



# SpyGlass™ Discover Digital Catheter

For Use With The SpyGlass Discover Digital Controller

## ***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 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 SpyGlass Discover Digital System is indicated for use in diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts. The SpyGlass Discover Digital System comprises two components: the SpyGlass Discover Digital Catheter and the SpyGlass Discover Digital Controller.

The SpyGlass Discover Digital Catheter is intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.

The SpyGlass Discover Digital Controller is intended to provide illumination and receive, process, and output images from the SpyGlass Discover Digital Catheter for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.

### ***Contraindications***

Contraindications associated with the use of this device include:

- Contraindications specific to pancreatico-biliary duct (including hepatic ducts) exploration and cannulation.

### ***Precautions***

Only use the SpyGlass Discover Digital Catheter in conjunction with the SpyGlass Discover Digital Controller. Connection to other devices may cause device or property damage or operator injury.

### ***Adverse Events***

Possible complications include, but may not be limited to:

- Pancreatitis
- Septicemia/infection
- Hematoma
- Perforation
- Cholangitis
- Allergic reaction to contrast medium
- Hemorrhage
- Mucous membrane damage

### ***Warnings***

Do not use the SpyGlass Discover Digital Catheter in the presence of uncontained flammable fluids or gases such as detergents, anesthetics, nitrous oxide (NO), or oxygen. Doing so can result in fire and burns to the operator and patient.