Phoenix atherectomy system
in-service guide
Phoenix atherectomy system
product overview
Phoenix atherectomy system: the next generation of atherectomy

Phoenix combines the benefits of existing atherectomy systems to tailor the treatment for each patient.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Phoenix</th>
<th>Directional</th>
<th>Orbital</th>
<th>Rotational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Front cutting for direct lesion access</td>
<td>✓️</td>
<td></td>
<td>✓️</td>
<td>✓️</td>
</tr>
<tr>
<td>Plaque removal</td>
<td>✓️</td>
<td>✓️</td>
<td></td>
<td>✓️</td>
</tr>
<tr>
<td>Directional cutting ability*</td>
<td>✓️</td>
<td>✓️</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single insertion</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>
</tr>
</tbody>
</table>

*available with Phoenix 2.4 mm 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>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vessel Injury</strong></td>
<td>▶ Front cutter clears tissue in a way that may help reduce potential trauma to the vessel</td>
</tr>
<tr>
<td><strong>Distal Embolization</strong></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><strong>Ease of Use</strong></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><strong>Deliverability</strong></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><strong>Versatility</strong></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
Phoenix family overview

Tracking (non-deflecting) catheters (1.8 mm, 2.2 mm and 2.4 mm)
- OTW system – 130 cm* and 149 cm 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 below the knee

Deflecting catheter (2.2 mm)
- OTW system – 130 cm working length
- Combines key features of non-deflecting, tracking catheters with deflection capability
- Cut initial pilot channel, then operate in four quadrant passes as needed to debulk larger diameter
- Designed to target eccentric lesions

Deflecting catheter (2.4 mm)
- OTW system – 127 cm 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

*2.4 mm only available in 130 cm working length
## 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>
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<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>
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<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>
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<tr>
<td>2.4 mm</td>
<td>7F (2.4mm) or larger</td>
<td>2.4 mm</td>
<td>130 cm</td>
<td>.014” (.36 mm)</td>
<td>3.0 mm</td>
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<tr>
<td>2.2 mm</td>
<td>6F (2.2 mm) or larger</td>
<td>2.2 mm</td>
<td>130 cm Deflected</td>
<td>3.0 mm</td>
<td>Femoral, Popliteal or distal arteries located below the knee</td>
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¹**Warning:** 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.

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<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 Deflected 127 cm Straight</td>
<td>3.0 mm</td>
<td>Femoral and Popliteal Arteries</td>
</tr>
</tbody>
</table>

¹**Warning:** 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, 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:** internal Archimedes screw allows you to clear plaque without having to remove the catheter and clean out debulked material

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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
- Second stage cutter located within housing has four flutes
  - Further macerates plaque to facilitate conveyance via Archimedes Screw
Product prep
Prepping the Phoenix atherectomy system

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

**Flush wire lumen**
- Attach 10 cc 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

 Device prep is the same for all Phoenix devices
Prepping the Phoenix atherectomy system

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

Snap catheter into handle

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
Compatible 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 2.2 and 2.4 mm 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
0.014” guidewires compatible for use with the Phoenix atherectomy system tracking catheters

<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</td>
<td>Phoenix guidewire light support</td>
<td>300 cm</td>
<td>PG14300LF</td>
<td>Light Support</td>
</tr>
<tr>
<td>Philips</td>
<td>Phoenix guidewire extra support</td>
<td>300 cm</td>
<td>PG14300LX</td>
<td>Supportive</td>
</tr>
<tr>
<td>Ev3</td>
<td>Nitrex guidewire</td>
<td>300 cm</td>
<td>N143001</td>
<td>Flexible</td>
</tr>
<tr>
<td>Asahi</td>
<td>Regalia XS1</td>
<td>300 cm</td>
<td>PAGP140300</td>
<td>Medium</td>
</tr>
<tr>
<td>Abbott Vascular</td>
<td>Hi-Torque Extra S’PORT</td>
<td>300 cm</td>
<td>22235M</td>
<td>Supportive</td>
</tr>
<tr>
<td>Abbott Vascular</td>
<td>Hi-Torque Iron Man</td>
<td>300 cm</td>
<td>1001311</td>
<td>Supportive</td>
</tr>
<tr>
<td>Abbott Vascular</td>
<td>Hi-Torque Standard</td>
<td>300 cm</td>
<td>22320H-901</td>
<td>Supportive</td>
</tr>
<tr>
<td>Asahi</td>
<td>Astato XS 20</td>
<td>300 cm</td>
<td>PAGH143392</td>
<td>Supportive</td>
</tr>
<tr>
<td>CSI</td>
<td>VIPER</td>
<td>335 cm</td>
<td>VPR-GW-14</td>
<td>Supportive</td>
</tr>
<tr>
<td>Abbott Vascular</td>
<td>Hi-Torque Floppy II ES</td>
<td>300 cm</td>
<td>22359M</td>
<td>Extra</td>
</tr>
<tr>
<td>Abbott Vascular</td>
<td>Hi-Torque Cross-IT</td>
<td>300 cm</td>
<td>1003310H</td>
<td>CTO</td>
</tr>
</tbody>
</table>

1. Test performed on the bench model
0.014” guidewires compatible for use with the Phoenix atherectomy system 2.2 and 2.4 mm deflecting catheter

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<thead>
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<tr>
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<td>Nitrex guidewire</td>
<td>300 cm</td>
<td>N143001</td>
<td>Flexible</td>
</tr>
<tr>
<td>US Endovascular</td>
<td>Nitinol Mandrel Wire</td>
<td>300cm</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
1.8, 2.2 and 2.4 mm tracking catheter product handling
Suggested tracking catheter case workflow

1. 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

2. 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

3. Under fluoroscopic guidance, turn system ON using switch on handle
   • Advance catheter at a rate of one mm per second 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
   • 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.
2.2 mm deflecting catheter product handling
Suggested 2.2 mm case workflow

1. Create pilot channel for the first pass
   • Same procedure as advancing tracking catheter
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
   • **To rotate:** adjust the position of the catheter tip by turning the knob 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 24 clicks of the knob.
3. Rotate and/or reposition the catheter tip as desired during cutting or between passes.
4. Once the lumen is opened up to the maximum diameter desired, turn OFF the Phoenix atherectomy system
5. Perform an angiogram and IVUS to assess the lumen
2.4 mm deflecting catheter
product handling
Phoenix 2.4 mm deflecting mechanism of action

2.4 mm 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 2.4 mm deflecting mechanism of action

- 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 one mm per second 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.
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 eight 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.
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 one 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 2 cm when moving from straight to deflected mode (from 127 cm working length to 125 cm 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 2.4 mm reduced profile device can cut forward, and, when deflected, backwards through a lesion
• 2.4 mm 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, 130 cm length
P22130K – 2.2mm Phoenix atherectomy system kit, 130 cm length
P18149K – 1.8mm Phoenix atherectomy system kit, 149 cm length
P22149K – 2.2mm Phoenix atherectomy system kit, 149 cm length
P24130K – 2.4mm Phoenix atherectomy system kit, 130 cm length
PD22130K – 2.2mm Phoenix atherectomy system kit, deflecting, 130 cm length
PD24127K – 2.4mm Phoenix atherectomy system kit, deflecting, 127cm length
PG14300LF – Phoenix light support guidewire, 300 cm length
PG14300XF – Phoenix extra support guidewire, 300 cm 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)