



Advanix™ Pancreatic Stent / NaviFlex™ RX Delivery System

Rx ONLY

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

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.

INTENDED USE/INDICATIONS FOR USE

The Advanix Pancreatic Stent used with the NaviFlex RX Delivery 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.

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 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. Failure to do so may result in patient injury.
- Any use of procedures other than those indicated in these instructions is not recommended as this may result in patient injury.

PRECAUTIONS

- The stent should be evaluated for replacement at threemonth intervals. This stent is not intended for use as a permanent implant.
- 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 package is opened or 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 push the stent barb cover into the duodenoscope as this may result in stent damage.
- Do not engage elevator while deploying stent as this may make the device difficult to use.
- Refrain from grabbing the stent from the barbs or barb area of the stent to avoid damage to the stent.

POTENTIAL ADVERSE EVENTS

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

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