Medtronic

Complete® SE

Vascular Stent System

Instructions for Use

EXPLANATION OF SYMBOLS ON PRODUCT LABELING

Refer to the device labeling to see which symbols apply to this product.

	Contents: One device
	Do not use if package is damaged
	Non-pyrogenic
	Peel here
	MR Conditional
	CAUTION: Federal (USA) law restricts this device for sale by or on order of a physician.
	Sterilized using irradiation
	Catalogue number
	Use by
	Do not reuse
	Manufacturer
	Manufactured In
	Consult instructions for use at: www.medtronic.com/manuals
	Lot number
	Do not use if indicator turns black
	Minimum sheath ID
	Store at room temperature in a dark, dry place
	Stent inner diameter
	Stent length

Complete® SE

Vascular Stent System - Superficial Femoral Artery (SFA)/Proximal Popliteal Artery (PPA)

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1. Device Description

The Complete SE Vascular Stent System is used to deliver a self-expanding stent to the superficial femoral/proximal popliteal arteries via a sheathed delivery system. The system is comprised of 2 main components: the implantable vascular stent (Figure 1) and the disposable delivery system (Figure 2). The stent is compressed and preloaded into the delivery system (Figure 3) and advanced to the target lesion, where the protective sheath is retracted. Upon deployment, the stent self-expands to provide a vessel support frame and to impart an outward radial force on the arterial lumen to establish patency.

1.1. Stent

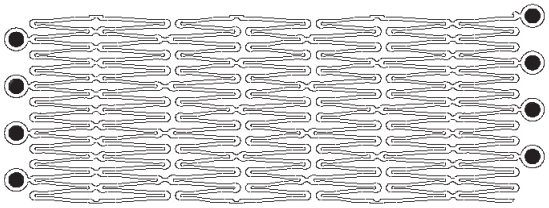


Figure 1. Complete SE Vascular Stent with Tantalum Markers

Note: This and all other product graphics appearing in this manual are not drawn to scale.

The Complete SE Vascular Stent is constructed of a nickel-titanium alloy (Nitinol) and has 4 tantalum radiopaque markers on each end to aid in visualization and facilitate placement. The series of segments, each connected to the next, allow for flexibility and vessel conformability. It is available in diameters of 5 mm to 8 mm and lengths of 20 mm to 150 mm. See Table 2 in Recommended Device Sizing (Section 10.2).

1.2. Delivery System

Figure 2. The Complete SE Vascular Stent Delivery System

1. Tip and flexible outer member sheath
2. Outer stability member
3. Strain relief
4. Front grip
5. Deployment rotation/slider mechanism
6. Deployment button
7. Safety lock

The Complete SE Vascular Stent Delivery System consists of a single-use, disposable catheter with an integrated handle to provide controlled deployment. It has a working length of either 80 cm or 130 cm and is compatible with a 6 Fr sheath and 0.035 in (0.89 mm) guidewire.

The over-the-wire retractable sheath delivery system is composed of a tip and flexible outer member sheath (braided) body attached to the strain relief handle, which includes the front grip and the deployment rotation/slider mechanism with a removable safety lock. The outer member sheath is retracted by engaging the deployment slider/rotation mechanism. Radiopaque marker bands are located on both the distal and proximal sides of the preloaded stent to aid placement (Figure 3).

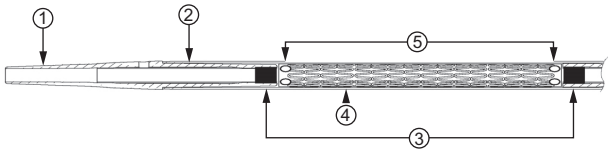


Figure 3. Complete SE Vascular Stent System

1. Tip
2. Stent sheath
3. Catheter radiopaque marker bands
4. Stent
5. Tantalum markers

The Complete SE Vascular Stent System does not contain natural rubber latex. However, during the manufacturing/assembly process, it may have incidental contact with latex-containing products.

2. Indications for Use

The Complete SE Vascular Stent System is indicated to improve luminal diameter in symptomatic patients with *de novo* and/or restenotic lesions or occlusions of the superficial femoral artery (SFA) or proximal popliteal artery (PPA) with reference diameters ranging from 4 mm to 7 mm and lesion lengths up to 140 mm.

3. Contraindications

The Complete SE Vascular Stent System is contraindicated in:

- patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system
- patients who cannot receive antiplatelet or anticoagulation therapy

Also consider patient selection information in Warnings and Precautions (Section 4).

4. Warnings and Precautions

Caution: Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may result in serious consequences or injury to the patient.

4.1. General

- The Complete SE Vascular Stent System should only be used by physicians and medical personnel trained in vascular interventional techniques (including advanced iliac or SFA angioplasty or stenting techniques) and trained on the use of this device. Specific training expectations are described in Physician Training Requirements (Section 10.1).
- **Caution:** Federal (USA) law restricts this device for sale by or on the order of a physician.

4.2. Warnings

- Do not use if the temperature indicator found on the inner pouch is changed from a gray square to a black square as this indicates the unconstrained stent diameter and stent release may be compromised.
- Administer appropriate antiplatelet/anticoagulation therapy pre- and post- procedure. Use of this device in patients who are unable to tolerate appropriate antiplatelet therapy is not recommended.
- Do not use the Complete SE Vascular Stent System in patients unable to undergo, or who will not be compliant with, the necessary preoperative and postoperative imaging and implantation procedures.
- Careful stent sizing is important. In vitro modeling has predicted the Complete SE Vascular Stent foreshortens between 0% (5 mm stents) and 8% (8 mm stents). See Table 2 for available diameters and lengths (Section 10.2).
- The use of overlapping stents with the Complete SE Vascular Stent System has not been formally evaluated in a clinical study; overlap stents have been evaluated on the bench/Finite Element Analysis (FEA) and results are on file at Medtronic.
- To achieve optimal sizing and apposition to the vessel wall, using an interference fit, stents should be at least 0.5 mm greater in diameter than the target vessel. Consideration should also be given to the length of the lesion to be treated when selecting the stent length. See Recommended Device Sizing (Section 10.2).
- To avoid kinking of the delivery system, stabilize the hub of the guiding catheter or introducer sheath, hold the catheter shaft just proximal, and use short strokes to advance the delivery catheter over the immobilized guidewire.
- Do not deploy the stent if it is not optimal or appropriate for the vessel. The stent cannot be repositioned once the stent has begun to appose the vessel wall.
- Use caution when placing a stent near a bifurcation, aneurysm, or bypass graft.
- Prior to stent deployment, use fluoroscopy to verify the stent has not been damaged or dislodged during positioning.
- If unable to initiate stent release, remove the entire system from the patient and advance a new stent delivery system.
- Once deployment is initiated, the stent cannot be recovered by the sheath. In the event of partial delivery of the stent, remove the entire delivery system from the patient. This may result in damage to the vessel wall and require surgical intervention.
- Prior to completion of the procedure, use fluoroscopy to ensure the stent is deployed in the proper position. If the target lesion is not completely covered by the stent, use additional Complete SE Vascular stent(s) as necessary to adequately treat the lesion.
- Should unusual resistance be felt at any time during placement or removal of the stent or delivery system, cautiously remove the entire system. Applying excessive force to the Complete SE vascular self-expanding stent system can potentially result in loss, damage, or partial deployment of the stent and the delivery system components.

4.3. Precautions

- The Complete SE Vascular Stent System should only be used by physicians and medical personnel trained in vascular interventional techniques (including SFA angioplasty or stenting techniques) and trained on the use of this device. Specific training expectations are described in Physician Training Requirements (Section 10.1).
- The long-term safety and effectiveness of the Complete SE Vascular Stent System has not been established beyond one year.
- The safety and effectiveness of this system has not been evaluated in patients who:
  - are less than 18 years old
  - are pregnant or lactating
  - have any condition that precludes safe access with PTA devices
  - have in-stent restenosis of the target lesion
  - have a known hypersensitivity to any component of the stent system (eg, nickel)
  - cannot tolerate aspirin and heparin
  - cannot tolerate contrast media and cannot be pretreated
  - have a history of bleeding diathesis or coagulopathy or will refuse blood transfusion
  - have creatinine >2.5 mg/dl
- Inappropriate patient selection may result in poor device performance or device performance otherwise not in accordance with the specifications.
- Thrombogenicity evaluations were conducted using a heparinized model. If your patient cannot be adequately anticoagulated, it is unknown whether thrombus formation may occur with this product.
- Caution must be taken when crossing the stented area with ancillary equipment to avoid dislodging the stent.

5. Adverse Events

5.1. Observed Adverse Events

Major adverse events observed in the clinical study supporting approval of the device are provided in Section 6.

5.2. Potential Adverse Events

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

- abrupt stent closure
- allergic reaction (contrast medium; drug; stent or filter material)

- amputation or limb loss
- aneurysm or pseudoaneurysm in vessel or at vascular access site
- angina or coronary ischemia
- arrhythmia (including premature beats, bradycardia, atrial or ventricular tachycardia, atrial or ventricular fibrillation)
- 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 of a system component or implantation in an unintended site
- emboli, distal (for example, air, tissue, plaque, thrombotic material, or stent)
- emergent bypass surgery to perfuse limb
- fever
- hematoma at vascular access site, with or without surgical repair
- hypotension or hypertension
- infection, local or systemic, including bacteremia or septicemia
- ischemia requiring intervention (bypass or amputation of toe, foot, or leg)
- myocardial infarction
- occlusion of SFA/PPA artery or distal vasculature
- pain (leg or foot)
- pain at catheter insertion site
- pulmonary embolism
- renal failure or insufficiency, secondary to contrast medium
- restenosis of vessel in stented segment
- stent malposition or migration, which may require emergency surgery to remove stent
- stent strut fracture
- stent thrombosis or occlusion
- stroke
- vascular thrombosis or occlusion at puncture site, treatment site, or remote site
- vessel dissection, perforation or rupture
- vessel spasm or recoil

5.3. Device-related Adverse Events

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

6. Summary of Clinical Study

The clinical evidence supporting the safety and effectiveness of the Complete SE Vascular Stent System for the treatment of de novo or restenotic lesions or occlusions (≤140 mm) in the SFA or PPA in subjects with symptomatic peripheral artery disease (PAD) is from the Complete SE SFA/PPA Study.

6.1. The Complete SE SFA Study

The Complete SE SFA Study is a nonrandomized, prospective, multicenter, single-arm study enrolling up to 196 subjects with symptomatic ischemic PAD (Rutherford class 2 through 4) with a lesion ≥50%, a target vessel reference diameter ≥4 mm and ≤7 mm, total lesion length ≥40 mm and ≤140 mm (visual estimates), and adequate distal runoff to the foot. Lesions were located above the knee and amenable to percutaneous treatment with angioplasty and vascular stent implantation. For treatment of multiple lesions, the combined lesion length must be ≤140 mm. The lesions must be in the same limb, and the treatment must not require more than 150 mm in combined stent length.

6.2. Patient Population

196 subjects were enrolled at 28 sites (United States, Belgium, and Germany) with a mean age of 69 years (range: 40 to 93), including 124 males (63%). Subject demographics, medical history, and risk factors are summarized (Figure 4).

Subject Demographic, Medical History and Risk Factors[a]	N = 196
Age (year)	
n	196
Mean ± SD	68.7 ± 10.5
Median	68.0
Min, Max	40, 93
Sex % (m/n)	
Male	63.3 (124/196)
Medical History and Risk Factors % (m/n)	
Diabetes Mellitus	45.4 (89/196)
Type I	1.5 (3/196)
Type II	43.9 (86/196)
Dyslipidemia	79.6 (156/196)
Hypertension	90.3 (177/196)
History of Tobacco Use	79.6 (156/196)
Former	52.6 (103/196)
Current	27.0 (53/196)
History of Coronary Artery Disease	62.8 (123/196)
History of COPD	21.4 (42/196)
Previous MI	26.2 (49/187)
Previous Peripheral Vascular Disease (other than SFA and PPA)	53.1 (103/194)
History of CVA	14.3 (28/196)
Previous PTA/Stenting to Target Limb	18.4 (36/196)
Previous Aorta/Peripheral Bypass to Target Limb	1.5 (3/196)
History of GI/GU Bleed	5.6 (11/196)

a Based on number of subjects with available data
N = Intent-To-Treat Population
Note: Site Reported Table

Figure 4. Subject Demographics, Medical History, and Risk Factors

6.3. Methods

Direct stent placement was at the discretion of the physician. The target lesion was to be predilated (with standard PTA balloons) if necessary to cross the lesion. Prior to the procedure, the subject was given an oral dose of aspirin (325 mg). Prior to stent placement, heparin was administered to achieve ACT. Target lesions were treated with 1 or 2 stents.

Angiographic Quantitative Analysis[a]	**Lesions[b]= 213**
Lesion Location (%)	
SFA Ostial	2.3 (5/213)
SFA Proximal	13.6 (29/213)
SFA Mid	34.4 (73/213)
SFA Distal	45.5 (97/213)
Proximal Popliteal Artery	4.2 (9/213)
Reference vessel diameter (mm)	
Mean±SD (n)	4.8±0.9 (209)
Minimum, maximum	2.2, 7.6
Lesion length (total) (mm)	
Mean±SD (n)	60.7±37.6 (209)
Minimum, maximum	5, 228
Lesion pre-procedure % stenosis	
Mean±SD (n)	79.7±16.1 (209)
Minimum, maximum	51.1, 100
Lesion post-procedure % stenosis	
Mean±SD (n)	16.9±9.3 (211)
Minimum, maximum	1.4, 40.5
Lesions treated with 1 study stent	203
Lesions treated with 2 study stents	11
Lesion Characteristic	**% (m/n)**
Eccentric	31 (65/210)
Ulceration	17.6 (37/210)
Calcification	91 (191/210)
None/Mild	9 (19/210)
Moderate	34.8 (73/210)
Severe	56.2 (118/210)
Thrombus	0 (0/210)
Total Occlusion	29.9 (60/201)
Dissection Grade	
0 (no dissection)	97.2 (205/211)
A	0 (0/211)
B	1.9 (4/211)
C	0.5 (1/211)
D	0.5 (1/211)
E	0 (0/211)
F	0 (0/211)

[a]Based on the number of lesions with available data.
[b]Lesions as Angiographic Core Laboratory Reported.

Figure 5. Lesion Characteristics

6.4. Study Results: Safety Endpoint

The primary safety endpoint is the major adverse event (MAE) rate at 12 months. MAE is defined as device or procedure related death (or any death occurring postprocedure through 30 days), target limb loss, and target lesion or target vessel revascularization. Primary safety endpoints are summarized in Figure 6.

Primary Safety Endpoint	N = 196 Lesions[b] = 213 % (m/n)[a]	Exact One-sided Upper 97.5% CI
MAE at 12 Months	11.0 (21/191)	16.3%
Death through 30 Days	0.0 (0/191)	1.9%
Death (Device and/or Procedure Related)	0.0 (0/191)	1.9%
Device Related	0.0 (0/191)	1.9%
Procedure Related	0.0 (0/191)	1.9%
Target Limb Loss	0.5 (1/191)	2.9%
TLR	9.4 (18/191)	14.5%
PTA	8.9 (17/191)	13.9%
Bypass Graft	0.5 (1/191)	2.9%
TVR	11.0 (21/191)	16.3%
PTA	10.5 (20/191)	15.7%
Bypass Graft	0.5 (1/191)	2.9%

[a] Percentage based on number of evaluable subjects for MAE. Subjects will be considered unevaluable for MAE at 12 months if a) the subject withdrew before 330 days without having MAE events or b) the subject was lost to follow-up before 330 days without having MAE events and had no contact thereafter or c) any device and/or procedure-unrelated death occurred after 30 days and before 330 days without having MAE events

[b] Lesions as reported by the Angiographic Core Laboratory

Figure 6. Primary Safety Endpoint

	Time after initial procedure (days)												
MAE	**0**	**30**	**60**	**90**	**120**	**150**	**180**	**210**	**240**	**270**	**300**	**330**	**365**
# Entered	196	196	195	194	193	188	188	183	178	172	171	170	167
# Censored	0	0	0	0	3	0	2	1	2	0	0	0	167
# Events (CEC adjudicated)	0	1	1	1	2	0	3	4	4	1	1	3	0
% Cumulative Incidence	0.0%	0.5%	1.0%	1.5%	2.6%	2.6%	4.1%	6.2%	8.4%	8.9%	9.4%	11.0%	11.0%
Standard Error	0.0%	0.5%	0.7%	0.9%	1.1%	1.1%	1.4%	1.7%	2.0%	2.1%	2.1%	2.3%	2.3%

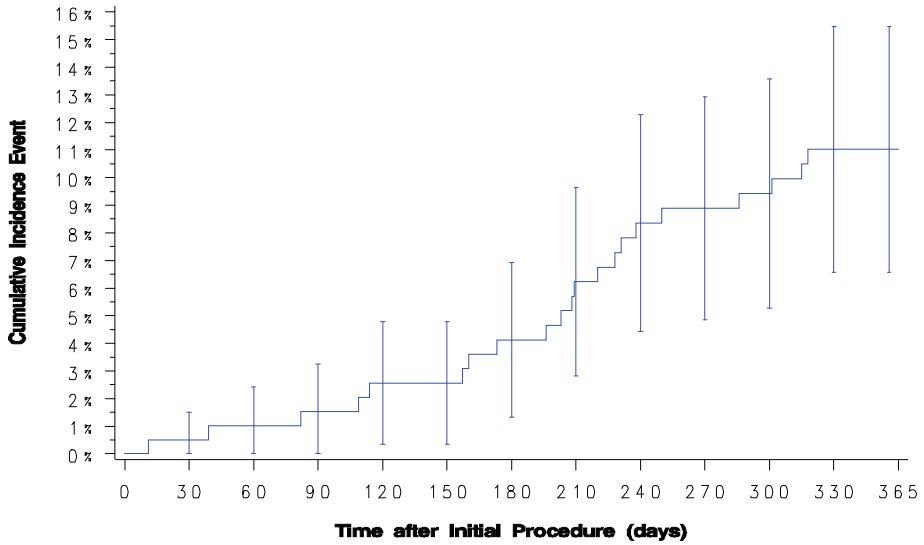


Figure 7. Cumulative Survival Distribution Function Estimate Over 365 Days Period for Subjects with MAE

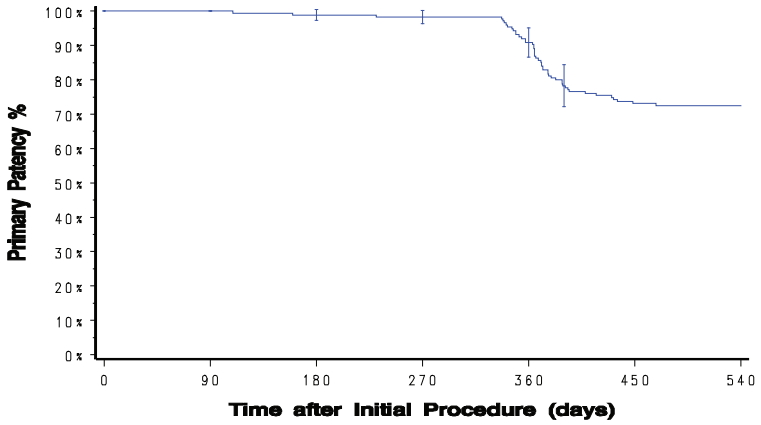
6.5. Study Results: Effectiveness Endpoint

The primary effectiveness endpoint is the primary patency rate at 12 months. Primary patency is defined as uninterrupted patency with 0 procedures performed on or at the margins of the treated segment, with 0 restenosis ≥50% as documented by peak systolic velocity ratio ≥2.0 as assessed by duplex ultrasound (DUS). The primary patency rate at 12 months is summarized in Figure 8.

Primary Effectiveness Endpoints	% (m/n)[a]	Exact One-sided Lower 97.5% CI
Primary Patency[b] Rate at 12 Months	72.6 (127/175)	65.3%

[a] Percentage based on number of subjects who had available duplex data (for subjects with more than one duplex scan analysis the worse case is counted)
[b] Defined as: uninterrupted patency with no procedures performed on or at the margins of the treated segment, with no restenosis ≥50% as documented by DUS peak systolic velocity ratio ≥2.0

Figure 8. Primary Effectiveness Endpoint



	Time after initial procedure (days)					
Patency	**0 - 90**	**91 - 180**	**181 - 270**	**271 - 360**	**361 - 390**	**>=391**
# Risk[1]	175	175	173	172	159	137
# Censored[2]	0	0	0	0	0	127
# Events	0	2	1	13	22	10
Kaplan-Meier Estimate[3]	100.0%	98.9%	98.3%	90.9%	78.3%	72.5%
Standard Error	0.0%	0.8%	1.0%	2.2%	3.1%	3.4%

[1]Number of subjects at risk at the beginning of an interval.
[2]Subjects are censored because their last follow-up has not reached the end of the time interval. Censored subjects will include those who withdraw, are lost to follow-up or die.
[3]Kaplan-Meier Estimate and Standard Error were calculated at the end of a time interval.

Figure 9. Kaplan-Meier Estimates of Primary Patency over time

6.6. Additional Measures of Safety and Effectiveness

The primary patency rate for this study using the PSVR ≥2.4 is 74.9% (131/175) with an exact one-sided 97.5% lower CI of 67.8% (Figure 10).

Primary Effectiveness Endpoints	% (m/n)[a]	Exact One-sided Lower 97.5% CI
Primary Patency[b] Rate at 12 Months	74.9 (131/175)	67.8%

[a] Percentage based on number of subjects who had available duplex data (for subjects with more than one duplex scan analysis the worse case is counted)
[b] Defined as: uninterrupted patency with no procedures performed on or at the margins of the treated segment, with no restenosis ≥50% as documented by DUS peak systolic velocity ratio ≥2.4

Figure 10. Primary Effectiveness Endpoint with cut-off of PSVR ≥2.4

6.7. Patency vs. Lesion Length

Figure 11 presents a lesion length terciles analysis based on Complete SE primary patency outcome and analyzed using PSVR threshold of 2.0 as well as using 2.4.

	Total N = 196 Total Lesions [a] = 213 Lesion Length Terciles		
	Lower (N = 65 Patients N= 71 Lesions)	Mid (N = 65 Patients N= 74 Lesions)	Upper (N = 66 Patients N= 68 Lesions)
Pre-Procedure Lesion Length (mm)			
n	71	73	65
Mean ± SD	27.31 ± 10.13	53.21 ± 13.75	105.65 ± 30.15
Median	28.0	55.0	99.1
Min, Max	5.0, 40.3	11.4, 73.4	37.3, 228.0
Primary Effectiveness Endpoint			
Primary Patency (PSVR ≥ 2.0)[b,c] Rate at 12 Months	83.6% (46/55)	68.9% (42/61)	66.1% (39/59)
Primary Patency (PSVR ≥ 2.4)[b,c] Rate at 12 Months	83.6% (46/55)	70.5% (43/61)	71.2% (42/59)

[a]Lesions as reported by the Angiographic Core Laboratory. In subjects with more than one lesion the longest lesion was used for categorizing them into lesion length terciles.
[b]Percentage based on number of subjects who had available duplex data (for subjects with more than one duplex scan analysis the worse case is counted)
[c]Defined as: uninterrupted patency with no procedures performed on or at the margins of the treated segment, with no restenosis >=50% as documented by DUS peak systolic velocity ratio >=2.0 or >=2.4
N = Intent-To-Treat Population
Note: Site, CEC, Duplex and Angiographic Core Laboratory Reported Table

Figure 11. Primary Patency to 12 Months as a Function of Lesion Length

6.8. Secondary Endpoints and Results

As presented (Figure 12), the 30-day MAE rate was 0.5% (1/196). The device, lesion and procedure success rates were between 89-90%. The secondary patency rate at 12 months was 78.9% (138/175). The clinically-driven target revascularization (TLR) rate at 12 months was 8.4% (16/191). Clinically-driven TLR is defined as those revascularizations in which the subject has ischemic symptoms consistent with changes within the target lesion as demonstrated by a changed (decrease from post-procedure) in the Rutherford scale by at least one category, or a change (decrease from post-procedure) in ABI/TBI ≥0.15.

There were 3 measures of Quality of Life observed at 12 months: Improvement in Rutherford Class by ≥1 category at 12 months was 90.9%; the increase in ankle-brachial index/toebrachial index (ABI/TBI) of ≥0.15 at 12 months was 64.5%; and the decline in Rutherford Class ≥1 at 30 days was 89.7%.

Analyses of all flat-plate X-rays by the Vascore core laboratory indicated that there were 8 (4.2%) stent fractures observed at 12 months, and of those fractures, 7 were grade 1, 1 was grade 2, and 0 were grade 3, grade 4, or grade 5. Medtronic conducted an additional stent fracture analysis and determined that there were zero fractures. For additional information, see Additional Stent Fracture Analysis (Section 6.8.1).

Secondary Endpoints	% (m/n)	Exact Two-sided 95% CI
MAE at 30 Days[a]	0.5 (1/196)	(0.0%, 2.8%)
MAE at 6 Months[b]	4.1 (8/194)	(1.8%, 8.0%)
Device Success[c]	90.0 (189/210)	(85.1%, 93.7%)
Lesion Success[d]	90.0 (190/211)	(85.2%, 93.7%)
Procedure Success[e]	89.1 (172/193)	(83.8%, 93.1%)
Assisted Primary Patency Rate at 12 Months[f]	78.3 (137/175)	(71.4%, 84.2%)
Secondary Patency Rate at 12 Months[g]	78.9 (138/175)	(72.1%, 84.7%)
Change in Quality of Life:		
Improvement in Rutherford Class by ≥1 Category at 12 Months[h]	90.9 (160/176)	(85.7%, 94.7%)
Increase in ABI or TBI ≥0.15 at 12 Months[h]	64.5 (107/166)	(56.7%, 71.7%)
Decline in Rutherford Class ≥1 Category at 30 Days[h]	89.7 (174/194)	(84.5%, 93.6%)
Stent integrity at 12 Months[i]	95.8 (181/189)	(91.8%, 98.2%)
Clinically-driven TLR at 12 Months[j]	8.4 (16/191)	(4.9%, 13.2%)

[a] Percentage based on number of evaluable subjects for MAE. Subjects are considered unevaluable for MAE at 30 days 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
[b] Percentage based on number of evaluable subjects for MAE. Subjects will be considered unevaluable for MAE at 6 months if a) the subject withdrew before 150 days without having MAE events or b) the subject was lost to follow-up before 150 days without having MAE events and had no contact thereafter or c) any device and/or procedure-unrelated death occurred after 30 days and before 150 days without having MAE events
[c] Device success defined as angiographic evidence of <30% final residual stenosis of the target lesion using only the assigned
[d] Lesion success defined as angiographic evidence of <30% final residual stenosis of the target lesion using either the Complete SE SFA Stent System or other standard percutaneous devices. Percentage based on number of lesions with available data
[e] Procedure success defined as angiographic evidence of <30% final residual stenosis of the target lesion after stent implantation and no occurrence of a procedure-related MAE prior to hospital discharge. Percentage based on number of subjects with available data (for subjects with more than one lesion stented the worse case is counted)
[f] Defined as vessel patency resulting from a procedure performed in the treated segment to restore blood flow after restenosis. For patients with multiple TLR events, only the earliest TLR will be considered for Assisted Primary Patency. Percentage based on number of subjects with available duplex data
[g] Defined as vessel patency resulting from any procedure that restores patency. Percentage based on number of subjects with available duplex data. For patients with multiple TLR events, any TLR will be considered for Secondary Patency.
[h] Percentage based on number of subjects with available data at related time point
[i] Percent free from strut fractures. Percentage based on number of stents implanted with flat plate x-ray follow-up
[j]Clinically-driven TLR is defined as those revascularizations in which the subject has ischemic symptoms consistent with changes within the target lesion as demonstrated by: a change (decrease from post-procedure) in the Rutherford scale by at least one category, or a change (decrease from post-procedure) in ABI/TBI ≥0.15
N = Intent-To-Treat Population
Note: Site, CEC, Duplex and Angiographic Core Laboratory Reported Table

Figure 12. Secondary Endpoints

6.8.1. Additional Stent Fracture Analysis

Medtronic and the Core Lab conducted an additional stent integrity analysis at 12 months and these conclusions were reviewed by the FDA. There were nine (9) Core Lab reported fractures at 1-year. As part of the additional analysis, Medtronic assessed the presence of calcification/atheroma, fracture location, oversizing, stretching, overlap/non-overlap, and occurrence of target lesion revascularization (TLR) for all reported events. Medtronic obtained images for all patients at the follow-up time points (i.e., 1 year, 2 year and 3 year) and evaluated the clinical images of each patient at multiple time-points and different views. Medtronic re-produced the fractures using bench testing/models and evaluated the safety factors utilizing FEA.

Of the 9 Core Lab reported fractures reported at 1 year, Medtronic has determined that 8 of the fractures were in fact cases of crown deflections resulting in stent conformation to calcium, which could be attributed to the interaction of the open cell design of the Complete SE stent and the lesion. This is supported by the time series of images which demonstrate the challenge of visual analysis of a fracture in a single plane. Figure 14, for example, demonstrates a suspected fracture that appeared at 12 months but diminished at 2 and 3 years. The other reported fractures were determined to not be fractures utilizing a similar methodology. In addition, one (1) fracture that was initially Core Lab reported was assessed to be a device other than a Medtronic Complete SE stent. Therefore, at 1 year, it was determined that there were zero fractures.

Fracture Reported by Core Lab at 1 year	*9*
Final Number of Suspected Fractures as Determined by Additional Analysis	*0*
Total Number of Fractures at 1 Year	***0***

*Test data on file at Medtronic

Figure 13. Fractures After Additional Analysis

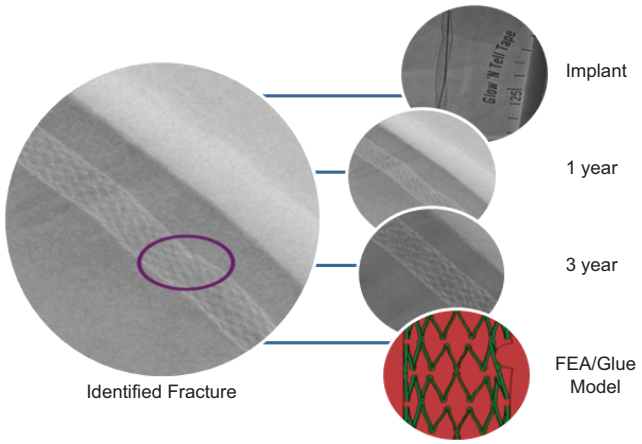


Figure 14. Suspected Fracture Dissipates Over Time

6.8.2. Rutherford Category

A majority of subjects had moderate-severe claudication at baseline based on the Rutherford Category (Category 2-3 94.9%) as summarized (Figure 15). At 30 days, 6 and 12 months post-procedure a majority of subjects were asymptomatic (Category 0).

	N = 196			
Rutherford Category[a]	**Baseline % (m/n)[b]**	**30 Days % (m/n)[b]**	**6 Months % (m/n)[b]**	**12 Months % (m/n)[b]**
0	0.0% (0/196)	56.2% (109/194)	58.1% (108/186)	54.5% (96/176)
1	0.0% (0/196)	27.3% (53/194)	26.9% (50/186)	28.4% (50/176)
2	33.2% (65/196)	10.8% (21/194)	9.1% (17/186)	11.4% (20/176)
3	61.7% (121/196)	5.2% (10/194)	5.4% (10/186)	4.5% (8/176)
4	3.6% (7/196)	0.0% (0/194)	0.0% (0/186)	0.0% (0/176)
5	1.5% (3/196)	0.5% (1/194)	0.5% (1/186)	1.1% (2/176)
6	0.0% (0/196)	0.0% (0/194)	0.0% (0/186)	0.0% (0/176)

[a] Rutherford clinical grades and categories:

Grade	Category	Clinical Description
0	0	Asymptomatic, no hemodynamically significant occlusive disease
I	1	Mild claudication
I	2	Moderate claudication
I	3	Severe claudication
II	4	Ischemic rest pain
III	5	Minor tissue loss; non-healing ulcer; focal gangrene with diffuse pedal ischemia
III	6	Major tissue loss extending above transmetarsal level; functional foot no longer salvageable

[b] Percentage based on number of subject with available data at related time point
N = Intent-To-Population
Note: Site Reported Table

Figure 15. Rutherford Category

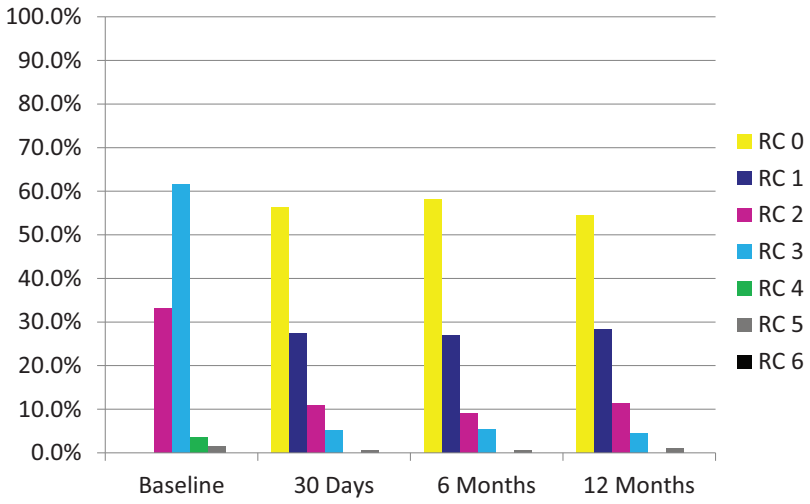


Figure 16. Rutherford Category

6.8.3. ABI/TBI

The overall improvement in ABI/TBI at the 30-day, 6 and 12-month follow-up visits was 0.2 to 0.3. Additionally, the median result at baseline was 0.7 and was improved to 1.0 at subsequent follow-ups.

			N = 196				
ABI/TBI Reading[a]	**Baseline**	**30 Days**	**6 Months**	**12 Months**	**Change From Baseline to 30 Days**	**Change From Baseline to 6 Months**	**Change From Baseline to 12 Months**
n	194	191	187	172	190	185	170
Mean ± SD	0.7 ± 0.2	1.0 ± 0.2	0.9 ± 0.2	0.9 ± 0.2	0.3 ± 0.2	0.2 ± 0.2	0.2 ± 0.2
Median	0.7	1.0	1.0	0.9	0.3	0.2	0.2
Min - Max	0.0, 1.8	0.2, 1.7	0.2, 1.7	0.3, 1.5	-1.3, 0.9	-1.4, 0.9	-0.7, 0.8

[a] Based on number of subjects with available data at related time point
N = Intent-To-Treat Population
Note: Site Reported Table

Figure 17. ABI/TBI through 12 Months

There is a large shift in the ABI/TBI cumulative frequency distribution from baseline to 30 days and the shift in distribution was maintained at 12 months.

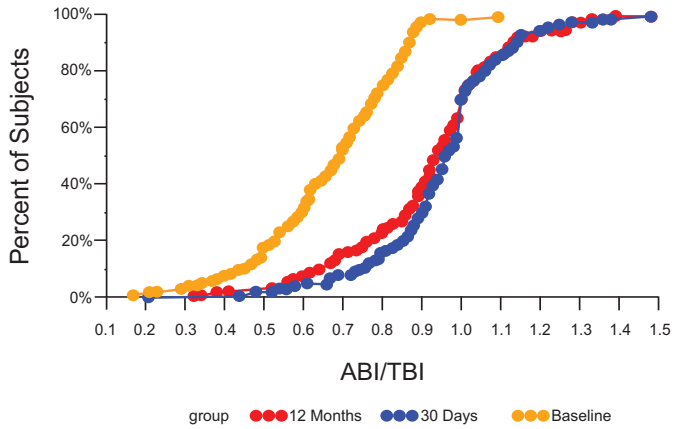


Figure 18. Cumulative Frequency Distribution of ABI/TBI through 12 months

6.8.4. Walking Assessment

To assess the degree of impairment in daily activities, due to claudication, subjects were assessed at pre-procedure (baseline) and again at 30-day, 6 and 12-month follow-up visits. Scores are on a scale from 0% (unable to perform due to severe claudication) to 100% (no impairment). Subjects reported an increase in their walking function from the baseline through the 12-month follow-up visit. On walking assessment measures, impairment improved by 36.8%, distance by 32.4%, speed by 21.8% and stair climbing by 23.3%.

	N = 196			
Walking Assessment[a]	**Baseline**	**30 Days**	**6 Months**	**12 Months**
Walking Impairment (%)				
n	196	193	187	175
Mean ± SD	39.2 ± 31.1	77.1 ± 30.2	74.2 ± 31.5	76.0 ± 31.4
Median	25.0	100.0	100.0	100.0
Min - Max	0.0 - 100.0	0.0 - 100.0	0.0 - 100.0	0.0 - 100.0
Walking Distance (%)				
n	196	189	185	174
Mean ± SD	22.8 ± 26.7	53.3 ± 39.9	56.1 ± 40.5	55.2 ± 39.9
Median	11.7	50.1	57.4	60.1
Min - Max	0.0 - 100.0	0.0 - 100.0	0.0 - 100.0	0.0 - 100.0
Walking Speed (%)				
n	194	186	180	169
Mean ± SD	19.7 ± 21.5	39.7 ± 30.5	39.8 ± 30.3	41.5 ± 31.3
Median	14.1	32.6	35.9	35.9
Min - Max	0.0 - 100.0	0.0 - 100.0	0.0 - 100.0	0.0 - 100.0
Stair Climbing (%)				
n	193	190	185	167
Mean ± SD	33.0 ± 32.6	56.1 ± 39.8	55.5 ± 37.5	56.3 ± 39.1
Median	25.0	62.5	58.3	62.5
Min - Max	0.0 - 100.0	0.0 - 100.0	0.0 - 100.0	0.0 - 100.0

[a] Based on number of lesions with available data
N = Intent-to-Treat Population
Note: Site Reported Table

Figure 19. Walking Assessment

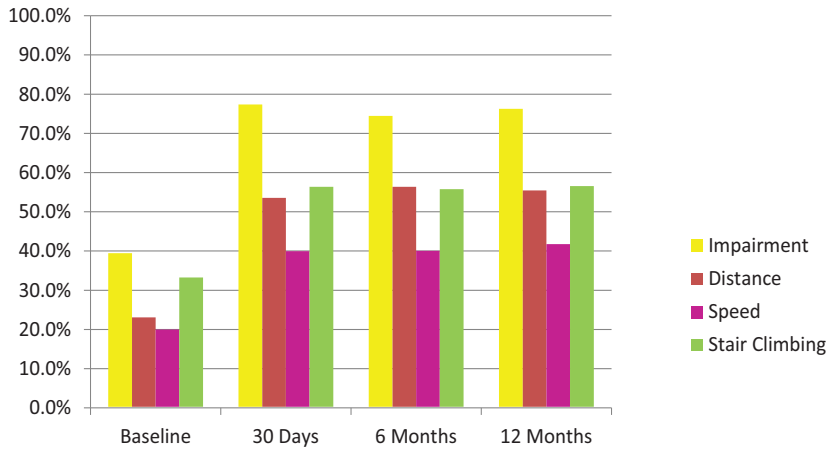


Figure 20. Walking Assessment

6.9. Summary of Adverse Events

An adverse event (AE) is defined as any untoward medical occurrence in a subject. Summary data on system organ class for AEs are summarized (Figure 21). The most common events were related to vascular disorders reported at 44.9%.

System Organ Class	N = 196 Total Adverse Events = 670 Subjects with at Least one Adverse Event = 156 Number of Subjects % (m/n)[a]
BLOOD AND LYMPHATIC SYSTEM DISORDERS	7.1 (14/196)
CARDIAC DISORDERS	19.4 (38/196)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0.5 (1/196)
EAR AND LABYRINTH DISORDERS	1.0 (2/196)
ENDOCRINE DISORDERS	1.0 (2/196)
EYE DISORDERS	1.0 (2/196)
GASTROINTESTINAL DISORDERS	18.4 (36/196)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	20.4 (40/196)
HEPATOBILIARY DISORDERS	2.0 (4/196)
INFECTIONS AND INFESTATIONS	15.3 (30/196)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	18.4 (36/196)
INVESTIGATIONS	4.1 (8/196)
METABOLISM AND NUTRITION DISORDERS	6.1 (12/196)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	24.0 (47/196)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	3.6 (7/196)
NERVOUS SYSTEM DISORDERS	15.3 (30/196)
PSYCHIATRIC DISORDERS	4.1 (8/196)
RENAL AND URINARY DISORDERS	8.2 (16/196)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2.0 (4/196)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	9.7 (19/196)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	6.6 (13/196)
SURGICAL AND MEDICAL PROCEDURES	3.6 (7/196)
VASCULAR DISORDERS	44.9 (88/196)

[a] Percentage based on number of subjects in ITT population
N = Intent-To-Treat Population
Note: Site Reported Table

Figure 21. Adverse Events to 12 months

6.10. Clinical Study Summary

The study design of the Complete SE SFA study is based on a literature search and review of tier-one level data performed by the VIVA Physicians Inc. (VPI) and utilizes the effectiveness performance goal and many of the endpoint assessments established and analyzed by VPI.

The primary safety objective was the rate of Major Adverse Events at 12 months. MAE was defined as device or procedure related death (or any death occurring postprocedure through 30 days), target limb loss, and target lesion or target vessel revascularization. Success of the Complete self-expanding stent system was to be accepted if the 12-Month MAE rate was less than 40%. The 12-Month MAE rate of 11.0% (21/191; 95% CI, 6.9%, 16.3%) with upper 97.5% CI 16.3% was lower than the pre-specified performance goal, thus indicating the study met its primary safety endpoint.

The primary effectiveness objective was to observe primary patency at 12 months defined as *uninterrupted* patency with no procedures performed on or at the margins of the treated segment, with no restenosis ≥ 50% as documented by peak systolic velocity ratio (PSVR) ≥2.0 assessed by duplex ultrasound. The VPI established a performance goal for SFA stenting of 66% or double the expected PTA rate. The primary patency rate at 12 months was 72.6% (127/175; 95% CI, 65.3%, 79.0%). The lower bound of the 97.5% CI for primary patency at 12 months of 65.3% was slightly below the PG of 66%.

A secondary analysis on the ITT population of primary patency using a PSVR cutoff of 2.4 revealed a rate of 74.9% (131/175; 95% CI, 67.8%, 81.1%) and lower bound of the 97.5% CI of 67.8%.

The Complete SE SFA Study evaluated a population with higher rates of diabetes, tobacco use, hypertension, and dyslipidemia when compared to the PTA population as reported by the VPI group. These risk factors have all been associated with higher rates of restenosis in the literature.

7. Patient Selection and Treatment

7.1. Individualization of Treatment

Each Complete SE Vascular Stent System must be ordered in the appropriate size to fit the patient's anatomy and should be oversized at least 0.5 mm larger than the vessel diameter. All lengths and diameters of the stent devices necessary to complete the procedure should be available to the physician, especially when preoperative case planning measurements (treatment diameters/lengths) are not certain. Use of this approach allows for greater intraoperative flexibility to achieve optimal procedural outcomes.

Proper sizing of the device is the responsibility of the physician. Refer to Recommended Device Sizing (Section 10.2). Medtronic may consult with physicians to determine proper stent dimensions based on the physician's assessment of the patient's anatomical measurements. The benefits and risks previously described should be carefully considered for each patient before use of the Complete SE Vascular Stent System.

Note: Due to the nature of the design and the flexibility of the Complete SE Vascular Stent System, the overall length of each stent may be shorter when deployed.

Complete SE stents are appropriate to cover lesion reference vessel diameters in the SFA/PPA ranging from 4 mm to 7 mm and lengths up to 140 mm. Deployed devices should be deployed at least 1 cm distal to the takeoff of the profunda femoris artery and at least 3 cm proximal to the distal cortical margin of the intercondylar femoral epiphysis.

8. Patient Counseling Information

The physician should review the following risks and benefits when counseling the patient about this endovascular device and procedure:

- patient age and life expectancy
- risks and benefits related to open surgical repair
- risks and benefits related to endovascular repair
- risks related to noninterventional treatment or medical management
- possibility that subsequent endovascular or open surgical repair may be required
- the long-term safety and effectiveness of the Complete SE Vascular Stent System has not been established beyond 1 year
- long-term, regular follow-up is needed to assess patient health status and stent performance

Medtronic recommends that the physician disclose to the patient, in written form, all risks associated with treatment using the Complete SE Vascular Stent System. Details regarding risks occurring during and after implantation of the device are provided in Adverse Events (Section 5).

9. How Supplied

9.1. Sterility

Each device is individually contained within a Complete SE System. It is sterilized using electron beam and is supplied sterile for single use only.

- Do not reuse or attempt to resterilize.
- If the device is damaged or the integrity of the sterile barrier has been compromised, do not use the product and contact a Medtronic representative for return information.

9.2. Contents

- one Complete SE Vascular Stent with Over-the-Wire (OTW) Delivery System
- one device implant card (Section 12)

9.3. Storage

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

Note: If the temperature indicator on the pouch has changed from a gray square to a black square, do not use the system.

10. Clinical Use Information

10.1. Physician Training Requirements

Caution: The Complete SE Vascular Stent System should only be used by physicians and medical personnel trained in vascular interventional techniques (including advanced iliac or SFA angioplasty or stenting techniques) and trained on the use of this device.

The following are the skill and knowledge requirements for physicians using the Complete SE Vascular Stent System:

- natural history of Peripheral Artery Disease (PAD), and comorbidities associated with PAD
- radiographic, fluoroscopic, and angiographic image interpretation
- appropriate use of radiographic contrast material
- access and closure techniques
- nonselective and selective guidewire and catheter techniques
- embolization
- angioplasty/POBA intervention
- stenting
- techniques to minimize radiation exposure
- device selection and sizing

10.2. Recommended Device Sizing

Careful stent sizing is important to successful stenting and is the responsibility of the physician. For additional questions about device sizing, refer to the contact information on the back cover of this document.

To achieve optimal sizing and apposition to the vessel wall, using an "interference" fit, a stent should be at least 0.5 mm larger than the vessel diameter. Lesion length should also be considered. When possible, use 1 appropriately sized stent to cover the lesion completely and avoid implanting multiple devices.

Table 1. Stent Foreshortening

Stent Diameter (mm)	Average
5	0%
6	3 to 4%
7	2 to7%
8	4 to 8%

Note: Shorter stents tend to foreshorten more than the longer stents when evaluated as a percent of stent length.

The Complete SE Vascular Stent System is designed to treat atherosclerotic de novo or restenotic lesions up to 140 mm long within reference vessel diameters of the SFA or PPA ranging from 4 mm to 7 mm.

Table 2. Complete SE Vascular Stent System Sizing

Unconstrained Stent Diameter (mm)	Stent Length (mm)	Minimum-Maximum Reference Vessel Diameter (mm)	Minimum Sheath ID (in)
5	20, 40, 60, 80, 100, 120, 150	4.0–4.5	0.084
6		4.0–5.5	
7		5.0–6.5	
8		6.0–7.0	

10.3. Device Inspection

Inspect the device and packaging to verify that no damage or defects exist. If the Use By date has elapsed, the device is damaged, or the sterile barrier has been compromised, do not use the device and contact a Medtronic representative for return or replacement information.

10.4. Additional Recommended Equipment

- additional Complete SE Vascular Stent Systems of various lengths and diameters
- heparinized saline solution
- assorted guidewires of adequate length
- temporary pacemaker
- Atropine
- Phenylephrine HCL

10.5. Magnetic Resonance (MR) Conditions of Use

The Complete SE Vascular Stent is MR Conditional as described in ASTM standard F2503. Patients with this device may be safely imaged in 1.5 T and 3 T whole-body-cylindrical MR systems using the body transmit coil under the following conditions:

- spatial gradient magnetic field of ≤3000 gauss/cm (30 T/m)
- whole body specific absorption rate (SAR) of 2 W/kg (landmark above umbilicus) or 1 W/kg (landmark below umbilicus)
- MR system in normal operating mode
- legs of patient are not in direct skin contact
- MR local transmit and receive coils are not placed directly above the implant

Note: Other implants or the patient's condition may require reduction of these limits.

Nonclinical testing of heating of the stent by the MRI Radio-Frequency Magnetic Field was measured in a phantom at 64 MHz (1.5 T) and 128 MHz (3 T) in accordance with ASTM F2182. At 64 MHz, the heating tests were made in a 1.5 T whole-body coil (GE Signa). At 128 MHz, the heating tests were made in a 3 T MR system (GE Signa HDx).

Based on the measured nonclinical temperature rises of the SAR distribution in the patient during MRI, the estimated maximum in-vivo temperature rise was determined to be <5°C for a maximum whole body specific absorption rate (SAR) of 2 W/kg (landmark above umbilicus) or 1 W/kg (landmark below umbilicus). The calculation of this rise did not incorporate the cooling effects of blood flow inside the stent and in the vascular bed outside the stent.

The magnetic force was measured in a 3 T MR system (GE Signa HDx). The maximal force was measured to be <4% of the stent weight with a static field of 1.43 T and a magnetic gradient of 4.7 T/m at the test location. Magnetic torque was not detected. Patients will not be at added risk from magnetic force and torque exerted on the frame during MRI.

Image artifact or distortion was measured in a 3 T MR system (GE Signa HDx). For the spin echo sequence, the lumen was slightly darkened and the distortion extended as much as 8 mm beyond the stent device. For gradient echo images, the lumen was obscured and the distortion extended as much as 6 mm beyond the stent device. Based on testing results, it may be necessary to optimize MR imaging parameters for the presence of a Complete SE device.

11. Implant Instructions

11.1. Preparation

The delivery system has a working length of 80 cm or 130 cm and is compatible with 0.035 in guidewires. Refer to Recommended Device Sizing (Section 10.2) for guiding catheter or sheath compatibility. Correct sizing must be determined before the procedure and additional Complete SE Vascular Stent Systems should be available in the case of system failure.

11.1.1. Patient Preparation

1. Under local anesthesia, prepare the femoral vascular access site according to standard PTA procedures.
2. If not already done, perform baseline angiograms of the superficial femoral/proximal popliteal arteries in the views that optimize visualization of artery to be treated.
3. At the discretion of the treating physician, predilatation of the lesion can be performed using standard PTA techniques.

Note: Administration of anticoagulant therapy pre- and post- procedure in accordance with standard industry practice is recommended and left to the discretion of the treating physician.

Note: Temporary pacemaker, atropine, and phenylephrine HCL should be available in case of bradycardia or asystole arising from effects of the procedure.

11.1.2. System Preparation

1. Check the Use By date on the package. Do not use this product if the device has expired.
2. Inspect the sterile package before opening. Do not use this product if any defects are noted.
3. Check the temperature indicator on the pouch. Do not use this product if the temperature indicator has changed from a gray square to a black square.
4. Using sterile technique, remove the Complete SE Vascular Stent System from the packaging and visually inspect the device to verify that the stent has not been inadvertently deployed. Stent segments should not be visible outside the catheter.

Note: Do not remove the red safety lock tab (Figure 22) on the system until the stent is positioned across the target lesion.

11.2. Procedure

11.2.1. Deliver

1. Flush the inner lumen with heparinized saline immediately before use. Do not use the delivery system if the saline flush is not observed exiting at the distal end of the catheter.
2. Insert the delivery system through the hemostatic valve adapter.
3. Carefully tighten the hemostatic valve adapter over the catheter outer member and ensure that the hemostatic valve adapter does not clamp down tightly on the outer sheath and impede its movement.

   Caution: Do not overtighten the hemostatic valve adapter.
4. After obtaining a road map image, advance the delivery catheter over the immobilized guidewire.

   Warning: Maintain the delivery system parallel to the patient and as straight as possible during the procedure to prevent delivery system catheter kinking.
5. Using fluoroscopy, advance and position the stent across the lesion using distal and proximal marker bands and overall device radiopacity to visualize the correct placement.

11.2.2. Deploy

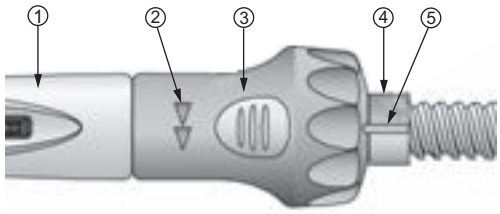


Figure 22. Complete SE Vascular Stent System Deployment Handle Detail

1. Front handle
2. Deployment directional arrows
3. Deployment button
4. Safety lock
5. Safety lock tab

Warning: Do not deploy the stent if it is not optimal or appropriate for the vessel. The stent cannot be repositioned once the stent has begun to appose the vessel wall.

1. Remove the stent release mechanism on the delivery handle by releasing the red safety lock.
   a. With 1 hand on the front handle, hold the delivery system stationary.
   b. With the other hand, push the safety lock tab to the side with the thumb.
   c. Once the safety lock tab is removed, verify proper position of the stent.
2. Deploy the stent.
   a. Rotate the deployment rotation/slider mechanism in the direction of the deployment arrows.

   Note: Keep the stent delivery catheter stationary during deployment. Do not hold the outer sheath of the delivery catheter during deployment as it must be free to move.
   b. Deploy 2 to 3 segments until the device is apposed to the vessel wall.

   Note: Once deployment is initiated, the stent cannot be recovered by the sheath. If unable to initiate stent release, remove the entire system from the patient and advance a new, previously unopened stent delivery system (starting with Section 11.1.2).

   Note: In the event of partial delivery of the stent, remove the entire delivery system from the patient. This may result in damage to the vessel wall requiring surgical intervention.
   c. Either continue to rotate the slider mechanism or, while holding the front grip of the delivery system stationary, squeeze the 2 deployment buttons and pull the slider back until the stent is completely deployed.

   Note: It may be necessary to use the slider buttons to complete the deployment.
3. Under fluoroscopy, confirm that the stent has been deployed at the target lesion and is fully expanded.
4. In the event the self-expanding stent does not cover or partially covers the lesion, remove the system and then repeat steps, beginning at System Preparation (Section 11.1.2), to use an additional Complete SE Vascular Stent to adequately treat the lesion.

11.2.3. Remove

1. Leave the sheath and guidewire in place.
2. Continue to hold the delivery system stationary with 1 hand on the front grip and the other hand on the slider mechanism, slowly remove the delivery catheter from the patient.
3. Discard the delivery system.
4. If additional stent-to-wall apposition is desired, postdilatation may be performed. If it is not needed, skip to next step.
   a. Choose a balloon catheter (packaged separately) matched to the diameter of the vessel and no larger than the expanded stent diameter.
   b. Dilate as needed and in accordance with the compliance chart accompanying the selected balloon catheter.

      Caution: Care must be exercised when crossing a newly deployed stent with other interventional devices to avoid disrupting the stent geometry and placement of the stent.
   c. Prior to completion of the procedure, view placement through fluoroscopy to ensure proper positioning of the deployed self-expanding stent.
5. Remove the guidewire.
6. Suspension of anticoagulant therapy postprocedure and removal of the introducer sheath should be performed per institutional protocol.
7. Seal the access site puncture per institutional protocol.

11.3. Postprocedure

1. Observation of the patient and fluoroscopy evaluation of the stent site should be performed periodically within the first 30 minutes after stent placement.
2. Physician experience and discretion will determine the appropriate postprocedure observation and drug regimen for each patient.
3. Subsequent restenosis may require repeat dilatation of the vessel containing the stent. Crossing a stent with an adjunct device must be performed with caution.
4. In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.

12. Patient Information

The Complete SE Vascular Stent System is packaged with a device implant card that includes both patient and stent information. Physicians should complete this card and instruct the patient to keep it in their possession at all times. The patients should refer to this card anytime they visit additional health practitioners, particularly for additional diagnostic procedures (eg, MRI).

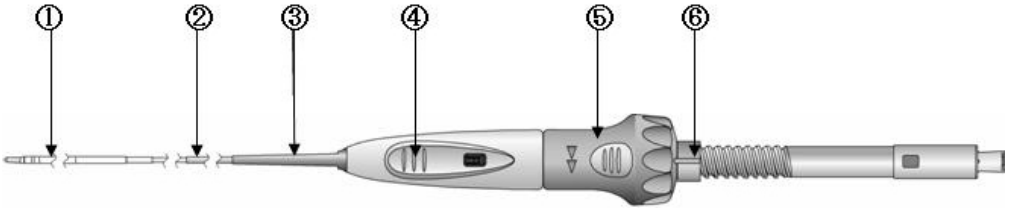
Complete® SE

Vascular Stent System - Iliac

TABLE OF CONTENTS

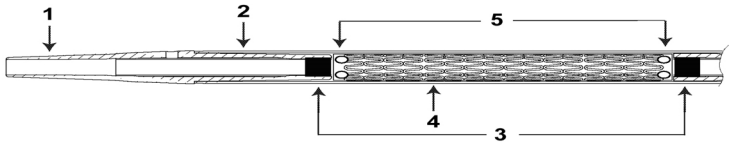
1.0. DEVICE DESCRIPTION

The Complete® SE Vascular Stent System is intended to deliver a self-expanding stent to the iliac arteries via a sheathed delivery system. The self-expanding stent is constructed of a nickel titanium alloy (nitinol), and is compressed and loaded into the delivery system. The Complete SE Vascular Stent System (Figures 1 and 2) includes a pre-loaded self-expanding nickel-titanium alloy (nitinol) stent with eight tantalum radiopaque markers (four on each end) (Figure 3) and an over-the-wire retractable sheath delivery system. The stent is delivered to the intended lesion site and then expanded by retraction of a protective sheath and remains as a permanent vessel scaffolding implant. Upon deployment, the stent imparts an outward radial force on the arterial lumen to establish patency.



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

Figure 1. The Complete SE Vascular Stent Delivery System



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

Figure 2. Complete SE Vascular Stent Detail

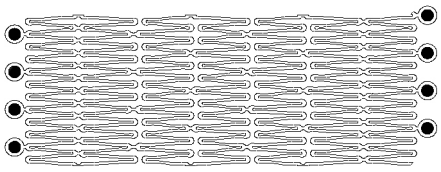


Figure 3. Complete SE Vascular Stent with Tantalum Markers

The stents are available in diameters of 6.0mm-10.0mm and lengths of 20mm-120mm (see Table 1).

Table 1. Complete SE Vascular Stent System Information

Unconstrained Stent Diameter (mm)	Stent Length (mm)	Minimum- Maximum Reference Vessel Diameter (mm)	Minimum Sheath I.D. (in)
6.0	20, 40, 60, 80, 100, 120	4.5- 5.5	0.087”
7.0	20, 40, 60, 80, 100, 120	5.6- 6.5	0.087”
8.0	20, 40, 60, 80, 100, 120	6.6- 7.5	0.087”

Table 1. Complete SE Vascular Stent System Information

Unconstrained Stent Diameter (mm)	Stent Length (mm)	Minimum- Maximum Reference Vessel Diameter (mm)	Minimum Sheath I.D. (in)
9.0	20, 40, 60, 80	7.6- 8.5	0.087”
10.0	20, 40, 60, 80	8.6- 9.5	0.087”

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. Radiopaque marker bands are located on both the distal and proximal sides of the self-expanding stent for correct anatomical placement (see Figures 2 and 3).

2.0. 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 110 mm.. The stent is intended as a permanent implant.

3.0. CONTRAINDICATIONS

There are no known contraindications.

4.0. WARNINGS

- The Complete SE Vascular Stent System is provided sterile for one procedure only. Do not re-sterilize. Use prior to the “Use By” date noted on the package.
- Use of the Complete SE Vascular Stent System requires advanced iliac angioplasty technical skills. The following instructions provide technical guidance but do not obviate the need for adequate training prior to use of the device.
- Do not use if the temperature indicator found on the inner pouch is changed from a gray square to a black square as this indicates the unconstrained stent diameter and stent release may be compromised.
- Persons with known hypersensitivities to nitinol and or its components (e.g. nickel, titanium) may suffer an allergic reaction to the Complete SE Vascular Stent.
- Maintain the delivery system parallel to the patient and as straight as possible during the procedure to prevent delivery system catheter kinking.
- Do not deploy the stent if it is not optimal or appropriate for the vessel. The stent cannot be repositioned once deployed.
- Care should be taken when stenting near a bifurcation, aneurysm or bypass graft.
- Prior to stent deployment, utilize fluoroscopy to verify the stent has not been damaged or dislodged during positioning.
- If unable to initiate stent release, remove the entire system from the patient and advance a new, previously unopened stent delivery system.
- Once deployment is initiated, the stent cannot be recovered by the sheath. In the event of partial delivery of the stent, remove the entire delivery system from the patient. This may result in damage to the vessel wall requiring surgical intervention.
- Prior to completion of the procedure, utilize fluoroscopy to ensure proper positioning of the deployed stent. If the target lesion is not completely stented, use additional Complete SE Vascular Stents as necessary to adequately treat the lesion.

5.0. PRECAUTIONS

- The Complete SE Vascular Stent System is intended for use by physicians familiar with iliac stenting techniques and the risks associated with stenting.
- Thrombogenicity evaluations were conducted using a heparinized model. If your patient cannot be adequately anticoagulated, it is unknown whether thrombus formation may occur with this product.
- The use of overlapping stents with the Complete SE Vascular Stent System has not been formally evaluated in a clinical trial.
- Caution must be taken when crossing the stented area with ancillary equipment to avoid dislodgment of the stent.

6.0. SYSTEM HANDLING AND STENT PLACEMENT PRECAUTIONS

6.1. Careful stent sizing is important, see Table 1 for available diameters and lengths.

6.2. In order to achieve optimum sizing as well as apposition of the stent to the vessel wall, using an “interference” fit, a stent should be selected at least 0.5 mm greater in diameter than the vessel. For example, a 6.0 mm stent should be selected to treat a 4.5-5.5 mm diameter vessel; a 7.0 mm stent should be selected to treat a 5.6-6.5 mm diameter vessel. Consideration should also be given to the length of the lesion to be treated when selecting the stent length.

6.3. In-vitro modeling has predicted the Complete SE Vascular Stent foreshortens between 3% (for 6 mm diameter stents) and 7% (for 10 mm diameter stents).

6.4. The delivery system has a working length of either 80cm or 130cm and is compatible with 0.035” guidewires. See Table 1 for guiding catheter or sheath compatibility.

6.5. Store in a cool, dry, dark place.

6.6. Check the expiration date on the package. DO NOT use if the device has expired.

6.7. Inspect the sterile package before opening. DO NOT use if any defects are noted.

6.8. Check the temperature indicator on the pouch. DO NOT use if the temperature indicator has changed from a gray square to a black square.

6.9. This product is designed for single use only. DO NOT re-use or re-sterilize.

7.0. POST-IMPLANT PRECAUTIONS

- Temporary pacemaker, atropine, and phenylephrine HCL should be available in case of bradycardia or asystole arising from effects of the procedure.
- Use caution if crossing a deployed stent with adjunctive devices.

8.0. SUMMARY OF 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 in the United States and established 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 was a confirmatory study conducted inside the United States. NOTE: The Complete SE Vascular Stent System reflects slight modifications to both the stent and delivery systems. 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. The modifications to the stent system were studied in the Complete SE Iliac Registry trial.

ILIAC STENTING IN STENOTIC LESIONS WITH THE BRIDGE SE SELF-EXPANDING STENT DELIVERY SYSTEM REGISTRY (ISIS-SE)

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.

Patient Population

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 2 and baseline target lesion characteristics in Table 3.

Table 2. 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.

Methods

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 followup 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.

Table 3. 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)

Table 3. Baseline Target Lesion Characteristics (ITT Population)

Parameter / Statistic	Result
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.

Results

Safety

The primary safety endpoint was the major adverse clinical events (MACE), defined as periprocedure 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 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: $P_t > 21\%$

HA: $Pt \leq 21\%$

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.

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 4. MACEs Through 12 Months: Adjudicated Events (ITT Population)

Event	Statistic n/N (%)[1]
Any MACE	5/150 (3.3%)
Death due to:	
Bleeding	0/150 (0.0%)
Vascular repair	0/150 (0.0%)
Transfusion reaction	0/150 (0.0%)
Bypass surgery	0/150 (0.0%)
Any death within 30 Days	0/150 (0.0%)

Table 4. MACEs Through 12 Months: Adjudicated Events (ITT Population)

Event	Statistic n/N (%)[1]
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.

Efficacy

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 α = 0.05, compared to a performance goal for iliac stenting derived from historical literature:

H0: Pt > 18.5%

HA: Pt ≤ 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 procedural success (all of which required a residual stenosis of <30%) was 86.6% among subjects in the ITT population. See Table 5 for the individual device, lesion, and procedure success rates.

Additionally, acute clinical success as defined by device, lesion and procedural success (all of which required a residual stenosis of <30%) was 86.6% among subjects in the ITT population. See Table 5 for the individual device, lesion, and procedure success rates.

Table 5. 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).

Summary of Adverse Events

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).

Table 6. 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%)

Table 6. Adverse Events Through 12 Months (ITT Population)

System Organ Class	Number of Patients n (n/N %)[1]
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).

The Medtronic Bridge SE Stent Delivery System was well tolerated among patients with symptomatic ischemic peripheral vascular disease due to iliac stenosis. Furthermore, the safety profile of the study device seen in this study was consistent with that reported in other clinical studies or registries of iliac stent systems.

THE COMPLETE SE ILIAC REGISTRY

The Complete SE Iliac Registry is ongoing; however, the primary endpoint for the 50 subject data was safety at 30 day as measured by the occurrence of major adverse events (MAE) defined as any death, target limb loss or clinically-driven TLR/TVR (target lesion revascularization/target vessel revascularization) with percutaneous transluminal angioplasty or aorto-iliac bypass graft for all subjects enrolled. Fifty-eight stents were delivered without complication in the first 50 subjects. No MAEs were reported through 30 days of follow-up.

The data for the first 50 subjects through 30 days of follow-up enrolled at 12 sites in the US are presented below.

Patient Population

Patients 18 years of age and older with symptomatic ischemic peripheral vascular disease having a stenotic lesion of ≥50% in the common or external iliac arteries or asymptomatic patients having a stenotic lesion of ≥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 7. Subject Demographic, Medical History and Risk Factors (ITT Population)

	ITT = 55
Age (year)[a]	
Mean ± SD (n)	66 ± 12 (55)
Median	68
Min - Max	43 - 89
Sex	
Male % (m/n)	60.0% (33/55)
Female % (m/n)	40.0% (22/55)
Medical History and Risk Factors[b]	
Diabetes Mellitus % (m/n)	32.7% (18/55)
Type I % (m/n)	1.8% (1/55)
Type II % (m/n)	27.3% (15/55)
Unknown % (m/n)	3.6% (2/55)
Dyslipidemia % (m/n)	85.5% (47/55)
Hypertension % (m/n)	90.9% (50/55)
Cigarette Smoking % (m/n)	85.5% (47/55)
Currently Smoking Cigarettes % (m/n)	45.5% (25/55)
History of Stroke or TIA % (m/n)	15.7% (8/51)
History of Coronary Artery Disease % (m/n)	70.4% (38/54)
Previous MI % (m/n)	42.4% (14/33)
Previous Peripheral Vascular Disease (other than iliac) % (m/n)	74.1% (40/54)
Previous PTA/Stenting to Target Limb % (m/n)	16.4% (9/55)

Table 7. Subject Demographic, Medical History and Risk Factors (ITT Population)

	ITT = 55
Previous Aorta/Peripheral Bypass to Target Limb % (m/n)	3.6% (2/55)

[a] Based on number of subjects with available data

[b] Percentage based on number of subjects with available data

Note: Different denominators are due to missing data

Methods

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 ±5 days. Ischemic testing, duplex scans, ABI, toe brachial index (TBI), or PVR measurements, and walking assessment 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.

Table 8. Angiographic Morphology Data (ITT Population)

Lesion Characteristic	ITT = 55 Lesions = 61 % (m/n)[a]
Pre Procedure Assessment	
Lesion Pre Procedure Percent Stenosis (most severe)	
Mean ± SD (n)	72.4 ± 14.6 (61)
Median	67.9
Min – Max	51.3 - 100.0
Subjects with Single Limb Stenting	89.1% (49/55)
Subjects with Bilateral Limb Stenting	10.9% (6/55)
Eccentric	24.6% (15/61)
Ulceration	0.0% (0/61)
Calcification	
None/mild	67.2% (41/61)
Moderate	19.7% (12/61)
Severe	13.1% (8/61)
Thrombus	0.0% (0/61)
Post Procedure Assessment	
Dissection Grade	
0 (no dissection)	95.1% (58/61)
A	0.0% (0/61)
B	3.3% (2/61)
C	1.6% (1/61)
D	0.0% (0/61)
E	0.0% (0/61)
F	0.0% (0/61)

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

Results

There were no MAEs in the first 50 subjects followed from enrollment through the 30-Day follow-up visit.

Table 9. Primary Endpoint and Details of Major Adverse Events through 30 Days

		ITT = 55
Major Adverse Events	**% (m/n)[a]**	**Exact 95% CI**
Any Major Adverse Event	0.0% (0/55)	(0.0%, 6.5%)
Any Death	0.0% (0/55)	(0.0%, 6.5%)

Table 9. Primary Endpoint and Details of Major Adverse Events through 30 Days

		ITT = 55
Major Adverse Events	**% (m/n)[a]**	**Exact 95% CI**
Target Limb Loss	0.0% (0/55)	(0.0%, 6.5%)
Target Lesion Revascularization (TLR)	0.0% (0/55)	(0.0%, 6.5%)
TLR by Percutaneous Transluminal Angioplasty (PTA)	0.0% (0/55)	(0.0%, 6.5%)
TLR by Iliac Bypass Graft	0.0% (0/55)	(0.0%, 6.5%)
Target Vessel Revascularization (TVR)	0.0% (0/55)	(0.0%, 6.5%)
TVR by PTA	0.0% (0/55)	(0.0%, 6.5%)
TVR by Iliac Bypass Graft	0.0% (0/55)	(0.0%, 6.5%)

[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

Table 10. Major Adverse Events and Primary Patency through 9 Months

	ITT = 55 Lesions - 61	
Primary Safety Endpoint	**% (m/n)[a]**	**Exact 95% CI**
Any Major Adverse Event	5.9% (3/51)	(1.2%, 16.2%)
Any Death within 30-Day	0.0% (0/55)	(0.0%, 6.5%)
Peri-Procedural Death from 31 to 270 days	0.0% (0/51)	(0.0%, 7.0%)
Target Limb Loss	0.0% (0/51)	(0.0%, 7.0%)
Target Lesion Revascularization (TLR)	3.9% (2/51)	(0.5%, 13.5%)
TLR by Percutaneous Transluminal Angioplasty (PTA)	3.9% (2/51)	(0.5%, 13.5%)
TLR by Iliac Bypass Graft	0.0% (0/51)	(0.0%, 7.0%)
Target Vessel Revascularization (TVR)	5.9% (3/51)	(1.2%, 16.2%)
TVR by PTA	5.9% (3/51)	(1.2%, 16.2%)
TVR by Iliac Bypass Graft	0.0% (0/51)	(0.0%, 7.0%)
Primary Efficacy Endpoint		
Primary Patency Rate	100.0% (53/53)	(93.3%, 100.0%)

[a] MAE percentage is based on the number of evaluable subjects and primary patency rate percentage is based on the number of lesions implanted with available data

In addition, the results for secondary endpoints of acute, clinical and hemodynamic success through 9 months are 87.3%, 88.5%, and 94.3% respectively.

Table 11. Secondary Endpoints (ITT Population)

	ITT = 55 Lesions as Site Reported = 61	
Secondary Endpoints	**% (m/n)[a]**	**Exact 95% CI**
Acute Success[b]	87.3% (48/55)	(75.5%, 94.7%)
Clinical Success at 9-Month[c]	88.5% (46/52)	(76.6%, 95.6%)
Hemodynamic Success at 9-Month[d]	94.3% (50/53)	(84.3%, 98.8%)

[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

Summary of Adverse Events

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 12. Adverse Events through 9 Months

	ITT = 55 Total Adverse Events = 128 Subjects with at Least one Adverse Event =32
System Organ Class	**Number of Subjects % (m/n)[a]**
Blood and Lymphatic System Disorders	5.5% (3/55)
Cardiac Disorders	18.2% (10/55)
Endocrine Disorders	1.8% (1/55)
Gastrointestinal Disorders	10.9% (6/55)
General Disorders and Administration Site Conditions	7.3% (4/55)
Hepatobiliary Disorders	1.8% (1/55)
Infections and Infestations	10.9% (6/55)
Injury, Poisoning and Procedural Complications	5.5% (3/55)
Investigations	1.8% (1/55)
Metabolism and Nutrition Disorders	1.8% (1/55)
Musculoskeletal and Connective Tissue Disorders	23.6% (13/55)
Neoplasms Benign, Malignant and Unspecified (including cysts and polyps)	3.6% (2/55)
Nervous System Disorders	7.3% (4/55)
Psychiatric Disorders	1.8% (1/55)
Renal and Urinary Disorders	5.5% (3/55)
Reproductive System and Breast Disorders	1.8% (1/55)
Respiratory, Thoracic and Mediastinal Disorders	7.3% (4/55)
Skin and Subcutaneous Tissue Disorders	9.1% (5/55)
Vascular Disorders	36.4% (20/55)

[a] Percentage is based on the total number of subjects in the ITT population.

Note: Site Reported Table

ITT Population = 55

Overall, the data demonstrated an acceptable safety and efficacy profile for the Complete SE Vascular Stent System. There have been no major adverse events (MAE) (death, target limb loss or clinically-driven TLR/TVR) through 30 days. There have been three MAEs reported through 9 months (270 days) resulting in a 5.9% (3/51) event rate confirmed by the CEC. Three subjects were reported as having clinically-driven TVR/TLR (subject 42-003 TVR at 177 days; subjects 40-003 and 44-202 TLR at days 228 and 142 respectively). Of the 53 target lesion segments evaluated at the 9-month follow-up time point all were found to be patent per analyses received from the Duplex Ultrasound Core Laboratory. These data indicate a 100.0% (53/53) primary patency rate for lesions treated with stent lengths including 120mm[1].

9.0. POTENTIAL COMPLICATIONS

The following complications may be associated with the use of iliac stenting devices or iliac angioplasty:

- 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

[1] One longer lesion subject was treated with an additional non-study stent.

- 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

10.0. DIRECTIONS FOR USE

10.1. Preparation of Stent Delivery System

The delivery system has a working length of either 80cm or 130cm and is compatible with 0.035” guidewires. See Table 1 for guiding catheter or sheath compatibility.

10.1.1. Check the expiration date on the package. **Do not use if the device has expired.**

10.1.2. Inspect the sterile package before opening. **Do not use if any defects are noted.**

10.1.3. Check the temperature indicator on the pouch. **Do not use if the temperature indicator has changed from a gray square to a black square.**

10.1.4. Visually inspect the device.

10.2. Patient Preparation

10.2.1. Administration of anticoagulant therapy pre- and post-procedure in accordance with standard industry practice is recommended and left to the discretion of the treating physician.

10.2.2. Temporary pacemaker, atropine, and phenylephrine HCL should be available in case of bradycardia or asystole arising from effects of the procedure.

10.3. Deployment Procedure

10.3.1. Under local anesthesia, prepare the vascular access site according to standard PTA procedures.

10.3.2. If not already done, perform baseline angiograms of both iliac arteries in the views that optimize visualization of artery to be treated.

10.3.3. At the discretion of the treating physician, pre-dilatation of the lesion can be performed using standard PTA techniques.

10.3.4. Using sterile technique, remove the Complete SE Vascular Stent System from packaging and inspect the distal end of the catheter to verify that stent has not been inadvertently deployed. No stent segments should be visible outside the catheter.

NOTE: Do not remove the red safety lock (Figure 4-4 below) on the system until the stent is positioned across the target lesion.

10.3.5. Flush the inner lumen with heparinized saline immediately before use. Do not use the delivery system if the saline flush is not observed exiting at the distal end of the catheter.

10.3.6. Insert the delivery system through the hemostatic valve adapter.

10.3.7. Carefully tighten the hemostatic valve adapter over the catheter outer member and ensure that the hemostatic valve adapter does not clamp down tightly on the outer sheath and impede its movement.

CAUTION: Do not over-tighten the hemostatic valve adapter.

10.3.8. After obtaining a road map image, advance the delivery catheter over the immobilized guidewire.

10.3.9. Maintain the delivery system parallel to the patient and as straight as possible during the procedure to prevent delivery system catheter kinking.

10.3.10. Using fluoroscopy, advance and position the stent across the lesion using distal and proximal marker bands and overall device radiopacity to visualize the correct placement.

10.3.11. Do not deploy the stent if it is not optimal or appropriate for the vessel. The stent cannot be repositioned once deployed.

10.3.12. Referring to Figure 4, remove the stent release mechanism on the delivery handle by releasing the red safety lock (Figure 4-4). Remove the red safety lock by firmly holding the handle (Figure 4-1) while pushing the safety lock tab (Figure 4-5) to one side with the thumb. Once the safety lock tab is removed (Figure 4-4), recheck for proper position of the stent. Deployment is initiated by rotating the deployment rotation/slider mechanism in the direction of the arrows (Figure 4-2). After the first two or three segments are deployed and apposed to the vessel wall, the stent can be fully deployed by simultaneously squeezing the two deployments buttons (Figure 4-3) and gently pulling the release mechanism towards the end of the handle.

10.3.13. If unable to initiate stent release, remove the entire system from the patient and advance a new, previously unopened stent delivery system.

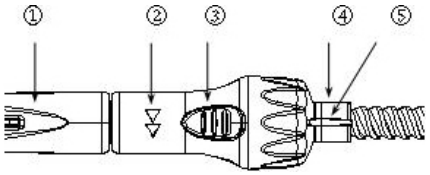


Figure 4. COMPLETE SE Vascular Stent System Deployment Handle Detail

NOTE: Keep the stent delivery catheter stationary during deployment. Do not hold the outer sheath of the delivery catheter during deployment as it must be free to move.

NOTE: Once deployment is initiated, the stent cannot be recovered by the sheath. If unable to initiate stent release, remove the entire system from the patient and advance a new, previously unopened stent delivery system.

NOTE: In the event of partial delivery of the stent, remove the entire delivery system from the patient. This may result in damage to the vessel wall requiring surgical intervention.

10.3.14. Under fluoroscopy, confirm that the stent has been deployed at the target lesion and is fully expanded.

10.3.15. In the event the self-expanding stent does not cover or partially covers the lesion, use an additional Complete SE Vascular Stent to adequately treat the lesion.

10.4. Device Removal Procedure

10.4.1. Leaving the guidewire in place, slowly remove the delivery catheter from the patient and discard the delivery system.

10.4.2. If additional stent-to-wall apposition is desired post-dilatation may be performed. Choose a balloon catheter matched to the diameter of the vessel and no larger than the expanded stent diameter. Dilate as needed in accordance with the compliance chart accompanying the selected balloon catheter.

10.4.3. Care must be exercised when crossing a newly deployed stent with other interventional devices to avoid disrupting the stent geometry and placement of the stent.

10.4.4. Prior to completion of the procedure, view placement through fluoroscopy to ensure proper positioning of the deployed self-expanding stent.

10.4.5. Suspension of anticoagulant therapy post-procedure and removal of the introducer sheath should be performed per institutional protocol.

10.4.6. Seal the access site puncture per institutional protocol.

10.5. Post Stent Placement

10.5.1. Observation of the patient and fluoroscopy evaluation of the stent site should be performed periodically within the first 30 minutes after stent placement.

10.5.2. Physician experience and discretion will determine the appropriate post-procedure observation and drug regimen for each patient.

10.5.3. Subsequent restenosis may require repeat dilatation of the vessel containing the stent. Crossing a stent with an adjunct device must be performed with caution.

10.5.4. In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.

11.0. PATIENT INFORMATION

In addition to these Instructions for Use, the Complete SE Vascular Stent System is packaged with a Patient Implant Card for the patient that contains specific information about the Complete SE Vascular Stent. All patients should keep this card in their possession at all times for the procedure/ stent identification.

12.0. MRI COMPATIBILITY

Non-clinical testing has demonstrated the Complete SE Vascular Stent is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 and 3 Tesla
- Spatial gradient magnetic field of 720-Gauss/cm or less
- Maximum whole body averaged specific absorption rate (SAR) of 3.7 W/kg and 3.0 W/kg or less at 1.5 Tesla and 3 Tesla respectively, for 15 minutes of scanning

MRI-Related Temperature Rise
1.5-Tesla: In non-clinical testing, the Complete SE Vascular Stent produced a maximum temperature rise of 1.4 ºC at a maximum whole body averaged specific absorption rate (SAR) of 3.7 W/kg, as assessed by calorimetry (calorimetry value of 1.54-W/kg) for 15 minutes of MR scanning in a 1.5-Tesla (1.5-Tesla/64-MHz, Magnetom, Siemens Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MR 2002B DHHS) MR scanner. The effect of heating in the MRI environment for overlapping stents or stents with fractured struts is not known.
3-Tesla: In non-clinical testing, the Complete SE Vascular Stent produced a maximum temperature rise of 1.8 ºC at a maximum whole body averaged specific absorption rate (SAR) of 3.0 W/kg, as assessed by calorimetry (calorimetry value of 2.8-W/kg) for 15 minutes of MR scanning in a 3.0-Tesla (3-Tesla/128-MHz, Excite, Software G3.0- 052B, General Electric Healthcare, Milwaukee, WI) MR scanner. The effect of heating in the MRI environment for overlapping stents or stents with fractured struts is not known.

Image Artifact

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Complete SE Vascular Stent. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.

13.0. HOW SUPPLIED

Contents: One (1) sterile Complete SE Vascular Stent with Over-the-Wire (OTW) Delivery System.

Sterile: This device is sterilized with electron beam radiation. Non-pyrogenic.

Storage: Store in a dry, dark, cool place.

Disclaimer of Warranty

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