



Refer to the device directions for use for complete instructions on device use.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Warning

Contents supplied STERILE using (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.

Caution

- Always make sure that a good return path to the electrosurgical unit is maintained.
- Do not use a guidewire, Jagtail High Performance Guidewire Extension or sphincterotome that has been cut, burned or damaged. Leakage current to the patient or user may increase at the site of the damaged insulation.
- Do not use with metal tip catheters. Withdrawing the guidewire through a metal tip catheter may damage surface of the guidewire.
- Use a single-use sphincterotome to ensure that the material between the lumens has not been compromised.
- If the wire is removed during sphincterotomy, turn the electrosurgical generator power down, and gradually increase until acceptable cutting effect is achieved.

Warning

The Jagwire High Performance Extendable Guidewire/Jagtail High Performance Guidewire Extension is intended for single-use. If reused, the jacket of the wire may be compromised and may not be properly insulated from electroconductivity during sphincterotomy.

Adverse Events

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

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



Jagwire™ High Performance Extendable Guidewire

Intended Use/ Indications For Use

The Jagwire High Performance Extendable Guidewire is indicated for use in selective cannulation of the biliary ducts including, but not limited to the common bile, cystic, right and left hepatic ducts. The Jagwire High Performance Extendable Guidewire is designed to be used during endoscopic biliary procedures for catheter introduction and exchanges.

Contraindications

None known.

Jagtail™ High Performance Guidewire Extension

Intended Use/ Indications For Use

The Jagtail™ High Performance Guidewire Extension attached to the extendable Jagwire™ 260 cm Guidewire is designed for use during endoscopic biliary procedures for nonrapid exchange catheter introduction and exchanges. The attachment of the Jagtail High Performance Guidewire Extension to the extendable Jagwire 260 cm guidewire creates an extended guidewire that can be used to exchange out a non-rapid exchange biliary catheter without removing the original guidewire from the associated duct. When the exchange is completed, the Jagtail High Performance Guidewire Extension can be detached and the original, extendable Jagwire 260 cm guidewire can be used in a conventional manner.

Contraindications

None known.

Precautions

- The Jagtail High Performance Guidewire Extension cannot be used alone. The Jagtail High Performance Guidewire Extension is designed to be used in conjunction with the Jagwire High Performance Extendable Guidewire.
- The Jagtail High Performance Guidewire Extension should be fully locked before removal of alignment tool.