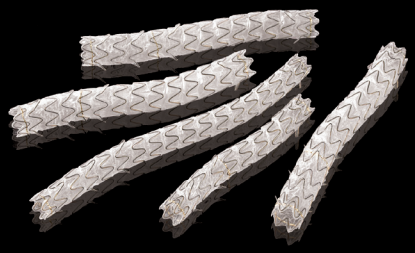


GORE® VIABIL® Biliary Endoprosthesis

PERFORMANCE through data

SIZING TABLE

Nominal Endoprosthesis Diameter[1]	Recommended Duct Diameter[2]	Nominal Endoprosthesis Lengths[3]	Sheath Size	Guidewire Diameter (Preferably Stiff or Extra Stiff)	Working Length of the Delivery Catheter	Recommended Balloon Diameter for Device Touch-up
8 mm	5.5 mm – 6.9 mm	4 cm, 6 cm, 8 cm, 10 cm	10 Fr	0.035" (0.89 mm)	40 cm	‹ 8 mm
10 mm	7.0 mm – 9.0 mm	4 cm, 6 cm, 8 cm, 10 cm	10 Fr	0.035" (0.89 mm)	40 cm	‹ 10 mm

[1] The outwardly directed anchoring fins extend slightly beyond the nominal diameter of the endoprosthesis

[2] Recommended device diametrical oversizing relative to the non-dilated duct is 10–30%

[3] Recommended endoprosthesis length should include ≥ 2 cm on each side of stricture

Note: If multiple devices are used, it is recommended that devices of the same diameter be used and are overlapped by at least 1 cm.

GORE
Creative Technologies Worldwide

W. L. Gore & Associates, Inc.
Flagstaff, AZ 86004

+65.67332882 (Asia Pacific)
00800.6334.4673 (Europe)
800.437.8181 (United States)
928.779.2771 (United States)

goremedical.com

INDICATIONS FOR USE:

USA: THE GORE® VIABIL® Biliary Endoprosthesis is indicated for the treatment of malignant biliary strictures.

EUROPE AND CANADA: The Removable GORE® VIABIL® Biliary Endoprosthesis 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.

Refer to *Instructions For Use* for a complete description of all warnings, precautions, and contraindications. ℞ Only

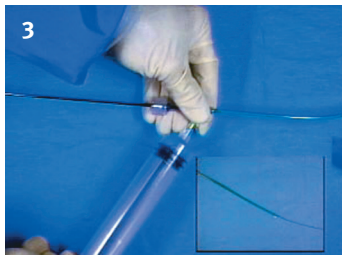
Products listed may not be available in all markets. For product availability in regions not listed, please contact W. L. Gore & Associates, Inc.

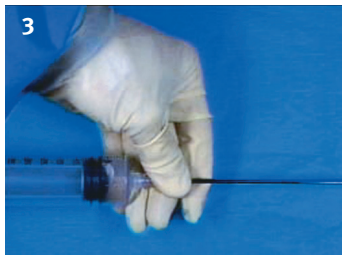
 AF5112-EN4 APRIL 2013

Percutaneous Implantation – Tips for Success

1 Measurements – Baseline Percutaneous Transhepatic Cholangiography (PTC)

- Place a guidewire across the obstruction and take the following measurements:
  - Proximal and distal native duct diameter
  - Length of stricture





2 Device Selection

- Select the appropriate device (diameter and length) from the sizing table (see reverse)
- When selecting device length, add 4 cm (2 cm on each side) to the length of the stricture unless extending device into duodenum.
- Transmural holes: when to use
  - To preserve flow in cases where deployment across a branch duct or the cystic duct is necessary
  - CONSIDERATIONS: Branch blockage → symptom recurrence, cholangitis vs. potential for tumor ingrowth
  - CONFIGURATION:
    - Present on the hepatic end (2 cm from end) of endoprosthesis
    - Radiopaque markers on the endoprosthesis indicate the location of the holes

3 Device Preparation

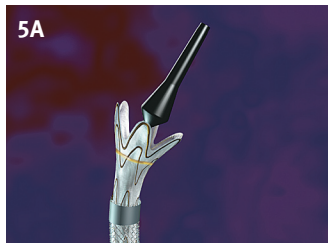
- Inspect for damage
- Flush stent port and guidewire lumens

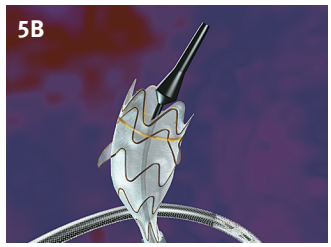
4 Insertion and Positioning of Device

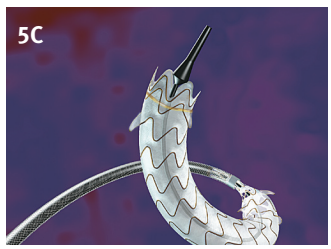
- 10 Fr introducer
- 0.035" (0.89 mm) stiff guidewire
- Position device across stricture using catheter markers and endoprosthesis markers
  - Ensure 2 cm of device extends beyond either side of stricture

5 Deployment

- Loosen vent cap
- Device Deployment: Hold the black inner shaft (steady in place) and pull back on outer green sheath/do not push the black inner shaft
- Marker band at the end of outer sheath denotes progress of deployment
- Deploy 2–5 mm of device, limited repositioning may be possible **(5A)**
- Deploy to 10 mm—first anchoring "fins" released, repositioning is not recommended **(5B)**
- Complete deployment **(5C)**:
  - To fully deploy the device to its labeled length, pull gently backward on the stiff portion of the inner catheter during deployment.
  - Pushing forward on the stiff portion during deployment may result in a device length shorter than the labeled length.







WARNINGS: • Cannot be recaptured once deployment is initiated
• Cannot be repositioned once deployment is complete

6 Catheter Removal

- Reseat the catheter tip at the leading end of the outer sheath and retract the catheter
- If difficulty is encountered removing the catheter immediately after deployment, waiting for approximately 1 minute may allow the prosthesis to open more completely.

7 Post-Deployment Balloon Touch-Up (Optional)

- Select the appropriate balloon size from the sizing table (see reverse)
- Dilate the entire length of the prosthesis at nominal balloon pressure

8 Completion Imaging

- Confirm positioning and patency of device
- Confirm ≥ 2 cm overlap beyond the stricture at each end
- Note: If placing a second endoprosthesis to provide adequate length coverage, ensure ≥ 1 cm overlap of the telescoping devices.

GORE VIABIL® BILIARY ENDOPROSTHESIS

FOR THE TREATMENT OF MALIGNANT BILIARY STRICTURES