The spring tip configuration isatraumatic, radiopaque, and can be shaped to form a steerable system. The wire shaft is constructed of stainless steel with a smooth finish. These guidewires, designed exclusively for the Rotabrator Rotational Atherectomy System, can be independently advanced and steered.

wireClip Torquer

The wireClip Torquer is a plastic device that attaches to guidewires that have shaft diameters from 0.009 in (0.24 mm) to 0.018 in (0.46 mm). The wireClip Torquer provides a convenient gripping surface for manipulating Peripheral RotaWire Guidewires (Reference Figure 1).

Table 1. Peripheral RotaWire Guidewires and wireClip Torquer Guidewire and Guidewire Manipulation Device

<table>
<thead>
<tr>
<th>Wire Type</th>
<th>Shaft Characteristic</th>
<th>Spring Characteristic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral</td>
<td>Long taper, minimum</td>
<td>Soft, 2.2 cm</td>
</tr>
<tr>
<td>RotaWire</td>
<td>guidewire bias (most flexible)</td>
<td></td>
</tr>
<tr>
<td>Floppy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extra Support</td>
<td>Short taper, stiffer,</td>
<td>Soft, 2.8 cm</td>
</tr>
<tr>
<td></td>
<td>and increased</td>
<td></td>
</tr>
<tr>
<td></td>
<td>guidewire bias (stiff)</td>
<td></td>
</tr>
</tbody>
</table>

The 0.009 in (0.24 mm) Peripheral RotaWire Guidewire is smaller in diameter than other commercially available guidewires used in angioplasty. Therefore, handle the guidewire carefully to prevent a tight loop, kink, or sharp bend (> 90°) from forming in the guidewire, which may cause it to fracture during use. Resulting wire fracture may require additional percutaneous intervention or surgery.

Do not allow the burr to remain in one location while rotating at high speeds, as this may lead to wear of the guidewire. Gently advance or retract the burr while it is in high-speed rotary motion. In instances when long ablation runs are required - particularly in calcified, angulated lesions - reposision the guidewire to expose a previously unused segment or extange the guidewire to prevent damage. Ensure that the free lumen rotational speed of the burr does not exceed 180,000 rpm for 1.25 mm to 2.0 mm burrs and 160,000 rpm for the 2.15 mm and larger burr sizes.

In patients with very small vessels take caution not to exceed the recommended burr-to-vessel ratio threshold of 0.7. The use of a relatively stiff Peripheral RotaWire Guidewire may straighten a vessel such that it places the point of attack of the burr on the lesser curvature of the vessel (burr bias) potentially inducing vasoospasm and pseudostenoses that result in perforation and/or dissection.

Care needs to be taken to maintain coaxial alignment of the guide sheath and Peripheral RotaWire/burr assembly during ablation. Failure to do so may cause a transient perforation. Peripheral RotaWire Guidewire that may result in embolism, dissection, and/or surgical intervention and in rare cases, death.

Do not torque, advance or withdraw guidewire if significant resistance is felt. Exercise care in handling of the Peripheral RotaWire Guidewire during the procedure to reduce the possibility of accidental bending, kinking, or loop making. A tight loop, kink or sharp bend greater than 90 degrees in the guidewire may cause fracture during use. Resulting wire fracture may require additional percutaneous intervention or surgery.

Never advance the rotating burr by pushing in on the sheath, as this may result in buckling of the guidewire and perforation or vascular trauma. Always advance the rotating burr by using the advance button.

Never advance the rotating burr to the point of contact with the guidewire spring tip, as this may result in distal detachment and embolization of the tip.

**PRECAUTIONS**

Do not use if package or device is opened or damaged. Do not advance the guidewire spring tip into distal, narrow vasculature unless treatment requires you to do so, as this may cause the spring to unravel or the guidewire to fracture. If the guidewire spring appears to be unraveling during removal, stop the removal procedure. Carefully place a balloon catheter or exchange catheter over the guidewire, positioning the device as distal as possible. If you use a balloon catheter, briefly inflate the balloon as necessary to relieve any spasms. When the spasm stops, continue to gently remove the guidewire.

The 0.009 in (0.24 mm) Peripheral RotaWire Guidewire is smaller in diameter than other commercially available guidewires used in angioplasty. Therefore, handle the guidewire carefully to prevent a tight loop, kink, or sharp bend (> 90°) from forming in the guidewire, which may cause it to fracture during use. Resulting wire fracture may require additional percutaneous intervention or surgery.

Do not proximally remove guidewire from carrier tube as it may result in kinked, bent guidewires or tips.

Do not operate the Rotablator Rotational Atherectomy System if there is a bend, kink, or loop in the guidewire or if the spring tip is prolapsed.

Table 1. Peripheral RotaWire Guidewires and wireClip Torquer Guidewire and Guidewire Manipulation Device

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<tbody>
<tr>
<td>Peripheral RotaWire Floppy</td>
<td>Long taper, minimum guidewire bias (most flexible)</td>
<td>Soft, 2.2 cm</td>
</tr>
<tr>
<td>Peripheral RotaWire Extra Support</td>
<td>Short taper, stiffer, and increased guidewire bias (stiff)</td>
<td>Soft, 2.8 cm</td>
</tr>
</tbody>
</table>

**CONTRAINDICATIONS**

Carefully read this document and refer to the Rotablator Rotational Atherectomy System Console “Directions for Use” and Peripheral RotaLink Plus “Directions for Use”, observing all Contraindications, Restrictions, Warnings, and Precautions for specific information on the use of these components.

**WARNINGS**

When advancing or removing the guidewire, always use fluoroscopic guidance with radiographic equipment that provides high resolution images. Never position the guidewire blindly, as this may result in misplacement, dissection or perforation. Since the guidewire functions as a balloon catheter/burr tracks over, it is imperative that you initially place the guidewire in the stenotic lumen or the virtual lumen of the vessel and not in a false channel.

During burr advancement and ablation, advance at a rate such that the burr speed is decreased no more than 500 rpm from the unloaded platform speed. Use extreme caution and careful judgment in patients for whom anticoagulation is not indicated.

In patients with very tortuous vessels, the relatively stiff Peripheral RotaWire Guidewire tends to straighten the vessel and places the point of attack of the burr on the lesser curvature of the vessel (burr bias). The floppy wire tends to minimize guidewire bias but may fail to control the travel of the burr leading to uncontrolled cutting of the greater curvature of the vessel.

Exercise care in handling of the guidewire during a procedure to reduce the possibility of accidental breakage, bending, kinking, or coil separation. Resulting guidewire fractures may require additional percutaneous intervention or surgery.

Do not allow the individual burr run time to exceed 30 seconds as this may lead to wire fracture/lop separation that may result in perforation, dissection, embolism and in rare cases, death. The Peripheral RotaWire Guidewire has an expected functional life of 5 minutes (total of individual burr run times).
INSTRUCTIONS FOR USE

Each guidewire is packaged in a sterile peel pouch that has a chevron seal. The wireClip Torquer is packaged with the guidewire on a holding card. Select the appropriate guidewire for the procedure; then follow these steps:

1. Using sterile technique, open the pouch and extract the packaging tube that contains the guidewire.
2. Unload the guidewire from the packaging coil as follows:
   A. Locate the proximal wire retainer on the inside diameter of the coil. Carefully remove the wire from the retainer. This will expose the proximal end of the guidewire.
   B. Locate the guard tubing on the outside of the coil. Grasp the tubing and pull back gently to release the end from the small distal anchor tube.
   C. Remove the guard tubing, sliding it forward off the coil. This will expose the distal end of the guidewire and the spring tip.
   D. Grasp the exposed distal guidewire near the end of the coil tube and gently pull it out of the package. Care should be taken to avoid grasping the spring tip.

3. The guidewires are coated with a thin film of lubricant which may appear as a white powder. Do not wipe off lubricious coating. The lubricant can cause the guidewire to adhere to the inside of the tube, making unloading difficult. If this happens, gently tap the outside of the coil to loosen the wire. Use care not to stretch or damage the spring tip.
4. Gently form the spring tip of the guidewire. Inspect the spring tip region for damage. If damaged, do not use. Handle the guidewire carefully to prevent a tight loop, kink, or sharp bend (> 90°) from forming. These will make passage of the wire through the advancer difficult and may cause it to fracture during use.
5. Using standard sterile angioplasty procedure, and under fluoroscopic guidance, gently advance the guidewire past the lesion, using a bare-wire or free-wire technique. The spring tip must be placed distal to the lesion.
6. Grasp the proximal tip of the guidewire and thread this end into the hole in the tip of the burr. Secure the guidewire in place while tracking the advancer over the guidewire and across the lesion. Continue feeding the wire into the Peripheral RotaLink™ Plus until it appears at the back of the advancer; then grasp and gently pull the exposed wire until the burr is a few centimeters from the guide sheath or introducer sheath.
7. If you have difficulty guiding the wire through the advancer, slide the advancer button back and forth while gently pushing the wire. This usually helps to ease the wire through the advancer. Remove any lubricant that may have built up on the Burr by gently wiping it with a gloved fingertip.
8. The advancer has an internal guidewire brake that is automatically applied when compressed gas is supplied from the console. This brake prevents the guidewire from rotating. Secure the guidewire in place while tracking the advancement of the advancer.
9. When using the Peripheral RotaLink Plus, a wireClip Torquer should always be placed on the guidewire. Attach a wireClip Torquer to the guidewire at a point a few centimeters behind the tip of the advancer. To attach the wireClip Torquer, squeeze the two handles to open the clip jaws, place the clip adjacent to the guidewire, then move the clip until the wire is entirely engaged in the groove. Release the handles to allow the wireClip Torquer to securely grasp the wire. This will facilitate steering and advancement of the wire, if the wire is not already placed distal to the lesion.
10. Manipulate the guidewire with the wireClip Torquer by firmly gripping only the cylindrical portion of the guidewire, not the coil. The clip can be repositioned as often as necessary. Always ensure that the wire is entirely engaged in the groove of the clip. If a loop forms in the guidewire, never pull to straighten it. To remove loop, follow these steps:
   Step 1. Using the wireClip™ Torquer, rotate the guidewire one-half turn clockwise (Reference Figure 2).
   Step 2. If the loop still exists, rotate the wire one-half turn in the other direction (counterclockwise) and reevaluate (Reference Figure 3).
   Step 3. With the loop removed, continue the procedure or withdraw the device. Be sure that the proximal end of the guidewire is at all times located on the sterile covering cloth or on a similar insulating protective material.

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
- Slow flow, no flow, abrupt vessel closure
- Stroke
- 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.

HOW SUPPLIED

Handling and Storage

Store in a cool, dry, dark place. Do not use if packaging is opened or damaged. Do not use if labeling is incomplete or illegible. Use the device prior to the “Use by” date noted on the product label.