

# REVOLUTION™

## Peripheral Atherectomy Guidewire

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### Instructions For Use

All instructions should be read before use

**CAUTION** – Investigational Device. Limited by Federal (or United States) law to investigational use.

#### **PRODUCT DESCRIPTION:**

The Revolution™ Peripheral Atherectomy Guidewire is made of a smoothly finished 335 cm stainless steel, 0.014" shaft diameter with a silicone outer coating. The spring tip allows for an atraumatic, radiopaque distal end that can be bent to form a steerable system. The Revolution™ Peripheral Atherectomy Guidewire is supplied with a standard plastic torque device, compatible with any guidewire of shaft diameter .009" to .018". The torque device attaches to the guidewire and provides a gripping surface for manipulating the guidewire.

#### **INDICATIONS FOR USE:**

The Revolution™ Peripheral Atherectomy Guidewire is intended for use with the Revolution™ Peripheral Atherectomy System. Carefully read these Instructions for Use, and refer also the Revolution™ Peripheral Atherectomy System Instructions for Use that are packaged with the Revolution™ Peripheral Atherectomy System, following all instructions and observing all precautions and warnings described in these documents.

#### **WARNINGS:**

- Ensure the patient is adequately anticoagulated prior to insertion of the Revolution™ Peripheral Atherectomy Guidewire into the patient's vasculature. Maintain adequate systemic anticoagulation until the device has been removed.
- Always use fluoroscopy when advancing the guidewire to avoid misplacement, dissection, or perforation. The Revolution™ Peripheral Atherectomy System tracks over the guidewire, so it is imperative that the guidewire be placed through the stenotic lumen.
- Never advance the Revolution™ Peripheral Atherectomy System to the point of contact with the Revolution™ Peripheral Atherectomy Guidewire spring tip as this may result in distal detachment and embolization of the tip.
- Inspect the guidewire prior to use for coil separation, kinking or breakage. If the wire is damaged, do not use.
- During operation of the Revolution™ Peripheral Atherectomy System, the handle should be continuously advanced. Activating the burr in a stationary position may lead to excessive wear and possible damage to the Revolution™ Peripheral Atherectomy Guidewire.

The Revolution™ Peripheral Atherectomy Guidewire is intended for use only with the Revolution™ Peripheral Atherectomy System. It should not be used with other atherectomy devices, as this may result in device damage and/or patient injury.

### **CONTRAINDICATIONS:**

The Revolution™ Peripheral Atherectomy Guidewire is contraindicated in the following situations:

- This system is contraindicated when, in the medical judgment of the physician, such a procedure may compromise the patient's condition.
- Occlusions through which a guidewire will not pass.
- This system is not intended for use in coronary arteries
- The target lesion is within a bypass graft or stent.
- In patients with angiographic evidence of significant dissection at the treatment site. The patient may be treated conservatively to permit the dissection to heal before treatment.
- This device is contraindicated in patients who cannot receive recommended anti-platelet and/or anticoagulant therapy.

### **PRECAUTIONS:**

- Carefully read all instructions prior to use. Observe all warnings and cautions noted throughout these instructions. Failure to do so may result in complications.
- Refer to the instructions supplied with the Revolution™ Peripheral Atherectomy System for its Intended Uses, contraindications, and potential complications.
- If the Revolution™ Peripheral Atherectomy Guidewire's sterile package appears damaged or shelf life has expired, do **not** use the guidewire.
- Follow standard hospital atherectomy policies and procedures, including those related to anticoagulation and vasodilator therapy.
- Because of the torque responsiveness of the guidewire, it is more difficult to handle than other commercially available guidewires used in peripheral angioplasty. Exercise care when using this guidewire. A tight loop, kink, or bend in the guidewire may cause damage and system malfunction during use.
- Hold the proximal end of the guidewire securely when the drive unit is activated using the supplied torque device, otherwise the guidewire may move or whip resulting in damage or loss of guide wire position.
- Ensure that the device tracks smoothly and easily over the guidewire during use. If the drive shaft does not track easily over the guidewire, immediately turn off the system and replace the device.

### **ADVERSE EVENTS**

- Practitioners must be aware of potential complications associated with use of a peripheral atherectomy guidewire including, but not limited to:

- Additional Intervention
- Allergic reaction
- Amputation
- Death
- Embolism
- Hematoma/Hemorrhage
- Hemodynamic changes
- Hemoglobinuria
- Bleeding complications
- Pain and tenderness
- Access site injury
- Hypotension
- Infection or fever
- Restenosis
- Stroke
- Slow, no flow, abrupt vessel closure
- Surgery including arterial bypass
- Thrombosis and vessel occlusion
- Vessel Trauma (vasospasm, dissection, perforation, pseudoaneurysm, arteriovenous fistula)

There also may be complications associated with distortion, kinks, and fracture of the guidewire, which can lead to patient injury.

## HOW SUPPLIED

The Revolution™ Peripheral Atherectomy Guidewire is packaged with a torque device.

## SUGGESTED PROCEDURE

### Revolution™ Peripheral Atherectomy Guidewire Procedure:

*The exact treatment procedure is to be determined by the physician. The following option describes how the procedure may be performed.*

1. Prepare the Revolution™ Peripheral Atherectomy System according to its instructions.
2. To remove the Revolution™ Peripheral Atherectomy Guidewire from the hoop dispenser, remove the tab holding the exposed segment of wire in place. Push on the exposed segment of wire until the distal tip and core of the wire exit the hoop. **Warning: Do not grasp the distal tip of the wire to remove it from the dispenser. Use care to not stretch or damage the spring tip while unloading.**
3. Gently shape the distal tip using standard tip shaping technique. Do not use a shaping instrument with a sharp edge.
4. Load the guidewire into a vascular introducer sheath in the vessel access site using standard puncture technique.
5. Using standard angioplasty procedure, and under fluoroscopic guidance, gently advance the guidewire past the target lesion location. **Precaution: The spring tip should be placed at least 10 cm distal to the lesion.**
6. Hold the guidewire in place and advance the Revolution™ Peripheral Atherectomy System (see further detail in the System IFU) until the ablation burr is positioned proximal to the lesion.
7. Load the torque device onto the proximal tip of the guidewire and tighten. The torque device should be tightened as close to the handle as possible and is not to exceed 10cm. Slide the torque device into the Revolution™ Peripheral Atherectomy System Torque Device Clip and secure to the surgical drape on the table.
8. The guidewire can be manipulated by firmly gripping the torque device. The torque device and guidewire can be repositioned as necessary.

9. When desired procedural results are achieved, withdraw the guidewire slowly.

**STORAGE:**

Store at controlled room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light.

**DISPOSAL:**

Dispose of the guidewire according to the standard institutional procedures for medical waste including single-use, blood contacting devices.

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Refer to the appropriate packaging for symbols that apply.



Lot Number



Model Number



Use-by date



Temperature limitation



Keep dry



Keep away from sunlight



Sterilized using Ethylene Oxide gas



Do not Re-Sterilize



Single use only



Refer to Instruction Manual/Booklet



Inspect package for damage



Biological hazard



Manufacturer

RxOnly

Federal (USA) law restricts this device to sale by, or on the order of, a physician



Defibrillation-Proof Type BF Applied Part



General Medical Electrical Equipment

Manufactured by:



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