PERIPHERAL ROTABLATOR™
Rotational Atherectomy System

Quick Reference Cards
Technical Assistance: 1.800.949.6708
Customer Service: 1.888.272.1001
Complaints: 1.800.811.3211
Common Considerations

- One burr approach is common
- Plaque modification vs. de-bulking (~70% native vessel)
- Adjunctive pharmaceuticals per hospital protocol
- Target free lumen speed of ~160,000 RPM
- Limit RPM drop to under 5,000 RPM
- 15-30 second runs (average)
- Limit total burr time to under 5 minutes

Procedure Checklist

- Set up console, foot pedal and air supply
- Connect advancer to console
- Connect saline to advancer
- Advance the RotaWire™ Guidewire beyond the lesion
- Backload burr and test (DRAW)
- Lock advancer knob forward and insert burr through sheath
- Release and pull back advancer knob when burr is proximal to the lesion
- Proceed with Rotational Atherectomy
- Remove burr in DynaGlide™ mode

Please review Directions for Use regarding full operating instructions
PERIPHERAL ROTABLATOR™ Console

- Rotational speed display (tachometer)
- Dynaglide™ indicator
- Event timer
- Procedure timer
- Reset button
- Turbine pressure gauge (delivered to advancer)
- Turbine pressure control knob (adjusts RPM)
- Power switch
- Power indicator
- Foot Pedal
  - On/Off pedal
  - Dynaglide button
- Back Panel
  - Incoming air supply
  - Power supply
  - Dynaglide connectors
PERIPHERAL ROTALINK™ PLUS Burr Catheter (Advancer)

- 135 cm catheter length
- 4.3 F (0.058”) protective sheath
- 8.9 cm throw length

<table>
<thead>
<tr>
<th>Burr Size (mm)</th>
<th>Guide Sheath or Introducer Sheath Size*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.25</td>
<td>5 F</td>
</tr>
<tr>
<td>1.50</td>
<td>5 F</td>
</tr>
<tr>
<td>1.75</td>
<td>6 F</td>
</tr>
<tr>
<td>2.00</td>
<td>7 F</td>
</tr>
<tr>
<td>2.25</td>
<td>7 F</td>
</tr>
<tr>
<td>2.50</td>
<td>8 F</td>
</tr>
</tbody>
</table>

* For a given French size guide sheath or introducer sheath, the internal lumen and hemostasis valve will vary from manufacturer to manufacturer. When using an introducer for the first time, it should be tested with the largest Peripheral RotaLink Plus burr intended to be used with it.
**PERIPHERAL ROTAWIRE™ Guidewire**

- 330 cm total length
- 0.009” body
- 0.014” spring tip

**Extra Support**
- A stiffer front line wire for distal lesions or heavily calcified proximal lesions

**Floppy Wire**
- More flexible and torqueable wire with reduced guide wire bias
Peripheral RotaGlide Lubricant

- Inject one 20 cc vial into 1000 cc saline flush bag
- Reduces friction and improves tactile feel
- Reduces sudden drops in RPMs caused by lesion feedback
- Reduces heat generation
- Ingredients: Olive oil, egg yolk phospholipids, sodium deoxycholate, L-histidine, disodium EDTA, sodium hydroxide, water
- Does not require refrigeration
- Contraindicated if patient is allergic to eggs or olive oil

Adjunctive Pharmaceuticals

Optional adjunctive pharmaceuticals may be added per hospital protocol. For more information, reference “Rotational and Directional Coronary Atherectomy” by Bersin and Simonton.¹

PERIPHERAL ROTABLATOR™ Procedure Steps

System Setup

Burr/Advancer Setup

Pressurize saline mixture to 200 mmHg

Monitors gas delivered to console (90-110 psi)

Monitors gas contained in tank (minimum 500 psi)
PERIPHERAL ROTABLATOR™ Procedure Steps

Procedure Prep

Burr Removal (DynaGlide™)

Test system outside of body with foot pedal activated:

- **D**rip
- **R**otation
- **A**dvancement
- **W**ire

Two options for brake defeat

- Hold button with thumb
- Lock button with WireClip™ torquer

Backload burr

DynaGlide button

DynaGlide indicator
Rotablator Peripheral Rotalink Plus
Rotablator Peripheral RotaWire Guidewire and wireClip Torquer
Rotablator Rotational Atherectomy System Console
Rotaglide Lubricant

CAUTION: Federal law (USA) restricts the use of this system to physicians who are credentialed in peripheral angioplasty and who have attended the Rotablator System Physician Training Program.

WARNINGS:
• The risks of Rotational Atherectomy can be reduced if the device and associated accessories are used in the appropriate patient population by a physician who has had adequate training. • If the Peripheral RotaWire Plus shows evidence of mechanical failure at any time prior to or during the angioplasty procedure, immediately discontinue use of the device and return it to Customer Service for evaluation.

CONTRAINDICATIONS AND RESTRICTIONS: Contraindications:
1. Occlusions through which a guidewire will not pass. 2. Use in coronary arteries. 3. Long (≥ 20 cm) total occlusions.
4. Angiographic evidence of thrombus prior to treatment with the Rotablator Rotational Atherectomy System. Such patients may be treated with thrombolytics (e.g., Urokinase). When the thrombus has been resolved for two to four weeks, the lesion may be treated with the Rotablator Rotational Atherectomy System.

5. Angiographic evidence of significant dissection at the treatment site. The patient may be treated conservatively for approximately four weeks to permit the dissection to heal before treating the lesion with the Rotablator Rotational Atherectomy System.

Lubricant CONTRAINDICATIONS: RotaglideTM lubricant is contraindicated in patients with known allergies to the lubricant ingredients: olive oil, egg yolk phospholipids, glycerin, sodium deoxycholate, L-histidine, disodium EDTA, sodium hydroxide, and water. Restrictions • Federal (USA) law restricts the use of this system to physicians who are credentialed in peripheral angioplasty and who have attended the Rotablator System Physician Training Program.

PRECAUTIONS:
• Use extreme caution and careful judgment in patients for whom anticoagulation is not indicated.

ADVERSE EVENTS:
Potential adverse reactions which may result from the use of this device include but are not limited to: • Additional intervention • Allergic reaction • Amputation • Death • Embolism • Hematoma/Hemorrhage • Hemodynamic changes • Hemoglobinuria • Infection • Restenosis • Stroke • Slow, no flow, abrupt vessel closure • Surgery including arterial bypass • Thrombosis and vessel occlusion • Vessel trauma (dissection, perforation, pseudoaneurysm, arteriovenous fistula) There may also be complications associated with distortion, kinks, and fracture of the guidewire and physical deterioration or malfunction of the device, which can lead to patient injury or death.

Rotablator, Rotalink, RotaWire, DynaGlide, RotaGlide and WireClip are registered or unregistered trademarks of Boston Scientific Corporation or its affiliates. All other trademarks are property of their respective owners.

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# Peripheral RotaLink™ Plus Burr Catheter • 135 cm catheter length, 0.009” OTW, 4.3 F (0.058”) protective sheath

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<th>Catalog</th>
<th>Description</th>
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<tr>
<td>08714729857808</td>
<td>140-125</td>
<td>1.25 mm Peripheral RotaLink Plus, 5 F</td>
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<tr>
<td>08714729838906</td>
<td>140-150</td>
<td>1.50 mm Peripheral RotaLink Plus, 5 F</td>
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<td>08714729838913</td>
<td>140-175</td>
<td>1.75 mm Peripheral RotaLink Plus, 6 F</td>
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<td>08714729838920</td>
<td>140-200</td>
<td>2.00 mm Peripheral RotaLink Plus, 7 F</td>
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<td>08714729838944</td>
<td>140-225</td>
<td>2.25 mm Peripheral RotaLink Plus, 7 F</td>
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<td>08714729838968</td>
<td>140-250</td>
<td>2.50 mm Peripheral RotaLink Plus, 8 F</td>
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# Peripheral RotaWire™ Guidewire and WireClip™ Torquer • 330 cm length, 0.009” diameter body with 0.014” spring tip

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<tr>
<td>08714729838890</td>
<td>137-332</td>
<td>Extra Support Peripheral RotaWire (Box of 5)</td>
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<td>08714729838883</td>
<td>137-331</td>
<td>Floppy Peripheral RotaWire (Box of 5)</td>
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## Rotablator Console

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<th>Description</th>
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<tr>
<td>08714729353300</td>
<td>22020-039</td>
<td>Rotablator Console Kit (includes console, foot pedal and 20 ft. air supply hose)</td>
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<tr>
<td>08714729076964</td>
<td>21600-003</td>
<td>20 ft Air Supply Hose – replacement</td>
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<td>08714729353317</td>
<td>22436-002</td>
<td>Dynaglide™ Foot Pedal – replacement</td>
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<tr>
<td>08714729229674</td>
<td>22151-001</td>
<td>Console Power Cord – replacement</td>
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## Accessories

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<tr>
<td>08714729847557</td>
<td>141-0006</td>
<td>Peripheral RotaGlide™ Lubricant (Box of 6)</td>
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<td>08714729263371</td>
<td>15901-01</td>
<td>HTI Regulator Kit</td>
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<td>08714729195535</td>
<td>22196-003</td>
<td>WireClip Torquer (Box of 5)</td>
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