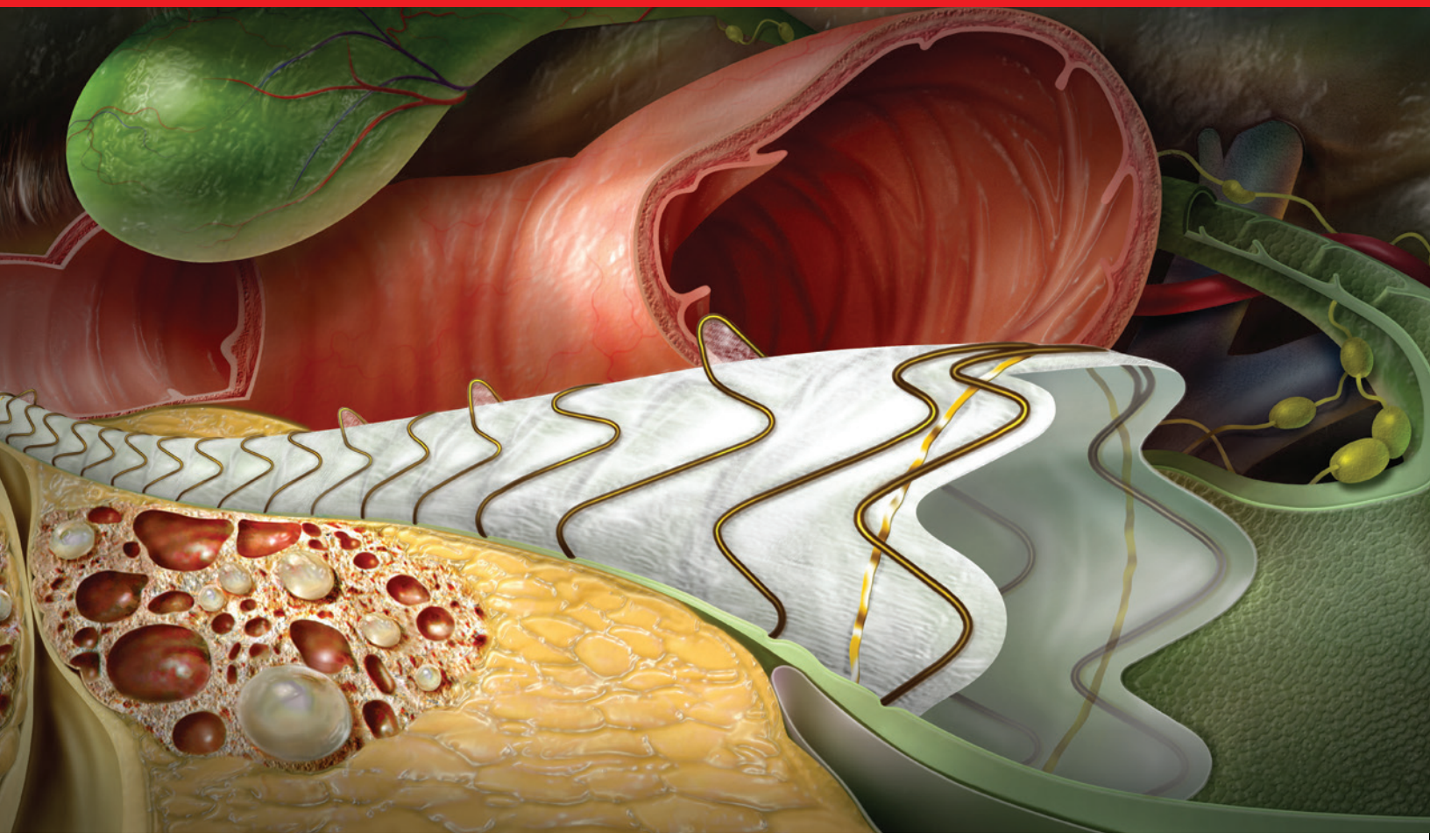
MAXIMIZE Control.
MINIMIZE Migration.

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® 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 provides optimal deployment positioning.

The outcomes you demand

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

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

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 0–31%.[1]

Optimal conformability

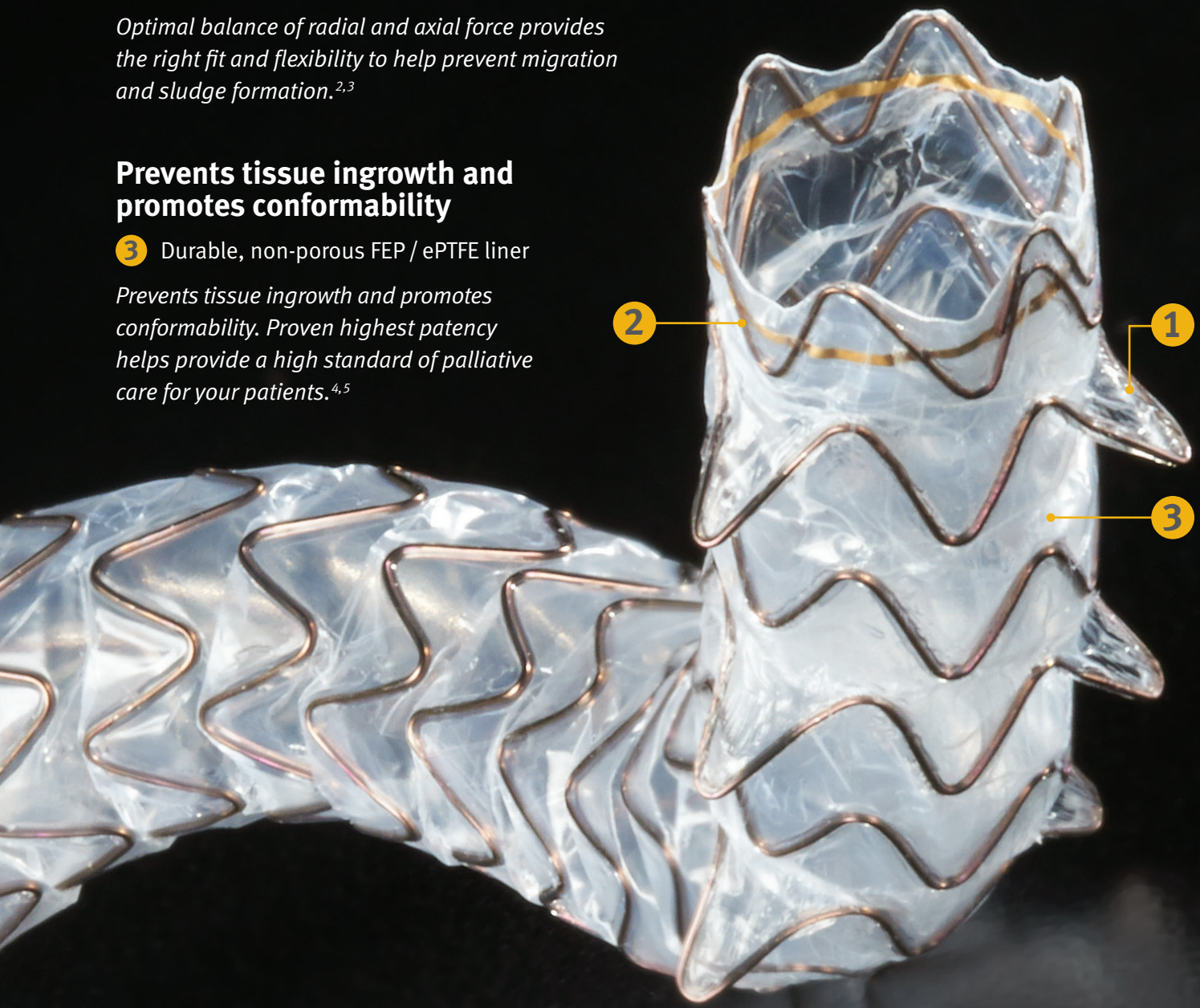
2 Nitinol wire based stent design

Optimal balance of radial and axial force provides the right fit and flexibility to help prevent migration and sludge formation.[2,3]

Prevents tissue ingrowth and promotes conformability

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.[4,5]



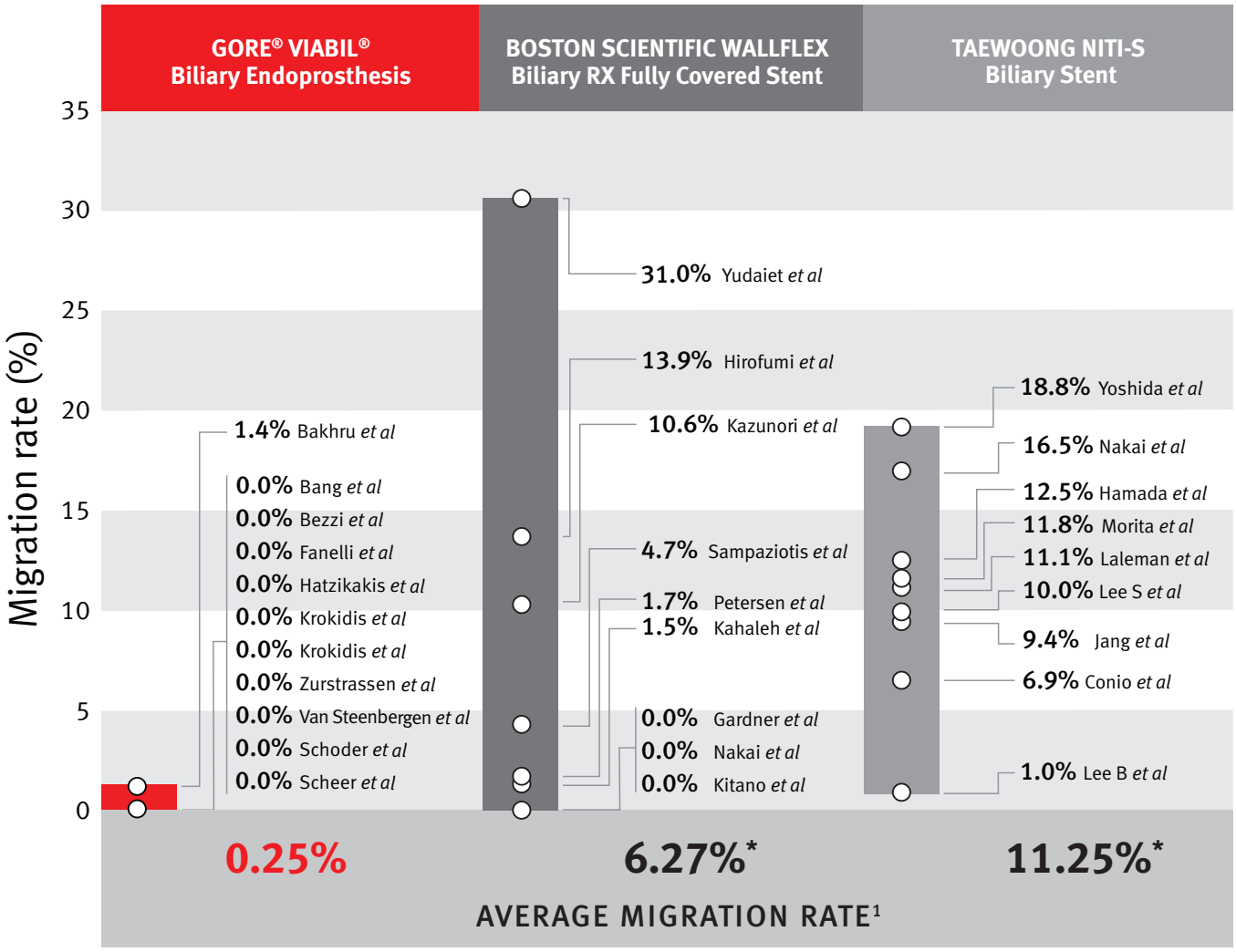
Unique combination for the treatment of biliary obstruction

Anti-migration design

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

Malignant biliary stricture migration rate comparison[1]

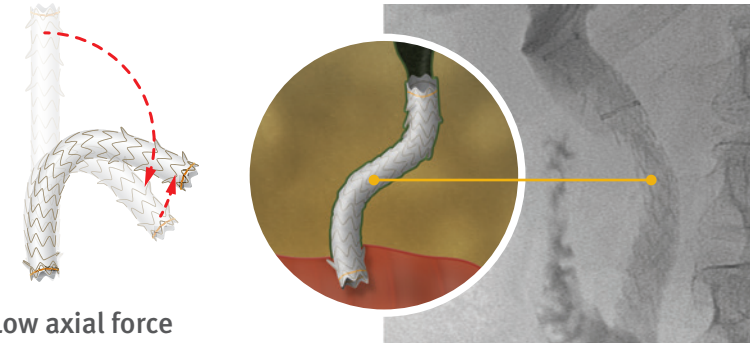
Based on 47 papers published from 2002 to 2018.



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

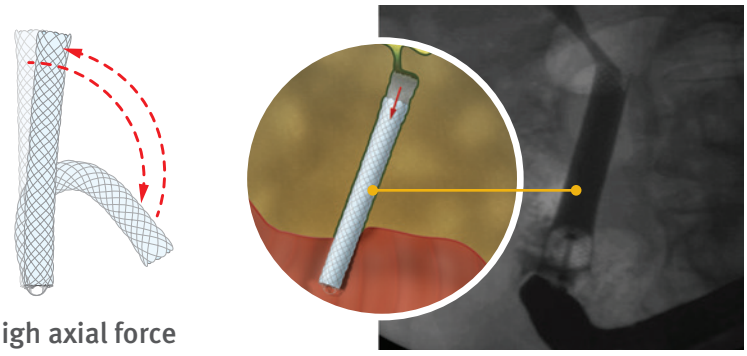
Preferred balance of axial and radial forces* conform to duct anatomy

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



Low axial force

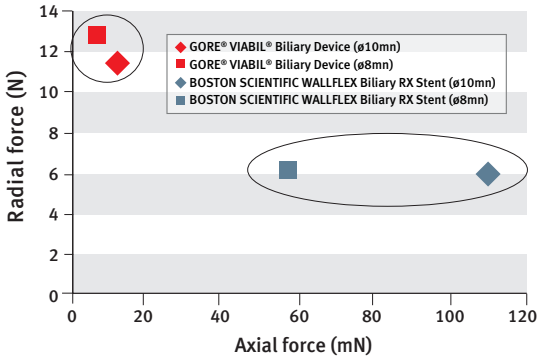
GORE® VIABIL® Biliary Endoprosthesis is the preferred combination of low Af and moderate Rf to minimize risk of migration, conforming naturally to the bile duct anatomy.[3]



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]

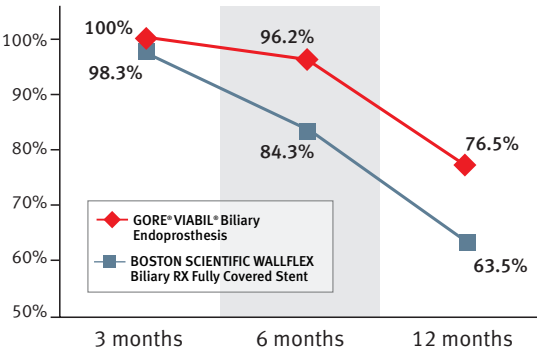
Preferred combination



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.**[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.**[4,5] 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 Percutaneus 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
Migration rate (average)[1]	0.25%	6.27%
Estimated number of reinterventions to manage migrations (per year)	1	6
Estimated patency at six months[4,5]	96.2%	84.3%
Estimated number of reinterventions to manage loss of patency (per year)	4	16
Total number of reinterventions expected per year	5	22
Estimated additional cost per year due to reinterventions (includes PTC + stent cost)*	**$39,600**	**$180,840**

Potential economic impact

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

ELIMINATE 17 REINTERVENTIONS
due to migrations and reduced patency, and

SAVE $141,240
versus using BOSTON SCIENTIFIC WALLFLEX Biliary RX Fully Covered Stent.

* Average cost of percutaneous reintervention is $5,668. Source: Premier Healthcare Database, 2019.

Sizing and specifications

Catalogue number	Endoprosthesis diameter (mm) × length (cm)	Working length of delivery catheter (cm)	Drainage holes located at the hilar region
VN0804040	8 × 4	40	No holes
VN0806040	8 × 6	40	No holes
VN0808040	8 × 8	40	No holes
VN0810040	8 × 10	40	No holes
VN1004040	10 × 4	40	No holes
VN1006040	10 × 6	40	No holes
VN1008040	10 × 8	40	No holes
VN1010040	10 × 10	40	No holes
VH0806040	8 × 6	40	Holes
VH0808040	8 × 8	40	Holes
VH0810040	8 × 10	40	Holes
VH1006040	10 × 6	40	Holes
VH1008040	10 × 8	40	Holes
VH1010040	10 × 10	40	Holes

Sizing, availability and pricing varies by country.
Please check with your field sales associate for availability.

References

1. W. L. Gore & Associates, Inc; *Biliary Fully Covered Metal Stents Systematic Review of the Clinical Literature.* Flagstaff, AZ; 2019. [Work plan]. WP111272
2. 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.
3. 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.
4. 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.
5. 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.

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