**Rotational Atherectomy System**

**Indications for Use**: The Rotational Atherectomy System is intended for percutaneous use in the peripheral vessels in patients with atherosclerotic disease who are candidates for endovascular procedures. **Rotational Atherectomy System** devices are intended for use with the Rotablator Rotational Atherectomy System. **Lubricant INDICATIONS**: Rotational Atherectomy System lubricant is intended for use with the Rotablator Rotational Atherectomy System, for the purpose of increasing the efficiency of the system.

**Restrictions**: Contraindications: 1. Occlusions through which a guidewire will pass into 2. Ulcer in coronary arteries. 3. Long (≥ 30mm) and tortuous lesions. 4. Arteriographic evidence of thrombus prior to treatment with the Rotablator Rotational Atherectomy System. Such patients may be treated with thrombolytic agents (e.g.: Urokinase). When the thrombolytic has been resolved for two to four weeks, the lesion may be treated with the Rotablator Rotational Atherectomy System. P. embolic or entrapment of the system on the distal tip of the burr or other complications.** Adverse Events**: Potential adverse reactions that may result from the use of this device include, but are not limited to, **a**. Embolism. **b**. Hematoma/hemorrhage. **c**. Allergic reaction. **d**. Amputation. **e**. Death. **f**. Mechanical failure or any tissue injury that may be caused by this device. **g**. Vessel perforation. **h**. Vessel trauma. **i**. Arterial dissection. **j**. Arterial ulceration. **k**. Arterial stenosis. **l**. Arterial occlusion. **m**. Arterial aneurysm. **n**. Arterial thrombus. **o**. Arterial embolism. **p**. Arterial spasm. **q**. Arterial spasm. **r**. Arterial hypertension. **s**. Arterial hypotension. **t**. Arterial hypoxia. **u**. Arterial ischemia. **v**. Arterial thrombosis. **w**. Arterial thrombosis. **x**. Arterial thrombosis. **y**. Arterial thrombosis. **z**. Arterial thrombosis. **AA**. Arterial thrombosis. **BB**. Arterial thrombosis. **CC**. Arterial thrombosis. **DD**. Arterial thrombosis. **EE**. Arterial thrombosis. **FF**. Arterial thrombosis. **GG**. Arterial thrombosis.

**Lubricant**: **Indications for Use**: Rotational Atherectomy System lubricant is intended for use with the Rotablator Rotational Atherectomy System to increase the efficiency of the system. **Contraindications**: Contraindications include patients with known allergies to the lubricant ingredients: olive oil, egg yolk phosphatidylcholine, glycerin, sodium deoxycholate, L-ascorbic acid, dibasic sodium phosphate, 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.

**WARNING**: The risks of Rotational Atherectomy can be reduced if the device and associated accessories are used in accordance with the operator's instructions. **Adverse Events**: Potential adverse reactions that may result from the use of this device include, but are not limited to, **a**. Embolism. **b**. Hematoma/hemorrhage. **c**. Allergic reaction. **d**. Amputation. **e**. Death. **f**. Mechanical failure or any tissue injury that may be caused by this device. **g**. Vessel perforation. **h**. Vessel trauma. **i**. Arterial dissection. **j**. Arterial ulceration. **k**. Arterial stenosis. **l**. Arterial occlusion. **m**. Arterial aneurysm. **n**. Arterial thrombus. **o**. Arterial embolism. **p**. Arterial spasm. **q**. Arterial spasm. **r**. Arterial hypertension. **s**. Arterial hypotension. **t**. Arterial hypoxia. **u**. Arterial ischemia. **v**. Arterial thrombosis. **w**. Arterial thrombosis. **x**. Arterial thrombosis. **y**. Arterial thrombosis. **z**. Arterial thrombosis. **AA**. Arterial thrombosis. **BB**. Arterial thrombosis. **CC**. Arterial thrombosis. **DD**. Arterial thrombosis. **EE**. Arterial thrombosis. **FF**. Arterial thrombosis. **GG**. Arterial thrombosis.

**Lubricant CONTRAINDICATIONS**: Rotational Atherectomy System lubricant is contraindicated in patients with known allergies to the lubricant ingredients: olive oil, egg yolk phosphatidylcholine, glycerin, sodium deoxycholate, L-ascorbic acid, dibasic sodium phosphate, 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.

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**Lubricant TRAINING PROGRAM**: Training Program.

**PI-208206-AD**

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**SYSTEM SETUP**

- Plug in console and turn on power switch.
- Connect air supply hose to compressed air or nitrogen (min 500 PSI in tank per procedure; 90 – 110 PSI flowing to console).
- Connect DynaGlide™ Foot Pedal hoses — green and blue to back of the console, pink to the front.
- Connect Peripheral RotaLink™ Plus fiber-optic cables and air line to front of console.
- Add Peripheral RotaGlide™ Lubricant and optional adjunctive pharmaceuticals (per hospital protocol) to 1 liter bag of sterile saline, then connect to Peripheral RotaLink™ Plus infusion port and pressurize to 200 mmHg.

**PROCEDURE PREP**

- Select sheath that will accommodate the largest burr size to be utilized (~70% of native vessel).

### Introcer/Guide Sheath Selection & Sizing

<table>
<thead>
<tr>
<th>Burr (mm)</th>
<th>Diameter (inches)</th>
<th>Minimum Recommended Introducer/Guide Sheath Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.25</td>
<td>0.049</td>
<td>5 F</td>
</tr>
<tr>
<td>1.50</td>
<td>0.059</td>
<td>5 F</td>
</tr>
<tr>
<td>1.75</td>
<td>0.069</td>
<td>6 F</td>
</tr>
<tr>
<td>2.00</td>
<td>0.079</td>
<td>7 F</td>
</tr>
<tr>
<td>2.25</td>
<td>0.089</td>
<td>7 F</td>
</tr>
<tr>
<td>2.50</td>
<td>0.098</td>
<td>8 F</td>
</tr>
</tbody>
</table>

- Advance the Peripheral RotaWire™ Guidewire beyond lesion and backload burr, stopping proximal to the sheath.
- Connect WireClip™ Torquer to the end of the wire.

**Test system outside body with foot pedal activated**

- **Drip** — check drip from catheter sheath tip and beneath advancer.
- **Rotation** — set burr speed to desired RPM level.
- **Advancer** — check free movement of advancer knob.
- **Wire** — check that wire is visible out of the advancer, torquer clip is attached, and tug on wire while rotating to ensure brake is activated.

### BURR REMOVAL

- Press DynaGlide button on foot pedal (green light will appear on console).
- Press brake defeat on advancer while holding WireClip Torquer.
- Press foot pedal for low-speed rotation in DynaGlide mode.
- Retract Peripheral RotaLink Plus Catheter while assistant simultaneously holds WireClip Torquer and advances the Peripheral RotaWire Guidewire to maintain position.
- Press DynaGlide button to reactivate normal mode after removing catheter.

**OTHER INFORMATION**

- Peripheral RotaWire Guidewire is a 0.008" wire with a 0.014" tip, 330 cm in length.
- The white substance on the Peripheral RotaWire is a lubricant called Hystrene™. This should not be removed from the guidewire.
- Peripheral RotaGlide Lubricant contains egg yolks and olive oil, therefore it is contraindicated for patients who are allergic to these substances.
- Rotablator System customer complaints should be forwarded to the Complaint Call Center 1.800.811.3211.

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* 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.

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**TROUBLESHOOTING**

**Advancer burr stops, stalls, or does not reach desired platform speed**

**Outside the body:**

- Check air source pressure (90-110 PSI) and air source volume (>500 PSI).
- Check all air lines and tubing to ensure they are kink free and connections are tight.
- Ensure DynaGlide mode is turned off.
- Check saline connection and make sure drip increases when burr is activated.
- Check for kinks in the drive shaft and guidewire.
- Confirm that burr is not in contact with the drapes or hemostasis valve.

**Inside the body:**

- If the burr has lodged in the lesion, cease use and remove burr from sheath.
- If the burr is 1.25 mm or 1.50 mm, the burr could be removed from the sheath by rotating burr control knob completely forward and re-advance the burr to the lesion.

**Console emits a hissing noise**

- Check air source pressure (90 - 110 PSI).
- Check all air lines and tubing to ensure they are kink free and connections are tight.
- Advancer may be defective (replace).

**Regulator/Air supply hissing**

- Tighten the regulator connection to the air supply until hissing stops. If hissing does not stop, replace the Teflon™ Tape around the fitting.
- Check the Rotablator Device quick disconnect in the regulator for leaking. If air leak is unresolved after tightening, remove the connector and replace the Teflon tape.