Maximize Control.
Minimize Migration.

New SHORT WIRE Delivery System

ConMed

Authorized Distributor of Gore Medical Products

GORE® VIABIL' BILIARY ENDOPROSTHESIS

Intended for palliation of malignant strictures in the biliary tree
Improved treatment of biliary strictures

The self-expanding, fully-covered metal stent is intended for palliation of malignant strictures in the biliary tree. The GORE® VIABIL® Short Wire Biliary Endoprosthesis is the only fully covered metal stent with anti-migration technology proven to minimize the risk of reintervention. Additionally, it offers substantiated evidence in studies that demonstrate sustained long-term patency.

The precision you expect.
Non-foreshortening* stent design and short wire delivery system provide optimal deployment positioning.

The outcomes you demand.
Designed to reduce the risk of migration and premature obstruction, while sustaining long-term patency.

The assurance you can count on.
With a 0.2% average reported migration rate¹, GORE® VIABIL® Short Wire Biliary Endoprosthesis is backed by a device replacement program if a migration occurs.²

We’re so confident, we now offer an ANTI-MIGRATION ASSURANCE PROGRAM Replacement if a device migrates within one full year post implantation**

*If deployed as instructed, the endoprosthesis will not appreciably foreshorten.
**See back for the details of the assurance program.
**Demonstrated low migrations**

1. Fully covered anchoring fins

   Securely holds the device within the duct to minimize the risk of migration, with a reported 0–1.4% migration rate range outperforming BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent migration rates ranging up to 0–13%.

**Optimal Conformability**

2. Nitinol Wire based stent design

   Optimal balance of Radial and Axial force provides the right fit and flexibility to help prevent migration and sludge formation.

3. Durable, non-porous FEP / ePTFE liner

   Prevents tissue ingrowth and promotes conformability.

Prevents tissue ingrowth and promotes conformability. Proven highest patency helps provide a high standard of palliative care for your patients.

**Precise delivery**

New short wire delivery system

Combined short wire delivery system and stent flexibility provides accurate delivery with optimal positioning and deployment.

**Non-foreshortening design**

for precision you can count on.

During delivery:

- Unlike other stents, eliminates repositioning associated with typical push / pull delivery
- Will not appreciably change in length
Unique combination for the treatment of biliary obstruction

Anti-migration design

Unique anti-migration design features atraumatic anchoring fins to help minimize the risk of migration and mitigate clinical challenges.

MIGRATION RATE COMPARISON

Based on 23 papers published from 2002 to 2015.

Average reported migration rate is $0.2\%$.¹

We're so confident, we now offer an ANTI-MIGRATION ASSURANCE PROGRAM

Replacement if a device migrates within one full year post implantation

GORE® VIABL® Biliary Endoprosthesis

0.0% Bezzi M et al.
0.0% Fanelli F et al.
0.0% Hatzidakis A et al.
0.0% Krokidis M et al.
0.0% Irurzun J et al.
0.0% Krokidis M et al.
0.0% Marzio A et al.
0.0% Scheer F et al.
0.0% Schoder M et al.
0.0% Van Steenbergen W
0.0% Zurstrassen CE et al.
1.4% Bakhru M et al.

BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent

Nakai et al. 0.0%
Kitano et al. 0.0%
Kahaleh et al. 1.5%
Petersen et al. 1.7%
Ogawa et al. 2.8%
Korenblit et al. 3.9%
Sampaziotis et al. 4.7%
Siddiqui et al. 5.0%
Lee et al. 7.0%
Chedid et al. 8.8%
Ryozawa et al. 13.0%

0–1.4% (0.2% weighted average)

0–13% (4.6% weighted average)
Preferred balance of Axial and Radial forces* conform to duct anatomy

According to studies by Isayama et al., 2012, stent migration and sludge formation is related to the device conformability in the bile duct, which is influenced by the device’s axial force (Af). A balance of low axial force and moderate radial force (Rf) is preferred for optimal performance.

Low axial force

GORE® VIABIL® Biliary Endoprosthesis is the preferred combination of low Af and moderate Rf to minimize risk of migration, conforming naturally to the bile duct anatomy.

High axial force

SEMS with high Af do not conform well in the curved bile duct, increasing the risk of stent migration. Additionally, the duct tends to kink at the proximal edge of the stent, causing sludge formation or cholangitis.

Preferred combination

Compared to the BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent, the GORE® VIABIL® Biliary Endoprosthesis has low Af and moderate Rf, the preferred combination for reducing migration and achieving higher patency.

Higher primary patency

Clinical performance demonstrates GORE® VIABIL® Biliary Endoprosthesis maintains higher primary patency than the leading competitor at 3, 6, and 12-months. Improved long-term patency can mean an improved quality of life for patients.

* Axial force is the recovery force that leads to straightening after being bent, while Radial force maintains and expands the luminal patency at the stricture once deployed.
Economic impact of migration

Assume your hospital does 100 endoscopic retrograde cholangiopancreatography (ERCP) with stent placements per year, with the average patient survival for malignant strictures being six months.

<table>
<thead>
<tr>
<th>Migration Rate (average)¹</th>
<th>GORE® VIABL® Short Wire Biliary Endoprosthesis</th>
<th>BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated number of reinterventions to manage migrations (per year)</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Estimated patency at six months⁵.⁶</td>
<td>96.2%</td>
<td>84.3%</td>
</tr>
<tr>
<td>Estimated number of reinterventions to manage loss of patency (per year)</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>Total number of reinterventions expected per year</td>
<td>5</td>
<td>21</td>
</tr>
<tr>
<td>Estimated additional cost per year due to reinterventions (includes ERCP + Stent cost)*</td>
<td>$32,205</td>
<td>$151,221</td>
</tr>
</tbody>
</table>

Potential economic impact

If GORE® VIABL® Short Wire Biliary Endoprosthesis was used to treat 100 patients with unresectable malignant biliary strictures, your institution is estimated to annually:

- Eliminate 16 reinterventions due to migrations and reduced patency, and
- Save $116,716 versus using BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent.

*Average cost of inpatient ERCP is $4649. Source: National Healthcare payer database, 2015

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## Sizing and specifications

### Endoscopic

<table>
<thead>
<tr>
<th>GORE® VIABIL® Short Wire Biliary Endoprosthesis Catalogue Number</th>
<th>GORE® VIABIL® Biliary Endoprosthesis Catalogue Number</th>
<th>Endoprosthesis Diameter (mm) × Length (cm)</th>
<th>Working Length of Delivery Catheter (cm)</th>
<th>Drainage Holes Located At the Hilar Region</th>
<th>Transmural Drainage Holes Length (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VSWVN0804</td>
<td>VN0804200</td>
<td>8 x 4</td>
<td>200</td>
<td>No holes</td>
<td>—</td>
</tr>
<tr>
<td>VSWVN0806</td>
<td>VN0806200</td>
<td>8 x 6</td>
<td>200</td>
<td>No holes</td>
<td>—</td>
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<tr>
<td>VSWVN0808</td>
<td>VN0808200</td>
<td>8 x 8</td>
<td>200</td>
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<td>—</td>
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<tr>
<td>VSWVN0810</td>
<td>VN0810200</td>
<td>8 x 10</td>
<td>200</td>
<td>No holes</td>
<td>—</td>
</tr>
<tr>
<td>VSWVN1004</td>
<td>VN1004200</td>
<td>10 x 4</td>
<td>200</td>
<td>No holes</td>
<td>—</td>
</tr>
<tr>
<td>VSWVN1006</td>
<td>VN1006200</td>
<td>10 x 6</td>
<td>200</td>
<td>No holes</td>
<td>—</td>
</tr>
<tr>
<td>VSWVN1008</td>
<td>VN1008200</td>
<td>10 x 8</td>
<td>200</td>
<td>No holes</td>
<td>—</td>
</tr>
<tr>
<td>VSWVN1010</td>
<td>VN1010200</td>
<td>10 x 10</td>
<td>200</td>
<td>No holes</td>
<td>—</td>
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<tr>
<td>VSWVH0806</td>
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<td>2</td>
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<tr>
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<td>8 x 8</td>
<td>200</td>
<td>Holes</td>
<td>2</td>
</tr>
<tr>
<td>VSWVH0810</td>
<td>VH0810200</td>
<td>8 x 10</td>
<td>200</td>
<td>Holes</td>
<td>2</td>
</tr>
<tr>
<td>VSWVH1006</td>
<td>VH1006200</td>
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<td>200</td>
<td>Holes</td>
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<tr>
<td>VSWVH1008</td>
<td>VH1008200</td>
<td>10 x 8</td>
<td>200</td>
<td>Holes</td>
<td>2</td>
</tr>
<tr>
<td>VSWVH1010</td>
<td>VH1010200</td>
<td>10 x 10</td>
<td>200</td>
<td>Holes</td>
<td>2</td>
</tr>
</tbody>
</table>

Sizing, availability, and pricing varies by country. Please check with your representative for availability.
ANTI-MIGRATION ASSURANCE PROGRAM DETAILS

Gore will provide a replacement device of identical dimensions for use with the patient whose device migrates within one year post implantation. The replacement device is only available if GORE® VIABIL® Biliary Endoprosthesis is implanted in accordance with the device Instructions for Use (The GORE® VIABIL® Biliary Endoprosthesis is intended for palliation of malignant strictures in the biliary tree) and the other terms of the program are satisfied. Replacement devices provided under this program are not eligible for the program. Claims under the program are limited to the replacement device. Upon receipt of the appropriate documentation, a replacement device will be provided pursuant to the program accompanied by a no-charge invoice shipped directly to the hospital. The hospital is responsible for reporting the no-charge replacement stent as a discount on the hospital’s cost report. All reports of migration will be documented appropriately within the Gore internal product surveillance process and additional information may be requested. Migrations are a known risk of any biliary endoprosthesis. The provision of a replacement device as part of the program does not constitute an admission that there was a device malfunction or defect or that Gore, its employees or agents, or the Gore device caused or contributed to any complications or injuries. Please see the device Instructions for Use for further information on the device contraindications, warnings, precautions, and potential adverse events. The program is subject to modification or termination by W. L. Gore & Associates without prior notification and this program is only applicable for the United States.

REFERENCES


