anatomic elements that may affect successful exclusion of the aneurysm include severe neck angulation, short aortic neck(s) and significant thrombus and/or calcium at the arterial implantation sites. In the presence of anatomical limitations, a longer neck length may be required to obtain adequate sealing and fixation.
- The use of this device requires administration of radiographic agents. Patients with preexisting renal insufficiency may have an increased risk of renal failure postoperatively
- The safety and effectiveness of this device in the treatment of dissections have not been established. In the first 10 years of clinical experience (OUS-commercial and US-investigational), there were 39 reported events of retrograde dissection in patients. Of the 39 reported events, 33 patients had a pre-existing aortic dissection.
- Inappropriate patient selection may contribute to poor device performance.
- The safety and effectiveness of the Talent Thoracic Stent Graft has not been evaluated in the following patient situations and/or populations in which:
  - Planned placement of the COVERED (top edge of fabric) portion of the stent graft requires implant to occur in zones 0 or 1 (See Figure 6).

Figure 6- Covered Portion (Top of Fabric) 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.

- Patient requires a planned aortic conduit.
- Patient has a thoracic aneurysm with a contained rupture.
- Patient has a connective tissue disease (e.g., Marfan's syndrome, medial degeneration).
- Patient has received a previous stent and/or stent graft or previous surgical repair in the descending thoracic aortic area.
- Patient requires treatment of an infra-renal aneurysm at the time of implant.
- Patient has had previous surgical or endovascular treatment of an infra-renal aortic aneurysm.
- Patient has a history of bleeding diathesis, coagulopathy, or refuses blood transfusions.
- Patient has had a recent (within three (3) months) Cerebral Vascular Accident (CVA).
- The patient has a known hypersensitivity or contraindication to anticoagulants or contrast media, which is not amenable to pre-treatment.
- The presence of significant and/or circumferential aortic mural thrombus at either the proximal or distal attachment sites that would compromise fixation and seal of the implanted stent graft.
- Pregnant females
- Patients less than 18 years old

- The long-term safety and effectiveness of this implant have not been established. All patients with endovascular aneurysm repair must undergo periodic imaging to evaluate the stent graft and aneurysm size. Significant aneurysm enlargement (>5 mm), the appearance of a new endoleak, or migration resulting in an inadequate seal zone should prompt further investigation and may indicate the need for additional intervention or surgical conversion.

- Intervention or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aneurysms and/or endoleak. An increase in aneurysm size and/or persistent endoleak may lead to aneurysm rupture.

5.3 Implant Procedure

- Oversizing of the stent graft to vessel more than 10% may be unsafe, especially in the presence of dissecting tissue or intramural hematoma.

- A seal zone less than 20mm could increase the risk of endoleak or migration of the stent graft. Migration may also be caused by deployment of the proximal spring into a thrombus-filled or severely angled vessel wall.

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

- Deployment of the Stent Graft in curvature, especially in the transverse arch, may result in misaligned deployment of the proximal stent structure. In rare instances, this may result in mal-apposition of the proximal stent(s) and incomplete seal with clinical impact, including evidence of endoleak or luminal narrowing of the endograft. In the first 10 years of clinical experience (OUS-commercial and US-investigational), there were 10 reported events of misaligned opening/deployment.

- Wrinkling of graft material may promote thrombus formation. Inflate a conformable balloon within the deployed stent graft lumen to reduce wrinkling of the graft material.

- Use the Reliant Stent Graft Balloon Catheter according to the instructions for use supplied with the Reliant Device. Do not attempt to use the Reliant Stent Graft Balloon Catheter before completely reading and understanding the information supplied with the Reliant Device.

- Do not use the Reliant Stent Graft Balloon Catheter in patients with history of thoracic dissection disease. Do not over-inflate the Reliant Stent Graft balloon within or outside of the graft material.
- 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 covered (graft fabric) portion of the prosthesis.
- Failure to align the connecting bar with the outer bend of the target vessel may increase the likelihood of endoleaks post implantation.
- Never advance the CoilTrac Delivery System by the pushrod; this may cause inadvertent deployment. Excessive bending or kinking of the delivery system may inhibit its ability to properly deploy the Talent Thoracic Stent Graft.
- 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.
- Do not advance the Talent Thoracic System with an exposed proximal stent as it may lead to misaligned deployment and/or aortic perforation. In the first 10 years of clinical experience (OUS-commercial and US-investigational), there were 10 reported events of misaligned opening/deployment and 8 reported events of aortic perforation.
- The proximal edge of the covered portion of the Stent Graft should not be placed beyond the origin of the left common carotid artery (i.e., Zone 0 or Zone 1, See Figure 6).
- Ensure that the proximal and distal springs are placed in an adequate landing zone comprised of healthy tissue. Healthy tissue is defined as tissue without evidence of circumferential thrombus, intramural hematoma, dissection, ulceration, and/or aneurysmal involvement. Failure to do so may result in inadequate exclusion or vessel damage, including perforation.
- Any endoleak left untreated during the implantation procedure must be carefully followed after implantation.

5.4 Magnetic Resonance Imaging (MRI)

MRI may be used on the graft only under specific conditions. See Section 13.5: MRI INFORMATION for details.

6.0 Potential Adverse Events

Adverse events associated with use of the Talent Thoracic Stent Graft System include, but are not limited to the following:

- Amputation
- Aneurysm Enlargement
- Balloon rupture
- Breakage of the metal portion of the device
- Cardiac Failure/Infarction
- Change in mental status
- Conversion to open surgery
- Death
- Deployment difficulties
- Edema
- Embolization
- Endoleak
- Erectile Dysfunction
- Erosion with fistula or pseudoaneurysm
- Failure to deploy
- Gastrointestinal complications, including: adynamic ileus, bowel (ileus, transient ischemic, infarction, necrosis)
- Graft twisting and/or kinking
- Hemorrhage/Bleeding
- Inaccurate placement
- Infection and fever
- Insertion and removal difficulties
- Intercostal pain
- Neurological complications, including: spinal cord ischemia with paraplegia, paraparesis and/or paresthesia, Cerebral Vascular Accidents (CVA), Transient Ischemic Attacks (TIA), neuropathy, and blindness
- Prosthetic thrombosis
- Pulmonary complications
- Renal failure
- Rupture of graft material
- Ruptured vessel/aneurysm sac enlargement
- Stent graft migration
- Vascular complications including: thrombosis, thromboembolism, occlusion (arterial and venous), vessel dissection[1] or perforation, collateral vessel occlusion, vascular ischemia, tissue necrosis, amputation
- Wound healing complications

Major Adverse Events observed in the VALOR Test Group are provided in Section 7.5.1 (page 23)

6.1 Adverse Event Reporting

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

[1] Aortic dissection is an infrequent but recognized risk of endovascular repair. In the first 10 years of clinical experience (OUS-commercial and US-investigational), there were 39 reported events of retrograde dissection in patients. Of the 39 reported events, 33 patients had a pre-existing aortic dissection

7.0 Summary of Pivotal US Clinical Study

The VALOR Pivotal Study (VALOR Test Group) was a multi-center, non-randomized clinical study conducted within the United States in order to evaluate the safety and effectiveness of the Talent Thoracic Stent Graft System when used in the treatment of subjects with descending thoracic aortic aneurysms (fusiform aneurysms and saccular aneurysms/penetrating ulcers). For the VALOR Test Group, 38 sites enrolled a total of 195 subjects. The primary safety endpoint was All-Cause Mortality at one year. The All-Cause Mortality rate of TAA repair with the Talent Thoracic Stent Graft was to be compared to the literature All-Cause Mortality rate for open surgical TAA repair, within one year of the initial procedure. The primary effectiveness endpoint, Successful Aneurysm Treatment[2], was compared to a fixed rate of 80%, derived from a control population from the Feasibility studies totaling 21 subjects with 1 year of follow-up, all of whom met the protocol definition of Successful Aneurysm Treatment.

In the VALOR Test Group, analysis of the primary endpoints used follow-up visits at 1, 6 and 12 months after the implant procedure and annually for a total of 5 years from the date of the initial implant. Clinical sites sent CT/MR and chest X-ray (CXR) images to an independent Core Laboratory to provide an assessment of patient data through one year post implantation. All major adverse events (MAEs) were adjudicated by an independent Clinical Events Committee (CEC) for device and procedure relatedness.

Original Literature Control

The original literature control compared the All-Cause Mortality rate of TAA repair of the Talent Thoracic Stent Graft with the literature All-Cause Mortality rate for open surgical TAA repair, within one year of the initial procedure. Based on the adequacy of information regarding disease etiology, length of follow-up information and definition of events, three articles were chosen, from which 608 subjects had atherosclerotic lesions that accurately fit the VALOR Test Group's intended patient population of descending thoracic aortic aneurysms. Of the 608 patients, the number of patients surviving at 12 months was estimated from the 12 month rates given in the Kaplan-Meier curves included in each article. Using this method, 181 patients were estimated to have died within one year, establishing an All-Cause Mortality rate of 29.8%. The result of Primary Safety Endpoint comparison between the VALOR Test Group and the Original Literature Control Group is included in Section 7.5.1 (page 20) below.

Retrospective Open Surgery Control

After the original VALOR Trial was conducted, additional retrospective open surgical data was gathered from selected surgical centers to serve as a comparator for Acute Procedural Outcomes and Acute Adverse Events, as well as to further compare early and 12-Month Mortality and Aneurysm-Related Mortality. This retrospective surgical control group included 189 subjects from 3 centers who matched selected inclusion/exclusion criteria of the VALOR study. The VALOR Test and Retrospective Open Surgery Groups included surgical candidates diagnosed with a thoracic aortic aneurysm of degenerative etiology. The VALOR Test Group candidates were of low to moderate risk (SVS 0, 1, and 2). The Demographics and Baseline Medical History comparison between the VALOR Test Group and Retrospective Open Surgery Group is included in Section 7.2. Baseline Aneurysm Data comparison is included in section 7.3. Safety information is compared in section 7.5.1 (page 21 onwards) and effectiveness data and procedural result comparison is provided in section 7.5.2 and 7.5.3.

[2] Successful Aneurysm Treatment was a composite endpoint defined as no aneurysm growth greater than 5 mm at the 12 month follow-up visit when compared to the one (1) month follow-up visit (after the initial Talent Thoracic Stent Graft implant) AND absence of a Type I endoleak for which a secondary procedure was performed before, at or as a result of the 12 month follow-up visit.

7.1 Subject Accountability and Follow-up

For the VALOR Test Group, 38 sites enrolled a total of 195 subjects. One (1) subject had technical failure and did not receive a stent graft and therefore did not have any imaging follow-up. Four (4) subjects died and one (1) withdrew from the study before the 1-month visit.

189 subjects were eligible for clinical and imaging follow-up at 1 month follow-up interval. Of these 189 subjects, 80.4% (152/189) had a clinical follow-up. Please note; three (3) additional patients who were not eligible for clinical follow-up had imaging follow-up within the expanded time windows (as footnoted within the Table 3 below).

At the 6 month follow-up interval, 173 subjects were eligible for clinical and imaging follow-up. Of these, 74.0% (128/173) had clinical follow-up and 73.8 % (127/173) had imaging follow-up. CT imaging was performed on 68.2% (118/173) subjects.

At the 12 month follow-up interval, 157 subjects were eligible for clinical and imaging follow-up. Of these 71.3% (112/157) had clinical follow-up and 90.4% (142/157) had imaging follow-up. CT imaging was performed on 82.8% (130/157) patients.

Detailed subject follow-up and accountability for 1, 6, and 12 months is provided in Table 3.

Table 3 - Subject and Imaging Accountability Table–VALOR Test Group Only

	Patient follow-up			Patients with imaging performed at time interval (Core Lab)		Patients with adequate imaging to assess the parameter				Patient events occurring before next visit[2]				
Treatment / Follow-up Interval	Eligible	Clinical Follow-up[2]	Imaging Follow-up[3]	CT Imaging[3]	KUB Imaging[2]	Aneurysm size increase[3]	Endoleak[3]	Migration[4]	Integrity[3]	Technical Failure	Conversion to Surgery	Death	Withdrawal	Lost to Follow-up
Originally Enrolled	195									1				
Events after implant but before 1 Month visit											0	4	1	0
1 Month	189	152	192	184	189		174	182	161					
Events after 1 Month visit but before 6 Month visit											0	14	2	0
6 Month	173	128	127	118	114	117	112	117	93					
Events after 6 Month visit but before 12 Month visit											1	13	1	1
12 Month	157	112	142	130	125	129	123	129	97					

1 Data analysis sample size varies for each of the time points above and in following tables. This variability is due to patient availability for follow-up, as well as, quantity and quality of images available from specific time points for evaluation. For example, the number and quality of images available for evaluation of endoleak at 6 months is different than the number and quality of images available at 12 months due to variation in the number of image exams performed, the number of images provided from the clinical site to the Core Lab, and/or the number of images with acceptable evaluation quality.

2 Protocol-defined time windows were used for clinical follow-up and patient events
1-month : 16days to 44 days
6 month: 153 days to 213 days
12-month: 335 days to 395 days

3 Expanded time windows were used for imaging follow-up and assessment of imaging-dependant parameters
1-month: 0 days to 122 days
6 month: 153 days to 213 days
12-month: 335 days to 480 days for CT, Endoleak and Aneurysm size increase
335 days to 760days for X-ray and Integrity

4 Number of subjects evaluable for migration assessment were based on CT performed in windows and Slice interval and thickness <5mm for 10mm evaluation

7.2 Demographics and Baseline Medical History

Table 4 to Table 7; provide the demographics of the VALOR Test Group and Retrospective Open Surgery Group subjects.

Table 4 - Subject Demographics: VALOR Test Group vs. Retrospective Open Surgery Group

	VALOR Test Group	Retrospective Open Surgery	p-value
AGE			
Total Population			
N	195	189	
Mean ± SD (years)	70.2 ± 11.1	69.6 ± 9.1	0.528
Median	73.0	71.0	
Min-Max	27 - 86	27 - 85	
Male			
N	115	99	
Mean ± SD (years)	69.3 ± 11.7	69.9 ± 8.5	0.680
Median	72.0	71.0	
Min-Max	27 - 85	40 - 84	
Female			
N	80	90	
Mean ± SD (years)	71.6 ± 10.1	69.3 ± 9.8	0.130
Median	74.0	71.0	
Min-Max	38 - 86	27 - 85	
Gender			
Males	59.0% (115)	52.4% (99)	0.218
Females	41.0% (80)	47.6% (90)	
Ethnicity			
White, non-Hispanic	83.1% (162)	93.7% (177)	0.007
Black- non-Hispanic	12.8% (25)	5.8% (11)	
Hispanic (White or Black)	2.6% (5)	0.5% (1)	
Asian/Pacific Islander	1.0% (2)	0% (0)	
Native American	0% (0)	0% (0)	
Other	0.5% (1)[1]	0% (0)	

[1]One subject had Ethnicity specified as "None given"

Table 5 - Subject Anatomic Lesion Type: VALOR Test Group Only

Thoracic Lesion	N	%
Fusiform	112	57.4
Saccular/Penetrating Ulcer	70	35.9
Both	13	6.7

Note: The Retrospective Open Surgery Group did not provide patient level data for Anatomic Lesion Type treated.

Table 6 - Baseline Medical History: VALOR Test Group vs. Retrospective Open Surgery Group

Body System / Condition	VALOR Test Group % (m/n)[1]	Retrospective Open Surgery % (m/n)[1]	p-value
Cardiovascular			
Angina	14.4% (28/195)	22.8% (26/114)	0.064
Arrhythmias	26.7% (52/195)	20.3% (37/182)	0.182
Carotid artery disease	5.6% (11/195)	Not Available	N/A
Congestive heart failure (CHF)	8.7% (17/195)	11.2% (21/187)	0.495
Coronary artery bypass grafting (CABG)	10.3% (20/195)	13.3% (25/188)	0.428
Coronary artery disease (CAD)	40.5% (79/195)	49.2% (91/185)	0.099
Hypertension	87.2% (170/195)	88.8% (166/187)	0.641
Myocardial infarction (MI)	13.8% (27/195)	20.9% (39/187)	0.079
Percutaneous coronary intervention (PCI)	5.6% (11/195)	Not Available	N/A
Peripheral vascular disease (PVD)	16.4% (32/195)	37.4% (70/187)	<0.001
Symptomatic thoracic aortic aneurysm	26.2% (51/195)	Not Available	N/A
Abdominal Aortic Aneurysm (AAA)	19.0% (37/195)	37.0% (70/189)	<0.001
Abdominal Aortic Aneurysm Repair	2.1% (4/195)	27.5% (52/189)	<0.001
Gastrointestinal conditions	53.8% (105/195)	Not Available	N/A
Renal insufficiency	17.4% (34/195)	16.0% (30/187)	0.784
Musculoskeletal conditions	53.8% (105/195)	Not Available	N/A
Neurological			
Cerebral vascular accident (CVA)	9.7% (19/195)	13.4% (25/186)	0.267
Paraplegia	1.0% (2/195)	0.5% (1/186)	1.000
Paraparesis	0.5% (1/195)	Not Available	N/A
Transient ischemic attack (TIA)	7.7% (15/195)	Not Available	N/A
Pulmonary			
Chronic obstructive pulmonary disease (COPD)	36.9% (72/195)	42.6% (80/188)	0.296
Tobacco use	76.9% (150/195)	75.9% (142/187)	0.904
Other abnormal body systems			
Hyperlipidemia	43.6% (85/195)	Not Available	N/A
Diabetes	15.9% (31/195)	8.6% (16/187)	0.030
Bleeding disorders	2.6% (5/195)	Not Available	N/A

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

Table 7 - Baseline Modified SVS Classification: VALOR Test Group Only

	n	SVS 0 % (m)	SVS 1 % (m)	SVS 2 % (m)	SVS 3 % (m)
Modified SVS	195	4.1% (8)	21.0% (41)	72.8% (142)	2.1% (4)

7.3 Baseline Aneurysm Data

Table 8 lists the initial aneurysm diameter sizes treated.

Table 8 - Baseline Maximum Aneurysm Diameters: VALOR Test Group vs. Retrospective Open Surgery

Aneurysm Diameter (mm)	VALOR Test Group		Retrospective Open Surgery %(m/n)	p-value Site-Reported VALOR vs. Retrospective Open Surgery[3]
	Site-Reported % (m / n)[1]	Core Lab Reported % (m / n)[2]		
10-17	0% (0/188)	0% (0/187)	0% (0/189)	<0.001
18-29	0% (0/188)	0.5% (1/187)	0% (0/189)	
30-39	4.3% (8/188)	7.5% (14/187)	0% (0/189)	
40-49	10.6% (20/188)	20.3% (38/187)	0.5% (1/189)	
50-59	34.6% (65/188)	34.8% (65/187)	13.8% (26/189)	
60-69	33.5% (63/188)	24.6% (46/187)	40.7% (77/189)	
70-79	12.2% (23/188)	10.2% (19/187)	24.3% (46/189)	
80-89	3.2% (6/188)	2.1% (4/187)	16.9% (32/189)	
90-99	1.1% (2/188)	0% (0/187)	0.5% (1/189)	
100-109	0.5% (1/188)	0% (0/187)	1.6% (3/189)	
110-119	0% (0/188)	0% (0/187)	0.5% (1/189)	
120+	0% (0/188)	0% (0/187)	1.1% (2/189)	

1 Denominator is 188 subjects with site reported data.

2 Denominator is 187 subjects with evaluable scans.

3 This p-value represents a Monte Carlo estimate of the p-value for the exact Mantel-Haenszel Chi-Square test for trend, based on 100,000 Monte Carlo repetitions.

Table 9 - Baseline Vessel Dimensions (Core Lab Reported): VALOR Test Group Only

Vessel Dimensions (mm)	n[1]	Mean ± SD	Median	Min	Max
Proximal neck diameter	187	31.2 ± 4.9	31.5	18.5	43.5
Aneurysm diameter	187	55.5 ± 11.6	56.0	26.2	88.8
Distal neck diameter	184	29.7 ± 5.0	29.5	17.0	42.5
Proximal neck length	187	80.0 ± 52.1	77.9	10.0	234.0
Aneurysm length	180	121.4 ± 72.7	107.7	8.0	297.5
Distal neck length	184	90.0 ± 62.9	73.5	9.0	255.0
Right external iliac minimum diameter	122	6.5 ± 1.5	6.5	2.9	11.0
Left external iliac minimum diameter	124	6.6 ± 1.5	6.5	3.3	10.9

1 Denominators are n specified from readable scans.

7.4 Devices Implanted

Table 10 provides details on the number of devices implanted per subject for the VALOR Test Group.

Table 10- Number of Devices Implanted at Initial Procedure: VALOR Test Group Only

Devices Implanted		
Number per subject	**%**	**(m)[1]**
0	0.5%	(1)
1	19.5%	(38)
2	28.7%	(56)
3	24.6%	(48)
4	17.4%	(34)
5	7.2%	(14)
6	1.5%	(3)
7+	0.5%	(1)

[1] m= number of subjects implanted & percentages based on total number of enrolled subjects (N=195)

Table 11 cross-tabulates the 194 subjects in the VALOR Test Group, who had Talent Stent Grafts implanted by the number of main sections and the number of extensions. For example, 38 subjects had a single main section implanted and no extensions, and 5 subjects had one main section and one extension. Similarly, 51 subjects had two main sections and no extensions and 6 had two main sections and one extension.

Table 11: Number of Main Sections and Number of Extensions Implanted at Initial Procedure: VALOR Test Group Only

m (%)[1]		Number of Extensions							
		0		**1**		**2**		**Total**	
Number of Main Sections	**1**	38	(19.59%)	5	(2.58%)	1	(0.52%)	44	(22.68%)
	2	51	(26.29%)	6	(3.09%)	5	(2.58%)	62	(31.96%)
	3	41	(21.13%)	11	(5.67%)	2	(1.03%)	54	(27.84%)
	4	18	(9.28%)	6	(3.09%)	0	(0.00%)	24	(12.37%)
	5	6	(3.09%)	1	(0.52%)	0	(0.00%)	7	(3.61%)
	6	2	(1.03%)	1	(0.52%)	0	(0.00%)	3	(1.55%)
	Total	156	(80.41%)	30	(15.46%)	8	(4.12%)	194	(100.00%)

1 m= number of subjects with tabulated number of main sections and extensions. Percentages based on total number of implanted subjects (N=194)

Table 12 and Table 13 provide details on the components (proximal main devices, proximal extension devices, distal main devices, and distal extension devices) implanted per subject for the VALOR Test Group.

Table 12 - VALOR Test Group: Talent Thoracic Stent Graft Devices Implanted

Diameter (mm)	Stent Graft Modular Component (Number Implanted)					
	Proximal Main		Proximal Extension		Distal Extension	
	%	(m)[1]	%	(m)[1]	%	(m)[1]
22	0.5%	(1)				
24	1.4%	(3)				
26	1.9%	(4)	0.0%	(0)	0.0%	(0)
28	2.8%	(6)	0.0%	(0)	12.0%	(3)
30	3.8%	(8)	4.8%	(1)	4.0%	(1)
32	8.1%	(17)	14.3%	(3)	8.0%	(2)
34	11.4%	(24)	4.8%	(1)	16.0%	(4)
36	16.1%	(34)	14.3%	(3)	8.0%	(2)
38	19.4%	(41)	19.0%	(4)	16.0%	(4)
40	11.4%	(24)	4.8%	(1)	12.0%	(3)
42	10.9%	(23)	4.8%	(1)	8.0%	(2)
44	5.2%	(11)	9.5%	(2)	8.0%	(2)
46	7.1%	(15)	23.8%	(5)	8.0%	(2)
Total Catalog Devices Implanted	211		21		25	

1 m=number of subjects implanted with specific type of device within each diameter category & denominator is the total number of the specific type of device implanted.

Table 13- VALOR Test Group: Distal Main Devices Implanted

Diameters[1] (mm)	Number of Devices % (m)[2]	
26 – 22	0.4%	(1)
28 – 24	0.8%	(2)
30 – 26	0.8%	(2)
32 – 28	0.4%	(1)
34 – 30	2.3%	(6)
36 – 32	5.4%	(14)
38 – 34	14.0%	(36)
40 – 36	16.3%	(42)
42 – 38	19.8%	(51)
44 – 40	15.1%	(39)
46 – 42	14.3%	(37)
46 – 44	10.5%	(27)

1 Proximal – distal.

2 m=number of subjects implanted and the denominator is 258 implanted distal main devices.

7.5 Study Results

Results of the safety and effectiveness of the Talent Thoracic Stent Graft are provided in Section 7.5.1 to Section7.5.3.

7.5.1 Safety

Primary Safety Endpoint

All-Cause Mortality at One Year: Talent Thoracic vs. Original Literature Control

The primary safety endpoint was All-Cause Mortality at 12 months. Based on the test of superiority of the All-Cause Mortality rate in the Test Group to that of the original literature control group with an All-Cause Mortality rate of 181 of 608 subjects, or 29.8% (H_0: $P_{TestArm} \geq P_{SurgicalGroup}$ versus H_A: $P_{TestArm} < P_{SurgicalGroup}$), the VALOR Test Group subjects met the pre-specified performance goal of 29.8%. The primary safety endpoint of the VALOR Study was met.

Through one year, subjects who received the Talent Thoracic Stent Graft experienced an All-Cause Mortality rate of 16.1% and the subjects who underwent open surgery experienced a rate of 29.8%.

All-Cause Mortality at 30 days and 12 months: Talent Thoracic vs. Retrospective Open Surgery Group

Table 14 and Figure 7 describe the 30-day mortality rates for the VALOR Test Group as compared to the Retrospective Open Surgery Group. The VALOR Test Group experienced a lower rate of early mortality (2% vs. 8%).

An analysis of freedom from All-Cause Mortality was performed, and a Kaplan-Meier plot of subject freedom from All-Cause Mortality is provided in Table 14 and Figure 7.

Table 14- All-Cause Mortality at 30 Days and 12 months: VALOR Test Group vs. Retrospective Open Surgery

	VALOR Test Group % (m/n)	Retrospective Open Surgery % (m/n)	95% Exact Confidence Interval of Difference[1,2]
All-cause mortality at 30 days	2.1% (4/195)	7.9% (15/189)	(-10.9%, -1.3%)
All-cause mortality at 12 months	16.1% (31/192)	20.6% (39/189)[3]	(-12.4%, -3.4%)

1 Confidence level was not adjusted for multiplicity. Confidence interval for difference (VALOR Test Group – Retrospective Open Surgery group) in percentage was calculated by the exact method.

2 Difference represents the (% of patients with mortality from any cause within the period in the population treated with the test device) - (% of patients with mortality from any cause within the period in the population treated with open surgery)

3 Of the 39 deaths, this data includes both information from the reporting centers and queries of the National Social Security Death Index database

Figure 7- Kaplan-Meier Plot of Freedom from All Cause Mortality at 30 Days and 12 Months: VALOR Test Group vs. Retrospective Open Surgery Group

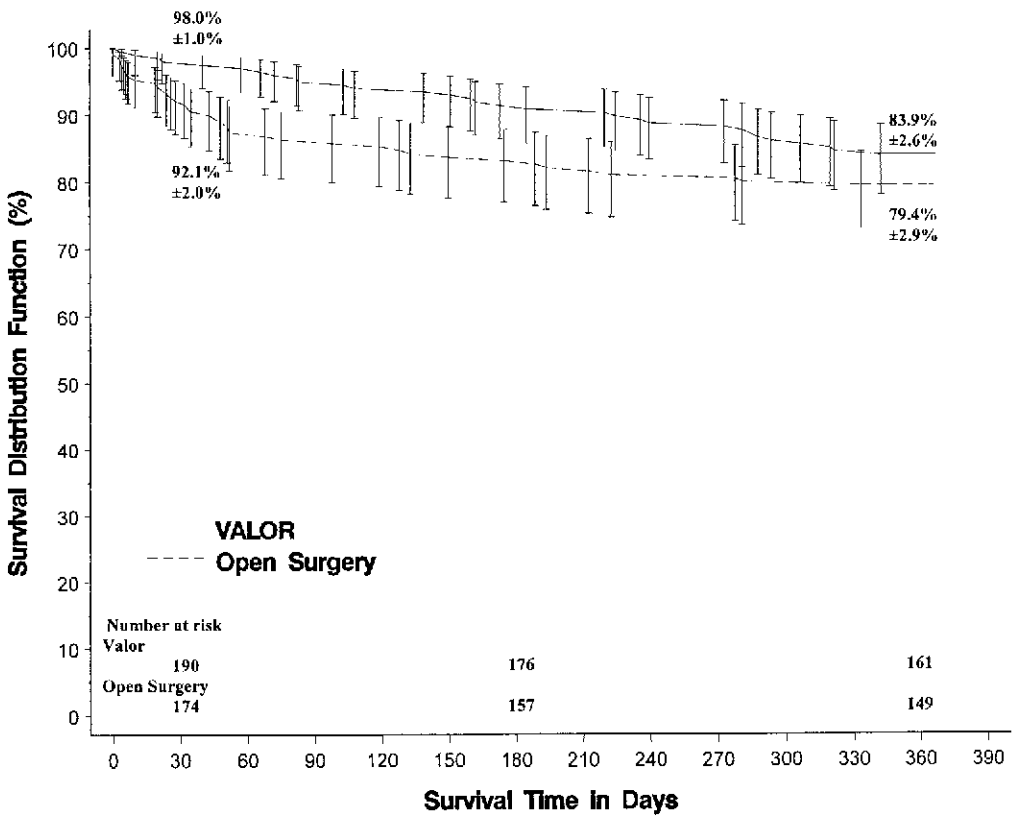


Table 15: Details of Kaplan-Meier Plot of Freedom from All Cause Mortality at 30 Days and 12 Months: VALOR Test Group vs. Retrospective Open Surgery Group

	VALOR Test Group			Retrospective Open Surgery		
	Treatment to 30 days	31 days to 182 days	183 days to 365 days	Treatment to 30 days	31 days to 182 days	183 days to 365 days
No. at Risk	195	190	176	189	174	157
No. of Events	4	13	14	15	17	7
No. Censored	1	1	1	0	0	1
Kaplan-Meier Estimate	0.980	0.912	0.839	0.921	0.831	0.794

Secondary Safety Endpoints

Major Adverse Events (MAE) at 30 days: VALOR Test Group vs. Retrospective Open Surgery Group

Adverse events were categorized by severity in the VALOR Trial and in the Retrospective Open Surgery Group using the following definitions. A Major Adverse Event (MAE) was 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 30 days 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
- Aneurysm rupture
- Gastrointestinal: bowel ischemia
- Major bleeding complication (procedural or post-procedural), coagulopathy
- Vascular complications

Table 16 is a comparison of 30-day MAE for Talent Thoracic subjects versus the Retrospective Open Surgical Group.

Table 16 - Summary of Major Adverse Events for VALOR Test Group vs. Retrospective Open Surgery Group (30 days)

Category	VALOR Test Group	Retrospective Open Surgery	95% Exact Confidence Interval of Difference[2,3]
	Major Adverse Events 0-30 days % (m/n) N=195	Major Adverse Events 0-30 days % (m/n) N=189[1]	
Any MAE	41.0% (80/195)	84.4% (151/179)	(-51.9%, -34.2%)
Respiratory complications	13.3% (26/195)	46.9% (84/179)	(-42.2%, -24.6%)
Renal complications	6.2% (12/195)	29.1% (52/179)	(-30.6%, -15.3%)
Cardiac complications	12.3% (24/195)	44.7% (80/179)	(-41.0%, -23.5%)
Neurological complications	11.8% (23/195)	20.1% (36/179)	(-16.0%, -0.7%)
GI complications	1.0% (2/195)	0.6% (1/179)	(-2.1%, 3.2%)
Bleeding complications	15.4% (30/195)	48.0% (86/179)	(-41.7%, -23.4%)
Vascular complications	21.0% (41/195)	12.3% (22/179)	(1.1%, 16.5%)
Target Lesion Aneurysm Rupture	0.0% (0/195)	0.6% (1/179)	(-3.1%, 1.4%)

1 10 patients were followed for less than 16 days without MAE so were eliminated from the analysis

2 Confidence level was not adjusted for multiplicity. Confidence interval for difference (VALOR Test Group – Retrospective Open Surgery group) in percentage was calculated by the exact method.

3 Difference represents the (% of patients free from MAEs within 30 days in the population treated with the test device) - (% of patients free from MAEs within 30 days in the population treated with open surgery)

One or more Major Adverse Events were reported in 80 of the 195 VALOR Test Group subjects available for evaluation, resulting in a probability of freedom from Major Adverse Events of 59%. In the Retrospective Open Surgery group, 151 of the 179 subjects had one or more Major Adverse Events, resulting in a freedom from Major Adverse Event rate of 15.6% in this group.

Table 17- Freedom from Major Adverse Events (MAE) at 30 days: VALOR Test Group vs. Retrospective Open Surgery Group

Parameter	VALOR Test Group	Retrospective Open Surgery	95% Exact Confidence Interval of Difference[1,2]
Number of subjects at start	195	179	
Number of subjects with one or more events	80	151	
Probability of freedom from event	59.0%	15.6%	(34.2%, 51.9%)

1 Confidence level was not adjusted for multiplicity. Confidence interval for difference (VALOR Test Group – Retrospective Open Surgery group) in percentage was calculated by the exact method.

2 Difference represents the (% of patients free from MAEs within 30 days in the population treated with the test device) - (% of patients free from MAEs within 30 days in the population treated with open surgery)

Figure 8 provides the Kaplan-Meier analysis of Freedom from Major Adverse Events at 30 Days: VALOR Test Group vs. Retrospective Open Surgery

Figure 8 – Kaplan-Meier Plot of Freedom from Major Adverse Events at 30 Days: VALOR Test Group vs. Retrospective Open Surgery

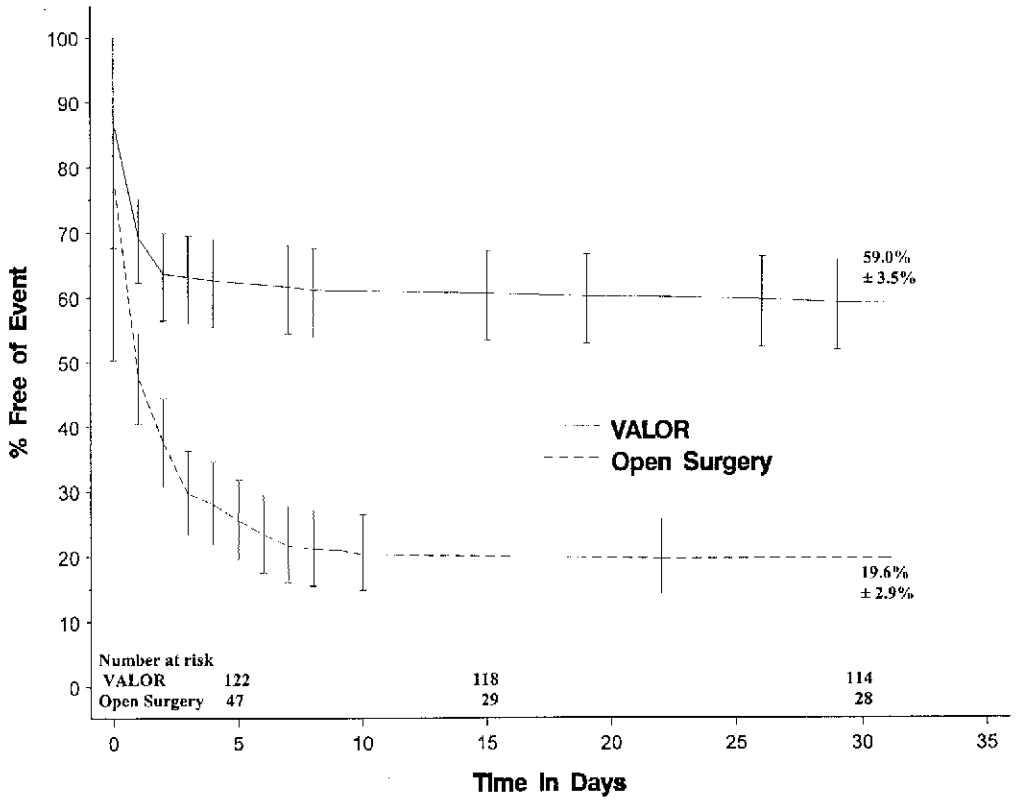


Table 18: Details of Kaplan-Meier Plot of Freedom from Major Adverse Events at 30 Days: VALOR Test Group vs. Retrospective Open Surgery

	VALOR Test Group			Retrospective Open Surgery		
	Treatment to 5 days	6 days to 15 days	16 days to 30 days	Treatment to 5 days	6 days to 15 days	16 days to 30 days
No. at Risk	195	122	118	189	47	29
No. of Events	73	4	3	141	9	1
No. Censored	0	0	1	1	9	0
Kaplan-Meier Estimate	0625	0.605	0.590	0.254	0.203	0.196

Serious Major Adverse Events: VALOR Test Group Only

VALOR MAEs were further stratified into more clinically severe events: Serious Major Adverse Events (Serious MAEs). These Serious MAEs were fatal, life-threatening, required in-patient hospitalization or prolongation of existing hospitalization, caused persistent or significant disability/incapacity, or resulted in a congenital anomaly/birth defect.

Major Adverse Events (MAE) were reviewed by the CEC and adjudicated as either device- and/or procedure-related as per the study protocol. A Major Adverse Event (MAE) that was identified as a Serious Adverse Event (SAE) by the clinical Investigator was defined as a Serious MAE.

The total number of subjects with one or more Serious MAEs in each category is summarized in Table 19.

Table 19 -Summary of Serious Major Adverse Events from VALOR Test Group Only

Category	0-30 days % (m) N=195 Serious Major Adverse Events		0-30 days 95% Exact CI[1]	0-365 days % (m) N=192 Serious Major Adverse Events		0-365 days 95% Exact CI[1]
Any Serious MAE	30.3%	(59/195)	(23.9%, 37.2%)	42.7%	(82/192)	(35.6%, 50.0%)
Respiratory complications	6.7%	(13/195)	(3.6%, 11.1%)	15.1%	(29/192)	(10.4%, 21.0%)
Renal complications	3.6%	(7/195)	(1.5%, 7.3%)	6.8%	(13/192)	(3.7%, 11.3%)
Cardiac complications	5.1%	(10/195)	(2.5%, 9.2%)	12.0%	(23/192)	(7.7%, 17.4%)
Neurological complications	9.7%	(19/195)	(6.0%, 14.8%)	13.5%	(26/192)	(9.0%, 19.2%)
GI complications	0.5%	(1/195)	(0.0%, 2.8%)	1.0%	(2/192)	(0.1%, 3.7%)
Bleeding complications	13.3%	(26/195)	(8.9%, 18.9%)	14.6%	(28/192)	(9.9%, 20.4%)
Vascular complications	9.2%	(18/195)	(5.6%, 14.2%)	10.4%	(20/192)	(6.5%, 15.6%)
Target Lesion Aneurysm Rupture	0.0%	(0/195)	(0.0%, 1.9%)	0.5%	(1/192)	(0.0%, 2.9%)

1 Confidence level was not adjusted for multiplicity. Confidence interval for the percentage was calculated by the exact (binomial) method.

During the VALOR Study, 59 of 195 evaluable subjects had one or more Serious Major Adverse Events within 30 days, giving a rate of Serious MAEs within 30 days of 30.3% (95% CI 23.9-37.2%). Eighty-two (82) of 192 evaluable subjects had one or more Serious MAEs within 12 months, providing a Serious MAE rate of 42.7% (95% CI 35.6-50.0%).

Table 20- Freedom from Serious Major Adverse Events (MAE) at 30 days and 12-months: VALOR Test Group Only

Parameter	Talent Thoracic	
	Serious MAE at 30 days	Serious MAE at 12-months
Number of subjects at start	195	192[1]
Number of subjects with one or more events	59	82
Probability of freedom from event	69.7%	57.3%
Exact 95% confidence interval for freedom from event[2]	(62.7%, 76.1%)	(49.1%, 63.4%)

1 192 subjects followed for the required time frame.

2 Confidence level was not adjusted for multiplicity. Confidence interval for the percentage was calculated by the exact (binomial) method.

Figure 9 – Kaplan-Meier Plot of Freedom from Serious Major Adverse Events: VALOR Test Group Only

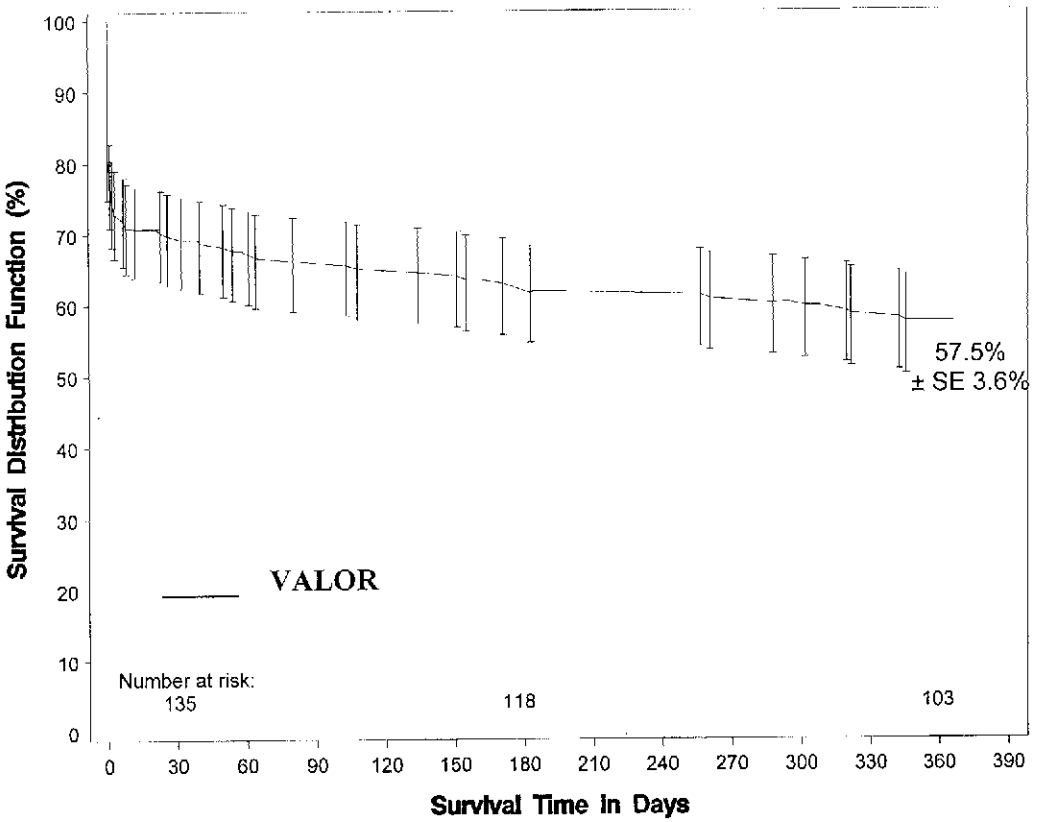


Table 21: Details of Kaplan-Meier Plot of Freedom from Serious Major Adverse Events: VALOR Test Group Only

	VALOR Test Group		
	Treatment to 30 days	31 days to 182 days	183 days to 365 days
No. at Risk	195	135	118
No. of Events	59	13	10
No. Censored	1	4	5
Kaplan-Meier Estimate	0.697	0.629	0.575

Aneurysm-Related Mortality

Table 22 and Figure 10 provide Aneurysm-Related Mortality information for the VALOR Test and Retrospective Open Surgery Groups. An analysis of freedom from Aneurysm-Related Mortality was performed, and a Kaplan-Meier plot of subject freedom from Aneurysm-Related Mortality is provided in Figure 10.

Table 22- Aneurysm-Related Mortality at 12 Months: VALOR Test Group vs. Retrospective Open Surgery Group

	VALOR Test Group[1] % (m/n)	Retrospective Open Surgery[2] % (m/n)	95% Exact Confidence Interval of Difference[3,4]
Aneurysm-Related Mortality at 12 Months	3.1% (6/192)	11.6% (22/189)	(-14.2%, -2.9%)

1 Aneurysm-related mortality was defined as any death within 30 days from initial implantation or occurring as a consequence of an aneurysm rupture, a conversion to open repair, or any other secondary endovascular procedure relative to the aneurysm that was treated by the Talent Thoracic Stent Graft System as evidenced by CT, angiography or direct observation at surgery or autopsy. Excluded are aneurysms in anatomic areas other than the targeted segment treated by the Talent Thoracic Stent Graft System.

2 The definition for Aneurysm Related Mortality for the Retrospective Open Surgery Group was any death within 30 days from the surgical procedure or any death caused by reintervention of the targeted aortic segment, or by complications related to the graft or the procedure (i.e., graft infections, rupture, pseudoaneurysm, aorto-eophageal fistula, aorto-bronchial fistula, etc.)

3 Confidence level was not adjusted for multiplicity. Confidence interval for difference (VALOR Test Group – Retrospective Open Surgery group) in percentage was calculated by the exact method.

4 Difference represents the (% of patients with aneurysm-related mortality within 12 months in the population treated with the test device) - (% of patients with aneurysm-related mortality within 12 months in the population treated with open surgery)

Figure 10 – Kaplan-Meier Plot of Freedom from Aneurysm-Related Mortality at 12 Months: VALOR Test Group vs. Retrospective Open Surgery Group

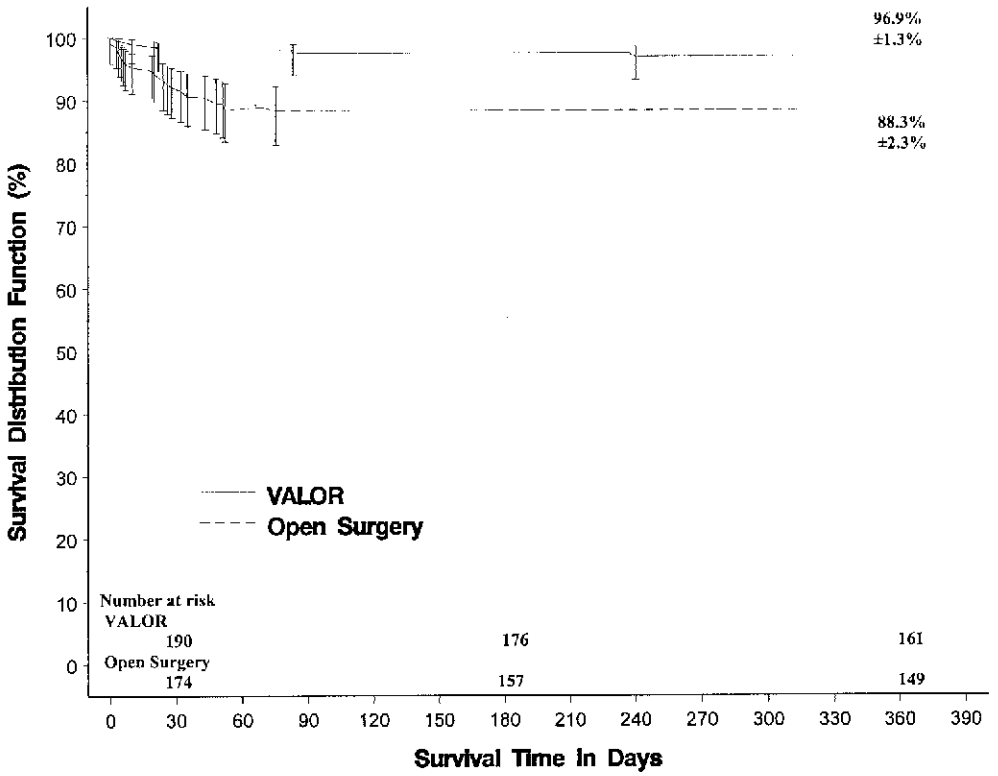


Table 23: Details of Kaplan-Meier Plot of Freedom from Aneurysm-Related Mortality at 12 Months: VALOR Test Group vs. Retrospective Open Surgery Group

	VALOR Test Group			Retrospective Open Surgery		
	Treatment to 30 days	31 days to 182 days	183 days to 365 days	Treatment to 30 days	31 days to 182 days	183 days to 365 days
No. at Risk	195	190	176	189	174	157
No. of Events	4	1	1	15	7	0
No. Censored	1	13	14	0	10	8
Kaplan-Meier Estimate	0.980	0.974	0.969	0.921	0.883	0.883

7.5.2 Effectiveness

Primary Effectiveness Endpoint: Successful Aneurysm Treatment

The primary effectiveness endpoint was met. This endpoint, Successful Aneurysm Treatment, was a composite endpoint consisting of:

- No aneurysm growth greater than 5 mm at the 12 month follow-up visit when compared to the one (1) month follow-up visit as assessed by the Core Lab (after the initial Talent Thoracic Stent Graft implant); and
- Absence of a Type I endoleak as assessed by the Core Lab for which a secondary procedure was performed before, at or as a result of the 12 month follow-up visit.

The rate of Successful Aneurysm Treatment in the VALOR Test Group, 89.2%, was higher than the 80% comparator (which was based on earlier feasibility studies). As shown is Table 24, the Talent Thoracic Stent Graft achieved a successful aneurysm treatment rate of 89.2%. Table 25 provides details regarding subjects who have failed the successful aneurysm treatment endpoint.

Table 24- Primary Effectiveness Endpoint: Successful Aneurysm Treatment: VALOR Test Group

Primary Effectiveness Endpoint	% (m / n) [95% CI]	95% Exact Confidence Interval[2]
Successful Aneurysm Treatment at 12 months	89.2% (116/130)[1]	[82.6% – 94.0%]

1 Eligible subjects for Successful Aneurysm Treatment required images depicting a one and twelve month aneurysm size, or had a Type I endoleak which required endovascular repair to be included in the analysis. Twenty-nine (29) subjects were missing a 12 month image at the Core Lab and were excluded from this analysis.

2 Confidence level was not adjusted for multiplicity. Confidence interval for the percentage was calculated by the exact (binomial) method.

Table 25- Summary of Subjects with Primary Effectiveness Failure: VALOR Test Group

Subjects with Primary Effectiveness Failure	n
Aneurysm growth > 5mm	10[1]
Type I endoleak requiring re-intervention	3
Aneurysm growth > 5mm and Type I endoleak requiring re-intervention	1[2]

1 Of the 10 subjects, four (4) had secondary procedures. Of the remaining six (6) subjects, one (1) patient died of cardiac arrest at approximately 24 months, and one died of cirrhosis at 14 months.

2 This subject is alive at 24 months

Other Effectiveness Data

Table 26 summarizes the other secondary endpoints from the VALOR Study.

Table 26 - Other Effectiveness Data: VALOR Test Group Only

Secondary Endpoint	Incidences % (m / n)	95% Exact CI[1]
Successful deployment and delivery of the stent graft at implantation	99.5% (194/195)[2]	(97.2%, 100.0%)
Secondary procedures due to endoleak at 30 days	0.0% (0/194)	(0.0%, 1.9%)
Conversion to open surgical repair within 12 months post-implantation	0.5% (1/192)[3]	(0.0%, 2.9%)
Aneurysm rupture within 12 months post-implantation	0.5% (1/192)[4]	(0.0%, 2.9%)
Stent graft migration between 1 and 12 months	3.9% (4/103)[5]	(1.1%, 9.6%)
• Proximal stent graft migration > 10 mm proximally	0.0% (0/103)	(0.0%, 3.5%)
• Proximal stent graft migration > 10 mm distally	1.9% (2/103)	(0.2%, 6.8%)
• Distal stent graft migration > 10 mm proximally	1.9% (2/103)	(0.2%, 6.8%)
• Distal stent graft migration > 10 mm distally	0.0% (0/103)	(0.0%, 3.5%)

1 Confidence level was not adjusted for multiplicity. Confidence interval for the percentage was calculated by the exact (binomial) method.

2 One (1) subject did not receive a stent graft due to extensive disease and heavy calcification of the iliac arteries.

3 One (1) subject was converted to surgery. The stent graft was explanted 9 months post initial procedure due to an apparent infection in the stented segment of the aorta.

4 One (1) subject experienced aneurysm rupture at the distal thoracic aorta, at the stent graft seal zone. Review of CT scans by the Core Lab revealed patient had a thoraco-abdominal aneurysm rather than an isolated descending thoracic aneurysm as well as an inadequate distal landing zone.

5 Migration is defined as proximal or distal movement of the stent graft (>10mm) relative to fixed anatomic landmarks. The 1-month CTA/MRA was used as the baseline for this determination.

- Two (2) subjects had no MAEs due to their device migration
- One (1) subject underwent a secondary procedure at Day 273. Two additional proximal main devices were implanted to resolve migration and cover a pseudoaneurysm. Repair was successful
- One (1) subject had no MAEs due to their device migration. Subject underwent a planned AAA open repair at approximately 2 months and expired at approximately 14 months from cirrhosis

Table 26 - Other Effectiveness Data: VALOR Test Group Only (Continued)

Secondary Endpoint	Incidences % (m / n)		95% Exact CI[1]
All endoleaks at 12 months (Core Lab reported)	12.2%	(15/123)	(7.0%, 19.3%)
• Type I	4.9%	(6/123)[6]	(1.8%, 10.3%)
• Type II	4.9%	(6/123)[7]	(1.8%, 10.3%)
• Type III	0.0%	(0/123)	(0.0%, 3.0%)
• Type IV	0.0%	(0/123)	(0.0%, 3.0%)
• Unknown	2.4%	(3/123)	(0.5%, 7.0%)
Secondary procedures due to endoleak between 31 days and 365 days	6.5%	(12/186)[8]	(3.4%, 11.0%)
Loss of patency of the stent graft at 12 months	0%	(0/107)	(0.0%, 3.4%)
Loss of stent graft integrity at 12 months[9]	2.1%	(2/97)[10]	(0.3%, 7.3%)
Change in maximum aneurysm diameter from 1 month image			
• Increase > 5 mm	8.5%	(11/129)	(4.3%, 14.7%)
• Stable	67.4%	(87/129)	(58.6%, 75.4%)
• Decrease > 5 mm	24.0%	(31/129)	(16.9%, 32.3%)

1 Confidence level was not adjusted for multiplicity. Confidence interval for the percentage was calculated by the exact (binomial) method.

6 None of the six (6) subjects with Type I endoleak underwent secondary procedure within 12 months

7 One (1) of the six (6) subjects with Type II endoleak underwent a secondary procedure at 140 days

8 The 12 subjects who received a secondary endovascular procedure are characterized as follows, all secondary repairs were successful:

- Two (2) patients had endoleaks detected at day 6 and 35, with secondary procedures at Day 84 and 186, respectively. Proximal mains were placed to correct Type I endoleaks (proximal).
- One (1) patient had endoleak detected at day 55, with secondary procedure at Day 334. Proximal extension was placed to correct Type I endoleak (proximal).
- Four (4) patients had endoleak detected at days 22, 29, 33 and 38, with secondary procedures at Day 140, 203, 116 and 253, respectively. Distal extensions were placed to correct three Type I endoleaks (distal) and one Type II endoleak.
- One (1) patient had endoleak detected at day 8, with secondary procedure at Day 113. Distal mains were placed to correct a Type III endoleak.
- Three (3) patients had endoleaks detected at day 19, 27 and 32, with secondary procedures at Day 56, 49 and 42, respectively. Proximal and distal mains were placed to correct one Type I (distal) endoleak and two Type I (proximal) endoleaks.
- One (1) patient had endoleak detected at day 155, with secondary procedure at Day 246. Proximal and Distal extensions were placed to correct a Type I (proximal) endoleak.

9 Loss of stent graft integrity is defined as the absence of stent fractures and/or graft fabric defects.

10 Of the two (2) subjects with loss of stent graft integrity, one was due to a nitinol spring fracture and the second was a connecting bar fracture. Neither subject had any adverse event related to these fractures. Both subjects are alive at 24 months

7.5.3 Supplementary Acute Procedural Data

Table 27 provides the Acute Procedural Data for VALOR Test Group and Retrospective Open Surgery Group. The VALOR Test Group showed reduced blood loss, reduced need for transfusions, as well as shorter ICU and hospital stays when compared to Open Surgery.

Table 27 - Supplementary Acute Procedural Data: VALOR Test Group vs. Retrospective Open Surgery Group

Parameter	VALOR Test Group	Retrospective Open Surgery	95% Confidence Interval of Difference[5,6]
Subjects requiring blood transfusion (%)	22.7% (44/194)	93.7% (164/175)	(-77.5%, -63.5%)
Blood loss during procedure (ml) (mean ± SD)[1]	371.2 ± 514.4	3054.9 ± 1702.4	(-2961.1, -2406.2)
Duration of implant procedure (min) (mean ± SD)[2]	154.2 ± 76.0	303.3 ± 97.6	(-166.9, -131.3)
Time in Intensive Care Unit (hours) for all assessable subjects (mean ± SD)[3]	46.8 ± 114.3	185.3 ± 204.7	
Overall hospital stay (days) (mean ± SD)[4]	6.4 ± 11.5	16.7 ± 15.0	(-12.9, -7.5)

1 189 VALOR Test Group subjects and 57 Retrospective Open Surgery subjects had known data for this parameter

2 194 VALOR Test Group subjects and 178 Retrospective Open Surgery subjects had known data for this parameter

3 193 VALOR Test Group subjects and 168 Retrospective Open Surgery subjects had known data for this parameter

4 195 VALOR Test Group subjects and 186 Retrospective Open Surgery subjects had known data for this parameter

5 Confidence level was not adjusted for multiplicity. Confidence intervals for difference (VALOR Test Group-Retrospective Open Surgery group) in means were calculated using a t-distribution. Confidence intervals for difference (VALOR Test Group-Retrospective Open Surgery group) in percentages were calculated by the exact method. Confidence interval for Time in ICU is not calculated due to a large number of ties in the data (i.e. large number of "0 hours" reported in the Test Group).

6 For Duration of Procedure and Overall Hospital Stay, difference represents the (mean of specific acute procedural parameter in the population treated with the test device) - (mean of specific acute procedural parameter in the population undergoing open surgical repair). For Patients Requiring Blood Transfusion, difference represents the (% of patients with the specific acute procedural parameter for the population treated with the test device) - (% of patients with the specific acute procedural parameter for the population undergoing open surgical repair).

7.6 VALOR Test Group Results by Lesion Type

The VALOR Test Group consisted of subjects with the following three groups of lesion types

- Subjects with fusiform thoracic aneurysms
- Subjects with saccular aneurysms and/or penetrating ulcers
- Subjects with multiple types of lesions (fusiform thoracic aneurysms and saccular and/or penetrating ulcers)

Section 7.6.1 and 7.6.2, provide demographic and lesion characteristics as well as safety and effectiveness endpoint analysis by lesion type.

7.6.1 Subject Demographics and Lesion Characteristics

Table 28 - Subject Demographics by Lesion Type – VALOR Test Group Only

	Fusiform	Saccular / Penetrating Ulcer	Multiple Lesion
AGE Total Population			
N	112	70	13
Mean ± SD (years)	71.7 ± 9.2	68.0 ± 13.4	69.4 ± 11.9
Median	74.0	72.0	74.0
Min-Max	39 – 86	27 – 85	46 – 85
Male			
N	63	44	8
Mean ± SD (years)	70.7 ± 8.9	67.8 ± 14.6	67.1 ± 13.9
Median	73.0	72.0	72.5
Min-Max	50 – 85	27 – 85	46 – 85
Female			
N	49	26	5
Mean ± SD (years)	73.1 ± 9.3	68.5 ± 11.5	73.0 ± 7.8
Median	75.0	70.5	75.0
Min-Max	39 – 86	38 – 82	64 – 84
Gender			
Males	56.3% (63)	62.9% (44)	61.5% (8)
Females	43.8% (49)	37.1% (26)	38.5% (5)
Ethnicity			
White, non-Hispanic	84.8% (95)	81.4% (57)	76.9% (10)
Black- non-Hispanic	12.5% (14)	12.9% (9)	15.4% (2)
Hispanic (White or Black)	1.8% (2)	2.9% (2)	7.7% (1)
Asian/Pacific Islander	0% (0)	2.9% (2)	0% (0)
Native American	0% (0)	0% (0)	0% (0)
Other	0.9% (1)[1]	0% (0)	0% (0)

1 One subject declined providing ethnicity

Table 29 - Baseline Vessel Dimensions by Lesion Type: VALOR Test Group Only (Core Lab Reported[1])

Vessel Dimension	n	Mean ± SD	Median	Min	Max
Proximal Neck Diameter (mm)					
Fusiform	107	32.1 ± 4.7	32.5	19.0	43.5
Saccular/Penetrating Ulcer	67	29.8 ± 5.2	30.5	18.5	43.5
Multiple Lesion	13	31.0 ± 4.1	30.0	25.0	37.7
Max Aneurysm Diameter (mm)					
Fusiform	107	60.3 ± 9.1	59.0	43.5	88.8
Saccular/Penetrating Ulcer	68	48.0 ± 11.9	44.8	26.2	79.8
Multiple Lesion	12	55.7 ± 7.1	55.7	44.4	71.3
Distal Neck Diameter (mm)					
Fusiform	104	31.0 ± 4.8	30.8	18.5	42.0
Saccular/Penetrating Ulcer	67	27.9 ± 4.9	27.5	17.0	42.5
Multiple Lesion	13	28.4 ± 4.5	26.4	22.0	38.0
Proximal Neck Length (mm)					
Fusiform	107	82.4 ± 50.9	78.0	12.9	234.0
Saccular/Penetrating Ulcer	67	76.2 ± 56.0	70.0	10.0	214.0
Multiple Lesion	13	79.9 ± 42.2	78.9	18.0	149.0
Aneurysm Length (mm)					
Fusiform	101	145.7 ± 71.6	157.9	30.0	297.5
Saccular/Penetrating Ulcer	66	86.8 ± 63.6	63.0	8.0	258.9
Multiple Lesion	13	107.7 ± 49.5	99.0	34.0	186.0
Distal Neck Length (mm)					
Fusiform	104	74.1 ± 51.9	62.2	10.9	225.0
Saccular/Penetrating Ulcer	67	114.5 ± 71.3	105.0	9.0	255.0
Multiple Lesion	13	90.7 ± 60.7	66.7	11.9	180.8
Right External Iliac Min Diameter (mm)					
Fusiform	71	6.5 ± 1.6	6.3	3.5	11.0
Saccular/Penetrating Ulcer	43	6.7 ± 1.5	6.5	2.9	9.7
Multiple Lesion	8	5.5 ± 1.5	5.4	4.0	7.9
Left External Iliac Min Diameter (mm)					
Fusiform	71	6.7 ± 1.5	6.5	4.0	10.9
Saccular/Penetrating Ulcer	45	6.5 ± 1.5	6.5	3.3	9.6
Multiple Lesion	8	5.8 ± 1.5	6.1	3.4	8.0

1 Denominators are n specified from readable scans.

Table 30: Baseline Vessel Shape by Lesion Type (Core Lab Reported[1]) – VALOR Test Group Only

Vessel Shape	Fusiform % (m/n)		Saccular/Penetrating Ulcer % (m/n)		Multiple Lesion % (m/n)	
Proximal Neck Shape						
Parallel	14.0%	(15/107)	41.8%	(28/67)	30.8%	(4/13)
Funnel	22.4%	(24/107)	22.4%	(15/67)	23.1%	(3/13)
Inverted Funnel	63.6%	(68/107)	35.8%	(24/67)	46.2%	(6/13)
Distal Neck Shape						
Parallel	27.9%	(29/104)	49.3%	(33/67)	46.2%	(6/13)
Funnel	54.8%	(57/104)	37.3%	(25/67)	38.5%	(5/13)
Inverted Funnel	17.3%	(18/104)	13.4%	(9/67)	15.4%	(2/13)

1 Denominators are n specified for readable scans

7.6.2 Primary and secondary safety and Effectiveness endpoint Analysis by Lesion Type

Table 31: Primary Safety Endpoint: All Cause Mortality by Lesion Type – VALOR Test Group Only

Lesion Type	% (m/n) [95% CI][1]
Fusiform	15.6% (17/109) [9.4%-23.8%]
Saccular/Penetrating Ulcer	15.7% (11/70) [8.1%-26.4%]
Multiple Lesion	23.1% (3/13) [5.0%-53.8%]

1 Confidence level was not adjusted for multiplicity. Confidence interval for the percentage was calculated by the exact (binomial) method.

Table 32: Primary Effectiveness Endpoint: Successful Aneurysm Treatment by Lesion Type – VALOR Test Group Only

Lesion Type	% (m/n) [95% CI][1]
Fusiform	89.0% (65/73) [79.5%-95.1%]
Saccular/Penetrating Ulcer	88.2% (45/51) [76.1%-95.6%]
Multiple Lesion	100.0% (6/6) [54.1%-100.0%]

1 Confidence level was not adjusted for multiplicity. Confidence interval for the percentage was calculated by the exact (binomial) method.

Table 33: Summary of Secondary Endpoints by Lesion Type – VALOR Test Group Only

Secondary Endpoints	Fusiform % (m/n) [95% CI][1]	Saccular / Penetrating Ulcer % (m/n) [95% CI][1]	Multiple Lesion % (m/n) [95% CI][1]
Successful deployment and delivery of the stent graft			
@ Implant	99.1% (111/112) [95.1%-100.0%]	100.0% (70/70) [94.9%-100.0%]	100.0% (13/13) [75.3%-100.0%]
"All-cause" Mortality			
Within 30 Days	0.0% (0/112) [0.0%-3.2%]	5.7% (4/70) [1.6%-14.0%]	0.0% (0/13) [0.0%-24.7%]
Aneurysm-related Death			
Within 12 months	0.9% (1/109) [0.0%-5.0%]	7.1% (5/70) [2.4%-15.9%]	0.0% (0/13) [0.0%-24.7%]
Paraplegia/paraparesis			
Paraplegia @ 30 Days	0.0% (0/112) [0.0%-3.2%]	2.9% (2/70) [0.3%-9.9%]	7.7% (1/13) [0.2%-36.0%]
Paraparesis @ 30 Days	9.8% (11/112) [5.0%-16.9%]	2.9% (2/70) [0.3%-9.9%]	7.7% (1/13) [0.2%-36.0%]
Secondary endovascular procedure due to endoleak			
Within 30 Days post implantation	0% (0/111) [0.0%-3.3%]	0% (0/70) [0.0%-5.1%]	0% (0/13) [0.0%-24.7%]
Between 31 days and 12 months post implantation	8.4% (9/107) [3.9%-15.4%]	4.5% (3/66) [0.9%-12.7%]	0% (0/13) [0.0%-24.7%]
One or more Major Adverse Events (MAE)			
Within 30 Days post implantation	46.4% (52/112) [37.0%-56.1%]	35.7% (25/70) [24.6%-48.1%]	23.1% (3/13) [5.0%-53.8%]
Within 12 Months post implantation	57.8% (63/109) [48.0%-67.2%]	48.6% (34/70) [36.4%-60.8%]	46.2% (6/13) [19.2%-74.9%]
One or more Serious Major Adverse Events (MAE)			
Within 30 Days post implantation	34.8% (39/112) [26.1%-44.4%]	24.3% (17/70) [14.8%-36.0%]	23.1% (3/13) [5.0%-53.8%]
Within 12 Months post implantation	46.8% (51/109) [37.2%-56.6%]	37.1% (26/70) [25.9%-49.5%]	38.5% (5/13) [13.9%-68.4%]
Conversion to open surgical repair			
Within 12 Months post implantation	0.0% (0/109) [0.0%-3.3%]	0.0% (0/70) [0.0%-5.1%]	7.7% (1/13) [0.2%-36.0%]
Migration of the stent graft			
Migration >10 mm between 1 and 12 months	5.6% (3/54) [1.2%-15.4%]	2.3% (1/44) [0.1%-12.0%]	0.0% (0/5) [0.0%-52.2%]
Loss of patency of the stent graft			
At 12 Month visit	0% (0/60) [0.0%-6.0%]	0% (0/42) [0.0%-8.4%]	0% (0/5) [0.0%-52.2%]
Aneurysm rupture			
Within 12 Months post implantation	0.9% (1/109) [0.0%-5.0%]	0.0% (0/70) [0.0%-5.1%]	0.0% (0/13) [0.0%-24.7%]
Endoleaks			
At 12 Month visit	13.2% (9/68) [6.2%-23.6%]	12.2% (6/49) [4.6%-24.8%]	0.0% (0/6) [0.0%-45.9%]

1 Confidence level was not adjusted for multiplicity. Confidence interval for the percentage was calculated by the exact (binomial) method.

Table 34: Persistent Paraplegia/Paraparesis at 12 Months or last Follow-up by Lesion Type – VALOR Test Group Only

Safety Endpoint	Fusiform % (m/n) [95% CI][1]	Saccular / Penetrating Ulcer % (m/n) [95% CI][1]	Multiple Lesion % (m/n) [95% CI][1]
Paraplegia (at 12 Months or last Follow-up)	0.9% (1/109) [0.0%-5.0%]	2.9% (2/70) [0.3%-9.9%]	7.7% (1/13) [0.2%-36.0%]
Paraparesis (at 12 Months or last Follow-up)	5.5% (6/109) [2.0%-11.6%]	0.0% (0/70) [0.0%-5.1%]	0.0% (0/13) [0.0%-24.7%]

1 Confidence level was not adjusted for multiplicity. Confidence interval for the percentage was calculated by the exact (binomial) method.

8.0 Patient Selection

8.1 Individualization of Treatment

Medtronic recommends that Talent Thoracic Stent Graft be used according to the Sizing Guidelines (see Table 35). All lengths and diameters of the devices necessary to complete the procedure should be available to the physician, especially when pre-operative case planning measurements (treatment diameters/lengths) are not certain. This approach allows for greater intraoperative flexibility to achieve optimal procedural outcomes. The warnings and precautions previously described in Section 3.0 should be carefully considered relative to each patient before use of the Talent Thoracic Stent Graft System. The risks and benefits should be carefully considered for each patient before use of the Talent Thoracic Stent Graft System.

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

- Patient age and life expectancy
- Co-morbidities (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/femoral access vessel morphology (minimal thrombus, calcium and/or tortuosity) that is compatible with vascular access techniques, devices, and/or accessories;
- non-aneurysmal aortic diameter in the range of 18 – 42mm;
- non-aneurysmal aortic proximal and distal neck lengths ≥ 20mm
- the final treatment decision is at the discretion of the physician and patient

9.0 Patient Counseling Information

The physician should consider the following points 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 (see Section 13.0 for additional imaging recommendations)
- Details contained in the patient information booklet regarding risks occurring after implantation of the device, e.g., cardiac complications, neurological complications, etc.
- Symptoms of aneurysm rupture.

Medtronic recommends that physicians use the Medtronic Patient Information Booklet to aid in describing risks associated with use of the Talent Thoracic Stent Graft System with the patient. Additionally Medtronic recommends that detailed patient specific risks also be discussed.

10.0 How Supplied

10.1 Sterility

Each Talent Thoracic Stent Graft is individually contained within a CoilTrac Delivery System. The CoilTrac Delivery Systems are sterilized using ethylene oxide and are supplied sterile for single use only.

- Do not reuse or attempt to resterilize.
- Do not use if package is opened or damaged.

10.2 Contents

The following items are supplied in an envelope with the Talent Thoracic Stent Graft System:

- One (1) set of patient tracking materials
- One (1) instructions for use reference

10.3 Storage

Store at room temperature in a dark, dry place.

11.0 Clinical Use Information

WARNING: CONSIDER HAVING A SURGICAL TEAM AVAILABLE DURING IMPLANTATION OR REINTERVENTION PROCEDURES IN THE EVENT THAT CONVERSION TO OPEN SURGICAL REPAIR IS NECESSARY.

11.1 Recommended Skills and Training

Physicians performing the Talent Thoracic Stent Graft System procedure must be trained in vascular interventional procedures and in the use of this device.

The recommended skill/knowledge requirements for physicians using the Talent Thoracic Stent Graft System are outlined below:

11.1.1 Patient Selection

- Knowledge of the natural history of thoracic aortic aneurysms and comorbidities associated with thoracic repair
- Knowledge of image interpretation, stent graft selection and sizing.

11.1.2 Physician Skills and Experience

Either the individual physician operator or a combined, multidisciplinary team should possess extensive procedural skills and experience with:

- Angioplasty
- Appropriate use of contrast material
- Embolization
- Endovascular stent graft placement
- Femoral cutdown, arteriotomy, and repair
- Live fluoroscopic and angiographic image interpretation
- Non-selective and selective catheterization
- Snare techniques
- Techniques to minimize radiation exposure.

11.2 Materials Recommended for Device Implantation

At the time of surgery, Medtronic recommends that the physicians have available:

- Additional Talent Thoracic Stent Grafts of various lengths and diameters which might be needed to customize the implant to fit the anatomy of the individual patient
- Assorted angiographic catheters, angioplasty catheters, graduated pigtail catheters
- Assorted guidewires of at least 260cm in length
- At least one additional Talent Thoracic Stent Graft (of the size intended for implantation) in the event that the device is damaged during attempted placement
- At least two additional Talent Thoracic Stent Grafts (one size larger and one size smaller) in the event that the original measurement underestimated or overestimated the vessel size
- Contrast media
- Fluoroscope with digital angiography capabilities and the ability to record and recall imaging
- Heparin and heparinized saline solution
- Intravascular Ultrasound catheter (IVUS)
- Introducer sheaths for vascular access to access arteries and to perform diagnostic imaging
- Reliant Stent Graft Balloon Catheter and other materials recommended by the Reliant Instructions for Use

NOTE: THE RELIANT STENT GRAFT BALLOON CATHETER IS RECOMMENDED FOR USE WITH THE TALENT THORACIC STENT GRAFT. DATA IS NOT AVAILABLE FOR USE WITH OTHER BALLOONS FOR REMODELING STENT GRAFTS.

- Sterile lubricant
- Stiff 0.035" diameter guidewires to support the CoilTrac Thoracic Delivery System in the aortic vasculature

11.3 Pre-Treatment Planning and Selection of Stent Graft

The specific stent graft diameter used for treatment should be oversized to the non-aneurysmal vessel using the sizing guidelines to ensure appropriate radial fixation. Table 35, Column 2 describes the stent graft to vessel over-sizing guidelines.

When multiple components are needed to exclude the target lesion, and the component junctions (overlapping connections) will not be supported by the vessel (i.e. in the aneurysm sac), a 4mm oversizing between overlapping stent grafts should be used, as shown in Column 3 of Table 35. If the component junctions will be supported by the vessel, sizing to the supporting native vessel should be used, as described in Table 35, Column 2. See

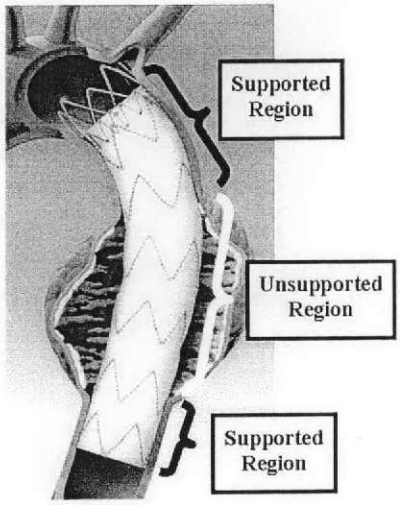
Figure 11 for a depiction of supported and unsupported regions.

Oversizing stent grafts greater than the stated guidelines could lead to increased stress on the springs or vessel damage. Undersizing of the stent graft may lead to device migration.

Table 35 - Sizing Guidelines

Column 1 Native Vessel Diameter (mm)	Column 2 Suggested Talent Thoracic Oversizing (mm)	Column 3 Suggested 4mm Oversizing for Unsupported Junction with Graft Sizes from Column 2 (mm)
18	22	26
19	22	26
20	24	28
21	24	28
22	26	30
23	26	30
24	28	32
25	28, 30	32, 34
26	30	34
27	30, 32	34, 36
28	32	36
29	32, 34	36, 38
30	34	38
31	34, 36	38, 40
32	36	40
33	38	42
34	38	42
35	40	44
36	40	44
37	42	46
38	42	46
39	44	
40	44	
41	46	
42	46	

Figure 11 - Regions for Modular Overlaps



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 36 should be followed to determine the order of deployment when using multiple stent graft component section.

Table 36 - Order of Deployment When Using Multiple Stent Graft Component Sections

	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 Table 35.*

NOTE: THE END CONFIGURATION FOR DEPLOYMENT WITHIN AN ADJACENT COMPONENT MUST BE A CLOSED WEB OR OPEN WEB.

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

12.0 Implantation Instructions

12.1 Pictorial References

For pictorial references of the Talent Thoracic Stent Graft components and CoilTrac Delivery System refer to Figure 1 to Figure 5.

12.2 Vascular Access, Anticoagulation and Initial Angiogram

Step 1- Establish Vascular Access

Establish vascular access for the CoilTrac Delivery System via a small oblique groin incision over the primary access artery. A secondary access should be used for diagnostic and imaging purposes. The choice of the location of the secondary access site is left to the physician's discretion (contralateral femoral artery, brachial, etc.).

Step 2- Provide Systemic Anticoagulation

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.

Step 3- Initial Angiogram

Using continuous fluoroscopy, traverse an 0.035" guidewire and graduated pigtail angiographic catheter (via the secondary access site) to confirm the target landing zones. Pre-operative CTA measurements (length/diameter) should be confirmed with angiographic images at this time. Confirm diameter and length of the selected Talent Thoracic Stent Graft for suitability. The angiographic catheter should be left in place during the procedure to aid in confirming position. During the Talent Thoracic Stent Graft implantation, these images may be used for road-mapping "on the table".

12.3 Device Preparation

Step 1- Inspection Prior to Use

Carefully inspect the sterile package for damage or defects before opening. Do not use product after the "Use By" date on the package. If the integrity of the sterile package has been compromised prior to the product "Use By" date or the packaging or product is defective, do not use the product and contact your Medtronic representative for return information.

Step 2 – Prepare Tip

Remove the package transport wire from the catheter tip. Then, hold the luer handle/push rod firmly and draw back the graft cover a few millimeters (no more than 5mm) to loosen the fit between the graft cover and the stent graft. Note that the tip will not be seated in the graft cover upon receipt (see Figure 12). Reseat the tip, holding the luer handle/push rod firmly and pulling back on the blue catheter until a smooth transition between the graft cover (sheath) and tip is achieved (see Figure 13). To aid reseating the tip while pulling the blue catheter, the tip can also be gently guided into the graft cover. Once the tip has been re-seated, make sure that the proximal spring of the stent graft does not lie between the tip and the graft cover. Also, make sure that the tip is within 0–3 mm from the first graft spring (see Figure 13). This is important to prevent a kink forming at this location; which may cause deployment difficulties.

Figure 12 - Delivery System as Packaged

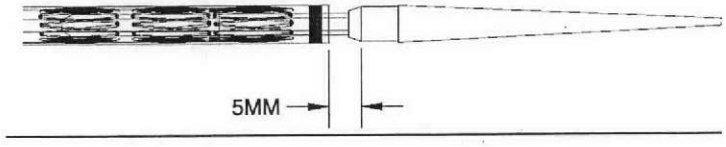
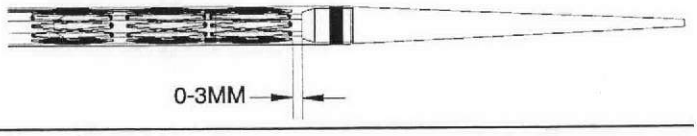


Figure 13 - Delivery System after Device Preparation



CAUTION: AFTER RESEATING THE TAPER TIP, MAKE SURE THAT THE PROXIMAL SPRING IS NOT CAUGHT BETWEEN THE TIP AND THE GRAFT COVER. THIS COULD CAUSE HIGH DEPLOYMENT FORCES OR INABILITY TO DEPLOY.

Step 3 – Flush Introducer Sheath

While holding the Talent Thoracic Stent Graft System upright, flush the graft cover using a syringe with heparinized saline solution (tapping the graft cover to aid in releasing air bubbles). Close stopcock and always leave the side port stopcock closed when not in use.

Step 4 – Flush Guidewire Lumen

Flush the guidewire lumen with heparinized saline.

Step 5 – Identify and Align Connecting Bar

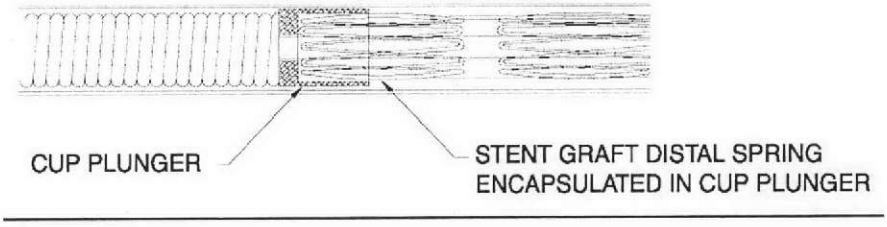
Inspect the radiopaque markers on the stent graft to identify positioning of the graft within the sheath. Identify the location of the connecting bar by visualization of the markers described in Section 4.0. The connecting bar position as packaged will initially be on the same side as the CoilTrac Delivery System catheter's side port. Before introducing the system into the patient's body, turn the delivery system to align the connecting bar with the outer bend of the target vessel for implantation.

CAUTION: FAILURE TO ALIGN THE CONNECTING BAR WITH THE OUTER BEND OF THE TARGET VESSEL MAY INCREASE THE LIKELIHOOD OF ENDOLEAKS POST IMPLANTATION.

Step 6 – Encapsulate End of Distal Stent Graft Spring in Cup Plunger

Ensure that the distal end of the distal stent graft spring is encapsulated in the cup plunger as shown in Figure 14. If the distal part of the stent graft spring is not encapsulated in the cup plunger, advance the luer handle/pushrod so that the distal end of the distal spring of the stent graft is encapsulated. Tighten the Tuohy Borst valve snugly, but do not over-tighten. Over-tightening the Tuohy Borst valve may interfere with the guidewire passage.

Figure 14 - Stent Graft Distal Spring Encapsulated in Cup Plunger



12.4 Device Insertion

Step 1 – Introducing System

CAUTION: MANIPULATION OF WIRES, BALLOONS, CATHETERS, AND ENDOGRAFTS IN THE THORACIC AORTA MAY LEAD TO VASCULAR TRAUMA INCLUDING AORTIC DISSECTION AND EMBOLIZATION.

NOTE: CAREFULLY MONITOR THE PATIENT'S VITAL SIGNS THROUGHOUT THE IMPLANTATION PROCEDURE.

NOTE: THE COILTRAC DELIVERY SYSTEM DOES NOT REQUIRE A SEPARATE INTRODUCER SHEATH FOR THE PRIMARY ACCESS SITE.

NOTE: IF NECESSARY, OPEN NARROW ILIAC VESSELS WITH PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) CATHETERS PRIOR TO TALENT THORACIC STENT GRAFT SYSTEM PLACEMENT, OR DILATE VESSELS WITH TAPERED VESSEL DILATORS WITH A STEP-UP APPROACH. ALTERNATIVELY, AN ILIAC CONDUIT MAY BE SEWN TO THE ILIAC ARTERY TO FACILITATE PLACEMENT OF THE DELIVERY SYSTEM.

Slowly insert the CoilTrac Delivery System over a 0.035" stiff or super-stiff guidewire. During insertion and advancement, it is important to align the connecting bar with the outside of the most severe bend of the target deployment area. Proper orientation of the connecting bar should be monitored during advancement. Proper alignment is key in order to avoid excessive twisting and manipulation of the CoilTrac Delivery System.

CAUTION: NEVER ADVANCE THE COILTRAC DELIVERY SYSTEM BY THE PUSHROD; THIS MAY CAUSE INADVERTENT DEPLOYMENT. EXCESSIVE BENDING OR KINKING OF THE DELIVERY SYSTEM MAY INHIBIT ITS ABILITY TO PROPERLY DEPLOY THE TALENT THORACIC STENT GRAFT.

CAUTION: IF AN OBSTRUCTION IN THE VESSEL (E.G., A TORTUOUS BEND, STENOSIS, CALCIFICATION, ETC.) PREVENTS ADVANCEMENT OF THE COILTRAC DELIVERY SYSTEM, DO NOT USE EXCESSIVE FORCE TO ADVANCE THE DELIVERY SYSTEM.

Step 2- Positioning the Stent Graft

Slowly advance the CoilTrac Delivery System to the targeted landing zone. For patients who do not have evidence of excessive calcification or thrombus, it is suggested to initially position the proximal edge of the covered portion of the stent graft slightly higher (a few millimeters) than the targeted landing zone.

CAUTION: DO NOT ADVANCE ACROSS THE AORTIC VALVE WITH THE COILTRAC DELIVERY SYSTEM TIP OR GUIDEWIRE.

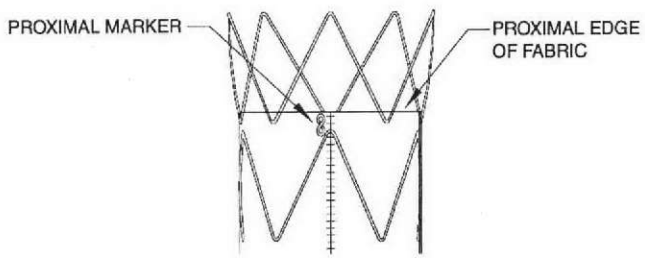
CAUTION: IT IS NOT RECOMMENDED TO POSITION THE DEVICE HIGHER IN THE PRESENCE OF EXCESSIVE CALCIFICATION OR THROMBUS, DUE TO THE INCREASED RISK OF DISLODGING MATERIAL DURING DISTAL REPOSITIONING OF THE STENT GRAFT.

Step 3 – Confirm Device Position and Verify Markers

Before deployment of the Talent Thoracic Stent Graft, confirm proper position of the device angiographically. When placing a main section, verify that the proximal markers indicate that the top edge of the fabric is at the desired location as shown in Figure 15.

While positioning, also verify that the connecting bar is oriented on the outside of the most severe bend of the vessel. The middle marker indicates the rotational position of the connecting bar. In the event accurate placement of the distal end of the graft is critical, it is also important to verify that the distal markers indicate that the bottom edge of the fabric is at the desired location.

Figure 15 - Proximal Marker Indicating the Top Edge of Covered Portion of the Stent Graft



[GRAPHICAL REPRESENTATION ONLY. MAY APPEAR DIFFERENTLY UNDER FLUOROSCOPY]

NOTE: WHEN POSITIONING THE TALENT THORACIC STENT GRAFT, BE SURE TO AVOID OR COMPENSATE FOR PARALLAX OR OTHER SOURCES OF VISUALIZATION ERROR.

12.5 Deploying the Talent Thoracic Stent Graft

Background

Misaligned Opening/Deployment is a rare phenomenon associated with the Talent Thoracic Stent Graft System. Using appropriate deployment technique and following the IFU can help avoid this event. Definitions and graphical representations are provided below:

DEFINITION OF MISALIGNED OPENING

Definition: Misaligned opening occurs when, during deployment, the proximal stent graft structure unfolds (opens) in an alignment that is not parallel to the wall of the aorta. In some instances, misaligned opening may result in misaligned stent graft deployment.

Explanation: Misaligned opening of any catheter-based prosthesis is possible in the irregular, three-dimensional geometry of the thoracic aorta. When placed in a curved anatomy, the straight, semi-flexible catheter will tend to hug one wall of the curvature. As the prosthesis is deployed, it will open from the mid-line of the catheter, adjacent to the curved wall of the aorta. The initial expansion of the graft will therefore occur away from the center-line of the aorta. The expansile forces, applied first against the adjacent and curved aortic wall, will normally "push" the graft away from the wall and into a more centered position within the vessel. This helps to ensure parallel implantation of the graft.

Clinical Sequelae: Misaligned opening is a phase which can occur during deployment of stent grafts in curved vessels, and no clinical sequelae have been observed as a result of misaligned opening.

DEFINITION OF MISALIGNED DEPLOYMENT

Definition: Misaligned deployment can occur when the proximal stent apices of a deployed stent graft remain significantly non-parallel to the wall of the aorta after deployment has been completed. Potential clinical sequelae of misaligned deployment range from negligible to significant and may present either acutely or chronically.

Severity 1: No clinical impact- unresolved mild asymmetry or stent apex protrusion into the aortic wall without clinical impact, including no evidence of endoleak, graft narrowing/occlusion or perforation.

Severity 2: Clinical impact- unresolved asymmetry or stent apex protrusion into the aortic wall with clinical impact, including evidence of endoleak or luminal narrowing of the endograft.

Explanation: There are two observed causes for misaligned deployment of the Talent Thoracic Stent Graft. The first cause involves an uncorrected misaligned opening. In this case, the stent graft fails to self-resolve an misaligned opening, and the operator fails to (or cannot) retract the stent graft in order to correct the asymmetry. The second observed cause of misaligned deployment occurs when a partially opened stent graft is pushed proximally. In this circumstance, forcing the proximal edge of a partially-deployed graft forward can force the graft to bend or buckle within the aorta.

Clinical Sequelae: The severity levels provided above describe the potential clinical consequences of misaligned deployment. In the majority of observed cases of misaligned deployment with the Talent Thoracic Stent Graft, the clinical consequences have been slight or nonexistent.

Figure 16: Misaligned Opening

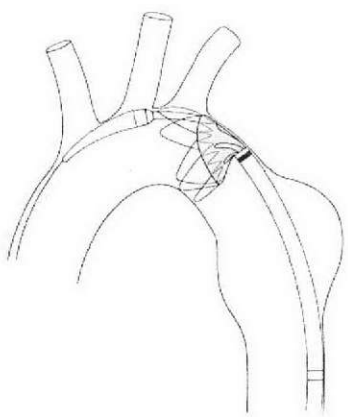


Figure 17: Misaligned Opening: Pull Back to Correct

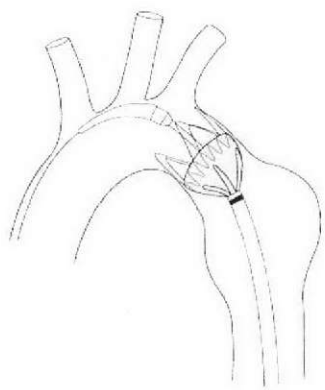
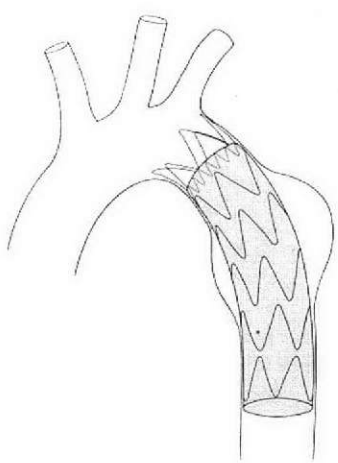


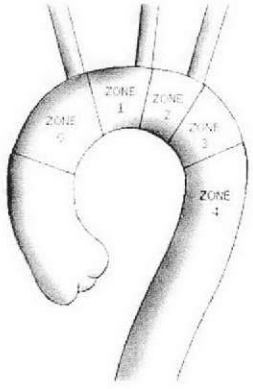
Figure 18: Misaligned Opening Corrected



WARNING: DO NOT ADVANCE THE TALENT THORACIC SYSTEM WITH AN EXPOSED PROXIMAL STENT AS IT MAY LEAD TO MISALIGNED DEPLOYMENT AND/OR AORTIC PERFORATION. IN THE FIRST 10 YEARS OF CLINICAL EXPERIENCE (OUS-COMMERCIAL AND US-INVESTIGATIONAL), THERE WERE 10 REPORTED EVENTS OF MISALIGNED OPENING/DEPLOYMENT AND 8 REPORTED EVENTS OF AORTIC PERFORATION.

WARNING: THE PROXIMAL EDGE OF THE COVERED PORTION OF THE STENT GRAFT SHOULD NOT BE PLACED BEYOND THE ORIGIN OF THE LEFT COMMON CAROTID ARTERY (I.E., ZONE 0 OR ZONE 1).

Figure 19: Covered Portion (Top of Fabric) Placement Zones



WARNING: ENSURE THAT THE PROXIMAL AND DISTAL SPRINGS ARE PLACED IN AN ADEQUATE LANDING ZONE COMPRISED OF HEALTHY TISSUE. HEALTHY TISSUE IS DEFINED AS TISSUE WITHOUT EVIDENCE OF CIRCUMFERENTIAL THROMBUS, INTRAMURAL HEMATOMA, DISSECTION, ULCERATION, AND/OR ANEURYSMAL INVOLVEMENT. FAILURE TO DO SO MAY RESULT IN INADEQUATE EXCLUSION OR VESSEL DAMAGE, INCLUDING PERFORATION.

Step 1 – Decrease Arterial Blood Pressure

Upon confirmation that the stent graft is properly positioned, it may be appropriate to momentarily decrease the patient's mean arterial blood pressure to approximately 80 mmHg (at the discretion of the physician) to avoid inadvertent displacement of the stent graft upon withdrawal of the sheath.

Step 2 – Re-verify Cup Plunger Position

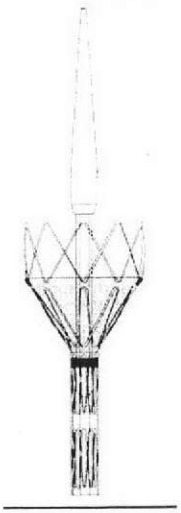
Re-verify that the cup plunger is encapsulating the distal stent graft spring and that the Tuohy Borst valve is tightened (see Figure 14). The end of the plunger is verified by fluoroscopic visualization of the end of the luer handle/push rod spring coil. A clearance of approximately 1.0mm will remain from the end of the coil and the beginning of the stent graft when the plunger is correctly placed.

CAUTION: IF THE CUP PLUNGER IS LOWER THAN THE DISTAL END OF THE GRAFT, THE GRAFT WILL MOVE DOWN UNTIL IT COMES IN CONTACT WITH THE PLUNGER AS THE SHEATH IS WITHDRAWN. THIS MAY RESULT IN INCORRECT PLACEMENT OF THE STENT GRAFT. IF THE PLUNGER IS TOO LOW, WHILE MAINTAINING THE SHEATH IN POSITION; ADVANCE THE PUSHROD UNTIL THE PLUNGER IS AGAINST THE GRAFT.

Step 3 – Deploy Proximal End

Deploy the proximal end of the stent graft by holding the luer handle/pushrod stationary with one hand while withdrawing the graft cover with the other hand using slow, steady and constant pressure. Initial force will be high, but will greatly diminish once the graft cover begins moving. Withdraw the graft cover only until the bare spring and the next covered spring have been deployed and the proximal edge of the graft material is fully expanded as shown in Figure 20.

Figure 20 - Initial Deployment of Main Section



[GRAPHICAL REPRESENTATION ONLY. MAY APPEAR DIFFERENTLY UNDER FLUOROSCOPY]

WARNING: DEPLOYMENT OF THE STENT GRAFT IN CURVATURE, ESPECIALLY IN THE TRANSVERSE ARCH, MAY RESULT IN MISALIGNED DEPLOYMENT OF THE PROXIMAL STENT STRUCTURE. IN RARE INSTANCES, THIS MAY RESULT IN MAL-APPOSITION OF THE PROXIMAL STENT(S) AND INCOMPLETE SEAL WITH CLINICAL IMPACT, INCLUDING EVIDENCE OF ENDOLEAK OR LUMINAL NARROWING OF THE ENDOGRAFT. IN THE FIRST 10 YEARS OF CLINICAL EXPERIENCE (OUS-COMMERCIAL AND US-INVESTIGATIONAL), THERE WERE 10 REPORTED EVENTS OF MISALIGNED OPENING/DEPLOYMENT.

CAUTION: IF THE STENT GRAFT IS DEPLOYED HIGHER THAN THE TARGETED LANDING ZONE, IT IS EXTREMELY IMPORTANT NOT TO DEPLOY MORE THAN THE FIRST TWO STENT SPRINGS (SEE FIGURE 20). FURTHER DEPLOYMENT OF THE GRAFT CAN IMPAIR THE ABILITY TO MOVE THE GRAFT TO THE DESIRED LANDING ZONE.

CAUTION: NEVER ADVANCE THE PUSH ROD; USE SUFFICIENT RESISTANCE ONLY TO HOLD IT STATIONARY. DO NOT ROTATE DELIVERY SHEATH DURING DEPLOYMENT.

CAUTION: IF THE SHEATH IS INADVERTENTLY WITHDRAWN, THE TALENT THORACIC STENT GRAFT WILL PREMATURELY DEPLOY AND WILL BE PLACED INCORRECTLY.

NOTE: IF NECESSARY, THE STENT GRAFT CAN BE RE-POSITIONED DISTALLY TO ITS DESIRED LOCATION BY RETRACTING IT, AS LONG AS NO MORE THAN TWO OF THE PROXIMAL SPRINGS OF THE STENT GRAFT HAVE BEEN DEPLOYED.

NOTE: DEPLOYMENT OF THE TALENT THORACIC 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.

Step 4 – Verify Stent Graft Position

Perform angiography to verify the position of the stent graft in relation to the desired location. If the stent graft was deployed higher than the targeted landing zone or has exhibited misaligned opening (Refer Figure 16 to Figure 18), gently pull on the entire delivery system until the proximal markers indicating the top edge of the fabric are at the desired position.

CAUTION: IF PULLING THE DELIVERY SYSTEM CAUSES THE GRAFT TO FURTHER DEPLOY INSTEAD OF MOVING THE GRAFT DISTALLY, DO NOT CONTINUE TO PULL ON THE INTRODUCER SYSTEM. LOOSEN THE TUOHY BORST VALVE AND PULL ON THE BLUE CATHETER UNTIL THE FULL DEVICE IS MOVED TO THE DESIRED LOCATION.

NOTE: IF PULLLING DOWN THE DELIVERY SYSTEM CAUSES THE GRAFT TO BE DEPLOYED PAST THE INTENDED LANDING ZONE THEN AN IMPLANTATION OF AN ADDITIONAL PROXIMAL EXTENSION SHOULD BE CONSIDERED AS PER SECTION 12.8 BELOW.

Step 5 – Finish Stent Graft Deployment

Before deploying the remainder of the stent graft, verify that the cup plunger is still encapsulating the bottom portion of the stent graft as shown in Figure 14. If the plunger base is not up against the distal end of the stent graft, while maintaining the sheath in position, carefully advance the pushrod until the plunger base is pushed against the graft.

Holding the luer handle/pushrod stationary, withdraw the graft cover until the distal spring is completely deployed (verify by the sheath marker band). Do not rotate the delivery sheath system during the deployment.

CAUTION: IN SOME INSTANCES, THE CUP PLUNGER MAY NOT IMMEDIATELY RELEASE THE DISTAL END OF THE GRAFT WHEN THE GRAFT COVER HAS BEEN FULLY RETRACTED. FOR THESE CASES, SLOWLY ROTATE THE PUSH ROD (LESS THAN 90°) AND PULL BACK THE PUSH ROD A FEW MILLIMETERS UNTIL THE SPRING RELEASES FROM THE CUP PLUNGER. ALTERNATIVELY, LOOSEN THE TUOHY BORST AND ADVANCE THE BLUE CATHETER (AND TIP) A FEW MILLIMETERS UNTIL THE SPRING RELEASES FROM THE CUP PLUNGER.

12.6 Removing the Delivery System

Step 1 – Catheter Withdrawal

Loosen the Tuohy Borst valve and withdraw the tip into the end of the graft cover, re-establishing the smooth transition of the tip with the graft cover. This can be verified by fluoroscopic examination of the sheath marker band aligning with the radiopaque tip. Tighten the Tuohy Borst valve.

CAUTION: THE RETRIEVAL OF THE TIP MUST BE CAREFULLY MONITORED WITH FLUOROSCOPIC GUIDANCE TO ENSURE THAT THE TIP DOES NOT CAUSE THE TALENT THORACIC STENT GRAFT TO BE INADVERTENTLY PULLED DOWN.

Step 2 – Complete Catheter Removal

Gently remove the CoilTrac Delivery System. Do not use excessive force. Using fluoroscopic imaging, confirm that no movement of the stent graft occurs during withdrawal. Do not remove the guidewire. The stent graft is now ready for modeling as needed.

12.7 Ancillary Balloon Catheter Modeling

The Reliant Stent Graft Balloon Catheter, packaged separately, may be used to assist in stent graft implantation by modeling the covered springs and removing wrinkles and folds from the graft material as needed. Sub-optimal apposition of the self-expanding stent graft may be improved by use of the Reliant Stent Graft Balloon. Refer to the *Instructions for Use* supplied with the Reliant Stent Graft Balloon Catheter for more information.

CAUTION: USE THE RELIANT STENT GRAFT BALLOON CATHETER ACCORDING TO THE INSTRUCTIONS FOR USE SUPPLIED WITH THE RELIANT DEVICE. DO NOT ATTEMPT TO USE THE RELIANT STENT GRAFT BALLOON CATHETER BEFORE COMPLETELY READING AND UNDERSTANDING THE INFORMATION SUPPLIED WITH THE RELIANT DEVICE.

NOTE: THE RELIANT STENT GRAFT BALLOON CATHETER IS RECOMMENDED FOR USE WITH THE TALENT THORACIC STENT GRAFT. DATA IS NOT AVAILABLE FOR USE WITH OTHER BALLOONS FOR REMODELING STENT GRAFTS.

If focal area narrowing of the stent graft is observed, re-balloon. If the area remains narrow following ballooning, place another Talent Thoracic Stent Graft inside that segment. Do not leave untreated any focal area with significant stent graft narrowing or abrupt kinks of the connecting bar. This can lead to thrombosis, damage of the stent graft or incomplete distal seal.

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 COVERED (GRAFT FABRIC) PORTION OF THE PROSTHESIS.

WARNING: DO NOT USE THE RELIANT STENT GRAFT BALLOON CATHETER IN PATIENTS WITH HISTORY OF THORACIC DISSECTION DISEASE. DO NOT OVER-INFLATE THE RELIANT STENT GRAFT BALLOON WITHIN OR OUTSIDE OF THE GRAFT MATERIAL.

12.8 Implanting Additional Component Sections

If two or more Talent Thoracic Stent Graft component sections are required to exclude the target lesion, use the following steps.

Step 1 - Device Preparation and Insertion

Complete all steps described above in Section 12.3, and Steps 1 and 2 of Section 12.4.

Slowly advance the Talent Thoracic Stent Graft System to the targeted landing zone. Advancement of the device within the previously implanted stent graft must be carefully monitored under fluoroscopy to ensure that the implanted stent graft does not move. Before deploying the stent graft, confirm proper position of the system.

Step 2 - Confirm Device Position and Verify Markers

When placing a distal main section radiographically, verify that the proximal alignment markers are aligned with or above the distal markers of the mating graft (see Appendix A). Also, verify that the distal markers that indicate the bottom edge of the graft material are at the desired location. Verify that the connecting bar is rotationally oriented on the outside of the most severe bend of the vessel.

When placing a proximal main or proximal extension, radiographically verify that the proximal markers that indicate the top edge of the graft material are at the desired location (see Appendix B). It may be necessary to perform an angiogram to ensure this. Also, verify that the alignment-marker of the proximal extension is aligned with, or below, the proximal markers of the main graft. Radiographically verify that the connecting bar is oriented on the outside of the most severe bend of the vessel.

When placing a distal extension, radiographically verify that the proximal alignment-marker is aligned with, or above, the distal markers of the mating graft (see Appendix C). Also, verify that the distal markers that indicate the bottom edge of the graft material are at the desired location. Verify that the connecting bar is rotationally oriented on the outside of the most severe bend of the vessel.

CAUTION: AT LEAST A MINIMUM OF 30MM OF OVERLAP IS REQUIRED. HOWEVER, IN AREAS OF ANGULATION OR CURVATURE AND/OR IF MORE THAN TWO (2) STENT GRAFTS ARE REQUIRED, ADDITIONAL OVERLAP IS RECOMMENDED (AT LEAST AN ADDITIONAL SPRING LENGTH-15MM). FAILURE TO PROVIDE SUFFICIENT OVERLAP MAY RESULT IN SEPARATION OF THE STENT GRAFTS AT THEIR JUNCTION. REFER TO Appendix A, Appendix B AND Appendix C

Step 3 - Remaining Steps

Follow procedures previously described in Sections 12.5, 12.6, and 12.7.

Step 4 – Final Angiogram

Upon completion of the final ballooning procedure, perform angiography to verify stent graft apposition and seals, and absence of endoleaks (Type I and Type III). 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 a stent graft extension. A minor leak that does not seal after re-ballooning may seal spontaneously within several days. If any adjunctive maneuvers were conducted, perform a final angiogram to confirm successful exclusion of the target lesion. Do not use high-pressure injections at the edges or within the Talent Thoracic Stent Graft immediately after implantation.

CAUTION: ANY ENDOLEAK LEFT UNTREATED DURING THE IMPLANTATION PROCEDURE MUST BE CAREFULLY FOLLOWED AFTER IMPLANTATION.

Step 5 – Entry Site Closure

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

13.0 Imaging Guidelines and Post-Operative Follow-up

13.1 General

All patients should be advised that endovascular treatment requires life-long, 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 TAAs.

Physicians should evaluate patients on an individual basis and prescribe follow-up relative to the needs and circumstances of each individual patient. The recommended imaging schedule is presented in Table 37. This schedule outlines the minimum requirement for patient follow-up and should be maintained even in the absence of clinical symptoms (e.g., pain, numbness, weakness). Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms, or changes in the structure or position of the stent graft) should receive follow-up at more frequent intervals.

Annual imaging follow-up may include chest X-ray and computed tomography angiogram (CTA). Magnetic resonance angiogram (MRA) may be used in patients with impaired renal function or intolerance to contrast media.

- 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 37 lists the minimum requirements for imaging follow-up for patients with the Talent Thoracic Stent Graft.

Table 37 - Imaging Recommendations

Visit	Imaging Modality		
	Angiogram	CTA/MRA[2,3]	Chest X-ray[2]
Pre-Treatment	X (optional)	X[1]	
Treatment	X		
1 Month		X[4]	X
12 Month (Annually thereafter)		X[4]	X

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

2 A six month follow-up with CT Scan and Chest X-ray is 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

4 If a Type I or III endoleak is present, prompt intervention and additional follow-up post-intervention is recommended. See Section 13.6

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.

13.2 Angiographic Imaging

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

13.3 CTA/MRA Images

CTA images are recommended pre-treatment (within 3 months of implant) to determine anatomic suitability for the Talent Thoracic Stent Graft. CTA with 3-D reconstruction is recommended in order to accurately assess the patient's anatomy.

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 38 for optimal CTA results. MRA may be indicated for patients with impaired renal function.

- Film sets should include all sequential images at the lowest possible slice thickness (<3mm). Do not perform large slice thickness (>3mm) and/or omit consecutive CT images/films sets, as this prevents precise anatomical and device comparisons over time.
- All images should include a scale for each film/image. Images should be arranged no smaller than 20:1 images on 14 inch X 17 inch sheets if film is used.
- Both non-contrast and contrast runs are required, with matching or corresponding table positions.
- Pre-contrast and contrast run slice thicknesses and intervals must match.

- DO NOT change patient orientation or re-landmark the patient between non-contrast and contrast runs.

Non-contrast and contrast enhanced baseline and follow-up imaging are important for optimal patient surveillance. It is important to follow accepted imaging protocols during the CT exam. Table 38 lists examples of accepted imaging protocols.

Table 38 - CTA Imaging Guidelines

Injection Volume (cc)	100-150
Injection Rate (cc/sec)	3-4 via 20G IV or larger
Bolus Timing	SmartPrep, Carebolus, or equivalent
Scan Range	Thoracic inlet to aortic bifurcation
Scan Diameter (FOV)	Large
DFOV (cm)	24
Scan Type	Helical
Rotation Speed (sec)	0.8
Slice Thickness	≤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)	1-2

13.4 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.

13.5 MRI Information

Non-clinical testing has demonstrated that the Talent Thoracic Stent Graft is MR Conditional. It can be scanned safely in both 1.5T & 3.0T MR systems under the following conditions:

1.5 Tesla Systems:

- Static magnetic field of 1.5 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.

Based on non-clinical testing, the device was determined to produce a temperature rise of less than 1°C at a maximum whole body averaged specific absorption rate (SAR) of 4 W/kg for 15 minutes of MR scanning in a 64MHz whole body transmit coil, which corresponds to a static field of 1.5T. The maximum whole body averaged specific absorption rate (SAR) was derived by calculation and verified by calorimetry.

3.0 Tesla Systems:

- Static magnetic field of 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, whatever is less).

Based on non-clinical testing, the device was determined to produce a temperature rise of less than 1°C at a maximum whole body averaged specific absorption rate (SAR) of 4 W/kg for 15 minutes of MR scanning in a 3 Tesla Siemens TrioTIM (VB 13 Software) MR scanner. The maximum whole body averaged specific absorption rate (SAR) was derived by calculation and verified by calorimetry.

Image Artifact (1.5 Tesla & 3 Tesla Systems):

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. The image artifact extends approximately 5 and 8 mm from the device, both inside and outside the device lumen when scanned in non-clinical testing using the sequence: spin echo and gradient echo, respectively in a 3.0T Siemens TrioTIM (VB 13 Software) MR system with a whole body coil.

Patients with Talent Thoracic Stent Grafts 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.

13.6 Additional Surveillance and Treatment

Additional surveillance and possible treatment is recommended for:

- Aneurysms with endoleak
- Aneurysm enlargement, > 5mm of maximum diameter (regardless of endoleak status)
- Migration
- Inadequate seal length
- Fracture

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

14.0 Device-Related Adverse Events Reporting

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

15.0 Patient Materials and Tracking Information

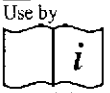
The Talent Thoracic Stent Graft System is packaged with additional specific information which includes:

- **Temporary Device Implant Card** that includes both patient and stent graft information. Physicians should complete this card and instruct the patient to keep this card in their possession at all times. The patients should refer to this card anytime they visit additional health practitioners, particularly for any additional diagnostic procedures (e.g. MRI). This temporary device implant 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 Talent Thoracic 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 device implant card.

Upon receipt of the device tracking form, Medtronic will mail the patient a **permanent device implant card**. This card includes important information regarding the implanted stent graft. Patients should refer to this card anytime they visit health practitioners, particularly for any diagnostic procedures (e.g. MRI). Patients should carry this card with them at all times. 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.

16.0 Explanation of Symbols

Use by



Consult instructions for use

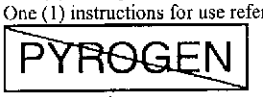
Do not reuse

℞ only

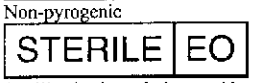
CAUTION: Federal (USA) law restricts this device for sale by or on order of a physician.

MR Conditional

Contents:
One (1) TALENT™ THORACIC Stent Graft System with COILTRAC
One (1) set of patient tracking materials
One (1) instructions for use reference



Non-pyrogenic



Sterilized using ethylene oxide

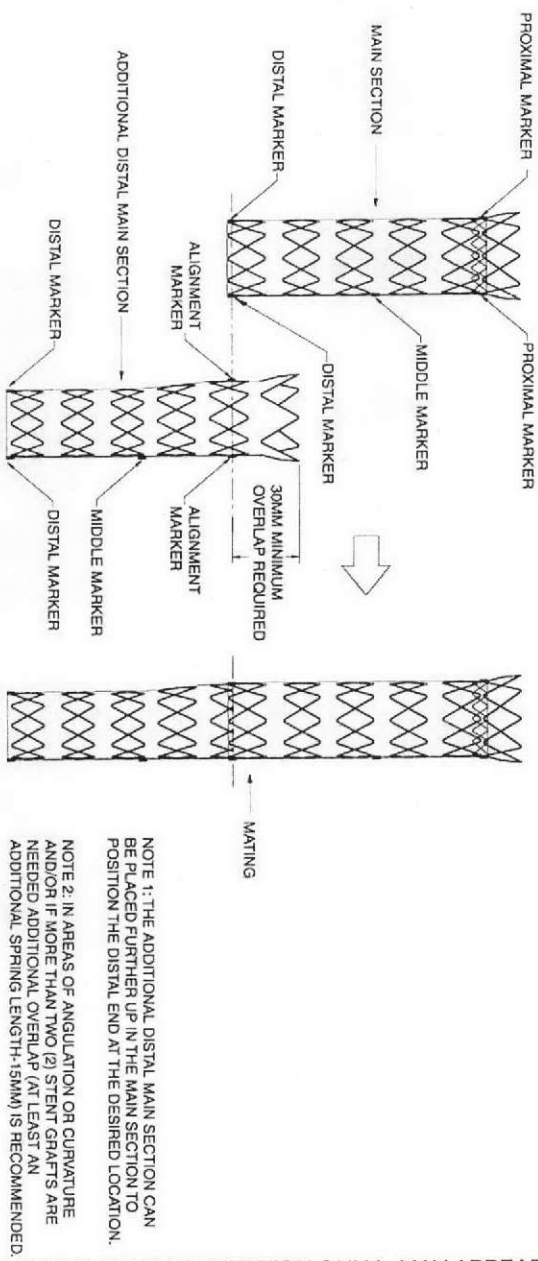
Do not use if package is damaged

Store at room temperature in a dark, dry place

Peel here

Pull tab to open

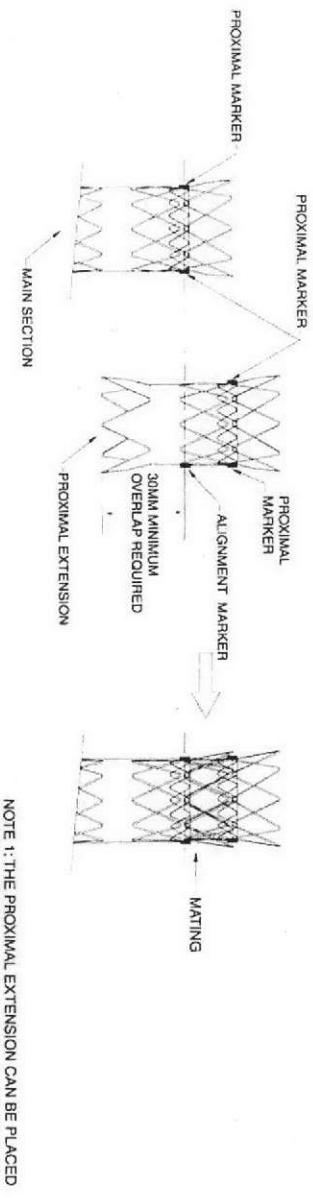
APPENDIX A



[GRAPHICAL REPRESENTATION ONLY. MAY APPEAR DIFFERENTLY UNDER FLUOROSCOPY]

APPENDIX B

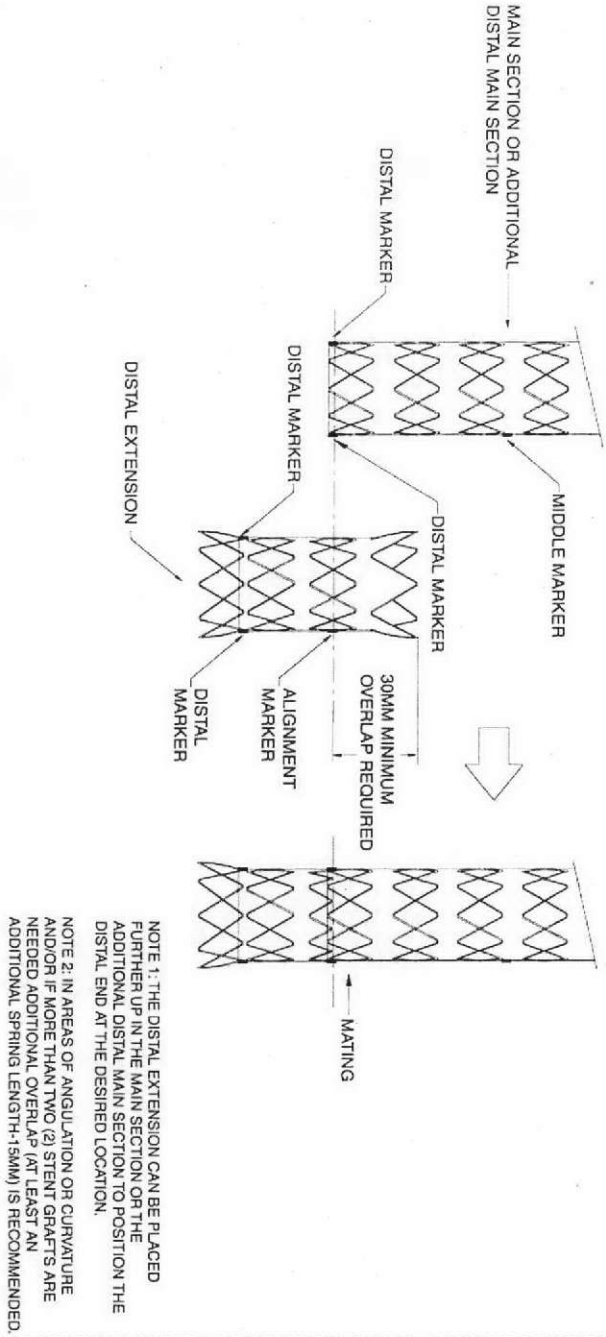
Mating Main Section and Proximal extension



[GRAPHICAL REPRESENTATION ONLY. MAY APPEAR DIFFERENTLY UNDER FLUOROSCOPY]

APPENDIX C

Mating Main Section or Additional Distal Main Section and Distal Extension



[GRAPHICAL REPRESENTATION ONLY. MAY APPEAR DIFFERENTLY UNDER FLUOROSCOPY]

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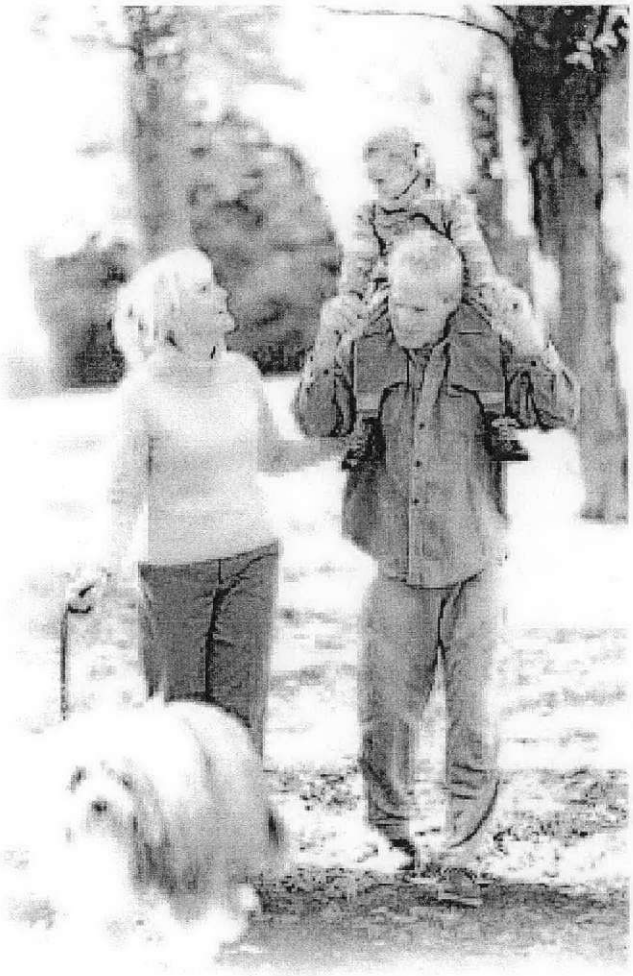
Medtronic

Alleviating Pain · Restoring Health · Extending Life

Patient Information Booklet



Endovascular Stent Grafts: A Treatment for Thoracic Aortic Aneurysms

Table of Contents

Table of Contents

Introduction

This booklet is provided to help you and your caregivers decide if a thoracic stent graft is right for you to treat a thoracic aortic aneurysm. Please read the booklet and discuss any questions with your doctor. Only a doctor can determine whether you are a good candidate for the procedure.

There is a glossary on page 20 that you can use to better understand some of the medical terms in this booklet. Words that are ***bolded*** *in the text are defined in the glossary.*

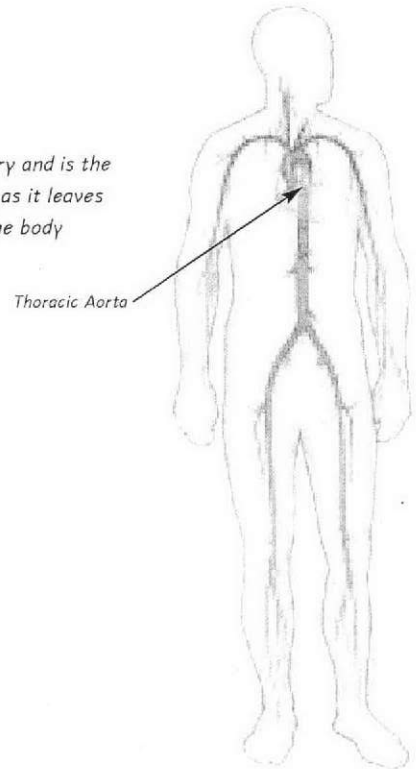
Anatomy of the Thoracic Aorta

The **aorta** is the largest **artery** in the body. An artery is a blood vessel that carries blood away from the heart. The **thoracic aorta** is the first blood vessel that the blood enters when it leaves the heart to circulate throughout the body. The thoracic aorta is the section of the aorta that sits within your chest (see **Figure 1**).

The thoracic aorta has several important blood vessels that provide blood to the heart, head, arms, and spinal cord. The thoracic aorta normally has a diameter (width) of about one inch. This diameter varies among individuals and increases slightly as you age.

FIGURE 1

The aorta is the body's largest artery and is the first blood vessel that blood enters as it leaves the heart to circulate throughout the body



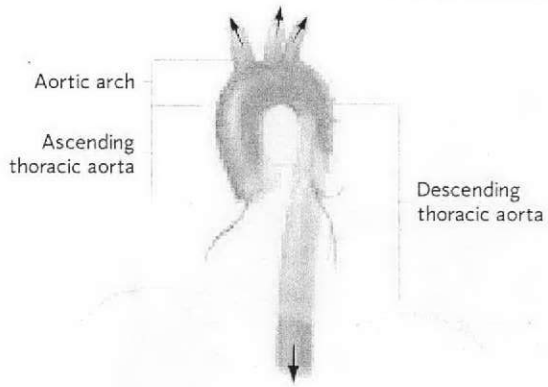
The thoracic aorta has three major sections: **the ascending thoracic aorta**, the **aortic arch**, and the **descending thoracic aorta** (see **Figure 2**). From the heart, the aorta curves upward and blood travels up toward the head. The aorta then curves downward and redirects blood flow to the feet.

The ascending thoracic aorta is the section of the aorta closest to the heart. Blood vessels that branch off from the ascending thoracic aorta also provide blood to the heart. The aorta then curves in the section called the **aortic arch**. Blood vessels that go to the head and arms originate off the aortic arch.

Blood flow is directed toward the feet in the descending thoracic aorta. Multiple blood vessels branch off from the descending thoracic aorta including vessels that send blood to the spinal cord. The Medtronic **Talent™ Thoracic Stent Graft** is designed for use in the descending thoracic aorta.

FIGURE 2

The thoracic aorta has three major sections: the ascending thoracic aorta, the aortic arch, and the descending thoracic aorta



Anatomy of the Thoracic Aorta

What Is an Aneurysm?

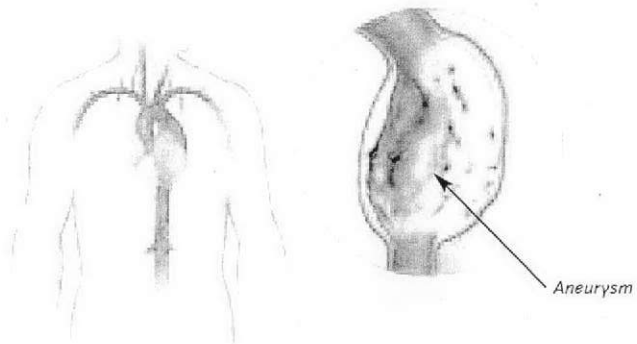
An **aneurysm** is a bulging or ballooning of a weakened area of a blood vessel. Aneurysms usually result when proteins that make the artery elastic break down. Aneurysm formation may also be related to heredity, trauma, or disease that weakens the vessel wall. Over time, the vessel wall loses its strength and the force of normal blood pressure in the aneurysm can cause it to burst.

If an aneurysm forms in the part of the aorta that flows through your chest, it is called a **thoracic aortic aneurysm** (see **Figure 3**). This term is often abbreviated as "**TAA**."

The descending aorta has an aneurysm when the diameter of the diseased part of the aorta is at least 1.5 times as wide as the healthy part of the aorta. An aneurysm is also likely when its diameter reaches approximately two inches or larger.

FIGURE 3

An aneurysm is a bulging or ballooning of a weakened area of a blood vessel



What Symptoms Are Associated with Thoracic Aortic Aneurysms?

Most people do not have any symptoms from thoracic aortic aneurysms. If symptoms do occur, they include back pain, chest pain, difficulty swallowing, and/or coughing up blood. Most aneurysms are diagnosed when doctors do tests (such as **CT scans** or **MRIs**) for other reasons. As an aneurysm gets wider, it has a higher chance of bursting, also called **aneurysm rupture**. When the aorta ruptures, blood leaks from the vessel and no longer travels to vital organs, and this often leads to death. Thoracic aortic aneurysms are treated when a doctor believes the aneurysm might rupture.

What Are the Current Treatments for Thoracic Aortic Aneurysms?

Not all thoracic aortic aneurysms need surgery. Your doctor may try medical management of your thoracic aortic aneurysm. However, medical management does not treat the aneurysm or the underlying disease, but rather it attempts to reduce the stresses on the diseased vessel. Common medical management includes:

- If your aneurysm is small, your doctor may decide to wait and watch carefully to see if there are any changes.
- If you have high blood pressure, your doctor may prescribe medication to lower it.
- If you smoke, your doctor may suggest that you find help in quitting.
- Your doctor may also ask you to make changes in your diet or exercise habits.

If the doctor feels there is a risk that the aneurysm will burst (or rupture), he or she may recommend one of two aneurysm repair methods:

- Open Surgery
- Thoracic Stent Graft Procedure

What Is Open Surgery?

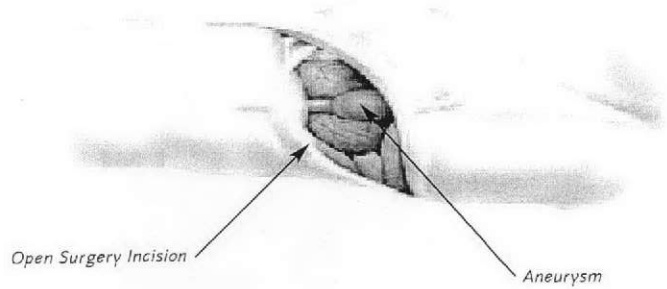
Open surgery (thoracotomy) is the traditional treatment used to replace the part of the vessel where the aneurysm has formed. Open surgery is performed under general anesthesia and typically takes four to six hours to complete.

A surgeon performs an operation to open the chest (see **Figure 4**). Then, the surgeon removes the aneurysm. Finally, the aneurysmal vessel is replaced with a fabric graft that is sewn into place. Surgical patients have follow-up one year later. If the surgery is successful at one year, follow-up is no longer necessary.

Patients typically spend one night in an intensive care unit and then remain in the hospital for five to seven days. It often takes at least three to six months for a patient to return to the quality of life that he or she had before surgery.

FIGURE 4

Open surgery is the traditional treatment for repairing a thoracic aortic aneurysm



What Are the Risks of Open Surgery?

Repairing an aneurysm surgically is a complicated process that requires an extended stay in the intensive care unit as well as a prolonged hospital stay. Please discuss with your doctor if this treatment method is right for you. Complications associated with open surgery include, but are not limited to the following:

- Neurological complications (for example, stroke or paraplegia)
- Cardiopulmonary complications (for example, heart attack)
- Wound healing complications
- Kidney failure
- Multi-system organ failure
- Infection
- Fever
- Shock
- Sexual dysfunction
- Death

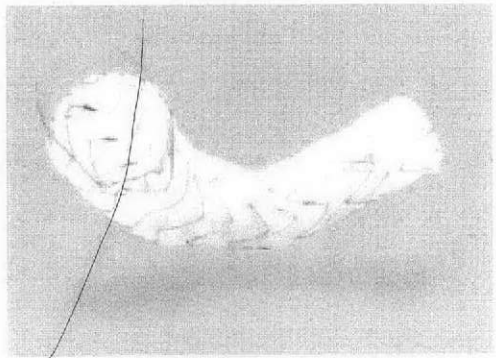
Open Surgery

Is There an Alternate Treatment to Open Surgery?

Yes, the alternate treatment is a **thoracic stent graft procedure (endovascular stent grafting)**. A fabric graft (see **Figure 5**) supported by a metal framework is placed within the length of the aneurysm without surgically opening the surrounding tissue. The Talent™ Thoracic Stent Graft System is used to reline the weakened wall of the vessel to prevent the aneurysm from rupturing.

FIGURE 5

The Talent™ Thoracic Stent Graft



Note: The stent graft shown in the figure is not representative of the actual size. The actual size of the Talent™ Thoracic Stent Grafts range from 80 mm to 130 mm in length

Are You a Good Candidate for the Talent™ Thoracic Stent Graft Procedure?

Anyone who is considering the Talent™ Thoracic Stent Graft procedure should:

- Be able to undergo a procedure that lasts one to three hours.
- Be able to attend regularly scheduled doctor's visits and tests after the procedure, including at least one visit annually for life.
- Be fully informed about the risks and benefits of the Talent™ Thoracic Stent Graft procedure as compared to open surgical repair.

Patients who have very large aneurysms and/or vessels with many bends or curves may not be good candidates for the stent graft procedure. Discuss with your doctor which treatment is best for you.

Discuss with your doctor which treatment is best for you

This booklet is not intended as a substitute for a thorough talk with your doctor about whether this procedure is right for you. Please read this page carefully, and then talk with your doctor.

Questions You Might Ask Your Doctor

- What are all of my options for treating my thoracic aneurysm?
- Is the Talent™ Thoracic Stent Graft System an appropriate treatment for my thoracic aortic aneurysm?
- What are the risks of rupture with a stent graft?
- Will I have any symptoms from the Talent™ Thoracic Stent Graft procedure?
- After the procedure, how often will I need to see my doctor?
- What follow-up tests will be needed?
- What if the aneurysm continues to grow after endovascular treatment?
- Will I have to limit my activities after the treatment? If so, for how long?
- How long can the stent graft remain implanted inside my body?
- How many Talent™ Thoracic Stent Graft procedures has this doctor performed?
- What are the advantages and disadvantages of open surgical repair compared to endovascular repair of a thoracic aneurysm?

Ask your doctor to explain all of your options thoroughly

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What Are the Contraindications?

A **contraindication** is a specific situation in which a drug, procedure, or surgery should not be used, because it may be harmful to the patient. The Talent™ Thoracic Stent Graft is contraindicated in patients:

- Who have a condition that can infect the stent graft.
- Who are allergic to the stent graft materials.[a]

Your doctor can help determine if the Talent™ Thoracic Stent Graft is safe for you.

Warnings and Precautions

Warning: All patients with endovascular aneurysm repair must undergo periodic imaging to evaluate the stent graft and aneurysm size. Follow-up is important because you may not have symptoms when there is a problem with your stent graft.

Warning: The use of this device requires administration of contrast dye used in imaging. Patients with preexisting kidney problems may have an increased risk of kidney failure after procedure.

Warning: The long-term risks of prolonged fluoroscopy have not been established.

Caution: A MRI may only be used on the graft under specific conditions. Please refer to the "Patient Implant Card" section (page 17) for information on MRI scans.

[a] The Talent Thoracic Stent Graft is made up of the following materials: nitinol, polyester, and platinum-iridium wire.

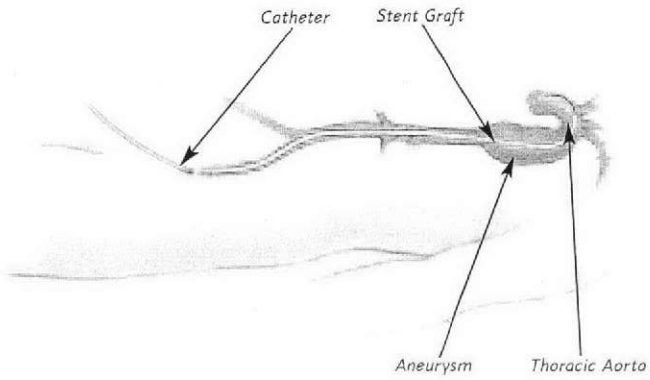
How Is the Talent™ Thoracic Stent Graft Procedure Performed?

The procedure is performed under regional or general anesthesia. Before the procedure, several tests are performed that let your doctor see the aneurysm and the area around it. These tests are usually performed using imaging such as a CT scan. A CT scan is an imaging technique that creates a series of X-rays that are used to form a picture of your aneurysm and adjacent blood vessels. A CT scan does not hurt and you will be awake for this testing.

To prepare for the stent graft procedure, a small cut is made in your groin to allow access for the stent graft **delivery catheter** into the **femoral artery**. Sometimes the doctor will use a **conduit** (a surgical graft attached to a larger artery in your pelvis) if the artery in your groin is too small to deliver the device. The doctor uses **fluoroscopy** (video-like X-rays) to see the device move through the blood vessel in your groin. The doctor also uses fluoroscopy to correctly position the device over the aneurysm in your descending thoracic aorta (see **Figure 6**).

FIGURE 6

The Talent™ Thoracic Stent Graft



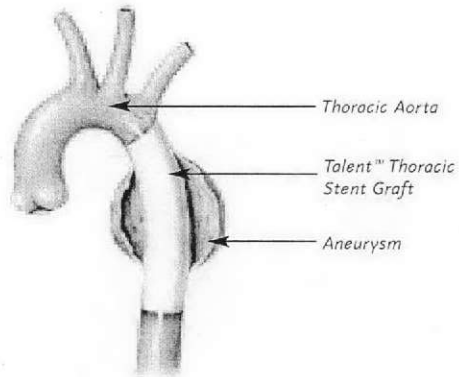
When the delivery catheter is properly placed, the Talent™ Thoracic Stent Graft is released slowly from the delivery catheter into the aorta. As the stent graft is released, it expands automatically to its proper size (see **Figure 7**) so that it fits snugly to the aorta both above and below the aneurysm.

Depending on the shape and size of your aneurysm, additional stent grafts may be used. This ensures that the stent grafts span the full length of the aneurysm and blood is no longer flowing into the aneurysm. Fluoroscopy is then performed to allow your doctor to see that the stent graft has been placed properly. The procedure typically takes one to three hours to complete.

Patients often leave the hospital within one or two days of the procedure. Patients can usually return to their normal quality of life within a few weeks.

FIGURE 7

Placement of the Talent™ Thoracic Stent Graft



The Procedure

What Are the Risks of a Thoracic Stent Graft Procedure?

There are a number of risks that are related to having a thoracic stent graft procedure. Complications associated with the use of the Talent™ Thoracic Stent Graft System include, but are not limited to the following:

Clinically Associated Events:

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

- Vascular complications (for example, blood clot)
- Neurological complications (for example, stroke or paraplegia)
- Cardiopulmonary complications (for example, heart attack)
- Gastrointestinal complications (for example, bowel obstruction)
- Pulmonary complications (for example, lung damage)
- Wound healing complications
- Kidney failure
- Bleeding
- Conversion to open surgery
- Death

Device Related Events:

Endovascular stent grafting is a new therapy. Therefore, long term safety and effectiveness of the Talent™ Thoracic Stent Graft has not been established. Please discuss with your doctor if this therapy is right for you. Possible complications of the device may include, but are not limited to the following:

- Leaking of blood around the graft ("**Endoleak**")
- Movement of the graft away from the desired location ("**Migration**")
- Additional procedures

What Are the Benefits of a Thoracic Stent Graft Procedure?

There are a number of benefits that are related to having a thoracic stent graft procedure:

- A lower risk of death compared to open surgery.[b]
- The patient loses less blood during the procedure.
- The patient will spend less time in the intensive care unit after the procedure.
- The patient will have a shorter hospital stay with faster recovery time compared with open surgery.[1]

Please discuss the benefits of all treatment options with your doctor so that you can determine which procedure is right for you.

[b] VALOR trial all cause mortality at 1 year was 16.1% for endovascular compared to 29.8% for open repair.

Reference: 1. Lopera J, Patino JH, Urbina C, et al. Endovascular treatment of complicated type-B aortic dissection with stent-grafts: mid-term results. *J Vasc Interv Radiol.* 2003;14(2):195-203.

What Can I Expect After the Thoracic Stent Graft Procedure?

Patients have reported feeling discomfort for the first few days after the procedure. Just after the procedure, your physician may tell you to lie flat for four to six hours to let your leg wound begin healing. You may feel side effects such as swelling at the incision at your groin, nausea, vomiting, leg pain or throbbing, lack of appetite, and/or absence of bowel movement for one to three days.

Follow-up After the Procedure

Scheduling Doctor Visits

Follow-up is an important part of determining the success of the Talent™ Thoracic Stent Graft. Your doctor will schedule follow-up visits after one month, six months, one year, and once each year for the rest of your life. At each appointment, an imaging study will be conducted to determine the performance of the stent graft. **Imaging** is defined as the use of X-rays, CT scans, MRI scans, or other techniques in order to obtain pictures of the inside of the body. If you have poor kidney function, you should make sure to ask your doctor about the dyes used in some of these imaging studies, as they may be harmful.

CT imaging may detect an endoleak in some patients. An endoleak means that a small amount of blood is still flowing into the **aneurysmal sac**. If your doctor thinks the endoleak needs treatment, it can often be treated with an additional thoracic stent graft procedure. Sometimes an endoleak cannot be treated with another stent graft. The doctor may need to repair the endoleak with open surgery.

Patient Implant Card

After your Talent™ Thoracic Stent Graft operation, your doctor will fill out a temporary patient implant card. You get one copy, your doctor gets one copy, and the third copy is mailed to Medtronic. The temporary patient implant card will tell you the size and number of your thoracic aortic implants.

Medtronic will mail you a permanent patient implant card to carry in your wallet. Your permanent card will list information about implant sizes, quantities, and MRI compatibility. It is important to know that the Talent™ Thoracic Stent Graft is "**MR Conditional.**" MR Conditional means under specific conditions it is safe for you to undergo an MRI scan after receiving a Talent™ Thoracic Stent Graft. Show your Medtronic patient implant card to your doctor before having surgery or undergoing an imaging procedure. Your doctor will consult with Medtronic to determine if it is safe for you to have the surgery or procedure.

What Symptoms Would Prompt Me to Call My Doctor?

If you experience any of the following symptoms, contact your doctor immediately:

- Pain, numbness, coldness, weakness, or loss of sensation in your legs.
- Any back, chest, abdominal, or groin pain.
- Dizziness, fainting, rapid heartbeat, or sudden weakness.

After the Procedure

Additional Information

Medtronic Patient Information

If you have questions about your particular condition and the Talent™ Thoracic Stent Graft, contact your doctor. If you have additional questions about the Talent™ Thoracic Stent Graft, feel free to contact Medtronic by mail, phone, or fax.

Medtronic Vascular
3576 Unocal Place
Santa Rosa, CA 95403
USA
Tel: 707.525.0111
www.Medtronic.com

Product Services
Tel: 888.283.7868
Fax: 800.838.3103

Additional Information

- The Society for Vascular Surgery (www.vascularweb.org)
  633 N. St. Clair, 24th Floor
  Chicago, IL 60611
  Tel: 800.258.7188
- The Society of Thoracic Surgeons (www.sts.org)
  633 N. St. Clair, Ste. 2320
  Chicago, IL 60611
  Tel: 312.202.5801
- The National Library of Medicine (www.nlm.nih.gov)
- WebMD (www.webmd.com)

Additional Information

Glossary

Aneurysm: A bulging or "ballooning" of a weakened area of a blood vessel.

Aneurysmal sac: The dialated area of the artery where an aneurysm is located.

Aneurysm rupture: A tear in the vessel wall near or at the location of the bulging or "ballooning" of the weakened area of the blood vessel (ie, thoracic aortic aneurysm).

Aorta: The main blood vessel of the arterial system of the body.

Aortic arch: The section of the aorta from which the blood vessels lead to the head and arms branch.

Artery: A blood vessel that carries blood from the heart to the rest of the body.

Ascending thoracic aorta: The section of the aorta closest to the heart.

Conduit: A fabric tube sewn onto a major blood vessel that provides an alternate way to insert the stent graft delivery system. A conduit is used if the femoral artery is too small to allow access.

CT scan (Computed Tomography): An imaging technique that creates a series of X-rays that are used to form a picture of your aneurysm and adjacent blood vessels.

Contraindication: A specific situation in which a drug, procedure, or surgery should not be used, because it may be harmful to the patient.

Delivery catheter: A long tube-like device that contains the stent graft. The device is used to deploy the stent graft in the aorta.

Descending thoracic aorta: The segment of the thoracic aorta in which blood flows down toward the feet.

Endoleak: Blood flow into the aneurysm after placement of a stent graft.

Femoral artery: A large artery in the muscles of the thigh. The delivery system for a stent graft is usually inserted via the femoral artery.

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Fluoroscopy: A real-time X-ray imaging technique that is viewed on a monitor.

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

Migration: The movement of the graft away from the desired location.

MR Conditional: A standard used to determine when it is safe to undergo an MRI Scan after receiving a Talent™ Thoracic Stent Graft.

MRI (Magnetic Resonance Imaging): An imaging technique that uses magnetic fields to form images of structures within the body.

Open surgery (Thoracotomy): A procedure in which a patient undergoes general anesthesia and the doctor accesses the aneurysm by opening the patient's chest. Then, the aneurysmal vessel is replaced with a fabric graft that is sewn into place.

Rupture: See "Aneurysm rupture."

TAA: See "Thoracic Aortic Aneurysm."

Talent™ Thoracic Stent Graft: A woven polyester tube (graft) supported by a tubular metal framework (stent). The stent graft is placed inside a thoracic aortic aneurysm without surgically opening the tissue surrounding it.

Thoracic aorta: The upper portion of the main artery in the body that extends through the chest.

Thoracic Aortic Aneurysm: A bulging or "ballooning" of a weakened area of the thoracic aorta. This term is often abbreviated as "TAA."

Thoracic Stent Graft Procedure (Endovascular stent grafting): A procedure in which a tube-shaped device is placed inside a diseased vessel non-surgically opening the tissue surrounding the diseased vessel. The patient is placed under regional or general anesthesia. The physician accesses the aneurysm through 2 small incisions at the patient's groin.

Thoracotomy: See "Open surgery."

Glossary

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Medtronic
Alleviating Pain · Restoring Health · Extending Life

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TEMPORARY DEVICE IDENTIFICATION CARD

I have a Medtronic Talent™ Abdominal Stent Graft(s).

In case of emergency, call 911.

My name: _____

Address: _____

City: _____ State: _____ Zip: _____

----------*fold line*----------

Dear Doctor or Nurse,
This is your patient's temporary device identification card. Please complete it and advise your patient to keep it where it may be readily located. Medtronic will mail your patient a permanent device identification card to replace this temporary card.
For additional safety and MRI information, please refer to www.medtronic.com

Medtronic Patient Toll-Free Number: 1-800-551-5544

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In case of medical question or emergency, please contact my doctor(s):

Doctor's Name: _____

Doctor's Phone: _____

I am taking blood thinning medications: ☐ Yes ☐ No

---------- *fold line* ----------

IMPLANT INFORMATION

MR Conditional

Lot Numbers (affix stickers here):

Non-clinical testing has demonstrated that the Talent Abdominal Stent Graft is MR Conditional. It can be scanned safely in both 1.5T & 3.0T MR systems under the following conditions:

1.5 Tesla Systems:
Spatial gradient field: 1000 G/cm
Maximum whole-body-averaged SAR of 4W/kg for 15 minutes of scanning.

3.0 Tesla Systems:
Spatial gradient field: 1000 G/cm
Maximum whole-body-averaged SAR of 4W/kg for 15 minutes of scanning (or the maximum SAR allowed by the MR System, whatever is less)

Patients may safely undergo MRI for Normal Mode and First Level Controlled Operating Mode of the MR System, as defined in IEC Standard. Please go to www.medtronic.com for the most recent MRI/Safety information updates.

DOE, JANE
MS V256
3550 VICTORIA ST N
SHOREVIEW MN 55126-2907

MR
MR Conditional

I HAVE A TALENT ABDOMINAL STENT GRAFT(S) IMPLANTED:

Implant Date	Serial #	Model #
31 JAN 2000	M9985644	YRBR2213135
31 JAN 2000	M9959096	YREC1355
31 JAN 2000	M9958274	YRIR1385

If medical questions or emergency call:
Margaret Smith, MD
(612) 754-0549
Jane Johnson, MD
(612) 871-2345

Please contact us with changes at 1-800-551-5544.

Talent Abdominal Stent Graft is MR Conditional.
It can be scanned safely in both 1.5T & 3.0T MR systems under the following conditions:
1.5 Tesla Systems: Spatial gradient field: 1000 G/cm
Maximum whole-body-averaged SAR of 4 W/kg for 15 minutes of scanning.

3.0 Tesla Systems: Spatial gradient field: 1000 G/cm
Maximum whole-body-averaged SAR of 4 W/kg for 15 minutes of scanning (or the maximum SAR allowed by the MR System, whatever is less).

Patients with Talent Abdominal Stent grafts implanted in the abdominal 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.

Please go to www.medtronic.com for the most recent MRI/Safety information updates.