

# Captivator™ EMR

## Endoscopic Mucosal Resection Device

**Rx ONLY**

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

### Reuse Warning

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.

### 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.

### Warnings

- Always follow the generator manufacturer's operation suggestions to prevent unnecessary hazard to the operator and/or the patient.
- When simultaneously using an electrosurgical unit and physiological monitoring equipment you should position any monitoring electrodes as far as possible from the surgical electrodes.
- 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 a possible thermal/ electrical injury.
- Consult the neutral electrode manufacturer about proper grounding of the patient. It 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 in order to avoid patient injury. The use of antistatic drapes is recommended in order to insulate the patient.
- The lines to the surgical electrodes should be fitted so that they do not touch the patient or other lines. Any active electrodes not currently in use should be put to one side so that they cannot touch the patient in order to avoid patient injury.

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- It is suggested that the operator and the assistant wear protective gloves to prevent accidental burns. Universal precautions should be used in all cases.
- Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the procedure in order to avoid thermal injuries to patients and/or users.
- 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.
- While operating the device, avoid contact with the patient in order to avoid user injuries such as electrical shock or burn.
- 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. This may lead to patient or user injuries such as burns.
- Gas embolism may occur as a result of over-insufflation of air during the procedure or during the presence of inert gas prior to high frequency surgery. 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.

## Precautions

- Consult the ESU manufacturer manual to ensure proper settings and recommendations by the manufacturer are followed.
- 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.
- The output power setting selected should remain under 50 Watts, and be as low as possible for the intended purpose.
- 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 recommended that the operator not use the device with any generator setting which may output a voltage exceeding the Maximum Accessory Voltage Rating. Maximum Accessory Voltage Rating: 3800 V peak (7600 V peak-to-peak). Active accessories should be selected that have an Accessory Voltage Rating equal to or greater than 3800 V peak. Consult the ESU manual for recommended monopolar settings.

## Adverse Events

Potential adverse events associated with EMR include, but are not limited to:

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|---------------|-----------------------|
| • Bleeding    | • Stricture Formation |
| • Infection   | • Tissue Damage       |
| • Pain        | • Transmural Burn     |
| • Perforation |                       |