

WallFlex™ Biliary RX Fully Covered Stent System RMV

The WallFlex Biliary RX Fully Covered Stent System RMV is the first and currently the only metal stent cleared in the U.S. for the treatment of benign biliary strictures secondary to chronic pancreatitis with indwell up to 12 months. In 2009, a large prospective, multinational study was initiated to assess the effectiveness and safety of fully covered self-expanding metal stents after an indwell of up to 12 months in biliary strictures resulting from chronic pancreatitis. The primary endpoint was stent removability. Secondary endpoints included stricture resolution during stent indwell and after stent removal. Patient follow-up is still ongoing.

"The study was a multi-center study, including eleven centers in ten countries. The centers were spread in Europe, Asia, Australia and Canada as well, so I think it's a good representation of the world."

PROF. GUIDO COSTAMAGNA, M.D. | ROME, ITALY

10 COUNTRIES
ON 4 CONTINENTS

11 TERTIARY
CENTERS

127 PATIENTS

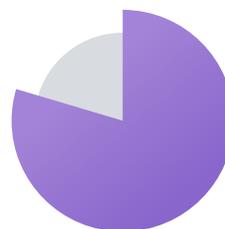
The following highlights key findings in the per-protocol* patient cohort (n=118):



STENT REMOVAL SUCCESS

90.7% *However, all stents were successfully removed.*
(107/118)

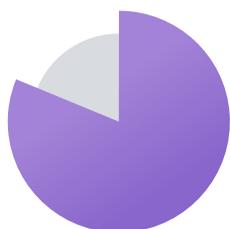
Removal success is defined as scheduled endoscopic stent removal with no removal-related serious adverse events (SAEs), or spontaneous stent passage without the need for immediate restenting.



STRICTURE RESOLUTION

79.7%
(94/118)

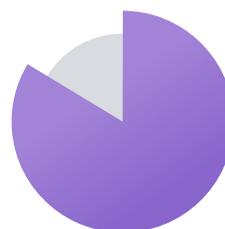
*At the end of indwell, stricture resolution **without the need for restenting** was achieved in 79.7% of patients*



STENT FUNCTIONALITY DURING STENT INDWELL

83.1%
(98/118)

Defined as lack of required reintervention during intended indwell or spontaneous stent passage without the need for immediate restenting within 6 days.



NO STRICTURE RECURRENCE

85.1%
(80/94)

*Of patients **maintained stent-free** status over a median follow-up period of **19 months** (range 0.9-29.7 months)*

"The results after one year of stent indwell patients with chronic pancreatitis, was that we were able to resolve the stricture in about 80% of cases, which is very high if you compare that with historical results that we obtained with plastic stents." **PROF. MARCO BRUNO, M.D. | AMSTERDAM, THE NETHERLANDS**

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Serious Adverse Events (SAEs)

SAEs that were deemed to be potentially device or procedure related occurred in 27.6% of patients during stent placement, indwell, removal or biliary reintervention. SAEs that were deemed to be potentially device or procedure related occurred in 14.2% of patients during the post stent removal follow-up period. In total, 36.2% intent-to-treat patients (n=127) and 36.4% per-protocol* patients (n=118) experienced 86 events as detailed below. There were no stent or stent removal related deaths; however, 7 patients died during the stent indwell period and an additional 3 patients died during the follow-up period due to non-device/procedure related causes.

“With high stricture resolution rate at removal, low rate of recurrence, and excellent safety profile; in my opinion, fully covered self-expanding metal stent placement should be considered as a treatment option offered to patients with biliary strictures due to symptomatic chronic pancreatitis.”

PROF. JACQUES DEVIERE, M.D.
BRUSSELS, BELGIUM

Stent Placement, Stent Indwell, or Biliary Reintervention SAEs		
SAE Term	Number of Events	Patient Incidence
Biliary leak	1	0.8% (1/127)
Gas embolism	1	0.8% (1/127)
Abdominal pain	12	5.5% (7/127)
Pancreatitis	14	10.2% (13/127)
Cholecystitis	3	2.4% (3/127)
Chest pain	1	0.8% (1/127)
Cholangitis	12	7.1% (9/127)
Cholelithiasis	1	0.8% (1/127)
Cholestasis	2	1.6% (2/127)
Peripancreatic abscess	1	0.8% (1/127)
Insufficient pancreatic drainage	1	0.8% (1/127)
Hepatic abscess	2	1.6% (2/127)
Peripancreatic cyst/pseudocyst	3	2.4% (3/127)
Sepsis	2	1.6% (2/127)
Bacterial Infection	1	0.8% (1/127)

Stent Removal		
SAE Term	Number of Events	Patient Incidence
Cholangitis	3	2.4% (3/127)
Abdominal pain	1	0.8% (1/127)

Post Stent Removal Follow-Up		
SAE Term	Number of Events	Patient Incidence
Biliary leak	1	0.8% (1/127)
Abdominal pain	4	3.1% (4/127)
Pancreatitis	10	7.1% (9/127)
Cholangitis	8	4.7% (6/127)
Hepatic Abscess	1	0.8% (1/127)
Peripancreatic pseudocyst	1	0.8% (1/127)

* The per protocol (PP) patient cohort has 118 patients. Nine (9) patients were excluded from the PP cohort due to: death due to unrelated causes (7), transition to palliative care in setting of pancreatic cancer (1) and withdrawal of consent (1).

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

INDICATIONS FOR USE in the United States:

The WallFlex Biliary RX Fully Covered Stent System RMV is indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms, relief of malignant biliary obstruction prior to surgery and for indwell up to 12 months in the treatment of benign biliary strictures secondary to chronic pancreatitis.

LIMITATIONS: The sale, distribution, and use of the device are restricted to prescription use in accordance with 21 CFR §801.109

Contraindications:

- The WallFlex Biliary RX Fully Covered Stent should not be placed in strictures that cannot be dilated enough to pass the delivery system, in a perforated duct, or in very small intrahepatic ducts.
- The WallFlex Biliary RX Fully Covered Stent System RMV should not be used in patients for whom endoscopic techniques are contraindicated.

Warnings: The safety and effectiveness of the stent has not been established for indwell periods exceeding 12 months. The WallFlex Biliary RX Fully Covered Stent System RMV is for single-use only. The safety and effectiveness of the WallFlex Biliary RX Fully Covered Stent System RMV for use in the vascular system has not been established. The safety and effectiveness of the WallFlex Biliary RX Fully Covered Stent System RMV has not been established in the treatment of benign biliary anastomotic strictures in liver transplant patients and benign biliary post abdominal surgery strictures. Testing of overlapped stents has not been conducted. The stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity

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