

Boston  
Scientific

Advancing science for life™

# WallFlex™

Biliary Transhepatic Stent System

Open  
to the  
Possibilities™

PIONEERING  
DESIGNS

WALLFLEX™ BILIARY TH  
APPROVED FOR  
**BENIGN**  
INDICATION  
FULLY COVERED STENT

CLINICAL  
EVIDENCE

ORDER  
INFORMATION

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## 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.

#### Flexibility

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

#### Full Length Radiopacity

To aid visibility during stent placement.

#### 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 up to 12 months after placement for the fully covered stent in benign biliary strictures.

#### Up to 120 mm length

Available in two outer diameters (8 mm and 10 mm) and five different lengths of 40 mm, 60 mm, 80 mm, 100 mm and 120 mm in three different versions uncovered, partially covered and fully covered.

### Percutaneous Delivery System

- **Reconstrainable up to 80 percent of deployment** to aid in repositioning.\*\*\*
- **Coaxial delivery system** assists in smooth delivery and control.
- **Has a 75 cm working length** and is compatible with 9 F (3.0 mm) introducer sheath.
- **Four radiopaque** markers aid in visualization and placement.

\* Flexibility varies by size of stent.

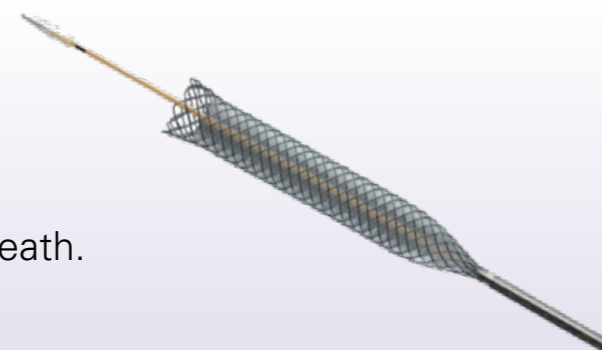
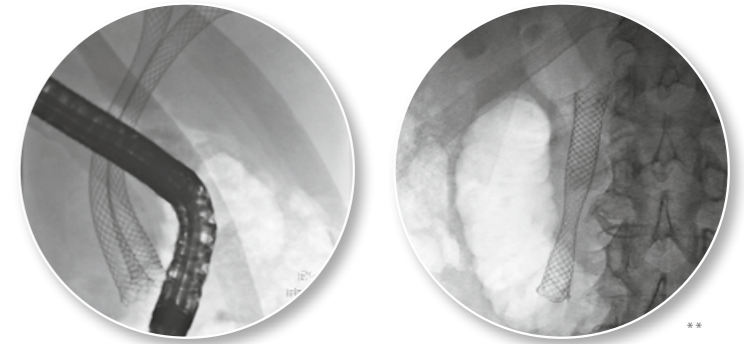
\*\* In the event of incorrect positioning during the initial stent placement procedure, the partially covered and fully covered stent options may be removed using forceps to grasp the retrieval loop on the end of the stent. Warning: No warranty is made with regard to removability of this device by endoscopic 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



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The WallFlex™ Biliary TH  
Fully Covered Stent

Removable up to



months post-deployment  
in benign biliary-strictures

The WallFlex™ Biliary TH Fully Covered Stent has been developed to meet the clinical and technical performance requirements of today's IR physicians.

## Designed for removal up to 12 months

The expanded benign indication for WallFlex™ Fully Covered represented a significant clinical milestone in achieving optimal treatment strategies for patients with benign bile duct strictures. Our unique stent design, with the **integrated retrieval loop** and **Permalume™** covering, is designed for **removal up to 12 months** post-deployment.

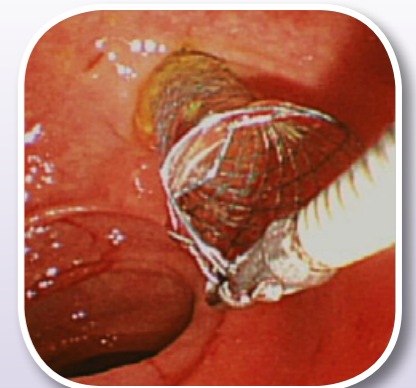
## The integrated Retrieval Loop

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.\*\*



## Successful Management of Benign Biliary Strictures With Fully Covered Self-Expanding Metal Stents – *Devière et al.*

Largest prospective study and 5 year follow-up for Self-Expandable Metal Stents for management of benign biliary strictures, identify patients at high-risk and low-risk migration of these stents after placement, and understand the risks and benefits of Fully Covered Self-Expandable Metal Stents versus plastic stents for management of chronic pancreatitis. **Clearly shows removability at 12 months is excellent. The stricture resolution rates for Chronic Pancreatitis is much higher than for plastic stents and completed in one procedure.** Gastroenterology 2014;147:385-395



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



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## Clinical evidence

### **Percutaneous Approach to the Diagnosis and Treatment of Biliary Tract Malignancies - Garcia et al.**

This article outlines the Transhepatic approach to treating bile duct malignancies. An overview of how patients are treated when they present to IR with bile duct strictures. Basic terms talking about when to use plastic stents, metal stents, internal, external, outcomes, complications and procedural considerations. – *Surg Oncol Clin N Am 18 (2009) 241–256.*

### **The Biodurability of Covering Materials for Metallic Stents in a Bile Flow Phantom - Bang et. Al**

Covered biliary metal stents have been introduced for the purpose of overcoming tumor ingrowth and treatment of benign biliary stricture. The aim of this study was to evaluate the biodurability of three commercially available biliary metal stent covering materials [e- PTFE (expanded polytetrafluoroethylene), silicone, and polyurethane] in a bile flow phantom. Conclusion: e-PTFE tended to form biofilms more frequently than polyurethane and silicone during bile exposure. e-PTFE seemed to be less durable than silicone and polyurethane. – *Dig Dis Sci DOI 10.1007/s10620-0111958-6.*

### **Risk factors for cholecystitis after metal stent placement in malignant biliary obstruction - Suk K.T. et al.**

The study measured many factors that could contribute to an increased risk of cholecystitis. Analysis showed that an obstruction across the cystic duct by tumour and the presence of gallbladder stone were the only statistically significant risk factors for the development of cholecystitis after metal stent placement. – *Gastrointest Endosc 2006; 64:522-9 – Dig Dis Sci DOI 10.1007/s10620-0111958-6.*

### **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 - Kitano et. al**

By preventing tumor ingrowth and migration, covered SEMSs with an anti-migration system 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. – *Am J Gastroenterol advance online publication, 17 September 2013; doi: 10.1038/ajg.2013.305*

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## Order information

### Fully Covered Stents with Permalume™ Covering

Order Number	Diameter Nomial (mm)	Length Nomial (mm)	Covered Length (mm) Partially Covered Only	Catheter Diameter (F)	Guidewire Diameter
M00574800	8	60	-	8.5 F (2.83 mm)	0.035" (0.89 mm)
M00574810	8	80	-	8.5 F (2.83 mm)	0.035" (0.89 mm)
M00576940	8	100	-	8.5 F (2.83 mm)	0.035" (0.89 mm)
M00576950	8	120	-	8.5 F (2.83 mm)	0.035" (0.89 mm)
M00574820	10	40	-	8.5 F (2.83 mm)	0.035" (0.89 mm)
M00574830	10	60	-	8.5 F (2.83 mm)	0.035" (0.89 mm)
M00574840	10	80	-	8.5 F (2.83 mm)	0.035" (0.89 mm)
M00576960	10	100	-	8.5 F (2.83 mm)	0.035" (0.89 mm)
M00576970	10	120	-	8.5 F (2.83 mm)	0.035" (0.89 mm)

### Partially Covered Stents with Permalume™ Covering

Order Number	Diameter Nomial (mm)	Length Nomial (mm)	Covered Length (mm) Partially Covered Only	Catheter Diameter (F)	Guidewire Diameter
M00574700	8	60	48	8.5 F (2.83 mm)	0.035" (0.89 mm)
M00574710	8	80	68	8.5 F (2.83 mm)	0.035" (0.89 mm)
M00576880	8	100	88	8.5 F (2.83 mm)	0.035" (0.89 mm)
M00576890	8	120	108	8.5 F (2.83 mm)	0.035" (0.89 mm)
M00574720	10	40	28	8.5 F (2.83 mm)	0.035" (0.89 mm)
M00574730	10	60	48	8.5 F (2.83 mm)	0.035" (0.89 mm)
M00574740	10	80	68	8.5 F (2.83 mm)	0.035" (0.89 mm)
M00576900	10	100	88	8.5 F (2.83 mm)	0.035" (0.89 mm)
M00576910	10	120	108	8.5 F (2.83 mm)	0.035" (0.89 mm)

### Uncovered Stents

Order Number	Diameter Nomial (mm)	Length Nomial (mm)	Covered Length (mm) Partially Covered Only	Catheter Diameter (F)	Guidewire Diameter
M00574620	8	40	-	8.0 F (2.67 mm)	0.035" (0.89 mm)
M00574630	8	60	-	8.0 F (2.67 mm)	0.035" (0.89 mm)
M00574640	8	80	-	8.0 F (2.67 mm)	0.035" (0.89 mm)
M00574650	8	100	-	8.0 F (2.67 mm)	0.035" (0.89 mm)
M00576920	10	120	-	8.0 F (2.67 mm)	0.035" (0.89 mm)
M00574660	10	40	-	8.0 F (2.67 mm)	0.035" (0.89 mm)
M00574670	10	60	-	8.0 F (2.67 mm)	0.035" (0.89 mm)
M00574680	10	80	-	8.0 F (2.67 mm)	0.035" (0.89 mm)
M00574690	10	100	-	8.0 F (2.67 mm)	0.035" (0.89 mm)
M00576930	10	120	-	8.0 F (2.67 mm)	0.035" (0.89 mm)

100 and 120mm lengths are manufactured and available on demand only

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