



Brief Summary Document

Overview

Product Rescue™ Single-Use Grasping Forceps – IFU AP30047B

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.

User Information

The intended user is a physician properly trained in endoscopic procedures.

Content

INTENDED USE/INDICATIONS FOR USE

Rescue Single-Use Grasping Forceps are intended to be used to grasp tissue and/or retrieve foreign bodies, excised tissue, and stents within the upper gastrointestinal (esophagus, stomach, small intestine) and lower gastrointestinal (colon, rectum) tract.

CONTRAINDICATIONS

None known within the scope of the indicated use.

WARNINGS

- Use same care as for any other surgical device to avoid punctures or cuts to hands, gloves, etc. Read this document in its entirety prior to use.
- For single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing, or re-sterilization 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.

- Inspect the package containing the forceps. If any damage is noticed, do not use the forceps as sterility may be compromised.
- DO NOT USE if any abnormalities are found or if the forceps are not operating properly.
- Do not force the forceps into an angulated scope as this could damage the endoscope.
- Do not use excessive force to close the jaws as this could damage the forceps.
- After use, this product may be a potential biohazard. Handle or dispose of it in accordance with accepted medical practices and applicable local, state and federal laws and regulations.

PRECAUTIONS

None known.

POTENTIAL ADVERSE EVENTS

None known.