


ARGON MEDICAL DEVICES, INC.
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Tel: +1 800-927-4669;
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www.argonmedical.com

 **Brasil Detentor da Notificação:** Ecomed
Comercio de Produtos Médicos Ltda.
Endereço: Av. Augusto Severo, 156 -
Lojas A/ B - Glória - Rio de Janeiro/ RJ
20021-040
Notificação nº: 10337850098

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

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

Co-Axial Introducer Needle

Intended Use/Purpose : Co-Axial Introducer Needle is used with either a side notch or full core biopsy needle device in performing soft tissue percutaneous biopsies.

Device Description : The Co-Axial Introducer Needle features an echogenic tip for accurate placement under ultrasound guidance, and a centimeter markings that provide reference for depth placement. The hubs are color coded for easy gauge size determination and it has an adjustable needle stop that allows the user to restrict the forward movement, effectively localizing the needle tip to the biopsy site.

Indications for Use : Co-Axial Introducer Needle is intended for a range of biopsy applications of soft tissue.

Warning

- Reuse or reprocessing has not been evaluated and may lead to its failure and subsequent patient illness, infection or other injury. Do not reuse, reprocess or re-sterilize this device.
- Inspect the package integrity before use.
- Do not use if package is open or damaged or if the expiry date has been exceeded.
- The instrument should be used by a physician familiar with the possible side effects, typical findings, limitations, indications and contraindications of core needle biopsy.
- Use only for core biopsies of soft tissue as determined by a licensed physician.
- Attempting to biopsy hard tissue or masses may reduce the performance, causing damage to the instrument or potentially harm the patient. This instrument is intended for soft tissue biopsy only.
- Incorrect setting of stroke length on the device may cause a sample to be incorrectly taken.
- Handle in a manner, which will prevent accidental puncture.

Note: The device compatibility been tested with Argon Biopsy products. Other manufacturer's biopsy instrument has not been tested for compatibility.

Precaution

- Verify integrity of needle before use. If needle is damaged, appropriately discard the entire device (see disposal section) and prepare a new instrument.
- The introduction of the needle into the body should be carried out under imaging control (ultrasound)
- Do not bend the needle.
- Do not contact the needle tips to a hard surface while expelling a sample.

Possible/Side Effect

- It is not uncommon for patients to experience:
 - Bleeding, infection at insertion site
 - Fever
 - Pain at the biopsy site
 - Swelling at the biopsy site,
 - Adjacent tissue injury
 - Hematoma.

***When used as intended by a physician, the benefits of using the Biopsy Instrument Needle outweigh the risks associated with the use of the device.

DIRECTIONS FOR USE:

1. Prepare the biopsy site appropriately and locate the target area.
2. Advance a Co-axial Introducer Needle, using standard technique, to a position proximal to the lesion. Position the adjustable needle stop proximal to the skin.
3. Remove the stylet from the Co-axial Introducer Needle, leaving the cannula in position.
4. Choose your complementary biopsy needle.
5. Insert the biopsy needle through the coaxial needle.
6. Fire and retrieve the biopsy sample with the biopsy needle.
7. Remove the biopsy needle.

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

Storage: Store at controlled room temperature.

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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