

# WallFlex™ Biliary RX Stent

Boston  
Scientific

Fully, Partially and Uncovered  
Self-Expanding Metal Stents



# WallFlex™ Biliary RX Stent

Fully, Partially and Uncovered Self-Expanding Metal Stents

The WallFlex Biliary RX Stent is a technology built on science and innovation to expand options for the palliative treatment of biliary strictures produced by malignant neoplasms.

Place your  
trust in  
**Experience**  
**Pioneering designs**  
**Clinical evidence**

## Pioneering Designs

### stent

#### Migration Resistance

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

#### Tissue In-Growth Prevention

Closed cell construction and Permalume™ covered options designed to resist tissue in-growth.<sup>4,6</sup>

#### Flexibility

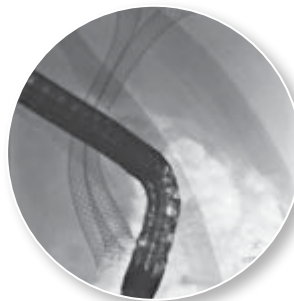
Platinol™ Wire construction provides greater flexibility aid placement in tortuous anatomies.\*

#### Radial Force

Radial force helps maintain stent patency and resist migration.

#### Removability

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



### delivery system

#### Stent Placement Accuracy

The RX biliary delivery system is reconstrainable up to 80% of deployment to aid in repositioning\*\*\* and is designed to facilitate physician control and locking of the guidewire.

#### Endoscopic Placement

Closed cell construction and Permalume covered options designed to resist tissue in-growth.<sup>4,6</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. Indications, contraindications, warnings and instructions for use can be found in the product labeling.

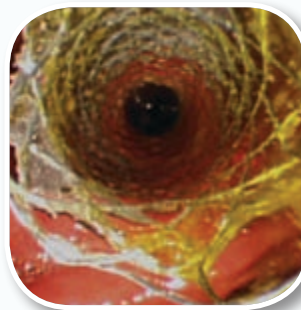
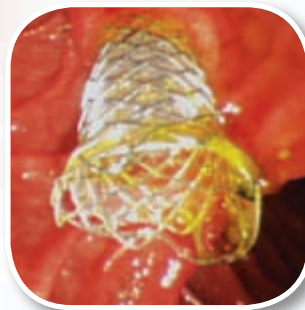
\*\*\* A stent cannot be reconstrained after the reconstraint line has been exceeded

\*\*\*\* Endoscopic and fluoroscopic images courtesy of Adrian Hatfield, MD and Thomas Kowalski, MD



Yellow Transition Zone

*"The WallFlex Biliary Fully Covered Stent yielded technically successful placement with uncomplicated acute removal where required, appropriate reduction in bilirubin levels, and low rates of stent migration and occlusion."<sup>8</sup>*



\*\*\*\*

## 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 during the initial placement.\*\*



## The Platinol™ Wire Difference

The unique Platinol Wire construction of the WallFlex™ Biliary RX Stent offers:

- **Flexibility** to aid placement in tortuous anatomies and maintain luminal patency
- Enhanced **full length radiopacity** to aid visibility during stent placement
- **Radial force** helps maintain stent patency and resist migration<sup>4,6</sup>

Platinum  
Core

Nitinol  
Encasement



## Clinical Evidence\*

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covered or uncovered metal stents

*“Covered SEMS are associated with more reduced resource utilization than uncovered SEMS in the treatment of malignant biliary obstruction. This may in part be due to lower incidence of cholangitis, lower rates of hospitalization, and shorter length of stays.”<sup>10</sup>*

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*“...[C]overed SEMS [WallFlex Biliary RX Partially Covered Stent]...had a longer duration of patency than uncovered SEMSs, which recommends their use in the palliative treatment of patients with biliary obstruction due to pancreatic carcinomas.”<sup>9</sup>*

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*“...the present data clearly suggest that covered stents overcome tumor ingrowth and reduce the rate of stent occlusion. Furthermore, the covered metal stent significantly reduced the number of reinterventions. It may contribute to improvement in quality of life of patients. Consequently, the total cost was also significantly smaller in the covered group.”<sup>7</sup>*

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## Clinical Evidence\*

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### plastic or metal stents

Clinical literature reports ease of placement, clinical benefits and cost effectiveness of endoscopically-placed biliary metal stents as superior to plastic stents for most patients with unresectable biliary malignancy.<sup>1,2,4,5,6</sup>

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*“Metallic stent performance was superior to plastic for hilar tumor palliation with respect to short-term outcomes, independent of disease severity, Bismuth class or drainage quality.”<sup>1</sup>*

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*“Metal stent placement is the most effective treatment of inoperable malignant common bile duct stricture...”<sup>2</sup>*

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*“The more effective [covered] SEMS are recommended in unresectable patients with malignant common bile duct strictures, who survive a median of 4.5 months.”<sup>6</sup>*

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\*Results from case studies are not predictive of results in other cases. Results in other cases may vary.

# WallFlex™ Biliary RX Stent

## Fully, Partially and Uncovered Self-Expanding Metal Stents



**Magnetic Resonance  
Conditional\***

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.

\*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.

### Ordering Information

#### Fully Covered Stents with Peralume™ Covering



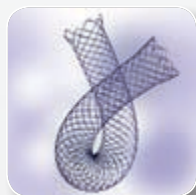
Order Number	Diameter (mm)	Length (mm)	Covered Length (mm) (PC Only)	Catheter Diameter (F)	Guidewire Diameter
M00570500	8	60	-	8.5F (2.83mm)	.035" (.89mm)
M00570510	8	80	-	8.5F (2.83mm)	.035" (.89mm)
M00570520	10	40	-	8.5F (2.83mm)	.035" (.89mm)
M00570530	10	60	-	8.5F (2.83mm)	.035" (.89mm)
M00570540	10	80	-	8.5F (2.83mm)	.035" (.89mm)

#### Partially Covered Stents with Peralume Covering



M00570700	8	60	48	8.5F (2.83mm)	.035" (.89mm)
M00570710	8	80	68	8.5F (2.83mm)	.035" (.89mm)
M00570720	10	40	28	8.5F (2.83mm)	.035" (.89mm)
M00570730	10	60	48	8.5F (2.83mm)	.035" (.89mm)
M00570740	10	80	68	8.5F (2.83mm)	.035" (.89mm)

#### Uncovered Stents



M00570600	8	40	-	8.0F (2.67mm)	.035" (.89mm)
M00570610	8	60	-	8.0F (2.67mm)	.035" (.89mm)
M00570620	8	80	-	8.0F (2.67mm)	.035" (.89mm)
M00570630	8	100	-	8.0F (2.67mm)	.035" (.89mm)
M00570890	10	40	-	8.0F (2.67mm)	.035" (.89mm)
M00570640	10	60	-	8.0F (2.67mm)	.035" (.89mm)
M00570650	10	80	-	8.0F (2.67mm)	.035" (.89mm)
M00570660	10	100	-	8.0F (2.67mm)	.035" (.89mm)

#### Recommended Guidewires

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

M00556021: Straight Dream Tip™

M00556031: Angled Dream Tip

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

M00556061: Straight Dream Tip

M00556071: Angled Dream Tip

#### References:

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4. Moss A.; Morris E.; MacMathuna P; Palliative biliary stents for obstructing pancreatic carcinoma. Cochrane Database Systematic Review, 25 Jan. 2006.
5. Kahaleh M., Efficacy and complications of covered Wallstents in malignant distal biliary obstruction. Gastrointestinal Endoscopy, 2005; 61: 528-533.
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8. Peterson et al. A Multicenter, Prospective Study of a New Fully Covered Expandable Metal Biliary Stent for the Palliative Treatment of Malignant Bile Duct Obstruction. Gastroenterology Research and Practice, 2013;2013:642428.
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10. Ryou M, Kumar N, Ou A, Ryan M, and Thompson C. Covered Versus Uncovered Metal Stents for Unresectable Malignant Biliary Obstruction: A Comparison of Resource Utilization. Gastrointestinal Endoscopy, 2012; 75; AB403.

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Indications, Contraindications, Warnings and Instructions for Use 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.**

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

The WallFlex Biliary Stent System is FDA-cleared in the US, and is indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms. The WallFlex Biliary Stent System is CE Marked (and approved in other regions – check for local availability), and is indicated for the palliative treatment of biliary strictures produced by malignant neoplasms and the fully covered stents are also indicated for treatment of benign biliary strictures.

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Boston Scientific Corporation  
One Boston Scientific Place  
Natick, MA 01760-1537  
www.bostonscientific.com/endo-resources

**Ordering Information**  
**1.888.272.1001**

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