

Guidewire

Description:

- FlexiGuide Standard- Straight Tip Guidewire
- FlexiGuide Standard- J Tip Guidewire
- Cobra Nitinol Guidewire
- TITAN Lunderquist Guidewire
- Schüller Guidewire

Guidewires are stainless steel or nitinol wires, with or without coating, straight or J tip in fixed core or movable core configuration.

Configuration:

See brochure

Intended use:

For percutaneous entry into vessel using the Seldinger technique or for endoscopic access.

Contraindications:

No known contraindications.

Complications:

- Perforation
- Acute Bleeding
- Hemorrhage
- Edema
- Tissue Trauma

Caution:

Federal (USA) law restricts this device to sale by or on the order of a physician.

Warning/ Precaution:

- Inspect the guidewire prior to use for tip shape, bends, kinks or coil separation. Do not use if there is evidence of bends, kinks or coil separation.
- Single use only.
- 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.
- Do not advance the guidewire against resistance without first determining the cause and taking remedial action.
- Do not use if package is opened or damaged.
- Dispose in accordance with recognized medical practice and under observance of applicable law and regulation.
- Only experienced surgeons should place this device
- Storage temperature between 5°C to 30°C.

Instruction for Use:

- Check compatibility of the device.
- Guidewire may be inserted especially with help of straightener via a needle / cannula or a dilator / sheath type percutaneous entry system.
- Using the working channel of an endoscope, the guidewire may be inserted into the tract.

Preparation for use (For Hydrophilic Coated Guide wires):

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






Do not reuse, reprocess & resterilize:

Reuse, Reprocessing & reesterilization 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.

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 **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

CE **0123**  ^{30°C} Temperature Limit

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