...the present data clearly suggest that...

...[C]overed SEMS [WallFlex Biliary RX Covered SEMS are associated with more...

was also significantly smaller in the...

with biliary obstruction due to...

Results in other cases may vary.

*Results from case studies are not predictive of...

Clinical Evidence*

reinterventions. It may contribute to...

reduced resource utilization than...

uncovered SEMS in the treatment of...

duration of patency than uncovered...

significantly reduced the number of...

Patients. Consequently, the total cost...

SEMSs, which recommends their use in...

malignant neoplasms. The WallFlex Biliary Stent System is CE Marked (and approved in other regions – check for local availability), and is...

CAUTION: Federal (USA) law restricts this device 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.

Dream Tip, Hydra Jagwire, Permalume, Platinol, and WallFlex are registered or unregistered trademarks of Boston Scientific Corporation or its...

References:


8. Peterson et al. A Multicenter, Prospective Study of a New Fully Covered Expandable Metal Biliary Stent for the Palliative Treatment of Malignant Bile...

9. Kitano et al. Covered Self-Expandable Metal Stents with an Anti-Migration System Improve Patency Duration without Increased Complications...

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2. Kassis et al. Plastic or metal stents for malignant stricture of the common bile duct? Results of a randomized prospective study. GI Endoscopy, 2003;...


Comparison of Resource Utilization. Gastrointestinal Endoscopy, 2012; 75; AB403.


Compared with Uncovered Stents for Distal Biliary Obstruction Caused by Pancreatic Carcinoma: A Randomized Multicenter Trial. The American ...


Gastroenterology, October 2008; Vol. 42, No. 9, 1040-1046.
The WallFlex Biliary RX Stent is a technology built on science and innovation to expand options for the palliative treatment of biliary strictures produced by malignant neoplasms.

Pioneering Designs

Migration Resistance
Looped and flared stent ends designed to reduce the risk of tissue trauma and stent migration.

Tissue In-Growth Prevention
Closed cell construction and Permalume™ covered options designed to resist tissue in-growth.

Flexibility
Platinol™ Wire construction provides greater flexibility aid placement in tortuous anatomies.

Radial Force
Radial force helps maintain stent patency and resist migration.

Removability
Fully and partially covered stents have an integrated retrieval loop, and may be removed during the initial placement procedure.

delivery system

Stent Placement Accuracy
The RX biliary delivery system is reconstrainable up to 80% of deployment to aid in repositioning and is designed to facilitate physician control and locking of the guidewire.

Endoscopic Placement
Closed cell construction and Permalume covered options designed to resist tissue in-growth.

Fluoroscopic Visualization
The four fluoroscopy markers and yellow transition zone are designed to aid in stent placement accuracy when deployed using endoscopic visualization.

* Flexibility varies by size of stent
** In the event of incorrect positioning during the initial stent placement procedure, the partially covered and fully covered stent options may be removed using forceps to grasp the retrieval loop on the end of the stent. Warning: No warranty is made with regard to removability of this device by endoscopic means or otherwise.
*** A stent cannot be reconstrained after the reconstrainment line has been exceeded.
**** Endoscopic and fluoroscopic images courtesy of Adrian Hatfield, MD and Thomas Kowalski, MD.
The Integrated Retrieval Loop

When tension is applied to the retrieval loop using forceps, it causes the entire length and diameter of the stent to narrow to help facilitate removal of the stent during the initial placement.**

The Platinol™ Wire Difference

The unique Platinol Wire construction of the WallFlex™ Biliary RX Stent offers:

- **Flexibility** to aid placement in tortuous anatomies and maintain luminal patency
- Enhanced **full length radiopacity** to aid visibility during stent placement
- **Radial force** helps maintain stent patency and resist migration

“*The WallFlex Biliary Fully Covered Stent yielded technically successful placement with uncomplicated acute removal where required, appropriate reduction in bilirubin levels, and low rates of stent migration and occlusion.*”

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**Platinol Core**

**Nitinol Encasement**

The WallFlex Biliary RX Stent is a technology built on science and innovation to expand options for the palliative treatment of biliary strictures produced by malignant neoplasms.

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Clinical literature reports ease of placement, clinical benefits and cost effectiveness of endoscopically-placed biliary metal stents as superior to plastic stents for most patients with unresectable biliary malignancy.1,2,4,5,6

“Metallic stent performance was superior to plastic for hilar tumor palliation with respect to short-term outcomes, independent of disease severity, Bismuth class or drainage quality.”1

“Metal stent placement is the most effective treatment of inoperable malignant common bile duct stricture…”2

“The more effective [covered] SEMS are recommended in unresectable patients with malignant common bile duct strictures, who survive a median of 4.5 months.”6

---

Platinum Core Nitinol Encasement

*Removability* Fully and partially covered stents have an integrated retrieval loop, and may be removed during the initial placement.**

---

The RX biliary delivery system is reconstrainable up to 80% of deployment to aid in repositioning*** and is designed to facilitate physician control and locking of the guidewire.

Endoscopic Placement

Closed cell construction and Permalume™ covered options designed to resist tissue in-growth.4,6

Fluoroscopic Visualization

The four fluoroscopy markers and yellow transition zone are designed to aid in stent placement accuracy when deployed using endoscopic visualization.

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The WallFlex Biliary Fully Covered Stent yielded technically successful placement with uncomplicated acute removal where required, appropriate reduction in bilirubin levels, and low rates of stent migration and occlusion.”8

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Removability

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Delivery system

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“Covered SEMS are associated with more reduced resource utilization than uncovered SEMS in the treatment of malignant biliary obstruction. This may in part be due to lower incidence of cholangitis, lower rates of hospitalization, and shorter length of stays.”

“…[C]overed SEMS [WallFlex Biliary RX Partially Covered Stent]…had a longer duration of patency than uncovered SEMSs, which recommends their use in the palliative treatment of patients with biliary obstruction due to pancreatic carcinomas.”

“…the present data clearly suggest that covered stents overcome tumor ingrowth and reduce the rate of stent occlusion. Furthermore, the covered metal stent significantly reduced the number of reinterventions. It may contribute to improvement in quality of life of patients. Consequently, the total cost was also significantly smaller in the covered group.”
The WallFlex™ Biliary RX Stent is a technology built on science and innovation to expand options for the palliative treatment of biliary strictures produced by malignant neoplasms.

When tension is applied to the retrieval loop using forceps, it causes the entire length and diameter of the stent to narrow to help facilitate removal of the stent during the initial placement.**

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**The WallFlex Biliary Fully Covered Stent yielded technically successful placement with uncomplicated acute removal where required, appropriate reduction in bilirubin levels, and low rates of stent migration and occlusion.”8

Place your trust in Experience

Pioneering designs
Clinical evidence

Platinum Core Nitinol Encasement

* Flexibility varies by size of stent
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“The more effective [covered] SEMS are recommended in unresectable patients with malignant common bile duct strictures, who survive a median of 4.5 months.”6

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Fully covered, partially covered and uncovered WallFlex Biliary RX Stents are available in multiple sizes to accommodate different anatomical and clinical requirements. These stents may be used with short or long guidewires.

### Ordering Information

#### Fully Covered Stents with Permalume® Covering

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<thead>
<tr>
<th>Order Number</th>
<th>Diameter (mm)</th>
<th>Length (mm)</th>
<th>Covered Length (mm) (PC Only)</th>
<th>Catheter Diameter (F)</th>
<th>Guidewire Diameter</th>
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#### Partially Covered Stents with Permalume Covering

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#### Uncovered Stents

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<td>100</td>
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<td>.035” (.89mm)</td>
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</tbody>
</table>

#### Recommended Guidewires

- **Hydra Jagwire® Guidewire Stiff Shaft .035” (.89mm)–260cm**
  - M00556021: Straight Dream Tip™
  - M00556031: Angled Dream Tip

- **Hydra Jagwire Guidewire Stiff Shaft .035” (.89mm)–450cm**
  - M00556061: Straight Dream Tip
  - M00556071: Angled Dream Tip

### References


### Dream Tip, Hydra Jagwire, Permalume, Platinitol, and WallFlex are registered or unregistered trademarks of Boston Scientific Corporation or its affiliates. All other trademarks are property of their respective owners.

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

The WallFlex Biliary Stent System is FDA-cleared in the US, and is indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms. The WallFlex Biliary Stent System is CE Marked (and approved in other regions – check for local availability), and is indicated for the palliative treatment of biliary strictures produced by malignant neoplasms and the fully covered stents are also indicated for treatment of benign biliary strictures.