Boston Scientific
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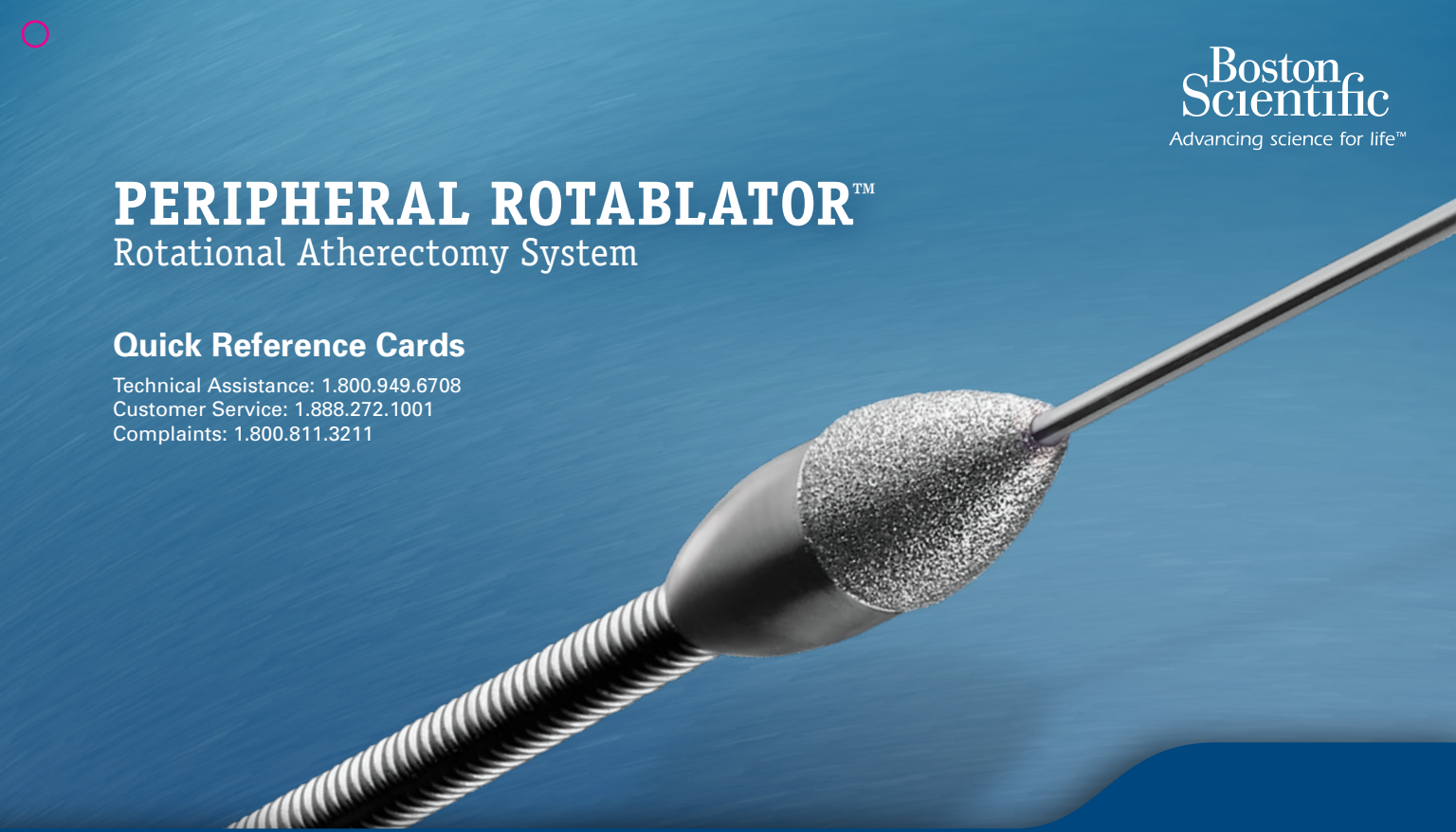
PERIPHERAL ROTABLATOR™

Rotational Atherectomy System

Quick Reference Cards

Technical Assistance: 1.800.949.6708
Customer Service: 1.888.272.1001
Complaints: 1.800.811.3211



PERIPHERAL ROTABLATOR™ Rotational Atherectomy System

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

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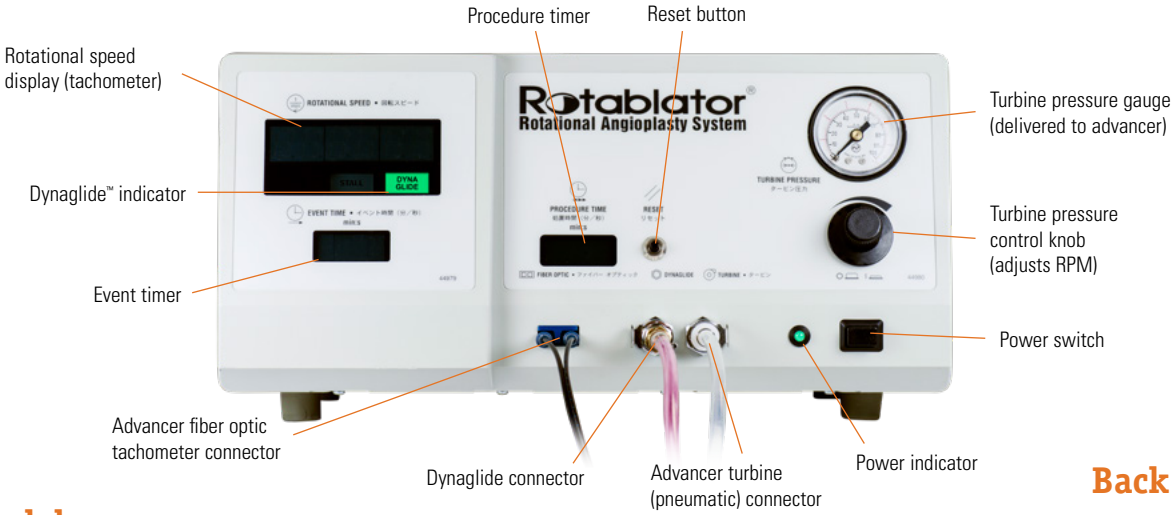
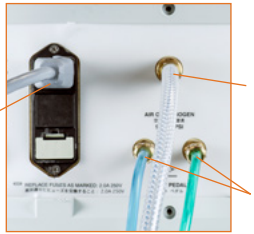
PERIPHERAL ROTABLATOR™ Console



Foot Pedal

Back Panel



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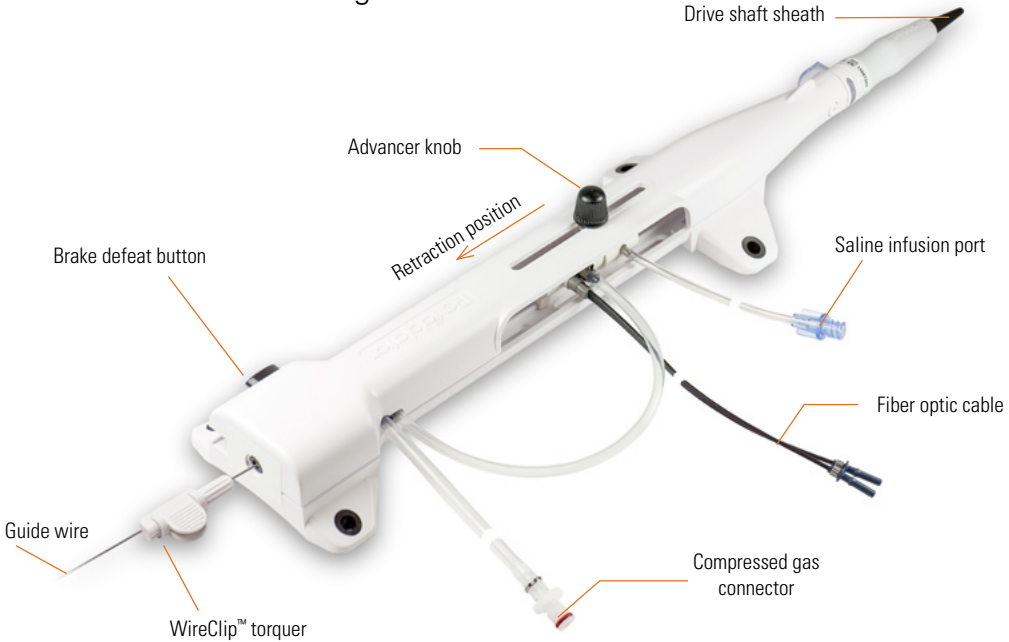
PERIPHERAL ROTALINK™ PLUS Burr Catheter (Advancer)

- 135 cm catheter length
- 4.3 F (0.058″) protective sheath
- 8.9 cm throw length



Burr Size (mm)	Guide Sheath or Introducer Sheath Size*
1.25	5 F
1.50	5 F
1.75	6 F
2.00	7 F
2.25	7 F
2.50	8 F

* 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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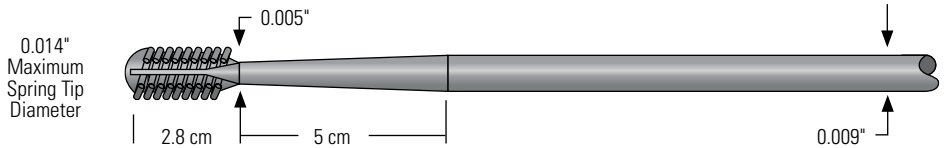
PERIPHERAL ROTAWIRE™ Guidewire

- 330 cm total length
- 0.009" body
- 0.014" spring tip

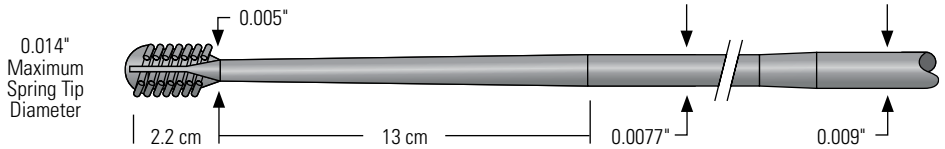
Extra Support

- 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



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PERIPHERAL ROTAGLIDE™ Lubricant

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]

[1] Bersin, Robert M. and Simonton, Charles A. Board Review: *Rotational and Directional Coronary Atherectomy*. Catheterization and Cardiovascular Interventions 2003;58:487.

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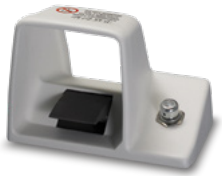
PERIPHERAL ROTABLATOR™ Procedure Steps

System Setup



Monitors gas delivered to console (90-110 psi)

Monitors gas contained in tank (minimum 500 psi)

Burr/Advancer Setup

Pressurize saline mixture to 200 mmHg

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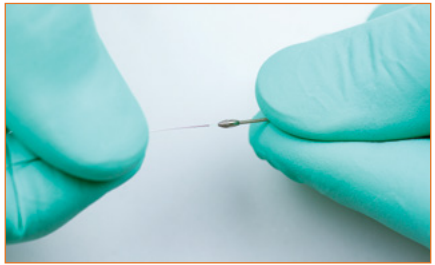
PERIPHERAL ROTABLATOR™ Procedure Steps

Procedure Prep



Backload burr

Test system outside of body with foot pedal activated:

Drip

Rotation

Advancement

Wire

Burr Removal (DynaGlide™)

DynaGlide button

DynaGlide indicator

Two options for brake defeat

Hold button with thumb

OR

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: 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.

Rotalink 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, psudoaneurysm, 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. AC**

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PERIPHERAL ROTABLATOR™ Rotational Atherectomy System

GTIN	Catalog	Description
Peripheral RotaLink™ Plus Burr Catheter • 135 cm catheter length, 0.009" OTW, 4.3 F (0.058") protective sheath		
08714729857808	140-125	1.25 mm Peripheral RotaLink Plus, 5 F
08714729838906	140-150	1.50 mm Peripheral RotaLink Plus, 5 F
08714729838913	140-175	1.75 mm Peripheral RotaLink Plus, 6 F
08714729838920	140-200	2.00 mm Peripheral RotaLink Plus, 7 F
08714729838944	140-225	2.25 mm Peripheral RotaLink Plus, 7 F
08714729838968	140-250	2.50 mm Peripheral RotaLink Plus, 8 F
Peripheral RotaWire™ Guidewire and WireClip™ Torquer • 330 cm length, 0.009" diameter body with 0.014" spring tip		
08714729838890	137-332	Extra Support Peripheral RotaWire (Box of 5)
08714729838883	137-331	Floppy Peripheral RotaWire (Box of 5)
Rotablator Console		
08714729353300	22020-039	Rotablator Console Kit (includes console, foot pedal and 20 ft. air supply hose)
08714729076964	21600-003	20 ft Air Supply Hose – replacement
08714729353317	22436-002	Dynaglide™ Foot Pedal – replacement
08714729229674	22151-001	Console Power Cord – replacement
Accessories		
08714729847557	141-0006	Peripheral RotaGlide™ Lubricant (Box of 6)
08714729263371	15901-01	HTI Regulator Kit
08714729195535	22196-003	WireClip Torquer (Box of 5)

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