

WallFlex[®] Biliary RX Uncovered Stent System

WALLFLEX BILIARY RX UNCOVERED STENT SYSTEM

Order Number	Diameter (mm)	Length (mm)	Catheter Diameter (Fr)	Guidewire Diameter (in)
M00570600.....	8.....	40.....	8.0.....	.035.....
M00570610.....	8.....	60.....	8.0.....	.035.....
M00570620.....	8.....	80.....	8.0.....	.035.....
M00570630.....	8.....	100.....	8.0.....	.035.....
M00570640.....	10.....	60.....	8.0.....	.035.....
M00570650.....	10.....	80.....	8.0.....	.035.....
M00570660.....	10.....	100.....	8.0.....	.035.....

Recommended Guidewires

- **Hydra Jagwire[®] Guidewire Stiff Shaft 0.035” – 260cm**
 - M00556021 Straight Dream Tip[™]
 - M00556031 Angled Dream Tip
 - **Hydra Jagwire Guidewire Stiff Shaft 0.035” – 450cm**
 - M00556061 Straight Dream Tip
 - M00556071 Angled Dream Tip
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INSTRUCTIONS FOR USE

Refer to the operator's manual for complete instructions for use.

INTENDED USE / INDICATIONS FOR USE

The WallFlex Biliary RX Uncovered Stent System is indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms.

CONTRAINDICATIONS

Contraindications may be found in the product labeling supplied with each device.

The WallFlex Biliary RX Uncovered Stent System is contraindicated for:

- Placement in biliary strictures caused by benign tumors, as the longterm effects of the stent in the bile duct is unknown.
- Placement in strictures that cannot be dilated enough to pass the delivery system.
- Placement in a perforated duct.
- Placement in very small intrahepatic ducts.
- Those patients for whom endoscopic techniques are contraindicated.
- Any use other than those specifically outlined under indications for use.

WARNINGS

Warnings may be found in the product labeling supplied with each device.

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

No warranty is made with regard to removability of this device by endoscopic means or otherwise.

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POTENTIAL COMPLICATIONS

Potential complications may be found in the product labeling with each device.

The following complications have been reported in the literature for biliary prostheses.

These include, but are not limited to:

- Pain
- Bleeding
- Fever
- Nausea
- Vomiting
- Infection
- Inflammation
- Recurrent obstructive jaundice
- Stent occlusion
- Tumor ingrowth through the stent
- Tumor overgrowth around ends of stent
- Mucosal hyperplasia
- Cholangitis
- Cholecystitis
- Pancreatitis
- Bile duct ulceration
- Perforation of duodenum or bile duct
- Stent migration
- Death (other than that due to normal disease progression)
- Stent misplacement

Please be aware that potential adverse effects may arise even with the proper use of medical devices. Accordingly, this device should only be used by persons qualified in the procedures for which it is indicated.

CAUTIONS

Cautions 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.

Excessive force should not be used to position or deploy the stent. This may cause inadvertent damage to the device and/or endoscope.

The sterile packaging and device should be inspected prior to use. If sterility or performance of the device is suspected to be compromised, it should not be used.

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Ordering Information
1.800.225.3226

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