



WallFlex™

Biliary RX Stents

Fully, Partially and Uncovered
Self Expanding Metal Stents



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▶ 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.⁴

Migration Resistance

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

Tissue In-growth Prevention

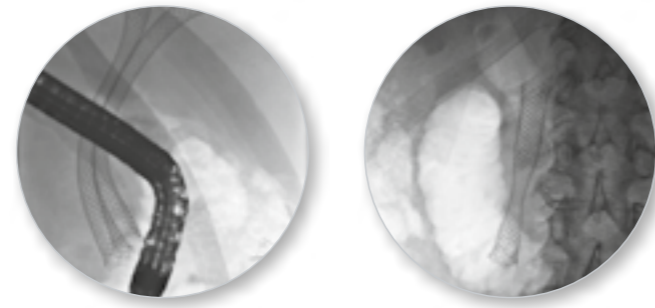
Closed cell construction and Permalume™ covered options designed to help resist tissue in-growth.^{1,2}

Flexibility

Platinol™ Wire construction provides flexibility to aid placement in tortuous anatomies.³

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 repositioning⁵ and is designed to help facilitate physician control and locking of the guidewire.

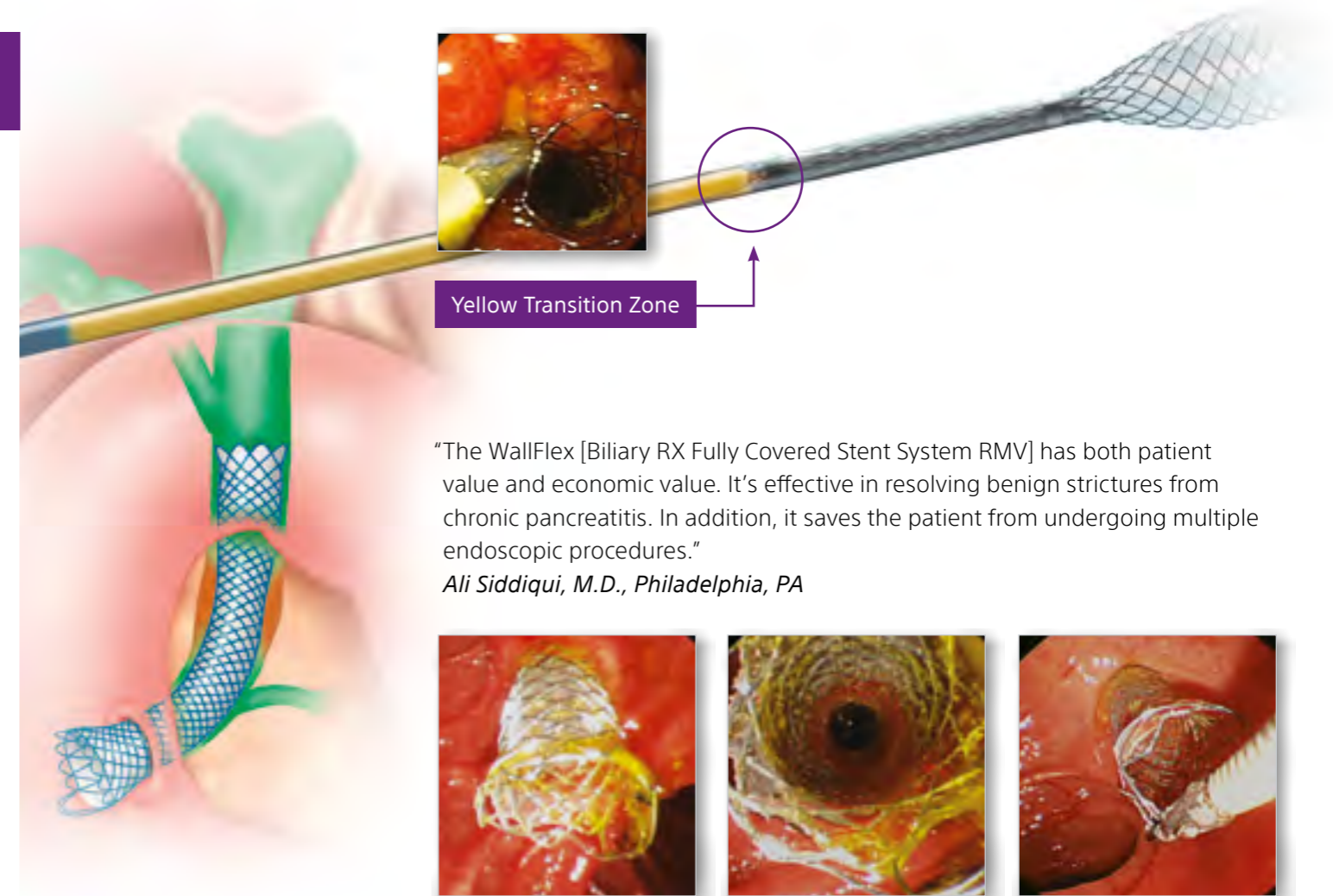
Endoscopic Placement

Closed cell construction and Permalume covered options designed to help resist tissue in-growth.^{1,2}

Fluoroscopic Visualization

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

WallFlex™ Biliary RX Stent Fully Covered Stent System RMV



"The WallFlex [Biliary RX Fully Covered Stent System RMV] has both patient value and economic value. It's effective in resolving benign strictures from chronic pancreatitis. In addition, it saves the patient from undergoing multiple endoscopic procedures."

Ali Siddiqui, M.D., Philadelphia, PA

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.⁴



Designed for Removability 12 Months Post-Placement

- ▶ The WallFlex Biliary RX Fully Covered Stent System RMV is approved to treat benign biliary strictures secondary to chronic pancreatitis, with indwell up to 12 months.
- ▶ This indication for use⁷ 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.



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

WallFlex™ Biliary RX Fully Covered Stent System RMV (Permalume™ Covering, includes benign indication)



Order Number	Diameter (mm)	Length (mm)	Covered Length (mm) (PC Only)	Catheter Diameter (F) / (mm)	Guidewire Diameter (in) / (mm)
M00574210†	6	40	–	8.5 / 2.83	.035 / 0.89
M00574230†	6	60	–	8.5 / 2.83	.035 / 0.89
M00574240†	6	80	–	8.5 / 2.83	.035 / 0.89
M00570450†	8	60	–	8.5 / 2.83	.035 / 0.89
M00570460†	8	80	–	8.5 / 2.83	.035 / 0.89
M00576800†	8	100	–	9.0 / 3.00	.035 / 0.89
M00576810†	8	120	–	9.0 / 3.00	.035 / 0.89
M00570470†	10	40	–	8.5 / 2.83	.035 / 0.89
M00570480†	10	60	–	8.5 / 2.83	.035 / 0.89
M00570490†	10	80	–	8.5 / 2.83	.035 / 0.89
M00576820†	10	100	–	9.0 / 3.00	.035 / 0.89
M00576830†	10	120	–	9.0 / 3.00	.035 / 0.89

† Product commercialised only in countries where benign indication is approved.

WallFlex™ Biliary RX Partially Covered Stent System (Permalume™ Covering)



M00570700	8	60	48	8.5 / 2.83	.035 / 0.89
M00570710	8	80	68	8.5 / 2.83	.035 / 0.89
M00576740	8	100	88	9.0 / 3.00	.035 / 0.89
M00576750	8	120	108	9.0 / 3.00	.035 / 0.89
M00570720	10	40	28	8.5 / 2.83	.035 / 0.89
M00570730	10	60	48	8.5 / 2.83	.035 / 0.89
M00570740	10	80	68	8.5 / 2.83	.035 / 0.89
M00576760	10	100	88	9.0 / 3.00	.035 / 0.89
M00576770	10	120	108	9.0 / 3.00	.035 / 0.89

Packaged one per box

Recommended Guidewire: .035in (0.89mm) Dreamwire™ High Performance Guidewire Stiff Shaft, 260cm or .035in (0.89mm) Dreamwire™ High Performance Guidewire, 260cm

Wallflex™ Biliary RX Uncovered Stent System



M00570600	8	40	–	8.0 / 2.67	.035 / 0.89
M00570610	8	60	–	8.0 / 2.67	.035 / 0.89
M00570620	8	80	–	8.0 / 2.67	.035 / 0.89
M00570630	8	100	–	8.0 / 2.67	.035 / 0.89
M00576780	8	120	–	8.0 / 2.67	.035 / 0.89
M00570890	10	40	–	8.0 / 2.67	.035 / 0.89
M00570640	10	60	–	8.0 / 2.67	.035 / 0.89
M00570650	10	80	–	8.0 / 2.67	.035 / 0.89
M00570660	10	100	–	8.0 / 2.67	.035 / 0.89
M00576790	10	120	–	8.0 / 2.67	.035 / 0.89

Packaged one per box

Recommended Guidewire: .035in (0.89mm) Dreamwire™ High Performance Guidewire Stiff Shaft, 260cm or .035in (0.89mm) Dreamwire™ High Performance Guidewire, 260cm

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

1. Isayama, H et al. "A prospective randomised study of „covered“ versus „uncovered“ diamond stents for the management of distal malignant biliary obstruction." Gut vol. 53,5 (2004): 729-34. doi:10.1136/gut.2003.018945.
2. Sakai, Yuji et al. "Uncovered versus covered metallic stents for the management of unresectable malignant distal biliary obstruction: a randomized multicenter trial." Scandinavian journal of gastroenterology vol. 56,10 (2021): 1229-1235. doi:10.1080/00365521.2021.1938207086
3. Flexibility varies by size of stent.
4. 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.
5. A stent cannot be reconstrained after the reconstraintment line has been exceeded.
6. 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.
7. 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.

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CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device or at www.IFU-BSCL.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.

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