en **Instructions for Use**

Chiba Needle

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Device Description
Chiba Needle is a sharp bevel edged; hollow tubular metal device designed to make the initial percutaneous puncture to access the collecting systems during percutaneous interventional procedures. It enables introduction of guide wire and drainage catheters for drainage.
Device is detectable by X-Ray or other means of fluoroscopy

Gage (G)	Length (cm)
16, 18, 21, 22 & 23	10, 15, 18, 20, 23 & 25

Intended Purpose & Duration
Device is intended to be used for fine aspiration for cytological study for a duration of less than 60 minutes.

Indications For Use & Contraindications
Indications for percutaneous drainage include the following: Diversion, obstruction, Access to the collecting system. No known contraindication.

Potential Complications
Potential complications include but not limited to vessel/duct 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 percutaneous access procedures with support from qualified technicians using aseptic technique. 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. By using ultrasound or CT scan, localize the Collection system to be aspirated. Mark and anesthetize the site.
3. By using scalpel blade, make a small incision. Insert the Chiba needle under fluoroscopic guidance and advance to the required location. After achieving the target location, remove the inner stylet and fix a syringe and aspirate the fluid required for testing.
4. If further intervention is required place the guidewire of appropriate size by removing the inner cannula of the needle. After placing the guidewire then remove the outer cannula of the needle and dispose as per the process.

Intended population group
Patients who require access to collecting system when it is recommended.

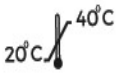
Supply and Storage
The device is packed in primary pack made of polyethylene and the secondary package made of polyethylene and Tyvek. Supplied sterilized by Ethylene Oxide gas in peel open package. Device shall be stored at temperature range from 20^0C to 40^0C and away from direct sunlight.

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

Symbol	Symbol Title
	Do not re sterilize
	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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