GORE® VIABIL®
Biliary Endoprosthesis

NOTEWORTHY POINTS FOR DEVICE USE

Together, improving life

Percutaneous Implantation

Noteworthy points for device use

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.

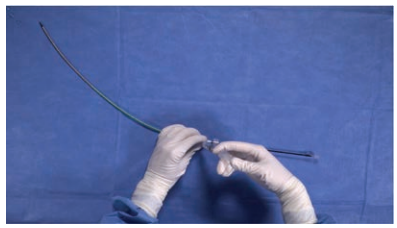


Figure 1

Device selection

- Select the appropriate device (diameter and length) from the sizing table (*see back page*).
- 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 versus 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.

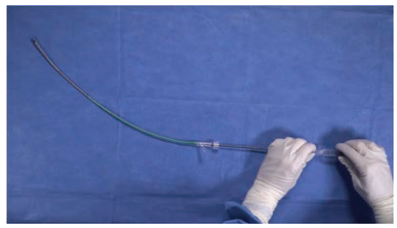


Figure 2

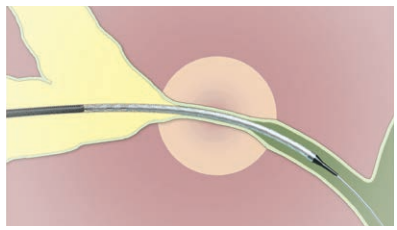


Figure 3

Device preparation (*see figures 1 and 2*)

- Inspect for damage.
- Flush stent port and guidewire lumens.

Insertion and positioning of device (*see figure 3*)

- 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.

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. (*See figure 4*)
- Marker band at the end of outer sheath denotes progress of deployment.
- Deploy 2–5 mm of device, limited repositioning may be possible. (*See figure 5*)
- Deploy to 10 mm — First anchoring "fins" released, repositioning is not recommended. (*See figure 6*)
- Complete deployment (*see figure 7*):
  - 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.

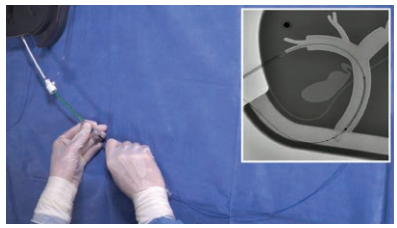


Figure 4

Figure 5

Figure 6

Catheter removal

- Reseat the catheter tip at the leading end of the outer sheath and retract the catheter. (*See figure 8*)
- If difficulty is encountered removing the catheter immediately after deployment, waiting for approximately one minute may allow the prosthesis to open more completely.

Figure 7

Post-deployment balloon touch-up (optional)

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

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.

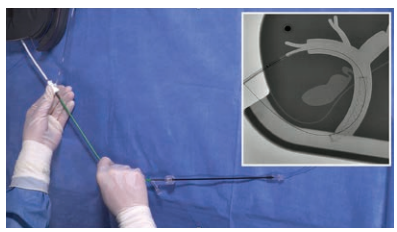


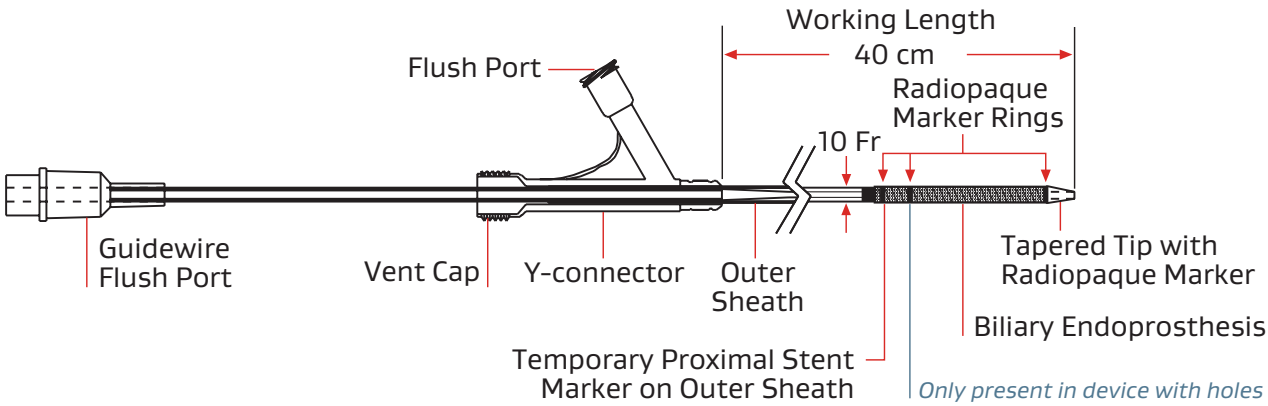
Figure 8

Sizing table

Nominal endoprosthesis diameter*	Recommended duct diameter†	Nominal endoprosthesis lengths‡	Sheath size	Guidewire diameter (preferably stiff or extra stiff)	Working length of the delivery catheter	Recommended balloon diameter for device touch-up
8 mm	5.5–6.9 mm	4 cm, 6 cm, 8 cm, 10 cm	10 Fr	0.035" (0.89 mm)	40 cm	< 8 mm
10 mm	7.0–9.0 mm	4 cm, 6 cm, 8 cm, 10 cm	10 Fr	0.035" (0.89 mm)	40 cm	< 10 mm

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® VIABIL® Biliary Endoprosthesis for percutaneous use



* The outwardly directed anchoring fins extend slightly beyond the nominal diameter of the endoprosthesis.

† Recommended device diametrical oversizing relative to the non-dilated duct is 10–30%.

‡ Recommended endoprosthesis length should include ≥ 2 cm on each side of stricture.

The steps described here may not be complete, and are not intended to be a replacement for the *Instructions for Use* or the education, training and professional judgment of healthcare providers (HCP). HCP remain solely responsible for making decisions about patient care and the use of medical technologies.

Consult Instructions for Use
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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.

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