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.
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.

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.

**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*

<table>
<thead>
<tr>
<th>Feature</th>
<th>Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multi-segment design</td>
<td>Auto-tapering</td>
</tr>
<tr>
<td>Micromesh geometry</td>
<td>Enhanced wall apposition</td>
</tr>
<tr>
<td>Peak-to-Valley design</td>
<td>Conformability</td>
</tr>
</tbody>
</table>

**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.‡

![Enhanced wall apposition in bifurcation](image)

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

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

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)

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

Landing Zone Comparison

15.4mm landing zone
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

<table>
<thead>
<tr>
<th></th>
<th>SAPPHIRE</th>
<th>CASES-PMS</th>
<th>SAPPHIRE WW (21,008 Patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Ipsilateral Stroke</td>
<td>0.6%</td>
<td>1.2%</td>
<td>1.2%</td>
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<tr>
<td>Minor Ipsilateral Stroke</td>
<td>2.4%</td>
<td>1.9%</td>
<td>1.4%</td>
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<tr>
<td>Death and Stroke</td>
<td>4.2%</td>
<td>4.5%</td>
<td>4.1%</td>
</tr>
</tbody>
</table>

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.**

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.

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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

<table>
<thead>
<tr>
<th>PRODUCT CODE</th>
<th>DIAMETER X LENGTH (mm)</th>
<th>RECOMMENDED VESSEL SIZE (mm)</th>
<th>SHEATH (F)/GUIDE COMPATIBILITY</th>
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<tbody>
<tr>
<td>PC0520RXC</td>
<td>5 x 20</td>
<td>3-4</td>
<td>5/7</td>
</tr>
<tr>
<td>PC0530RXC</td>
<td>5 x 30</td>
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<td>5/7</td>
</tr>
<tr>
<td>PC0540RXC</td>
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<td>5/7</td>
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<tr>
<td>PC0620RXC</td>
<td>6 x 20</td>
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<td>5/7</td>
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<tr>
<td>PC0630RXC</td>
<td>6 x 30</td>
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<td>5/7</td>
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<tr>
<td>PC0640RXC</td>
<td>6 x 40</td>
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<td>5/7</td>
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<tr>
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<td>PC0730RXC</td>
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<td>PC0740RXC</td>
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<tr>
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<td>PC0930RXC</td>
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<tr>
<td>PC1040RXC</td>
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<td>8-9</td>
<td>6/8</td>
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</tbody>
</table>

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

### Cordis ANGIOGUARD® RX Emboli Capture Guidewire System

<table>
<thead>
<tr>
<th>PRODUCT CODE</th>
<th>PRODUCT CODE</th>
<th>GUIDEewire DIAMETER</th>
<th>SYSTEM LENGTH (in)</th>
<th>FILTER BASKET DIAMETER (mm)</th>
<th>RECOMMENDED DIAMETER FOR PLACEMENT (mm)</th>
<th>CROSSING PROFILE</th>
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<tbody>
<tr>
<td>Medium Support</td>
<td>Extra Support</td>
<td>(in)</td>
<td>(cm)</td>
<td>(mm)</td>
<td>(mm)</td>
<td>(F)</td>
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<td>401814RMC</td>
<td></td>
<td>0.014</td>
<td>180</td>
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<td>3 to ≤ 3.5</td>
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<td>180</td>
<td>5</td>
<td>3.5 to ≤ 4.5</td>
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<tr>
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<td>5.5 to ≤ 6.5</td>
<td>3.7</td>
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<tr>
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<td>801814REC</td>
<td>0.014</td>
<td>180</td>
<td>8</td>
<td>6.5 to ≤ 7.5</td>
<td>3.9</td>
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<td>0.014</td>
<td>300</td>
<td>4</td>
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<td>3.2</td>
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<td>300</td>
<td>7</td>
<td>5.5 to ≤ 6.5</td>
<td>3.9</td>
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<tr>
<td>803014MC</td>
<td></td>
<td>0.014</td>
<td>300</td>
<td>8</td>
<td>6.5 to &lt; 7.5</td>
<td>3.7</td>
</tr>
</tbody>
</table>

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 is used in conjunction with the ANGIOGUARD® RX Emboli Capture Guidewire System and is indicated for the treatment of patients at high risk for adverse events from carotid endarterectomy when the carotid artery stenosis measured by ultrasound or angiogram meet the criteria outlined below.

- Patients with critical neurological symptoms and ≥ 50% stenosis of the common or internal carotid artery by ultrasound or angiogram OR patients without neurological symptoms and ≥ 60% stenosis of the common or internal carotid artery by ultrasound or angiogram.
- Patients must have a vessel diameter of 6.0 mm or less at the target lesion.
- The vessel distal to the lesion must be within the range of 5.0 mm and 7.7 mm to allow for placement of the ANGIOGUARD® RX Emboli Capture Guidewire System.

CONTRAINDICATIONS

Use of the Cordis PRECISE PRO RX® Nitinol Stent System in the following patients:
- Patients in whom anticoagulant and/or antithrombotic therapy is contraindicated.
- Patients in whom the guide catheter is unable to be placed.
- Patients with uncorrected bleeding disorders.
- Patients with known allergies to the stent systems.
- Lesions in 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® RX device have not been demonstrated with embolus protection systems other than the Cordis ANGIOGUARD® system.
- The long-term clinical benefit of stenting for 50% stenosis has not 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, embolization or migration from the site of implantation into 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, thrombolytic therapy may be indicated.
- Oversizing of the stent will result in an increase in the risk of embolization.
- The stent deployment and embolic protection system should be administered per pre-procedure and post procedure.
- In the event of complications such as infection, pseudoaneurysm or fistulation, surgical removal of the stent may be required.

Patient Selection

- Safety and effectiveness of the Cordis PRECISE PRO RX® Nitinol Stent System have 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 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 neurological symptoms or stroke or who experienced a stroke within 48 hours.
- Patients with an intramural lesion (i.e., aneurysm, tumor or infectious or aneurysm (<8mm) or patients with anterior-aortic malformations in the territories of the target carotid artery.
- Patients with coagulopathies.
- Patients with a poor renal function, who, in the physician's opinion, may be at high risk for a reaction to contrast medium.
- Patients with peripherally vessels need protection by embolization.
- Patients with aneurysmal dilatation immediately proximal or distal to the lesion.
- Pregnant patients or patients under the age of 18.

Access Characteristics

- Patients with known peripheral vascular; supra- and infra- common carotid artery tortuosity that would preclude the use of catheter-based techniques.
- Patients in whom femoral or brachial access is not possible.
- Risk of data embolization may be higher if the Cordis PRECISE PRO RX® Nitinol Stent System device cannot be used in conjunction with the ANGIOGUARD® RX Emboli Capture Guidewire System during the carotid stenting procedure.

Device Use Warnings

- Use of smaller then indicated accessory device can lead to introduction of air into the device that the stent delivery system is advanced.
- Do not use a less stiff catheter than the sheath introducer grounding catheter.
- Ensure that the catheter system is flush and not integrated to the sheath system in "Introduction of Stent Delivery System". Failure to do so could result in entering the sheath introducer grounding catheter.
- Ensure that there is a tight seal between the PRECISE RX® R catheter and the valve for the sheath introducer grounding 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 administration on the stents barrier (e.g., broken seal, torn, bristle or burst product).
- This device is intended for one-time use only. Do not re-process or re-sterilize. Structural integrity and/or function may be impaired through misuse 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 the Cordis PRECISE PRO RX® Nitinol Stent System if the "Use By" date specified on the package.
- Do not use if the pouch is opened or damaged.
- Store in a cool, dark, dry area.

Stent Placement Warnings

- Venous access should be available during carotid stenting in order to manage bradyarrhythmia and/or hypotension either by pharmacological intervention or placement of a temporary pacemaker, if needed.
- When catheters are in the body, they should be manipulated only under fluoroscopy. Radionuclide 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 blood 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

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 re-use the device.
- The Cordis PRECISE PRO RX® Nitinol Stent System is shipped with the "Fushy Bond valve in the open position. Care should be taken not to pre-deploy the stent. The device should be packaged 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 area.

CONTRAINDICATIONS

- Lesions in the common carotid artery.
- Lesions in the common carotid artery.

CAUTION:

- Cordis USA Llc reserves the right to make changes to this device at any time for any reason without notification.
- 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.

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 ANGIOGUARD® RX Emboli Capture Guidewire System

Essential Prescriptive Information

INDICATIONS

The Cordis ANGIOGUARD® RX Emboli Capture Guidewire System is indicated for use as a guidewire and embolic protection system with carotid stenting procedures, for treatment of lesions in the ostium of the common carotid artery, for protection of the carotid arteries during carotid angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter placement should be from 3mm to 7.7mm (see instructions for use for basketed system).

CONTRAINDICATIONS

- Patients in whom anticoagulant and/or antithrombotic therapy is contraindicated.
- Patients in whom the guide catheter is unable to be placed.
- Patients with uncorrected bleeding disorders.
- Patients with known allergies to the stent systems.
- Lesions in the common carotid artery.

WARNINGS

- Patients 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 embolus 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 Emboli Capture Guidewire System have not been demonstrated with other stent systems other than the PRECISE® Stent System.
- Oversizing of the stent may result in rupture and life-threatening bleeding.
- Patient ACT of ≥300 seconds is needed to be maintained during ANGIOGUARD® RX Emboli Capture Guidewire System deployment.
- Do not attempt to close the guidewire protection system until the device has been deployed and the stent has been positioned within the desired location.

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 common carotid.
- Patients with highly calcified lesions resistant to PTA.
- Concurrent treatment of bilateral lesions.

Device Use Warnings

- Do not reuse the Cordis ANGIOGUARD® RX Emboli Capture Guidewire System in the same patient, as reused or breached access is not possible.
- Risk of embolism may be high if the ANGIOGUARD® RX Guidewire System is not used during carotid stenting procedures.
- The device is removed over a one-time catheter. Do not re-use and/or re-sterilize the delivery system.
- Structural integrity and/or function may be impaired through misuse or cleaning.
- Do not attempt to close the guide wire basket with the shunt introduced. This could result in air entering the sheath.
- Patient ACT of ≥300 seconds is needed to be maintained during ANGIOGUARD® RX Emboli Capture Guidewire System deployment.

PRECAUTIONS

- Confirm the compatibility of the ANGIOGUARD® RX Guidewire System with the interventional device before actual use.
- If dislocation of supra-aortic branches or dissection of the main branch of the Wakemed, the ANGIOGUARD® RX Guidewire System may have reached its maximum capacity to contain emboli. Remove and replace with a new ANGIOGUARD® RX Guidewire System.
- 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 remove 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.