



ARGON Nitinol Access Guidewire Instructions

[Home](#) » [ARGON](#) » ARGON Nitinol Access Guidewire Instructions 



Stainless Steel Access Guidewire Nitinol Access Guidewire

Intended Use/Purpose

The Access Guidewire is intended for use in the placement of non-vascular percutaneous drainage catheters.

Device Description

The Access Guidewires features a high torque-control and smooth transition from rigid core to radiopaque coil tip that provides excellent maneuverability.

Indication for use

The product is only for non-vascular procedures.

Duration

Transient, less than 60 minutes.

Warnings

- This device was designed, tested, and manufactured for single use. 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

- 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 guidewire, catheter, or vessel
- Do not withdraw a guidewire through a needle. Straighten the guidewire in order to withdraw the needle.
- Make sure the product is compatible with other equipment.
- The product must only be used by qualified personnel who are familiar with the technique.

Potential Complications

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

- Puncture site hematoma
- Infection
- Perforation of the adjacent vessel wall, tissues/organs
- Minor pain/discomfort
- Minor bleeding

Preparation

- Make sure that the guidewire is undamaged.
- Loosen the straightener together with the guidewire.
- Inject saline with a syringe in a vertical position.
- Stainless Steel Wire – Shape the tip into a 3-curve using your fingers if necessary.
- Nitinol Wire
- Form the tip by running the coil over the edge of the colored plastic straightener.
- Activate the coating by saline.

Directions for Use

1. Insert the flexible end of the guidewire into the device. Avoid overly vigorous manipulation of the guidewire to prevent damage of vessel or
2. Advance the guidewire through the device.
3. Position the guidewire.
4. Hold the guidewire in place and withdraw the device.
5. Advance the catheter over 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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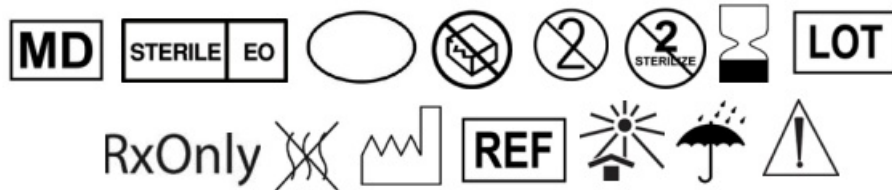
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<https://www.argonmedical.com/resources/product-information>

The symbols glossary is located electronically at www.argonmedical.com/symbols

Contents

- [1 Documents / Resources](#)
- [2 Related Posts](#)

Documents / Resources



[ARGON Nitinol Access Guidewire](#) [pdf] Instructions
Nitinol Access Guidewire, Stainless Steel Access Guidewire