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 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>4 F/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>6 F/7 F</td>
</tr>
<tr>
<td>2.25</td>
<td>7 F</td>
</tr>
<tr>
<td>2.50</td>
<td>7 F/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

- System Setup
  - Monitors gas delivered to console (90-110 psi)
  - Monitors gas contained in tank (minimum 500 psi)
**PERIPHERAL ROTABLATOR™** Procedure Steps

### Procedure Prep

![Backload Burr](image)

Test system outside of body with foot pedal activated:

- **Drip**
- **Rotation**
- **Advancement**
- **Wire**

### Burr Removal (DynaGlide™)

![DynaGlide Button](image)

DynaGlide button

![DynaGlide Indicator](image)

DynaGlide indicator

### Two options for brake defeat

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

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**PERIPHERAL ROTABLATOR™ Rotational Atherectomy System**

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

**CAUTION:**

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

**INSTRUCTIONS: USE/INDICATIONS FOR USE: The Rotablator Rotational Atherectomy System is intended for percutaneous use in the peripheral vessels in patients with occlusive atherosclerotic disease who are acceptable candidates for endovascular procedures.**

**CONTRAINDICATIONS AND RESTRICTIONS: Contraindications: 1. Occlusions through which a guidewire will not pass. 2. Use in coronary arteries. 3. Long (≥ 20 cm) total occlusions.**

**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 RotaLink 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. Do NOT attempt to use a damaged Peripheral RotaLink Plus; use may result in device malfunction and/or patient injury.
- Never operate the Peripheral RotaLink Plus without saline infusion. Flowing saline is essential for cooling and lubricating the working parts of the device. Operation of the device without proper saline infusion may result in permanent damage to the device.
- Never operate the Peripheral RotaLink Plus with the Rotablator Rotational Atherectomy System in Dynaglide™ mode or operate the guidewire brake defeat button unless you have a firm grip on the guidewire using the wireClip™ Torquer. The wireClip Torquer may be held with the fingers or inserted completely into the docking port after the brake button is depressed. Defeating the brake, or operating the Peripheral RotaLink Plus with the Rotablator Rotational Atherectomy System in Dynaglide mode, without securing the guidewire may result in rotation and entanglement of the guidewire.
- During setup of the Peripheral RotaLink Plus never grip or pull on the flexible shaft. The burr at the distal tip of the Peripheral RotaLink Plus is capable of rotating at very high speeds. Do NOT allow parts of the body or clothing to come in contact with the burr. Contact may result in physical injury or entanglement.
- Never advance the rotating burr to the point of contact with the guidewire spring tip. Contact could result in distal detachment and embolization of the tip.
- If the Peripheral RotaLink Plus stops and the red STALL light on the console illuminates, retract the burr and immediately discontinue treatment. Check the advancer for proper connection to the console. If the connections are correct, use fluoroscopy to analyze the situation. Never force the system when rotational or translational resistance occurs, as vessel perforation may occur. Never advance the rotating burr by advancing the sheath. GuideWire buckling may occur and perforation or vascular trauma may result. Always advance the rotating burr by using the advance knob.
- If resistance is encountered, retract the burr and stop treatment immediately. Use fluoroscopy to analyze the situation. Never force the Peripheral RotaLink Plus when rotational or translational resistance occurs, as vessel perforation, vessel trauma or embolism due to burr detachment or fractured wire may occur and in rare instances may result in surgical intervention and death.
- The use of Rotaglide 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:** Operating the device in close proximity to other equipment may cause interference or accidental activation.
- **Adverse Events:** There may 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.

**CONTRAINDICATIONS:**

- **Federal (USA) law restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete “Directions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.**

**Lubricant CAUTIONS:**

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- **Precautions:** Operating the device in close proximity to other equipment may cause interference or accidental activation.
- **Adverse Events:** There may 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.

**RotaWire WARNINGS:**

- Use only normal saline as the infusate. Never inject contrast agent, or any other substance that is not approved as part of the Rotablator Rotational Atherectomy System, into the infusion port or saline infusion bag as this may cause permanent damage to the Peripheral RotaLink Plus.
- **Console PRECAUTIONS:** User should take precautions when using the console in conjunction with other medical electrical equipment.

**CONTRAINDICATIONS FOR USE:**

- **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:** Operating the device in close proximity to other equipment may cause interference or accidental activation.
- **Adverse Events:** There may 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.

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**Rotaglide Lubricant**

- **Federal law (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.**
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**Lubricant Adverse Events:**

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**Lubricant Operator’s Instructions:**

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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>Description</th>
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<tr>
<td>08714729857808</td>
<td>140-125</td>
<td>1.25 mm Peripheral RotaLink Plus, 4/5 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, 6/7 F</td>
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<td>08714729838944</td>
<td>140-225</td>
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<tr>
<td>08714729838968</td>
<td>140-250</td>
<td>2.50 mm Peripheral RotaLink Plus, 7/8 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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<th>Description</th>
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<tr>
<td>08714729838890</td>
<td>137-332</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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<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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<tr>
<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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</table>

**Accessories**

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