Wallflex™ Biliary RX Stents

Prescriptive Information

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

Intended Use/Indications for Use

The WallFlex Biliary RX Stents are indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms.

Contraindications

Contraindications may be found in the product labeling supplied with each device.

The WallFlex Biliary RX Stents are 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

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.

The safety and effectiveness of this device for use in the vascular system has not been established. Consult the Directions for Use for additional Warnings.

Potential Adverse Events

Potential complications may be found in the product labeling supplied with each device.

For the WallFlex Biliary RX Uncovered Stent, the following complications have been reported in the literature for biliary prostheses. For the WallFlex Biliary RX Partially Covered and Fully Covered Stents, the following complications have been reported in the literature for biliary prostheses or have been observed in the Boston Scientific clinical trial of this device.

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Injection Gold Probe™
Bipolar Electrohemostasis Catheter
Prescriptive Information

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Potential Adverse Events (Continued)

These include, but are not limited to:

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

Please be aware that potential adverse effects may arise even with the proper use of medical devices. Accordingly, this device should only be used by persons qualified in the procedures for which it is indicated.

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

Cautions

Cautions can be found in the product labeling supplied with each device. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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.

MR Conditional

Through non-clinical testing, the covered 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
- 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

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MR Conditional (Continued)

The covered 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.

For All WF (except WF LE):

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 2.6 °C when the local SAR was scaled to 2 W/kg for a stent length of 80 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 4.0 °C with an uncertainty upper bound temperature of 5.5 °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 2.8 °C when the local SAR was scaled to 2 W/kg for a stent length of 144 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 2.4 °C with an uncertainty upper bound temperature of 3.3 °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.

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MR Conditional (Continued)

For WF LE:

3.0 Tesla Temperature Information:

Non-clinical testing of RF-induced heating was performed at 128 MHz in a 3.0 Tesla GE Signa™ System (HDxt MR), software 15.0._M4_0910.a. The 120 mm covered stent was 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 phantom material approximately 0.5 S/m. The phantom average SAR calculated using calorimetry was 2.3 W/kg. The maximum in-vitro temperature rise was 2.2 °C when the local SAR was scaled to 2 W/kg for a stent length of 120 mm. 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 3.3 °C with an uncertainty upper bound temperature of 4.5 °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™ System Philips Medical Systems), software version Release 12.6.1.4 05-Nov-2012 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. The phantom average SAR calculated using calorimetry was 2.1 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 120 mm. 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 1.6 °C with an uncertainty upper bound temperature

of 2.2 °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 30 mm from the perimeter of the device diameter and 3 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 8 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 Philips Achieva™ System (3T MR) with software version 2.6.3.7 2010-11-24.