

## Instruction for Use

### Biopsy Gun

#### Device Description

Biopsy Gun is a single use system for histological core biopsies. It has a throw (advancement) of 25mm and is used in conjunction with a single use needle. This device is used to obtain tissue core biopsy of the prostate using needle. Sterile, Intended for single use. Duration of Contact with the body is less than 60 minutes. The configurations available include:

Family	Size (G)	Length (cm)	Catalogue Number
Biopsy Gun (BIG)	16	10	AMPLGP012
	18	16	
		20	
		25	

#### Intended Purpose

Biopsy Gun is single use system for histological core biopsies. The core needle biopsy device is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various.

#### Performance Characteristics of the Device

Biopsy Gun aids to obtain a large quality, reliable core sample with minimal distortion of the cellular pattern. Available in various gauge and lengths for procuring multiple samples with single insertion. Angled sample notch for enhanced needle action. Biopsy Gun has an innovative handle design with lightweight handle for easier manipulation during biopsy procedure. Improved control and grip with ribs design.

#### Indications

- Abnormal digital rectal exam (DRE),
- Increased prostatic-specific antigen (PSA)
- Clinical suspicion of prostate cancer.

#### Contraindications

- Uncorrectable bleeding diathesis.
- Uncontrollable severe hypertension.
- Active renal or perirenal infection.
- Uncooperative Patient.

#### Precautions & Warnings

Carefully read all instructions for use and product labeling. The device shall only be applied for its intended use and in accordance with these instructions. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

##### Precautions:

- All medical staff is responsible for using the appropriate technique and deciding on the indication for use of this device based on own experience, training and medical judgement. The doctor must be trained in the proper use of the device.
- The intended user of the device must be a Urologist specializing in the treatment of urinary system disorders and related urological procedures.
- Do not use the device if there is any indication that the sterility of the device has been compromised.

##### Warnings:

- The device is for Single-use only.
- The product must not be re-used. Reusing single use device can lead to potentially serious consequences for the patient: Bio-contamination due to release of infectious agents from device into the body which further may result in infection.
- This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the physician is practicing.

#### Intended Patient Population

- Biopsy Gun is used in patients during surgical procedures to collect samples of testicular tissue.
- It is intended for use in patients to diagnose cancer and identify other conditions such as lumps, infections, inflammatory and autoimmune disorders. They may also be used in patients to identify the causes of infertility.
- The usage of 18-gauge biopsy gun is preferred in infants and young children while the thicker bore can be used for all other age groups.

#### Shelf-life and storage condition of the Product

The shelf life of the Biopsy Guns is 3 years (Indicated on product label with the use-by symbol and date).

Store the Biopsy Guns at a dry, cool place at 12-35°C. Avoid extended exposure to sun light.

#### Sterility – This product is Sterile unless the package has been opened or damaged

- The Biopsy Guns have been sterilized by Exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change color from blue to brown after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct color.
- Exposure to high levels of Ethylene Oxide may result in presence of residual ETO which leads to Toxic Reaction in the body resulting in tissue damage of Urinary System.
- If the sterile package is damaged or possibly opened, do not use. Contact "Manufacturer or Distributor" and replace the product.
- The Biopsy Guns are packed single. Product in each pack must be utilized immediately when opened.

#### Directions for Use

- Open the package at the Chevron Side ('V' Notch) of the pouch.
- Suggested instructions for using Biopsy Guns:
- 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, and check for other imperfections that would prevent the proper operation of the needle assembly.
- Open the lid of the biopsy device, load needle set into the biopsy device, closed lid, and remove protective sheath.
- Safety button must be set in the unlocked (right) position before cocking.

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- Cock the actuator handles twice 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 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.
- The needle needs not to be removed from the device to retrieve sample.
- After removing the needle from the patient, reset safety button and 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.
- Duration of contact with the body is less than 60 min.


















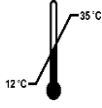



### Removal Instructions

Retrieve Biopsy Gun gently by pulling without getting any damage, if resistance is encountered during removal of the Biopsy Gun, stop and determine cause of resistance before proceeding.

### Disposal Instructions

Dispose of all equipment, in appropriate containers. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

### Explanation of symbols used on label

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
	Catalogue Number		CE Mark		Do not Re sterilize		Country of Manufacture		Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use		Unique Device Identifier
	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		Authorized Representative in the European community
	Humidity Limit								



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### Bibliography

- Contraindications: <https://emedicine.medscape.com/article/2093338-overview#a6>
- Single Use Medical Device: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/956268/Single\\_use\\_medical\\_devices.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956268/Single_use_medical_devices.pdf)
- EN ISO 15223-1:2021 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
- EN ISO 20417:2020 – Medical Devices- Information to be supplied by the manufacturer.