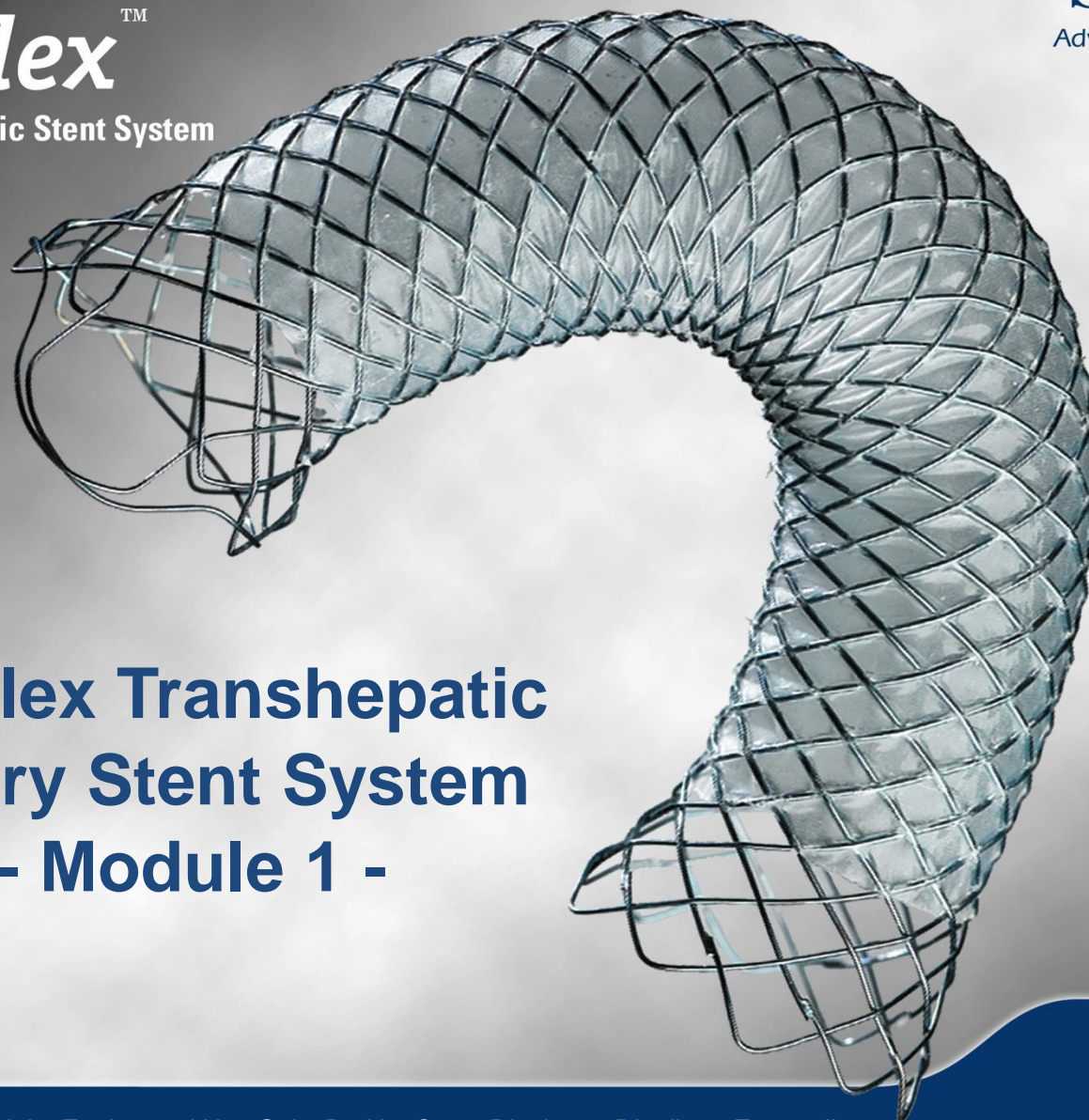


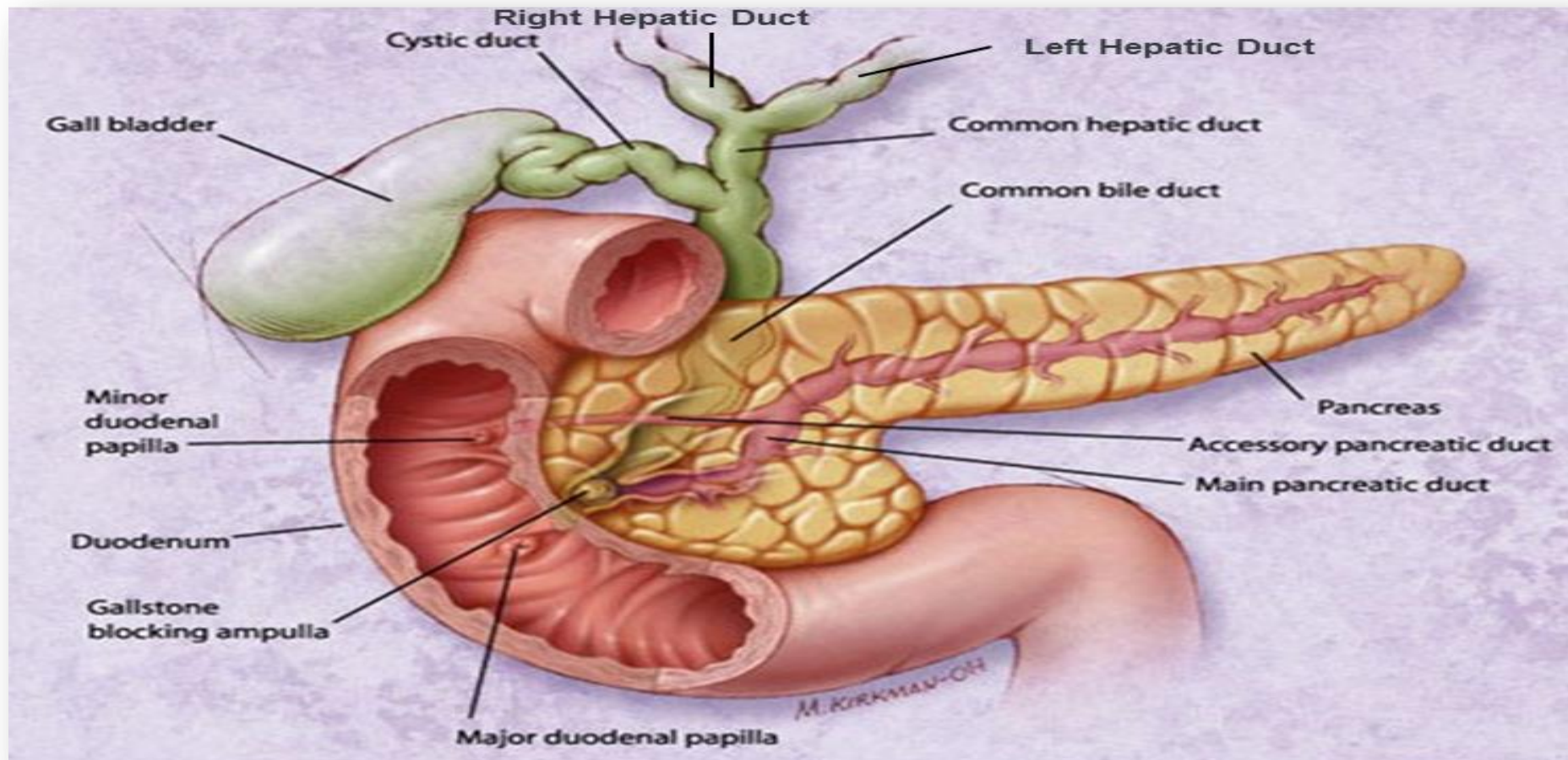
WallFlexTM

Biliary Transhepatic Stent System

**Boston
Scientific**
Advancing science for lifeTM



Wallflex Transhepatic Biliary Stent System - Module 1 -



Biliary strictures are an abnormal narrowing of the common bile duct which might obstruct the drainage of bile from the liver to the small intestine or duodenum.

Obstructive diseases:

☐ **Malignant strictures:**

- Pancreatic cancer – #1 cause of biliary strictures
- Cholangiocarcinoma (cancer of the bile duct)
- Gallbladder cancer
- Liver cancer

☐ **Benign strictures:**

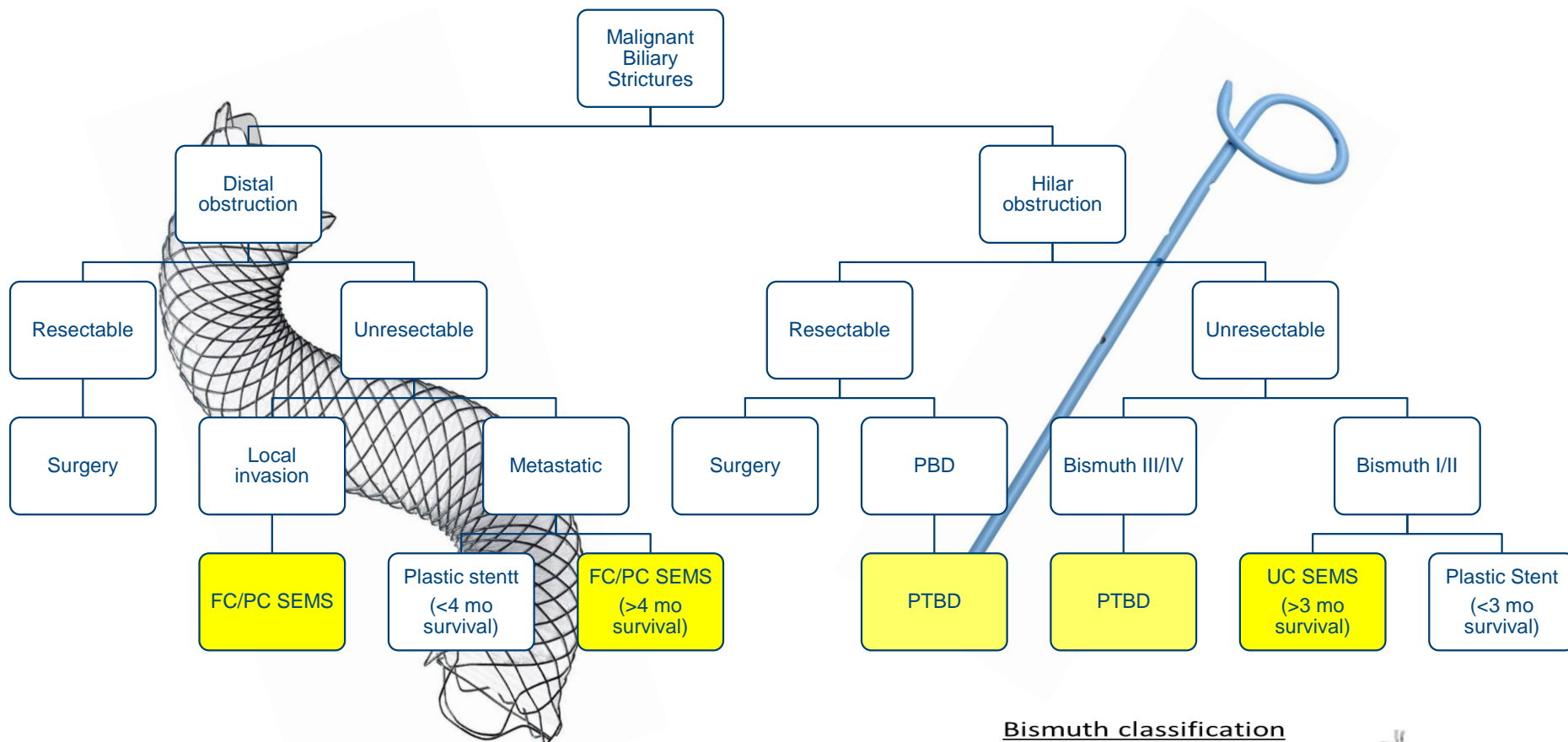
- Chronic pancreatitis
- Post-operative effects
- Liver transplant

Treatment Prognosis:

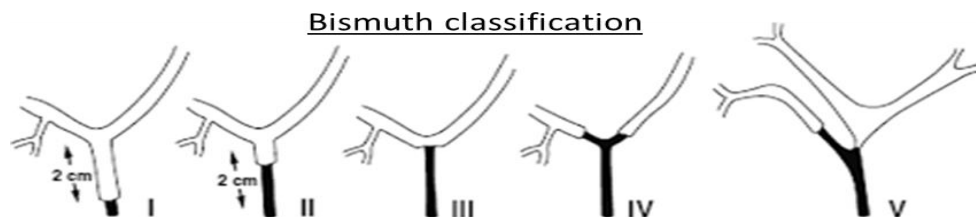
- Palliative care – typically 3 - 15 months for malignant disease
- Patient comfort and quality of life are the primary objectives

Malignant Biliary Strictures Treatment Algorithm →

BSC IO opportunity

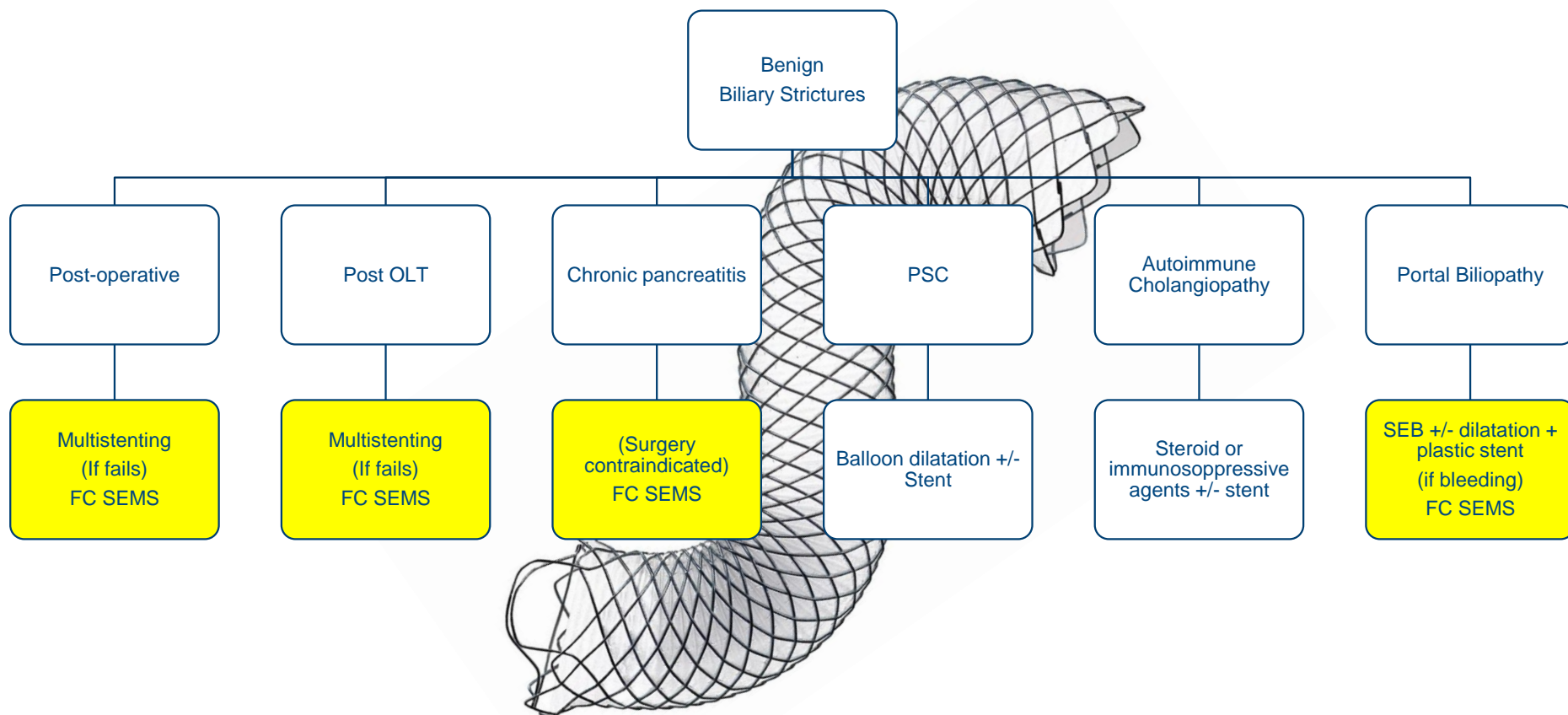


SEMS: Self-Expandable Metallic Stent
 PBD: Preoperative Biliary Decompression
 PTBD: Percutaneous Transhepatic Biliary Drainage



Benign Biliary Strictures Treatment Algorithm →

BSC IO opportunity



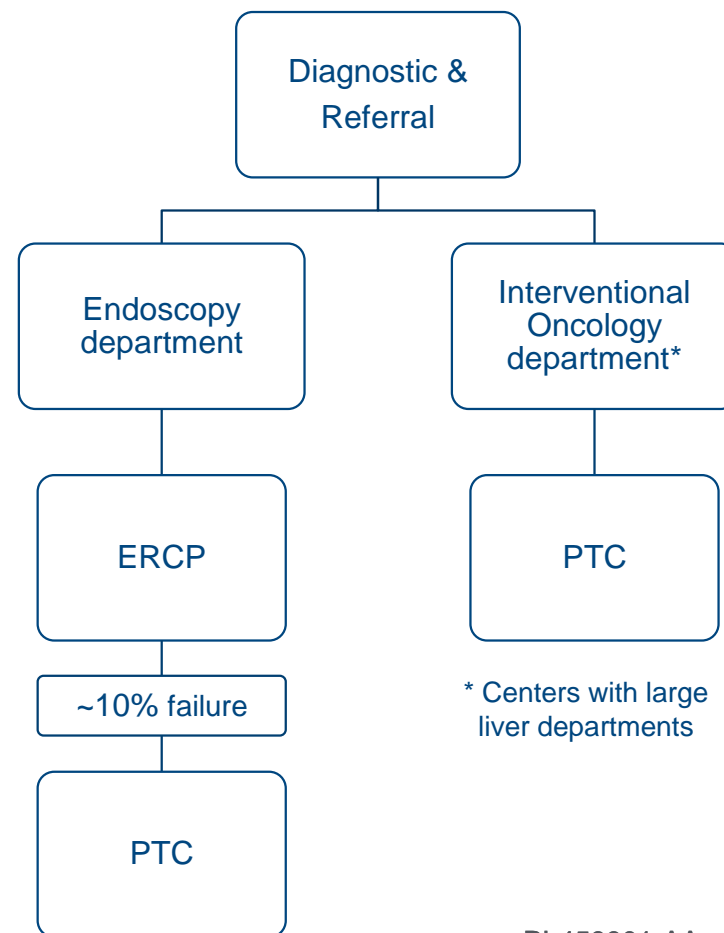
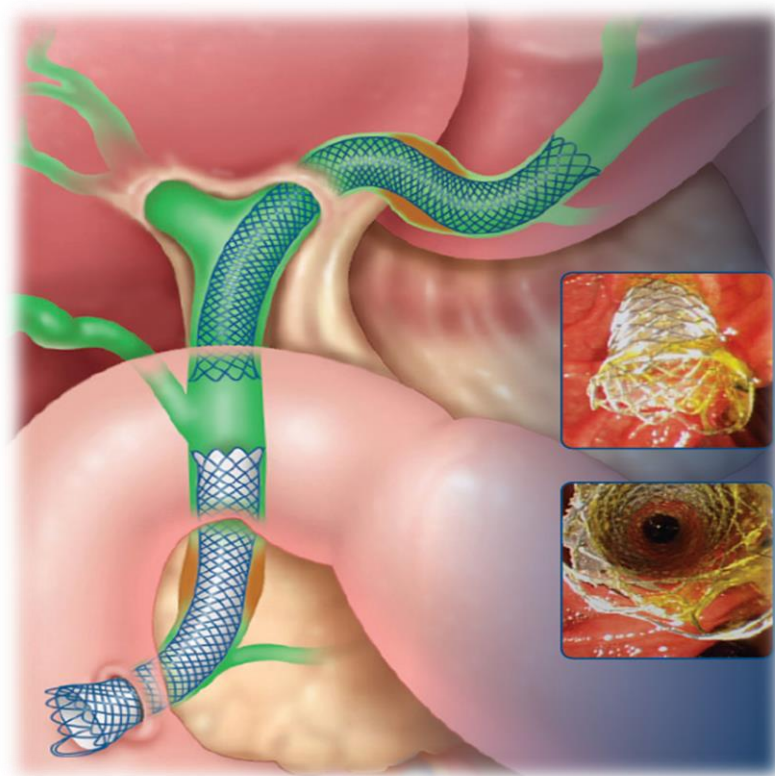
FC SEMS: Fully Covered Self-Expandable Metallic Stent

POST OLT: Post Liver Transplantation Obstruction

PSC: Primary Sclerosing Cholangitis

SEB: Self-Expandable Balloon

Biliary stenting is necessary when tumors or strictures compress the biliary ducts and obstruct bile drainage. **The main purpose is: Restart bile flow.**



ERCP: Endoscopic retrograde cholangiopancreatography
PTC: Percutaneous transhepatic cholangiogram

1. Prefer drains

- Continually use drainage catheters, replacing every 4-6 weeks.
- Bad experience with uncovered stents that could not be removed.
- Because drains are in their comfort zone.

2. Drain prior to stent

- Drain first to decompress, then stent 1-3 days later.
- Use of plastic, non-covered, vascular or covered stents.
- Biliary drainage catheters & stents are complementary products.

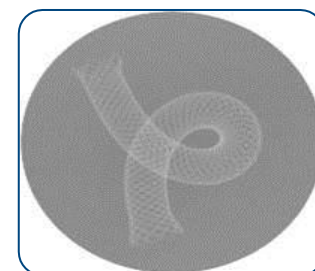
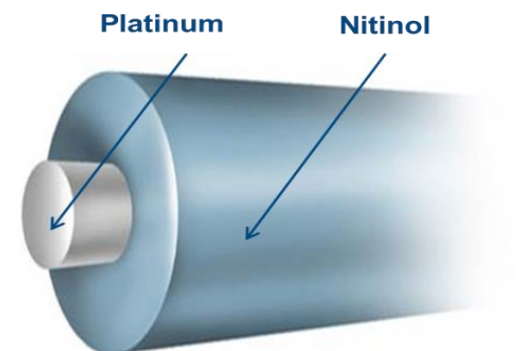
3. Primary stenter

- Use of plastic, non-covered, vascular or covered stents.
- Rarely use of drainage catheters. Uncomfortable for the patient.

Indicated for use in the **palliative treatment** of **biliary strictures** produced by **malignant neoplasms** and, in case of **fully covered** version, approved for the treatment of **benign strictures**



- **Flexibility**
 - Aids in placement in tortuous anatomy
- **Full-length radiopacity**
 - Platinum core aids visibility during stent placement
- **Braided construction**
 - Designed to resist compression and maintain stent patency
- **Closed-cell construction and Permalume™ Covering**
 - Help resist tissue ingrowth
- **Looped and flared stent ends**
 - Designed to reduce the risk of stent migration and tissue trauma



- Integrated retrieval loop

- Fully and partially covered stents only
- Located at distal stent end (in duodenum)
- FC version → Approved for Benign Indication

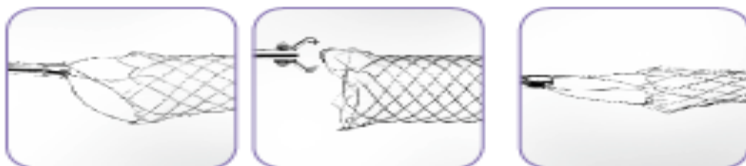


The WallFlex™ Biliary TH
Fully Covered Stent

Removable up to

12

months post-deployment
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*

Matrix & Ordering Info

Order Number	Diameter Nominal (mm)	Length Nominal (mm)	Covered Length (mm) <i>Partially Covered Only</i>	Catheter Diameter (F)	Guidewire Diameter
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

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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. Information for the use only in countries with applicable health authority product registrations. Material not for use in France.