Cordis®
A Cardinal Health company

Cordis **Carotid Systems**

Conformability like no other.

Design matters.

PRECISE PRO RX® Nitinol Stent System
and **ANGIOGUARD® RX** Emboli Capture
Guidewire System

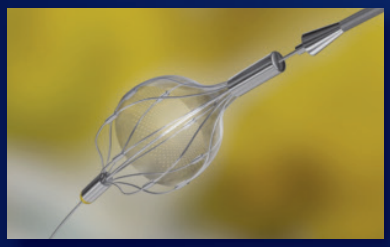
The Cordis **Carotid Artery Stent System**

The Cordis **Carotid Artery Stent System** offers a unique design ideally suited to the challenges of Carotid Artery Stenting.*

Cordis **PRECISE PRO RX®** Stent

A unique design for enhanced contourability, increased longitudinal stability and uniform scaffolding.

- 36 struts / 6 alternating bridges
- 1 mm flare at stent end
- Offset peak-to-valley design



Cordis **ANGIOGUARD® RX** Guidewire System

The short landing zone and small pore size work in unique combination with the PRECISE PRO RX® Stent to offer greater control and ease of use.

Learn what sets the Cordis **Carotid Systems** apart from the rest.
Contact Customer Services at 800.327.7714.

For information on indications, contraindications, warnings, precautions, and adverse events, see *Essential Prescribing Information* in back pocket.

** The safety and effectiveness of the ANGIOGUARD® RX Guidewire System has not been established for patients with known tortuousity precluding the use of catheter-based techniques.*

Precision design. **Proven outcomes.**

Carotid Artery Stenting

A procedure like no other requires a solution like no other.

The art of stenting complex carotid vessels requires a skill like no other. It also requires products specifically designed for this tortuous region.[1] Rigid stents may cause kinking and unnatural wall apposition, potentially posing an increased risk of complications.[2]

Choose the stent that conforms to the supra-aortic anatomy and preserves the angulation between the Common Carotid Artery (CCA), the Internal Carotid Artery (ICA).

The Cordis **PRECISE PRO RX®** Stent, with its multi-segmented, auto-tapering design, offers the best combination of conformability and wall apposition.

The PRECISE PRO RX® Stent, coupled with the short landing zone of the ANGIOGUARD® RX Guidewire System, creates a combination that's suitable for virtually any CAS procedure.

Cordis CAS... a sound choice

The Challenge of CAS

- Complex carotid anatomy
- Abrupt changes in vessel diameter
- Severe angulations
- Arch type degree variances
- Bifurcation challenges

Why Cordis CAS?

- Ideal for challenging arterial landscapes
- Durable outcomes
- Improved autotapering
- Easier centering

[1] Safety and effectiveness have not been established for patients with known tortuosity precluding the use of catheter-based techniques.

[2] *Conformity of Carotid Stents with Vascular Anatomy: Evaluation in Carotid Models,* AJNR Am J Neuroradiol 25:604-607, April 2004

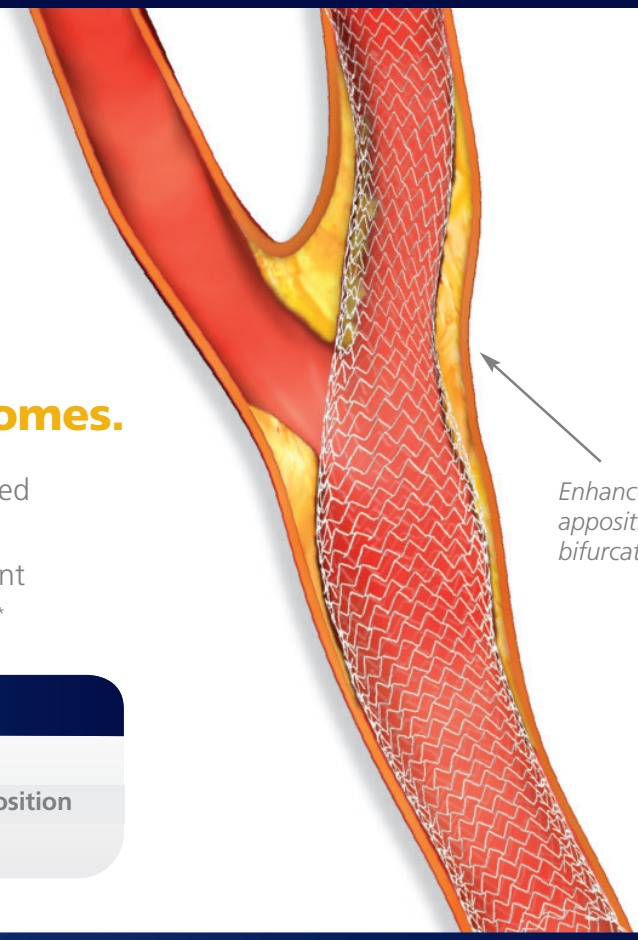
A better way to manage **tortuous anatomy.**

PRECISE PRO RX®
Stent

Simplicity of use, precision placement, and proven outcomes.

With its unique peak-to-valley design and segmented micromesh geometry, the PRECISE PRO RX® Stent provides simplicity of use, autotapering and excellent flexibility through tortuous anatomical challenges.[3*]

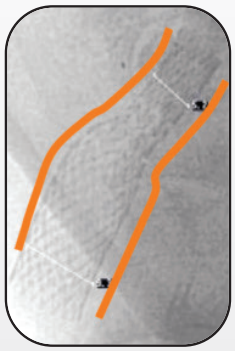
Feature	Benefit
Multi-segment design	Auto-tapering
Micromesh geometry	Enhanced wall apposition
Peak-to-Valley design	Conformability



Enhanced wall apposition in bifurcation

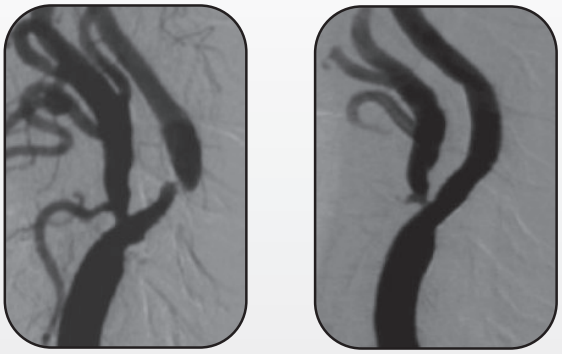
Unique **autotapering design** enhances conformability in bifurcation

Autotapering design follows the vessel wall for enhanced conformability and wall apposition in the bifurcation, preserving complex angulations, and maintaining original wall anatomy.[‡]



2mm segments act as individual stents

Excellent wall apposition



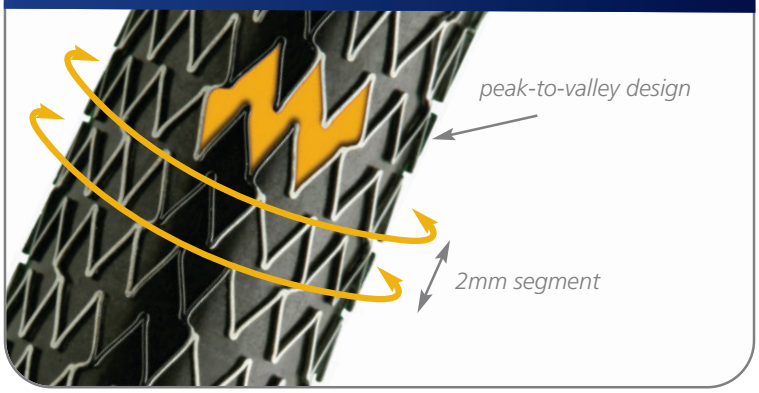
Before and after use of PRECISE PRO RX® Stent, showing enhanced conformity to original anatomy.

‡ *Stents in Bifurcation Aid Test Report,* March 4, 2007.

[3] *Conformity of Carotid Stents with Vascular Anatomy: Evaluation in Carotid Models,* AJNR Am J Neuroradiol 25:604-607, April 2004

* The safety and effectiveness of the ANGIOGUARD® RX Guidewire System has not been established for patients with known tortuousity precluding the use of catheter-based techniques.

Micromesh technology



THE **DESIGN** DIFFERENCE

Unique design reduces fish scaling and kinking in the bend, preserving the complex angulation between the CCA and ICA.

PRECISE PRO RX® Stent offers:

Simplicity of use

- Autotapering provides precision guidance and remarkable placement accuracy
- Excellent flexibility
- Rapid exchange technology permits a single operator procedure

Micro-mesh multi-segmented design

- The lowest profile system on the market, with a lower sheath fit
- Each 2mm segment acts as its own stent to contour against the original wall anatomy
- Peak-to-valley micromesh design reduces recoil and kinking in the bends.
- Maintains best-in-class wall apposition with gentle, consistent outward force on the vessel wall

ANGIOGUARD® RX Guidewire System

Offering one of the shortest landing zones.

When used in combination with the PRECISE PRO RX® Stent, the ANGIOGUARD® RX Guidewire System from Cordis provides control, ease of insertion, and precise placement.

- Self-centering design makes placement easy
- 100 micron pore size captures more emboli, while maintaining continuous blood flow
- Excellent crossability (3.2F to 3.9F)

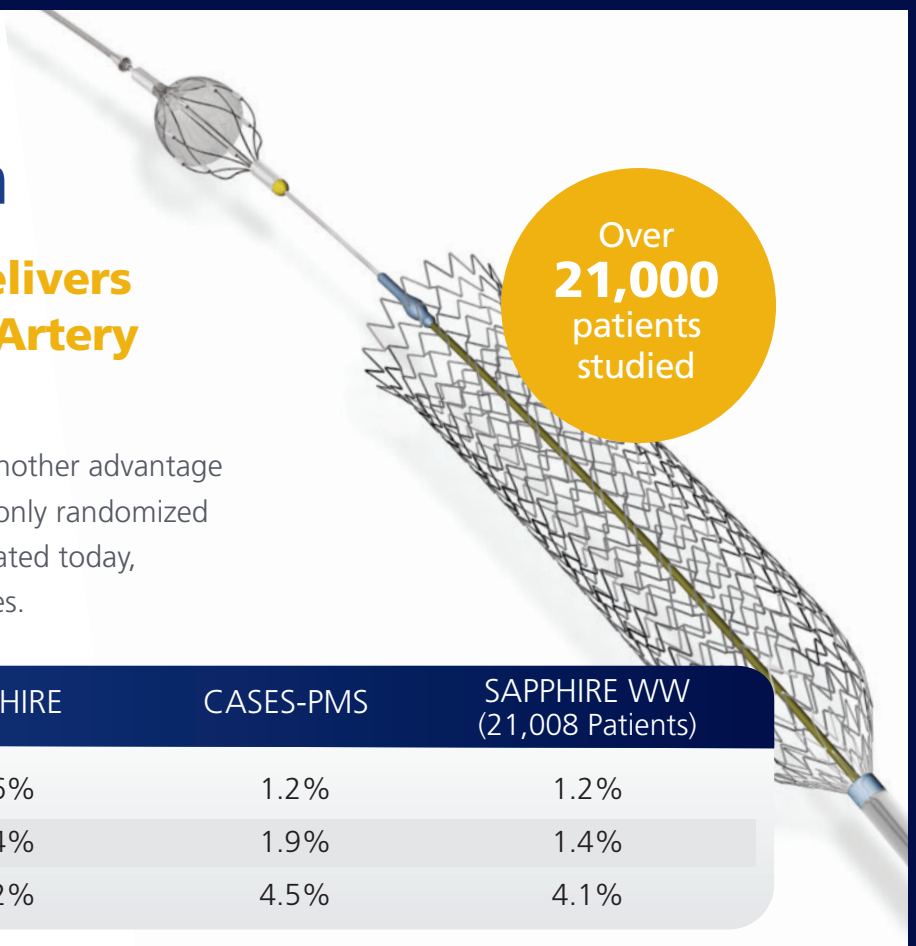
Landing Zone Comparison

Durable outcomes.

Cordis **CAS System**

Time after time, Cordis delivers proven results in Carotid Artery Stenting.

An extensive body of clinical evidence is yet another advantage of the Cordis CAS system. From the first and only randomized high-risk trial (SAPPHIRE) to data being generated today, Cordis continues to deliver improved outcomes.



30 Day Outcomes	SAPPHIRE	CASES-PMS	SAPPHIRE WW (21,008 Patients)
Major Ipsilateral Stroke	0.6%	1.2%	1.2%
Minor Ipsilateral Stroke	2.4%	1.9%	1.4%
Death and Stroke	4.2%	4.5%	4.1%

SAPPHIRE twice published in NEJM • SAPPHIRE WW published in CCI (Catheterization and Cardiovascular Interventions) Journal • Data presented at Vascular Interventional Advances (VIVA), Las Vegas, NV, Aug. 2015

The Cordis PRECISE PRO RX® Stent and ANGIOGUARD® RX Guidewire System deliver durable, consistent outcomes out to 3 years.

No statistical differences for CAS vs. CEA at 3 years.[4]

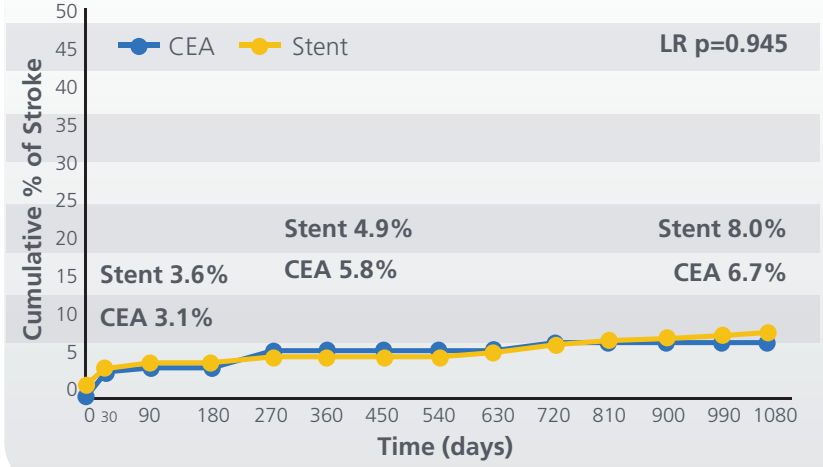
CAS is a durable procedure out to 3 years, with similar long-term risk of stroke* as CEA (8.0% vs. 6.7%, LR p=0.799) respectively.

Current CMS reimbursement is limited to symptomatic patients at high risk of surgery with > 70% stenosis of the carotid artery.

SAPPHIRE

Cumulative % of Stroke to 30 days and Ipsilateral Stroke from 31 to 1080 Days

Randomized Patients



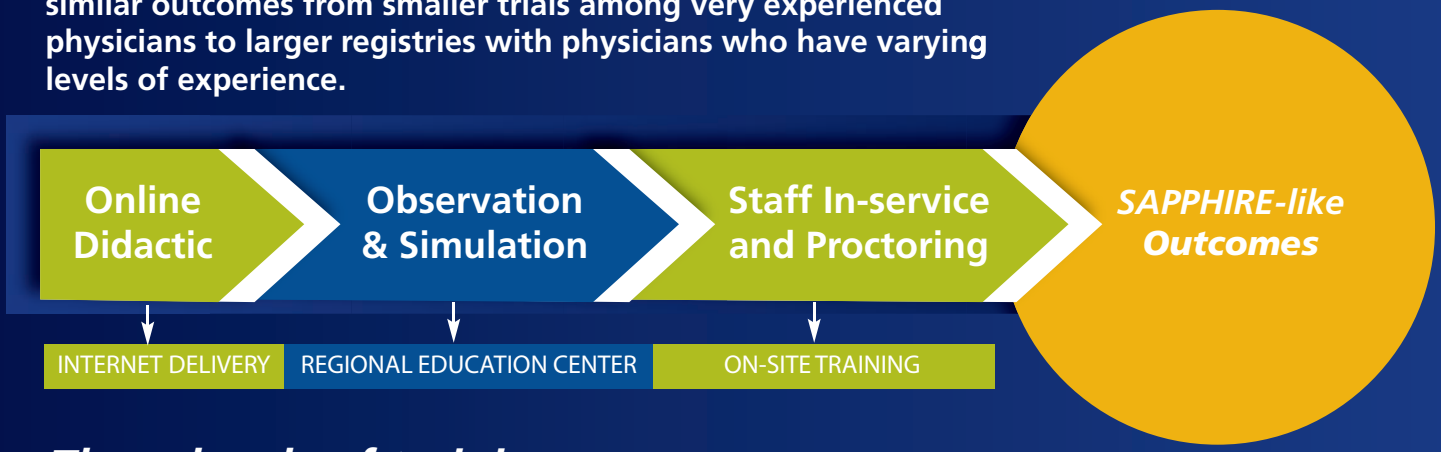
[4] Gurm HS,Yadav JS, Fayad P, Katzen BT, Mishkel GJ,Bajwa TK, et al. ***Long-term Results of Carotid Stenting Versus Endarterectomy in High-Risk Patients.*** N Engl J Med 2008; 358: 1572-1579.

CORDIS CASES®

Carotid Artery Stenting Education System

Training

Carotid Artery Stenting, through the CORDIS CASES® Carotid Artery Stenting Education System, continues to demonstrate similar outcomes from smaller trials among very experienced physicians to larger registries with physicians who have varying levels of experience.



Three levels of training.

Similar quality outcomes among varying levels of expertise.

Cordis **PRECISE PRO RX®** Nitinol Stent System
Cordis **ANGIOGUARD® RX** Emboli Capture Guidewire
Ordering Information

Cordis **PRECISE PRO RX®** Nitinol Stent System

PRODUCT CODE	DIAMETER X LENGTH (mm)	RECOMMENDED VESSEL SIZE (mm)	SHEATH (F)/GUIDE COMPATIBILITY
PC0520RXC	5 x 20	3-4	5/7
PC0530RXC	5 x 30	3-4	5/7
PC0540RXC	5 x 40	3-4	5/7
PC0620RXC	6 x 20	4-5	5/7
PC0630RXC	6 x 30	4-5	5/7
PC0640RXC	6 x 40	4-5	5/7
PC0720RXC	7 x 20	5-6	5/7
PC0730RXC	7 x 30	5-6	5/7
PC0740RXC	7 x 40	5-6	5/7
PC0820RXC	8 x 20	6-7	5/7
PC0830RXC	8 x 30	6-7	5/7
PC0840RXC	8 x 40	6-7	5/7
PC0920RXC	9 x 20	7-8	6/8
PC0930RXC	9 x 30	7-8	6/8
PC0940RXC	9 x 40	7-8	6/8
PC1020RXC	10 x 20	8-9	6/8
PC1030RXC	10 x 30	8-9	6/8
PC1040RXC	10 x 40	8-9	6/8

5F and 6F crossing profile. 135cm catheter working length. 0.014" guidewire acceptance. 3F proximal shaft.

Cordis **ANGIOGUARD® RX** Emboli Capture Guidewire System

PRODUCT CODE	PRODUCT CODE	GUIDEWIRE DIAMETER	SYSTEM LENGTH	FILTER BASKET DIAMETER	RECOMMENDED VESSEL DIAMETER FOR PLACEMENT	CROSSING PROFILE
Medium Support	*Extra Support*	*(in)*	*(cm)*	*(mm)*	*(mm)*	*(F)*
401814RMC		0.014	180	4	3 to ≤ 3.5	3.2
501814RMC	501814REC	0.014	180	5	3.5 to ≤ 4.5	3.3
601814RMC	601814REC	0.014	180	6	4.5 to ≤ 5.5	3.5
701814RMC	701814REC	0.014	180	7	5.5 to ≤ 6.5	3.7
801814RMC	801814REC	0.014	180	8	6.5 to ≤ 7.5	3.9
403014MC		0.014	300	4	3 to ≤ 3.5	3.2
503014MC		0.014	300	5	3.5 to ≤ 4.5	3.5
603014MC		0.014	300	6	4.5 to ≤ 5.5	3.7
703014MC		0.014	300	7	5.5 to ≤ 6.5	3.9
803014MC		0.014	300	8	6.5 to < 7.5	3.7

Eight Nitinol struts. Available in medium and extra support. 100 micron basket pore size.

Cordis **PRECISE PRO RX®** Nitinol Stent System

INDICATIONS FOR USE
The Cordis PRECISE PRO RX® Nitinol Stent System used in conjunction with the ANGIOGUARD® RX Emboli Capture Guidewire 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.

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

CONTRAINDICATIONS
Use of the Cordis PRECISE PRO RX® Nitinol Stent Systemis contraindicated in the following patients:

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

WARNINGS

- 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.

- The safety and efficacy of the PRECISE® stent have not been demonstrated with embolic protection systems other than the Cordis ANGIOGUARD® device.
- The long-term performance (>3 years) of carotid stents has not yet been established.
- As with any type of vascular implant, infection secondary to contamination of the stent may lead to thrombosis, pseudoaneurysm or rupture.
- The stent may cause a thrombus, distal embolization or may migrate from the site of implant down the arterial lumen. Appropriate sizing of the stent to the vessel is required to reduce the possibility of stent migration. In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.
- Overstretching of the artery may result in rupture and life-threatening bleeding.
- 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.
- The appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure.
- In the event of complications such as infection, pseudoaneurysm or fistulization, surgical removal of the stent may be required.

Patient Selection Warnings

- Safety and effectiveness of the Cordis PRECISE PRO RX® 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 (>9mm).
- 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.
- Risk of distal embolization may be higher if the Cordis PRECISE PRO RX® Nitinol Stent System device cannot be used in conjunction with the ANGIOGUARD® RX Guidewire System during the carotid stenting procedure.

Device Use Warnings

- Use of 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.
- Do not use a leaflet-type valve with the sheath introducer/guiding catheter.
- 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/guiding catheter.
- Ensure that there is a tight seal between the PRECISE PRO RX® catheter and the valve for the sheath introducer/guiding catheter during aspiration. Failure to do so could result in air entering the accessory device.
- 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 preprogrammed stent diameter may have been compromised.
- Do not use the device if there are abnormalities in the sterile barrier (e.g. broken seal, torn or breached barrier) or product.
- 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.
- Do not use the Cordis PRECISE PRO RX® Nitinol Stent System after the "Use By" date specified on the package.
- Do not use with Ethiodol or Lipiodol* contrast media, which may adversely affect the stent delivery system.
- Do not expose the delivery system to organic solvents (e.g. alcohol) as structural integrity and/or function of the device may be impaired.
- The stent is not designed for dragging or repositioning.
- Once the stent is partially deployed, it cannot be recaptured using the stent delivery system.
- As with any type of vascular implant, infection secondary to contamination of the stent may lead to thrombosis, pseudoaneurysm or rupture.
- When multiple stents are used, they should be of similar composition.
- Long-term outcomes following repeat dilatation of endothelialized stents are unknown.

PRECAUTIONS

Stent Handling Precautions

- The Cordis PRECISE PRO RX® Nitinol Stent System is supplied sterile and is intended for single use only. Do not resterilize and/or reuse the device.
- The Cordis PRECISE PRO RX® Nitinol 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.
- Do not use the Cordis PRECISE PRO RX® Nitinol Stent System after the "Use By" date specified on the package.
- Do not use if the pouch is opened or damaged.
- Store in a cool, dark, dry place.

Stent Placement Precautions

- 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.
- When catheters are in the body, they should be manipulated only under fluoroscopy. Radiographic equipment that provides high quality images is needed.
- The delivery system is not designed for the use of power injection. Use of power injection may adversely affect device performance.
- If resistance is met during delivery system introduction, the system should be withdrawn and another system used.
- Prior to stent deployment, remove all slack from the catheter delivery system.
- When treating multiple lesions, the distal lesion should be initially stented, followed by the proximal lesion. Stenting in this order obviates the need to cross the proximal stent in placement of the distal stent, reducing the chance for dislodging stents that have already been placed.
- Overlap of sequential stents is necessary, but the amount of overlap should be kept to a minimum (approximately 5mm). In no instance should more than 2 stents overlap.
- Fractures of this stent may occur. Fractures may also occur with the use of multiple overlapping stents. In the PRECISE® Stent, they have been reported most often in clinical uses for which the safety and effectiveness have not been established. The causes and clinical implications of stent fractures are not well characterized. Care should also be taken when deploying the stent as excessive force could, in rare instances, lead to stent deformation and/or fracture.

Post Stent Placement Precautions

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

MRI Safety and Compatibility

- 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.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
See package insert for full product information and complete list of warnings and precautions.
*The third-party trademarks used herein are trademarks of their respective owners.

Cordis **ANGIOGUARD® RX** Emboli Capture Guidewire System

Essential Prescribing Information

INDICATIONS
The Cordis ANGIOGUARD® RX Emboli Capture Guidewire System is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing carotid artery angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be from 3mm to 7.5mm (see Instructions for Use for basket/vessel sizing).

CONTRAINDICATIONS

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

WARNINGS

- 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.

- The safety and effectiveness of this device as an emboli protection system has not been established in the coronary, cerebral, or peripheral vasculature, other than carotid arteries.
- The safety and efficacy of the ANGIOGUARD® RX Guidewire System have not been demonstrated with stent systems other than the PRECISE® Stent System.
- Overstretching of the artery may result in rupture and life-threatening bleeding.
- Patient ACT of >300 seconds needs to be maintained during ANGIOGUARD® RX Guidewire System deployment.
- Safety and effectiveness of the angioplasty and carotid stenting procedure 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 (>9mm).
- 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.

- Risk of distal embolization may be higher if the ANGIOGUARD® RX Guidewire System is not used during carotid stenting procedures.
- 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.
- Observe all guidewire movement in the vessels using fluoroscopic guidance
- DO NOT TORQUE THE GUIDEWIRE.
  - — Do not torque a guidewire without observing corresponding movement of the tip; otherwise, vessel trauma could occur.
  - — Torquing a guidewire against resistance may cause guidewire damage and/or guidewire tip separation. Always advance or withdraw the guidewire slowly. Never push, auger, withdraw or torque a guidewire that meets resistance. Resistance may be felt and/ or observed using fluoroscopy by noting any buckling of the guidewire tip. Determine the cause of resistance under fluoroscopy and take the necessary remedial action.
- Before the guidewire is moved, tip movement should be examined using fluoroscopy.
- Perform all exchanges slowly to prevent air from entering the catheter system.
- When introducing the guidewire, confirm that the guiding catheter or interventional sheath introducer tip is free within the vessel lumen and not against the vessel wall. Failure to do so may result in vessel trauma upon guidewire exit from the tip. Use the radiopaque marker of the interventional device to confirm position.

PRECAUTIONS

- Confirm the compatibility of the ANGIOGUARD® RX Guidewire System with the interventional device before actual use.
- If distal perfusion of dye is significantly reduced or no dye is perfusing past the distal marker band of the filter basket, the ANGIOGUARD® RX Guidewire System may have reached its maximum capacity to contain emboli. Remove and replace with a new ANGIOGUARD® RX Guidewire System (per Instructions for use).
- Do not attempt to close the filter basket with the Deployment Sheath. The ANGIOGUARD® RX Guidewire System should only be removed using the Capture Sheath.
- Care during diagnostic or interventional device exchanges must be practiced to minimize movement of the guidewire/filter basket.
- Use caution when withdrawing the ANGIOGUARD® RX Guidewire System device through the deployed stent.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
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The third-party trademarks used herein are trademarks of their respective owners.

Cordis®
A Cardinal Health company

Endovascular

Contact your Cordis sales representative for availability and ordering.
For Customer Service, call 1-800-327-7714, or visit us at www.cordis.com

Cordis®

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Source documents on file at Cordis, a Cardinal Health company.

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