Uncovered Stents

Options

Fully covered, partially covered and uncovered stents in multiple sizes are available to accommodate different anatomical and clinical requirements.

Ordering Information

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Diameter (mm)</th>
<th>Length (mm)</th>
<th>Partially Covered Only</th>
<th>Covered Length (mm)</th>
<th>Catheter Diameter (F)</th>
<th>Guidewire Diameter</th>
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</thead>
<tbody>
<tr>
<td>M00574770</td>
<td>8 60</td>
<td>48</td>
<td>8.5 F (2.8 mm)</td>
<td>0.035&quot; (0.89 mm)</td>
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</table>

WallFlex™ Biliary Transhepatic Stent System

INDICATIONS FOR USE: The uncovered, partially covered and fully covered WallFlex Biliary Transhepatic Stent Systems are indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms. CONTRAINDICATIONS: The uncovered, partially covered and fully covered WallFlex Biliary Transhepatic Stent Systems are contraindicated for: Partially covered and fully covered stenting of a perforated duct; Stenting of a perforated duct when drainage from the duct could be associated with the stricture and leakage could occur across the neck of the uncovered stent; All of the customary contraindications associated with the percutaneous transhepatic manipulation of introduction sheaths and delivery systems (e.g., bleeding disorders unresponsive to Vitamin K or blood products therapy); Removal of stents in biliary strictures caused by benign strictures, as the long-term effects of the stent in the bile duct are unknown. REMOVABILITY OF THIS DEVICE BY ENDOSCOPIC MEANS OR OTHERWISE. Attempts to remove a partially deployed stent through the liver could cause significant bleeding. The safety and efficacy of the material has not been established in the vascular system. Use thoroughly before using the WallFlex Biliary Transhepatic Stent System. The WallFlex Biliary Transhepatic Stent System should only be used by or under the supervision of physicians thoroughly trained in biliary procedure placement. A thorough understanding of the technical principles, clinical applications, and risks associated with this procedure is necessary before use. WARNINGS: Visually inspect the system for any signs of damage. DO NOT USE if the system has any visible signs of damage. Failure to observe this warning may result in patient injury. Passage of a second stent delivery system through a just deployed stent may cause device damage or obstruction of the delivery system; Passage of a second stent delivery system through a just deployed stent may cause device damage or obstruction of the delivery system. Use caution when placing stent over ductal branches to avoid obstruction of the duct. Placement of a partially covered or fully covered biliary stent across a branch duct or major lobarization may result in complications due to blockage of flow from the branch duct and potential entrapment or transhepatic access in future procedures; Stenting across a major lobarization may result in blockage of enteral access or other complications. A detached uncovered stent may cause significant bleeding; The safety and effectiveness of this device for use in the vascular system have not been established; NO WARRANTY IS MADE WITH REGARD TO THE REMOVABILITY OF THIS DEVICE BY ENDOSCOPIC MEANS OR OTHERWISE. Use with care when removing a stent from an intrinsic malignant tumor. Removal may result in perforation, bleeding, tissue abrasion or other patient injury; The uncovered, partially covered or fully covered WallFlex Biliary Transhepatic Stents should not be moved or removed after completion of the initial stent placement procedure in intrinsic malignant tumors. Manipulating, repositioning or removal of the stent may result in perforation, bleeding, tissue abrasion or other patient injury; The uncovered, partially covered or fully covered WallFlex Biliary Transhepatic Stents should not be moved or removed after completion of the initial stent placement procedure in intrinsic malignant tumors. Manipulating, repositioning or removal of the stent may result in perforation, bleeding, tissue abrasion or other patient injury; The device is intended for single use only. Do not attempt to reload or use this device; 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; The device is intended for single use only. Do not attempt to reload deployed stents onto the delivery system; Excessive force should not be used to position or deploy the stent. This may cause inadvertent damage to the device and injury to the patient. ADVERSE EVENTS: Potential Complications associated with the use of this device and transhepatic procedures such as Stent occlusion due to tumor overgrowth; Tumor ingrowth; granulation tissue or sludge formation; Perihepatic bile leak or herniation; the intervention due to embolism; Hepatic Sclerosing Pneumonitis; Nausea; Vomiting; Infection; Inflammation; Recurrent obstructive jaundice; Mucosal hyperplasia; Cholangitis; Cholecystitis; Porocarcinoma; Infection of the gallbladder or bile ducts; Perforation of the biliary ducts or bile ducts; Stent migration or dislodgement; Leak from the stent tract; Leaking from the stent tract; Leaking from the stent tract; Fractures; Abcesses; CAUTION: Federal law restricts these devices to sale by or on the order of a physician. WARNINGS: The safety and effectiveness of this device for use in the vascular system has not been established.
WallFlex™ Biliary Transhepatic Stent System

WallFlex Biliary Stents—the most frequently implanted biliary metal stent throughout the U.S., Canada and Europe—are now available with a transhepatic delivery system designed specifically to meet the needs of Interventional Radiologists. This third-generation stent platform from Boston Scientific was built on clinical evidence and industry-leading innovation. The WallFlex Stents are available in fully covered, partially covered and uncovered options for the palliative treatment of biliary strictures produced by malignant neoplasms.

Clinical Evidence

- “The use of self-expanding metal stents (SEMS) was shown in this meta-analysis to provide a survival advantage when compared to plastic stents—this has never been shown in individual trials, probably due to insufficient statistical power, but bears significant clinical implications.”

- “In endoscopic stent comparisons, metal biliary stents appear to have a lower risk of recurrent biliary obstruction than plastic stents.”

- “…covered SEMS offer superior patency compared with uncovered stents.”

DESIGN FEATURE | INTENDED BENEFIT
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**Innovative Stent Design** | • Looped and flared stent ends—Designed to reduce risk of tissue trauma and stent migration
• Integrated retrieval loop—Fully covered and partially covered stents
• Closed-cell construction and Permalume Covering help resist tissue ingrowth into the stent

**Platinol™ Wire Construction** | • Flexible to aid placement in tortuous anatomies
• Enhanced full-length radiopacity to aid visibility during stent placement
• Platinol™ Wire braid designed to resist compression and maintain stent patency

**Percutaneous Delivery System** | • Reconstrainable up to 80 percent of deployment to aid in repositioning
• Coaxial delivery system assists in smooth delivery and control
• Has a 75 cm working length and is compatible with 9 F introducer sheath

**Catheter Markers** | • Four radiopaque markers aid in visualization and placement

References:

Endoscopic and fluoroscopic images courtesy of Thomas Kowalski, MD.