

Epic™ Biliary Endoscopic Stent System

REFER TO THE DEVICE DIRECTIONS FOR USE FOR COMPLETE INSTRUCTIONS ON DEVICE USE. RX ONLY.
CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Warning

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 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.

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

Device Description

The Epic Biliary Endoscopic Stent System is comprised of two components: the implantable stent and the stent delivery system. The stent is a laser cut self-expanding stent composed of a nickel titanium alloy (nitinol). On both the proximal and distal ends of the stent, radiopaque markers increase visibility of the stent to aid in placement. The stent is constrained within a 6 F (0.082 in, 2.1 mm maximum OD) delivery system. The delivery system is a coaxial design with an exterior shaft to protect and constrain the stent prior to deployment. The delivery system is compatible with 0.035 in (0.89 mm) guidewires.

When ready to be implanted, the stent is deployed by retracting the exterior shaft of the delivery system. A radiopaque marker at the distal end of the delivery system aids in visibility during deployment. As the stent is exposed to body temperature, it expands to appose the duct wall.

Intended Use

The Epic Biliary Endoscopic Stent System is intended to treat patients with biliary strictures created by malignant neoplasms and is to be delivered endoscopically.

Indications for Use

The Epic Biliary Endoscopic Stent System is indicated for palliation of malignant neoplasms in the biliary tree.

Contraindications

Contraindications for the use of the Epic Biliary Endoscopic Stent System include:

- Placement in biliary strictures caused by benign tumors, as the long-term effects of the stent in the bile duct is unknown
- Placement in strictures that cannot be dilated enough to pass the delivery system
- Placement in a perforated duct

- Those patients for whom endoscopic techniques are contraindicated
- Any use other than those specifically outlined under indications for use

Warnings

- The safety and effectiveness of this device for use in the vascular system have not been established.
- The stent is not designed for repositioning.
- Once the stent is partially deployed, it cannot be “recaptured” or “resheathed” using the stent delivery system.
- This device contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.
- Stenting across a major bile duct branch could lead to compromised future diagnostic or therapeutic procedures.
- Do not use if the temperature exposure indicator dot is red, indicating that stent expansion may have been compromised.
- Do not use if the temperature exposure indicator dot is missing.
- This device is not intended to be deployed through the wall of a previously placed metal stent. Doing so could result in difficulty or inability to deploy stent and/or remove delivery system.

Precautions

- Use prior to the ‘use by’ date on the package label.
- The device is intended for use by physicians who have received appropriate training.
- Do not use a kinked delivery system.
- Only advance the stent delivery system over a guidewire.
- The catheter should only be manipulated under fluoroscopy when in the body using radiographic equipment that provides high quality images.
- When treating multiple lesions, the most distal lesions should be stented first followed by the stenting of proximal lesions. Stenting in this order eliminates the need to cross and reduces the chance of dislodging stents that have already been placed.
- Prior to completion of the procedure, utilize fluoroscopy to ensure proper positioning of the stent.
- Premature removal of the safety lock may result in an unintended deployment of the stent.

Magnetic Resonance Imaging (MRI)

Non-clinical testing has demonstrated that the Epic™ Stent is MR Conditional. A patient with this device can be safely scanned under the following conditions:

- Static magnetic field of 1.5 tesla and 3.0 tesla only
- Maximum spatial gradient magnetic field of 2500 G/cm (25 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of < 2 W/kg (Normal Operating Mode).

Under the scan conditions defined above, the Epic Stent is expected to produce a maximum temperature rise in a patient of less than 6° C after 15 minutes of continuous scanning.

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In non-clinical testing, the worst case image artifact will be less than 5% for the stent length on each end (parallel to the main magnetic field) in a gradient echo sequence and less than 20% from the diametrical edge (perpendicular to the main magnetic field). The image artifact will obscure the device lumen.

Adverse Events

Procedures requiring endoscopic therapy should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure. Potential complications may include, but are not limited to:

- Abscess
- Cholecystitis
- Infection
- Perforation
- Stent Occlusion
- Biliary Obstruction
- Hemorrhage
- Pain
- Sepsis
- Tumor/Tissue Ingrowth
- Cholangitis
- Hyperplasia
- Pancreatitis
- Stent Migration/Dislodgement
- Tumor/Tissue Overgrowth

Select Proper Stent System

Labeled Diameter (mm)	Labeled Length (mm)	Undeployed Constrained Length (mm)	% Foreshortening
6	40	43	3
	60	63	3
	80	83	3
	100	103	3
8	40	42	4
	60	64	4
	80	85	4
	100	104	4
10	40	43	6
	60	64	5
	80	85	5
	100	104	5

Table 1. Stent Foreshortening

Fluoroscopy can be used to locate the stricture with the aid of a contrast medium.

Warranty

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**