Advanix™ Biliary Stent with NaviFlex™ RX Delivery System

Prescriptive Information

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

Intended Use/Indications for Use

The Advanix™ Biliary Stent with NaviFlex™ RX Delivery System is intended for delivery of the stent to the biliary tract for drainage of the bile duct, for splinting of a bile duct during healing, or for providing bile duct patentcy in a stricture or past a stone.

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 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. Reuse, reprocessing or re-sterilization 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.

Potential Adverse Events

Potential complications associated with Endoscopic Retrograde Cholangiopancreatography (ERCP) may include but may not be limited to:

- Allergic reaction to contrast medium
- Bile duct occlusion or obstruction
- Cholangitis
- Pancreatitis
- Stent migration
- Perforation of bile ducts, liver and/or duodenum
- Hemobilia
- Bile peritonitis
- Hematoma
- Hemorrhage
- Septicema/infection

Cautions

When long-term use is necessary, the stent should be evaluated for replacement at three-month intervals. This stent is not intended for use as a permanent implant.

Check for proper position of the stent and delivery system using endoscopy and fluorscopy. Insertion and placement in an improper location may lead to patient injury.

If resistance is met during the procedure, do not advance the guidewire or the Advanix Biliary Stent with NaviFlex RX Delivery System without first determining the cause of resistance and taking remedial action.

The Advanix Biliary Stent with NaviFlex RX Delivery System should only be used by or under the supervision of physicians thoroughly trained in endoscopic biliary procedures. A thorough understanding of the technical principles, clinical applications, and risks associated with endoscopic biliary stent procedures is necessary before using this device.

Any use of procedures other than those indicated in these instructions is not recommended.

It is recommended that repositioning of the stent occurs prior to the change in color on the pull wire. Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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