StruXure™ Spring Coil Guidewire
J Curved Guidewire Device

Instructions for Use

Product Description:
Guidewire is constructed using stainless steel and nickel titanium alloys. The guidewire is packaged in a spiral hoop fitted with a “J”-Straightener, where applicable, to aid in insertion of the guidewire into the puncture needle.

Indications for Use:
To facilitate the placement of devices during diagnostic or interventional procedures.

Contraindications:
This wire is not intended for use in the cerebrovasculature or coronary arteries.

Warnings:
• Contents supplied STERILE. Do not use if sterile barrier is damaged.
• Intended for Single Patient Use. DO NOT RESTERILIZE AND/OR REUSE.
• Do not alter the guidewire during insertion, use, or removal.
• After use, this product may be a potential biohazard. Handle and discard with accepted medical practice and applicable local, state, and federal laws and regulations.

Cautions:
• Carefully read and follow all instructions prior to use.
• Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
• Only qualified healthcare practitioners should insert, manipulate and remove these devices.
• Never advance the guidewire against resistance. Excessive force against resistance may result in separation of the guidewire tip, guidewire fracture, damage to the catheter, or vessel damage.
• Avoid withdrawing the guidewire through metal needles; guidewires may shear against the needle bevel.
• Use the device prior to the “Use By” date noted on the package.

Precautions:
• Inspect the guidewire prior to use for tip shape, bends, kinks, or coil separation. Do not use if damaged.
• Perform exchanges slowly to prevent air entry and/or trauma.
• Do not allow the guidewire tip to remain in a prolapsed condition.

Possible Complications:
• Air Embolism
• Bleeding
• Brachial Plexus Injury
• Cardiac Arrhythmia
• Cardiac Tamponade
• Catheter Occlusion
• Catheter Related Sepsis
• Endocarditis
• Extravasation
• Guidewire Embolism
• Hematoma Formation
• Intolerance Reaction to Implanted Device
• Laceration of Vessels or Viscus
• Perforation of Vessels or Viscus
• Thoracic Duct Injury
• Thromboembolism
• Vascular Thrombosis
• Vessel Erosion
• Risks Normally Associated with Local and General Anesthesia, Surgery, and Post-Operative Recovery

Directions for Use:
1. Identify the insertion site for the catheter and prepare the site using proper aseptic technique and local anesthesia as required.
2. Insert the introducer needle into the desired vein.
   Caution: If the artery is entered, withdraw the needle and apply manual pressure for several minutes.
3. Remove the guidewire tip protector from the guidewire hoop, advance the guidewire forward exposing the J-Tip and inspect J-Tip for tip shape, bends, kinks, or coil separation. Retract J-Tip into the J-Tip advancer/straightener.
4. Insert the J-Tip straightener into the introducer needle. Slowly advance the guidewire into the vein until desired depth is achieved.
5. Gently withdraw and remove the introducer needle while holding the guidewire in position.
   Caution: If the guidewire must be withdrawn while the needle is inserted, remove both the needle and guidewire as a unit to prevent the needle from damaging or shearing the guidewire.
6. Continue procedure per the primary device’s Instructions for Use.

An issue or revision date for these instructions is included for the user’s information. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems, Inc. to see if additional product information is available.

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Non-pyrogenic
Sterilized Using Ethylene Oxide
Do not use if package is damaged
This product and packaging is not made with natural rubber latex
Do not reuse
Rx only
Do Not Resterilize
Consult instructions for use

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