Advanix™ Pancreatic Stent
NaviFlex™ RX Delivery System

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.

Warnings

Content 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 a patient.

Do not push the stent barb cover into the duodenoscope working channel.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Intended Use/Indications for Use

The Advanix Pancreatic Stent used with the NaviFlex™ RXDelivery System is intended for delivery of the stent to the pancreatic duct (PD):Used to drain pancreatic ducts.

Contraindications

Placement in pancreatic strictures caused by benign tumors, as the long term effect of the stent in the PD is unknown. Placement in strictures that cannot be adequately dilated to pass the delivery system. Patient with coagulopathy or other contraindications to EGD or ERCP. Any use other than those specifically outlined under indications for use.

Precautions

- 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 fluoroscopy. 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 Pancreatic Stent and NaviFlex RX Delivery System without first determining the cause of resistance and taking remedial action.
- The Advanix Pancreatic Stent and NaviFlex RX Delivery System should only be used by or under the supervision of physicians thoroughly trained in endoscopic retrograde cholangiopancreatography (ERCP) procedures. A thorough understanding of the technical principles, clinical applications, and risks associated with ERCP procedures is necessary before using this device.

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

- Any use of procedures other than those indicated in these instructions is not recommended.
- The stents may not be compatible with any other competitor devices.
- The Advanix™ Pancreatic Stent and NaviFlex™ RX Delivery System are supplied sterile. 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. Device Preparation
- 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 no use the stent or delivery system.
- Do not engage elevator while deploying stent.
- Refrain from grabbing the stent from the barbs or barb area of the stent.

Adverse Events

Potential complications associated with Endoscopic Retrograde Cholangiopancreatography (ERCP) may include:

- Allergic reaction to contrast medium
- PD occlusion or obstruction
- Cholangitis
- Pancreatitis
- Stent migration
- Hemorrhage
- Perforation
- Erosion

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