

Guide wire

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 available in Stainless Steel PTFE coated Ever Green, Nitinol Hydrophilic coated, Zebra and Black & White. 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 (")	Length (cm)	Tip	Types	Catalogue Number
Guide Wire (GW)	0.018 0.025 0.028 0.032 0.035 0.038	(80 PTFE & Nitinol only) 150 (250 PTFE only) 260	J-Tip (J) Straight Tip (S)	Evergreen PTFE- Straight/J Tip Nitinol - Straight/J Tip Hydro tip- Black and white Hydro tip- Blue and white Hydro tip- Yellow and Black Hydrophilic Coated- Straight Tip/ J Tip Lunderquist Guide Wire- Straight Tip/ J Tip	AMPLGW001

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).

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

Urological 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. 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.
- Do not use the device if there is any indication that the sterility of the device has been compromised.
- When exchanging or withdrawing an instrument over the guide wire secure and maintain the guide wire in place under fluoroscopy in order to avoid unexpected guide wire displacement. Manipulation of guide wire 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.
- These guide wires are not intended for coronary artery, vascular or neurological use.
- Do not use this product without reading and understanding the complete instructions enclosed herein.

Warnings:

- The device is for single use only.
- The product must not be re-used. Reusing of single-use devices can lead to potentially serious consequences for the patient such as: Bio-contamination due to release of infectious agents from the device into the body which further may result in Infection.
- 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.
- 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.

Groups of patients and diseases to be diagnosed

- Guide Wire is used for the urology procedures.
- 0.018-inch Guide Wire is used for infants till 12yrs
- 0.018-0.025 Inch Guide Wire is used for children from 12 to 18 yrs. 0.028 to 0.038 Inch Guide Wire is used for patients above 18yrs.

Shelf-life and storage condition of the Product

The shelf life of the Guide Wire is 3 years (Indicated on product label with the following use-by symbol).

Store the Guide Wire at a temperature between 12-35°C and a Humidity range of 30-75%.

Store the Guide Wire at a dry, cool place. Avoid extended exposure to sun light.

Instruction for Use

Guide wire

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

- The Guide Wires have been sterilized by exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change color from blue to brown after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct color.
- Exposure to high levels of Ethylene Oxide may result in presence of 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. Contact “Manufacturer or Distributor” and replace the product.
- The “Guide Wires” are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

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. Remove the guide wire from the holder. Duration of Contact with body is less than 60 Minutes
- Advance the flexible end of the guide wire into the device and position to the desired anatomical location.
- Note: End hole size and length of the device be taken into consideration to ensure proper fit between guide wire and device. After guide wire use is complete, remove from patient and discard.


















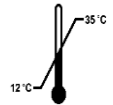



Removal Instructions

Retrieve cystoscopically by gently pulling on Guide wire or retrieval line with grasping forceps or equivalent. If resistance is encountered during removal of the Guide wire, 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
	Catalogue Number		CE Mark		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		Unique Device Identifier
	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		Authorized Representative in the European community
	Humidity Limit								



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 80-42062716
 Email: info@astermedispro.net
 Web: www.astermedispro.net



M/sCMC Medical Devices & Drugs S.L.
 located in C/Horacio Lengo N° 18, CP29006,
 Málaga, Spain
 Tel : +34951214054, Fax: +34952330100
 E-mail : mmateos@cmcmedicaldevices.com
 Web : www.cmcmedicaldevices.com

Bibliography

- Single Use Medical device:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956268/Single_use_medical_devices.pdf

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- 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.