Summary of Safety and Effectiveness Data (SSED)

I. GENERAL INFORMATION

Device Generic Name:	Endovascular Graft
Device Trade Name:	Talent™ Abdominal Stent Graft System
Applicant Name and Address:	Medtronic Vascular 3576 Unocal Place Santa Rosa, CA 95403 USA
Premarket Approval Application (PMA) Number:	P070027
Date of Panel Recommendation:	None
Date of Notice of Approval to Applicant:	April 15, 2008
Expedited:	Not applicable

II. INDICATIONS FOR USE

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 ≥ 10 mm;
- Proximal aortic neck angulation ≤ 60°;
- Distal iliac artery fixation length of ≥ 15 mm;
- An aortic neck diameter of 18–32 mm and iliac artery diameters of 8–22 mm; and
- Vessel morphology suitable for endovascular repair.

III. 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.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Talent™ Abdominal Stent Graft System labeling (Instructions for Use).

V. DEVICE DESCRIPTION

General System Description

The Talent Abdominal Stent Graft System is comprised of two main components: an implantable stent graft (Talent Abdominal Stent Graft) and a disposable delivery system (CoilTrac 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.

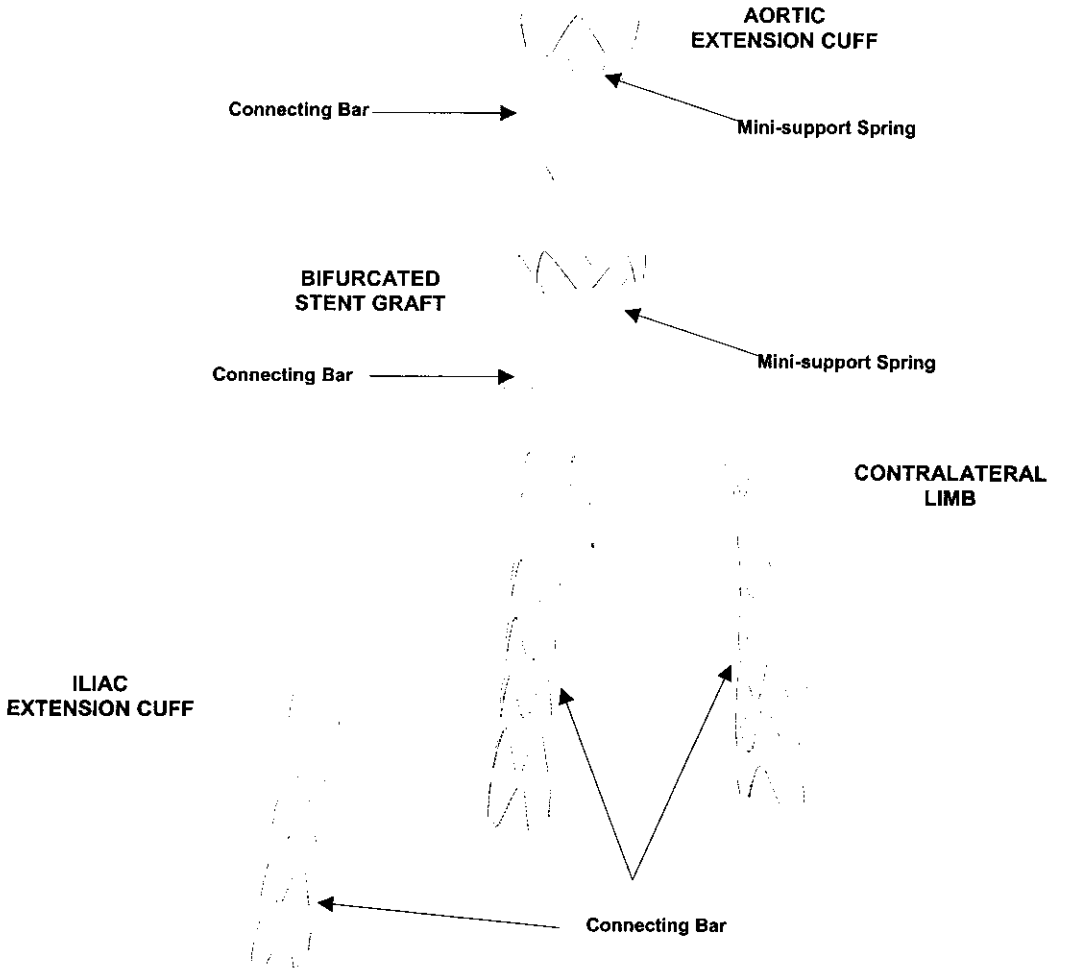
The Talent Abdominal Stent Graft System is modular and consists of four stent graft component configurations:

- 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 in order 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 (referred to as 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 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.

Figure 1: Talent Abdominal Stent Graft – All Configurations

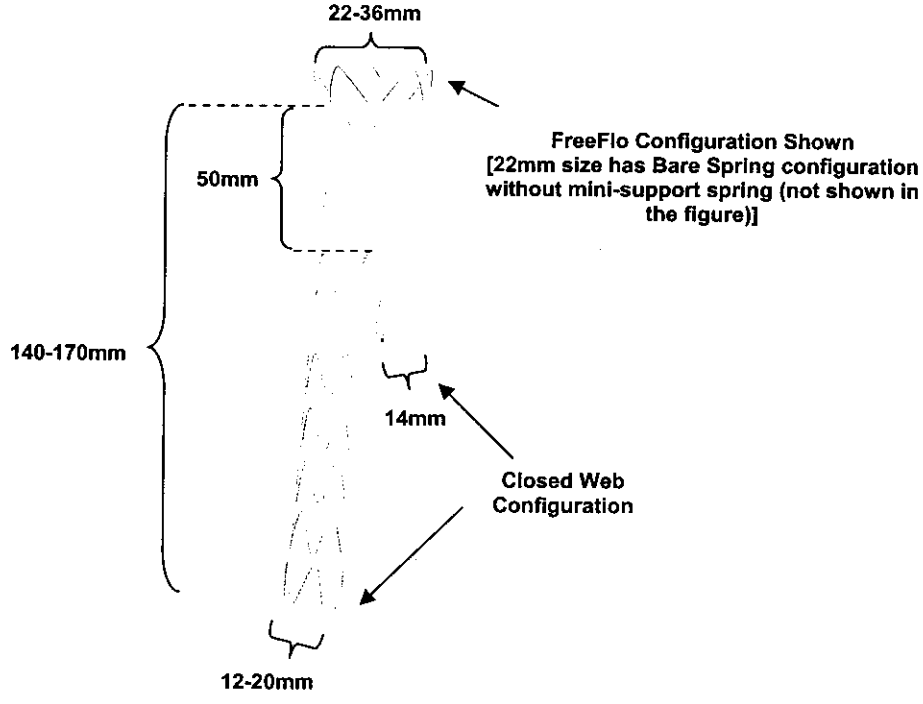


Bifurcated Stent Graft

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

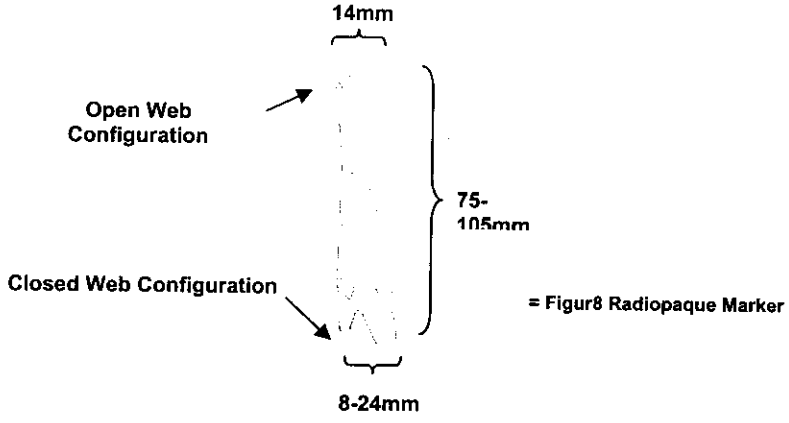


Contralateral Iliac Limb

The contralateral iliac limb component is implanted after the bifurcated component in order to provide a conduit for blood flow into the contralateral iliac artery. See Figure 3. The contralateral iliac limb is introduced though 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 14 mm for all sizes of limbs, so that all limbs can dock with all available bifurcated stent graft configurations. The distal end of the limb has a Closed Web configuration.

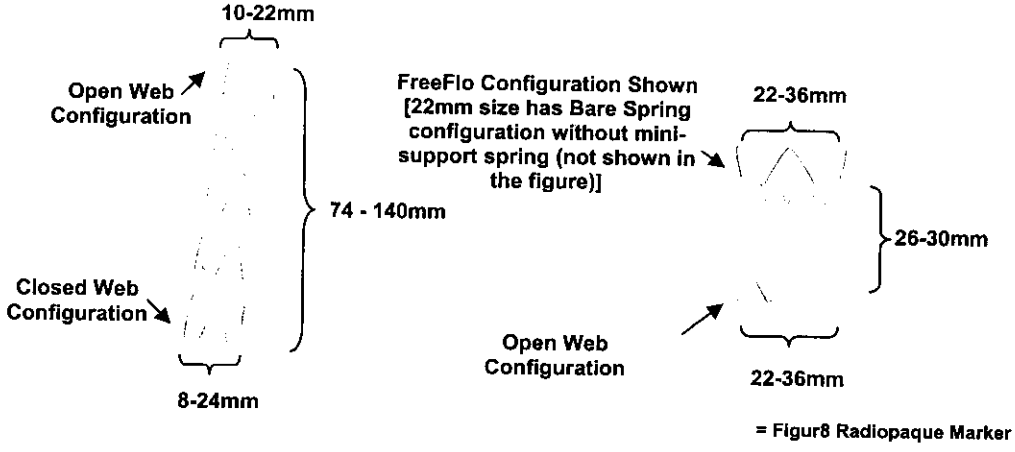
Figure 3: Talent Abdominal Contralateral Iliac Limb



Aortic and Iliac Extension Cuffs

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

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



CoilTrac 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

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the treatment of abdominal aortic aneurysms (AAA): endovascular repair using another endovascular grafting system; surgical implantation of a synthetic graft within the aneurysmal vessel; and medical management. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

VII. MARKETING HISTORY

The current version of the Talent Abdominal Stent Graft System has been made commercially available since 2002 in over 80 countries outside of the United States. The Talent Abdominal Stent Graft System has not been withdrawn from any market for reasons related to safety or effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

The potential adverse effects (e.g., complications) that may occur and/or require intervention with the use of this device 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).

For the specific adverse events that occurred in the clinical studies, please see Section X, below.

IX. SUMMARY OF PRECLINICAL STUDIES

A. Biocompatibility

Toxicology and biocompatibility testing were conducted for materials in the Talent Abdominal Stent Graft System. Testing was conducted in accordance with Good Laboratory Practices (21 CFR §58) and ANSI/AAMI/ISO 10993-1: 2003 *Biological Evaluation of Medical Devices*. The Talent Abdominal Stent Graft was classified per ISO 10993-1 *Biological Evaluation of Medical Devices* as an implant device in permanent contact (> 30 days) with blood. The CoilTrac Delivery System was classified as an externally communicating device in limited contact (< 24 hours) with circulating blood.

Table 1 summarizes the test results for the Talent Abdominal Stent Graft. Table 2 summarizes the test results for the CoilTrac Delivery System.

Table 1: Summary of Biocompatibility Testing – Talent Abdominal Stent Graft

Test	Purpose	Results	Pass/ Fail
Cytotoxicity: Colony Assay	Evaluate effect of leaching substances on colony formation (Chinese hamster lung cell)	Average colony formation (% of controls): 91-109%	Pass
MHLW Maximization Sensitization	Determine test article potential to cause delayed dermal sensitization (guinea pig)	1%, 10% and 100% test article extracts showed no evidence of causing sensitization. All test animals were graded 0.	Pass
Irritation/ Intracutaneous Toxicity	Determine local dermal irritant effects of leachables extracted from the test article (rabbit)	Difference between test and control scores: • Saline: 0.0 • Sesame Oil: 0.0	Pass
MHLW Systemic Toxicity	Determine potential of leachables extracted from the test article to cause acute systemic toxicity (mouse (strain Crl:CF-1BR))	No evidence of mortality or systemic toxicity	Pass
4-wk Sub-Chronic Toxicity (Subcutaneous Implantation)	Evaluate potential sub-chronic toxicity (rat)	• No evidence of systemic toxicity • Local Macroscopic tissue reaction was not significant compared to the negative control • Microscopically considered a slight irritant	Acceptable

Test	Purpose	Results	Pass/ Fail
Genotoxicity: Bacterial Reverse Mutation Study	Determine whether extract causes mutagenic changes in the test strains in the presence or absence of S9 metabolic activation (*Salmonella typhinurium* strains TA98, TA 100, TA1535, and TA1537; *Escherichia coli* strain WP2*uvr*A)	No case of ≥ 2-fold increase in mean # of revertants	Pass
Genotoxicity: Chromosomal Aberration	Determine whether the test extract causes genotoxicity in the presence and absence of S9 metabolic activation. (chinese hamster ovary cells)	Test extracts were concluded to be negative for the induction of structural chromosome aberrations: χ^2= 0.5 and 1.2.	Pass
Genotoxicity: Mouse Peripheral Blood Micronucleus	Evaluate test extract potential to cause genotoxic changes in the chromosomes or the mitotic apparatus of murine polychromatic erythrocytes (mouse (strain Crl:CD-1(ICR) BR))	No statistically significant increase in the # of MN-RETs for each test group	Pass
12 week ISO Muscle Implantation	Evaluate evidence of irritation or toxicity, post-implantation (rabbit)	• Macroscopic Score: 0.0 = 'not significant' • Microscopic Score: 4.4 = 'slight irritant'	Acceptable
Hemocompatibility: MHLW *In Vitro* Hemolysis	Evaluate if test article extract causes hemolysis (rabbit)	• 1 hr & 2 hrs: 0% • 4 hrs: 1.1%	Pass
C3a Complement Activation Assay	Ensure that the potential extractables did not activate the complement system (Extract: Normal Human Serum (NHS))	C3a concentration not significantly higher than controls	Pass
In Vivo Thromboresistance	Evaluate the potential of the test device to resist thrombus formation when placed in the vasculature	• Grade 1, 2, and 2. • Test article was thromboresistant.	Pass
USP Pyrogen Study	Determine if the test solution induced a pyrogenic response (rabbit)	• Initial test: 1 rabbit was 0.6°C above baseline temperature. • Retest: 1 rabbit had an increase of 0.5°C or above. • Total rise for all 8 rabbits was 1.3°C.	Pass

Table 2: Summary of Biocompatibility Testing – CoilTrac Delivery System

Test Method	Purpose	Result	Pass/Fail
MHLW Cytotoxicity: Colony Assay	Evaluate effect of leaching substances on colony formation (chinese hamster lung cell)	Average colony formation (% of controls): 88-106%	Pass
MHLW Maximization Sensitization	Determine test article potential to cause delayed dermal sensitization (guinea pig)	No evidence of delayed dermal contact sensitization for 0.1%, 1% or 10% solutions	Pass
ISO Intracutaneous Reactivity	Determine local dermal irritant effects of leachables extracted from the test article (rabbit)	Difference between test and control score: • Saline: 0.0 • Sesame Oil: 0.1	Pass
MHLW Systemic Toxicity	Determine potential of leachables extracted from the test article to cause acute systemic toxicity (mouse)	No evidence of systemic toxicity or mortality	Pass
Hemocompatibility: MHLW *In vitro* Hemolysis	Evaluate if test article extract causes hemolysis (rabbit)	1 hr, 2 hrs & 4 hrs: 0%	Pass
C3a Complement Activation Assay	Ensure that the potential extractables did not activate the complement system	Not significantly higher than the negative control (p-value > 0.05)	Pass
Partial Thromboplastin Time Assay	Detect material mediated effects on the intrinsic coagulation pathway	Shortened clotting time compared to plasma control.	Acceptable
In vivo Thromboresistance w/Platelet Count	Evaluate the potential of the test device to resist thrombus formation when placed in the vasculature (dog)	Grade 0, 0, and 1. Test article was thromboresistant.	Pass
USP Pyrogen Study	Determine if the test solution induced a pyrogenic response (rabbit)	All animals showed <0.5°C increase.	Pass

B. Product Testing

Medtronic conducted comprehensive preclinical, bench and analytical testing on the Talent Abdominal Stent Graft System. The *in vitro* testing was intended to verify that the performance attributes of the Talent Abdominal Stent Graft System are sufficient to minimize adverse events under anticipated clinical conditions. This testing included both the stent graft and the delivery system. All testing was conducted in accordance with national and international standards and guidances.

The comprehensive testing detailed in Table 3 verified that the Talent Abdominal Stent Graft System (implant and delivery systems) met its product performance and design specifications. Results obtained from in vitro testing provided evidence supporting the safety and effectiveness of the Talent Abdominal Stent Graft System.

Table 3: Summary of Testing of Talent Abdominal Stent Graft System

Test	Samples Tested	Specification / Acceptance Criteria	Summary Test Results
Stent Graft Visual Integrity	(30) contralateral iliacs (30) aortic extension cuffs (30) aortic extension cuffs (30) bifurcated	• No broken stents • 5-13 sutures/cm density (springs) • Loose sutures are allowable if they continue to attach the stent and/or RO marker to the graft material. • No graft holes or tears • Support springs may contain deformation if the spring remains attached to the graft material	All samples met the acceptance criteria.
Spring Radial Force	(10) 20 mm springs (10) 28 mm springs (10) 36 mm springs	Characterization study	The mean forces were found to be 1.63 lbf, 1.56 lbf and 1.39 lbf for the 20mm, 28mm and 36 mm springs, respectively. This testing demonstrates the ability of the Talent Stent Graft to exert an outward non-zero radial force on the graft, allowing the Talent Stent Grafts to expand and maintain an open lumen and provide sealing in a variety of patient anatomies.
Stent Graft Dimensional Verification	(30) contralateral iliacs (30) aortic extension cuffs (30) aortic extension cuffs (30) bifurcated	Aortic sections: expanded diameter must be ≥ 1mm below the labeled nominal diameter Iliac sections: expanded diameter must be ≥ labeled nominal diameter	All samples met the acceptance criteria.
Stent Graft Conformability	(10) bifurcated (10) contralateral iliacs	Characterization study	This testing characterized the minimum radius of curvature that the stent graft can accommodate without kinking. All kinks occurred with a radius of curvature of 1 cm or less, demonstrating the ability of the stent graft to maintain an open lumen in tortuous anatomy.
Stent Graft Migration Resistance	(10) bifurcated	Characterization study	This testing characterized the ability of the bifurcated stent graft to resist migration. The peak force required to displace the proximal section of the bifurcated stent graft ranged from 754.0 to 928.2 gf.

Test	Samples Tested	Specification / Acceptance Criteria	Summary Test Results
Stent Graft Joint Strength	(10) bifurcated with (10) aortic extension cuffs (10) bifurcated with (10) contralateral iliacs	Characterization study	This testing characterized the ability of the modular components of the Talent Stent Graft System to resist separation. The peak force required to displace the contralateral limb from the bifurcated main body ranged from 461.4 to 831.4 gf. The peak force required to displace an aortic cuff from the bifurcated main body ranged from 221.6 to 313.2 gf.
Spring Attachment Strength	(10) bare springs (10) body springs	Characterization study	This testing characterized the attachment strength of the Talent springs to the graft material. The strength ranged from 31.10 to 38.02 lbf for bare springs and from 59.46 to 80.29 lbf for body springs.
Crimp Strength	20 crimps	Crimp strength LTL must be greater than 4.91 lbs.	All samples met the acceptance criteria.
Nitinol Alloy Material and Surface Analysis	Three separate lots of wire material	**Property-Requirement** Chemical Composition • Nickel: 55.9% reference • Titanium: Balance • Carbon: <0.05% • Oxygen: <0.05% • Any single trace element: <0.05% • Total trace elements (Other than Ni, Ti, C, and O): <0.4% Transformation Property • A_s temperature: -15 +/- 5°C Mechanical Properties • UTS (ksi): 206 – 246 ksi • Elongation (%): 4% min	All samples met the acceptance criteria.
Surface Analysis	Three separate lots of wire material	Must be smooth and uniform in color with no blotches, spotting or pinholes	All samples met the acceptance criteria.
Potentiodynamic Polarization Corrosion	(6) springs	Characterization Test	This testing evaluated, per ASTM F2129, the general resistance of springs to pitting in the simulated clinical conditions. The test results indicate that the stent springs used in the Talent Abdominal Stent Grafts have a high resistance to localized corrosion under simulated in-vivo conditions.

Test	Samples Tested	Specification / Acceptance Criteria	Summary Test Results
MRI	(1) bifurcated with contralateral iliac limb (3) bifurcated with contralateral iliac limb and aortic extension cuff	The presence of the stent graft must not pose an additional unacceptable risk to patients when subjected to 1.5T and 3.0T magnetic fields.	All samples met the acceptance criteria. The device has therefore been determined to be MRI-conditional.
Graft Component Tensile Strength	(10) seamed loops	Characterization study	Graft component tensile strength testing was conducted to characterize the tensile strength of the graft material. The mean tensile strength of material used for the bifurcated, iliac limb, aortic cuff and iliac extension cuff was 55.19 lbf.
Stent Graft Permeability	(10) bifurcated – bifurcation region (10) bifurcated – ipsilateral iliac region	Characterization study	Stent graft permeability testing was characterized to evaluate the rate of water flow through the Talent Abdominal Stent Graft under a pressure of 120 mm Hg. The mean rate of leakage per unit area was calculated as 521.0 ml/min/cm^2 for the bifurcated device and 541.0 ml/min/cm^2 for the ipsilateral leg.
Stent Graft Burst	(10) stent grafts	Stent graft burst pressure LTL $\geq$ 18.8 psi	All samples met the acceptance criteria.
Finite Element Analysis	N/A – computer analysis of springs	Characterization study	Finite element analysis was used to determine the location and magnitude of the maximum strains in the Nitinol wire frame as a function of radial compression when subjected to catheter loading and an *in vivo* pulsatile loading environment. The peak strains at simulated catheter loading were determined to be below the yield strain of the Nitinol springs. Maximum strain locations and values determined from the simulated *in vivo* pulsatile loading were subsequently used as a reference in appropriate *in vitro* testing including pulsatile fatigue testing.
Whole Spring Fatigue	(16) 24mm (16) 46mm	No fractures over 400 million cycles of clinically relevant loading conditions.	All samples met the acceptance criteria.
Graft Material and Seam Fatigue Testing	(20) seam samples	No unacceptable (based on individual sample evaluation) seam damage, suture propagation, or suture-hole elongation over 400 million cycles of clinically relevant loading conditions.	All samples met the acceptance criteria.

Test	Samples Tested	Specification / Acceptance Criteria	Summary Test Results
Whole Device Fatigue Testing	(12) bifurcated	Must demonstrate structural integrity over 400 million cycles. No structural failures of the device that would compromise, spring to graft attachment or patency. No graft material failure as a result of interaction of stent-graft components with each other.	All samples met the acceptance criteria.
Delivery Catheter Tensile Bond Strength Tests	Varies depending upon specific test (samples included 18Fr, 20Fr, 22Fr, and 24Fr delivery catheters)	Varies depending upon specific test (Acceptance criteria ranged from 5.0 lbf to 30 lbf.)	All results met the acceptance criteria.
Delivery Catheter Torsional Bond Strength Tests	(10) 18Fr (10) 20Fr (10) 22Fr (10) 24Fr	Ultimate Torsional Strength > 1.62 lb•in	All samples met the acceptance criteria.
Sheath Marker Visualization	(2) 18Fr (2) 20Fr (2) 22Fr	Characterization study	The radiopacity of the introducer sheath (graft cover) radiopaque marker was evaluated in cadavers under fluoroscopy. The results indicated that the radiopacity of the delivery system is sufficient for clinical use.
Balloon Inflation Time	(15) 20mm balloons (15) 30mm balloons	Characterization study	Balloon inflation time testing was conducted to characterize the time required to inflate the compliant balloon to its maximum diameter. The mean time to inflate the balloon to its maximum diameter was 43.07 sec for the 20mm size and 60.46 sec for the 30 mm size.
Balloon Deflation Time	(15) 20mm balloons (15) 30mm balloons	Balloon deflation time must be < 45 seconds	All samples met the acceptance criteria.
Volume to Leak/Burst Balloon	(15) 20mm balloons (15) 30mm balloons	Leak/Burst volume of balloon and catheter must be: > 5mL for 20mm balloon > 31mL for 30mm balloon	All samples met the acceptance criteria.

Test	Samples Tested	Specification / Acceptance Criteria	Summary Test Results
Multiple Inflations of Balloon to Maximum Diameter	(30) 20mm balloons (30) 30mm balloons	The balloon must be able to undergo 16 cycles of inflation to recommended maximum diameter (20mm for 20mm balloon, 40mm for 30mm balloon) for 30 seconds and then deflated without leak/burst.	All samples met the acceptance criteria.
Stent Graft Modeling	(5) 20mm balloons (5) 30mm balloons	Characterization study	Stent graft modeling testing was conducted to characterize the ability of the CoilTrac balloon to model the Talent Abdominal Stent Graft as evidenced by visual examination. All samples expanded the stent graft without any balloon leakages.
Graft Cover Tensile Strength	(10) 18Fr (10) 20Fr (10) 22Fr (10) 24Fr	Yield Strength LTL > Deployment Force UTL	All samples met the acceptance criteria.
Delivery System Hemostasis	(30) 18Fr (30) 20Fr (30) 22Fr (30) 24Fr	Water leakage flow rate < 2 ml/min	All samples met the acceptance criteria.
Trackability / Pushability	(10) 18Fr contralateral limbs (10) 20Fr contralateral limbs (10) 20Fr aortic extension cuffs (10) 20Fr iliac extensions (10) 22Fr bifurcated (10) 22Fr aortic extension cuffs (10) 24Fr bifurcated	Characterization study	Trackability/pushability testing was conducted to characterize the force required to track the delivery system over a guidewire through a tortuous path. The mean force required for pushability and trackability of the delivery systems under worse case scenarios (largest diameter and longest length stent grafts) ranged from 368.49 gf to 911.26 gf.
Guidewire Acceptance	(30) 18Fr-contralateral limbs (30) 20Fr-aortic extension cuffs (30) 22Fr-aortic extension cuffs (30) 24Fr-bifurcated	Delivery system must pass 0.035" diameter guidewire with minimal resistance and without damaging the delivery system or guidewire.	All samples met the acceptance criteria.

Test	Samples Tested	Specification / Acceptance Criteria	Summary Test Results
Deployment Force	(10) 18Fr-contralateral limbs (10) 20Fr-contralateral limbs (10) 20Fr-aortic extension cuffs (10) 20Fr-iliac extensions (10) 22Fr-bifurcated (10) 22Fr-aortic extension cuffs (10) 24Fr-bifurcated	Deployment Force UTL must be less than Sheath to Hub Bond Strength LTL and Graft Cover Yield Strength LTL	All samples met the acceptance criteria.
Delivery System Torquability	(3) 18Fr (3) 20Fr (3) 22Fr (3) 24Fr	Characterization study	Delivery system torquability testing was conducted to characterize the torque (rotational) response of the stent graft system within simulated vasculature. Results of the testing were found to be sufficient for clinical use.
Delivery System Kink Radius	(10) 18Fr-contralateral limbs (10) 24Fr-bifurcated	Characterization study	Delivery system kink radius testing was conducted to characterize the delivery system kink radius by determining the minimum radius of curvature to forcefully produce a kink. For the worst case (largest diameter stent with largest diameter delivery system) the mean radius to create a kink was observed to be 8.20cm.
Crossing Profile	(30) 18Fr-contralateral limbs (30) 20Fr-aortic extension cuffs (30) 22Fr-aortic extension cuffs (30) 24Fr-bifurcated	The maximum outer diameter must be less than 1 Fr size over the nominal size.	All samples met the acceptance criteria.
Working Length	(30) 18Fr-contralateral limbs (30) 20Fr-aortic extension cuffs (30) 22Fr-aortic extension cuffs (30) 24Fr-bifurcated	Working length must be $\geq$ 44 and $\leq$ 45.4 cm	All samples met the acceptance criteria.

Test	Samples Tested	Specification / Acceptance Criteria	Summary Test Results
Distal Kink	(10) 18Fr-contralateral limbs (10) 24Fr-bifurcated	Characterization study	Distal kink testing was conducted to characterize the kink resistance of the distal end of a loaded stent graft system. The testing measures the radius of curvature at which the loaded delivery system kinks. The mean curvature at which this kinking occurred for the smallest and largest delivery systems was recorded as 55.01 mm and 71.96 mm respectively.
Deployment Accuracy	(10) 24Fr-bifurcated (10) 22Fr-aortic extension cuffs	Characterization study	Deployment accuracy testing was conducted to characterize the deployment accuracy of the stent graft. Under the worst case conditions, the mean deployment accuracy for bifurcated and aortic cuff stent grafts was 4.78 mm and 3.24 mm respectively.

C. Animal Studies

Preclinical *in vivo* animal testing, using prototypes of the final device design, was conducted in 25 animals to evaluate acute technical success (deployment), stent graft integrity, and histopathological response of the Talent Abdominal Stent Graft System in the porcine and canine aortic artery models for up to 8 months. The results demonstrated the ability to access the target anatomical location, adequate handling and visualization of the delivery system and implant, and deployment accuracy. Stent graft integrity and histopathological response were acceptable. The results support the safety and expected performance of the Talent Abdominal Stent Graft System.

D. Packaging, Shelf Life, and Sterilization Testing

Sterilization is accomplished with a validated sterilization process using 100% Ethylene Oxide. This process has demonstrated a sterility assurance level of 10^{-6}. Product and package stability testing of the Talent Abdominal Stent Graft was performed and validated for a 2-year shelf life.

X. SUMMARY OF PRIMARY CLINICAL STUDY

A. Study Design

Primary Test Group: Talent Abdominal Stent Graft

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 the Major Adverse Events (MAE) for the Test Group.

The primary analysis included endpoints that were modified from the endpoints listed in the original investigational device exemption (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.[1] Other study endpoints and analyses were presented based on follow-up at pre-discharge, 1 month, 6 months, and 12 months.

Primary Control Group: SVS Control

The Control Group (SVS Control) was a compilation of the open surgical control groups from three approved abdominal aortic aneurysms (AAA) endograft 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.

CoilTrac 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. For additional information on this analysis, refer to Section XI.

B. 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. One hundred sixty-two (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 4.

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[1] 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).

Table 4: Patient and Imaging Accountability – Test Group[1]

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[2])	142	138	132	130	112	128	120	128	110					

[1] 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.

[2] 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 5 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 5: 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		

C. Demographic and Baseline Medical History Data

Tables 6 through 8 provide the demographics and baseline medical characteristics of the Test Group and SVS Control patients. Medtronic observed the two groups, and found the Test Group was older and had more co-morbidities than the patients within the SVS Control.

Table 6: Patient Demographics, Test Group vs. SVS Control

Parameter	Statistics/Category	Test Group	SVS Control	p-value
Age (years)				
	n	166	243	
	Mean ± SD	74.1 ± 7.49	70.1 ± 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 7: Baseline Medical History, Test Group vs. SVS Control

Body System / Condition	Test Group %(m/n) [1]	SVS Control %(m/n) [1]	p-value
Cardiovascular			
Angina	16.9% (28/166)	17.4% (23/132)	> 0.999
Arrhythmia	44.0% (73/166)	11.5% (28/243)	< 0.001
Cardiac revascularization[2]	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
Renal[3]			
Renal insufficiency	54.8% (91/166)	N/A	N/A
Renal failure	N/A	4.1% (10/243)	N/A
Neurological[3]			
Cerebral vascular accident	22.9% (38/166)	N/A	N/A
Cerebrovascular disease	N/A	12.8% (31/243)	N/A
Other abnormal body systems			
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

[1] Denominator is 166 patients in the Test Group and 243 patients in the SVS Control.
[2] Cardiac Revascularization includes Coronary Artery Bypass Grafting (CABG) or PTCA.
[3] SVS Control reported "Renal Failure" and "Cerebrovascular Diseases," but Test Group reported "Renal Insufficiency" and "Cerebral Vascular Accident," respectively. This information was excerpted from the medical history records (checklist) and no specific definitions were provided. Although there may be an overlap between these categories, no direct comparisons can be made.

Table 8: 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)

D. Baseline Aneurysm Data

Tables 9 through 11 provide the baseline aneurysm diameters and morphologies of the Test Group and SVS Control patients.

Table 9: 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 10: 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 11: Baseline Aneurysm Characteristics, Test Group

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

E. Baseline Devices Implanted Data

Table 12 provides a breakdown of the Talent Abdominal Stent Grafts implanted.

Table 12: Total Number of Talent Abdominal Stent Grafts Implanted at Initial Procedure

Number of Devices Implanted	Test Group %(m/n)[1]
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)

[1] Denominator is 162 patients with implanted devices.

F. Safety Results

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. Tables 13 through 14 provide an analysis of Freedom from MAEs within 30 days.

Table 13: 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[1,2]
Freedom from MAEs within 30 Days	89.2% (148/166)	44.0% (107/243)	(36.9%, 52.6%)

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

[2] Difference represents the (% of patients free from MAEs within 30 days in the population treated with the test device) - (% of patients free from MAEs within 30 days in the population undergoing open surgical repair)

Table 14: Primary Safety Endpoint: MAE Components within 30 Days, Test Group vs. SVS Control

Major Adverse Event (MAE) within 30 Days[1]	Test Group N = 166 %(m/n)	SVS Control N = 243 %(m/n)	95% Exact Confidence Interval of Difference[2,3]
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%)

[1] A patient may report multiple MAEs; hence, number of patients with any MAE may not be the sum of those in each MAE category.
[2] Confidence level was not adjusted for multiplicity. Confidence intervals for difference (Test - SVS Control) in percentage were calculated by the exact method.
[3] 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 15 provides an analysis of freedom from MAE's at 365 days, Figure 6 depicts the corresponding Kaplan-Meier plot, and Table 17 provides the details for the Kaplan-Meier plot. Table 16 provides the MAE rates at 365 days.

Table 15: 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[1,2]
Freedom from MAEs within 365 Days	80.4% (123/153)	41.7% (100/240)	(29.4%, 47.2%)

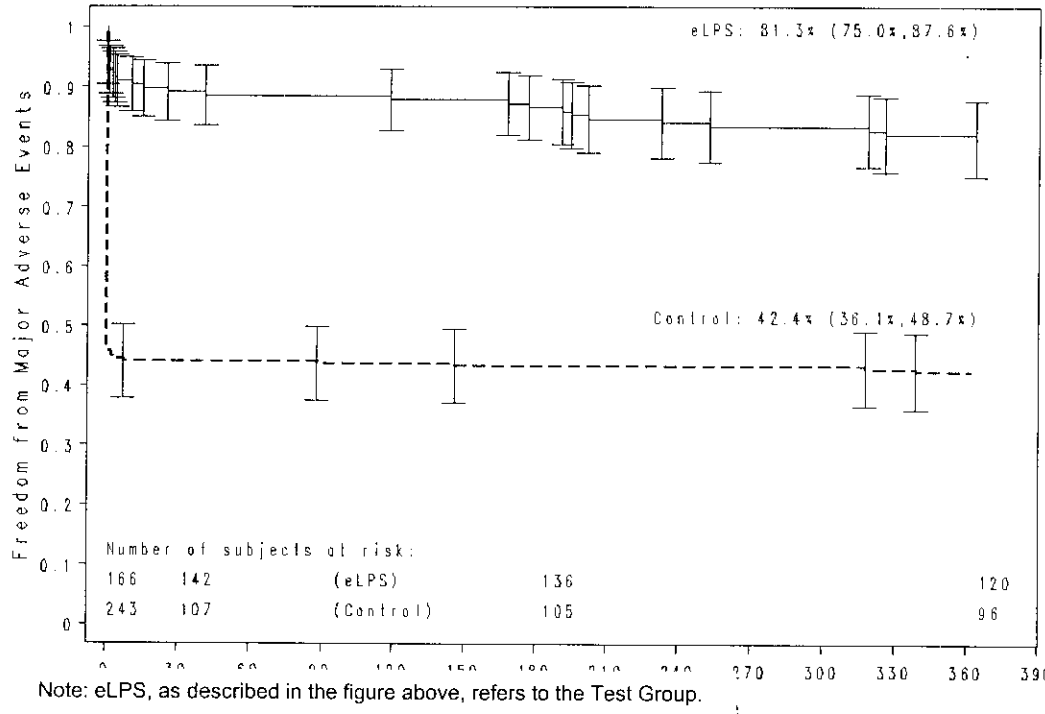
[1] Confidence level was not adjusted for multiplicity. Confidence interval for difference (Test - SVS Control) in percentage was calculated by the exact method.
[2] Difference represents the (% of patients free from MAEs within 365 days in the population treated with the test device) - (% of patients free from MAE within 365 days in the population undergoing open surgical repair)

Table 16: MAE Components within 365 Days, Test Group vs. SVS Control

MAEs within 365 Days[1]	Test Group N = 166 % (m/n)	SVS Control N = 243 % (m/n)	95% Exact Confidence Interval of Difference[2,3]
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%)

[1] A patient may report multiple MAEs; hence, number of patients with any MAE may not be the sum of those in each MAE category.
[2] Confidence level was not adjusted for multiplicity. Confidence intervals for difference (Test - SVS Control) in percentage were calculated by the exact method.
[3] 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 17: 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 18 below provides a summary of patients with freedom from all-cause mortality at 30 days for the Test Group and SVS Control.

Table 18: 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[1,2]
Freedom from All-Cause Mortality within 30 Days	98.2% (163/166)	97.1% (236/243)	(-2.8%, 4.4%)

[1] Confidence level was not adjusted for multiplicity. Confidence interval for difference (Test - SVS Control) in percentage was calculated by the exact method.
[2] 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

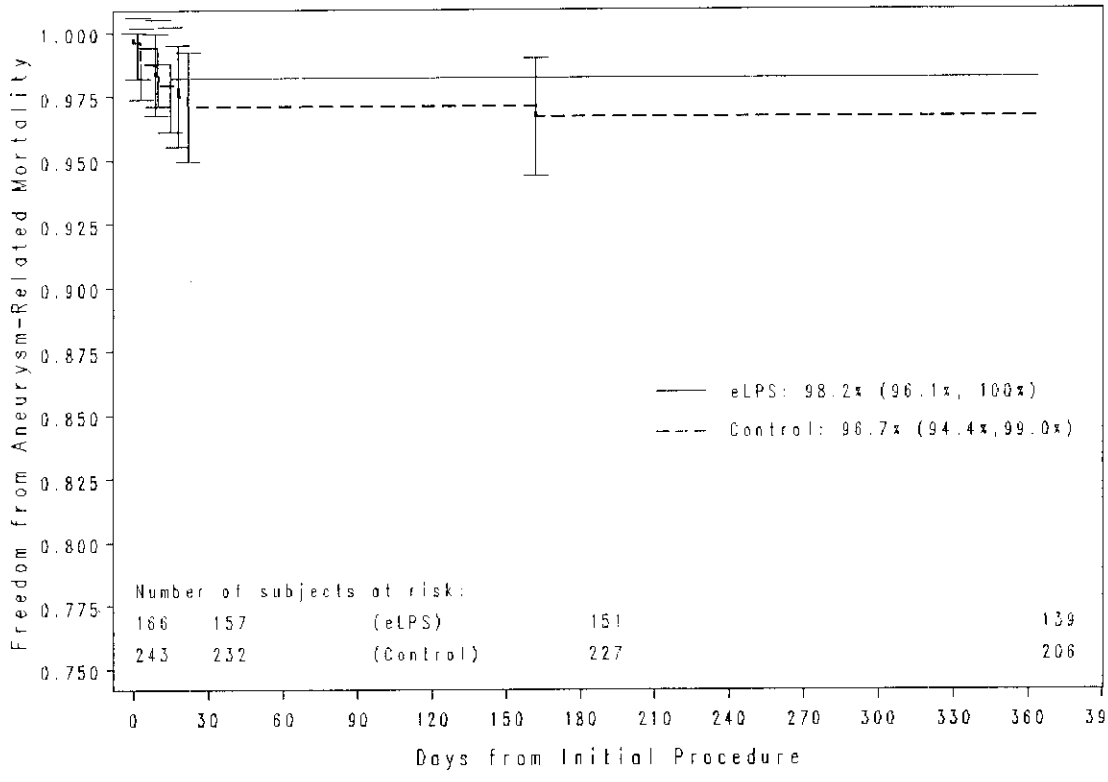
Table 19 and Figure 7 provide the analysis and Kaplan-Meier plot of freedom from aneurysm-related mortality at 365 days. Additional detail is provided in Table 20. Notably, there were no conversions to surgery or aneurysm ruptures in the Test Group within 365 days. See Table 31 for aneurysm rupture results.

Table 19: 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[1,2]
Freedom from Aneurysm-Related Mortality within 365 Days	97.9% (143/146)	96.4% (217/225)	(-2.8%, 5.4%)

[1] Confidence level was not adjusted for multiplicity. Confidence interval for difference (Test - SVS Control) in percentage was calculated by the exact method.
[2] 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 20: 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

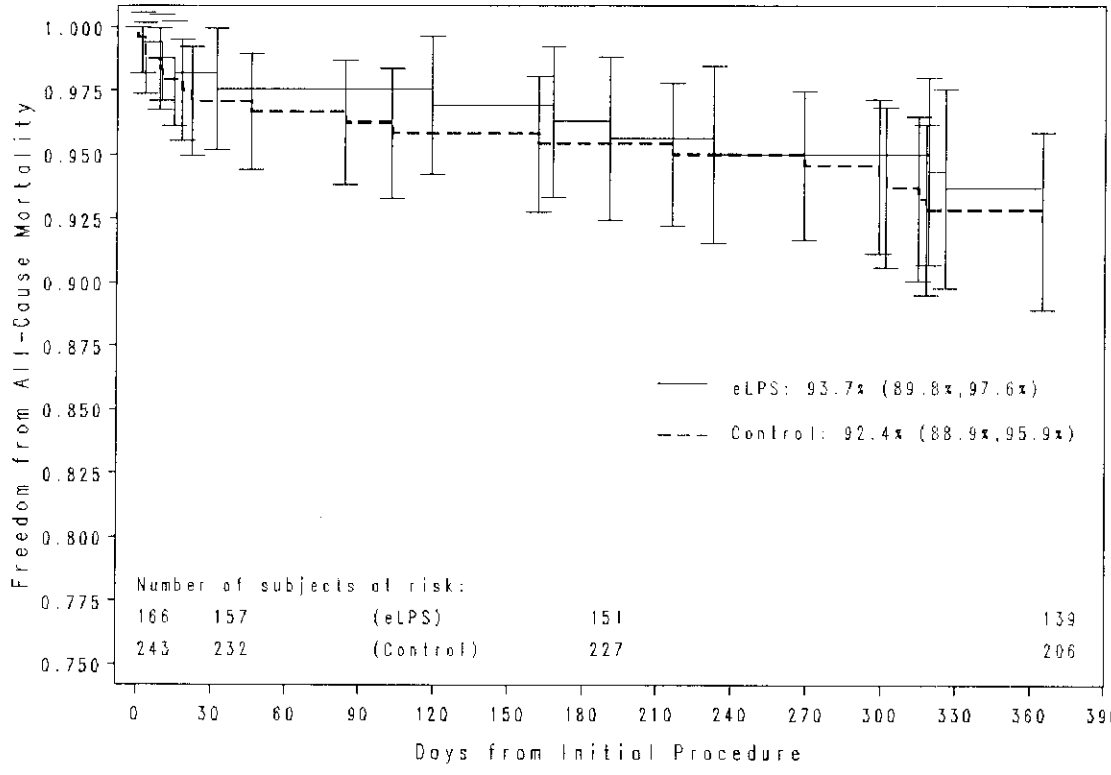
Table 21, Figure 8, and Table 22 depict freedom from all-cause mortality for the Test Group and SVS Control.

Table 21: 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[1,2]
Freedom from All-Cause Mortality within 365 Days	93.5% (143/153)	92.5% (222/240)	(-5.0%, 6.1%)

[1] Confidence level was not adjusted for multiplicity. Confidence interval for difference (Test - SVS Control) in percentage was calculated by the exact method.
[2] 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 22: 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

G. Effectiveness Results

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).

As shown in Table 23, the Talent Abdominal Stent Graft achieved a successful aneurysm treatment rate of 90.2%. Table 24 provides details regarding patients who were reported to have failed the successful aneurysm treatment endpoint.

Table 23: Primary Effectiveness Endpoint: Successful Aneurysm Treatment, Test Group

Primary Effectiveness Endpoint	**Test Group %(m/n)**	**95% Exact Confidence Interval[1]**
Successful Aneurysm Treatment	90.2% (110/122)	(83.4%, 94.8%)
[1] Confidence level was not adjusted for multiplicity. Confidence interval for the percentage was calculated by the exact (binomial) method.		

Table 24: 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[1]	3.3% (4/122)
Aneurysm Growth > 5mm at 12 Months (Core Lab)	2.5% (3/122)[2]
Post-Operative Interventions To Correct Type I/III Endoleaks	4.1% (5/122)
[1] All four technical failures were due to access difficulties. Note: These failures were associated with a prior iteration delivery system. [2] 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

Other clinically relevant measures of stent graft effectiveness were also evaluated and are provided below in Tables 25 through 32.

Table 25: Migration-Free at 12 Months, Test Group (Core Lab)

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

[1] Migration is defined as evidence of proximal or distal movement of the stent graft > 10mm relative to fixed anatomic landmarks.
[2] At three-year follow-up, the patient was admitted for endovascular repair of Type I endoleak (proximal).
[3] Confidence level was not adjusted for multiplicity. Confidence interval for the percentage was calculated by the exact (binomial) method.

Table 26: Stent Graft Patency at 12 Months, Test Group (Core Lab)

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

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

Table 27: Freedom from Secondary Endovascular Procedures within 365 Days, Test Group

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

[1] 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.

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

Table 28: Loss of Stent Graft Integrity at 12 Months, Test Group (Core Lab)

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

[1] 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.

[2] 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.

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

Table 29: Type I/III Endoleak-Free at 12 Months, Test Group (Core Lab)

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

[1] 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.

[2] 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 24 and Table 27) and 3 patients that did not require secondary procedures.

[3] 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 4.

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

Table 30: Summary of All Endoleaks at 1 Month and 12 Months, Test Group (Core Lab)

Endoleaks at 12 Months	Core Lab Reported at 1 Month[1] %(m/n)	Core Lab Reported at 12 Months[1] %(m/n)
Endoleaks of any type	19.3% (29/150)	9.2% (11/120)
Type I	9.3% (14/150)	2.5% (3/120)[2,3]
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)

[1] Endoleaks reported are not cumulative but represent the number of endoleaks present at each time point.

[2] Of these 3 patients, one patient withdrew from the study (post a 3-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.

[3] The 5 patients that required secondary procedures to treat their endoleaks (previously referenced in Table 24 and Table 27) are not captured in this table because their endoleaks had been resolved prior to the 12 month time point.

Table 31: Aneurysm Rupture within 365 Days, Test Group

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

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

Table 32: 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)
Stable1	60.9% (81/133)	64.1% (82/128)
Decrease More than mm	34.6% (46/133)	33.6% (43/128)

[1] Stable refers to no change (increase or decrease) of more than 5 mm.

H. 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 33 for further information.

Table 33: Acute Procedural Data, Test Group and SVS Control

Acute Procedural Data	Statistics	Test Group	SVS Control	95% Confidence Interval of Difference [1,2]
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	
	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	

[1] 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).

[2] 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).

I. Evaluation of Gender Bias

The occurrence of AAA disease is known to be higher in men than women and the ratio of men to women enrolled in this study reflects the general population.[2] In order to more carefully evaluate possible gender-based differences in outcome of treatment with the Talent Abdominal Stent Graft, a gender subset analysis was performed on the primary safety and effectiveness endpoints. The analysis reported that the Freedom from MAEs at 30 Days rate for female patients was 78.6% (11/14) for the Test Group and 40.0% (18/45) for the SVS Control. Successful Aneurysm Treatment was reported to be 70.0% (7/10) for female patients in the Test Group. The results, as described above, show that the benefits of AAA therapy, in terms of Freedom from MAEs and Successful Aneurysm Treatment, in the female patient subset are consistent with the results of the overall pivotal analysis; however, since the number of female patients treated was small in the Test Group, additional analyses of the performance of this device in female patients will be conducted as part of a post-approval study.

XI. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

A. Long-Term Results of Primary Clinical Study

Overview of Long-Term Data and Follow-Up

Patients in the Talent Abdominal pivotal study are to be followed through five years as a condition of approval. Substantial data has already been gathered on patients beyond the study's 1-year endpoints. At the 2 year follow-up interval, 120 patients were eligible for clinical and imaging follow-up. Of these, 87.5% (105/120) had clinical follow-up and CT imaging was performed on 75.8% (91/120) patients. At the 3 year follow-up interval, 108 patients were eligible for clinical and imaging follow-up. Of these, 88.9% (96/108) had clinical follow-up and CT imaging was performed on 82.4% (89/108) patients. At the 4 year follow-up interval, 94 patients were eligible for clinical and imaging follow-up. Of these, 60.6% (57/94) had clinical follow-up and CT imaging was performed on 51.1% (48/94) patients. At the 5 year follow-up interval, 37 patients were eligible for clinical and imaging follow-up. Of these, 35.1% (13/37) had clinical follow-up and CT imaging was performed on 27.0% (10/37) patients.

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

[2] Lee, et al, Stent-graft migration following endovascular repair of aneurysms with large proximal necks: anatomical risk factors and long-term sequelae; J Endovasc Ther 2002; 9:62-664

Table 34: Post 1-Year Patient and Imaging Accountability, Test Group

Interval	Patient follow-up			Patients with imaging performed at time interval (site reported)		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	Not Due for Next Visit
Originally Enrolled	166									4					
Events before 2 year visit[1]											1	16	21	4	0
2 year (Day 548-913)	120	105	91	91	74	89	90	88	72						
Events after 2 year visit but before 3 year visit											0	8	3	1	0
3 year (Day 914-1278)	108	96	93	89	70	85	87	84	68						
Events after 3 year visit but before 4 year visit											0	5	7	2	0
4 year (Day 1279-1644)	94	57	51	48	43	47	44	43	39						
Events after 4 year visit but before 5 year visit											0	2	1	0	54
5 year (Day 1654-2009)	37	13	11	10	10	10	10	10	9						

[1] "Events before 2 year visit" includes all events in the 1 Year Patient and Imaging Accountability (Table 4) and additional events that occurred after the 1 year visit but prior to the 2 year visit.

Key Long-Term Safety and Efficacy Outcomes

Data collected beyond the study's one year follow-up period continues to support the safety and efficacy of the Talent Abdominal Stent Graft within the indicated patient population. See Figure 9 through Figure 13 and Tables 35 through 40 for further information.

Table 35: All-Cause Mortality Post 1 Year

	Within Year 2 (366 to 731 days)	Within Year 3 (732 to 1096 days)	Within Year 4 (1097 to 1461 days)	Within Year 5 (1462 to 1826 days)	Post 1 Year (366 to 1826 days)
All-Cause Mortality % (m/n)	4.3% (6/139)	8.5% (10/118)	5.6% (5/89)	2.1% (1/47)	15.8% (22/139)

Figure 9: Kaplan-Meier Estimate of Post 1-Year Freedom from All-Cause Mortality, Test Group

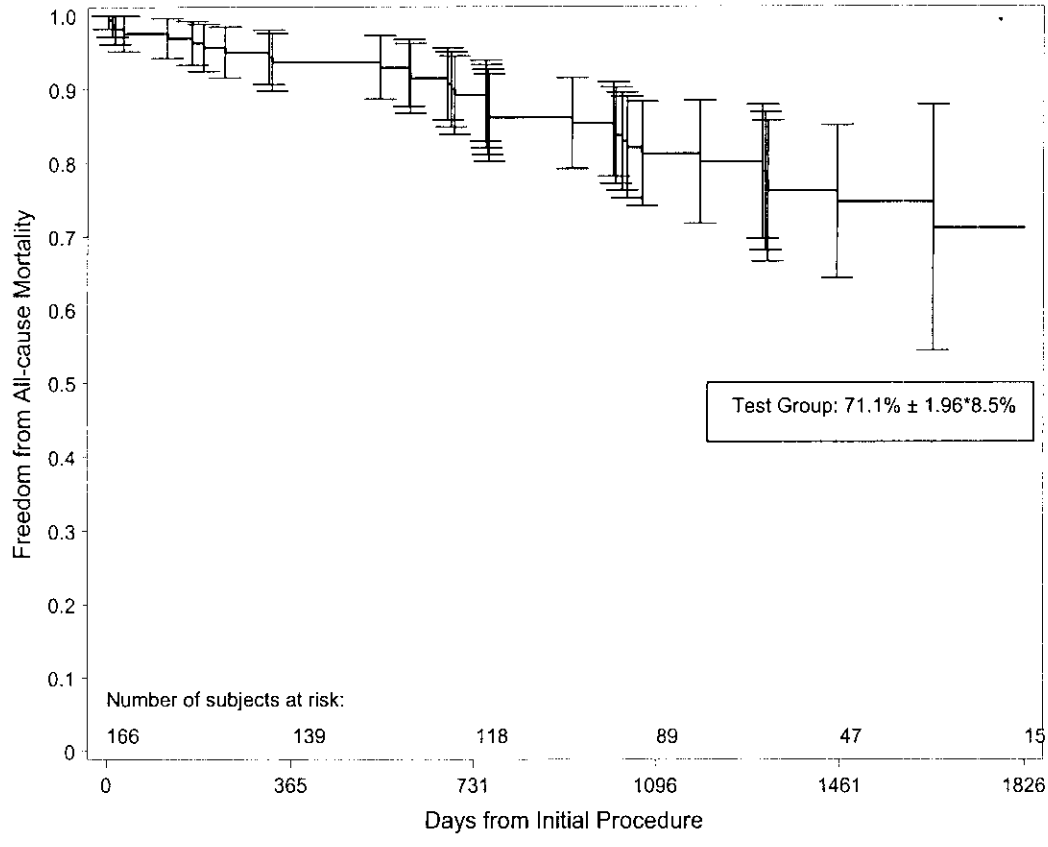


Table 36: Details of Kaplan-Meier Estimate of Post 1-Year Freedom from All-Cause Mortality, Test Group

	366 to 731 days	732 to 1096 days	1097 to 1461 days	1462 to 1826 days
No. at Risk	139	118	89	47
No. of Events	6	10	5	1
No. Censored	15	19	37	31
Kaplan-Meier Estimate	0.892	0.812	0.746	0.711

Figure 10: Kaplan-Meier Estimate of Post 1-Year Freedom from Aneurysm-Related Mortality, Test Group

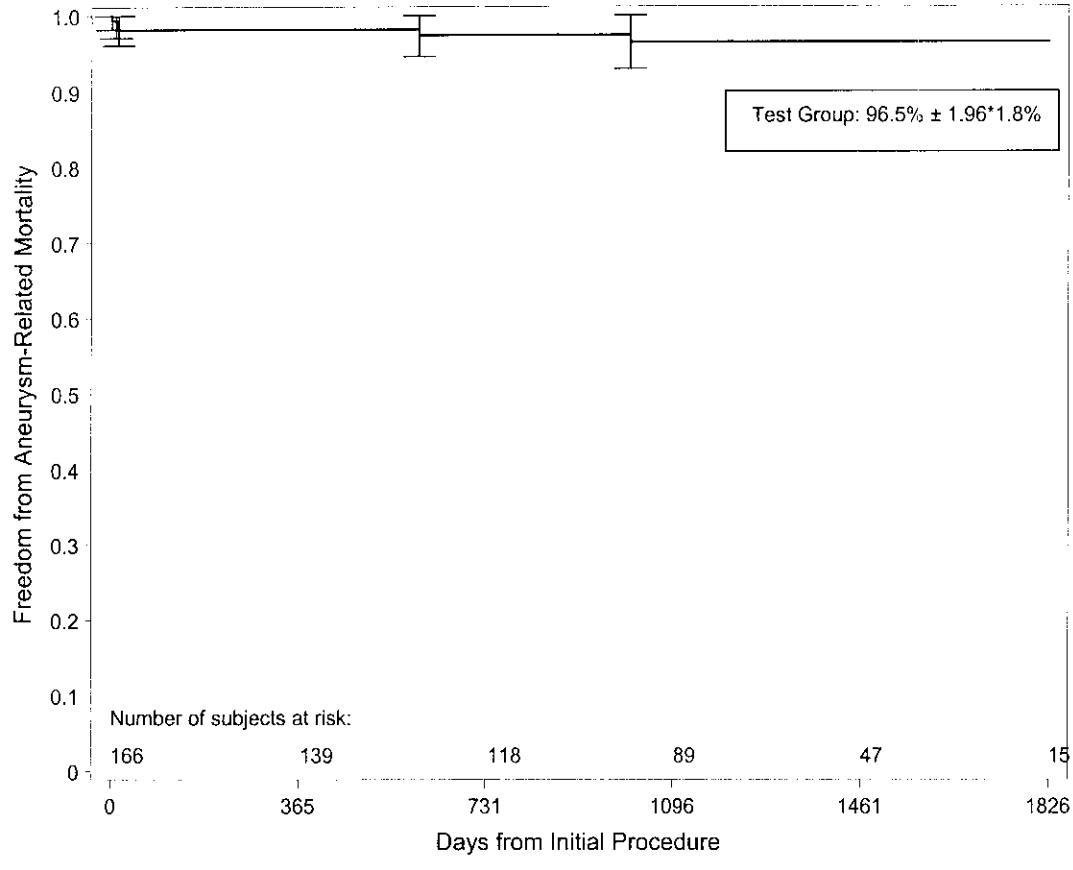


Table 37: Details of Kaplan-Meier Estimate of Post 1-Year Freedom from Aneurysm-Related Mortality, Test Group

	366 to 731 days	732 to 1096 days	1097 to 1461 days	1462 to 1826 days
No. at Risk	139	118	89	47
No. of Events[1]	1	1	0	0
No. Censored	20	28	42	32
Kaplan-Meier Estimate	0.974	0.965	0.965	0.965

[1] Two patients had aneurysm related mortality post 1-year.
One patient died of AAA rupture 600 days post implant. This patient was reported to have a Type II endoleak following procedure, but this was resolved at the time of hospital discharge. At 6 months, AAA size was reported to have decreased compared to pre-discharge. Although there was a 12 month visit, no diagnostic imaging was performed at that time.
One patient died of a AAA rupture at 1012 days post-procedure. It was reported that the patient has a small Type II endoleak that resolved by the 6 month follow-up. At 24 months, CT revealed a Type I endoleak, with aneurysm expansion. Patient decided not to undergo any further treatment.

Figure 11: Kaplan-Meier Estimate of Post 1-Year Freedom from Aneurysm Rupture, Test Group

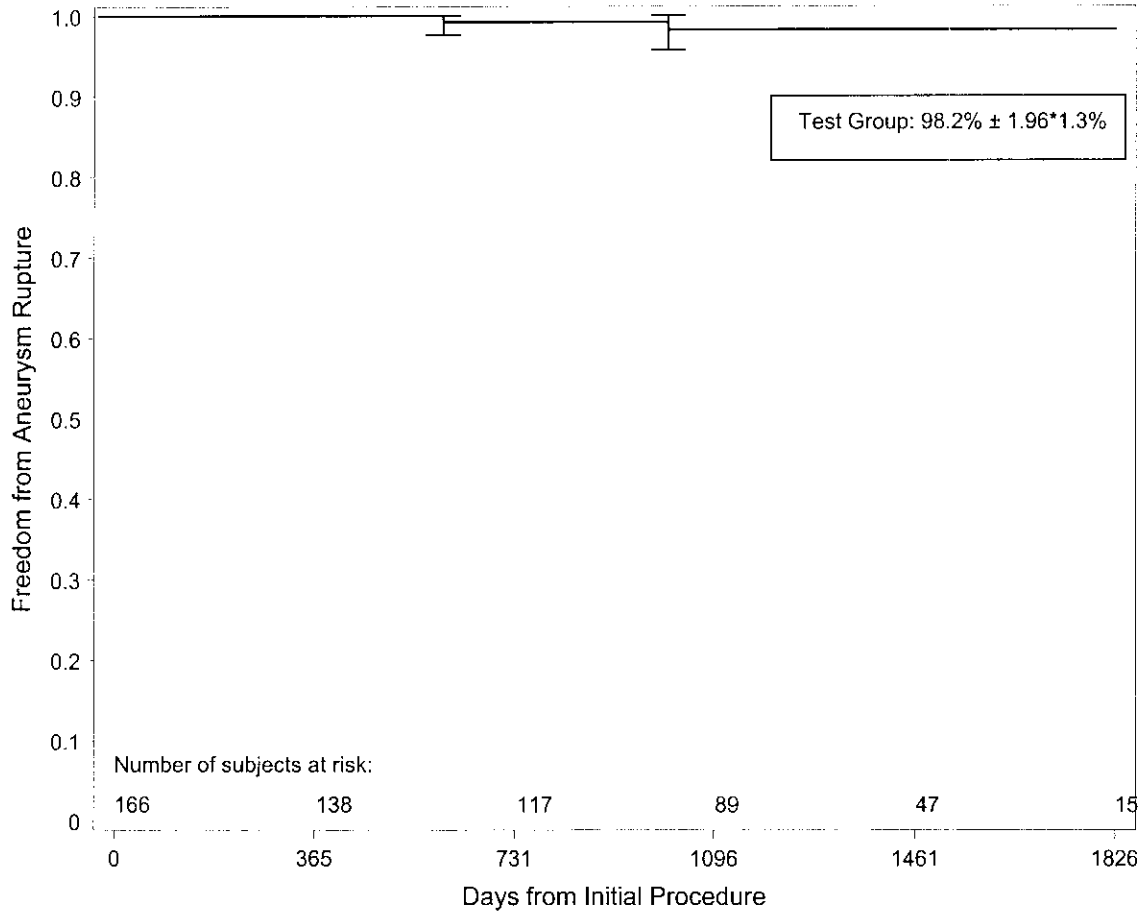


Table 38: Details of Kaplan-Meier Estimate of Post 1-Year Freedom from Aneurysm Rupture, Test Group

	366 to 731 days	732 to 1096 days	1097 to 1461 days	1462 to 1826 days
No. at Risk	138	117	89	47
No. of Events	1	1	0	0
No. Censored	20	27	42	32
Kaplan-Meier Estimate	0.992	0.982	0.982	0.982

[1] Two patients had aneurysm rupture post 1-year (these two patients are identical to the patients reported in Table 37 above)

One patient died of AAA rupture 600 days post implant. This patient was reported to have a Type II endoleak following procedure, but this was resolved at the time of hospital discharge. At 6 months, AAA size was reported to have decreased compared to pre-discharge. Although there was a 12-month visit, no diagnostic imaging was performed at that time.

One patient died of an AAA rupture at 1012 days post-procedure. It was reported that the patient has a small Type II endoleak that resolved by the 6 month follow-up. At 24 months, CT revealed a Type I endoleak, with aneurysm expansion. Patient decided not to undergo any further treatment.

Figure 12: Kaplan-Meier Estimate of Post 1-Year Freedom from Secondary Procedure, Test Group

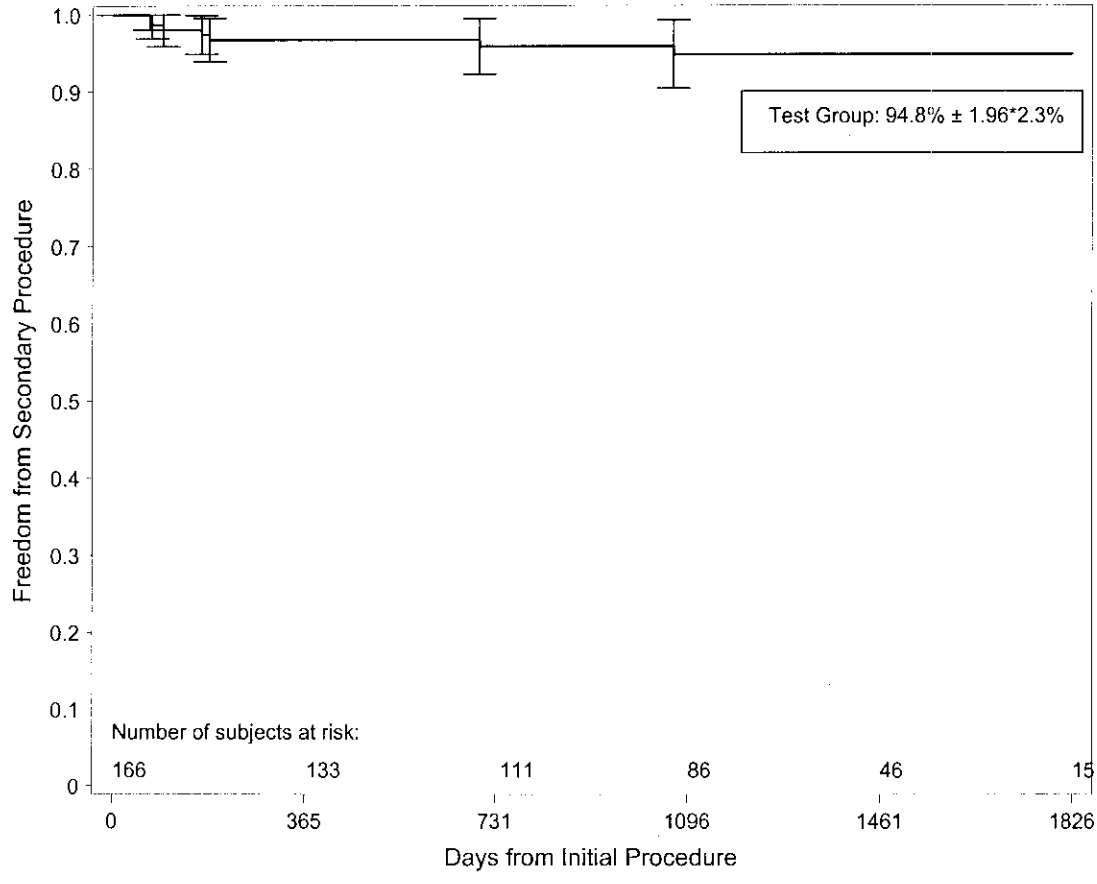


Table 39: Details of Kaplan-Meier Estimate of Post 1-Year Freedom from Secondary Procedure, Test Group

	366 to 731 days	732 to 1096 days	1097 to 1461 days	1462 to 1826 days
No. at Risk	133	111	86	46
No. of Events[1]	1	1	0	0
No. Censored	21	24	40	31
Kaplan-Meier Estimate	0.959	0.948	0.948	0.948

[1] Two patients had secondary procedures post 1-year.
Site reported that one patient underwent a secondary procedure at 700 days post implant. However, no additional information regarding this secondary procedure was provided.
One patient experienced a persistent endoleak of unknown origin through 3 years. A Type I and a Type III endoleak were detected at 3 years. Placement of 2 iliac limb extensions corrected the endoleaks. No other serious adverse events are reported for this patient.

Figure 13: Kaplan-Meier Estimate of Post 1-Year Freedom from Surgical Conversion, Test Group

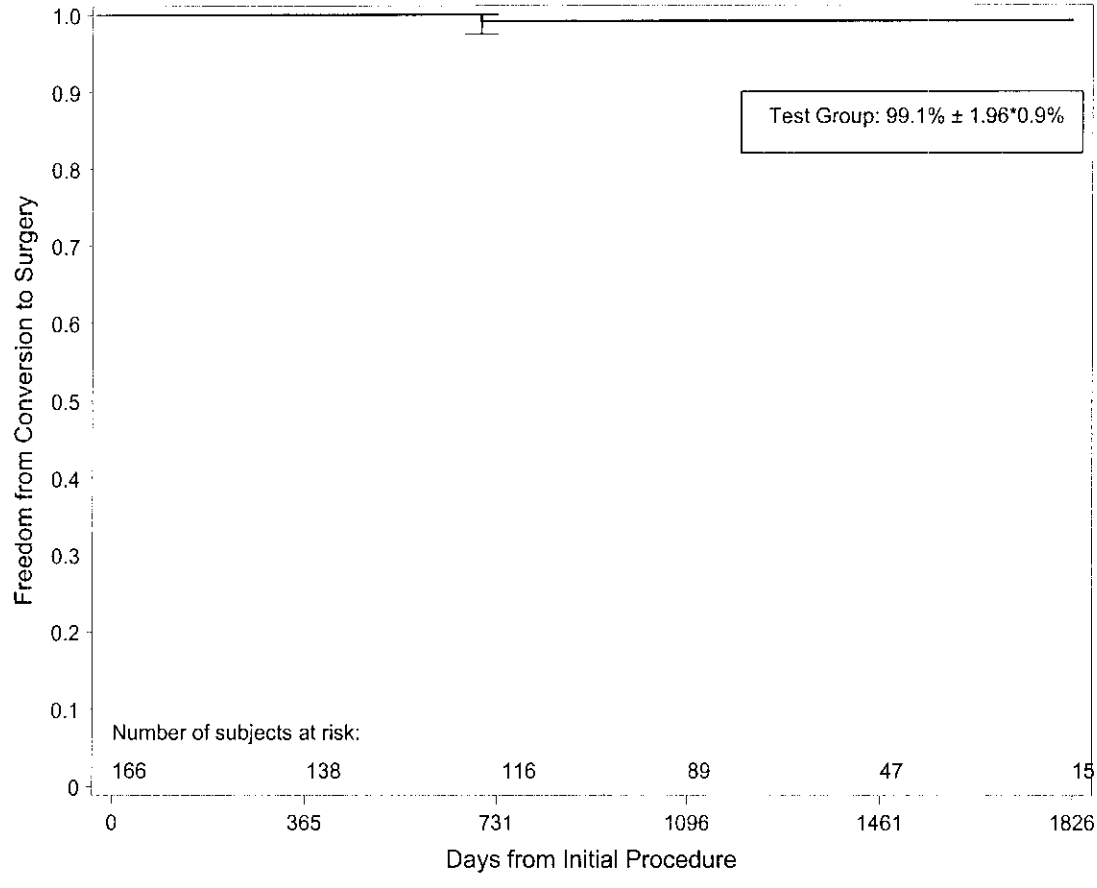


Table 40: Details of Kaplan-Meier Estimate of Post 1-Year Freedom from Surgical Conversion, Test Group

	366 to 731 days	732 to 1096 days	1097 to 1461 days	1462 to 1826 days
No. at Risk	138	116	89	47
No. of Events[1]	1	0	0	0
No. Censored	21	27	42	32
Kaplan-Meier Estimate	0.991	0.991	0.991	0.991

[1] One patient underwent a surgical conversion at 700 days post implant, to correct persistent Type I and Type II endoleaks.

B. CoilTrac Delivery System Performance Data

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 41 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 41: CoilTrac Delivery System: Delivery and Deployment Success

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

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

Clinically Relevant Adverse Events within 30 Days

Table 42 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 42: CoilTrac Delivery System: Patients with Clinically Relevant Adverse Events [within 30 Days]

Category	N = 137 %(m/n)
All-cause mortality	1.5% (2/137) [1]
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) [2]
Access site wound infection	2.2% (3/137)
Access site wound hematoma	3.6% (5/137)

[1] Both deaths were unrelated to the aneurysm, procedure, or device.
[2] Type I endoleak = 7 patients, Type III endoleak = 0 patients, Unknown Type endoleak = 5 patients

XII. PANEL MEETING RECOMMENDATION

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory Systems Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

The primary safety data from the Talent Abdominal study showed that, through 30 days, patients who received the Talent Abdominal Stent Graft experienced a lower rate of MAE's than patients treated with open surgery, as well as generally lower rates of mortality and morbidity. 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.

Effectiveness of the aneurysm treatment using the Talent Abdominal Stent Graft System was greater than 90%. The Talent Abdominal Stent Group was 99.2% migration-free at 12 months and had 100% stent graft patency at 12 months. Additionally, there were no aneurysm ruptures or conversions to surgery at 12 months. Data beyond the 1 year endpoints continues to support device safety and efficacy.

The independent analysis of the CoilTrac Delivery System demonstrated a 100% delivery and deployment success rate, with low adverse event rates.

XIV. CDRH DECISION

CDRH issued an approval order on April 15, 2008. The final conditions of approval cited in the approval order are described below.

- Medtronic must provide a clinical update to physician users at least annually. At a minimum, this update will include, for their pivotal study cohort and their post-approval

study cohort, a summary of the number of patients for whom data are available, with the rates of aneurysm rupture, secondary endovascular procedures, conversion to surgical repair, aneurysm-related mortality, major adverse events, endoleak, aneurysm enlargement, prosthesis migration, and patency. Reports of losses of device integrity, reasons for conversion and causes of aneurysm-related death and rupture are to be described. A summary of any explant analysis findings are to be included. Additional relevant information from commercial experience within and outside of the US is also to be included. The clinical updates for physician users and the information supporting the updates must be provided in supplements to their PMA.

- Medtronic must perform a post-approval study for Talent™ Abdominal to evaluate the longer-term safety and effectiveness of the Talent™ Abdominal Stent Graft System through five years of implantation. The primary endpoint for this study is freedom from aneurysm-related mortality at 5 years. Aneurysm-related mortality is defined as:

  Death from rupture of the abdominal aortic aneurysm or from any procedure intended to treat the AAA. If a death occurred within 30 days of any procedure intended to treat the AAA, then it is presumed to be aneurysm related.

  This study is expected to include 260 patients, 166 endovascular patients from the original pivotal study cohort, as well as enrollment of an additional 94 patients at up to 30 investigational sites. At 1 month, 12 months, and, at each annual visit, a contrast enhanced CT scan, abdominal x-ray and physical examination will be conducted. All data will be entered into a database, analyzed, and submitted in post-approval reports to the FDA, and a final report will be submitted after completion of the follow-up and analysis. This follow-up plan will allow an evaluation of aneurysm-related mortality, major adverse events, migration, patency, endoleaks, device integrity, aneurysm enlargement, aneurysm rupture, secondary endovascular procedures and conversion to open surgical repair over time. Upon completion of this post-approval study, Medtronic must provide a supplement with revised labeling that reflects the study findings.

- Medtronic must perform an evaluation to better understand the overall outcomes in females and non-Caucasians undergoing endovascular aneurysm repair (EVAR) with the Talent Abdominal Stent Graft System. This will include a subset evaluation of the females and non-Caucasians enrolled in the post-approval study described above, as well as a summary of the current literature research results of females and non-Caucasians having undergone EVAR. This evaluation is to include descriptive statistics to summarize literature-derived outcomes in patients with the EVAR therapy, literature-derived Talent Abdominal Stent Graft-specific outcomes, and post-approval study outcomes in female and non-Caucasians populations. Findings of this evaluation must be provided with each regular post-approval study report update until the completion of the post-approval study described above.

The applicant's manufacturing facilities were inspected and found to be in compliance with the Quality System Regulation (21 CFR 820).

XV. APPROVAL SPECIFICATION

Directions for Use: See device labeling.

Hazards to Health from Use of Device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in the labeling.

Post Approval Requirements and Restrictions: See approval order.