

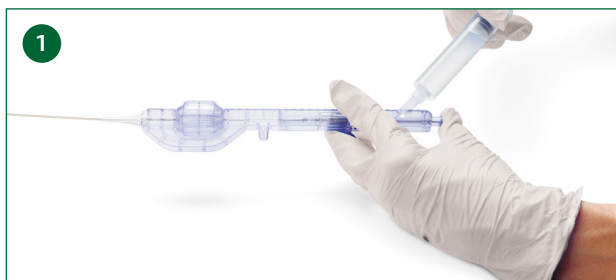
PHILIPS

Phoenix

Atherectomy catheter

PHOENIX
ATHERECTOMY SYSTEM

Preparation and procedural instructions for Phoenix atherectomy catheters¹



1. Flush guidewire and disposal ports

- Attach 10cc syringe filled with heparinized saline to disposal port
- Flush slowly with gentle pressure until saline drips out of proximal guidewire lumen
- Cover central guidewire port with a finger and flush until saline drips out of distal tip of guidewire lumen



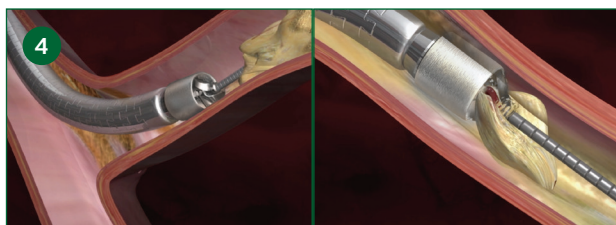
2. Assembly

- Turn on the handle and ensure it can be activated
- Snap catheter into handle, matching "C" in handle with control knob. Verify that catheter is completely inserted into handle (2 hard clicks). Snap in from front or back, remove from back
- Attach disposal bag or tube (no locking connection)
- Attach guidewire clip



3. Preparation for treatment:

- Advance catheter proximal to the lesion
- Form a 10-15 cm guidewire loop that spans from the guidewire exit port of the catheter into the wire support clip. Tighten the torque screw and confirm the wire does not spin
- Under fluoroscopic guidance, proximal to the lesion, turn the catheter on using the switch on the handle for 5-10 seconds. Make sure fluid exits out of the disposal outlet
- Confirm that the distal tip of the wire is positioned a minimum of 20 cm from the distal tip of the catheter.

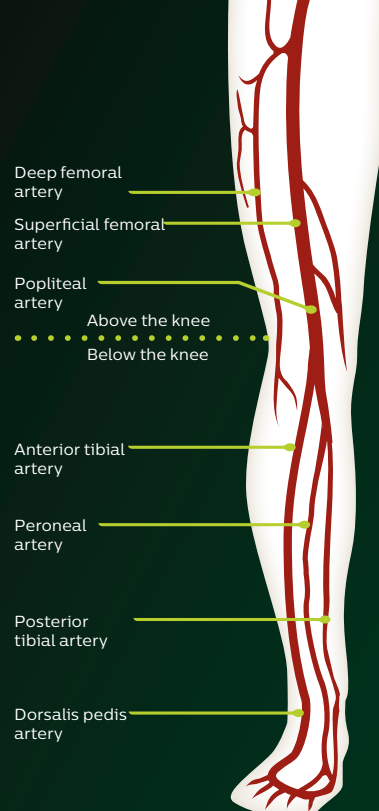


4. Procedural instructions

- Advance catheter at a rate of 1mm/sec until the distal tip of the catheter has crossed the lesion
- Withdraw the catheter until the distal tip is proximal to the lesion. Image the lumen and/or repeat if desired.
- The Phoenix Atherectomy System must remain ON in order to effectively remove plaque.
- Warning for deflecting models: When the catheter is deflected and the System is ON, do not leave the cutter head stationary

5. If intention is to use the Phoenix catheter again for the same patient after removal from the patient's body, then re-prime the catheter as follows:

- Submerge the tip of the catheter into a bowl with heparinized saline.
- Turn system on for 20-30 seconds to clear inside from debris (watch saline dripping out of disposal port)
- Do NOT flush the guidewire lumen



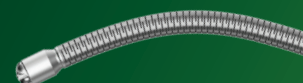
2.4 mm deflecting catheter

Minimum introducer size	Working length	Guide wire diameter	Minimum vessel diameter ^{1,2}
7F (>2.4 mm)	127 cm	0.014"	3.0 mm



2.2 mm deflected catheter

Minimum introducer size	Working length	Guide wire diameter	Minimum vessel diameter ^{1,2}
6F (>2.2 mm)	130 cm	0.014"	3.0 mm



2.2 mm tracking catheter

Minimum introducer size	Working length	Guide wire diameter	Minimum vessel diameter ^{1,2}
6F (>2.2 mm)	130 or 149 cm	0.014"	3.0 mm



1.8 mm tracking catheter

Minimum introducer size	Working length	Guide wire diameter	Minimum vessel diameter ^{1,2}
5F (>1.8 mm)	130 or 149 cm	0.014"	2.5 mm



1.5 mm tracking catheter

Minimum introducer size	Working length	Guide wire diameter	Minimum vessel diameter ^{1,2}
4F (>1.5 mm)	149 cm	0.014"	2.0 mm



Guidewires for the Phoenix atherectomy system

Recommended 0.014" guidewires for Phoenix tracking catheters^{1,3}

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
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	300 cm	1003310H	CTO

Recommended 0.014" guidewires for the Phoenix 2.4mm deflecting and 2.2 deflected catheter^{1,3}

Brand	Product	Length	Part number	Wire support level
Philips	Phoenix guidewire- Light support	300 cm	PG143000LF	Light support
Ev3	Nitrex guidewire	300 cm	N143001	Flexible
CSI	VIPER	335 cm	VPR-GW-14	Supportive

Note: Phoenix 2.2 deflecting: flexible guidewire to facilitate deflection. Using a stiff guidewire will resist deflection and straighten out catheter tip.

1. Refer to product IFU for detailed instructions

2. Warning: do not use the Phoenix atherectomy system in vessels smaller than the indicated size or harm to patient (vessel perforation, dissection or injury) could occur.

3. Test performed on the bench model. Data on file at Philips. Bench test results not indicative of clinical performance.

Product subject to country availability. Please contact your local sales representative.



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