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)**

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:

II.A Description: Cordis **S.M.A.R.T.® CONTROL®** Vascular Stent System
II.B Description: Cordis **S.M.A.R.T.®** Vascular Stent System
II.C Available Product Sizes and Catalog Numbers

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

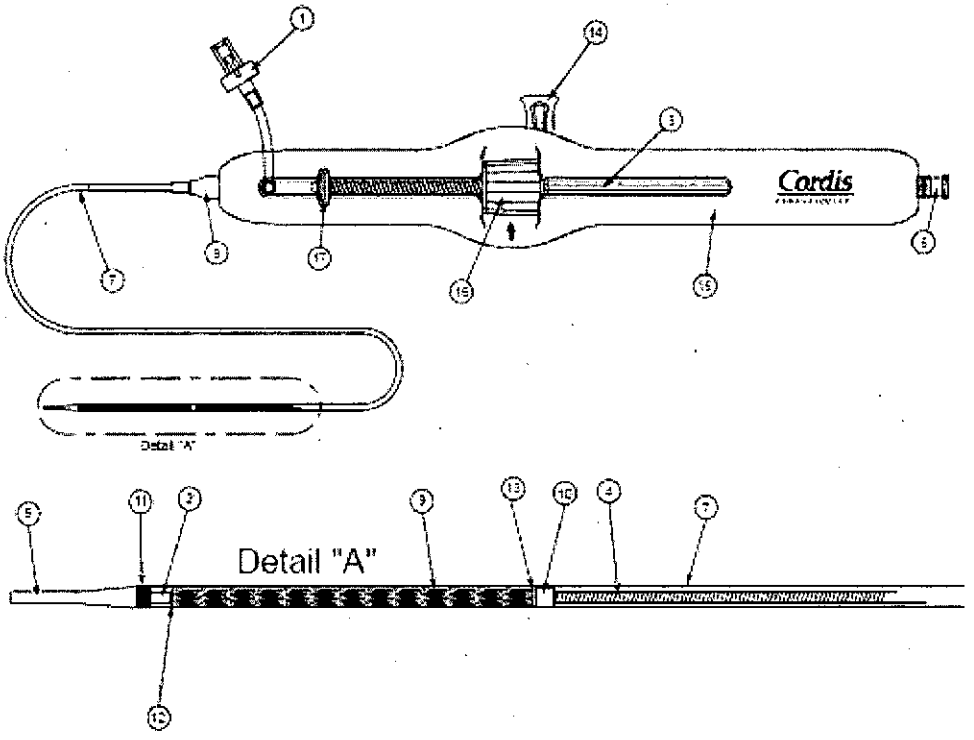
The Cordis **S.M.A.R.T.® CONTROL®** Vascular Stent System is designed to deliver a self-expanding stent to the superficial femoral arteries and/or proximal popliteal arteries via a 6F (2.0 mm) sheathed delivery system. The self-expanding stent is composed of a nickel titanium alloy (nitinol). A total 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

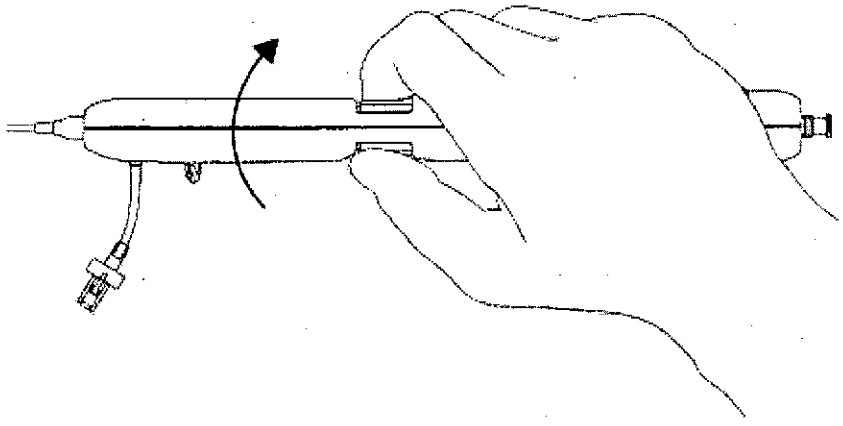


Figure 3. Stent Deployment Using Deployment Lever

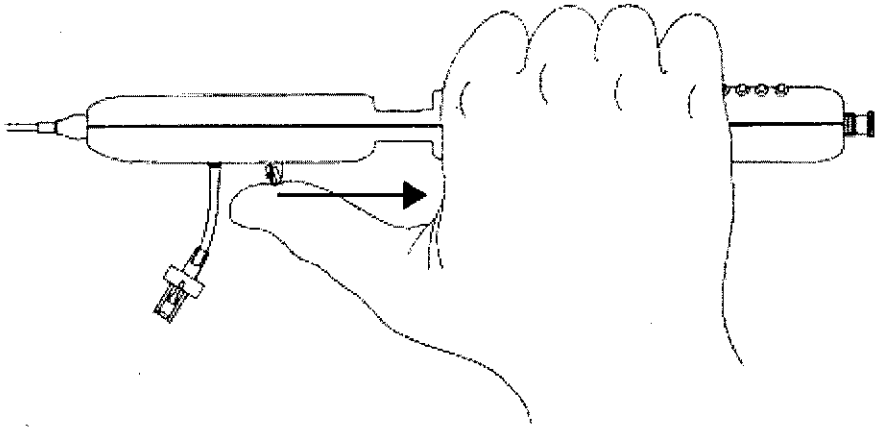
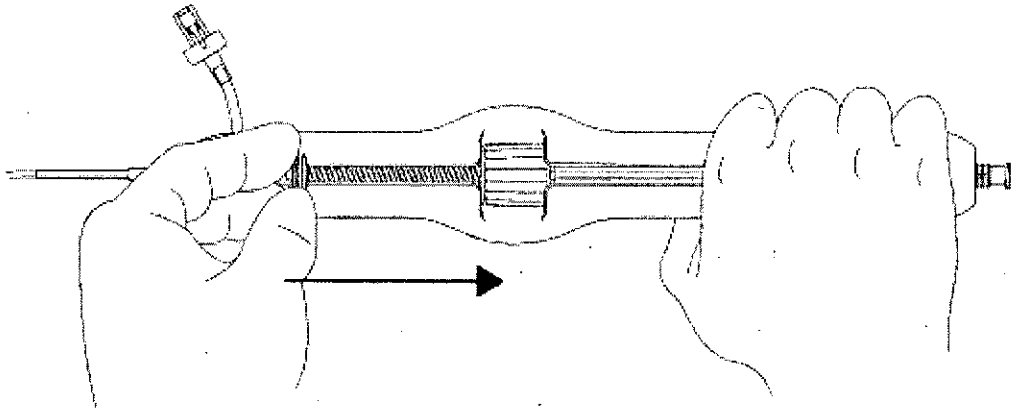


Figure 4. Stent Deployment Using Two Hands ("Pin and Pull")

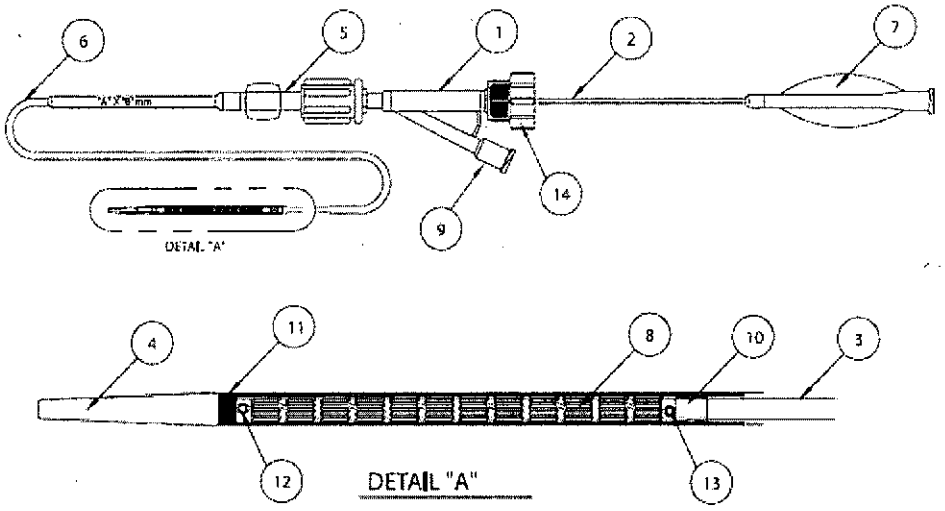


II.B DESCRIPTION: Cordis S.M.A.R.T.® Vascular Stent System

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).

II.C 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 hypercoaguability 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.

- 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* 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.

* Ethiodol and Lipiodol are trademarks of Guerbet S.A.

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
- 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 / bacterimia (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.cordislabeling.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.

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.

   f. 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	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.	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 COMPATIBILITY

Non-clinical testing has demonstrated that the **S.M.A.R.T.®** Stent is MR Conditional in single and overlapped configuration up at a maximum of 290mm as defined in ASTM F2503-08. It can be scanned immediately after implantation under the following conditions:

- Static magnetic field of 1.5 Tesla or 3 Tesla
- Spatial gradient field of 3000 Gauss/cm or less
- Maximum whole-body-averaged specific absorption rate (WB-SAR) of 2 W/kg for 15 minutes of scanning for patient landmarks above umbilicus
- Maximum WB-SAR of 1 W/kg for 15 minutes of scanning for patient landmarks below umbilicus
- Whole body MR coil. Local coils should not be placed directly over the implanted stent.

3.0 Tesla Temperature Rise

Non-clinical testing of RF-induced heating was performed on single and overlapped stents up to 290mm according to ASTM F2182-11a at 128 MHz in a GE Signa HDx 3.0 T MR system. The phantom average SAR was 2.3 W/kg.

Calculation of in-vivo heating in a digitized human model using worst-case assumptions for the interactions during MRI of the electromagnetic fields in the body with the stent resulted in a worst-case in-vivo rise of less than 4.5° (3.3°C $\pm$ 36%) for the SAR limits above. These calculations do not take into consideration the cooling effects of blood flow.

1.5 Tesla Temperature Rise

Non-clinical testing of RF-induced heating was performed on single and overlapped stents up to 290mm according to ASTM F2182-11a at 64 MHz in a GE whole body coil. The phantom average SAR was 2.1 W/kg.

Calculation of in-vivo heating in a digitized human model using worst-case assumptions for the interactions during MRI of the electromagnetic fields in the body with the stent resulted in a worst-case in-vivo rise of less than 6°C (4.4°C + 36%) for the SAR limits above. These calculations do not take into consideration the cooling effects of blood flow.

Additional Information

The heating effect in the MRI environment for fractured stents is not known.

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 **S.M.A.R.T.®** Stent. Non-clinical testing according to ASTM F2119-07 of 8x150 mm **S.M.A.R.T.®** Stents within a GE Signa 3T MR Scanner produced maximum image artifact of 9 mm beyond each side of the stent when parallel to the magnetic field, and a maximum image length artifact of 8 mm beyond each side of the stent when perpendicular to the magnetic field. The area within the stent is characterized by an image void. It may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

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 4-7mm, in the US 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.

12.1 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 percutaneous transluminal angioplasty (PTA) and primary stenting with the S.M.A.R.T.® Nitinol Stent System to performance goals of PTA alone in the treatment of atherosclerotic lesions of the native superficial femoral artery (SFA) or the superficial femoral and proximal popliteal arteries. The safety and performance goals were based on an aggregate of published trial data as described by VIVA physicians Inc. (VPI). STROLL was conducted at 39 US investigational sites. A total of 250 subjects were enrolled. 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 from 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, and 12 months, and will continue with annual follow-up for up to 3 years.

Patients were treated between August 14, 2008 and March 15, 2010. The database for this PMA reflected data collected through June 18, 2012 and included 250 patients. There were 39 investigational sites.

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 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 effectiveness against the VIVA performance goal of 66%, using a one-sided significance level of 0.025. The results were evaluated using the Intent-to-Treat (ITT) population. The 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 whether the patient received the S.M.A.R.T.® Stent or not).

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).

1. 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 4.0-15.0 cm by visual estimate. The stenosis had to be treatable with no more than two stents, minimizing the stent overlap whose combined length should not 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).

2. Follow-up Schedule
All patients were scheduled to return for follow-up examinations at 30 days, 6 months, 1, 2 and 3 years post-procedure. Table 5 provides a summary of the study requirements at each stage of the study.

Table 5: 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 profileand 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 be completed within seven (7) days prior to the day of the index procedure
[2] Only serum creatinine will be checked at 30 days
[3] If WBC is within normal limits (WNL), differential is not required.
[4] Plavix® or Ticlid® is recommended for at least one month post procedure; ASA recommended for all patients indefinitely. If Ticlid® is used, the product label should be followed for appropriate patient follow-up
[5] Patients known to be pregnant should be excluded from study participation – for women of child bearing potential, a pregnancy test must be completed within 7 days of index procedure
[6] In the event of a stent fracture, X-rays will be conducted every 6 months
[7] To be 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

3. Clinical Endpoints

The primary safety endpoint was freedom from all causes of death, index limb amputation and clinically driven target lesion revascularization (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 target vessel revascularization (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.

A. 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 6** summarizes the study compliance for all follow-up time points. **Tables 7, 8, and 9** show detailed patient accountability for the 30-day, 12-month, and 24 month visits, respectively. Tables 6-9 reflect study compliance data obtained on September 24, 2012.

Table 6: Summary of Subject Compliance

Time	Compliance
Procedure	250/250 (100%)
Discharge	250/250 (100%)
30 Days	242/250 (96.8%)
6 Months	219/250 (87.6%)
1 Year	219/250 (87.6%)
2 Year	203/250 (81.2%)
3 Year[1]	85/250 (34%)

[1]3-Year follow-up was ongoing at the time of data export.

Table 7: 30-Day Follow-Up Compliance

30-day Follow-Up	N=250
Available	242/250 (96.8%)
Unavailable	8/250 (3.2%)
Died	0/250 (0.0%)
Lost-to-Follow-Up	0/250 (0.0%)
Missed Visit	6/250 (2.4%)
Withdrew	2/250 (0.8%)

Two (2) patients withdrew consent prior to their 30 day visit, resulting in a total of 248 patients with sufficient data for evaluation of the 30-day primary safety endpoint.

Table 8: 12-Month Follow-Up Compliance

12-month Follow-Up	N=250
Available	219/250 (87.6%)
Unavailable	31/250 (12.4%)
Died	5/250 (2.0%)
Lost-to-Follow-Up	0/250 (0.0%)
Missed Visit	16/250 (6.4%)
Withdrew	10/250 (4.0%)

By the 12-month visit, a total of 5 patients died and 10 withdrew consent, for a total of 235 eligible patients in the 12-month population (see Figure 4). A total of 236 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 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.

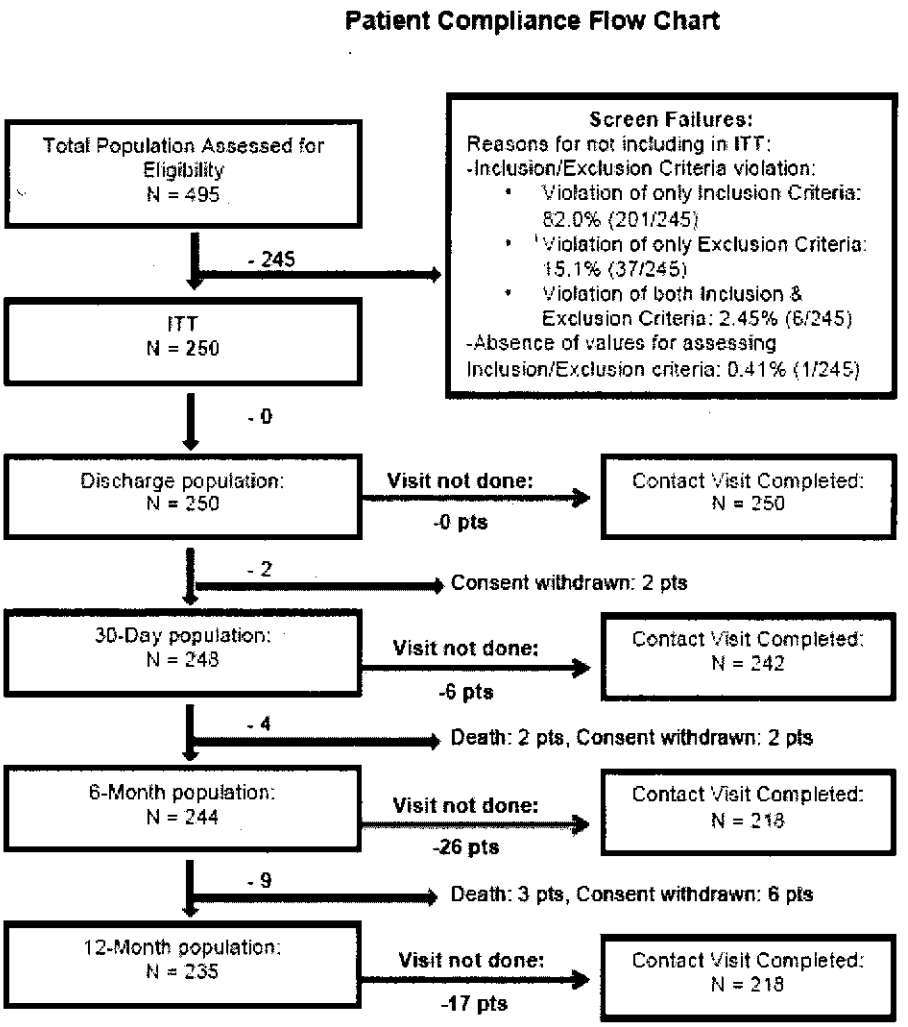
Table 9: 24-Month Follow-Up Compliance

24-month Follow-Up	N=250
Available	203/250 (81.2%)
Unavailable	47/250 (18.8%)
Died	10/250 (4.0%)
Lost-to-Follow-Up	2/250 (0.8%)
Missed Visit	19/250 (7.6 %)
Withdrew	14/250 (5.6%)
Exit the study due to other reasons*	2/250 (0.8%)

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

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. A total of 225 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 htorugh 675 days, the start of the 24-month window.

Figure 4. Patient compliance flow chart up to 12-months



Note:

1. Each N represents the population at the beginning of that visit.

2. The ITT population was designed to include all screened patients who met eligibility criteria and had the guidewire 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).

12.2 Study Population Demographics and Baseline Parameter

Baseline demographics and clinical characteristics for all patients enrolled in the STROLL study are summarized in **Table 10. Table 11** 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 10: Demographics and Baseline Clinical Characteristics

Patient Characteristic	SMART® Stent (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 11: Baseline Target Lesion Characteristics

Lesion Characteristics	SMART® (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[1]	

Lesion Characteristics	SMART® (N=250 Patients N=250 Lesions)
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).

[1] 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 total number 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 12.**

Table 12: Subjects who have exited the study

Exited Study	**Subjects**
Died	22/250 (8.8%)
Lost-to-Follow-Up (LTFU)	3/250 (1.2%)
Withdrew	23/250 (9.2%)
Other*	3/250 (1.2%)
Total	**51/250 (20.4%)**

*Two (2) patients were withdrawn by the Investigator due to safety concerns and one (1) patient had medical records review at the 3-year follow-up visit.

The number of patients 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*	10
Non-Diagnostic Duplex at 1-year	3
Missing 1-year Duplex Ultrasound Assessment and no interim TVR	17
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.

12.3 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

12.4 Safety and Effectiveness Results

Safety Results

The primary analysis of safety was based on the 248 subjects available for the 30-day evaluation. The key safety outcomes are presented below in **Tables 14 and 15**. Adverse effects are presented in **Tables 16 and 17**.

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=250 Patients N=250 Lesions)	95% Confidence Interval*	Performance Goal	Objective Met
Absence of 30-Day Major Complications	100.0% (248/248)	[98.2%,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 14.4% (34/236) and is presented in **Table 15**.

Table 15 – Major Adverse Event Rate at 1 Year

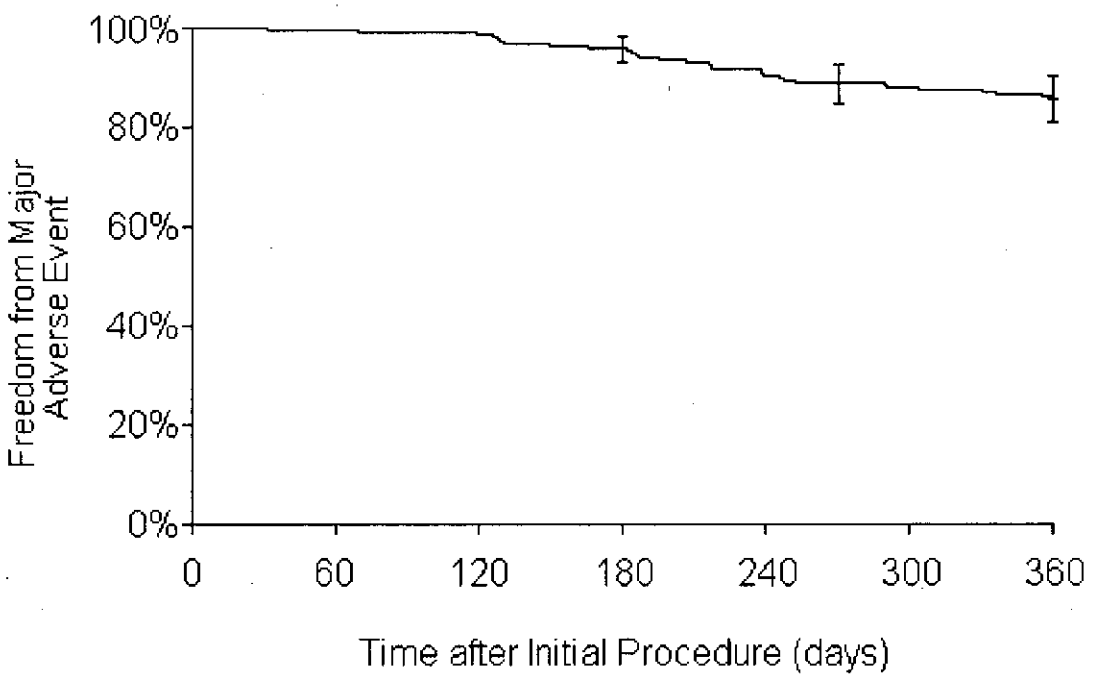
1 Year MAE	N=236
Subjects with MAE at 1-Year	14.4% (34/236)
Death	2.1% (5/236)
Limb ischemia or amputation of the target limb	0.4% (1/236)
TLR through 12 months	13.6% (32/236)
Significant embolic events (e.g., causing ulceration or gangrene)	0.0% (0/236)

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).

Figure 5 below is a Kaplan-Meier plot showing freedom from Major Adverse Event to 360 days:

Figure 5. Freedom from Major Adverse Event to 360 Days

Major Adverse Event	0	7	30	180	270	360
# Entered	250	250	249	245	232	210
# Censored	0	1	4	3	5	36
# Incomplete	0	0	0	0	0	0
# At Risk	250	250	247	244	230	192
# Events	0	0	0	10	17	7
# Events/Month	--	0.0	0.0	2.0	5.7	2.3
% Survived	100.00%	100.00%	100.00%	95.89%	88.79%	85.68%
SE	0.00%	0.00%	0.00%	1.28%	2.05%	2.51%



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.

Table 16 provides 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 and at 1 year.

Table 16: Summary of Adverse Events

System Organ Class	Events ≤ 30 Days[1]		Events ≤ 1 Year[2]	
	Number of Events	Number of Patients (N=248 Patients)	Number of Events	Number of Patients (N=236 Patients)
Any AE	35	10.1% (25/248)	113	31.8% (75/236)
Blood and lymphatic system disorders	2	0.8% (2/248)	2	0.8% (2/236)
Anaemia	2	0.8% (2/248)	2	0.8% (2/236)

System Organ Class	Events ≤ 30 Days[1]		Events ≤ 1 Year[2]	
	Number of Events	Number of Patients (N=248 Patients)	Number of Events	Number of Patients (N=236 Patients)
Cardiac disorders	1	0.4% (1/248)	3	1.3% (3/236)
Acute myocardial infarction	0	0.0% (0/248)	1	0.4% (1/236)
Arrhythmia	0	0.0% (0/248)	1	0.4% (1/236)
Bradycardia	1	0.4% (1/248)	1	0.4% (1/236)
Gastrointestinal disorders	1	0.4% (1/248)	1	0.4% (1/236)
Upper gastrointestinal haemorrhage	1	0.4% (1/248)	1	0.4% (1/236)
General disorders and administration site conditions	2	0.8% (2/248)	3	1.3% (3/236)
Oedema peripheral	1	0.4% (1/248)	1	0.4% (1/236)
Pain	0	0.0% (0/248)	1	0.4% (1/236)
Pyrexia	1	0.4% (1/248)	1	0.4% (1/236)
Infections and infestations	0	0.0% (0/248)	2	0.8% (2/236)
Gangrene	0	0.0% (0/248)	1	0.4% (1/236)
Sepsis	0	0.0% (0/248)	1	0.4% (1/236)
Injury, poisoning and procedural complications	12	4.8% (12/248)	55	19.9% (47/236)
Arterial restenosis	0	0.0% (0/248)	1	0.4% (1/236)
Catheter site haematoma	5	2.0% (5/248)	5	2.1% (5/236)
Catheter site haemorrhage	4	1.6% (4/248)	4	1.7% (4/236)
Device failure	1	0.4% (1/248)	2	0.8% (2/236)
In-stent arterial restenosis	1	0.4% (1/248)	39	15.3% (36/236)
Stent occlusion	0	0.0% (0/248)	3	1.3% (3/236)
Vessel perforation	1	0.4% (1/248)	1	0.4% (1/236)
Musculoskeletal and connective tissue disorders	7	2.8% (7/248)	10	4.2% (10/236)
Muscle haemorrhage	1	0.4% (1/248)	1	0.4% (1/236)
Pain in extremity	6	2.4% (6/248)	9	3.8% (9/236)
Neoplasms benign, malignant and unspecified (incl. cysts and polyps)	0	0.0% (0/248)	1	0.4% (1/236)
Lung neoplasm malignant	0	0.0% (0/248)	1	0.4% (1/236)
Renal and urinary disorders	2	0.8% (2/248)	2	0.8% (2/236)
Renal failure acute	2	0.8% (2/248)	2	0.8% (2/236)
Vascular disorders	8	3.2% (8/248)	34	11.0% (26/236)
Arterial thrombosis limb	0	0.0% (0/248)	1	0.4% (1/236)
Arteriosclerosis	0	0.0% (0/248)	1	0.4% (1/236)
Femoral arterial stenosis	0	0.0% (0/248)	1	0.4% (1/236)
Femoral artery dissection	4	1.6% (4/248)	4	1.7% (4/236)
Femoral artery occlusion	0	0.0% (0/248)	2	0.8% (2/236)
Hypotension	1	0.4% (1/248)	1	0.4% (1/236)
Intermittent claudication	1	0.4% (1/248)	16	5.9% (14/236)
Peripheral arterial occlusive disease	0	0.0% (0/248)	1	0.4% (1/236)
Peripheral ischaemia	0	0.0% (0/248)	5	1.3% (3/236)
Vascular pseudoaneurysm	2	0.8% (2/248)	2	0.8% (2/236)

[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).

As indicated in **Table 17** below, three patients (3/202, 1.49%) experienced a Type I stent fracture by 6 months. Only one of these three patients experienced major adverse events (MAEs) - clinically driven target lesion and target vessel revascularizations - before 12 months. However, angiographic imaging for this patient confirmed that the restenosis was in a different location than the stent fracture. A fourth patient experienced a Type I stent fracture between 6 and 12 months, resulting in a cumulative stent fracture rate of 2.03% (4/197) by 12 months. This fourth patient did not experience an MAE. An additional Type 1 fracture was identified in a fifth patient at three year follow-up. This fifth patient did not experience an MAE.

Table 17: Stent Fractures (Cumulative Assessment)

Stent Fracture	1-month	6-month	12-month
Type I	N/A	1.49% (3/202)	2.03% (4/197)
Type II	N/A	0.0% (0/202)	0.0% (0/197)
Type III	N/A	0.0% (0/202)	0.0% (0/197)
Type IV	N/A	0.0% (0/202)	0.0% (0/197)
Type V	N/A	0.0% (0/202)	0.0% (0/197)
Any Stent Fracture	N/A	1.49% (3/202)	2.03% (4/197)

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

Effectiveness Results

The analysis of primary effectiveness was based on 215 evaluable patients at the 12-month time point, as shown in **Table 18** 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 60.0%. 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 18** below.

Table 18 – 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)	[60.0%,72.5%]	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	86.1% (199/231)	[81.0%,90.3%]	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	87.4% (202/231)	[82.5%,91.4%]	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 stent 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 within the stented segment) at 12 months was 79.5%. 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 was 81.7%

Figure 6 below is a Kaplan-Meier plot showing freedom from clinically driven target lesion revascularization to 360 days:

Figure 6. Freedom from Clinically Driven Target Lesion Revascularization to 360 Days

Clinically Driven TLR	0	7	30	180	270	360
# Entered	250	250	249	245	232	210
# Censored	0	1	4	3	5	36
# Incomplete	0	0	0	2	2	1
# At Risk	250	250	247	243	229	192
# Events	0	0	0	8	15	6
# Events/Month	–	0.0	0.0	1.6	5.0	2.0
% Survived	100.00%	100.00%	100.00%	96.69%	90.35%	87.60%
SE	0.00%	0.00%	0.00%	1.16%	1.94%	2.39%

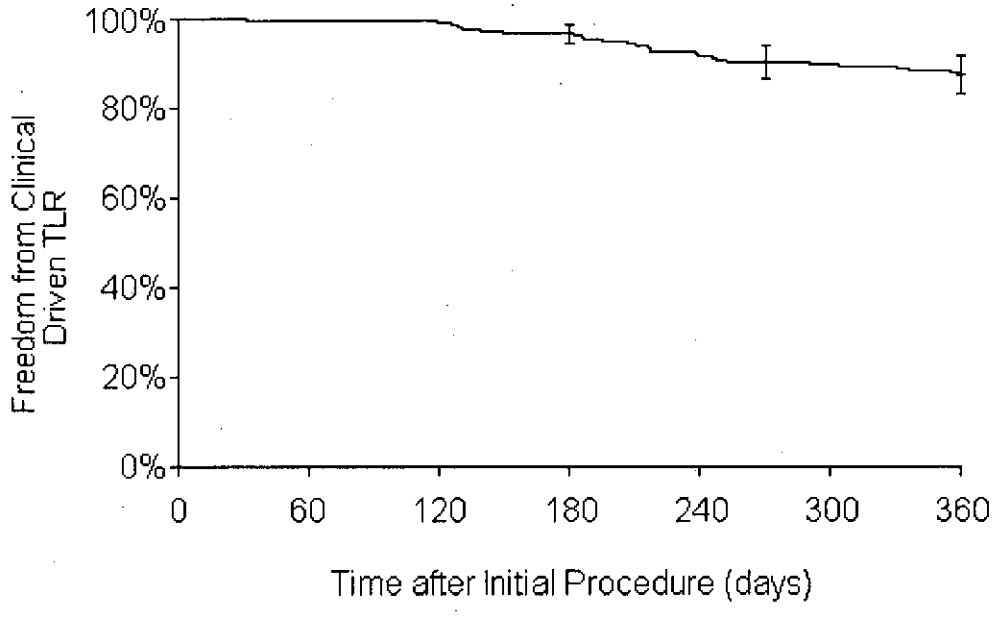


Table 19 presents a lesion length tercile analysis based on STROLL outcomes and analyzed using a PSV ratio threshold of 2.0 and clinically driven TVR as well as using modified VIVA criteria using a higher PSV ratio (2.5) and no further clinically driven TLR.

Table 19: Primary Effectiveness as a Function of Lesion Length

	Lower (N= 83 Patients N= 83 Lesions)	Mid (N= 84 Patients N= 84 Lesions)	Upper (N= 83 Patients N= 83 Lesions)
Pre-Procedure Lesion Length(mm)			
Mean±SD (N)	39.4±9.9 (83)	74.0±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	92.1% (70/76)	88.6% (70/79)	77.6% (59/76)

Table 19: Primary Effectiveness as a Function of Lesion Length			
	Lower (N= 83 Patients N= 83 Lesions)	**Mid (N= 84 Patients N= 84 Lesions)**	**Upper (N= 83 Patients N= 83 Lesions)**
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	93.4% (71/76)	89.9% (71/79)	78.9% (60/76)

[1] "Available cases" for primary effectiveness includes in the denominator all the patients that had evaluable ultrasound assessment performed between 271 days and 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.

Table 19a presents an analysis based on the same STROLL outcomes as presented in **Table 19** but in two different groups: patients with lesion length ≤ 150 mm and patients with lesion length > 150 mm.

Table 19a: Primary Effectiveness as a function of Lesion Length (≤ 150 mm and > 150 mm)

	Subjects with Lesion Length ≤ 150 mm (N= 247 Subjects) (N= 247 Lesions)	**Subjects with Lesion Length > 150 mm (N= 3 Subjects) (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	86.4% (197/228)	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	87.7% (200/228)	66.7% (2/3)

[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 20** below:

Table 20 – Acute Procedural Success Endpoint		
	S.M.A.R.T.® (N=250 Patients N=250 Lesions)	**95% Confidence Interval**
Lesion Success	100.0% (250/250)	[98.5%, 100%]
Device Success	93.2% (232/249)	[89.3%, 96.0%]
Procedure Success	100.0% (250/250)	[98.5%, 100%]
Technical (lesion) success is defined as the attainment of <50% residual stenosis by Quantitative Angiography (QA) using any percutaneous method. **Device success** is defined as achievement of a final residual diameter stenosis of <50% (by QA), using the assigned treatment only. **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.		

Table 21 below provides a summary of results of the ABI assessment from pre-procedure through 12 months:

Table 21 - Summary of ABI Data				
Measures	**Pre-Procedure**	**1 Month**	**6 Month**	**12 Month**
ABI(Resting or Exercise)				
<0.4	6.1% (15/247)	0.0% (0/236)	0.5% (1/214)	0.5% (1/211)
0.4-0.8	84.6% (209/247)	10.2% (24/236)	17.3% (37/214)	18.5% (39/211)
>0.8	9.3% (23/247)	89.8% (212/236)	82.2% (176/214)	81.0% (171/211)
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)
Median	0.67	0.98	0.96	0.95
Range (min,max)	(0.24,1.32)	(0.52,1.38)	(0.35,1.36)	(0.11,1.90)

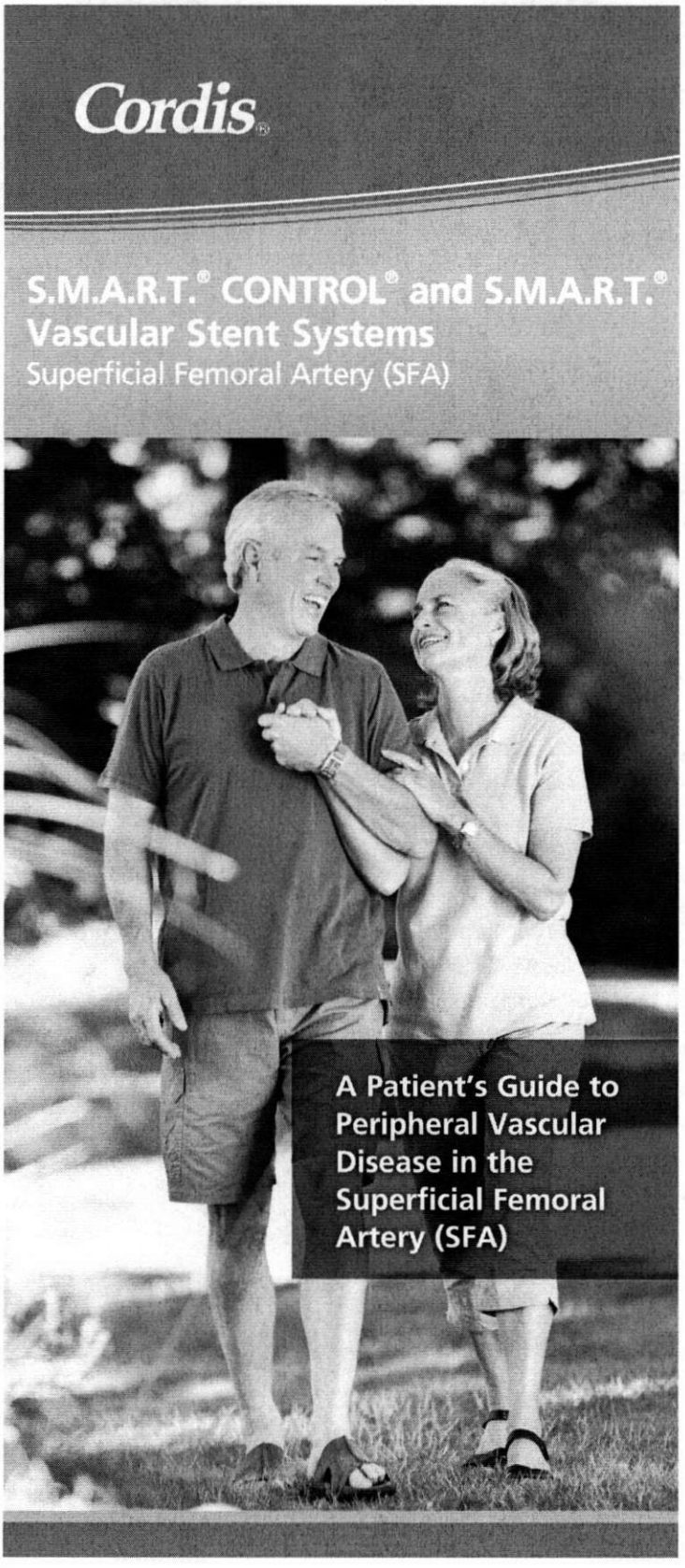
Table 22 below provides a summary of results of the Rutherford/Becker Classification from pre-procedure through 12 months:

Table 22- Summary of Rutherford/Becker Classification Data					
Rutherford/Becker Category	**Pre-Procedure**	**Discharge**	**1 Month**	**6 Month**	**12 Month**
0	0.0% (0/249)	44.6% (104/233)	64.6% (157/243)	63.3% (136/215)	58.4% (125/214)
1	0.0% (0/249)	13.3% (31/233)	16.0% (39/243)	20.9% (45/215)	18.2% (39/214)
2	45.8% (114/249)	21.5% (50/233)	15.6% (38/243)	10.2% (22/215)	15.0% (32/214)
3	51.4% (128/249)	19.3% (45/233)	3.3% (8/243)	5.1% (11/215)	7.5% (16/214)
4	2.8% (7/249)	1.3% (3/233)	0.4% (1/243)	0.5% (1/215)	0.5% (1/214)
5	0.0% (0/249)	0.0% (0/233)	0.0% (0/243)	0.0% (0/215)	0.5% (1/214)
6	0.0% (0/249)	0.0% (0/233)	0.0% (0/243)	0.0% (0/215)	0.0% (0/214)
Absolute Value					
Mean±SD (N)	2.57±0.55 (249)	1.19±1.23 (233)	0.59±0.90 (243)	0.59±0.90 (215)	0.75±1.04 (214)
Median	3.00	1.00	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)
Index Limb Ischemia (3,4,5,6)	54.2% (135/249)	20.6% (48/233)	3.7% (9/243)	5.6% (12/215)	8.4% (18/214)
Change from					

Baseline					
Mean±SD (N)	N/A	-1.38±1.17 (233)	-1.99±1.01 (242)	-1.99±1.04 (214)	-1.83±1.15 (213)
Median	N/A	-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)

12.5 Conclusion

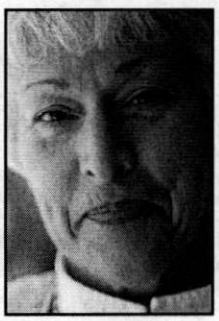
Overall, the results from non-clinical and clinical evaluations provide reasonable assurance that the **S.M.A.R.T.®** **CONTROL®** and **S.M.A.R.T.®** Vascular Stent Systems is safe and effective. While the prespecified effectiveness endpoint was not met, the study results are similar to the results 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).


Cordis
S.M.A.R.T.® CONTROL® and S.M.A.R.T.®
Vascular Stent Systems
Superficial Femoral Artery (SFA)
A Patient's Guide to
Peripheral Vascular
Disease in the
Superficial Femoral
Artery (SFA)

this guidebook...

... is proudly brought to you and your family by Cordis Corporation.

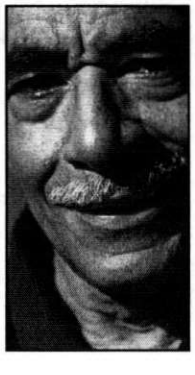
If you or a member of your family has been diagnosed with peripheral vascular disease (PVD), you may have questions about the disease and its treatment, especially if your doctor has recommended angioplasty and possible stent implantation. This guidebook answers some of the questions patients with PVD often ask.



NOTE: The contents of this patient brochure are applicable to the Cordis S.M.A.R.T.® CONTROL® and S.M.A.R.T.® Vascular Stent Systems. For information on indications, contraindications, warnings, precautions, and adverse events, see Essential Prescribing Information on the last page of this Patient Brochure.

table of contents

this guidebook answers some of the questions patients with PVD often ask



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introduction

This guidebook is designed to help you and your family understand peripheral vascular disease (PVD) and treatment with a vascular stent. If you have any questions as you read, please write them down and discuss them with your doctor or nurse.

peripheral vascular disease

PVD is caused by the build-up of fatty substances that collect and adhere to the linings of the arteries, in a process known as *atherosclerosis*. You may also hear the terms *plaque*, *blockage*, *lesion*, or *stenosis*. As the build-up continues, the internal lining of the artery thickens, which causes the artery to narrow and limit blood flow to vital tissues and organs.

peripheral vascular disease (continued)

Some of the more commonly affected arteries are those which are located in the legs, arms, neck, and kidneys. The symptoms from these blockages depend on what artery is affected and the severity of the blockage causing limited blood flow.

Some of the symptoms from an SFA stenosis that you may experience in the affected areas are:

- A dull, cramping pain in the hips, thighs, buttock, or calf muscles (*claudication*)
- Numbness/tingling in the leg, foot, or toes
- Changes in skin color, such as paleness or bluish color in leg, foot, or toes
- Changes in skin temperature of leg, foot, or toes
- *Ulceration* or *gangrene* due to sores that have not healed

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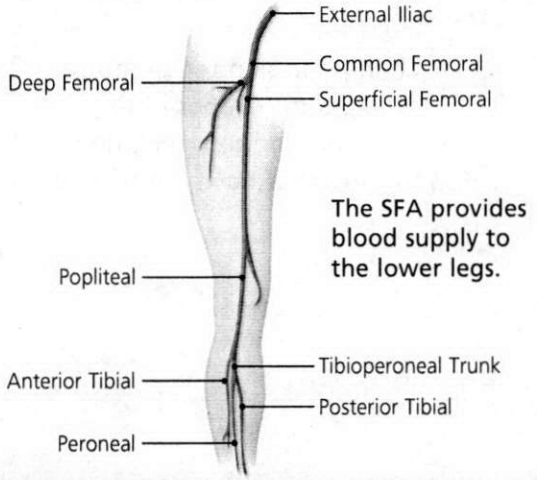
peripheral vascular disease—risk factors

You are at the greatest risk for PVD if you:

- Are diabetic
- Are obese
- Smoke
- Have high blood pressure
- Have a family history of the disease
- Are inactive
- Have coronary artery disease
- Have high cholesterol

the superficial femoral artery (SFA)

Arteries are vessels that carry oxygen-rich blood away from the heart. The SFA is a direct continuation of the common femoral artery that moves down the thigh and eventually becomes the popliteal artery. The SFA provides blood supply to the lower legs.



superficial femoral artery narrowing (stenosis)

When atherosclerotic plaque builds up in the SFA, it begins to narrow and restrict blood flow to the legs. This is called SFA stenosis. Severe SFA stenosis can lead to complete blockage and loss of function.

diagnosis

Patients should be screened for SFA stenosis if they have:

- Pain in legs with exertion or walking, which is relieved with rest
- Diminished leg pulses or other abnormal sounds of blood flow heard through a stethoscope placed over the SFA
- Slow wound healing on legs

The following diagnostic tests may be performed if SFA disease is suspected.

Ultrasound: A sound wave test that produces an image of the SFA onto a screen. This test allows the size of the vessel to be measured and the flow of blood to the pelvis and legs to be tracked. This can be helpful in identifying narrowing in the SFA. This test is painless and does not require the use of needles, dye, or x-rays.

diagnosis (continued)

Angiography: An *angiogram* is an x-ray image obtained by injecting dye through a small tube (*catheter*) inserted into an artery in the groin or arm. This procedure will determine exactly where the narrowing is located and will help to guide further treatment. You will be awake for the test, although you may be given a light sedative. The injection of dye is expected to cause a warm sensation and you may get a metallic taste in your mouth. After the test is complete you will need to lie flat for 5 to 6 hours to allow the puncture site in the arm or groin to heal. Instead of this, the doctor may also choose to use a vascular closure device to help close the entire site and enable you to get up more quickly.

treatment options

There are four basic treatment options for patients with SFA *stenosis*.

1. **Diet Modification and Exercise:** Decreasing the amount of fat and cholesterol in your diet in combination with walking exercises are the cornerstones of treating SFA stenosis. Your doctor will make specific dietary and exercise recommendations for you. Other life style changes may also need to be made, especially the discontinuation of smoking.

treatment options (continued)

2. **Medical Management:** Medicine can be prescribed to help dilate the blood *vessels* in your legs in order to improve blood flow. Additionally, medications that help to lower your cholesterol and fats may be prescribed. If you have diabetes, your physician may recommend modifications to medications to help reduce your blood sugar levels.

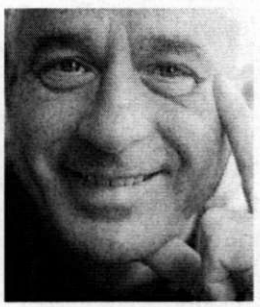
3. **SFA Bypass Surgery:** A man-made graft, one of your own veins, or a synthetic material will be used to act as a detour to create new channels to carry blood to the pelvis and legs.

4. **SFA Balloon Angioplasty and Stenting:** This procedure uses a small tube (catheter) with a small balloon on the end to open the narrowed SFA by compressing the plaque against the vessel wall. This process reduces the narrowing until it no longer interferes with blood flow. The balloon is deflated and removed from the artery.

treatment options (continued)

SFA Balloon Angioplasty and Stenting: *(continued)*

In most cases, a stent, which is a metallic wire-mesh tube, is then placed into the opened artery. When expanded in the artery, the stent acts as a brace to keep the artery open, restoring normal blood flow. Over several weeks, the healthy inner lining of the artery will grow over the stent, permanently incorporating it into the vessel.



In approximately 23% of cases, patients show re-narrowing or blockage of the SFA 24 months after Cordis S.M.A.R.T.® CONTROL® and S.M.A.R.T.® Vascular Stent Systems usage.[1]

1. Duda SH, Bosiers M, Lammer J, et al. Drug-eluting and bare nitinol stents for the treatment of atherosclerotic lesions in the superficial femoral artery: long-term results from the SIROCCO trial. *J Endovasc Ther*. 2006;13(6):701-710.

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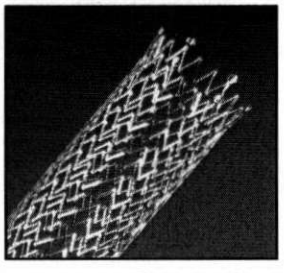
Be sure to ask your doctor to explain the risks and benefits of your treatment options and to answer any questions you or your family may have.

Cordis S.M.A.R.T.® CONTROL® and S.M.A.R.T.® Vascular Stent Systems for SFA

The Cordis S.M.A.R.T.® CONTROL® and S.M.A.R.T.® Vascular Stent Systems for SFA are made of a metal alloy called nitinol (nickel titanium). The stent is contained in a delivery system for passage into the body to the SFA.



Cordis S.M.A.R.T.® CONTROL® and S.M.A.R.T.® Vascular Stent Systems

Cordis S.M.A.R.T.® CONTROL® and S.M.A.R.T.® Vascular Stent Systems should only be used by physicians who are trained in angioplasty and stent placement. You may wish to ask your doctor about his or her experience with this stent and the procedure used for its placement. If you are pregnant, speak to your doctor about this before undergoing the angioplasty or stent placement procedure.

Cordis S.M.A.R.T.® CONTROL® and S.M.A.R.T.® Vascular Stent Systems for SFA (continued)

Whether or not you are eligible for stent placement surgery will depend on the everyday practice at your hospital or center.

Patients with 1 or more of the following characteristics **might** not be suitable candidates for stent placement:

- Poor kidney or liver function
- Severe high blood pressure
- Recent stroke
- Pregnancy
- Previous stent placements
- History of low number of white blood cells, low number of platelets, or significantly low number of red blood cells
- Allergy or sensitivity to nitinol (nickel titanium alloy)
- 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

It is important to inform your doctor about your entire medical history, which includes all medications you are presently taking.

before your procedure

Upon admission to the hospital, you usually will have undergone tests such as SFA ultrasound, angiography, and routine blood tests. Be sure to tell your doctor what medications you are currently taking and any allergies you might have. You will probably be asked not to eat or drink anything after midnight on the night before your procedure. You may be asked to take aspirin for 1 to 2 days prior to the procedure. If you are a patient who requires the use of medications called antacids or H-2 blockers (medication used to reduce stomach acid levels), please ensure that your doctor is aware of this and all other prescribed and over-the-counter medications you are taking. Your doctor will be able to advise you whether or not to stop this medication.

The procedure will be performed in a *catheterization* laboratory or a radiology suite. You will lie on an x-ray table, and an x-ray camera (*fluoroscope*) will move over your body during the procedure. Your heart and blood pressure will be monitored during the procedure.

risks of the procedure

Be sure that your doctor has discussed the procedure in detail with you in addition to the approximate time the procedure takes. The possible risks and benefits will be explained to you to answer any questions you may have.

The procedure itself usually involves little to moderate pain in addition to the discomfort usually experienced during the first few hours following angioplasty. During the procedure, you may be injected with the same dye as the one given during any of the previous angiograms. Although rare, dye injection may produce an allergic-type reaction causing low blood pressure, skin rashes and disturbances of heart beat.

risks and benefits
will be explained
to you to answer any
questions
you may have

risks of the procedure (continued)

The angioplasty procedure you will undergo may involve risks. These possible risks include, but are not limited to:

- Bleeding at the access (puncture) site in your groin or arm
- Bruising, swelling at the puncture site
- Pain in your legs
- Rupture of the SFA (dissection)
- Excessive bleeding (hemorrhage)
- Infection/fever
- Recurrence of the blockage (restenosis)
- Reaction to dye (*contrast* media)
- Plaque dislodgment
- Clot formation
- Stroke
- Unexpected limb loss
- Nerve damage (peripheral neuropathy)
- Heart attack (myocardial ischemia/infarction)
- Death

risks of the procedure (continued)

The risks associated with stent implantation include all risks listed on the previous page with the addition of the following:

- Increased risk of clot formation
- Breakage/fracture/bending of stent
- Movement of the stent
- Allergic reaction to the metal of the stent
- Damage to the SFA
- Failure to deliver the stent to the site of the blockage
- Persistent vessel spasm
- Expansion of 1 or more layers of the vessel wall (pseudoaneurysm)
- Dislodgment of the stent into your arterial *circulation*, with the stent becoming permanently wedged into a small branch vessel in your body

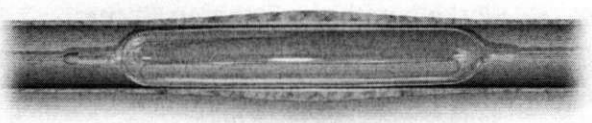
Be sure that your doctor has discussed the procedure in detail with you to ensure that you understand the possible risks and benefits and get your questions answered.

the angioplasty procedure

Your procedure will be performed in a room equipped with special instruments and x-ray equipment. Once you enter this room, you will be moved onto an x-ray table. You will be covered with sterile sheets and the area where the catheter will be inserted (groin, arm, or wrist) will be shaved and washed with an antiseptic solution to prevent infection. A numbing medication (*local anesthetic*) will be used at the site where the catheter is inserted. You may feel a stinging sensation during the administration of the medication. After the medication takes effect, you should only feel dull pressure where the doctor is working with the catheters. If the insertion is made in your inner thigh, a small tube called a sheath will be inserted into the vessel. The balloon catheter will then be placed through the sheath. If the incision is made in your arm or wrist, a guiding catheter will be inserted into the artery and advanced to the SFA. Dye injected through the catheter will allow the doctor to see the area of blockage in your vessels.

the angioplasty procedure (continued)

An x-ray machine called a fluoroscope with a TV screen allows the doctor to see your vessels and the catheter as it is moved forward in your vessel. Your doctor may ask you to take a deep breath and hold it for a few seconds. When the catheter reaches the diseased area to be treated, a tiny balloon on the tip of the catheter will be inflated. The balloon applies pressure to the plaque in the vessel, causing the vessel to open and increase blood flow. It is normal to experience some pain during the balloon inflation. Please tell your doctor if you feel any pain during the procedure.



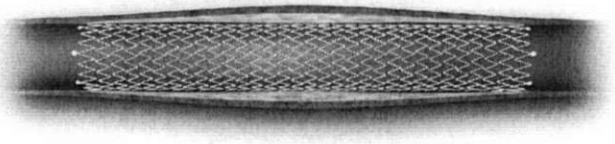
Inflated balloon catheter applying pressure to the vessel with plaque

You will be awake during your procedure. Your doctor or a hospital member may give you instructions. It is important to listen for these instructions and do what is asked.

stent implantation procedure

The procedure for stent implantation is similar to a standard angiogram procedure.

The Cordis S.M.A.R.T.® CONTROL® and S.M.A.R.T.® Vascular Stent Systems are introduced into the SFA on a catheter-based delivery system and advanced to the blocked area of the artery. The stent is self-expanding and will open to fit the artery. One or more stents may be implanted in the SFA depending on the extent of the disease. The delivery system is withdrawn from the body, while the expanded stent remains in the SFA.



Stented vessel

Your doctor may choose to further expand the stent with a balloon catheter similar to the one used in the angioplasty procedure. This procedure is called post-dilatation and ensures that the stent is in full contact with the vessel wall. The Cordis S.M.A.R.T.® CONTROL® and S.M.A.R.T.® Vascular Stent Systems stay in place permanently, holding the vessel open and improving the flow of blood. The angioplasty and stent procedure will usually take approximately 60 to 90 minutes.

after your procedure

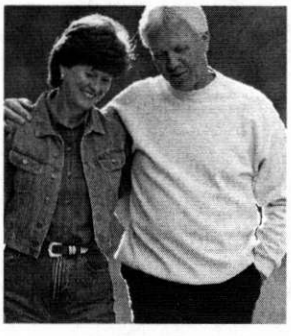
After the procedure, you will be moved to a special care unit where you will be closely monitored by the hospital staff. Your blood pressure and heart rhythm will be monitored continuously.

If your groin was used as an access site for the procedure, you can expect to stay in bed for several hours. The sheath usually will be removed within 6 hours after the procedure but may be left in longer if heparin, a medication given during the procedure, is continued. While the sheath is in place, and for about 6 hours after its removal, you will have to lie flat on your back, keeping the sheath straight and still. You will not be allowed to bend your leg. As the sheath is removed, the doctor or nurse will apply pressure to the puncture site for 20 to 30 minutes, until the bleeding has stopped. A sandbag may be placed over the puncture site to keep pressure on it. In place of this manual compression, the doctor may also choose to use a vascular closure device to help close the puncture site.

you will be
closely monitored
by the
hospital staff

precautions

- Should you see or feel any blood at the puncture site, notify the hospital staff immediately.
- Do not try to sit up until your nurse or doctor asks you to do so.
- It is important to lie flat and keep still, preventing bleeding from your vessel.
- If your arm was used for the procedure, you may be allowed to sit up afterwards, but you may be asked to stay in bed for several hours.
- You may drink and eat foods that are light until you are fully able to sit upright. Drink all of the fluids that are offered to you. The fluids will help flush out the x-ray dye that was used during your procedure.
- Your doctor may allow you to walk within 12 to 24 hours after your procedure, providing your puncture site is healing. A member of the hospital staff will be there to assist you.



your doctor may
allow you
to walk
within
12 to 24 hours
after the procedure

your recovery

Before you leave the hospital, your doctor will give you guidelines for activity, diet, and medications. You will be asked to avoid demanding activities like heavy lifting for at least a week. You will be advised when you can resume normal activity and return to work. Your doctor will prescribe medications for you to take to prevent blood clots from forming in your newly opened vessel. Please notify your doctor if these medications cause unpleasant reactions. **Do not stop taking your medications unless your doctor advises you to do so**. Different medications may be prescribed that suit you better.

Patients who undergo angioplasty and stent implantation are usually discharged from the hospital the next day. You should arrange to have someone take you home rather than driving yourself. After you leave the hospital your progress will continue to be monitored by medical personnel. **It is important to keep all of your scheduled follow-up appointments.**

usually
discharged
from the hospital
the next day

your recovery (continued)

If you have any pain, discomfort, or bleeding from your puncture site, call your doctor immediately. If your doctor cannot be reached, call 911 to be taken to the nearest hospital emergency room. You will also be asked to take aspirin. The amount of the dose will vary from 81 to 325 mg/day and will need to be taken for at least 3 months after your procedure. Your doctor will advise you about the exact amount of aspirin you should be taking.

The healthy lining of the vessel will slowly grow over the stent, permanently incorporating it into the vessel wall. You will not feel the stent and your daily activities will not be affected. Patients who have had a vascular stent implant should tell this to any doctor who treats them in the future.

If you require magnetic resonance imaging (MRI), the stent does not interfere with, nor is it affected by, the operation of an MRI device. If you plan to have an MRI after implantation of the Cordis S.M.A.R.T.® CONTROL® and S.M.A.R.T.® Vascular Stent Systems, provide the stent implant card given to you by your doctor to the MRI technician.

After stent placement, you will be followed closely to monitor your recovery. An ultrasound, identical to the one performed prior to the procedure, may be performed to determine if any narrowing has occurred.

lifestyle changes

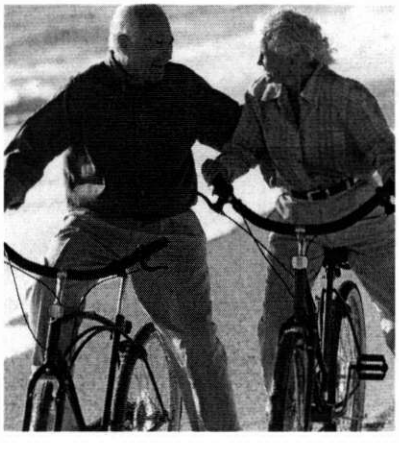
You and your doctor have formed a team in an effort to reduce the risk of restenosis (recurring blockage) in the area of your stent.

To help yourself stay healthy in the future, you are encouraged to make important diet, exercise and lifestyle changes. Some patients may need few modifications, while others may need to make many changes. Those patients who are able to reduce the fats and cholesterol in their diets are less likely to redevelop blockages in the stent. A low-fat, low-cholesterol diet can lower the levels of fat in your blood and reduce your risk. Choosing to eat healthy foods in the right proportions will also help you to achieve and maintain a healthy weight.

In addition to a healthy diet, it is extremely important to avoid smoking. If you need help quitting, please notify your health care provider.

conclusion

You have a very important role to play in order to ensure that your angioplasty and stent implantation will be successful. It is essential that you cooperate with your doctor and follow through with your responsibilities as part of the patient/medical team. Keep your appointments and adopt a healthy lifestyle. If you have any questions or concerns, please contact your doctor to discuss them. It is important that you get the most benefit from your treatment and join the thousands of people with PVD who are leading healthy, productive lives.



glossary

Angiogram: A procedure in which contrast dye is injected into the arteries to diagnose a narrowing or blockage of the artery.

Angioplasty: A procedure whereby a dilation catheter is passed through to the blocked area of an artery. Once the balloon is inflated, the catheter opens the blocked area in the artery. Also called percutaneous transluminal angioplasty (PTA).

Anticoagulant: A substance that slows or prevents the clotting of blood.

Antiplatelet: A medicine that reduces the clumping of platelets in the blood. An antiplatelet medicine helps thin the blood to prevent clot formation.

Atherosclerosis: The process of fatty deposits and/or calcium build-up (plaque) on the inside of the arteries.

Balloon catheter: A tube used for gaining access to the arteries with a tiny balloon on its tip. The balloon is gently inflated after the catheter is in position.

Blood vessel: An artery or vein.

Catheter: A hollow tube used for gaining access to a blood vessel.

Catheterization: A procedure that involves passing a tube (catheter) through blood vessels and injecting dye to detect blockages.

Cholesterol: A substance that circulates in the blood and plays a role in the formation of blockages. Cholesterol originates in foods that are rich in animal fat.

Circulation: The movement of blood through the vessels of the body, which is produced by the pumping action of the heart, enabling the flow of nutrients and oxygen through the body.

Claudication: Pain in the leg that occurs with work or exercise, but may also occur when resting.

Contrast: X-ray dye used to view the arteries during an angiogram.

Diabetes: A disease affecting one's metabolism of glucose (sugar), which causes changes in the blood vessels. These changes may aid in the development of PVD.

Dilation catheter: A catheter with a balloon on the end that can be inflated.

Doppler ultrasound: A non-invasive test using sound waves to determine the presence of arterial narrowing.

Fluoroscope: Equipment used in a catheterization procedure that captures a "motion picture" x-ray image of the arteries.

Gangrene: Tissue death (necrosis), usually due to inadequate or lack of blood supply.

Guiding catheter: A hollow tube through which fluids or objects can be introduced or removed from the body.

Hypertension: High blood pressure.

Lesion: A blockage in a blood vessel. Also known as a plaque or stenosis.

Local anesthetic: A substance used to numb the area to which it is applied.

Lumen: The inner channel or cavity of a vessel or tube.

Magnetic resonance imaging (MRI): A diagnostic test that uses magnetic fields to obtain images of the inside of your body.

Percutaneous: Performed through a small opening in the skin.

Peripheral vascular disease: Vascular disease which affects the blood vessels, especially those of the extremities.

Plaque: An accumulation or buildup of fatty deposits, calcium and/or cell debris in an artery that leads to narrowing of the lumen.

Platelet inhibitors: Medications to prevent blood cells called platelets from sticking together and blocking the artery.

Restenosis: The recurrence of a narrowing or blockage in an artery after treatment.

Stenosis: A narrowing of any canal, especially one of the superficial femoral artery.

Stent: An expandable, metallic, tubular-shaped device that provides structural support for a vessel.

Thrombus: A blood clot.

Transluminal: Through the inside opening of an artery.

Triglycerides: Substances in the blood that are a component of the "bad" type of cholesterol.

Ulceration: The formation or development of an ulcer.

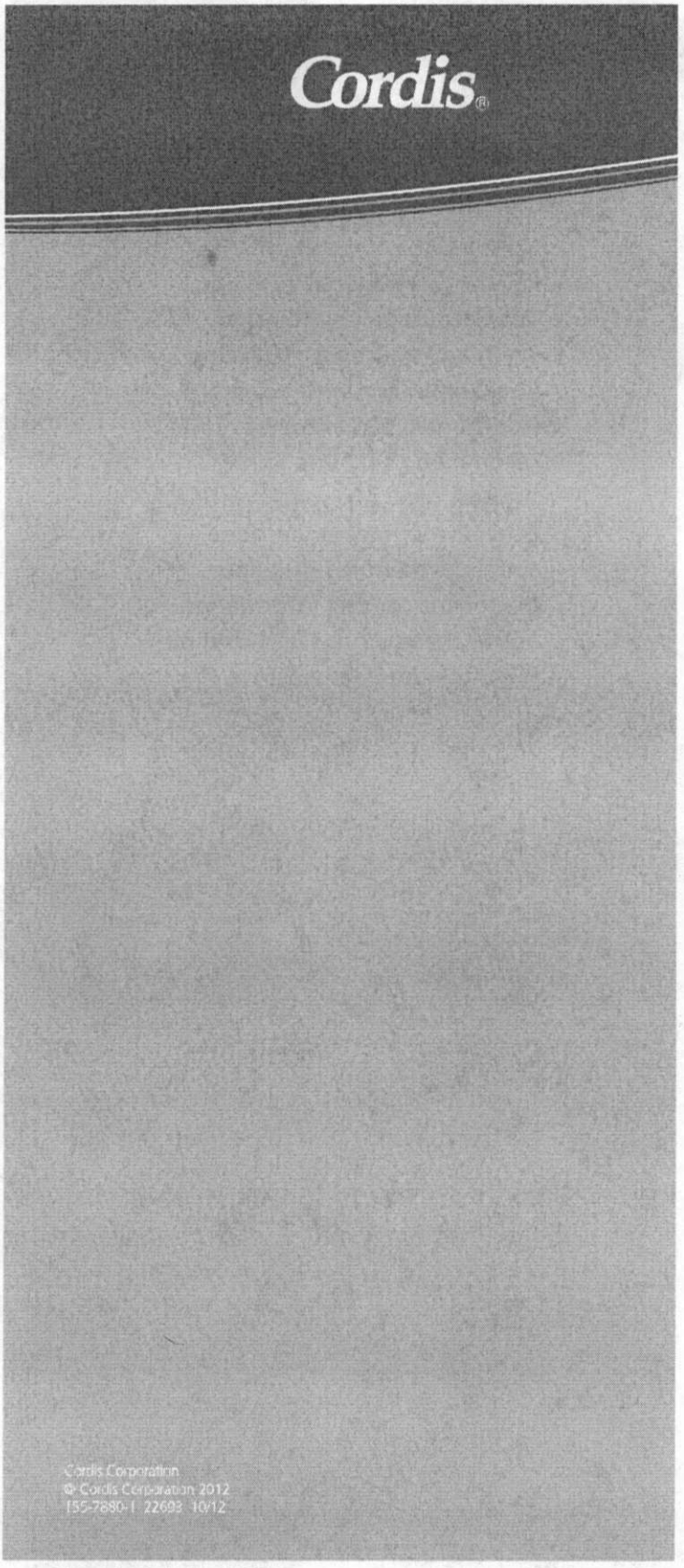
Vascular closure device: A device used to seal or close the artery puncture after an angiogram or angioplasty. Made from either collagen plugs (special fiber that seals the puncture site) or internal sutures (stitches).

Vascular System: The heart, blood, and network of blood vessels that lead to and from the heart.

contact information

Your doctor or nurse will review this material with you. We encourage you to ask them any questions regarding your treatment and recovery. Additionally, your doctor may recommend that you join a support group to speak with others who have undergone similar procedures. Ask your doctor for contact information about these groups and possible website addresses.

The S.M.A.R.T.® CONTROL® and S.M.A.R.T.® Vascular Stent Systems
Essential Prescribing Information (EPI):
The use of this device carries the risks associated with peripheral stenting. Please consult the Instructions for Use label (IFU) provided at www.cordislabeling.com for indications, contraindications, potential complications, warnings/precautions, and information for use. You may also call 877-DEVICE-5 to request a paper version.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