

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.

	Phoenix	Directional	Orbital	Rotational
Front cutting for direct lesion access	✓		✓	✓
Plaque removal	✓	✓		✓
Directional cutting ability*	✓	✓		
Single insertion	✓		✓	✓
No need for capital equipment	✓	✓		

*available with Phoenix 2.4 mm deflecting catheter

The Phoenix solution

Phoenix was created to address physicians' clinical concerns and challenges

CLINICAL CONCERN	PHOENIX SOLUTION
Vessel Injury	<ul style="list-style-type: none"> ▶ Front cutter clears tissue in a way that may help reduce potential trauma to the vessel¹
Distal Embolization	<ul style="list-style-type: none"> ▶ Continuous capture and passive clearance of debulked material into the catheter resulted in a 1% rate of symptomatic distal emboli¹ in the EASE trial
 Ease of Use	<ul style="list-style-type: none"> ▶ Single insertion – no need to remove and clean out debulked material ▶ Battery powered handle operated - No capital equipment or additional procedural accessories required
Deliverability	<ul style="list-style-type: none"> ▶ Low profile, front cutting design allows for direct lesion access without having to first pass a nosecone ▶ OTW design aids in trackability and pushability of catheter
Versatility	<ul style="list-style-type: none"> ▶ Treat a range of tissue types from soft plaque to calcified arteries ▶ Treat most peripheral vasculature with only 3 catheter diameters²

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 knee¹

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

Catheter Tip Diameter	Minimum Introducer Size	Crossing Profile	Working Length	Maximum Guide Wire Diameter	Minimum Vessel Diameter ¹	Anatomical Locations
1.8 mm	5F (1.8 mm) or larger	1.8 mm	130 cm	0.014" (0.36 mm)	2.5 mm	Femoral, popliteal, or distal arteries located below the knee
2.2 mm	6F (2.2 mm) or larger	2.2mm	130 cm	0.014" (0.36 mm)	3.0 mm	
1.8 mm	5F (1.8 mm) or larger	1.8 mm	149 cm	0.014" (0.36 mm)	2.5 mm	
2.2 mm	6F (2.2 mm) or larger	2.2mm	149 cm	0.014" (0.36 mm)	3.0 mm	
2.4 mm	7F (2.4mm) or larger	2.4mm	130 cm	.014" (.36 mm)	3.0 mm	

Catheter Tip Diameter	Minimum Introducer Size	Crossing Profile	Working Length	Minimum Vessel Diameter ¹	Anatomical Locations
2.2 mm	6F (2.2 mm) or larger	2.2 mm	130 cm Deflected	3.0 mm	Femoral, Popliteal or distal arteries located below the knee

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.

Catheter Tip Diameter	Minimum Introducer Size	Crossing Profile	Working Length	Minimum Vessel Diameter ¹	Anatomical Locations
2.4 mm	7F (2.5 mm) or larger	2.4 mm	125 cm Deflected 127 cm Straight	3.0 mm	Femoral and Popliteal Arteries

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.

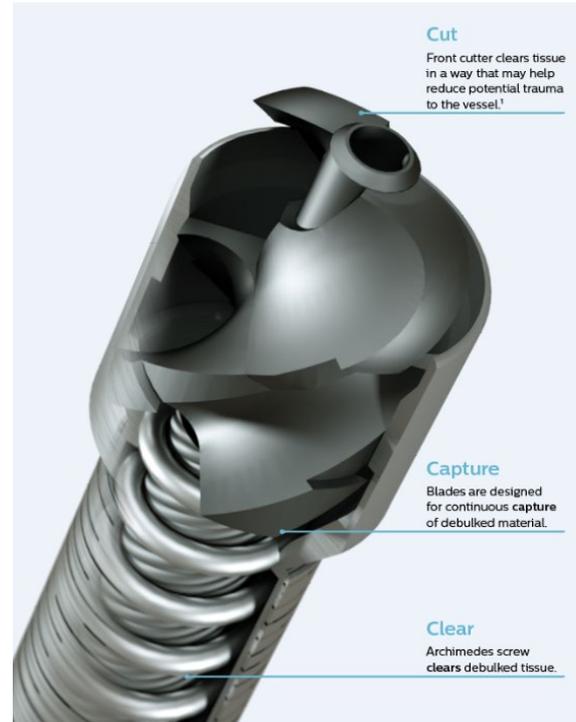
Cut, capture, clear mechanism of action

Cut: front cutter clears tissue in a way that may help reduce potential trauma to the vessel¹

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 catheters¹

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

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 catheter¹

Brand	Product	Length	Part Number	Wire Support Level
Philips	Phoenix guidewire light support	300 cm	PG14300LF	Light support
Ev3	Nitrex guidewire	300 cm	N143001	Flexible
US Endovascular	Nitinol Mandrel Wire	300cm	USEGS14-300A	Flexible

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

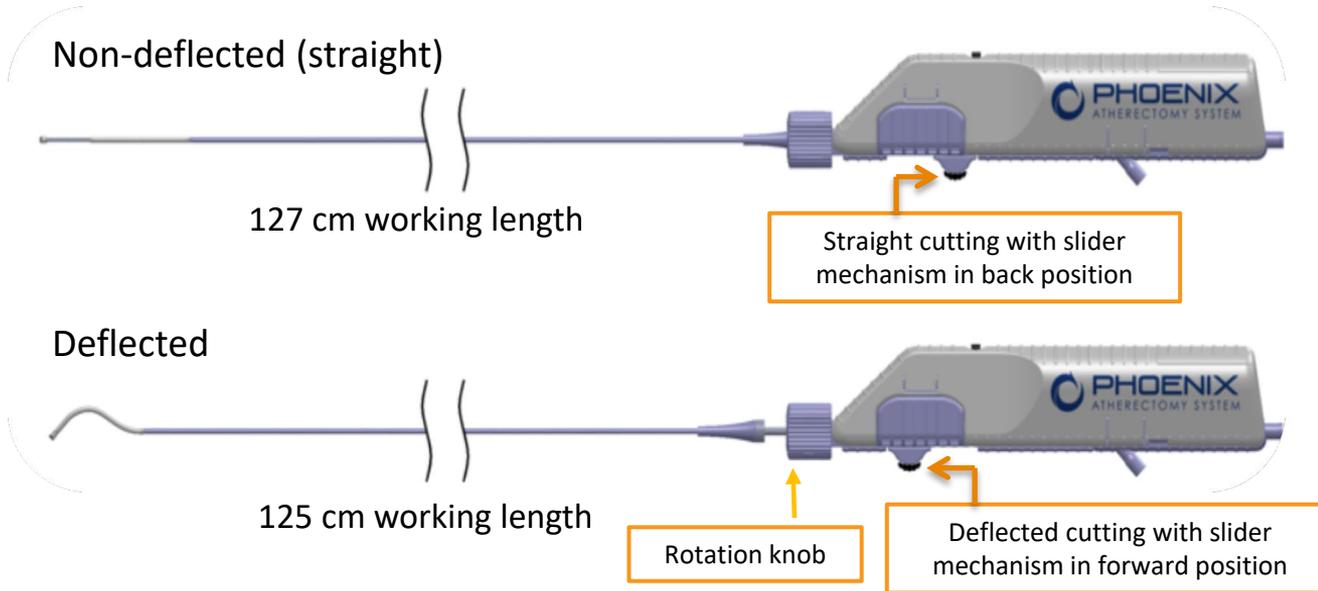
1. Straight cutting with outer sleeve retracted



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.



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 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.



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 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

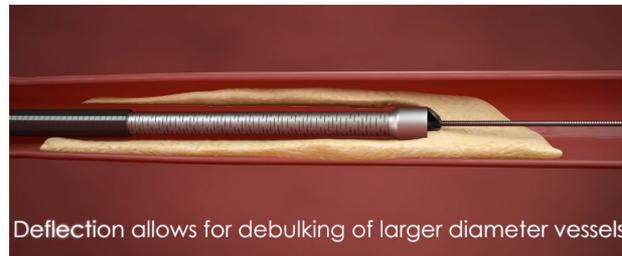
- Recognize that cutter head will retract proximally by 2 cm when moving from straight to deflected mode (from 127 cm working length to 125 cm working length)
- Pay attention to ability of cutter head to rotate
 - In extreme cases of iliac tortuosity or in situations with smaller vessel diameters¹, rotation 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 – 2.4 mm 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)



