



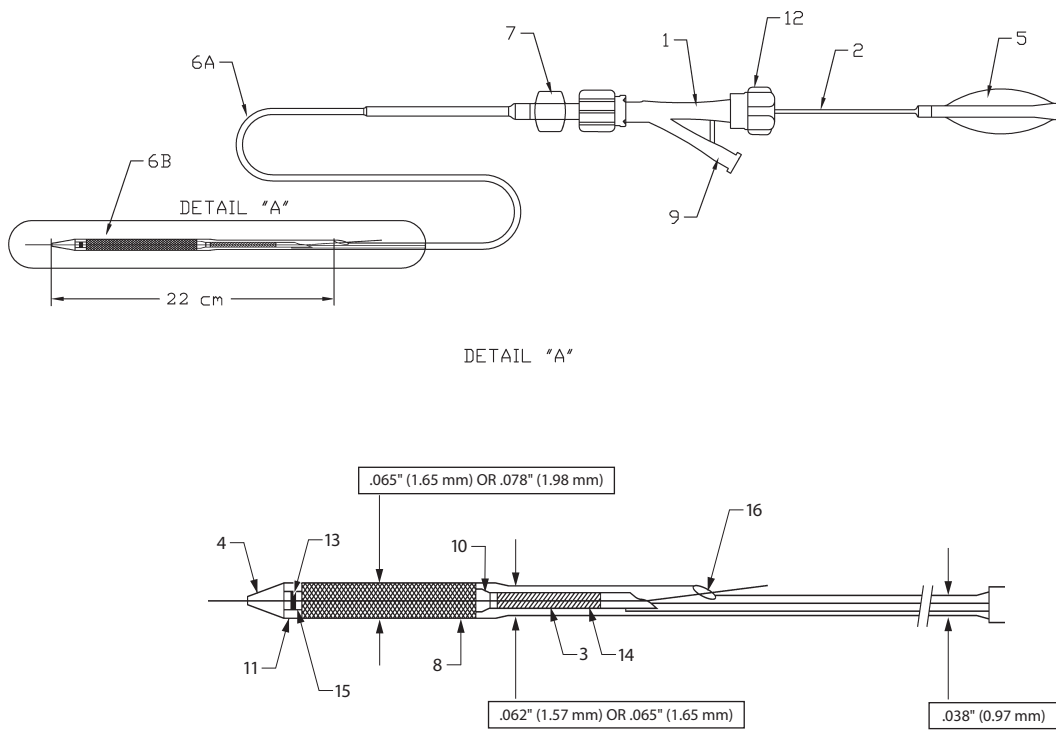
Cordis[®]
A Cardinal Health company

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Instructions for Use
















Cordis PRECISE[®] PRO Rx Nitinol Stent System

Figure 1



1. Tuohy Borst valve
2. Hypotube
3. Coil
4. Catheter inner shaft tip
5. Inner shaft hub
- 6A. Proximal shaft
- 6B. Distal outer sheath
7. Outer sheath Luer hub
8. Pod housing crimped stent
9. Tuohy Borst Y-connection
10. Proximal inner shaft marker (stop) marks trailing end of stent
11. Outer sheath radiopaque marker (BRITE TIP®)
12. Proximal valve end
13. Distal inner shaft stent marker
14. Coil sleeve
15. Wire lumen
16. Guidewire exit port

Explanation of symbols on labels and packaging:

	Do not use if package is damaged
	Keep dry
	Keep away from sunlight
	Sterilized using ethylene oxide
	Do not re-use
	Lot number
	Use-by date
	Catalogue number
	Caution
	Do not re-sterilize
	Consult instructions for use
	n units per box
	Manufacturer
	Non-Pyrogenic
	MR Conditional

English

STERILE. Sterilized with ethylene oxide gas. Nonpyrogenic. Radiopaque. For one use only. Do not resterilize. Store in a cool, dark, dry place. Not for sale in the U.S.A.

I. Device Name

The device brand name is Cordis **PRECISE® PRO Rx** Nitinol Stent System.

II. Description

The Cordis **PRECISE PRO Rx** Nitinol Stent System consists of a nitinol self-expanding stent preloaded on a .065" (1.65 mm) or .078" (1.98 mm) sheathed delivery system. The delivery system consists mainly of an inner shaft and an outer sheath with radiopaque markers, and a Tuohy Borst valve. The inner shaft consists of a support member and wire lumen. The proximal portion of the support member is comprised of a hub connected to a stainless steel wire and hypotube and distally of a stainless steel coil. The wire lumen originates distally in a catheter tip and terminates proximally at a guidewire exit port designed to accept a .014" (0.36 mm) guidewire. The outer sheath has a proximal shaft and distal outer sheath with a nominal working length of 135 cm. The self-expanding **PRECISE** stent is constrained within the space between the inner shaft and the distal outer sheath, located between distal and proximal stent markers on the inner shaft. The stent expands to its unconstrained diameter when released from the deployment catheter into the vessel. Upon deployment, the stent forms an open lattice and pushes outward on the luminal surface, helping to maintain the patency of the vessel. Due to the self-expanding behavior of nitinol, the stents are indicated for placement into vessels that are 1–2 mm smaller in diameter than the unconstrained diameter of the stent. Device depictions and components are provided in **Figure 1**.

III. Indications for Use

The Cordis **PRECISE PRO Rx** Nitinol Stent System is indicated for use in patients with stenotic lesions of the carotid artery(ies) who are at increased risk for surgery.

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.
- Patients with uncorrected bleeding disorders.
- Stenting of intra-cranial arteries.

V. Warnings

- The black dotted pattern on the grey temperature exposure indicator, found on the pouch, must be clearly visible. Do not use if entire circle is completely black as the unconstrained stent diameter may have been compromised.
- The Cordis **PRECISE PRO Rx** 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 re-sterilization after

initial use. Reuse of this product, including after reprocessing and/or re-sterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information all of which present a potential risk to patient safety.

- Do not use if the pouch is opened or damaged.
- Use the stent and delivery system prior to the "Use By" date specified on the package.
- Do not use with Ethiodol or Lipiodol* contrast media.
- Do not expose the delivery system to organic solvents (e.g. alcohol).
- Use of a smaller than indicated accessory device can lead to introduction of air into that device as the stent delivery system is advanced, which may not be removed during air aspiration.
- The stent is not designed for dragging or repositioning.
- Once the stent is partially deployed, it cannot be recaptured using the stent delivery system.
- As with any type of vascular implant, infection, secondary to contamination of the stent, may lead to thrombosis, pseudoaneurysm or rupture.
- The stent may cause a thrombus, distal embolization, or may migrate from the site of implant down the arterial lumen.
- Overstretching of the artery may result in rupture and life-threatening bleeding.
- Persons with allergic reaction to nickel titanium (Nitinol) may suffer an allergic response to this implant.

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

- Patients with poor renal function, who, in the physician's 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 the use of power injection systems.
- The delivery system is not recommended for use with a leaflet type valve.
- 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 distal lesion should be initially stented, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent in placement of the distal stent and reduces the chance for dislodging stents which may have already been placed.
- Recrossing a deployed stent with adjunct devices must be

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

- 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 H2-antagonists before or immediately after stent placement, oral absorption of antiplatelet agents (e.g. aspirin) may be adversely affected.
- Venous access should be available during carotid stenting in order to manage bradycardia and/or hypotension either by pharmaceutical intervention or placing of a temporary pacemaker, if needed.
- Both **PRECISE PRO Rx** Nitinol Stent Systems are shipped with the hemovalve in the **OPEN** position (see "Preparation of the Stent Delivery System").
- Prior to stent deployment remove all slack from the catheter delivery system (see "Stent Deployment").
- Ensure that the catheter system is flushed according to the steps outlined in "Introduction of Stent Delivery System" and "Preparation of Stent Delivery System." Failure to do so could result in air entering the access catheter.
- Ensure that there is a tight seal between the **PRECISE PRO Rx** catheter and the valve for the access catheter during aspiration. Failure to do so could result in air entering the access catheter.
- 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:

- Death
- Respiratory arrest
- Emergency artery bypass graft surgery
- Hemorrhagic or embolic stroke / TIA
- Renal failure
- Sepsis / infection
- Embolism
- Coronary ischemia
- Arrhythmia
- Drug reactions, allergic reaction to contrast medium or to the implanted device
- Vascular injury, including perforation, rupture, and dissection
- Disseminated intravascular coagulation
- New or worse encephalopathy
- G.I. bleeding from anticoagulation / antiplatelet medication
- Hemorrhage
- Parenchymal hemorrhage
- Aneurysm and pseudoaneurysm formation
- Intimal tear / dissection
- Stent migration / embolization
- Thrombosis
- Bradycardia and hypotension
- Arteriovenous fistula
- Tissue necrosis
- Stent misplacement
- Vessel occlusion, restenosis or recurrent stricture

- Hematoma
- Carotid artery spasm

VIII. Directions for Use

Pre- Procedure

The patient should be started on nonbuffered, nonenteric-coated aspirin 72 hours prior to the procedure per standard hospital dosing guidelines or as prescribed by a physician. Antiplatelet therapy should be administered 24-48 hours prior to the procedure, according to hospital protocol. Antiplatelet therapy following a carotid stenting procedure should be administered per physician instructions.

The percutaneous placement of the stent in a stenotic carotid 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. 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.

1. Inject Contrast Media

Perform a percutaneous angiogram using standard technique.

2. Identify and mark the lesion

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

Device Selection and Preparation

1. 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 which has an unconstrained diameter that is 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
3.0–4.0 mm	5.0 mm	1.2 %
4.0–5.0 mm	6.0 mm	2.4 %
5.0–6.0 mm	7.0 mm	4.1 %
6.0–7.0 mm	8.0 mm	6.2 %
7.0–8.0 mm	9.0 mm	5.8 %
8.0–9.0 mm	10.0 mm	8.0 %

Refer to product labeling for stent length.

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

2. Preparation of Stent Delivery System

CAUTION: The stent delivery system is shipped with the Tuohy Borst valve **OPEN**. Be careful not to prematurely deploy the stent during preparation. Prep the device in the tray per instructions below. Close the Tuohy Borst valve prior to removing the device from the tray.

- 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.

- c. After careful inspection of the pouch looking for damage to the sterile barrier, carefully peel open the pouch and remove the tray. If it is suspected that the sterility or performance of the device has been compromised, the device should not be used.
- d. While in the tray, attach a stopcock to the Y connection on the Tuohy Borst valve.
- e. Attach a 5-cc syringe filled with heparinized saline to the open stopcock and apply positive pressure until saline weeps from the proximal end of the Tuohy Borst valve. Lock the Tuohy Borst valve.
- f. Close the stopcock attached to the Tuohy Borst Y connection.
- g. Extract the stent delivery system from the tray. Examine the device for any damage. 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 Cordis **ANGIOGUARD™ RX** Emboli Capture Guidewire System.
 - a. Access the treatment site utilizing the appropriately sized accessory equipment. See Table "Recommended Accessory Catheter Sizing."

Table 1: Recommended Accessory Catheter Sizing

PRECISE PRO Rx Stent Diameter	Minimum Sheath Introducer	Minimum Guiding Catheter I.D.
5, 6, 7, 8 mm	5F (1.98 mm)	.078" (1.98 mm)
9 & 10 mm	6F (2.21 mm)	.087" (2.21 mm)

- b. Insert an appropriately sized Cordis **ANGIOGUARD RX** Emboli Capture Guidewire System via the introducer sheath or guiding catheter.

NOTE: PLEASE REFER TO THE CORDIS **ANGIOGUARD RX** INSTRUCTIONS FOR USE FOR PLACEMENT PROCEDURE AND USE OF THE DEVICE.
- c. The Cordis **PRECISE PRO Rx** Nitinol Stent System is compatible with a .014" (0.36 mm) or smaller guidewire.

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.

3. Introduction of Stent Delivery System

- a. Flush the guidewire lumen of the stent delivery system with heparinized saline by connecting a 5-cc syringe filled with heparinized saline solution to the stopcock attached to the Y connection (9) on the Tuohy Borst valve (1) to expel air. Ensure that the Tuohy Borst valve (1) is in the locked position to prevent premature stent deployment. Apply positive pressure to the syringe until saline weeps from the guidewire exit port (16). While covering the guidewire exit port (16) with thumb and forefinger, apply positive pressure to the syringe until

saline weeps from the catheter tip (4) and the space between the outer sheath radiopaque marker (11) and the catheter tip (4). Continue to flush to ensure all air is removed from the system, then close the stopcock attached to the Y connection (9) on the Tuohy Borst valve (1).

- b. 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.
- c. Advance the **PRECISE PRO Rx** System over the .014" (0.36 mm) **ANGIOGUARD RX** Emboli Capture Guidewire System until the guidewire exit port (16) is just outside the accessory device's Tuohy Borst valve. Adjust the accessory device's Tuohy Borst valve to maintain a snug seal about the **PRECISE PRO Rx** System. Look for and confirm back flow through the guidewire exit port (16) opening.
- d. After confirming back flow, advance the **PRECISE PRO Rx** System. Again adjust the accessory device's Tuohy Borst valve to maintain a snug seal, now over the .038" (0.97 mm) proximal shaft (6A) and continue to advance the **PRECISE PRO Rx** System to the lesion site.
- e. Prior to contrast injection, confirm again a snug seal between the .038" (0.97 mm) proximal shaft (6A) of the **PRECISE PRO Rx** System and the accessory device's Tuohy Borst valve.

FAILURE TO DO SO COULD RESULT IN AIR INTRODUCTION DURING ASPIRATION, RESULTING FROM A POOR SEAL.

NOTE: If resistance is met during delivery system introduction, the system should be withdrawn and another system should be used.

4. Slack Removal

- a. Advance the stent delivery system past the lesion site.
- b. Pull back the stent delivery system until the radiopaque inner shaft markers (leading and trailing ends) move in position so that they are proximal and distal to the target lesion.
- c. Ensure that the stent delivery system 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 lesion site.

5. Stent deployment

NOTE: When ready to proceed with stent deployment, heparin may be administered per standard hospital practice or as prescribed by a physician. Heparin may be continued following stent deployment if so indicated by a physician or hospital protocol.

- a. Verify that the delivery system's radiopaque inner shaft 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.
- c. Ensure that the access sheath or guiding catheter does not move during deployment.
- d. Initiate stent deployment by retracting the outer sheath while holding the inner shaft in a fixed position. Deployment is complete when the outer sheath marker passes the proximal inner shaft stent marker.

NOTE: The mechanism for stent deployment is outer sheath retraction. Deployment is completed by maintaining inner shaft position while retracting the outer sheath and allowing the stent to expand (often referred to as the "pin-and-pull"

method).

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. In no instance, should more than two (2) stents ever overlap.

6. Post-deployment Stent Dilatation

- a. While using fluoroscopy, withdraw the entire delivery system as one unit, over the guidewire and out of the body. Remove the delivery device from the guidewire.

NOTE: If any resistance is met during delivery system withdrawal, advance the outer sheath until the outer sheath marker contacts the catheter tip and withdraw the system as one unit. (Do not remove 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.
- d. Select an appropriately sized PTA balloon catheter and dilate the lesion with conventional technique. The inflation diameter of the PTA balloon catheter used for post dilatation should approximate the diameter of the reference vessel. Remove the PTA balloon catheter from the patient.

7. Post Stent Placement

- a. A post stent angiogram should be obtained.
- b. Remove the **ANGIOGUARD RX** Emboli Capture Guidewire System in accordance with **ANGIOGUARD RX** Instructions for Use. Remove the sheath and establish hemostasis.
- c. Discard the delivery system, guidewire, and sheath.
NOTE: Physician experience and discretion will determine the appropriate post procedure drug regimen for each patient.

IX. MRI Compatibility

Through non-clinical testing, the Cordis **PRECISE** Nitinol Stent has been shown to be MRI conditional at field strengths of 3 Tesla or less and a maximum whole body averaged specific absorption rate (SAR) of 0.8W/kg for 20:00 minutes of MRI. The **PRECISE** stent should not migrate in this MRI environment. Non-clinical testing has not been performed to rule out the possibility of stent migration at field strengths higher than 3 Tesla. In this testing, the stent produced a temperature rise of 0.5 degrees C at a maximum whole body averaged SAR of 0.8W/kg for 20:00 minutes of MRI. 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 stent. The effect of heating in the MRI environment for overlapping stents or stents with fractured struts is not known.

X. How supplied

The Cordis **PRECISE PRO Rx** Nitinol Stent System is supplied sterile (by ethylene oxide gas) and is intended for ONE USE ONLY.

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