

WallFlex™ Biliary RX

Uncovered Stent System

Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

Caution/Rx Only:

Federal Law (USA) restricts this device to sale by or on the order of a physician.

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 longterm 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. 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.

Warnings

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.

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

The safety and effectiveness of this device for use in the vascular system has not been established.

Passing a second stent delivery system through a just deployed stent is not recommended and could cause the stent to dislodge.

Use caution when placing stent near ductal branches to avoid obstruction of duct.

A stent cannot be reconstrained after the reconstraint limit has been exceeded.

The WallFlex Biliary RX Uncovered Stent should not be moved or removed during the procedure. Manipulating, repositioning or removal of the stent may result in perforation, bleeding, tissue abrasion or other patient injury.

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 abrasion or other patient injury.

WallFlex™ Biliary RX Uncovered Stent System

Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

Device description

The WallFlex™ Biliary RX Uncovered 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 stent has a flare at both ends to aid in preventing migration after the stent has been placed in the bile duct (Figure 1). The WallFlex Biliary RX Uncovered Stent System is an RX compatible system only. The WallFlex Biliary RX Uncovered Stent System is provided sterile using ethylene oxide and is a single use device.

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 reconstraint 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 reconstraint is no longer possible. The interior tube has a single central lumen to accommodate a 0.035 in (0.89 mm) guidewire.

Caution: Read the entire Directions for Use thoroughly before using the WallFlex 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.

MR Conditional

Through non-clinical testing, the uncovered WallFlex Biliary RX Stent has been shown to be MR Conditional (poses no known hazards under specified conditions). The conditions are as follows:

- Field strengths of 3 Tesla and 1.5 Tesla
- Static magnetic field gradient < 30 T/m

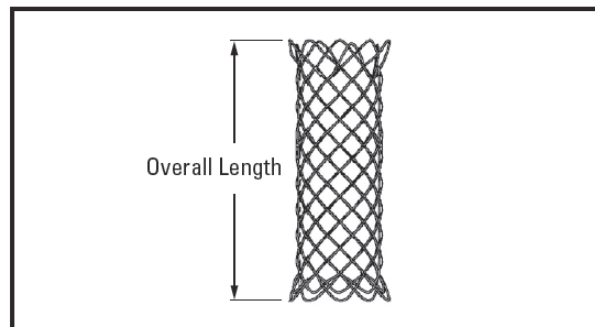


Figure 1. WallFlex Biliary RX Uncovered Stent

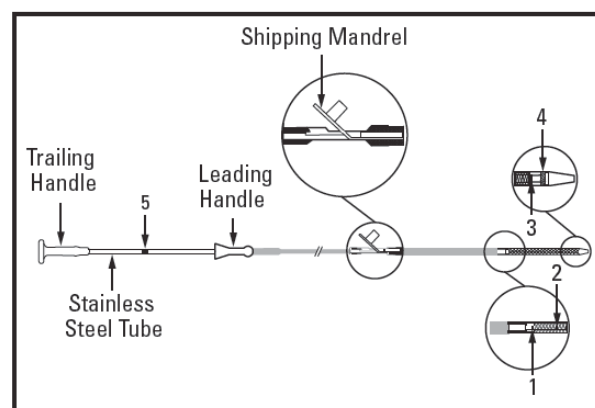


Figure 2. WallFlex Biliary RX Stent System

WallFlex™ Biliary RX

Uncovered Stent System

Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

- Product of static magnetic field and static magnetic field gradient < 90 T2/m
- A rate of change of magnetic field (dB/dt) approximately 60 T/s or less along the axis of the cylindrical bore. (This criteria is met for cylindrical bore MR systems with gradient slew rate of 200 T/m/s or less.)
- Normal operating mode of the MR system and use of transmit/receive head coil and/or whole body transmit coils

The uncovered WallFlex™ Biliary RX Stent should not migrate in this Magnetic Resonance Imaging (MRI) environment, as magnetic force and torque in the non-clinical tests was less than the values exerted by the earth's gravity. MR imaging within these conditions may be performed immediately following the implantation of the stent. This stent has not been evaluated to determine if it is MR Conditional beyond these conditions. No tests have been performed on possible nerve or other tissue stimulation possible to be activated by strong gradient magnetic fields and resulting induced voltages.

3.0 Tesla Temperature Information

Non-clinical testing of RF-induced heating was performed at 123 MHz in a 3.0 Tesla Magnetom Trio™, Siemens Medical Solutions MR system, software version Numaris/4, Syngo™ MR A30. The stents were in a location and orientation in the phantom that produced the worst case Radio Frequency (RF) heating. RF power was applied for 15 minutes with the conductivity of the phantom material 0.49 S/m. The phantom average SAR calculated using calorimetry was 4.2 W/kg. The maximum in-vitro temperature rise was 2.5 °C when the local SAR was scaled to 2 W/kg for a stent length of 100 mm. Other stent lengths exhibited a lower temperature rise.

In-vivo temperature rises were determined based on these non-clinical tests and computer simulation of the patient exposure to the electromagnetic fields in MRI. For landmarks at the chest the calculated temperature rise was 3.4 °C with an uncertainty upper bound temperature of 4.6 °C for a whole body average SAR value of 2.0 W/kg and a continuous scan time of 15 minutes. The actual in vivo rise is expected to be less than these values as the calculations did not include the cooling effects due to fluid flow in the lumen of the stent and blood perfusion in the tissue outside the stent.

1.5 Tesla Temperature Information

Non-clinical testing of RF-induced heating was performed at 64 MHz in a 1.5 Tesla Intera™ Philips Medical Systems, software version Release 12.6.1.3 2010-12-02 whole body coil MR scanner. The stents were in a location and orientation in the phantom that produced the worst case RF heating.

RF power was applied for 15 minutes with the conductivity of the phantom material about 0.49 S/m. The phantom average SAR calculated using calorimetry was 3.9 W/kg. The maximum in-vitro temperature rise was 3.0 °C when the local SAR was scaled to 2 W/kg for a stent length of 180 mm. Other stent lengths exhibited a lower temperature rise.

In-vivo temperature rises were determined based on these non-clinical tests and computer simulation of the patient exposure to the electromagnetic fields in MRI. For landmarks at the chest the calculated temperature rise was 2.1 °C with an uncertainty upper bound temperature of 2.8 °C for a whole body average SAR value of 2.0 W/kg and a continuous scan time of 15 minutes. The actual in vivo rise is expected to be less than these values as the calculations did not include the cooling effects due to fluid flow in the lumen of the stent and blood perfusion in the tissue outside the stent.

Image Artifact Information

The maximum image artifact extends approximately 10 mm from the perimeter of the device diameter and 2 mm beyond each end of the length of the stent when scanned in non-clinical testing using a Spin Echo sequence.

With a Gradient Echo sequence the image artifact extends 10 mm beyond the perimeter of the diameter and 2 mm beyond each end of the length with both sequences partially shielding the lumen in a 3.0 Tesla Siemens Magnetom Trio, Siemens Medical Solutions, software version Numaris/4 Syngo MR A30, COEM VD20F, Syngo VE31G, N4 VA30A_LATEST with a transmit/receive head coil.

WallFlex™ Biliary RX

Uncovered Stent System

Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

Contents

One (1) WallFlex Biliary RX Uncovered Stent System.

Potential Complications

The following complications have been reported in the literature for biliary prostheses.

These include, but are not limited to:

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

Cautions

Excessive force should not be used to position or deploy the stent. This may cause inadvertent damage to the device and/or endoscope.

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.

Pre-Procedure Notes

Radiography of pertinent anatomy performed no more than 10 days before the procedure should be available.

WallFlex™ Biliary RX

Uncovered Stent System

Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

Initial preparation of delivery system

- Carefully remove the delivery system from the protective packaging
- Visually inspect the device for damage or defects
- Visually check that the leading end of the stent is covered by the exterior tube
- Ensure that no stent wires have perforated the exterior tube

Note: DO NOT remove the shipping mandrel from the leading end of the device (Figure 2), this will help facilitate guidewire access.

RO markers are used to aid in positioning the stent across the stricture.

During deployment, these RO markers indicate when the reconstraint limit is reached and when the stent is fully deployed. The RO markers are fully described in the Device Description section of these directions.

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.