ANGUIS Guidewire

Instruction for use

CE 2265

1. DESCRIPTION OF COMPONENTS

The Anguis guidewire is designed to direct a catheter to the desired anatomical location in the peripheral vasculature during diagnostic or interventional procedures. This product is manufactured from nitinol alloy, polyurethane and is coated with hydrophilic, when wet, a hydrophilic coating increases the lubricity of the guidewire surface.

2. INDICATIONS FOR USE

Anguis guidewire is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is not intended for neurovascular or coronary arteries.

3. CONTRAINDICATIONS

This device is not intended for neurovascular or coronary arteries.

4. COMPLICATIONS

It should be careful in the following potential complications during use of this device.

Angiography or intravascular therapy may be accompanied by guidewire, but not limited to, the following:

- General discomfort
- Headache
- Nausea and vomiting
- Fever and chill
- Shock
- Infection and pain at the puncture site
- Hemorrhage at the puncture site
- Dissection or perforation of the vessel wall
- Air embolism
- Hematoma
- Infection
- Thrombus formation
- Tissue trauma
- Embolism
- Allergic reaction

5. WARNING

- Contents supplied “STERILE” using an ethylene oxide(EO) process.
- Do not use if sterile barrier is damaged.
- Verify the cause of resistance by fluoroscopy, or remove the catheter and the guidewire together.
- If there is any doubt whether catheter, or wire guide has been damaged, use a new catheter or guidewire.
- Do not manipulate the guidewire through a metal introducer or a metal dilator. Manipulation or withdrawal through a metal introducer or a metal dilator may result in destruction or separation of the outer polyurethane coating requiring retrieval. A plastic introducer is recommended when using this wire for initial placement.
- For single patient use only.
- Do not reuse, reprocess or re-sterilize.
- Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.
- Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.
- Contamination of the device may lead to injury, illness or death of the patient

6. PRECAUTIONS FOR USE

- This device is intended for use by physicians who have got appropriate training.
- Do not use opened or damaged packages.
- Use the device prior to the “expiration date” noted on the package.
- Prior to a procedure, all equipment to be used for the procedure should be carefully examined to verify proper function and integrity.
- Inspect guidewire prior to use for any surface irregularities and bends or kinks. Any guidewire damage may decrease the desired performance characteristics.
- Exercise care in handing of the guidewire during a procedure to reduce the possibility of accidental breakage, bending, or kinking. Do not use a guidewire that has been damaged.
- Do not attempt to move the guidewire without observing the resultant tip response.
- Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Excessive force against resistance may result in separation of the guidewire tip, damage to the catheter, or vessel perforation.
- Due to the variations in the inner diameter of some catheters, abrasion of the hydrophilic coating may be caused by a tight catheter. It is advisable to stop using such catheters.
- Excessive tightening of the torque device onto the guidewire may result in abrasion of the coating on the guidewire.

7. INSTRUCTIONS FOR USE

1. Remove the guidewire and holder together from the package.
2. Prior to inserting the guidewire into a catheter, flush the holder with heparinized saline. This will prime the catheter and also provide smooth movement of the guidewire within the catheter.
3. Gently remove the guidewire from the guidewire holder and inspect the guidewire prior to use to verify that it is undamaged.
4. Carefully insert and advance the guidewire into the catheter. The guidewire introducer may be used to facilitate the introduction of guidewires into catheter hubs or hemostatic valves.
5. If desired, the guidewire can be used with the torque device, to use the torque device, slip the device over the proximal end of the guidewire. When the torque device is in the desired location on the guidewire, tighten the cap to secure the torque device in place. The torque device may be repositioned or removed by loosening the cap and retightening the cap.
6. Insert the wire slowly into the catheter while wetting it with heparinized saline.
7. When the wire reaches the selected position, move the using equipment.
8. When not in use during the procedure, wipe the guidewire with heparinized saline and store in the holder in a saline bath. This guidewire should only be used for the same patient and procedure.

8. STORAGE

Avoid exposure to water, direct sunlight, extreme temperatures and high humidity during storage. Store under controlled room temperature.

9. WARRANTY

SUNGJIN-HITECH CO., LTD. warrants that reasonable care has been used in the design and manufacture of this instrument.

[Symbol]

 Consult instruction for use

 Attention, consult instruction for use

 Do not reuse

 Do not resterilize

 Use by (Expiration Date)

 Date of Manufacture

 Manufacture

Catalog No.

Sterilized using ethylene oxide

Batch code

 Do not use if package is damaged

 Keep away from sunlight

 Keep dry

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