en **Instructions for Use**

Coaxial Needle

BLUENEEM®
Clinicians Trust. Patients Wellbeing

Device Description
The Coaxial Needle includes both sharp and blunt needle. Coaxial Needle is a sharp edged, hollow tubular metal device designed to make the initial percutaneous puncture to access the region during a percutaneous procedure. It enables introduction of Biopsy Needle for sample collection. Coaxial Blunt Needle is also used to manipulate through soft tissues.
Note: Device is detectable by X-Ray or other means of fluoroscopy.

Gage (G)	Length (cm)	Models
13, 15, 17, 19	05, 10, 15 & 20,	**Sharp needle with blunt rod**

Intended Purpose & Duration
The Coaxial Needle is a device intended to make the initial percutaneous puncture to access the region and obtain multiple samples through a single puncture site while minimizing trauma to surrounding tissues

Indications For Use & Contraindications
Indications for as a guiding needle in obtaining core biopsy samples from soft tissues such as liver, kidney, prostate, spleen, breast, lung, lymph nodes and various soft tissue tumors. No known contraindications.

Potential Complications
Potential complications include but not limited to organ puncture, Haemorrhage, Tissue injury, Bleeding and Edema.

Warnings And Precautions
- Do not reuse the device. Reuse can cause severe infection. Intended use may fail on reuse. Do not use if package is opened or found defected. Do not use the product if there is suspect that the device is not sterile.
- Device is not intended for permanent use.
- The Biopsy Instrument should be used by a physician who is completely familiar with the indications, findings and possible side effects of core needle biopsy, in particular, those relating to the specific tissue being biopsied.
- The introduction of the needle into the body should be carried out under imaging guidance.
- Inspect the needle for bends and other possible damage. Please do not use the product if the device is found damaged.
- On completion of the procedure, dispose off the device and its components, if any, as per institutional and local regulatory guidelines for bio-hazardous medical waste disposal.
- Inspect the needle for bends and other possible damage. Please do not use the product if the device is found damaged.

Instructions For Use
1. Under ultrasound or CT scan, localize the region to be accessed.
2. Anesthetize the marked skin site.
3. With the help of scalpel, make a small incision.
4. Insert the Coaxial needle under fluoroscopic guidance and advance to the required location. After achieving the puncture, remove the inner needle.
5. Then the coaxial outer cannula is ready for multiple biopsies.
6. Once number of samples taken, remove the cannula from the desired location.

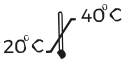
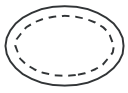
Intended population group
Adult/paediatric Male and Female patients

Supply and Storage
The device is packed in primary pack made of polyethylene and the secondary package made of polyethylene and Tyvek. Supplied sterilized by Ethylene Oxide gas in peel open package. Device shall be stored at temperature range from 20^0C to 40^0C and away from direct sunlight.

Report Any Serious Incident
If problems occur using this device or any serious incidents or adverse events, please contact our customer relations department or call to the contact provided in our manufacturing address and competent authority of the Member State in which the user and/or patient is established.

Symbol Glossory And Definations

Standard Reference:
ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by the manufacturer

	Do not resterilize
	Do not use if package is damaged and consult instructions for use
	Consult instructions for use
	Temperature limit
	Keep away from sunlight
	Do not re-use
	Not made with natural rubber latex
	Sterilized using ethylene oxide
	Non-pyrogenic
	Keep dry
	Medical device
	Single sterile barrier system with protective packaging inside
	Does not contain DEHP
	Unique device identifier
	Date of Manufacture
	Use-by date
	Batch code

	Catalogue number
	Authorized Representative in the European Community/ European Union
	Manufacturer
	Caution
	Prescription

- This device is to be sold by/on the directions of a physician. Sterile (ETO) if package is unopened or undamaged.
- Read all the instructions before use.
- On completion of the procedure, dispose off device and its components if any as per institutional and local regulatory guidelines for bio-hazardous medical waste dispose.

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