Preparing the Console

1. First plug in the console to an outlet and press the on button on the front side of the console.

2. Then attach the foot pedal to the console. To do this, there are 3 lines that will need to be connected. The pink line connects to the Dynaglide port on the front side of the console. The blue and green lines connect to the back of the console.

3. Connect your air supply by attaching one end of the air hose to the regulator and the other end to the gas port on the back panel of the console. **NOTE: the dual stage regulator should already be attached to the tank.**

4. Open the valve of the gas tank to pressurize the system. There should be a minimum of 500 psi remaining in the tank and 90-110 psi delivered to the console for each procedure.

Preparing the Saline Bag with Rotaglide™

Rotaglide lubricant is intended for use with the Rotablator atherectomy system, for the purpose of increasing the lubricity of the system.

**How to prepare the saline bag:**

- Using sterile technique, inject the contents of one vial of Rotaglide into 1000 milliliter saline bag.
- Mix the solution thoroughly by rolling the bag several times until the solution is uniformly white in color.

**Note:** Peripheral RotaGlide Lubricant contains egg yolks and olive oil; therefore it is contraindicated for patients who are allergic to these substances.
### PRE PROCEDURE SETUP

1. Remove the Rotawire guidewire from its packaging. **NOTE:** This wire was designed exclusively for use with the Rotablator system. No other guidewire should be used with this system.

2. Insert the distal tip of the wire into the body and advance past the lesion.

3. **Next, prepare the advancer for the case:**
   - First, attach the advancer connections to the console. The black fiber optic cable connects to the front panel of the console.
   - The compressed gas connector connects to the turbine port on the front of the console as well.
   - Attach the saline infusion port of the advancer to the IV tubing of the irrigation source.

4. Slide the pressure cuff in place over the saline bag and inflate to approximately 200 millimeters mercury.

5. Open the irrigation line to allow fluid to flow into the advancer and catheter, which will allow easier loading of the burr catheter onto the wire.

6. Next, remove the distal gripper from the burr.

7. Then backload the burr catheter onto the guidewire until the guidewire appears at the rear of the advancer.

8. Once it appears, connect the wire clip torquer by squeezing the wing tabs to open and allowing the mouth to close carefully over the guidewire.

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**Test the system using the DRAW Acronym**

- **D**rip: Verify that there is irrigation at the distal tip of the burr catheter. The DRIP rate should increase once the system is activated with the foot pedal.
- **R**otation: Verify that the ROTATION speed is at the desired rotation level by adjusting the knob on the front of the console.
  - Small burr (1.25-2.0 mm): 160,000 – 180,000 RPM
  - Large burr (≥ 2.15 mm): 140,000 – 160,000 RPM
- **A**dvancement: Confirm that the ADVANCER knob and burr move freely. Position the advancer knob approximately one inch from the proximal end of the advance slot and tighten.
- **W**ire: Verify the break is holding the WIRE while the burr is spinning.

The test is now complete.

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Once the test is complete, advance the burr forward inside the body to the lesion. When advancing the burr, hold the wire, and do not activate burr while in a guide sheath or introducer sheath. When the burr is proximal to the lesion, relieve any forward tension on the drive shaft by unlocking the advancer knob and pulling it back. Ensure the distal tip of the Rotawire is far enough beyond the lesion to avoid contact with the rotating burr.
**POST PROCEDURE**

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**Catheter Removal using Dynaglide**

- To remove the burr catheter from the patient, put the catheter in Dynaglide mode by stepping on the Dynaglide foot switch on the right side of the foot pedal. This will reduce the rotation speed to between 60,000 and 90,000 RPMs. **NOTE:** The guidewire must be held firmly whenever using Dynaglide mode.

- Press and hold the break defeat button on the distal end of the advancer, step on the foot pedal, and remove the catheter from the patient while maintaining wire position.

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**Catheter Removal using the Docking Port in the Advancer**

- Ensure the torquer is at the end of the guidewire.

- Push the break defeat button and insert the wire clip torquer into the docking port. This eliminates the need to hold the break defeat button manually during removal.

- Step on the foot pedal and remove the burr catheter while maintaining wire position in the patient.

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**Key Considerations**

- Runs should last from 15-30 seconds while advancing the burr in a smooth pecking motion until all the way through the lesion.

- Limit the total burr time to under 5 minutes.

- Monitor the RPMs during the procedure. RPM drop should be limited to under 5,000 RPMs of platform speed.

- Peripheral RotaWire Guidewire is a 0.009” 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.

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For more information please contact your Boston Scientific sales representative.
PI-796401-AA

Peripheral Interventions
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

To order product or for more information contact customer service at 1.888.272.1001.
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PI ROTABLATOR - COMBINED

CAUTION: Federal law (USA) 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.

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. RotaWire INDICATIONS FOR USE / INTENDED USE: These guidewires are intended for use with the Rotablator Rotational Atherectomy System. Lubricant INDICATIONS FOR USE: RotaGlide lubricant is intended for use with the Rotablator atherectomy system, for the purpose of increasing the lubricity of the system. 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: 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. 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 advancer. Operation of the advancer without proper saline infusion may result in permanent damage to the advancer. • 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. Such 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 advancer 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 intended for use with the Rotablator Rotational Atherectomy System for in-stent restenosis might lead to damage of stent components and/or Peripheral RotaLink Plus, which may lead to patient injury. • Always keep the burr advancing or retracting while it is rotating. Maintaining the burr in one location while it is rotating may lead to excessive tissue removal or damage to the Peripheral RotaLink Plus or embolism of the Peripheral RotaLink Plus. It is best to advance and retract the burr no more than 3 cm at a time in a smooth pecking motion, being careful to engage the lesion only minimally when resistance is met. Do not allow the individual burr run time to exceed 30 seconds with total rotational procedure time not to exceed five minutes. RotaWire WARNINGS: Use extreme caution and careful judgment in patients for whom anticoagulation is not indicated. Console WARNINGS: Never use oxygen as the propellant for the Rotablator Rotational Atherectomy System. The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the Rotablator System as replacement parts for internal components, may result in increased emissions or decreased immunity of the Rotablator System. This device is not to be used in the presence of flammable anesthetics. Do NOT operate the Rotablator Console with gas pressures in excess of 758.4 kPa (110 psi) • Do not modify or repair. Lubricant WARNINGS: Discard vial if there are particulates in the emulsion or if an oozing-out of emulsion has occurred. 91059041 Rev/Ver. AC

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