

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
- 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

This checklist is not intended to replace the Directions for Use. Please refer to the Rotablator™ System DFU in the product package for complete Directions for Use.

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

ROTABLATOR™ ROTATIONAL ATHERECTOMY SYSTEM

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.

Rotablink Plus INTENDED 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. **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 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 entrapment of the Peripheral RotaLink Plus. It is best to advance and retreat 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 oiling-out of emulsion has occurred. **PRECAUTIONS:** • Percutaneous rotational angioplasty with the Rotablator Rotational Atherectomy System should only be carried out at medical facilities where prompt treatment can be immediately performed in the event of a potentially injurious or serious complication. • Appropriate drug therapy including (but not limited to) anticoagulant and vasodilator therapy must be provided to the patient during all phases of patient care. • When the Peripheral RotaWire™ Guidewires and/or Peripheral RotaLink Plus are in the body, they should only be manipulated while they are under fluoroscopic observation with radiographic equipment that provides high resolution images. • 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. • The Rotablator Console needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in Appendix D in the DFU. **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. **91059041 Rev/Ver. 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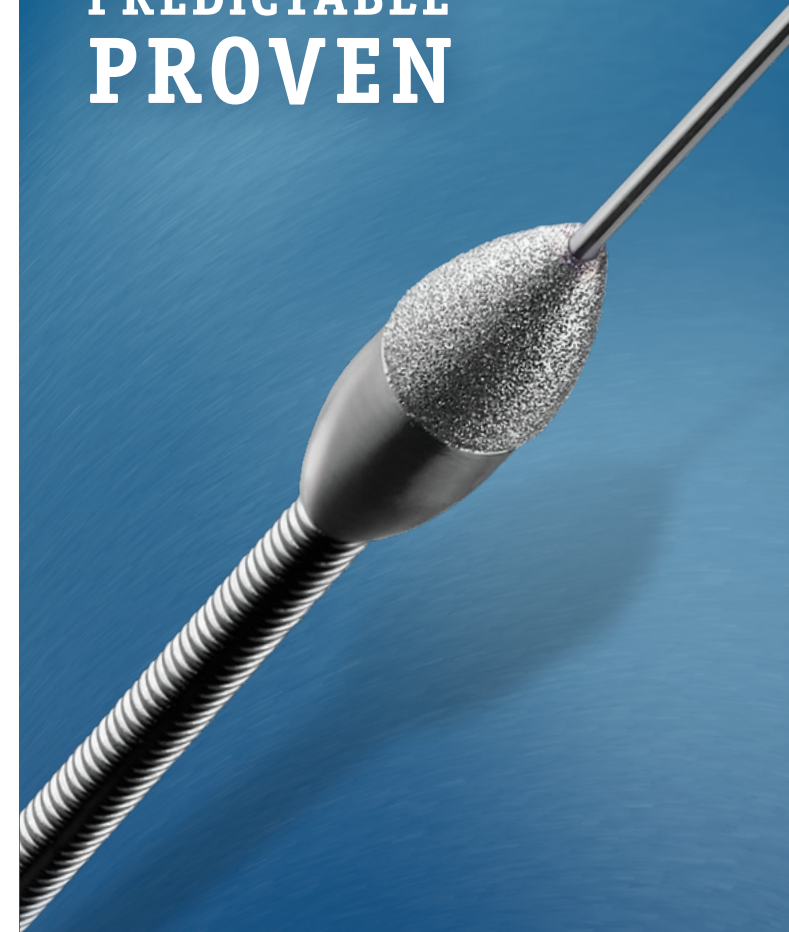
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PERIPHERAL ROATABLATOR™
Rotational Atherectomy System

**PRECISE
PREDICTABLE
PROVEN**



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).

Introducer/Guide Sheath Selection & Sizing

Burr (mm)	Diameter (inches)	Minimum Recommended Introducer/Guide Sheath Size*
1.25	0.049	5 F
1.50	0.059	5 F
1.75	0.069	6 F
2.00	0.079	7 F
2.25	0.089	7 F
2.50	0.098	8 F

- 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.

* 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.

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 0.009" 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.
- **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 regulator for leaking. If air leak is unresolved after tightening, remove the connector and replace the Teflon tape.