Phoenix Atherectomy System
Product Overview
Phoenix Atherectomy System-
The next generation of atherectomy

*The first hybrid atherectomy system available – Combines the benefits of existing atherectomy systems to tailor the treatment for each patient.*

<table>
<thead>
<tr>
<th>feature</th>
<th>Hybrid</th>
<th>Directional</th>
<th>Laser</th>
<th>Orbital</th>
<th>Rotational</th>
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</thead>
<tbody>
<tr>
<td>Front cutting for direct lesion access</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Plaque removal</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Directional cutting ability*</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single insertion</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>No need for capital equipment</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
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</tr>
</tbody>
</table>

*Available with Phoenix 2.4 deflecting catheter.*
The Phoenix Solution

Phoenix was created to address physicians’ clinical concerns and challenges.

<table>
<thead>
<tr>
<th>CLINICAL CONCERN</th>
<th>PHOENIX SOLUTION</th>
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<tbody>
<tr>
<td>Vessel Injury</td>
<td>- Front cutter clears tissue in a way that may help reduce potential trauma to the vessel.</td>
</tr>
<tr>
<td>Distal Embolization</td>
<td>- Continuous capture and passive clearance of debulked material into the catheter resulted in a 1% rate of symptomatic distal emboli in the EASE trial</td>
</tr>
<tr>
<td>Ease of Use</td>
<td>- Single insertion – no need to remove and clean out debulked material</td>
</tr>
<tr>
<td></td>
<td>- Battery powered handle operated - No capital equipment or additional procedural accessories required</td>
</tr>
<tr>
<td>Deliverability</td>
<td>- Low profile, front cutting design allows for direct lesion access without having to first pass a nosecone</td>
</tr>
<tr>
<td></td>
<td>- OTW design aids in trackability and pushability of catheter</td>
</tr>
<tr>
<td>Versatility</td>
<td>- Treat a range of tissue types from soft plaque to calcified arteries</td>
</tr>
<tr>
<td></td>
<td>- Treat most peripheral vasculature with only 3 catheter diameters</td>
</tr>
</tbody>
</table>

1. Endovascular Atherectomy Safety and Effectiveness Study (EASE), ClinicalTrials.gov Identifier NCT01541774 (accessed 23Oct2015). Results presented at the Vascular Interventional Advances (VIVA) Conference in October of 2013 (Las Vegas, NV) by Stephen Williams, MD
2. Phoenix Atherectomy device is indicated for vessels 2.5mm in diameter and above.
Phoenix System Components

1. **Atherectomy Catheter**
   - Distal cutting element rotates at 10,000 - 12,000 RPM
   - Cutting element made of stainless steel alloy with proprietary carbon coating

2. **Battery-Powered Handle**
   - Powers rotation of cutting element
   - Small, handheld form factor
   - Compatible with all Phoenix catheter sizes
   - IFU recommended maximum run time is 20 minutes
Phoenix System Components

3. **Wire Support Clip**
   - Serves as system ‘brake’
   - Provides for single user operation
   - Integrated torque clip

4. **Debris collection bag**
   - External bag collects debulked material as it is continuously captured and cleared from body
First Hybrid Atherectomy Catheter System

Tracking (non-deflecting) Catheters (1.8mm and 2.2mm)

- OTW system – 130cm and 149cm working length
- Tracks directly over the guidewire- this helps keep catheter centered in vessel lumen (when guidewire is centered)
- Rotational front cutter restores straight line flow to the foot\(^1\)

Deflecting Catheter (2.4mm)

- OTW system – 127cm working length (straight)
- Combines key features of non-deflecting, tracking catheters with deflection capability
- Cut initial straight channel, then deflect and rotate catheter tip as needed to debulk larger diameter and/or target eccentric lesions

1. Phoenix Atherectomy Device is indicated for vessels 2.5mm in diameter and above
Phoenix Indications for Use

**Indication:**
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.

<table>
<thead>
<tr>
<th>Catheter Tip Diameter</th>
<th>Minimum Introducer Size</th>
<th>Crossing Profile</th>
<th>Working Length</th>
<th>Maximum Guide Wire Diameter</th>
<th>Minimum Vessel Diameter¹</th>
<th>Anatomical Locations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.8 mm</td>
<td>5F (1.8 mm) or larger</td>
<td>1.8 mm</td>
<td>130 cm</td>
<td>0.014” (0.36 mm)</td>
<td>2.5 mm</td>
<td>Femoral, popliteal, or distal arteries located below the knee</td>
</tr>
<tr>
<td>2.2 mm</td>
<td>6F (2.2 mm) or larger</td>
<td>2.2 mm</td>
<td>130 cm</td>
<td>0.014” (0.36 mm)</td>
<td>3.0 mm</td>
<td></td>
</tr>
<tr>
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<tr>
<td>2.4 mm</td>
<td>7F (2.5 mm) or larger</td>
<td>2.4 mm</td>
<td>125 cm Deflected 127 cm Straight</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.
Cut, Capture and Clear Mechanism of Action

**Cut:** Front cutter clears tissue in a way that may help reduce potential trauma to the vessel.¹

**Capture:** Unique cutter head design allows for continuous capture of debulked material.

**Clear:** The internal Archimedes screw allows you to clear plaque without having to remove the catheter and clean out debulked material.

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¹ Endovascular Atherectomy Safety and Effectiveness Study (EASE), ClinicalTrials.gov Identifier NCT01541774 (accessed 23Oct2015). Results presented at the Vascular Interventional Advances (VIVA) Conference in October of 2013 (Las Vegas, NV) by Stephen Williams, MD.
Cutting Element

- Proprietary carbon coating on stainless steel alloy
- Rotation of blades debulks diseased material
- Shape of blades serves as impeller to bring material into catheter housing
- Two flutes on distal cutter
- 2nd stage cutter located within housing has 4 flutes
  - Further macerates plaque to facilitate conveyance via Archimedes Screw
Product Prep
Prepping the Phoenix System

Simple set-up, prep is similar to other interventional devices

Flush wire lumen
• Attach 10cc syringe filled with heparinized saline to disposal port
• Flush slowly until saline drips out of proximal guidewire lumen
• Occlude guidewire port, and flush until saline drips out of distal tip of guidewire lumen

Snap catheter into handle
• Submerge catheter tip into bowl of heparinized saline
• Turn system ON until saline drips out of disposal port

DEVICE PREP IS THE SAME FOR ALL PHOENIX DEVICES
Prepping the Phoenix System

Simple set-up, prep is similar to other interventional devices

Attach disposal bag
• Attach disposal bag to catheter by pushing tubing into disposal port

Assemble catheter
• Snap integrated wire support clip onto handle
• Feed wire through the torque device
• Form a 10-15 cm support loop that spans from the guidewire exit port of the catheter to the wire support clip

• Do not use any device found to be broken or non-functional during the preparation steps
1.8 and 2.2. Tracking Catheter Product Handling
Suggested Tracking Catheter Case Workflow

Insertion

• Insert the appropriately-sized sheath with a cross-cut hemostasis valve using standard techniques
• Advance a 0.014” guidewire through the sheath beyond the lesion to be treated, taking care to remain intraluminal
• 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 introducer sheath
Suggested Tracking Catheter Case Workflow

• Crossing the lesion and debulking
  – While under fluoroscopy, advance catheter over guidewire until it is positioned proximally to the lesion
  – Confirm that the guidewire is intraluminal, confirm that the distal tip of the guidewire is positioned a minimum of 20 cm from distal tip of Catheter

• Advancing device
  – Under fluoroscopic guidance, turn system ON using switch on handle
    • Advance catheter at a rate of 1mm/sec carefully through the lesion
    • In highly stenosed lesions or lesions ≥ 10cm in length, periodically pause and withdraw the Catheter slightly to allow improved blood flow and plaque removal during cutting.
    • The Phoenix Atherectomy System must remain ON to remove plaque
    • Withdraw the catheter until the distal tip is proximal to the lesion. Image the lumen and repeat cutting through the lesion if desired.
2.4mm Deflecting Catheter
Product Handling
Deflecting Mechanism of Action

2.4mm deflecting catheter with nitinol tip outer deflecting sleeve

1. Straight cutting with outer sleeve retracted

2. Deflected cutting with outer sleeve advanced toward tip
Phoenix 2.4mm Deflecting Mechanism of Action

Non-Deflected (Straight)

127 cm working length

Straight cutting with slider mechanism in back position

Deflected

125 cm working length

Deflected cutting with slider mechanism in forward position

Rotation knob

- In deflected position, rotation knob controls tip direction/angle of deflection for directional debulking
- 360° of rotation provided through 8 detents or “clicks”
- Knob can be rotated in either direction
- Square shape design makes rotation easier
Suggested 2.4 mm Case Workflow

**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 of the wire is positioned a minimum of 20 cm from the distal tip of the catheter.

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.
Suggested 2.4 mm Case Workflow

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.
Suggested 2.4 mm Case Workflow

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.
Suggested 2.4 mm Case Workflow

**Debulking to Larger Diameter (Deflected Cutting)**

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.
Points to Consider: Using the Catheter

• Recognize that cutter head will retract proximally by 2cm when moving from straight to deflected mode (from 127cm working length to 125cm working length)

• Pay attention to ability of cutter head to rotate
  – In extreme cases of iliac tortuosity or in situations with smaller vessel diameters\(^1\), rotation of cutter head can be impeded when in deflected mode
  – In these situations above, the catheter tip should be placed in “straight mode” for rotation on distal side of the lesion. Interaction with tortuosity can be overcome if the knob is rotated with cutter head in straight mode

1. 2.4mm Phoenix Atherectomy Device is indicated for vessels 3mm in diameter and above
Points to Consider: Using the Catheter

• The 2.4mm reduced profile device can cut forward, and, when deflected, backwards through a lesion.

• 2.4mm Deflection Catheter device should be removed only in straight mode through the vessel and should not be run when going through the sheath, particularly through the aortic bifurcation.
Ordering Information
Product Offering and Part Numbering Nomenclature

**P18130K** – 1.8mm Phoenix Atherectomy System kit, 130cm length
**P22130K** – 2.2mm Phoenix Atherectomy System kit, 130cm length
**P18149K** – 1.8mm Phoenix Atherectomy System kit, 149cm length
**P22149K** – 2.2mm Phoenix Atherectomy System kit, 149cm length
**PD24127K** – 2.4mm Phoenix Atherectomy System kit, Deflecting, 127cm length
**PG14300LF** – Phoenix Light Support Guidewire, 300cm length

P = Phoenix, D = Deflecting
1.8mm, 2.2mm, or 2.4mm = Cutter head diameter
130cm, 149cm, or 127mm = Device working length
K = Kit (catheter, handle, clip and bag)
Guidewires
Positioning the Phoenix Guidewire

Compatible with the Phoenix Atherectomy System
• Use with deflecting and tracking catheters

Simple to Use
• Catheter is directed over the guidewire with ease
• Light support allows the 2.4mm deflecting Phoenix Catheter to deflect over the wire

Efficient Vessel Navigation
• Provides tactile feedback needed to help with vessel navigation
• Design of wire allows for torque and rotation required to navigate to target lesion

601-0100.116/LB
Guidewire Selection

Physician may select a flexible or light support guidewire when:
- the 2.4 mm deflecting Phoenix catheter is being used
- navigating extreme tortuosity

Physician may select a supportive or extra supportive guidewire when:
- working distally
- extra pushability would be helpful for vessel navigation
- attempting to straighten a tortuous segment and prevent possible vessel interaction
- the 2.4 mm deflecting catheter is used in non-deflected mode
0.014” Guidewires Compatible for Use with the Phoenix Atherectomy System Tracking Catheters¹

<table>
<thead>
<tr>
<th>Brand</th>
<th>Product</th>
<th>Length</th>
<th>Part Number</th>
<th>Wire Support Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Philips Volcano</td>
<td>Phoenix Guidewire- Light Support</td>
<td>300 cm</td>
<td>PG14300LF</td>
<td>Light Support</td>
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<tr>
<td>Ev3</td>
<td>Nitrex Guidewire</td>
<td>300 cm</td>
<td>N143001</td>
<td>Flexible</td>
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<tr>
<td>Asahi</td>
<td>Regalia XS1</td>
<td>300 cm</td>
<td>PAGP140300</td>
<td>Medium</td>
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<tr>
<td>Abbott Vascular</td>
<td>Hi-Torque Extra S’PORT</td>
<td>300 cm</td>
<td>22235M</td>
<td>Supportive</td>
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<tr>
<td>Abbott Vascular</td>
<td>Hi-Torque Iron Man</td>
<td>300 cm</td>
<td>1001311</td>
<td>Supportive</td>
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<tr>
<td>Abbott Vascular</td>
<td>Hi-Torque Standard</td>
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<td>22320H-901</td>
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<td>Asahi</td>
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<td>335cm</td>
<td>VPR-GW-14</td>
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<tr>
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<td>G08801 RSTF-14-300</td>
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<td>Hi-Torque Cross-IT</td>
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¹ Test performed on the bench model.
0.014” Guidewires Compatible for Use with the Phoenix Atherectomy System 2.4 mm Deflecting Catheter

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<td>N143001</td>
<td>Flexible</td>
</tr>
<tr>
<td>US Endovascular</td>
<td>Nitinol Mandrel Wire</td>
<td>300 cm</td>
<td>USEGS14-300A</td>
<td>Flexible</td>
</tr>
</tbody>
</table>

- Flexible guidewire required to facilitate deflection
  - Using a stiff guidewire will resist deflection and straighten out catheter tip

(1) Test performed on the bench model.
Guidewire Data

• Wire is silicone coated with nitinol core

• Part number is PG14300LF

• Diameter: .014”

• Length: 300cm

• Tip: 5.5cm

• Style: Light support

• Tip Load: 1 to 2 gr

• For use with the Phoenix tracking and deflecting catheters