



GORE® VIABIL®
Biliary Endoprosthesis

MAXIMIZE CONTROL.
MINIMIZE MIGRATION.



Together, improving life



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® Biliary Endoprosthesis** is a fully covered metal stent with anti-migration technology proven to reduce the risk of reintervention.^{1,2} Additionally, it offers substantiated evidence in studies that demonstrate sustained long-term patency.¹

The precision you expect.

Non-foreshortening[†] stent design and delivery system provides precise 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 percent average reported migration rate for malignant biliary strictures, GORE® VIABIL® Biliary Endoprosthesis has the lowest reported migration rates in the literature.³

* 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.⁴

Optimal conformability

2

Nitinol wire based stent design

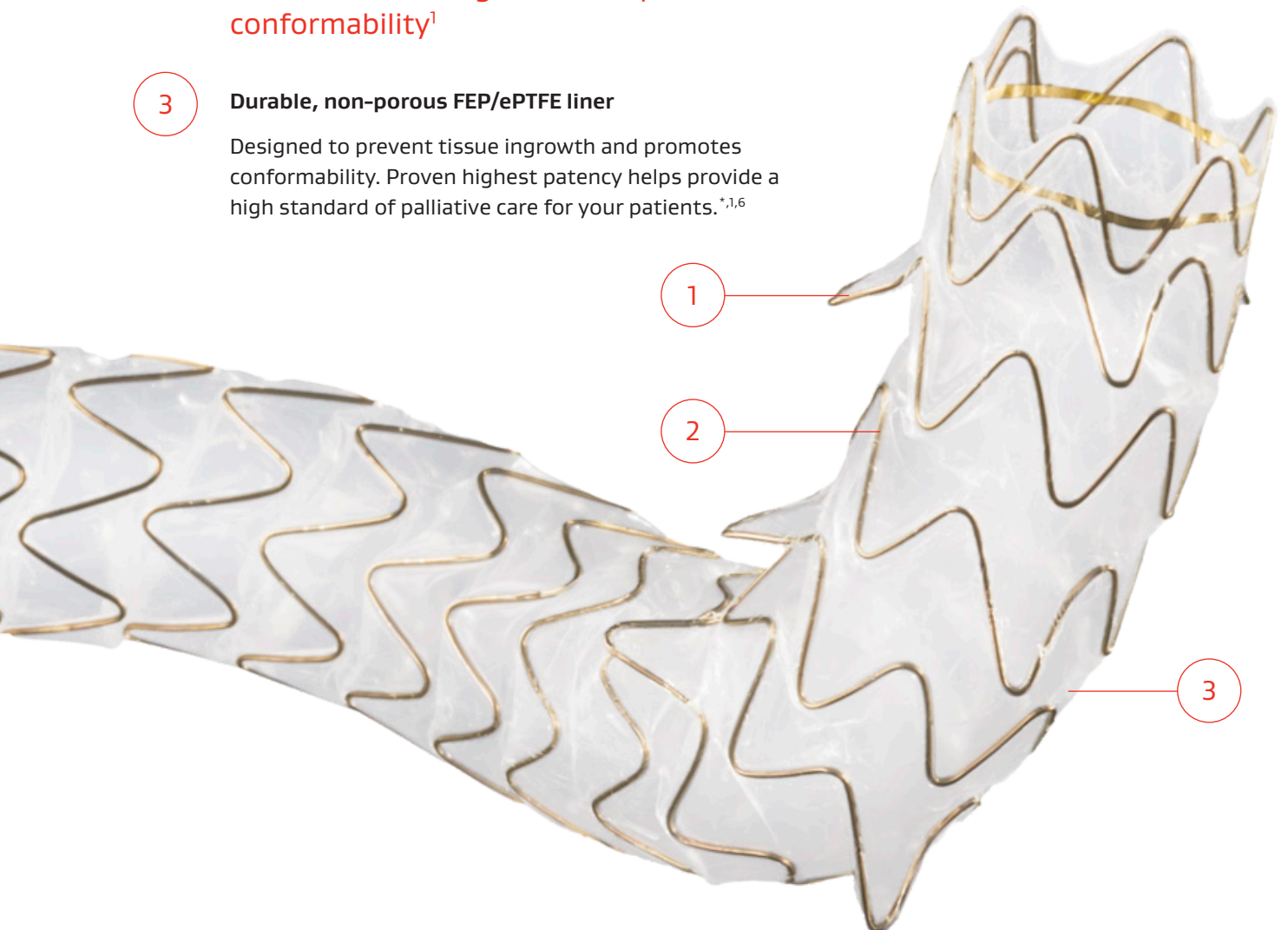
Balance of radial and axial force provides the fit and flexibility to help prevent migration and sludge formation.^{2,5}

Prevents tissue ingrowth and promotes conformability¹

3

Durable, non-porous FEP/ePTFE liner

Designed to prevent tissue ingrowth and promotes conformability. Proven highest patency helps provide a high standard of palliative care for your patients.^{*,1,6}



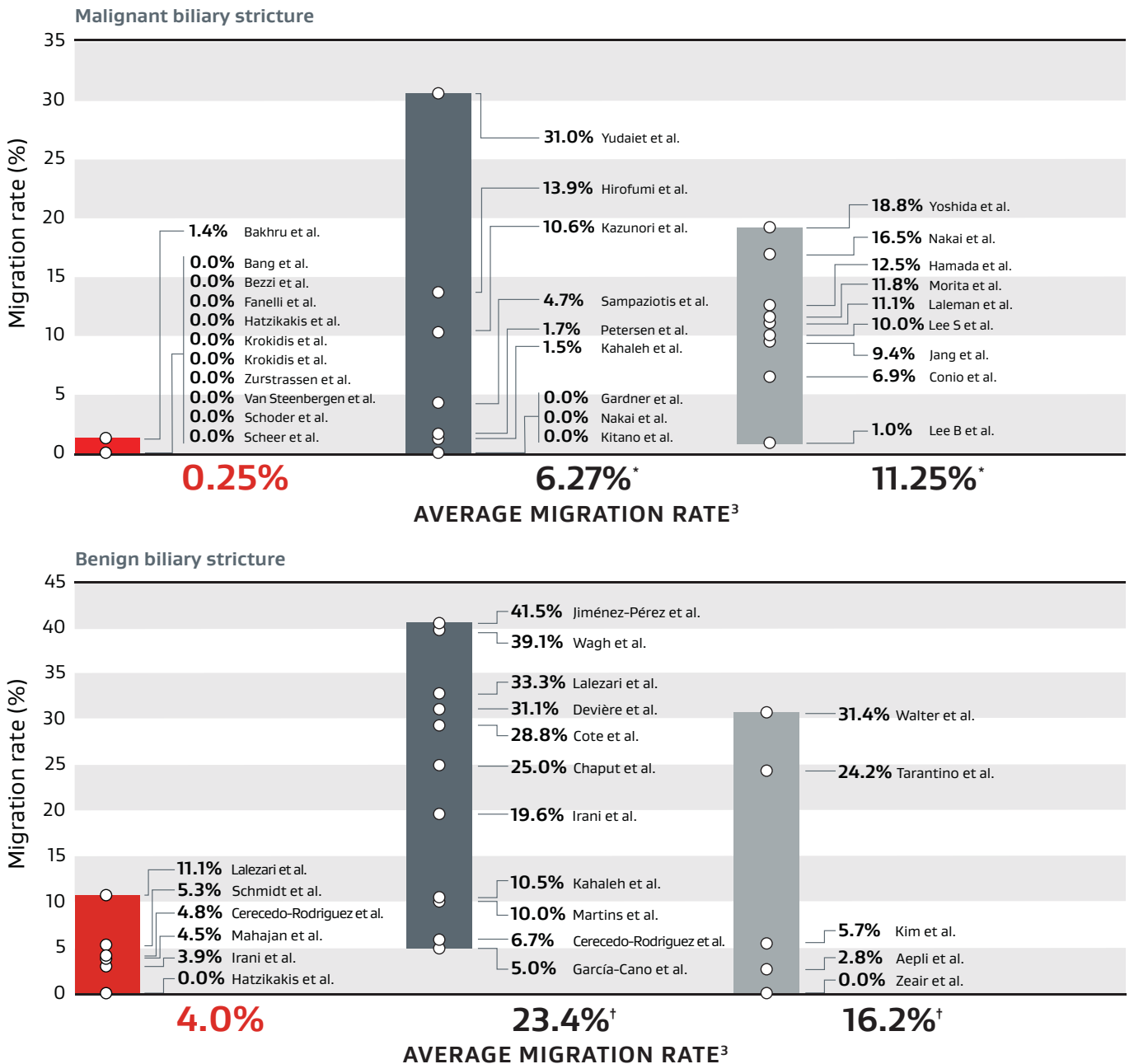
* Placement of the Non-Removable GORE® VIABIL® Biliary Endoprosthesis with transmural drainage holes in patients with intent to remove the device post implantation is not recommended since ductile tissue/tumor ingrowth through the side holes over time may impede device removal. Attempting removal of a device with holes may result in procedural difficulty while attempting removal and other related serious harms.

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 comparison³ (based on 47 papers published from 2002–2018)



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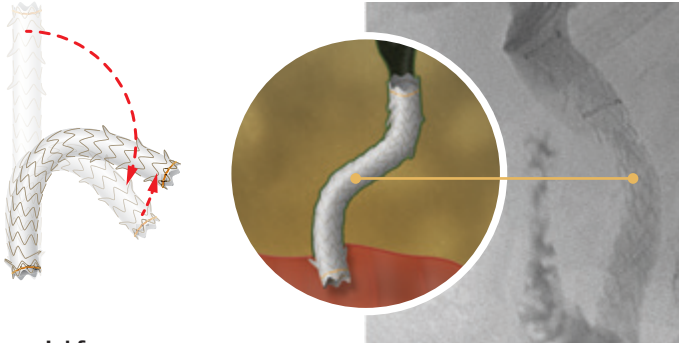
* $P < .00000001$, when compared to GORE® VIABIL® Biliary Endoprosthesis migration rates.

† $P < .0005$, when compared to GORE® VIABIL® Biliary Endoprosthesis migration rates.

- GORE® VIABIL® Biliary Endoprosthesis
- BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent
- TAEWOONG NITI-S Biliary Stent

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).² A balance of low axial force and moderate radial force (Rf) is preferred for optimal performance.⁵



Low axial force

GORE® VIABIL® Biliary Endoprosthesis combines low Af and moderate Rf to minimize risk of migration, conforming naturally to the bile duct anatomy.⁵



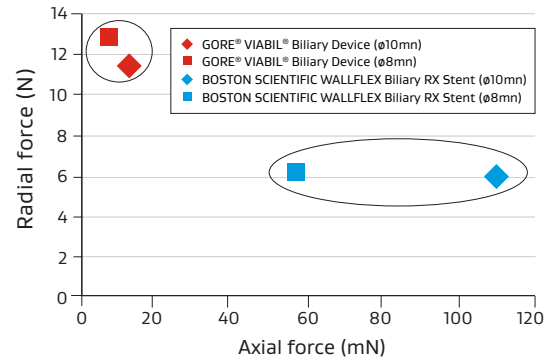
High axial force

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.²

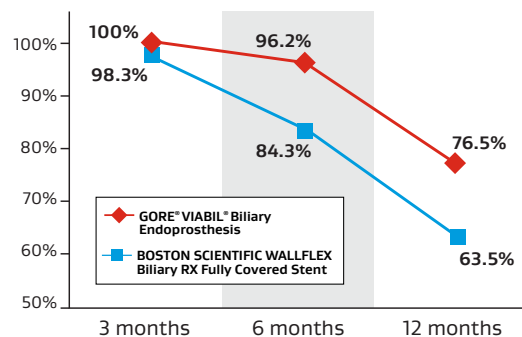
Higher primary patency†

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.^{1,6}

Preferred combination⁷



Compared to the BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent, the GORE® VIABIL® Biliary Endoprosthesis has low Af and moderate Rf⁷, a combination for reducing migration and achieving higher patency.⁵



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* 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.

† There are no head-to-head studies comparing these two products. Instead, these two studies were chosen as a comparison because of the study similarities (all patients had pancreatic carcinomas).

Economic impact of migration

Assume your hospital does 100 percutaneous transhepatic cholangiography (PTC) with stent placements per year, with the average patient survival for malignant strictures being six months.

	GORE® VIABIL® Biliary Endoprosthesis	BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent
Malignant migration rate (average) ³	0.25%	6.27%
Benign migration rate (average) ³	4%	23.4%
Estimated number of reinterventions to manage migrations (per year) ³	5	30

Potential economic impact

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

Eliminate 25 reinterventions

due to migrations versus using BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent.

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