Boston Scientific

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Rotablator™

Rotational Atherectomy System

Peripheral RotaWire™ Guidewire and wireClip™ Torquer

Guidewire and Guidewire Manipulation Device

℞ ONLY

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

CAREFULLY READ AND UNDERSTAND ALL INSTRUCTIONS, INDICATIONS, CONTRAINDICATIONS, RESTRICTIONS, WARNINGS, PRECAUTIONS, ADVERSE EVENTS AND DIRECTIONS FOR USE PRIOR TO USING THE GUIDEWIRE IN THE PERIPHERAL ROTALINK™ PLUS AND THE ROTABLATOR CONSOLE DIRECTIONS FOR USE. FAILURE TO DO SO COULD RESULT IN COMPLICATIONS.

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

Guidewire

The Peripheral RotaWire Guidewires available for use with the Peripheral RotaLink Plus are: Floppy and Extra Support Peripheral RotaWire Guidewires.

These guidewires are all 0.009 in (0.24 mm) in diameter with an enlarged distal spring tip of 0.014 in (0.36 mm) diameter. The overall length of the guidewire is 330 cm. The guidewires are differentiated on the basis of the spring tip length and the stiffness of the shaft proximal to the spring. A comparison of the guidewires is shown in Table 1.

Table 1.

Wire Type	Shaft Characteristic	Spring Characteristic
Peripheral RotaWire Floppy	Long taper, minimum guidewire bias (most flexible)	Soft, 2.2 cm
Peripheral RotaWire Extra Support	Short taper, stiffer, and increased guidewire bias (stiff)	Soft, 2.8 cm

The spring tip configuration is atraumatic, 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 Rotablator 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).

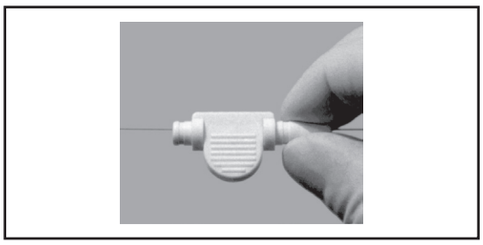

Figure 1. wireClip Torquer

Contents

One (1) Peripheral RotaWire Guidewire

One (1) wireClip Torquer

INDICATIONS FOR USE/INTENDED USE

These guidewires are intended for use with the Rotablator Rotational Atherectomy System.

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 monorail that the advancer/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 5000 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 might 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/tip 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).

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 vasospasm 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 Guidewire/burr assembly during ablation. Failure to do so may cause a transected 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 advancer 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.

Never operate the guidewire brake release unless you have a firm grip on the guidewire using the wireClip Torquer. Releasing the brake without first securing the guidewire may result in rotation and entanglement of the guidewire.

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 - reposition the guidewire to expose a previously unused segment or exchange 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.

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 spasm. 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.

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).

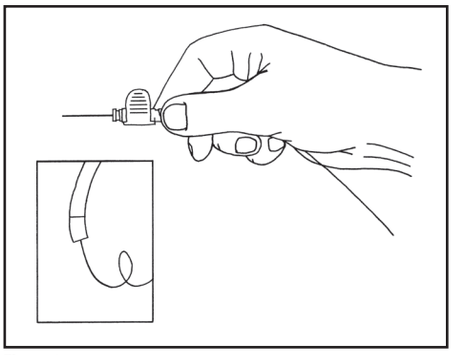

Figure 2.

Step 2. If the loop still exists, rotate the wire one-half turn in the other direction (counterclockwise) and reevaluate (Reference Figure 3).

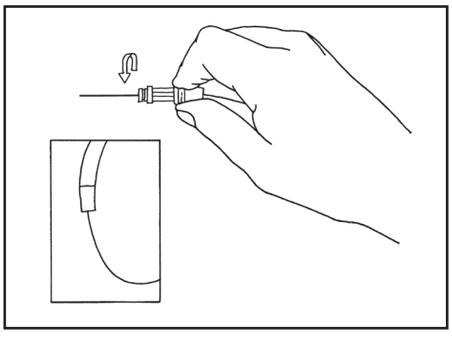

Figure 3.

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 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, 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.

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.

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.

   Distal Unloading

   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.

   Note: The guidewire may be unloaded directly from the package into the guide sheath (Reference Figure 4). Inspect the guidewire for damage. If damaged, do not use.

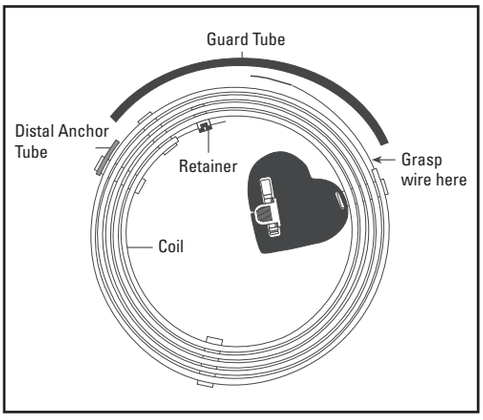

Figure 4.

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 during operation 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 end 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 wireClip Torquer. The clip can be repositioned as often as necessary. Always ensure that the wire is entirely engaged in the groove of the clip.
11. To test the internal guidewire brake, grasp the wireClip Torquer while the Peripheral RotaLink Plus is running and attempt to retract the guidewire at the point where it exits from the back of the advancer. During normal operation, the wire is securely gripped by the internal automatic brake and resists any attempts at rotation or advancement. In some cases, however, you may want to release the brake in order to better steer the guidewire or to exchange the advancer. When you use the brake release, always ensure that you attach the wireClip Torquer properly and hold the wireClip Torquer firmly to prevent the guidewire from rotating. Secure the guidewire in place while tracking the interventional device over the guidewire and across the lesion.
12. Once the procedure is completed, first remove the wireClip Torquer from the Peripheral Rotawire Guidewire before removing the Peripheral Rotalink Plus and Peripheral RotaWire Guidewire assembly.
13. After use, dispose of all products and packaging in accordance with hospital, administrative and/or local government policy.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose**. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments**.

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Do not use if package is damaged.

Recyclable Package

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