

WALLSTENT[®] RX Biliary Endoprosthesis

With PERMALUME[®] Covering and UNISTEP[®] Plus Delivery System

WALLSTENT RX SINGLE-USE BILIARY ENDOPROSTHESIS WITH PERMALUME COVERING

Order Number	Description	Diameter (mm)	Total Length (mm)	Cover Length	Delivery System (Fr)	Working Length(cm)
M00569670.....	WALLSTENT RX w/ Permalume.....	8.....	40.....	30.....	8.....	194....
M00569680.....	WALLSTENT RX w/ Permalume.....	8.....	60.....	50.....	8.....	194....
M00569690.....	WALLSTENT RX w/ Permalume.....	8.....	80.....	70.....	8.....	194....
M00569700.....	WALLSTENT RX w/ Permalume.....	10.....	40.....	30.....	8.....	194....
M00569710.....	WALLSTENT RX w/ Permalume.....	10.....	60.....	50.....	8.....	194....
M00569720.....	WALLSTENT RX w/ Permalume.....	10.....	80.....	70.....	8.....	194....

WALLSTENT RX SINGLE-USE BILIARY ENDOPROSTHESIS

Order Number	Description	Diameter (mm)	Total Length (mm)	Delivery System (Fr)	Working Length(cm)
M00569610.....	WALLSTENT RX Biliary.....	8.....	40.....	8.....	194..
M00569620.....	WALLSTENT RX Biliary.....	8.....	60.....	8.....	194..
M00569630.....	WALLSTENT RX Biliary.....	8.....	80.....	8.....	194..
M00569640.....	WALLSTENT RX Biliary.....	10.....	40.....	8.....	194..
M00569650.....	WALLSTENT RX Biliary.....	10.....	60.....	8.....	194..
M00569660.....	WALLSTENT RX Biliary.....	10.....	80.....	8.....	194..
M00569810.....	WALLSTENT RX Biliary.....	10.....	100.....	8.....	194....

WALLSTENT SINGLE-USE BILIARY ENDOPROSTHESIS WITH PERMALUME COVERING & UNISTEP PLUS DELIVERY SYSTEM (Standard)

Order Number	Description	Unconstrained Diameter (mm)	Nominal Unconstrained Length (mm)	Delivery System (Fr)	Working Length (cm)	Cover Length(mm)
H965430700.....	WALLSTENT Biliary w/ Permalume.....	8.....	40.....	8.....	194.....	30
H965430800.....	WALLSTENT Biliary w/ Permalume.....	8.....	60.....	8.....	194.....	50
H965430900.....	WALLSTENT Biliary w/ Permalume.....	8.....	80.....	8.....	194.....	70
H965431000.....	WALLSTENT Biliary w/ Permalume.....	10.....	40.....	8.....	194.....	30
H965431100.....	WALLSTENT Biliary w/ Permalume.....	10.....	60.....	8.....	194.....	50
H965431200.....	WALLSTENT Biliary w/ Permalume.....	10.....	80.....	8.....	194.....	70

WALLSTENT SINGLE-USE BILIARY ENDOPROSTHESIS WITH UNISTEP PLUS DELIVERY SYSTEM

Order Number	Description	Unconstrained Diameter (mm)	Nominal Unconstrained Length (mm)	Delivery System Diameter (Fr)	Working Length (cm)
H965430100.....	WALLSTENT Biliary.....	8.....	40.....	7.5.....	194.....
H965430200.....	WALLSTENT Biliary.....	8.....	60.....	7.5.....	194.....
H965430300.....	WALLSTENT Biliary.....	8.....	80.....	7.5.....	194.....
H965430400.....	WALLSTENT Biliary.....	10.....	40.....	7.5.....	194.....
H965430500.....	WALLSTENT Biliary.....	10.....	60.....	7.5.....	194.....
H965430600.....	WALLSTENT Biliary.....	10.....	80.....	7.5.....	194.....

Recommended Guidewire .035" Jagwire[®] Guidewire

WALLSTENT® RX Biliary Endoprosthesis

With PERMALUME® Covering and UNISTEP™ Plus Delivery System

INSTRUCTIONS FOR USE

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

INDICATIONS

Indicated for use in the treatment of biliary strictures produced by malignant neoplasms.

CONTRAINDICATIONS

Contraindicated for associated with the use of Wallstent RX Biliary Endoprosthesis, with or without Permalume Covering, include:

- Use of the device in very small intrahepatic ducts
- Stenting of a perforated duct, where leakage from the duct could be exacerbated by the prosthesis and leakage could occur across the uncovered mesh of the stent
- All of the customary contraindications associated with the endoscopic manipulation of 8F (2.7mm) caliber catheters within the biliary system

WARNINGS

Our devices are designed, manufactured, tested, validated and labeled for single use only. These devices should not be reused, reprocessed or resterilized. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

Stenting across a major bifurcation may prevent or hinder future endoscopic access or other procedures.

Final stent placement resulting in an excessive length of stent protruding into the duodenum or misplacement of the entire stent into the duodenum may damage or obstruct the intestinal tract.

A stent cannot be repositioned or removed after the deployment threshold has been exceeded.

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

POTENTIAL ADVERSE EFFECTS

Potential adverse effects may include infection or sepsis, stent misplacement, stent migration, stent obstruction secondary to tumor ingrowth through the stent, tumor overgrowth at the stent ends, sludge occlusion, bile duct perforation or ulceration, bleeding, cholangitis, or pancreatitis.

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.

**Boston
Scientific**

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Ordering Information
1.800.225.3226

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