EN English - Instructions for use

Accoat Guide Wire

Caution:
Federal (USA) law restricts this device to sale by or on 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.

Description:
Guide wire. The device is sterile and non-pyrogenic.

Indications for use:
The Accoat Guide Wire is indicated for general intravascular and coronary arterial use to aid in the selective placement of catheters during diagnostic and/or therapeutic procedures.

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 the Accoat Guide Wire is used.

Warning:
SINGLE USE. This device is intended for single use only. Do no resterilize or reuse the device. Reusing the guide wire involves high risk of contamination and locking of the wire inside the catheter or human body due to guide wire kinking. Discard the product after use according to local instructions for hazardous waste. Do not withdraw PTFE coated guide wire through a metal cannula. Never advance or withdraw the guide wire against resistance until the cause of the resistance is determined by fluoroscopy. Do not attempt to move the guide wire without observing the resultant tip response. 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 guide wire for bends, kinks or other damages. Do not use if the package is broken. Do not use damaged guide wires.
The device should only be used by experienced physicians, trained in invasive techniques, the use of guide wires and familiar with side effects and hazards commonly associated with interventional procedures.
When using movable-core guide wires, do not advance the movable core when the tip is in a curved shape. Never twist or apply excessive force as the core might penetrate the coil and cause vessel damage.
To avoid arterial damage, make sure that the movable core is sufficiently retracted when the device is in the proximity of the heart.
The Accoat Guide Wire contains a metallic core, do not use with any inappropriate equipment (e.g. MRI).

Storage:
To be stored under cool, dark and dry conditions. To be kept away from heat.

Potential side-effects:
Possible complications include, but are not limited to the following:
- Vessel wall perforation - Thrombus formation - Infection
- Haematoma at puncture site - Vasospasm - Ischemia
- Arteriovenous fistula - Myocardial infarction - Stroke

Compatibility:
Confirm the compatibility of the guide wire 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) Carefully remove the guide wire from the dispenser.
2) Inspect the guide wire thoroughly to make certain that it is not kinked or otherwise damaged.

Directions for use:
1) When introducing the guide wire into the catheter and introducer sheath, ensure that at least 2 centimetres of guide wire extend from the proximal hub. This will prevent the guide wire 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 guide wire as it is advanced forward.
3) To prevent contrast agent crystallization/ clotting, a continuous saline flush should be maintained between the catheter/interventional device and the guide wire 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 guide wire in a saline-filled container, or fill the dispenser with saline, using the luer lock provided in the package and reinsert the guide wire in the dispenser, distal end first. Make sure to leave a segment of the proximal end outside the dispenser to facilitate identification.

Liability:
SP Medical A/S 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. SP Medical A/S disclaims liability for direct or indirect injuries that may occur as a consequence of the product being modified or wrongly used.

Explanation of the symbols used on the package labels:


Caution

Guide wire length and diameter


Contents


Shaft stiffness - Stiff


Shaft stiffness - Standard

Reference number

Lot number

Single use only


Do not use if pack is open or damaged

Sterilized by ethylene oxide gas


Expiry date


Manufacturing date


Manufactured by


Keep away from sunlight


Keep dry


Tip shape: Straight


Tip shape: J


Tip shape: J and straight