



Overview

Product

AutoCap™ RX

Integrated Biopsy Cap and Guidewire Locking Device – IFU 51474204

Rx ONLY

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 licensed practitioner.

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 AutoCap RX Integrated Biopsy Cap and Guidewire Locking Device is intended to facilitate placement of the guidewire and lock it into place during ERCP procedures. The device also provides access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port throughout the ERCP procedure, and provides access for irrigation.

CONTRAINDICATIONS

None known.

WARNINGS

None known.

PRECAUTIONS

- Any use of this device, other than those indicated in these instructions, is not recommended.

ADVERSE EVENTS

None known.

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