

Instruction for Use

Metal Straightener

Device Description

Metal straightener is made of Stainless steel which is used to straighten the catheter to pass inside the body easily without damaging the catheter. The configurations available include:

Family	Size(FR)	Length (Cm)	Color
Metal Straightener (MS)	12	33	Sliver
	13		
	14		
	15		
	16		

Intended purpose

Metal Straightener is used to straighten the catheter to pass inside the body easily.

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

- Assists in the smooth introduction of catheters during urological procedures without causing damage to the catheter.
- Facilitates catheter placement in cases of urinary obstruction due to strictures or enlarged prostate.
- Supports postoperative management by enabling safe catheter insertion after urological surgeries.

Performance Characteristics of the Device

The **Metal Straightener** is designed to temporarily straighten flexible catheters, ensuring smooth and traumatic insertion into the urinary tract. It is made of medical-grade stainless steel, providing strength, durability, and compatibility with various catheter sizes. The device is sterile, single-use, and ergonomically designed for safe and efficient clinical handling.

Indications

- The metal straightener is intended to temporarily straighten catheters, introducers, or similar flexible medical devices to facilitate their insertion into the patient's body.
- It helps in guiding the catheter smoothly through the anatomical pathway without causing kinking or damage.
- Used during interventional or diagnostic procedures where controlled catheter insertion is required.
- Suitable for single-use in sterile environments during surgical or interventional procedures.

Contraindications

- Not to be used directly inside the patient's body
- Should not be used if the packaging is damaged or sterility is compromised.
- Not suitable for reuse or re-sterilization
- Not intended for patients with known hypersensitivity or adverse reaction to stainless steel.
- Should not be used if the device shows signs of damage, bending, or corrosion before use.

Precautions, Warnings & Complications

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

- For use only by qualified healthcare professionals trained in catheter-based procedures.
- Inspect the device carefully before use; do not use if bent, corroded, or damaged.
- Handle gently; avoid applying excessive force during catheter straightening.
- Maintain strict aseptic technique during handling to prevent infection.
- Ensure proper catheter positioning before insertion to minimize trauma or device malfunction.
- Dispose of the device immediately after single use in accordance with hospital biomedical waste protocols.

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Warnings

- Do not use the device if the sterile packaging is opened or damaged, as sterility may be compromised.
- The metal straightener is not intended to remain inside the patient's body. It must be removed immediately after catheter insertion.
- Reuse or re-sterilization of this device can lead to loss of mechanical integrity, device malfunction, or risk of cross-contamination/infection.
- Improper use may cause catheter damage which can lead to procedural complications.
- Use only with compatible catheters and accessories as specified; incompatibility may result in procedural failure or patient injury.
- This device is not a substitute for medical judgment – incorrect handling may cause harm to the patient.

Intended Patient Population

Intended for use in patients of all age groups.

Shelf-life of the Product

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

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

- The Metal Straightener 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 Metal Straightener are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

Directions for Use

- Advance the Guide Wire directly from the enclosed holder.
- Introduce the flexible tip of the Guide Wire in to the urethral meatus and gently manipulate it beyond the obstruction and into the bladder. (The safety index mark, 39cm from the Guide Wire's flexible tip will be externally visible under normal circumstances)
- Note:- The Guide Wire can also be placed through a cystoscope and maintained in position as the scope is removed.
- Once the Guide Wire is placed, the Catheter is inserted through the Guide Wire.
- To place the trocar or cannula into the catheter, a pig-tail straightener is placed on the outside of the catheter tube body which straighten the pigtail/ Flower Shape of catheter.
- Pigtail catheters are fitted with a straightener. It is split for easy removal after the catheter tip is on the guide wire. Slide straightener forward until pigtail is straight.
- Once the catheter is straighten, insert the metal straightener inside the catheter tube without damaging the inner surface of the catheter tube.
- A practitioner slides the pig-tail straightener along the tube body to the distal end of the tube body, thereby straightening any bends or pig-tail loops in the tube body. The pig-tail straightener is positioned proximate the distal end of the tube body.
- The metal straightener is then placed inside of the Catheter tube body through the proximal end. With the metal straightener in place, the pig-tail straightener may then be removed from the catheter entirely.
- The catheter is thus retained in an extended, rigid position.
- Once the Catheter is placed in the right position which is visualized through ultrasound or CAT scan, the metal straightener is removed and catheter remains its original shape inside the Kidney

Removal Instructions

Retrieve cystoscopically by gently pulling on Metal Straightener or retrieval line with grasping forceps or equivalent. If resistance is encountered during removal of the Metal Straightener, 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.

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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		



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