



Brief Summary Document

Overview

Product **WallFlex™ Biliary PLUS RX Fully Covered Stent System – IFU 52015820**

Audience: Health Care Professional (HCP):

Rx Statement ***CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.*

***USER INFORMATION:** Read the entire Instructions for Use thoroughly before using the Wall Flex Biliary PLUS RX Fully Covered Stent System. The WallFlex Biliary PLUS RX Fully Covered Stent System should only be used by or under the supervision of physicians thoroughly trained in biliary prosthesis placement. A thorough understanding of the technical principles, clinical applications, and risks associated with this procedure is necessary before using this device. This device is intended for use in adult patient populations.*

Content

INTENDED USE/INDICATIONS FOR USE

The WallFlex Biliary PLUS 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.

CONTRAINDICATIONS

The WallFlex Biliary PLUS RX Fully 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.

REUSE WARNING

For single use only. Do not reuse, reprocess or sterilize. Reuse, reprocessing or sterilization 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 sterilization 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.

WARNINGS

- This device contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.
- The WallFlex Biliary PLUS 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.

- 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.
- Excessive force should not be used to position or deploy the stent. This may cause inadvertent damage to the device, endoscope, and/ or patient injury.
- Do not push forward on the delivery system with the stent partially deployed. The stainless steel tube must be immobilized securely. Pushing on the delivery system may cause misalignment of the stent and possible duct damage. The stent should deploy easily. Do not deploy the stent if unusual force is required, since this may indicate a failed device.
- No warranty is made with regard to removability of this device by endoscopic means or otherwise. Careful consideration must be taken when removing a stent from an intrinsic malignant tumor. Removal may result in perforation, bleeding or tissue damage.

PRECAUTIONS


- Passing a second stent delivery system through a just deployed stent is not recommended and could cause the stent to dislodge.
- A stent cannot be reconstrained after the reconstraint limit has been exceeded.
- 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.
- Attempting to place the WallFlex Biliary PLUS RX Stent in patients with severe anatomical angulation may prevent the stent from deploying or cause damage to the device.
- Do not restrain around tortuous anatomy as it may cause damage to the device.
- Do not allow the unconstrained stent to re-enter the endoscope during the reconstraint process.
- A stent cannot be reconstrained after the reconstraint limit has been exceeded. Stent reconstraint can be completed twice, allowing a total of three deployment attempts.

POTENTIAL ADVERSE EVENTS

Potential adverse events include but are not limited to:

- Allergic Reaction
- Bile duct ulceration
- Bleeding
- Cholangitis
- Cholecystitis*
- Death (other than that due to normal disease progression)
- Fever
- Infection
- Inflammation
- 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
- Stent misplacement
- Stent occlusion
- Tissue Damage
- Tumor ingrowth through the stent
- Tumor overgrowth around ends of stent
- Vomiting
- *Note: In a small clinical trial of the WallFlex Biliary RX 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.

MRI SAFETY INFORMATION

 MRI Safety Information A person with the <i>WallFlex Biliary Stent</i> may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.	
Device Name	<i>WallFlex Biliary Stent</i>
Static Magnetic Field Strength (B_0)	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	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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