Boston Scientific

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Advanix™

Biliary Stent with Naviflex™ RX Delivery System

℞ 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.

DEVICE DESCRIPTION

Contents

The Advanix Biliary Stent with NaviFlex RX Delivery System are packaged in two configurations.

(1) Advanix Biliary Stent with NaviFlex RX Delivery System

Or

(1) Advanix Biliary Stent

(1) NaviFlex RX Delivery System

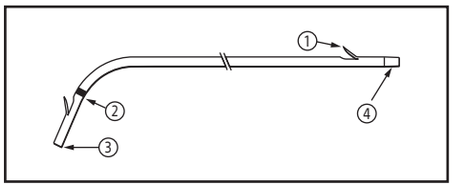
Operating Principle

Stent

The Advanix Biliary Stent with NaviFlex RX Delivery System is designed for biliary drainage.

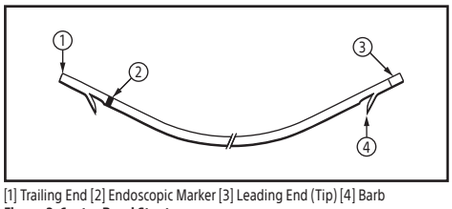
The stent is constructed of a radiopaque polymer; the leading end has a tapered tip and the trailing end of the stent has an endoscopically visible marker to aid placement.

The stent is available in three different shapes: duodenal bend, center bend, and double-pigtail. Diagrams of each shape and features are shown below.



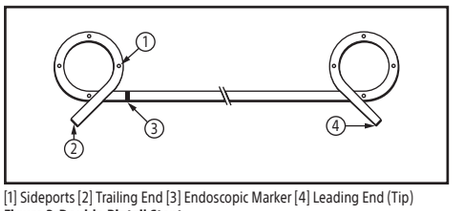
[1] Barb [2] Endoscopic Marker [3] Trailing End [4] Leading End (Tip)

Figure 1. Duodenal Bend Stent



[1] Trailing End [2] Endoscopic Marker [3] Leading End (Tip) [4] Barb

Figure 2. Center Bend Stent



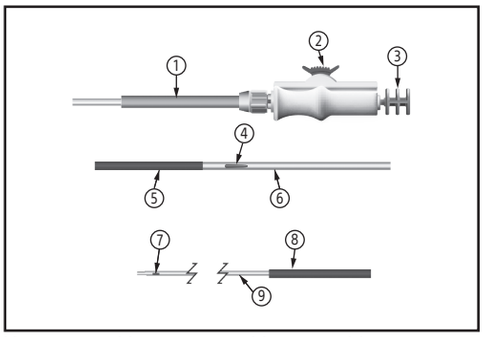
[1] Sideports [2] Trailing End [3] Endoscopic Marker [4] Leading End (Tip)

Figure 3. Double Pigtail Stent

If the stent is packaged separate from the delivery system, it must be loaded by the operator onto the delivery system.

Delivery Systems

The Advanix Biliary Stent with NaviFlex RX Delivery System is available either with a stent preloaded onto the delivery system or stent and delivery system packaged individually from each other. The preloaded system gives the operator the option of repositioning the stent if desired.



[1] Stent Barb Cover [2] Locking Mechanism [3] Pull Wire Cap [4] Guidewire Exit Port [5] Blue Push Catheter [6] White Push Catheter [7] Guide Catheter RO Marker [8] Push Catheter RO Marker [9] Guide Catheter

Figure 4. Delivery system

The delivery system consists of a guide catheter connected proximally to a stainless-steel pull wire, and an outer push catheter connected proximally to a locking mechanism. The locking mechanism is designed to keep the guide catheter in the position desired while being delivered to the deployment site. The stent can be deployed by disengaging the locking mechanism and retracting the guide catheter. A stent barb cover is provided to facilitate placement of the stent into the endoscope. With the Advanix Biliary Stent with NaviFlex RX Delivery System, the guidewire exits from a port denoted by a change in push catheter color from blue to white and then runs along the side of the device for its remaining length.

The radiopaque (RO) marker on the distal tip of the guide catheter can aid in fluoroscopic stent placement. Deployment can be confirmed as the RO marker located on the guide catheter aligns with the RO marker located on the outer push catheter.

The preloaded stent system offers an additional feature of being able to reposition the stent prior to deployment. This is achieved by a suture that holds the stent in place until the guidewire and guide catheter are fully retracted into the push catheter. It is recommended that repositioning of the stent occurs prior to the change in color on the pull wire.

The Advanix Biliary Stent with NaviFlex RX Delivery System is designed for use with endoscopes that have a minimum working channel as shown below:

Stent Size	Minimum Working Channel
7F (2.3 mm)	3.2 mm
8.5F (2.8 mm)	3.2 mm
10F (3.3 mm)	4.2 mm

Materials

7F and 8.5F Duodenal and Center Bend

Implantable Material	% Weight (0.22 g-0.68 g)
High Density Polyethylene	37.3
Linear Low Density Polyethylene	30.5
Bismuth Oxychloride	30.0
Colorant (Blue and White)	2.2

10F Duodenal and Center Bend

Implantable Material	% Weight (0.41 g-1.09 g)
Low Density Polyethylene	76
Bismuth Subcarbonate	22
Colorant (Blue and White)	2

7F and 10F Double Pigtail

Implantable Material	% Weight (0.39 g-1.41 g)
Thermoplastic Elastomer	70-80
Bismuth Oxychloride	18-23
Blue Colorant	2-5

Contains cobalt: CAS No. 7440-48-4; EC No. 231-158-0. Defined as a 1B carcinogen and reproductive toxicant according to the European Commission in a concentration above 0.1 % weight by weight.

Note: This device is made with stainless steel which contains cobalt. Current scientific evidence supports that stainless steels used in medical devices, do not cause an increased risk of cancer or adverse reproductive effects.

User Information

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.

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.

Clinical Benefit Statement

The clinical Benefit of Advanix Biliary Stent with NaviFlex RX delivery System is to facilitate the delivery of the stent to allow biliary tract for drainage of the bile ducts, for splinting of a bile duct to during healing, or for providing bile duct patency in a stricture or past a stone.

Summary of Safety and Clinical Performance

For customers in the European Union, use the device name found in the labeling to search for the device's Summary of Safety and Clinical Performance, which is available on the European database on medical devices (EUDAMED) website: (https://ec.europa.eu/tools/eudamed).

The Summary of Safety and Clinical Performance for the Advanix Biliary Stent can be found on the EUDAMED website using the following search term: Advanix Biliary.

CONTRAINDICATIONS

None known.

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.

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

HOW SUPPLIED

The Advanix Biliary Stent with NaviFlex RX Delivery System are packaged in two configurations, either with a stent preloaded onto the delivery system or with the stent and delivery system packaged individually. The packages are supplied sterile by ethylene oxide (EO) gas.

Device Details

Do not use if package is damaged or unintentionally opened before use.
Do not use if labeling is incomplete or illegible.

Handling and Storage

This product has no special handling or storage requirements. Check device label for expiration date.

OPERATIONAL INSTRUCTIONS

Preparation

Caution: 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.

1. Ensure that an RX Locking Device has been attached to the scope.
2. After a standard ERCP study, a 0.035 in (0.89 mm) by 260 cm guidewire should be introduced and advanced endoscopically and fluoroscopically into the common bile duct (CBD). A guidewire should be used in all situations, a Boston Scientific guidewire is recommended.
3. Choose a stent of the appropriate shape, length, and diameter. Ideally, the leading barb should lie above the stricture, stone, or injury while the trailing barb should exit into the duodenum. When placing a double pigtail stent, the trailing pigtail should exit into the duodenum.

Note: Stent length is determined by measuring between the two barbs or between the inner margins of the pigtail loops.

4. Fluoroscopy is recommended for more accurate stent placement.

Procedure

1. Confirm guidewire placement above the stricture, stone, or injury fluoroscopically. Lock guidewire into place using the RX Locking Device.
2. Remove the product(s) from the packaging. If delivery system is not preloaded with stent, load stent onto the guide catheter, trailing end first.
3. Pull back on the pull wire cap to adjust the length of the guide catheter in front of the stent and engage the NaviFlex RX Delivery System locking mechanism. Slide the stent barb cover so it is on the distal end of the blue push catheter near the stent.
4. With the guidewire positioned and locked in the RX Locking Device, backload the delivery system over the guidewire until the guidewire exits through the guidewire exit port. The guidewire exit port is denoted by a change in push catheter color from blue to white.
5. Grasp the guidewire and slide the delivery system over the guidewire until it reaches the RX Locking Device.
6. Unlock the guidewire from the RX Locking Device. Advance the delivery system using the standard exchange method and insert the tapered tip into the scope. Slide the stent barb cover over the trailing barb, to assist with stent introduction into the scope. Once the trailing barb has been introduced into the scope, slide the stent barb cover back and out of the way.
7. Once the guidewire exit port has entered the scope, relock the guidewire to the RX Locking Device and continue advancing the delivery system using 2 cm-3 cm short strokes until the stent exits the endoscope and enters the common bile duct (CBD). The guide catheter RO marker and stent can be visualized fluoroscopically.

8. Unlock the NaviFlex RX Delivery System locking mechanism. Advance the stent into the desired location in the duct using the push catheter. Simultaneously, maintain the guide catheter RO marker position in the desired ductal location by retracting the guide catheter. Continue advancing the delivery system until the endoscopic marker on the trailing end of the stent remains visible outside the papilla.

Note: FOR PRELOADED SYSTEM ONLY: If the stent is advanced too far up the CBD, relock the NaviFlex RX Delivery System locking mechanism and retract the entire delivery system to pull the stent back down to the appropriate position.

Caution: Do not engage elevator while deploying stent.

Note: FOR PRELOADED SYSTEM ONLY: The point where there is a color change on the pull wire indicates when the stent can still be repositioned. The stent is fully deployed when the guide catheter RO marker is adjacent to the push catheter RO marker fluoroscopically.

Deployment Options
Option A:
Prior to deployment, completely retract guidewire into endoscope.
Option B:
Prior to deployment, leave guidewire in place, once the guide catheter is fully retracted, retract the guidewire through the stent and out of the delivery system.

9. To initiate deployment, ensure the NaviFlex RX Delivery System locking mechanism is unlocked. Retract the guide catheter by pulling on the pull wire cap. The stent will be released when the guide catheter RO marker is aligned with the push catheter RO marker, and the guidewire is completely retracted into the endoscope. Endoscopically confirm the stent position.

Caution: FOR PRELOADED SYSTEM ONLY: If the guidewire is not completely retracted into the endoscope, the stent cannot be fully deployed.

Caution: 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.

Stent Removal
The Advanix Biliary Stent can be removed via standard stent removal techniques by a trained physician in endoscopic biliary procedures.

Disposal
To minimize the risk of infection or microbial hazards after use, dispose device and packaging as follows: After use, device may contain biohazardous substances. The device and packaging should be treated and disposed of as biohazardous waste or have them treated and disposed of in accordance with any applicable hospital, administrative, and/or local government regulations. Use of a biohazardous container with biological hazard symbol is recommended. Untreated biohazardous waste should not be disposed of in the municipal waste system.

Post-Procedure
Any serious incident that occurs in relation to this device should be reported to the manufacturer, and to the relevant local regulatory authority.

MRI SAFETY INFORMATION
The Advanix Biliary Stent is MR safe.

PATIENT COUNSELING INFORMATION
Provide the patient with the completed implant card to carry and explain that the Boston Scientific website has additional patient information with the summary of stent safety and clinical performance.
Inform the patient to present the implant card it to their Healthcare professionals (doctors, dentist, technicians) including at MRI scans so they can take the necessary precautions.
Inform the patient if any serious incident that occurs in relation to this device should be reported to the manufacturer, and to the relevant local regulatory authority.
Brief the patient on any relevant post-procedure instructions, contraindications, warnings, precautions and/or adverse events found within this Instructions for Use (IFU), pertaining to the patient.

Implantable Device Patient Information
Advise the patient that additional information may be available to them on the Boston Scientific website (www.bostonscientific.com/patientlabeling).

Implant Card Instructions
- Apply the peel-off label from the product onto the supplied patient implant card.
- Fill in the implantation date, patient name, name, and address of healthcare institution and/or physician information.
- Give the completed card to the patient.

WARRANTY
For device warranty information, visit www.bostonscientific.com/warranty.

SYMBOL DEFINITIONS
Commonly used medical device symbols that appear on the labeling are defined at www.bostonscientific.com/SymbolsGlossary.

Table 1. Symbol Definitions

	Contents
	Minimum Required Working Channel
	Recommended Guidewire

REF

M00532870	M00532880	M00532890	M00532900
M00532910	M00532920	M00532930	M00532940
M00532950	M00532960	M00532970	M00532980
M00532990	M00533000	M00533010	M00533020
M00533030	M00533040	M00533230	M00533240
M00533250	M00533260	M00533270	M00533280
M00533290	M00533300	M00533310	M00533320
M00533330	M00533340	M00533350	M00533360
M00533370	M00533380	M00533390	M00533400
M00533560	M00533570	M00533580	M00532160
M00532180	M00532190	M00532210	M00532220
M00532230	M00532240	M00532260	M00532270
M00532290	M00532300	M00532310	M00534200
M00534210	M00534220	M00534230	M00534240
M00534250	M00534260	M00534270	M00534280
M00534290	M00534300	M00534310	M00534320
M00534330	M00534340	M00534350	M00534360
M00534370	M00534560	M00534570	M00534580
M00534590	M00534600	M00534610	M00534620
M00534630	M00534640	M00534650	M00534660
M00534670	M00534680	M00534690	M00534700
M00534710	M00534720	M00534730	

AR REP

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link bostonscientific.com/arg

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