Cordis®
A Cardinal Health company

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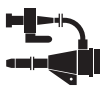
Instructions for Use

Cordis **S.M.A.R.T.® CONTROL®** Vascular Stent System **(6F, 20–100mm stents)**

Cordis **S.M.A.R.T.®** Vascular Stent System **(6F, 120–150mm stents)**

Explanation of symbols on labels and packaging:

	**Lot number**
	**Catalogue number**
	**Do not re-use**
	**Do not resterilize**
	**Use-by date**
	**Keep away from sunlight**
	**Keep dry**
	**Do not use if package is damaged**
	**Sterilized using ethylene oxide**
	**Non-Pyrogenic**
	**Caution**
	**Consult instructions for use**
	**Manufacturer**
	**Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.**
	**MR Conditional**
	**n units per box**
	**Recommended Sheath Size**

STERILE. The Cordis S.M.A.R.T.® CONTROL® / S.M.A.R.T.® Vascular Stent System is provided STERILE. Sterilized with ethylene oxide gas. Nonpyrogenic. Radiopaque. For one use only. Do not resterilize and/or reuse the device.
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

I. DEVICE NAME

The device brand name is the Cordis **S.M.A.R.T.® CONTROL® / S.M.A.R.T.®** Vascular Stent System.

II. DESCRIPTION

This section contains the following sub-sections:
1) Description: Cordis **S.M.A.R.T.® CONTROL®** Vascular Stent System
2) Description: Cordis **S.M.A.R.T.®** Vascular Stent System
3) Available Product Sizes and Catalog Numbers

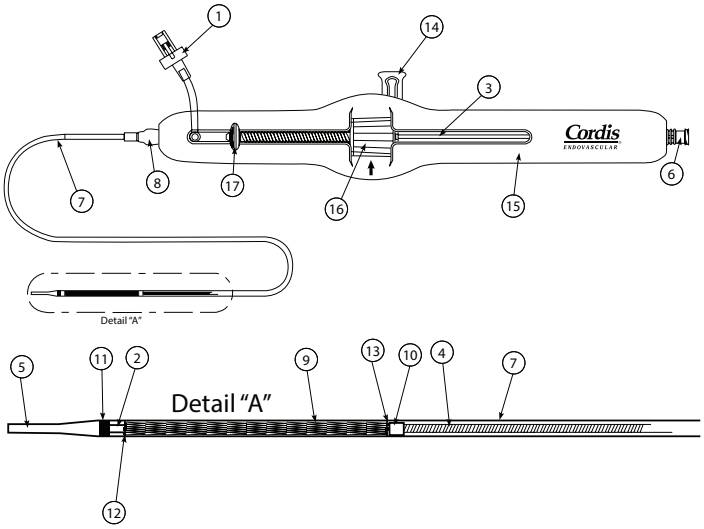
1. DESCRIPTION: Cordis S.M.A.R.T.® CONTROL® Vascular Stent System

The Cordis **S.M.A.R.T.® CONTROL®** Vascular Stent System is designed to deliver a self-expanding stent to the superficial femoral arteries and/or proximal popliteal arteries via a 6F (2.0 mm) sheathed delivery system. The self-expanding stent is composed of a nickel titanium alloy (nitinol). A total of 12 (6 at each end) tantalum radiopaque markers are located on the ends of the stent. The stent is a flexible, fine mesh tubular prosthesis that expands upon deployment to appose the vessel wall. Upon deployment, the stent imparts an outward radial force on the luminal surface of the vessel to establish patency.

Figures 1 – 4 show and describe the Cordis **S.M.A.R.T.® CONTROL®** Vascular Stent System; the numbers in parentheses in the section below refer to the numbers in **Figure 1**.

The 6F (2.0 mm) outer sheath (7) connects proximally to the flushing valve (1) via a Luer hub (8). The self-expanding stent (9) is constrained within the space between the polymeric tube (2) and the outer sheath (7). This space is flushed prior to the procedure by injecting fluid via the flushing valve (1). Stent movement during sheath retraction is restricted by an inner shaft stent stop (10) connected to the inner shaft. The outer sheath has a radiopaque marker (11) at its distal end. Stent positioning about the target lesion is achieved prior to deployment utilizing the distal stent markers (12) and the proximal stent markers (13). For stent deployment, the locking pin (14) must be removed. Sheath retraction is achieved by grasping the handle (15) in a fixed position with the tuning dial (16) held between the thumb and index finger. Deployment is initiated by rotating the tuning dial (16) with the thumb and index finger [see **Figure 2**] in a clockwise direction until the distal stent markers (12) and the distal end of the stent visibly appose the vessel wall. With the distal stent markers (12) and the distal end of the stent apposing the vessel wall, stent deployment continues by pulling back on the deployment lever (17) [see **Figure 3**]. Complete deployment of the stent is achieved when the proximal end of the stent and the proximal stent markers (13) visibly appose the vessel wall, and the outer sheath radiopaque marker (11) is proximal to the inner shaft stent stop (10).

Figure 1. (Pre-deployment position)



1. Flushing valve
2. Inner shaft: polymeric tube
3. Inner shaft: metallic tube
4. Inner shaft: metallic coil
5. Catheter tip (distal wire lumen)
6. Luer hub (proximal wire lumen)
7. Outer sheath
8. Luer hub (outer sheath)
9. **S.M.A.R.T.®** Stent
10. Inner shaft stent stop
11. Distal radiopaque marker
12. Distal stent markers
13. Proximal stent markers
14. Locking pin
15. Handle
16. Tuning dial
17. Deployment lever

Figure 2. Stent Deployment Using Tuning Dial

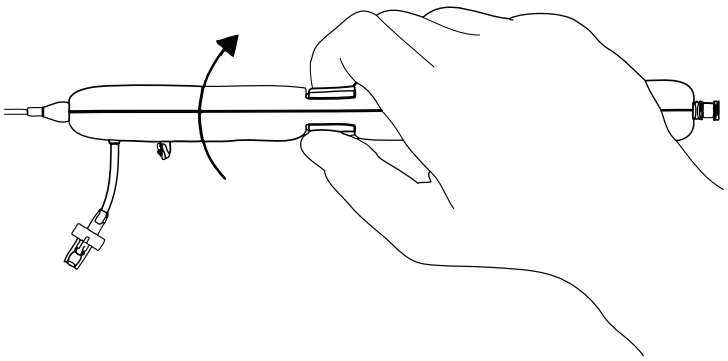


Figure 3. Stent Deployment Using Deployment Lever

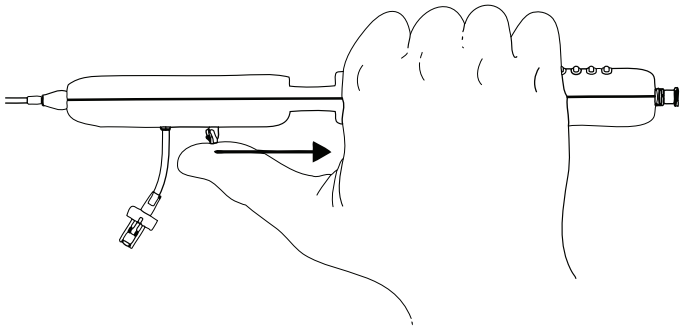
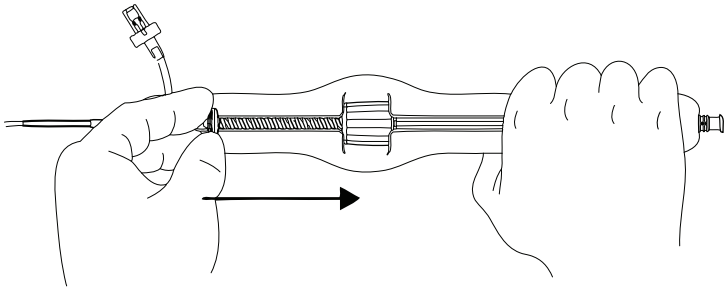


Figure 4. Stent Deployment Using Two Hands ("Pin and Pull")

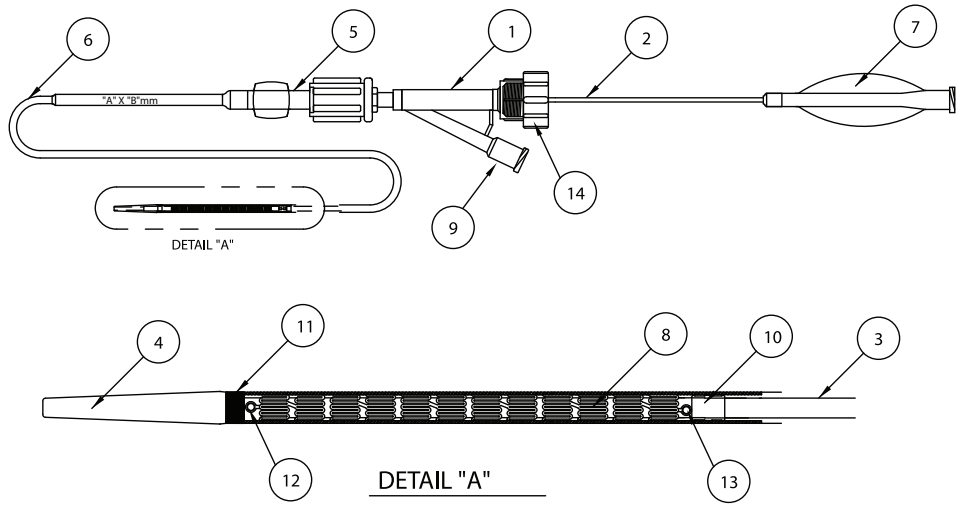


2. DESCRIPTION: Cordis S.M.A.R.T.® Vascular Stent System

The Cordis **S.M.A.R.T.®** Vascular Stent System is designed to deliver a self-expanding stent to the superficial femoral arteries and/or proximal popliteal arteries via a 6F (2.0 mm) sheathed delivery system. The self-expanding stent is composed of a nickel titanium alloy (nitinol). A total of 12 (6 at each end) tantalum radiopaque markers are located on the ends of the stent. The stent is a flexible, fine mesh tubular prosthesis that expands upon deployment to appose the vessel wall. Upon deployment, the stent imparts an outward radial force on the luminal surface of the vessel to establish patency.

Figure 5 shows and describes the Cordis **S.M.A.R.T.®** Vascular Stent System; the numbers in parentheses in the section below refer to the numbers in **Figure 5**.

Figure 5. S.M.A.R.T.® Vascular Stent Delivery System



1	Tuohy Borst valve	8	**S.M.A.R.T.®** Stent
2	Stainless steel tube	9	Y connection on the Tuohy Borst valve
3	Polymeric shaft	10	Inner shaft stent stop
4	Catheter tip	11	Distal radiopaque marker
5	Luer hub (Outer sheath)	12	Distal stent marker
6	Outer sheath	13	Proximal stent marker
7	Luer hub (Proximal)	14	Proximal Valve of the Tuohy Borst valve

The delivery system, as shown in **Figure 5**, is comprised of an inner shaft and an outer sheath that are locked together with a Tuohy Borst valve (1). The inner shaft is comprised proximally of a stainless steel tube (2) and distally, of a polymeric shaft (3). The inner shaft terminates distally in a catheter tip (4) and originates proximally in a Luer hub (7) designed to accept a .035" (0.89 mm) guidewire.

The 6F outer sheath (6) connects proximally to the Tuohy Borst valve (1) via a Luer hub (5). The self-expanding stent (8) is constrained within the space between the inner shaft (3) and the outer sheath (6). This space is flushed prior to the interventional procedure by injecting fluid via the Y connection (9) on the Tuohy Borst valve. Stent movement during sheath retraction is restricted by an inner shaft stent stop (10) connected to the inner shaft. The outer sheath has a radiopaque marker (11) at its distal end.

Stent positioning about the target lesion is achieved prior to deployment utilizing the distal stent markers (12) and the proximal stent markers (13). For stent deployment, the Tuohy Borst valve (1) is unlocked on the inner shaft by a counter-clockwise rotation of the proximal valve end (14). Sheath retraction is achieved by grasping the Luer hub (7) in a fixed position and moving the outer sheath proximally relative to the inner shaft. During sheath retraction, it may be necessary to slightly advance the entire delivery system to maintain stent positioning. Complete deployment of the stent is achieved when the proximal end of the stent and the proximal stent markers (13) visibly appose the vessel wall, and the outer sheath radiopaque marker (11) is proximal to the inner shaft stent stop (10).

3. Available Product Sizes and Catalog Numbers

Table 1 - Product Catalog Numbers

Delivery System Length	Stent Diameter (mm)	Stent Length (mm)							
		S.M.A.R.T.® CONTROL® Stent						S.M.A.R.T.® Stent	
		20 mm	30 mm	40 mm	60 mm	80 mm	100 mm	120 mm	150 mm
120 cm	6	C06020ML	C06030ML	C06040ML	C06060ML	C06080ML	C06100ML	C06120ML	C06150ML
80 cm		C06020SL	C06030SL	C06040SL	C06060SL	C06080SL	C06100SL		
120 cm	7	C07020ML	C07030ML	C07040ML	C07060ML	C07080ML	C07100ML	C07120ML	C07150ML
80 cm		C07020SL	C07030SL	C07040SL	C07060SL	C07080SL	C07100SL		
120 cm	8	C08020ML	C08030ML	C08040ML	C08060ML	C08080ML	C08100ML	C08120ML	C08150ML
80 cm		C08020SL	C08030SL	C08040SL	C08060SL	C08080SL	C08100SL		

III. INDICATIONS FOR USE

The Cordis **S.M.A.R.T.® CONTROL®** / **S.M.A.R.T.®** Vascular Stent System is indicated for use to improve luminal diameter in the treatment of patients with *de novo* or restenotic native lesion(s) of the superficial femoral artery and/or proximal popliteal artery with total length up to 150 mm and with a reference vessel diameter ranging from 4 mm to 7 mm.

IV. CONTRAINDICATIONS

- Patients with a known hypersensitivity to nickel titanium
- Patients who cannot receive antiplatelet or anticoagulation therapy.
- 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.

V. WARNINGS / PRECAUTIONS

- It is not recommended that stents be used in patients with a history of contrast media allergy/intolerance not amenable to pretreatment with steroids and/or antihistamines.
- Safety and effectiveness has not been demonstrated in patients with:
  - Lesions that are either totally or densely calcified
  - Patients with uncontrollable hypercoagulability and/or other coagulopathy
  - Patients with confirmed pregnancy
  - Pediatric patients
- Caution should be taken when stenting patients with poor renal function who, in the physician's opinion, may experience further deterioration of renal function.
- It is important to use the correct stent size, as recommended in the Stent Size Selection Table (**Table 2** provided in Section X –Instructions for Use). The stent may cause a thrombus or distal embolization, or it may migrate from the site of an implant down the arterial lumen.
- The device should only be used by physicians who are trained in such interventional techniques as percutaneous transluminal angioplasty and placement of intravascular stents.
- When catheters are in the body, they should be manipulated only under fluoroscopy.
- Failure to pre-dilate the lesion may impair the ability to remove the stent system after stent deployment.
- Before insertion of the primary dilatation catheter, the appropriate antiplatelet and anticoagulant therapy should be administered.
- To avoid the possibility of dissimilar metal corrosion, do not implant stents of different metals in tandem where overlap or contact is possible, with an exception of stents made of 316L stainless steel which are compatible with stents made of nickel titanium alloy.
- The long-term outcome following repeat dilatation of endothelialized stents is unknown at present.
- Do not use the delivery system with a power injection system.

Stent Storage and Preparation

- The Cordis **S.M.A.R.T.® CONTROL®** / **S.M.A.R.T.®** Vascular Stent System is designed and intended for single use only. DO NOT re-sterilize and/or reuse the device.
- This product is designed and intended for single use. It is not designed to undergo reprocessing and re-sterilization after initial use. Reuse of this product, including after reprocessing and/or re-sterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information all of which present a potential risk to patient safety.
- **Store in a cool, dark, dry place.**
- Do not use if the entire temperature exposure indicator is completely black as the unconstrained stent diameter may have been compromised. The black dotted pattern on the gray temperature exposure indicator found on the pouch must be clearly visible.
- Do not use if the pouch is opened or damaged. If it is suspected that the sterility or performance of the device has been compromised, the device should not be used.
- Use the stent system prior to the "Use By" date specified on the package.

Stent Handling

- Do not use if the stent is partially deployed upon removal from the package, or before starting the deployment procedure.
- Avoid contaminating the stent. As with any type of vascular implant, infection, secondary to contamination of the stent, may lead to thrombosis or pseudoaneurysm.
- Do not use with Ethiodol or Lipiodol[1] contrast media to avoid possible damage to the stent delivery system components.
- Do not expose the delivery system to organic solvents (e.g. alcohol).

Stent Placement

- If resistance is encountered at any time during the insertion procedure, do not force passage. Resistance may cause damage to stent or vessel. Carefully withdraw the stent system without deploying the stent.
- If resistance is felt when beginning deployment, do not force deployment. Carefully withdraw the stent system without deploying the stent.
- The stent is not designed to be lengthened or shortened past its nominal length. Excessive stent lengthening or shortening may increase the risk of stent fracture.
- Do not attempt to drag or reposition the stent, as this may result in unintentional stent deployment.
- Once the stent is partially deployed, it **cannot** be recaptured using the stent delivery system. Do not attempt to recapture the stent once the stent is partially deployed.
- Avoid stent placement that may obstruct access to a vital side branch.
- Overstretching of the artery may result in rupture and life threatening bleeding. Do not overstretch the stent.
- In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.
- When treating multiple lesions, the most distal lesion should be stented first followed by the stenting of proximal lesions. Stenting in this order eliminates the need to cross and reduces the chance of dislodging stents which have already been placed. Overlap of sequential stents is necessary but the amount of overlap should be kept to a minimum.

Stent / System Removal

- In the event of complications such as infections, pseudoaneurysm or fistulization, surgical removal of the stent may be required. Standard surgical procedure is appropriate.

Post Implant

- Re-crossing a stent with adjunct devices must be performed with caution to avoid stent damage or migration.
- In patients requiring the use of antacids and/or H2-antagonists before or immediately after stent placement, oral absorption of antiplatelet agents (e.g. aspirin) may be adversely affected.
- Antiplatelet therapy should be maintained for at least three months post-procedure.

VI. POTENTIAL COMPLICATIONS

The following complications may be associated with intravascular stent implantation:

- Abrupt closure
- Access failure
- Allergic / anaphylactoid reaction to anticoagulant and/or antithrombotic therapy or contrast medium
- Allergic reaction to nitinol
- Amputation
- Anemia
- Aneurysm

[1] *Ethiodol and Lipiodol are trademarks of Guerbet S.A.*

- Angina / coronary ischemia / myocardial infarction
- Arrhythmia
- Arterial occlusion / thrombus
- Arterial restenosis
- Arterial spasm
- Arterial stenosis, or dissection
- Arteriosclerosis
- Arteriovenous fistula
- Blue toe syndrome
- Bradycardia
- Worsened claudication or rest pain
- Death
- Disseminated intravascular coagulation
- Edema, peripheral
- Embolism
- Emergent repeat hospital intervention
- Encephalopathy (new or worse)
- Fever
- Fistulization
- Gangrene
- Gastrointestinal bleed from anticoagulation/antiplatelet medication
- Hematoma/hemorrhage
- Hypotension / hypertension
- Infection/ abscess at insertion site
- Ischemia requiring intervention (bypass or amputation of toe, foot, or leg)
- Multi-organ failure
- Muscle hemorrhage
- Pain
- Pseudoaneurysm
- Renal failure
- Respiratory arrest
- Septicemia / bacteremia (sepsis)
- Stent embolization
- Stent migration
- Stent occlusion
- Tissue necrosis
- Trauma to adjacent structures
- Stroke /TIA (hemorrhagic/embolic)
- Vascular injury, including perforation, rupture and dissection
- Venospasm
- Venous occlusion / thrombosis, puncture site (restenosis or recurrent stricture)

VII. INFORMATION FOR THE PATIENT

The following is available in hard copy and online (at www.mycardinalmsds.com):

- A Stent Implant Card that includes both patient and **S.M.A.R.T.®** Stent-specific information. All patients will be expected to keep this card in their possession at all times for procedure /stent identification.
- A Patient Information Guide, which includes information about the implant procedure and the **S.M.A.R.T.® CONTROL®** / **S.M.A.R.T.®** Vascular Stent System.

VIII. HOW SUPPLIED

The Cordis **S.M.A.R.T.® CONTROL®** / **S.M.A.R.T.®** Vascular Stent System is supplied sterile inside a pouch. The device is sterilized via Ethylene Oxide. The device is non-pyrogenic. The packaged device should be stored in a dry, dark, cool place. **CAUTION:** Do not use if the package is damaged. Contact Cordis Customer Service at 1-800-327-7714, Option 1. Also, included in the packaging: One (1) stent implant card

IX. SELECTION OF STENT SIZE

The available stent diameters are 6 mm to 8 mm with stent lengths of 20 mm to 150 mm. See **Table 2** for guidance for stent diameter selection.

X. INSTRUCTIONS FOR USE

Pre-Procedure

1. The patient may be started on enteric-coated or nonenteric-coated aspirin 81-325 mg one or two days prior to the procedure and 300-375 mg of Clopidogrel bisulfate or 250 mg of Ticlopidine within 24 hours of the procedure, if deemed appropriate by the physician.

2. The percutaneous placement of the stent in a stenotic or obstructed artery should be done in an angiography procedure room. Angiography should be performed to map out the extent of the lesion(s) and the collateral flow. If thrombus is present or suspected, thrombolysis should precede stent deployment using standard acceptable practice. Access vessels must be sufficiently patent, or sufficiently recanalized, to proceed with further intervention. Patient preparation and sterile precautions should be the same as for any angioplasty procedure.

Procedure

1. Initial Angioplasty

a. After local anesthesia is administered, the femoral artery is entered with a puncture needle.

b. A guidewire is introduced into the femoral artery through the needle and should be advanced across the stenosis.

c. The needle is removed and a straight catheter is introduced and advanced over the guidewire into the distal aorta.

d. An injection of contrast media through the catheter should be done in order to confirm the intraluminal position.

e. The catheter should then be exchanged for a catheter sheath introducer (CSI) with a check valve and a side-arm adapter.

f. An angioplasty balloon catheter should be selected to correspond to the diameter of the superficial femoral artery proximal to the lesion. The side arm of the introducer should be connected to a pressure transducer to record the arterial pressure distal to the obstruction. An initial dilation of the lesion should be made with an appropriate sized balloon catheter. Whenever there is doubt about the dispensability of the lesion, the smallest appropriate balloon catheter should be used for the initial dilatation. **Note:** Stent placement is not indicated if the primary angioplasty is not technically successful. A technically successful angioplasty is one in which the guidewire and dilation catheter are passed through the lesion and dilatation of the lesion produces a lumen adequate to accommodate introduction of the stent delivery system.

g. Following dilatation of the lesion, an arteriographic image should be recorded in order to determine the adequacy of the primary procedure.

2. Select Stent Size

a. Measure the length of the target lesion to determine the length of stent required. Size the stent length to extend slightly proximal and distal to the lesion.

b. The appropriate stent length should be selected based on covering the entire obstructed segment with a single stent.
Note: Should more than one stent be required, place the stent most distal from the puncture site first, followed by the placement of the proximal stent in tandem.

c. Determine the diameter of the lesion (by visual estimation using angiography or as determined by intravascular ultrasound) and consult **Table 2** to select the appropriate stent size.
Note: Because of the behavior of Nitinol, which imparts an outward radial force, the stents are indicated for placement into vessels that are 1-2 mm smaller than the unconstrained diameter of the stent. Consult **Table 2** for available device sizes.

Table 2 - Stent Size Selection Guide

Vessel Lumen Diameter	Unconstrained Stent Diameter
4.0 – 5.0 mm	6 mm
5.0 – 6.0 mm	7 mm
6.0 – 7.0 mm	8 mm
Note: Refer to product labeling for stent length information	

3. Preparation of Stent Delivery System

a. Open the outer box to reveal the pouch containing the stent and delivery system.

b. Check the temperature exposure indicator on the pouch to confirm that the black dotted pattern with a grey background is clearly visible. See ***Warnings*** section.

c. After careful inspection of the pouch to look for damage to the sterile barrier, carefully peel open the pouch and extract the stent delivery system from the tray. Examine the device for any damage. If it is suspected that the sterility or performance of the device has been compromised, the device should not be used.

d. Flush the delivery system with heparinized saline to expel air:

S.M.A.R.T.® CONTROL®	S.M.A.R.T.®
Flush through the flushing valve until heparinized saline weeps from the distal catheter end.	Flush through the Tuohy Borst Y valve until saline exits through the proximal valve. Lock the Tuohy Borst proximal valve and continue to flush until heparinized saline weeps from the distal catheter end.
Flush the guidewire lumen of the stent delivery system with heparinized saline until saline flows out of the wire lumen at the distal catheter tip.	Flush the guidewire lumen until heparinized saline flows out of the wire lumen at the distal catheter tip.

e. Evaluate the distal end of the catheter to ensure that the stent is contained within the outer sheath. Do not use if the stent is partially deployed.
Note for the S.M.A.R.T.® system: If a gap between the catheter tip and outer sheath tip exists, open the Tuohy Borst valve and gently pull the inner shaft in a proximal direction until the gap is closed. Lock the Tuohy Borst valve after the adjustment by rotating the proximal valve end in a clockwise direction.

4. Insertion of Introducer Sheath or Guide Catheter and Guidewire

a. Access the treatment site utilizing the appropriate accessory equipment compatible with the 6F (2.0 mm) delivery system.

b. Place a .035" (0.89 mm) guidewire of sufficient length across the lesion to be stented via the introducer sheath or guide catheter.

5. Dilation of Lesion

a. If appropriate, pre-dilate the lesion using standard PTA techniques.

b. Remove the PTA balloon catheter from the patient while maintaining lesion access with the guidewire.

6. Introduction of Stent Delivery System

S.M.A.R.T.® CONTROL®	S.M.A.R.T.®
a. Ensure locking pin is still in place.	**a.** Access the treatment site utilizing the appropriate accessory equipment compatible with the 6F (2.0 mm) delivery system.
b. Advance the device over the guidewire through the hemostatic valve and sheath introducer to the lesion site. **Note:** If resistance is met during delivery system introduction, the system should be withdrawn and another system should be used. **Caution:** Always use an introducer sheath for the implant procedure to protect puncture site. An introducer sheath of a 6F (2.0 mm) or larger size is recommended.	**b.** Insert a .035" (0.89 mm) guidewire of sufficient length across the lesion to be stented via the introducer sheath or guide catheter. **Note:** If resistance is met during delivery system introduction, the system should be withdrawn and another system should be used. **Caution:** Always use an introducer sheath for the implant procedure to protect puncture site. An introducer sheath of a 6F (2.0 mm) or larger size is recommended.

7. Slack Removal

a. Advance the stent delivery system past the lesion site.

b. Pull back the stent delivery system until the radiopaque stent markers (leading and trailing ends) move in position so that they are proximal and distal to the target lesion site.

c. Ensure the device outside the patient remains flat and straight.
Caution: Slack in the catheter shaft, either outside or inside the patient, may result in deploying the stent beyond the target lesion site.

8. Stent Deployment

S.M.A.R.T.® CONTROL®	S.M.A.R.T.®
a. Verify that the delivery system's radiopaque stent markers (leading and trailing ends) are proximal and distal to the target lesion.	**a.** Verify that the delivery system's radiopaque stent markers (leading and trailing ends) are proximal and distal to the target lesion.
--	**b.** Unlock the Tuohy Borst valve connecting the inner shaft and outer sheath of the delivery system.
b. Ensure that the access sheath or guiding catheter does not move during deployment.	**c.** Ensure that the access sheath or guiding catheter does not move during deployment.
c. Remove locking pin from handle.	**d.** Initiate stent deployment by retracting the outer sheath while holding the inner shaft in a fixed position. While using fluoroscopy, maintain position of the radiopaque stent markers relative to the target lesion site. Watch for the distal radiopaque markers to begin separating. Separation of the distal stent markers signals that the stent is unsheathed. Continue deploying the stent until the distal end of the stent obtains full apposition with the vessel wall. Continue deploying the stent until the proximal end of the stent obtains full apposition with the vessel wall. **Note:** Failure to maintain a fixed hub position or constraining the catheter shaft during deployment may result in stent compression (shortening) or elongation. **Note:** When more than one stent is required to open the stricture, the more distal stent should be placed first. Overlap of sequential stents is necessary but the amount of overlap should be kept to a minimum.
d. Initiate stent deployment by rotating the tuning dial with thumb and index finger in a clockwise direction (direction of arrow in Figure 2) while holding the handle in a fixed position. **Note:** Failure to maintain a fixed handle position or constraining the catheter shaft during deployment may result in stent compression (shortening) or elongation.	
e. While using fluoroscopy, maintain position of the radiopaque stent markers relative to the target lesion site. Watch for the distal radiopaque markers to begin separating. Separation of the distal stent markers signals that the stent is deploying. Continue turning the tuning dial to cause further separation of the distal radiopaque markers until the distal end of the stent obtains full wall apposition.	
f. With the distal end of the stent apposing the vessel wall and continuing to maintain a fixed handle position, pull back the deployment lever to deploy the remainder of the stent (Figure 3).	
g. Deployment is complete when the proximal markers oppose the vessel wall and the outer sheath radiopaque marker is proximal to the inner shaft stent stop. **Note:** When more than one stent is required to open the lesion, the more distal stent should be placed first. Overlap of sequential stents is necessary but the amount of overlap should be kept to a minimum.	

9. Post-deployment Stent Dilatation

S.M.A.R.T.® CONTROL	S.M.A.R.T.®
a. Advance the deployment lever to its pre-deployment position (**Figure 1**) while maintaining the handle in a fixed position. Recover the delivery system by pushing the lever as far forward as possible and then turning the dial counterclockwise, while keeping pressure on the lever, until the lever reaches the end of the slot and the tip is re-sheathed. While using fluoroscopy, withdraw the entire delivery system as one unit, over the guidewire, into the catheter sheath introducer and out of the body. Remove the delivery device from the guidewire.	**a.** While using fluoroscopy, advance the outer sheath until the outer sheath marker contacts the catheter tip and withdraw the entire delivery system as one unit, over the guidewire and out of the sheath introducer. Remove the delivery device from the guidewire.
b. Using fluoroscopy, visualize the stent to verify full deployment.	**b.** Using fluoroscopy, visualize the stent to verify full deployment.
c. If incomplete expansion exists within the stent at any point along the lesion, post deployment balloon dilatation (standard PTA technique) can be performed. **Note:** Only areas within the stent length should receive post-deployment balloon dilatation.	**c.** If incomplete expansion exists within the stent at any point along the lesion, post deployment balloon dilatation (standard PTA technique) can be performed. **Note:** Only areas within the stent length should receive post-deployment balloon dilatation.
d. Select an appropriate size PTA balloon catheter and dilate the lesion with conventional technique. The inflation diameter of the PTA balloon used for post-dilatation should approximate the diameter of the reference vessel. Remove the PTA balloon from the patient.	**d.** Select an appropriate size PTA balloon catheter and dilate the lesion with conventional technique. The inflation diameter of the PTA balloon used for post-dilatation should approximate the diameter of the reference vessel. Remove the PTA balloon from the patient.

10. Post Stent Placement

a. Remove the guidewire and sheath from the body.

b. Close entry wound as appropriate.

c. Discard the delivery system, guidewire and sheath.

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

XI. MRI Safety Information

A patient with the **S.M.A.R.T.** stent may be safely scanned under the following conditions.
Failure to follow these conditions may result in injury to the patient.

Name/identification of device	Cordis S.M.A.R.T. Stents
Nominal values of static magnetic field (T)	1.5 T and 3.0 T
Maximum spatial field gradient (T/m) and (Gauss/cm)	30 T/m (3000 Gauss/cm)
RF excitation	Circularly polarized (CP)
RF transmit coil type	Whole body transmit coil Head RF transmit-receive coil
RF receive coil type	Any receive only coil may be used
Maximum whole body SAR (W/kg)	2.0 W/kg
Limits on scan duration	15 minutes of continuous RF (a sequence or back to back series/scan without breaks) followed by a wait time of 10 minutes if this limit is reached
MR image artifact	The presence of this implant produced an image artifact of approximately 9 mm when imaged with a spin echo pulse sequence and a 3.0 T MRI system
Non-Clinical testing has demonstrated that the **S.M.A.R.T.** Stent is MR Conditional in single and overlapped configuration up to a maximum of 290 mm as defined in ASTM F2503-13.	
If information about a specific parameter is not included, there are no conditions associated with that parameter	

XII. SUMMARY OF CLINICAL STUDY

Cordis performed a clinical study to establish a reasonable assurance of the safety and effectiveness of the S.M.A.R.T. ® CONTROL® and S.M.A.R.T. ® Vascular Stent Systems for improving luminal diameter in the treatment of de novo or restenotic lesion(s) up to 150mm in length in the native superficial femoral artery and/or proximal popliteal arteries with reference vessel diameters ranging from 4 to7mm, in the U.S. under IDE G060033. Data from this clinical study were the basis for the PMA approval decision. A summary of the clinical study is presented below.

1. Study Design

Cordis conducted a study titled **S.M.A.R.T.®** Nitinol **S**elf-Expandable Stent in the **TR**eatment of **O**bstructive Superficia**L** Femora**L** Artery Disease **(STROLL)**. STROLL was a prospective, multi-center, non-randomized, unblinded, single arm study comparing primary stenting with the **S.M.A.R.T.®** Vascular Stent System to performance goals of PTA alone in the treatment of atherosclerotic lesions of the native superficial femoral artery (SFA) and/or the proximal popliteal arteries. The safety and performance goals were based on an aggregate of published trial data as described by VIVA physicians Inc. (VPI). A total of 250 subjects were enrolled between August 14, 2008 and March 15, 2010 at 39 U.S. investigational sites. Eligible subjects either had stenotic, restenotic (non-stented) or occluded lesions. The reference vessel diameter of the treated subjects was to be 4.0 – 6.0 mm and the lesion length as 4-15 cm. Subjects with Rutherford/Becker Clinical Categories of 2-4 were included in the study. Subject follow-up occurred at 30 days, 6 months, 12 months, 24 months and 36 months post-procedure.

The primary study endpoints were as follows:

- The primary safety endpoint was major adverse event rate at 30 days, defined as freedom from all causes of death, index limb amputation and clinically driven target lesion revascularization (TLR) through 30 days post-procedure.
- The primary effectiveness endpoint at 12 months was defined as primary Duplex ultrasound (DUS) stent patency rate, and no further clinically driven target vessel revascularization (TVR) performed in the interim. Primary DUS stent patency rate was defined as binary restenosis (>50% diameter stenosis) with a peak systolic velocity ratio (PSVR) > 2.0, as measured by Duplex ultrasound.

For the 30-day safety endpoint, the Agresti-Coull method was used to compare the observed 30-day safety rate against the VIVA performance goal of 88%, using a one-sided significance level of 0.025. For the primary effectiveness endpoint, the Agresti-Coull method was used to compare the observed primary effectivenessagainst the VIVA performance goal of 66%, using a one-sided significance level of 0.025. The results were evaluated using the Modified Intent-to-Treat (ITT) population. The Modified ITT population was designed to include all screened patients who met eligibility criteria, had the guidewire positioned across the target lesion(s) and located intraluminally within the distal vessel (regardless of whether the patient received the **S.M.A.R.T.®** Stent or not).

The STROLL Post-Approval study aimed to demonstrate that the **S.M.A.R.T.®** Vascular Stent System in the treatment of patients with obstructive SFA disease meets the long term safety performance criteria set for SFA stenting based on the incidence of a clinical safety endpoint (defined as a composite of death, index limb amputation, and clinically driven TLR) of 57%. This outcome was assessed in patients enrolled into the STROLL study and followed throughout 3 years.

The STROLL study was monitored by a Clinical Research Organization (CRO). Independent core laboratories reviewed and analyzed key study variables. An independent Data Safety Monitoring Board (DSMB) was used to review study data on an ongoing basis and identify any potential safety trends. Final adjudication of major adverse events was conducted by an independent Clinical Events Committee (CEC).

Clinical Inclusion and Exclusion Criteria

Enrollment in the STROLL study was limited to patients who met the following inclusion criteria:

- The subject was 30 years of age or older.
- For women of child bearing potential, a pregnancy test done within 7 days prior to the study procedure and negative test results to be eligible.
- Symptomatic leg ischemia by Rutherford/Becker Classification categories 2-4 (mild to severe claudication) with a resting or exercise ABI < 0.8
- A single superficial femoral artery lesion with > 50% stenosis or total occlusion.
- Stenotic lesion or occluded length within the same vessel (one long or multiple serial lesions) ranging from 4.0 to15.0 cm by visual estimate. The stenosis had to be treatable with no more than two stents, minimizing the stent overlap, whose combined length was not to exceed 170 mm.
- Reference vessel diameter ranging from 4.0 to 6.0 mm, by visual assessment.
- All lesions located at least three centimeters proximal to the superior edge of the patella.
- There must have been a patent infrapopliteal and popliteal artery, i.e. at least one vessel runoff with at least one of three vessels patent (< 50% stenosis) to the ankle or foot.

- The guidewire must have been across the target lesion(s) and located intraluminally within the distal vessel.
- Poor aortoiliac or common femoral "inflow" (i.e. angiographically defined > 50% stenosis of the iliac or common femoral artery) that would be deemed inadequate to support a femoropopliteal bypass graft was successfully treated prior to treatment of the target lesion. After treatment of the inflow lesion, if the peak to peak pressure gradient across the inflow lesion was < 20 mmHg and the peak to peak pressure gradient across the SFA target lesion was > 20 mmHg, then the patient could be included in the study.
- A patient with bilateral obstructive SFA disease was eligible for enrollment into the study.
- A patient must have been eligible for standard surgical repair, if necessary.
- A patient who required a coronary intervention should have had it performed at least 7 days prior to the treatment of the target lesion.
- Patient or authorized representative provided written informed consent and written HIPAA authorization prior to initiation of study procedures.
- Patient was willing to comply with the specified follow-up evaluation schedule.

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

- The patient showed evidence of thrombophlebitis, uremia, or deep venous thrombus, within 30 days prior to the index procedure.
- The patient was receiving dialysis or immunosuppressant therapy.
- Thrombolysis of the target vessel within 72 hours prior to the index procedure where complete resolution of the thrombus was not achieved.
- The patient had a stroke within 90 days prior to the index procedure.
- The patient had femoral, iliac or aortic aneurysm or aneurysm in the SFA or popliteal artery within 5 years prior to the index procedure.
- The patient required stent placement via a popliteal approach or required stent placement across or within 0.5 cm of the SFA / PFA bifurcation.
- The patient had procedures which were pre-determined to require stent-in-stent placement to obtain patency, such as severe calcification which is resistant to stenting, or for in-stent restenosis.
- The patient had significant vessel tortuosity or other parameters prohibiting access to the lesion or 90° tortuosity which would prevent delivery of the stent device.
- The patient had a previously deployed stent within the SFA of the target limb.
- The patient had known allergies to the following: aspirin, clopidogrel bisulfate (Plavix®) or ticlopidine (Ticlid®), heparin, nitinol (nickel titanium), contrast agent that could not have been medically managed.
- The patient had presence of thrombus prior to crossing the lesion
- The patient had serum creatinine level > 2.5 mg/dl at time of screening visit.
- The patient had known or suspected active infection at the time of the procedure.
- The patient had bleeding diathesis.
- The patient had presence of an aortic, iliac or femoral artificial graft
- The patient had a life expectancy less than one year, or any other factors preventing clinical follow up.
- The patient required the use of cryoplasty, laser, or atherectomy devices on the target vessel at the time of index procedure.
- The patient had in-stent restenotic lesions at the time of procedures or had a restenotic lesion that had previously been treated by atherectomy, laser, or cryoplasty within 90 days prior to the index procedure.
- The patient was unwilling or unable to comply with procedures specified in the protocol or had difficulty or inability to return for follow-up visits as specified by the protocol.
- The patient was known to be pregnant, incarcerated, mentally incompetent, and/or an alcohol or drug
- abuser.
- The patient was currently participating in any another investigational drug or medical device study that
- had not completed primary endpoint(s) evaluation or which clinically interfered with the endpoints from
- this study or future participation in such studies prior to the completion of this study.
- The patient had major surgical or interventional procedures unrelated to this study within 30 days prior
- to this study or planned surgical or interventional procedures within 30 days of entry into this study.
- Interventional procedures performed to the ipsilateral iliac artery to provide access were allowed.
- The patient had tissue loss due to ischemic disease (Rutherford/Becker category 5 or 6).

Follow-up Schedule

All patients were scheduled to return for follow-up examinations at 30 days and 6, 12, 24 and 36 months post-procedure. **Table 3** provides a summary of the study requirements at each stage of the study.

Table 3 - Follow Up Schedule

	Baseline/Treatment			Follow-up				
Event	**Screen**	**Index Procedure**	**Prior to Discharge or within 7 days post-procedure**	**30 Day (+/- 7 days)**	**180 Days (+/- 15 days)**	**360 Days (+/- 30 days)**	**720 Days (+/- 45 days)**	**1080 Days (+/- 60 days)**
Informed Consent	X							
Inclusion/Exclusion Criteria[5]	X							
Vascular Examination	X[8]			X	X	X	X	X
Demographics & Medical History	X							
Physical Examination[1]	X							
Screening laboratory tests including lipid profile and serum creatinine	X			X [2]				
CBC with differential and platelet count[3]	X							
Concomitant Anti-platelet Medication[4]	X		X	X	X	X	X	X
Rutherford/Becker Classification	X		X	X	X	X	X	X
ABI (Resting or Exercise)	X[8]			X	X	X	X	X
Angiography (QA)		X						
Procedural Data		X						
Duplex Ultrasound			X[7]	X[7]	X	X	X	X
X-Ray of stented region[6]					X	X	X	X
Peripheral Artery Questionnaire, Walking Impairment Questionnaire SF-12, EQ-5D	X			X	X	X	X	X
Adverse Event Monitoring		X	X	X	X	X	X	X

[1] Must have been completed within seven (7) days prior to the day of the index procedure
[2] Only serum creatinine was checked at 30 days
[3] If WBC was within normal limits (WNL), differential was not required.
[4] Plavix® or Ticlid® was recommended for at least one month post procedure; ASA recommended for all patients indefinitely. If Ticlid® was used, the product label was to be followed for appropriate patient follow-up
[5] Patients known to be pregnant were to be excluded from study participation – for women of child bearing potential, a pregnancy test must have been completed within 7 days of index procedure
[6] In the event of a stent fracture, X-rays were to be conducted every 6 months
[7] To have been done prior to hospital discharge OR on or before the 30 day visit
[8] Less than or equal to 30 days prior to index procedure

Clinical Endpoints

The primary safety endpoint was freedom from all causes of death, index limb amputation and clinically driven TLR through 30 days post-procedure.

Secondary safety endpoints included:

- Major adverse event (MAE) defined as death, limb ischemia/amputation of target limb, TLR; significant embolic events, defined as causing end-organ damage, (e.g. lower extremity ulceration or gangrene) at 6 months and 1, 2, and 3 year follow-up
- Stent fracture rate assessed by x-ray evaluation at 6 months and 1, 2, and 3 year follow-up

The primary effectiveness endpoint was primary patency at the 1 year follow-up time point, and was defined as no significant reduction of flow detectable by Duplex ultrasound (DUS) through the index lesion and no further clinically driven TVR. Significant reduction of flow was determined as binary restenosis, defined as the diameter stenosis > 50% with a peak systolic velocity ratio (PSVR) > 2.0 as measured by DUS.

Secondary effectiveness endpoints included:

- Device success, defined as achievement of a final residual diameter stenosis of <50% (by QA), using the assigned treatment only
- Limb ischemia by Rutherford/Becker Classification at 6 months and 1, 2, and 3 year follow-up
- Ankle-Brachial Index (ABI) at 1 month, 6 months and 1, 2, and 3 year follow-up
- Patency of the target vessel defined as no significant reduction of flow detectable by Duplex ultrasound, and no further clinically driven target vessel revascularization performed in the interim. Significant reduction of flow was determined as binary restenosis, defined as the diameter stenosis > 50% with a peak systolic velocity ratio > 2.0 as measured by DUS at 6 months and 2 and 3 year follow-up

Patient-reported, health-related quality of life (HRQOL) outcomes on physical limitations, physical and social function, symptoms and general HRQOL were also measured and evaluated in the STROLL study using validated instruments such as the Walking Impairment Questionnaire (WIQ).

With regard to success/failure criteria, the STROLL study was designed to compare the primary clinical endpoints to a pre-established performance goal of 88% for safety and 66% for effectiveness.

Accountability of PMA Cohort

A total of 250 patients signed the informed consent and were enrolled in the STROLL study. These patients comprise the ITT population. **Table 4** summarizes the study compliance for all follow-up time points. **Tables 5, 6, 7, 8 and 9** show detailed patient accountability for the 30-day, 6-month, 12-month, 24-month and 36-month visits, respectively.

Table 4 - Summary of Study Compliance	
Time	**Compliance (N=250)**
Procedure	250/250 (100%)
Discharge	250/250 (100%)
30 Days	242/248 (97.6%)
6 Months	219/244 (89.8%)
1 Year	219/234 (93.6%)
2 Year	203/224 (90.6%)
3 Year	190/209 (90.9%)

Two (2) patients withdrew consent prior to their 30-day visit, resulting in a total of 248 eligible patients in the 30-day population (see **Figure 6**). A total of 248 patients also had sufficient follow-up data to be included in the evaluation of the 30-day primary safety endpoint. This includes patients who died prior to the 30-day visit or who had adequate follow-up through 23 days, the start of the 30-day visit window.

Table 5 - Subject Accountability at 30 Days	
30-day Follow-Up	**N=250**
Available	242/250 (96.8%)
Unavailable	8/250 (3.2%)
Died	0/250 (0.0%)
Withdrew	2/250 (0.8%)
Missed Visit	6/250 (2.4%)

By the 6-month visit, a total of 2 patients died and 4 withdrew consent, for a total of 244 eligible patients in the 6-month population (see **Figure 6**). A total of 246 patients had sufficient follow-up data to be included in the evaluation of the 6-month clinical safety endpoints. This includes patients who died prior to the 6-month visit or who had adequate follow-up through 165 days, the start of the 6-month visit window.

Table 6 - Subject Accountability at 6 months	
6-month Follow-Up	**N=250**
Available	219/250 (87.6%)
Unavailable	31/250 (12.4%)
Died	2/250 (0.8%)
Withdrew	4/250 (1.6%)
Missed Visit	25/250 (10.0%)

By the 12-month visit, a total of 5 patients died and 11 withdrew consent, for a total of 234 eligible patients in the 12-month population (see **Figure 6**). A total of 238 patients had sufficient follow-up data to be included in the evaluation of the 12-month clinical safety endpoints. This includes patients who died prior to the 12-month visit or who had adequate follow-up through 330 days, the start of the 12-month visit window.

Only those patients for whom an evaluable Duplex Ultrasound Assessment was obtained at 12 months follow-up or who had a clinically-driven Target Vessel Revascularization (TVR) performed within 360 days post-index procedure were included in the assessment of the primary effectiveness endpoint for the pivotal STROLL study.

Table 7 - Subject Accountability at 12 months	
12-month Follow-Up	**N=250**
Available	219/250 (87.6%)
Unavailable	31/250 (12.4%)
Died	5/250 (2.0%)
Withdrew	11/250 (4.4 %)
Missed Visit	15/250 (6.0%)

By the 24-month visit, a total of 10 patients died, 14 withdrew consent, and 2 were withdrawn by the Investigator due to safety concerns for a total of 224 eligible patients in the 24-month population (see **Figure 6**). A total of 231 patients had sufficient follow-up data to be included in the evaluation of the 24-month clinical safety endpoints. This includes patients who died prior to the 24-month visit or who had adequate follow-up through 675 days, the start of the 24-month visit window.

Table 8 - Subject Accountability at 12 months	
24-month Follow-Up	**N=250**
Available	203/250 (81.2%)
Unavailable	47/250 (18.8%)
Died	10/250 (4.0%)
Withdrew	14/250 (5.6 %)
Exit the study due to other reasons*	2/250 (0.8%)
Missed Visit	21/250 (8.4%)

*Two (2) patients were withdrawn by the Investigator due to safety concerns

By the 36-month visit, a total of 17 patients died, 22 withdrew consent, and 2 were withdrawn by the Investigator due to safety concerns for a total of 209 eligible patients in the 36-month population (see **Figure 6**). A total of 218 patients had sufficient follow-up data to be included in the evaluation of the 36-month clinical safety endpoints. This includes patients who died prior to the 36-month visit or who had adequate follow-up through 1020 days, the start of the 36-month visit window.

Table 9 - Subject Accountability at 36 months	
36-month Follow-Up	**N=250**
Available	190/250 (76.0%)
Unavailable	60/250 (24.0%)
Died	17/250 (6.8%)
Withdrew	22/250 (8.8 %)
Exit the study due to other reasons*	2/250 (0.8%)
Missed Visit	19/250 (7.6%)

*Two (2) patients were withdrawn by the Investigator due to safety concerns

The total numbers of subjects who withdrew from the study, were lost to follow-up, or died, regardless of the follow-up visit or visit-window status through the duration of the study are provided in **Table 10**.

Eight (8) patients were considered lost-to-follow-up after completion of their 36-month visit windows. Five (5) patients died between 1020 and 1080 days post procedure and were therefore considered eligible for the 3-year visit and not counted with the patients that died prior to the 3-year visit. Three (3) patients withdrew consent after 1020 days post procedure and were therefore considered eligible for the 3-year visit and not counted with the patients that withdrew consent prior to the 3-year visit. Additionally, three (3) patients were exited from the study for other reasons (one due to lack of insurance coverage and two due to refusal to return for a clinic visit) after 1020 days post procedure and were therefore considered eligible for the 3-year visit and not counted with the patients that were exited for other reasons prior to the 3-year visit.

Table 10 - Study Exit Summary	
Exited without 3-year data	**N=250**
Withdrew consent before treatment	0.0% (0/250)
Withdrew consent after treatment	9.6% (24/250)
Death	8.8% (22/250)
Withdrew from study secondary to adverse event	0.4% (1/250)
Other*	2.0% (5/250)
Lost-to-Follow Up	3.2% (8/250)

*'Other' includes 2 patients who were withdrawn from the study by the Principal Investigator due to safety concerns, 2 patients who refused to return for in-clinic visits at 3 years and 1 patient who exited due to lack of insurance coverage.

Figure 6. Patient Compliance Flow Chart - Modified ITT Population

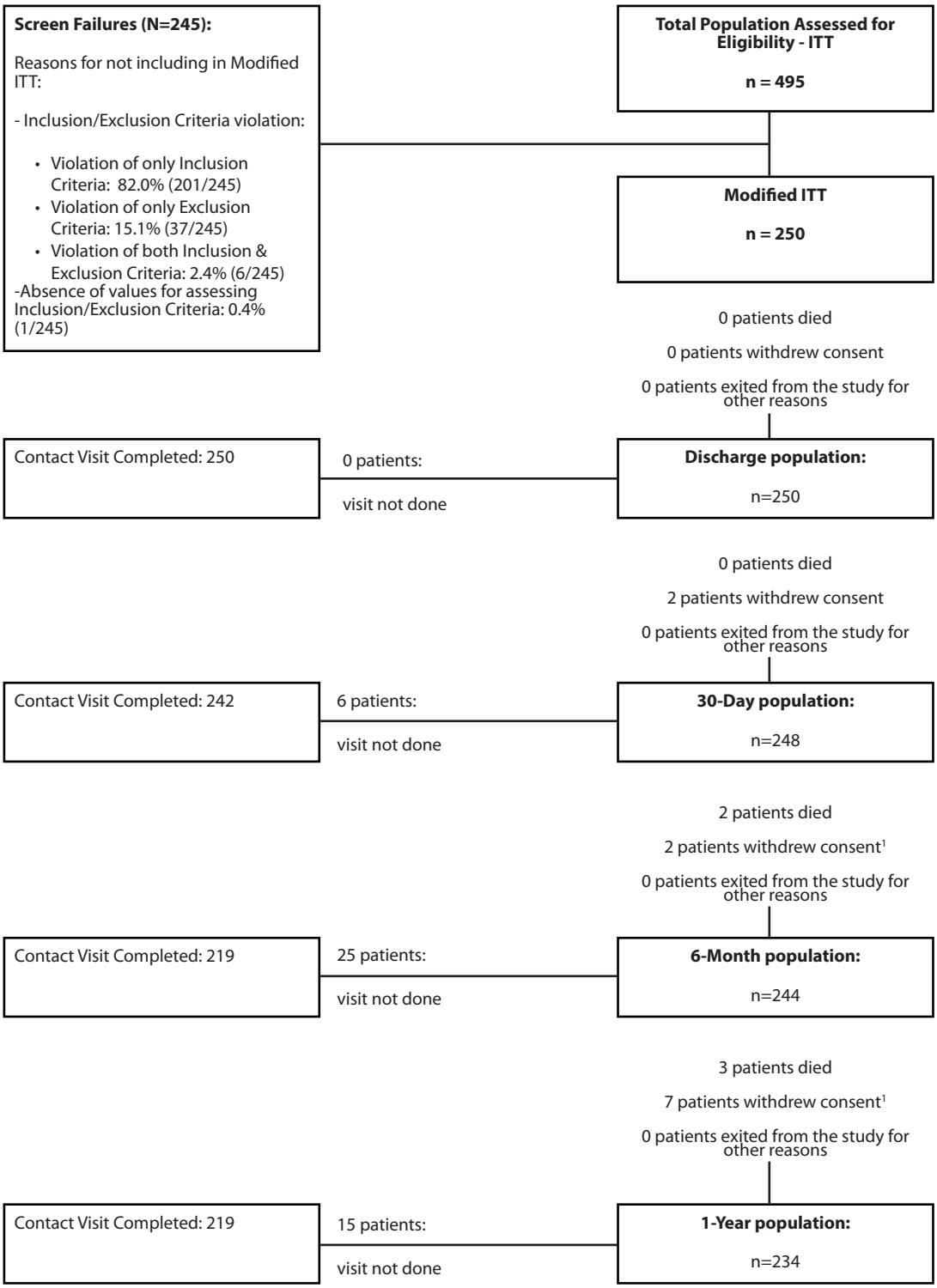
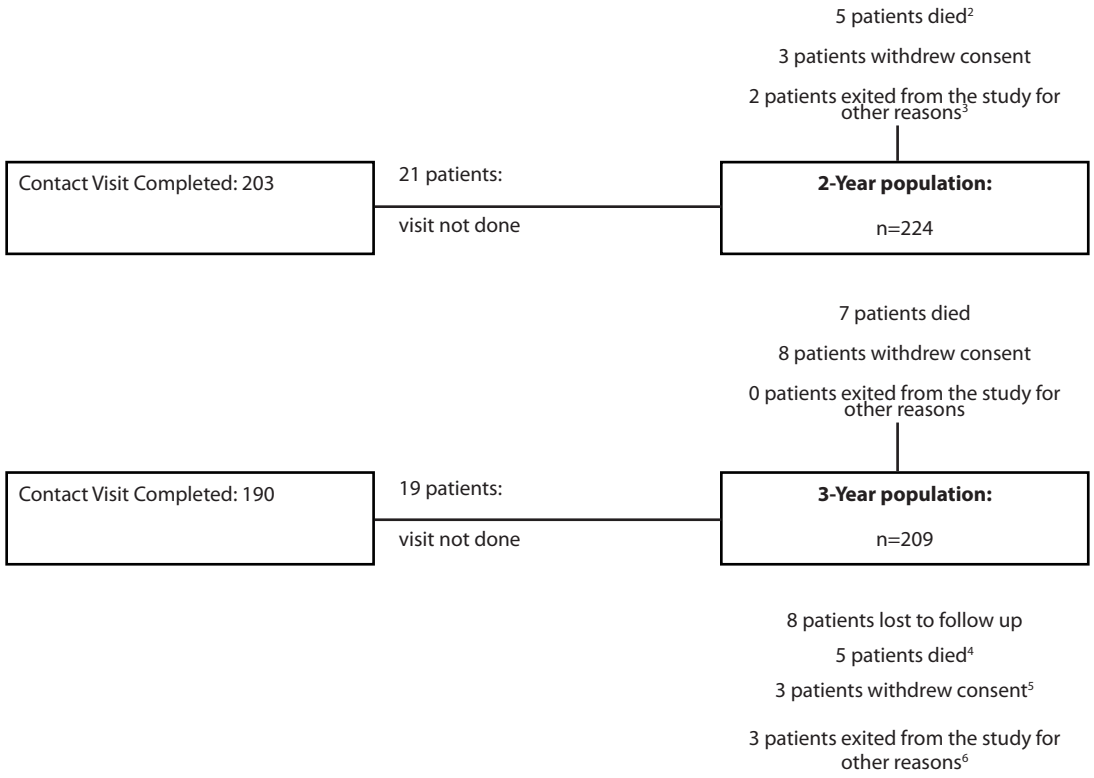


Figure 6. Patient Compliance Flow Chart - Modified ITT Population



Each n represents the population at the beginning of that visit.

[1] One of the two patients that withdrew from the study did so secondary to an adverse event.

[2] Patient 469-1 died on day 678 post procedure, which is greater than 675 days and was therefore considered eligible for the 2-year visit. He is not counted with the patients that died prior to the 2-year visit but rather with the patients that died prior to the 3-year visit.

[3] One patient was withdrawn by the PI due to safety concern; another patient was withdrawn by the PI due to terminal lung cancer.

[4] These five patients died between 1020 and 1080 days post procedure. They were therefore considered eligible for the 3-year visit and were not counted with the patients that died prior to the 3-year visit.

[5] These three patients withdrew consent after 1020 days post procedure. They were therefore considered eligible for the 3-year visit and were not counted with the patients that withdrew consent prior to the 3-year visit.

[6] These three patients were exited from the study for other reasons (one due to lack of insurance coverage and two due to refusal to return for a clinic visit) after 1020 days post procedure. They were therefore considered eligible for the 3-year visit and were not counted with the patients that were exited for other reasons prior to the 3-year visit.

The Modified ITT population was designed to include all screened patients who met eligibility criteria and had the guide-wire across the target lesion(s) and located intraluminally within the distal vessel (regardless of whether the patient received the S.M.A.R.T. ® Stent or not).

2. Study Population Demographics and Baseline Parameters

Baseline demographics and clinical characteristics for all patients enrolled in the STROLL study are summarized in **Table 11**. **Table 12** presents baseline lesion characteristics (assessed by the angiographic core laboratory, except as otherwise noted), including lesion location, length, and pre-procedure vessel diameter. The demographics, and baseline clinical and lesion characteristics are considered to be typical of interventional peripheral vascular studies conducted in the United States.

Table 11 - Demographics and Baseline Clinical Characteristics	
Patient Characteristics	**S.M.A.R.T.® (N=250 Patients N=250 Lesions)**
Age (Years), Mean +/- SD (N)	67.71±10.32 (N=250)
Gender (Male)	61.6% (154/250)
Race	
Asian	0.4% (1/250)
Black or African American	12.4% (31/250)
White or Caucasian	85.6% (214/250)
Middle Eastern	0.4% (1/250)
Hispanic	1.2% (3/250)
BMI	29.48 ± 5.81 (250)
Risk Factors	
Diabetes	47.2% (118/250)
Hypercholesterolemia	87.4% (216/247)
Hypertension	88.8% (222/250)
History of Smoking	84.8% (212/250)
Medical History	
Allergies	47.4% (117/247)
Carotid disease (carotid artery stenosis >50%)	31.0% (67/216)
Q-wave or non-Q wave Myocardial infarction (MI)	22.5% (54/240)
Previous coronary percutaneous revascularization	39.9% (97/243)
Previous CABG	26.1% (65/249)
Previous peripheral vascular interventions	89.6% (224/250)
Previous peripheral vascular (low extremity) interventions	39.2% (98/250)
Clinical Characteristics	
Target Limb ABI[1], Mean +/- SD (N); Range (min, max)	0.66 ± 0.15 (247) (0.24, 1.32)
<0.4	6.1% (15/247)
0.4-0.8	84.6% (209/247)
>0.8	9.3% (23/247)
Rutherford/Becker Scale[2]	
2 = Moderate claudication	45.8% (114/249)
3 = Severe claudication	51.4% (128/249)
4 = Ischemic rest pain	2.8% (7/249)

Note: Numbers are % (counts/sample size) or Mean ± SD (sample size).

1 Baseline target limb ABI was not available for three (3) patients - ABI was not recorded for one patient, not done for the second patient and was recorded as "0.00" for the third patient.

2 Baseline Rutherford/Becker assessment was not performed for one patient.

Table 12 - Baseline Target Lesion Characteristics	
Lesion Characteristics	**S.M.A.R.T.® (N=250 Patients N=250 Lesions)**
Lesion Location	
Proximal 1/3 of SFA	10.8% (27/250)
Middle 1/3 of SFA	68.0% (170/250)
Distal 1/3 of SFA	20.0% (50/250)
Lesions extending into proximal popliteal	15.6% (39/250)
Lesion length (mm), normal-to-normal, by core lab*	
Mean +/- SD (N)	77.31 ± 35.31 (250)
Range (min, max)	(15.73, 200.10)
Pre-procedural Reference Vessel Diameter, RVD (mm)	
Mean +/- SD (N)	4.87 ± 0.68 (250)
Range (min, max)	(2.71, 8.54)
Pre-procedural Minimum Lumen Diameter, MLD (mm)	
Mean +/- SD (N)	1.17 ± 0.82 (250)
Range (min, max)	(0.00, 3.53)
Pre-procedural Diameter Stenosis (%)	
Mean +/- SD (N)	76.05 ± 16.07 (250)
Range (min, max)	(44.10, 100.00)
Eccentric	20.4% (51/250)
Bend (≥45 degrees)	0.4% (1/250)
Thrombus	0.0% (0/249)
Calcification	
None/Mild	59.2% (141/238)
Moderate	21.4% (51/238)
Severe	19.3% (46/238)
Ulceration Present	1.6% (4/249)
Aneurysm Present	0.0% (0/249)
Total Occlusion	23.6% (59/250)

Numbers are % (counts/sample size) or Mean ± SD (sample size).

* Measured by quantitative angiography (CMS) as the distance (in millimeters) from the proximal to the distal shoulder of the lesion in the projection that demonstrates the stenosis in its most elongated segment

The number of subjects who did not complete the 12-month follow-up is listed in **Table 13**, along with the reason for the missing data.

Table 13 - Reasons for Missing Data for Primary Effectiveness Endpoint	
Reason	Number of Subjects
Exited study	
Death (≤ 390 days post-index procedure)	5
Withdrawal of consent*	11
Non-Diagnostic Duplex Ultrasound at 1-year	3
Missing 1-year Duplex Ultrasound Assessment and no interim TVR	16
TOTAL	35

* Patient 469-3 withdrew consent at 320 days post procedure but experienced a TVR at 187 days, thus this patent was included in the analysis.

3. Medication Regimen

The recommended medication regimen used in the STROLL study is as follows:

Pre-Procedure	Aspirin [1]	81-325 mg (non-enteric coated water-soluble) starting at least 24 hours prior to the procedure **AND**
	Clopidogrel bisulfate (Plavix®)[2]	Loading dose of 300-375 mg within 24 hours pre-procedure **OR**
	Ticlopidine (Ticlid®)[3]	Loading dose of 250 mg within 24 hours pre-procedure
During Procedure	Heparin[4] (If administered)	Initial bolus IV with additional boluses to maintain an ACT >250 seconds
Post-Procedure	Clopidogrel bisulfate (Plavix®)	75 mg qd **OR**
	Ticlopidine (Ticlid®)	250 mg b.i.d.
After Discharge	Aspirin	81-325 mg qd indefinitely **AND**
	Clopidogrel Bisulfate (Plavix®)	75mg qd for at least 30 days **OR**
	Ticlopidine (Ticlid®)	250 mg b.i.d. for at least 30 days

[1] If a patient has historically been on enteric-coated aspirin, this therapy should be continued.
[2] If the patient has been on clopidogrel bisulfate for at least 48 hours prior to the procedure, the daily dose should be continued and no additional dose given prior to the procedure.
[3] If Ticlid® is used, the product label should be followed for appropriate patient follow-up.
[4] On-label use of direct thrombin inhibitors or low molecular weight heparin is permitted in place of unfractionated heparin.

4. Safety and Effectiveness Results

Safety Results

The primary analysis of safety in the STROLL IDE study was based on the 248 subjects available for the 30-day evaluation, for which the key outcomes are presented below in **Table 14**.

The primary safety endpoint was freedom from all causes of death, index limb amputation, and clinically driven Target Lesion Revascularization (TLR) through 30 days. Among the subjects for whom 30-day safety data were available, the rate of freedom from death, amputation and TLR was 100% with a lower 95% Agresti-Coull Confidence Interval of 98.2%. This is higher than the performance goal of 88%. Therefore, the primary safety endpoint was met. Per protocol, two (2) subjects who did not have reported adverse events or a reintervention prior to 30 days, and who did not complete the 30 day follow-up visit and were without any further follow-up information were not included in this analysis.

Table 14 – Primary Safety Endpoint

1-Month (30-Day) Primary Safety Endpoint	S.M.A.R.T.® (N=248 Patients N=248 Lesions)	95% Confidence Interval*	Performance Goal	Objective Met
Absence of 30-Day Major Complications	100.0% (248/248)	[98.5%,100.0%]	88.0%	Yes

For each parameter in the safety measures, the denominator is the number of enrolled patients who had sufficient follow-up (at least 23 days for 1 month visit) plus any patients who had an event prior to the milestone visit.
*Agresti-Coull method was used to calculate the 95% CI of the point estimate for the primary safety endpoint.

Additional safety endpoints are discussed below.
The one year MAE rate was 14.2% (34/240) and is presented in **Table 15**.

Table 15 – Major Adverse Event Rate at 1 Year	
1 Year MAE	**N=240**
Subjects with MAE at 1-Year	14.2% (34/240)
Death	2.1% (5/240)
Limb ischemia or amputation of the target limb	0.4% (1/240)
TLR through 12 months	13.3% (32/240)
Significant embolic events (e.g. causing ulceration or gangrene)	0.0% (0/240)
For each parameter in the safety measures, the denominator is the number of enrolled subjects who had sufficient follow-up (at least 330 days for the 12 month visit) plus any subjects who had an event prior to the milestone visit.	

The two year MAE rate was 24.0% (56/233) and is presented in **Table 16.**

Table 16 – Major Adverse Event Rate at 2 Year	
2 Year MAE	**N=233**
Subjects with MAE at 2-Year	24.0% (56/233)
Death	4.7% (11/233)
Limb ischemia or amputation of the target limb	0.9% (2/233)
TLR through 24 months	21.9% (51/233)
Significant embolic events (e.g. causing ulceration or gangrene)	0.0% (0/233)

The three year MAE rate was 31.5% (70/222) and is presented in **Table 17.**

Table 17 – Major Adverse Event Rate at 3 Year	
3 Year MAE	**N=222**
Subjects with MAE at 3-Year	31.5% (70/222)
Death	9.9% (22/222)
Limb ischemia or amputation of the target limb	0.9% (2/222)
TLR through 36 months	24.8% (55/222)
Significant embolic events (e.g. causing ulceration or gangrene)	0.0% (0/222)

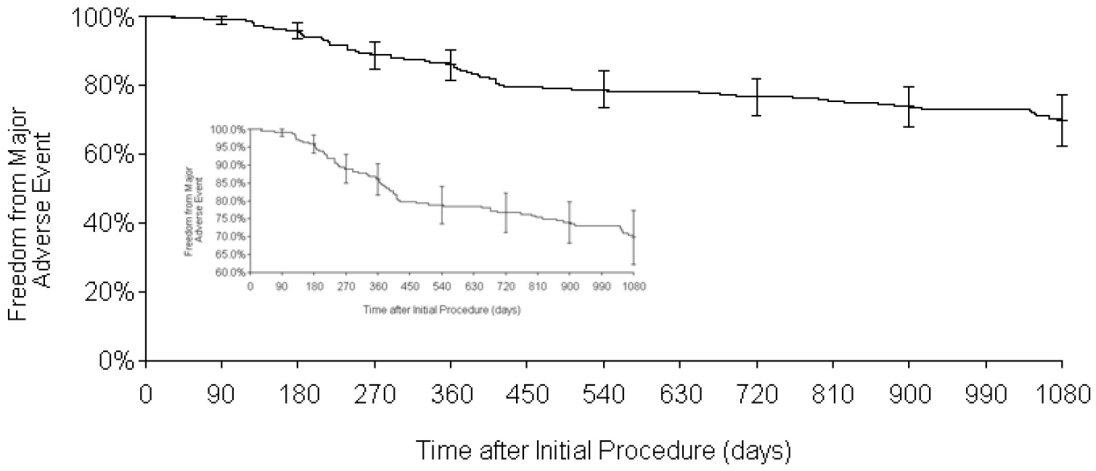
Figure 7 below is a Kaplan-Meier plot showing freedom from Major Adverse Event to 1080 days.

Figure 7. Freedom from Major Adverse Event to 1080 Days

Major Adverse Event	0	30	90	180	270	360	540	720	900	1080
# Entered	250	250	247	244	235	213	206	184	175	161
# Censored	0	3	1	1	5	0	5	4	8	53
# Incomplete	0	0	0	0	0	0	0	0	0	0
# At Risk	250	249	247	244	233	213	204	182	171	135
# Events	0	0	2	8	17	7	17	5	6	8
# Events/Month	--	0.0	1.0	2.7	5.7	2.3	2.8	0.8	1.0	1.3
% Survived	100.00%	100.00%	99.19%	95.94%	88.93%	86.01%	78.85%	76.69%	73.98%	69.74%
SE	0.00%	0.00%	0.58%	1.27%	2.04%	2.25%	2.67%	2.80%	2.97%	3.84%

Primary Endpoint Results of the Post-Approval Study
The key outcomes of the post-approval study are presented below in **Table 18**. At 3 years, 31.5% (70/222, onesided upper bound of 97.5% CI: 38.1%) of the subjects experienced death, index limb amputation, or clinically driven TLR. This rate is significantly lower than the pre-specified performance metric of 57% ($p<0.001$). As a secondary analysis of the primary endpoint of the STROLL Post-Approval study, the Kaplan Meier estimate of the composite of death, index limb amputation, and clinically driven TLR was calculated. The estimate for the cumulative composite primary post-approval safety endpoint at 1080 days was 30.3%. These results demonstrate that the **S.M.A.R.T.®** Vascular Self-Expandable Stent in treating subjects with Obstructive Superficial Femoral Artery Disease meets the pre-specified post-approval safety performance criteria.

Table 18 – 36-Month Composite Endpoint			
	S.M.A.R.T® (N=222 Patients N=222 Lesions)	**95% Confidence Interval**	**K-M Estimated Event Rate**
36-Month Composite Endpoint	31.5% (70/222)	38.1%*	30.3%
36-Month Death	9.9% (22/222)	[6.3%,14.6%]	
36-Month Clinically Driven TLR	22.5% (50/222)	[17.2%,28.6%]	
36-Month Index Limb Amputation	0.9% (2/222)	[0.1%,3.2%]	
*One-sided, upper-bound 97.5% Confidence Interval			



Adverse effects that occurred in the PMA clinical study:
There have been twenty-two (22) subject deaths reported in this study. All deaths have been classified by the Clinical Events Committee (CEC) as unrelated to the **S.M.A.R.T.®** stent.

Tables 19 and 20 provide a summary of the adverse events documented in the study. The data are presented as the total number of events as well as the percentage of subjects experiencing an AE at 30 days, 1 year, 2 years and 3 years.

Table 19 - Summary of Adverse Events

System Organ Class	Events ≤ 30 Days[1]		Events ≤ 1 Year[2]	
	Number of Events	Number of Patients (N=249 Patients)	Number of Events	Number of Patients (N=244 Patients)
Any AE	41	12.05% (30/249)	119	31.97% (78/244)
Blood and lymphatic system disorders	2	0.8% (2/249)	2	0.82% (2/244)
Anaemia	2	0.8% (2/249)	2	0.82% (2/244)
Cardiac disorders	1	0.4% (1/249)	3	1.23% (3/244)
Acute myocardial infarction	0	0.0% (0/249)	1	0.41% (1/244)
Arrhythmia	0	0.0% (0/249)	1	0.41% (1/244)
Bradycardia	1	0.4% (1/249)	1	0.41% (1/244)
Gastrointestinal disorders	1	0.4% (1/249)	1	0.41% (1/244)
Upper gastrointestinal haemorrhage	1	0.4% (1/249)	1	0.41% (1/244)
General disorders and administration site conditions	2	0.8% (2/249)	3	1.23% (3/244)
Oedema peripheral	1	0.4% (1/249)	1	0.41% (1/244)
Pain	0	0.0% (0/249)	1	0.41% (1/244)
Pyrexia	1	0.4% (1/249)	1	0.41% (1/244)
Infections and infestations	0	0.0% (0/249)	2	0.82% (2/244)
Gangrene	0	0.0% (0/249)	1	0.41% (1/244)
Sepsis	0	0.0% (0/249)	1	0.41% (1/244)
Injury, poisoning and procedural complications	13	4.8% (12/249)	56	19.26% (47/244)
Arterial restenosis	0	0.0% (0/249)	8	2.87% (7/244)
Catheter site haematoma	5	2.0% (5/249)	5	2.05% (5/244)
Catheter site haemorrhage	4	1.6% (4/249)	4	1.64% (4/244)
Device failure	1	0.4% (1/249)	2	0.82% (2/244)
In-stent arterial restenosis	0	0.0% (0/249)	31	12.30% (30/244)
Procedural hypotension	1	0.40% (1/249)	1	0.41% (1/244)
Stent occlusion	1	0.0% (1/249)	4	1.64% (4/244)
Vessel perforation	1	0.4% (1/249)	1	0.41% (1/244)
Musculoskeletal and connective tissue disorders	8	3.2% (8/249)	11	4.51% (11/244)
Muscle haemorrhage	1	0.4% (1/249)	1	0.41% (1/244)
Pain in extremity	7	2.8% (7/249)	10	4.10% (10/244)
Neoplasms benign, malignant and unspecified (incl. cysts and polyps)	0	0.0% (0/249)	2	0.82% (2/244)
Hepatic neoplasm malignant	0	0.0% (0/249)	1	0.41% (1/244)
Lung neoplasm malignant	0	0.0% (0/249)	1	0.41% (1/244)
Renal and urinary disorders	2	0.8% (2/249)	2	0.82% (2/244)

Table 19 - Summary of Adverse Events				
System Organ Class	**Events ≤ 30 Days[1]**		**Events ≤ 1 Year[2]**	
	Number of Events	**Number of Patients (N=249 Patients)**	**Number of Events**	**Number of Patients (N=244 Patients)**
Nephropathy	1	0.4% (1/249)	1	0.41% (1/244)
Renal failure acute	1	0.4% (1/249)	1	0.41% (1/244)
Vascular disorders	12	4.8% (12/249)	37	11.07% (27/244)
Arterial thrombosis limb	0	0.0% (0/249)	3	0.82% (2/244)
Arteriosclerosis	0	0.0% (0/249)	1	0.41% (1/244)
Femoral arterial stenosis	0	0.0% (0/249)	1	0.41% (1/244)
Femoral artery dissection	9	3.6% (9/249)	9	3.69% (9/244)
Femoral artery occlusion	0	0.0% (0/249)	2	0.82% (2/244)
Hypotension	0	0.0% (0/249)	0	0.0% (0/244)
Intermittent claudication	1	0.4% (1/249)	16	5.74% (14/244)
Peripheral arterial occlusive disease	0	0.0% (0/249)	0	0.0% (0/244)
Peripheral ischaemia	0	0.0% (0/249)	3	1.23% (3/244)
Vascular pseudoaneurysm	2	0.8% (2/249)	2	0.82% (2/244)

[1] Denominator for events at ≤ 30 days includes subjects who died or who had adequate follow-up for 30-day visit (through 23 days).

[2] Denominator for events at ≤ 1 year includes subjects who died or who had adequate follow-up for 1-year visit (through 330 days).

Table 20 - Summary of Adverse Events				
System Organ Class	**Events ≤ 2 Years[1]**		**Events ≤ 3 Years[2]**	
	Number of Events	**Number of Patients (N=237 Patients)**	**Number of Events**	**Number of Patients (N=228 Patients)**
Any AE	160	40.51% (96/237)	188	49.56% (113/228)
Blood and lymphatic system disorders	2	0.84% (2/237)	2	0.88% (2/228)
Anaemia	2	0.84% (2/237)	2	0.88% (2/228)
Cardiac disorders	5	2.11% (5/237)	6	2.63% (6/228)
Acute myocardial infarction	1	0.42% (1/237)	1	0.44% (1/228)
Arrhythmia	1	0.42% (1/237)	1	0.44% (1/228)
Bradycardia	1	0.42% (1/237)	1	0.44% (1/228)
Cardiac failure	1	0.42% (1/237)	1	0.44% (1/228)
Cardio-respiratory arrest	0	0.0% (0/237)	1	0.44% (1/228)
Cardiovascular disorder	1	0.42% (1/237)	1	0.44% (1/228)
Gastrointestinal disorders	1	0.42% (1/237)	1	0.44% (1/228)
Upper gastrointestinal haemorrhage	1	0.42% (1/237)	1	0.44% (1/228)
General disorders and administration site conditions	7	2.53% (6/237)	8	3.07% (7/228)
Death	1	0.42% (1/237)	2	0.88% (2/228)
Multi-organ failure	1	0.42% (1/237)	1	0.44% (1/228)
Oedema peripheral	1	0.42% (1/237)	1	0.44% (1/228)
Pain	3	0.84% (2/237)	3	0.88% (2/228)
Pyrexia	1	0.42% (1/237)	1	0.44% (1/228)
Infections and infestations	3	1.27% (3/237)	4	1.75% (4/228)
Gangrene	1	0.42% (1/237)	1	0.44% (1/228)
Sepsis	2	0.84% (2/237)	2	0.88% (2/228)
Septic shock	0	0.0% (0/237)	1	0.44% (1/228)
Injury, poisoning and procedural complications	75	24.05% (57/237)	85	28.51% (65/228)
Arterial restenosis	10	3.80% (9/237)	12	4.39% (10/228)
Catheter site haematoma	5	2.11% (5/237)	5	2.19% (5/228)
Catheter site haemorrhage	4	1.69% (4/237)	4	1.75% (4/228)
Device failure	2	0.84% (2/237)	2	0.88% (2/228)
In-stent arterial restenosis	47	16.46% (39/237)	55	20.18% (46/228)
Procedural hypotension	1	0.42% (1/237)	1	0.44% (1/228)
Stent occlusion	4	1.69% (4/237)	4	1.75% (4/228)
Thrombosis in device	1	0.42% (1/237)	1	0.44% (1/228)
Vessel perforation	1	0.42% (1/237)	1	0.44% (1/228)
Musculoskeletal and connective tissue disorders	14	5.49% (13/237)	14	5.70% (13/228)
Muscle haemorrhage	1	0.42% (1/237)	1	0.44% (1/228)
Pain in extremity	13	5.06% (12/237)	13	5.26% (12/228)

Table 20 - Summary of Adverse Events				
System Organ Class	**Events ≤ 2 Years[1]**		**Events ≤ 3 Years[2]**	
	Number of Events	**Number of Patients (N=237 Patients)**	**Number of Events**	**Number of Patients (N=228 Patients)**
Neoplasms benign, malignant and unspecified (incl. cysts and polyps)	2	0.84% (2/237)	8	3.51% (8/228)
Adenoma benign	0	0.0% (0/237)	1	0.44% (1/228)
Gastric cancer	0	0.0% (0/237)	1	0.44% (1/228)
Glioblastoma	0	0.0% (0/237)	1	0.44% (1/228)
Hepatic neoplasm malignant	1	0.42% (1/237)	1	0.44% (1/228)
Lung neoplasm malignant	1	0.42% (1/237)	2	0.88% (2/228)
Mesothelioma malignant	0	0.0% (0/237)	1	0.44% (1/228)
Urethral cancer metastatic	0	0.0% (0/237)	1	0.44% (1/228)
Nervous system disorders	1	0.42% (1/237)	1	0.44% (1/228)
Hypoaesthesia	1	0.42% (1/237)	1	0.44% (1/228)
Renal and urinary disorders	2	0.84% (2/237)	2	0.88% (2/228)
Nephropathy	1	0.42% (1/237)	1	0.44% (1/228)
Renal failure acute	1	0.42% (1/237)	1	0.44% (1/228)
Respiratory, thoracic and mediastinal disorders	1	0.42% (1/237)	2	0.88% (2/228)
Chronic obstructive pulmonary disease	0	0.0% (0/237)	1	0.44% (1/228)
Pneumonia aspiration	1	0.42% (1/237)	1	0.44% (1/228)
Vascular disorders	47	15.19% (36/237)	55	18.42% (42/228)
Arterial thrombosis limb	3	0.84% (2/237)	3	0.88% (2/228)
Arteriosclerosis	1	0.42% (1/237)	1	0.44% (1/228)
Femoral arterial stenosis	2	0.84% (2/237)	3	1.32% (3/228)
Femoral artery dissection	10	4.22% (10/237)	10	4.39% (10/228)
Femoral artery occlusion	2	0.84% (2/237)	3	1.32% (3/228)
Intermittent claudication	24	8.86% (21/237)	30	11.40% (26/228)
Peripheral ischaemia	3	1.27% (3/237)	3	1.32% (3/228)
Vascular pseudoaneurysm	2	0.84% (2/237)	2	0.88% (2/228)

[1] Denominator for events at ≤ 2 years includes subjects who died or who had adequate follow-up for 2-year visit (through 675 days).
[2] Denominator for events at ≤ 3 years includes subjects who died or who had adequate follow-up for 3-year visit (through 1020 days).

As indicated in **Table 21** below, three (3) subjects (3/202, 1.5%) experienced a Type I stent fracture by 6 months. Only one of these three subjects experienced major adverse events (MAEs) - clinically driven target lesion and target vessel revascularizations – after the point of stent fracture identification and before 12 months. However, angiographic imaging for this patient confirmed that the restenosis was in a different location than the stent fracture. A fourth subject experienced a Type I stent fracture between 6 and 12 months, resulting in a cumulative stent fracture rate of 2.0% (4/197) by 12 months. This fourth patient did not experience an MAE. Additional Type I fractures were identified in two more subjects at three year follow-up. These two subjects also did not experience MAEs after point of stent fracture identification (one of the two had MAE of in-stent restenosis prior to stent fracture).

Table 21 - Stent Fractures (Cumulative Assessment)*					
Stent Fracture	**1-month**	**6-month**	**12-month**	**24-month**	**36-month**
Type I	N/A	1.5% (3/202)	2.0% (4/197)	2.3% (4/177)	3.6% (6/169)
Type II	N/A	0.0% (0/202)	0.0% (0/197)	0.0% (0/177)	0.0% (0/169)
Type III	N/A	0.0% (0/202)	0.0% (0/197)	0.0% (0/177)	0.0% (0/169)
Type IV	N/A	0.0% (0/202)	0.0% (0/197)	0.0% (0/177)	0.0% (0/169)
Type V	N/A	0.0% (0/202)	0.0% (0/197)	0.0% (0/177)	0.0% (0/169)
Any Stent Fracture	N/A	1.5% (3/202)	2.0% (4/197)	2.3% (4/177)	3.6% (6/169)

Type I Single Strut fracture
Type II Multiple single Strut fracture
Type III Complete transverse linear separation without stent displacement
Type IV Complete transverse linear fracture with stent displacement
Type V Spiral dissection of stent

* When reporting cumulative incidence rates of stent fractures for each time point, the denominator for these calculations include all patients who had an x-ray evaluation at that time point and all patients who did not have an x-ray then but had a known stent fracture from a prior x-ray evaluation.

Effectiveness Results

The analysis of primary effectiveness was based on 215 evaluable patients at the 12-month time point, as shown in **Table 22** below.

The primary effectiveness of the **S.M.A.R.T.®** stent system was compared to the predetermined VIVA Objective Performance Goal (OPG) of 66% primary patency, using a Peak Systolic Velocity (PSV) ratio ≤ 2.0 and no further clinically driven Target Vessel Revascularization (TVR). The mean primary patency rate as a measure of primary effectiveness at 12 months was 66.5%, with a lower two-sided 95% CI of 59.8%. The lower confidence interval was not greater than the performance goal of 66%, so the effectiveness endpoint was not met.

In further consideration of the overall device performance as well as to allow the application of a more modern study design, a secondary analysis of the data was also performed. The secondary analysis applied the modified VIVA criteria which uses a higher PSV ratio and also uses Target Lesion Revascularization (TLR) in place of TVR. Using these modified criteria of a PSV ratio < 2.5 and no further clinically driven TLR, the mean primary patency rate as a measure of primary effectiveness at 12 months was 71.2% with a lower 95% CI of 64.8%. See **Table 22** below.

Table 22 – Primary Effectiveness Endpoint				
	S.M.A.R.T.® (N=250 Patients N=250 Lesions)	**95% Confidence Interval[3]**	**Performance Goal**	**Objective Met**
Primary Endpoint				
12-Month Primary Effectiveness[1] (protocol-defined)	66.5% (143/215)	[59.8%,72.8%]	66%	No
Primary DUS Stent Patency[2] (PSV ratio ≤ 2.0)	77.0% (144/187)	[70.3%,82.8%]	n/a	
Absence of Clinically Driven TVR	86.4% (203/235)	[81.3%,90.5%]	n/a	
12-Month Primary Effectiveness[1] (modified VIVA criteria)	71.2%(153/215)	[64.8%,76.8%]	66%	No
Primary DUS Stent Patency[2] (PSV ratio < 2.5)	81.1% (154/190)	[74.7%,86.4%]	n/a	
Absence of Clinically Driven TLR	87.7% (206/235)	[82.8%,91.6%]	n/a	

[1] 12-month primary effectiveness, a composite endpoint, is based on 215 available patients in the modified ITT population. There were 35 patients who were not included in the analysis of 12-month primary effectiveness:
- 5 patients died
- 30 patients did not complete 12-month follow-up (withdrew consent, no Duplex ultrasound assessment at 12 months)

The number of available patients for this endpoint is the sum of the number of patients who had ultrasound within the 12-month window and the number of patients whose TLR/TVR was evaluable but who had no ultrasound by 12 months (i.e. patients had revascularization within 360 days or had sufficient follow-up for revascularization evaluation by 330 days). There were four (4) patients who overlap and met both criteria.

[2] Primary DUS stent non-patency is binary restenosis defined as diameter stenosis > 50% with a specific peak systolic velocity ratio as measured by Duplex ultrasound.

[3] Agresti-Coull method was used to calculate the 95% CI of the point estimate for the primary effectiveness endpoint; exact (binomial) method was used to calculate the 95% CI of the point estimate for other endpoints.

The primary patency rate was also analyzed using the Kaplan Meier method. The analysis cohort consisted of all enrolled subjects. In analysis conducted using the protocol-defined primary effectiveness endpoint, the freedom from loss of primary patency (PSVR ≤ 2.0 and no clinically driven TVR) at 12 months was 86.7%. Using the modified VIVA criteria for defining 12-month primary patency (PSVR < 2.5 and no clinically driven TLR), the freedom from loss of primary patency at 12 months was 87.9%

Figure 8 below is a Kaplan-Meier plot showing freedom from clinically driven target lesion revascularization to 1080 days:

Figure 8. Freedom from Clinically Driven Target Lesion Revascularization to 1080 Days

Clinically Driven TLR	**0**	**30**	**90**	**180**	**270**	**360**	**540**	**720**	**900**	**1080**
# Entered	250	250	247	244	235	213	206	184	175	161
# Censored	0	3	1	1	5	0	5	4	8	53
# Incomplete	0	0	1	1	2	1	3	2	3	7
# At Risk	250	249	246	243	232	213	202	181	170	131
# Events	0	0	1	7	15	6	14	3	3	1
# Events/Month	--	0.0	0.5	2.3	5.0	2.0	2.3	0.5	0.5	0.2
% Survived	100.00%	100.00%	99.60%	96.73%	90.47%	87.91%	81.87%	80.50%	79.07%	78.50%
SE	0.00%	0.00%	0.41%	1.15%	1.92%	2.14%	2.57%	2.69%	2.85%	3.64%

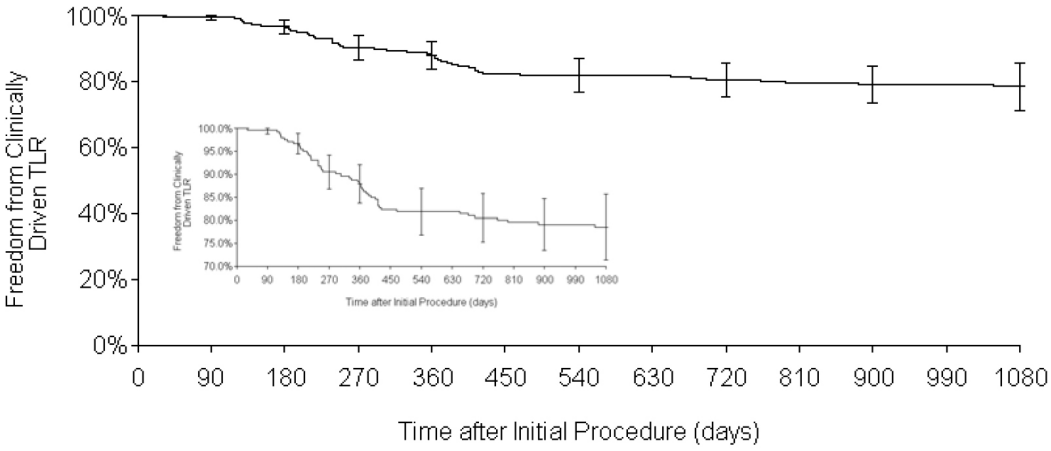


Table 23 presents a lesion length tercile analysis based on STROLL outcomes and analyzed using a PSV ratio threshold of 2.0 and clinically driven TVR as well as using modified VIVA criteria using a higher PSV ratio (2.5) and no further clinically driven TLR.

Table 23 - Primary Effectiveness as a Function of Lesion Length

	Lower (N= 83 Subjects N= 83 Lesions)	**Mid (N= 84 Subjects N= 84 Lesions)**	**Upper (N= 83 Subjects N= 83 Lesions)**
Pre-Procedure Lesion Length(mm)			
Mean±SD (N)	39.4 ± 9.9 (83)	74.1 ± 12.0 (84)	118.5 ± 19.1 (83)
Median	42.0	74.3	115.5
Range (min,max)	(15.7,55.0)	(55.5,93.3)	(94.1,200.1)
Primary Endpoint			
12-Month Primary Effectiveness[1] (protocol-defined)	75.0% (51/68)	72.6% (53/73)	52.7% (39/74)
Primary DUS Stent Patency[2] (PSV ratio ≤ 2.0)	81.0% (51/63)	82.8% (53/64)	66.7% (40/60)
Absence of Clinically Driven TVR	92.2% (71/77)	88.9% (72/81)	77.9% (60/77)
12-Month Primary Effectiveness[1] (modified VIVA criteria)	79.4% (54/68)	78.1% (57/73)	56.8% (42/74)
Primary DUS Stent Patency[2] (PSV ratio < 2.5)	84.4% (54/64)	87.7% (57/65)	70.5% (43/61)
Absence of Clinically Driven TLR	93.5% (72/77)	90.1% (73/81)	79.2% (61/77)

Note: Absence of clinically driven TVR/TLR rates at 12 months were updated as a result of additional data. Dictall

[1] "Available cases" for primary effectiveness include patients that had evaluable ultrasound assessment performed between 271 days and 540 days, or patients that either had revascularization within 360 days, or had sufficient follow up for revascularization evaluation (≥ 330 days).

[2] Primary DUS stent non-patency is binary restenosis defined as diameter stenosis > 50% with a specific peak systolic velocity ratio as measured by Duplex ultrasound.

Table 23a presents an analysis based on the same STROLL outcomes as presented in Table 23 but in two different groups: subjects with lesion length ≤ 150 mm and patients with lesion length > 150 mm.

Table 23a - Primary Effectiveness as a Function of Lesion Length (≤ 150 mm and > 150 mm)		
	Patients with Lesion Length ≤ 150 mm (N= 247 Patients) (N= 247 Lesions)	**Patients with Lesion Length > 150 mm (N= 3 Patients) (N= 3 Lesions)**
Pre-Procedure Lesion Length (mm)		
Mean±SD (N)	76.02 ± 33.46 (247)	183.56 ± 20.60 (3)
Median	72.96	190.10
Range (min,max)	(15.73,149.22)	(160.49,200.10)
Primary Endpoint		
12-Month Primary Effectiveness[1] (protocol-defined)	66.5% (141/212)	66.7% (2/3)
Primary DUS Stent Patency[2] (PSV ratio ≤ 2.0)	76.8% (142/185)	100.0% (2/2)
Absence of Clinically Driven TVR	86.6% (201/232)	66.7% (2/3)
12-Month Primary Effectiveness[1] (modified VIVA criteria)	71.2% (151/212)	66.7% (2/3)
Primary DUS Stent Patency[2] (PSV ratio < 2.5)	80.9% (152/188)	100.0% (2/2)
Absence of Clinically Driven TLR	87.9% (204/232)	66.7% (2/3)

Note: Absence of clinically driven TVR/TLR rates at 12 months were updated as a result of additional data. Dictall

[1] "Available cases" for primary effectiveness includes in the denominator all the patients that had evaluable ultrasound assessment performed between 271 days to 540 days, and all patients who either had revascularization within 360 days, or who had sufficient follow-up for revascularization evaluation (330 days).

[2] Primary DUS stent non-patency is binary restenosis defined as diameter stenosis > 50% with a specific peak systolic velocity ratio as measured by Duplex ultrasound.

Secondary Effectiveness Endpoints

Acute success was one of the secondary endpoints for the STROLL study. Acute success is comprised of 3 components, as indicated in **Table 24** below:

Table 24 – Acute Procedural Success Endpoint		
	S.M.A.R.T.® (N=250 Patients N=250 Lesions)	**95% Confidence Interval**
Device Success	99.2% (248/250)	[97.1%, 99.9%]
Technical (Lesion) Success	100.0% (250/250)	[98.5%, 100.0%]
Procedural Success	100.0% (250/250)	[98.5%, 100.0%]
Device success is defined as achievement of a final residual diameter stenosis of <50% (by QA), using the assigned treatment only for the intended purpose of treating the target lesion, regardless of whether any non-study stents were used to treat complications or lesions outside the target limb SFA. **Technical (lesion) success** is defined as the attainment of <50% residual stenosis by Quantitative Angiography (QA) using any percutaneous method. **Procedural success** is defined as achievement of a final diameter stenosis of <50% (by QA) using any percutaneous method, without the occurrence of death, index limb amputation or repeat revascularization of the target lesion during the hospital stay.		

As indicated in **Table 25** below, when using the protocol-defined criteria of target vessel patency (PSV ratio ≤ 2.0; TVR), the rate at 2 years was 61.0% (125/205). When using the modified VIVA criteria (PSV ratio < 2.5; TLR), the target vessel patency rate at 2 years was 64.7% (132/204).

Table 25 – 24-month Target Vessel Patency

	Point Estimate (N=250 Patients)	95% CI
24-month Target Vessel Patency[1] (protocol-defined)	61.0% (125/205)	
DUS Stent Non-Patency (PSV Ratio ≤ 2.0)[2]	80.6% (125/155)	
Absence of Clinically Driven TVR	77.7% (174/224)	
24-month Target Vessel Patency1 (modified VIVA criteria)	64.7% (132/204)	[57.9%,70.9%]
DUS Stent Non-Patency (PSV Ratio < 2.5)[2]	83.5% (132/158)	[76.8%,89.0%]
Absence of Clinically Driven TLR	79.5% (178/224)	[73.6%,84.6%]

[1] "Available cases" for evaluating target vessel patency includes in the denominator all the patients that had evaluable ultrasound assessment performed between 541 days to 900 days, and all patients who either had revascularization within 720 days, or who had sufficient follow-up for revascularization evaluation (675 days).
[2]DUS stent non-patency is binary restenosis defined as diameter stenosis > 50% with a specific peak systolic velocity ratio as measured by Duplex ultrasound.

The 24-month patency rate was also analyzed using the Kaplan Meier method. The analysis cohort consisted of all enrolled subjects. In analysis conducted using protocol-defined patency, the freedom from loss of patency (PSVR ≤ 2.0 and no clinically driven TVR) at 24 months was 78.8%. Using the modified VIVA criteria for defining 24-month patency (PSVR < 2.5 and no clinically driven TLR), the freedom from loss of patency at 24 months was 80.5%.

As indicated in **Table 26** below, when using the protocol-defined criteria of target vessel patency (PSV ratio ≤ 2.0; TVR), the rate at 3 years was 57.2% (107/187). When using the modified VIVA criteria (PSV ratio < 2.5; TLR), the target vessel patency rate at 3 years was 61.1% (113/185).

Table 26 – 36-month Target Vessel Patency

	Point Estimate (N=250 Patients)	95% CI
36-month Target Vessel Patency[1] (protocol-defined)	57.2% (107/187)	
DUS Stent Non-Patency (PSV Ratio ≤ 2.0)[2]	82.0% (109/133)	
Absence of Clinically Driven TVR	73.1% (152/208)	
36-month Target Vessel Patency1 (modified VIVA criteria)	61.1%(113/185)	[53.9%,67.8%]
DUS Stent Non-Patency (PSV Ratio < 2.5)[2]	83.9% (115/137)	[76.7%,89.7%]
Absence of Clinically Driven TLR	75.8% (157/207)	[69.4%,81.5%]

[1] "Available cases" for evaluating target vessel patency includes in the denominator all the patients that had evaluable ultrasound assessment performed between 901 days to 1260 days, and all patients who either had revascularization within 1080 days, or who had sufficient follow-up for revascularization evaluation (1020 days).

[2]DUS stent non-patency is binary restenosis defined as diameter stenosis > 50% with a specific peak systolic velocity ratio as measured by Duplex ultrasound.

The 36-month patency rate was also analyzed using the Kaplan Meier method. The analysis cohort consisted of all enrolled subjects. In analysis conducted using protocol-defined patency, the freedom from loss of patency (PSVR ≤ 2.0 and no clinically driven TVR) at 36 months was 69.4%. Using the modified VIVA criteria for defining 36-month patency (PSVR < 2.5 and no clinically driven TLR), the freedom from loss of patency at 36 months was 72.7%.

Table 27 below provides a summary of results of the ABI assessment from pre-procedure through 36 months. ABI results remained fairly constant at 3 years post-procedure with 76.5% (137/179) of the patients having ABI of > 0.8, 22.3% (40/179) having ABI of 0.4 to 0.8 and only 1.1% (2/179) having ABI of < 0.4.

Table 27 - Summary of ABI Data

Measures	Pre-Procedure	1 Month	6 Month	12 Month	24 Month	36 Month
ABI(Resting or Exercise)						
<0.4	6.1% (15/247)	0.0% (0/236)	0.0% (0/214)	0.5% (1/211)	0.5% (1/197)	1.1% (2/179)
0.4-0.8	84.6% (209/247)	10.2% (24/236)	18.2% (39/214)	19.0% (40/211)	18.8% (37/197)	22.3% (40/179)
>0.8	9.3% (23/247)	89.8% (212/236)	81.8% (175/214)	80.6% (170/211)	80.7% (159/197)	76.5% (137/179)
Absolute Value						
Mean±SD (N)	0.66 ± 0.15 (247)	0.98 ± 0.14 (236)	0.94 ± 0.15 (214)	0.93 ± 0.18 (211)	0.93 ± 0.18 (197)	0.92 ± 0.20 (179)
Median	0.67	0.98	0.96	0.95	0.93	0.94
Range (min, max)	(0.24,1.32)	(0.52,1.38)	(0.48,1.36)	(0.17,1.90)	(0.39, 1.74)	(0.26, 1.65)

Table 28 below provides a summary of results of the Rutherford/Becker Classification from pre-procedure through 36 months. At 3 years post-procedure, the majority of patients, 57.8% (104/180), were classified as Rutherford/Becker category 0, 20.0% (36/180) were classified as Rutherford/Becker 1, 11.7% (21/180) were classified as Rutherford/Becker 2, 9.4% (17/180) were classified as Rutherford/Becker 3 and 1.1% (2/180) were classified as Rutherford/Becker 4.

Table 28 - Summary of Rutherford/Becker Classification Data

Rutherford/ Becker Category	Pre-Procedure	Discharge	1 Month	6 Month	12 Month	24 Month	36 Month
0	0.0% (0/249)	44.6% (104/233)	64.6% (157/243)	63.3% (136/215)	58.4% (125/214)	63.6% (126/198)	57.8% (104/180)
1	0.0% (0/249)	13.3% (31/233)	16.0% (39/243)	20.9% (45/215)	18.2% (39/214)	18.2% (36/198)	20.0% (36/180)
2	45.8% (114/249)	21.5% (50/233)	15.6% (38/243)	9.8% (21/215)	15.0% (32/214)	9.1% (18/198)	11.7% (21/180)
3	51.4% (128/249)	19.3% (45/233)	3.3% (8/243)	5.6% (12/215)	7.5% (16/214)	9.1% (18/198)	9.4% (17/180)
4	2.8% (7/249)	1.3% (3/233)	0.4% (1/243)	0.5% (1/215)	0.5% (1/214)	0.0% (0/198)	1.1% (2/180)
5	0.0% (0/249)	0.0% (0/233)	0.0% (0/243)	0.0% (0/215)	0.5% (1/214)	0.0% (0/198)	0.0% (0/180)
6	0.0% (0/249)	0.0% (0/233)	0.0% (0/243)	0.0% (0/215)	0.0% (0/214)	0.0% (0/198)	0.0% (0/180)
Absolute Value							
Mean ± SD (N)	2.57 ± 0.55 (249)	1.19 ± 1.23 (233)	0.59 ± 0.90 (243)	0.59 ± 0.91 (215)	0.75 ± 1.04 (214)	0.64 ± 0.98 (198)	0.76 ± 1.06 (180)
Median	3.00	1.00	0.00	0.00	0.00	0.00	0.00
Range (min, max)	(2.00,4.00)	(0.00,4.00)	(0.00,4.00)	(0.00,4.00)	(0.00,5.00)	(0.00,3.00)	(0.00,4.00)
Index Limb Ischemia (3,4,5,6)	54.2% (135/249)	20.6% (48/233)	3.7% (9/243)	6.0% (13/215)	8.4% (18/214)	9.1% (18/198)	10.6% (19/180)
Change from Baseline							
Mean ± SD (N)	N/A	-1.38 ± 1.17 (233)	-1.99 ± 1.01 (242)	-1.98 ± 1.05 (214)	-1.83 ± 1.15 (213)	-1.93 ± 1.07 (197)	-1.83 ± 1.13 (179)
Median	N/A	-2.00	-2.00	-2.00	-2.00	-2.00	-2.00
Range (min, max)	N/A	(-4.00, 0.00)	(-4.00,1.00)	(-4.00,1.00)	(-4.00, 2.00)	(-4.00, 1.00)	(-4.00, 2.00)

Study Strengths and Limitations. The outcomes of the STROLL Post-Approval Study were assessed in the same patients enrolled into the STROLL study and followed throughout 3 years (36 months). The STROLL study enrolled a total of 250 subjects between August 14, 2008 and March 15, 2010 at 39 U.S. investigational sites. The sample size provided sufficient power to perform the long-term safety analysis of the primary endpoint of the STROLL Post-Approval Study. However, this sample size may be considered relatively small for collecting post-market data. In addition, while the data were collected with high quality, the patient population treated in the real-world setting could be more complex.

5. Conclusion

Overall, the results from non-clinical and clinical evaluations provide reasonable assurance that the **S.M.A.R.T.® CONTROL®** and **S.M.A.R.T.®** Vascular Stent Systems are safe and effective. While the prespecified effectiveness endpoint was not met, the study results are similar to the results for other US marketed stents intended for use in patients with SFA and proximal popliteal artery lesions. The benefits of use of the **S.M.A.R.T.® CONTROL®** and **S.M.A.R.T.®** Vascular Stent Systems for the target population outweigh the risk of illness or injury when used as indicated in accordance with the labeling and Instructions for Use (IFU).

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