

Boston Scientific Receives Expanded Indication in the U.S. for the

WallFlex Biliary RX Fully Covered Stent System RMV

The current standard of care used by about 80 percent of physicians in the United States when treating benign biliary strictures due to chronic pancreatitis is to place multiple plastic stents. These plastic stents often require replacement an average of five times per year due to clogging¹. Multiple stent procedures not only impact patients, who may undergo multiple endoscopic retrograde cholangiopancreatography (ERCP) procedures in a year, but may also impact time and care workflows for physicians.

The treatment of benign biliary strictures secondary to chronic pancreatitis, however, is evolving in the United States. Boston Scientific was the first and is currently the only company to receive U.S. FDA clearance for an indication of a metal stent, the WallFlex™ Biliary RX Fully Covered Stent System RMV, to treat benign biliary strictures due to chronic pancreatitis. This is a significant clinical milestone and demonstrates Boston Scientific's commitment to advancing endoscopic GI therapies.

Ali A. Siddiqui, M.D., professor at Thomas Jefferson University in Philadelphia, has changed his protocol for determining which stent to place. “In the past, I would place plastic stents. However, now for any patient who has a stricture of the bile duct from chronic pancreatitis, I do not bother using plastic stents. I opt for the WallFlex Biliary RX Fully Covered Metal Stent.”

How does the metal stent compare to plastic stents when resolving benign strictures due to chronic pancreatitis? Designed with an integrated retrieval loop, the WallFlex Biliary RX Fully Covered Stent System RMV, with its larger diameter, may be left in place for up to 12 months before it needs to be removed, unlike most plastic stents that may require replacement every few months due to clogging. In fact, this fully covered self-expanding metal stent has the radial dilation equivalent to that of at least three side-by-side plastic stents². Therefore, placing the WallFlex Biliary RX Fully Covered Stent from Boston Scientific may reduce the number of reinterventions, potentially contributing to quality of life improvements for patients.

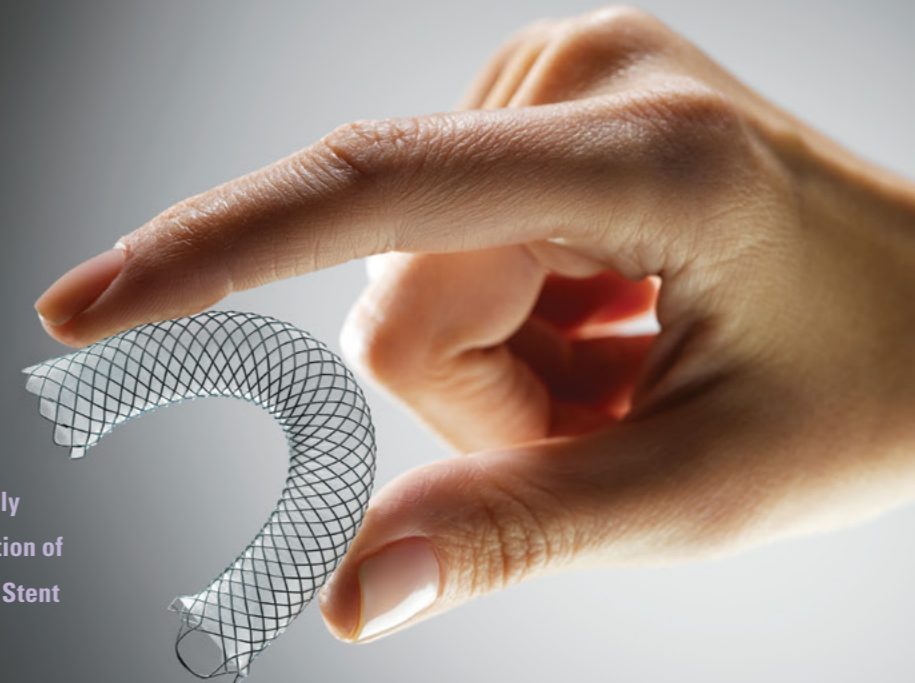
This reduction in repeat procedures each year may also yield economic benefits. In fact, initial placement of a fully covered self-expanding metal stent for benign biliary strictures secondary to chronic pancreatitis may help to avoid the cost of multiple ERCP with stent placement procedures.

“If you look at the overall economic value, it's clearly been shown that the fully covered stents are most cost effective because they can potentially save patients from having recurrent endoscopic procedures. It also may help to improve the patient's overall quality of life as they undergo treatment for resolving strictures,” said **Prof. Siddiqui**.

In the United States, the WallFlex Biliary RX Fully Covered Stent System RMV is also cleared for use in the palliative treatment of biliary strictures produced by malignant neoplasms, and relief of malignant biliary obstruction prior to surgery.



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A large prospective, multinational study sponsored by Boston Scientific is currently underway. The study includes 11 centers in 10 countries in Europe, Asia, Australia and North America. Marco J. Bruno, professor of Gastroenterology and Hepatology and head of the department of gastroenterology and hepatology at the Erasmus Medical Centre in Rotterdam, Netherlands, an investigator in the study says, “The results after one year of stent indwelling in patients with chronic pancreatitis, was that we were able to resolve the stricture in 80 percent of cases. This is very high compared with historical results obtained with plastic stents, where the maximum success rate would be 30 or 40 percent.”

An abstract highlighting the three-year follow-up data (“Self-expanding metal stents for treatment of benign biliary strictures secondary to chronic pancreatitis – long-term results in a multi-center study”³) was presented at Digestive Disease Week™ in May 2016. The abstract noted that “[i]n patients with symptomatic chronic pancreatitis associated bile duct strictures treated with a single fully covered self-expanding metal stent for one year, stricture resolution obtained at the time of stent removal (80% of patients) is maintained without relapsing symptoms in 83% of patients at a median follow-up of 3 years³.”

References:

1. Deviere J, Nageshwar Reddy D, Puspok A, et al. Successful management of benign biliary strictures with fully covered self-expanding metal stents. *Gastroenterology* 2014; 147:385-395.
2. Cote G., et al. Effect of Covered Metallic Stents Compared With Plastic Stents on Benign Biliary Stricture Resolution: A Randomized Clinical Trial. *JAMA*. 2016;315(12):1250-1257.
3. **Abstract:** Self-expanding metal stents for treatment of benign biliary strictures secondary to chronic pancreatitis – long term results in a multi-center study. Jacques Deviere, D. Nageshwar Reddy, Andreas Püspök, Thierry Ponchon, Marco J. Bruno, Michael J. Bourke, Horst Neuhaus, André Roy, Ferrán González-Huix Lladó, Paul Kortan, Joyce Peetermans, Sundeep Lakhtakia, Daniel Blero, Werner Dolak, and Guido Costamagna.

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.

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

Information Related to the WallFlex™ Biliary RX Fully Covered Stent System RMV:

Warning: Use caution when placing stent near ductal branches to avoid obstruction of duct. Placement of a fully covered biliary stent across a branch duct or major bifurcation may result in complications due to blockage of flow from the branch duct and prevent endoscopic or transhepatic access for future procedures.

Warning: The safety and effectiveness of the stent for benign stricture treatment has not been established for indwell periods exceeding 12 months.

Information related to the WallFlex Biliary Stents.

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

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Results from case studies are not predictive of results in other cases. Results in other cases may vary.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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 use only in countries with applicable health authority registrations. Material not intended for use in France.

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