

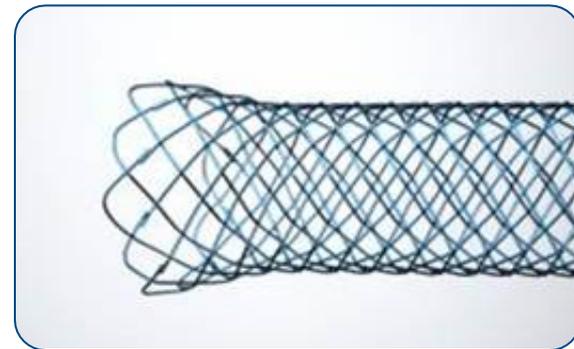
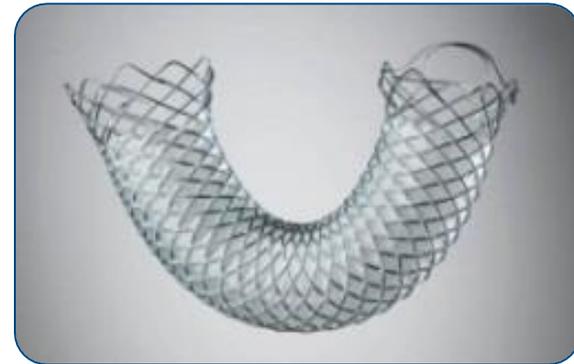
WallFlexTM
Biliary Transhepatic Stent System

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Advancing science for lifeTM



In-Service Presentation

- **WallFlex™ Biliary Transhepatic Stent indication**
- **Product features**
 - Closed-cell, braided design
 - Looped and flared stent ends
 - Platinol™ Technology
 - Percutaneous delivery system
- **Clinical support**
 - Procedure images
 - Clinical literature summary
- **Matrix & ordering info**



The WallFlex™ Biliary Transhepatic Stent System is indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms as well as for benign strictures.

The safety and effectiveness of this device for use in the vascular system have not been established.

Closed-Cell, Braided Design

- **Closed cell design and Permalume™ Covering**

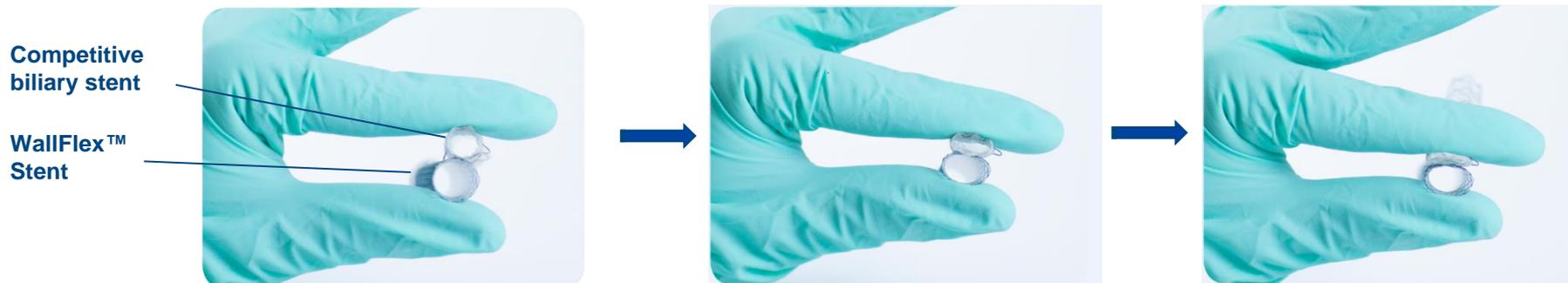
- Fully-covered, partially-covered and uncovered options
- Helps resist tissue ingrowth^{1,2}
- Designed to resist compression^{1,2}

- **Braided design**

- Engineered to maintain lumen diameter, even on a curve
- Designed to offer flexibility to conform to tortuous anatomy



Compression Resistance Illustration



1. Moss A.; Morris E.; MacMathuna P.; Palliative biliary stents for obstructing pancreatic carcinoma. Cochrane Database Systematic Review, 25 January 2006.

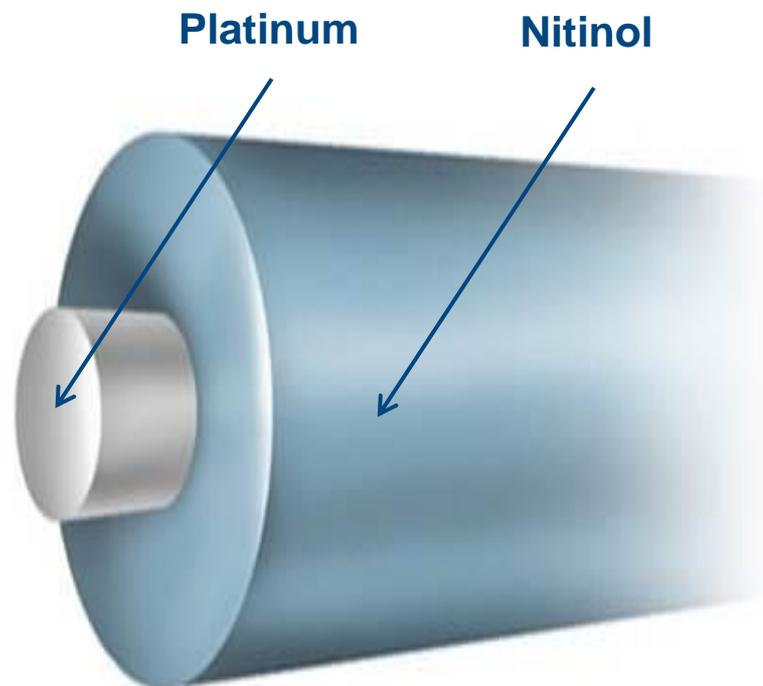
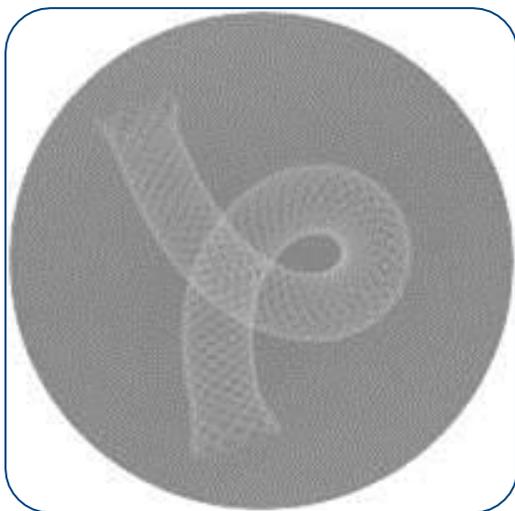
2. Soderlund K., Linder S.; Covered metal versus plastic stents for malignant common bile duct stenosis: a prospective, randomized, controlled trial. Gastrointestinal Endoscopy, 2006; 63: 986-995

Looped and Flared Stent Ends

- **Looped ends designed to reduce trauma to tissue**
- **Flared ends designed to resist migration**
 - **Proximal end:**
 - **Gradual flare to allow for conformability**
 - **2 / 2.4 mm larger than stent diameter**
 - **Distal end:**
 - **Step-flare to reduce the risk of tissue trauma and stent migration**
 - **1.3 / 1.7 mm larger than stent diameter**

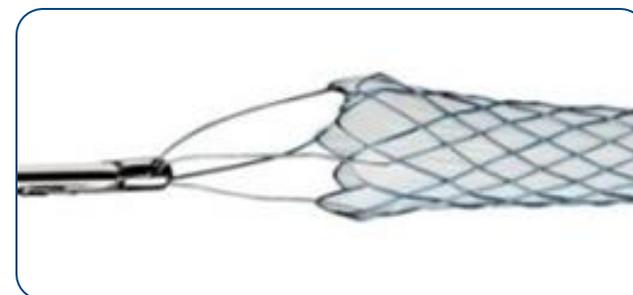


- **Platinol Wire: Platinum-cored Nitinol**
- **Benefits**
 - **Flexibility**
 - **Full-length radiopacity**
 - **Compressive strength**



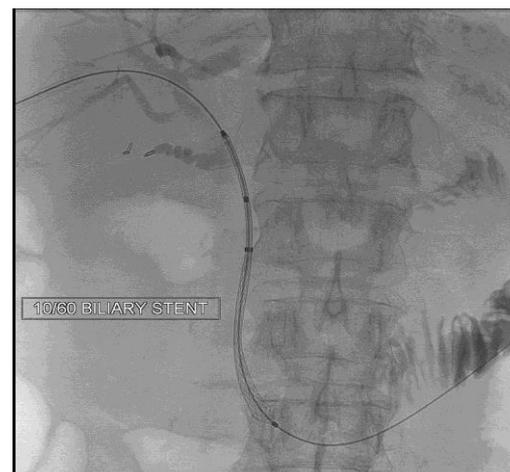
Percutaneous Delivery System

- **Reconstrainable** up to 80% of deployment to aid in repositioning
- **Coaxial delivery system** assists in smooth delivery and control
- **75 cm working length**, compatible with a 9 F introducer sheath
- **Retrieval loop** for endoscopic removal or repositioning during the initial placement procedure in patients that may have an ERCP performed



WARNING: The WallFlex™ Biliary Transhepatic Stent has a retrieval loop for endoscopic removal or repositioning during the initial placement procedure in patients that may have an ERCP performed. 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.

Procedural Images



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

Images provided by Dr. Rajiv Biswal and Jersey Shore University Medical Center

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PI-379301-AA EU MAR2016

Covered Stents provide longer patency than uncovered

- **Saleem**, et al. “Meta-analysis of randomized trials comparing the patency of covered and uncovered self-expandable metal stents for palliation of distal malignant bile duct obstruction”
- **Isayama et al.** “A prospective randomized study of “covered” versus “uncovered” diamond stents for the management of distal malignant biliary obstruction”

e-PTFE tends to form biofilm more frequently during bile exposure and is less durable than silicone and polyurethane

- **Bang**, et al. “The Biodurability of Covering Materials for Metallic Stents in a Bile Flow Phantom”

Stent type (covered vs. uncovered) is not related to the risk of cholecystitis

- **Suk**, et al. “Risk factors for Cholecystitis After Metal Stent Placement in Malignant Biliary Obstruction”

Matrix & Ordering Info

Order Number	Diameter Nominal (mm)	Length Nominal (mm)	Covered Length (mm)	Catheter Diameter (F)	Guidewire Diameter
<i>Partially Covered Only</i>					
Fully Covered Stents with Permalume™ Covering					
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					
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					
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	8	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

Abbreviated Statement

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Material not for use in France

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