Prescriptive Information

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

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

Cautions can be found in the product labeling supplied with each device.

Warning

Use same care as for any other surgical device to avoid punctures or cuts to hands, gloves, etc.

Please read the instructions for use in its entirety prior to use.

Intended Use

This device is intended for use in the ligation, electro-cautery, resection and removal of tissue within the digestive tract. Do not use this instrument for any purpose other than its intended use.

Contraindications

None known within the scope of the indicated use.

CAUTION

Before using this instrument, the operator must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in endoscopic technique.

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 cross contamination of the device and/or cause patient infection or cross infection, including, but not limited to: the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death.

When applied to a patient with a pacemaker implanted, the electrosurgical snare may cause malfunction or failure of the pacemaker, seriously affecting the patient. Before proceeding, always confirm that it is safe to do so with a cardiologist or the manufacturer of the pacemaker.

When using the instrument in the vicinity of the heart, be sure to use it with the minimum necessary output. Spark discharge during operation may affect the heart.

When using an electrocardiograph or other physiological monitoring equipment simultaneously with the instrument, any monitoring electrodes should be placed as far away as possible from the electrodes used with the electrosurgical unit. Needle monitoring electrodes should not be used, as they may cause patient burns. Physiological equipment incorporating high-frequency current limiting devices are recommended.

Ensure a proper path from the patient return electrode (grounding pad) to the electrosurgical unit is connected and maintained throughout the procedure.

Use only with banana type active cord plug. Recommended active cord: EndoChoice REF DAC-103

CAUTION

Do not use this instrument and active cord at an output above the rated high frequency voltage (see above).

Do not coil the catheter with a diameter of less than 15 cm.