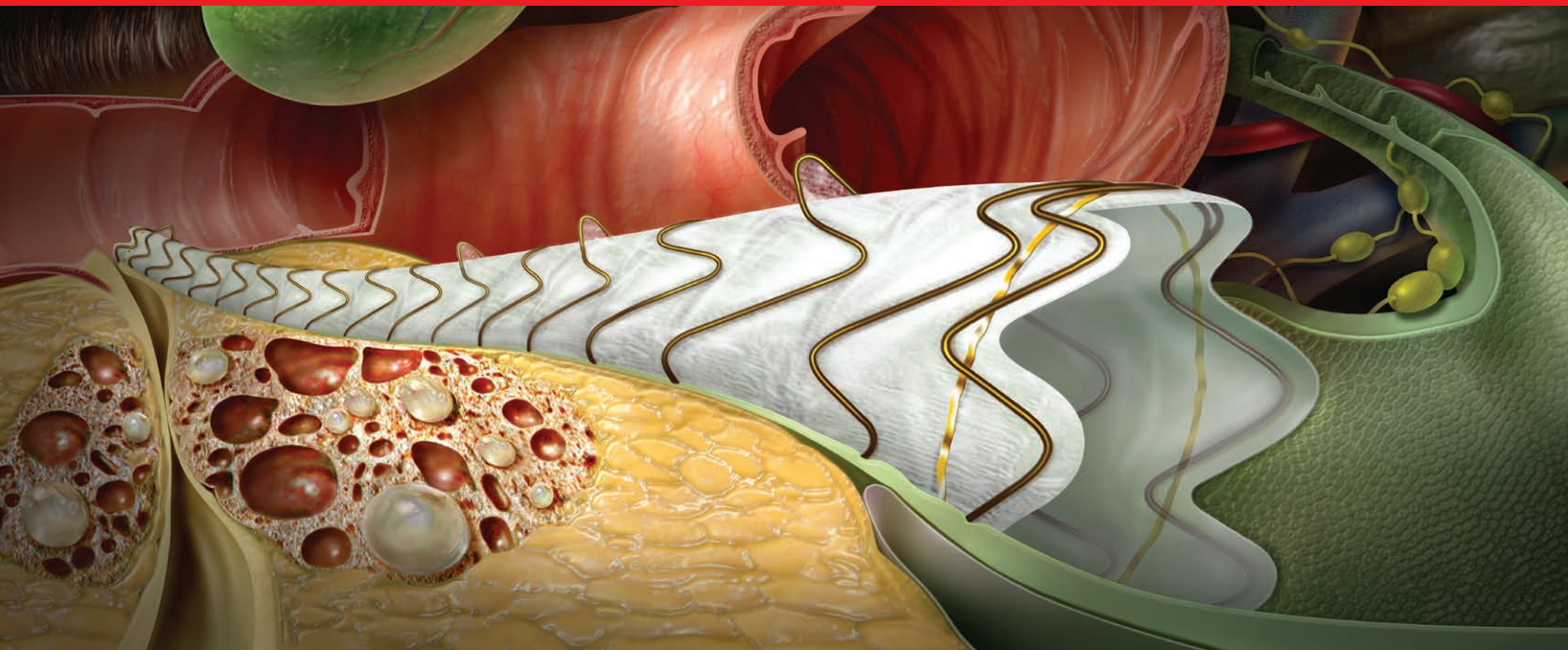


Maximize Control.
Minimize Migration.



GORE® VIABIL® Short Wire Biliary Endoprosthesis
Short Wire Delivery System





Improved treatment of biliary strictures

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 self-expanding, fully covered metal stent is intended for palliation of malignant strictures in the biliary tree.

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,¹ **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†

» More Details on Anti-Migration Assurance Program

* 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%.¹

Optimal conformability

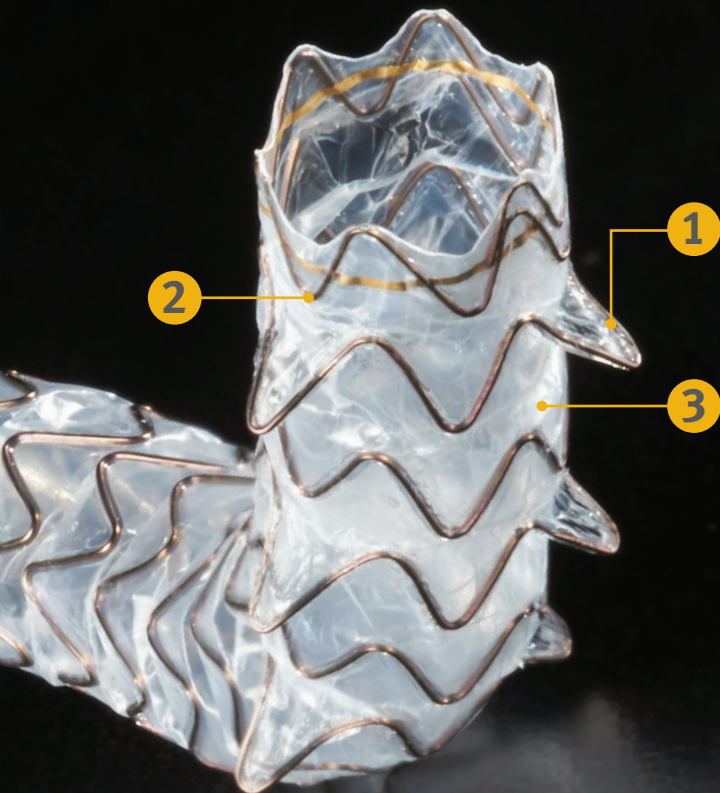
2 Nitinol Wire based stent design

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

Prevents tissue ingrowth and promotes conformability

3 Durable, non-porous FEP/ ePTFE liner

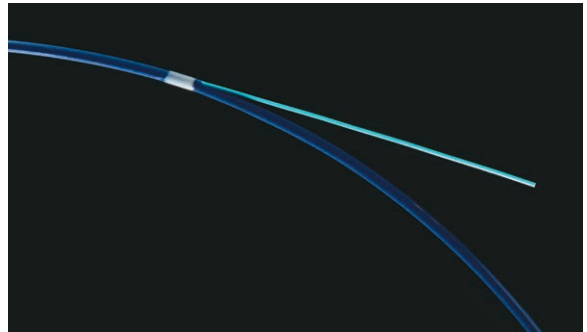
Prevents tissue ingrowth and promotes conformability. Proven highest patency helps provide a high standard of palliative care for your patients.^{5,6}



Precise delivery

New short wire delivery system

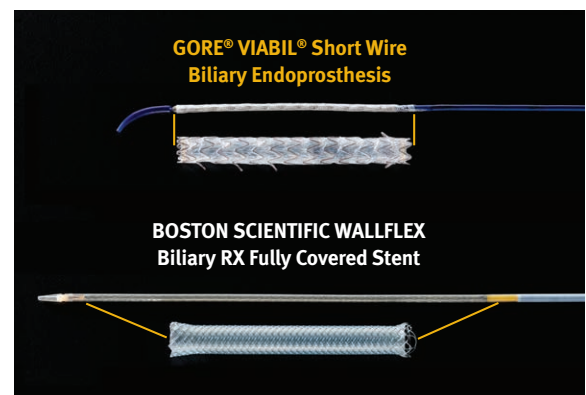
Combined short wire delivery system and stent flexibility provides accurate delivery with optimal positioning and deployment.



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



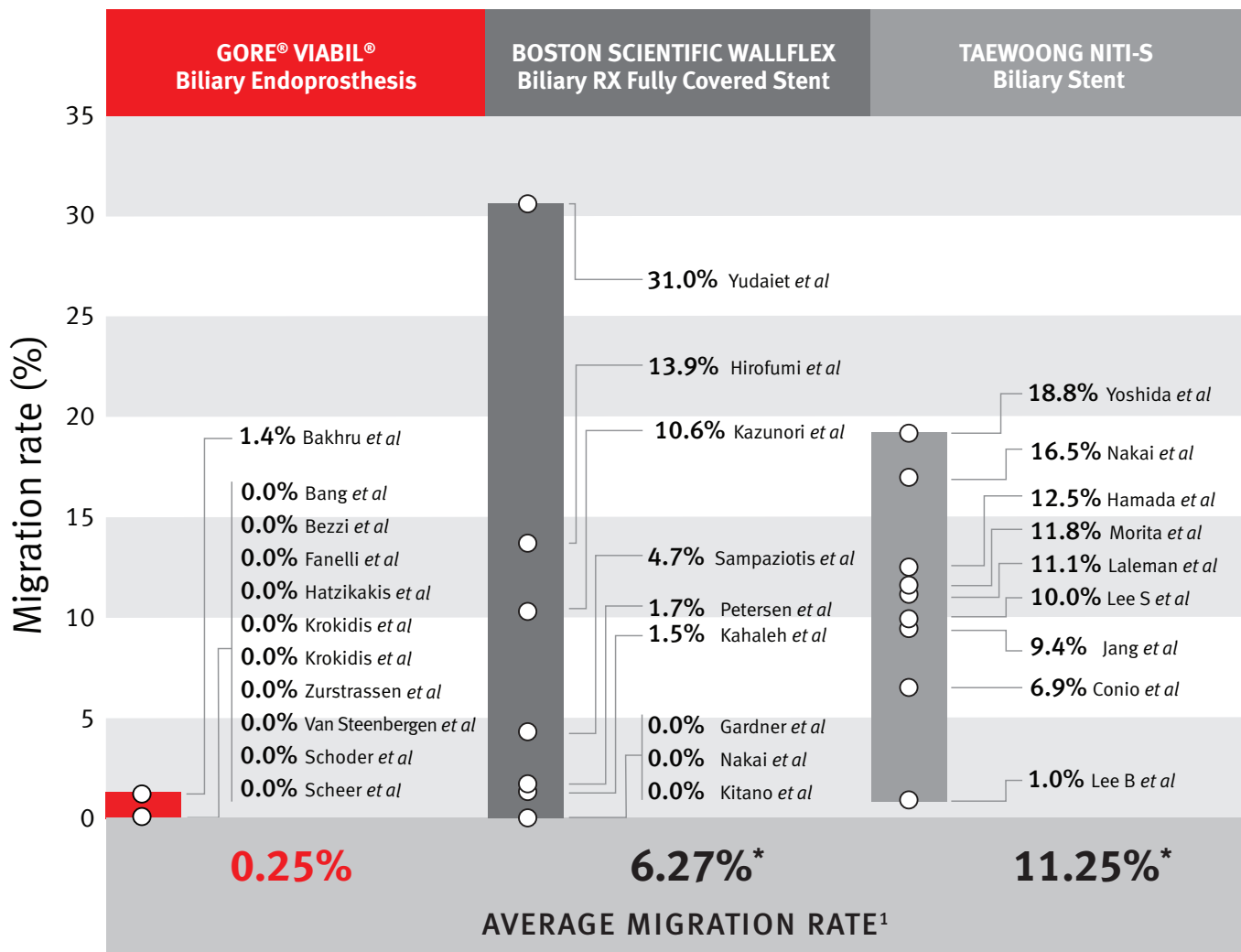
Unique combination for the treatment of biliary obstruction

Anti-migration design

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

Malignant biliary stricture migration rate comparison¹

Based on over 25 scientific publications between 2002 and 2018.

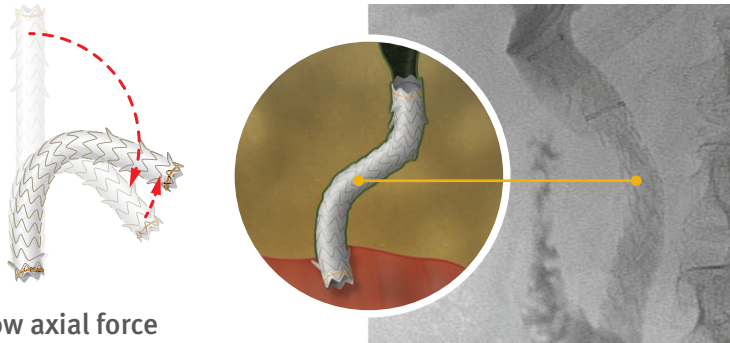


* p < 0.00000001, when compared to GORE® VIABIL® Biliary Endoprosthesis migration rates

BOSTON SCIENTIFIC and WALLFLEX are trademarks of Boston Scientific Corporation. TAEWOONG and NITI-S are trademarks of Taewoong Medical Co., Ltd.

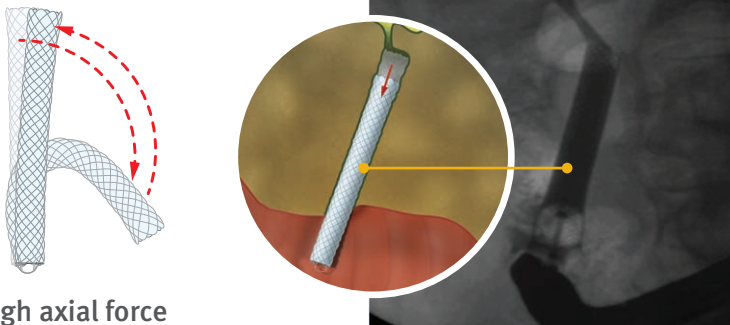
Preferred balance of axial and radial forces* conform to duct anatomy

According to published studies by Isayama et al, 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

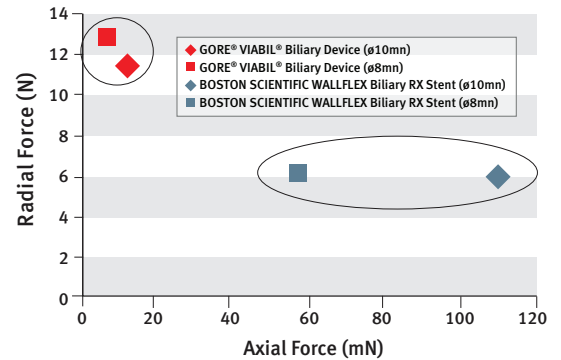
GORE® VIABIL® Biliary Endoprosthesis is the preferred combination of low Af and moderate Rf to minimize risk of migration, conforming naturally to the bile duct anatomy.⁴



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

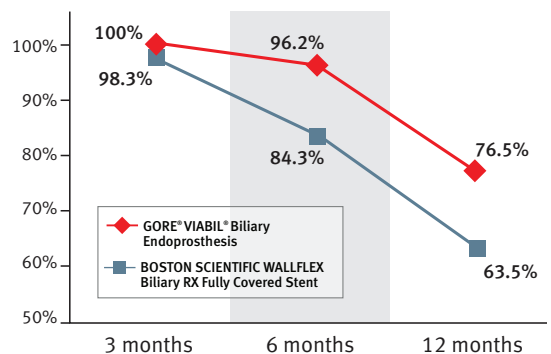
Preferred combination



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.⁴

Higher primary patency

Clinical performance demonstrates GORE® VIABIL® Biliary Endoprosthesis maintains higher primary patency than the leading competitor at 3, 6, and 12-months.^{5,6} 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.

	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	7
Estimated patency at six months ^{5,6}	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	23
Estimated additional cost per year due to reinterventions (includes ERCP + stent cost)*	\$34,750	\$164,563

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 18 REINTERVENTIONS
due to migrations and reduced patency, and
SAVE \$130,000
versus using BOSTON SCIENTIFIC
WALLFLEX Biliary RX Fully Covered Stent.

* Average cost of inpatient ERCP is \$4,649. Source: National Healthcare payer database, 2015. Based off of U.S. prices.

Gore has used reasonable efforts to ensure the completeness and accuracy of the information contained herein as of the date this document was prepared. Gore is not liable for any claims or actions attributable to the use of this, nor for any errors or omissions involved in the use of the information, or the results. Payment policies are variable depending on the payer, geographic location and provider specific contracts. The models provided here are for illustrative purposes only and are not intended to be indicative of payment from any payer.

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)
VSWVN0804	VN0804200	8 × 4	200	No holes	—
VSWVN0806	VN0806200	8 × 6	200	No holes	—
VSWVN0808	VN0808200	8 × 8	200	No holes	—
VSWVN0810	VN0810200	8 × 10	200	No holes	—
VSWVN1004	VN1004200	10 × 4	200	No holes	—
VSWVN1006	VN1006200	10 × 6	200	No holes	—
VSWVN1008	VN1008200	10 × 8	200	No holes	—
VSWVN1010	VN1010200	10 × 10	200	No holes	—
VSWVH0806	VH0806200	8 × 6	200	Holes	2
VSWVH0808	VH0808200	8 × 8	200	Holes	2
VSWVH0810	VH0810200	8 × 10	200	Holes	2
VSWVH1006	VH1006200	10 × 6	200	Holes	2
VSWVH1008	VH1008200	10 × 8	200	Holes	2
VSWVH1010	VH1010200	10 × 10	200	Holes	2

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

1. W. L. Gore & Associates, Inc., *Biliary Fully Covered Metal Stents Systematic Review of the Clinical Literature*. Flagstaff, AZ; 2019. [Work plan]. WP11272.
2. W. L. Gore & Associates, Inc. Reduce the risk of reintervention. *GORE® VIABIL® Biliary Endoprosthesis Assurance Brochure*. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2017. [Flyer]. AW0165-EN2.
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. 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.

 Consult Instructions
for Use
eifu.goremedical.com

Physicians should refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available.^{® Only}

Products listed may not be available in all markets.

WALLFLEX is a trademark of Boston Scientific Corporation.
CONMED and designs are trademarks of CONMED Corporation.

GORE, VIABIL and designs are trademarks of W. L. Gore & Associates.
© 2021 W. L. Gore & Associates, Inc. 2024827-EN FEBRUARY 2021



W. L. GORE & ASSOCIATES, INC.
Flagstaff, AZ 86004

+65 67332882 (Asia Pacific)
1 800 680 424 (Australia/New Zealand)
00800 6334 4673 (Europe)
800 437 8181 (United States)
928 779 2771 (United States)

goremedical.com