

SUMMARY OF SAFETY AND EFFECTIVENESS (SSED)

I. GENERAL INFORMATION

Device Generic Name: Iliac Stent

Device Trade Name: Complete[®] SE Vascular Stent System

Applicant's Name and Address: Medtronic Vascular
3576 Unocal Place
Santa Rosa, CA 95403
USA

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P090006

Date of FDA Notice of Approval: March 17, 2010

Expedited: Not applicable

II. INDICATIONS FOR USE

The Medtronic Vascular Complete[®] SE Vascular Stent System is indicated for improving luminal diameter in patients with iliac stenosis in previously unstented lesions with vessel reference diameters between 4.5 mm and 9.5 mm and lesion lengths up to 90 mm. The stent is intended as a permanent implant.

III. CONTRAINDICATIONS

There are no known contraindications.

IV. WARNINGS AND PRECAUTIONS

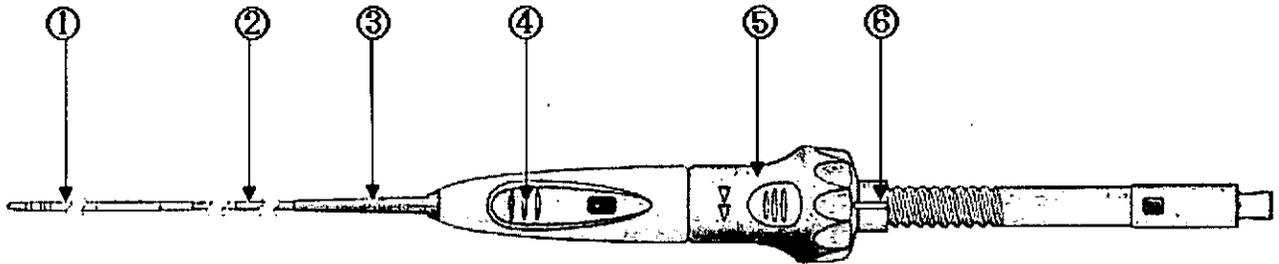
The warnings and precautions can be found in the Complete SE Vascular Stent System labeling.

V. DEVICE DESCRIPTION

The Complete SE Vascular Stent System (Figure 1 and Figure 2) includes a pre-loaded self-expanding stent (Figure 3) and an over-the-wire retractable sheath delivery system. The Complete SE stent is an electropolished, self-expanding, flexible stent made of medical grade Nickel-Titanium alloy (Nitinol) that expands to its preset diameter upon exposure to body temperature.

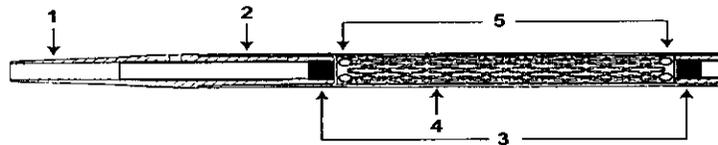
9

The stent delivery system, as shown in Figure 1, is composed of a multi-tubular coaxial convertible system that is compatible with a 0.035" guidewire and a stabilizing member that facilitates ease of use during deployment. A selectable rotation and slide deployment handle with a safety lock allows for deployment of the stent. Eight tantalum radiopaque markers (four on each end) are located on both the distal and proximal sides of the self-expanding stent for correct anatomical placement (see Figure 2 and Figure 3).



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|--|--|
| 1 Tip and Flexible Outer Member Sheath | 4 Front Grip |
| 2 Outer Stability Member | 5 Deployment Rotation/Slider Mechanism |
| 3 Strain Relief | 6 Safety Lock |

Figure 1: The Complete SE Vascular Stent Delivery System



- | | |
|-----------------|-------------------------------------|
| 1. Tip | 3. Catheter Radiopaque Marker Bands |
| 2. Stent Sheath | 4. Stent |
| | 5. Tantalum Markers |

Figure 2: Complete SE Vascular Stent Detail



Figure 3: Complete SE Vascular Stent with Tantalum Markers

The product line has a range of diameters (6-10 mm) and lengths (20-100 mm). The delivery system is available in working lengths of 80 cm and 130 cm and is designed to be used with 6F introducer sheaths and 0.035" (0.89 mm) guidewires. Table 1 and Table 2 below list the product codes and stent sizes.

6

Table 1: Model Numbers - 80cm Length Catheter

Stent Diameter	Stent Length				
	20 mm	40 mm	60 mm	80 mm	100 mm
6 mm	SC620FV	SC640FV	SC660FV	SC680FV	SC6100FV
7 mm	SC720FV	SC740FV	SC760FV	SC780FV	SC7100FV
8 mm	SC820FV	SC840FV	SC860FV	SC880FV	SC8100FV
9 mm	SC920FV	SC940FV	SC960FV	SC980FV	Not offered
10 mm	SC1020FV	SC1040FV	SC1060FV	SC1080FV	

Table 2: Model Numbers - 130cm Length Catheter

Stent Diameter	Stent Length				
	20 mm	40 mm	60 mm	80 mm	100 mm
6 mm	SC620LV	SC640LV	SC660LV	SC680LV	SC6100LV
7 mm	SC720LV	SC740LV	SC760LV	SC780LV	SC7100LV
8 mm	SC820LV	SC840LV	SC860LV	SC880LV	SC8100LV
9 mm	SC920LV	SC940LV	SC960LV	SC980LV	Not offered
10 mm	SC1020LV	SC1040LV	SC1060LV	SC1080LV	

The Complete SE delivery system is designed to deliver a self-expanding stent percutaneously to the iliac artery via a sheathed catheter. The outer member sheath of the delivery system is retracted via the two-mode deployment slider/rotation mechanism, thus enabling the clinician to release the self-expanding stent upon proper positioning. The delivery system has two handle sizes, long and short. The short handle is used to deploy stent lengths of 20 mm through 80 mm and the long handle is used to deploy the 100 mm stent lengths.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

Alternative practices and procedures for treatment of Peripheral Vascular Disease (PVD) include percutaneous transluminal angioplasty (PTA) alone, PTA accompanied by stenting, stenting with another stent for which there is an approved indication, bypass surgery, exercise therapy, and pharmacotherapy. Atherosclerotic risk factors may be reduced through lifestyle modifications such as cessation of smoking, weight reduction, lipid control, blood pressure control, and diabetes management.

VII. MARKETING HISTORY

The Complete SE Vascular Stent System received CE Mark in September, 2006 and thereby began commercial distribution in the European Union. The Complete SE device has remained in continuous distribution since international (outside of the United States) launch and has never been withdrawn from market. The list of countries where the Complete SE Stent System is approved for commercial distribution is provided below.

Table 3: Geographies where Complete SE is approved for Iliac indication

Australia	Austria	Belgium	Brazil
Bulgaria	Chile	China	Cyprus
Czech Republic	Denmark	Estonia	Finland
France	Georgia	Germany	Greece
Hong Kong	Hungry	Iceland	India
Ireland	Israel	Italy	Jordan
Latvia	Liechtenstein	Lithuania	Luxembourg
Macedonia	Malaysia	Malta	Netherlands
New Zealand	Norway	Poland	Portugal
Romania	Serbia	Singapore	Slovakia
Slovenia	South Africa	Spain	Sweden
Switzerland	Turkey	United Kingdom	

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device.

- Abrupt stent closure
- Allergic reaction (contrast medium; drug; stent or filter material)
- Amputation/limb loss
- Aneurysm or pseudoaneurysm in vessel or at vascular access site
- Angina/ Coronary ischemia
- Arrhythmia (including premature beats, bradycardia, atrial and/or ventricular tachycardia, atrial and/or ventricular fibrillation [VF])
- Asystole or bradycardia requiring placement of a temporary pacemaker
- Arteriovenous fistula
- Bleeding complications from anticoagulant or antiplatelet medication requiring transfusion or surgical intervention
- Death
- Detachment and/or implantation of a component of the system
- Emboli, distal (air, tissue, plaque, thrombotic material, stent)
- Fever
- Hematoma at vascular access site, with or without surgical repair
- Hemorrhagic event, with or without transfusion
- Hypotension/hypertension
- Infection, local or systemic including bacteremia or septicemia
- Ischemia requiring intervention (bypass or amputation of toe, foot, or leg)
- Myocardial infarction
- Pain (leg/foot)
- Pain at catheter insertion site

- Pulmonary embolism
- Renal failure/ insufficiency secondary to contrast medium
- Stent malposition/ migration
- Stent strut fracture
- Stroke
- Vascular thrombosis/ occlusion at puncture site, treatment site, or remote site
- Vessel dissection, perforation or rupture
- Vessel spasm or recoil
- Worsened claudication/rest pain

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

IX. SUMMARY OF PRECLINICAL STUDIES

A. Laboratory Studies

Biocompatibility

Biocompatibility of the Complete SE Vascular Stent System was evaluated per the requirements of AAMI/ISO 10993 and FDA Blue Book Memorandum G-95-1. Medtronic Vascular conducted biocompatibility testing on the finished, sterile Complete SE Vascular Stent System. All testing was conducted at NAMSA and Nelson Labs in accordance with FDA good laboratory practice (GLP) regulations (21 CFR, Part 58).

Tests conducted on the Complete SE Vascular Stent System were appropriate for an externally communicating device that is in limited contact with circulating blood (<24 hours) and on an implant device that is in permanent contact with circulating blood (>30 days). Table 4 below contains a summary of the biocompatibility testing that was performed to ensure that the raw material, manufacturing processes and sterilization processes result in biocompatible product.

All test results indicated that the materials and processes used to manufacture the Complete SE Vascular Stent and delivery system are biocompatible and suitable for their intended use.

Table 4: Summary of Biocompatibility Testing and Results

Biological effect category	Test Methods	Delivery System with Stent	Stent	Delivery System	Results
Cytotoxicity	MHLW Cytotoxicity, Colony Assay		X	X	Pass
Sensitization	MHLW Maximization Sensitization Study		X	X	Pass

Table 4: Summary of Biocompatibility Testing and Results

Biological effect category	Test Methods	Delivery System with Stent	Stent	Delivery System	Results
Irritation/ Intracutaneous Reactivity	ISO Intracutaneous Reactivity Study		X	X	Pass
Systemic Toxicity	MHLW Acute System Toxicity Study		X	X	Pass
Systemic Toxicity	USP Pyrogen Study – Material Mediated	X	X		Pass
Hemocompatibility	MHLW In vitro Hemolysis Study		X	X	Pass
Hemocompatibility	ASTM Partial Thromboplastin Time Assay	X			Pass
Hemocompatibility	C3a Complement Activation Assay		X	X	Pass
Hemocompatibility	Sc5b-9 Complement Activation Assay	X	X		Pass
Hemocompatibility	C3a/SCb-9 Complement activation Assay		X	X	Pass
Hemocompatibility	In vivo Thromboresistance Study	X		X	Pass
Cytotoxicity	ISO MEM Elution Study		X		Pass
Hemocompatibility	ASTM In vitro Hemolysis Study		X		Pass
Systemic Toxicity	USP&ISO Acute Systemic Toxicity Study		X		Pass
Systemic Toxicity	MHLW Acute Systemic Toxicity Study		X		Pass
Genotoxicity	Mouse Peripheral Blood Micronucleus Study		X		Pass
Genotoxicity	Bacterial Reverse Mutation Study		X		Pass
Genotoxicity	Mouse Lymphoma Assay		X		Pass

In vitro bench testing

In vitro bench testing to support the Complete SE Vascular Stent System was developed based on Medtronic Vascular’s Product Development Process and is consistent with the FDA January 2005 Guidance, “Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems,” and the applicable ASTM standards. The relevant tests outlined in the guidance were conducted to demonstrate the safety and effectiveness of this device in an *in vitro* setting. All test units were sterilized by E-Beam radiation prior to testing. Table 5 below summarizes the bench testing performed on the Complete SE Vascular Stent and delivery system. As illustrated in the table, all results support the safety and effectiveness of the device.

Table 5: Summary of *In Vitro* Testing

In Vitro Test	Functional Requirement	Summary of Test Result
Material Composition (Stent)	Durability of the implanted stent	The compositions of the Nitinol and Tantalum materials used to manufacture the Complete SE stent were evaluated against industry standards for compositional requirements. These materials met the industry standards.
Material Composition (Delivery System)	Integrity of the delivery system	The compositions of the materials used to manufacture the Complete SE delivery system were evaluated against industry standards for compositional requirements. These materials met the industry standards.
Shape Memory and Superelasticity	Stent functionality	The Complete SE stent functions <i>in vivo</i> in a superelastic mode as it expands when released to its intended size and shape at a temperature of 37 °C (human body temperature).
Corrosion Resistance	Durability of the implanted stent	The Complete SE stent was evaluated for the ability of the stent to withstand the potentially corrosive effects of the <i>in vivo</i> environment. Complete SE showed comparable or better corrosion resistance to a known standard.
Percent Surface Area	Effectiveness of the deployed stent Patency of the stented vessel	The percent metal coverage predicts that the stent will support the vessel.
Foreshortening	Effectiveness of the deployed stent Patency of the stented vessel Appropriate sizing of the stent	The length of the Complete SE stent was measured in the loaded and unloaded condition. These values were used to calculate the foreshortening of the stent. All samples met specifications.
Stent Integrity	Durability of the implanted stent Effectiveness of the implanted stent	The Complete SE stent was inspected for defects both prior to loading and following stent deployment. All samples met specifications.
Radial Stiffness and Radial Strength	Effectiveness of the deployed stent Patency of the stented vessel Appropriate sizing of the stent	The outward force of the Complete SE stent was measured and compared to specifications. All samples met specifications.
Mechanical Properties	Integrity of stent material composition	The Nitinol material used to manufacture the Complete SE stent was evaluated. All samples met specifications.

Table 5: Summary of *In Vitro* Testing

In Vitro Test	Functional Requirement	Summary of Test Result
Stress Analysis	Durability of the implanted stent Integrity of implanted stent	The durability and integrity of the Complete SE stent was evaluated using Finite Element Analysis (FEA). The FEA evaluated the ability of the stent to withstand crimping into the catheter, deployment, and the loading that it may experience <i>in vivo</i> . The results showed that the maximum strains anticipated were within acceptable limits.
Fatigue Analysis	Durability of the implanted stent Integrity of implanted stent	The durability and integrity of the Complete SE stent were evaluated using accelerated cycle-to-life endurance testing (S/N) and analysis. The S/N testing evaluated the highest strain location of the stent. The results indicated that the stent will withstand greater than 420 million cycles (simulating 10 years of pulsatile cycles) of the <i>in vivo</i> condition.
Accelerated Durability Testing	Durability of the implanted stent	The Complete SE stents were overlapped in a simulated artery and then placed in an accelerated radial fatigue durability test for 420 million cycles (to simulate 10 years of pulsatile cycles). All samples met specifications.
MRI Safety and Compatibility	Effectiveness of the deployed stent Durability of the implanted stent Integrity of the implanted stent	The Complete SE stent was tested at 1.5 and 3 Tesla. The results are reflected in the Instructions For Use (IFU) as MR Conditional, according to ASTM F2503-05
Radiopacity	Effectiveness of the deployed stent Ability to correctly position the stent	The radiopacity of the Complete SE stent was evaluated during animal testing. The testing determined the radiopacity to be adequate.
Kink Resistance	Effectiveness of the deployed stent Patency of the stented vessel	The Complete SE stent was forced to conform to kink conditions and then compared to the freely expanded diameter. All samples met specifications.
Delivery, Deployment and Retraction – Deployment Force	Integrity of the delivery system Ability to deploy the stent	The amount of force required to deploy the Complete SE stent was measured and evaluated against specifications. All samples met specifications.
Delivery, Deployment and Retraction – Deployment Accuracy	Ability to deploy the stent Accuracy of stent placement	The deployment accuracy of the Complete SE stent was measured and evaluated against specifications. All samples met specifications.
Bond Strength	Integrity of the stent and delivery system Ability to deploy the stent	The tensile strengths of the Complete SE delivery system bonds and stent marker bonds were measured and evaluated against specifications. All samples met specifications.

12

Table 5: Summary of *In Vitro* Testing

In Vitro Test	Functional Requirement	Summary of Test Result
Crossing Profile	Integrity of the delivery system Ability to deliver the stent to the intended site	The maximum crossing profile of the Complete SE delivery system was measured and evaluated against specifications. All samples met specifications.
Dimensional Verification	Effectiveness of the deployed stent Appropriate sizing of the stent	The stent length, marker band spacing, catheter working length, and overall system length were measured and evaluated against specifications. All samples met specifications. The maximum gap between adjacent stent crowns, percent metal coverage, and cell size area were measured for characterization purposes only. There were no acceptance criteria for these tests.
Simulated Use	Ability to deliver the stent to the intended site Ability to deploy the stent	Guidewire compatibility, sheath compatibility, and trackability were evaluated against specifications. All samples met specifications.
Stent Flexibility	Effectiveness of the deployed stent Patency of the stented vessel	The force and displacement were recorded as a pin placed perpendicular to the stent was brought into contact with the stent. This test had no acceptance criteria and was for characterization only. A linear relationship between the bending load and deflection was noted.

Sterilization

The Complete SE Vascular Stent System is E-beam sterilized in compliance with ANSI/AAMI/ISO 11137:2006 and ANSI/AAMI/ISO TIR 15843:2000. Quarterly sterilization dose audits and continuous monitoring of bioburden levels are performed to confirm that the sterilization process is effective in eradicating viable microorganisms. Based on the design, manufacturing and sterilization method of the Complete SE Vascular Stent System, the test results indicate that the device will maintain a Sterility Assurance Level (SAL) of 10^{-6} when sterilized at a minimum dose of 25kGy.

Packaging and device shelf-life

The Complete SE Vascular Stent System is packaged in a thermoformed tray and sealed within a multi-layer poly-film pouch. Qualification testing was performed for packaging design performance, packaging shelf-life and device shelf-life for the Complete SE. A two year shelf-life has been established for the product.

B. Animal Studies

The Complete SE Vascular Stent System was subjected to a series of acute and chronic animal studies. The intent of the studies was to demonstrate safety of the device by acceptable functional performance of the subject devices in an *in vivo* setting. Additionally, the studies were intended to ensure that the devices do not cause adverse hemodynamic, vascular or other biological (e.g. thrombotic events, etc.) responses.

Medtronic Vascular has conducted six (6) preclinical studies which evaluated the safety of the Bridge SE (an earlier device design) and subsequent design enhancements that culminated in the Complete SE product. These studies include: three (3) 28-day GLP studies, one (1) 180-day GLP study, and two (2) acute non-GLP studies. The four (4) chronic studies were conducted in accordance with Good Laboratory Practices (GLP) per 21 CFR§ 58. All stents were deployed successfully, and all animals survived to the pre-determined study endpoints. The devices did not elicit any untoward hemodynamic, vascular or other biological (e.g. thrombotic events, etc.) responses. Table 6 outlines the animal studies performed.

Table 6: Complete SE – Summary of Animal Studies Performed

Study Type	Test Articles	# of Animals and # of Stents	Follow-up Duration	Relevant Findings
Acute Safety and Efficacy	Bridge SE	8 swine 11 stents +controls	28 days	This study demonstrated that the Bridge SE stents in healthy porcine peripheral arteries over 28 days had significantly better performance both subjectively and morphometrically when compared to the control device.
Chronic Safety and Efficacy Artery Model	Bridge SE	6 swine 6 stents +controls	180 days	This study demonstrated that the Bridge SE device had acute and chronic performance equivalent to the control device in healthy porcine peripheral arteries over 180 days.
Acute Evaluation	Bridge SE (with gold markers)	10 swine 10 stents +controls	28 days	This study demonstrated acceptable performance of the Bridge SE device with markers throughout all phases of the experimental study.
Acute Safety	Complete SE	8 swine 8 stents +controls	28 days	This study demonstrated that acute performance of the Complete SE device was similar to the control articles.
Acute Performance	Complete SE	2 swine 18 stents +controls	Acute	This study demonstrated that the Complete SE Stent and Delivery System's acute performance was equivalent to or better than the control stent systems in healthy porcine peripheral arteries.

Table 6: Complete SE – Summary of Animal Studies Performed

Study Type	Test Articles	# of Animals and # of Stents	Follow-up Duration	Relevant Findings
Acute Performance	Complete SE	2 swine 3 stents +controls	Acute	This study demonstrated that longer stent lengths had acceptable acute performance in healthy porcine iliac arteries.

Animal studies were conducted using both the Bridge SE and Complete SE Vascular Stents. Bench testing demonstrated that the two stents have comparable characteristics and performance. Although some of the animal studies were conducted using the Bridge SE Stent, FDA determined that the data support the approval of the Complete SE Stent.

X. SUMMARY OF PRIMARY CLINICAL STUDIES

Two clinical studies were conducted to support the safety and efficacy of the Complete SE Vascular Stent System. The Iliac Stenting in Stenotic Lesions with the Bridge SE Self-Expanding Stent Delivery System Registry (ISIS-SE) study enrolled 158 patients at 19 sites in the United States and evaluated the safety and efficacy of treating stenotic iliac lesions with the Bridge SE Self-Expanding Stent (a precursor to the Complete SE Vascular Stent). The Complete SE Iliac Registry is an ongoing confirmatory study being conducted inside the United States to evaluate the safety of treating stenotic iliac lesions with the Complete SE Stent. The Complete SE Vascular Stent System reflects slight modifications to both the stent and delivery systems from the Bridge SE Self-Expanding Stent System. The modifications to the stent include the addition of 8 tantalum markers (4 on each side), and modifications to the stent cut pattern and crown connections. The modifications to the delivery system include a lower crossing profile, additional radiopaque markers, and a modified handle (rotating slider ring) and outer sheath. Preclinical bench and animal testing demonstrated that the two stents have comparable characteristics and performance. Although the majority of the clinical data was collected on the Bridge SE Stent, FDA determined that the data support the approval of the Complete SE stent.

Iliac Stenting in Stenotic Lesions with the Bridge SE Self-Expanding Stent Delivery System Registry (ISIS-SE)

A. Study Design

The ISIS-SE Registry was a prospective, multi-center study designed to evaluate the safety and efficacy of the Medtronic Bridge SE Stent Delivery System for the treatment of symptomatic ischemic peripheral vascular disease due to iliac stenosis.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the ISIS-SE study was limited to patients who met the following key inclusion criteria:

- The patient had lesion(s) located in the common iliac (≥ 5 mm from the bifurcation) or external iliac artery.
- The patient had lesion stenosis $> 50\%$ and $< 100\%$, by visual estimate.
- Target vessel reference diameter was > 4.0 mm and < 9.0 mm (by visual estimate), appropriate for treatment with available stent diameter of 6.0 mm to 10.0 mm.
- Target lesion could have been *de novo* or restenotic (not in-stent). Any previous intervention to target lesion must have occurred at least 6 months prior to enrollment.
- Lesion length was ≤ 100 mm (10 cm) and covered by placement of no more than 2 Medtronic investigational iliac stents.
- Multiple lesions in the target vessel may have been treated, provided that all lesions were covered by no more than 2 stents and the total lesion length was ≤ 100 mm.

Patients were not permitted to enroll in the ISIS-SE study if they met any of the following key exclusion criteria:

- The patient had any tissue loss in the extremity being treated, defined as a category 5 or 6 on the Rutherford scale.
- The target lesion had a previous stent, was within a prosthetic vascular bypass graft, or was within 1 cm of a graft anastomosis.
- The target lesion was totally occluded, located within an aneurysm, or associated with an aneurysm in the vessel segment either proximal or distal to the target lesion.
- The target lesion was severely calcified.
- The patient had a previous ipsilateral iliac artery bypass surgery which involved the target lesion.
- The patient had occlusion of both ipsilateral profunda femoral and superficial femoral arteries by angiography, which was evident by disruption of distal run-off.

2. Follow-up Schedule

Subjects underwent stent placement using standard procedures (according to the Instructions for Use) for percutaneous interventional procedures. Prior to the procedure, subjects were given an oral dose of 325mg aspirin. After catheter introduction, supplemental anti-coagulation was administered at the discretion of the Investigator. No more than 2 stents were to be used to treat the target lesion; additional stents were used only in the event of a bailout procedure.

Duplex scans and ankle brachial index (ABI) or pulse volume recording (PVR) measurements were completed within 30 days post-procedure. After hospital discharge, subjects had follow-up visits on Day 30 and at 9-12 months. In addition, subjects receiving Ticlid had a follow-up on Day 14 for laboratory evaluation (WBC with differential and platelet count). Ischemic testing and walking assessment were performed at Day 30 and at 9-12 months. Duplex scans and ABI or PVR measurements also were performed at the Day 30 visit (if not previously conducted pre-discharge) and at 9-12 months. Angiograms were performed at follow-up visits as needed. Four additional follow-up telephone assessments were to be conducted at 6-month intervals starting after the 9-12 month visit. A summary of subject accountability is provided in Table 7.

3. Clinical Endpoints

The primary safety endpoint was the major adverse clinical events (MACE); defined as peri-procedure death, target limb loss or tissue necrosis, and clinically-driven TLR (target lesion revascularization with percutaneous transluminal angioplasty [PTA] or ipsilateral iliac bypass graft) rate as measured through 12 months.

The primary efficacy endpoint was the 9-12 month patency rate as measured by color duplex ultrasound scan.

B. Accountability of PMA Cohort

Table 7: Subject Accountability - Site Reported (Subjects Enrolled, N=158)

Subjects	30 Days Follow-up	9-12 Months Follow-up
Eligible (n)	157	152
Death (n)	1	5
Withdrawal (n)	0	1
Lost to Follow-up (LTF) (n)	0	3
Follow-up visit within window (n)	139	125
Clinical Compliance % (n/N)	88.5% (139/157)	82.2% (125/152)
Note 1: Deaths, withdrawal and LTF are cumulative, and include subjects from beginning of study to follow-up time point		
Note 2: Within window visits are defined as: 30 days (20-40 days) and 9-12 month (270-365 days)		

C. Study Population Demographics and Baseline Parameters

158 subjects were enrolled at 19 sites in the United States with a mean age of 66 years (range: 31-90 years), including 99 males (62.7%). Study subject demographics are summarized in Table 8 and baseline target lesion characteristics are summarized in Table 9.

Table 8: Demographics and Medical History (ITT Population)

Patient Characteristic	Result
Age (yr)	
Mean±SD (n)	66 ±11 (158)
Minimum, maximum	31, 90
Gender, n/N (%)¹	
Male	99/158 (62.7%)
Female	59/158 (37.3%)
Medical history, n/N (%)²	
Diabetes mellitus	50/158 (31.6%)
Type I	4/158 (2.5%)
Dyslipidemia requiring medication	110/157 (70.1%)
History of hypertension	126/158 (79.7%)
Cigarette smoking	127/157 (80.9%)
Currently smoking	57/155 (36.8%)
Family history of premature atherosclerotic disease	40/92 (43.5%)
History of coronary artery disease	116/157 (73.9%)
Previous MI	43/150 (28.7%)
Previous coronary PTCA	51/151 (33.8%)
Previous CABG	43/157 (27.4%)
Previous peripheral vascular disease	156/158 (98.7%)
Previous PTA/stenting to target limb	8/158 (5.1%)
Previous aorta/peripheral bypass to target limb	1/158 (0.6%)

¹ Percentage based on number of patients enrolled.

² Percentage based on number of patients assessed for the related parameter.

18

Table 9: Baseline Target Lesion Characteristics (ITT Population)

Parameter / Statistic	Result
Reference vessel diameter (mm)	
Mean±SD (n)	7.8±1.1 (165)
Minimum, maximum	4.8, 10.2
Lesion length (total) (mm)	
Mean±SD (n)	25.4±14.6 (164)
Minimum, maximum	5.1, 98.8
Lesion % stenosis (most severe)	
Mean±SD (n) ¹	62.5±14.1 (165)
Minimum, maximum	26.6, 100.0
Patients with single lesion stenting	151 (95.6%)
Patients with bilateral lesions stenting	7 (4.4%)
Lesion characteristics, n/N (%) ¹	
Eccentric	29/165 (17.6%)
Ulceration	14/165 (8.5%)
Calcification	39/155 (25.2%)
None / Mild	116/155 (74.8%)
Moderate	26/155 (16.8%)
Severe	13/155 (8.4%)
Thrombus present	4/165 (2.4%)
Dissection	24/123 (19.5%)
0	99/123 (80.5%)
A ²	0/24 (0.0%)
B ²	17/24 (70.8%)
C ²	6/24 (25.0%)
D ²	1/24 (4.2%)
E ²	0/24 (0.0%)
F ²	0/24 (0.0%)

¹ Unless otherwise specified, percentages based on number of lesions that were attempted and had available data.

² Percentage based on number of lesions with dissection.

D. Safety and Effectiveness Results

1. Safety Results

The primary safety endpoint was the MACE rate at 9-12 months post procedure. The following hypotheses were established to test the MACE rate at 9-12 month in the test device, using exact confidence intervals (one-sided) at $\alpha = 0.05$, compared to a performance goal for iliac stenting derived from historical literature:

$$H_0: P_t > 21\%$$

$$H_A: P_t \leq 21\%$$

Where P_t was the observed 9-12 month MACE rate in ISIS-SE.

The subject-based MACE rate through 365 days was 3.3% (5 of 150 subjects) for the intent to treat (ITT) population. The upper bound of the 1-sided 95% confidence interval on the MACE rate through 12 months was 6.9%. Since the upper limit of the 1-sided 95% confidence interval on the observed 9-12 month MACE rate did not exceed 21%, the device met the performance goal for safety.

Additionally, no subject in the ITT population experienced a MACE through 30 days. No deaths were reported within 30 days post-procedure, nor were any deaths associated with a complication of the index procedure or the device.

Table 10: MACEs Through 12 Months: Adjudicated Events (ITT Population)

Event	Statistic n/N (%) ¹
Any MACE	5/150 (3.3%)
Death due to:	
Bleeding	0 (0.0%)
Vascular repair	0 (0.0%)
Transfusion reaction	0 (0.0%)
Bypass surgery	0 (0.0%)
Any death within 30 Days	0 (0.0%)
Target limb loss	1/150 (0.7%)
Target limb tissue necrosis	2/150 (1.3%)
Target lesion revascularization with PTA	2/150 (1.3%)
Target lesion revascularization with iliac bypass graft	1/150 (0.7%)

¹ Based on number of patients enrolled with available data.

Adverse effects that occurred in the PMA clinical study:

An independent Clinical Events Committee (CEC) developed specific criteria for the categorization of clinical events and clinical endpoints in this study, including procedural death, vascular complications, target limb loss or tissue necrosis, and target lesion/vessel revascularization. Sites also reported study-specific serious adverse event (SAEs) related to the device and/or procedure. Study-specific SAEs included death, target limb loss, repeat percutaneous revascularization of the target lesion or vessel, iliac bypass surgery, major bleeding events requiring transfusion (within 30 days), and target limb tissue necrosis.

Adverse events through 12 months post-procedure are summarized by System Organ Class (SOC) below.

20

Table 11: Adverse Events Through 12 Months (ITT Population)

System/Organ Class	Number of Patients n (n/N %) ¹
At least one adverse event	70
Blood and lymphatic system disorders	5 (3.2%)
Cardiac disorders	9 (5.7%)
Eye disorders	1 (0.6%)
Gastrointestinal disorders	3 (1.9%)
General disorders	1 (0.6%)
Infections	1 (0.6%)
Injury, poisoning and procedural complications	8 (5.1%)
Investigations	1 (0.6%)
Metabolism and nutritional disorders	1 (0.6%)
Musculoskeletal and connective tissue disorders	5 (3.2%)
Neoplasms, benign, malignant	5 (3.2%)
Nervous system disorders	2 (1.3%)
Psychiatric disorders	1 (0.6%)
Renal and urinary disorders	6 (3.8%)
Reproductive system disorders	1 (0.6%)
Respiratory, thoracic disorders	10 (6.3%)
Skin and subcutaneous tissue disorders	3 (1.9%)
Surgical and medical procedures	12 (7.6%)
Vascular disorders	35 (22.2%)

¹ Percentages based on number of patients enrolled (N =158).

2. Effectiveness Results

The primary efficacy endpoint was the 9-12 month patency rate, as measured by Duplex ultrasound (DUS). The following hypotheses were established to test the patency rate at 9-12 months in the test device, using exact confidence intervals (one-sided) at $\alpha = 0.05$, compared to a performance goal for iliac stenting derived from historical literature:

$$H_0: P_t > 18.5\%$$

$$H_A: P_t \leq 18.5\%$$

Where P_t was the observed 9-12 month patency failure rate in ISIS-SE.

The primary efficacy endpoint, the 9-12 month patency rate as measured by color duplex ultrasound scan for the ITT evaluable population and the PP population was 100.0%. The upper bound of the one-sided 95% confidence interval on the patency failure rate through 9-12 months was 2.2% and 2.3% for the ITT evaluable and PP populations, respectively. Since the upper bound of the one-sided 95% confidence interval on the patency failure rate through 9-12 months did not exceed 18.5%, the device met the performance goal for effectiveness.

Additionally, acute clinical success as defined by device, lesion and procedure success (all of which required a residual stenosis of <30%) was 86.6% among subjects in the ITT population. See Table 12 below for the individual device, lesion, and procedure success rates.

Table 12: Acute Clinical Success (ITT Population)

Secondary Endpoint Parameter / Statistic	Result
	N=158 patients, N _b =166 lesions
Acute clinical success	
Device success, n/N _b (%) ¹	142/164 (86.6%)
Lesion success, n/N _b (%) ¹	144/164 (87.8%)
Procedure success, n/N (%) ²	135/155 (87.1%)

N = Number of patients enrolled

N_b = Number of lesions as reported by Angiographic Core Laboratory

¹ Percentage based on number of lesions implanted for which data were available for the related parameter.

² Percentage based on number of patients enrolled for which data were available (for patients with bilateral stenting, the worse case was counted).

Overall, the Medtronic Bridge SE Stent Delivery System was associated with a low incidence of MACEs through 12 months post-procedure (3.3%). Furthermore, the Bridge SE Stent Delivery System was associated with high patency rates (100.0%) at 9-12 months post-procedure. A decrease in the mean percent diameter stenosis from 62.5% at baseline to 19.1% post-procedure was seen, with an accordant increase in the mean lumen diameter from 2.9 mm at baseline to 6.4 mm post-procedure. Thus, the study device was effective in increasing patency and reducing the degree of iliac artery stenosis, thereby suggesting benefit for patients.

The Complete SE Iliac Registry

A. Study Design

The Complete SE Iliac study is an ongoing confirmatory study. Fifty-eight stents were delivered without complication in the first 50 subjects at 12 sites in the US. No MAEs were reported through 30 days of follow-up.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the Complete SE study was limited to patients who met the following key inclusion criteria:

- The lesion(s) is either *de novo* or restenotic in nature, located in either the common iliac artery (> 5 mm from the bifurcation) or the external iliac artery AND is ≥ 50% stenosed.
- The target vessel reference diameter ≥ 4.5 mm and ≤ 9.5 mm by visual estimate and it appropriate for treatment with available stent diameters of 6.0 mm, to 10 mm.
- The subject is either asymptomatic with a lesion stenosis ≥ 70% or symptomatic with a lesion stenosis ≥ 50% and has an ABI < 0.90 or a TBI < 0.80 or an abnormal PVR for those subjects in which the ABI/TBI cannot be obtained.
- The lesion length is no greater than 110 mm (11 cm) and able to accommodate placement of a single stent; multiple lesions in the target vessel may be treated provided all lesions are covered by no more than one stent and the total lesion length is no more than 110 mm in length.

Patients were not permitted to enroll in the Complete SE study if they met any of the following key exclusion criteria:

- The subject has any tissue loss in the extremity being treated as defined as a category 5 or 6 on the Rutherford scale.
- The target lesion has a previous stent, or is located within a prosthetic vascular bypass graft or within 1 cm of a graft anastomosis.
- The lesion requires treatment with a non-standard device associated with PTA prior to stent placement.
- The subject has a previous iliac artery bypass surgery that involves the target lesion or target vessel.

2. Follow-up Schedule

After a series of screening assessments and administration of written informed consent, subjects underwent stent placement using standard procedures (according to the Instructions for Use) for percutaneous interventional procedures. After catheter introduction, supplemental anti-coagulation was administered at the discretion of the Investigator. No more than one stent was to be used to treat the target lesion(s); additional stents were used only in the event of a bailout procedure.

After hospital discharge, patients were required to return to the study center for clinical assessments on Day 30 \pm 5 days. Ischemic testing, duplex scans, ABI, toe brachial index (TBI), or PVR measurements, and walking assessments were performed at the Day 30 visit. Additionally, an angiogram was performed as needed to assess the safety and efficacy of the Complete SE Vascular Stent.

3. Clinical Endpoints

The primary endpoint for this study is the incidence of MAE at 30 days post-procedure, including any death, target limb loss or clinically-driven TLR/TVR with PTA or aorto-iliac bypass graft for all subjects enrolled into the registry (a minimum of 50 subjects enrolled). The secondary endpoints are acute success, and overall clinical and hemodynamic success at 30 days postprocedure for all subjects enrolled.

B. Accountability of PMA Cohort

Table 13: Accountability of the PMA Cohort

	ITT = 50
Subjects	30-Day Follow-up
Eligible Subjects (n)	50
Death (n)	0
Withdrawal (n)	0
Follow-up visit within window (n)	43
Follow-up Compliance (%)	86.0%

C. Study Population Demographics and Baseline Parameters

Patients 18 years of age and older with symptomatic ischemic peripheral vascular disease having a stenotic lesion of $\geq 50\%$ in the common or external iliac arteries or asymptomatic patients having a stenotic lesion of $\geq 70\%$ in the common or external iliac arteries that were amenable to treatment by percutaneous stenting were eligible for this study. Multiple vessel disease, *de novo* target lesions, restenotic lesions that have not undergone any percutaneous interventional treatment using the same access site to any vessel within a minimum of 30 days prior to enrollment into the study were included. The minimum reference vessel diameter was between 4.5 mm and 9.5 mm and therefore appropriate for treatment with available stent diameters of 6.0 mm to 10.0 mm.

Table 14: Subject Demographic, Medical History and Risk Factors (ITT Population)

	ITT = 50
Age (year)	
Mean \pm SD (n)	66 \pm 12 (50)
Median	67
Min – Max	43 - 89
Gender	
Male % (n/N)	56.0% (28/50)
Female % (n/N)	44.0% (22/50)
Medical History and Risk Factors	
Diabetes Mellitus % (n/N)	34.0% (17/50)
Type I % (n/N)	2.0% (1/50)
Type II % (n/N)	28.0% (14/50)
Unknown % (n/N)	4.0% (2/50)
Dyslipidemia % (n/N)	84.0% (42/50)
Hypertension % (n/N)	90.0% (45/50)
Cigarette Smoking % (n/N)	86.0% (43/50)
Currently Smoking Cigarettes % (n/N)	48.0% (24/50)
History of Stroke or TIA % (n/N)	15.2% (7/46)
History of Coronary Artery Disease % (n/N)	69.4% (34/49)
Previous MI % (n/N)	43.3% (13/30)
Previous Peripheral Vascular Disease (other than iliac) % (n/N)	75.5% (37/49)
Previous PTA/Stenting to Target Limb % (n/N)	16.0% (8/50)
Previous Aorta/Peripheral Bypass to Target Limb % (n/N)	4.0% (2/50)

Note: Different denominators are due to missing data

Table 15: Angiographic Morphology Data (ITT Population)

Lesion Characteristic	ITT = 50
	Lesions as Angiographic Core Laboratory Reported = 55 % (n/N) ^a
Pre Procedure Assessment	
Lesion Pre Procedure Percent Stenosis (most severe)	
Mean ± SD (n)	72.5 ± 14.6 (55)
Median	69.6
Min – Max	51.3 - 100.0
Subjects with Single Limb Stenting	88.0 (44/50)
Subjects with Bilateral Limb Stenting	12.0 (6/50)
Eccentric	25.5% (14/55)
Ulceration	0.0% (0/55)
Calcification	32.7% (18/55)
None/mild	67.3% (37/55)
Moderate	20.0% (11/55)
Severe	12.7% (7/55)
Thrombus	0.0% (0/55)
Post Procedure Assessment	
Dissection	
0	94.5% (52/55)
A	0.0% (0/55)
B	3.6% (2/55)
C	1.8% (1/55)
D	0.0% (0/55)
E	0.0% (0/55)
F	0.0% (0/55)

^a Percentage is based on the number of lesions attempted and for which data were available.

25

D. Safety and Effectiveness Results

There were no major adverse events (MAEs) in the first 50 subjects followed from enrollment through the 30-Day Follow-Up Visit.

Table 16: Primary Endpoint and Details of Major Adverse Events through 30-Day (ITT Population)

Major Adverse Events	ITT = 50	
	% (n/N) ^a	Exact 95% CI
Any Major Adverse Event	0.0% (0/50)	(0.0%, 7.1%)
Any Death	0.0% (0/50)	(0.0%, 7.1%)
Target Limb Loss	0.0% (0/50)	(0.0%, 7.1%)
Target Lesion Revascularization (TLR)	0.0% (0/50)	(0.0%, 7.1%)
TLR by Percutaneous Transluminal Angioplasty (PTA)	0.0% (0/50)	(0.0%, 7.1%)
TLR by Iliac Bypass Graft	0.0% (0/50)	(0.0%, 7.1%)
Target Vessel Revascularization (TVR)	0.0% (0/50)	(0.0%, 7.1%)
TVR by PTA	0.0% (0/50)	(0.0%, 7.1%)
TVR by Iliac Bypass Graft	0.0% (0/50)	(0.0%, 7.1%)

^a Percentage based on number of evaluable subjects for MAE. The subjects without available result (missing data) for MAE are excluded from analysis. Subjects are considered unevaluable for MAE if a) withdrawn before 25 days without having MAE events or b) lost to follow-up before 25 days without having MAE events and had no contact thereafter

In addition, the results for the endpoints of acute, clinical and hemodynamic success are 89.8%, 85.2% and 100% respectively.

Table 17: Secondary Endpoints (ITT Population)

Secondary Endpoints	ITT = 50	
	Lesions as Site Reported =56	
	% (n/N) ^a	Exact 95% CI
Acute Success ^b	89.8% (44/49)	(77.8%, 96.6%)
Clinical Success at 30-Day ^c	85.2% (46/54)	(72.9%, 93.4%)
Hemodynamic Success at 30-Day ^d	100.0% (55/55)	(93.5%, 100.0%)

^a Percentage based on number of lesions implanted and had available data (acute success on subject level)

^b Acute success defined as Angiographic evidence of <30 % final residual stenosis of the target lesion after stent placement and no occurrence of a device- related or procedure-related MAE or vascular event (stent thrombosis, major bleeding complications, etc.) prior to hospital discharge for all subjects enrolled into the registry

^c Clinical success an improvement of the Rutherford scale by ≥ 1 category between pre-procedure (baseline) and the scheduled follow-up visits

^d Hemodynamic success an improvement in ankle-brachial Index (ABI) or toe-brachial index (TBI) >0.10 over pre-procedure level OR deterioration of ≤ 0.15 from first post-procedure exam **OR** pulse volume recording (PVR) distal to the target lesion treated maintained at ≥ 5 mm above pre-procedure tracing for those subjects with no pre-procedure ABI/TBI (Note: Site, CEC and Angiographic Core Laboratory Reported Table)

Adverse effects that occurred in the PMA clinical study:

An independent Clinical Events Committee (CEC) developed specific criteria for the categorization of clinical events and clinical endpoints in this study. The specific criteria related to death, target limb loss, and target lesion/vessel revascularization. Sites also reported study-specific serious adverse event (SAEs) related to the device and/or procedure.

Table 18: Adverse Events

	ITT = 50 Total Adverse Events = 42 Subjects with at Least one Adverse Event = 15
System Organ Class	Number of Subjects % (n/N) ^a
Blood and Lymphatic System Disorders	2.0% (1/50)
Cardiac Disorders	8.0% (4/50)
Gastrointestinal Disorders	6.0% (3/50)
General Disorders and Administration Site Conditions	2.0% (1/50)
Hepatobiliary Disorders	2.0% (1/50)
Infections and Infestations	2.0% (1/50)
Injury, Poisoning and Procedural Complications	2.0% (1/50)
Musculoskeletal and Connective Tissue Disorders	10.0% (5/50)
Neoplasms Benign, Malignant and Unspecified (including cysts and polyps)	2.0% (1/50)
Nervous System Disorders	4.0% (2/50)
Psychiatric Disorders	2.0% (1/50)
Renal and Urinary Disorders	2.0% (1/50)
Respiratory, Thoracic and Mediastinal Disorders	6.0% (3/50)
Skin and Subcutaneous Tissue Disorders	6.0% (3/50)
Vascular Disorders	10.0% (5/50)

^a Percentage based on total number of subjects in ITT population

Overall, the data support the study objective to demonstrate the safety of the Complete SE Iliac Stent for the treatment of *de novo* and restenotic lesions in the iliac arteries in subjects with peripheral vascular disease.

XI. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

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 System Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Safety and Effectiveness Conclusion

The non-clinical studies indicate that the Complete SE Vascular Stent System meets or exceeds safety and performance specifications. Multi-center clinical trials have demonstrated that the Complete SE Vascular Stent System is safe and effective for its intended use as a treatment for iliac artery disease in the indicated population. Results from non-clinical and clinical evaluations provide valid scientific evidence and reasonable assurance that the device is safe and effective; therefore, it is reasonable to conclude that the benefits of use of the device for the target population outweigh the risk of illness or injury when used as indicated in accordance with the labeling and Instructions for Use (IFU).

XIII. CDRH DECISION

CDRH issued an approval order on March 17, 2010. The final conditions of approval cited in the approval order are described below.

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

XIV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

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

Post-approval Requirements and Restrictions: See approval order.