ARGON Pointer Nitinol Guidewires Instruction Manual

Pointer Nitinol Guidewires
Instruction Manual

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Intended Use/Purpose

Pointer™ Nitinol Guidewires are intended to facilitate the percutaneous placement and guidance of a catheter in the peripheral vasculature.

Device Description

Pointer™ Nitinol Guidewires have excellent visibility through high radiopaque coil tips. The device consists of a Hydrophilic coating tip for less traumatic path finding and PTFE coated nitinol shaft for minimal friction during device introduction.

Indication for use

The product is for catheter guiding in peripheral vessels.

Duration

Transient, less than 60 minutes.

Warnings

- This device was designed, tested, and manufactured for single use only. Reuse or reprocessing has not been evaluated and may lead to its failure and subsequent patient illness, infection, or another injury. Do not reuse, reprocess or re-sterilize this device.
- Inspect the package integrity before use.
- Do not use if the package appears open or if the expiry date has been exceeded.
- Do not continue to use if any of the components are damaged during the procedure.
- Do not advance the wire against resistance until the cause of the resistance has been determined by fluoroscopy. Excess force against resistance may result in damage to the guidewire, catheter, or vessel perforation.
- Do not withdraw a guidewire through a needle. Straighten the guidewire in order to withdraw the needle.
- The product must only be used by qualified personnel who are familiar with the technique.
- Make sure the product is compatible with other equipment.
- Not to be used with Rotarex®

Potential Complications

Potential complications include, but are not limited to the following:

- Perforation of a vessel or arterial wall
- Thrombus formation
- Puncture site hematoma
- Vasospasm
- Infection
- Vessel dissection

Preparation

- Make sure the guidewire is undamaged.
- Loosen the straightener together with the guidewire.
- Inject saline with a syringe in a vertical position.
- Form the tip by running the coil over the edge of the colored plastic straightener.
- Activate the coating with saline.

Procedure

1. Introduce the guidewire, soft end first, through an appropriate access device.
2. Advance the guidewire using fluoroscopy. Rotating the guidewire makes the advancement easier. Use the

torque to lead the tip of the guidewire.

Storage: Store at controlled room temperature.

Disposal: After use, this product may be a potential biohazard. Handle in a manner, which will prevent accidental puncture. Dispose of in accordance with applicable laws and regulations.

NOTE: In the event, a serious incident related to this device occurs, the event should be reported to Argon Medical at quality.regulatory@argonmedical.com as well as to the competent health authority where the user/patient resides.

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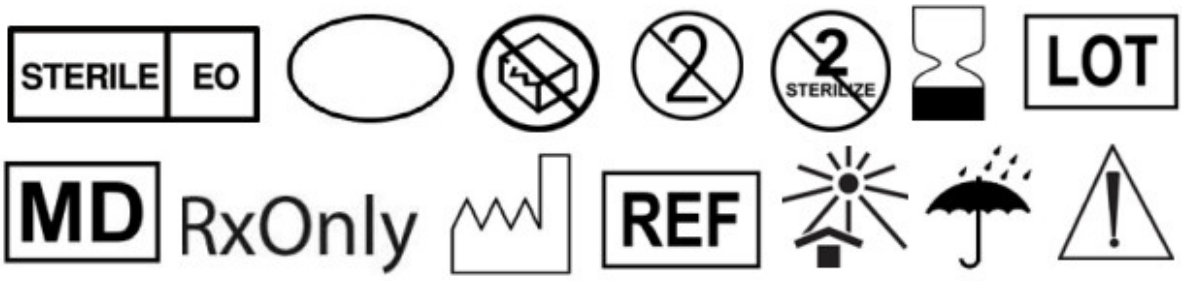

https://www.argonmedical.com/resources/product-information

Documents / Resources

	ARGON Pointer Nitinol Guidewires [pdf] Instruction Manual Pointer Nitinol Guidewires

References

- Home Page
- Product Symbols | Argon Medical Devices
- Product Information