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.

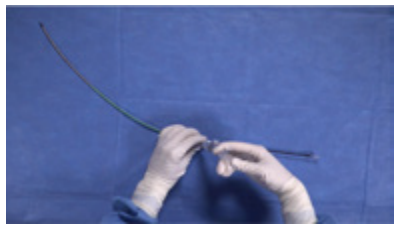


Figure 1

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 (including 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.

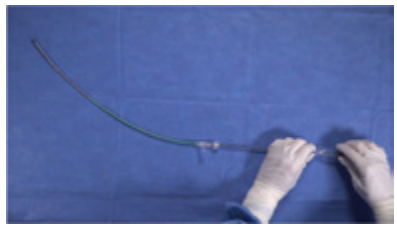


Figure 2

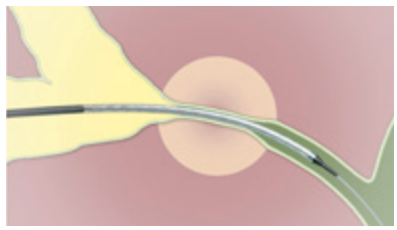


Figure 3

Device preparation (see *Figure 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 completed.
- Note: Once deployment has started, repositioning should not be attempted.

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.

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 4

Figure 5

Figure 6

Figure 7

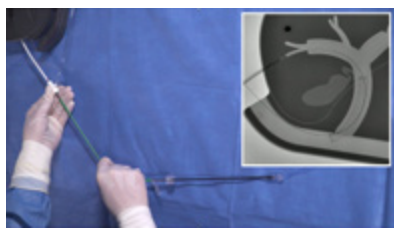


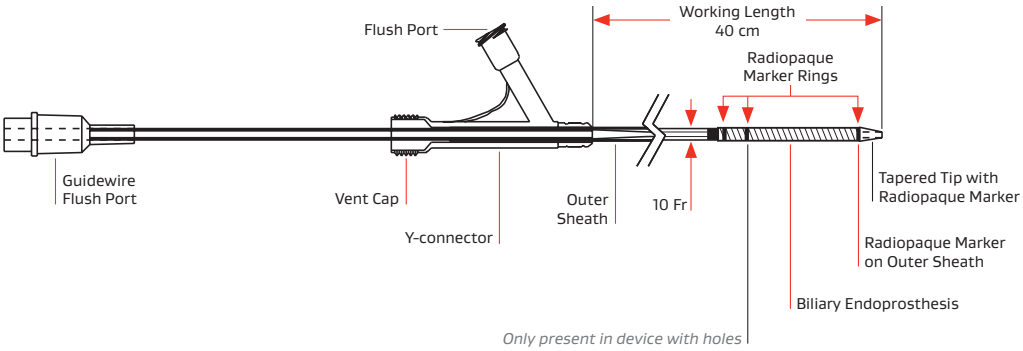
Figure 8

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 covered anchoring fins extend slightly beyond the nominal diameter of the endoprosthesis.
† The recommended duct diameters are based on a 10–30% oversizing.
‡ The 4, 6, 8, and 10 cm Removable endoprostheses are available with lining along the entire length of the endoprosthesis.
§ This represents the nominal undeployed and deployed length of the endoprosthesis. If the device is deployed as instructed, the endoprosthesis will not appreciably foreshorten.

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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