Attention - Before using this device, Consult Instructions for Use

PHOENIX 2.4MM DEFLECTING ATERECTOMY SYSTEM

INSTRUCTIONS FOR USE

DEVICE NAMES
Phoenix Atherectomy Deflecting Catheter
Phoenix Atherectomy Handle
Phoenix Wire Support Clip

CAUTION: FEDERAL (US) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON ORDER OF A PHYSICIAN.

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE, NOTING ALL WARNINGS AND PRECAUTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

INDICATIONS
The Phoenix Atherectomy System is intended for use in atherectomy of the peripheral vasculature. The system is not intended for use in the coronary, carotid, iliac or renal vasculature.

CONTRAINDICATIONS
The use of the Phoenix Atherectomy System is contraindicated where introduction of any catheter would constitute an unacceptable risk to the patient. Contraindications include but are not limited to:

- Recent history of myocardial infarction or thrombotic or hemorrhagic stroke
- Any evidence or history of intracranial bleeding or aneurysm
- Known hypercoagulable state or coagulopathy
- Bleeding diathesis, platelet dysfunction, thrombocytopenia, or thrombocytosis
- Patients in whom antiplatelet, anticoagulant, or thrombolytic therapy is contraindicated
- Allergy or intolerance to contrast agents or medications used to perform endovascular procedures
- Do NOT operate the Phoenix Atherectomy System in vessels smaller than the indicated size as perforation, dissection or injury may occur.

SYSTEM DESCRIPTION
The Phoenix Atherectomy System has two main components: the Phoenix Atherectomy Deflecting Catheter and the Phoenix Atherectomy Handle. The Phoenix Wire Support Clip is an accessory to the Handle to facilitate guidewire management during the procedure. All system components are sterile, single-use devices designed for atherectomy of the peripheral vasculature.

The Phoenix Atherectomy Deflecting Catheter is a long, flexible catheter with an outer deflecting shaft and an inner shaft that contains a torque shaft which is attached to a metal cutting element at the distal Catheter tip. When activated, the torque shaft rotates, causing the cutting element to excise diseased plaque from the artery. The excised diseased material is brought into the Catheter where it is mechanically conveyed from the patient using an Archimedes Screw that is fixed on the outer surface of the torque shaft. The catheter tip can be deflected to various degrees and rotated so that the cutter can debulk eccentrically to a larger diameter than the catheter itself. The control for rotation is operated via the outer sheath sweep knob. The control for deflection is operated by the outer sheath slider located on the bottom of the Catheter Handle and can be locked in the straight or deflected position.
The central lumen accommodates a standard 0.014” guidewire. The distal section of the Catheter (including the cutter head at the Catheter tip) is radiopaque for fluoroscopic visualization of the Catheter position and tip orientation. The proximal end of the Catheter is composed of an adapter with two ports; a side port for debris conveyance and a central port for guidewire introduction. The Catheter installs into the Handle by snapping the Catheter’s adapter at the proximal end into the Handle.

The Phoenix Handle includes a battery-operated motor for driving the cutter of the Phoenix Atherectomy Catheter at a nominal speed of 10,000 to 12,000 rpm. The Phoenix System is activated by sliding the ON/OFF slider switch on the top of the Handle.

The Phoenix Wire Support Clip is an accessory, which can be used to help support and secure the guidewire in position during the procedure using a commercially available guidewire torque device.

See Figure 1 for the assembled Phoenix Atherectomy System with the Phoenix Atherectomy Catheter, Handle and Wire Support Clip loaded with torque device and guide wire accessories.

### Table 1. Phoenix 2.4mm Deflecting Atherectomy Catheter Key Specifications

<table>
<thead>
<tr>
<th>Catheter Tip Diameter</th>
<th>Minimum Introducer Size</th>
<th>Crossing Profile</th>
<th>Working Length</th>
<th>Minimum Vessel Diameter¹</th>
<th>Anatomical Locations</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.4 mm</td>
<td>7F (2.5 mm) or larger</td>
<td>2.4 mm</td>
<td>125 cm</td>
<td>3.0 mm</td>
<td>Femoral and Popliteal Arteries</td>
</tr>
</tbody>
</table>

¹Warning: Do not use the Phoenix Atherectomy Catheter in vessels smaller than the indicated size or harm to patient (vessel perforation, dissection or injury) could occur.

Figure 1: Phoenix 2.4mm Deflecting Atherectomy System: Catheter distal tip (left) and Handle (right), shown with the Catheter inserted into Handle and Wire Support Clip attached.

**WARNINGS**

- The Phoenix Atherectomy System is intended for one-time use only. Do NOT resterilize and/or reuse. Resterilization or reuse may potentially compromise device performance and safety and may increase the risk of infection.
- Use the Phoenix Atherectomy System products prior to the “Use By” (“Expires”) date specified on each individual package label.
- Do NOT operate the Phoenix Atherectomy System if the guidewire is subintimal as perforation, dissection or injury may occur.
- Do NOT operate the Phoenix Atherectomy System in vessels smaller than the indicated size as perforation, dissection or injury may occur.
- When the Phoenix Atherectomy Catheter is exposed to the vascular system, it should not be advanced or retracted except under direct fluoroscopic observation. If resistance is met during advancement or retraction, determine the cause of the resistance before continuing.
• Do NOT turn ON the Phoenix Atherectomy System except under fluoroscopy.
• Do NOT leave the distal tip of Catheter in a stationary position with System turned ON, or vessel perforation, dissection or injury may occur.
• Do NOT turn ON the Phoenix Atherectomy System unless the Phoenix Atherectomy Catheter is tracked over a guidewire and the distal tip of the guidewire is placed in an appropriate section of the vessel.
• All air must be removed from all catheter lumens by priming the Catheter as described in the Instructions for Procedure section prior to inserting the Catheter into the patient.
• Do not use, or attempt to correct, a Phoenix Atherectomy Catheter if it is bent or kinked or has any evidence of damage as this may result in breakage or compromised performance.
• The Phoenix Catheter only may be used with the Phoenix Handle.
• The Phoenix Atherectomy System is not to be used in the presence of combustible or flammable gases, anesthetics, or cleaners/disinfectants.

PRECAUTIONS
• Prior to use, all Phoenix Atherectomy System components should be examined to verify functionality.
• For use only by physicians trained in the use of the Phoenix Atherectomy System and percutaneous peripheral interventional procedures.
• Test the Phoenix Catheter prior to insertion into the patient as described in the Instructions for Procedure section.
• Close the hemostatic valve tight enough to prevent blood leakage around the Catheter shaft, but still allow axial movement of the Catheter through the valve. Special care should be taken when adjusting the valve tightness if a Tuohy-Borst valve is used.
• Take care not to immerse the Handle because damage to the electrical components of the Handle could occur.
• As in all atherectomy procedures, the duration of the procedure should be determined by the physician based on patient condition.
• The maximum recommended length of run time for the Phoenix Handle during a procedure is 20 minutes.
• Use only listed compatible guidewires with the Phoenix Atherectomy System. Use of any guidewires not listed as compatible may compromise performance of or damage the Phoenix Atherectomy System.
• Use of PTFE-coated guidewires is not recommended, unless the guidewire is specifically indicated for atherectomy.
• Hold the proximal end of the guidewire securely with a torque device when the Handle is ON. Failure to do so may result in guidewire rotation and/or loss of position within the vessel.
• Ensure the Catheter tracks smoothly and easily over guidewire during Handle operation. If the Catheter does not track easily over the guidewire, immediately turn OFF the System and replace the System.
• The Phoenix System must be OFF while advancing forward through the Introducer Sheath.
• Carefully monitor the Catheter tip and guidewire under fluoroscopy during Handle operation. If rotation or “whipping” of the guidewire is suspected, immediately turn OFF the system and investigate. Do not turn ON the System unless the Catheter is verified to track easily over the guidewire.
• Monitor flow of excised material into the disposal reservoir during operation of the Catheter. If flow of excised material ceases during the procedure, this is a sign that the Catheter drive system (cutter, torque shaft, or Handle motor drive) may not be operating properly.
  • Pull the Catheter back or proximal to the lesion to re-establish blood flow.
  • If flow of excised material is not re-established, turn OFF the Handle. Remove the Catheter from the patient. Otherwise embolization or an inability to remove excised plaque could occur.
• Hold the guidewire firmly with a torque device during the Catheter removal process either by hand or with the Phoenix Wire Support Clip if it is used. Failure to do so may result in guidewire rotation and/or loss of position within the vessel.

ADVERSE EFFECTS
Potential adverse effects associated with the use of this device and other interventional catheters include but are not limited to the following (alphabetical order):
• Access site injury, including pain
• Arterial dissection
• Arterial occlusion
• Arterial perforation or pseudoaneurysm
• Arterial restenosis
• Arterial rupture
• Arterial spasm or abrupt or sub-acute closure
• Bleeding complications which require transfusion
• Death
• Embolism, including thrombus, plaque, air, device, etc.
• Emergency or non-emergency arterial bypass surgery
• Fracture of any component of the device that may or may not lead to serious injury or surgical intervention
• Hematoma
• Hypotension
• Infection or fever
• Ischemia
• Reaction to contrast media, procedure medications or Catheter materials, including allergic reaction.
• Vascular injury which may require surgical repair

The occurrence of these adverse effects may lead to the need for repeat catheterization/angioplasty, emergency bypass surgery, or death.
HOW SUPPLIED, STERILIZATION, AND EXPIRATION
The Phoenix Atherectomy Catheter, Handle and Wire Support Clip are packaged and sterilized individually. The Phoenix Atherectomy Catheter, Handle, and Wire Support Clip are sterilized using ethylene oxide gas. Each device is sterile if the sealed pouch is unopened and undamaged. All are intended for single use only and should not be reused or re-sterilized. Use before the “Use by” dated printed on the package labels. Store in a dry, cool place.

SUPPLIES REQUIRED FOR THE PHOENIX ATHERECTOMY PROCEDURE:
NOTE: The Phoenix Atherectomy System is protected against electrical shock (Type CF applied part)
Item description (Single use items only - Do not re-sterilize or reuse):
1. A Phoenix Atherectomy Catheter and Handle
2. Disposal bag (250 ml or larger) for material conveyed out of the Catheter’s disposal outlet
3. 7F or larger introducer sheath with cross-cut valve
4. Sterile heparinized (10,000 IU/L) 0.9% normal saline for priming the Catheter prior to use
5. 10cc or larger slip-tip syringe for priming the Catheter prior to use
6. Hemostasis valve
7. Compatible 0.014” sized, exchange length guidewire (260 cm minimum):
   • Ev3 Nitrex Guidewire (300 cm)
   • CSI ViperWire Guide Wire (300 cm)
   • Phoenix Wire (300 cm)
8. Torque device
9. Phoenix Wire Support Clip

INSTRUCTIONS FOR PROCEDURE:

INSETION OF PHOENIX ATHERECTOMY SYSTEM COMPONENTS
Prior to use, all equipment to be used for the procedure should be examined carefully for defects. Examine the packaging for cuts, tears, or other breach of the sterile barrier. Examine the Phoenix Atherectomy Catheter for bends, kinks or other damage. Examine the Handle for sign of damage. Turn ON the Handle and ensure that it can be activated. Do not use any defective equipment.

PREPARATION OF THE PHOENIX ATHERECTOMY CATHETER
Complete the following steps using aseptic technique to prepare the Catheter for use:
1. Withdraw the Catheter from the sterile protective packaging and set the Catheter on the sterile table.
2. Priming the Phoenix Catheter: Attach a 10cc syringe filled with heparinized saline onto the disposal outlet and flush slowly with gentle pressure until saline drips out of the guidewire port. Cover the central guidewire port with a finger and continue to flush until saline drips out of the distal tip of the Catheter.
3. System Test: Insert the Catheter tip into a basin filled with heparinized saline. Insert the proximal end of the Catheter into the Handle. Ensure the proximal end of the Catheter is snapped into the Handle completely.
4. Turn System ON to spin the cutter for 10 to 20 seconds. Make sure that saline drips out of the disposal outlet and that all components are functional and remain intact. Do not use any device found to be broken or non-functional during this preparation.
5. Attach the disposal bag to the disposal outlet.

INSERTION AND OPERATION
I. Insertion
1. Insert a 7Fr or larger introducer sheath with a cross-cut hemostasis valve using standard techniques.
2. Advance a 0.014” guidewire through the sheath beyond the lesion to be treated, taking care to remain intraluminal.
3. Verify the catheter is in the Straight Position by moving the Slider fully proximal before inserting the catheter into the introducer Sheath.
4. Backload the end of the guidewire into the distal tip and out of the proximal end of the Phoenix Atherectomy Catheter guidewire lumen. Insert the distal tip of the Phoenix Atherectomy Catheter into the introducer sheath with the Phoenix System OFF until the tip exits the Intoducer Sheath.

II. Guidewire Preparation
1. While holding the guidewire stationary and using fluoroscopic guidance, advance the Phoenix Atherectomy Catheter distal tip over the guidewire to within a few millimeters proximal to the target lesion.
2. Adjust the guidewire position relative to the lesion as needed. Confirm that the guidewire is intraluminal.
3. Confirm that the distal tip of the guidewire is positioned a minimum of 20 cm from the distal tip of the Catheter.
4. Apply torque device tightly to the guidewire approximately 20 cm to 30 cm from central guidewire port.
5. Loop the guidewire back through 180°, creating a backwards ‘C’ shape. With the Torque Device locked on guidewire, place the Torque Device into the Wire Support Clip or fixed to the table to prevent guidewire rotation. This configuration provides wire support and allows the Catheter to track more easily over the guidewire (see Figure 1 for resulting guidewire loop).

6. Use of Wire Support Clip to prevent guidewire rotation:
   a. Snap the Wire Support Clip onto the Handle as it appears in Figure 1.
   b. Feed a torque device over the proximal end of the wire and form a support loop of about 10-15 cm that spans from the central guidewire exit port (of the Catheter) to the Wire Support Clip.
   c. Slide the torque device into the torque device slot on the Wire Support Clip.
   d. Tighten the torque device onto the guidewire.
e. Verify that the torque device does not spin in the Wire Support Clip. Replace torque device if it is not firmly secured in the Wire Support Clip.

Warning: Do Not Operate the Phoenix Atherectomy System if the guidewire is subintimal as perforation or dissection of the vessel may occur. A second angiographic viewing angle prior to device insertion to confirm wire placement is recommended.

Precaution: Monitor the smooth tracking of the Catheter over the guidewire during operation. If resistance is encountered during the procedure, remove Catheter and flush guidewire lumen by using the Catheter Preparation Method for System Test, Steps 3 and 4 above, where the System is turned ON with the Catheter tip completely submerged in heparinized saline to actively clear blood and/or debris that may be within the catheter lumen.

Precaution: Hold the proximal end of the guidewire securely with a torque device when the Handle is ON. Failure to do so may result in guidewire rotation and/or loss of position within the vessel.

III. Crossing the Lesion and Debulking (Straight Cutting)
1. Verify the catheter is in the Straight Position by moving the Slider fully proximal before inserting the catheter into the introducer Sheath.
2. While holding the guidewire stationary and using fluoroscopic guidance, advance the Phoenix Atherectomy Catheter distal tip to within a few millimeters proximal to the target lesion.
3. Adjust the guidewire position relative to the lesion as needed. Confirm that the guidewire is intraluminal.
4. Confirm that the distal tip position relative to the lesion as needed. Confirm that the guidewire is intraluminal.
5. Under fluoroscopic guidance, turn ON the Phoenix Atherectomy System using the switch on the Handle. Advance the Catheter slowly at a rate of 1 mm/sec and carefully through the lesion. In highly stenosed lesions or lesions > 10 cm in length, periodically pause and withdraw the Catheter slightly to allow improved blood flow and plaque removal during cutting. Continue to advance until the distal tip of Catheter has crossed the lesion.
6. The Phoenix Atherectomy System must remain ON to remove plaque.
7. Withdraw the Catheter until the distal tip is proximal to the lesion. Image the lumen and/or repeat straight cutting through the lesion if desired.
8. Turn OFF the Phoenix Atherectomy System with the switch on the Handle.

IV. Debulking to Larger Diameter (Deflected Cutting)
1. When moving to deflected cutting, the use of a flexible ("light") guidewire allows maximum deflection of the Catheter tip. Exchange guidewire if desired.
2. While holding the guidewire stationary and using fluoroscopic guidance, advance the Phoenix Atherectomy Catheter distal tip to within a few millimeters proximal to the target lesion.
3. To Deflect: Using the Slider, slide the Outer Sheath distal to increase deflection (bend tip) and backward to decrease deflection (straighten tip). The Slider features a trigger lock to maintain selected position.
4. To Rotate: Adjust the position of the Catheter tip by turning the knob on the Outer Sheath clockwise or counterclockwise. As the knob is rotated, a tactile click will be felt by the user. A 360 degree rotation of the Catheter tip can be achieved with 8 clicks of the knob. If there is resistance to rotating the tip, decrease deflection (straighten tip) prior to rotating and then re-adjust to desired deflection.
5. Under fluoroscopic guidance, turn ON the Phoenix Atherectomy System.

Warning: When the catheter is deflected and the System is ON, do not leave the cutter head stationary or perforation may occur.
6. The Catheter may be advanced and retracted while at a fixed deflection setting to debulk. Advance the Catheter slowly and carefully while debulking. Always monitor the Catheter tip deflection position during cutting, in order to ensure the setting does not need to be adjusted as debris is removed and there is less resistance to deflection. Rotate and/or reposition the Catheter tip as desired during cutting or between passes. If there is resistance to rotating the tip, decrease deflection (straighten tip).
7. The Phoenix Atherectomy System must remain ON in order to effectively remove plaque.
8. Once the lumen is opened up to the maximum diameter desired, turn OFF the Phoenix Atherectomy System.
9. Retract the Catheter at least 1 cm proximal to the lesion.
10. Perform an angiogram to assess the lumen.
11. Continue debulking if desired and reassess the lumen with an angiogram.

V. Phoenix Atherectomy Catheter Removal
1. To remove the Phoenix Atherectomy Catheter, stabilize the guidewire across the lesion, straighten the Catheter tip by sliding the Outer Sheath to the fully proximal position, and carefully remove the Phoenix Atherectomy Catheter out of the sheath under fluoroscopic guidance use a standard over-the-wire guidewire management technique. Hold the guidewire firmly during the Catheter removal process by manually securing the guidewire or securing ("locking") a torque device to the guide wire.
2. Removal of the Catheter should be accomplished by switching ON the Handle ("running the handle") per the following steps:
   a. Lock a torque device on the proximal end of the guidewire a distance back from the introducer Sheath.
   b. Hold the torque device manually or with the Wire Support Clip to prevent guidewire rotation, and turn ON the Phoenix Atherectomy System using the switch on the handle.
   c. Under fluoroscopy, remove the Catheter by feeding the wire into the handle until the Catheter tip exits the Introducer Sheath.
   d. Turn OFF the Phoenix Atherectomy System with the switch on the Handle.
e. **Note:** The Wire Support Clip should be used as described in **Step II.6** to immobilize the guidewire from rotation and secure the torque device during Catheter removal. Use of Wire Support Clip for Catheter removal (if not already attached):

   i. Snap the Wire Support Clip onto the Handle as it appears in Figure 1.
   ii. Feed a torque device over the proximal end of the wire and form a support loop of about 10-15 cm that spans from the central guidewire exit port (of the Catheter) to the Wire Support Clip.
   iii. Slide the torque device into the torque device slot on the Wire Support Clip.
   iv. Tighten the torque device onto the guidewire.
   v. Verify that the torque device does not spin in the Wire Support Clip. Replace torque device if it is not firmly secured in the Wire Support Clip.

3. Perform a post-atherectomy angiogram.

4. If the Phoenix System is used to treat multiple lesions where the Catheter is removed and re-inserted through the Introducer Sheath, the Catheter must be flushed between re-insertions using the Catheter Preparation Method for System Test, Steps 3 and 4, where the System is turned ON with the Catheter tip completely submerged in heparinized saline to actively clear blood and/or debris that may be within the catheter lumen.

VI. **Post-Phoenix Atherectomy Procedure**

1. If adjunctive angioplasty or stenting is judged to be necessary by the physician, insert the device of choice over the guidewire. Perform angioplasty or stenting per standard practice.
2. Perform a post-procedure angiogram.

VII. **Removing the Sheath**

Leave the sheath in situ until the hemodynamic profile becomes normal. Close the puncture site per routine practice.

**CLINICAL DATA:**

The EASE clinical study was a prospective, multi-center, non-randomized, single-arm study to evaluate the safety, effectiveness, and performance of the Phoenix Atherectomy System in the percutaneous atherectomy treatment of de novo and restenotic atherosclerotic lesions of infra-inguinal lower extremity arteries. 128 total patients were enrolled across 16 centers for treatment. 105 subjects (with 123 treated lesions) comprising the Per-Protocol group were enrolled in accordance with the vessel sizing and anatomic location requirements corresponding to each Phoenix Catheter device size. The primary safety endpoint was freedom from major adverse events (MAE) at 30 days, as assessed by an independent physician adjudicator. The primary effectiveness endpoint was acute technical success, defined as the ability to achieve a residual diameter stenosis ≤50% as assessed by the study investigator at the time of treatment with the Phoenix Atherectomy System (prior to any adjunctive therapy) using quantitative angiography or visual estimate. Patients were monitored for 6 months following baseline atherectomy treatment.

The 30-day freedom from MAE rate was 94.3% (99/105) and technical success was achieved in 95.1% (117/123) of the lesions treated in the per protocol group. Both primary endpoints met the predefined IDE study success criteria. Table 2 summarizes the safety and effectiveness data resulting from the EASE study.

Following treatment of the first 36 subjects enrolled in the EASE Study, a higher than anticipated complication was observed. Of the first 36 subjects treated, there were 19 serious procedure or device related adverse events and 6 adverse events met the definition of major adverse events (MAE). Specific to the MAE, there have been 5 dissections/perforations and one vessel occlusion requiring treatment. AtheroMed initiated a review of available data to assess the underlying causes. The analysis of these early results led to additional sizes of the Phoenix Atherectomy Catheter being added to the EASE Study protocol, as well as updated recommendations regarding minimum vessel diameters and anatomical locations for device use (as reflected in Table 1 of this document).
Table 2: Per Protocol Summary of Safety and Effectiveness in EASE (n=105 patients and 123 lesions)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Results (n=105 patients, 123 lesions)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographics:</strong></td>
<td></td>
</tr>
<tr>
<td>% Male</td>
<td>60% (63/105)</td>
</tr>
<tr>
<td>Age</td>
<td>71.7 yr ± 10.0 years</td>
</tr>
<tr>
<td>% CLI</td>
<td>32% (34/105)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>53% (56/105)</td>
</tr>
<tr>
<td><strong>Target Lesion Locations &amp; Diameters</strong></td>
<td></td>
</tr>
<tr>
<td>SFA</td>
<td>28.5% (35)</td>
</tr>
<tr>
<td>Popliteal</td>
<td>19.5% (24)</td>
</tr>
<tr>
<td>Tibial-Peroneal Trunk</td>
<td>11.4% (14)</td>
</tr>
<tr>
<td>Anterior Tibial</td>
<td>17.1% (21)</td>
</tr>
<tr>
<td>Posterior Tibial</td>
<td>14.6% (18)</td>
</tr>
<tr>
<td>Peroneal</td>
<td>8.9% (11)</td>
</tr>
<tr>
<td>RVD - proximal</td>
<td>3.6 ± 0.7 mm</td>
</tr>
<tr>
<td>RVD - distal</td>
<td>3.5 ± 0.7 mm</td>
</tr>
<tr>
<td>Target Lesion Length</td>
<td>34 ± 30 mm</td>
</tr>
<tr>
<td>Pre-Phoenix % Diameter Stenosis</td>
<td>89.1% ± 9.8%</td>
</tr>
<tr>
<td>Post-Phoenix % Diameter Stenosis</td>
<td>34.6% ± 16.2%</td>
</tr>
<tr>
<td>Final Post-Procedural % Diameter Stenosis</td>
<td>10.5% ± 9.8%</td>
</tr>
<tr>
<td>Phoenix Treatment Time</td>
<td>5.9 ± 4.7 minutes</td>
</tr>
<tr>
<td>Technical Success (lesions, Phoenix Catheters)</td>
<td>95.1% (117/123)</td>
</tr>
<tr>
<td>Procedural Success (lesions)</td>
<td>99.2% (122/123)</td>
</tr>
<tr>
<td><strong>Clinical Results</strong></td>
<td></td>
</tr>
<tr>
<td>ABI</td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>0.70 ± 0.23</td>
</tr>
<tr>
<td>30 day</td>
<td>0.96 ± 0.21</td>
</tr>
<tr>
<td>6 mo.</td>
<td>0.84 ± 0.29</td>
</tr>
<tr>
<td>Rutherford Score</td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>3.3 ± 1.1</td>
</tr>
<tr>
<td>6 mo.</td>
<td>1.2 ± 1.4</td>
</tr>
<tr>
<td>Rutherford Class Improvement ≥ 1 at 6 months</td>
<td>80%</td>
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<tr>
<td><strong>MAE through 30 Days (by type):</strong></td>
<td></td>
</tr>
<tr>
<td>Clinically-Driven TLR</td>
<td>0.9% (1/105)</td>
</tr>
<tr>
<td>Perforation</td>
<td>1.9% (2/105)</td>
</tr>
<tr>
<td>Grade C or Greater Dissection</td>
<td>0.9% (1/105)</td>
</tr>
<tr>
<td>Symptomatic Distal Emboli</td>
<td>0.9% (1/105)</td>
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<tr>
<td>Unplanned (Toe) Amputation</td>
<td>2.9% (5/105)</td>
</tr>
<tr>
<td>Abrupt closure/Occlusion</td>
<td>0% (0/105)</td>
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<tr>
<td><strong>MAE through 6 mo. (by type), Cumulative:</strong></td>
<td></td>
</tr>
<tr>
<td>Clinically Driven TLR</td>
<td>12% (12/101)</td>
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<tr>
<td>Perforation</td>
<td>2% (2/101)</td>
</tr>
<tr>
<td>Grade C or Greater Dissection</td>
<td>1% (1/101)</td>
</tr>
<tr>
<td>Symptomatic Distal Emboli</td>
<td>1% (1/101)</td>
</tr>
<tr>
<td>Unplanned (Toe) Amputation</td>
<td>4% (4/101)</td>
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<tr>
<td>Abrupt closure/Occlusion</td>
<td>0% (0/101)</td>
</tr>
<tr>
<td>Cardiovascular Related Death</td>
<td>1% (1/101)</td>
</tr>
<tr>
<td>Freedom from TLR at 6 mo</td>
<td>88%</td>
</tr>
<tr>
<td>Freedom from TVR at 6 mo</td>
<td>86%</td>
</tr>
</tbody>
</table>

1Residual Stenosis ≤ 50% post-Phoenix
2Residual Stenosis ≤ 30% final
3Clinical signs or symptoms of distal emboli detected in treated limb distal to the treated lesion after the index procedure and requiring mechanical or pharmacological means to improve flow.
4Kaplan-Meier Estimates

**SPECIAL PATIENT POPULATIONS:**
The safety and effectiveness of the Phoenix Atherectomy System has not been established in the following patient populations:
- Patients with known allergies to metals (such as Nitinol, stainless steel or other stent materials)
- Patient unable to take appropriate anti-platelet therapy
- Patients with no distal run-off
- Patients with in-stent restenosis at the peripheral vascular site
- Patients with severe, persistent hypertension (systolic pressure > 180 mm Hg)
- Patients with a history of coagulopathy or hypercoagulable blood disorder
- Patients receiving hemodialysis or with impaired renal function (creatinine is >2.5mg/dL) at the time of treatment
- Patients with evidence of intracranial or gastric intestinal bleeding within the past three months
- Patients with severe trauma, fracture, major surgery or biopsy of a parenchymal organ within the past 3 months.
- Patients who are pregnant or nursing a child
- Patients < 18 years

**DEVICE DISPOSAL:**
The Phoenix Atherectomy Catheter is disposable per hospital biohazard procedures. The Phoenix Handle is NOT disposable per standard biohazard procedures but should be disposed per standard hazardous waste procedures.

**CAUTION:** Do not incinerate the Phoenix Handle. It contains Lithium batteries and should be disposed per standard hospital hazardous waste procedures.

The Phoenix Atherectomy System has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/EEC (IEC/EN 60601-1-2). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses and can radiate radiofrequency energy and, if not used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular setting.

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**Use Before Date**

<table>
<thead>
<tr>
<th>Use Before Date</th>
<th>Nonpyrogenic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Store in a dry, dark, cool place</td>
<td>Content: One (1)</td>
</tr>
<tr>
<td>Do not use open or damaged packages</td>
<td>Do not Re-Sterilize</td>
</tr>
<tr>
<td>Catalogue number</td>
<td>Batch Code</td>
</tr>
<tr>
<td>Sterilized using Ethylene Oxide</td>
<td>Single Use Only</td>
</tr>
<tr>
<td>Type CF Applied Part</td>
<td>Prescription Only</td>
</tr>
</tbody>
</table>

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The PHOENIX AATHERECTOMY System (including components and/or methods thereof) may be protected under one or more pending United States Patent Applications, as well as corresponding international patent applications.

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