WallFlex™ Biliary

RX Fully Covered Stent System

Boston Scientific
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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.

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.

Device Description

Content: One (1) WallFlex Biliary RX Partially Covered Stent System.

Operating Principle:

The WallFlex Biliary RX Fully Covered Stent System consists of a flexible delivery system preloaded with a self-expanding biliary metal stent. The stent is made from a metallic radiopaque material that is formed into a cylindrical mesh. The WallFlex Biliary RX Fully Covered Stent is offered fully covered with Permalume Coating, a translucent silicone polymer, to reduce the potential for tumor ingrowth through the stent (Figure 1). The WallFlex Biliary RX Fully Covered Stent has a retrieval loop for removal during the initial stent placement procedure, to be used in the event of incorrect placement. The stent has a flare at both ends to aid in preventing migration after the stent has been placed in the bile duct. The WallFlex Biliary RX Fully Covered Stent System is an RX compatible system only. The WallFlex Biliary RX Fully Covered Stent is provided sterile using ethylene oxide and is a single use device.

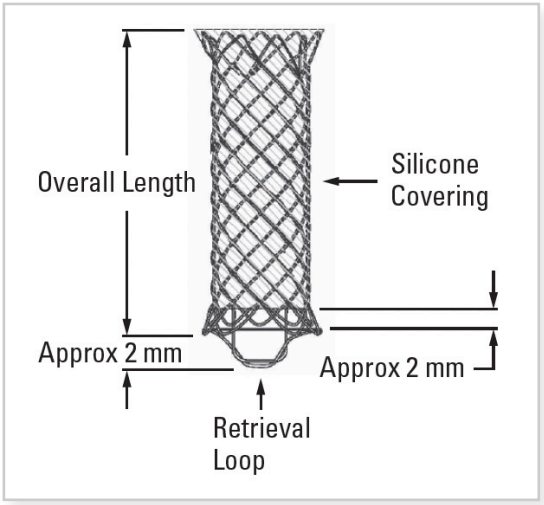

Figure 1. WallFlex Biliary RX Fully Covered Stent

The delivery system is a coaxial tube design. The exterior tube is used to constrain the stent before deployment and reconstrain the stent, if stent repositioning is necessary, after partial deployment. The exterior tube has a clear section so that the constrained stent is visible. A yellow transition zone on the inner tube of the delivery system is visible between the stent and the blue outer sheath. There are four radiopaque (RO) markers to aid in the deployment of the stent while using fluoroscopy (Figure 2). There are two RO markers on the inner tube of the delivery system identifying the ends of the constrained stent (Figure 2, marker 1 and 3). Between these RO markers is an additional RO marker that indicates at what point reconstrainment is no longer possible (Figure 2, marker 2). The fourth RO marker at the leading end of the exterior tube indicates how far the stent has been deployed (Figure 2, marker 4). There is one visual marker on the interior tube between the handles to aid in the deployment of the stent (Figure 2, marker 5). The visual marker indicates the point at which reconstrainment is no longer possible. The interior tube has a single central lumen to accommodate a 0.035 in (0.89 mm) guidewire.

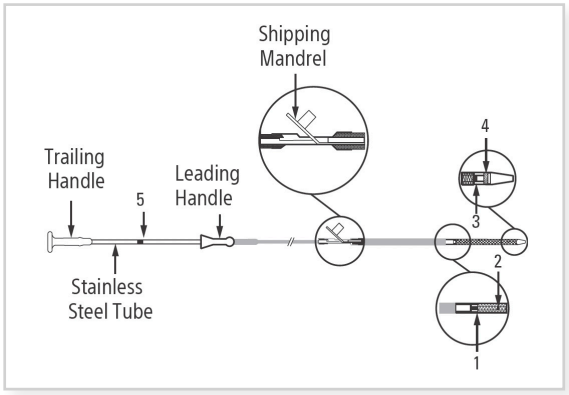

Figure 2. WallFlex Biliary RX Stent System

Intended Use/ Indications For Use

The WallFlex Biliary RX Fully Covered Stent System is indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms and relief of malignant biliary obstruction prior to surgery.

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Contraindications

The WallFlex Biliary RX Fullly Covered Stent System is contraindicated for:

- 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.
- Placement in very small intrahepatic ducts.
- Those patients for whom endoscopic techniques are contraindicated.
- Any use other than those specifically outlined under indications for use.

Warnings

The WallFlex Biliary RX Fully Covered Stent should not be moved or removed after completion of the initial stent placement procedure. Manipulating, repositioning or removal of the stent may result in perforation, bleeding, tissue damage or other patient injury.

NO WARRANTY IS MADE WITH REGARD TO REMOVABILITY OF THIS DEVICE BY ENDOSCOPIC MEANS OR OTHERWISE.

Careful consideration must be taken if removing a stent from an intrinsic malignant tumor. Removal may result in perforation, bleeding or tissue damage.

Visually inspect the system for any signs of damage. DO NOT USE if the system has any visible signs of damage. Failure to observe this warning may result in patient injury.

The safety and effectiveness of this device for use in the vascular system has not been established. Failure to observe this warning may result in patient injury.

Use caution when placing stent near ductal branches to avoid obstruction of duct. Placement of a fully covered biliary stent across a branch duct or major bifurcation may result in complications due to blockage of flow from the branch duct and prevent endoscopic or transhepatic access for future procedures.

The sterile packaging and device should be inspected prior to use. If sterility or performance of the device is suspected to be compromised, it should not be used.

Adverse Events

These include, but are not necessarily limited to:

- Allergic Reaction
- Bile duct ulceration
- Bleeding
- Cholangitis
- Cholecystitis*
- Death (other than that due to normal disease progression)
- Fever
- Infection
- Mucosal hyperplasia
- Nausea
- Pain
- Pancreatitis
- Perforation of duodenum or bile duct
- Perforation of the gallbladder due to the stent covering the cystic duct*
- Recurrent obstructive jaundice
- Stent migration
- Tumor ingrowth through the stent
- Tumor overgrowth around ends of stent
- Vomiting
- Stent misplacement
- Stent occlusion
- Tissue Damage
- Inflammation

***Note:** In a small clinical trial of this device, two out of four (50%) subjects who had a stent placed across the cystic duct developed cholecystitis. One of these subjects suffered a perforated gallbladder due to the stent covering the cystic duct, requiring a drain to be placed.

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How Supplied

The WallFlex Biliary Stent system is supplied sterile using an ethylene oxide (EO) process. See product label for expiration date. Do not use if labeling is incomplete or illegible. Do not use if package is damaged or unintentionally opened before use.

MRI Safety Information

MR **MRI Safety Information**

A person with the WallFlex Stent(s) may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	WallFlex Stent
Static Magnetic Field Strength (B0)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Cylindrical Whole-body Coil Cylindrical Head Coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration / Temperature Rise	Under scan conditions defined above, WallFlex Stent can be used for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	Image artifact caused by device may extend approximately 20 mm from the perimeter and 5 mm from the end of the stent with a spin and gradient echo pulse sequence

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