ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use

Biopsy Needle

Device Description

Used to obtain core biopsies of prostatic tissue. Light weight and compact biopsy needle design facilitates one handed operation. Precise, rapid firing mechanism provides intact core tissue sample. 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 Needle (BIN)	18 20	20 25	AMPLGP005

Intended Purpose

The Biopsy Needle is intended for obtaining percutaneous or surgical histological core samples from soft tissues. This device is not intended for use in bone. Used to obtain core biopsies of prostatic tissue. It is intended for use in patients to diagnose cancer and identify other conditions such as infections, inflammatory and autoimmune disorders. They may also be used in patients to match organ tissue before a transplant and to look for signs of organ rejection following a transplant.

Performance Characteristics of the Device

Biopsy Needle aids to obtain tissue samples that can help diagnose whether a nodule is benign (non-cancerous) or malignant. A needle biopsy is less invasive than open and closed surgical biopsies, both of which involves a larger incision in the skin and local or general anesthesia.
Light weight and compact biopsy needle design facilitates one handed operation. Precise, rapid firing mechanism provides intact core tissue sample. Beveled point stylet permits easy penetration into the specimen with less trauma to surrounding tissue.

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.
- Skin Infection at Biopsy site.
- Uncooperative or excessively apprehensive patient.
- Surgical absence of a rectum or presence of rectal fistula

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 judgment. 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 devices 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 Needle is used in patients diagnosed with Nephrotic Syndrome, Acute Nephritic Syndrome, Prostate Cancer and in Kidney Failure.
- The use of 18 gauge and 20 gauge is preferred in infants and young children while the thicker bore (16 and 18 gauge) can be used for all other age groups.

Shelf-life and Storage Condition of the Product

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

Store the Biopsy Needle at a temperature between 12-35^{0}C and a Humidity range of 30-75%.

Store in a dry, cool place. Avoid extended exposure to sun light.

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

- The Biopsy Needles 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 Needles are packed single. Product in each pack must be utilized immediately when opened. Product should not be re- sterilized.

Directions for Use

Instruction for Use

CE 2803

Biopsy Needle

- Open the Package at the Chevron Side ('V' Notch) of the pouch.
- Suggested instructions for using Biopsy Needles:
- Prior to insertion, prepare the biopsy needle by pulling back on the plunger until firm click is felt indicating that the needle spring is locked into ready position.
- With the stylet fully retracted, so that the specimen notch is completely covered by the cutting cannula, advance the needle proximal to the area to be biopsied. Do not advance stylet until biopsy needle is in position.
- While maintaining needle position, advance stylet with thump, to expose specimen notch within the area to be biopsied. Fire the
- Cutting cannula by fully depressing the plunger with thump to capture tissue within the specimen notch.
- Withdraw the needle from biopsy area. To remove tissue specimen, pull back on the plunger until firm click is felt to indicate the cutting cannula is locked into position. Push stylet forward to expose tissue specimen with in the notch. Remove tissue from specimen notch.
- Duration of contact with the body is less than 60 min.

Removal Instructions

Remove gently by pulling the needle, if resistance is encountered during removal of the Biopsy Needle, 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
REF	Catalogue Number	CE 2803	CE Mark	2 STERILIZE	Do not Re sterilize	CC	Country of Manufacture	MD	Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
LOT	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use	UDI	Unique Device Identifier
STERILE EO	Sterilized using ethylene oxide		Consult Instructions for Use	35°C 12°C	Temperature Limit		Do Not Use if Package is Damaged	EC REP	Authorized Representative in the European community
75% 30%	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
- 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.