Synchro SELECT™ Guidewire

RX ONLY

See package insert for complete indications, contraindications, warnings and instructions for use.

Indications for use

The Synchro SELECT Guidewire series is intended for general intravascular use, including neurovascular and peripheral vasculatures. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neurovasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.

Contraindications

The Synchro SELECT Guidewire series is not intended for use within the coronary vasculature. If another interventional device is used with the Synchro SELECT Guidewire, then refer to that product labeling for intended use, contraindications and potential complications associated with the use of that interventional device.

Potential adverse events

Clinical complications may result from improper use of the device. Follow instructions for use carefully. Potential adverse events associated with guidewire use include, but are not limited to: aneurysm perforation/rupture; death; embolus; hemorrhage; infection; ischemia; neurological/intracranial sequelae; pseudoaneurysm; stroke; transient ischemic attack; vasospasm; vessel trauma, occlusion, perforation, dissection; other procedural complications including, but not limited to anesthetic and contrast media risks, hemodynamic compromise, renal insufficiency, access site complications.

Use of device requires fluoroscopy which presents potential risks to physicians and patients associated with x-ray exposure. Possible risks include, but are not limited to, the following:

Alopecia; Burns ranging in severity from skin reddening to ulcers; Cataracts; Delayed neoplasia.

Cautions/precautions

- Confirm the compatibility of the guidewire with the microcatheter before use. The wire should move freely within the catheter.
- Securely fasten the torque device onto the wire to prevent slippage of the torque device and to avoid product damage (i.e., core wire abrasion/peeling of PTFE, etc.)
- Maintain a continuous saline flush between the guiding catheter and the interventional device and between the interventional device and the guidewire during the procedure. Flushing prevents contrast crystal formation and/or clotting on the guidewire and the catheter lumen.
- Verify that package integrity has not been compromised prior to use. Do not use a product after the expiration date.
- Inspect the guidewire for any visible damage prior to use, and do not use a wire that is damaged.
- Carefully examine all equipment for defects prior to the interventional procedure. Do not use any defective equipment.
- This device requires use under fluoroscopic guidance. Limit the exposure to X-ray radiation doses to patients and physicians by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors when possible.
- Avoid wiping the device with dry gauze as this may damage the device coating.
- Avoid excessive wiping of the coated device.
- Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the device because this may cause unpredictable changes in the coating which could affect the device safety and performance.
- Avoid pre-soaking devices for longer than instructed, as this may impact the coating performance.

Warnings

- Contents supplied STERILE, using an ethylene oxide (EO) process. Non-Pyrogenic. Do not use if sterile barrier is damaged. If damage is found, call your Stryker Neurovascular representative
- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization 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 resterilization 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.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.
- As with all guidewires used in interventional procedures, complications can occur.
- Before a guidewire is advanced or withdrawn, verify tip movement under fluoroscopy to prevent the possibility of vessel perforation or guidewire damage. Do not torque a guidewire without observing corresponding movement of the distal guidewire tip; otherwise, guidewire damage, such as tip separation, and/or vessel trauma may occur.
- Always advance or withdraw the guidewire slowly and carefully. Never advance, auger, withdraw, or torque a guidewire which meets resistance. Resistance may be felt and/or observed under fluoroscopy by noting any buckling or prolapse of the guidewire tip. Excessive force against resistance may result in damage to the guidewire, such as separation of the guidewire tip, damage to the interventional device and/or vessel perforation. Determine the cause of the resistance under fluoroscopy and take any necessary remedial action.
- The torque device and the introducer are included to aid in the use of the guidewire and are not intended to enter the patient's body at any time.
- Observe all guidewire movement in the vessels using fluoroscopy. Do not move or torque a guidewire without observing corresponding movement of the distal guidewire tip; otherwise, guidewire damage, such as tip separation, and/or vessel trauma may occur. Always advance or withdraw the guidewire slowly and carefully.
- This device is coated with a hydrophilic coating at the distal end of the device. For Synchro SELECT Soft and Synchro SELECT Standard, the hydrophilic coating length is 50 cm and for the Synchro SELECT Support, it is 51 cm. Please refer to Preparations for Use and Directions for Use Sections for further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.