Brief Summary Document

Overview

Product Injection Gold Probe – IFU 51571632

Rx Statement

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

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

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

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
- Allergies to injection agents.

WARNINGS

- Use the bipolar generator's recommended power settings for electrohemostasis. 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 using direct endoscopic vision. Performing electrohemostasis or injection in an improper location or injecting too deeply may lead to patient injury.
- Do not use the device with any generator setting which may output a voltage exceeding the Maximum Voltage Rating. Injection Gold Probe 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. Exceeding the maximum voltage rating of 250V (500V peak to peak) may lead to patient injury.
- Always follow the manufacturer's suggestions for the operation of the unit to prevent unnecessary hazard to the operator and/or the patient.
- 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 as this may lead to patient and/or operator injury and may cause a fire.
- Fluid and Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the procedure and mopped prior to use of the device. Endogenous gases should be sucked away, if possible, prior to procedure. Failure to do so may lead to fire and possible harm to the patient and user such as burns.
- Any use of this device, other than those indicated in these instructions, is not recommended as this may contribute to patient or operator injury.
- Possible safety hazards may result from gas embolism caused by over insufflation of air, inert gas prior to high frequency surgery, etc.
- Patient leakage currents from endoscope, as well as energized Injection Gold Probe are additive. Consult the endoscope manufacturer about the proper grounding of the endoscope.
- Avoid incidental contact between Bipolar Cable Adapter and the patient's body, or any other electrodes as this may cause patient injury such as burns.
- No modification of this equipment is allowed.
- Universal precautions should be used in all cases.
- Skin-to-skin contact should be avoided (for example between the patient's arms and body) by way of dry cloth or gauze in order to prevent possible thermal/electrical injury.
- Monitoring electrodes should be placed as far from the surgical area as possible. Failure to do so may result in injury or electrical shock to the patient or procedural room personnel.
- For use with the bipolar sockets of electrosurgical generators only. This device should never be used in a monopolar mode of operation.
- Monopolar diathermy or electrosurgical cautery in patients with pacemaker or implantable cardiac defibrillators can result in electrical reset of the cardiac device, inappropriate sensing and/or therapy, tissue damage around the implanted electrodes, or permanent damage to the pulse generator. A cardiologist should be consulted prior to using Injection Gold Probe in these patients.

PRECAUTIONS

- The Injection Gold Probe must be used in conjunction with a Type BF or CF generator.
- When a Bipolar Cable Adapter (sold separately) is used, ensure that the Injection Gold Probe 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.
- The device 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.

- Please review the operations and service manuals of the electrosurgical generator for proper set and operation prior to using the Injection Gold Probe.
- Because the electrosurgical effect is greatly influenced by the size and configuration of the active electrode, it is impossible to determine the exact effect achieved in a given control setting. It is very important that if the proper setting of the generator is not known, one should set the unit at a power setting lower than the recommended range and cautiously increase the power until the desired effect is achieved.

POTENTIAL ADVERSE EVENTS

Possible complications include, but may not be limited to:

- Aspiration pneumonia
- Bleeding
- Dysphagia
- Embolism
- Esophageal strictures
- Esophageal ulcers
- Hepatic failure
- Pain
- Perforation
- Pleural effusion; other respiratory difficulties
- Post-injection ulceration with delayed bleeding
- Septicemia/infection
- Tissue Damage

Possible electrosurgical adverse effects include:

- Burns
- Cardiac arrhythmia
- Fulguration
- Stimulation

ADDITIONAL WARNINGS / PRECAUTIONS

Warnings

- Any electrocautery device constitutes a potential electrical hazard to the patient and operator.
- The tip of the product will become hot during cauterization. It may remain hot for a period of time after. Avoid contact with tissue not intended to be cauterized to avoid patient/user injury.
- Turn the electrosurgical generator off during insertion of the Injection Gold Probe to prevent electrical or thermal injury.
- Ensure proper technique is used during injection to prevent occurrence of an embolism.
- If the needle fails to retract after trying various scope positions, straighten the scope to fully retract the needle. If this does not work, then pull the Injection Gold Probe just inside the distal tip of the endoscope, so that the needle tip is no longer visible. This will minimize patient injury. Remove the endoscope and the Injection Gold Probe as a unit from the patient. Keeping the endoscope as straight as possible, slowly and carefully remove the Injection Gold Probe from the endoscope.
- To ensure patient safety, inspect the bipolar electrosurgical generator for proper set-up and operation before using the Injection Gold Probe.
- Do not cauterize with the needle extended as this may cause thermal/electrical injury.
- Before removing the device from the endoscope, ensure that the bipolar generator is inactive to prevent electrical and thermal injury.

Precautions

- If saline bubbles are not observed, check the electrical connection to the generator.
- If there still is no power, please review the service and operations manual of the bipolar electrosurgical generator to ensure proper generator set-up and operation.
- If saline bubbles still are not observed, do not use the device and contact Boston Scientific Customer Service.

- Please review the service manual and operator's manual for proper set-up and operation of the mechanical irrigation system.
- Do not force the injection needle to extend from the probe tip.
- Once the needle is fully extended, do not apply additional force to the "injection" hub. Additional force will not advance the needle further but may damage the Injection Gold Probe.
- Do not use the Injection Gold Probe through a duodenoscope. The elevator angle will damage the device. Kinks in the catheter will hinder the irrigation and spiral electrode.
- Pull back on the "Injection" hub until the hub locks into position to ensure that the injection needle is completely retracted into the probe tip to avoid inadvertent scope damage.
- Advance the Injection Gold Probe through the endoscope using short, deliberate 2 cm to 3 cm movements to prevent inadvertent damage to the catheter.
- In difficult scope positions, needle extension may be limited. Straighten scope to fully extend needle, then reposition. If this does not work, remove the unit and use a new Injection Gold Probe to complete the procedure.
- Once the needle is fully extended, do not apply additional force to the "injection" hub. Additional force will not advance the needle further, but may damage the Injection Gold Probe and the endoscope. If needed, straighten scope position.
- Before removing the device from the endoscope ensure the "Injection" hub is pulled back until it locks so that the needle is completely retracted into the probe tip. The probe should be removed from the endoscope slowly using short, deliberate 2 cm to 3 cm movements to prevent inadvertent damage to the endoscope.