

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.

Cautions can be found in the product labeling supplied with each device

The Optiflo Hemostasis Catheter should only be used by or under supervision of physicians thoroughly trained in endoscopic gastrointestinal injection therapy. A thorough understanding of the technical principles, clinical applications, and risks associated with injection therapy is necessary before using this device.

Any use of this device, other than those indication in these instructions is not recommended.

Warning

Contents supplied STERILE using an ethylene oxide 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 diseases(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.

If injection needle extends beyond indicated maximum length, please return Optiflo Hemostasis Catheter to Boston Scientific and use a new Optiflo Hemostasis Catheter to complete procedure.

If injection needle **does not completely retract**, verify that the product is completely uncoiled. If coiled, uncoil sheath and retract injection needle. If injection needle still does not completely retract into the sheath, please return Optiflo Hemostasis Catheter to Boston Scientific and use a new Optiflo Hemostasis Catheter to complete procedure.

Check for proper position of Optiflo Hemostasis Catheter using direct endoscopic vision. Injecting in an improper location or too deeply may lead to patient injury.

Intended Use

The Optiflo Hemostasis Catheter is intended for endoscopic introduction of a sclerotherapy agent.

Indications for Use

The Optiflo Hemostasis Catheter is used endoscopically to introduce a sclerosing agent or vasoconstrictor into selected sites to control actual or potential bleeding lesions in the digestive system.

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 vasoconstricting agents and with patients with lesions inappropriate for injection therapy.

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

Precaution

A thorough understanding of technical principals, clinical applications, and risks associated with endoscopic injection therapy is necessary before using this product.

The Optiflo Hemostasis Catheter is packaged sterile in a pouch. Before using, inspect pouch for any breach of package to ensure a sterile product.

Potential Adverse Events

Possible complications include, but may not be limited to: bleeding, post-injection ulceration with delayed bleeding; perforation; aspiration pneumonia; pleural effusion; other respiratory difficulties; hepatic failure; septicemia; chest pain; esophageal ulcers; esophageal stricture; and dysphagia.