Boston Scientific

WallFlex™ Biliary Transhepatic

FULLY COVERED

Stent System RMV

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Boston Scientific (Master Brand DFUTemplate 3in x 9in Global, 90106040AK), DFU, MB, WallFlex Biliary Trans FC RMV, Global, 90964377-01A

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℞ ONLY

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

INTENDED USE/INDICATIONS FOR USE

The fully covered WallFlex Biliary Transhepatic Stent System RMV is indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms, and for treatment of benign biliary strictures.

CONTRAINDICATIONS

The fully covered WallFlex Biliary Transhepatic Stent System RMV is contraindicated for:

- Stenting of a perforated duct.
- All of the customary contraindications associated with the percutaneous transhepatic manipulation of introducer sheaths and delivery systems (e.g., bleeding disorders unresponsive to Vitamin K or blood product therapy).
- Placement in strictures that cannot be dilated enough to pass the delivery system.
- Placement in very small intrahepatic ducts.
- 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.
- 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. 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.
- Stenting across a major bifurcation may prevent or hinder future endoscopic access or other procedures.
- 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.
- The fully covered WallFlex Biliary Transhepatic 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 fully covered WallFlex Biliary Transhepatic stent should not be moved or removed after completion of the initial stent placement procedure in intrinsic malignant tumors. Manipulating, repositioning or removal of the stent may result in perforation, bleeding, tissue abrasion or other patient injury.

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- Final stent placement resulting in an excessive length of stent protruding into the duodenum or misplacement of the entire stent into the duodenum may damage or obstruct the intestinal tract.
- Careful consideration must be taken when removing a stent from an intrinsic malignant tumor. Removal may result in perforation, bleeding or tissue abrasion.
- Attempts to remove a partially deployed stent through the liver could cause significant bleeding.
- The safety and effectiveness of this device for use in the vascular system have not been established.

DEVICE DESCRIPTION

The fully covered WallFlex™ Biliary Transhepatic Stent System RMV is comprised of two components: the implantable metallic stent and the delivery system. The 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 A**). The fully covered WallFlex Biliary Transhepatic stent is offered fully covered with Permalume™ Coating, a translucent silicone polymer, to reduce the potential for tumor ingrowth through the stent. The WallFlex Biliary Transhepatic stent has a retrieval loop for endoscopic removal or repositioning during the initial placement procedure in patients that may have an ERCP performed and for endoscopic removal from benign strictures up to 12 months.

The delivery system consists in part of two coaxial tubes. The exterior tube serves to constrain the stent until retracted during delivery. Radiopaque marker bands situated on the interior and exterior tubes aid in imaging during deployment. The stent wires have a radiopaque core to improve radiopacity. The interior tube of the coaxial system contains a central lumen which will accommodate a 0.035 in (0.89 mm) guidewire.

The exterior tube is easily retracted by immobilizing the stainless tube in one hand, grasping the valve body with the other hand, and gently sliding the valve body along the stainless steel tube. Retraction of the exterior tube permits the open end of the exterior tube to release the stent from constrainment. A single operator can thus control deployment and implant the stent. The deployment process can be reversed if repositioning is desired. The stent can be reconstrained by the exterior tube if the stent deployment threshold has not been exceeded. The stent deployment threshold, the point beyond which the stent cannot be reconstrained, is identified by the location of the limit marker band (**Figure A**). Once reconstrained, the stent can be repositioned either distally or proximally and the deployment process restarted. Reversing the deployment process can be completed twice, allowing a total of three deployment attempts.

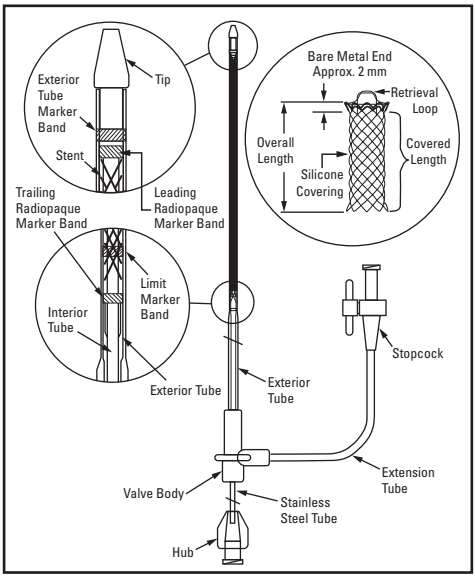

Figure A. Fully Covered WallFlex Biliary Transhepatic Stent System RMV

There are four radiopaque (RO) markers to aid in the deployment of the stent while using fluoroscopy (**Figure B**).

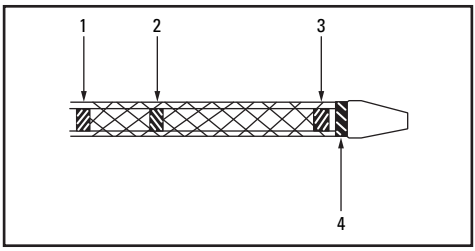

Figure B. WallFlex™ Biliary Transhepatic RO Markers

There are two RO markers on the inner tube of the delivery system identifying the ends of the constrained stent (**Figure B**, **marker 1** and **3**). Between these RO markers is an additional RO marker that indicates at what point reconstrainment is no longer possible (**Figure B**, **marker 2**). The fourth RO marker at the leading end of the exterior tube indicates how far the stent has been deployed (**Figure B**, **marker 4**).

MR Conditional

Through non-clinical testing, the covered WallFlex Biliary Transhepatic 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 T^2/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 covered WallFlex Biliary Transhepatic 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 2.6 °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.

Contents

One (1) fully covered WallFlex™ Biliary Transhepatic Stent System RMV.

PRECAUTIONS

- Read the entire Directions for Use thoroughly before using the fully covered WallFlex Biliary Transhepatic Stent System RMV.
- The fully covered WallFlex Biliary Transhepatic Stent System RMV 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.
- 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.
- The device is intended for single use only. Do not attempt to reload deployed stents onto the delivery system.
- Excessive force should not be used to position or deploy the stent. This may cause inadvertent damage to the device and injury to the patient.

ADVERSE EVENTS

Potential Complications associated with the use of the fully covered WallFlex Biliary Transhepatic Stent System RMV may include the usual complications reported for conventional metal stent placement and transhepatic procedures such as:

- Stent occlusion due to tumor overgrowth, tumor ingrowth, granulation tissue or sludge formation
- Perihepatic bile leak or hematoma
- Re-intervention due to occlusion
- Hemobilia
- Sepsis
- Pain
- Hemorrhage
- Fever
- Nausea
- Vomiting
- Infection
- Inflammation
- Recurrent obstructive jaundice
- Mucosal hyperplasia
- Cholangitis
- Cholecystitis
- Pancreatitis
- Ulceration of duodenum or bile duct
- Perforation of duodenum or bile duct
- Stent migration or dislodgement
- Death (other than that due to normal disease progression)
- Stent misplacement
- Perforation of the gallbladder due to the stent covering the cystic duct
- Stent Fracture
- Hepatic abscess

Potential Complications associated with Endoscopic Stent Removal

These include but are not limited to:

- Pain
- Hemorrhage

- Fever
- Nausea
- Vomiting
- Infection
- Inflammation
- Recurrent obstructive jaundice
- Mucosal hyperplasia
- Cholangitis
- Cholecystitis
- Pancreatitis
- Ulceration of duodenum or bile duct
- Perforation of duodenum or bile duct
- Death (other than that due to normal disease progression)
- Impaction to the common bile duct wall

HOW SUPPLIED

The device is supplied sterile. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in a cool, dry, dark place.

OPERATIONAL INSTRUCTIONS

Pre-Procedure Notes

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

Required Equipment

- 10 cm^3 (10 cc) syringe filled with sterile saline
- Non-hemostatic 9F (3.0 mm) introducer sheath, approximately 10-12 cm long
- 0.035 in (0.89 mm) guidewire of appropriate length
- Fully Covered WallFlex™ Biliary Transhepatic Stent System RMV containing a stent of the appropriate length and diameter
- Fluoroscopic capability for pre-stent placement and stent placement confirmation

Choosing the Appropriate Stent

Fluoroscopy can be used to locate the stricture with the aid of a contrast medium. Measure the stricture using fluoroscopy. Determine the stent length necessary to adequately cover the lesion. The stent length should allow for further lesion development.

Also, allow for shortening of the stent due to continued stent expansion post-implant. Deployed lengths reflect expansion to nominal stent diameter: constricting the stent to a smaller diameter will cause a longer deployment length, depending upon the degree of constriction. Table 1 below provides the approximate % foreshortening from the implanted lumen diameter to the nominal stent diameter.

Labeled Diameter (mm)	Lumen Diameter (mm)	% Foreshortening
8	7	19
	6	28
10	9	18
	8	26

Table 1. Approximate Implanted Stent Foreshortening

In the event a single stent will not adequately cover the stricture, a second stent of the same diameter should be implanted providing adequate overlapping (minimum 10 mm) of the initially placed stent to ensure a smooth transition between the stents. The second stent should be placed to ensure complete tumor coverage. It is recommended that the distal stent be placed first followed by the proximal stent.

WARNING

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

Initial Preparation of Delivery System

- Carefully remove the delivery system from its protective packaging.
- Visually inspect the entire 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: RO markers are used to aid in positioning the stent across the stricture. During deployment, these RO markers indicate when the reconstrainment limit is reached and when the stent is fully deployed. The RO markers are fully described in the Device Description section of these directions.

Flushing the Delivery System

- Attach a 10 cm^3 (10 cc) syringe filled with sterile saline to stopcock on extension tube.
- After flushing the delivery system, close the stopcock and remove the syringe.
- Reverify that the leading end of the stent is covered by the exterior tube. Do not use the device if the open end of the exterior tube has moved exposing stent wires. Proper device function cannot be assured during implant, and such use may cause lumen injury.

TRANSHEPATIC PROCEDURE

Guidewire Placement

1. Place a 0.035 in (0.89 mm) exchange guidewire transhepatically into the duodenum and remove the drainage catheter. Dilate the liver tract if indicated.
2. Dilate the biliary stricture with a balloon catheter measuring 10-20% less than the nominal stent diameter, using accepted technique and protocol.
3. Remove the balloon catheter, leaving the guidewire in place.
4. Having prepared the delivery system as previously described, insert it into the introducer sheath and over the guidewire.

Caution: Attempting to place the WallFlex™ Biliary Transhepatic Stent System RMV in patients with severe anatomical angulation may prevent the stent from deploying or cause damage to the device.

Stent Positioning

1. Use the radiopaque marker bands to position the stent across the stricture.

   Note: Always use an introducer sheath for the implant procedure, to protect both the liver tract and the puncture site, in the event a partially deployed stent were to be removed.
2. Guidelines for stent positioning:
   A. Advance the stent across the site of the lesion, positioning the leading marker band a minimum of two (2) centimeters beyond the distal boundary of the dilated segment.
   B. The marker bands identify the constrained length of the stent. Since the stent shortens upon deployment, these markers should only be used as approximate markers of the final stent position. To assure precise stent placement, radioscopic visualization of the stent itself is necessary.

WARNING

Final stent placement resulting in an excessive length of stent protruding into the duodenum or misplacement of the entire stent into the duodenum may damage or obstruct the intestinal tract.

   C. Maintain the delivery system as straight as possible during deployment of the stent.

Stent Deployment

Monitor the stent position fluoroscopically during the deployment process. There are RO markers to aid in the deployment of the stent while using fluoroscopy (**Figure C**).

To begin stent deployment, immobilize the stainless steel tube in one hand, grasp the valve body with the other hand, and gently slide the valve body back along the stainless steel tube until the reconstrainment limit is reached. Fluoroscopically, this point is reached when marker 4 meets marker 2 (**Figure C3**).

WARNING

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.

Caution: *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. To remove the device, see Delivery System Removal section.

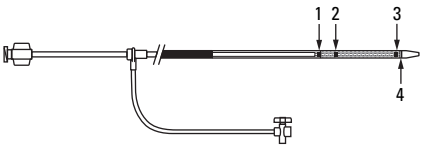

Figure (C1). Markers 1 and 3 identify the ends of the constrained stent.

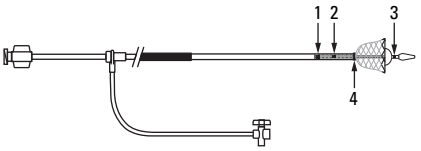

Figure (C2). Marker 4 indicates to what extent the stent has been deployed.

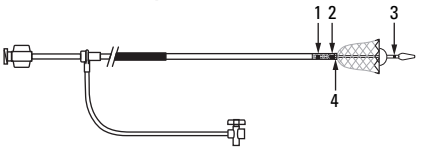

Figure (C3). Marker 4 meets marker 2 when the reconstrainment limit has been reached.

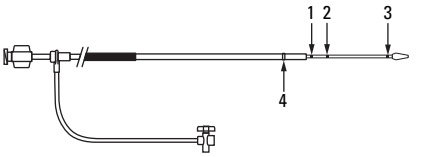

Figure (C4). Marker 4 moves distally past marker 1 when the stent is fully deployed.

Figure C. WallFlex™ Biliary Transhepatic Stent System Deployment

Stent Positioning Assessment/Repositioning

1. Assess stent position and reposition if desired. When the reconstrainment limit is reached, check the position of the stent fluoroscopically.

   If the position of the RO markers and stent are correct, then complete deployment (**Figure C4**). If the position is not correct, reposition the stent system. To reposition, first reconstrain the stent by holding the stainless steel tube stationary and gently sliding the valve body forward along the stainless steel tube. It may be necessary to guide the delivery system into the introducer sheath. Under fluoroscopy, the exterior tube marker band will be seen to move over the stent until even with the leading marker band (**Figure C1**).

   When fully constrained, the delivery system can be moved either proximally or distally and the deployment process restarted. Repositioning can be completed twice, allowing a total of three deployment attempts.

   As an alternative method for proximal repositioning only, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.

WARNINGS

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.

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

Cautions

Do not reconstrain around tortuous anatomy as it may cause damage to the device.

A stent cannot be repositioned after the deployment threshold has been exceeded.

2. To complete stent deployment immobilize the stainless steel tube with one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube.

WARNINGS

The fully covered WallFlex™ Biliary Transhepatic 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 fully covered WallFlex Biliary Transhepatic stent should not be moved or removed after completion of the initial stent placement procedure in intrinsic malignant tumors. Manipulating, repositioning or removal of the stent may result in perforation, bleeding, tissue abrasion or other patient injury.

Removing a Partially Deployed Stent

To remove a partially deployed stent, first reconstrain the stent (see Stent Positioning Assessment/Repositioning section). The entire delivery system can be pulled into the introducer sheath. The delivery system and introducer sheath can then be removed, with the guidewire left in place.

As an alternative method for stent removal, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.

WARNING

Attempts to remove a partially deployed stent through the liver could cause significant bleeding.

Delivery System Removal

After the stent is correctly positioned and fully deployed, and while monitoring under fluoroscopic guidance the delivery system may be closed and removed.

Note: If during delivery system withdrawal, the delivery system is not free of the stent and/or the stent begins to move proximally in the bile duct, immediately stop retraction of the delivery system. Advance the inner sheath of the delivery system forward by advancing the hub of the delivery system while holding the valve body (outer sheath) stationary. Carefully advance the inner sheath forward approximately 1 cm and commence retraction of the delivery system again. Repeat until the inner sheath can be retracted without interfering with the position of the deployed stent.

Post Procedure Monitoring

1. Using standard operative procedures, perform routine cholangiography to demonstrate location and patency of the stent.
2. The implanted stent length should allow for adequate overlapping into the non-strictured duct to compensate for further tumor progression and stent shortening. In the event the stent does not adequately cover the stricture, a second stent should be implanted providing adequate overlapping of the initially placed stent.
3. When passing balloon catheters or additional (undeployed) stents within the lumen of an implanted stent, always use an introducer sheath to protect the balloon or delivery catheter.

ENDOSCOPIC PROCEDURE

Endoscopic Removal of Stent from Benign Strictures up to 12 months post-deployment

Using a rat-tooth forceps, grasp the retrieval loop on the end of the stent (**Figure A**). Gently pull the stent back with the scope to remove.

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.**