



Overview

Product Interject™ Injection Therapy Needle Catheter - IFU 52099381

Audience: Health Care Professional (HCP):

Rx Statement

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

Prior to use, please refer to all applicable “Instructions for Use” for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator’s Instructions.

Content

INTENDED USE/INDICATIONS FOR USE

The Interject Injection Therapy Needle Catheter is used for endoscopic injection into gastrointestinal mucosa and submucosa to:

- Introduce a sclerosing agent, vasoconstrictor, or other Injection solutions into selected sites to control actual or potential bleeding lesions in the digestive system
- Aid in Endoscopic Mucosal Resection (EMR), Endoscopic Submucosal Dissection (ESD), or polypectomy procedures
- 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

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.

GENERAL WARNINGS

- Check for proper position of the Interject Injection Needle Catheter using direct endoscopic vision. Injecting in an improper location or too deeply may lead to patient injury.
- If the injection needle does not completely retract into the outer sheath, please return the Interject Injection Needle Catheter to Boston Scientific and use a new Interject Injection Needle Catheter to complete the procedure.
- Ensure that the endoscope and the catheter tip are in the appropriate positions to avoid inadvertent patient injury.
- If the injection needle and the transparent inner sheath fail to extend the appropriate length upon pushing in on the needle hub, safely position the endoscope so that it is in the straightest possible position, and repeat step four (4). This will facilitate needle extension, while ensuring that the patient is not inadvertently injured. If the injection needle still fails to extend the appropriate length, please return the Interject Injection Needle Catheter to Boston Scientific and use a new Interject Injection Needle Catheter to complete the procedure.
- If the injection needle fails to retract completely into the outer sheath upon pulling back on the needle hub, safely position the endoscope so that it is in the straightest possible position, and repeat step (5). This will facilitate retracting the needle completely, while ensuring that the patient is not inadvertently injured. If the injection needle still fails to retract completely into the outer sheath, then pull the injection needle just inside the distal tip of the endoscope so that the needle tip is no longer endoscopically visible. This ensures the needle is completely inside the working channel to ensure that the patient is not inadvertently injured. To prevent inadvertent damage to the endoscope working channel, do not pass the exposed injection needle through the endoscope.

PRECAUTIONS

- 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.
- The Interject Injection Therapy Needle Catheter is not recommended for use with cyanoacrylate adhesives (e.g. Histoacryl).
- The Interject Injection Needle Catheter should be advanced through the endoscope using short, deliberate 2 to 3 cm movements to prevent inadvertent damage to the catheter.
- Prior to injecting, repeat endoscopic irrigation may be necessary to clear the visual field. Removal of the Interject Injection Needle Catheter from the working channel of the endoscope will facilitate enhanced endoscope irrigation and suctioning. Prior to injecting, repeat endoscopic irrigation may be necessary to clear the visual field. Removal of the Interject Injection Needle Catheter from the working channel of the endoscope will facilitate enhanced endoscope irrigation and suctioning.

POTENTIAL ADVERSE EVENTS

Possible complications include, but may not be limited to:

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