

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 Hydra Jagwire™ 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 Hydra Jagwire Guidewire is indicated for use in selective cannulation of the biliary ducts including the common bile, pancreatic, cystic, right and left hepatic ducts and to aid in the placement of diagnostic and therapeutic devices during bronchoscopic procedures.

Contraindications:

None known.

Cautions:

Inappropriate use of the Hydra Jagwire guidewire may result in wire/tip breakage in the gastrointestinal tract or tracheobronchial tree.

Adverse Events:

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

- Infection
- Bleeding
- Breakage with retention of fragment
- Perforation
- Peritonitis
- Inflammation
- Edema
- Hemorrhage
- Pancreatitis
- Tissue Trauma
- Wire Fracture
- Failure to Pass
- Hemothorax
- Pneumothorax
- Foreign Object in Body
- Septicemia