



Brief Summary Document

Overview

Product Cold Snare – IFU AP30370A in LAR 97530273

Rx Statement

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.*

The device is intended for use under the direct supervision of a suitably trained physician only. A thorough understanding of the technical principles, clinical applications, and associated risks is expected before usage

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

The device is used without diathermic energy for the endoscopic resection of polyp tissue in the gastrointestinal tract.

CONTRAINDICATIONS

Include, but may not be limited to:

- Those with poor physical fitness, serious heart or/and lung diseases, and unable to tolerate endoscopy and endoscopic treatment.
- Patients with bleeding tendency, prolonged bleeding clotting time, or thrombocytopenia or prolonged prothrombin that cannot be corrected by treatment
- If the polyp/polyp base is too large, the base of the polyp >9mm

- Patients with advanced polypoid carcinoma infiltrating tissues or organs
- Patients with diabetes, regardless of euglycemia, should be classified as relative contraindications (poor healing capacity).
- The device is not intended for pediatrics populations.

WARNINGS

- Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. 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.
- Do not insert the device into the endoscope unless you have a clear endoscopic field of view. Insertion without a clear endoscopic field of view could cause patient injury, such as perforation, hemorrhage or mucous membrane damage. It may also damage the endoscope and/or device.
- Care should be exercised when snaring tissue to avoid inadvertently snaring tissue not intended for resection.
- Do not use this device for any purpose other than its intended use
- The device is only intended for adult populations
- The device contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.

CAUTION: This material not intended for use in France.

POTENTIAL ADVERSE EVENTS

Include, but may not be limited to:

- Arrhythmia
- Cardiac Arrest
- Hemorrhage
- Hypotension
- Infection
- Perforation
- Respiratory Depression or Apnea
- Septicemia