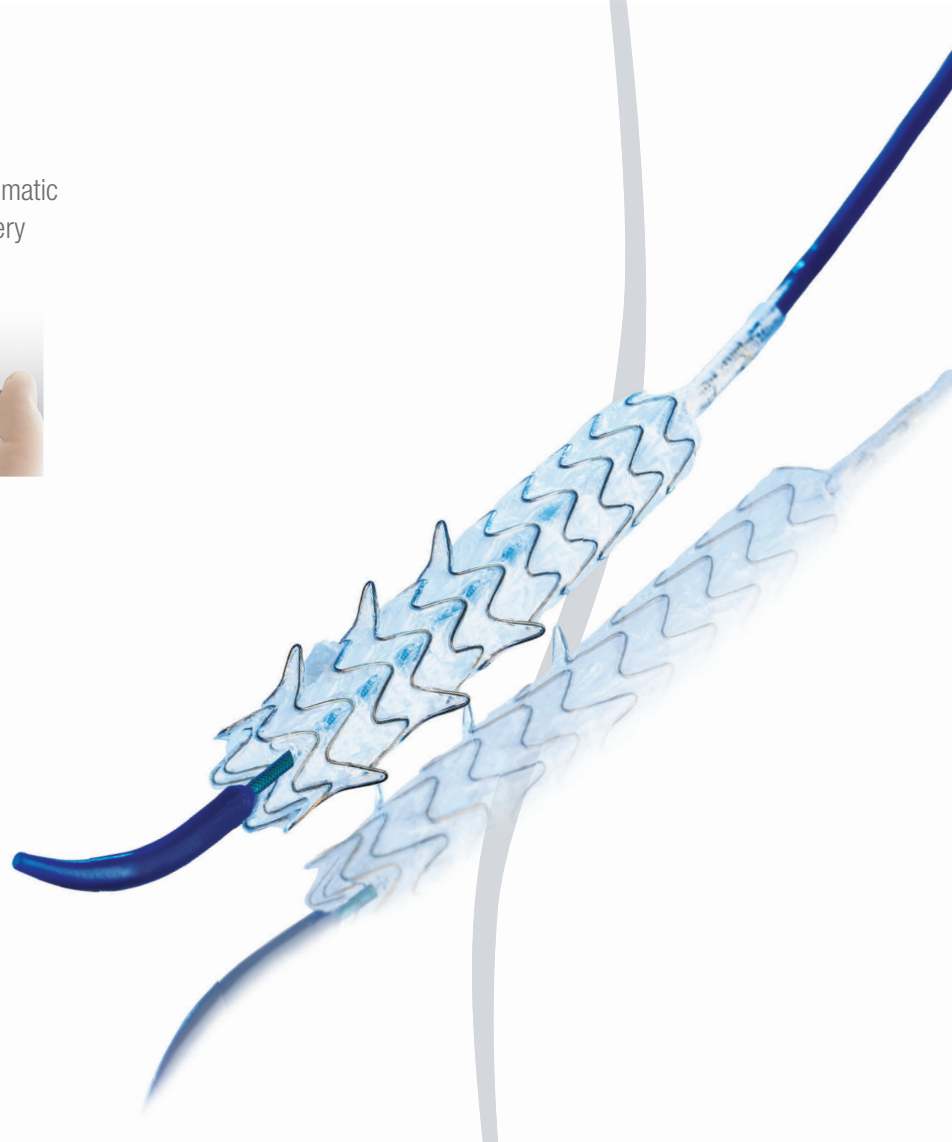


# Gore<sup>®</sup> Viabil<sup>®</sup> Biliary Endoprosthesis

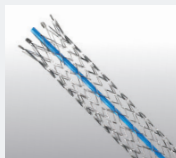
A revolutionary fully covered biliary stent with atraumatic anti-migration anchoring fin technology and delivery system like no other.



**GORE VIABIL<sup>®</sup>**  
BILIARY ENDOPROSTHESIS



**FLEXXUS<sup>®</sup>**  
METAL BILIARY STENTS



**HYDRODUCT<sup>®</sup>**  
PLASTIC BILIARY STENT



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GORE<sup>®</sup> VIABIL<sup>®</sup> Biliary  
Endoprosthesis and other  
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BILIARY  
ENDOPROSTHESIS



## GORE® VIABIL® Biliary Endoprosthesis is a Clinician's Most Balanced Biliary Stent.

Engineered of proprietary design and material, the fully covered GORE® VIABIL® Biliary Endoprosthesis has helped revolutionize the palliation of symptoms caused by malignant biliary obstruction.

### Demonstrated anti-migration

- Atraumatic, deformable anchoring fin technology\*\*

### Accurate easy delivery

- Non shortening stent design\*\*
- Exclusive pull line deployment\*\*
- Radiopaque markers enable precise placement

### Exceptional conformability with uncompromised radial strength

- Nitinol wire exoskeleton with an ultrathin ePTFE/FEP covering\*\*
- Continuous wire stent design naturally follows tortuous anatomy

### Proven long-term patency

- Impermeable ePTFE/FEP covering\*\*
- Prevents tumor ingrowth
- Resists initial bacterial attachment minimizing the risk of bio-sludge occlusion
- High radial strength resists tumor progression

### Minimal risk of branch duct exclusion

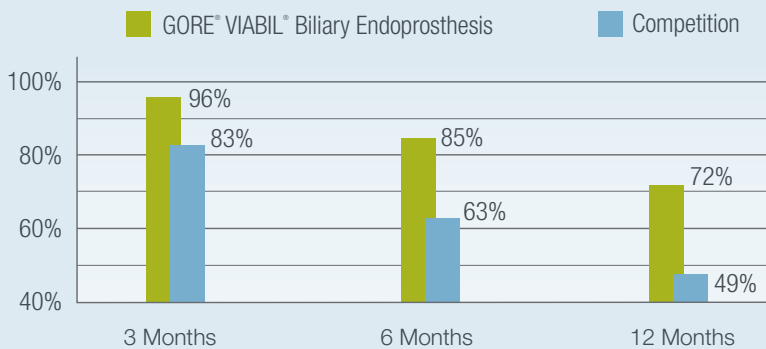
- Optional fenestrations help maintain transmural drainage
- Additional radiopaque marker ensures proper positioning

In the last ten years, more than 700,000 GORE® ePTFE stent grafts<sup>†</sup> have been implanted worldwide.



Available with or without transmural drainage holes

## GORE® VIABIL®<sup>1</sup> Biliary Endoprosthesis vs. Competition<sup>2</sup>

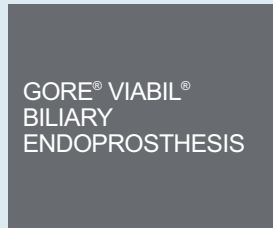


### Proven long-term patency<sup>1</sup>

- Two prospective randomized trials
- Significantly longer patency than bare metal
  - Reduced reintervention rate
  - Cost effective for patients with longer expected survival
  - Improved quality of life

Scientific review of published literature on 663 patients in malignancy<sup>1</sup>

- Lifetime palliation of 87%
- Mean patency
- 3 mo 96% (range 91-100%)
- 6 mo 85% (range 76-100%)
- 12 mo 72% (range 66-91%)



<sup>1</sup> MCM2011100 RevA, © 2012

<sup>2</sup> Kahaleh et al. , Evaluation of Fully Covered Self-Expanding Metal Stent in Malignant Biliary Obstruction, Follow up of a Multi-Center Study, GASTROINTESTINAL ENDOSCOPY Volume 73, No 4S 2011

## A Smooth, Precision Controlled Deployment Platform – Unique To GORE® VIABIL® Biliary Endoprosthesis

The first fully-covered metal stent with a proprietary pull-line deployment system – it is obvious why GORE® VIABIL® Biliary Endoprosthesis is a trusted leader in fully-covered, self-expandable metal stents in the Interventional Endoscopy Market.



Step 1



Step 2



Step 3



Step 4





Eliminates the time and training required with typical push-pull delivery systems.

#### Simple

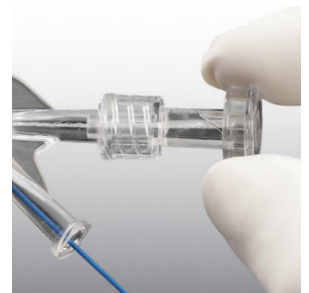
- Accurate positioning  
Promotes a seamless, coordinated deployment process between physician and assistant
- Non foreshortening stent design
- Eliminates repositioning associated with typical push-pull delivery systems
- Precise placement

#### Controlled

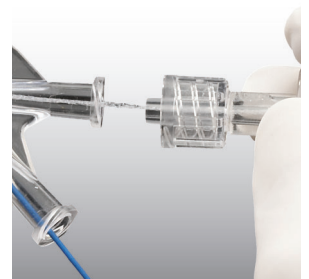
- Gradual, controlled deployment  
Intentional, incremental release of the biliary endoprosthesis  
Offers an easy-to-use alternative to traditional push/pull deployment systems

#### Proprietary

- Proprietary, curved tip  
Navigates challenging biliary anatomy and transitions for smoother catheter advancement and placement
- Ultra-thin, tubular filament pull-line  
Deploys the stent as the interlocking braid is pulled

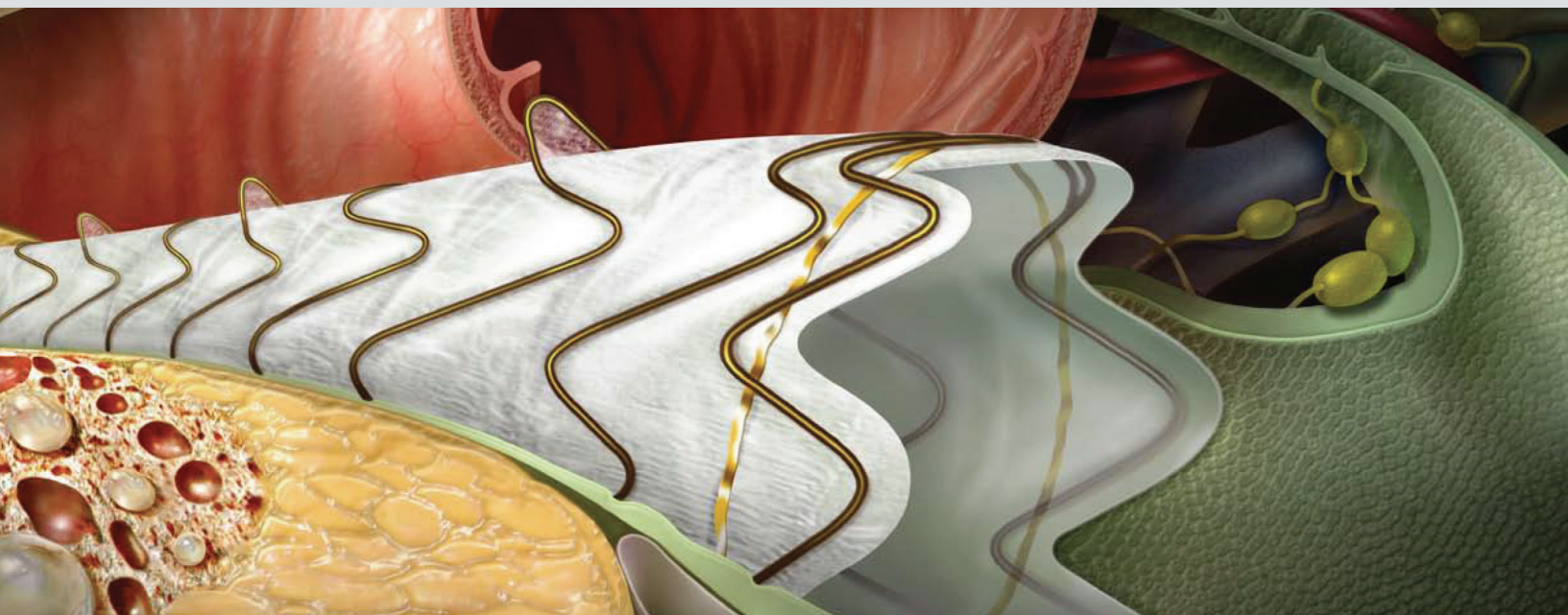


Turn the hub to unlock the deployment system

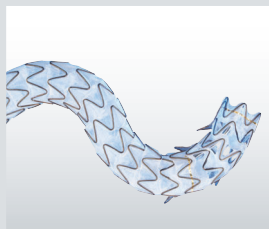


Pull steadily to deploy the prosthesis





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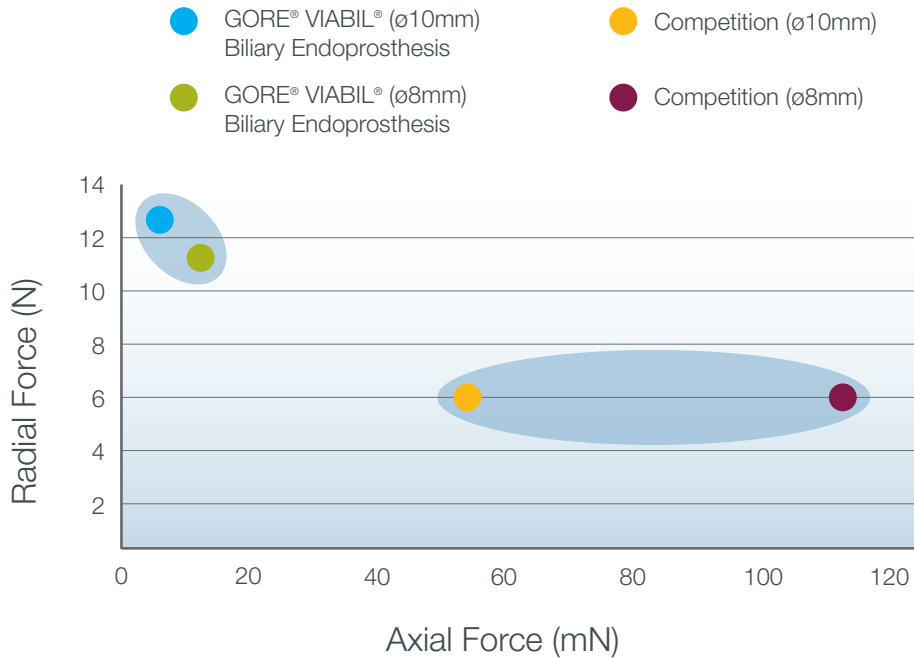


## Atraumatic Anchoring Fin Technology Minimize Migration

Stent migration can offer a number of clinical challenges, including but not limited to the risk of unresolved biliary stricture, pancreatitis, small bowel perforation, bowel obstruction, and peritonitis.

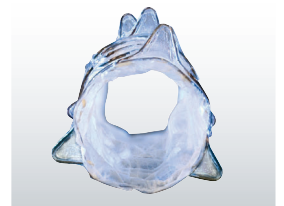
The only endoprosthesis with atraumatic anti-migration technology, GORE® VIABIL® Biliary Endoprosthesis reduces the risk of migration and helps mitigate these clinical challenges. A scientific review of published literature on 663 patients reported an average migration rate of 0.3% compared up to 13%<sup>5</sup>. As a therapeutic option, GORE® VIABIL® Biliary Endoprosthesis allows ease-of-mind while providing proven clinical benefits to your patients.

## GORE® VIABIL® Biliary Endoprosthesis offers a preferred balance of radial strength and conformability.\*



Stents that conform to the biliary tract are less likely to have biliary wall damage, sludge formation and migration.<sup>1</sup> Radial force (RF) and Axial force (AF) are believed to have an effect on the clinical performances such as patency and complications.<sup>1</sup>

- RF maintains and expands the luminal patency at the stricture once the SEMS is deployed.<sup>1</sup>
- AF is the recovery force that leads to a SEMS straightening after being bent.<sup>2</sup>
- With high axial force, the bile duct tends to kink at the proximal edge of the straightening stent, which can cause sludge formation or cholangitis.<sup>2</sup>
- SEMS with high axial force do not fit well in the curved bile duct, which also increases the risk of stent migration.<sup>2</sup>



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\* Data courtesy of W. L. Gore. Data on file, WP103837

<sup>1</sup> Isayama et. al. Measurement of radial and axial forces of biliary self-expandable metallic stents. *Gastrointestinal Endoscopy* 2009;70(1):37-44.

<sup>2</sup> Isayama et. al. Comparison of partially covered Nitinol stents with partially covered stainless stents as a historical control in a multicenter study of distal malignant biliary obstruction: the WATCH study. *Gastrointestinal Endoscopy* 2012 Apr 4 [Epub ahead of print].

## GORE® VIABIL® Biliary Endoprosthesis Ordering Information

Stent Diameter x Length	Catheter Length	O.D.	Unit	Catalog Number
<b>Holes</b>				
8mm x 60mm	200cm	8.5F	1/Box	VH0806200
8mm x 80mm	200cm	8.5F	1/Box	VH0808200
8mm x 100mm	200cm	8.5F	1/Box	VH0810200
10mm x 60mm	200cm	8.5F	1/Box	VH1006200
10mm x 80mm	200cm	8.5F	1/Box	VH1008200
10mm x 100mm	200cm	8.5F	1/Box	VH1010200
<b>No Holes</b>				
8mm x 40mm	200cm	8.5F	1/Box	VN0804200
8mm x 60mm	200cm	8.5F	1/Box	VN0806200
8mm x 80mm	200cm	8.5F	1/Box	VN0808200
8mm x 100mm	200cm	8.5F	1/Box	VN0810200
10mm x 40mm	200cm	8.5F	1/Box	VN1004200
10mm x 60mm	200cm	8.5F	1/Box	VN1006200
10mm x 80mm	200cm	8.5F	1/Box	VN1008200
10mm x 100mm	200cm	8.5F	1/Box	VN1010200

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