



SpyGlass™ Discover Balloon Dilation Catheter Over-The-Wire

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.

Reuse Warning

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.

Intended Use/ Indications For Use

The SpyGlass Discover Balloon Dilation Catheter is indicated for laparoscopic and open surgical procedures for the dilation of the cystic duct to facilitate common bile duct exploration.

Contraindications

- Peritonitis
- Severe cholangitis
- Severe acute pancreatitis
- Known or suspected perforation of the cystic and/or bile ducts
- Previous abdominal operations which prevent safe abdominal access or progression of the procedure
- Inability to advance the balloon into the cystic duct
- Coagulopathy

Adverse Events

The complications that may result from a balloon dilation procedure include, but are not limited to:

- Allergic Reaction
- Bile leak
- Embolism
- Hemorrhage
- Inflammation
- Pain
- Pancreatitis
- Perforation
- Septicemia/Infection
- Tissue damage

Precautions

Carefully inspect the catheter prior to use to verify that the catheter has not been damaged during shipment and that its size, shape and condition are suitable for the procedure for which it is to be used.

Warnings

Carefully read all instructions prior to use. Please review below warnings and precautions. Failure to do so could lead to complications and/or patient injury. Any use for procedures other than those indicated in these instructions is not recommended.

- This product is not intended for use in the vasculature.