Wallstent™ RX Biliary

RX BILIARY Endoprosthesis Partially Covered and Uncovered Stent 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.

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 patient 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.

Indications for Use

The WALLSTENT RX BILIARY Stent System, with or without PERMALUME™ Covering, is indicated for use in the treatment of biliary strictures produced by malignant neoplasms.

Contraindications

Contraindications associated with the use of the WALLSTENT RX BILIARY, with or without PERMALUME Covering, include:

- Use of the device in very small intrahepatic ducts.
- Stenting of a perforated duct, where leakage from the duct could be exacerbated by the prosthesis and leakage could occur across the uncovered mesh of the stent.
- All of the customary contraindications associated with the endoscopic manipulation of 8F (2.7 mm) caliber catheters within the biliary system.

Warnings

- Stenting across a major bifurcation may prevent or hinder future endoscopic access or other procedures.
- A stent cannot be repositioned or removed after the deployment threshold has been exceeded.
- Final stent placement resulting in an excessive length of stent protruding into the duodenum or misplacement of the entire stent into the duodenum may damage or obstruct the intestinal tract.
- The safety and effectiveness of this device for use in the vascular system have not been established.

Precautions

- The device is intended for use by physicians who have received appropriate training on endoscopic placement of the WALLSTENT RX BILIARY and the Rapid Exchange Procedure.
- The sterile packaging and device should be inspected prior to use. If sterility or performance of the device is suspect to be compromised, it should not be used.

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Adverse Events

Complications associated with the use of the WALLSTENT RX BILIARY, with or without PERMALUME™ Covering, may include the usual complications reported for conventional biliary stents and endoscopic procedures such as:

- Infection
- Sepsis
- Stent Misplacement
- Stent Migration
- Stent obstruction secondary to tumor ingrowth through the stent
- Tumor overgrowth at the stent ends
- Sludge occlusion
- Bile duct perforation or ulceration
- Bleeding
- Cholangitis
- Pancreatitis

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