VOLCANO

Attention - Before using this device, Consult Instructions for Use

PHOENIX GUIDEWIRE

INSTRUCTIONS FOR USE

PHOENIX ATHERECTOMY SYSTEM

DEVICE NAMES
Phoenix Guidewire, Floppy Tip, Light Support

CAUTION: FEDERAL (US) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON ORDER OF A PHYSICIAN.

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE, NOTING ALL WARNINGS AND PRECAUTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

INDICATIONS

The Phoenix Guidewire family is designed for percutaneous entry into the peripheral vascular system as an intravascular device by gently negotiating the vascular system while maintaining enough strength and rigidity to enable a catheter to be directed over the guidewire with ease.

CONTRAINDICATIONS

This device is not intended for use in the coronary or neurovascular arteries.

DESCRIPTION

The Phoenix family is an 0.014 inch diameter X 300 cm length guidewires made of a Silicone coated Nitinol core wire that is tapered at the distal tip where a coil is secured to the distal end. The distal coil is 5.5 cm and consist of Palladium. The tip and wire support of the guidewire are found on product labels and are summarized in Table 1.

Table 1: Phoenix Guidewire Models and Configurations.

Catalog No.	Tip and Wire Support Configurations	Wire Tip	Core Material	Diameter	Length
PG14300LF	Soft Tip /Light Support	5.5 cm	Nitinol	0.36mm (0.014")	300 cm

WARNINGS

- The Phoenix Guidwire is supplied sterile and intended for one-time use only. Do NOT resterilize and/or reuse. Resterilization or reuse may potentially compromise device performance and safety and may increase the risk of infection.
- Use the Phoenix Guidewire products prior to the "Use By" ("Expires") date specified on each individual package label.
- When the Phoenix Guidewire is exposed to the vascular system, it should not be advanced or retracted except under direct fluoroscopic observation. If resistance is met during advancement or retraction, determine the cause of the resistance before continuing.
- Do not withdraw guidewires through a metal trocar or metal needle.

- Do not advance or withdraw guidewires against resistance until the cause of the resistance has been determined. Excessive force against resistance may result in damage to guidewire and catheter or vessel perforation.
- Volcano does not recommend a particular technique for the use of this device. The steps contained in the preceding directions discuss the Seldinger Technique of percutaneous entry are for information purposes only. Each physician should evalute their appropriateness according to individual patient condition and his or her medical training and experience.
- Phoenix guidewires incorporate various performanc characteristics from tip shape to body stiffness. Extreme care must be taken in choosing the correct guidewire or to minimize the risk of vessel perforation or vascular damage.
- Guidewires by nature of their construction will collect blood and other foreign matter in the coiled tip . No type of cleaning will completely remove this material. Therefore, they are intended for single patient or one time use only. DO NOT RESTERILIZE.
- Do not use, or attempt to correct, a Phoenix Guidewire if it is bent or kinked or has any evidence of damage as this may result in breakage or compromised performance

CAUTIONS
- Prior to use, the Phoenix Guidewire should be inspected damage. If damaged, DO NOT USE.
- For use only by physicians trained in percutaneous peripheral interventional procedures.
- Carefully read all instructions pior to use. Observe all warnings and cautions. Failure to do so may result in complications

ADVERSE EFFECTS
Potential adverse effects associated with the use of this device and other interventional catheters include but are not limited to the following (alphabetical order):
- Access site injury, including pain
- Arterial dissection
- Arterial perforation or pseudoaneurysm
- Arterial spasm or abrupt or sub-acute closure
- Death
- Embolism, including thrombus, plaque, air, device, etc.
- Fracture of any component of the device that may or may not lead to serious injury or surgical intervention
- Hematoma requiring surgery
- Myocardial infarction
- Arrthythmia
- Renal Failure
- Myoglobinuria
- Reaction to contrast media, procedure medications or wire materials, including allergic reaction
- Revascularization or vascular injury which may require surgical repair or emergency surgery

The occurrence of these adverse effects may lead to the need for repeat catheterization/angioplasty, emergency bypass surgery, or death.

HOW SUPPLIED, STERILIZATION, AND EXPIRATION

The Phoenix Guidewire is packaged and sterilized individually. **NOTE:** Guidewire, length, diameter, tip and wire support configurations are indicated on the product label. The Phoenix Guidewire is sterilized using ethylene oxide gas. Each device is sterile if the sealed pouch is unopened and undamaged. All are intended for single use only and should not be reused or re-sterilized. Use before the "Use by" dated printed on the package labels. Store in a dry, cool place.

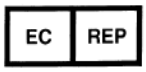
INSTRUCTIONS FOR PROCEDURE

INSPECTION OF PHOENIX GUIDEWIRE COMPONENTS
Prior to use, all equipment to be used for the procedure should be examined carefully for defects. Examine the packaging for cuts, tears, or other breach of the sterile barrier. Examine the Phoenix Guidewire for bends, kinks or other damage. Do not use any defective guidewire

DIRECTIONS FOR USE:
1. Inspect guidewire prior to use for tip shape, bends, kinks, coil separation. If damaged, DO NOT USE.
2. Using sterile technique, localize and puncture the vessel with a needle cannula.
3. Remove the needle, leaving the cannula in place.
4. Insert distal end of the guidewire through the cannula and into vessel.
5. Remove the cannula, leaving the guidewire within the lumen of the vessel.
6. Pass the catheter over the guidewire within the lumen of the vessel under fluoroscope guidance to the desired position.
7. With the guidewire in place, follow the instructions for use provided by the manufacture of the introducer, catheter or other devices, as well as the medical facility's standard procedure for these types of devices.

DEVICE DISPOSAL:
The Phoenix Guidewire is disposable per hospital biohazard procedures.

	Use Before Date		Nonpyrogenic
	Store in a dry, dark, cool place		Content: One (1)
	Do not use open or damaged packages		Do not Re-Sterilize
	Catalogue number		Batch Code
	Sterilized using Ethylene Oxide		Single Use Only
	Prescription Only		

 Manufactured for:	Volcano AtheroMed, Inc. 1455 Adams Dr. #1120 Menlo Park CA 94025 USA (800) 228-4728 (916) 638 8112 fax	 Authorized Representative	Volcano Europe BVBA/SPRL Excelsiorlaan 41 B-1930 Zaventem, Belgium +32.2.679.1076 +32.2.679.1079 fax

The PHOENIX ATHERECTOMY System and PHOENIX GUIDEWIRE (including components and/or methods thereof) may be protected under one or more pending United States Patent Applications, as well as corresponding international patent applications.

LIMITED WARRANTY AND DISCLAIMER

Volcano AtheroMed, Inc. warrants that reasonable care has been used in the design and manufacture of this medical device.

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