


















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Instructions for Use

Cordis S.M.A.R.T.[®] CONTROL[®] Vascular Stent System

Explanation of symbols on labels and packaging:

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

STERILE. The Cordis S.M.A.R.T.® CONTROL® 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.

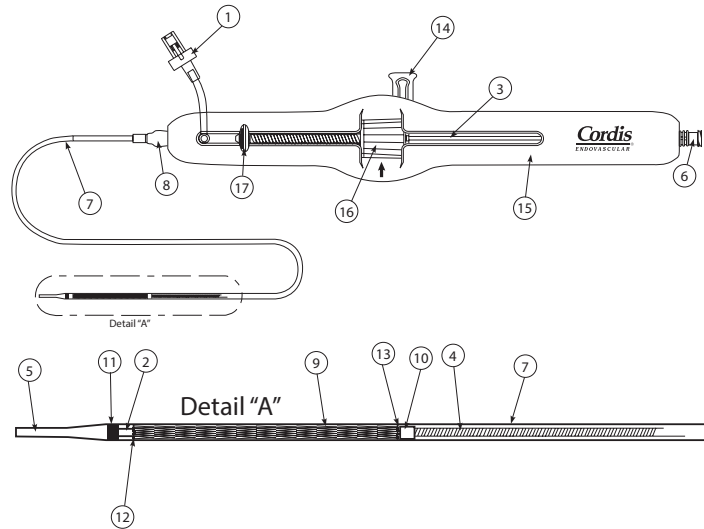
I. Device Name

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

II. Description

The Cordis **S.M.A.R.T.® CONTROL® Vascular Stent System** is designed to deliver a self-expanding stent to the iliac 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, which achieves its unconstrained diameter upon deployment. Upon deployment, the stent imparts an outward radial force on the luminal surface of the vessel to establish patency.

Figure 1. (Pre-deployment position)



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

Figure 2. Stent Deployment Using Tuning Dial

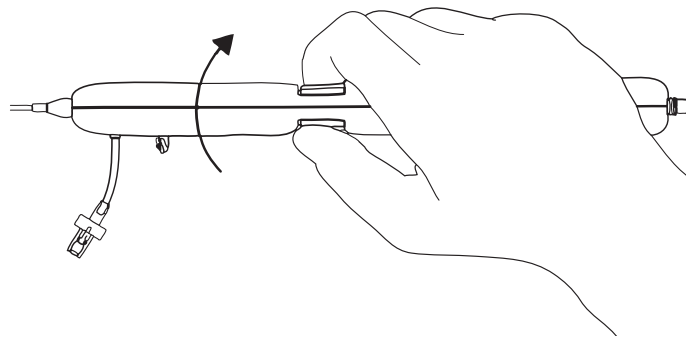


Figure 3. Stent Deployment Using Deployment Lever

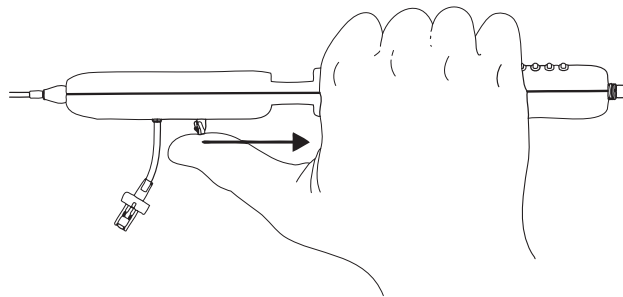
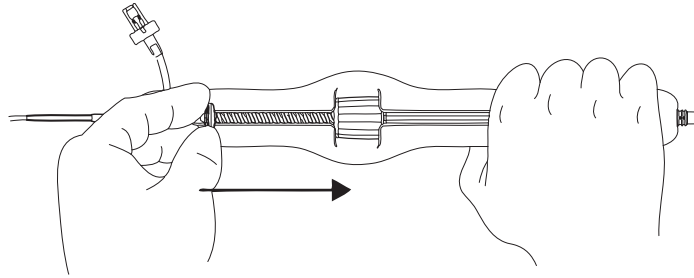


Figure 4. Stent Deployment Using Two Hands (“Pin and Pull”)



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).

III. Indications for Use

The **S.M.A.R.T.® CONTROL® Vascular Stent System** is indicated for improving luminal diameter in patients with symptomatic atherosclerotic disease of the common and/or external iliac arteries up to 126 mm in length, with a reference vessel diameter of 4 to 9 mm, and angiographic evidence of a patent profunda or superficial femoral artery.

IV. Contraindications

There are no contraindications known at this time based on the clinical data.

V. Warnings/ Precautions

- It is not recommended that stents be used in patients with a history of contrast not amenable to pretreatment with steroids and/or antihistamines, or a hypersensitivity to Nitinol (nickel titanium).
- Safety and effectiveness has not been demonstrated in patients with:
 - Lesions that are either totally or densely calcified
 - Patients with uncontrollable hypercoagulability and/or other coagulopathy
 - Patients with confirmed pregnancy
 - Pediatric patients
- Caution should be taken when stenting patients with poor renal function who, in the physician's opinion, may be at risk for a contrast medium reaction.
- It is important to use the correct stent size, as recommended in the Stent Size Selection Table provided in Section VIII - Directions 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.
- The long-term outcome following repeat dilatation of endothelialized stents is unknown at present.
- 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.
- Before insertion of the primary dilatation catheter, the appropriate antiplatelet and anticoagulant therapy should be administered. Aspirin may be used as antiplatelet therapy.
- When catheters are in the body, they should be manipulated only under fluoroscopy. Radiographic equipment that provides high quality imaging is needed.
- Do not use the delivery system with a power injection system.

Stent Handling

- 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).
- **Store in a cool, dark, dry place.**
- Do not use if 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. The **S.M.A.R.T.® CONTROL® Vascular Stent System** is intended for single use only. DO NOT re-sterilize and/or reuse the device.
- This product is designed and intended for single use. It is not designed to undergo reprocessing and resterilization after initial use. Reuse of this product, including after reprocessing and/or re-sterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information all of which present a potential risk to patient safety.
- 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 Placement

- 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.

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

- Fractures of this stent may occur. Fractures may also occur with the use of multiple overlapping stents. In the **S.M.A.R.T.®** stent, they have been reported most often in clinical uses for which the safety and effectiveness have not been established. The causes and clinical implications of stent fractures are not well characterized. Care should also be taken when deploying the stent as excessive force could, in rare instances, lead to stent deformation and/or fracture.

Stent / System Removal

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

Post Implant

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

VI. Adverse Effects of the Device on Health

Potential Adverse Events

The following ANTICIPATED adverse events (AEs) have been identified as possible complications of intravascular stent implantation:

- | | |
|--|---|
| • Allergic / anaphylactoid reaction | • Hematoma bleed, puncture site: vascular procedure |
| • Aneurysm | • Hypotension / hypertension |
| • Angina / coronary ischemia | • Intimal injury / dissection |
| • Arterial occlusion / thrombus, puncture site | • Ischemia / infarction of tissue/organ |
| • Arterial occlusion / thrombus, remote from puncture site | • Local infection |
| • Arterial occlusion / restenosis of the treated vessel | • Malposition (failure to deliver the stent to the intended site) |
| • Arteriovenous fistula | • Migration |
| • Arrhythmia | • Pulmonary embolism |
| • Death related to procedure | • Pseudoaneurysm |
| • Death unrelated to procedure | • Renal failure |
| • Embolization, arterial | • Septicemia / bacteremia |
| • Embolization | • Stroke |
| • Stent fever | • Vasospasm |
| • Hematoma bleed, remote site | • Venous occlusion / thrombosis, remote from puncture site |
| • Hematoma bleed at needle, device path: nonvascular procedure | • Venous occlusion / thrombosis, puncture site |

Observed Adverse Events

A total of 203 patients were enrolled in the CRISP-US study, a multicenter, randomized, concurrently controlled study comparing the **S.M.A.R.T.® Vascular Stent System** to the Schneider WALLSTENT Iliac Endoprosthesis. Patients with a suboptimal PTA result during the treatment of a de novo or restenotic lesion in the common and/or external iliac artery were randomized to either the **S.M.A.R.T.® Nitinol Stent** (N=102) or the WALLSTENT (N=101). This CRISP-US study, together with preclinical data showing the design equivalence of the **S.M.A.R.T.® Vascular Stent System** and the **S.M.A.R.T.® CONTROL® Vascular Stent System**, was used to provide reasonable assurance of the safety and effectiveness of the **S.M.A.R.T.® CONTROL® Vascular Stent System**.

Table 1 below summarizes major adverse events reported in both treatment groups to 9 months. Two patients in the **S.M.A.R.T.® Nitinol Stent** treatment group died within the first 30 days. One patient developed acute renal insufficiency and died in the hospital 4 days after the procedure. A second patient was discharged but returned to the emergency room 2 days after his procedure. The patient's condition deteriorated, and the patient died 3 days after the procedure of unknown causes. Both deaths were believed to be procedure-related. Other major adverse events reported in the **S.M.A.R.T.® Nitinol Stent** treatment group include amputation of the target limb (n=1), target vessel revascularization (n= 2), and stent thrombosis (n= 1). Other major adverse events reported in the WALLSTENT treatment group include target vessel revascularization (n=4) and stent thrombosis (n=1).

There were seven additional deaths that were not related to the device or the procedure, two in the **S.M.A.R.T.® Nitinol Stent** treatment group and five in the WALLSTENT treatment group. The two deaths in the **S.M.A.R.T.® Nitinol Stent** treatment group were non-cardiac: one patient died at 229 days of complications secondary to congestive heart failure and one patient died at 246 days of a lymphoproliferative disorder. Three of the deaths in the WALLSTENT treatment group were cardiac: one patient died at 92 days following an MI, one patient died at 302 days due to cardiac arrest, and one patient died at 465 days due to coronary atherosclerosis. The remaining two deaths in the WALLSTENT treatment group were non-cardiac: one patient died at 253 days following surgery for bladder cancer and one patient died at 306 days from lung cancer.

Table 1. Major Adverse Events In-Hospital and Out-of-Hospital (to 9 months)

Description of Event	S.M.A.R.T.® (N=102)	WALLSTENT (N=101)	All Randomized (N=203)	Relative Risk [95% C.I.]	P-Value
In-Hospital Complications					
MAIE	1.0% (1/102)	0.0% (0/101)	0.5% (1/203)	N/A	1.000
Death	1.0% (1/102)	0.0% (0/101)	0.5% (1/203)	N/A	1.000
MI (in-hospital)	0.0% (0/102)	0.0% (0/101)	0.0% (0/203)	N/A	—
Amputation of the target limb	0.0% (0/102)	0.0% (0/101)	0.0% (0/203)	N/A	—
Target vessel revascularization	0.0% (0/102)	0.0% (0/101)	0.0% (0/203)	N/A	—
Stent thrombosis	0.0% (0/102)	0.0% (0/101)	0.0% (0/203)	N/A	—
Major bleeding complications	0.0% (0/102)	0.0% (0/101)	0.0% (0/203)	N/A	—
Major vascular complications	0.0% (0/102)	0.0% (0/101)	0.0% (0/203)	N/A	—
CVA / TIA	0.0% (0/102)	0.0% (0/101)	0.0% (0/203)	N/A	—
Out-of-Hospital Complications (to 9 months)					
MAIE	3.9% (4/102)	4.0% (4/101)	3.9% (8/203)	1.0 [0.3, 3.9]	1.000
Death (30 days)	1.0% (1/102)	0.0% (0/101)	0.5% (1/203)	N/A	1.000
Amputation of the target limb	1.0% (1/102)	0.0% (0/101)	0.5% (1/203)	N/A	1.000
Target vessel revascularization	2.0% (2/102)	4.0% (4/101)	3.0% (6/203)	2.0 [0.4, 10.8]	0.445
Stent thrombosis	1.0% (1/102)	1.0% (1/101)	1.0% (2/203)	1.0 [0.1, 15.9]	1.000
Major bleeding complications	0.0% (0/102)	0.0% (0/101)	0.0% (0/203)	N/A	—
Major vascular complications	0.0% (0/102)	0.0% (0/101)	0.0% (0/203)	N/A	—
CVA / TIA	0.0% (0/102)	0.0% (0/101)	0.0% (0/203)	N/A	—
Cumulative Complications (to 9 months)					
MAIE	4.9% (5/102)	4.0% (4/101)	4.4% (9/203)	0.8 [0.2, 3.0]	1.000
Death (30 days)	2.0% (2/102)	0.0% (0/101)	1.0% (2/203)	N/A	0.498
MI (in-hospital)	0.0% (0/102)	0.0% (0/101)	0.0% (0/203)	N/A	—
Amputation of the target limb	1.0% (1/102)	0.0% (0/101)	0.5% (1/203)	N/A	1.000
Target vessel revascularization	2.0% (2/102)	4.0% (4/101)	3.0% (6/203)	2.0 [0.4, 10.8]	0.445
Stent thrombosis	1.0% (1/102)	1.0% (1/101)	1.0% (2/203)	1.0 [0.1, 15.9]	1.000
Major bleeding complications	0.0% (0/102)	0.0% (0/101)	0.0% (0/203)	N/A	—
Major vascular complications	0.0% (0/102)	0.0% (0/101)	0.0% (0/203)	N/A	—
CVA / TIA	0.0% (0/102)	0.0% (0/101)	0.0% (0/203)	N/A	—

A subject was counted at most once for multiple occurrences of an adverse event.

All variables were judged by the Clinical Events Committee (CEC).

MAIE (Major Adverse Ischemic Event) was defined as death within 30 days, in-hospital myocardial infarction, amputation of the target limb, or target vessel revascularization.

Relative risk = Risk of event in the WALLSTENT group as compared to the S.M.A.R.T.® stent; SE= $\sqrt{(1-p_1)/n_1 + (1-p_2)/n_2}$

CI=RR*exp(±1.96SE)

Observed Device Malfunctions

There were no delivery failures or device malfunctions observed with the S.M.A.R.T.® Vascular Stent System. There were four failures to deploy at the intended location observed with the Schneider WALLSTENT Iliac Endoprosthesis. In two cases, the stent was removed and a non-study stent was placed. In the other two cases, an additional WALLSTENT was placed.

VII. Summary of Clinical Investigations Involving Human Subjects

A multi-center, randomized, concurrently controlled study was conducted at 20 sites in the US (The CRISP-US Study). The primary objective of this study was to assess the equivalent performance of the S.M.A.R.T.® Vascular Stent System and the Schneider WALLSTENT Iliac Endoprosthesis, in patients with de novo or restenotic lesions in the common and/or external iliac artery, based on a composite of 1) 9-month restenosis rate via duplex ultrasound or angiography, and 2) the presence of any adverse clinical outcome defined as a) peri-procedural (30 day) death or b) repeat revascularization of the target vessel at the 9-month follow-up visit. A total of 203 subjects with 226 lesions were treated in the study. 102 patients with 114 lesions were randomized to receive the S.M.A.R.T.® Nitinol Stent while 101 patients with 112 lesions were randomized to receive the WALLSTENT device. This CRISP-US study, together with preclinical data showing the design equivalence of the S.M.A.R.T.® Vascular Stent System and the S.M.A.R.T.® CONTROL® Vascular Stent System, was used to provide reasonable assurance of the safety and effectiveness of the S.M.A.R.T.® CONTROL® Vascular Stent System.

Study Endpoints: The primary endpoint was a composite of 9-month restenosis rate, peri-procedural (30 day) death, and target vessel revascularization at the 9-month follow-up visit. Secondary endpoints included adverse events and clinical and hemodynamic status at 1, 6, 9, and 12 months as determined by changes in the Ankle/Brachial Index (ABI), Thigh/Brachial Index (TBI), Rutherford/Becker Scale and Walking Impairment Questionnaire.

An independent clinical events committee adjudicated all of the major adverse events (MAEs) and deaths. All duplex and angiographic measurements were determined by independent central laboratories. Endpoints were analysed on an intent-to-treat basis.

Patients Studied: Eligible patients had either de novo or restenotic lesions in the common and/external iliac artery of up to 145 mm in length with a documented suboptimal PTA result, a reference vessel diameter of 4 to 9 mm, and angiographic evidence of a patent profunda or superficial femoral artery. Baseline characteristics for the patients in the CRISP-US study are presented in Table 2.

Table 2. Baseline Demographics and Clinical Characteristics

Patient Characteristic	S.M.A.R.T.® (N=102)	WALLSTENT (N=101)	All Randomized (N=203)	Difference [95% C.I.]	P-Value
Age (years)*					
Mean±SD (N)	65.8 ± 11.00 (102)	66.6 ± 9.67 (101)	66.2 ± 10.34 (203)	0.8% [0.2%, 3.0%]	0.597
Number of men*	62.7% (64/102)	61.4% (62/101)	62.1% (126/203)	-1.3% [-15%, 12.1%]	0.817
History of Peripheral Vascular Disease (PVD)*	89.2% (91/102)	94.1%(95/101)	91.6% (186/203)	4.9%[-2.7%, 12.5%]	0.031
Diabetes mellitus*	21.6% (22/102)	30.7% (31/101)	26.1% (53/203)	9.1%[-2.9%, 21.1%]	0.164
History of smoking*	90.2% (92/102)	92.1% (93/101)	91.1% (185/203)	1.9%[-5.9%, 9.7%]	0.768
Reference vessel diameter (mm)**					
Mean±SD (N)	7.9 ± 1.71(118)	7.4 ± 2.12(114)	7.7±1.93(232)	-0.5 [-1.0, -0.0]	0.072
Minimal lumen diameter (mm)**					
Mean±SD (N)	2.9 ± 1.42(118)	2.5 ± 1.50(114)	2.7 ± 1.47(232)	-0.4 [-0.8, -0.0]	0.041
Lesion length (mm)**					
Mean±SD (N)	24.7 ± 15.60(115)	24.5 ± 19.11(114)	24.6 ± 17.39(229)	-0.2 [-4.7, 4.3]	0.921
Percent diameter stenosis (mm)**					
Mean±SD (N)	62.6 ± 17.20(118)	65.7 ± 15.45(114)	64.1 ± 16.40(232)	3.1 [-1.1, 7.3]	0.149

*Variables are counted by patient

**Variables are counted by lesion

Methods: Informed consent, baseline demographics and medical history data were collected prior to treatment. Patients eligible for the study underwent a PTA and were randomized following an angiographically documented suboptimal result defined by the presence of an unfavorable lesion morphology such as: a) a documented inadequate angiographic and/or hemodynamic result as defined by a 30% or greater residual stenosis resultant to PTA, lesion recoil or intimal flaps and/or b) flow limiting dissections post PTA longer than the initial lesion length, and/or c) a 5 mm Hg, or greater mean transtenotic pressure gradient post PTA. Lesions treated could be single, multiple, and/or bilateral. Baseline quantitative angiography was performed pre-procedure, post-PTA, and post-procedure in all patients. Duplex Ultrasound was performed prior to discharge.

Clinical follow-up visits were conducted at 1, 6, 9 and 12 months post-procedure. Patients were to receive aspirin (81 to 325 mg/day) for at least 3 months following hospital discharge. Duplex Ultrasound was utilized in all patients to make an initial determination of restenosis at the 9-month follow-up. If restenosis was observed by Duplex Ultrasound, or if the Duplex Ultrasound was non-diagnostic, a confirmatory angiogram was performed to document the amount of restenosis present. Computer assisted quantitative angiographic analysis (QA) and Duplex Ultrasound were performed at central laboratories.

Results: Visit compliance at 9 months was 88.2% (90/102) vs. 81.2% (82/101) in the S.M.A.R.T.® Nitinol Stent vs. WALLSTENT groups, respectively; of the returning patients, compliance to duplex/angiographic follow-up was 84.7% (83/98) and 78.8% (78/99) patients, respectively. Based on analysis of a composite of 1) 9-month restenosis rate and 2) death within 30 days of the procedure or repeat revascularization of the target vessel (TVR), there was no difference between outcomes for patients receiving either the S.M.A.R.T.® Nitinol Stent vs. the WALLSTENT after suboptimal PTA of a lesion in the iliac artery (6.9% vs. 5.9%). Both groups had comparably low rates of restenosis (3.5% vs. 2.7%), death (2.0% vs. 0.0%), and TVR (2.0% vs. 4.0%), respectively. Acute procedural success was achieved in 98.2% of patients receiving the S.M.A.R.T.® Nitinol Stent compared to 87.5% in the WALLSTENT group, a difference of -11% (95% CI=-17% to -4.1%). Primary patency was maintained in 95% of all patients at 9 months. One patient in the S.M.A.R.T.® group experienced a major adverse ischemic event in the hospital; at 9 months the occurrence was 4.9% vs.4.0% in the S.M.A.R.T.® and WALLSTENT groups, respectively. The principal effectiveness and safety results are presented in **Table 3**. The freedom from major adverse ischemic events Kaplan-Meier curve is presented in Figure 5.

A higher percentage of males (62%) than females (38%) were included in the trial. Evaluation of 9-month restenosis by gender showed no significant difference between groups of either gender, although incidents of restenosis occurred more frequently in males in the WALLSTENT group (4 to 0, male to female). Acute procedural success was more likely to occur in males in the S.M.A.R.T.® Nitinol Stent group, which had 100% success compared with 81.5% in the WALLSTENT group, a significant difference of -19% (95% CI=-28%, -9.1%). There were no significant differences between the females in either treatment group in acute procedural success, or in the early or late clinic success rates for either gender. The occurrence of major adverse events was comparable between treatment groups for both males and females. A larger percentage of females experienced events than did males overall, although the total number of events was too small to make this difference statistically significant.

Table 3. Principal Effectiveness and Safety Results - All Patients Treated (N=203)

Effectiveness Measure	S.M.A.R.T.® (N=102)	WALLSTENT (N=101)	Difference [95% CI]	P-Value
Composite Endpoint*	6.9% (7/102)	5.9% (6/101)	-1.0% [-7.7%, 5.7%]	1.000
9-month restenosis rate**	3.5% (4/114)	2.7% (3/112)	-0.8% [-5.3%, 3.7%]	1.000
Death within 30 days*	2.0% (2/102)	0.0% (0/101)	-2.0% [-4.7%, 0.7%]	0.498
TV-revascularization at 9 months*	2.0% (2/102)	4.0% (4/101)	2.0% [-2.7%, 6.7%]	0.445
Effectiveness Measures				
Acute procedural success**	98.2% (112/114)	87.5% (98/112)	-11% [-17%, -4.1%]	0.002
Early clinical success**	81.6% (93/114)	75.9% (85/112)	-5.7% [-16%, 4.9%]	0.331
Late clinical success**	64.9 (74/114)	66.1 (74/112)	1.2% [-11%, 13.6%]	0.889
Primary Patency to 9 months**	94.7% (108/114)	94.6% (106/112)	-0.1% [-6.0%, 5.8%]	1.000
Revascularization within 9 months**	0.0% (0/114)	2.7% (3/112)	2.7% [-0.3%, 5.7%]	0.120
Bypass within 9 months**	1.8% (2/114)	0.9%(1/112)	-0.9% [-3.9%, 2.1%]	1.000
Safety Measures				
In-hospital MAIEs*	1.0% (1/102)	0.0% (0/101)	-1.0% [-2.9%, 0.9%]	1.000
Out-of-hospital MAIEs to 9 months*	3.9% (4/102)	4.0% (4/101)	-0.04% [-5.4%, 5.3%]	1.000
Cumulative MAIEs to 9 months*	4.9% (5/102)	4.0% (4/101)	-0.9% [-6.6%, 4.8%]	1.000
Stent thrombosis*	1.0% (1/102)	1.0% (1/101)	0.0% [-2.7%, 2.7%]	1.000
Major bleeding complications*	0.0% (0/102)	0.0% (0/101)	0.0% [0.0%, 0.0%]	—
Major vascular complications*	0.0% (0/102)	0.0% (0/101)	0.0% [0.0%, 0.0%]	—
CVA/TIA*	0.0% (0/102)	0.0% (0/101)	0.0% [0.0%, 0.0%]	—

*Variables are counted by patient.

** Variables are counted by lesion.

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

Relative risk = Risk of event in WALLSTENT group as compared to S.M.A.R.T.® stent; SE=sqrt[(1-p₁)/n₁+(1-p₂)/n₂]

CI=RR*exp(±1.96SE)

Difference=WALLSTENT-S.M.A.R.T.®; SE=sqrt(p1•q1/n1+p2•q2/n2) CI=Diff±1.96•SE

Primary Endpoint = A composite of 1) nine-month restenosis rate via duplex ultrasound of the CFA and 2) the presence of any adverse clinical outcome defined as a) periprocedural (30-day) death or b) repeat revascularization of the target vessel at the 9-month follow-up visit.

Acute Procedural Success = Vessels with 30% residual stenosis immediately after stent placement. Mean transtenotic pressure gradient < 5mmHg and no occurrence of a procedure related adverse event within the Lab. This is determined at both clinical site and the core lab.

Early Clinical Success = Vessels with Rutherford/Becker Classification ≥1 at the latest follow-up between baseline and 30-day posttreatment follow-up.

Late Clinical Success = Maintenance of achieved improvement in the appropriate segmental limb pressure index (ABI and TBI) which if not normalized (>.90) must have increased by at least 0.10 over the initial preoperative level and not have deteriorated by more than 0.15 from the maximum early post-procedure level.

MAIE = Major adverse ischemic events = Death to 30 days, in-hospital MI, TVR, or amputation.

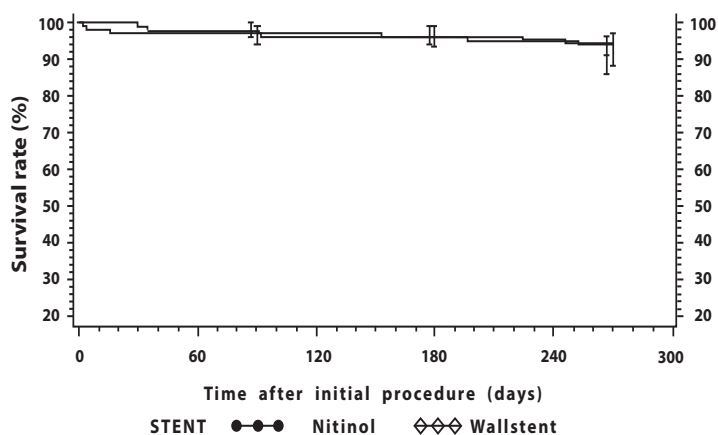
Primary patency = continuous flow without revascularization, determined as any patient who did not die, and did not have a revascularization, amputation, or bypass within the first 9 months. Presented as proportion of patients with primary patency.

Revascularization = continuous flow assisted by revascularization within the first 9 months, excluding bypass ("Primary assisted patency").

Bypass = reestablishment of flow to distal arteries following bypass of the target vessel ("Secondary patency")

Note: 9-month patency endpoints unavailable for lesions in patients not surviving to 9 months (S.M.A.R.T.® =4, WALLSTENT=2).

Figure 5. Freedom from Major Adverse Ischemic Events - All Patients Treated (N=203)



S.M.A.R.T.®

Category	90 Days	180 Days	270 Days
# Entered	102	98	98
# Censored	0	0	96
# At Risk	102	98	50
# Events	4	0	2
# Events / Month	1.333	0	0.6667
% Survived	96.1	96.1	92.2
SE %	1.9	1.9	3.2

WALLSTENT

Category	90 Days	180 Days	270 Days
# Entered	101	99	97
# Censored	0	0	95
# At Risk	101	99	49
# Events	2	2	2
# Events / Month	0.667	0.6667	0.6667
% Survived	98.0	96.0	92.2
SE %	1.4	1.9	3.3

Test of Equality over Strata

Test	Chi-Square	DF	Pr>Chi-Square
Log-rank	0.1065	1	0.7442
Wilcoxon	0.0929	1	0.7605
-2Log(LR)	0.1089	1	0.7414

VIII. Directions for Use

Pre-Procedure

1. The patient may be started on enteric coated or nonenteric-coated aspirin 81-325 mg daily, one or two days prior to the procedure if deemed appropriate by the physician.
2. The percutaneous placement of the stent in a stenotic or obstructed iliac 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 iliac 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 a CSI.
- 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 (see Stent Selection Table).
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. Measure diameter of the lesion to determine the appropriately sized stent and delivery system.
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 the Stent Selection Table for available devices.

Stent Size Selection Table

Vessel Lumen Diameter	Unconstrained Stent Diameter	% Length Foreshortening
4.0 – 5.0 mm	6 mm	1.1 %
5.0 – 6.0 mm	7 mm	1.8 %
6.0 – 7.0 mm	8 mm	2.8 %
7.0 – 8.0 mm	9 mm	4.0 %
8.0 – 9.0 mm	10 mm	5.5 %

Refer to product labeling for stent length.

Note: The percent foreshortening of stent length is based upon a mathematical calculation.

3. Preparation of Stent Delivery System

- a. Open the 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 looking 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 flushing valve of the stent delivery system with heparinized saline using a 3 cc syringe to expel air. Continue to flush until saline weeps from the distal catheter end.

- e. Flush the guidewire lumen of the stent delivery system with heparinized saline using a 20 cc syringe to expel air. Continue to flush until the 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.
- 4. Insertion of Introducer Sheath and Guidewire**
- a. Access the treatment site utilizing the appropriate accessory equipment compatible with a 6F (2.0 mm) delivery system.
 - b. Insert 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 technique.
 - b. Remove the PTA balloon catheter from the patient maintaining lesion access with the guidewire.
- 6. Introduction of Stent Delivery System**
- a. Ensure locking pin is still in place.
 - b. Advance the device over the guidewire through the hemostatic valve and sheath introducer.
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.
 - 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**
- a. Verify that the delivery system's radiopaque stent markers (leading and trailing ends) are proximal and distal to the target lesion.
 - b. Ensure that the introducer sheath does not move during deployment.
 - c. Remove locking pin from handle.
 - d. Initiate stent deployment by rotating the tuning dial with thumb and index finger in a clockwise direction (direction of arrow) 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 targeted 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.
 - 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.
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**
- 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 counter-clockwise, while keeping pressure on the lever, until the lever reaches the end of the slot and the tip is resheathed. 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.
 - b. Using fluoroscopy, visualize the stent to verify full deployment.
 - c. If incomplete expansion exists within the stent at any point along the lesion, post deployment balloon dilatation (standard PTA technique) can be performed.
Note: Only areas within the stent length should receive post-deployment balloon dilatation.
 - 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 drug regimen for each patient.

IX. MRI Safety Information 

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

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

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