

**2.1**  
**Physician Labeling**



# Medtronic

## Talent™ Abdominal Stent Graft System

### Instructions for Use

STERILE	EO
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**IMPORTANT!**

- Do not attempt to use the **Talent Abdominal Stent Graft with the CoilTrac Delivery 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 this 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 catheters in accordance with hospital, administrative, and/or government policy. Do not resterilize.
- Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician

# Talent™ Abdominal Stent Graft System

## Instructions for Use

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## 1.0 DEVICE DESCRIPTION

The Talent™ Abdominal Stent Graft System is comprised of two main components: an implantable stent graft and a disposable delivery system. The pre-loaded stent graft is advanced to the aneurysm location over a guidewire and, upon retraction of an introducer sheath (graft cover), expands to the indicated diameter. During deployment and expansion, the stent graft is intended to form proximal and distal seal zones surrounding the aneurysm location.

The Talent Abdominal Stent Graft System is modular and consists of four stent graft component configurations:

- Bifurcated (aorto-iliac)
- Contralateral iliac limb
- Iliac extension cuff
- Aortic extension cuff

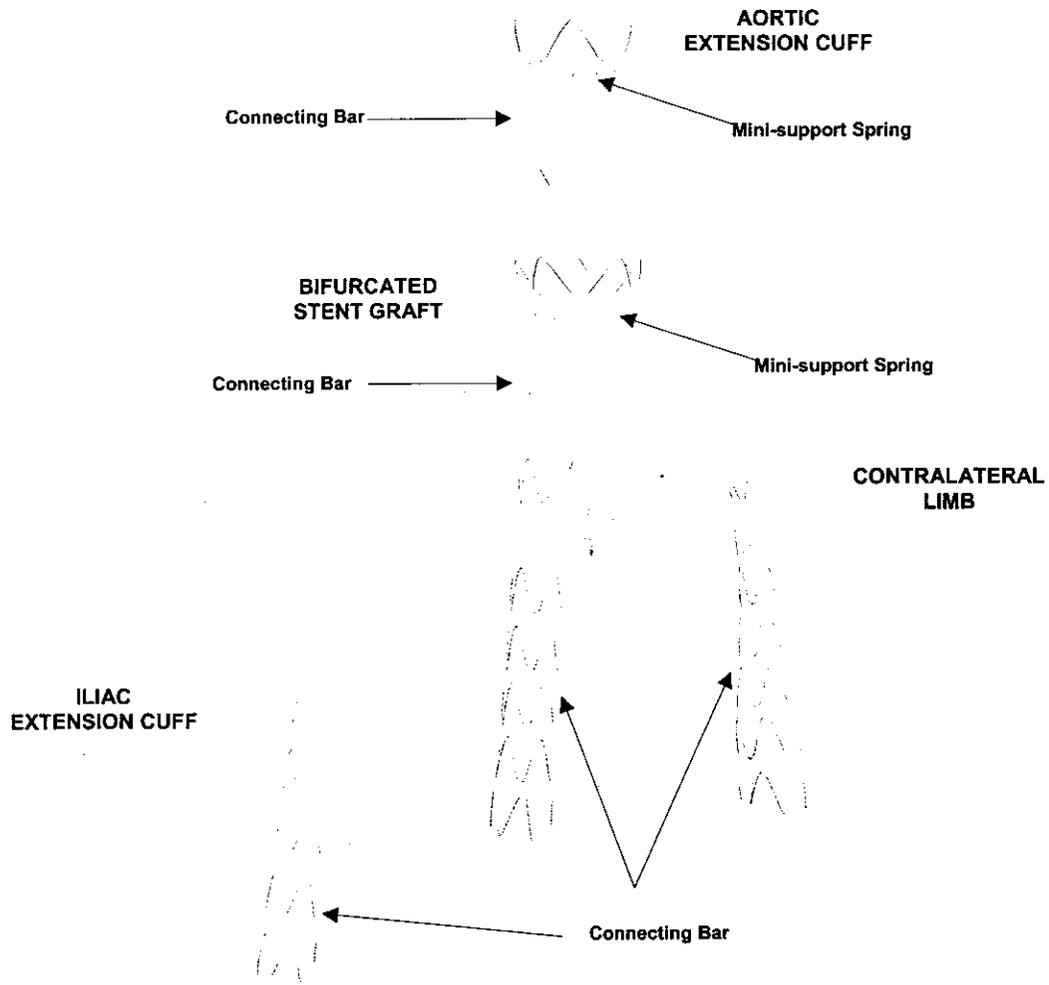
Each component is introduced separately into the patient's vascular system. Each stent graft component is comprised of nitinol metal springs attached to polyester fabric graft material. For all configurations the proximal and distal springs are attached to connecting bars to provide additional columnar strength to the stent graft. The springs are sewn to the polyester fabric graft using polyester suture material. Radiopaque markers, made out of platinum-iridium in the shape of a figure eight (aka, Figur8), are sewn onto the stent graft to aid in visualization of the stent graft under fluoroscopy and to facilitate accurate placement of the device. See Table 1 for a listing of stent graft materials and Figure 1 for an overview of stent graft components.

The stent graft is designed to be placed in the native vessel such that the unconstrained stent graft diameter is larger than the diameter of the native vessel into which it is to be placed. This "oversizing" helps to exclude the aneurysm from aortic blood flow and ensure that the stent graft is held in place. The amount of oversizing required is dependent on the diameter of the native vessel. See Table 34 for oversizing guidelines and Section 15.0 available device configurations.

**Table 1: Stent Graft Materials**

Stent Graft Component	Material
Springs	Nitinol wire
Connecting Bar	Nitinol wire
Mini-Support Spring (FreeFlo only)	Nitinol wire
Stent Fabric	Woven polyester
Sutures	Braided polyester suture
Figur8 Radiopaque Markers	Platinum-Iridium wire

Figure 1: Overview of Talent Abdominal Stent Graft Components



= Figur8 Radiopaque Marker

### 1.1 Device Components

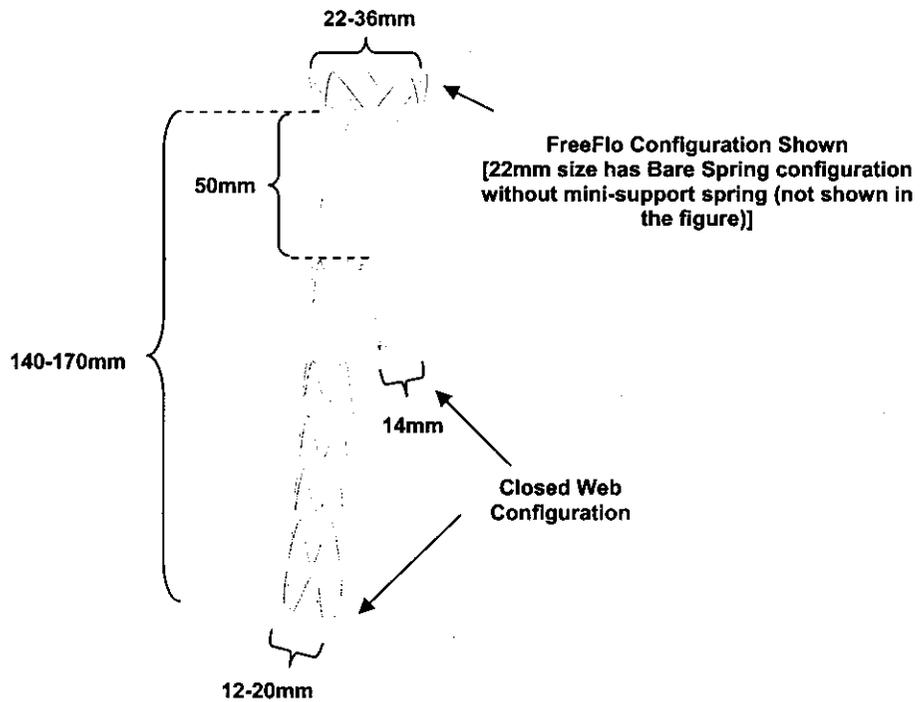
Each of the four stent graft configurations is described in the following section.

#### 1.1.1 Bifurcated Stent Graft

The bifurcated component (Figure 2) is the primary component which is inserted into the patient's aorta. The proximal end of all bifurcated stent grafts has a bare spring that is not covered with graft material to allow for supra-renal fixation. Bifurcated stent grafts with a proximal diameter greater than 22mm have a mini-support spring to aid in sealing. The proximal end configuration in which a bare spring and mini-support spring are present is called the 'FreeFlo' configuration. The proximal end configuration in which a bare spring is present without a mini-support spring is called a 'Bare Spring' configuration.

The stent graft bifurcates into two smaller iliac diameters; one of which is placed into the ipsilateral iliac artery, and the other of which is available to receive the contralateral iliac component. The distal end of the short contralateral leg is 14mm in diameter for all sizes of stent grafts so that it can receive all available contralateral limb stent graft configurations. In contrast the distal end of the ipsilateral leg is available in 12, 14, 16, 18 and 20mm diameters. The distal iliac ends of the stent graft have Closed Web configurations.

Figure 2: Talent Abdominal Bifurcated Stent Graft

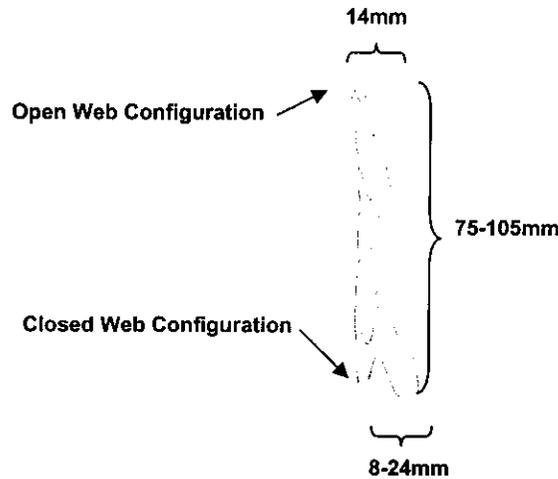


1.1.2 Contralateral iliac limb

The contralateral iliac limb component (Figure 3) is implanted after the bifurcated component to provide a conduit for blood flow into the contralateral iliac artery. The contralateral iliac limb is introduced through the patient's contralateral iliac artery and mated to the short contralateral stub leg on the bifurcated stent graft.

The proximal end of the contralateral iliac limb has an Open Web configuration in which the outline of the most proximal spring is covered. The proximal diameter is 14mm for all limb sizes, so that all limbs can dock with all available bifurcated stent graft configurations. The distal end of the limb has a Closed Web configuration.

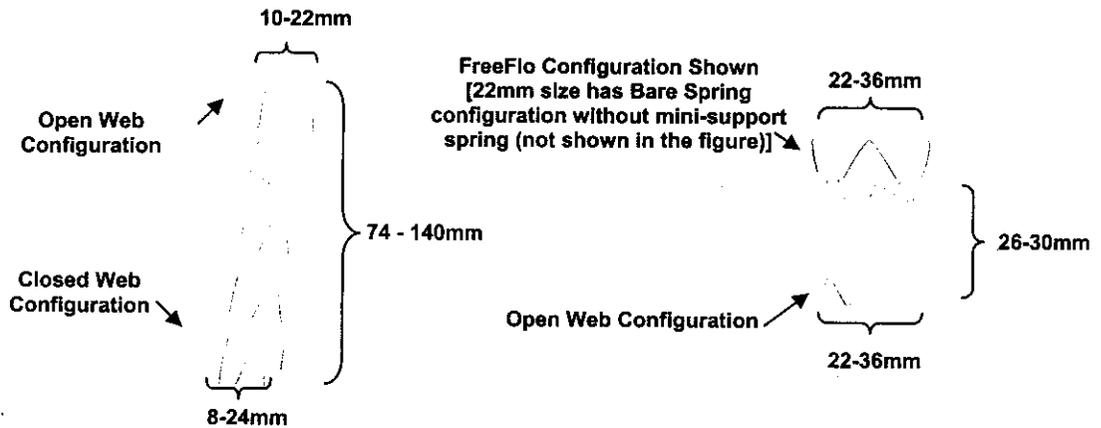
Figure 3: Talent Abdominal Contralateral Iliac Limb



1.1.3 Aortic and Iliac Extension Cuffs

1.1.3.1 The aortic and iliac extension cuff components (Figure 4) are used to extend the lengths of implanted devices as needed based on the patient's anatomy.

Figure 4: Talent Abdominal Iliac (Left) and Aortic (Right) Extension Cuffs

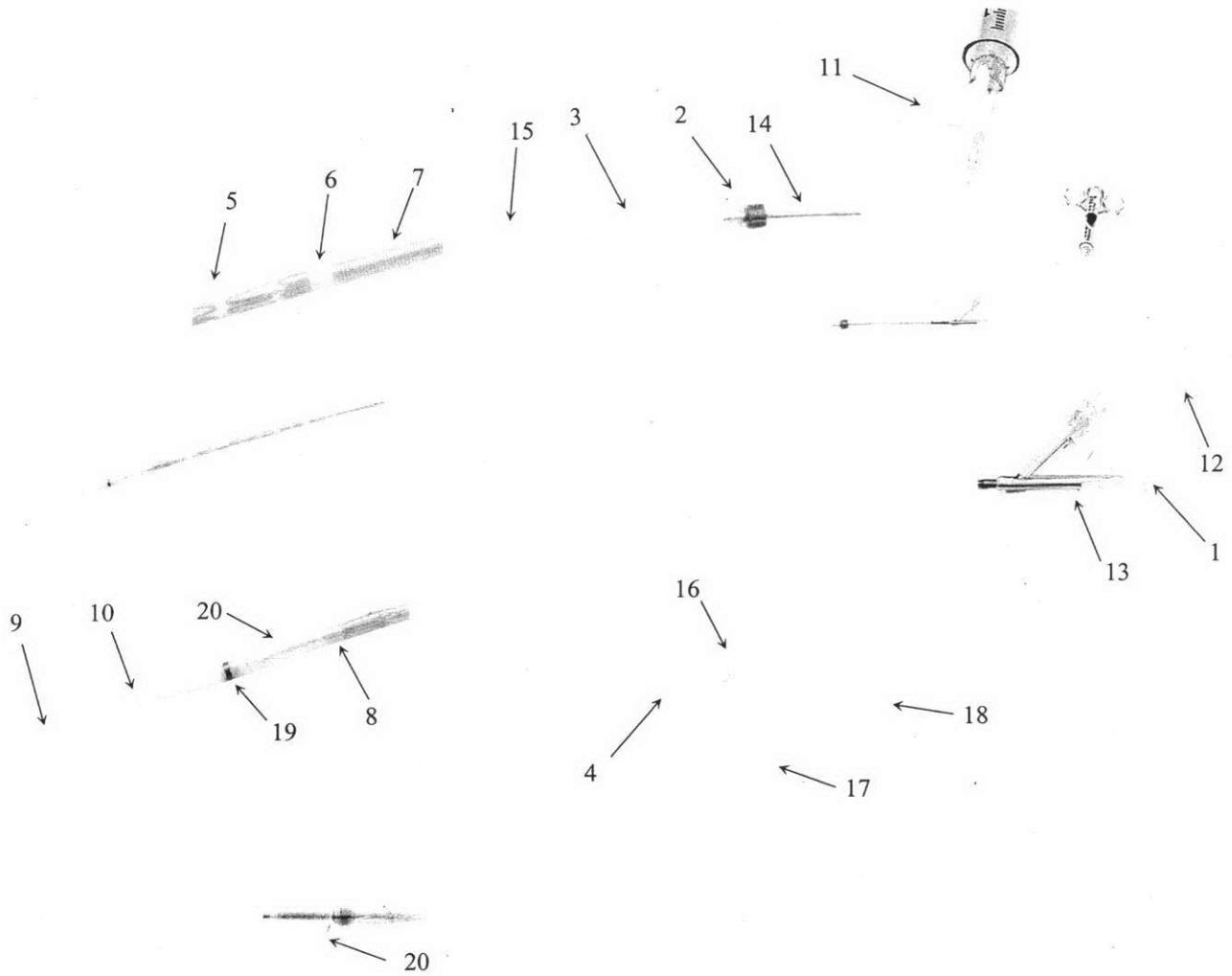


## 1.2 Delivery System

The CoilTrac Delivery System is a single use, disposable system used to deliver all stent graft configurations.

The CoilTrac Delivery System is shown in Figure 5. It is a flexible catheter constructed of three concentric, single lumen, polymer shafts (an outer introducer sheath [graft cover], a pushrod, and a guidewire lumen). A metallic coil with cup plunger is attached to the distal end of the pushrod to maintain stent graft position during deployment. A polymeric, atraumatic tapered tip is attached to the guidewire lumen at the distal end of the delivery system to facilitate tracking through tortuous and calcified vessels. The radiopaque, tapered tip and marker on the distal end of the introducer sheath (graft cover) aid in fluoroscopic visualization. A compliant balloon is located on the distal end of the delivery system to aid in stent graft modeling if necessary. Various valves contained within the delivery system maintain hemostasis and prevent blood loss and leaking during the procedure.

Figure 5: CoilTrac Delivery System



1	Guidewire Exit Port	11	Stopcock
2	Tuohy Borst	12	Inflation Port
3	Luer Handle	13	Y-Connector
4	Sheath Hub	14	Guidewire Lumen
5	Introducer Sheath (Graft Cover)	15	Pushrod
6	Cup Plunger	16	Hemostasis Valve
7	Pushrod Coil Spring	17	Stopcock
8	Radiopaque "Bullet"	18	Sideport Extension
9	Distal Point	19	Radiopaque Marker
10	Tapered Tip	20	Balloon

## 2.0 INDICATIONS

The Talent Abdominal Stent Graft is indicated for the endovascular treatment of abdominal aortic aneurysms with or without iliac involvement having:

- Iliac/femoral access vessel morphology that is compatible with vascular access techniques, devices, and/or accessories;
- A proximal aortic neck length of  $\geq 10$ mm;
- Proximal aortic neck angulation  $\leq 60^\circ$ ;
- Distal iliac artery fixation length of  $\geq 15$ mm;
- An aortic neck diameter of 18–32mm and iliac artery diameters of 8–22mm; and
- Vessel morphology suitable for endovascular repair.

## 3.0 CONTRAINDICATIONS

The Talent Abdominal 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).

## 4.0 WARNINGS AND PRECAUTIONS

### 4.1 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 Abdominal Stent Graft System should only be used by physicians and teams trained in vascular interventional techniques, including training in the use of the device. Specific training expectations are described in Section 10.1.
- Always have a vascular surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary

### 4.2 Patient Selection, Treatment, and Follow-Up

- The Talent Abdominal Stent Graft System is not recommended in patients unable to undergo or who will not be compliant with the necessary preoperative and postoperative imaging and implantation studies as described in Section 12.0.
- The Talent Abdominal 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 Abdominal 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 10.3. Key anatomic elements that may affect successful exclusion of the aneurysm include severe proximal neck angulation ( $> 60^\circ$ ); short proximal aortic neck ( $< 10$ mm); and thrombus and/or calcium at the arterial implantation sites, specifically the proximal aortic neck and distal iliac artery interface. Irregular calcification and/or plaque may compromise the fixation and sealing of the implantation sites. Necks exhibiting these key anatomic elements may be more conducive to graft migration.
- Iliac conduits may be used to ensure the safe insertion of the delivery system if the patient's access vessels (as determined by treating physician) preclude safe insertion of the delivery system.
- Inappropriate patient selection may contribute to poor device performance.
- The safety and effectiveness of the Talent Abdominal Stent Graft System has not been evaluated in patients who:
  - Are less than 18 years of age
  - Are pregnant or lactating
  - Have a dominant patent inferior mesenteric artery and an occluded or stenotic celiac and/or superior mesenteric artery
  - Have aneurysmal involvement or occlusion (surgically performed or naturally occurring) of the bilateral internal iliac arteries
  - Have vessels and/or aneurysm dimensions that cannot accommodate the Talent Abdominal Stent Graft as per the indications in Section 2.0.
  - Have no distal vascular bed (one vessel lower extremity run-off required)
  - Have contraindications for use of contrast medium or anticoagulation drugs
  - Have an uncorrectable coagulopathy
  - Have a mycotic aneurysm
  - Have circumferential mural thrombus in the proximal aortic neck
  - Have had a recent (within 3 months) myocardial infarction (MI), cerebral vascular accident (CVA), or major surgical intervention
  - Have traumatic aortic injury
  - Have leaking, pending rupture or ruptured aneurysms

- Have pseudoaneurysms resulting from previous graft placement
- Require a revision to previously placed endovascular stent grafts.
- Have genetic connective tissue disease (e.g., Marfan's or Ehlers-Danlos' Syndromes)
- Have concomitant thoracic aortic or thoracoabdominal aneurysms
- Are patients with active systemic infections
- The long-term performance of endovascular grafts has not yet been established. All patients should be advised that endovascular treatment requires lifelong, regular follow-up to assess their health and the performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms or changes in the structure or position of the endovascular graft) should receive enhanced follow-up. Specific follow-up guidelines are described in Section 12.0.
- After endovascular graft placement, patients should be regularly monitored for perigraft flow, aneurysm growth or changes in the structure or position of the endovascular graft. At a minimum, annual imaging is required, including: 1) abdominal radiographs to examine device integrity (stent fracture, separation between bifurcated device and proximal cuffs or limb extensions, if applicable), and 2) contrast and non-contrast CT to examine aneurysm changes, perigraft flow, patency, tortuosity and progressive disease. If renal complications or other factors preclude the use of image contrast media, abdominal radiographs and duplex ultrasound may provide similar information.
- Patients experiencing reduced blood flow through the graft limb and/or leaks may be required to undergo secondary interventions or surgical procedures.
- 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.

#### 4.3 Implant Procedure

- Exercise care in handling and delivery technique to aid in the prevention of vessel rupture.
- Studies indicate that the danger of micro-embolization increases with increased duration of the procedure.
- Renal complications may occur:
  - From an excess use of contrast agents.
  - As a result of emboli or a misplaced stent graft. The radiopaque marker along the edge of the stent graft should be aligned immediately below the lower-most renal arterial origin.
- Inadequate seal zone may result in increased risk of leakage into the aneurysm or migration of the stent graft. Other possible causes of migration are deployment of the proximal spring into a thrombus-filled or severely angled vessel wall.
- Systemic anticoagulation should be used during the implantation procedure based on hospital and physician preferred protocol. If heparin is contraindicated, an alternative anticoagulant should be considered.
- Minimize handling of the constrained endoprosthesis during preparation and insertion to decrease the risk of endoprosthesis contamination and infection.
- Improper placement of the stent graft may also cause an endoleak or occlusion of arteries (other than the renals), which may prevent blood flow necessary to organs and extremities, necessitating surgical removal of the device.
- During general handling of the CoilTrac Delivery System, avoid bending or kinking the introducer sheath (graft cover) because it may cause the Talent Abdominal Stent Graft to prematurely and improperly deploy.
- Never advance or retract the CoilTrac Delivery System from the vasculature without the use of fluoroscopy.
- Do not continue advancing any portion of the delivery system if resistance is felt during advancement of the guidewire or delivery system. Stop and assess the cause of resistance. Vessel or catheter damage may occur. Exercise particular care in areas of stenosis, intravascular thrombosis or in calcified or tortuous vessels.
- The balloon must be DEFLATED before initiating deployment of the stent graft. If resistance is experienced during initial deployment, check to ensure that the modeling balloon is completely deflated.
- Do not retract the introducer sheath (graft cover) before placing the delivery system in the proper anatomical position, as this will initiate deployment of the stent graft. The Talent Abdominal Stent Graft cannot be reconstrained or drawn back into the introducer sheath (graft cover), even if the stent graft is only partially deployed. If the introducer sheath (graft cover) is accidentally withdrawn, the device will prematurely deploy and could be placed too high or too low.
- Do not rotate the introducer sheath (graft cover) during deployment, as this may torque the device and cause it to spin on deployment or cause twisting of the iliac limb.
- High pressure injections of contrast media made at the edges of the stent graft immediately after implantation can cause endoleaks.
- When ballooning the stent graft, 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 stent graft.
- Do not exceed maximum inflation diameter (40mm for the 30mm balloon and 20mm for the 20mm balloon). Rupture of the balloon may occur. Adhere to balloon inflation parameters as described in this

booklet and on the product label. Over-inflation may result in damage to the vessel wall and/or vessel rupture, or damage to the stent graft.

- Any endoleak left untreated during the implantation procedure must be carefully monitored after implantation.

#### 4.4 Magnetic Resonance Imaging (MRI) Safety Section

MRI may be used on the graft only under specific conditions. See Section 12.5 for details.

## 5.0 ADVERSE EVENTS

### 5.1 Observed Adverse Events

The clinical study for the Test Group was a multicenter, prospective study conducted at 13 sites across the US, which included 166 test patients. Major adverse events observed in this study are provided in Section 6.7.

### 5.2 Potential Adverse Events

Adverse events that may occur and/or require intervention include, but are not limited to:

- Amputation
- Anesthetic complications and subsequent attendant problems (e.g., aspiration)
- Aneurysm enlargement
- Aneurysm rupture and death
- Aortic damage, including perforation, dissection, bleeding, rupture and death
- Arterial or venous thrombosis and/or pseudoaneurysm
- Arteriovenous fistula
- Bleeding, hematoma or coagulopathy
- Bowel complications (e.g., ileus, transient ischemia, infarction, necrosis)
- Cardiac complications and subsequent attendant problems (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension, hypertension)
- Claudication (e.g., buttock, lower limb)
- Death
- Edema
- Embolization (micro and macro) with transient or permanent ischemia or infarction
- Endoleak
- Fever and localized inflammation
- Genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection)
- Hepatic failure
- Impotence
- Infection of the aneurysm, device access site, including abscess formation, transient fever and pain
- Lymphatic complications and subsequent attendant problems (e.g., lymph fistula)
- Neurologic local or systemic complications and subsequent attendant problems (e.g., confusion, stroke, transient ischemic attack, paraplegia, paraparesis, paralysis)
- Occlusion of device or native vessel
- Pulmonary/respiratory complications and subsequent attendant problems (e.g., pneumonia, respiratory failure, prolonged intubation)
- Renal complications and subsequent attendant problems (e.g., artery occlusion, contrast toxicity, insufficiency, failure)
- Stent graft: improper component placement; incomplete component deployment; component migration; suture break; occlusion; infection; stent fracture; graft twisting and/or kinking; insertion and removal difficulties; graft material wear; dilatation; erosion; puncture and perigraft flow
- Surgical conversion to open repair
- Vascular access site complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula, dissection.
- Vascular spasm or vascular trauma (e.g., iliofemoral vessel dissection, bleeding, rupture, death)
- Vessel damage
- Wound complications and subsequent attendant problems (e.g., dehiscence, infection, hematoma, seroma, cellulitis)

### 5.3 Device-Related Adverse Events Reporting

See Section 13.0

## 6.0 SUMMARY OF CLINICAL STUDY

### 6.1 Stent Graft Analysis

The clinical study for the Test Group was a multicenter, prospective study conducted at 13 sites across the US. The Test Group included patients diagnosed with abdominal aortic aneurysms, with or without involvement of the iliac arteries. A total of 166 patients were enrolled in this study. An independent core lab reviewed CT scans and abdominal x-rays to assess aneurysm changes, device position and integrity, and endoleaks. A Clinical Events Committee (CEC) adjudicated Major Adverse Events (MAEs) for the Test Group.

The Control Group (SVS Control) was a compilation of the pivotal open surgical control groups from three approved abdominal aortic aneurysm (AAA) endograft Premarket Approval (PMA) submissions. The SVS Control represented a change from the original IDE protocol, and was used because the SVS Control was more comprehensive than the original IDE Control Group. The data aggregation and analysis were conducted under the auspices of the Society for Vascular Surgery (SVS). Outcomes from a total of 243 patients treated at facilities across the US were included in the SVS Control.

The pivotal analysis included endpoints that were modified from the endpoints listed in the original IDE protocol to endpoints and other metrics that are consistent with current literature and other EVAR clinical studies. The primary safety endpoint for this analysis was the proportion of patients free from a MAE within 30 days of the index procedure (based on a composite MAE rate), compared to the open surgical control. The primary effectiveness endpoint for this analysis was successful aneurysm treatment<sup>1</sup>. Other study endpoints and analyses were presented based on follow-up at pre-discharge, 1 month, 6 months, and 12 months.

### 6.2 Delivery System Analysis

Subsequent to enrollment in the pivotal trial, the delivery system was updated to the CoilTrac Delivery System. In order to evaluate the clinical performance of the CoilTrac Delivery System, a single-center cohort of 137 patients from an independent data set was evaluated.

The analysis of this independent data set supports the clinical performance of the CoilTrac Delivery System, demonstrated by delivery and deployment success rate, as well as, clinically relevant adverse events rates observed within the 30 day post-procedure period.

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<sup>1</sup> Successful aneurysm treatment was a composite endpoint including patients who had technical success (successful delivery and deployment of the Talent Stent Graft) at the initial procedure and were free from:

- Aneurysm growth > 5mm at 12 months, as evaluated by the core lab; and
- Post-operative interventions to correct Type I/III endoleaks at anytime up to 12 months (Type II endoleaks are generally considered to be non-device related).

**6.3 Patient Accountability and Follow-Up**

For the Test Group, 13 sites enrolled a total of 166 patients. Four (4) patients had technical failure and did not receive a stent graft and therefore did not have any imaging follow-up. 162 patients who received the stent graft were eligible for clinical and imaging follow-up at 1 month follow-up interval. Of these 162 patients, 100% (162/162) had a clinical follow-up and 98.8% (160/162) had imaging follow-up. CT imaging was performed on 96.3% (156/162) patients.

At the 6 month follow-up interval, 152 patients were eligible for clinical and imaging follow-up. Of these, 90.1% (137/152) had clinical follow-up and 81.6 % (124/152) had imaging follow-up. CT imaging was performed on 78.9% (120/152) patients.

At the 12 month follow-up interval, 142 patients were eligible for clinical and imaging follow-up. Of these 97.2% (138/142) had clinical follow-up and 93.0% (132/142) had imaging follow-up. CT imaging was performed on 91.5% (130/142) patients.

Detailed patient accountability and follow-up is provided in Table 2

**Table 2: Patient and Imaging Accountability – Test Group<sup>1</sup>**

Interval (Analysis Window)	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				
	Eligible	Clinical Follow-up	Imaging Follow-up	CT Imaging	KUB Imaging	Aneurysm size increase	Endoleak	Migration	Integrity	Technical Failure	Conversion to Surgery	Death	Withdrawal	Lost to Follow-up
Originally Enrolled	166									4				
Events after implant but before a 1 Month visit											0	0	0	0
1 Month (Day 1-90)	162	162	160	156	141		150	143	136					
Events after 1 Month visit but before a 6 Month visit											0	5	5	0
6 Month (Day 91-304)	152	137	124	120	103	118	114	120	101					
Events after 6 Month visit but before a 12 Month visit											0	5	5	0
12 Month (≥ Day 305 <sup>2</sup> )	142	138	132	130	112	128	120	128	110					

<sup>1</sup> Data analysis sample size varies for each of the timepoints above and in the following tables. This variability is due to patient availability for follow-up, as well as, quantity and quality of images available from specific timepoints 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.

<sup>2</sup> In cases where 12 month imaging follow-up data were not available, subsequent imaging follow-up data were used.

The SVS Control included 243 patients. Detailed patient accountability and follow-up is provided in Table 3 below. At the 1 month follow-up interval, 239 patients were eligible and 98.7% (236/239) had clinical follow-up. At the 6 month follow-up interval, 230 patients were eligible and 90.9% (209/230) had clinical follow-up. At the 12 month follow-up interval, 219 patients were eligible and 97.7% (214/219) had clinical follow-up.

**Table 3: Patient Accountability – SVS Control**

Interval (Analysis Window)	Patient follow-up		Patients with events occurring before next visit	
	Eligible	Clinical Follow-up	Death	Withdrawal/ Lost to Follow-up
Originally enrolled	243			
Events after procedure but before 1 Month visit			4	0
1 Month visit (Day 1-90)	239	236		
Events after 1 Month visit but before 6 Month visit			7	2
6 Month visit (Day 91-304)	230	209		
Events after 6 Month visit but before 12 Month visit			5	6
12 Month visit (≥ Day 305)	219	214		

#### 6.4 Demographic and Baseline Medical History Data

Table 4 through Table 6 provide the demographics and baseline medical characteristics of the Test Group and SVS Control patients. Medtronic observed that the Test Group was older and had more co-morbidities than the patients within the SVS Control.

**Table 4: Patient Demographics, Test Group vs. SVS Control**

Parameter	Statistics/Category	Test Group	SVS Control	p-value
Age (years)				
	n	166	243	
	Mean $\pm$ SD	74.1 $\pm$ 7.49	70.1 $\pm$ 7.49	< 0.001
	Median	76.0	70.0	
	Min, max	51, 89	46, 86	
Gender % (m/n)				
	Male	91.6% (152/166)	81.5% (198/243)	0.004
Ethnicity % (m/n)				
	White, non-Hispanic	92.8% (154/166)	94.9% (168/177)	0.501
	Non-White	7.2% (12/166)	5.1% (9/177)	

Table 5: Baseline Medical History, Test Group vs. SVS Control

Body System / Condition	Test Group %(m/n) <sup>1</sup>	SVS Control %(m/n) <sup>1</sup>	p-value
<b>Cardiovascular</b>			
Angina	16.9% (28/166)	17.4% (23/132)	> 0.999
Arrhythmia	44.0% (73/166)	11.5% (28/243)	< 0.001
Cardiac revascularization <sup>2</sup>	38.6% (64/166)	46.1% (112/243)	0.154
Congestive heart failure	28.3% (47/166)	4.9% (12/243)	< 0.001
Coronary artery disease	56.0% (93/166)	61.3% (149/243)	0.306
Hypertension	83.7% (139/166)	66.7% (162/243)	< 0.001
Myocardial infarction	38.6% (64/166)	34.2% (83/243)	0.401
Peripheral vascular disease	46.4% (77/166)	15.6% (38/243)	< 0.001
<b>Renal<sup>3</sup></b>			
Renal insufficiency	54.8% (91/166)	N/A	N/A
Renal failure	N/A	4.1% (10/243)	N/A
<b>Neurological<sup>3</sup></b>			
Cerebral vascular accident	22.9% (38/166)	N/A	N/A
Cerebrovascular disease	N/A	12.8% (31/243)	N/A
<b>Other abnormal body systems</b>			
Diabetes	15.7% (26/166)	11.9% (29/243)	0.303
Chronic obstructive pulmonary disease	39.2% (65/166)	30.0% (73/243)	0.070
Tobacco use	84.9% (141/166)	85.6% (208/243)	0.887

<sup>1</sup> Denominator is 166 patients in the Test Group and 243 patients in the SVS Control.

<sup>2</sup> Cardiac Revascularization includes Coronary Artery Bypass Grafting (CABG) or PTCA.

<sup>3</sup> SVS Control reported "Renal Failure" and "Cerebrovascular Diseases", but Test Group reported "Renal Insufficiency" and "Cerebral Vascular Accident", respectively. These categories are not comparable.

**Table 6: Baseline SVS Classification, Test Group Only**

SVS Classification	Test Group %(m/n)
SVS 0	6.0% (10/166)
SVS 1	47.6% (79/166)
SVS 2	41.0% (68/166)
SVS 3	5.4% (9/166)

**6.5 Baseline Aneurysm Data**

Table 7 through Table 9 provide the baseline aneurysm diameters and morphologies of the Test Group and SVS Control.

**Table 7: Baseline Maximum Aneurysm Diameters, Test Group vs. SVS Control (Site Reported)**

Aneurysm Characteristics	Statistics	Test Group Site Reported	SVS Control Site Reported	p-value
Maximum aneurysm diameter (mm)	n	166	214	
	Mean ± SD	57.1±8.49	56.9±11.59	0.826
	Median	55.0	54.8	
	Min, max	43, 87	31, 100	

**Table 8: Distribution of Baseline Maximum Aneurysm Diameters, Test Group vs. SVS Control (Site Reported)**

Maximum Aneurysm Diameter	Test Group Site-Reported %(m/n)	SVS Control Site-Reported %(m/n)
< 30mm	0.0% (0/166)	0.0% (0/214)
30-39mm	0.0% (0/166)	2.3% (5/214)
40-49mm	14.5% (24/166)	21.5% (46/214)
50-59mm	51.8% (86/166)	42.5% (91/214)
60-69mm	22.3% (37/166)	20.1% (43/214)
70-79mm	8.4% (14/166)	8.4% (18/214)
80-89mm	3.0% (5/166)	3.3% (7/214)
≥ 90mm	0.0% (0/166)	1.9% (4/214)

Table 9: Baseline Aneurysm Characteristics, Test Group

Dimension	Statistics	Site Reported	Core Lab Reported
Maximum aneurysm diameter (mm)	n	166	156
	Mean $\pm$ SD	57.1 $\pm$ 8.49	55.0 $\pm$ 9.26
	Median	55	53
	Min, Max	43, 87	38, 88
Proximal neck diameter (mm)	n	165	156
	Mean $\pm$ SD	25.6 $\pm$ 3.35	25.3 $\pm$ 3.58
	Median	26	26
	Min, Max	16, 32	16, 32
Right iliac diameter (mm)	n	164	155
	Mean $\pm$ SD	9.3 $\pm$ 1.55	9.2 $\pm$ 1.53
	Median	9	9
	Min, Max	6, 16	6, 14
Left iliac diameter (mm)	n	164	155
	Mean $\pm$ SD	9.3 $\pm$ 1.46	9.3 $\pm$ 1.55
	Median	9	9
	Min, Max	6, 14	6, 15
Proximal neck length (mm)	n	166	154
	Mean $\pm$ SD	23.9 $\pm$ 12.88	22.9 $\pm$ 12.48
	Median	20	21
	Min, Max	3, 85	3, 75
Aortic neck angle (°)	n	157	127
	Mean $\pm$ SD	18.7 $\pm$ 15.40	30.5 $\pm$ 15.80
	Median	19	30
	Min, Max	0, 60	0, 72

**6.6 Devices Implanted**

Table 10 provides a breakdown of the number of Talent Abdominal Stent Grafts implanted per patient.

**Table 10: Total Number of Talent Abdominal Stent Grafts Implanted at Initial Procedure**

Number of Devices Implanted	Test Group %(m/n) <sup>1</sup>
1	0.0% (0/162)
2	42.0% (68/162)
3	32.7% (53/162)
4	22.2% (36/162)
5	3.1% (5/162)
≥ 6	0.0% (0/162)

<sup>1</sup> Denominator is 162 patients with implanted devices.

## 6.7 Study Results

Results for the safety and effectiveness of the Talent Abdominal Stent Graft are presented in Section 6.8 and 6.9 below.

### 6.8 Safety

#### Primary Safety Endpoint: Freedom from MAEs within 30 Days

Through 30 days, patients who received the Talent Abdominal Stent Graft experienced a lower rate of MAEs than patients treated with open surgery. Table 11 and Table 12 provide an analysis of freedom from MAEs within 30 days.

**Table 11: Primary Safety Endpoint: Freedom from MAEs within 30 Days, Test Group vs. SVS Control**

Freedom from Major Adverse Event (MAE) within 30 Days	Test Group N = 166 % (m/n)	SVS Control N = 243 % (m/n)	95% Exact Confidence Interval of Difference <sup>1,2</sup>
Freedom from MAEs within 30 Days	89.2% (148/166)	44.0% (107/243)	(36.9%, 52.6%)

<sup>1</sup> Confidence level was not adjusted for multiplicity. Confidence interval for difference (Test - SVS Control) in percentage was calculated by the exact method.

<sup>2</sup> 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 undergoing open surgical repair)

**Table 12: Primary Safety Endpoint: MAE Components within 30 Days, Test Group vs. SVS Control**

Major Adverse Event (MAE) within 30 Days <sup>1</sup>	Test Group N = 166 %(m/n)	SVS Control N = 243 %(m/n)	95% Exact Confidence Interval of Difference <sup>2,3</sup>
MAE rate at 30 days	10.8% (18/166)	56.0% (136/243)	N/A
All-cause Death	1.8% (3/166)	2.9% (7/243)	(-4.4%, 2.8%)
Myocardial Infarction	1.8% (3/166)	5.3% (13/243)	(-7.6%, 0.4%)
Renal Failure	1.8% (3/166)	2.9% (7/243)	(-4.4%, 2.8%)
Respiratory Failure	3.0% (5/166)	5.8% (14/243)	(-7.0%, 1.7%)
Paraplegia	0.0% (0/166)	0.4% (1/243)	(-2.3%, 2.0%)
Stroke	1.2% (2/166)	1.2% (3/243)	(-2.6%, 3.3%)
Bowel Ischemia	0.6% (1/166)	0.0% (0/243)	(-1.0%, 3.6%)
Procedural Blood Loss ≥ 1000cc	5.4% (9/166)	51.0% (124/243)	(-52.6%, -38.1%)

<sup>1</sup> A patient may report multiple MAEs; hence, number of patients with any MAE may not be the sum of those in each MAE category.

<sup>2</sup> Confidence level was not adjusted for multiplicity. Confidence intervals for difference (Test - SVS Control) in percentage were calculated by the exact method.

<sup>3</sup> Difference represents the (% of patients with MAEs within 30 days in the population treated with the test device) - (% of patients with MAEs within 30 days in the population undergoing open surgical repair)

**Freedom from MAEs within 365 Days**

At 365 days, treatment with the Talent Abdominal Stent Graft continued to perform favorably when compared to open surgery. Table 13 and Table 14 provide an analysis of freedom from MAEs at 365 days, and Figure 6 and Table 15 depict the corresponding Kaplan-Meier plot.

**Table 13: Freedom from MAEs within 365 Days,  
Test Group vs. SVS Control**

Freedom from MAEs within 365 Days	Test Group N = 166 % (m/n)	SVS Control N = 243 % (m/n)	95% Exact Confidence Interval of Difference <sup>1,2</sup>
Freedom from MAEs within 365 Days	80.4% (123/153)	41.7% (100/240)	(29.4%, 47.2%)

<sup>1</sup> Confidence level was not adjusted for multiplicity. Confidence interval for difference (Test - SVS Control) in percentage was calculated by the exact method.

<sup>2</sup> Difference represents the (% of patients free from MAEs within 365 days in the population treated with the test device) - (% of patients free from MAE within 365 days in the population undergoing open surgical repair)

**Table 14: MAE Components within 365 Days,  
Test Group vs. SVS Control**

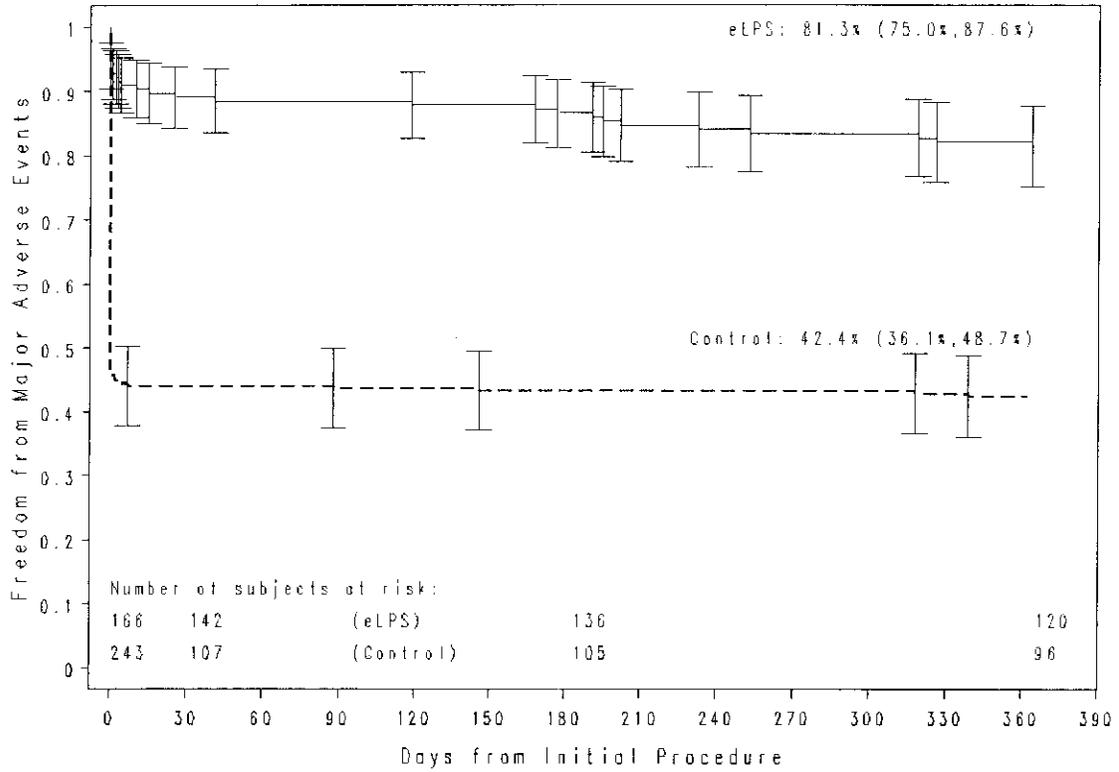
MAEs within 365 Days <sup>1</sup>	Test Group N = 166 % (m/n)	SVS Control N = 243 % (m/n)	95% Exact Confidence Interval of Difference <sup>2,3</sup>
MAE rate at 365 days	19.6% (30/153)	58.3% (140/240)	N/A
All-cause Death	6.5% (10/153)	7.5% (18/240)	(-6.1%, 5.0%)
Myocardial Infarction	3.9% (6/153)	7.9% (19/240)	(-8.9%, 1.4%)
Renal Failure	3.3% (5/153)	2.9% (7/240)	(-3.2%, 5.0%)
Respiratory Failure	3.9% (6/153)	6.3% (15/240)	(-6.8%, 3.0%)
Paraplegia	0.0% (0/153)	0.4% (1/240)	(-2.4%, 2.2%)
Stroke	2.6% (4/153)	1.7% (4/240)	(-2.1%, 5.0%)
Bowel Ischemia	0.7% (1/153)	0.0% (0/240)	(-0.9%, 3.9%)
Procedural Blood Loss ≥1000 cc	5.9% (9/153)	51.7% (124/240)	(-52.9%, -38.1%)

<sup>1</sup> A patient may report multiple MAEs; hence, number of patients with any MAE may not be the sum of those in each MAE category.

<sup>2</sup> Confidence level was not adjusted for multiplicity. Confidence intervals for difference (Test - SVS Control) in percentage were calculated by the exact method.

<sup>3</sup> Difference represents the (% of patients with MAEs within 365 days in the population treated with the test device) - (% of patients with MAEs within 365 days in the population undergoing open surgical repair)

Figure 6: Kaplan-Meier Estimates of Freedom from MAEs (0 to 365 Days), Test Group vs. SVS Control



Note: eLPS, as described in the figure above, refers to the Test Group.

Table 15: Details of Kaplan-Meier Estimates of Freedom from MAEs (0 to 365 Days), Test Group vs. SVS Control

	Test Group			SVS Control		
	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	166	142	136	243	107	105
No. of Events	18	4	8	136	2	2
No. Censored	6	2	8	0	0	7
Kaplan-Meier Estimate	0.891	0.866	0.813	0.440	0.432	0.424

**Freedom from All-Cause Mortality within 30 Days**

Table 16 provides the summary of patients with freedom from all-cause mortality at 30 days for the Test Group and SVS Control.

**Table 16: Freedom from All-Cause Mortality within 30 Days, Test Group vs. SVS Control**

Secondary Endpoint	Test Group %(m/n)	SVS Control %(m/n)	95% Exact Confidence Interval of Difference <sup>1,2</sup>
Freedom from All-Cause Mortality within 30 Days	98.2% (163/166)	97.1% (236/243)	(-2.8%, 4.4%)

<sup>1</sup> Confidence level was not adjusted for multiplicity. Confidence interval for difference (Test - SVS Control) in percentage was calculated by the exact method.

<sup>2</sup> Difference represents the (% of patients free from all-cause mortality within 30 days in the population treated with the test device) - (% of patients free from all-cause mortality within 30 days in the population undergoing open surgical repair)

**Freedom from Aneurysm-Related Mortality within 365 Days**

Table 17 and Figure 7 provide the analysis and Kaplan-Meier plot of freedom from aneurysm-related mortality at 365 days. Additional detail is provided in Table 18.

Notably, there were no conversions to surgery or aneurysm ruptures in the Test Group within 365 days. See Table 29 for aneurysm rupture results.

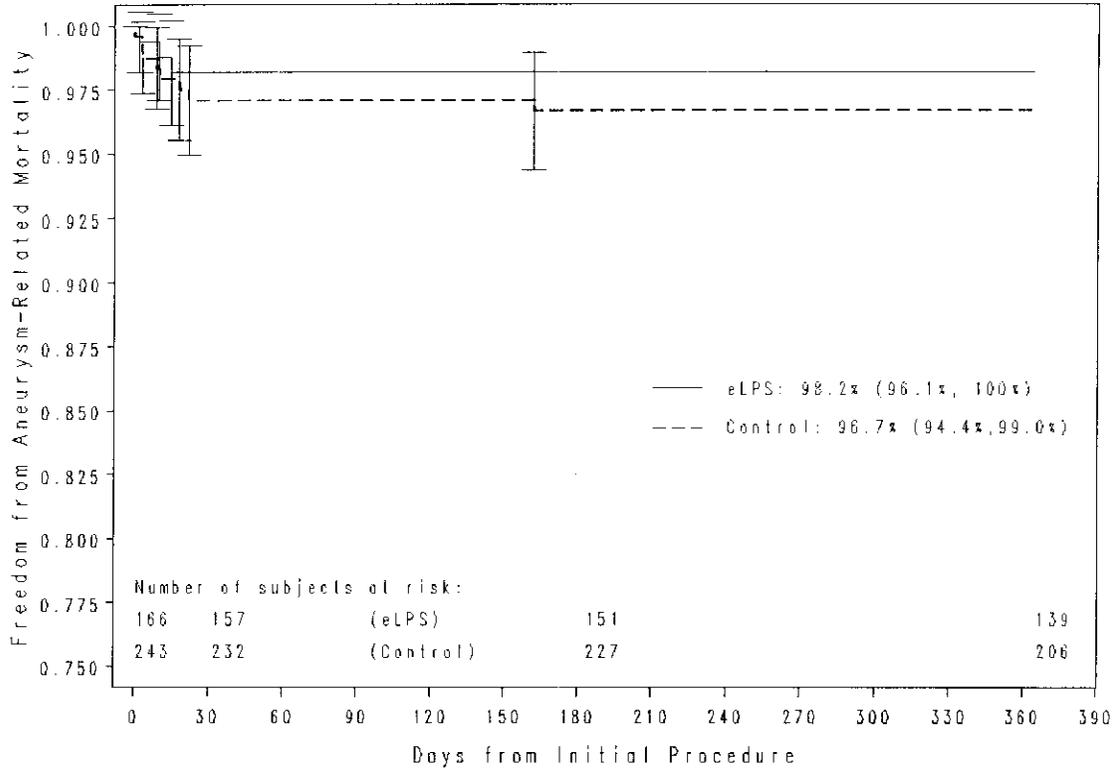
**Table 17: Freedom from Aneurysm-Related Mortality within 365 Days, Test Group vs. SVS Control**

Secondary Endpoint	Test Group N = 166 % (m/n)	SVS Control N = 243 % (m/n)	95% Exact Confidence Interval of Difference <sup>1,2</sup>
Freedom from Aneurysm-Related Mortality within 365 Days	97.9% (143/146)	96.4% (217/225)	(-2.8%, 5.4%)

<sup>1</sup> Confidence level was not adjusted for multiplicity. Confidence interval for difference (Test - SVS Control) in percentage was calculated by the exact method.

<sup>2</sup> Difference represents the (% of patients free from aneurysm-related mortality within 365 days in the population treated with the test device) - (% of patients free from aneurysm-related mortality within 365 days in the population undergoing open surgical repair)

Figure 7: Kaplan-Meier Estimates of Freedom from Aneurysm-Related Mortality within 365 Days, Test Group vs. SVS Control



Note: eLPS, as described in the figure above, refers to the Test Group.

Table 18: Details of Kaplan-Meier Estimates of Freedom from Aneurysm-Related Mortality within 365 Days, Test Group vs. SVS Control

	Test Group			SVS Control		
	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	166	157	151	243	232	227
No. of Events	3	0	0	7	1	0
No. Censored	6	6	12	4	4	21
Kaplan-Meier Estimate	0.982	0.982	0.982	0.971	0.967	0.967

**Freedom from All-Cause Mortality within 365 Days**

Table 19 and Figure 8 provide the analysis and Kaplan-Meier plot of freedom from all-cause mortality at 365 Days. Additional detail is provided in Table 20.

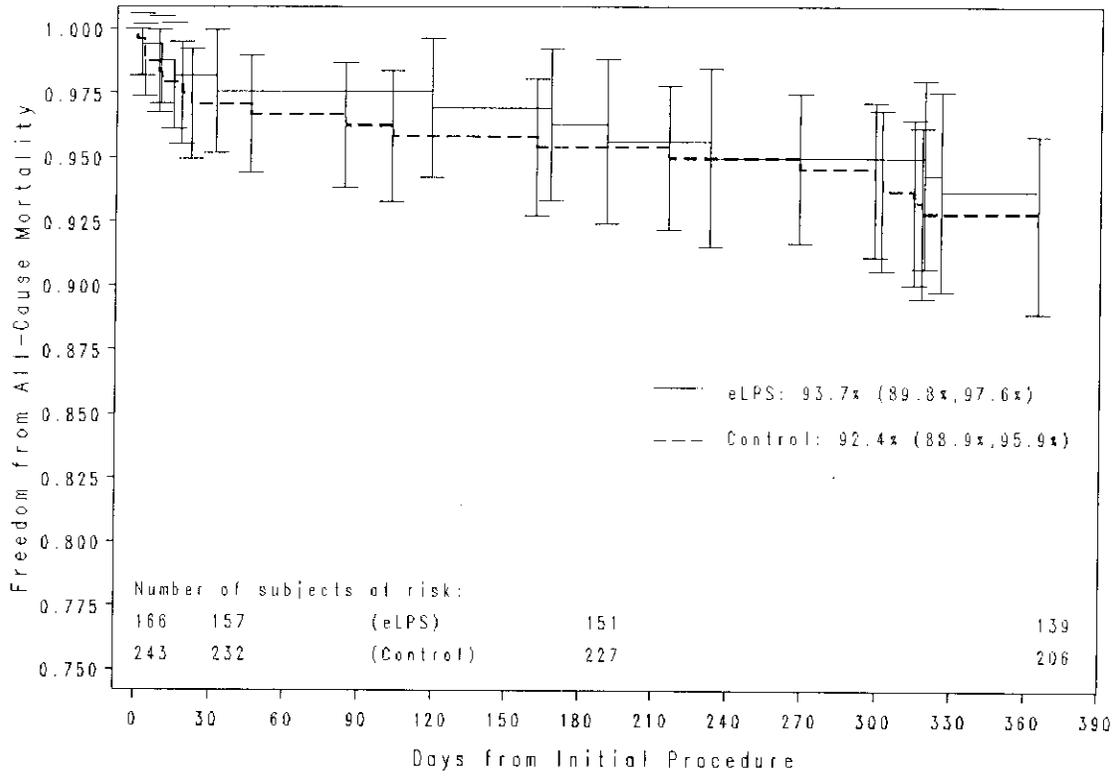
**Table 19: Freedom from All-Cause Mortality within 365 Days, Test Group vs. SVS Control**

Related Analysis	Test Group % (m/n)	SVS Control % (m/n)	95% Exact Confidence Interval of Difference <sup>1,2</sup>
Freedom from All-Cause Mortality within 365 Days	93.5% (143/153)	92.5% (222/240)	(-5.0%, 6.1%)

<sup>1</sup> Confidence level was not adjusted for multiplicity. Confidence interval for difference (Test - SVS Control) in percentage was calculated by the exact method.

<sup>2</sup> Difference represents the (% of patients free from all-cause mortality within 365 days in the population treated with the test device) - (% of patients free from all-cause mortality within 365 days in the population undergoing open surgical repair)

Figure 8: Kaplan-Meier Estimates of Freedom from All-Cause Mortality within 365 Days, Test Group vs. SVS Control



Note: eLPS, as described in the figure above, refers to the Test Group.

Table 20: Details of Kaplan-Meier Estimates of Freedom from All-Cause Mortality within 365 Days, Test Group vs. SVS Control

	Test Group			SVS Control		
	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	166	157	151	243	232	227
No. of Events	3	3	4	7	4	7
No. Censored	6	3	8	4	1	14
Kaplan-Meier Estimate	0.982	0.963	0.937	0.971	0.954	0.924

## 6.9 Effectiveness

### Primary Effectiveness Endpoint: Successful Aneurysm Treatment

The primary effectiveness endpoint, successful aneurysm treatment, was a composite endpoint including patients who had technical success (successful delivery and deployment of the Talent Stent Graft) at the initial procedure and were free from:

- Aneurysm growth > 5mm at 12 months, as evaluated by the core lab; and
- Post-operative interventions to correct Type I/III endoleaks at anytime up to 12 months (Type II endoleaks are generally considered to be non-device related).

Other clinically relevant measures (see Table 23 through Table 30) of stent graft effectiveness were also evaluated and are provided separately in the sections below.

As shown in Table 21, the Talent Abdominal Stent Graft achieved a successful aneurysm treatment rate of 90.2%. Table 22 provides details regarding patients who have failed the successful aneurysm treatment endpoint.

**Table 21: Primary Effectiveness Endpoint: Successful Aneurysm Treatment, Test Group**

Primary Effectiveness Endpoint	Test Group %(m/n)	95% Exact Confidence Interval <sup>1</sup>
Successful Aneurysm Treatment	90.2% (110/122)	(83.4%, 94.8%)

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

**Table 22: Primary Effectiveness Endpoint: Successful Aneurysm Treatment, Test Group**

Patients with Primary Effectiveness Failure	Test Group %(m/n)
Unsuccessful (Failure) Aneurysm Treatment	9.8% (12/122)
Technical Failure <sup>1</sup>	3.3% (4/122)
Aneurysm Growth > 5mm at 12 Months (Core Lab)	2.5% (3/122) <sup>2</sup>
Post-Operative Interventions To Correct Type I/III Endoleaks	4.1% (5/122)

<sup>1</sup> All four technical failures were due to access difficulties. Note: These failures were associated with a prior iteration delivery system.

<sup>2</sup> Of these three patients, two died at day 600 and 692, respectively. One patient death was attributed to a possible device-related cause (patient refused further treatment). No additional adverse events were identified with the other patient death.

Other Effectiveness Data**Table 23: Migration-Free at 12 Months, Test Group (Core Lab)**

Other Effectiveness Data	Test Group %(m/n)	95% Exact Confidence Interval <sup>3</sup>
Migration-Free at 12 Months <sup>1</sup>	99.2% (128/129) <sup>2</sup>	(95.8%, 100.0%)

<sup>1</sup> Migration is defined as evidence of proximal or distal movement of the stent graft > 10mm relative to fixed anatomic landmarks.

<sup>2</sup> At three-year follow-up, the patient was admitted for endovascular repair of Type I endoleak (proximal).

<sup>3</sup> Confidence level was not adjusted for multiplicity. Confidence interval for the percentage was calculated by the exact (binomial) method.

**Table 24: Stent Graft Patency at 12 Months, Test Group (Core Lab)**

Other Effectiveness Data	Test Group %(m/n)	95% Exact Confidence Interval <sup>1</sup>
Stent Graft Patency at 12 Months	100.0% (120/120)	(97.0%, 100.0%)

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

**Table 25: Freedom from Secondary Endovascular Procedures within 365 Days, Test Group**

Other Effectiveness Data	Test Group %(m/n)	95% Exact Confidence Interval <sup>2</sup>
Secondary Endpoint: Freedom from Secondary Endovascular Procedures within 365 days	96.5% (138/143) <sup>1</sup>	(92.0%, 98.9%)

<sup>1</sup> The 5 patients who received a secondary endovascular procedure are characterized as follows:

Three (3) patients had endoleaks detected at day 1, 1, and 32, with secondary procedures at Day 69, 74, and 95, respectively. Aortic cuffs were placed to correct Type I endoleaks (proximal). Repairs were successful.

One (1) patient had endoleak detected at day 103, with a secondary procedure at day 168. Two (2) iliac limb extensions were placed to correct the Type I endoleak (distal). Repair was successful.

One (1) patient had graft-blush detected post-procedure, with a secondary procedure at day 183. An aortic cuff and iliac extension were placed to correct graft blush and stitch hole endoleak. Repair was successful.

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

**Table 26: Loss of Stent Graft Integrity at 12 Months, Test Group (Core Lab)**

Other Effectiveness Data	Test Group %(m/n)	95% Exact Confidence Interval <sup>3</sup>
Loss of Stent Graft Integrity at 12 Months <sup>1</sup>	2.7% (3/110) <sup>2</sup>	(0.6%, 7.8%)

<sup>1</sup> Loss of stent graft integrity is defined as the occurrence of stent graft wire and/or connecting bar fracture. Of these 3 patients, 2 had a connecting bar fracture – one at the proximal main body and the other at the level of the left iliac (source for locations is patient files). The third patient had a graft wire fracture, located on the second spring row at the proximal aspect of the graft.

<sup>2</sup> Of the 3 patients with loss of stent graft integrity, one patient expired at approximately 2 years due to stroke (CVA). The stent graft did not cause or contribute to the patient death. Another patient had no endoleak reported at the 1, 6 or 12 month visits. At the 4 year follow-up there were no endoleaks reported. The remaining patient withdrew from the study 2 years and four months following the procedure. This patient had no clinical sequelae reported during follow-up.

<sup>3</sup> Confidence level was not adjusted for multiplicity. Confidence interval for the percentage was calculated by the exact (binomial) method.

**Table 27: Type I/III Endoleak-Free at 12 Months, Test Group (Core Lab)**

Other Effectiveness Data	Test Group %(m/n)	95% Exact Confidence Interval <sup>4</sup>
Endoleak-Free (Type I/III) at 12 Months <sup>1</sup>	93.4% (113/121) <sup>2, 3</sup>	(87.4%, 97.1%)

<sup>1</sup> Endoleak-free (Type I/III) at 12 months is defined as patients who did not have Type I/III endoleak at 12 months time point **and** did not have a secondary endovascular intervention to treat a Type I/III endoleak.

<sup>2</sup> The 8 patients that were not endoleak-free, include 5 patients that required a secondary endovascular procedure to treat their endoleaks (previously referenced in Table 22 and Table 25) and 3 patients that did not require secondary procedures.

<sup>3</sup> One (1) patient had a secondary procedure to correct an endoleak at 6 months post implant. However this patient was not assessable for endoleak at the 12 month follow-up visit. This represents an increase of 1 in the denominator in the above table as compared to the number of patients assessable for endoleaks in Table 2

<sup>4</sup> Confidence level was not adjusted for multiplicity. Confidence interval for the percentage was calculated by the exact (binomial) method.

Table 28: Summary of All Endoleaks at 1 Month and 12 Months, Test Group (Core Lab)

Endoleaks at 12 Months	Core Lab Reported at 1 Month <sup>1</sup> %(m/n)	Core Lab Reported at 12 Months <sup>1</sup> %(m/n)
Endoleaks of any type	19.3% (29/150)	9.2% (11/120)
Type I	9.3% (14/150)	2.5% (3/120) <sup>2,3</sup>
Type II	8.7% (13/150)	5.8% (7/120)
Type III	0.0% (0/150)	0.0% (0/120)
Type IV	0.0% (0/150)	0.0% (0/120)
Indeterminate	1.3% (2/150)	0.8% (1/120)

<sup>1</sup> Endoleaks reported are not cumulative but represent the number of endoleaks present at each time point.

<sup>2</sup> Of these 3 patients, one patient withdrew from the study (post a three year follow-up) prior to a secondary procedure to treat the endoleak. For the remaining two patients no secondary procedures were reported and no additional clinical sequelae were reported. All three Type I endoleaks at 12 months were persistent from a previous follow-up visit, of which one was a secondary endoleak.

<sup>3</sup> The 5 patients that required secondary procedures to treat their endoleaks (previously referenced in Table 22 and Table 25) are not captured in this table because their endoleaks had been resolved prior to the 12 month time point.

**Table 29: Aneurysm Rupture within 365 Days, Test Group**

Other Effectiveness Data	Test Group %(m/n)	95% Exact Confidence Interval <sup>1</sup>
Aneurysm rupture within 365 days post implantation	0.0% (0/143)	(0.0%, 2.5%)

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

**Table 30: Aneurysm Change from 1 Month to 12 Months,  
Test Group (Core Lab and Site-Reported)**

Change in Maximum Aneurysm Diameter from 1 Month to 12 Months	Site Reported %(m/n)	Core Lab Reported %(m/n)
Increase More than 5mm	4.5% (6/133)	2.3% (3/128)
Stable <sup>1</sup>	60.9% (81/133)	64.1% (82/128)
Decrease More than mm	34.6% (46/133)	33.6% (43/128)

<sup>1</sup> Stable refers to no change (increase or decrease) of more than 5 mm.

### 6.10 Acute Procedural Data

As shown below, the clinical utility measures of the Talent Abdominal Stent Graft are improved as compared to surgery with respect to procedure duration, blood loss, length of time in the ICU and hospital, and usage of general anesthesia. See Table 31 for further information.

**Table 31: Acute Procedural Data, Test Group and SVS Control**

Acute Procedural Data	Statistics	Test Group	SVS Control	95% Confidence Interval of Difference <sup>1,2</sup>
Duration of procedure (min)	N	166	241	
	Mean ± SD	167.3 ± 53.17	196.4 ± 82.99	(-43.5, -14.8)
	Median	155.0	180.0	
	Min, max	85, 417	57, 498	
Contrast Use (cc)	N	163		
	Mean ± SD	152.7 ± 81.50		
	Median	150.0		
	Min, max	15, 370		
Patients receiving general anesthesia	% (m/n)	40.4% (67/166)	98.7% (222/225)	(-65.7%, -50.4%)
Estimated blood loss (cc)	N	165	241	
	Mean ± SD	335.0 ± 282.36	1347.5 ± 1346.91	
	Median	250.0	1000.0	(-800.0, -600.0)
	Min, max	25, 1750	50, 10763	
Patients requiring blood transfusion	% (m/n)	18.2% (30/165)	56.8% (75/132)	(-48.6%, -28.0%)
Time in ICU (hours)	N	166	243	
	Mean ± SD	19.3 ± 73.88	74.3 ± 178.41	
	Median	0.0	36.0	
	Min, max	0, 864	0, 1728	
Overall hospital stay (days)	n	166	225	
	Mean ± SD	3.6 ± 6.38	8.2 ± 7.97	(-6.1, -3.2)
	Median	2.0	6.0	
	Min, max	1, 79	0, 72	

<sup>1</sup> Confidence level was not adjusted for multiplicity. Confidence intervals for difference (Test-SVS Control) in means were calculated using a t-distribution. Confidence intervals for difference (Test-SVS Control) in percentages were calculated by the exact method. Confidence intervals for difference (Test-SVS Control) in medians were calculated using Hodges-Lehmann estimation of location shift. 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).

<sup>2</sup> 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 Receiving General Anesthesia and 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). For Estimated Blood Loss, difference represents the median shift of estimated blood loss between the two treatment groups (Test-SVS Control).

## 6.11 CoilTrac Delivery System Performance Data

### 6.11.1 Delivery and Deployment Success

Subsequent to enrollment in the pivotal trial, the delivery system was updated to the CoilTrac Delivery System. In order to evaluate the clinical performance of the CoilTrac Delivery System, a single-center cohort of 137 patients from an independent data set was evaluated. The analysis of this independent data set supports the clinical performance of the CoilTrac Delivery System, demonstrated by delivery and deployment success rate, as well as, clinically relevant adverse events rates observed within the 30 day post-procedure period.

Table 32 presents the rate of successful delivery and deployment of the Talent Abdominal Stent Graft using the CoilTrac Delivery System. A 100% success rate was achieved in 137 patients treated. Successful delivery and deployment was defined as an initial successful implant procedure that was not aborted and did not involve delivery system malfunction.

**Table 32: CoilTrac Delivery System: Delivery and Deployment Success**

Device	Performance Measure (Site-Reported)	N = 137 % (m/n)	95% Exact Confidence Interval <sup>1</sup>
Talent Abdominal Stent Graft with the CoilTrac Delivery System	Successful Stent Graft Delivery and Deployment	100.0% (137/137)	(97.3%, 100.0%)

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

### 6.11.2 Clinically Relevant Adverse Events Within 30 Days

Table 33 presents the clinically relevant adverse events occurring intra-and peri-operatively for the patients implanted with the Talent Abdominal Stent Graft using the CoilTrac Delivery System.

The overall rate of patients with at least one clinically relevant adverse event is 15.3% (21/137) with a two-sided 95% exact confidence interval (9.7%, 22.5%). There were no reports of rupture, surgical conversion, branch vessel occlusion or migration.

**Table 33: CoilTrac Delivery System: Patients with Clinically Relevant Adverse Events [Within 30 Days]**

Category	N = 137 %(m/n)
All-cause mortality	1.5% (2/137) <sup>1</sup>
AAA rupture	0.0% (0/137)
Conversion to open repair	0.0% (0/137)
Branch vessel occlusion: renal artery/superior mesenteric artery	0.0% (0/137)
Stent graft occlusion	1.5% (2/137)
Stent graft migration	0.0% (0/137)
Device-specific endoleaks	8.8% (12/137) <sup>2</sup>
Access site wound infection	2.2% (3/137)
Access site wound hematoma	3.6% (5/137)

<sup>1</sup> Both deaths were unrelated to the aneurysm, procedure, or device.

<sup>2</sup> Type I endoleak = 7 patients, Type III endoleak = 0 patients, Unknown Type endoleak = 5 patients

## 7.0 PATIENT SELECTION

### 7.1 Individualization of Treatment

Medtronic recommends that the Talent Abdominal Stent Graft System component diameters be selected as described in Table 34. The length of the Talent Abdominal Stent Graft should extend from the distal edge of the lowest renal artery to just above the origin of the internal iliac (hypogastric) artery. In addition, the aortic length should be > 1.0cm longer than the main body portion of the chosen bifurcated model. 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 4.0 should be carefully considered relative to each patient before use of the Talent Stent Graft System. Additional considerations for patient selection include, but are not limited to:

- Patient's age and life expectancy
- Co-morbidities (e.g., cardiac, pulmonary or renal insufficiency prior to surgery, morbid obesity)
- Patient's suitability for open surgical repair
- Patient's anatomical suitability for endovascular repair
- The risk of aneurysm rupture compared to the risks of endovascular repair
- Ability to tolerate general, regional or local anesthesia
- Iliofemoral access vessel size and morphology (minimal thrombus, calcium and/or tortuosity) should be compatible with vascular access techniques of the various delivery catheter profiles. The Talent Abdominal Stent Graft System is delivered through a vascular introducer sheath (graft cover).
- Adequate iliac/femoral access compatible with the required delivery systems (a diameter of > 7 mm)
- Non-aneurysmal aortic neck between the renal arteries and the aneurysm:
  - A proximal aortic neck length of  $\geq 10$ mm
  - Proximal aortic neck angulation  $\leq 60^\circ$
  - An aortic diameter of 18–32mm
- Common iliac artery distal fixation site:
  - Distal iliac artery fixation length of  $\geq 15$ mm
  - Iliac artery diameters of 8–22mm
- Freedom from significant femoral/iliac artery occlusive disease that would impede flow through the vascular graft.

The final treatment decision is at the discretion of the physician and patient.

## 8.0 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
  - Risks related to non-interventional treatment (medical management)
- Pros and cons of open surgical repair and endovascular repair, including the fact that endovascular repair possesses potential advantages related to its minimally invasive approach. It is possible that subsequent endovascular or open surgical repair of the aneurysm may be required. Regular follow-up, including imaging of the device, should be performed as recommended in Table 36 (Section 12.0), or more frequently in patients with enhanced surveillance needs.
- The long term effectiveness of endovascular repair has not been established
- Symptoms of aneurysm rupture
- Further counseling information can be found in the Patient Information Booklet

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

## 9.0 HOW SUPPLIED

### 9.1 Contents

The Talent Abdominal System components are available in the configurations identified in Section 15.0.

In addition to the device, each carton contains:

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

## 9.2 Sterility and Storage

- Never attempt to resterilize a Talent Abdominal Stent Graft or CoilTrac Delivery System. Resterilization may adversely affect the proper mechanical function of the stent graft or delivery system and could result in patient injury and/or conversion to an open surgical procedure.
- For single use only. Delivery systems are disposable; do not reuse.
- Store at room temperature in a dark, dry place

## 10.0 CLINICAL USE INFORMATION

### 10.1 Recommended Skills and Training

Physicians using the Talent Abdominal Stent Graft System must be trained in vascular interventional procedures and in the use of this device.

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

#### 10.1.1 Patient selection:

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

#### 10.1.2 Physician skills and experience

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

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

### 10.2 Material Recommended for Device Implantation

At the time of surgery, it is recommended that physicians have available:

- At least one additional set of Talent Abdominal Stent Grafts (of the sizes intended for implantation) in the event that a device is contaminated or damaged during attempted placement
- Additional Talent Abdominal Stent Grafts (one size larger and one size smaller) in the event that the original measurement underestimated or overestimated vessel sizes
- Additional aortic and iliac extension cuffs of various lengths and diameters to customize the implant in order to fit the anatomy of the individual patient
- Fluoroscope with digital angiography capabilities and the ability to record and recall imaging
- Contrast media
- Introducer sheaths for vascular access to access arteries and to perform diagnostic imaging
- Assorted angiographic catheters, angioplasty catheters, graduated pigtail catheters
- Assorted guidewires
- Reliant® Stent Graft Balloon Catheter and other materials recommended by the Reliant Instructions for Use
- Heparin and heparinized saline solution
- Sterile lubricant
- Surgical instruments and supplies

### 10.3 Pre-Treatment Planning

Correct sizing of the aorta and iliac vessels must be determined before implantation of the Talent Abdominal Stent Graft System. Medtronic Vascular recommends using spiral computer aided tomography (CT) as well as angiograms of both the iliacs and aorta. These images should be available for review during the procedure.

Each Talent Abdominal Stent Graft System must be sized appropriately to fit the patient's anatomy. Sizing must be to the vessel wall, not thrombus. Proper sizing of the device is the responsibility of the physician. See the recommended oversizing guidelines in Table 34.

- Vessel over-distension and damage may be caused by excessive oversizing of the stent graft in relation to the diameter of the blood vessel.
- Undersizing of the stent graft may lead to device migration and/or endoleaks.

Physicians may consult Medtronic Vascular for guidance in determining proper device dimensions based on the physician's assessment of the patient's anatomical measurements.

**Table 34: Talent Abdominal Stent Graft System Oversizing Guidelines**

Native Vessel Diameter (mm)	Recommended Talent Diameter (mm)	
	Iliac	Aorta
8	8	
9-10	10	
11-12	12	
13-14	14	
15	16	
16-17	18	
18-19	20	22
20-21	22	24
22	24	26
23		28
24-25		30
26-27		32
28-29		34
30-31		36
32		

Relevant materials should be readily available as listed in Section 10.2. Cutdown and vessel access are required and in some cases vessel by-pass may be required. A vascular surgical team should be readily available (i.e., within the same facility) in case of emergency conversion to an open surgical repair.

To reduce the risk of thromboembolism, it is recommended that patients are anticoagulated during the procedure, at the discretion of the physician.

If necessary, open narrow iliac vessels with standard Percutaneous Transluminal Angioplasty (PTA) catheters prior to Talent Abdominal Stent Graft System placement (according to standard endovascular procedures). If necessary, dilate the vessel with a tapered vessel dilator. A step-up approach is recommended for vessel dilation.

## 11.0 DIRECTIONS FOR USE – STENT GRAFT SYSTEM

### 11.1 Pictorial References

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

### 11.2 Vascular Access and Arteriotomy

Following aseptic procedural guidelines perform arteriotomies at the access sites. Place a guidewire in the ipsilateral femoral artery and advance it above the renal arteries. From the contralateral side femoral artery, place a second guidewire directed to the abdominal aorta. Over the guidewire, place an angiography catheter above the renal arteries.

### 11.3 Implantation of the Bifurcated Stent Graft

#### 11.3.1 Preparation of the CoilTrac Delivery System

- 11.3.1.1 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 or the packaging or product is defective, do not use the product. Contact your Medtronic Vascular representative for return information.
- 11.3.1.2 Remove the package transport wire from the catheter tip. Then, hold the push rod firmly and draw the introducer sheath (graft cover) back a few millimeters (no more than 5mm) to loosen the fit between the graft cover and the stent graft.
- 11.3.1.3 Prepare balloon.
  - 11.3.1.3.1 Connect an inflation device to the opened stopcock on the balloon inflation port. Draw a vacuum on the balloon and close the stopcock.
  - 11.3.1.3.2 Fill the inflation device with heparinized saline solution and open the stopcock.
  - 11.3.1.3.3 Hold the catheter with the distal tip and balloon pointing down.
  - 11.3.1.3.4 Partially inflate the balloon.
  - 11.3.1.3.5 Draw back on the inflation device to deflate the balloon.
  - 11.3.1.3.6 Repeat steps 11.3.1.3.3 through 11.3.1.3.5 until all air in the balloon is removed. Each time these steps are repeated, more air is displaced with liquid. Some changes in the catheter orientation may be necessary to vent all the air.
  - 11.3.1.3.7 When all air in the balloon has been removed, draw a vacuum in the balloon (using the connected inflation device) and close the stopcock.

**CAUTION: Ensure a vacuum is drawn on the balloon before proceeding, as pressure in the balloon could interfere with deployment of the stent graft.**

- 11.3.1.4 Connect a syringe filled with heparinized saline solution to the stopcock on the sideport extension and open the stopcock.
- 11.3.1.5 While holding the device upright, flush the introducer sheath (graft cover) with the heparinized saline solution (tapping the sheath to aid in releasing air bubbles). Close the stopcock and remove the syringe. Always leave the stopcock closed when not in use.
- 11.3.1.6 Re-seat the tip by holding the sheath hub firmly and pulling back on the guidewire lumen until a smooth transition with the sheath and tip is achieved. Place the cup plunger such that the distal stent graft spring is encapsulated in the cup plunger. Tighten the tuohy borst valve.
- 11.3.1.7 Connect a syringe filled with heparinized saline solution to the guidewire exit port. Flush the guidewire lumen with the heparinized saline solution and remove the syringe.

**CAUTION: When re-seating the tip, ensure that the proximal graft spring does not overlap the radiopaque "bullet". This may prevent the stent graft from deploying properly.**

#### 11.3.2 Align the stent graft radiopaque markers with the patient's anatomy

11.3.2.1 Before inserting the device into the vasculature, visualize the radiopaque markers on the stent graft to identify positioning of the device within the sheath.

#### 11.3.2.2 Alignment

Turn the delivery system to align the marker on the short stub leg with the patient's contralateral iliac artery

#### 11.3.3 Introduce System

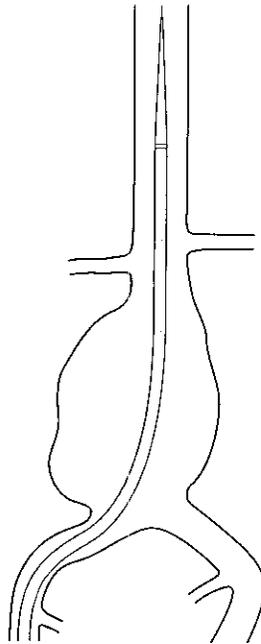
11.3.3.1 Advance the delivery system over the guidewire so that the most proximal spring of the stent graft and the radiopaque markers are visualized at the target location in the proximal aortic neck (Figure 9).

**CAUTION:** Never advance or retract the CoilTrac Delivery System from the vasculature without the use of fluoroscopy.

**CAUTION:** Do not continue advancing any portion of the delivery system if resistance is felt during advancement of the guidewire or delivery system. Stop and assess the cause of resistance. Vessel or catheter damage may occur. Exercise particular care in areas of stenosis, intravascular thrombosis or in calcified or tortuous vessels.

**CAUTION:** Never use the pushrod to advance the delivery system through the patient's anatomy; this may cause inadvertent deployment. The Talent Abdominal Stent Graft cannot be reconstrained or drawn back into the introducer sheath (graft cover), even if the stent graft is only partially deployed. The sheath hub should be used to advance the system.

Figure 9: Position the System



11.3.3.2 Inject contrast media into the abdominal aorta and mark the position of the target location, either on the imaging screen or on the patient's body. Adjust the position of the stent graft such that the top edge of the graft fabric, as indicated by two radiopaque markers, is just below the lowest renal artery.

**CAUTION:** When aligning the position of the CoilTrac Delivery System so that the Talent Abdominal Stent Graft is in proper position for deployment within the vessel, BE SURE THAT THE FLUOROSCOPE IS ANGLED PERPENDICULARLY TO THE CENTER LINE OF THE INFRARENAL AORTA TO AVOID PARALLAX OR OTHER SOURCES OF VISUALIZATION ERROR. ALIGN THE TARGET AREA/FIXATION ZONE (E.G., NECK) IN THE CENTER OF THE FIELD. Some cranial-caudal angulation of the I-I tube may be necessary to achieve this, especially if there is anterior angulation of the aneurysm neck.

**NOTE:** Contrast media may be injected to identify the location of the lower renal artery and verify the position before fully deploying the device. Once the proper proximal position has been identified, do not move the patient or imaging

equipment. The angiographic catheter can be removed prior to deployment. However, if the angiographic catheter is not removed until after deployment, ensure that the tip is straightened (pigtail catheter) with a guidewire before removal so that the stent graft is not pulled down.

#### 11.3.3.3 Confirm Position

Ensure that the distal portion of the contralateral stub leg is above the aortic bifurcation and within the aneurysmal sac, and not within the iliac vessel. Rotate the delivery system until the radiopaque marker on the distal-most spring of the short leg is aligned with the contralateral iliac artery

**CAUTION:** Before initial deployment, position the stent graft slightly higher than the targeted location.

**NOTE:** Conformance of the Talent Abdominal Stent Graft to the morphology of a patient's vasculature is enhanced when the connecting bar is oriented on the outside of the most severe bend of the vessel.

#### 11.3.4 Deploy Proximal End

11.3.4.1 Prior to drawing back the introducer sheath (graft cover) to deploy the stent graft, verify that the end of the push rod plunger is firmly positioned against the bottom of the stent graft and that the tuohy borst valve is tightened. Under fluoroscopy, proper positioning is indicated by a clearance of approximately 1mm between the push rod coil spring and stent graft distal spring.

**CAUTION:** Failure to seat the plunger against the stent graft end may result in incorrect positioning.

11.3.4.2 Prior to deployment, at the discretion of the physician it may be appropriate to decrease the patient's blood pressure to avoid inadvertent displacement of the stent graft upon withdrawal of the sheath.

11.3.4.3 Verify that the balloon is deflated. Holding the push rod stationary with one hand while slowly withdrawing the introducer sheath (graft cover) with the other hand, align the introducer sheath (graft cover) marker band with the middle of the radiopaque bullet. This will indicate that the balloon is free of the introducer sheath (graft cover) and the stent graft is positioned for deployment.

**WARNING:** The balloon must be DEFLATED before initiating deployment of the stent graft. If resistance is experienced during initial deployment, check to ensure that the modeling balloon is completely deflated.

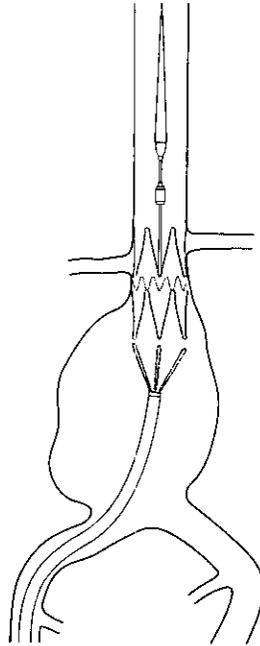
**CAUTION:** Never advance the push rod; use sufficient resistance only to hold it stationary. Do not rotate the introducer sheath (graft cover) during deployment.

11.3.4.4 Hold the push rod stationary with one hand while slowly withdrawing the introducer sheath (graft cover) with the other hand until the two proximal-most springs are past the introducer sheath (graft cover) radiopaque marker.

**CAUTION:** Do not retract the introducer sheath (graft cover) before placing the delivery system in the proper anatomical position, as this will initiate deployment of the stent graft. The Talent Abdominal Stent Graft cannot be reconstrained or drawn back into the introducer sheath (graft cover), even if the stent graft is only partially deployed. If the introducer sheath (graft cover) is accidentally withdrawn, the device will prematurely deploy and could be placed too high or too low.

11.3.4.5 Use angiography to verify the position of the stent graft in relation to the renal arteries. If the stent graft position is too high, loosen the tuohy borst valve and pull down on the guidewire lumen only, see Figure 10. This will pull the entire system down. Verify that the balloon is deflated before pulling down. Ensure that the distal edge of the contralateral stub leg of the bifurcated stent graft remains above the aortic bifurcation.

Figure 10: Deploy the Proximal End



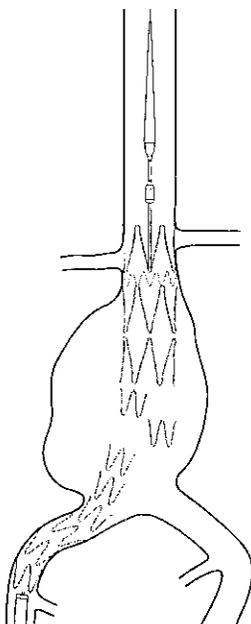
#### 11.3.5 Deploy Distal End

11.3.5.1 After confirming the correct position of the stent graft, also confirm that the push rod's cup plunger is still encapsulating the bottom of the stent graft. Under fluoroscopy, proper positioning is indicated by a clearance of approximately 1mm between the push rod coil spring and stent graft distal spring. Tighten the tuohy borst valve.

11.3.5.2 Once the proximal end of the stent graft has been positioned, continue to withdraw the introducer sheath (graft cover) until the distal spring is released from the plunger. If the distal spring does not fully release from the plunger, slowly rotate (less than 90°) and pull back on the push rod a few millimeters until the distal-most spring releases from the plunger. See Figure 11.

**CAUTION:** Do not rotate the introducer sheath (graft cover) during deployment, as this may torque the device and cause it to spin on deployment or cause twisting of the iliac limb.

Figure 11: Deploy the Distal End



### 11.3.6 Angiogram

- 11.3.6.1 Using angiography, determine if any endoleaks are present, and verify the position of the implanted stent graft.

**CAUTION: High pressure injections of contrast media made at the edges of the stent graft immediately after implantation can cause endoleaks.**

If endoleaks are detected, they should be treated by using the balloon to model the stent graft against the vessel wall. See Section 11.3.7. A minor endoleak that does not seal after re-ballooning may seal spontaneously within several days. Major endoleaks that cannot be corrected by ballooning may be corrected by adding a Talent Abdominal Stent Graft extension cuff to the previously placed stent graft. Placing an extension immediately is the most reliable course of endoleak management for both minor and major endoleaks.

If balloon modeling of the stent graft is not performed, proceed to Section 11.3.8.

### 11.3.7 Balloon Modeling of Stent Graft

- 11.3.7.1 Open the tuohy borst valve (turn counter-clockwise) to allow free movement of the guidewire lumen.
- 11.3.7.2 Move the guidewire lumen distally until the balloon is within the first covered spring.

**WARNING: When ballooning the stent graft, 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 stent graft.**

- 11.3.7.3 Open the stopcock on the inflation port. Inflate the balloon to firmly model the proximal covered spring, see Figure 12. Using fluoroscopy, watch for stent graft movement. Proper modeling should show very slight outward expansion of stent graft with balloon inflation. **Be careful not to over inflate-stop inflation upon observation of stent graft expansion.** Over inflation of balloon can cause graft tears and/or vessel dissection or rupture.

**WARNING: Do not exceed maximum inflation diameter (40mm for the 30mm balloon and 20mm for the 20mm balloon). Rupture of the balloon may occur. Adhere to balloon inflation parameters as described in this booklet and on the product label. Over-inflation may result in damage to the vessel wall and/or vessel rupture, or damage to the stent graft.**

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

The table below is a guideline for determining the volume of solution (25% contrast/ 75% saline is recommended) required to obtain a given balloon expansion diameter:

**Table 35: Guideline for balloon diameter to volume**

20mm Balloon		30mm Balloon	
Diameter	CC's (ml) <sup>1</sup>	Diameter	CC's (ml) <sup>1</sup>
10mm	2	10mm	2
15mm	3	20mm	6
20mm	5	30mm	15
--	--	40mm	31

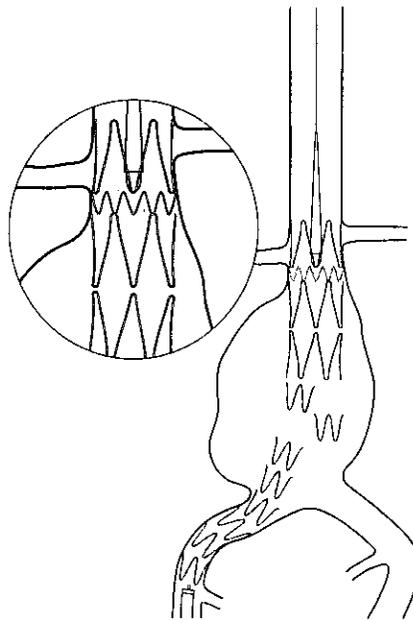
<sup>1</sup> Syringe accuracy +/- 5%

**CAUTION:** Table 35 is only a guide. Balloon expansion should be carefully monitored with the use of fluoroscopy.

11.3.7.4 Fully deflate balloon. If further modeling is required, move the balloon distally to the next location requiring modeling. Inflate the balloon to firmly model the spring to the aortic wall. Using fluoroscopy, watch for stent graft movement. Proper modeling should show very slight outward expansion of the stent graft with balloon inflation. Over inflation of balloon can cause graft tears and/or vessel dissection or rupture.

11.3.7.5 As necessary, repeat steps 11.3.7.3 and 11.3.7.4 until the entire stent graft has been modeled.

**Figure 12: Modeling the Stent Graft with the Balloon**



11.3.7.6 If desired, an angiogram may be performed following balloon modeling using the procedure described in Section 11.3.6.

11.3.7.7 If there is any focal area narrowing, use a PTA balloon (inflated diameter < graft diameter). If the area is still narrow after ballooning, place a stent graft extension. Do not leave any focal area untreated with significant narrowing or abrupt kinks of the connecting bar; this can lead to thrombosis, damage of the stent graft, or result in an incomplete distal seal.

### 11.3.8 Delivery System Removal

- 11.3.8.1 Ensure the balloon is deflated. Close the stopcock on the inflation port.
- 11.3.8.2 Withdraw the guidewire lumen into the introducer sheath (graft cover), re-establishing the smooth transition of the tip with the introducer sheath (graft cover). This can be verified by fluoroscopic examination of the introducer sheath (graft cover) marker band aligning with the radiopaque tip.
- 11.3.8.3 Tighten the tuohy borst Valve.
- 11.3.8.4 Gently remove the CoilTrac Delivery System. Do not use excessive force. Use fluoroscopy to ensure that the stent graft does not move during the withdrawal.

**NOTE:** Maintain vessel access until all Talent Abdominal Stent Graft components are placed.

### 11.4 Implantation of the Contralateral Limb

#### 11.4.1 Prepare the CoilTrac Delivery System

Prepare the CoilTrac Delivery System using the procedure described in Section 11.3.1.

#### 11.4.2 Align the stent graft radiopaque markers with the patient's anatomy

- 11.4.2.1 Visualize the radiopaque markers on the stent graft to identify positioning of the device within the sheath.
- 11.4.2.2 Turn the delivery system until the radiopaque markers, indicating the location of the connecting bar, are oriented on the outside of the most severe bend of the vessel.
- 11.4.2.3 Observe the position of the delivery system's side port; use it as a reference in case the sheath turns during advancement in the aorta.

#### 11.4.3 Introduce System

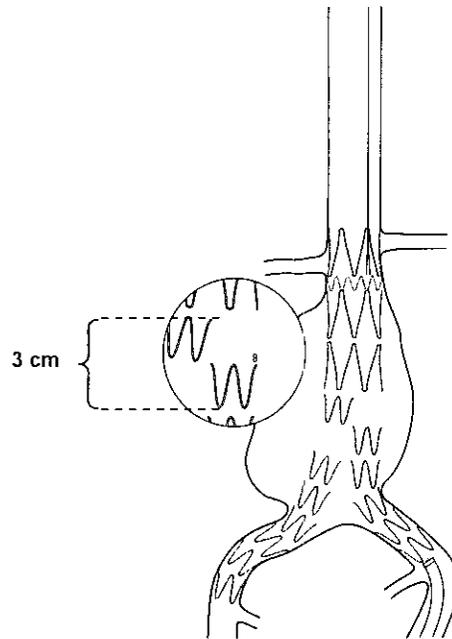
- 11.4.3.1 On the patient's contralateral side, insert a guidewire through the short stub leg and the aortic neck portion of the previously placed bifurcated Talent Abdominal Stent Graft.
- 11.4.3.2 Advance the CoilTrac Delivery System over the guidewire and into the short stub leg of the deployed bifurcated stent graft. The connecting bar should always be oriented on the outside of the most severe bend of the vessel.

**CAUTION:** Do not continue advancing any portion of the delivery system if resistance is felt during advancement of the guidewire or delivery system. Stop and assess the cause of resistance. Vessel or catheter damage may occur. Exercise particular care in areas of stenosis, intravascular thrombosis or in calcified or tortuous vessels.

#### 11.4.4 Confirm Position

To ensure proper docking of the contralateral limb, align the stub leg radiopaque marker with the proximal contralateral limb marker, ensuring at least 3cm of overlap between the components. The proximal spring of the iliac mating section should be inside and completely above the distal spring of the short leg. See Figure 13.

Figure 13: Proper Docking of Contralateral Limb to Contralateral Leg



#### 11.4.5 Deploy Stent Graft

Hold the push rod stationary and begin to slowly draw back the introducer sheath (graft cover), verifying that the proximal spring is deploying in the correct position within the short leg. When deployed, the proximal-most spring of the iliac section should open inside of and just proximal to the distal-most spring of the short stub leg, "interconnecting" the two sections together. Complete deployment of the contralateral iliac segment.

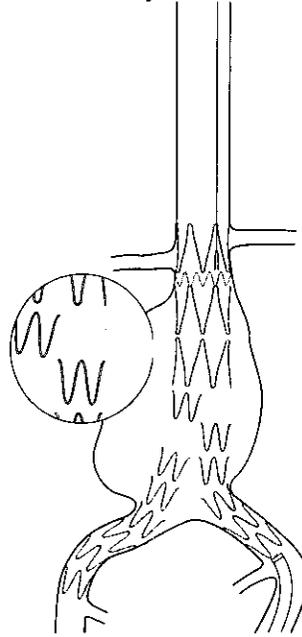
**CAUTION:** Ensure through fluoroscopic visualization that the proximal section of the stent graft is not pulled down when deploying the contralateral limb in the short stub leg (contralateral side).

**NOTE:** Do not rotate the delivery system during deployment, as this may alter the orientation of the connecting bar.

#### 11.4.6 Model Contralateral Limb

As necessary, the contralateral iliac limb can be modeled (see Figure 14) using the procedure outlined in Section 11.3.7.

**Figure 14: Talent Stent Graft System with the Modeling Balloon**



#### 11.4.7 Delivery System Removal

Remove the delivery system using the procedure described in Section 11.3.8.

#### 11.4.8 Procedure Completion for Implantation of Stent Graft Main Body

At the completion of the procedure, perform angiography to assess the Talent Abdominal Stent Graft for proximal and distal endoleaks and to verify the position of the implanted stent graft in relation to the aneurysm and renal arteries. Endoleaks at the attachment or connection sites should be treated by using a modeling balloon, such as the Reliant Stent Graft Balloon Catheter, to model the stent graft against the vessel wall. Major endoleaks that cannot be corrected by re-ballooning may be treated by adding Talent Stent Graft Extension Cuff(s) to the previously placed stent graft.

**CAUTION:** Any endoleak left untreated during the implantation procedure must be carefully monitored after implantation.

If aortic and/or iliac extensions are needed, proceed to Section 11.5, otherwise continue to Section 11.4.9.

#### 11.4.9 Close the Entry Site

11.4.9.1 Remove the introducer and the guidewire. Repair the entry site with standard closure techniques.

11.4.9.2 If, during placement of the Talent Abdominal Stent Graft, the arteries used for access to the aorta are injured, additional endovascular and/or surgical procedures to repair the injury will need to be performed. If vascular repair becomes necessary, follow appropriate institutional guidelines, including guidelines regarding continuation or termination of the overall stent graft procedure.

### 11.5 Aortic and Iliac Extensions

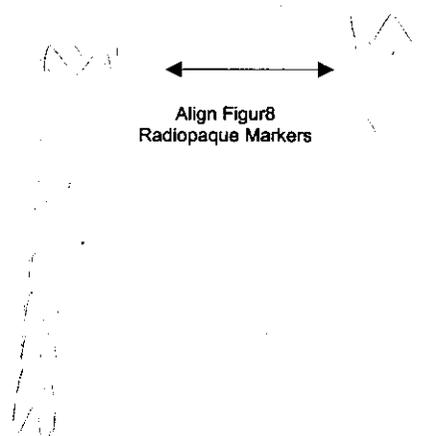
#### 11.5.1 Usage of Radiopaque Markers to Ensure Minimum Overlap

In the event that an extension (iliac or aortic extension cuff) is used, the mating sections are joined by aligning specific radiopaque markers. These radiopaque markers indicate the MINIMUM recommended overlap. The radiopaque markers used for mating are offset 30mm from the end of the extension. The edges of the graft material and the connecting bar are indicated by the proximal and distal radiopaque markers. See Figure 15 and Figure 16 for orientation of iliac and aortic cuffs.

**Figure 15: Orienting Iliac Extension Cuff**



**Figure 16: Orienting the Aortic Extension Cuff**



**11.5.2 Close the Entry Site**

11.5.2.1 Close the entry site using the procedure described in Section 11.4.9.

## 12.0 IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP

### 12.1 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 AAAs.

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 36. 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 abdominal radiographs and both contrast and non-contrast CT examinations and duplex ultrasounds. If renal complications or other factors preclude the use of image contrast media, abdominal radiographs, non-contrast CT, and duplex ultrasound should be used.

- 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 abdominal radiographs provide information on device integrity (separation between components and stent fracture).
- Duplex ultrasound imaging may provide information on aneurysm diameter change, endoleak, patency, tortuosity and progressive disease. In this circumstance, a non-contrast CT may be performed to use in conjunction with the ultrasound, since ultrasound may be less reliable. Ultrasound may be a less reliable and sensitive diagnostic method compared to CT.

Table 36 lists the minimum requirements for imaging follow-up for patients with the Talent Abdominal Stent Graft.

**Table 36: Recommended Imaging Schedule for Endovascular Graft Patients**

Interval	Angiogram	CT <sup>1</sup> [Contrast & Non-Contrast]	Abdominal Radiographs
Pre-procedure		X <sup>2</sup>	
Procedural	X		
1 Month		X <sup>3,4</sup>	
12 Months (annually thereafter)		X <sup>3,4</sup>	X

<sup>1</sup>A six month follow-up with CT Scan is recommended if an endoleak is reported at 1 month after the procedure

<sup>2</sup>Imaging should be performed within 6 months before the procedure.

<sup>3</sup>Duplex ultrasound may be used for those patients experiencing renal failure or who are otherwise unable to undergo contrast enhanced CT scan. With ultrasound, non-contrast CT is still recommended.

<sup>4</sup>If a Type I or III endoleak is present, prompt intervention and additional follow-up post-intervention is recommended. See Section 12.6..

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.

### 12.2 Contrast and Non-Contrast CT Recommendations

- 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/film 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 37 lists examples of accepted imaging protocols.

**Table 37: Accepted Imaging Protocols**

	Non-Contrast	Contrast
IV contrast	No	Yes
Acceptable machines	Spiral capable of > 40 seconds	Spiral capable of > 40 seconds
Injection volume	N/A	150cc
Injection rate	N/A	> 2.5cc/sec
Injection mode	N/A	Power
Bolus timing	N/A	Test bolus: SmartPrep, C.A.R.E. or equivalent
Coverage - start	Diaphragm	1 cm superior to celiac axis
Coverage - finish	Proximal femur	Profunda femoris origin
Collimation	<3mm	<3mm
Reconstruction	2.5 mm throughout - soft algorithm	2.5mm throughout - soft algorithm
Axial DFOV	32cm	32cm
Post-injection runs	None	None

### 12.3 Abdominal Radiographs

The following views are suggested:

- Four films: supine-frontal (AP), cross-table lateral, 30 degree LPO and 30 degree RPO views centered on the umbilicus.
- Record the table-to-film distance and use the same distance at each subsequent examination.

Ensure the entire device is captured on each single image (formatted lengthwise).

If there is any concern about the device integrity (e.g., kinking, stent breaks, migration), it is recommended to use magnified views. The attending physician should evaluate films for device integrity (entire device length including components) using 2-4X magnification visual aid.

### 12.4 Ultrasound

Ultrasound imaging may be performed in place of contrast CT when patient factors preclude the use of image contrast media. In order to help support accurate evaluation, ultrasound images should be paired with non-contrast CT images. A complete aortic duplex should be videotaped and analyzed for maximum aneurysm diameter, endoleaks, stent patency and stenosis. Included on the videotape should be the following information as outlined below:

- Transverse and longitudinal imaging should be obtained from the level of the proximal aorta, including complete imagery from the mesenteric and renal arteries to the iliac bifurcations to determine if endoleaks are present. Utilize color flow and color power angiography (if available).
- Spectral analysis confirmation should be performed for any suspected endoleaks.
- Transverse and longitudinal imaging of the maximum aneurysm should be obtained.

### 12.5 MRI Safety and Compatibility

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:

- Static magnetic field of 1.5 Tesla
- Spatial gradient field of 1000 Gauss/cm
- Maximum whole-body-averaged specific absorption rate (SAR) of 4W/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 4W/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 8mm 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 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.

**12.6 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.

**13.0 DEVICE-RELATED ADVERSE EVENTS REPORTING**

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

**14.0 PATIENT MATERIALS AND TRACKING INFORMATION**

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

- **Temporary Patient Identification 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 identification card should only be discarded when 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 Abdominal Stent Graft (as required by Federal Regulation). The hospital's submission of the device tracking form to Medtronic is also required for a patient to receive the permanent identification card.

Upon receipt of the device tracking form, Medtronic will mail the patient a **permanent identification 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](http://www.medtronic.com)). This booklet provides patients with basic information on abdominal aortic aneurysms and endovascular repair therapy.

15.0 CONFIGURATIONS AVAILABLE

Table 38: Bifurcated Stent Grafts with the CoilTrac Delivery System

OD (Fr.)	Bifurcated (mm x mm)	Covered Length (mm)	Proximal Configuration	Distal Configuration
24	36x20 36x18	155, 170	FreeFlo	Closed Web
	34x20 34x18 34x16			
	32x20 32x18 32x16 32x14			
	30x20 30x18 30x16 30x14			
22	28x20 28x18 28x16 28x14	140, 155, 170	FreeFlo	Closed Web
	26x18 26x16 26x14 26x12			
	24x14 24x12			
	22x14 22x12	140, 155	Bare Spring	

The delivery system working length is 45cm. The total length of the stent graft can be determined by adding approximately 15mm to the covered length shown above.

Table 39: Contralateral Limbs with the CoilTrac Delivery System

OD (Fr.)	Contralateral Limb (mm x mm)	Covered Length (mm)	Proximal Configuration	Distal Configuration	
20	14x24 14x22	75, 90, 105	Open Web	Closed Web	
18	14x20 14x18 14x16 14x14 14x12				
	14x10 14x8				105

The delivery system working length is 45cm. The total length of the stent graft can be determined by adding approximately 15mm to the covered length shown above.

**Table 40: Iliac Extension Cuffs with CoilTrac Delivery System**

OD (Fr.)	Iliac Extension (mm x mm)	Covered Length (mm)	Proximal Configuration	Distal Configuration
20	22x22	79	Open Web	Closed Web
	22x18	74		
	18x24 18x22	80		
	18x18 18x16 18x14 18x12	140		
18	20x16	74		
	20x20	79		
	18x20 18x18 18x16	80		
	18x14	75		
	18x12	80		
	16x16			
	16x12	75		
	14x14	80		
	14x10	75		
	12x12	81		
	12x08	75		
10x10	81			

The delivery system working length is 45cm. The total length of the stent graft can be determined by adding approximately 15mm to the covered length shown above.

**Table 41: Aortic Extension Cuffs with CoilTrac Delivery System**

OD (Fr.)	Aortic Extension (mm x mm)	Covered Length (mm)	Proximal Configuration	Distal Configuration
22	36x36	26	FreeFlo	Open Web
	34x34	28		
	32x32			
	30x30			
20	28x28	29		
	26x26	30		
	24x24			
	22x22			

The catheter working length is 45cm. The total length of the stent graft can be determined by adding approximately 30mm to the covered length shown above.

## 16.0 EXPLANATION OF SYMBOLS

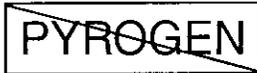
Explanation of symbols that may appear on product labeling.



Contents



Do not use if package is damaged



Non-pyrogenic



Peel here



Pull tab to open



Store at room temperature in a dark, dry place



MR Conditional

**Rx** only

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

M707213B001

**MANUFACTURER:**

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Rev A

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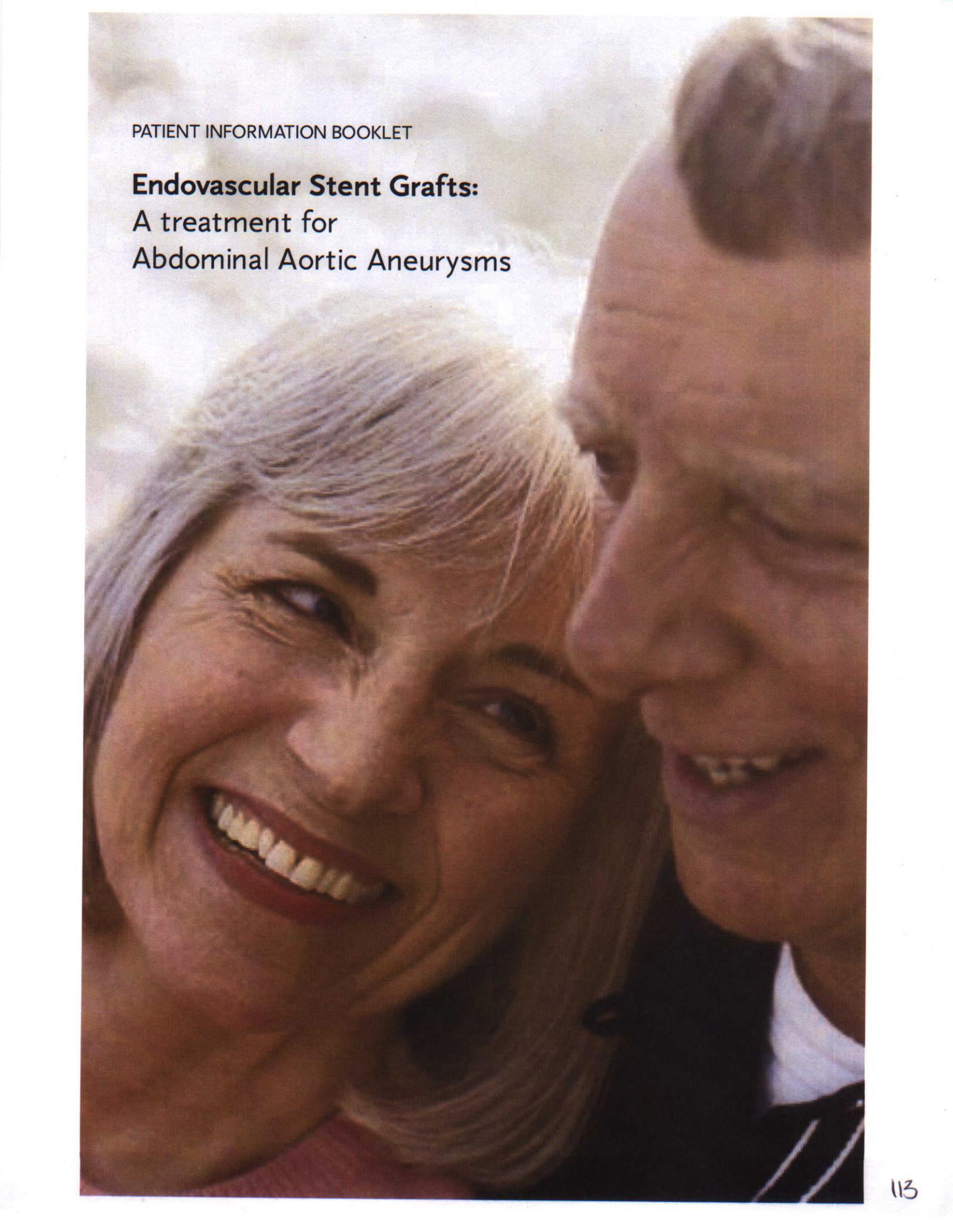
## 2.2 Patient Labeling

**INL** No. A0566

**Project** Medtronic US

**Description** talent booklet

[www.inl-agency.com](http://www.inl-agency.com)



PATIENT INFORMATION BOOKLET

**Endovascular Stent Grafts:**  
A treatment for  
Abdominal Aortic Aneurysms

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## Introduction

You have discussed having a stent graft procedure to treat an **abdominal aortic aneurysm (AAA)** with your doctor. Your doctor has given you this guide to help you further understand the device and procedure.

Only a doctor can determine if the patient is a good candidate for a **stent graft** procedure.

A Glossary is provided on Page 16 to help you understand the medical terms used in this book. Words that are bolded in the text are defined in the Glossary.

## What is the Abdominal Aorta?

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

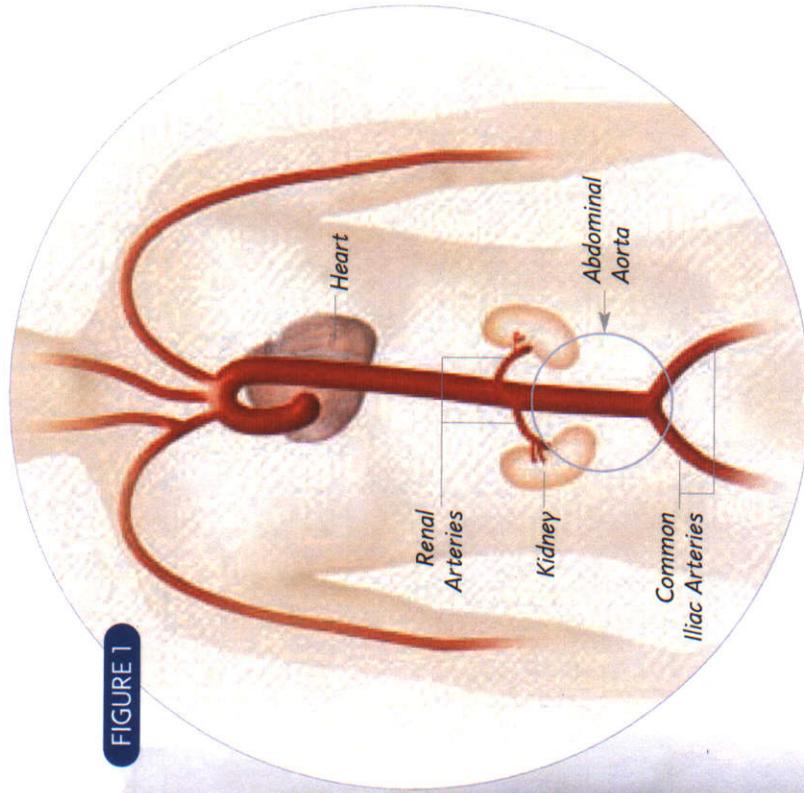


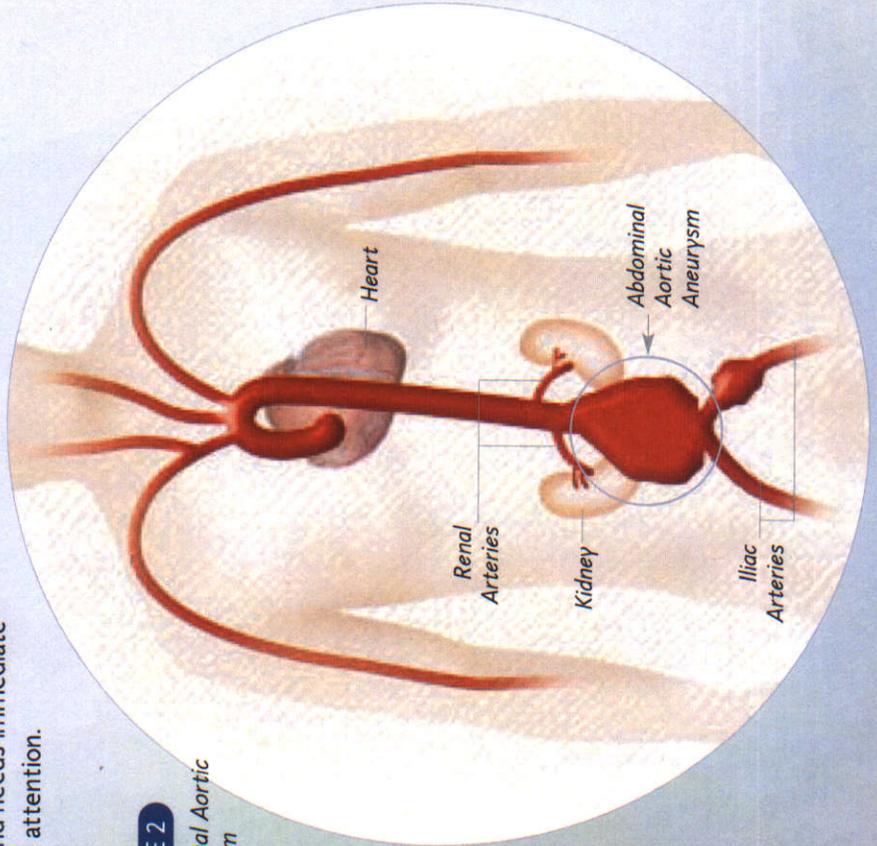
FIGURE 1



## What is an Abdominal Aortic Aneurysm (AAA)?

An **aneurysm** is the bulging or ballooning of a weakened area of a blood vessel. The wall of the **aorta** can become weak due to age, disease or trauma. This may cause the aortic wall to bulge leading to an **abdominal aortic aneurysm (AAA)**, see Figure 2. As the bulge grows, the wall of the aorta becomes weaker. This may cause the aorta to **rupture** and lead to massive internal bleeding. A ruptured aneurysm can cause death and needs immediate medical attention.

**FIGURE 2**  
Abdominal Aortic Aneurysm



## What causes an AAA?

The risk of developing an **AAA** increases with age. AAA usually affects people over 50 years of age and is more common in men than in women. Other risks include smoking and high blood pressure. A patient with a family history of AAA is at higher risk and should consult a doctor.

## What symptoms are associated with AAAs?

In most cases, patients have no symptoms of an **AAA**. However for those patients that have symptoms, the most common one is pain in the abdomen, back or chest. The pain may range from mild to severe. Some patients might feel the **aneurysm** as a throbbing mass in their abdomen. An AAA is often discovered during an examination being done for other unrelated health reasons. Your doctor may feel a bulge or pulsation (throbbing) in your abdomen. Most often, aneurysms are found during a medical test such as a **CT scan** or **ultrasound**.

## What are the treatment options for repair of AAAs?

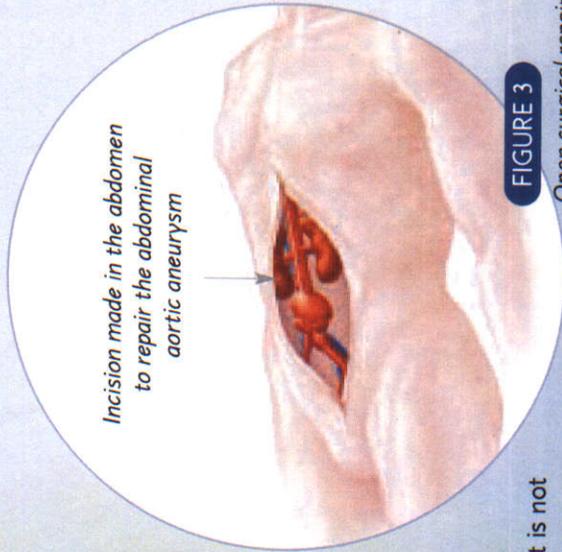
If your doctor thinks there is a risk that your AAA may rupture, he may recommend treatment. There are two primary treatment options available depending on your doctor's diagnosis: **OPEN SURGERY** or **ENDOVASCULAR STENT GRAFTING**

### OPEN SURGERY:

In this treatment option, the doctor repairs the aorta by making a large cut in the abdomen (see Figure 3). The aneurysm section of the aorta is removed and replaced with a fabric graft.

The fabric graft is sewn into place and acts as a replacement blood vessel. The blood flow through the aorta is stopped while the graft is put in place.

**Open Surgery** is typically performed under general anesthesia. It takes about three to four hours to complete. Patients usually spend three days in an intensive care unit and remain in the hospital for at least one week. Patients may require two to three months to recover completely. Open repair is a proven medical procedure. However, since it requires major surgery, it is not well tolerated by all patients.



**FIGURE 3**

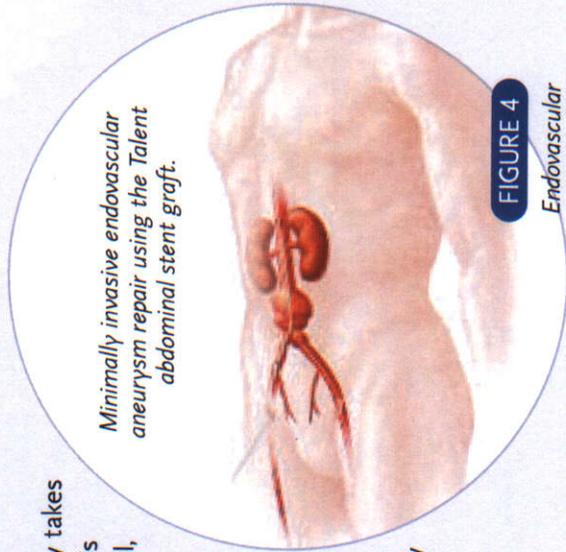
*Open surgical repair*

### ENDOVASCULAR STENT GRAFTING:

This is a **minimally invasive** procedure. A **stent graft** (such as the **Talent™ Abdominal Stent Graft**) is placed inside the aneurysm without surgically opening the tissue surrounding it (see Figure 4). The stent graft is a fabric tube supported by a metal framework.

This procedure usually takes about two hours and is performed under local, regional or general anesthesia.

A patient may not have to spend time in the intensive care unit. The hospital stay is typically two to four days. Recovery time is typically four to six weeks.



**FIGURE 4**

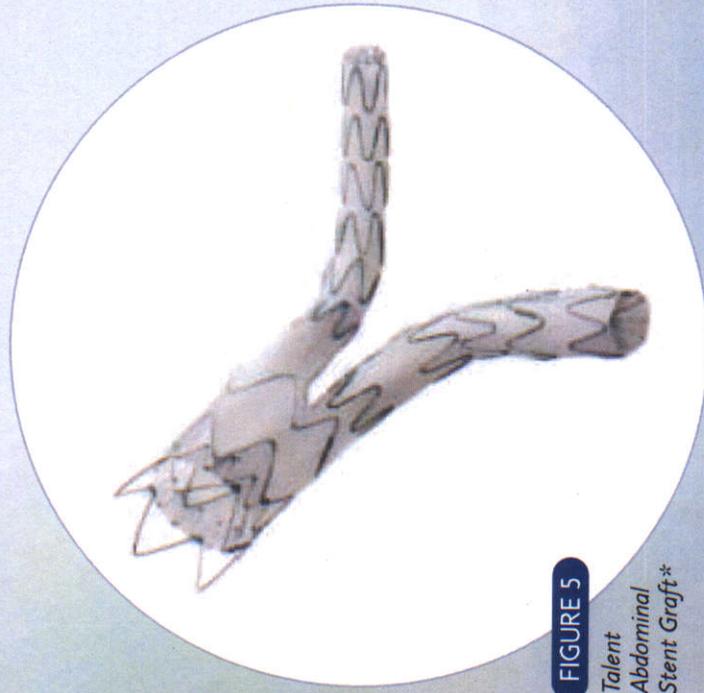
*Endovascular Stent Grafting*

Risks and benefits are associated with both treatment options. Patients should talk with their doctor about which option is best for them.

## What is the Talent Abdominal Stent Graft?

The **Talent Abdominal Stent Graft** is a fabric tube supported by a metal framework (Figure 5). The **stent graft** is designed to **exclude the aneurysm** and reinforce the weakened wall of the **aorta**. The **stent graft** reduces the pressure on the **aneurysm** and provides a new pathway for blood flow. This reduces the risk of rupture.

The **stent graft** is placed in the **aorta** using a device called a **delivery system**. The delivery system is a long thin tube-like device that contains the compressed stent graft.

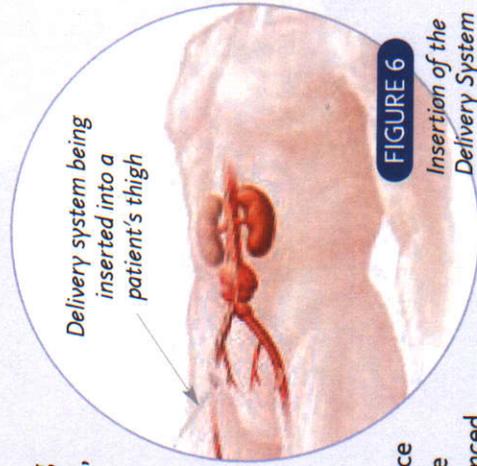


**FIGURE 5**  
Talent Abdominal Stent Graft\*

\*NOTE: The stent graft shown in the figure above is not representative of the actual size. The actual size of the Talent Abdominal Stent Grafts range from 154mm to 186mm in length.

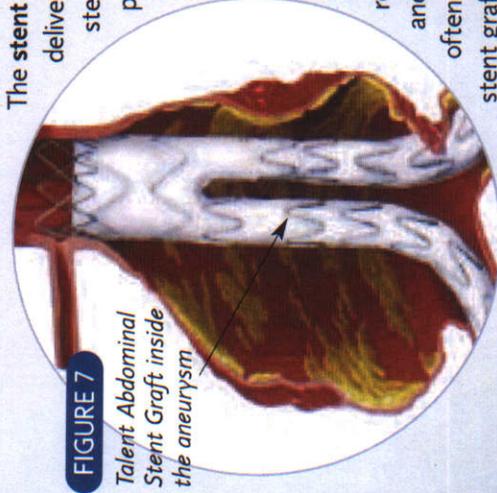
## How is the Talent Abdominal Stent Graft procedure performed?

This procedure is performed using anesthesia. Prior to the procedure, **imaging tests like CT scans** are performed. These tests allow the doctor to assess the **aneurysm**. A small cut is made in both upper thighs to prepare for the stent grafting procedure. **Fluoroscopy** is used to guide the **delivery system** to the **AAA**. The delivery system is a long thin tube like device used to place the **stent graft** in the **aorta**. The delivery system is advanced through the large vessel in the patient's thigh (**femoral artery**) to reach the abdominal aneurysm (see Figure 6).



**FIGURE 6**  
Insertion of the Delivery System

The **stent graft** is slowly released from the delivery system into the **aorta**. As the stent graft is released, it expands to its proper size so that it snugly fits into the **aorta** both above and below the **aneurysm**. The delivery system is then removed from the body. The stent graft remains inside the **aorta** permanently (see Figure 7). Additional stent grafts may be required to completely **exclude** the aneurysm. **Imaging** procedures are often performed to check whether the stent graft is properly placed.



**FIGURE 7**  
Talent Abdominal Stent Graft inside the aneurysm

## What are the Risks of the Talent Abdominal Stent Graft?

As with any **endovascular stent graft**, the **Talent Abdominal Stent Graft** comes with risks. Please discuss all risks with your doctor. Major risks associated with abdominal **endovascular stent grafts** include, but are not limited to:

- **Endoleaks:** An **endoleak** is the leaking of blood around the graft into the **aneurysm sac**. Endoleaks can be detected using **CT scans**. Most endoleaks do not require treatment. Your doctor can decide if you need any treatment.
- **Stent Graft Movement:** This is the movement of the **stent graft** from its original position over time. This can be assessed using **imaging** techniques like **CT scans**. Your doctor can decide if you need any treatment.
- **Device Related Issues** (example: breaking of sutures or metal portion of the **stent graft**): Device related issues can be detected using **imaging** techniques such as X-rays. Your doctor can decide if you need any treatment.
- **Aneurysm Rupture**
- Additional **endovascular** or surgical procedures may be required

## What are the Benefits of the Talent Abdominal Stent Graft Procedure?\*

There are a number of benefits to having a **Talent Abdominal Stent Graft** procedure, some of which are listed below:

- The procedure is **minimally invasive**
- Procedure can be performed under local anesthesia
- Lower surgical complication rate compared to **open surgery**<sup>†</sup>
- The patient may lose less blood during the procedure<sup>†</sup>
- The patient may spend less time in the intensive care unit after the procedure<sup>†</sup>
- The patient may have a shorter hospital stay with faster recovery time compared to **open surgery**<sup>†</sup>

## Are you a good candidate for the Talent Abdominal Stent Graft?

Based on your **anatomy**, your doctor can decide if you are a good candidate for this procedure. Anyone who is considering the **Talent Abdominal Stent Graft** procedure should:

- Be able to undergo a procedure that typically lasts between one to three hours
- Be able to go for regular follow-up visits after the procedure
- Be fully informed about the risks and benefits of the **Talent Abdominal Stent Graft** procedure.

## What can you expect after a stent graft procedure?

Immediately after recovery from the stent grafting procedure, you may be required to lay flat for four to six hours.

This will allow the leg wounds to start healing. Some mild discomfort may be felt at the wounds in the groin. This usually resolves in two days. Side effects may include swelling of the upper thighs, numbness of the legs, nausea, vomiting, leg pain or throbbing, lack of appetite, fever and / or absence of bowel movement for one to three days.

## What kind of follow-up will you need after a stent graft procedure?

It is important to schedule regular follow-up visits with your doctor. Long-term results of this **stent graft** have not been yet established. Thus follow-up is important to determine the success of your stent graft.

Most problems with **endovascular** repair do not have symptoms. Follow-up visits will help the doctor to check your **aneurysm** and **stent graft** on a regular basis. Some problems that might occur are listed in the "What are the Risks of the Talent Abdominal Stent Graft?" section of this booklet, page 10.

Your doctor will schedule follow-up visits depending on your condition, most often these will occur at 1 month, 1 year and annually thereafter. At each visit, **imaging** such as **CT scans** will be carried out to determine the performance of the **stent graft**. If you have poor kidney function, you should ask your doctor about the dyes used in some of these imaging studies as they may be harmful.

## What symptoms should prompt you to call your doctor after the procedure?

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

- Pain, numbness, coldness or weakness in the legs or buttocks.
- Any back, chest, abdominal, or groin pain.
- Dizziness, fainting, rapid heartbeat or sudden weakness.

A doctor should also be called if the patient needs to reschedule a follow-up visit for any reason.

## What is the Patient Identification Card?

After your **Talent Abdominal Stent Graft** procedure, your doctor will give you a temporary patient identification (ID) card. The temporary patient ID card will tell you the size and number of your abdominal aortic **stent graft** implants.

Medtronic will mail you a permanent patient ID card to carry in your wallet. Your permanent ID card will list information about:

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

Be sure to tell all of your health care providers that you have the **stent graft** and show them your patient ID card. You should keep your patient ID card available at all times.

## Can I undergo Magnetic Resonance Imaging (MRI)?

After being implanted with the Talent stent graft, it is still safe to have most MRI procedures, under certain conditions. MRI information is provided on your patient ID card. Show your patient ID card to your health care providers.

## 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 Abdominal Stent Graft is contraindicated in patients who have a condition that can infect the stent graft and in patients who are allergic to the stent graft materials<sup>1</sup>. Your doctor can help determine if the Talent Abdominal Stent Graft is safe for you.

## Warnings

**Warning:** All patients with **endovascular aneurysm repair** must undergo periodic imaging to evaluate the **stent graft** and **aneurysm** size. (**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).

**Warning:** The use of this device requires use of dyes used for **imaging**. Patients with kidney problems may be at risk of kidney failure after procedure

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

**Warning:** Perforation and/or dissection of the blood vessels is a risk with any catheter-based procedure. This risk may increase with the use of large-sized catheters.

<sup>1</sup>The Talent Abdominal Stent Graft is made up of the following materials: nitinol, polyester and platinum-iridium wire.

## Questions you may want to discuss with your doctor

- What are the other options for treatment of AAA?
- Which stent grafts are approved for treatment of AAA?
- What are the risks (including rupture) with a stent graft?
- Will health insurance pay for part or all of the cost associated with this procedure?
- After the procedure, how often must a doctor follow up with the patient, and which types of tests will need to be performed?
- Does a patient have to limit activities after the treatment? If yes, for how long?
- How long can the stent graft remain implanted in the body?
- How many stent graft procedures has this facility performed?

This guide is not a substitute for detailed discussions between you and your doctor. Only your doctor can decide if this procedure is suitable for you.



## Glossary

**Abdominal Aortic Aneurysm (AAA):** A bulging or “ballooning” of a weakened area of the abdominal aorta. This term is often abbreviated to “AAA”.

**Anatomy:** The study of the structure of the body and the relationship between its body parts.

**Aneurysm:** A bulging or “ballooning” of a weakened area of a blood vessel.

**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.

**Aneurysm Sac:** A pouch or bulge formed in the blood vessel due to the aneurysm.

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

**CT scan:** An imaging technique that creates a series of computerized X-rays that form a picture of the aneurysm and adjacent blood vessels.

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

**Delivery system:** A long, tube-like device that assists in the placement of the stent graft within the blood vessels.

**Endoleak:** Blood flow into the aneurysm (bulge or “ballooning” of the weakened area of the blood vessel) after placement of a stent graft.

**Endovascular:** Inside or within a blood vessel.

**Endovascular stent grafting:** A minimally invasive procedure in which a tube shaped device is placed inside a diseased vessel without surgically opening the tissue surrounding the diseased vessel.

**Exclude/exclusion:** Shutting off or removing from the main part.

**Femoral Arteries:** blood vessels that carry blood to the thigh region of each leg. Doctors can use the femoral arteries as a path to reach the iliac arteries and the aorta.

**Fluoroscopy:** A real-time X-ray image that is viewed on a monitor. Fluoroscopy is an imaging technique generally used by the doctors to visualize the placement of the stent graft during endovascular procedures.

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

**Minimally Invasive:** Involving puncture or cut of the skin without exposing the internal organs.

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

**Open Surgery / Open Surgical**

**Repair:** A type of surgery performed to repair an aneurysm.

The doctor repairs the aorta by making a large cut in the abdomen. The aneurysm section of the aorta is removed and replaced with a fabric graft. The graft is sewn into place and acts as a replacement blood vessel.

**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.

**Stent graft / Talent Abdominal Stent Graft:** A woven polyester tube (graft) supported by a tubular metal web (resilient springs commonly referred to as stents) that is placed inside of a diseased (aneurysmal) vessel without surgically opening the surrounding tissue. After being placed in the artery, the stent graft expands to a pre-established diameter. The stent graft relieves the pressure on the aneurysm by providing a new pathway for blood flow.

**Ultrasound:** An imaging technique that creates an image through the use of high-frequency sound waves.

## Additional information

Additional information regarding AAA can also be found at the following websites:

[www.mediclineplus.gov](http://www.mediclineplus.gov)  
[www.fda.gov](http://www.fda.gov)

### CONTACTING MEDTRONIC:

If you have any questions concerning your **Talent Abdominal Stent Graft** you should contact your doctor. It is Medtronic's mission to alleviate pain, restore health, and extend life. If there is anything that we as a community can do to assist you, please feel free to contact us:

Medtronic Vascular  
3576 Unocal Place  
Santa Rosa, CA 95403  
USA  
[www.Medtronic.com](http://www.Medtronic.com)  
Tel: 888-283-7868  
Fax: 800-838-3103

Customer Services/  
US Product Inquiries  
Tel: (800) 961-9055  
Fax: (800) 929-2133

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