

Dreamwire™

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 Dreamwire High Performance 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 and gastrointestinal procedures.

Contraindications

None known.

Adverse Events

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

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

Caution

Do not wipe guidewire with dry gauze.

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

Caution: Do not use the guidewire if any defect is found during inspection. Please return any defective product to BSC for replacement.