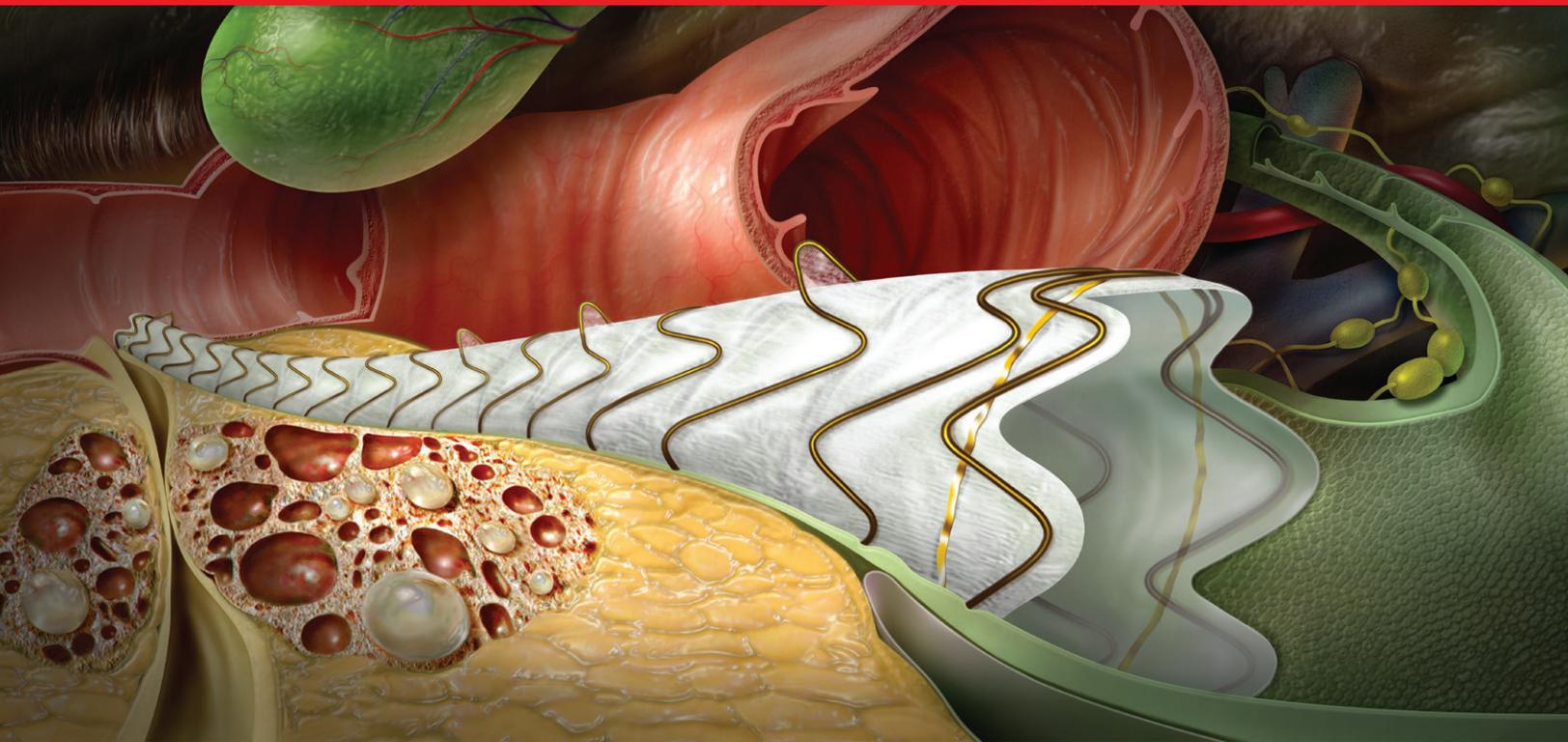


Maximize Control.
Minimize Migration.



New
**SHORT
WIRE**
Delivery System

GORE
VIABIL[®]
SHORT WIRE
BILIARY ENDOPROSTHESIS



Improved treatment of biliary strictures

The self-expanding, fully covered metal stent is indicated for the treatment of benign and malignant biliary strictures and can be removed from such strictures for up to one year post implant.* 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.¹

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 0.25% average reported migration rate for malignant biliary strictures, **GORE® VIABIL® Short Wire Biliary Endoprosthesis** has the lowest reported migration rates in the literature.²

* The non-removable configurations (devices with holes) are intended for palliation of malignant strictures in the biliary tree.

** If deployed as instructed, the endoprosthesis will not appreciably foreshorten.

Demonstrated low migrations

- 1 Fully covered atraumatic anchoring fins

Securely holds the device within the duct to minimize the risk of migration, while the atraumatic covered fins enable easy and safe removal.

Optimal Conformability

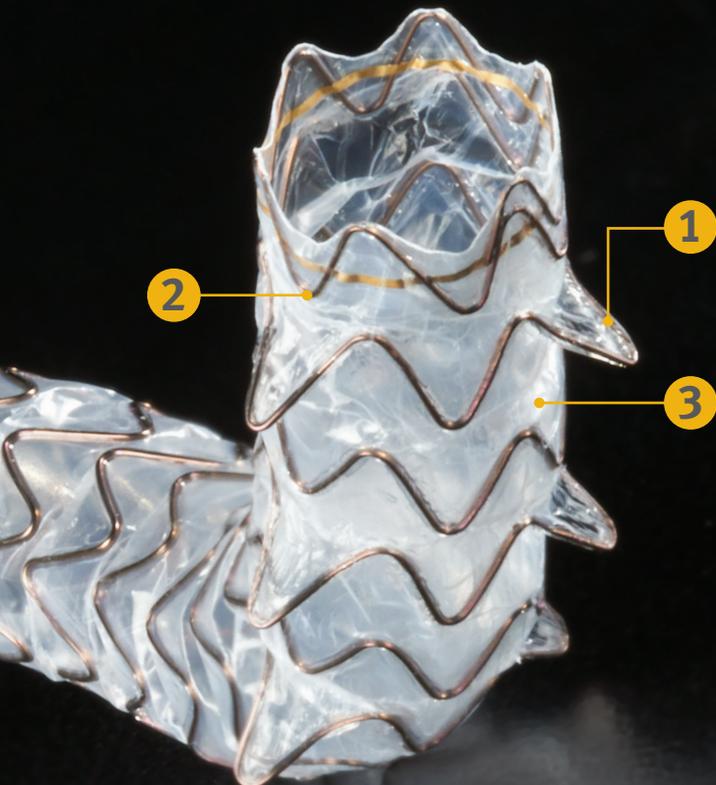
- 2 Nitinol Wire based stent design

Optimal balance of Radial and Axial force provides the right fit and flexibility to help prevent migration and sludge formation.^{3,4}

Prevents tissue ingrowth and promotes conformability¹

- 3 Durable, non-porous FEP / ePTFE liner

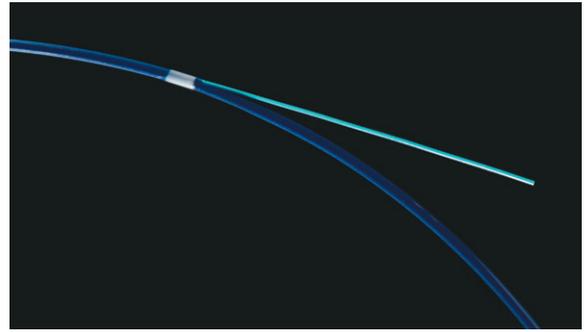
Prevents tissue ingrowth and promotes conformability. Proven highest patency helps provide a high standard of palliative care for your patients.^{,1,5}*



Precise delivery

New short wire delivery system

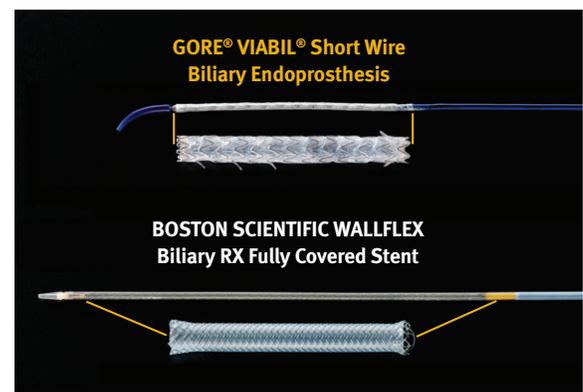
Combined short wire delivery system and stent flexibility provides accurate delivery with optimal positioning and deployment.



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



* Placement of the Non-Removable GORE® VIABIL® Biliary Endoprosthesis with transmural drainage holes in patients with intent to remove the device post implantation is not recommended since ductile tissue ingrowth through the side holes over time may impede device removal.

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Unique combination for the treatment of biliary obstruction

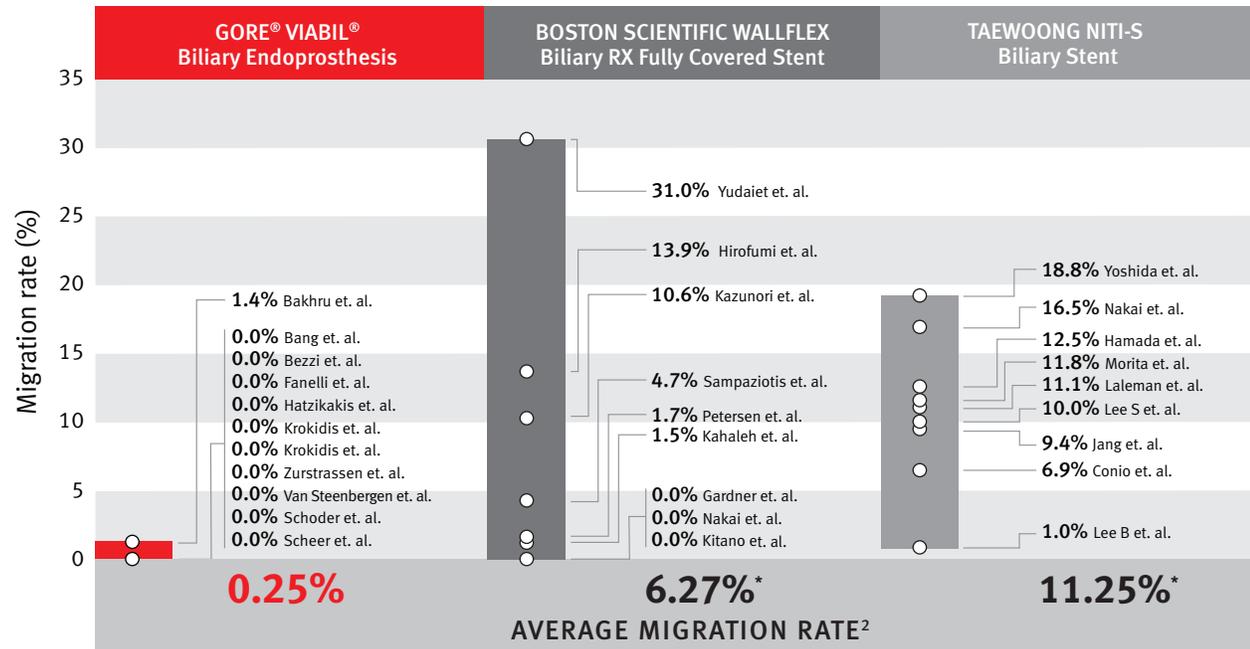
Anti-migration design

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

MIGRATION RATE COMPARISON ²

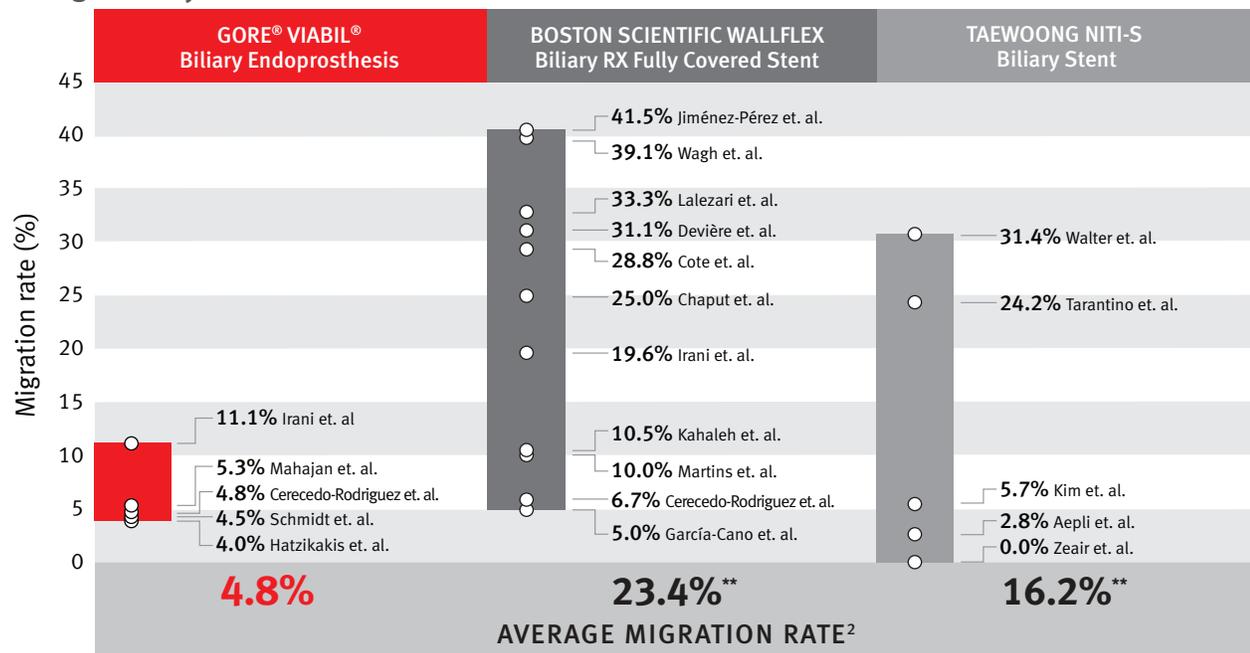
Based on 47 papers published from 2002 to 2018.

Malignant biliary stricture



*p<0.00000001, when compared to GORE® VIABIL® Biliary Endoprosthesis migration rates

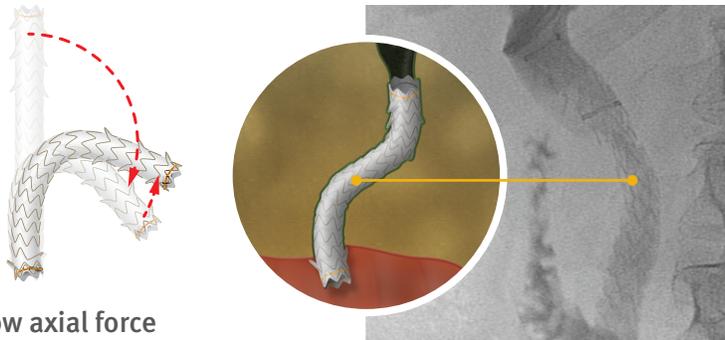
Benign biliary stricture



**p<0.0005, when compared to GORE® VIABIL® Biliary Endoprosthesis migration rates

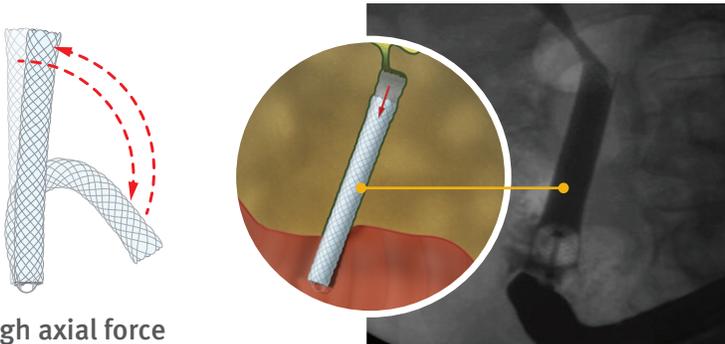
Preferred balance of Axial and Radial forces* conform to duct anatomy

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).³ A balance of low axial force and moderate radial force (Rf) is preferred for optimal performance.⁴



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.⁴

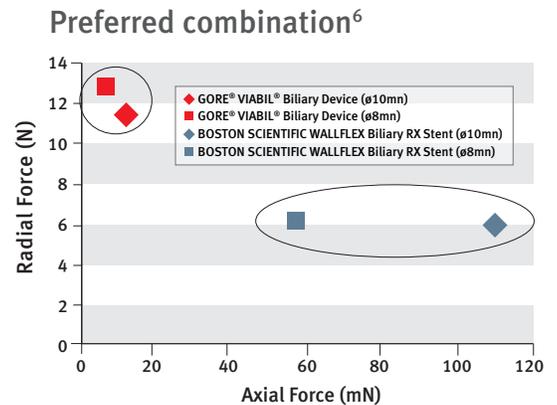


High axial force

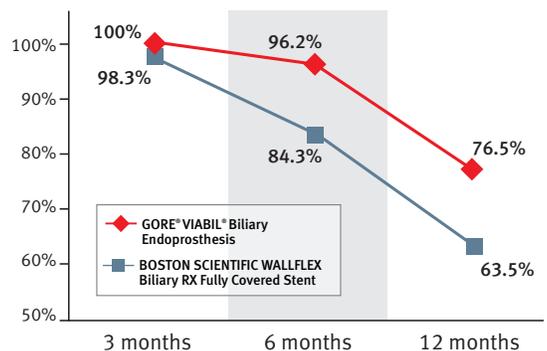
SEMS with high Af do not conform well in the curved bile duct, increasing the risk of stent migration. Additionally, the duct tends to kink at the proximal edge of the stent, causing sludge formation or cholangitis.³

Higher primary patency

Clinical performance demonstrates GORE® VIABIL® Biliary Endoprosthesis maintains higher primary patency than the leading competitor at 3, 6, and 12-months for malignant biliary strictures.^{1,5} Improved long-term patency can mean an improved quality of life for patients.



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.**⁴



* 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.

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Economic impact of migration

Assume your hospital does 100 endoscopic retrograde cholangiopancreatography (ERCP) with stent placements per year.*

	GORE® VIABIL® SHORT WIRE BILIARY ENDOPROSTHESIS	BOSTON SCIENTIFIC WALLFLEX BILIARY RX FULLY COVERED STENT
Malignant migration rate (average) ²	0.25%	6.12%
Benign migration rate (average) ²	4.79%	23.4%
Estimated number of reinterventions to manage migrations (per year) ²	5	29
Estimated additional cost per year due to reinterventions from migrations (includes ERCP + Stent cost)**	\$34,505	\$208,829

Potential economic impact

If GORE® VIABIL® Short Wire Biliary Endoprosthesis was used to treat 100 patients with benign and malignant biliary strictures², your institution is estimated to annually:

ELIMINATE 24 REINTERVENTIONS due to migrations and

SAVE \$174,324

versus using BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent.

*Assume half the ERCP procedures are benign strictures and half are malignant strictures

**Average cost of inpatient ERCP is \$4649. Source: National Healthcare payer database, 2015. Based off of U.S. prices.

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Sizing and specifications

Endoscopic

GORE® VIABIL® SHORT WIRE BILIARY ENDOPROSTHESIS CATALOGUE NUMBER	GORE® VIABIL® BILIARY ENDOPROSTHESIS CATALOGUE NUMBER	ENDOPROSTHESIS DIAMETER (MM) × LENGTH (CM)	WORKING LENGTH OF DELIVERY CATHETER (CM)	DRAINAGE HOLES LOCATED AT THE HILAR REGION	TRANSMURAL DRAINAGE HOLES LENGTH (CM)
REMOVABLE					
VSWVN0804R	VN0804200R	8 x 4	200	No holes	—
VSWVN0806R	VN0806200R	8 x 6	200	No holes	—
VSWVN0808R	VN0808200R	8 x 8	200	No holes	—
VSWVN0810R	VN0810200R	8 x 10	200	No holes	—
VSWVN1004R	VN1004200R	10 x 4	200	No holes	—
VSWVN1006R	VN1006200R	10 x 6	200	No holes	—
VSWVN1008R	VN1008200R	10 x 8	200	No holes	—
VSWVN1010R	VN1010200R	10 x 10	200	No holes	—
NON-REMOVABLE					
VSWVH0806	VH0806200	8 x 6	200	Holes	2
VSWVH0808	VH0808200	8 x 8	200	Holes	2
VSWVH0810	VH0810200	8 x 10	200	Holes	2
VSWVH1006	VH1006200	10 x 6	200	Holes	2
VSWVH1008	VH1008200	10 x 8	200	Holes	2
VSWVH1010	VH1010200	10 x 10	200	Holes	2

Sizing, availability, and pricing varies by country.
Please check with your representative for availability.

REFERENCES

1. Krokidis M, Fanelli F, Orgera G, Bezzi M, Passariello R, Hatzidakis A. Percutaneous treatment of malignant jaundice due to extrahepatic cholangiocarcinoma: covered Viabil stent versus uncovered Wallstents. *Cardiovascular & Interventional Radiology* 2010;33(1):97-106.
2. W. L. Gore & Associates, Inc; *Biliary Fully Covered Metal Stents Systematic Review of the Clinical Literature*. Flagstaff, AZ; 2019. [Work plan]. WP111272.
3. Isayama H, Mukai T, Itoi T, *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;76(1):84-92.
4. Isayama H, Nakai Y, Toyokawa Y, *et al.* Measurement of radial and axial forces of biliary self-expandable metallic stents. *Gastrointestinal Endoscopy* 2009;70(1):37-44.
5. Kitano M, Yamashita Y, Tanaka K, *et al.* Covered self-expandable metal stents with an anti-migration system improve patency duration without increased complications compared with uncovered stents for distal biliary obstruction caused by pancreatic carcinoma: a randomized multicenter trial. *Am J Gastroenterol.* 2013 Nov;108(11):1713-22.
6. W. L. Gore & Associates, Inc; *Radial Force and Bend Stiffness Characterization of Biliary Stents*. Flagstaff, AZ; 2012. [Work plan]. WP103837.



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