

Jagwire™ Revolution

High Performance Guidewire

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 Jagwire Revolution High Performance Guidewire is indicated for use in selective cannulation of the biliary ducts 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 pancreatobiliary procedures for catheter introduction, exchanges of catheters, cannulas, and sphincterotomes, and to aid in the placement of diagnostic and therapeutic devices.

Contraindications

None known.

Caution

- The guidewire should only be used by physicians thoroughly trained in endoscopy.
- Do not use with metal-tip catheters. Withdrawing the guidewire through a metal tip catheter may damage the surface of guidewire.
- Do not wipe guidewire with dry gauze as this may decrease surface lubricity or may cause damage to the wire tip.
- Do not use the guidewire if any defect is found during inspection. Please return any defective product to Boston Scientific for replacement.

Warning

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.

Precautions

Inappropriate use of the guidewire may result in damage to wire/tip, interfacing device and/or duct.

Adverse Events

Potential adverse events which may result from the use of the device include but are not limited to:

- Bleeding
- Edema
- Hemorrhage
- Infection
- Perforation
- Peritonitis
- Pancreatitis
- Tissue trauma
- Wire Fracture
- Failure to Pass