ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use

PCNL Dilator Set

Device Description

Percutaneous Nephrolithotomy (PCNL) used in a minimally invasive urology procedure. Delivered in sterile peel-open tray packs. Intended for single use. Duration of Contact with the body is 1 day. The configurations available include:

Family	Dilator Size (Fr)	Length (Cm)	Peel Away Sheath Dilator (Catheter/Sheath)		IPN (2 Part) Trocar Tip		IPN 2 Part Chiba Tip		J Tip Lunder Quist Guidewire		Accessories
			Size (Fr)	Length(cm)	Size (G)	Length(cm)	Size (G)	Length(cm)	Size (G)	Length(cm)	
PCNL Dilator Set	8 10 12 14 16 18 20 22 24	18.5	22/24	17.5	18	20	22	19	0.035	81	Peel away sheath, Initial Puncture Needle, Dilators, Guidewire

Intended Purpose

PCNL Dilator set is used to dilate skin and subcutaneous tissue to establish a working channel between skin and kidney.

Intended User

This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the physician is practicing.

Medical Conditions to Be Treated

- Kidney stones requiring percutaneous access (e.g., PCNL procedures)
- Conditions requiring percutaneous catheter or device insertion into the kidney
- Urinary tract obstructions needing tract dilation for intervention

Performance Characteristics of the Device

The device is designed in such a way that the tapered end and smooth surface provides ease of introduction. Optimal radiopacity for better visualization. The peel away sheath allows uniform peeling during removal. The ergonomically designed sheath hub provides easy splitting.

Indications

- It is intended for the percutaneous introduction of balloon or any other devices and closed or non-tapered end catheters into the desired position.

Contraindications

- If the patient has a known or suspected obstruction in the vessel.
- Uncorrected Bleeding Diathesis
- Severe Hyperkalaemia
- Uncontrolled Arrythmia
- Pregnancy
- Uncooperative Patient

Precautions, Warnings & Complications

Carefully read all instructions for use and product labelling. Do not use this product without reading and understanding the complete instructions enclosed herein. 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/ experienced in diagnostic and interventional techniques who is authorized by the Competent Authority of the country in which the physician is practicing.
- Confirm the information on the label and that the product has not reached its expiration date and there is no damage to the packaging or device.
- Store the PCNL Dilator Set at a temperature between 12-35^{0}C and a Humidity range of 30-70%.
- Store in a dry, cool place. Avoid extended exposure to sun light.
- The guidewire should not be withdrawn through the needle once it has been placed beyond the needle tip.
- The maximum diameter of the instrument or catheter to be introduced should be determined to ensure its passage through the introducer.
- When inserting, manipulating or withdrawing a device through an introducer, always maintain introducer position.

Warnings:

- Do not alter this device in any way.
- Do not withdraw the guidewire through a metal needle, the guidewire may shear or unravel.
- The device is intended 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 use the device if there is any indication that the sterility of the device has been compromised. If the sterile package is damaged or possibly opened, do not use. Contact “Manufacturer or Distributor” and replace the product.
- 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.
- If you encounter resistance during insertion, do not force the device.

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Intended Patient Population

- PCNL Dilator Set is used in adult patients. The device can be used in both male and female patients.

Shelf-life

The shelf life of the PCNL Dilator Set is 3 years (Indicated on product label with the following use-by date symbol).

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

- The PCNL Dilator Set have been sterilized by Exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change colour from blue to brown after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct colour.
- Exposure to high levels of Ethylene Oxide may result in residual ETO which leads to Toxic Reaction in the body resulting in tissue damage.
- If the sterile package is damaged or possibly opened, do not use.
- The PCNL Dilator Set is packed single. Product in each pack must be utilized immediately when opened.

Directions for Use

- Prep and drape the access site according to hospital protocol.
- Introduce an access needle into the target anatomy.
- Introduce a guide wire through the needle and into the target anatomy.
- Withdraw the needle, leaving the guidewire in place. If desired, enlarge the skin access site with a scalpel blade.
- Introduce the Peel-away sheath and dilator assembly over the guidewire. With a twisting motion, advance the assembly into the target anatomy.
- Leaving the sheath in place, remove the dilator and guidewire.
- Introduce the desired catheter/ device into the sheath to the desired depth within the target anatomy.

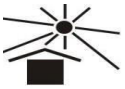
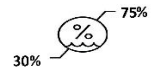
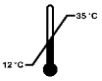
Removal Instructions

- Peel the sheath away from the catheter by grasping the two wings of the sheath and pulling outward and upward.
- Once the sheath is removed, the catheter/device position may need to be adjusted.
- If any resistance is encountered during the withdrawal, stop and determine the cause for the resistance before proceeding further.

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
	Catalogue Number		Unique Device Identifier		Do not re sterilize		Country of Manufacture		Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use		Humidity Limit
	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		

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 80-2979550
Email:info@astermedispor.net
Web:www.astermedispor.net

Bibliography

- 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.