Brief Summary Document

Overview

Product WallFlex™ Biliary RX Uncovered Stent System – IFU 51505800

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 RX Uncovered Stent System. The WallFlex Biliary RX Uncovered 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 RX Uncovered 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 RX Uncovered 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 nitinol, an alloy of nickel and titanium. Persons with allergic reactions to these metals may suffer an allergic reaction to this implant. Prior to implantation, patients should be counseled on the materials contained in the device, as well as potential for allergy/hypersensitivity to these materials.

- The WallFlex Biliary RX Uncovered 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.
- 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.
- 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.
- 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.

PRECAUTIONS

- Passing a second stent delivery system through a just deployed stent is not recommended and could cause the stent to dislodge.
- Attempting to place the WallFlex Biliary RX Stent in patients with severe anatomical angulation may prevent the stent from deploying or cause damage to the device.
- Do not reconstrain around tortuous anatomy as it may cause damage to the device.
- Do not allow the unconstrained stent to re-enter the endoscope during the reconstrainment process.
- A stent cannot be reconstrained after the reconstrainment limit has been exceeded. Stent reconstrainment 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
- Recurrent obstructive jaundice
- Stent migration
- Stent misplacement
- Stent occlusion
- Tissue Damage
- Tumor ingrowth through the stent
- Tumor overgrowth around ends of stent
- Vomiting

MRI SAFETY INFORMATION

MRI Safety Information
A person with the *WallFlex Biliary Stent* may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	*WallFlex Biliary Stent*
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