allwin® Medical Devices

Supremo Nitinol Hydrophilic Guidewire

Description:
Supremo Nitinol Hydrophilic coated Guidewire are single ended wires are without hydrophilic coating in the proximal end. Double ended wires are hydrophilic coated all over. The device is sterile and non-pyrogenic.

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 Supremo Hydrophilic Nitinol Guidewire is used.

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

- Vessel wall perforation
- Thrombus formation
- Infection
- Hematoma at puncture site
- Vasospasm
- Ischemia
- Arteriovenous fistula
- Myocardial infection
- Stroke

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 guidewire performance and lead to serious consequences or injury to the patient.

Warnings:

- SINGLE USE. This device is intended for single use only. Reusing the guide wire 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 guidewire without observing the resultant tip response.
- Never advance or withdraw the guidewire 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 guidewire in the saline- filled dispenser, distal end first.
- Do not use alcohol, antiseptic solutions or other solvents on the guidewire, 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.
- Supremo Hydrophilic Nitinol 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 guidewire, 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 guidewire to hydrate for at least 30 seconds.
2. Carefully remove the guide wire from the dispenser.
3. Inspect the guide wire thoroughly to make certain that it is not kinked or otherwise damaged.

Instruction for Use:

1. When introducing the guidewire into the catheter and introducer sheath, ensure that at least 2 centimeters of guidewire extend from the proximal hub. This will prevent the guidewire from slipping inside the catheter.
2. To aid in the selective placement of the catheter into a particular vessel, gently rotate the proximal end of the guidewire as it is advanced forward.
3. To prevent contrast agent, unsterilization / clotting, a continuous saline flush should be maintained between the catheter / interventional device and the guidewire during the procedure. The size of the syringe used to flush the catheter lumen should be adapted to the length and diameter of the catheter.
4. Between uses, during the same procedure, place the guidewire in a saline filled container, or fill the dispenser with saline and reinsert the guide wire in the dispenser, distal end first. Avoid wiping with damp cloths; particulate from the cloth can adhere to the surface of the guidewire. Make sure to leave a segment of the proximal end outside the dispenser to facilitate identification.

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:

REF Catalogue Number | LOT Batch Code | Date of Manufacture | Use By | Do not re-use | Do not Re-Sterilize | Rx only — Caution: Federal Law restricts this device to sale by or on the order of a physician or a practitioner trained in its use.

Consult Instruction for use | Do not use if Packing is damaged | Caution | Keep out of sunlight | Keep Dry | STERILE EO — Sterilized using ethylene oxide

EC REP
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Temperature Limit

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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.

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Temperature Limit

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