Injection Gold Probe™
Bipolar Electrohemostasis Catheter
Prescriptive Information

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

Caution/Rx Only:
Federal Law (USA) restricts this device to sale by or on the order of a physician.

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.

Use the bipolar generator's recommended power settings for electrocautery. Excess power may lead to patient injury. Exceeding the maximum voltage rating of 250V (500V peak to peak) may lead to patient injury.

Check for proper position of the Injection Gold Probe™ Catheter using direct endoscopic vision. Performing electrohemostasis or injection in an improper location or injecting too deeply may lead to patient injury.

Safe and effective electrohemostasis and injection therapy is dependent not only on equipment design but also, to a large extent, on factors directly under the control of the operator.

- No modification of this equipment is allowed.

This device is not intended to be used in the presence of flammable liquid, in an oxygen enriched atmosphere, or in the presence of explosive gases.

The maximum voltage rating for this device is 250V (500Vpeak to peak).

Intended Use / Indications for Use:
The Injection Gold Probe Catheter is indicated for use in endoscopic injection therapy (to deliver pharmacological injection agents, such as vasoconstrictors) and endoscopic electrohemostasis (cauterization of tissue and coagulation of blood) of actual or potential bleeding sites in the gastrointestinal tract. These sites include the following:

- Peptic Ulcers
- Dieulafoy Lesions
- Mallory-Weiss Tears
- Bleeding Polyp Stalks
- Arteriovenous Malformations (AVMs)
- Angiomata

The Injection Gold Probe Catheter also has irrigation capability. Any other use is not recommended.

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Contraindications:

Contraindications for this device are those specific to injection therapy and bipolar electrohemostasis treatments. These contraindications include, but are not limited to: non-focal bleeding sites, esophageal/gastric varices, diffuse lesions and allergies to injection agents.

Precautions:

The Gold Probe Catheter must be used in conjunction with a Type BF or CF generator. Universal precautions should be used in all cases. When a Bipolar Cable Adapter (sold separately) is used, ensure that the Gold Probe Catheter plug is pushed onto the connector as far as possible so that none of the connecting pin is visible. The other end of the Bipolar Cable Adapter is inserted into the generator. Always follow the manufacturer's suggestions for the operation of the unit to prevent unnecessary hazard to the operator and/or the patient.

Avoid incidental contact between Bipolar Cable Adapter and the patient's body, or any other electrodes. Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the procedure.

Possible safety hazards may result from gas embolism caused by over-insufflation of air, inert gas prior to high frequency surgery, etc. Endogenous gases should be sucked away if possible prior to procedure. Patient leakage currents from endoscope, as well as energized Gold Probe Catheter are additive. Consult the endoscope manufacturer about the proper grounding of the endoscope.

It is recommended that the operator not use the device with any generator setting which may output a voltage exceeding the Maximum Voltage Rating. Gold Probe Catheter Maximum Voltage Rating: 250V (500V peak to peak). Active accessories (such as Bipolar Cable Adapter) should be selected that have an Accessory Voltage Rating equal to or greater than 250V peak.

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

The 7F (2.3 mm) probe is designed for use with endoscopes that have a working channel of at least 2.8 mm and the 10F (3.3 mm) probe is designed for use with at least a 3.7 mm working channel.

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

- Please review the operations and service manuals of the electrosurgical generator for proper set and operation prior to using the Gold Probe.

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Adverse Events:

Possible complications include, but may not be limited to:

- Perforation
- Bleeding
- Post-injection ulceration with delayed bleeding
- Aspiration pneumonia
- Pleural effusion
- Other respiratory difficulties
- Hepatic failure
- Septicemia/infection
- Chest pain
- Esophageal ulcers
- Esophageal strictures.

Any electrocautery device constitutes a potential electrical hazard to the patient and operator. Possible adverse effects include: dysphagia; ulguration; burns; stimulation; cardiac arrhythmia.

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