

Clinical Evidence

*"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."*⁸

"The WallFlex™ Biliary benign stricture indication, supported by Boston Scientific's strong investment in clinical trials, gives confidence to physicians to place metal stents for a broad range of biliary strictures, including treatment of patients who would have previously waited for a confirmed diagnosis."

Prof. Jacques Devière
Erasmus Hospital, Brussels, Belgium

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.^{1,2,4,5,6}

*"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."*¹

*"Metal stent placement is the most effective treatment of inoperable malignant common bile duct stricture..."*²

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

Covered or Uncovered Metal Stents

*"...[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."*⁹

*"...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."*⁷

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.



*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 Permalume™ Covering



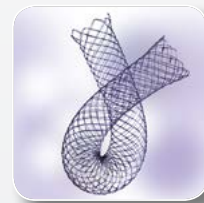
Order Number	Diameter (mm)	Length (mm)	Covered Length (mm) (PC Only)	Catheter Diameter	Guidewire Diameter
M00570450	8	60	-	8.5F (2.83mm)	.035" (.89mm)
M00570460	8	80	-	8.5F (2.83mm)	.035" (.89mm)
M00576800	8	100	-	9.0F (3.00mm)	.035" (.89mm)
M00576810	8	120	-	9.0F (3.00mm)	.035" (.89mm)
M00570470	10	40	-	8.5F (2.83mm)	.035" (.89mm)
M00570480	10	60	-	8.5F (2.83mm)	.035" (.89mm)
M00570490	10	80	-	8.5F (2.83mm)	.035" (.89mm)
M00576820	10	100	-	9.0F (3.00mm)	.035" (.89mm)
M00576830	10	120	-	9.0F (3.00mm)	.035" (.89mm)

Partially Covered Stents with Permalume Covering



M00570700	8	60	48	8.5F (2.83mm)	.035" (.89mm)
M00570710	8	80	68	8.5F (2.83mm)	.035" (.89mm)
M00576740	8	100	88	9.0F (3.00mm)	.035" (.89mm)
M00576750	8	120	108	9.0F (3.00mm)	.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)
M00576760	10	100	88	9.0F (3.00mm)	.035" (.89mm)
M00576770	10	120	108	9.0F (3.00mm)	.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)
M00576780	8	120	-	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)
M00576790	10	120	-	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

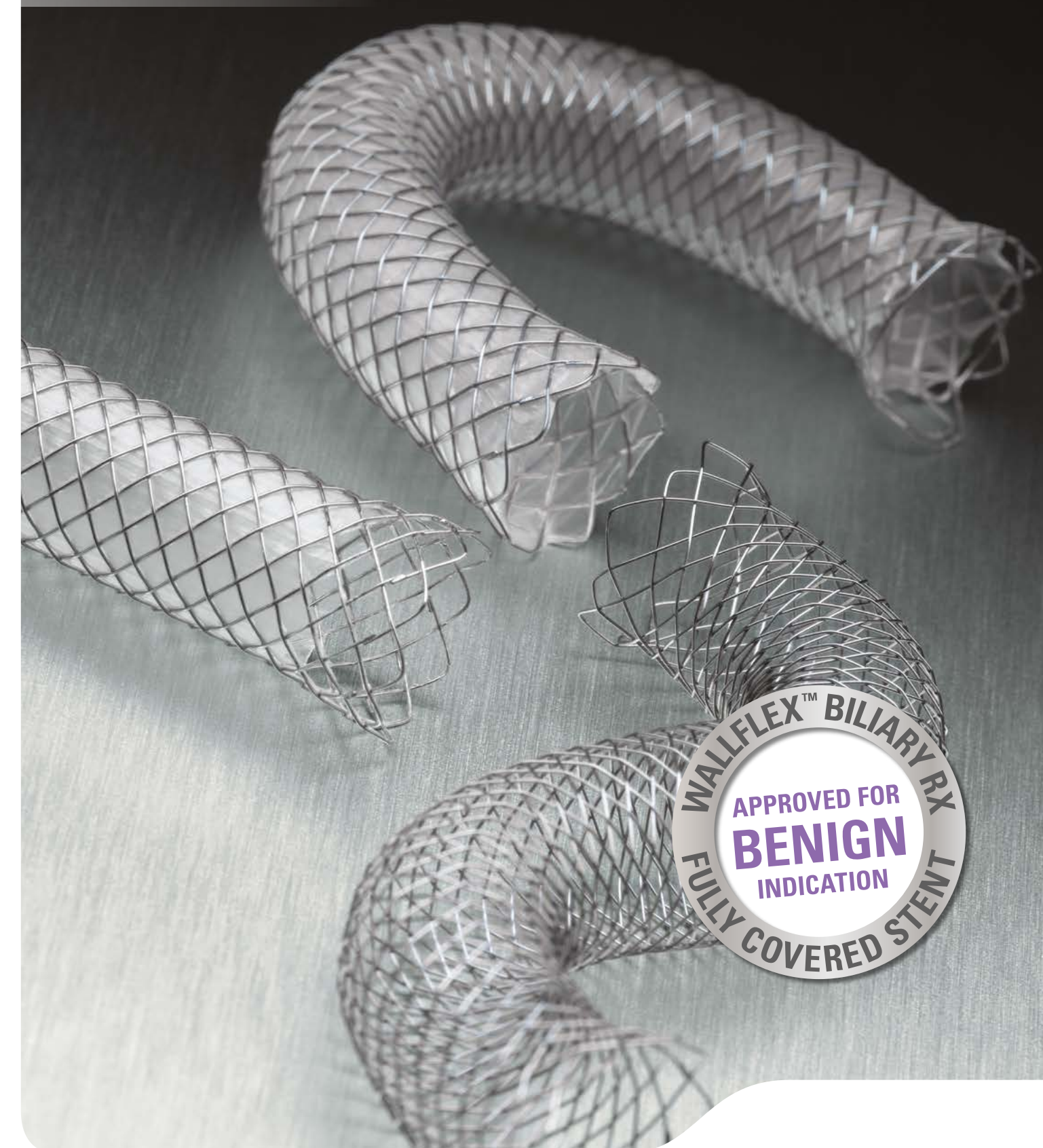
M00556061: Straight Dream Tip

M00556071: Angled Dream Tip

WallFlex™ Biliary RX Stent

Fully, Partially and Uncovered Self Expanding Metal Stents

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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.

The WallFlex Biliary RX Fully Covered Stent is also approved for the treatment of benign strictures.



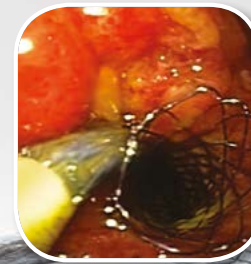
Physician Experiences

"Metal stent placement is the most effective treatment of inoperable malignant common bile duct stricture."²

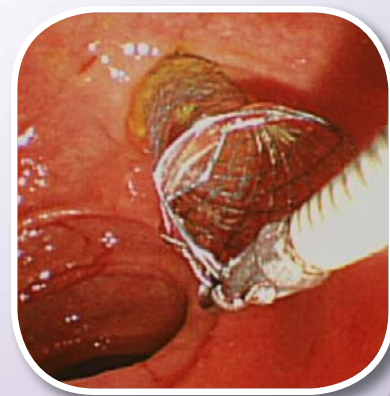
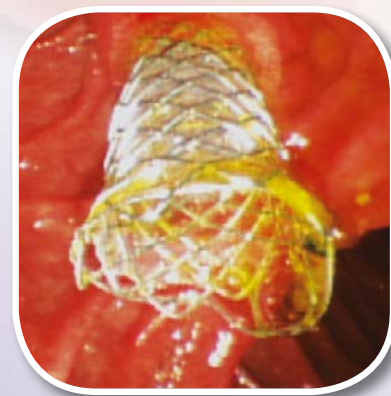
"The use of SEMS was shown in this meta-analysis to provide a survival advantage when compared to plastic stents – this has never been shown in individual trials, probably due to insufficient statistical power, but bears significant clinical implications."³

"In endoscopic stent comparisons, metal biliary stents appear to have a lower risk of recurrent biliary obstruction than plastic stents..."⁴

"...covered SEMS offer superior patency compared with uncovered stents."⁵



Yellow Transition Zone



References:
 1. Perdue D, Freeman M, DiSario J et al. Plastic Versus Self-expanding Metallic Stents for Malignant Hilar Biliary Obstruction. *Journal of Clinical Gastroenterology*, October 2008; Vol. 42, No. 9, 1040-1046. 2. Kassis et al. Plastic or metal stents for malignant stricture of the common bile duct? Results of a randomized prospective study. *GI Endoscopy*, 2003; 57: 178-182. 3. Waschke K.A., Da Silveira E., Toubouti Y., Rahme E, Martel M, Barkun, A (Presenter), Poster MON-E-397, UEGW 2006. 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. 6. 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. 7. Isayama H., Komatsu Y.

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.^{4,6}

Flexibility

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

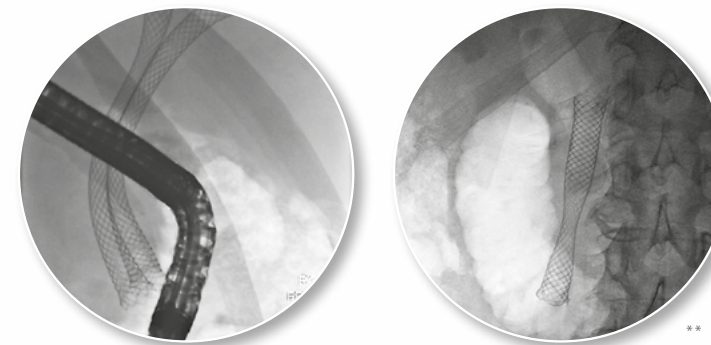
Radial Force

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.**

Removability indication up to 12 months after placement for the fully covered stent in benign biliary structures.



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.^{4,6}

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.

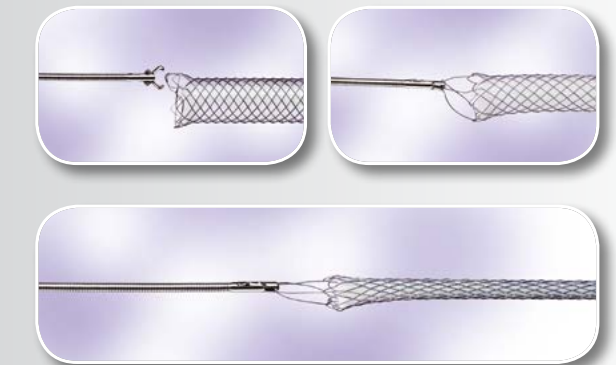
Endoscopic and fluoroscopic images courtesy of Adrian Hatfield, MD and Thomas Kowalski, MD

Place your trust in

- Experience
- Pioneering designs
- Clinical evidence

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 in malignant biliary strictures and up to 12 months in benign biliary strictures.**



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^{4,6}

Platinum Core



Nitinol Encasement

Tsujiro T., Sasahira N., Hirano K., Toda N. et al. A prospective randomized study of "covered" versus "uncovered" diamond stents for the management of distal malignant biliary obstruction. *Gut* 2004; 53: 729-734. 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. 9. Kitano et al. Covered Self-Expandable Metal Stents with an Anti-Migration System Improve Patency Duration without Increased Complications Compared with Uncovered Stents for Distal Biliary Obstruction Caused by Pancreatic Carcinoma: A Randomized Multicenter Trial. *The American Journal of Gastroenterology*, 2013 Nov;108(11):1713-22. Dream Tip, Hydra Jagwire, Permalume, Platinol, WallFlex and WALLSTENT are registered or unregistered trademarks of Boston Scientific Corporation or its affiliates. All other trademarks are property of their respective owners.