



Brief Summary Document

Overview

Product RescueNet™ Retrieval Device – IFU 52084303

Rx Statement

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

This device is intended for use in endoscopic retrieval of foreign objects, food bolus, tissue fragments and excised tissue such as polyps.

CONTRAINDICATIONS

Contraindications include those specific to the primary endoscopic procedure to be performed in gaining access to the desired site.

WARNINGS

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.

- Do not use this device for any purpose other than the stated intended use.
- Avoid blindly passing the device past any foreign object, particularly if the entire lumen is blocked to avoid patient injuries.
- Use care to avoid inadvertently grasping tissue or organs not intended for retrieval to avoid patient injuries such as bleeding, tissue damage, etc.
- Keep gentle traction on the device during retrieval so that the retrieved object does not become loosened, dislodged or aspirated into the trachea causing injuries such as obstruction, respiratory distress, and/or inflammation.
- Do not use this device for the removal of sharp objects as this can cause injuries such as perforation, bleeding, and/or tissue damage. Sharp objects may also damage the net and could cause the retrieved object to dislodge inside the patient.

PRECAUTIONS

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

- After extraction, if the retrieved material does not exit the net upon deployment, the material should be removed from the net by rinsing the net in a basin of water; do not “pick” retrieved material from the net with a finger or tool as this may damage the net.
- Remove the endoscope and net simultaneously. Do not attempt to pull the net and captured object through the working channel.

POTENTIAL ADVERSE EVENTS

Adverse Events

- Aspiration
- Bleeding
- Infection (including pneumonia)
- Inflammation/Edema
- Obstruction
- Pain
- Perforation
- Respiratory Distress/Insufficiency
- Tissue Damage