Instruction for Use

CE 2803

Initial Puncture Needle

Device Description

Used for initial puncture vertically through a small incision in the skin prior to the percutaneous placement of a pigtail catheter or Malecot catheter in the renal pelvis for nephrostomy drainage. 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)	Type(Point)	Color of Needle Hub	Color of sheath hub	Color of Needle	Catalogue Number
Initial Puncture Needle (IPN)	16 18 20 22	15 18 20 22	2 Part Trocar Tip Chiba Tip	Pink Yellow	Pink Transparent	Silver	AMPLGP006
	16 18 20 22	15 18 20 22	3 Part Trocar Tip Chiba Tip	Pink Pink. Red	Pink Pink, Red	Silver	

Intended Purpose

Used for initial puncture vertically through a small incision in the skin prior to the percutaneous placement of a pigtail catheter or Malecot catheter in the renal pelvis for nephrostomy drainage. Intended for Single use.

Performance Characteristics of the Device

Intended to make the initial percutaneous puncture to access the kidney and to enable the introduction of a guidewire during urological procedures. The needles are available as two part and three parts. The beveling of the Chiba needle results in superior steering.
The trocar needle aids urologists to perform targeted puncture more elegantly and accurately.

Indications

- Used for Percutaneous Nephrostomy
- Cyst Puncture
- Deep tissue access

Contraindications

- Uncorrected Bleeding Diathesis (most commonly, uncontrollable coagulopathy)
- Severe Hyperkalemia
- 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:

- The Intended User of the device must be a Urologist specializing in the treatment of urinary system disorders and related urological procedures, authorized by the competent authority of the country in which the physician is practicing.
- Do not use the device if there is any indication that the sterility of the device has been compromised.
- Inspect the needle for bends and other possible damage. Do not use the product if it is damaged.
- Do not use this product without reading and understanding the complete instructions enclosed herein.

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 such as: Bio-contamination due to release of infectious agents from device into the body which further may result in Infection.
- Do not reprocess or re-sterilize, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to failure which, in turn, may result in patient injury.

Intended Patient Population

- Initial Puncture Needle is used for incision of skin for percutaneous nephrostomy procedures in patients diagnosed with Ureteral Obstruction and in case of urinary diversion or injury and neurogenic bladder.
- The device is used in patients above 18yrs. Not intended for use in patients below the age of 18.

Shelf-life and Storage condition of the Product

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

Store the Initial Puncture 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 Initial Puncture 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 Initial Puncture Needles are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

Directions for Use

- Open the package at the chevron side ('V' Notch) of the pouch.
- By retrograde pyelogram, ultrasound or CT scan, localize the kidney to be drained.
- After pyelogram, the location where nephrostomy is to be performed is identified and marked. Anesthetize the marked skin site.
- With the help of scalpel, make a small incision.
- Insert the Initial puncture needle under fluoroscopic guidance and advance to the required location. After achieving the puncture, remove the inner needle and observe for urine aspiration. If 3-part needle is used, remove both the inner cannula and needle.
- After confirmed aspiration, pass the guidewire through the outer cannula of the IP Needle.

Removal Instructions

On reaching the desired position, remove the outer cannula of the needle gently by maintaining the guidewire position, if resistance is encountered during removal of the Initial Puncture 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	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								

Aster Medispro Pvt. Ltd
S.P.181, 10th Main, 1st Stage,
DR.B.R.Ambedkar Industrial Estate (KSSIDC)
Jigani Industrial area, Jigani,
Bangalore- 560105, Karnataka, India.
Tel: +91 80-42062716
Email: info@astermedispro.net
Web: www.astermedispro.net

EC REP
M/sCMC Medical Devices& Drugs S.L.
located in C/Horacio Lengo N° 18, CP29006,
Málaga, Spain
Tel : +34951214054, Fax: +34952330100
E-mail : mmateos@cmcmedicaldevices.com
Web : www.cmcmedicaldevices.com

Bibliography

- Contraindications: https://radiopaedia.org/articles/percutaneous-nephrostomy
- 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.