



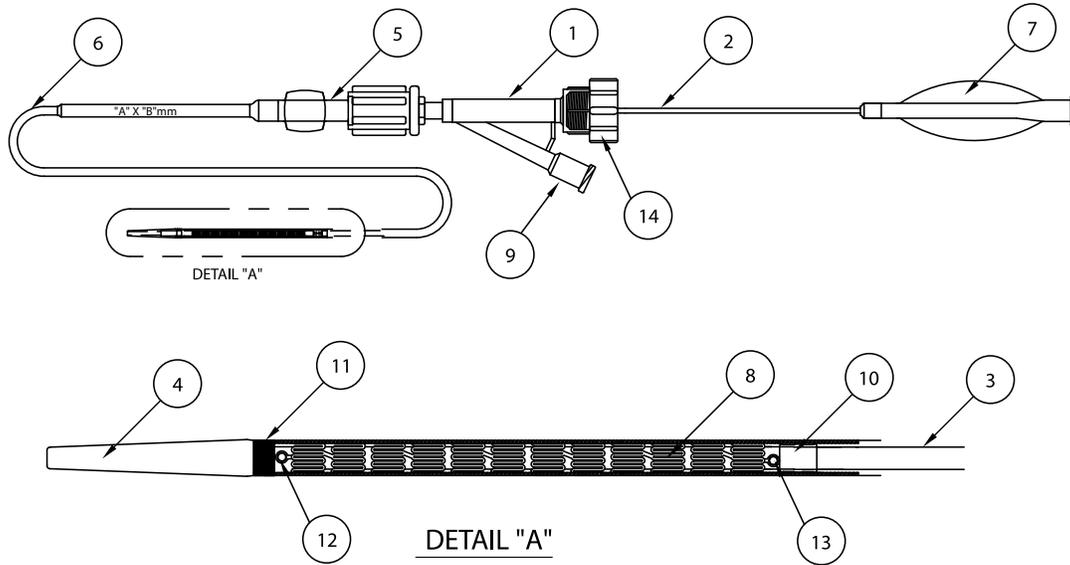
***Cordis***<sup>®</sup>  
*A Cardinal Health company*

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Instructions for Use

**Cordis S.M.A.R.T.<sup>®</sup> Nitinol Stent System**

**Figure 1. S.M.A.R.T.® Stent Delivery System**



1. Tuohy Borst Valve
2. Inner Shaft - Stainless Steel Tube
3. Inner Shaft - Stainless Steel Coil
4. Catheter Tip (Distal Wire Lumen)
5. Luer Hub (Outer Sheath)
6. Outer Sheath
7. Luer Hub (Proximal Wire Lumen)
8. S.M.A.R.T. Self-Expanding Stent
9. Y-Connection (on Tuohy Borst Valve)
10. Radiopaque Marker (Inner Shaft Stent Stop)
11. Distal Radiopaque Marker (Outer Sheath)
12. Distal Stent Marker
13. Proximal Stent Marker
14. Proximal Valve (of the Tuohy Borst Valve)

**Explanation of symbols on labels and packaging:**

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

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**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.**

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## I. Device Name

The device brand name is the Cordis **S.M.A.R.T.**<sup>®</sup> Nitinol Stent System.

## II. Description

The Cordis **S.M.A.R.T.** Nitinol Stent System is designed to deliver a self-expanding stent to the peripheral vasculature 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 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.

The delivery system, as shown in Figure 1, 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 stainless steel coil covered with a polymeric tube (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 a radiopaque marker (10) connected to the inner shaft. The outer sheath has a radiopaque marker (11) at its distal end.

Stent positioning about the target stricture is achieved prior to deployment utilizing the distal stent markers (12) and the proximal stent markers (13). For stent deployment, the Tuohy Borst valve is unlocked on the inner shaft by a counter clockwise rotation of the proximal valve end (14). Sheath retraction is achieved by grasping the inner shaft (7) in a fixed position and moving the outer sheath proximally relative to the inner shaft. During sheath retraction, prior to stent apposition to the wall, 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).

## III. Indications for Use

The Cordis **S.M.A.R.T.** Nitinol Stent System is indicated for use in patients with atherosclerotic disease of peripheral arteries, including iliac and superficial femoral, for TIPSS<sup>™\*</sup> procedures and for palliation of malignant neoplasms in the biliary tree.

## IV. Contraindications

Generally, contraindications to PTA are also contraindications for stent placement. Contraindications include, but may not be limited to:

- Patients with highly calcified lesions resistant to PTA.
- Patients with a target lesion with a large amount of adjacent acute or subacute thrombus.
- Stenting of a perforated biliary duct where leakage from the duct could be exacerbated by the stent.
- Patients with uncorrected bleeding disorders.
- Stenting of the bile duct in the presence of severe ascites.
- Stenting of intra-cranial arteries.

## V. Warnings

- Persons with allergic reactions to nickel titanium (nitinol) may suffer an allergic response to this implant.
- Placing multiple overlapping stents in the SFA may increase the possibility of stent fracture.
- The black dotted pattern on the grey temperature exposure indicator, found on the pouch, must be clearly visible. Do not use if entire temperature exposure indicator is completely black as the unconstrained stent diameter may have been compromised.
- The Cordis **S.M.A.R.T.** Nitinol Stent System is intended for single use only. DO NOT resterilize 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.
- Use the stent system prior to the "Use By" date specified on the package.
- Do not use with Ethiodol or Lipiodol<sup>†</sup> contrast media.
- Do not expose the delivery system to organic solvents (e.g. alcohol).

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\* TIPSS is Transjugular Intrahepatic Portosystemic Shunt

<sup>†</sup> Ethiodol and Lipiodol are trademarks of Guerbet S.A.

- The stent is not designed for repositioning or recapturing.
- Once the stent is partially deployed, it cannot be recaptured using the stent delivery system.
- Avoid stent placement that may obstruct access to a vital side branch.
- As with any type of vascular implant, infection, secondary to contamination of the stent, may lead to thrombosis, pseudoaneurysm or rupture into a neighboring organ or the retroperitoneum.
- The stent may cause a thrombus, distal embolization or may migrate from the site of the implant down the arterial lumen.
- Overstretching of the artery may result in rupture and lifethreatening bleeding.
- Stenting across a major bile duct branch could lead to compromised future diagnostic or therapeutic procedures.
- Insufficient clinical data exists to support use of the Cordis **S.M.A.R.T.** Nitinol Stent System in renal arteries.

It is not recommended that the stent be used in patients with the following characteristics:

- Patients with poor renal function, who, in the physicians opinion, may be at risk for a reaction to contrast medium.
- Pregnant patients.
- Patients with bleeding disorders or patients who cannot receive anticoagulation or antiplatelet aggregation therapy.
- Patients with perforated vessels evidenced by extravasation of contrast media.
- Patients who have aneurysmal dilation immediately proximal or distal to the lesion.

## **VI. Precautions**

- The device is intended for use by physicians who have received appropriate training in such interventional techniques as percutaneous transluminal angioplasty and placement of intravascular stents.
- The delivery system is not designed for use with power injection systems.
- When catheters are in the body, they should be manipulated only under fluoroscopy.
- Radiographic equipment that provides high quality images is needed.
- 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.
- Recrossing a partially or fully deployed stent with adjunct devices must be performed with caution.
- In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.
- In the event of complications such as infection, pseudoaneurysm or fistulization, surgical removal of the stent may be required. Standard surgical procedure is appropriate.
- In patients requiring the use of antacids and/or H<sub>2</sub>- antagonists before or immediately following stent placement, oral absorption of antiplatelet agents (e.g. aspirin) may be adversely affected.
- Prior to stent deployment remove all slack from the catheter delivery system (see "Stent Deployment Procedure").
- **Store in a cool, dark, dry place.**

## **VII. Potential Complications**

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure. Potential complications may include, but are not limited to:

- Amputation
- Aneurysm and pseudoaneurysm formation
- Arrhythmia
- Arteriovenous fistula
- Bile duct perforation
- Blue toe syndrome
- Coronary ischemia
- Death
- Disseminated intravascular coagulation
- Drug reactions, allergic reaction to contrast medium or to the implanted device
- Embolism
- Emergency artery bypass graft surgery
- G.I. bleeding from anticoagulation/antiplatelet medication
- Hematoma
- Hemobilia
- Hemorrhage
- Hemorrhagic or embolic stroke/ TIA
- Iliac artery spasm
- Intimal tear/dissection
- Liver abscess
- New or worse encephalopathy
- Pancreatitis
- Parenchymal hemorrhage
- Pneumothorax
- Renal failure
- Respiratory arrest

- Sepsis/infection
- Sludge occlusion
- Stent migration/embolization
- Stent misplacement
- Stent obstruction secondary to tumor growth
- Subcapsular liver hematoma
- Thrombosis
- Tissue necrosis
- Tumor overgrowth at the stent ends
- Vascular injury, including perforation, rupture and dissection
- Vessel occlusion, restenosis or recurrent stricture

## VIII. Directions for Use

### Pre-procedure

The patient may be started on nonbuffered, nonenteric-coated aspirin one or two days prior to the procedure per standard hospital dosing guidelines or as prescribed by a physician.

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 accepted 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. Inject Contrast Media

Perform a percutaneous angiogram using standard technique. For biliary procedures the biliary tree may be injected.

#### 2. Identify and mark the lesion or stricture

Fluoroscopically identify and mark the lesion, observing the most distal level of the stenosis or stricture.

#### 3. Select Stent Size

Measure the length of the target lesion to determine the length of stent(s) required.

Measure the diameter of the reference vessel (proximal and distal to the lesion). It is necessary to select a stent that has an unconstrained diameter at least 1 mm larger than the largest reference vessel diameter to achieve secure placement according to the following Stent Size Selection Table.

**Stent Size Selection Table**

Vessel Lumen Diameter	Unconstrained Stent Diameter	% Length Foreshortening	% Free Area
4.0 – 5.0 mm	6.0 mm	1.2%	79%
5.0 – 6.0 mm	7.0 mm	2.0%	82%
6.0 – 7.0 mm	8.0 mm	3.1%	84%

Refer to product labeling for stent length.

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

#### 4. Preparation of Stent Delivery System

- Open the outer box to reveal the pouch containing the stent and delivery system.
- 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.
- 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.
- Flush the Tuohy Borst Y valve with heparinized saline using a 3-cc syringe to expel air. Lock the Tuohy Borst 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 using a 10-cc syringe to expel air. Continue to flush until heparinized saline flows out of the wire lumen at the distal catheter tip.
- 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. 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.

### Stent Deployment Procedure

#### 1. Insertion of Introducer Sheath or Guiding Catheter and Guidewire

- Gain access at the appropriate site utilizing the appropriate accessory equipment compatible with the 6F delivery system.

b. Insert a .035" (.89 mm) guidewire of an appropriate length through the introducer sheath or guide catheter.

## 2. Dilation of Lesion

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

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

**Note:** No predilation is generally done with malignant biliary strictures. However, if the physician determines that predilation is necessary, standard PTA techniques may be used.

**Caution:** During dilation, never expand the balloon such that dissection complication could occur.

## 3. Introduction of Stent Delivery System

a. Ensure that the Tuohy Borst valve, connecting the inner shaft and outer sheath, is locked by rotating the proximal valve end in a clockwise direction to prevent premature stent deployment.

b. Advance the device over the guidewire 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 appropriate size introducer sheath for the implant procedure to protect vessel and access site.

## 4. 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.

## 5. 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 access sheath or guiding catheter does not move during deployment.

c. Unlock the Tuohy Borst valve connecting the inner shaft and outer sheath of the delivery system.

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 targeted 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 inner shaft 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 cover the lesion, the more distal stent should be placed first. Efforts should be taken to minimize the stent overlap.

## 6. Post-deployment Stent Dilatation

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.

**Caution:** The delivery system is not designed for the use of power injection.

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.

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.

## 7. Post Stent Placement

a. A post stent angiogram should be obtained.

b. Remove the guidewire and sheath and establish hemostasis.

**Note:** Physician experience and discretion will determine the appropriate post-procedure 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)	1.0 W/kg for patient landmarks below the umbilicus 2.0 W/kg for patient landmarks above the umbilicus
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
If information about a specific parameter is not included, there are no conditions associated with that parameter	

## X. How supplied

The Cordis **S.M.A.R.T.** Nitinol Stent System is supplied sterile (by ethylene oxide gas) and is intended for ONE USE ONLY. Also, included in the packaging: One (1) stent implant card.

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