ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use

Guiding Catheter

Device Description

Guiding Catheter or introducer sheath is used to dilate the tract before endoscopic renal procedure to adapt the passage of Nephroscope and accessories. Guiding Catheter or introducer sheath is used for progressive dilatation of the nephrostomy tract.

Family	Size(Fr)	Length (Cm)	Color
Guiding Catheter (GC)	6	70	Blue
	8	80	Milky White
	10	85	Black
		90	

Intended Purpose

Guiding Catheter or introducer sheath is used for progressive dilatation of the nephrostomy tract. Dilate the tract before endoscopic renal procedure to adapt the passage of Nephroscope and accessories.

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

- Urethral or ureteral strictures – to guide placement of dilators, stents, or other catheters.
- Obstructive uropathy – due to stones, tumors, or anatomical narrowing requiring intervention.
- Hydronephrosis – to facilitate drainage catheter or stent placement.
- Post-surgical urinary diversion or reconstruction – to support safe catheter or stent delivery.

Performance Characteristics of the Device

Guiding catheters are specifically designed for navigating the urinary tract, featuring biocompatible materials for patient safety and flexibility for easy maneuverability. They come in various lengths and French sizes to suit different procedures, with smooth, lubricious surfaces to facilitate insertion.

Indicatrions

- Facilitating entry to the urinary tract.
- Removing urine or fluid from the bladder or kidneys.
- Placing a stent to maintain urinary passage.
- Supporting various urological interventions, such as stone removal or biopsy.

Contraindications

No Known Contraindications

Precautions

- Use only by trained urologists with experience in catheter-guided procedures.
- Always select the appropriate size and type of guiding catheter for the intended application.
- Employ strict aseptic technique to minimize risk of urinary tract infection.
- Avoid excessive manipulation to reduce the risk of trauma to urethra, ureter, or bladder.
- Device is sterile and **single-use only**; do not reuse or resterilize.

Warnings

- Do not use if sterile packaging is opened or damaged.
- Improper placement or forceful insertion may cause urethral or ureteral perforation.
- Prolonged use increases risk of infection, hematuria, or encrustation.
- Contraindicated in patients with active urinary tract infection or severe urethral/ureteral injury.
- Incorrect handling may result in serious complications such as obstruction, bleeding, or false passage.

Intended Patient Population

- The Guiding catheter can be used in patients of all age groups based on doctors' decision.

Shelf-life of the Product

- The shelf life of the Guiding Catheter is 3 years (Indicated on product label with the use-by symbol and date). Store the Guiding Catheter at dry, cool place. Avoid extended exposure to light.

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

- The Guiding Catheter 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.
- If the sterile package is damaged or possibly opened, do not use. Contact "Distributor" and replace the product.
- The Guiding Catheter are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

Directions for Use

- After puncturing the tract to the kidney and application of the guide wire, start dilatation with sequential dilation starting with Fascial dilator followed from smaller size to bigger size of renal dilators (18 Fr to30Fr.).
- Insert the guiding catheter over the Guide Wire.
- Complete system dilatation over the catheter till requested size.

- Dilate the Nephrostomy tract completely using the Guiding catheter.
- Gently remove Guiding catheter from accessory channel.
- Duration of Contact with the body is during operational procedure.

Removal Instructions

Retrieve cystoscopically by gently pulling on Catheter or retrieval line with grasping forceps or equivalent. If resistance is encountered during removal of the Catheter, 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	UDI	Unique Device Identifier		Do not re sterilize		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	30% 75%	Humidity Limit
STERILE EO	Sterilized using ethylene oxide		Consult Instructions for Use	12 °C 35 °C	Temperature Limit		Do Not Use if Package is Damaged		

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Bibliography

- https://www.bostonscientific.com/en-US/products/catheters--guide/convey-guiding-catheter/convey -guiding-catheter.html
- 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.