Hybrid Safety & Warnings

Contraindications

EU :

"HYBRID" guide wires may be contra indicated depending on the physician professional opinion who may estimate that a procedure

using the device may decrease the patient health especially in those cases:

- Incompatible vascular anatomy with the advancement of the guide wire

- Thin blood vessel

- Patient allergic to Nickel

These devices are contraindicated for neonates, premature neonates and infants.

US :

• Patient allergic to Nickel

• The device is not indicated to be used in coronary arteries.

• If another interventional device is used with the HYBRID Guidewire, then refer to that product labeling for intended use, contraindications and potential complications associated with the use of that interventional device.

Potential Complications

Potential complications include but are not limited to:

- Vessel or aneurysm perforation

- Vasospasm

- Hematoma at the site of entry

- Embolism

- Ischemia

- Intracerebral/intracranial hemorrhage

- Pseudoaneurysm

- Seizure

- Stroke

- Infection

- Death

- Thrombus formation

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- Vasospasm
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- Intracerebral/intracranial hemorrhage
- Pseudoaneurysm
- Seizure
- Stroke
- Infection
- Death
- Thrombus formation
- Sterile inflammation or granulomas at the access site and tissue necrosis
- This device requires the use with fluoroscopy. Potential complications related to angiographic and fluoroscopic X-ray radiation doses include, but are not limited to, alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia. The probability of occurrence of complications may increase as procedure time and number of procedures increase.

Precautions for Use

-  Do not use if the pouch is open or damaged. These products are sterile when the packaging is not damaged.

- This product is intended for single use only. Do not reuse. Any reuse of the device cause a high risk of microbiological contamination for the patient as well as a risk of loss of the device characteristics.

- Do not resterilize.

- Store in a dry place at room temperature and away from light.

- Do not use the product after the expiry date.

- These products must be used by specialist physicians in interventional neuroradiology and / or specialist physicians in interventional radiology.

- Never force an intravascular device against resistance without first determining the cause through angiographic inspection. Working against resistance can damage the guidewire and the catheter or cause lesions in the patient.

- Never use a damaged guidewire.

- Follow the instructions for the devices used with the guidewire.

- Observe the tip response when turning the guidewire and avoid turning in the same direction more than three times, when the tip is stationary.

- Avoid repeated bending, at the same point in order to avoid damage or separation of the guidewire.

US :

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- Never use a damaged guidewire.
- Follow the instructions for the devices used with the guidewire.
- Observe the tip response when turning the guidewire and avoid turning in the same direction more than three times, when the tip is stationary.
- Avoid repeated bending at the same point, in order to avoid damage or separation of the guidewire.
- Avoid wiping the device with dry gauze as this may damage the device coating.
- Avoid excessive wiping of the distal segment containing hydrophilic coating.
- 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.
- Ensure that the device is rinsed as stated in this directions for use to avoid any potential impact to the coating performance.
- 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 pre-soaking devices for extended durations when the device is not in use, as this may impact the coating safety and performance.

Warnings

US :

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 Balt USA representative.

For single 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.

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.

This device is coated with a hydrophilic coating at the distal end. Please see Table 1 for specific coating measurements. Please refer to the Directions for Use section 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.

The torquer 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.