

1.0 INTENDED USE

The UROMED™ guide wires are designed to assist in the placement and navigation of medical devices within urological systems. They are particularly useful in accessing difficult or tortuous anatomy due to their lubricious coating.

2.0 DEVICE DESCRIPTION

Basic UDI-DI: 890615570GWYX

Variants :

1. PTFE Guide Wire
2. Hydrophilic Guide wire
3. Zebra Guide Wire
4. Hydro tip Zebra Guide Wire
5. Lundquist guide Wire
6. Non-Coated Guide Wire

Sterilization: Ethylene Oxide (EO) sterilized, single-use device

Tip Configuration: Straight , angled and J tip

Size : 0.018”,0.025”,0.028”,0.032”,0.035” and 0.038”

Length : 70,80,90,150cm

The UROMED™ Guidewire is a flexible, radiopaque guidewire intended to support safe and accurate placement of compatible medical devices during minimally invasive procedures performed via **natural orifice and percutaneous access routes**. It provides a stable pathway for the advancement of dilators and other compatible instruments. The guidewire features radiopaque construction for

imaging visibility, a flexible distal tip to facilitate atraumatic navigation, and proximal identification marking for easy handling and device exchange.

3.0 CONTRAINDICATIONS

Not intended for use in patients with known sensitivity to the materials used.

Not suitable for use in anatomy that cannot accommodate the guide wire’s diameter or length.

Avoid use in areas with suspected or confirmed active infection

4.0 WARNINGS AND PRECAUTIONS

Warnings

The guide wire is for **single use only**. Reuse or reprocessing may compromise its integrity and increase the risk of infection.

Do not use if the sterile package is damaged or the expiry date has passed.

Avoid excessive force during insertion to prevent damage to the guide wire or patient injury.

Do not insert over metallic dilator or needle. The product is non-pyrogenic.

Precautions:

Always handle the guide wire **under aseptic conditions** to maintain sterility.

Hydrate the hydrophilic coating with sterile saline or water before use to activate its lubricious properties.

Inspect the guide wire for **damage or kinks before use**. Do not use if defects are observed.

Use imaging guidance (e.g., fluoroscopy)

during insertion and navigation.

5.0 INSTRUCTIONS FOR USE:

5.1 Preparation:

Confirm the guide wire specifications (length, diameter, and tip configuration) match the clinical requirements.

Check the sterile packaging for integrity. Open only in a sterile environment.

Hydrate the guide wire by immersing it in sterile saline or water to activate the hydrophilic coating.

5.2 Insertion Procedure:

Under imaging guidance, introduce the guide wire into the intended anatomical location.

Gently advance the guide wire, ensuring minimal resistance. Rotate or reposition if necessary to navigate tortuous anatomy.

Avoid excessive bending or kinking to maintain wire integrity.

5.3 Post-Procedure Handling:

Carefully remove the guide wire from the patient while maintaining sterility.

Dispose of the used guide wire in accordance with local regulations for medical waste.

6.0 HANDLING AND STORAGE:

6.1 Handling Precautions:

- Handle with care to avoid damage to the hydrophilic coating.

- Avoid contact with abrasive surfaces to preserve the coating’s integrity.

6.2 Storage Conditions:

Store in a cool, dry place at temperatures

between 0°C and 45°C.

Keep away from direct sunlight and moisture.

Keep in aseptic, clean, dry and withing the specified temperature

7.0 INTENDED USERS

The product has to be used by trained personnel experienced in diagnostic, interventional urological procedures and techniques

8.0 CLINICAL ADVANTAGES

Enhanced Navigation: The hydrophilic coating significantly reduces friction, allowing the guide wire to glide smoothly through internal tissues and organs. This minimizes trauma to delicate structures.

Improved Access: Facilitates the efficient and safe access to internal organs and tissues, enabling precise navigation through complex anatomical pathways.

Precise Placement: Supports the accurate positioning of medical devices such as catheters, stents, or implants, ensuring optimal procedural outcomes.

Interventional Excellence: Enhances the effectiveness of minimally invasive procedures, reducing surgical complexity and improving patient recovery times.

Diagnostic Assistance: Aids in diagnosing lesions, infections, or other internal abnormalities by providing a reliable pathway for diagnostic tools or imaging devices.

7.0 POTENTIAL COMPLICATIONS:

Vessel or tissue perforation due to improper use.

Infection due to compromised sterility.

Allergic reaction to materials used.

Device malfunction if the guide wire is damaged.

8.0 DISPOSAL

Dispose of the guide wire and packaging following local regulations for medical waste to ensure environmental safety.

The disposal of used guide wire as to take place according to biomedical waste disposal regulation

Environmentally friendly disposal of the product has to takes place

SHELF LIFE: The device has a shelf life of 5 years from the date of sterilization.

9.0 MANUFACTURER'S INFORMATION:

 **MANISH MEDI INNOVATION PVT LTD**

(LEGAL MANUFACTURER)

SY No. 150/2, No. 53,54, 55, 68, 69 and 70, Bannerghatta Main Road, ABT Layout, Hullahalli Village, CK Palya, Bannerghatta, Bengaluru Urban, Bengaluru – Karnataka 560083, INDIA.

(MANUFACTURING SITE)

 **MANISH MEDI INNOVATION**
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Bangalore, Karnataka 560076, India

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EC REP


















CMC Medical Device

C/Horacio Lengo N° 18, CP 29006,

Málaga, Spain

Email: mmateos@cmcmmedicaldevices.com

INSTRUCTIONS FOR USE –GUIDE WIRE

Sr. No.	Symbol	Meaning
1.		Sterilised with ethylene oxide
2.		Do not re-sterilize
3.		Do not use if package is damaged
4.		Consult electronic instruction for use
5.		Temperature limit
6.		Single use only
7.		Keep In clean and dry condition
8.		Keep away from straight rays from sun
9.		Non-pyrogenic
10.		CE Mark with notified body number
11.		Symbol for “Reference number”
12.		Symbol for “Batch code”
13.		Symbol for “Date of manufacture”
14.		Symbol for “Use Before”
15.		Symbol for “Manufacturer”
16.		Symbol for Medical device
17.		Symbol for Single Sterile Barrier System with protective Packing inside

INSTRUCTIONS FOR USE –GUIDE WIRE

