



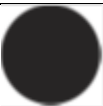
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Instructions for Use (eIFU)

PRECISE® PRO Transcarotid Stent System

Explanation of symbols on labels and packaging:

	Do not use if package is damaged and consult instructions for use
	Keep dry
	Keep away from sunlight
	Sterilized using ethylene oxide
	Do not re-use
	Lot number
	Use-by date
	Catalog number
	Caution
	Do not re-sterilize
	Consult instructions for use or consult electronic instructions for use
	Caution: Federal (USA) law restricts this device to sale by or on order of a physician.
	n units per box
	Manufacturer
	MR Conditional
	Non-Pyrogenic
	Medical Device
	Single sterile barrier system; Sterilized using Ethylene Oxide
	Contains Hazardous Substances
	Length

	Diameter
	OK for Use
	Do not Use

STERILE. The **PRECISE® PRO Transcarotid Stent Systems** are sterilized with ethylene oxide gas.
Nonpyrogenic. The stent is radiopaque.

FOR ONE USE ONLY. DO NOT RESTERILIZE. Store in a cool, dark, dry place.

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.

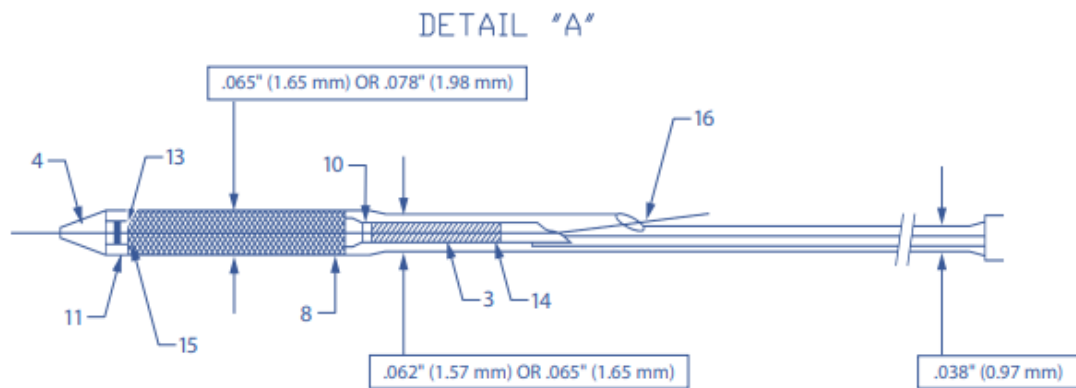
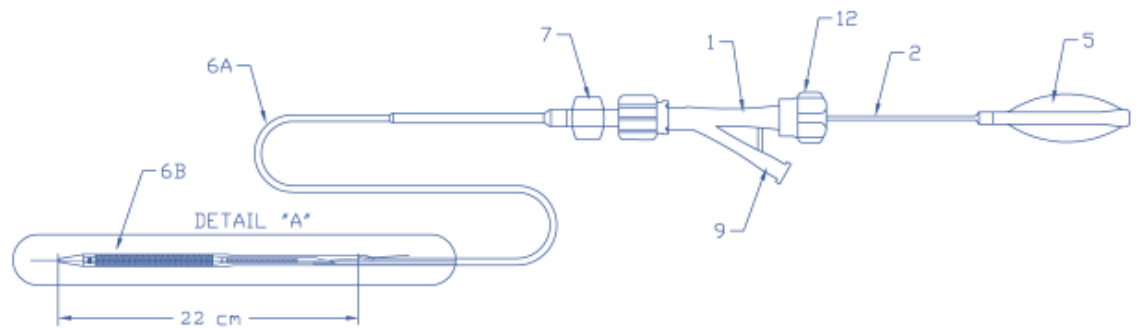
I. Device Name

The device brand name is **PRECISE® PRO Transcarotid Stent System**.

II. Description

The Cordis **PRECISE® PRO Transcarotid Stent System** consists of a nitinol (Maximum Stent Composition: Nickel 57.0% weight/weight, Titanium 45.5% weight/weight) self-expanding stent preloaded on a 5F (.065"/ 1.65 mm) or 6F (.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 57 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 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 components are provided in **Figure 1**, which follows.

Figure 1: **PRECISE® PRO Transcarotid Stent System**



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

III. Indications for Use

The **PRECISE® PRO Transcarotid Stent System** used in conjunction with the ENROUTE® Transcarotid Neuroprotection System (NPS), is indicated for the treatment of patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization and meet the criteria outlined below.

1. Patients with neurological symptoms and $\geq 50\%$ stenosis of the common or internal carotid artery by ultrasound or angiogram OR patients without neurological symptoms and $\geq 80\%$ 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,
AND
3. Carotid bifurcation is located at minimum 5cm above the clavicle to allow for placement of the ENROUTE Transcarotid NPS.

The **PRECISE® PRO Transcarotid Stent System** is provided as noted in **Table 1** below.

Table 1 PRECISE® PRO Transcarotid Stent System
57cm Working Length
Guidewire Lumen: Accepts .014" (0.36 mm) Guidewire

5F (.065"/1.65 mm) PRECISE® PRO Transcarotid	UNCONSTRAINED STENT DIMENSIONS Diameter x Length (mm)	% STENT FREE AREA	CROSSING PROFILE
PC0520RXT	5 x 20	84.02	5F (.078", 1.98 mm)
PC0530RXT	5 x 30	82.45	5F (.078", 1.98 mm)
PC0540RXT	5 x 40	82.96	5F (.078", 1.98 mm)
PC0620RXT	6 x 20	86.53	5F (.078", 1.98 mm)
PC0630RXT	6 x 30	85.21	5F (.078", 1.98 mm)
PC0640RXT	6 x 40	85.63	5F (.078", 1.98 mm)
PC0720RXT	7 x 20	88.24	5F (.078", 1.98 mm)
PC0730RXT	7 x 30	87.10	5F (.078", 1.98 mm)
PC0740RXT	7 x 40	87.48	5F (.078", 1.98 mm)
PC0820RXT	8 x 20	89.49	5F (.078", 1.98 mm)
PC0830RXT	8 x 30	88.44	5F (.078", 1.98 mm)
PC0840RXT	8 x 40	88.79	5F (.078", 1.98 mm)
6F (.078"/1.98 mm) PRECISE® PRO Transcarotid	UNCONSTRAINED STENT DIMENSIONS Diameter x Length (mm)	% STENT FREE AREA	CROSSING PROFILE
PC0920RXT	9 x 20	85.8	6F (.087", 2.21 mm)
PC0920RXT	9 x 30	86.1	6F (.087", 2.21 mm)
PC0920RXT	9 x 40	86.6	6F (.087", 2.21 mm)
PC1020RXT	10 x 20	86.9	6F (.087", 2.21 mm)
PC1030RXT	10 x 30	87.2	6F (.087", 2.21 mm)
PC1040RXT	10 x 40	87.8	6F (.087", 2.21 mm)

IV. Patient Target Group

The patient target group includes individuals with stenotic lesions of the carotid artery(ies). The patient target group of this device is based on the patient's anatomy and compatibility with the device.

V. Contraindications

Use of the **PRECISE® PRO Transcarotid Stent System** is contraindicated in the following patients:

1. Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.
2. Patients in whom the ENROUTE Transcarotid NPS 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.

VI. Warnings

6.1 General Warnings

1. Only physicians who have received appropriate training for transcrotid 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® PRO Transcarotid Stent System have not been demonstrated with embolic protection systems other than the ENROUTE Transcarotid NPS.
3. Refer to the instructions supplied with all interventional devices to be used with the PRECISE® PRO Transcarotid Stent System for their intended uses, contraindications, and potential complications.
4. The long-term performance (> 3 years) of carotid stents has not yet been established.
5. As with any type of vascular implant, infection secondary to contamination of the stent may lead to thrombosis, pseudoaneurysm or rupture.
6. 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 10.3** of these instructions). In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.
7. Overstretching of the artery may result in rupture and life-threatening bleeding.
8. 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.
9. The appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure as suggested in **Section 10.1** of these instructions.
10. In the event of complications such as infection, pseudoaneurysm or fistulization, surgical removal of the stent may be required.
11. Persons with allergic reactions to nickel titanium (Nitinol) may suffer an allergic response to this implant.
12. This device contains the following substance defined as CMR 1A and/or CMR 1B and/or endocrine disrupting substances in a concentration above 0.1% weight by weight: Cobalt; CAS No. 7440-48-4; EC No. 231-158-0.

6.2 Patient Selection Warnings

1. Safety and effectiveness of the Cordis **PRECISE® PRO Transcarotid 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.
- Patient has had a recent (<7 days) stroke of sufficient size (on CT or MRI) to place him or her at risk of hemorrhagic conversion during the procedure.
- Patients with ipsilateral intracranial or extracranial arterial stenosis greater in severity than the lesion to be treated, cerebral aneurysm > 5mm, AVM (arteriovenous malformation) of the cerebral vasculature, or intracranial tumor.
- 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 internal carotid artery tortuosity that would preclude the use of catheter-based techniques.
 - Patients with known common carotid or internal carotid artery tortuosity that would preclude the use of catheter-based techniques.
 - Patients in whom common carotid access is not possible.
2. Risk of distal embolization may be higher if the **PRECISE® PRO Transcarotid Stent System** cannot be used in conjunction with the ENROUTE Transcarotid NPS during the carotid stenting procedure.

6.3 Device Use Warnings

1. 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.
2. Ensure that the catheter system is flushed according to the steps outlined in "Introduction of Stent Delivery System" (**Section 10.4, #3**). Failure to do so could result in air entering the sheath introducer.
3. Ensure that there is a tight seal between the **PRECISE® PRO** catheter and the valve for the sheath introducer during aspiration. Failure to do so could result in air entering the sheath introducer.
4. 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.
5. Do not use the device if there are abnormalities in the sterile barrier (e.g. broken seal, torn or breached barrier) or product.
6. 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.

7. Do not use the **PRECISE® PRO Transcarotid Stent System** after the "Use By" date specified on the package.
8. Do not use with Ethiodol™ or Lipiodol™ contrast media, which may adversely affect the stent delivery system.
9. Do not expose the delivery system to organic solvents (e.g. alcohol) as structural integrity and/or function of the device may be impaired.
10. The stent is not designed for dragging or repositioning.
11. Once the stent is partially deployed, it cannot be recaptured using the stent delivery system.
12. As with any type of vascular implant, infection secondary to contamination of the stent may lead to thrombosis, pseudoaneurysm or rupture.
13. When multiple stents are used, they should be of similar composition.
14. Long-term outcomes following repeat dilatation of endothelialized stents are unknown.

VII. Precautions

7.1 Stent Handling Precautions

1. The **PRECISE® PRO Transcarotid Stent System** is supplied STERILE and is intended for single use only. DO NOT resterilize and/or reuse the device.
2. The **PRECISE® PRO Transcarotid Stent System** is shipped with the Tuohy Borst valve in the **OPEN** position. Care should be taken not to pre-deploy the stent. The device should be prepped in the tray. (See **Section 10.3**, #2 of these instructions).
3. Do not use the **PRECISE® PRO Transcarotid 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.

7.2 Stent Placement Precautions

1. 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.
2. When catheters are in the body, they should be manipulated only under fluoroscopy. Radiographic equipment that provides high quality images is needed.
3. The delivery system is not designed for the use of power injection. Use of power injection may adversely affect device performance.
4. If resistance is met during delivery system introduction, the system should be withdrawn and another system used.
5. Prior to stent deployment, remove all slack from the catheter delivery system (see **Section 10.4**, #4 of these instructions).
6. Adequate distance must be maintained from the distal tip of the transcarotid access sheath and the proximal edge of the stent to avoid stent delivery within the lumen of the sheath.
7. 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.
8. 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.

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

7.3 Post Stent Placement Precautions

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

VIII. Adverse Events

8.1 Potential Adverse Events

Adverse Events (in alphabetical order) that may be associated with the use of the **PRECISE® PRO Transcarotid Stent System** 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 dissection
- 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
- congestive Heart Failure
- damage to emboli capture device
- death
- embolization, arterial
- embolization, stent
- emergent repeat hospital intervention
- fever
- gastrointestinal disorders
- GI bleeding from anticoagulation/antiplatelet medication
- hallucination
- hematoma bleed, access site
- hematoma bleed, remote site
- hemorrhage
- hyperperfusion syndrome
- hypomagnesaemia
- hypophosphatemia
- 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
- nausea
- oxygen saturation decrease
- pain
- pseudoaneurysm
- rales
- renal failure
- respiratory infection
- restenosis of the vessel (> 50% obstruction)
- rhinorrhea
- seizure
- severe unilateral headache
- stent migration
- stent thrombosis
- stroke
- transient ischemic attack
- transient intolerance to reverse flow
- urinary tract infection
- vasospasm
- venous occlusion/thrombosis, at puncture site
- venous occlusion/thrombosis, remote from puncture site
- vessel rupture, dissection, perforation
- vomiting
- wheezing

8.2 Device Related Adverse Event Reporting

Any adverse event (clinical incident) involving the **PRECISE® PRO Transcarotid Stent System** should be reported to Cordis US Corp. immediately. To report an incident, call the Product Quality Services Department at 1-800-327-7714.

The **PRECISE® PRO Transcarotid Stent System** platform is based on the FDA approved Cordis PRECISE Nitinol Stent System. The two systems are identical with the exception of the shaft working length. The overall working length of the **PRECISE® PRO Transcarotid Stent System** is 57cm versus 135cm for the PRECISE Nitinol Stent System.

The **PRECISE® PRO Transcarotid Stent System** is also identical to the FDA approved ENROUTE Transcarotid Stent System (by Boston Scientific) including the working length of the delivery system. The ENROUTE Transcarotid Stent System is a stenting platform based upon the FDA-approved Cordis PRECISE Nitinol Stent System (PRECISE). The ENROUTE Transcarotid Stent System is identical to the PRECISE Stent System with the exception of the working length of the delivery system. The ENROUTE Transcarotid Stent System has a working length of 57 cm whereas the PRECISE Stent System has a working length of 135 cm.

Refer to the ENROUTE Transcarotid Stent System Instructions For Use for adverse event information.

IX. Clinical Study Information

The PRECISE® PRO Transcarotid Stent System has not been the subject of a new clinical study. Cordis US Corp. relied on using the “six-year rule” to leverage the clinical data supporting the previous PMA application (P140026 – approved May 18, 2015) for the Boston Scientific ENROUTE Transcarotid Stent System, which is a modified version of the Cordis PRECISE Pro Rx device. P140026 was supported by leveraged data from the preceding approval of the Cordis PRECISE Nitinol Stent system (P030047 – approved September 22, 2006) and data from the ROADSTER study. A brief overview of the ROADSTER study follows. Additional details regarding the data supporting the above marketing applications can be found in their respective labels and Summaries of Safety and Effectiveness Data (SSEDs).

As described in the SSED for P140026, the ROADSTER clinical study was conducted by Boston Scientific to evaluate the safety and effectiveness of the PRECISE Stent System when used with the ENROUTE Transcarotid NPS. The PRECISE Stent System was used as a surrogate for the ENROUTE Transcarotid Stent System as the two systems differ only in the working length. Refer to the ENROUTE Transcarotid Stent System Instructions For Use for the complete clinical study data.

A. Study Design

The ROADSTER study was a prospective, single-arm, multi-center clinical trial of the ENROUTE Transcarotid NPS used in conjunction with all FDA-approved carotid artery stents used for revascularization in patients with carotid disease who are at high risk for complications from carotid endarterectomy (CEA). A sub-study of those subjects, those treated with a combination of the ENROUTE Transcarotid NPS and the Cordis PRECISE stent, was conducted to establish a reasonable assurance of safety and effectiveness of the ENROUTE Transcarotid Stent System. In the ROADSTER study, the PRECISE stent system was used as a surrogate for the ENROUTE Transcarotid Stent System as the only difference between the devices was the length of the delivery system with all other components being the same. Data from this clinical sub-study were the basis for the PMA approval decision for P140026.

The ROADSTER enrolled patients between November 2012 and July 2014. Eighteen (18) lead-in and 34 pivotal subjects at high risk for complications from CEA were treated with the PRECISE Stent at eight (8) sites in the United States and were included in the sub-study cohort.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the ROADSTER study was limited to patients who met the following inclusion criteria:

1. Patient must meet one of the following criteria regarding neurological symptom status and degree of stenosis:
Symptomatic: Stenosis must be >50% as determined by angiogram and the patient has a history of stroke (minor or non-disabling), TIA and/or amaurosis fugax within 180 days of the procedure.
OR

Asymptomatic: Stenosis must be >70% as determined by angiogram without any neurological symptoms within the prior 180 days.

2. Target vessel must meet diameter requirements for stent (refer to selected stent IFU for diameter requirements).
3. Patient has a discrete lesion located in the internal carotid artery (ICA) with or without involvement of the contiguous common carotid artery (CCA).
4. Patient is >18 years of age.
5. Patient has no childbearing potential or has a negative pregnancy test within one week prior to the study procedure.
6. Patient understands the nature of the procedure and has provided a signed informed consent using a form that has been reviewed and approved by the Investigational Review Board/Ethics Committee of the respective clinical site prior to the procedure. This will be obtained prior to participation in the study.
7. Patient is willing to comply with the protocol requirements and return to the treatment center for all required clinical evaluations.
8. Patient meets at least one of the surgical high-risk criteria listed below.

Anatomic High Risk Inclusion Criteria:

- A. Contralateral carotid artery occlusion
- B. Tandem stenoses >70%
- C. High cervical carotid artery stenosis
- D. Restenosis after carotid endarterectomy
- E. Bilateral carotid artery stenosis requiring treatment (Treatment of the contralateral vessel must be scheduled at least 30 days post index procedure).
- F. Hostile Necks which the Investigator deems safe for transcervical access including but not limited to:
 - Prior neck irradiation
 - Radical neck dissection
 - Cervical spine immobility

Clinical High Risk Inclusion Criteria:

- G. Patient is ≥ 75 years of age
- H. Patient has > 2-vessel coronary artery disease and history of angina of any severity
- I. Patient has a history of angina
 - Canadian Cardiovascular Society (CCS) angina class 3 or 4
 - Or
 - unstable angina
- J. Patient has congestive heart failure (CHF) - New York Heart Association (NYHA)
 - Functional Class III or IV
- K. Patient has known severe left ventricular dysfunction
 - LVEF <30%.
- L. Patient has had a myocardial infarction > 72 hours and < 6 weeks prior to procedure.
- M. Patient has severe pulmonary disease (COPD) with either:
 - FEV1 <50% predicted or
 - chronic oxygen therapy or

- resting PO₂ of ≤60 mmHg (room air)
- N. Patient has permanent contralateral cranial nerve injury
- O. Patient has chronic renal insufficiency (serum creatinine > 2.5 mg/dL).

Patients were not permitted to enroll in the ROADSTER study if they met any of the following exclusion criteria:

1. Patient has chronic atrial fibrillation.
2. Patient has had any episode of paroxysmal atrial fibrillation within the past 6 months, or history of paroxysmal atrial fibrillation requiring chronic anticoagulation.
3. Patient has an evolving stroke.
4. Patient has severe dementia.
5. Patient has a history of spontaneous intracranial hemorrhage within the past 12 months.
6. Patient has had a recent (<7 days) stroke of sufficient size (on CT or MRI) to place him or her at risk of hemorrhagic conversion during the procedure.
7. Patient had hemorrhagic transformation of an ischemic stroke within the past 60 days.
8. Patient has active bleeding diathesis or coagulopathy or will refuse blood transfusion.
9. Patient had or will have CABG, endovascular stent procedure, valve intervention or vascular surgery within 30 days before or after the intervention.
10. Patient has had a recent GI bleed that would interfere with antiplatelet therapy.
11. Life expectancy of < 12 months post procedure.
12. Patient has history of intolerance or allergic reaction to any of the study medications or stent materials (refer to stent IFU), including aspirin (ASA), ticlopidine, clopidogrel, prasugrel, statin or contrast media (that can't be pre medicated). Patients must be able to tolerate statins and a combination of ASA and ticlopidine, ASA and clopidogrel or ASA and prasugrel.
13. Myocardial Infarction within 72 hours prior to the intervention.
14. Presence of a previous placed intravascular stent in target vessel or the planned arteriotomy site.
15. Patient has had neurologic illnesses within the past two years characterized by fleeting or fixed neurologic deficit which cannot be distinguished from TIA or stroke (e.g. partial or secondarily generalized seizures, complicated or classic migraine, tumor or other space-occupying brain lesions, subdural hematoma, cerebral contusion or other post-traumatic lesions, intracranial infection, demyelinating disease, moderate to severe dementia, or intracranial hemorrhage).
16. Patient with a history of major stroke (CVA or retinal embolus) with major neurological deficit likely to confound study endpoints within 1 month of index procedure.
17. Patient has Hgb <10 g/dl, platelet count <125,000/μl, uncorrected INR >1.5, bleeding time >1 minute beyond upper limit normal, or heparin-associated thrombocytopenia.
18. Patient has an intracranial tumor.
19. Patient is actively participating in another drug or device trial (IND or IDE) that has not completed the required protocol follow-up period.
20. Patient has inability to understand and cooperate with study procedures or provide informed consent.
21. Occlusion or [Thrombolysis In Myocardial Infarction Trial (TIMI 0)] "string sign" >1cm of the ipsilateral common or internal carotid artery.

22. Patient has vertebrobasilar insufficiency symptoms only, without clearly identifiable symptoms referable to the study carotid artery.
23. Knowledge of cardiac sources of emboli e.g. left ventricular aneurysm, intracardiac filling defect, cardiomyopathy, aortic or mitral prosthetic heart valve, calcific aortic stenosis, endocarditis, mitral stenosis, atrial septal defect, atrial septal aneurysm, or left atrial myxoma).
24. Recently (<60 days) implanted heart valve (either surgically or endovascularly), which is a known source of emboli as confirmed on echocardiogram.
25. Ostium of Common Carotid Artery (CCA) requires revascularization.
26. Presence of extensive or diffuse atherosclerotic disease involving the proximal common carotid artery that would preclude the safe introduction of the study device.
27. The patient has less than 5cm between the clavicle and bifurcation, as assessed by duplex Doppler ultrasound.
28. Bilateral carotid stenosis if intervention is planned within 37 days of the index procedure.
29. An intraluminal filling defect (defined as an endoluminal lucency surrounded by contrast, seen in multiple angiographic projections, in the absence of angiographic evidence of calcification) that is not associated with an ulcerated target lesion.
30. Abnormal angiographic findings: ipsilateral intracranial or extracranial arterial stenosis greater in severity than the lesion to be treated, cerebral aneurysm > 5 mm, AVM (arteriovenous malformation) of the cerebral vasculature, or other abnormal angiographic findings.
31. Patient has had a previous intervention in the ipsilateral proximal CCA.
32. Patient has had a TIA or amaurosis fugax within 48 hours prior to the procedure.
33. Patient has contralateral lateral recurrent, laryngeal or vagus nerve injury.
34. Patient is otherwise unsuitable for intervention in the opinion of the investigator.

2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at 30 days (+7 days) postoperatively. In addition, patients suspected of having a stroke were followed at 3 months (± 14 days) and patients suspected of having a cranial nerve injury were followed at 6 months (± 30 days).

Table 2 below list all pre-procedure and post-procedure evaluations performed in relation to the index procedure.

Table 2: ROADSTER Study - Schedule of Events

PROCEDURE/TEST	Pre-Procedure (within # of days)				Procedure	Post-Procedure					Follow-up Visits		
	60 days	30 days	7 days	24 hrs		6- 9 hrs	12- 16 hrs	20- 24 hrs	Within 24 hrs	Prior to Discharge	30- days (+7 days)	3- month (±14 days)	6- month (±30 days)
Patient Informed Consent	X	X	X	X									
Neurological Examinations¹													
NIH Stroke Scale Barthel ADL Index Modified Rankin Scale Cranial Nerve Injury Evaluation			X						X		X	X ²	X ³
Lab Assessments													
RBC, Hemoglobin, Hematocrit, Platelet count, Creatinine		X								X			
WBC, Fasting Glucose, PT, PTT (must include INR), Pregnancy test ⁴		X											
CK, CKMB, Troponin				X		X	X	X					
Imaging													
Carotid Angiogram ⁵					X								
Duplex Ultrasound ⁶	X									X ⁷	X		
CT Angiogram / Angiogram (optional)	X												
Other Assessments													
Medical History		X											
Physical Examination		X								X			
12 lead ECG ⁸				X						X	X		
Medications	X	X	X	X	X	X	X	X	X	X	X		
Adverse events					X	X	X	X	X	X	X		

- ¹ Must be performed by a Neurologist or NIHSS-certified personnel
- ² 3-month visit is only required for patients suspected of having a stroke
- ³ 6-month visit is only required for patients suspected of having a cranial nerve palsy
- ⁴ For women of childbearing potential only
- ⁵ Must be labeled and submitted to the Angiographic Core Laboratory
- ⁶ Must be labeled and submitted to the Ultrasound Core Laboratory
- ⁷ Submitted to Sponsor
- ⁸ Must be labeled and submitted to ECG Core Laboratory

The key timepoints are shown below in the tables summarizing safety and effectiveness.

3. Clinical Endpoints

The safety and effectiveness of the Cordis PRECISE stent was established through a randomized clinical trial, Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE), supporting PMA approval for that device (P030047) and further supported through large, multi-center, post-market registries. Therefore, the ROADSTER sub-study was intended to evaluate the safety and effectiveness of transcatheter delivery of the PRECISE stent that was then extrapolated to the ENROUTE Transcatheter Stent System because it differed only in the length of the delivery system.

With regards to safety, the primary endpoint for the ROADSTER sub-study was major adverse events (defined as a composite of any stroke, myocardial infarction and death) during a 30-day post-procedural period. Additional information related to adverse events and access site complications were also collected.

With regards to effectiveness, the primary effectiveness outcomes for the ROADSTER sub-study were acute device success, technical success, and procedural success. Acute device success was defined as the ability to insert the NPS device, establish flow reversal, and remove the device. Technical success was defined as acute device success plus the ability to deliver interventional tools. Procedural success was defined as technical success in the absence of a Major Adverse Event (MAE defined as death, stroke, or MI).

B. Accountability of PMA Cohort

At the time of database lock, of 52 patients enrolled in the ROADSTER sub-study, 100% (52) patients were available for analysis at the completion of the study. All subjects in the sub study population (those treated with a PRECISE Stent) completed their 30-day follow-up visit. When applicable, all subjects in the sub-study experiencing a stroke during the 30-day follow-up period (1/52) returned for the 90-day follow-up visit. No patients in the sub-study were suspected of experiencing a cranial nerve injury requiring 6-month follow-up.

Table 3: Roadster Sub-study - Patient Follow-up and Accountability

30-Day Follow-Up		90-Day Follow-Up ¹		6-Month Follow-Up ²	
N	%	N	%	N	%
52/52	100%	1/1	100%	N/A	N/A

¹ For only those subjects suspected of having a stroke.

² For only those patients suspected of having a Cranial Nerve Injury (CNI)

C. Study Population Demographics and Baseline Parameters

The demographics of the sub-study population are typical for a high surgical risk carotid artery stenting study performed in the US. Please see **Table 4** and **Table 5** below for additional details.

Table 4: Roadster Sub-study – Patient Demographics

Observation	All PRECISE Stent Patients in ROADSTER (N=52)
Age (Years)	73.0 ± 9.07
Symptomatic	23.1%
Male	57.7%
Diabetes	34.6%
Hypertension	94.2%
History of Peripheral Artery Disease	34.6%
History of Coronary Artery Disease	48.1%
History of Angina	19.2%
Congestive Heart Failure	11.5%
Recent MI	1.9%
Severe Pulmonary Disease	9.6%
Dyslipidemia	88.5%
History of Stroke	15.4%
History of TIA	21.2%
History of Amaurosis Fugax	13.5%
Current Nicotine Use	25.0%
Age >75 Years	51.9%
Age >80 Years	23.1%
Contralateral Carotid Occlusion	9.6%
High Cervical Carotid Stenosis	15.4%
Restenosis after CEA	28.8%
Bilateral Stenosis Requiring Treatment	32.7%
Hostile Neck	15.4%
>2 Vessel Coronary Disease	7.7%
Chronic Renal Insufficiency	1.9%

Table 5: Roadster Sub-study - Summary of Baseline Vessel and Lesion Characteristics

Observation	All PRECISE Stent Subjects (N=52)
Target Lesion Location	
Left	27 (51.9%)
Right	25 (48.1%)
Vessel to be Treated	
ICA	37 (71.2%)
ICA + CCA	15 (28.8%)

Observation	All PRECISE Stent Subjects (N=52)
Distance between clavicle and bifurcation (cm)	
N	52
Mean	6.6
Standard Deviation	1.21
Median	6.5
Minimum, Maximum	5, 10
95% Confidence Interval	(6.3, 6.9)
Target Vessel Calcification	
Normal	26 (50.0%)
Mild	17 (32.7%)
Moderate	6 (11.5%)
Severe	1 (1.9%)
Unknown / NA	2 (3.8%)
Target Vessel Tortuosity	
Normal	10 (19.2%)
Mild	26 (50.0%)
Moderate	10 (19.2%)
Severe	2 (3.8%)
Unknown / NA	4 (7.7%)
Pre-Procedure Vessel Diameter (mm)	
N	52
Mean	6.7
Standard Deviation	1.78
Median	6.8
Minimum, Maximum	4, 11
95% Confidence Interval	(6.2, 7.2)
Target Lesion Length (mm)	
N	52
Mean	18.7
Standard Deviation	8.05
Median	17.6
Minimum, Maximum	5, 39
95% Confidence Interval	(16.4, 20.9)
Pre-Procedure Percent Stenosis (%)	
N	52
Mean	86.1
Standard Deviation	9.01
Median	90.0
Minimum, Maximum	60, 99
95% Confidence Interval	(83.6, 88.6)

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on the sub-study cohort of 52 patients receiving the PRECISE Stent available for the 30-day evaluation. The key outcomes for this study are presented below in **Table 6**. Adverse effects are reported in Tables 7 and 8. No formal statistical analysis was planned or conducted; therefore, only descriptive outcomes are presented.

Table 6: Roadster Sub-study – Primary and Secondary Endpoints

Observations (at 30 days)	All PRECISE Stent Patients in ROADSTER (N=52)
PRIMARY ENDPOINTS	
Safety:	
30 Day MAE (Stroke, Death, or MI)	1 (1.9%)
Effectiveness:	
Acute Device Success	52 (100%)
Technical Success	52 (100%)
Procedural Success	51 (98.1%)
SECONDARY ENDPOINTS	
All Death (non-hierarchical)	0 (0.0%)
All Stroke (non-hierarchical)	1 (1.9%)
All Myocardial Infarction (non-hierarchical)	0 (0.0%)
All Cardiac Death (non-hierarchical)	0 (0.0%)
Ipsilateral Stroke (non-hierarchical)	1 (1.9%)
Access Site Complications	
Oozing	0 (0.0%)
Limited Surgical Wound Hematoma	0 (0.0%)
Surgical Wound Hematoma	0 (0.0%)
Arterial Access Site Hematoma	0 (0.0%)
Femoral Vein Access Site Hematoma	0 (0.0%)
Re-bleeding	1 (1.9%)
Contrast Usage (cc)	
N	47
Mean	66.1
Standard Deviation	42.14
Median	55.0
Minimum, Maximum	12, 220

Adverse effects that occurred in the PMA clinical study:

Table 7 below summarizes all adverse events reported for the sub-study population. This table includes all adverse events including those deemed to be Serious Adverse Events by the protocol definition. Twenty-one (21) subjects experienced one or more adverse events (40.4%). A separate tabulation of Serious Adverse Events follows in **Table 8**.

Table 7: Summary of All Adverse Events (Sub-study Subjects)

System Organ Class Preferred Term	All PRECISE Stent Subjects (N=52)
Number (%) of Subjects with one or more Adverse Events	21 (40.4%)
Blood And Lymphatic System Disorders	2 (3.8%)
Anaemia	2 (3.8%)
Cardiac Disorders	1 (1.9%)
Atrial Fibrillation	1 (1.9%)
Cardiac Failure Congestive	1 (1.9%)
Gastrointestinal Disorders	6 (11.5%)
Nausea	5 (9.6%)
Vomiting	3 (5.8%)
General Disorders And Administration Site Conditions	5 (9.6%)
Pain	5 (9.6%)
Infections And Infestations	3 (5.8%)
Adenoviral Upper Respiratory Infection	1 (1.9%)
Infection	1 (1.9%)
Urinary Tract Infection	1 (1.9%)
Injury, Poisoning And Procedural Complications	1 (1.9%)
Post Procedural Haemorrhage	1 (1.9%) ¹
Investigations	3 (5.8%)
Blood Creatine Phosphokinase Increased	1 (1.9%)
Oxygen Saturation Decreased	1 (1.9%)
Troponin Increased	1 (1.9%)
Metabolism And Nutrition Disorders	1 (1.9%)
Hypomagnesaemia	1 (1.9%)
Hypophosphataemia	1 (1.9%)
Nervous System Disorders	4 (7.7%)
Cerebrovascular Accident	1 (1.9%) ²
Headache	3 (5.8%)
Psychiatric Disorders	1 (1.9%)
Hallucination, Visual	1 (1.9%)
Respiratory, Thoracic And Mediastinal Disorders	3 (5.8%)
Atelectasis	1 (1.9%)
Rales	1 (1.9%)
Rhinorrhoea	1 (1.9%)
Wheezing	1 (1.9%)
Vascular Disorders	8 (15.4%)
Artery Dissection	1 (1.9%) ³
Hypotension	6 (11.5%)
Orthostatic Hypotension	1 (1.9%)

¹ One subject was noted to have post-operative bleeding from the incision site. The subject received two (2) units of blood post-operatively.

This event is also tabulated as an access site complication.

² One subject had a minor ipsilateral stroke during the 30-day follow-up period.

³ An arterial dissection was noted for Subject 324-502 following Transcarotid Arterial Sheath placement. A 0.014" wire was used to traverse the dissection in the true lumen. A PRECISE Stent was placed to treat the index lesion and a second PRECISE Stent was placed to tack down the dissection flap. There was no clinical sequelae related to the dissection or placement of a second stent (confirmed by ultrasound).

Table 8: Roadster Sub-study – Summary of all Serious Adverse Events

System Organ Class Preferred Term	All PRECISE Stent Subjects in ROADSTER (N=52)
Number (%) of Subjects with one or more Serious Adverse Events	7 (13.5%)
Blood And Lymphatic System Disorders	1 (1.9%)
Anemia	1 (1.9%)
Cardiac Disorders	1 (1.9%)
Cardiac Failure Congestive	1 (1.9%)
Injury, Poisoning And Procedural Complications	1 (1.9%)
Post Procedural Hemorrhage	1 (1.9%)
Nervous System Disorders	1 (1.9%)
Cerebrovascular Accident	1 (1.9%)
Respiratory, Thoracic And Mediastinal Disorders	1 (1.9%)
Atelectasis	1 (1.9%)
Vascular Disorders	2 (3.8%)
Artery Dissection	1 (1.9%)
Hypotension	1 (1.9%)

It should be noted that the safety of the device for transcarotid delivery was not based on this sample alone, but rather on all the data available for the device to date, including data from the PRECISE stent.

2. Effectiveness Results

The analysis of effectiveness was based on the 52 evaluable subjects at the 30-day time point. Effectiveness outcomes are presented **Table 9**.

Table 9: Roadster Sub-study - Acute Device, Technical and Procedural Success

Observations	All PRECISE Stent Subjects (N=52)
Acute Device Success	52 (100%)
Technical Success	52 (100%)
Procedural Success	51 (98.1%)

E. Supplementary Clinical Information

As described in Section XI of the P140026 SSED, the Boston Scientific Embolic Protection System: First In Man Study (PROOF) was a prospective, single arm first-in-man study that collected procedural data from 75 patients in Germany using an early design of their ENROUTE Transcarotid NPS. A subset of patients in the PROOF study (n=13) were treated with a combination of PRECISE stent system and the ENROUTE Transcarotid NPS, which served as supplementary clinical information that supported the P140026 approval.

The primary endpoint was a composite of any major stroke, myocardial infarction, and death during the 30-day post-procedural period. The three secondary endpoints included:

- Acute Device Success, defined as “the ability to establish a reverse flow circuit as demonstrated by blood flow (arterial to vein) through the shunt circuit before and after stent implantation”,
- Procedural Success, defined as “the ability to deliver therapeutic devices (balloons, stents, etc.) through the arterial sheath and the ability to provide embolic protection throughout the procedure with the freedom from device related Major Adverse Events (major stroke, myocardial infarction, or death) at 30 days, and
- Tolerance To Reverse Flow, where intolerance to reverse flow was defined as “the inability to complete the procedure with the reverse flow circuit in either the high flow or low flow setting” due to intolerance by the patient.

Tables 10-12 below summarize the outcomes from the PROOF sub-study of patients where a combination of the earlier generation ENROUTE Transcarotid NPS and PRECISE stent were used.

Table 10: PROOF Sub-study – Patient Demographics and Baseline Parameters

Parameters and Statistics	PROOF population with PRECISE Stent (N=13)
Male Gender	7 (53.8%)
Caucasian Race	13 (100.0%)
Symptomatic Neurological Status	3
Median Height in cm	170
Median Age in years	67.16
Median weight in kg	86

Table 11: PROOF Sub-study – Results

Parameters and Statistics	PROOF population with PRECISE Stent (N=13)
Number of Patients who experienced an MAE	0 (0%)
Number of Patients who died within 30 days of the Index Procedure	0 (0%)
Number of Patients who had a major stroke within 30 days of the Index Procedure	0 (0%)
Number of Patients who had an MI within 30 days of the Index Procedure	0 (0%)
Acute Device Success	13 (100.0%)
Procedural Success	13 (100.0%)
Tolerance to Reverse Flow	13 (100.0%)

Table 12: PROOF Sub-study – Observed Adverse Events

System Organ Class and Severity	PROOF population with PRECISE Stent (N=13)
Number (%) of Subjects $\geq$ 1 Treatment Emergent Adverse Events	13
Cardiac Disorders	2 (15.4)
Gastrointestinal Disorders	2 (15.4)
General Disorders and Administration Site Conditions	1 (7.7)
Infections and Infestations	1 (7.7)
Investigations	2 (15.4)
Nervous System Disorders	7 (53.8)
Respiratory, Thoracic, and Mediastinal Disorders	1 (7.7)
Skin and Subcutaneous Tissue Disorders	2 (15.4)
Surgical and Medical Procedures	1 (7.7)
Vascular Disorders	7 (53.8)

X. 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.

10.1 Peri-Procedural Care

Patients may be started on aspirin 75-325 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.

Pre procedure medication note: A 650 mg loading dose of aspirin, provided that it is not enteric coated or extended release, at least 4 hours prior to procedure is acceptable if 325 mg dosing was not administered prior to procedure or per the Institution's standard of care.

Post procedure medication note: Aspirin dosage may be adjusted at the discretion of the Investigator and/or if warranted by the patient's medical condition, i.e., documented intolerance, GI bleed, etc. All change in medications are to be documented on the Concomitant Medication CRF.

Oral anti-platelet agent, such as clopidogrel (75 mg q.d.), given 72 hours prior to the procedure and continued after the procedure for a minimum of four weeks.

Pre procedure medication note: A 450 mg clopidogrel loading dose at least 4 hours prior to procedure is acceptable if 75 mg dosing was not administered prior to procedure. The physician may substitute prasugrel, ticlopidine, or a generic version of clopidogrel per the manufacturer's published guidelines. If ticlopidine is prescribed, it must be administered with the appropriate safety monitoring at two weeks and at one month.

Post procedure medication note: Clopidogrel dosing may extend at physician's discretion. The physician may substitute prasugrel, ticlopidine, or a generic version of clopidogrel per the manufacturer's published guidelines.

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

*As stated in the "2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS guideline on the management of patients with extracranial carotid and vertebral artery disease: executive summary." and "ESVS Guidelines. Invasive Treatment for Carotid Stenosis: Indications, Techniques."

10.2 Pre-procedure

Refer to **Section 10.1** of these instructions for the suggested pre-procedure pharmacological treatment regimen. The 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.

10.3 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 13**).

Table 13		
Stent Size Selection Table		
Vessel Lumen Diameter	Unconstrained Stent Diameter	% Length Foreshortening*
3.0-4.0	5.0mm	1.2%
4.0-5.0	6.0mm	2.4%
5.0-6.0	7.0mm	4.1%
6.0-7.0	8.0mm	6.2%
7.0-8.0	9.0mm	5.8%
8.0-9.0	10.0mm	8.0%
* Mathematical calculation.		

2. Preparation of Stent Delivery System

CAUTION: The **PRECISE® PRO Transcarotid 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 **PRECISE® PRO Transcarotid Stent System** prior to the “Use By” date specified on the package. Do not use if the pouch is opened or damaged.

CAUTION: The **PRECISE® PRO Transcarotid Stent System** is shipped with the Tuohy Borst valve OPEN. Be careful not to prematurely deploy the stent during preparation. The system should be prepped in the sterile tray per the instructions below. Close the Tuohy Borst valve 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. Without removing the device from the tray, examine the device for any damage. If it is suspected that the sterility or performance of the device has been compromised, the device should not be used.
- d. With the device in the tray, attach a stopcock to the Y connection on the Tuohy Borst valve.
- e. With the device still in the tray, attach a 5-cc syringe filled with heparinized saline to the opened stopcock and apply positive pressure until heparinized 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.

10.4 Stent Deployment Procedure

WARNING: Ensure that the catheter system is flushed according to the steps outlined in "Introduction of Stent Delivery System". Failure to do so could result in air entering the sheath introducer.

WARNING: Ensure that there is a tight seal between the **PRECISE PRO** catheter and the valve for the sheath introducer during aspiration. Failure to do so could result in air entering the accessory device.

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

† Ethiodol and Lipiodol are Trademarks of Gerbert S.A.

WARNING: Do not expose the delivery system to organic solvents (e.g. 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 ENROUTE Transcarotid Neuroprotection System

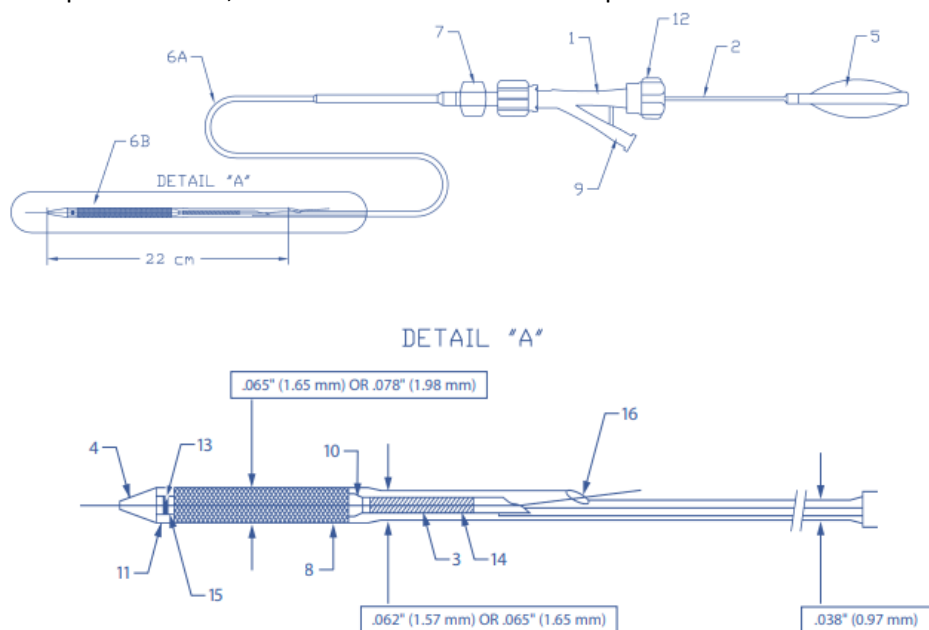
- Access the treatment site utilizing the ENROUTE Transcarotid NPS in accordance with the Instructions for Use.
- The **PRECISE® PRO Transcarotid Stent System** is compatible with a .014" (0.36 mm) or smaller guidewire.

2. Dilation of Lesion

- If appropriate, pre-dilate the lesion using standard PTA techniques.
- Remove the PTA balloon catheter from the patient maintaining lesion access with the guidewire.

3. Introduction of Stent Delivery System

Refer to device depiction below, which includes the device components referenced in this section.



- 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 proximal end valve (12) 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 the Tuohy Borst valve (1) connecting the inner shaft and outer sheath is locked by rotating the proximal valve end (12) in a clockwise direction to prevent premature stent deployment.
- c. Advance the **PRECISE® PRO Transcarotid Stent System** over the .014" (0.36 mm) guidewire until the guidewire exit port (16) is just outside the accessory device's valve. Look for and confirm back flow through the guidewire exit port (16) opening.
- d. After confirming back flow, advance the **PRECISE PRO** System to the lesion site.
- e. Perform contrast injections in accordance to ENROUTE Transcarotid NPS Instructions for Use.

CAUTION: If resistance is met during delivery system introduction, the system should be withdrawn and another system should be used, while the ENROUTE Transcarotid NPS 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 stent delivery system 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 ENROUTE Transcarotid NPS. 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 250 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. Verify that the delivery system's radiopaque inner shaft marker (trailing end) is distal to the radiopaque marker at the tip of the Sheath introducer.
- c. Unlock the Tuohy Borst proximal valve end connecting the inner shaft and outer sheath of the delivery system.
- d. Ensure that the Sheath introducer does not move during deployment.
- e. 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

WARNING: Long-term outcomes following repeat dilatation of endothelialized stents are unknown.

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 dilatation catheter and dilate the lesion with conventional technique. The inflation diameter of the PTA balloon dilatation catheter 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 ENROUTE Transcarotid NPS in accordance with that device's Instructions for Use.
- c. After use, all components used and packaging materials may be a potential biohazard. Handle and dispose of in accordance with the accepted medical practice and with applicable local, state and federal laws and regulations.
- d. Follow the suggested post-procedure pharmacological treatment regimen described in **Section 10.1** 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.

XI. Magnetic Resonance Imaging (MRI) Safety Information



A patient with the **PRECISE** 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 PRECISE Stents
Nominal values of static magnetic field (T)	1.5 T and 3.0 T
Maximum spatial field gradient (T/m) and (Gauss/cm)	40 T/m (4000 Gauss/cm)
Radio Frequency (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 Specific Absorption Rate (SAR) (W/kg)	2.0 W/kg
Limits on scan duration	15 minutes of continuous RF (a sequence or back to back series/ scan without breaks) followed by a wait time of 10 minutes if this limit is reached
Magnetic Resonance (MR) image artifact	The presence of this implant produced an image artifact of approximately 16 mm when imaged with a gradient echo pulse sequence and a 3.0 T MRI system
Non-Clinical testing has demonstrated that the PRECISE Stent is MR Conditional in single and overlapped configuration up to a maximum of 60 mm as defined in ASTM F2503-13.	
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

XII. Patient Information

In addition to these Instructions for Use, the **PRECISE® PRO Transcarotid Stent System** is packaged with a Stent Implant Card for the patient that contains specific information about the **PRECISE® PRO Transcarotid 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 **PRECISE® PRO Transcarotid Stent System** is available from Cordis and can be obtained by accessing www.cordis.com or by contacting Cordis at 1-800-327-7714.

XIII. How Supplied

The Cordis **PRECISE® PRO Transcarotid 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.

XIV. DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

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