PRESCRIPTIVE INFORMATION

NaviPro™
Hydrophilic Guidewire

Boston Scientific
Advancing science for life™

REFER TO THE DEVICE DIRECTIONS FOR USE FOR COMPLETE INSTRUCTIONS ON DEVICE USE. RX ONLY.
CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Warning

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific 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.

Intended Use/Indications for Use

The endoscopic guidewire is intended for use in selective cannulation of the biliary ducts including, but not limited to the common bile, pancreatic, cystic, right and left hepatic ducts. The endoscopic guidewire is designed to be used during endoscopic pancreatico-biliary procedures for catheter introduction and exchanges of catheters, cannulas, and sphincterotomes.

Contraindications

The endoscopic guidewire is contraindicated for all vascular applications.

Warnings

To prevent possible tissue damage, care should be taken when manipulating a device over a guidewire during the device's placement and withdrawal. If resistance is felt during device placement, discontinue the procedure and determine the cause of resistance before proceeding. If the cause of resistance cannot be determined, remove the guidewire and device as a unit to prevent possible damage and/or complications.

Do not use alcohol, antiseptic solutions, and contrast agents containing alcohol or other solvents on hydrophilic-coated guidewires because they may adversely affect or damage the coating.

Avoid manipulating or withdrawing the hydrophilic guidewire back through a metal needle or cannulas. A sharp edge may scrape the coating or shear the guidewire. A catheter, introducer sheath or vessel dilator should replace the needle as soon as the guidewire has been inserted.

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Precautions

- Always advance or withdraw the guidewire slowly.
- Do not push, auger, withdraw or torque a guidewire entrapped in the duct.
- Do not advance, withdraw or torque the guidewire against resistance until the cause of the resistance has been determined. Excessive force against resistance may result in damage to the guidewire, interfacing device and/or duct.
- Do not allow the guidewire to remain in a prolapsed position as this may result in damage to the guidewire.
- Confirm that the interventional devices are compatible with guidewire diameter before use.
- Do not use the guidewire after the expiration date indicated on the label. Discard guidewires that exceed the expiration date.
- Do not wipe guidewire with dry gauze.
- If using a torque device, it is recommended that a plastic torque device be used to handle the hydrophilic guidewire. Use of a metal torque device may damage the wire.

Adverse Events

Use of guidewires in the gastrointestinal tract may be associated with the following complications:

- Infection
- Perforation
- Edema
- Tissue Trauma
- Foreign Object in Body
- Bleeding
- Peritonitis
- Hemorrhage
- Wire Fracture
- Additional Surgical Intervention
- Breakage with retention of fragment
- Inflammation
- Pancreatitis
- Failure to Pass
- Death

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