

RX Locking Device and Biopsy Cap

Locking Device and Biopsy Cap for Use with RX Biliary System™

Prescriptive Information

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

Caution/Rx Only:

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

Warnings:

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

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.

Intended Use / Indications for Use:

These devices are accessories used with RX Biliary System. Read appropriate Directions for Use.

Contraindications:

None known.

Precautions:

- The RX Locking Device and Biopsy Cap should only be used by or under the supervision of physicians trained in Endoscopic Retrograde Cholangiopancreatography (ERCP) or Endoscopic Sphincterotomy (ES). A thorough understanding of the technical principles, clinical applications and risks associated with ERCP/ES is necessary before using this device.
- The RX Locking Device and Biopsy Cap is compatible with 0.035 in (0.90 mm) and 0.025 in (0.63 mm) guidewires.
- Any use of these devices, other than those indicated in these instructions, is not recommended.