

# Gold Probe™, Gold Probe 350cm Bipolar Electrohemostasis Catheter

REFER TO THE DEVICE DIRECTIONS FOR USE FOR COMPLETE INSTRUCTIONS ON DEVICE USE. RX ONLY.  
CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

## Warning

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.

## Intended Use/Indications for Use

The Gold Probe Catheter and the Gold Probe 350cm Catheter are indicated for use in transendoscopic electrohemostasis of visible bleeding and non-bleeding sites in the gastrointestinal tract including the esophagus, stomach, duodenum, and colon. The indications include:

- Peptic Ulcers
- Angiomata
- Mallory-Weiss Tears
- Watermelon Stomach
- Arteriovenous Malformations (AVMs)
- Barrett's Esophagus
- Dieulafoy Lesions
- Angiodysplasia
- Bleeding Polyp Stalks
- Esophageal Tumors

## Contraindications

Contraindications known for these devices are those specific to bipolar electrohemostasis treatment. These contraindications include, but are not limited to non-focal bleeding sites, esophageal/gastric varices, diffuse lesions, and use of these devices with monopolar electrical generators.

# Gold Probe™, Gold Probe 350cm

## Bipolar Electrohemostasis Catheter

### 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 probe using direct endoscopic vision. Performing electrohemostasis in an improper location may lead to patient injury.
- Safe and effective hemostasis is dependent not only on equipment design but also, to a large extent, on factors under the control of the operator.
- No modification of this equipment is allowed.

### Warnings

- 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 350V (500V peak to peak).

### Precautions

**Precaution:** 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.

**Precaution:** 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.

### Precautions

- The device should only be used by or under the supervision of physicians trained in endoscopic gastrointestinal electrohemostasis. A thorough understanding of the technical principles, clinical applications and risks associated with bipolar hemostasis 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.

# Gold Probe™, Gold Probe 350cm

## Bipolar Electrohemostasis Catheter

### Adverse Events

- Possible complications include, but may not be limited to: perforation, bleeding, aspiration pneumonia, and septicemia/infection.
- Any electrohemostasis device constitutes a potential electrical hazard to the patient and operator. Possible adverse effects include: fulguration, burns, stimulation, and cardiac arrhythmia.