

Refer to the device directions for use for complete instructions on device use.

SpyGlass System Consumable Devices:

SpyGlass Direct Visualization Probe and Ocular

Intended Use/Indications for Use

The SpyGlass Probe and Ocular have been designed to examine the biliary system and associated ducts and organs.

The SpyGlass Probe and Ocular are intended to provide direct visualization for examination for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.

Contraindications

Contraindications associated with the use of the SpyGlass Probe and Ocular include:

- Patients for whom endoscopic procedures are medically contraindicated.
- Patients for whom endoscopic retrograde cholangiopancreatography (ERCP) is medically contraindicated.
- Any use other than those specifically outlined under the Indications for Use.

SpyScope™ Access and Delivery Catheter

Intended Use/Indications for Use

The device is intended to guide the SpyGlass Direct Visualization Probe or other visualization probe and various accessory devices into the pancreatico-biliary duct system during endoscopic pancreatico-biliary duct exploration procedures.

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

Contraindications

Contraindications for this device are those specific to endoscopic pancreatico-biliary duct exploration and cannulation.

SpyGlass System Capital Components:

SpyGlass Camera System

Intended Use/Indications for Use

The SpyGlass Camera System is for use during diagnostic and/or surgical procedures when endoscopic video assistance is required.

Contraindications

None known.

Refer to the device directions for use for complete instructions on device use.

SpyGlass System Capital Components (ctd.):

SpyGlass Camera System (ctd.)

Warnings

Operators who are not trained and qualified to perform endoscopic procedures should not use this device. Always exercise safety precautions when using electrical equipment to prevent operator and patient shock, fire hazard, or equipment damage. When implemented for therapeutic applications, a second equivalent camera should be available in case the primary camera stops working.

SpyGlass Lightsource

Intended Use/Indications for Use

Boston Scientific SpyGlass Light Source is designed to supply high-intensity white light to a fiber optic cable for illumination of a surgical field or other area of examination. Boston Scientific SpyGlass Light Source delivers 300-Watts of cool white IR filtered light. The lamp is housed in a lamp module that can be easily removed and replaced by the user without special tools.

Warnings

Operators who are not trained and qualified to perform endoscopic procedures should not use this device.

When implemented for therapeutic applications, a second equivalent light source should be available in case the primary light source stops working.

Contraindications

None known.

Irrigation Pump and Footswitch

Intended Use/Indications for Use

To provide irrigation during endoscopic surgical procedures.

Warnings

Operators who are not trained and qualified to perform endoscopic procedures should not use this device.

Contraindications

None known.

Refer to the device directions for use for complete instructions on device use.

SpyGlass System Capital Components (ctd.):

Isolation Transformer

Intended Use/Indications for Use

The Isolation Transformer is intended for applications where medical devices require improved electrical isolation and/or reduced leakage current to comply with existing safety standards. With the Isolation Transformer connected between the device and the wall outlet where the device is installed, the leakage current and the electrical isolation of the installed device will be that of the Isolation Transformer.

SpyGlass Light Cable

Intended Use/Indications for Use

SpyGlass Light Cable is for use with cystoscope, arthroscopes, pediatric endoscopes, and others.

Warnings

Operators who are not trained and qualified to perform endoscopic procedures should not use this device. Always exercise safety precautions when using electrical equipment to prevent operator and patient shock, fire hazard, or equipment damage. When implemented for therapeutic applications, a second equivalent light cable should be available in case the primary light cable stops working.

Contraindications

None known.

Potential Complications

Please be aware that potential complications may arise even with the proper use of medical devices. Accordingly, these devices should only be used by persons qualified in the procedures for which is indicated.

Cautions

Cautions can be found in the product labeling supplied with each device. CAUTION: Federal(USA) law restricts these devices to sale by or on the order of a physician.