

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.

Intended Use / Indications for Use:

The NovaGold Guidewire is intended 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 endoscopic procedures.

Contraindications:

None known.

Precautions:

- Always advance or withdraw the guidewire slowly.
- Do not use metal-tip catheters. Withdrawing the guidewire through a metal tip catheter may damage surface of guidewire.
- Do not wipe guidewire with dry gauze.
- Caution: Inappropriate use of the guidewire may result in wire/tip breakage in the gastrointestinal tract.
- Caution: Do not use the guidewire if any defect is found during inspection. Please return any defective product to BSC for replacement.
- Caution: The guidewire should only be used by physicians thoroughly trained in endoscopy.

Adverse Events:

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

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