allwin® Medical Devices

HyGuide Hydrophilic Guidewire

Description:
HyGuide Hydrophilic Guidewire is a stainless steel guidewire with hydrophilic coating, used for urological procedures.

Configuration:
See brochure

Intended use:
Used for access ureter during routine and difficult cases.

Contraindications:
Not for use in the cerebral vasculature. It is always the physician's responsibility to determine and ensure the patient's suitability for the procedure where HyGuide Hydrophilic Guidewire is used.

Complications:
Possible complications include, but are not limited to the following:

- Vessel wall perforation
- Infection
- Bleeding
- Edema
- Tissue trauma

Caution:
Federal (USA) law restricts this device to sale by or on the order of a physician. Read the instructions for use carefully prior to using the device. Interventional techniques always involve a risk and the equipment should only be used as described in the instructions for use. Not following the instructions, warnings and precautions properly may compromise guide wire performance and lead to serious consequences or injury to the patient.

Warnings:

- SINGLE USE. This device is intended for single use only. Reusing the guidewire involves high risk of contamination and locking of the wire inside the catheter due to wear-out of the hydrophilic coating.
- Attempt to resterilize a single use device may compromise its structural integrity and/or lead to device failure which may result in patient injury or illness.
- Discard the product after use according to local instructions for hazardous waste.
- Do not withdraw through a metal needle.
- Do not attempt to move the guide wire without observing the resultant tip response.
- Never advance or withdraw the guide wire against resistance until cause of the resistance is determined by fluoroscopy.
- To be used before the expiry date stated on the package.

Precautions:

- Prior to opening, the sterile package should be checked to see if it is still intact.
- Prior to use, carefully inspect the guidewire for bends, kinks or other damages.
- Do not use if the package is broken.
- Do not use damaged guidewires.
- Before removing the guidewire from the dispenser, fill the dispenser with (sterile) saline solution. After use, reinsert the guide wire in the saline- filled dispenser, distal end first.
- Do not use alcohol, antiseptic solutions or other solvents on the guide wire, as this may damage the hydrophilic coating.
- The device should only be used by experienced physicians, trained in invasive techniques, the use of guidewires and familiar with side effects and hazards commonly associated with interventional procedures.
- HyGuide Hydrophilic Guidewire contains a metallic core, do not use with any inappropriate equipment (e.g. MRI).
- Storage temperature between 5ºC to 30ºC.

Compatibility:
Confirm the compatibility of the guidewire diameter with the interventional device before actual use. There should be at least 0.0004" (0.01 mm) clearance between the lumen of the catheter and the guide wire, regardless the type of over-the-wire micro catheter used.

Preparations for use:

1. Before removing the guidewire from the dispenser, use a 20 ml syringe to fill the dispenser with saline and allow the guide wire to hydrate for at least 30 seconds.
2. Carefully remove the guidewire from the dispenser.
3. Inspect the guidewire thoroughly to make certain that it is not kinked or otherwise damaged.

Instruction for Use:

1. Introduce the guidewire in the urinary tract or the working channel of an endoscope, via the flexible end
2. Position the guidewire in the desired anatomical location by gentle advancement
3. Confirm the location of the guidewire either visually or using fluoroscopy
4. Withdraw the guidewire carefully

Liability:
Allwin is not liable for defects/ deterioration resulting from abnormal use or modifications made to the product and under these circumstances not covered by the guarantee. Allwin disclaims liability for direct or indirect injuries that may occur as a consequence of the product being modified or wrongly used.

Do not reuse, reprocess & resterilize:
Reuse, Reprocessing & resterilization may compromise the structural integrity, can also create risk of contamination & may not give desired result or create complications, infections which may result in injury, illness or death.

Limited Express Warranty:
The limited express warranty as set forth herein is exclusive and in lieu of all warranties of merchantability and fitness for use, remedies, obligations and liabilities for consequential damages.
The products are being sold only for the purpose described herein and such limited express warranty runs only to the original user. In no event shall ALLWIN be liable for any breach of warranty in any amount exceeding the purchase price of the product. ALLWIN reserves the right to make design changes to products without liability to incorporate said changes in ALLWIN products previously designed or sold.

Read Instruction | For Single Use Only | Do not Re-Sterilize | Use By | Sterile unless package is opened or damaged | Caution : Federal (USA) law restricts device to sale by or on the order of a physician

STERILE EO Sterilized using ethylene oxide | Keep out of sunlight | Keep Dry | LATEX Not made with natural rubber latex | CE 2460

EC REP
CMC Medical Devices & Drugs S. L.
C/Horacio Lengo N' 18, CP 29006, Malaga, Spain
Tel.: +34 951 214 054
E-mail : info@cmcmedicaldevices.com

allwin® Medical Devices
Allwin Medical Devices
3305 E. Miraloma Ave., Suite 176 Anaheim, CA 92806 (USA)
Tel. : +1 714-572-1709 | Fax : +1 714-572-1732
Email : info@allwinmedical.com | www.allwinmedical.com