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Instructions for Use

Initial Puncture Needle

BLUENEEM®
Clinicians Trust. Patients Wellbeing

Device Description

Initial Puncture Needle is a sharp edged, hollow tubular metal device designed to make the initial percutaneous puncture to access the kidney during a percutaneous urological procedure. It enables introduction of guide wire and nephrostomy catheter for urinary drainage. Echogenic tip of needle enhances visualization of needle tip when used with ultrasonic imaging equipment. Initial Puncture needles gage and length varies by configurations.

Gage (G)	Length (cm)	Models
12, 14, 16, 18	10, 15, 18, 20, 23 & 25	**2-Part and 3-Part**

Intended Purpose & Duration

Initial Puncture Needle is a device intended to make the initial percutaneous puncture to access the kidney and to enable the introduction of a guidewire during urological procedures for a duration of less than 60 minutes.

Indications For Use & Contraindications

Indications for percutaneous nephrostomy include the following: Urinary Diversion, Urinary obstruction, Access to the collecting system. Contraindicated in the presence of conditions which create unacceptable risk during percutaneous nephrostomy procedure.

Potential Complications

Potential complications include but not limited to Renal perforation, 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.
- Device is intended to be used by physicians trained and experienced in the use of urologic and percutaneous access procedures with support from qualified technicians using aseptic technique and not intended by unauthorized or untrained personnel. 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. Remove the device from it sterile packaging by using aseptic technique.
2. Before using the device, perform Ultrasound or fluoroscopy to visualize the target site of puncture. Immediate to this imaging technique, the site where nephrostomy is to be performed is identified and marked. Then anesthetize the marked skin site.
3. By using scalpel blade, make a small incision. Insert the Initial Puncture needle under fluoroscopic guidance and advance to the required location. After achieving the target location, remove the inner stylet and observe for urine aspiration and ensure correct placement of the needle. If 3-part needle is used, remove both the inner cannula and needle.
4. Pass an appropriately sized guidewire through the needle cannula to achieve access into the collection system and allow placement of subsequent devices which are required for nephrostomy procedure.
5. On reaching the desired position in collecting system, remove the cannula of the needle maintaining the guidewire in position so that the collecting system can be gauged.

Intended population group

Patients who require access to collecting system when nephrostomy procedure is recommended.

Supply and Storage

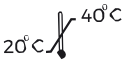
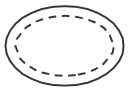
The device is packed in primary pack made of polyethylene and the secondary package made of polyethylene and Tyvek. Supplied sterilized by Ethylene Oxide gas in peel open package. Device shall be stored at temperature range from 20^0C to 40^0C and away from direct sunlight.

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 barriersystem 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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