Boston Scientific

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Rotablator™

Rotational Atherectomy System

Peripheral RotaLink™ Plus

Pre-Connected Exchangeable Burr Catheter
and Burr Advancing Device

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The Rotablator Rotational Atherectomy System is a catheter-based angioplasty device utilizing a diamond-coated elliptical burr at the tip of a flexible drive shaft. Tracking coaxially over a guidewire and rotating at up to 190,000 RPM, the burr ablates plaque into fine particles that are disposed of by the body's reticuloendothelial system. The Peripheral RotaLink Plus is provided STERILE and non-pyrogenic unless the package has been opened or damaged. It is intended for one procedure use only. Do NOT attempt to reuse or resterilize it.

Contents

Peripheral RotaLink Plus

(1) Peripheral RotaLink Plus Assembly

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.

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.

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.

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.

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.

CLINICAL BACKGROUND

Complications

As with all interventional devices, serious complications, sometimes leading to death, may be associated with the use of the Rotablator Rotational Atherectomy System. Complications associated with the use of the Rotablator Rotational Atherectomy System have been compiled from literature, clinical trials, and reports received through the complaint handling system.

Slow flow represents a reduction of flow, post Rotablator Rotational Atherectomy System treatment, by one to two TIMI grades from the baseline antegrade egress of dye. No flow represents the complete cessation of flow into the distal circulation of the treated vessel not associated with

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mechanical obstruction (dissection flap). Both these events may be associated with a combination of several factors working in synergy, including vasospasm and overburdening of the distal microcirculation with particulate debris. Slow flow and no flow can be minimized by using a technique of slow advancement of the burr, and by limiting the decrement in revolutions per minute to no greater than 5,000. The time of treatment and the interval between treatments should be balanced to allow adequate ablation of the plaque and permit clearance of the debris. A strategy of undersizing the initial burr, and advancing to larger burrs, the use of side hole catheters, maintaining adequate perfusion pressure, and use of vasodilators such as nitroglycerin all act to reduce the incidence and adverse effects of this phenomenon.

Therapies for slow flow should be directed at maintaining and enhancing perfusion pressure. These therapies include volume expansion, bolus flushes of saline or arterial blood through the guide sheath or introducer sheath, intracoronary nitroglycerin to relieve vasospasm, and distal to proximal low pressure balloon inflations. Balloons other than perfusion balloons should be chosen for this purpose, as perfusion balloons may exacerbate the slow flow. Balloon inflations should be short, 20 seconds - 30 seconds. If a perfusion balloon is chosen for other reasons, special attention should be given to maintaining short inflation times.

In addition to these clinical complications there have been complications associated with the guidewire including distortion, kinks, and fracture. Additionally, physical deterioration or malfunction of the device, including detachment of the burr, has been reported.

DESCRIPTION OF THE ROTABLATOR™ ROTATIONAL ATHERECTOMY SYSTEM

The Rotablator Rotational Atherectomy System has four main components. These include the Peripheral RotaWire™ Guidewire, Peripheral RotaLink™ Plus and Rotablator Rotational Atherectomy System Console, which includes the control console, foot pedal and compressed gas supply. The Peripheral RotaLink Plus has been designed to allow the catheter to be separated from the advancer to allow multiple catheters with various burr sizes to be attached to a single advancer during a procedure. The catheter is connected to the advancer to provide an integral system. The advancer and catheter are described below. For descriptions and specifications of the Peripheral RotaWire Guidewires, see the Peripheral RotaWire Guidewire and wireClip™ Torquer "Directions for Use". For descriptions and specifications of the Rotablator Rotational Atherectomy System Console, refer to the "Directions for Use".

DESCRIPTION OF THE COMPONENTS OF THE PERIPHERAL ROTALINK PLUS

Advancer: Illustrated in Figure 1, the advancer acts as a support for the air turbine and as a guide for the sliding elements which control burr extension. A brake within the advancer body holds the guidewire firmly during burr rotation, except in Dynaglide™ mode, to prevent the wire from spinning or moving. Manipulation of the advancer knob allows independent extension of the burr, and manipulation of the wireClip Torquer allows independent movement of the guidewire tip.

The air turbine uses compressed gas to generate the high rotational speeds necessary for ablation. Using compressed gas allows for the use of low, inertial, mass-driving elements which can be quickly started and stopped. The advancer air hose is flexible, allowing convenient placement of the advancer.

The advancer must be used only with guidewires especially designed for and approved for use with the Rotablator Rotational Atherectomy System.

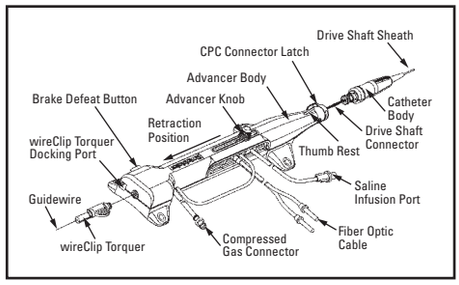

Figure 1. Advancer

Catheter: This includes the burr and helical drive shaft, the sheath, the catheter connection, and the catheter body. As indicated in Figure 2, the diamond-coated burr consists of a tapered body coated with fine diamond particles. The burr spins at high speed and ablates occlusive tissue into fine particles that are carried distally and removed by the reticuloendothelial system. The burr is driven by a flexible helical drive shaft which has a central lumen that permits passage of the guidewire. The advancer connection, in conjunction with the catheter connection, allows the catheter to be separated from and reconnected to the advancer.

The drive shaft and burr can be delivered through the vascular system to the site of a lesion. The Peripheral RotaLink Plus is capable of transmitting rotary motion at speeds up to 190,000 RPM, which results in fine particle ablation of atheromatous tissue by the diamond-coated burr. Burrs are available in the following sizes: 1.25 mm, 1.5 mm, 1.75 mm, 2.0 mm, 2.15 mm, 2.25 mm, 2.38 mm, and 2.5 mm. The catheter is 135 cm in length.

The sheath is 1.4 mm (0.058 in) in diameter and is beveled at the tip to allow easy passage in the vessel. The sheath acts as a conduit to guide the helical drive from the point of entry to the lesion site, protects arterial tissue from the spinning drive shaft, and permits the passage of saline to lubricate the drive. The proximal end of the catheter sheath is permanently attached to the catheter body, and subsequently attached to the advancer.

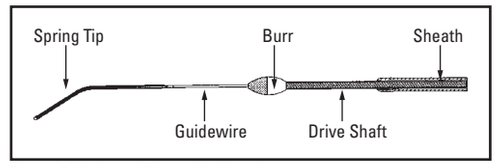

Figure 2. Catheter Tip and Guidewire

HOW SUPPLIED

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and Storage

1. Store in a cool, dry, dark place.
2. Catheters have an expected functional life of 5 minutes for the 1.25 mm - 2.5 mm devices, and the advancer has an expected functional life of 10 minutes. The functional life is the length of time the device will operate within the rotational speed range detailed in Step 5 of the "Clinical Procedure With the Rotablator Rotational Atherectomy System" section of this manual.
3. All disposable portions of the system (advancer, catheter, guidewire, and wireClip Torquer) should be discarded according to hospital practice.

INSTRUCTIONS FOR USE

Setup of the Rotablator Rotational Atherectomy System

1. **Choose a Peripheral RotaLink Plus pre-Connected exchangeable catheter that has a burr appropriately sized for the procedure.**

   A smaller burr may be used to begin treatment. The final burr size used to treat an atherosclerotic artery should have a diameter 70% - 85% of the native artery size.

2. **Select a guide sheath or a introducer sheath with a french size compatible with the largest burr being used in the procedure (see Appendix A). Position the guide sheath or introducer sheath in the vessel.**

3. **Place the guidewire.**

   Place a Peripheral RotaWire Guidewire using standard endovascular procedures. The Peripheral RotaWire Guidewires were designed exclusively for use with the Rotablator Rotational Atherectomy System; other guidewires should never be used.

4. **Remove the Peripheral RotaLink Plus from its shelf box.**

   Open the Peripheral RotaLink Plus shelf box, and remove the tray in its sterile pouch.

   Peel the corner of the sterile pouch until the majority of the tray is exposed.

   Invert the pouch and allow the tray to slide onto a sterile drape, or, alternatively, a person using sterile technique can pull the tray from the pouch and place it on a sterile drape.

   To expose the Peripheral RotaLink Plus, peel away the lid, remove the foam blocks, and gently invert the tray onto the drape. Lift and discard the tray.

   Gently remove the distal gripper from the burr.

   Inspect the Peripheral RotaLink Plus for damage. If there is damage, do not use.

5. **Load the Peripheral RotaLink Plus onto the guidewire.**

   Grasp the proximal tip of the guidewire and thread this end into the hole in the tip of the burr. Continue feeding the wire into the catheter until it appears at the rear of the advancer, then grasp the exposed wire and pull it gently until the burr is a few centimeters from the entrance to the guide sheath or introducer sheath.

   If it is difficult to guide the wire through the advancer, slide the advancer knob back and forth while gently pushing the wire. This will usually ease the wire through the advancer. Remove any lubricant that may have built up on the burr during the guidewire loading. This can be done by gently wiping with a gloved fingertip.

6. **Attach a wireClip Torquer.**

   Attach a wireClip Torquer to the end of the guidewire. While using the Peripheral RotaLink Plus, a torquer should always be in place on the guidewire. The docking port may be used to hold the torquer/guidewire combination. To use the docking port, position the torquer on the proximal end of the wire, as shown in Figure 3, ensuring that no wire extends proximally from the torquer. Gently slide the torquer into the docking port until resistance is felt. **Do NOT depress the brake button and do not force the torquer into the docking port.** With the torquer in the docking port, the guidewire will form a gentle loop. If the docking port is not used, make sure the torquer is lying on the table when attached to the guidewire. Once the torquer is attached, test for successful connection of the advancer and catheter by unlocking the advancer knob and checking advancer motion by moving the burr forward and backwards.

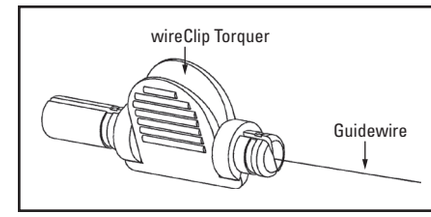

Figure 3. Peripheral RotaWire Guidewire with wireClip Torquer

7. **Connect the air hose.**

   Remove the tie wrap from the air hose on the advancer and uncoil the hose.

   Have nonsterile circulating personnel connect the quick-disconnect to the receptacle labeled TURBINE connector on the front of the console. See Rotablator Rotational Atherectomy System Console "Directions for Use" for location of the connector.

8. **Connect the fiber optic cable.**

   Remove the tie wrap from the black fiber optic tachometer cable on the advancer.

   Have nonsterile circulating personnel insert the fiber optic connectors into the receptacles labeled FIBER OPTIC on the front of the console until they snap securely into place.

   Polarity of the connection is not significant.

9. **Connect the saline infusion bag.**

   Using sterile technique, attach an infusion set to administer normal saline, and connect it to the infusion port on the advancer. The saline should be pressurized with an IV pressure bag to ensure steady infusion against arterial pressure. The recommended pressure is 20 kPA - 26.7 kPA (150 mmHg - 200 mmHg).

   Wait until the saline flows through the advancer and catheter sheath, and exits from the catheter sheath tip running bubble free before beginning procedure. The seals of the advancer are designed to slowly weep saline.

   Never operate the Peripheral RotaLink Plus without saline infusion. Flowing saline is essential for cooling and lubricating the working parts of the Peripheral RotaLink Plus. Operating the Peripheral RotaLink Plus without proper saline infusion may result in permanent damage.

10. **Test the system.**

    Test the system, as outlined in the following section, including setting the optimal burr speed.

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THE ROTABLATOR™ ROTATIONAL ATHERECTOMY SYSTEM TEST PROCEDURE

The Rotablator Rotational Atherectomy System must be tested prior to inserting the burr into the guide sheath or introducer sheath. Before operating the Peripheral RotaLink™ Plus, refer to the "Warnings" and "Precautions" sections of these instructions.

1. **Check console controls.**

   With gas pressure and electricity applied to the console (power switch ON), depress the Dynaglide™ button several times.

   - Note that the green DYNAGLIDE indicator is alternately illuminated and extinguished on the console front panel.
   - Push the Dynaglide button so that the DYNAGLIDE indicator is extinguished.
   - Verify that the catheter sheath tip is in free air and that the burr and guidewire are not in contact with any objects.
   - Turn the turbine pressure adjustment control knob located on the console fully counterclockwise. This will prevent the burr from rapidly spinning if the foot pedal is accidentally depressed.
   - Always ensure that there is a free flow of saline before operating the advancer.

2. **Check air pressure and initial burr speed.**

   Loosen the advancer knob on the top of the advancer, and then slide it back to the fully retracted position.

   Hold the guidewire distal to the burr and hold the distal sheath to provide support for the burr.

   Rotate the turbine pressure knob clockwise to obtain a reading on the turbine pressure gauge of approximately 40 psi (275.8 kPa).

   Place your foot on the foot pedal just enough to completely cover the pedal and fully depress.

   Adjust the turbine pressure knob until the burr is spinning at the correct speed.

1.25 mm - 2.0 mm burrs	190,000 RPM
2.15 mm burrs and larger	180,000 RPM

   Release the foot pedal.

   If the device does not run and the red STALL indicator light is illuminated, release the foot pedal and check all of the advancer connections before trying again.

3. **Check the advancer knob and burr response.**

   After setting the speed adjustment to give the proper burr rotation speed, practice advancing the burr while it is rotating. Loosen the advancer knob and step on the foot pedal. While the burr is rotating, slowly push the advancer knob forward and note the corresponding advancement of the burr along the guidewire to ensure free movement.

4. **Check the automatic brake.**

   While the Peripheral RotaLink Plus is running, attempt to retract the guidewire at the point where it exits from the back of the advancer.

   During normal operation, except in Dynaglide mode, the wire is securely gripped by the internal automatic brake and resists any attempts at rotation or advancement. In some cases, however, it is advantageous to defeat this automatic brake in order to enhance steering of the guidewire or exchange of the advancer.

5. **Check the brake defeat.**

   When using the brake defeat during an exchange procedure, the Dynaglide feature should be activated to provide a rotational speed of approximately 60,000 RPM - 90,000 RPM. During this test, the Peripheral RotaLink Plus may run as fast as 90,000 RPM due to the unloaded state of the burr.

   - Attach the wireClip™ Torquer to the proximal end of the guidewire. Firmly grip the guidewire using the wireClip Torquer prior to operating the device to ensure that the wire will not rotate.
   - Actuate the Dynaglide button to illuminate the DYNAGLIDE indicator on the console front panel.
   - Fully depress the foot pedal and verify that the advancer rotational speed is in the range of approximately 60,000 RPM - 90,000 RPM.
   - Securely grip the guidewire using the wireClip Torquer when defeating the guidewire brake, as the wire may have a tendency to rotate under some conditions.
   - To defeat the automatic guidewire brake, simply depress the guidewire brake defeat button at the back of the advancer while the advancer is running. Now the guidewire, with the aid of the wireClip Torquer, can be manipulated easily.
   - The docking port may be used to maintain the brake in the defeated position. While depressing the brake defeat button, slide the wireClip Torquer/guidewire combination completely into the docking port (see Figure 4). The brake defeat button will remain depressed. **Do not use this feature during ablation.**
   - Release the foot pedal and the brake defeat buttons, allowing the unit to come to a stop.
   - Actuate the Dynaglide button to extinguish the DYNAGLIDE indicator.

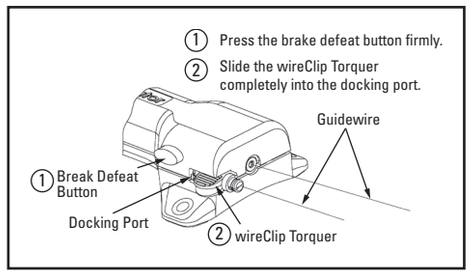

Figure 4. Brake Defeat Button and wireClip Docking Port

Never operate the advancer in Dynaglide mode or operate the guidewire brake defeat unless you have a firm grip on the guidewire using the wireClip Torquer. The wireClip Torquer may be held with the fingers or completely inserted into the docking port after the brake button is depressed. Defeating the brake, or operating the advancer in Dynaglide mode, without securing the guidewire may result in rotation and entanglement of the guidewire.

The burr and helical drive may whip if they are not confined to the lumen of a sheath or vessel at excessive speeds or extensions. When operating the system outside the body, always support the guidewire to prevent whipping.

Note that the drip rate of the saline in the IV set increases when the Peripheral RotaLink Plus is running. This enhanced flow is caused by an internal infusion pump in the advancer that ensures a generous flow of saline during operation. The IV drip chamber should be checked during initial set-up and testing to verify this increase in flow.

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.

This completes the system test procedure. The Rotablator Rotational Atherectomy System can now be used in a percutaneous rotational angioplasty procedure.

CLINICAL PROCEDURE WITH THE ROTABLATOR ROTATIONAL ATHERECTOMY SYSTEM

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 Peripheral RotaLink Plus. Operation of the Peripheral RotaLink Plus without proper saline infusion may result in permanent damage.

1. **Adjust the advancer knob.**

   Prior to inserting the Peripheral RotaLink Plus into the guide sheath or introducer sheath, move the advancer knob forward by approximately 2 cm - 3 cm, and lock it in that position.

2. **Introduce the catheter through the guide sheath or introducer sheath.**

   Advance the catheter through the guide sheath or introducer sheath gently.

   Note: If a hemostasis valve is present then advance the catheter through the hemostasis valve and gently tighten the valve around the catheter sheath to prevent blood loss.

   If the hemostasis valve is tightened excessively, it can crush the catheter sheath around the drive shaft and cause permanent damage to the Peripheral RotaLink Plus. The hemostasis valve should be closed just tight enough to prevent blood loss, but still allow the Peripheral RotaLink Plus to slide through the valve.

3. **Under fluoroscopic guidance, gently push the burr through the guide sheath or introducer sheath to a point immediately proximal to the lesion.**

   Never activate the burr while exiting the guide sheath or introducer sheath.

   Check that the size of the burr is compatible with the vessel diameter by contrast injection.

   Verify that the guidewire tip (Figure 2 Spring Tip) is distal to the lesion and will not come in contact with the rotating burr.

4. **Stop the burr in free lumen.**

   When the burr is 1 cm to 2 cm proximal to the lesion, retract the advancer knob fully. This will prevent the burr from darting forward when activated.

5. **Check the free lumen speed.**

   Fully depress the foot pedal switch to activate the burr. Retract your foot slightly for optimum positioning on the foot pedal. Recheck the rotational speed reading to verify that the rotation rate is appropriate for the burr size and lesion type, and adjust the operating speed.

1.25 mm - 2.0 mm burrs	160,000 RPM up to 180,000 RPM
2.15 mm burrs and larger	140,000 RPM up to 160,000 RPM

6. **Burr advancement and ablation technique.**

   Slowly push the advancer knob forward and observe progress of the burr fluoroscopically. Advance at a rate such that the burr speed is decreased no more than 5,000 RPM from the unloaded, platform speed. This can be determined initially by observing the console display, and subsequently, by listening to the corresponding drop in audible pitch.

   Maximum blood flow should be maintained during the procedure to facilitate the distal flushing of particles generated during treatment with the Rotablator Rotational Atherectomy System.

   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 Peripheral RotaLink Plus. Guidewire buckling may occur and perforation or vascular trauma may result. Always advance the rotating burr by using the advancer knob. If resistance to motion is encountered, retract the burr and stop treatment immediately. Use fluoroscopy to analyze the situation.

   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.

   By keeping the rotational speed within 5,000 RPM of the free lumen platform speed, the operator can:

   - Minimize torque stress on the vessel.
   - Maximize the polishing effect on the lumen.
   - Minimize the particle size.
   - Optimize overall procedural control.

   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 engage the lesion only minimally when resistance is met. Short individual runs of less than 30 seconds are recommended with total rotational procedure time not to exceed five minutes.

7. **Check treatment with fluoroscopy.**

   Retract the burr and inject contrast through the guide sheath or introducer sheath side arm to assess the effectiveness of treatment.

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Black (K) ΔE ≤5.0

Manual withdrawal of the burr may be difficult following ablation of a lesion when performing an exchange procedure. Removal difficulties may include: an episode of extreme artery spasm around the burr, a burr to artery ratio too great for a heavily calcified tortuous vessel.

Excessive or sharp pulling of the Peripheral RotaLink™ Plus during manual removal can cause separation of the burr from the drive shaft.

It is also possible for the burr to become entrapped at the guide sheath/introducer sheath tip or in a kink in the guide sheath. If significant resistance is felt during removal, stop manual retraction and move the Peripheral RotaLink Plus forward to attain a coaxial position with the guide sheath or introducer sheath, and again manually retract the burr.

8. **Complete treatment with the first burr.**

   If luminal patency is adequate, withdraw the burr and advancer sheath from the vessel.

   Treatment can be repeated by exchanging to a Peripheral RotaLink Plus with a larger burr until the lumen is enlarged to the point of hemodynamic relief. A finished lumen equal to 70% - 85% of the native diameter is considered optimal.

9. **Exchange procedure.**

   To exchange the Peripheral RotaLink Plus, first attempt to remove the Peripheral RotaLink Plus by pushing the guidewire into the rear of the advancer while simultaneously retracting the burr to the guide sheath or introducer sheath. Fluoroscopic surveillance will assist in maintaining the guidewire in position while the burr is being withdrawn.

   If the guidewire does not move readily in this situation due to the tortuosity of the vasculature, an alternative feature (Dynaglide™) is available.

10. **Use the Dynaglide feature to exchange, if needed.**

    When the Dynaglide feature is activated the Rotablator™ Rotational Atherectomy System will rotate at reduced speed, 60,000 RPM - 90,000 RPM, and the guidewire will advance readily while the advancer is withdrawn. The guidewire must be held in a firm grip using the wireClip™ Torquer whenever the advancer is operated in Dynaglide mode.

    Activate the Dynaglide feature by pressing the button on the foot pedal. The DYNAGLIDE indicator on the console will illuminate. With the wireClip Torquer/guidewire combination in the docking port, depress the brake defeat button and push forward on the torquer until it stops, locking the brake defeat button in the depressed position. This eliminates the need to hold the brake defeat button manually. The burr may then be withdrawn over the guidewire until a 7 cm or larger loop of wire remains. Release the foot pedal.

11. **Remove Peripheral RotaLink Plus from the guidewire.**

    Before removing the Peripheral RotaLink Plus from the guidewire, ensure that the Dynaglide feature has been deactivated by pressing the button on the foot pedal. Press on the brake defeat button and remove the wireClip Torquer from the docking port. Release the guidewire from the torquer and complete the removal of the Peripheral RotaLink Plus.

12. **If another burr is required to complete the procedure and a Peripheral RotaLink Plus is to be utilized, prepare the device as described starting in Step 4 of "Setup of the Rotablator Rotational Atherectomy System".**

13. **Prepare for treatment with the next Peripheral RotaLink Plus.**

    Confirm that the DYNAGLIDE indicator on the console is extinguished. Reset the burr rotational speed to the normal ablation range prior to operating the new Peripheral RotaLink Plus.

1.25 mm - 2.0 mm burrs	160,000 RPM up to 180,000 RPM
2.15 mm burrs and larger	140,000 RPM up to 160,000 RPM

    Always test the new Peripheral RotaLink Plus prior to use as described in the preceding portions of this manual. Throughout the course of the percutaneous rotational angioplasty procedure with the Rotablator Rotational Atherectomy System, periodically check the pressure of the advancer saline infusate. The recommended pressure is 20 kPA - 26.7 kPA (150 mmHg - 200 mmHg).

    If complimentary or adjunctive balloon angioplasty is required or deemed desirable to achieve the final result after rotational angioplasty, it is recommended that a slightly oversized angioplasty balloon inflated to 101.3 kPa (1 atm/bar) be used to reduce vessel wall barotrauma.

14. **Completing the procedure.**

    You must extinguish the DYNAGLIDE light on the console front panel. This is done by pressing the button on the foot pedal. Turn off the console and the control console system. The console and foot pedal should be cleaned as described in the appropriate section of the Rotablator Rotational Atherectomy System Console "Directons for Use".

TROUBLE SHOOTING

Blood in the Catheter Sheath

If blood is observed in the catheter sheath, treatment should be discontinued. Verify that the saline infusion is properly connected, pressurized, and flowing. If the device is properly connected and blood continues to flow up the catheter sheath, replace the Peripheral RotaLink Plus with a new device.

Stalled Console

If the console STALL indicator illuminates, release the foot pedal to clear the stall condition. Examine the airhose for kinking, check advancer connections and then depress the foot pedal to continue. If the STALL indicator is still illuminated, discontinue procedure and contact your sales representative.

Burr Detachment

The Peripheral RotaWire™ employs a tip to retain the burr if the burr becomes separated from the drive shaft. If the burr detaches, do not turn on the air turbine. Carefully advance the non-rotating drive shaft and retract the burr and guidewire until the distal tip of the drive shaft and proximal tip of the burr are in contact. Withdraw the drive shaft, burr, and guidewire as a unit with tension applied on the guidewire to keep the burr adjacent to the distal end of the drive shaft. Inject IV nitroglycerin to relieve any spasm.

Burr Lodged in the Catheter Sheath

If a 1.25 mm or 1.5 mm burr becomes lodged in the catheter sheath, attempt to free it by retracting the Peripheral RotaLink Plus into the straight section of the guide sheath or introducer sheath, and push the advancer knob fully forward. While reinserting the Peripheral RotaLink Plus, leave the advancer knob pushed fully forward until the burr is just proximal to the lesion. Retract the advancer knob and readjust the Peripheral RotaLink Plus so that the burr remains in position proximal to the lesion. Verify that the DYNAGLIDE indicator on the console is extinguished. If not, depress the Dynaglide button.

Blank RPM Display During Procedure

The RPM display will go blank during burr rotation if the user inadvertently lifts his foot, releasing pressure on the foot pedal switch. Should this occur, fully depress the foot pedal again to regain the RPM display.

Burr Spins After Foot Pedal is Released

In the unlikely event that during a Rotablator Rotational Atherectomy System procedure the burr continues to spin after the foot pedal has been fully released, take the following action: turn down the rotational speed on the console to the burr exchange speed (60,000 RPM to 90,000 RPM range); retract the burr from the artery using the same technique as the burr exchange procedure, discontinue use of the Rotablator Rotational Atherectomy System. Return the foot pedal to Customer Service for a replacement.

Burr Not Spinning

In the unlikely event that the burr does not spin when the foot pedal is depressed, and the turbine in the advancer is turning, perform procedure outlined in Step 5 of the "Setup of the Rotablator Rotational Atherectomy System" section.

EXPIRATION DATING

The Peripheral RotaLink Plus is intended to be a single-use device and should be disposed of after a single procedure. The Peripheral RotaLink Plus should be used prior to the expiration date indicated on the shelf box and tray lid label. **DO NOT RESTERILIZE.**

Appendix A. Recommended Guide Sheath or Introducer Sheath Sizes

Burr Size (mm)	Guide Sheath or Introducer Sheath Size French*
1.25	5F
1.50	5F
1.75	6F
2.00**	7F
2.15	7F
2.25	7F
2.38	8F
2.50	8F

* 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.
** The 2.00 mm Peripheral RotaLink Plus burr size allows for use with a 6F Terumo Destination™ guide sheath. In all other cases a 7F guide sheath or introducer sheath should be used with the 2.00 mm burr size.

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