Jagwire™ Revolution

℞ **ONLY**

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

REUSE WARNING: For single use only. Do not reuse, reprocess or sterilize. Reuse, reprocessing or 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 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.

Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE

The Jagwire Revolution High Performance Guidewire is indicated for use throughout the alimentary tract as well as for selective cannulation of the pancreatico-biliary system including the common bile duct, pancreatic duct, cystic duct, and right and left hepatic ducts. The endoscopic guidewire is designed to be used during endoscopic pancreatico-biliary as well as gastrointestinal procedures for introduction and exchange of catheters, cannulas, and sphincterotomes, and to aid in the placement of diagnostic and therapeutic devices.

CONTRAINDICATIONS

None known.

WARNINGS

- The Jagwire Revolution High Performance Guidewire is intended for single-use. If reused, the coating of the wire may be compromised and may not be properly insulated for electroconductivity during sphincterotomy.

- This device contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.

- Inappropriate use of the guidewire might result in damage to the endoscope, abrasion of the hydrophilic coating, release of plastic fragments from the guidewire, damage to or breakage/separation of the guidewire and/or tip, all of which may result in patient harm and necessitate intervention.

- Do not manipulate, advance and/or withdraw the guidewire through a metal cannula or needle. Manipulation, advancement, and/or withdrawal through a metal device may result in destruction and/or separation of the outer polymer jacket requiring retrieval.

- Do not reshape the guidewire by any means. Attempting to reshape the wire may cause damage, resulting in the release of wire fragments into the alimentary tract, or the pancreaticobiliary anatomy, and may result in patient harm.

- The guidewire should be advanced through the scope using short, deliberate 2-3 cm movements to prevent inadvertent damage to the device or injury to the patient.

- Do not use a guidewire which has been damaged or if any defect is found during inspection. Damage will prevent a guidewire from performing with accurate torque or tactile response and may cause injury. Return any defective product to Boston Scientific for replacement.

PRECAUTIONS

- Any use of this device, other than those indicated in these instructions is not recommended.

- Do not wipe guidewire with dry gauze as this may decrease surface lubricity or may cause damage to the wire tip.

- Free movement of the guidewire within a catheter is an important feature of a guidewire because it gives the user valuable tactile information. Test the system for any resistance prior to use.

- Do not forcibly advance or withdraw a guidewire. To do so may result in complications. If resistance is encountered, STOP, determine the cause and take remedial action before continuing. If necessary, remove guidewire and ancillary device or scope as a complete unit to avoid complications.

POTENTIAL ADVERSE EVENTS

- Allergic Reaction
- Edema
- Hemorrhage
- Infection
- Inflammation
- Obstruction
- Pancreatitis
- Perforation
- Peritonitis
- Tissue damage

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