# Captivator™ EMR

## Endoscopic Mucosal Resection Device

*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:

The Captivator EMR Band Ligator and Captivator EMR Pathology Kit are supplied non-sterile. The Captivator EMR Snare is 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.

- It is suggested that the operator and the assistant wear protective gloves to prevent accidental burns. Universal precautions should be used in all cases. While operating the device, avoid contact with the patient.
- It is highly recommended that the user consult the current medical literature on recommended monopolar settings and techniques.
- No modification of this equipment is allowed.
- Fluids or flammable agents that may pool under the patient or in body depressions or cavities should be mopped prior to using the Captivator™EMR Device.
- This device is not intended to be used in the presence of flammable liquid, inan oxygen enriched atmosphere or in the presence of explosive gases.

### Intended Use / Indications for Use:

The Captivator EMR Device is indicated for endoscopic mucosal resection in the upper GI tract. This device is intended for single use only.

### Contraindications:

Contraindications include those specific to the primary endoscopic procedure that must be performed to gain access to the desired site for mucosal resection. Contraindications specific to esophageal banding include, but are not limited to: cricopharyngeal or esophageal narrowing or stricture, tortuous esophagus, esophageal varices, diverticula, known or suspected esophageal perforation, asymptomatic rings or webs, coagulopathy, and patients with bleeding disorders, unless the bleeding disorder is first identified and treated appropriately. Contraindications to upper GI electrosurgical resection include, but are not limited to: coagulopathy.

### Precautions:

The Captivator EMR Snare must be used in conjunction with a Type BF or CF generator; see Generator Compatibility section. The generator connector (Active Cord sold separately) is connected to the snare handle by a plug pushed onto the connector as far as possible so none of the connecting pin is visible. The opposite end of the active cord is inserted into the generator. Always follow the generator manufacturer's operation suggestions to prevent unnecessary hazard to the operator and/or the patient. Consult the neutral electrode manufacturer about proper grounding of the patient. It

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is recommended that a monitoring neutral electrode be used, if a contact quality monitor is available, or built into the generator. The entire area of the neutral electrode should be attached reliably to the patient's body, and as close to the operating field as possible. The patient should not come into contact with metal parts or objects that may be grounded to earth. The use of antistatic sheeting is recommended for this purpose.

Skin-to-skin contact should be avoided (for example between the patient's arms and body) by way of dry cloth or gauze. Monitoring electrodes should be placed as far from the surgical area as possible. Needle monitoring electrodes are not recommended. Avoid incidental contact between Active Cords and the patient's body, or any other electrodes. The output power setting selected should remain under 50 Watts, and be as low as possible for the intended purpose. Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the procedure. 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. It is highly recommended that the user consult the current medical literature on recommended monopolar settings.

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. Leakage current to patient from endoscope, as well as energized polypectomy snare, are additive. Consult the endoscope manufacturer about the proper grounding of the endoscope.

Monopolar diathermy or electrosurgical cautery in patients with pacemakers 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 Captivator EMR Snare in these patients.

## Adverse Events:

Potential adverse events associated with EMR include, but are not limited to: pain, tissue damage, infection, perforation, stricture formation, acute bleeding, delayed bleeding, and transmural burn.