



# WallFlex™

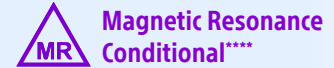
## Biliary RX Stents

Fully, Partially and Uncovered  
Self-Expanding Metal Stents





The WallFlex Biliary RX Stent technology is built on science and innovation to expand options for the treatment of biliary strictures.



## Pioneering Designs

### Stent

#### Removability

Fully and partially covered stents have an integrated retrieval loop, and may be removed during the initial placement procedure.\*\*

#### Migration Resistance

Looped and flared stent ends designed to help reduce the risk of tissue trauma and stent migration.

#### Tissue In-Growth Prevention

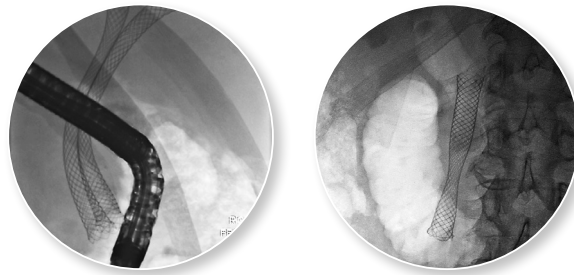
Closed cell construction and Permalume™ covered options designed to help resist tissue in-growth.<sup>1,2</sup>

#### Flexibility

Platinol™ Wire construction provides flexibility to aid placement in tortuous anatomies.\*

#### Radial Force

Radial force helps maintain stent patency and resist migration.



### Delivery System

#### Stent Placement Accuracy

The RX biliary delivery system allows for the stent to be reconstrained up to 80% when deployment has occurred to aid in repositioning\*\*\* and is designed to help facilitate physician control and locking of the guidewire.

#### Endoscopic Placement

Closed cell construction and Permalume covered options designed to help resist tissue in-growth.<sup>1,2</sup>

#### Fluoroscopic Visualization

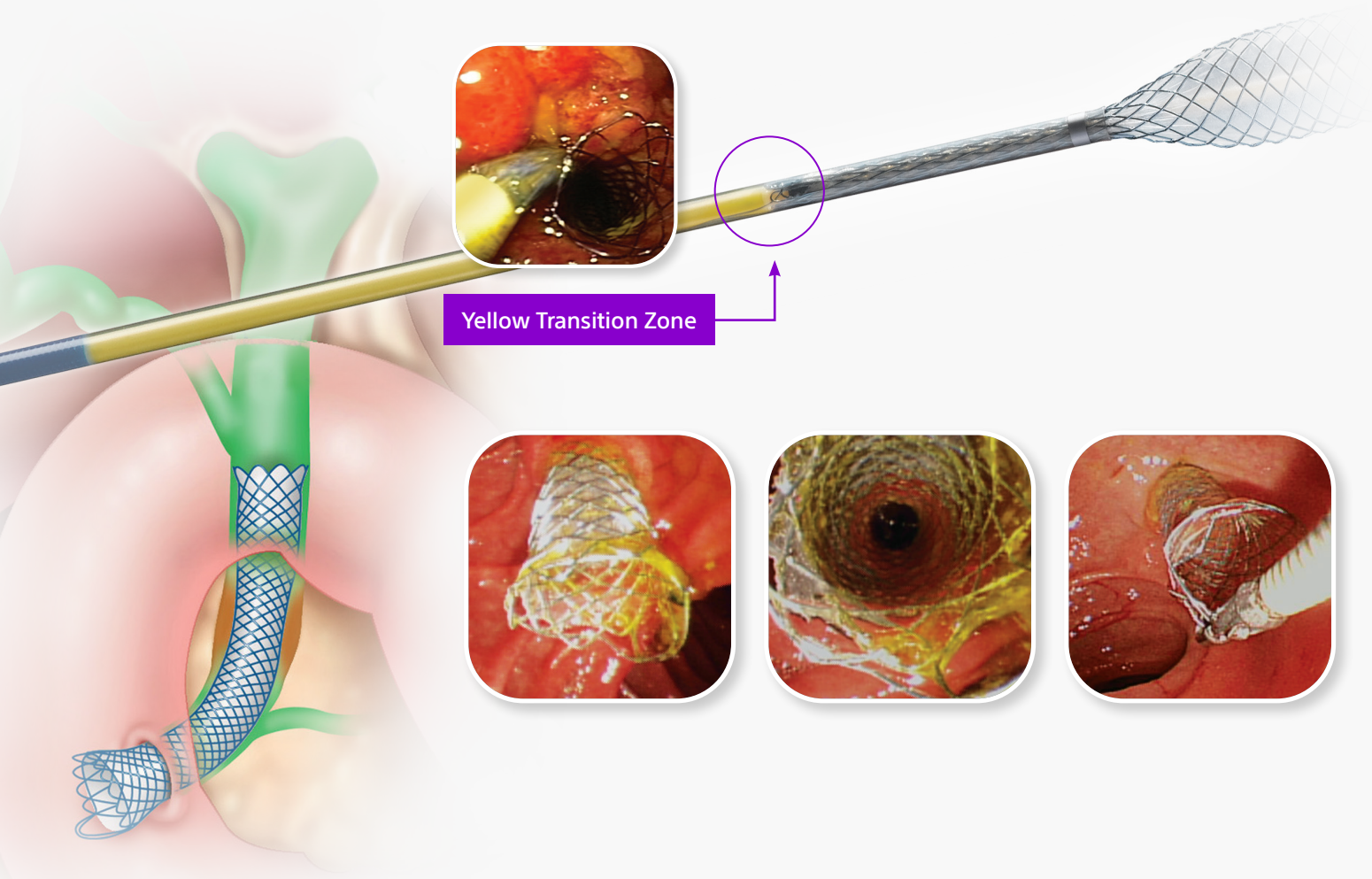
The four fluoroscopy markers and yellow transition zone are designed to aid in stent placement accuracy when deployed using endoscopic visualization.

\* Flexibility varies by size of stent

\*\* In the event of incorrect positioning during the initial stent placement procedure, the partially covered and fully covered stent options may be removed using forceps to grasp the retrieval loop on the end of the stent. Warning: No warranty is made with regard to removability of this device by endoscopic means or otherwise in partially covered or uncovered stents. Indications, contraindications, warnings and instructions for use can be found in the product labeling. The WallFlex Biliary RX Fully Covered Stent System RMV is removable following 12 months of indwell in benign biliary strictures secondary to chronic pancreatitis.

\*\*\* A stent cannot be reconstrained after the reconstraintment line has been exceeded

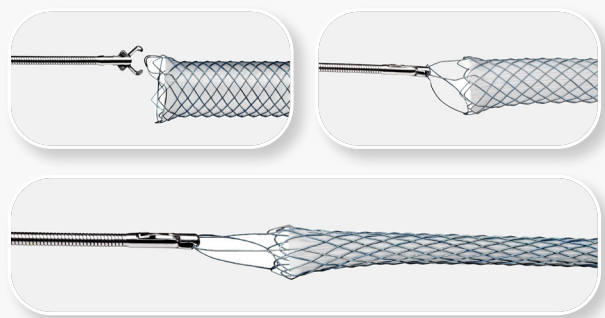
\*\*\*\* Non-clinical testing has demonstrated that the WallFlex Biliary Stent System with Anchor Lock Delivery System is MR Conditional. It can be scanned safely under the conditions outlined in the Directions For Use.



Yellow Transition Zone

## The Integrated Retrieval Loop

When tension is applied to the retrieval loop using forceps, it causes the entire length and diameter of the stent to narrow to help facilitate removal of the stent.\*\*



## Designed for Removability 12 Months Post-Placement

- The WallFlex Biliary RX Fully Covered Stent System RMV is the first and currently the only biliary metal stent approved in the U.S.† to treat benign biliary strictures secondary to chronic pancreatitis, with indwell up to 12 months.
- This indication for use\*\*\*\*\* of the fully covered stents in the treatment of benign biliary strictures secondary to chronic pancreatitis may eliminate the need for repeat procedures and may reduce the number of ERCPs per patient than treatment using multiple plastic stents.

†. As of June, 2024

\*\*\*\*\* INDICATIONS FOR USE in the United States: The WallFlex Biliary RX Fully Covered Stent System RMV is indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms, relief of malignant biliary obstruction prior to surgery and for indwell up to 12 months in the treatment of benign biliary strictures secondary to chronic pancreatitis.

Contraindications:  
· The WallFlex Biliary RX Fully Covered Stent should not be placed in strictures that cannot be dilated enough to pass the delivery system, in a perforated duct, or in very small intrahepatic ducts.  
· The WallFlex Biliary RX Fully Covered Stent System RMV should not be used in patients for whom endoscopic techniques are contraindicated.



# WallFlex™ Biliary RX Stent

Fully, Partially and Uncovered Self-Expanding Metal Stents

Fully covered, partially covered and uncovered WallFlex Biliary RX Stents are available in multiple sizes to accommodate different anatomical and clinical requirements. These stents may be used with short or long guidewires.

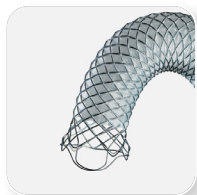
## Ordering Information

### Fully Covered Stent System RMV with Permalume™ Covering



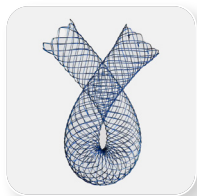
Order Number	Diameter (mm)	Length (mm)	Covered Length (mm) (PC Only)	Catheter Diameter (Fr/mm)	Guidewire Diameter (in/mm)
<b>M00570340</b>	8	60	-	8.5 (2.83)	.035" (.89)
<b>M00570350</b>	8	80	-	8.5 (2.83)	.035" (.89)
<b>M00547460*</b>	8	100	-	9.0 (3.0)	.035" (.89)
<b>M00570360</b>	10	40	-	8.5 (2.83)	.035" (.89)
<b>M00570370</b>	10	60	-	8.5 (2.83)	.035" (.89)
<b>M00570380</b>	10	80	-	8.5 (2.83)	.035" (.89)
<b>M00547480*</b>	10	100	-	9.0 (3.0)	.035" (.89)

### Partially Covered Stents with Permalume Covering



<b>M00570700</b>	8	60	48	8.5 (2.83)	.035" (.89)
<b>M00570710</b>	8	80	68	8.5 (2.83)	.035" (.89)
<b>M00547420</b>	8	100	88	9.0 (3.0)	.035" (.89)
<b>M00570720</b>	10	40	28	8.5 (2.83)	.035" (.89)
<b>M00570730</b>	10	60	48	8.5 (2.83)	.035" (.89)
<b>M00570740</b>	10	80	68	8.5 (2.83)	.035" (.89)
<b>M00547440</b>	10	100	88	9.0 (3.0)	.035" (.89)

### Uncovered Stents



<b>M00570600</b>	8	40	-	8.0 (2.67)	.035" (.89)
<b>M00570610</b>	8	60	-	8.0 (2.67)	.035" (.89)
<b>M00570620</b>	8	80	-	8.0 (2.67)	.035" (.89)
<b>M00570630</b>	8	100	-	8.0 (2.67)	.035" (.89)
<b>M00570890</b>	10	40	-	8.0 (2.67)	.035" (.89)
<b>M00570640</b>	10	60	-	8.0 (2.67)	.035" (.89)
<b>M00570650</b>	10	80	-	8.0 (2.67)	.035" (.89)
<b>M00570660</b>	10	100	-	8.0 (2.67)	.035" (.89)

### Recommended Guidewires

Hydra Jagwire® Guidewire Stiff Shaft .035" (.89mm)-260cm

M00556021: Straight Dream Tip™

Hydra Jagwire Guidewire Stiff Shaft .035" (.89mm)-450cm

M00556061: Straight Dream Tip

M00556071: Angled Dream Tip

\*Indicated for the palliative treatment of biliary strictures produced by malignant neoplasms and relief of malignant biliary obstruction prior to surgery.

#### References:

1. Moss A.; Morris E.; MacMathuna P.; Palliative biliary stents for obstructing pancreatic carcinoma. Cochrane Database Systematic Review, 25 Jan. 2006.
2. Soderlund K., Linder S.; Covered metal versus plastic stents for malignant common bile duct stenosis: a prospective, randomized, controlled trial. Gastrointestinal Endoscopy, 2006; 63: 986-995.

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CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician. Limitations: The sale, distribution, and use of the device are restricted to prescription use in accordance with 21 CFR §801.109. Warnings: The safety and effectiveness of the stent has not been established for indwell periods exceeding 12 months when used in the treatment of benign biliary strictures secondary to chronic pancreatitis. The WallFlex Biliary RX Fully Covered Stent System RMV is for single-use only. The safety and effectiveness of the WallFlex Biliary RX Fully Covered Stent System RMV for use in the vascular system has not been established. The safety and effectiveness of the WallFlex Biliary RX Fully Covered Stent System RMV has not been established in the treatment of benign biliary anastomotic strictures in liver transplant patients and benign biliary post abdominal surgery strictures. Testing of overlapped stents has not been conducted. The stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity. PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS