Overview

Product	Advanix™ Biliary Stent with NaviFlex™ RX Delivery System – IFU 52145090-01A

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.

Content

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 patency in a stricture or past a stone.

CONTRAINDICATIONS

None known

WARNINGS

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.

GENERAL WARNINGS

- Check for proper position of the stent and delivery system using endoscopy and fluoroscopy. Insertion and placement in an improper location may lead to a 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. Failure to do so can result in a patient injury.
- Any use of procedures other than those indicated in these instructions is not recommended as this may result in a patient injury.

PRECAUTIONS

- 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.
- It is recommended that repositioning of the stent occurs prior to the change in color on the pull wire.
- Carefully examine the product to verify that neither the contents nor the sterile package has been damaged in shipment. DO NOT USE if damaged. Immediately return damaged product to Boston Scientific. Care should be taken to prevent any damage to the stent and/or delivery system prior to or during placement. If any damage occurs, such as kinking, do not use the stent or delivery system.
- Do not engage elevator while deploying stent.
- FOR PRELOADED SYSTEM ONLY: If the guidewire is not completely retracted into the endoscope, the stent cannot be fully deployed.

POTENTIAL ADVERSE EVENTS

Potential complications may include but may not be limited to:

- Allergic reaction to contrast medium
- Cholangitis
- Hematoma
- Hemobilia
- Hemorrhage
- Occlusion or obstruction
- Pancreatitis
- Perforation
- Peritonitis
- Septicemia/infection
- Stent migration
- Tissue Damage
- Inflammation
- Pain