

GORE® VIABIL® Biliary Endoprosthesis

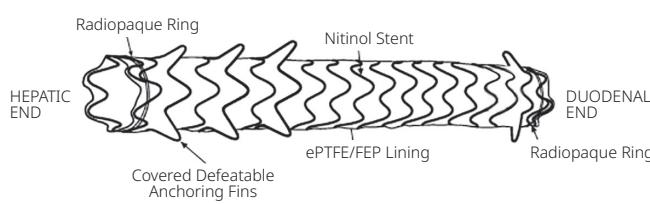
Quick Reference Guide

Note: This guide is only a summary of the Instructions for Use. Refer to the Instructions for Use for a complete description of applicable indications, warnings, precautions and contraindications for the markets where this product is available.

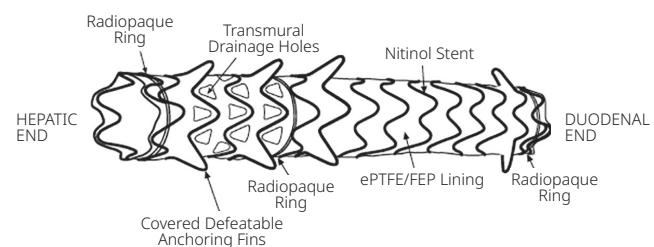
Indications for Use: The GORE® VIABIL® Biliary Endoprosthesis and the GORE® VIABIL® Short Wire Biliary Endoprosthesis are indicated for palliation of malignant strictures in the biliary tree.



Without Transmural Drainage Holes



With Transmural Drainage Holes



Stent Selection

1. ERCP should be performed prior to endoprosthesis placement to characterize the biliary tract morphology and extent of the malignant disease.
2. Proper endoprosthesis diameter and length should be determined using cholangiographic maps of the biliary system.
3. The endoprosthesis should extend at least 2 cm proximal and distal to the margins of the stricture. Endoprosthesis diameter is recommended to be 10–30 % oversized relative to duct diameter.
4. Positioning should not result in excessive length into the duodenum; approximately 1 cm is recommended.
5. An endoprosthesis with transmural drainage holes may be selected if it is necessary to place the endoprosthesis across branch ducts or a bifurcation.

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Preparation



6. Confirm desired endoprosthesis size and remove coil from pouch.



7. Remove the delivery catheter from the coil by grasping the knob and gently pulling to release the hub from the connector tubing. Continue pulling until the entire device has been removed from the coil. Inspect device, do not use if damaged.

Introduction of the Delivery System



8. For the long wire delivery system,* flush the delivery catheter with saline using the flushing port on the catheter hub prior to guidewire insertion. For the short wire delivery system, proceed to Step 9.



9. While holding the delivery system straight, insert the stiff 0.035" guidewire into the tip of the delivery catheter. Carefully advance the endoprosthesis along the guidewire. For the short wire delivery system, advance until the guidewire exits the exit port marked by the white band near the distal end of the catheter. For the long wire delivery system,* advance until the guidewire exits the port near the deployment knob.



10. Carefully advance the delivery system into the endoscope working channel and into the biliary papilla.

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Stent Deployment



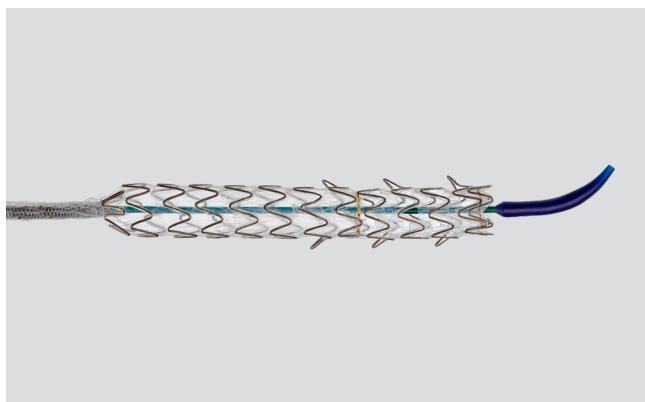
Short Wire Delivery System



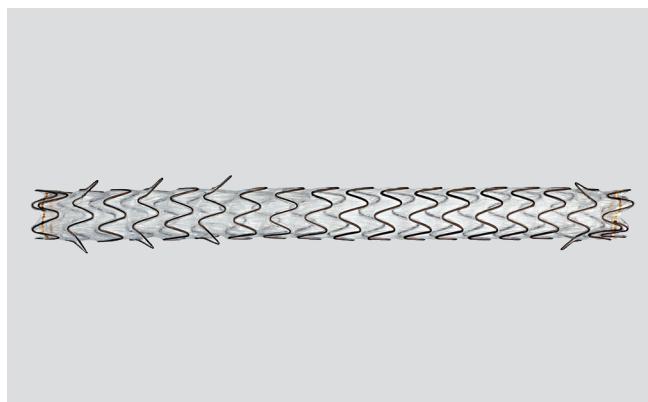
Long Wire Delivery System*



11. Under endoscopic and fluoroscopic guidance, position the device across the target stricture. Untwist the screw-connector and relax the elevator. While keeping the segment of the catheter outside the endoscope working channel straight, slowly pull the deployment knob away from the hub.



12. The deployment line incorporates a double layer of line over the constrained endoprosthesis. It will be necessary to pull 10–25 cm of deployment line (depending on endoprosthesis length) to release the first layer of line from the catheter. Continue to pull the deployment line until the endoprosthesis is fully deployed starting at the hilar end and finishing at the duodenal end. Approximately 25–65 cm (depending on endoprosthesis length) of total deployment line pull is necessary for complete deployment of the endoprosthesis.



13. Maintain position of the guidewire across the treated stricture. Carefully withdraw the delivery catheter through the lumen of the endoprosthesis and remove through the working channel of the endoscope. Using standard cholangiographic procedures, the position and patency of the endoprosthesis should be verified.

Complications associated with the use of the GORE® VIABIL® Biliary Endoprosthesis may include complications associated with the use of other biliary endoprostheses. These complications may include (in alphabetical order) allergic reaction, bleeding due to vascular erosion, endoprosthesis fracture, endoprosthesis migration, endoprosthesis misplacement, endoprosthesis occlusion, and obstruction of branch ducts or bowel. Please consult the Instructions for Use for more information

References

* Long wire delivery system version is not currently available for distribution in the US market

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Consult Instructions for Use
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RX Only



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GORE® VIABIL® Biliary Endoprosthesis is manufactured by W. L. Gore & Associates, Inc and distributed by Olympus America, Inc.

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Printed in USA OAIET1225QRG59195