ASTER MEDISPRO PRIVATE LIMITED

# Instruction for Use

## Hydro Tip Guidewire/ Lunder Quist Guidewire/ Blue & White Guidewire/ Black & White Guidewire/ PTFE Coated & Uncoated Guidewire, Hydrophilic Coated Guide wires

### Device Description

Guide wires are used to gain ureteral access to establish a tract and to assist in the placement, replacement and exchange of medical devices during urological procedures. These guide wires are not intended for PTCA (Percutaneous transluminal coronary angioplasty) use. Guide wires are delivered in sterile peel-open packages. Intended for single use. Duration of Contact with the body is 1 day. The configurations available include:

| Family | Size(G) | Length (Cm) | Types | |
|---|---|---|---|---|
| Hydro Tip Guide wire/Lunder Quist Guide Wire/Blue & White Guide Wire/Black & White Guide Wire/ PTFE Coated& Uncoated Guidewire | 0.018<br>0.025<br>0.028<br>0.032<br>0.035<br>0.038 | 45<br>80<br>150<br>250<br>260<br>450<br>460 | Straight Tip, J Tip, Angle Tip | Hydrotip Guidewire, Lunder Quist Guidewire, Blue & White Guidewire, Black & White Guidewire, PTFE Coated and uncoated guide wires, Hydrophilic Coated guide wires |
| | | | Yellow & Black | Hydrotip Guidewire |
| | | | Blue & White | Hydrotip Guidewire |
| | | | Black & White | Hydrotip Guidewire |
| | | | Hydrophilic Tip | Lunder Quist Guidewire, Blue & White Guidewire, Black & White Guidewire |
| | | | Lunder Qusit (PTFE) Uncoated J Tip | Lunder Quist Guidewire |
| | | | Lunder Quist (PTFE) Uncoated Angle Tip | Lunder Quist Guidewire |
| | | | Both End Flexible | PTFE Coated & uncoated, Hydrophilic Coated Guide wires |

### Intended Purpose

Guide wires are used to gain ureteral access, to establish a tract, and to assist in the placement, replacement, and exchange of medical devices during urological procedures. These guide wires are not intended for PTCA (Percutaneous transluminal coronary angioplasty).

#### 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

- Used in cases of ureteral or urethral strictures to provide access for dilation, stent, or catheter placement.
- Assists in managing obstructive uropathy and hydronephrosis by guiding drainage devices into position.
- Facilitates safe passage during urological interventions for urinary stones or tumors causing obstruction.
- Supports procedures in post-surgical or anatomically difficult urinary tracts where direct catheter placement is challenging.

### Performance Characteristics of the Device

The Guide Wire has a smooth surface for the easy navigation into the body. It is designed in such a way that it provides steerability, trackability, torque, support to the device, flexibility, stiffness based on the diameter, trackability and torque control of the guidewire, Malleability. It also provides radio-opacity for better visualization.

### Indications

- The Guidewires are intended to facilitate the placement of endourological instruments during diagnostic or interventional procedures.

### Contraindications

- No known contraindications

### Precautions & Warnings

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 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.
- Each Physician is responsible for using the appropriate technique and deciding on the indication for use of this device.
- 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.
- When exchanging or withdrawing an instrument over the guide wire secure and maintain the guide wire in place fluoroscopy in order to avoid unexpected guidewire displacement. Manipulation of guidewire requires appropriate imaging control. Use caution not to force or over manipulate the guide wire when gaining access as it may result in separation of the guidewire tip.
- Store the Guidewires 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.

**Warnings:**

- 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.

# Instruction for Use

## Hydro Tip Guidewire/ Lunder Quist Guidewire/ Blue & White Guidewire/ Black & White Guidewire/ PTFE Coated & Uncoated Guidewire, Hydrophilic Coated Guide wires

- 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.
- These guidewires are not intended for coronary artery, vascular or neurological use.
- Do not attempt to use the guidewire if it has been bent, kinked or damaged. Use of a damaged wire may result in damage to the linings and associated tissue, channels or ducts or release of wire fragments into the urinary system.

**Intended Patient Population**

- The Guidewires is intended for use in adult patients. The device can be used in both male and female patients.

**Shelf-life**

The shelf life of the Guidewires 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 Guidewires 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 of Urinary System.
- If the sterile package is damaged or possibly opened, do not use.
- The Guidewires is packed single. Product in each pack must be utilized immediately when opened.

**Directions for Use**

- Open the package at the Chevron side ('V' Notch) of the pouch.
- Using aseptic technique, remove the wire from its outer packing and place in the sterile field.
- Introduce the guidewire through the working channel of the cystoscope or ureteroscope and is placed in the desired position under fluoroscopy guidance.
  Note: End hole size and length of the device be taken into consideration to ensure proper fit between guide wire and the device.

**Removal Instructions**

- Retrieve cystoscopically by gently pulling on Guidewire with grasping forceps or equivalent. If resistance is encountered during removal of the Guidewire, 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 | 75% 30% | Humidity Limit |
| STERILE EO | Sterilized using ethylene oxide | | Consult Instructions for Use | 35 °C 12 °C | 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

- 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.