

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

### Caution/Rx Only:

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

### Warnings:

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.

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

### Intended Use / Indications for Use:

The Jagwire High Performance 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 Guidewire is designed to be used during endoscopic biliary procedures for catheter introduction and exchanges.

### Contraindications:

None Known

### 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