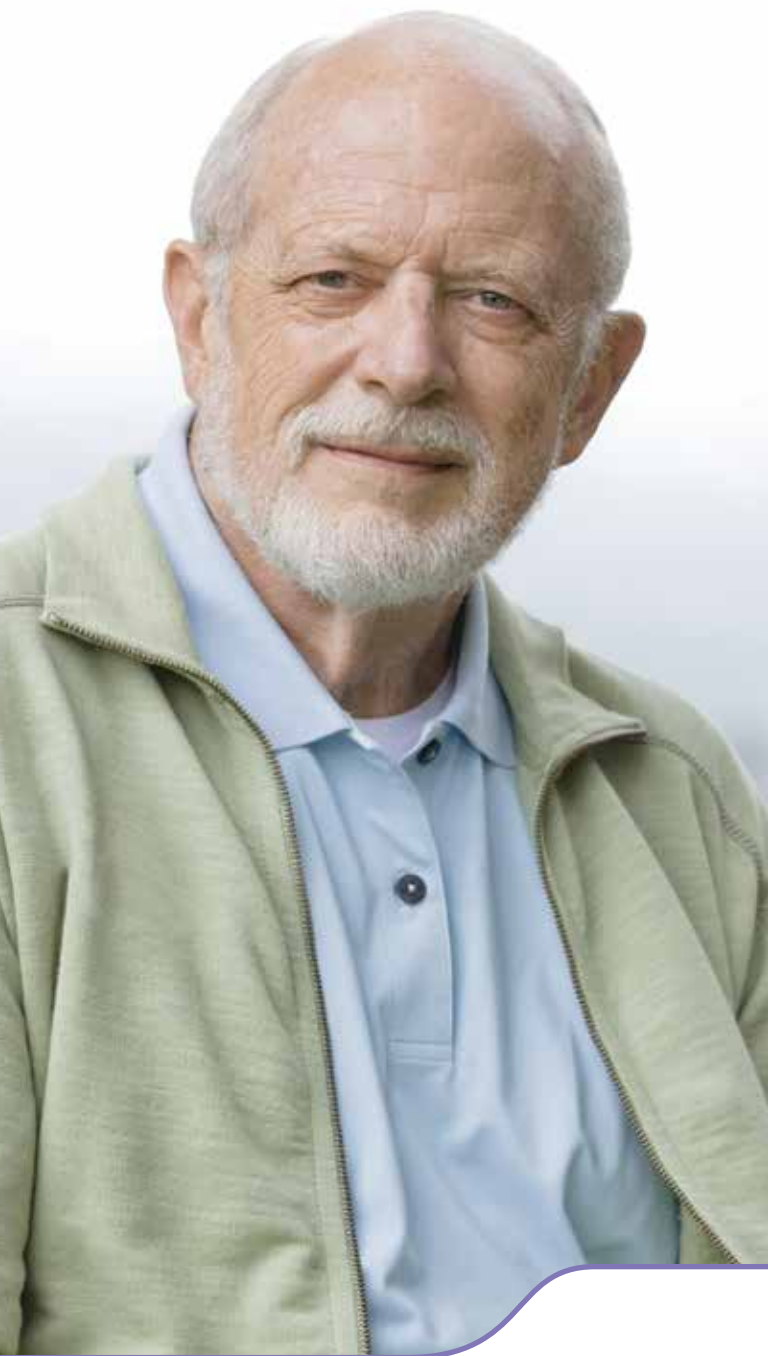


*A Guide for Patients
Living with a
Biliary Metal Stent*



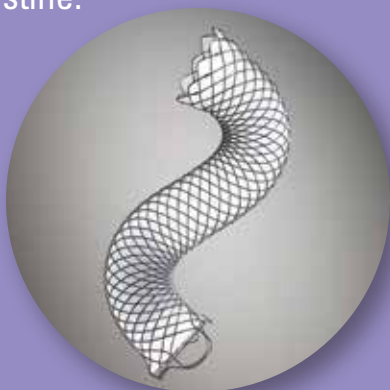
What is a biliary metal stent?

A biliary metal stent (also known as a “bile duct stent”) is a flexible metallic tube specially designed to hold your bile duct open, which has been blocked or partially blocked.

When a blockage occurs in the bile duct, fluids like bile (bilirubin) are unable to flow into the duodenum to aid in digestion.

This may cause bile to build up in the liver and produce symptoms such as jaundice (yellow coloring of the skin), abdominal pain and nausea.

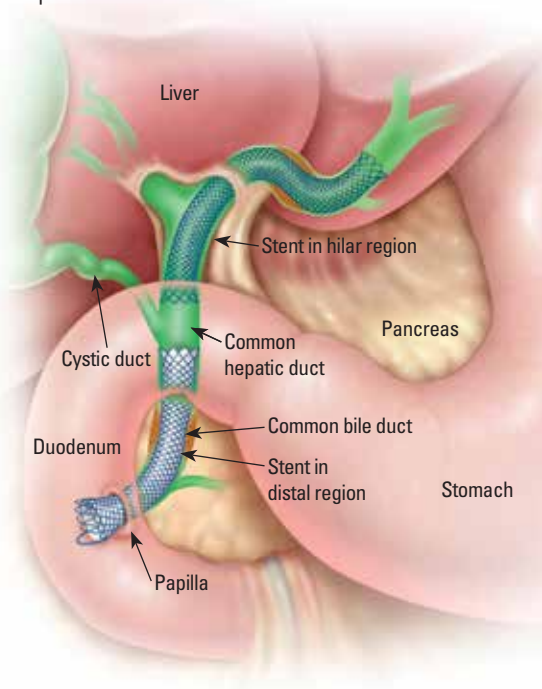
A biliary stent is inserted to reduce or eliminate this blockage. Once it is in place in the obstructed area, the stent is designed to expand and open the channel so that fluids can continue to move to the intestine.



What should I expect during the procedure?

Your metal stent will be implanted in the distal region or the hilar region of the bile duct by a doctor who is specially trained in this procedure. The endoscopic retrograde cholangiopancreatography (ERCP) procedure is typically performed under general anesthesia.

During the ERCP procedure, an endoscope will be inserted into your esophagus through your mouth. An endoscope is a flexible thin lighted tube designed to allow your doctor to see your GI tract. The endoscope is advanced through your stomach into your duodenum. The physician will then advance a thin wire (called a guidewire) through the papilla and into the bile duct. The stent is placed over the wire and guided into position. Once in place, your doctor will open the stent in the obstructed area. The stent is designed to stay in place and maintain the opening for a period of time.



Are there any risks to the procedure?

As with any medical procedure there are risks associated with metal stent placement, and you should talk to your doctor about what they are. Your doctor will be able to explain the risks and answer your questions.

Potential complications that may be experienced with a biliary metal stent placement/ERCP procedure include, but are not limited to:

- › **Pain**
- › **Bleeding**
- › **Fever**
- › **Nausea**
- › **Vomiting**
- › **Infection**
- › **Inflammation**
- › **Recurrent obstructive jaundice**
- › **Stent occlusion**
- › **Tumor overgrowth around ends of stent**
- › **Tumor ingrowth through the stent**

Please note that these are not the only complications associated with metal stent placement. Indications, Contraindications, Warnings and Instructions for Use can be found in the product labeling supplied with each device.

What if my stent becomes blocked?

For various reasons, your stent might become blocked after some time. This is normal, but it is important for you to know when it blocks so that you do not become sick as a result of the blockage. If your stent blocks, you should go to the hospital immediately and inform the staff that you have been fitted with a biliary metal stent.

You might experience any of the following symptoms as a result of biliary stent blockage:

- **Yellow or itchy skin (jaundice)**
- **Upper right abdominal pain**
- **Biliary colic** – spasmodic upper abdominal pain
- **Fever**
- **Nausea and vomiting**
- **Flatulence or pale stool**
- **Pain under right shoulder blade**

Please note that these are not the only symptoms of bile duct stent blockage. If you have other symptoms, consult your doctor.

Questions for your doctor

Below are some questions to ask your doctor, as well as space to write your own questions. Your doctor is the best source of information regarding your condition.

What should I expect in terms of recovery?

After my biliary metal stent is placed, will I need further treatment?

Questions for your doctor

Should I restrict my activity?

When may I resume normal activity and eating?

*Please carry this card
with you at all times*

This card has important information
about your biliary metal stent that
healthcare providers will need to know
in order to care for you. This card is
conveniently sized to fit in a wallet.

*Patient ID Card
Adhered Here
(Doesn't Print)*

Physician Name:

Phone Number:

WallFlex is a registered or unregistered trademark of Boston Scientific Corporation or its affiliates.

Warning: The safety and effectiveness of the WallFlex Biliary Stent for use in the vascular system has not been established.

Illustrations are for informational use only – not indicative of actual clinical outcome.

Indications, Contraindications, Warnings and Instructions for Use can be found in the product labeling supplied with each device.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.



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*Patient with a
Biliary Metal Stent*

- ▶ The owner of this card has been fitted with a biliary metal stent.



Patient Name: _____

DOB: _____ Placement Date: _____

Stent Name: _____

Stent Size: _____

Physician Name: _____

Phone: _____

Magnetic Resonance Conditional: Through non-clinical testing, the WallFlex Biliary RX Stent has been shown to be MR Conditional (poses no known hazards under specified conditions), when used under the conditions outlined in the Directions for Use.

ENDO-228606-AA March 2014