Cordis®
a Johnson & Johnson company

10368453-2

**Endovascular**

Instructions for Use

# Cordis PRECISE® Nitinol Stent System (5.5F and 6F)

**Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.**

**Read all instructions carefully. Failure to properly follow the instructions, warnings and precautions may lead to serious consequences or injury to the patient.**

**STERILE. Cordis PRECISE® Nitinol Stent Systems are sterilized with ethylene oxide gas. Nonpyrogenic. Radiopaque. FOR ONE USE ONLY. DO NOT RESTERILIZE. Store in a cool, dark, dry place.**

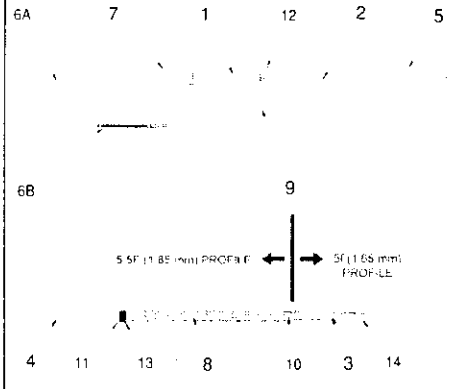
### 1.0 Device Name

The device brand name is the Cordis **PRECISE** Nitinol Stent System.

### 2.0 Description

The Cordis **PRECISE** Nitinol Stent System consists of a nitinol self-expanding stent preloaded on a 5.5F (1.85 mm) or 6F (2.0 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 terminates distally in a catheter tip and originates proximally in a Luer hub designed to accept a .018" (0.46 mm) guidewire. The delivery system has a nominal working length of 135 cm. The self-expanding **PRECISE** stent is constrained within the space between the inner shaft and the 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 carotid artery. Upon deployment, the stent forms an open lattice and pushes outward on the luminal surface, helping to maintain the patency of the artery. 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 their components are provided in **Figures 1 and 2**, which follow.

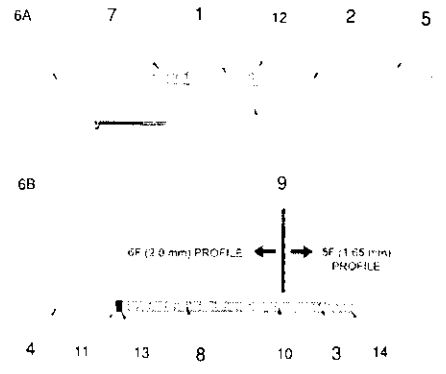
**Figure 1**
**5.5F (1.85 mm) Cordis PRECISE Nitinol Stent System**




DETAIL "A"

1. Tuohy Borst valve
2. Hypotube
3. Coil
4. Catheter inner shaft tip
5. Luer hub
6A. Proximal OD
6B Distal OD
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

**Figure 2**
**6F (2.0 mm) Cordis PRECISE Nitinol Stent System**




DETAIL "A"

1. Tuohy Borst valve
2. Hypotube
3. Coil
4. Catheter inner shaft tip
5. Luer hub
6A. Proximal OD
6B. Distal OD
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

The Cordis **PRECISE** Nitinol Stent System is provided as noted in **Tables 1 and 2** below.

**TABLE 1**
**5.5F (1.85 mm) Cordis PRECISE® Nitinol Stent System**
**135 cm Working Length**
**Guidewire Lumen: Accepts .018" (0.46 mm) Guidewire**

| 5.5F PRECISE® CATALOG CODES | UNCONSTRAINED STENT DIMENSIONS Diameter x Length (mm) |
|---|---|
| P05020XC | 5 x 20 |
| P05030XC | 5 x 30 |
| P05040XC | 5 x 40 |
| P06020XC | 6 x 20 |
| P06030XC | 6 x 30 |
| P06040XC | 6 x 40 |
| P07020XC | 7 x 20 |
| P07030XC | 7 x 30 |
| P07040XC | 7 x 40 |
| P08020XC | 8 x 20 |
| P08030XC | 8 x 30 |
| P08040XC | 8 x 40 |
| P68T30XC (Tapered) | 8 proximal, 6 distal x 30 mm |

**TABLE 2**
**6F (2.0 mm) Cordis PRECISE® Nitinol Stent System**
**135 cm Working Length**
**Guidewire Lumen: Accepts .018" (0.46 mm) Guidewire**

| 6F PRECISE® CATALOG CODES | UNCONSTRAINED STENT DIMENSIONS Diameter x Length (mm) |
|---|---|
| P09020XC | 9 x 20 |
| P09030XC | 9 x 30 |
| P09040XC | 9 x 40 |
| P10020XC | 10 x 20 |
| P10030XC | 10 x 30 |
| P10040XC | 10 x 40 |
| P79T30XC (Tapered) | 9 proximal, 7 distal x 30 mm |
| P710T30XC (Tapered) | 10 proximal, 7 distal x 30 mm |

### 3.0 Indications for Use

The Cordis **PRECISE** Nitinol Stent System used in conjunction with the **ANGIOGUARD™ XP** Emboli Capture Guidewire is indicated for the treatment of patients at high risk for adverse events from carotid endarterectomy (see Section 8.2 of these instructions) who require carotid revascularization and meet the criteria outlined below.

1. Patients with neurological symptoms and ≥ 50% stenosis of the common or internal carotid artery by ultrasound or angiogram **OR** patients without neurological symptoms and ≥ 80% stenosis of the common or internal carotid artery by ultrasound or angiogram, **AND**

2. Patients must have a vessel diameter of 4-9 mm at the target lesion. The vessel distal to the target lesion must be within the range of 3 mm and 7.5 mm to allow for placement of the **ANGIOGUARD XP** Emboli Capture Guidewire.

### 4.0 Contraindications

Use of the Cordis **PRECISE** Nitinol Stent System is contraindicated in the following patients:

1. Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.
2. Patients in whom the guide catheter is unable to be placed.
3. Patients with uncorrected bleeding disorders.
4. Patients with known allergies to nitinol.
5. Lesions in the ostium of the common carotid artery.

### 5.0 Warnings

### 5.1 General Warnings

1. Only physicians who have received appropriate training for carotid stenting and who are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device.
2. The safety and efficacy of the **PRECISE** Stent have not been demonstrated with embolic protection systems other than the Cordis **ANGIOGUARD** device.
3. The long-term performance (> 3 years) of carotid stents has not yet been established.
4. As with any type of vascular implant, infection secondary to contamination of the stent may lead to thrombosis, pseudoaneurysm or rupture.
5. The stent may cause a thrombus, distal embolization or may migrate from the site of implant down the arterial lumen. Appropriate sizing of the stent to the vessel is required to reduce the possibility of stent migration (see Section 9.3 of these instructions). In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.
6. Overstretching of the artery may result in rupture and life-threatening bleeding.
7. 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.
8. The appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure as suggested in Section 9.1 of these instructions.
9. In the event of complications such as infection, pseudoaneurysm or fistulization, surgical removal of the stent may be required.

### 5.2 Patient Selection Warnings

10. Safety and effectiveness of the Cordis **PRECISE** Nitinol Stent System has **NOT** yet been established in patients with the characteristics noted below.

Lesion Characteristics:

- Patients with evidence of intraluminal thrombus thought to increase the risk of plaque fragmentation and distal embolization.
- Patients whose lesion(s) may require more than two stents.
- Patients with total occlusion of the target vessel.
- Patients with lesions of the ostium of the common carotid.
- Patients with highly calcified lesions resistant to PTA.
- Concurrent treatment of bilateral lesions.

Patient Characteristics:

- Patients at low-to-moderate risk for adverse events from carotid endarterectomy.
- Patients experiencing acute ischemic neurologic stroke or who experienced a stroke within 48 hours.
- Patients with an intracranial mass lesion (i.e. abscess, tumor, or infection) or aneurysm (> 9 mm).
- Patients with arterio-venous malformations in the territory of the target carotid artery.
- Patients with coagulopathies.
- Patients with poor renal function, who, in the physician's opinion, may be at high risk for a reaction to contrast medium.
- Patients with perforated vessels evidenced by extravasation of contrast media.
- Patients with aneurysmal dilation immediately proximal or distal to the lesion.
- Pregnant patients or patients under the age of 18.

Access Characteristics:

- Patients with known peripheral vascular, supra-aortic or internal carotid artery tortuosity that would preclude the use of catheter-based techniques.
- Patients in whom femoral or brachial access is not possible.

11. Risk of distal embolization may be higher if the Cordis **PRECISE** Nitinol Stent System cannot be used in conjunction with the **ANGIOGUARD XP** Emboli Capture Guidewire during the carotid stenting procedure.

### 5.3 Device Use Warnings

12. The black dotted pattern on the gray temperature exposure indicator found on the pouch must be clearly visible. Do not use if entire circle is completely black as the pre-programmed stent diameter may have been compromised.
13. Do not use the device if there are abnormalities in the sterile barrier (e.g. broken seal, torn or breached barrier) or product.
14. This device is intended for one-time use only. Do not re-sterilize and/or reuse. Structural integrity and/or function may be impaired through reuse or cleaning.
15. Do not use the Cordis **PRECISE** Nitinol Stent System after the "Use By" date specified on the package.
16. Do not use with Ethiodol or Lipiodol* contrast media, which may adversely affect the stent delivery system.
17. Do not expose the delivery system to organic solvents (e.g. alcohol) as structural integrity and/or function of the device may be impaired.
18. The stent is not designed for dragging or repositioning.
19. Once the stent is partially deployed, it cannot be recaptured using the stent delivery system.
20. As with any type of vascular implant, infection secondary to contamination of the stent may lead to thrombosis, pseudoaneurysm or rupture

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

## 6.0 Precautions

### 6.1 Stent Handling Precautions

1. The Cordis **PRECISE®** Nitinol Stent System is supplied **STERILE** and is intended for single use only. DO NOT resterilize and/or reuse the device.
2. The 5.5F (1.85 mm) delivery system is shipped with the Tuohy Borst valve in the **OPEN** position. The 6F (2.0 mm) delivery system is shipped with the Tuohy Borst valve in the **LOCKED** position. Care should be taken not to pre-deploy the stent. The device should be prepped in the tray. (See Section 9.3, #2 of these instructions).
3. Do not use the Cordis **PRECISE** Nitinol Stent System after the "Use By" date specified on the package.
4. Do not use if the pouch is opened or damaged.
5. Store in a cool, dark, dry place.

### 6.2 Stent Placement Precautions

6. Venous access should be available during carotid stenting in order to manage bradycardia and/or hypotension either by pharmaceutical intervention or placement of a temporary pacemaker, if needed.
7. When catheters are in the body, they should be manipulated only under fluoroscopy. Radiographic equipment that provides high quality images is needed.
8. The delivery system is not designed for the use of power injection. Use of power injection may adversely affect device performance.
9. If resistance is met during delivery system introduction, the system should be withdrawn and another system used.
10. Prior to stent deployment, remove all slack from the catheter delivery system (see Section 9.4, #4 of these instructions).
11. 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 that have already been placed.
12. Overlap of sequential stents is necessary, but the amount of overlap should be kept to a minimum (approximately 5 mm). In no instance should more than 2 stents overlap.

### 6.3 Post Stent Placement Precautions

13. Recrossing a deployed stent with adjunct devices must be performed with caution.
14. In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.

### 6.4 MRI Safety and Compatibility

15. The Cordis **PRECISE** Stent was evaluated through bench testing and has been shown to be MR safe at field strengths of 1.5 Tesla or less, with a maximum spatial gradient of 3 T/m, gradient magnetic fields of 33 mT/m or less, a temporal magnetic field gradient (dB/dt) of 80 T/m/s, and a maximum whole body averaged specific absorption rate (SAR) of 1.33 W/kg for 16:40:00 min of MR imaging. MR imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the **PRECISE** Stent. The **PRECISE** Stent has not been evaluated to determine if it is safe in MRI systems with field strengths greater than 1.5 Tesla.

## 7.0 Adverse Events

### 7.1 Observed Adverse Events

Carotid stenting with distal protection was conducted on a total of 573 patients with carotid artery disease who were at high risk for adverse events from carotid endarterectomy (CEA) in the SAPPHIRE clinical study (Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy). The study was conducted to evaluate the safety and effectiveness of the Cordis **PRECISE** Nitinol Stent System and the **ANGIOGUARD™ XP** Emboli Capture Guidewire.

The study included a randomized arm that compared stent patients to CEA patients (334 patients). The study also included a non-randomized stent arm for patients who met the same entry criteria as the randomized patients, but who were determined by the surgeon at the study site to be at too high a risk for adverse events from CEA (406 patients). Patients meeting the same inclusion criteria as the randomized patients, but determined by the interventionalist to be inappropriate for stent treatment, were entered into a non-randomized surgical arm (7 patients). The major adverse event (MAE) rate in all study arms was defined as death, stroke, or MI (Q-wave or non-Q-wave) to 30 days and death or ipsilateral stroke from 31 days to 360 days.

Only 7 patients were enrolled in the non-randomized surgical arm of the SAPPHIRE study. The 360-day MAE rate for these patients was 14.3%. The MAE rates of the SAPPHIRE Randomized Study arm (167 stent patients vs. 167 CEA patients) and the non-randomized stent arm (406 patients) are shown in **Table 3**, which follows.

**Table 3 - Randomized & Non-Randomized Patient Events**

| 30-Day Complications | Randomized Stent (N=167) | Randomized CEA (N=167) | P-value* | Non-Randomized Stent (N=406) |
|---|---|---|---|---|
| MAE[1] | 4.8% (8) | 9.6% (16) | 0.14 | 6.9% (28) |
| Death (All Cause) | 1.2% (2) | 2.4% (4) | 0.68 | 2.2% (9) |
| Myocardial Infarction (Q or Non-Q) | 2.4% (4) | 6.0% (10) | 0.17 | 1.7% (7) |
| Q Wave MI | 0.0% (0) | 1.2% (2) | 0.50 | 0.2% (1) |
| Non-Q Wave MI | 2.4% (4) | 4.8% (8) | 0.38 | 1.5% (6) |
| Stroke | 3.6% (6) | 3.0% (5) | >0.99 | 4.9% (20) |
| Major Ipsilateral Stroke | 0.6% (1) | 1.2% (2) | >0.99 | 2.5% (10) |
| Major Non-Ipsilateral Stroke | 0.6% (1) | 0.6% (1) | >0.99 | 0.5% (2) |
| Minor Ipsilateral Stroke | 2.4% (4) | 0.6% (1) | 0.37 | 1.7% (7) |
| Minor Non-Ipsilateral Stroke | 0.6% (1) | 0.6% (1) | >0.99 | 0.5% (2) |
| Transient Ischemic Attack (TIA) | 3.6% (6) | 2.4% (4) | 0.75 | 5.4% (22) |
| Target Lesion Revascularization | 0.0% (0) | 0.0% (0) | - | 0.5% (2) |
| Surgery | 0.0% (0) | 0.0% (0) | - | 0.0% (0) |
| PTA | 0.0% (0) | 0.0% (0) | - | 0.5% (2) |
| Target Vessel Revascularization (not involving Target Lesion) | 0.0% (0) | 0.0% (0) | - | 0.0% |
| Surgery | 0.0% (0) | 0.0% (0) | - | 0.0% |
| PTA | 0.0% (0) | 0.0% (0) | - | 0.0% |
| Stent Thrombosis | 0.0% (0) | 0.0% (0) | - | 0.7% (3) |
| Major Bleeding[2] | 9.0% (15) | 10.2% (17) | 0.85 | 12.8% (52) |
| Cranial Nerve Injury | 0.0% (0) | 4.2% (7) | 0.01 | 0.0% (0) |
| Severe Hypotension | 17.4% (29) | 3.0% (5) | <0.01 | 15.0% (61) |
| Bradycardia | 8.4% (14) | 3.0% (5) | 0.06 | 3.2% (13) |
| Vascular Complications[3] | 5.4% (9) | N/A | - | 2.5% (10) |
| Device/Procedure Related Adverse Events[4] | 0.0% (0) | - | - | 0.0% (0) |
| **31 to 360-Day Complications[5]** | **Randomized Stent (N=165)[5]** | **Randomized CEA (N=163)[5]** | **P-value*** | **Non-Randomized Stent N=397[5]** |
| MAE[1] | 7.3% (12) | 12.3% (20) | 0.14 | 10.6% (42) |
| MAE without Non-Neurologic Deaths from 31-360 days[6] | 1.2% (2) | 3.7% (6) | 0.17 | 4.0% (16) |
| Death (All Cause) | 6.1% (10) | 10.4% (17) | 0.16 | 8.1% (32) |
| Myocardial Infarction (Q or Non-Q) | 0.6% (1) | 1.8% (3) | 0.37 | 1.0% (4) |
| Q Wave MI | 0.0% (0) | 0.0% (0) | - | 0.3% (1) |
| Non-Q Wave MI | 0.6% (1) | 1.8% (3) | 0.37 | 0.8% (3) |
| Stroke | 2.4% (4) | 4.9% (8) | 0.26 | 4.3% (17) |
| Major Ipsilateral Stroke | 0.0% (0) | 1.8% (3) | 0.12 | 0.8% (3) |
| Major Non-Ipsilateral Stroke | 0.0% (0) | 0.6% (1) | 0.50 | 0.8% (3) |
| Minor Ipsilateral Stroke | 1.2% (2) | 1.2% (2) | >0.99 | 2.3% (9) |
| Minor Non-Ipsilateral Stroke | 1.2% (2) | 1.8% (3) | 0.68 | 0.5% (2) |
| Transient Ischemic Attack (TIA) | 3.0% (5) | 0.6% (1) | 0.21 | 1.8% (7) |
| Target Lesion Revascularization | 0.6% (1) | 3.7% (6) | 0.07 | 0.3% (1) |
| Surgery | 0.6% (1) | 0.6% (1) | >0.99 | 0.0% (0) |
| PTA | 0.0% (0) | 3.1% (5) | 0.03 | 0.3% (1) |
| Target Vessel Revascularization (not involving Target Lesion) | 0.0% (0) | 0.0% (0) | - | 0.0% (0) |
| Surgery | 0.0% (0) | 0.0% (0) | - | 0.0% (0) |
| PTA | 0.0% (0) | 0.0% (0) | - | 0.0% (0) |
| Stent Thrombosis | 0.0% (0) | 0.0% (0) | - | 0.0% (0) |
| Major Bleeding[2] | 0.0% (0) | 0.0%(0) | - | 0.5% (2) |
| Cranial Nerve Injury | 0.0% (0) | 0.6% (1) | - | 0.0% (0) |
| Severe Hypotension | 0.6% (1) | 0.0% (0) | 0.99 | 0.8% (3) |
| Bradycardia | 0.0% (0) | 0.0% (0) | - | 0.3% (1) |
| Vascular Site Complications[3] | 0.0% (0) | N/A | - | 0.0% (0) |
| Device/Procedure Related Adverse Events[4] | 0.0% (0) | 0.0% (0) | - | 0.0% (0) |

**Table 3 (Continued) - Randomized Patient Events**

| Combined Complications to 360 Days | Randomized Stent (N=167) | Randomized CEA (N=167) | P-value* | Non-Randomized Stent (N=406) |
|---|---|---|---|---|
| MAE[1] | 12.0% (20) | 19.2% (32) | 0.10 | 15.8% (64) |
| MAE without Non-Neurologic Deaths from 31 days to 360 days[6] | 6.0% (10) | 12.6% (21) | 0.06 | 10.3% (42) |
| Death (All Cause) | 7.2% (12) | 12.6% (21) | 0.14 | 10.1% (41) |
| Myocardial Infarction (Q or Non-Q) | 3.0% (5) | 7.2% (12) | 0.13 | 2.7% (11) |
| Q Wave MI | 0.0% (0) | 1.2% (2) | 0.50 | 0.5% (2) |
| Non-Q Wave MI | 3.0% (5) | 6.0% (10) | 0.29 | 2.2% (9) |
| Stroke | 6.0% (10) | 7.2% (12) | 0.83 | 9.1% (37) |
| Major Ipsilateral Stroke | 0.6% (1) | 3.0% (5) | 0.21 | 3.2% (13) |
| Major Non-Ipsilateral Stroke | 0.6% (1) | 1.2% (2) | 1.00 | 1.2% (5) |
| Minor Ipsilateral Stroke | 3.6% (6) | 1.8% (3) | 0.50 | 3.9% (16) |
| Minor Non-Ipsilateral Stroke | 1.8% (3) | 2.4% (4) | 1.00 | 1.0% (4) |
| Transient Ischemic Attack (TIA) | 6.6% (11) | 3.0% (5) | 0.20 | 6.9% (28) |
| Target Lesion Revascularization | 0.6% (1) | 3.6% (6) | 0.12 | 0.7% (3) |
| Surgery | 0.6% (1) | 0.6% (1) | 1.00 | 0.0% (0) |
| PTA | 0.0% (0) | 3.0% (5) | 0.06 | 0.7% (3) |
| Target Vessel Revascularization (not involving Target Lesion) | 0.0% (0) | 0.0% (0) | - | 0.0% (0) |
| Surgery | 0.0% (0) | 0.0% (0) | - | 0.0% (0) |
| PTA | 0.0% (0) | 0.0% (0) | - | 0.0% (0) |
| Stent Thrombosis | 0.0% (0) | 0.0% (0) | - | 0.7% (3) |
| Major Bleeding[2] | 9.0% (15) | 10.2% (17) | 0.85 | 13.3% (54) |
| Cranial Nerve Injury | 0.0% (0) | 4.8% (8) | 0.01 | 0.0% (0) |
| Severe Hypotension | 17.4% (29) | 3.0% (5) | 0.00 | 15.5% (63) |
| Bradycardia | 8.4% (14) | 3.0% (5) | 0.06 | 3.4% (14) |
| Vascular Complications[3] | 5.4% (9) | N/A | - | 2.5% (10) |
| Device/Procedure Related Adverse Events[4] | 0.0% (0) | 0.0% (0) | - | 0.0% (0) |

* P-value displayed refers to comparison of randomized arms.

(1) Major Adverse Events (MAE) = Death, MI or stroke to 30 days and death or ipsilateral stroke from 31-360 days.

(2) Major Bleeding = Any non-access site-related bleeding resulting in a 25% or more decline in HCT or requiring transfusion.

(3) Vascular Complications = Events related to bleeding or vascular injury at the percutaneous access site.

(4) There were no device or procedure related events. In 17 of 19 initial stent delivery failures, a subsequent attempt was successful. In one case, the patient was treated with CEA. In the other case, the patient was treated with balloon angioplasty alone. One stent fracture was noted from one-year ultrasound films, with no adverse effect to the patient.

(5) Rates minus patient deaths to 30 days.

(6) MAE without Non-Neurological Deaths >31 Days – The vast majority of deaths occurring from 31 days to 360 days were attributed to the co-morbidities of this high-risk population. The 'adjusted' 360 day MAE rate includes all cause death, MI and all strokes to day 30, and ***only neurologic*** deaths and ipsilateral strokes from days 31-360.

**Table 3A - Causes of Death through 360 Days[1]**

| Cause of Death | Randomized Stent | Randomized CEA | Non-Randomized Stent |
|---|---|---|---|
| Neurologic | 1 | 3 | 8 |
| Cardiac | 8 | 10 | 18 |
| Respiratory Failure | 1 | 3 | 4 |
| Cancer | 2 | 1 | 5 |
| Renal Failure | 0 | 1 | 1 |
| Multi-System Failure | 0 | 3 | 2 |
| Exsanguination | 0 | 0 | 1 |
| Unknown | 0 | 0 | 2 |

[1] None of the deaths were attributed to the device or the procedure.

### 7.2 Potential Adverse Events

Adverse Events (in alphabetical order) that may be associated with the use of the Cordis **PRECISE®** Nitinol Stent System when used in conjunction with the **ANGIOGUARD™ XP** Emboli Capture Guidewire include, but may not be limited to:

- air embolism
- allergic/anaphylactoid reaction
- aneurysm
- angina/coronary ischemia
- arrhythmia (including bradycardia, possibly requiring need for a temporary or permanent pacemaker)
- arterial occlusion/restenosis of the treated vessel
- arterial occlusion/thrombus, at puncture site
- arterial occlusion/thrombus, remote from puncture site
- arteriovenous fistula
- bacteremia or septicemia
- cerebral edema
- damage to emboli capture device
- death
- embolization, arterial
- embolization, stent
- emergent repeat hospital intervention
- fever
- GI bleeding from anticoagulation/antiplatelet medication
- hematoma bleed, puncture site
- hematoma bleed, remote site
- hemorrhage
- hyperperfusion syndrome
- hypotension/hypertension
- infection
- intimal injury/dissection
- ischemia/infarction of tissue/organ
- local infection and pain at insertion site
- malposition (failure to deliver the stent to the intended site)
- myocardial infarction
- pain
- pseudoaneurysm
- renal failure
- restenosis of the vessel (≥ 50% obstruction)
- seizure
- severe unilateral headache
- stent migration
- stent thrombosis
- stroke
- transient ischemic attack
- vasospasm
- venous occlusion/thrombosis, at puncture site
- venous occlusion/thrombosis, remote from puncture site
- vessel rupture, dissection, perforation

### 7.3 Device Related Adverse Event Reporting

Any adverse event (clinical incident) involving the Cordis **PRECISE** Nitinol Stent System should be reported to Cordis Corporation immediately. To report an incident, call the Product Quality Services Department at 1-800-327-7714, option 4.

## 8.0 Clinical Study Information

### 8.1 Objectives

The primary objective of the pivotal clinical study (SAPPHIRE) was to compare the safety and effectiveness of the Cordis **PRECISE** Nitinol Stent Systems, used in conjunction with the **ANGIOGUARD XP** Emboli Capture Guidewire, to carotid endarterectomy (CEA) in the treatment of carotid artery disease in patients at increased risk for adverse events from CEA. Study hypotheses examined whether the major adverse events (MAE) rate of randomized stent patients was not inferior to randomized CEA patients. Safety evaluations included assessments of major clinical events occurring during the procedure, prior to discharge, within 30 days, six months, one year and every 12 months thereafter for a total of three years; access site vascular complications: independent neurological assessments at 24 hours, 30 days, six months and one year post-procedure. Effectiveness evaluations included assessments of successful stent deployment at the target lesion, less than 30% residual diameter stenosis at the completion of the procedure as measured by carotid angiography; and restenosis (≥ 50%) as determined by carotid ultrasound at 30 days, six months and one year post-procedure and every 12 months thereafter for a total of three years.

### 8.2 Study Design

The pivotal SAPPHIRE study was a multi-center, prospective, randomized, triangular sequential trial comparing patients at increased risk for adverse events from CEA who received a stent to a surgical (CEA) control. The safety and effectiveness of the Cordis **PRECISE** Nitinol Stent System, used in conjunction with the **ANGIOGUARD XP** Emboli Capture Guidewire in the treatment of *de novo* or restenotic obstructive carotid artery disease in these patients was evaluated.

The study also included a non-randomized stent arm, which included those patients who met entry criteria but who were determined by the surgeon at the study site to be at too high a risk for adverse outcomes from surgery and therefore inappropriate for randomization. Likewise, patients meeting the entry criteria, but determined by the interventionalist to be unacceptable candidates for stenting and therefore not randomizable, had the option of entering a non-randomized surgical arm.

SAPPHIRE entry criteria were identical for all patients. All patients were evaluated to determine whether they met the entry criteria by a multi-disciplinary team consisting of a neurologist, interventionalist, and vascular surgeon. Patients meeting the criteria were either randomized to treatment by stent or CEA, or placed into the non-randomized stent or CEA arms, based on the medical judgment of the interventionalist and surgeon as noted above. Patients who were entered into this study were either asymptomatic with a ≥ 80% diameter stenosis or symptomatic with a ≥ 50% diameter stenosis. Symptomatic patients were defined as those patients who have one or more TIAs, characterized by distinct focal neurological dysfunction or monocular blindness with clearing of signs and symptoms within 24 hours or one or more completed strokes with persistence of symptoms or signs for more than 24 hours. In addition, ALL patients must also have had at least one anatomic or co-morbid risk factor placing them at high-risk for adverse events from CEA. These risk factors are as follows:

- Congestive Heart Failure (Class III/IV), and/or known severe left ventricular dysfunction < 30%
- Open-heart surgery within 6 weeks
- Recent myocardial infarction (>24 hours and <4 weeks)
- Unstable angina (CCS class III/IV)
- Synchronous severe cardiac and carotid disease requiring open heart surgery and carotid revascularization
- Severe pulmonary disease to include any of the following:
  - Chronic oxygen therapy
  - Resting P02 of ≤ 60 mmHg
  - Baseline hematocrit ≥ 50%
  - FEV1 or DLCO ≤ 50% of normal
- Contralateral carotid occlusion
- Contralateral laryngeal palsy
- Post-radiation treatment
- Previous CEA recurrent stenosis
- High cervical ICA lesions
- CCA lesions below the clavicle
- Severe tandem lesions
- Abnormal stress test

The primary endpoint was a composite of MAE including death, any stroke, or myocardial infarction (MI), in the first 30 days following treatment and death or ipsilateral stroke between 31 days and 12 months. An independent Clinical Events Committee adjudicated all MAE's and other events. Endpoints were analyzed on an intent-to-treat basis.

A total of 747 patients were enrolled in the SAPPHIRE study at 29 centers in the United States. The randomized population included 334 patients (167 stent/167 CEA), 310 of who were treated per protocol. The primary reasons why the remaining 24 patients were not treated were: 1) Eleven patients withdrew consent; 2) Six patients were found not to meet inclusion criteria subsequent to randomization. 3) Five patients' conditions deteriorated and they became too high a risk for any treatment; and 4) Two patients were randomized to surgery that was never performed. The non-randomized stent arm included 406 patients and the non-randomized CEA arm included seven patients.

Follow-up evaluations were scheduled at 30 days, six months and one-year post procedure, and annually thereafter for three years. Patient follow-up and accountability at 30 days and 360 days are presented in **Table 4**, as these were the primary data analysis time points.

Imaging data provided in this summary are based on findings from two independent centralized Core Laboratories, which reviewed ultrasound and angiographic films. A third independent laboratory analyzed trapped material contained in a percentage of all **ANGIOGUARD™ XP** filter baskets. A Clinical Events Committee (CEC) adjudicated all clinical events and an independent Data Safety Monitoring Board (DSMB) monitored safety.

**Table 4 - SAPPHIRE Patient Follow-Up and Accountability**

| | 0 days | 30 days | 360 days |
|---|---|---|---|
| **# Patients Alive at Time Interval** | | | |
| • Randomized stent | 167 | 165 (99.0%) | 155 (93.0%) |
| • Randomized CEA | 167 | 163 (98.0%) | 146 (87.4%) |
| • Non-randomized stent | 406 | 397 (98.1%) | 365 (90.0%) |
| **Clinical Evaluation** | | | |
| • Randomized stent | 167 (100%) | 158 (96.0%) | 145 (94.0%) |
| • Randomized CEA | 167 (100%) | 145 (89.1%) | 125 (86.0%) |
| • Non-randomized stent | 406 (100%) | 389 (98.1%) | 342 (94.1%) |
| **Angiographic Evaluation (Core Lab)** | | | |
| • Randomized stent | 149 (89.2%) | N/A | N/A |
| • Randomized CEA | N/A | N/A | N/A |
| • Non-randomized stent | 386 (95.1%) | N/A | N/A |
| **Ultrasound Evaluation (Core Lab)** | | | |
| • Randomized stent | 142 (85.0%) | N/A | 125 (81.0%) |
| • Randomized CEA | 141 (84.4%) | N/A | 101 (69.2%) |
| • Non-randomized stent | 341 (84.0%) | N/A | 287 (79.0%) |
| **Neurological Evaluation** | | | |
| • Randomized stent | 165 (99.0%) | 148 (90.0%) | 126 (81.3%) |
| • Randomized CEA | 155 (93.0%) | 131 (80.4%) | 96 (66.1%) |
| • Non-randomized stent | 398 (98.0%) | 361 (91.0%) | 293 (80.3%) |

**8.3 Patient Demographics**

**Table 5** provides the subject characteristics of randomized patients and non-randomized stent patients enrolled in the SAPPHIRE trial.

**Table 5 - SAPPHIRE Patient Demographics***

| Patient Characteristics | Randomized Stent | Randomized CEA | P-value** | Non-Randomized Stent |
|---|---|---|---|---|
| Age (Years) | 72.5 ± 8.3 | 72.3 ± 9.1 | 0.86 | 71.4 ± 9.8 |
| % Male | 66.9% (111/166) | 67.1% (108/161) | 1.00 | 64.3% (261/406) |
| Diabetes | 25.3% (42/166) | 27.5% (44/160) | 0.71 | 30.8% (125/406) |
| Coronary Artery Disease | 85.8% (133/155) | 75.5% (111/147) | 0.03 | 68.9% (259/376) |
| Previous PTCA (Coronary) | 34.8% (56/161) | 23.4% (37/158) | 0.03 | 21.2% (83/392) |
| Previous CABG | 43.4% (72/166) | 30.8% (49/159) | 0.02 | 31.5% (128/406) |
| Previous Q-Wave or Non Q-Wave MI | 29.7% (46/155) | 35.3% (54/153) | 0.33 | 33.4% (122/365) |
| Angina at a Low Workload or Unstable Angina | 24.1% (20/83) | 14.7% (11/75) | 0.16 | 31.5% (41/130) |
| Congestive Heart Failure | 17.5% (29/166) | 17.4% (28/161) | 1.00 | 18.2% (74/406) |
| Coexistent Severe Coronary Artery Disease Requiring Carotid and Coronary Revascularization | 15.9% (26/164) | 16.5% (26/158) | 1.00 | 12.8% (51/400) |
| Systolic Blood Pressure | 151.7 ± 26.0 | 153.5 ± 26.9 | 0.54 | 148.2 ± 27.2 |
| History of Dyslipidemia | 78.5% (128/163) | 76.9% (123/160) | 0.79 | 73.9% (289/391) |
| Previous CEA/Recurrent Stenosis | 22.6% (37/164) | 22.2% (35/158) | 1.00 | 37.7% (151/401) |
| Post-Radiation Treatment | 4.3% (7/164) | 5.7% (9/158) | 0.61 | 16.2% (64/401) |
| Prior CEA | 28.3% (47/166) | 26.7% (43/161) | 0.80 | 45.2% (183/405) |
| Contralateral Carotid Occlusion | 23.6% (39/165) | 25.3% (40/158) | 0.80 | 16.3% (65/400) |
| History of Stroke | 27.1% (45/166) | 23.8% (38/160) | 0.53 | 32.3% (129/399) |
| History of TIA | 31.1% (50/161) | 34.0% (53/156) | 0.63 | 34.5% (138/400) |
| High Cervical ICA Lesions | 4.3% (7/164) | 4.4% (7/158) | 1.00 | 12.7% (51/401) |
| CCA Lesions Below the Clavicle | 0.0% (0/164) | 0.0% (0/158) | - | 3.0% (12/401) |
| Other Co-morbid Risk Factors Precluding CEA | 0.0% (0/164) | 0.0% (0/160) | - | 7.9% (32/404) |
| Renal Insufficiency | 6.0% (10/166) | 7.5% (12/160) | 0.66 | 7.4% (30/405) |
| Current Cigarette Use | 16.9% (27/160) | 16.4% (26/159) | 1.00 | 13.5% (54/399) |
| Patients >80 years | 19.3% (32/166) | 20.5% (33/161) | 0.78 | 19.2% (78/406) |

* The denominator represents the total number of responses to a question in the case report form.
**P-value displayed refers to comparison of randomized arms.

**8.4 Study Results**

The 360-day major adverse events (MAE) rate, defined as death, stroke, or MI (Q-wave or non-Q-wave) to 30 days and death or ipsilateral stroke from 31 days to 360 days was 12.0% for the randomized stent patients compared with 19.2% for the control group. These results demonstrate non-inferiority (p=0.004) of carotid stenting to carotid endarterectomy (CEA) with the pre-specified non-inferiority delta of 3%.

The MAE rate at 360 days for the non-randomized stent patients was 15.8%. In a test of the primary endpoint against the Objective Performance Criteria (OPC), despite the fact that the rate was numerically less than the OPC plus the delta, the p-value was found to be 0.2899. In a test of the MAE rate when post 30-day non-neurological deaths are not included, the p-value was found to be <0.0001. The causes of these non-neurological deaths are well documented, and consist of cardiac deaths, cancer deaths, renal failure, and respiratory failure.

A comparison of the non-randomized stent arm and the randomized CEA arm was conducted utilizing a propensity score analysis that accounted for baseline imbalances due to the non-randomized (i.e., more observational) nature of group membership. The analysis found the treatment difference (non-randomized stent minus CEA) in 360-day MAE was −5.3%, with an adjusted 95% confidence interval of −13.4% to 3.0%. Thus, after adjusting for the higher risk of patients in the non-randomized stent arm, 360-day MAE outcomes were non-inferior to the CEA arm of the randomized study within a 3% delta.

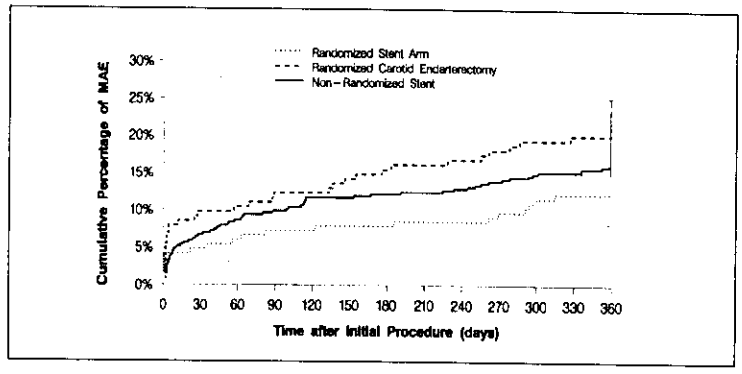
Principal safety and effectiveness results to 360 days are presented in **Table 6**, which follows. The cumulative percentage of MAE through 360 days for the randomized and non-randomized stent patients is presented in **Figure 3**, which follows. Non-randomized CEA patient event rates are not provided in **Table 6** since only seven patients were enrolled in that study arm and the data are insufficient for statistical analysis. For informational purposes, the MAE rate for non-randomized CEA patients to 360 days was 14.3% (1/7). **Figures 4 and 5** present the cumulative percentage of MAE through 360 days for randomized asymptomatic and symptomatic patients.

**Table 6 - Principal Safety & Effectiveness Results To 360 Days (Intent to Treat)**

| **Safety Measures & Other Clinical Events to 360 Days** | **Randomized Stent (N=167)** | **Randomized CEA (N=167)** | **P-value*** | **Non-Randomized Stent (N=406)** |
|---|---|---|---|---|
| MAE[1] | 12.0% (20/167) | 19.2%(32/167) | 0.10 | 15.8% (64/406) |
| Death (All Cause) | 7.2% (12/167) | 12.6% (21/167) | 0.14 | 10.1% (41/406) |
| Stroke | 6.0% (10/167) | 7.2% (12/167) | 0.83 | 9.1% (37/406) |
| Major Ipsilateral Stroke | 0.6% (1/167) | 3.0%(5/167) | 0.21 | 3.2% (13/406) |
| Minor Ipsilateral Stroke | 3.6% (6/167) | 1.8% (3/167) | 0.50 | 3.9% (16/406) |
| Myocardial Infarction (Q or Non-Q) | 3.0% (5/167) | 7.2% (12/167) | 0.13 | 2.7% (11/406) |
| TIA | 6.6% (11/167) | 3.0% (5/167) | 0.20 | 6.9% (28/406) |
| Major Bleeding[2] | 9.0% (15/167) | 10.2% (17/167) | 0.85 | 13.3% (54/406) |
| Cranial Nerve Injury | 0.0% (0/167) | 4.8% (8/167) | 0.01 | 0.0% (0/406) |
| Severe Hypotension | 17.4% (29/167) | 3.0% (5/167) | <0.01 | 15.5% (63/406) |
| Bradycardia | 8.4% (14/167) | 3.0% (5/167) | 0.06 | 3.4% (14/406) |
| Vascular Complications[3] | 5.4% (9/167) | N/A | - | 2.5% (10/406) |
| Device/Procedure Related Adverse Events[4] | 0.0% (0) | 0.0% (0) | - | 0.0% (0) |
| **Efficacy Measures** | **Randomized Stent (N=167)** | **Randomized CEA (N=167)** | **P-Value*** | **Non-Randomized Stent (N=406)** |
| Lesion Success [5] | 91.8% (145/158) | N/A | N/A | 90.4% (368/407) |
| Procedure Success [6] | 88.1% (140/159) | N/A | N/A | 87.9% (355/404) |
| Device Success[7] | 91.2% (145/159) | N/A | N/A | 89.6% (363/405) |
| **ANGIOGUARD™** Success[8] | 95.6% (152/159) | N/A | N/A | 91.6% (372/406) |
| Post-Procedure In-Lesion Minimal Lumen Diameter (MLD in mm) Mean±SD (N) Range (min, max) | 3.9±0.8 (147) (2.1,7.3) | N/A | N/A | 3.8±0.8 (385) (2.0, 8.1) |
| Post-Procedure In-Lesion Percent Diameter Stenosis (%DS)[9] Mean±SD (N) Range (min, max) | 17.2±11.3(147) (1.5, 49.3) | N/A | N/A | 18.5± 12.6 (385) (-12.1, 64.7) |
| Post-Procedure In-Stent Minimal Lumen Diameter (MLD in mm) Mean±SD (N) Range (min, max) | 4.3±0.9 (147) (2.1, 7.9) | N/A | N/A | 4.1±0.8 (381) (2.2, 8.1) |
| Post-Procedure In-Stent Percent Diameter Stenosis (%DS)[10] Mean±SD (N) Range (min, max) | 8.3±16.7 (147) (-42.0, 46.6) | N/A | N/A | 10.9±14.2 (381) (-34.9, 43.8) |
| Binary Ultrasound In-Vessel Restenosis at 360 days[11] | 19.7% (24/122) | 31.3% (30/96) | 0.06 | 27.7% (78/282) |
| Binary Ultrasound In-Stent Restenosis at 360 days[11] | 15.6% (19/122) | 13.5% (13/96) | 0.70 | 18.4% (52/282) |
| Cumulative % of TLR at 360 days**[12] | 0.6% | 4.3% | 0.04 | 0.8% |
| Cumulative % of MAE[1] at 360 days** | 12.2% | 20.1% | 0.05 | 16.0% |

Numbers are % (counts/sample size).
*P-value displayed refers to comparison of randomized arms.
**Cumulative percentage estimates are by Kaplan-Meier methods with standard error estimates by Peto formula.
(1) Major Adverse Events (MAE) = Death, MI or stroke to 30 days and death or ipsilateral stroke from 31-360 days.
(2) Major Bleeding = Any non-access site related bleeding resulting in a 25% or more decline in HCT or requiring transfusion.
(3) Vascular Complications = Events related to bleeding or vascular injury at the percutaneous access site.
(4) There were no device or procedure related events. In 17 of 19 initial stent delivery failures, a subsequent attempt was successful. In one case, the patient was treated with CEA. In the other case, the patient was treated with balloon angioplasty alone. One stent fracture was noted from one-year ultrasound films, with no adverse effect to the patient.
(5) Lesion Success = The attainment of a final residual stenosis of <30% using any percutaneous method. If no in-stent measurements were available, in-lesion measurements were used, and if no QCA was available, visual estimates were used.
(6) Procedure Success = The attainment of a final residual stenosis of <30% and no in-hospital MAE. If no in-stent measurements were available, in-lesion measurements were used, and if no QCA was available, visual estimates were used.
(7) Device Success = The attainment of a final residual stenosis of <30% using only the assigned device. If no in-stent measurements were available, in-lesion measurements were used, and if no QCA was available, visual estimates were used.
(8) **ANGIOGUARD™** Success = Successful deployment and retrieval of the **ANGIOGUARD™** device.
(9) In-lesion % DS Measurement = Defined as the % diameter stenosis either within the stented segment or within 5mm proximal or distal to the stent edges.
(10) In-stent % DS Measurement = Defined as the % diameter stenosis within the stented segment.
(11) Binary Restenosis is defined by Ultrasound as % diameter stenosis >50%.
(12) TLR – Target Lesion Revascularization

Figure 3
Cumulative Percentage of MAE* at 360 days

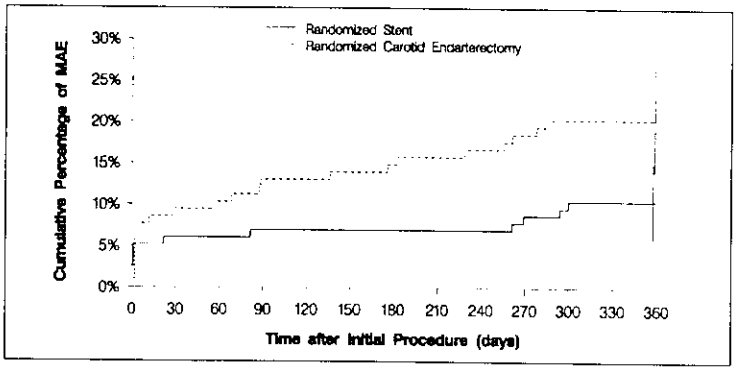



| Time After Procedure (Days) – Randomized Patients | | | | |
|---|---|---|---|---|
| Stent | 0 | 30 | 180 | 360 |
| N at risk | 167 | 158 | 152 | 143 |
| % with events | 1.8 | 4.2 | 7.9 | 12.2 |
| CEA | | | | |
| N at risk | 167 | 146 | 136 | 118 |
| % with events | 0.6 | 9.8 | 15.5 | 20.1 |
| Test Between Groups | | | | |
| Log-Rank P-Values | 0.053 | | | |

| Time After Procedure (Days) – Non-Randomized Patients | | | | |
|---|---|---|---|---|
| | 0 | 30 | 180 | 360 |
| Stent | | | | |
| N at risk | 406 | 382 | 352 | 329 |
| % with events | 1.5 | 6.9 | 12.2 | 16.0 |

* Major Adverse Events (MAE) = Death, MI or stroke to 30 days and death or ipsilateral stroke from 31-360 days.

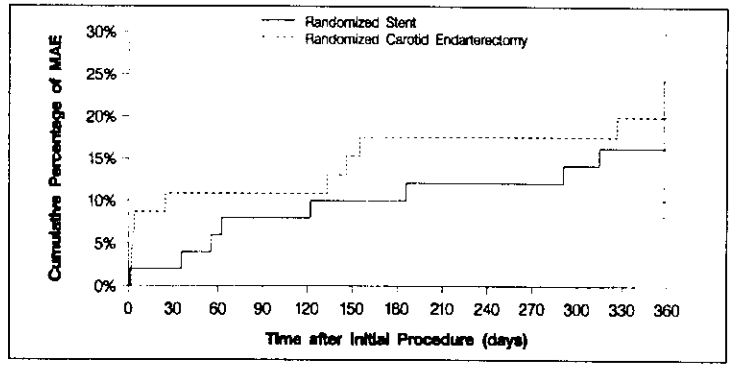
Figure 4
Cumulative Percentage of MAE* at 360 days – Asymptomatic Randomized Stent and CEA Patients




| Time After Procedure (Days) | | | |
|---|---|---|---|
| | 0 | 30 | 360 |
| Stent | | | |
| N at Risk | 117 | 109 | 100 |
| % with Events | 2.6 | 6.0 | 10.5 |
| CEA | | | |
| N at Risk | 119 | 103 | 84 |
| % with Events | 0.8 | 9.4 | 20.3 |
| Test Between Groups | | | |
| Log-Rank P-Values | 0.044 | | |

* Major Adverse Events (MAE) = Death, MI or stroke to 30 days and death or ipsilateral stroke from 31-360 days.

Figure 5
**Cumulative Percentage of MAE* at 360 Days – Symptomatic Randomized Stent & CEA Patients**




| | Time After Procedure (Days) | | |
|---|---|---|---|
| | 0 | 30 | 360 |
| **Stent** | | | |
| N at risk | 50 | 49 | 42 |
| % with events | 0.0 | 2.0 | 16.3 |
| **CEA** | | | |
| N at risk | 46 | 42 | 32 |
| % with events | 0.0 | 10.9 | 20.0 |
| **Test Between Groups** | | | |
| Log-Rank P-value | 0.582 | | |

* Major Adverse Events (MAE) = Death, MI or stroke to 30 days and death or ipsilateral stroke from 31-360 days.

### 9.0 Directions for Use

Only physicians who have received appropriate training for carotid stenting and who are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device.

### 9.1 Peri-Procedural Care

SAPPHIRE study patients were started on aspirin 81-325 mg daily, 72 hours prior to the procedure and continued indefinitely after the procedure unless the patient had an allergy to it or could not tolerate it. Another oral anti-platelet agent, such as ticlopidine (250 mg b.i.d.) or clopidogrel (75 mg q.d.), was given pre-procedure (beginning at least 24 hours prior to the procedure, but 48 hours was recommended) and continued after the procedure for two weeks. If clopidogrel was used, a 300 mg dose was also given post-stent deployment. If a second oral antiplatelet agent was not given prior to the procedure, then a loading dose such as clopidogrel 300 mg was given immediately post-stent-deployment and continued at the usual daily dose for two weeks. If clopidogrel 75 mg q.d. was administered for at least two days prior to the stent procedure, the 300 mg dose was not necessary.

In addition to usual care and the suggested peri-procedure pharmacological regimen, special attention to diagnosis and management of the following conditions are critical for optimal patient care:

- Bradycardia/tachycardia
- Hypertension or hypotension
- Acute and subacute stent thrombosis
- Hyperperfusion syndrome

### 9.2 Pre-procedure

Refer to Section 9.1 of these instructions for the suggested pre-procedure pharmacological treatment regimen. The percutaneous placement of the stent in a stenotic or obstructed 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. If thrombus is present, do not proceed with stent deployment. 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.

**CAUTION:** Venous access should be available during carotid stenting in order to manage bradycardia and/or hypotension either by pharmaceutical intervention or placement of a temporary pacemaker if needed.

**CAUTION:** When catheters are in the body, they should be manipulated only under fluoroscopy. Radiographic equipment that provides high quality images is needed.

a) **Inject contrast media** – Perform an angiogram using standard technique.
b) **Identify and mark the lesion** – Fluoroscopically identify and mark the lesion, observing the most distal level of the stenosis.

### 9.3 Device Selection and Preparation

**1. Select Stent Size**

Measure the length of the target lesion to determine the length of stent(s) required. When more than one stent is required to cover 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 (approximately 5 mm).

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 1 to 2 mm larger than the largest reference vessel diameter to achieve secure placement according to the following Stent Size Selection Table (**Table 7**).

**Table 7**
**Stent Size Selection Table**
Straight Stent Sizes - 20, 30, & 40 mm lengths
Tapered Stents - 30 mm length

| Vessel Lumen Diameter | Unconstrained Stent Diameter | % Length Foreshortening* |
|---|---|---|
| **5.5F (1.85 mm) Delivery System** | | |
| 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% |
| 4 – 5 mm distal<br>6 – 7 mm proximal<br>(Tapered Vessel) | 6 mm distal<br>8 mm proximal<br>(Tapered Vessel) | 4.1% |
| **6F (2.0 mm) Delivery System** | | |
| 7.0-8.0 mm | 9.0 mm | 5.8% |
| 8.0-9.0 mm | 10.0 mm | 8.0% |
| 5 – 6 mm distal<br>7 – 8 mm proximal<br>(Tapered Vessel) | 7 mm distal<br>9 mm proximal<br>(Tapered Stent) | 4.1% |
| 5 – 6 mm distal<br>8 – 9 mm proximal<br>(Tapered Vessel) | 7 mm distal<br>10 mm proximal<br>(Tapered Stent) | 4.8% |

* Mathematical calculation.

**Use of Tapered Stents:**
The **PRECISE®** 6-8 mm x 30 mm, 7-9 x 30 mm and 7-10 x 30 mm tapered stents are specifically designed to stent lesions at or near the carotid bifurcation when trying to avoid over-sizing in the internal carotid by more than 1-2 mm as a result of vessel mismatch (>1 mm) between the common and internal carotid arteries. Placement of the distal end of the stent should be high enough above the disease such that the distal end of the stent is placed well within the healthy portion of the internal carotid (see **Figure A**, which follows). Placement as shown in **Figure B** is not recommended.

The distal end of the stent (6 or 7 mm) should be oversized 1-2 mm to the reference vessel in the internal carotid. Likewise the proximal end of the stent (8, 9 or 10 mm) should be oversized 1-2 mm to the reference vessel in the common carotid. See **Figure A**, which follows.

**Placement of a Tapered Stent**

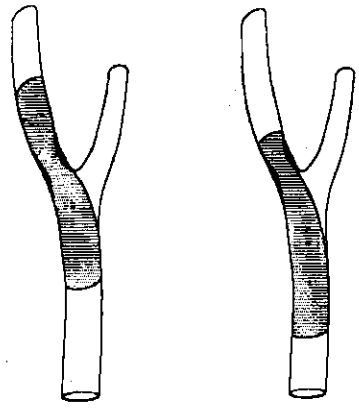


Figure A - Recommended placement for a tapered stent

Figure B - Placement Not Recommended for a tapered stent

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

**2. Preparation of Stent Delivery System.**

**CAUTION:** The Cordis **PRECISE** Nitinol Stent System is supplied **STERILE** and is intended for single use only. DO NOT resterilize and/or reuse the device. Assure that the device had been properly stored in a cool, dark, dry place prior to use.

**CAUTION:** Use the Cordis **PRECISE** Nitinol Stent System prior to the "Use By" date specified on the package. Do not use if the pouch is opened or damaged.

**CAUTION: The 5.5F (1.85 mm) and 6F (2.0 mm)Cordis PRECISE Nitinol Stent Systems are shipped with the Tuohy Borst valve in different positions.** The 5.5F (1.85 mm) stent delivery system is shipped with the Tuohy Borst valve in the OPEN position, and the 6F (2.0 mm) stent delivery system is shipped with the Tuohy Borst valve in the LOCKED position. Be careful not to prematurely deploy the stent during preparation. The systems should be prepped in the sterile tray per the instructions below. For the 5.5F (1.85 mm) system, close the Tuohy Borst valve prior to removing the device from the tray. For the 6F (2.0 mm) system, ensure the Tuohy Borst valve is closed prior to removing the device from the tray.

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 gray background is clearly visible. Do not use if entire temperature exposure indicator is completely black as the unconstrained stent diameter may have been compromised.
c) After careful inspection of the pouch looking for damage to the sterile barrier, carefully peel the pouch open and remove 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) With the device in the tray, unlock the Tuohy Borst valve. (**NOTE:** This is only necessary for the 6F (2.0 mm) **PRECISE®** device as the Tuohy Borst valve on the 5.5F (1.85 mm) **PRECISE®** device is shipped in the open position.)
e) While in the tray, attach a stopcock to the Y connection on the Tuohy Borst valve.
f) With the device still in the tray, attach a 3-cc syringe filled with heparinized saline to the open stopcock and apply positive pressure until heparinized saline weeps from the back end of the Tuohy Borst valve. Lock the Tuohy Borst valve. While viewing the distal end of the catheter, flush again until heparinized saline weeps from the distal catheter end.
g) Close the stopcock attached to the Tuohy Borst Y connection.
h) 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.

**9.4 Stent Deployment Procedure**

**WARNING:** Do not use with Ethiodol or Lipiodol[1] contrast media, which may adversely affect the stent delivery system.

**WARNING:** Do not expose the delivery system to organic solvents (alcohol), as structural integrity and/or function of the device may be impaired.

**CAUTION:** The delivery system is not designed for the use of power injection. Use of power injection may adversely affect device performance.

**1. Insertion of Introducer Sheath or Guiding Catheter and Cordis ANGIOGUARD™ XP Emboli Capture Guidewire**
a) Access the treatment site utilizing the appropriate accessory equipment compatible with a 5.5F (1.85 mm) or 6F (2.0 mm) stent delivery system

b) Insert and deploy the **ANGIOGUARD™ XP** Emboli Capture Guidewire System via the introducer sheath or guiding catheter in accordance with the Cordis **ANGIOGUARD XP Emboli Capture Guidewire Instructions for Use. Refer to the ANGIOGUARD XP Emboli Capture Guidewire Instructions for Use for detailed placement procedure and use of that device.**
c) The Cordis **PRECISE®** Nitinol Stent System is compatible with a .018" (0.46 mm) or smaller guidewire.

**2. Dilation of Lesion**
a) 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 utilizing a 10-cc syringe to expel air.
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 device over the **ANGIOGUARD XP** Emboli Capture Guidewire system to the lesion site.

**CAUTION:** If resistance is met during stent delivery system introduction, the stent delivery system should be withdrawn and another system should be used, while the **ANGIOGUARD XP** Emboli Capture Guidewire remains in place.

**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 the device outside the patient remains flat and straight.

**CAUTION:** Prior to stent deployment, remove all slack from the catheter delivery system. Slack in the catheter shaft either outside or inside the patient may result in deployment of the stent beyond the lesion site.

**5. Stent Deployment**

**WARNING:** The stent is not designed for dragging or repositioning. Once the stent is partially deployed, it cannot be recaptured using the stent delivery system.

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.

**NOTE:** It is recommended that heparin (intravenous) be given during the procedure immediately after guiding catheter cannulation. The initial bolus dose of heparin should be approximately 3,000 to 5,000 units (with necessary weight adjustments). Additional bolus doses of heparin should be given to maintain an ACT near 300 seconds during the entire procedure. No heparin should be given after the procedure until hemostasis at the puncture site is achieved.

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.

**CAUTION:** When more than one stent is required to cover the lesion, or if there are multiple lesions, the more distal stent should be placed first. 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 that have already been placed.

**CAUTION:** Overlap of sequential stents is necessary but the amount of overlap should be kept to a minimum (approximately 5 mm). In no instance, should more than two (2) stents ever overlap.

**6. Post-deployment Stent Dilatation**
**CAUTION:** The delivery system is not designed for the use of power injection. Use of power injection may adversely affect device performance.

**CAUTION:** Re-crossing a deployed stent with adjunct devices must be performed with caution.

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 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 **ANGIOGUARD XP** Emboli Capture Guidewire system **in accordance with that device's Instructions for Use.** Remove the sheath and compress the puncture site to achieve hemostasis.
c) Discard the delivery system, guidewire, and sheath.
d) Follow the suggested post-procedure pharmacological treatment regimen described in Section 9.1 of these instructions.

**WARNING:** In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.

**WARNING:** In the event of complications such as infection, pseudoaneurysm or fistulization, surgical removal of the stent may be required.

**10.0 Patient Information**
In addition to these Instructions for Use, the Cordis **PRECISE** Nitinol Stent System is packaged with a Stent Implant Card for the patient that contains specific information about the Cordis **PRECISE** Nitinol Stent System. All patients should be instructed to keep this card in their possession at all times for procedure/stent identification.

A Patient Brochure, which includes information on carotid artery disease, the carotid stent implant procedure, and the Cordis **PRECISE** Nitinol Stent System is available from Cordis and can be obtained by accessing www.cordislabeling.com or by contacting Cordis at 1-800-372-7714.

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

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