Instructions for Use
GUIDE WIRE

Manufactured by Mais India Medical Devices Pvt. Ltd.

General Device Description:
A Guide wire is a flexible, steerable wire used to guide the placement of a catheter in place safely and accurately, minimizing trauma and ensuring correct catheter positioning. Variants may include Stainless Steel, Nitinol, PTFE-coated and Hydrophilic-coated guide wires with straight or J-tip configurations.

Product Name: Guide Wire

Product Variants:
1.With J-tip
2.With Straight tip

Size Specifications: 50, 70, 150, 180 & 260 cm.

Intended Use:
A Guide wire is a flexible, steerable wire used to guide the placement of a catheter in place safely and accurately, minimizing trauma and ensuring correct catheter positioning.

Material of Construction:
Stainless Steel and / or Nitinol core wire, stainless steel coil, PTFE coating and/or hydrophilic coating depending on model.

Indications for Use:
Use in peripheral vascular access and percutaneous transluminal angioplasty (PTA) procedures.

Contraindications:
- Nickel hypersensitivity
- Patients with bleeding disorders

Intended Patient Population: Infant/Pead/Adult.

Intended Users:
Qualified healthcare professionals trained in vascular access and intravascular procedures.

Use Environment: Proper Healthcare Setup.

Instructions for Use:
1. Verify package integrity and expiry date.
2. Remove the sterile device from packaging.
3. Open the package using aseptic technique and carefully remove the guide wire.
4. Visually inspect the guide wire for bends, kinks, surface damage, coating defects, or any other abnormalities. Do not use a damaged guide wire.
5. Flush and prepare the compatible introducer, catheter, or access device according to the manufacturer's instructions.
6. For hydrophilic-coated guide wire models, activate and maintain the coating by moistening with sterile saline solution prior to and during use as required.
7. Introduce the guide wire through a compatible needle, introducer, sheath, or catheter using standard vascular access techniques.
8. Advance the guide wire carefully under fluoroscopic guidance while observing the guide wire tip position at all times.
9. If resistance is encountered, do not force, torque excessively, withdraw, or advance the guide wire until the cause of resistance has been identified.
10. Once the guide wire has reached the desired position, advance, exchange, or position the compatible catheter or interventional device over the guide wire in accordance with standard clinical practice.
11. Maintain guide wire position during device exchange procedures as clinically required.
12. After completion of the procedure, carefully withdraw the guide wire while monitoring for smooth removal.
13. Inspect the guidewire after removal to verify device integrity.
14. Dispose of the used guide wire as potentially infectious biomedical waste in accordance with applicable local regulations and institutional procedures.

Intended Clinical Benefits to the patients:
Provides a track for safe and controlled introduction, positioning, and exchange of catheters and other compatible interventional devices, thereby supporting efficient vascular access during diagnostic and therapeutic procedures.

Clinical Safety:
- Device Design and Material Safety.
- Biocompatible products.
- Our device is a single use device.
- Our product is non-toxic, sterile & non-pyrogenic.

Performance Characteristics
- Designed to facilitate the introduction, positioning, and exchange of catheters and other compatible interventional devices within the vasculature.
- Provides flexibility and steerability to support navigation through vascular anatomy.
- Available in straight-tip and J-tip configurations and in various diameters and lengths to meet procedural requirements.
- PTFE-coated variants are designed to reduce friction during device advancement.
- Hydrophilic-coated variants are designed to enhance lubricity when activated with sterile saline solution.

Warnings:
- Single use only.
- Do not use if package is damaged.
- Use under fluoroscopic guidance.
- Do not force against resistance.
- Use only compatible catheters and accessories.
- Avoid contact with sharp instruments.
- Read instructions before use.
- The product should not be reprocessed.
- The product is non-toxic, sterile & non-pyrogenic.
- Do not Clean or re-sterilize. For single use only. Discard after use.
- The product should be used immediately after its packaging is opened.

MAIS INDIA disclaims any responsibility for possible consequences resulting from improper use.

Cautions:
- Do not use if package is damaged.
- Discard after single use.

Limitations:
The guide wire is intended for single-use vascular access and device placement procedures only and is not intended for use in the coronary vasculature.

Potential Side Effects:
- Vessel perforation
- Dissection
- Bleeding
- Infection
- Embolism
- Thrombosis
- Hematoma
- allergic reaction

Storage Conditions:
Store in a cool & dry place.
Keep away from sunlight

Sterility and Shelf Life:
Sterilized using Ethylene Oxide (EO). Sterile, non-toxic and non-pyrogenic.

Shelf life:
5 years when stored under recommended conditions.

Duration of use:
Transit use only.

Disposal:
Dispose as potentially infectious biomedical waste according to applicable local regulations and institutional procedures.

Notice to Users and/ or Patients:
Any serious incident related to the device should be reported to the manufacturer and applicable competent authority.

Explanation of symbols used:

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Consult instructions for use (Indicates the need for the user to consult the instructions for use)		Latex free (Indicates a medical device that is Latex free)
	Caution (To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.)		Date of manufacture (Indicates the date when the medical device was manufactured)
	Sterilized using ethylene oxide (Indicates a medical device that has been sterilized using ethylene oxide)		Use-by date (Indicates the date after which the medical device is not to be used)
	Do not re-sterilize (Indicates a medical device that is not to be re-sterilized)		Batch Number (Indicates the manufacturer's batch number so that the batch or lot can be identified)
	Do not re-use (Indicates a medical device that is intended for one single use only)		Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified)
	Single sterile barrier system (Indicates a single sterile barrier system)		Keep away from sunlight (Indicates a medical device that needs protection from light sources)
	Do not use if packaging is damaged and consult instructions for use. (Indicates a medical device that should not be used if its packaging has been damaged or opened, and that the user should consult the instructions for use for additional information)		Manufacturer (Indicates the medical device manufacturer) Manufacturing Unit: 525P, Sector-37, Pace City II, Gurgaon, Haryana-122001, India. Contact Details.: +91 8527589990 Fax No.: 0124 404 7533 Email ID: info@maisindia.com Website:www.maisindia.com

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Keep dry (Indicates a medical device that needs to be protected from moisture)		Non-pyrogenic (Indicates a medical device that is non- pyrogenic)
	Unique Device Identifier (Indicates a carrier that contains Unique Device Identifier information)		Medical device (Indicates the item is a medical device)
	Country of manufacture (To identify the country of manufacture of products)		Fragile, handle with care (Indicates a medical device that can be broken or damaged if not handled carefully)
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