

Interject™ Sclerotherapy Needle

Prescriptive Information

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

Intended Use/Indications for Use

Indications for endoscopy to introduce a sclerosing agent or vasoconstrictor into selected sites to control actual or potential bleeding lesions in the digestive system; and the injection of saline to aid in Endoscopic Mucosal Resection (EMR), polypectomy procedures and to control non-variceal hemorrhage.

Contraindications

Contraindications for this device are those applicable to injection therapy and include, but may not be limited to, those patients allergic to sclerosing or vasoconstriction agents and patients with lesions inappropriate for injection therapy with sclerosing or vasoconstriction agents.

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.

Potential Adverse Events

The following potential adverse effects include but are not limited to:

- Bleeding
- Perforation
- Pleural effusion
- Hepatic failure
- Chest pain
- Post-injection ulceration with delayed bleeding
- Esophageal stricture
- Aspiration pneumonia
- Dysphasia
- Septicemia
- Esophageal Ulcers
- Other respiratory difficulties

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

Cautions

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. The Interject Injection Therapy Needle Catheter should only be used by or under the supervision of physicians thoroughly trained in endoscopic gastrointestinal injection therapy. Monitor injection therapy under the direct vision of an endoscope. The Interject Injection Therapy Needle Catheter is not recommended for use with duodenoscopes. A thorough understanding of the technical principles, clinical applications, and risks associated with endoscopic injection therapy is necessary before using this product.