ROTATIONAL Atherectomy SYSTEM

Common Considerations for Peripheral Rotablator™ Rotational Atherectomy System

- 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

**Pre-Procedure Checklist**

- SET UP CONSOLE, FOOT PEDAL AND AIR SUPPLY
- CONNECT ADVANCE TO CONSOLE
- CONNECT SALINE TO ADVANCER
- ADVANCE THE ROTAWIRE™ GUIDEWIRE BEYOND THE LESION
- LOCK ADVANCE KNOB FORWARD AND INSERT BURR THROUGH SHEATH
- RELEASE AND PULL BACK ADVANCE KNOB WHEN BURR IS PROXIMAL TO THE LESION
- PROCEED WITH ROTATIONAL ATERECTOMY
- REMOVE BURR IN DYNAGLIDE™ MODE

**Lubricant INDICATIONS FOR USE:**

- Peripheral Interventions
- Percutaneous rotational angioplasty with the Rotablator Rotational Atherectomy System in Dynaglide™ mode
- Used in the appropriate patient population by a physician who has had adequate training

**Lubricant PRECAUTIONS:**

- Peripheral Interventions
- Discard vial if there are particulates in the emulsion or if an oily film on the vial wall is observed
- Do not modify or repair
- Do not modify or repair
- Do not modify or repair

**Lubrication Restrictions:**

- Peripheral Interventions
- Use only normal saline as the infusate. Never inject contrast agent, radiocontrast agent, or infusate through the angiomax™ guidewire

**ADVERSE EVENTS:**

- Peripheral Interventions
- Discard vial if there are particulates in the emulsion or if an oily film on the vial wall is observed
- Do not modify or repair
- Do not modify or repair
- Do not modify or repair

**CONTRAINDICATIONS:**

- Peripheral Interventions
- Known allergies to olive oil, egg yolk phospholipids, glycerin, sodium deoxycholate, L-histidine, disodium EDTA, sodium hydroxide, and water

**DISCONTINUATION:**

- Peripheral Interventions
- May result in permanent damage to the tissue

**Operator’s Instructions:**

- Peripheral Interventions
- Oxygen is contraindicated in patients with known allergy to the lubricant ingredients: olive oil, egg yolk phospholipids, glycerin, sodium deoxycholate, L-histidine, disodium EDTA, sodium hydroxide, and water.

**Adverse Events:**

- Peripheral Interventions
- Any potential complications associated with the use of a rotating burr should be anticipated and addressed in the planning and treatment of the patient.

**Radiographic Equipment:**

- Peripheral Interventions
- Prior to use, the Rotablator™ System DFU in the product package for complete Directions for Use.

**Boston Scientific**

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Peripheral Interventions

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To order product or for more information contact customer service at 1.888.272.1001.

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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).

<table>
<thead>
<tr>
<th>Introducer/Guide Sheath Selection &amp; Sizing</th>
<th>Minimum Recommended Introducer/Guide Sheath Size*</th>
<th>Diameter (inches)</th>
<th>Burr (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.25</td>
<td>0.049</td>
<td>5 F</td>
<td>1.800</td>
</tr>
<tr>
<td>1.50</td>
<td>0.059</td>
<td>5 F</td>
<td>2.000</td>
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<tr>
<td>1.75</td>
<td>0.069</td>
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<td>2.250</td>
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<tr>
<td>2.00</td>
<td>0.079</td>
<td>6 F / 7 F</td>
<td>2.500</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 advancement.
- **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, torque clip is attached, and tug on wire while rotating to ensure brake is activated.

**BURR POSITIONING**

- Lock advancer knob 2 – 3 cm forward before advancing into guide sheath or introducer sheath.
- Advance burr forward while holding the wire — do not activate burr in guide sheath or introducer sheath.
- When burr is proximal to the lesion, relieve any forward tension on drive shaft by unlocking advancer knob and pulling it back. Ensure the distal tip of the Peripheral RotaWire is far enough beyond the lesion to avoid contact with the rotating burr.

**ABLATION PROCEDURE**

- With 15-30 second runs, advance burr in a smooth pecking motion until all the way through the lesion. Limit total burr time to under 5 minutes. Limit RPM drop to under 5,000 of platform speed (~160,000 RPM).

**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.

**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 carefully attempt to remove the device. Never attempt to start the burr spinning if it has stalled within the lesion.
- Check that the hemostasis valve is not overly tightened to avoid crimping the catheter.
- Evaluate the introducer or guide sheath for kinks.
- Determine if the saline flush was infusing during testing; if not, the motor drive may be affected.
- If the burr is 1.25 mm or 1.50 mm, the burr could be lodged within the sheath. Pull the burr control knob completely forward to dislodge the burr. Leave the 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 tubing to ensure a tight connection.
- Replace the regulator for leaking. If air leak is unresolved after tightening, remove the connector and replace the Teflon tape.

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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.