# Phoenix Atherectomy System Certification Guide for Reps

The trainee should be able to verbalize the following:

Identify Indications per IFU

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

Device Description

* Phoenix system components include Atherectomy Catheter, Atherectomy Handle, Wire Support Clip and Disposal Bag. All system components are sterile, single-use devices designed for atherectomy of the peripheral vasculature
* The Phoenix Catheter is a flexible double-lumen catheter that contains a torque shaft that is attached to a metal cutting element at the distal tip and a centralized guidewire lumen. An Archimedes Screw is fixed on the outer surface of the torque shaft. The distal cutter head is a true front cutting design incorporating 2 helical shaped blades on the distal tip, 4 blades within the cutter head which further macerates excised plaque. When activated, the torque shaft rotates, causing the cutting element to cut, capture and continuously clear plaque through passive conveyance via the Archimedes Screw.
* The Phoenix Handle includes a battery – operated motor/handle that drives rotation of the cutter 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 Clip is an accessory which can help support and secure the guidewire position during the procedure.
* Phoenix Atherectomy Catheter sizes, lengths and sheath compatibility include:
* 1.8mm tracking, 130 and 149cm, 5fr sheath
  + Minimum vessel diameter 2.5mm
* 2.2mm tracking, 130 and 149cm, 6fr sheath
  + Minimum vessel diameter 3.0mm
* 2.4 tracking, 130cm,7 fr sheath
  + Minimum vessel diameter, 3.0mm
* 2.2mm deflecting, 130 cm,6 fr sheath
  + Minimum vessel diameter 3.0mm
* 2.4mm deflecting, 127cm straight -125cm deflected, 7fr sheath
  + Minimum vessel diameter 3.0mm
* Catheter is OTW system
* Accommodates 300cm 0.014” guidewires
* Refer to approved guidewires listed on IFU

Device Prep

* Confirm valid device expiration date
* 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
* In a sterile fashion, open sterile packages containing Phoenix catheter, handle, wire support clip and disposal bag
* Priming the Phoenix Catheter
* Attach 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 centralized guidewire port with a finger and continue to flush until saline drips out of the distal tip of the catheter
* Attach handle
* Assembly of Phoenix Catheters
* Remove white tape covering on/off switch
* Snap catheter into handle matching “C” in handle with sweep knob
* Verify that Catheter is completely inserted into handle, listen for 2 clicks
* Snap handle on from front to back, remove from back to front
* Use of Wire Support Clip
* Slide or snap 0.014 compatible torque device into Wire Support Clip
* Snap Wire Support Clip onto handle
  + Feed the proximal end of the wire into the torque device and form a support loop of about 10-15cm that spans from the central guidewire exit port of the Catheter to the Wire Support Clip
  + Tighten the torque device onto the guidewire
  + 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
* Attach disposal bag to disposal port
* Post Procedure Flushing
* **When removing device from patient, if additional use is remotely possible, submerge tip of catheter in heparinized saline and activate motor drive unit to flush debris from internal components. Avoid contact with bowl and contents within bowl.**
* Help prevent debris in internal components from clotting
* Debulked material will be forced out of Archimedes Screw into device catheter shaft and laser cuts. This can create perforations in catheter shaft PTFE coating
* **Verbalize:** If the Phoenix System is used to treat multiple lesions in the same patient, 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 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.
* It is important that we reinforce this more strongly because common practice is to flush lumen for all devices before going back in and we need to reinforce this message as the proper procedure is to flush.

Procedural Steps

* Insertion
* Insert the appropriately–sized sheath with a cross cut hemostasis valve using standard techniques
* Advance an approved 300cm 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 with the Phoenix System OFF until the tip exits the Introducer Sheath.
* Guidewire Preparation
* 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
* Confirm that the guidewire is intraluminal. A second angiographic viewing angle to confirm wire placement is recommend
* Confirm that the distal tip of the guidewire is positioned a minimum of 20cm from the distal tip of the Catheter
* Apply torque device tightly to the guidewire approximately 20 cm to 30 cm from central guidewire port.
* Monitor the smooth tracking of Catheter over guidewire during operation .If resistance is encountered during the procedure, remove Catheter and flush guidewire lumen by running the Catheter within a heparinized saline bowl 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 withinthe catheter lumen.
* Crossing the Lesion and Debulking
* Under fluoroscopic guidance, turn ON the Phoenix Atherectomy Catheter using the switch on the Handle. Advance the Catheter slowly at a rate of 1mm/sec through the lesion. In highly stenotic lesions or lesions > 10 cm in length, periodically pause and withdraw the Catheter to allow improved blood flow and plaque removal during cutting. Continue to advance distal tip of Catheter until it has crossed the lesion
* 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 (Flush the catheter before repeating).
* Phoenix Atherectomy Catheter Removal
* Removal of the Catheter should be accomplished by running the device off the wire in ON mode
* Use a standard over-the-wire guidewire management technique to remove the Catheter out of the sheath under fluoroscopic guidance.
* Utilize Wire Support Clip with torque device while removing Catheter to prevent wire spinning. Adjust position of torque device, while device is off, to feed wire into the handle until the Catheter tip exits the Introducer Sheath
* Turn OFF the Phoenix Atherectomy System with the switch on the Handle
* Perform a post- atherectomy angiogram
* Debulking to Larger Diameter (Deflected Cutting) Phoenix 2.2mm Deflecting
  + When moving to deflected cutting, the use of a flexible (“light”) guidewire allows maximum deflection of the Catheter tip. Exchange guidewire if desired.
  + 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 on the Catheter Handle 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.
  + 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.**
  + Advance the Catheter slowly and carefully while debulking. Always monitor the Catheter tip deflection position during cutting Rotate and/or reposition the Catheter tip as desired during cutting or between passes.
  + The Phoenix Atherectomy System must remain ON in order to effectively remove plaque.
  + Once the lumen is opened up to the maximum diameter desired, turn OFF the Phoenix Atherectomy System.
  + Retract the Catheter at least 1 cm proximal to the lesion.
  + Perform an angiogram to assess the lumen.
  + Continue debulking if desired and reassess the lumen with an angiogram.
* Debulking to Larger Diameter (Deflected Cutting) Phoenix 2.4mm Deflecting
  + When moving to deflected cutting, the use of a flexible guidewire allow maximum deflection of the Catheter tip. Exchange guidewire if desired.
  + While holding the guidewire stationary and using fluoroscopic guidance, advance the Phoenix deflecting Catheter distal tip to within a few millimeters proximal to the target lesion.
  + 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.
  + To Rotate: Adjust the position of the Catheter tip by turning the knob on the Outer Sheath clockwise or counter clockwise. As the knob is rotated, a tactile click will be felt by the user. 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
  + 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.**
  + The Catheter may be advanced and retracted while at a fixed deflection setting to debulk.
  + Always monitor the Catheter tip deflection position during cutting, 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).
  + The Phoenix Atherectomy System must remain ON in order to effectively remove plaque.
  + Once the lumen is opened up to the maximum diameter desired, turn OFF the System.
  + Retract the Catheter at least 1 cm proximal to the lesion.
  + Perform an angiogram to assess the lumen.
  + Continue debulking if desired and reassess the lumen with angiogram.
* Phoenix Atherectomy Catheter Removal
  + Stabilize the guidewire across the lesion, straighten the Catheter tip by sliding the Outer Sheath to the fully proximal position, and carefully remove the Catheter out of the sheath under fluoroscopic guidance using standard over- the wire technique.
  + Hold the guidewire firmly during the Catheter removal process by manually securing the guidewire or securing (“locking”) a torque device to the guidewire.
  + Removal of the Catheter should be accomplished by running the device off the wire in ON mode per the following steps:
    - Lock a torque device on the proximal end of the guidewire a distance back from the Introducer Sheath.
    - 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
  + Under fluoroscopy, remove the Catheter by feeding the wire into the handle until the Catheter tips exits the Introducer Sheath.
  + Turn OFF the Phoenix Atherectomy System with the switch on the Handle
  + Perform a post-atherectomy angiogram

Practice Grade: \_\_\_\_ Pass: \_\_\_\_\_\_ Fail: \_\_\_\_\_\_