

Hurricane™ RX

Biliary Dilation Catheter

Prescriptive Information

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 physician.

Warning

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

The Hurricane™ RX Biliary Balloon Dilatation Catheter is recommended for endoscopic dilatation of strictures of the biliary tree and the Sphincter of Oddi. The Hurricane RX Biliary Balloon Dilatation Catheter may be used for injection of contrast medium for fluoroscopic visualization of the bile ducts.

Contraindications

None known.

Precautions

A thorough understanding of the technical principles, clinical applications and risks associated with balloon dilatation of the biliary tract is necessary before using this product. Any use of this product for procedures other than those indicated in these instructions is not recommended.

Potential Adverse Events

The adverse events that may result from a balloon dilatation procedure include but may not be limited to:

- perforation
- hemorrhage
- pain and tenderness
- sepsis/infection
- allergic reaction to contrast medium