

**HƯỚNG DẪN SỬ DỤNG BẢN TIẾNG ANH (BẢN GỐC)
CỦA TRANG THIẾT BỊ Y TẾ: KIM SINH THIẾT DÙNG
CHO SÚNG SINH THIẾT LỖI TỰ ĐỘNG.**



GIÁM ĐỐC
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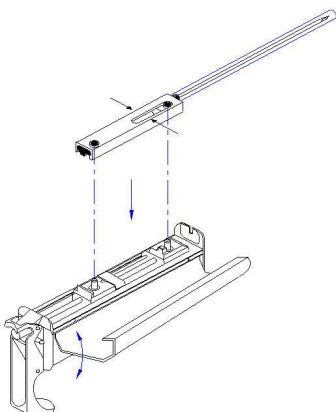


Figure 1 - Pro-Mag™ Needle



Figure 2 - ACN™ Needle

STERILE EO     RxOnly

MD    REF   LOT

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

**Pro-Mag™ Biopsy Needle,
Pro-Mag™ Short Throw Biopsy Needle,
ACN™ Biopsy Needle**

Intended Use/Purpose

Pro-Mag™ Biopsy Needle, Pro-Mag™ Short Throw Biopsy Needle and ACN™ Biopsy Needle are intended to be used in conjunction with Pro-Mag™ Ultra Automatic Biopsy Instrument to harvest high quality histological specimens.

Device Description

This product features a high quality core biopsy needles that provide histological specimens for diagnosis of suspect lesions. It has centimeter markings provide reference for accurate depth placement, each needle has an echogenic tip for accurate placement under ultrasound guidance, hubs are color coded for easy gauge size determination and all needle types can be utilized with compatible echogenic Co-Axial introducer needles.

The device are used in conjunction with the following accessories:

- **Pro-Mag™ Biopsy Needle** is used in conjunction with Pro-Mag™ Ultra Automatic Biopsy Instrument or other compatible, commercially available biopsy instrument.
- **ACN™ Biopsy Needles** is used in conjunction with Pro-Mag™ Ultra 2.2 Automatic Biopsy Instrument or other compatible, commercially available biopsy instrument.
- **Pro-Mag™ Short Throw Biopsy Needle** is used in conjunction with Pro-Mag™ Ultra Short Throw Automatic Biopsy Instrument or other compatible, commercially available biopsy instrument.

Indication for Use

The Pro-Mag™ Biopsy Needle, Pro-Mag™ Short Throw Biopsy Needle and ACN™ Biopsy Needle are indicated to obtain core samples from soft tissue such as the liver, kidney, prostate, breast and various soft tissue lesions.

Contra-indications for Use

For use only for core biopsies of soft tissue as determined by a licensed physician. The instrument should be used by a physician familiar with the possible side effects, typical findings, limitations, indications and contraindications of core needle biopsy. Physician judgement is required when considering biopsy on patients with bleeding disorder or receiving anti-coagulant medications.

Warning

- Contents are supplied sterile and are intended for single use only. Do not re-sterilize.
- Reuse or reprocessing has not been evaluated and may lead to its failure and subsequent patient illness, infection or other injury.
- Inspect the package integrity before use.
- Do not use if package is open or damaged and if the expiration date has passed.
- Hard tissue biopsy is considered an off-label misuse of the device.

Precautions

- The product must only be used by licensed, knowledgeable physician and qualified personnel who are familiar with possible side effects, typical findings, limitations, indications and contraindications of needle core biopsy.
- The device will typically be utilized in an outpatient clinical environment and in the following clinical areas:
 - **Urology** – Transrectal or transperineal biopsy of the prostate.
 - **Radiology** – Percutaneous kidney, liver and breast biopsy.
- The user is instructed to inspect the devices for damage prior to use.
- Before loading needles into the instruments, slide cannula over the stylet several times noting the proper free movement when necessary.
- DO NOT use if needles specimen notch does not pass into the outer cannula freely. (Note: A slight drag may be felt in the final 6mm of needle set closure.)
- Each device can be reused in the same procedure on the same patient for multiple biopsies.
- When used repeatedly in the same patient, the devices should be inspected for damage or wear after each sample is taken.
- Never test fire automatic reusable biopsy instrument while loaded with a needle set, damage to needle set may occur.
- Patient movement may affect the outcome of the procedure relating to quality of sample but no risk to patient.

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 and hematoma after the biopsy. 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.

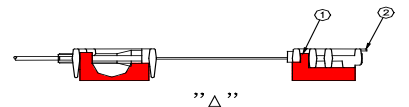
Pre-Procedure Preparation

- Inspect the product package for damage
- If undamaged, open the package using proper aseptic technique.
- Remove the needle from the pouch. Inspect the stylet for damage to the point, the cannula for damage to the cutting edge, or other imperfections that would prevent proper operation of the needle assembly.
- Open the lid of the biopsy instrument device, load the needle into the biopsy instrument device.

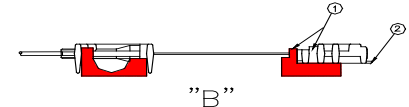
Note: Pro-Mag™ Needle Spacer is integral. However, the ACN™ Needle Spacer must be removed once the needle is in place into the instrument.



- **ACN™ Biopsy Needle** – The drawing A and B illustrate the correct and incorrect stylet hub placement in the carrier blocks :
 - **Drawing "A" is the correct position** - The hub inserted over tab on carrier block and tang in up position.



- **Drawing "B" is the incorrect position** - The hub behind carrier block tab or tang in down position.



- Close the lid and remove protective sheath on the needle.
- Safety button must be set in the position indicated by the arrow on the lid before cocking.

Procedure

- Cock the actuator handle twice in order to activate the device for firing (this automatically sets the safety).
- Release the safety by pushing the "Safety Release Button" located on the side of the instrument device.
- Firing the device can be achieved by pushing in on either the front trigger button or the rear trigger button. This action will trigger the spring mechanism, propelling the needle forward for a core biopsy sample.
 - Note:** The needle need not be removed from the biopsy device to retrieve the sample.
- After removing the needle from the patient, reset the safety button.
- Cock the actuator handle once to expose the biopsy notch located at the distal end of the needle. This action exposes the specimen for removal.
- Cocking the actuator handle a second time will activate the device for a second biopsy.

Disposal

After use, handle and dispose in accordance with hospitals policies and procedures concerning biohazard materials and waste.

Storage

Store in 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.