

INSTRUCTIONS FOR USE FOR:



BILIARY ENDOPROSTHESIS

en

English

The GORE VIABIL® Biliary Endoprosthesis is indicated for the treatment of malignant biliary strictures.

bg

Български

Ендопротезата за жлъчен проток VIABIL® на GORE е показана за лечение на злокачествени стриктури на жлъчните пътища.

cz

Čeština

Biliární endoprotéza GORE VIABIL® je určena k použití při léčbě maligních biliárních striktur.

dk

Dansk

GORE VIABIL® biliær endoprotese er indiceret til behandling af maligne galdevejsstrikturer.

nl

Nederlands

De GORE VIABIL® biliare endoprothese is geïndiceerd voor de behandeling van maligne galwegstrikturen.

ee

Eesti

Sapiteede endoprotees GORE VIABIL® on näidustatud sapiteede pahaloomulise ahendi raviks.

fi

Suomi

GORE VIABIL® -sappitie-endoproteesia käytetään pahanlaatuisten kasvainten aiheuttamien sappitiekouroumien hoitoon.

fr

Français

L'endoprothèse biliaire GORE VIABIL® est indiquée pour le traitement des rétrécissements biliaires malins.

de

Deutsch

Die GORE VIABIL® Gallenendoprothese ist für die Behandlung maligner Gallenstrikturen indiziert.

gr

Ελληνικά

Η ενδοπρόθεση χοληφόρων GORE VIABIL® ενδείκνυται για τη θεραπεία κακοήθων στενώσεων των χοληφόρων.

hu

Magyar

A GORE VIABIL® epeúti endoprotézis rosszindulatú epeúti szűkületek kezelésére szolgál.

it

Italiano

L'uso dell'endoprotesi biliare GORE VIABIL® è indicato nel trattamento delle stenosi biliari maligne.

lt

Lietuvių

GORE VIABIL® biliarinis endoprotezas yra skirtas gydyti piktybinių tulžies latakų striktūras.

no

Norsk

GORE VIABIL® galleendoprotese er til bruk for behandling av ondartete gallestrikturer.

pl

Polska

Endoproteza drog żółciowych GORE VIABIL® jest przeznaczona do leczenia zwężeń dróg żółciowych spowodowanych przez nowotwory złośliwe.

pt

Português

A Endoprotése Biliar GORE VIABIL® é indicada para o tratamento de estenoses biliares malignas.

ro

Română

Endoproteza biliară GORE VIABIL® este indicată în tratamentul stenozelor biliare maligne.

sk

Slovenčina

Biliárna endoprotéza GORE VIABIL® je určená na použitie pri liečbe maligných biliárnych striktúr.

es

Español

La endoprotésis biliar GORE VIABIL® está indicada para el tratamiento de estenosis biliares neoplásicas malignas.

se

Svenska

GORE VIABIL® endoprotés för gallgång är indicerad för behandling av maligna gallgångstrikturer.

INSTRUCTIONS FOR USE FOR:**GORE VIABIL® Biliary Endoprosthesis**

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

DESCRIPTION

The GORE VIABIL® Biliary Endoprosthesis is a flexible, self-expanding endoprosthesis that is compressed and secured onto the distal end of a delivery catheter. The catheter provides a means for implanting the GORE VIABIL® Biliary Endoprosthesis at the target site in the biliary tract. Two catheter types and lengths are offered, allowing for either the endoscopic or the percutaneous delivery of the GORE VIABIL® Biliary Endoprosthesis.

The endoprosthesis consists of an expanded polytetrafluoroethylene (ePTFE) and fluorinated ethylene propylene (FEP) tubular lining that is externally supported along its length by a nitinol stent and incorporates radiopaque rings at both ends (Figure 1). Covered anchoring fins are incorporated into the nitinol stent to reduce the risk of endoprosthesis migration.

Some sizes of the GORE VIABIL® Biliary Endoprosthesis are available with transmural drainage holes in the lining for 2 cm along the proximal end of the endoprosthesis (Figure 2). These holes are triangular in shape and are intended to allow for endoprosthesis placement across a branch duct under appropriate anatomical circumstances. A third radiopaque ring is present on endoprostheses with transmural drainage holes to fluoroscopically identify the boundaries of the holed region.

For endoscopic delivery, the delivery system consists of a 200 cm length, 8.5 Fr diameter, single (guidewire) lumen catheter with deployment knob and line. To facilitate accurate endoscopic endoprosthesis placement, radiopaque markers are present on the distal and proximal ends of the endoprosthesis (Figure 3a). For percutaneous delivery, a 40 cm length, 10 Fr diameter retractable outer sheath diameter and an inner catheter configuration is available (Figure 3b). To facilitate accurate percutaneous endoprosthesis placement, radiopaque markers are present on the distal ends of both the outer sheath and the inner catheter. The outer sheath is fitted with a Y-connector on the proximal end, which allows for flushing of the space between the outer sheath, the inner catheter and the loaded endoprosthesis.

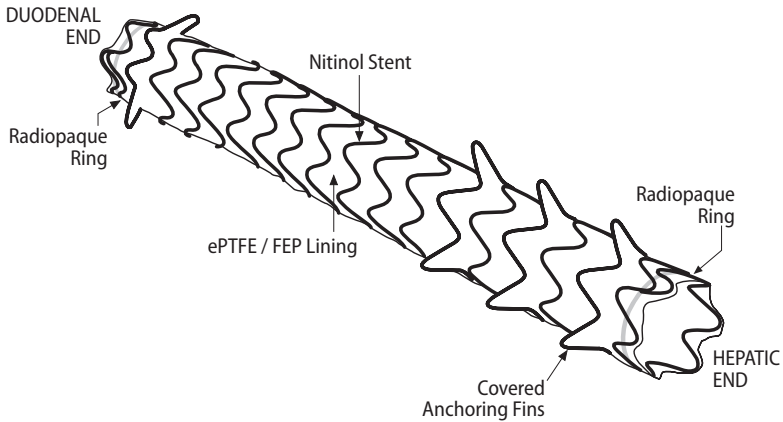
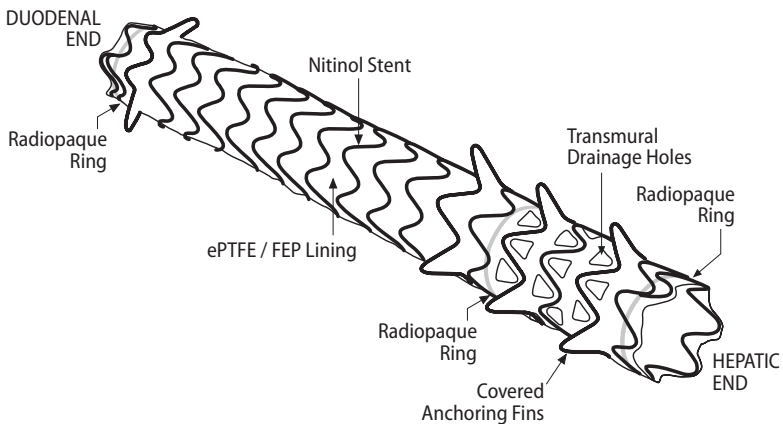
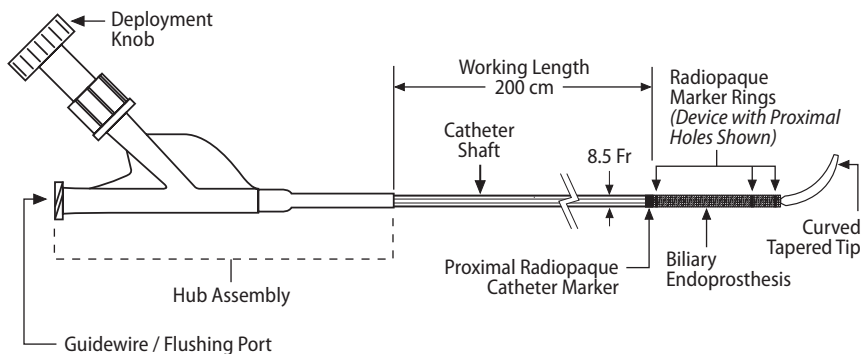
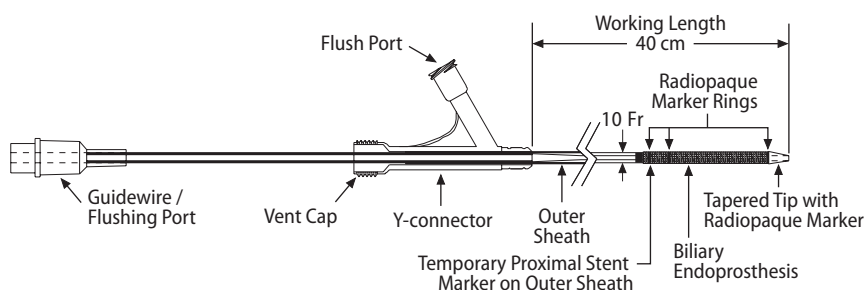
FIGURE 1: GORE VIABIL® BILIARY ENDOPROSTHESIS**FIGURE 2: GORE VIABIL® BILIARY ENDOPROSTHESIS WITH TRANSMURAL DRAINAGE HOLES**

FIGURE 3A: GORE VIABIL® BILIARY ENDOPROSTHESIS ENDOSCOPIC DELIVERY CATHETER SYSTEM

FIGURE 3B: GORE VIABIL® BILIARY ENDOPROSTHESIS PERCUTANEOUS DELIVERY CATHETER SYSTEM


ENDOPROSTHESIS SIZING METHOD

Percutaneous / Transhepatic (40 cm catheter working length)

Percutaneous transhepatic cholangiography (PTC) should be performed prior to placement of the GORE VIABIL® Biliary Endoprosthesis to characterize the biliary tract morphology and extent of the malignant disease. PTC should be used to determine the proper diameter and length of the GORE VIABIL® Biliary Endoprosthesis needed for treatment (Table 1).

The GORE VIABIL® Biliary Endoprosthesis should extend at least 2 cm proximal and distal to the margins of the stricture. Positioning should not result in excessive length into the duodenum. A guidewire with radiopaque markers at known intervals can be used to assist in these measurements. Mapping out the biliary tract cholangiographically is also necessary to determine whether a branch duct may be excluded by placement of the endoprosthesis. Based on the likelihood of excluding a branch duct, a GORE VIABIL® Biliary Endoprosthesis with transmural drainage holes may be selected to decrease the probability of branch duct exclusion. Delivery of the endoprosthesis should be performed using fluoroscopic guidance, and proper endoprosthesis placement and patency should be confirmed using cholangiography immediately following deployment.

Endoscopic (200 cm catheter working length)

Endoscopic retrograde cholangiopancreatography (ERCP) should be performed prior to placement of the GORE VIABIL® Biliary Endoprosthesis to characterize the biliary tract morphology and extent of the malignant disease. ERCP should be used to determine the proper diameter and length of the GORE VIABIL® Biliary Endoprosthesis needed for treatment (Table 1).

The GORE VIABIL® Biliary Endoprosthesis should extend at least 2 cm proximal and distal to the margins of the stricture. Positioning should not result in excessive length into the duodenum. A guidewire with radiopaque markers at known intervals can be used to assist in these measurements. Mapping out the biliary tract cholangiographically is also necessary to determine whether a branch duct may be excluded by placement of the endoprosthesis. Based on the likelihood of excluding a branch duct, a GORE VIABIL® Biliary Endoprosthesis with transmural drainage holes may be selected to decrease the probability of branch duct exclusion. Delivery of the endoprosthesis should be performed using endoscopic and fluoroscopic guidance, and proper placement and patency should be confirmed using cholangiography immediately following deployment.

TABLE 1: ENDOPROSTHESIS SIZING TABLE

Nominal Endoprosthesis Diameter (mm) ¹	Recommended Duct Diameter (mm) ²	Nominal Endoprosthesis Lengths (cm) ³	Profile of Delivery Catheter (Fr)	Working Lengths of Delivery Catheter (cm)
8	5.5 – 6.9	4 / 6 / 8 / 10	10	40
10	7.0 – 9.0	4 / 6 / 8 / 10	10	40
8	5.5 – 6.9	4 / 6 / 8 / 10	8.5	200
10	7.0 – 9.0	4 / 6 / 8 / 10	8.5	200

¹ The outwardly directed covered anchoring fins extend slightly beyond the nominal diameter of the endoprosthesis.

² The recommended duct diameters are based on a 10 – 30% oversizing.

³ The 4, 6, 8, and 10 cm endoprostheses are available with lining along the entire length of the endoprosthesis. The 6, 8 and 10 cm endoprostheses are also available with transmural drainage holes in the lining for 2 cm along the proximal (hepatic) end of the endoprosthesis.

INDICATIONS

The GORE VIABIL® Biliary Endoprosthesis is indicated for the treatment of malignant biliary strictures.

CONTRAINDICATIONS

The GORE VIABIL® Biliary Endoprosthesis is contraindicated for:

- ALL CARDIOVASCULAR APPLICATIONS.
- Ducts less than 5.5 mm in diameter or greater than 9 mm in diameter.

WARNINGS

- The safety and effectiveness of this device for use in the vascular system has not been established.
- The GORE VIABIL® Biliary Endoprosthesis should not be cut prior to use and should only be implanted using the catheter system supplied with the endoprosthesis.
- The GORE VIABIL® Biliary Endoprosthesis cannot be recaptured once deployment is initiated and cannot be repositioned once deployment is complete.
- Endoprosthesis placement resulting in excessive length of the endoprosthesis protruding into the duodenum may obstruct the intestinal tract.
- Placement of a fully lined endoprosthesis (without holes) across a branch duct or major bifurcation may result in complications due to blockage of flow from the branch duct and prevent endoscopic or transhepatic access for future procedures.
- Physicians should carefully consider the decision to implant the GORE VIABIL® Biliary Endoprosthesis in patients with active infections or other co-morbidities involving the hepatobiliary system. Physicians should also consider the standard precautions associated with the endoscopic transpapillary manipulation of an 8.5 Fr catheter, and percutaneous transhepatic manipulation of a 10 Fr catheter in the biliary tract.

PRECAUTIONS

- The GORE VIABIL® Biliary Endoprosthesis is designed for single use only and should not be re-sterilized. Do not use after the labeled "use by" (expiration) date. It should be carefully inspected prior to use to verify that the sterile package has not been damaged and that the appropriate endoprosthesis size and delivery catheter length have been selected.
- The GORE VIABIL® Biliary Endoprosthesis should only be used by physicians trained in interventional or endoscopic techniques.
- Catheter manipulation in the body should only be performed using high quality fluoroscopic equipment and / or high quality endoscopic equipment.
- Care should be taken to ensure that an appropriately sized introducer sheath or an endoscope with the appropriate channel size is used prior to advancing the delivery catheter into the body.

MRI SAFETY AND COMPATIBILITY



MR Conditional

Non-clinical testing has demonstrated that the GORE VIABIL® Biliary Endoprosthesis is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Spatial gradient field of ≤ 720 Gauss / cm
- Maximum scanner displayed whole-body-averaged specific absorption rate (SAR) of 3.0 W / kg for 15 minutes of scanning.

3.0 Tesla Temperature Rise:

In non-clinical testing, the GORE VIABIL® Biliary Endoprosthesis produced a temperature rise of 0.4° C at an MR system reported maximum whole body averaged specific absorption rate (SAR) of 3.0 W / kg for 15 minutes of MR scanning in a 3.0 Tesla, Excite, General Electric active-shield, horizontal field MR scanner using G3.0-052B Software and placed in a worst-case location in a phantom designed to simulate human tissue. The SAR calculated using calorimetry was 2.8 W / kg.

1.5 Tesla Temperature Rise:

In non-clinical testing, the GORE VIABIL® Biliary Endoprosthesis produced a temperature rise of 1.9° C at an MR system reported maximum whole body averaged specific absorption rate (SAR) of 2.8 W / kg for 15 minutes of MR scanning in a 1.5 Tesla, Magnetom, Siemens Medical Solutions, active-shield, horizontal field MR scanner using Numaris / 4 Software and placed in a worst-case location in a phantom designed to simulate human tissue. The SAR calculated using calorimetry was 1.5 W / kg.

HAZARDS AND ADVERSE EVENTS

Complications associated with the use of the GORE VIABIL® Biliary Endoprosthesis may include complications associated with other biliary endoprostheses, including but not limited to: endoprosthesis misplacement, endoprosthesis migration, endoprosthesis fracture, obstruction of branch ducts, bleeding due to vascular erosion, and endoprosthesis occlusion due to biofilm / sludge formation, extrinsic compression or tumor overgrowth at the endoprosthesis ends.

Complications may also include those often associated with any endoscopic or transhepatic procedure performed on the biliary tract. These complications include: infection, bleeding, duct perforation, hematoma, hemobilia, cholangitis, pancreatitis, fever, trauma to ductal system or duodenum, and death.

DIRECTIONS FOR USE — I. PERCUTANEOUS TRANSHEPATIC DELIVERY (40 cm CATHETER)

Materials Required for Endoprosthesis Placement

- GORE VIABIL® Biliary Endoprosthesis
- Sterile syringe
- Introducer sheath appropriately sized for delivery catheter (10 Fr or larger)
- 0.035" (0.89 mm) guidewire at least 180 cm long (preferably stiff or extra stiff)
- Appropriate diagnostic catheters, dilators and accessories
- Saline solution
- Radiopaque contrast solution

A. Percutaneous Transhepatic Cholangiography (PTC)

1. A percutaneous needle stick is made to gain access into the biliary system.
2. Through the injection of contrast solution, define the anatomy of the patient's biliary tract. If the initial injection site proves unsuitable for endoprosthesis delivery, a second puncture site may be used.
3. Through the use of various guidewires, catheters and dilators, place a 0.035" (0.89 mm) guidewire across the biliary stricture and into the duodenum. Pre-dilatation of the stricture may be performed at the discretion of the implanting physician.
4. Using the cholangiographic maps of the biliary system, select the appropriate length and diameter GORE VIABIL® Biliary Endoprosthesis to use. An endoprosthesis with transmural drainage holes may be selected if it is necessary to place the endoprosthesis across branch ducts or a bifurcation.

B. Preparation of Endoprosthesis and Deployment Catheter

1. Prior to Opening Sterile Package:
Check that the endoprosthesis diameter, endoprosthesis length and catheter length are appropriate for the specific procedure before removing it from the packaging. It is recommended that the endoprosthesis extend at least 2 cm past the margins of the stricture and that the diameter is slightly oversized (see Table 1). However, if the stricture is located in close proximity to the major duodenal papilla (papilla of Vater), care should be taken to prevent excessive endoprosthesis length from extending into the duodenum. Ensure that the selected endoprosthesis does not have transmural drainage holes in the lining component unless they are specifically desired.
2. Opening the Sterile Package:
Carefully inspect the packaging for damage to the sterile barrier. Peel back the outer pouch and remove the inner pouch. Using sterile technique, peel back the inner pouch and gently remove the delivery catheter containing the pre-mounted endoprosthesis.
3. Inspection Prior to Use:
Prior to using the GORE VIABIL® Biliary Endoprosthesis, all materials to be used for the procedure should be carefully examined for bends, kinks, breaks or other damage. Do not use any defective materials.
4. Preparation of the GORE VIABIL® Biliary Endoprosthesis delivery catheter.
 - a. Check to ensure that the vent cap of the outer sheath is tightened against the inner catheter. Flush the space between the inner catheter and outer sheath with saline by attaching a syringe to the flushing port on the hub of the outer sheath. Continue flushing until a steady stream of saline exits the leading end of the catheter.
 - b. After flushing the catheter, remove the syringe.
 - c. Flush the guidewire lumen with saline by attaching a 10 cc syringe to the guidewire flush port on the end of the inner catheter. Continue flushing until a steady stream of saline exits the leading end of the catheter. Remove the syringe.

C. Introduction of the Delivery System and Deployment of the Endoprosthesis

1. If the existing guidewire is not 0.035" (0.89 mm) in diameter, replace it with a 0.035" (0.89 mm) guidewire. A guidewire of the stiff or extra stiff variety is recommended.
2. Using appropriate catheters and standard techniques, perform PTC if it has not already been performed or additional cholangiographic data is needed.
3. While maintaining position of the guidewire across the stricture, remove any catheters.
4. With the delivery catheter held as straight as possible, insert the guidewire into the tip of the delivery catheter. Carefully advance the delivery catheter over the guidewire, and through the introducer sheath. Note: If excessive resistance is felt upon introduction through the introducer sheath or the valve, remove and inspect the delivery system for damage. Do not use if damaged. Use of an introducer sheath with a softer valve may facilitate introduction.
5. Using fluoroscopic guidance, advance the delivery system over the guidewire via the introducer sheath into the biliary tract. Advance cautiously, especially if resistance is encountered.
6. Position the GORE VIABIL® Biliary Endoprosthesis across the stricture using the radiopaque rings on the ends of the loaded endoprosthesis. Using fluoroscopy, verify that the leading edge of the indwelling introducer sheath does not overlie any portion of the loaded endoprosthesis. **The GORE VIABIL® Biliary Endoprosthesis should extend at least 2 cm proximal and distal to the margins of the stricture. Positioning should not result in excessive length into the duodenum.** If an endoprosthesis with transmural drainage holes is selected, the middle and hepatic end radiopaque rings demarcate the boundaries of the holed region.
7. Once the optimal endoprosthesis position is verified fluoroscopically, it is ready to be deployed. Loosen and slide back the vent cap on the outer sheath. Should it become necessary to remove the GORE VIABIL® Biliary Endoprosthesis catheter from the biliary tract prior to deployment, it may be withdrawn through the introducer sheath. **Once deployment has been initiated, the GORE VIABIL® Biliary Endoprosthesis cannot be recaptured or removed.**
8. To deploy the GORE VIABIL® Biliary Endoprosthesis, first stabilize the inner catheter by firmly grasping the stiff portion on the trailing end of the catheter. While keeping the external segment of the catheter as straight as possible and the inner catheter stationary, grasp the Y-connector on the outer sheath and slowly pull back the outer sheath until approximately 2 – 5 mm of the endoprosthesis has been deployed. As the outer sheath is withdrawn, the endoprosthesis will deploy from the leading end toward the trailing end of the catheter. Once 2 – 5 mm of the endoprosthesis have been deployed, the covered anchoring fins at the leading end will not have deployed and some limited repositioning may be possible. Once the device position is appropriate, continue to slowly pull back on the outer sheath until approximately 10 – 12 mm of the endoprosthesis is deployed. At this point, one row of three covered anchoring fins will have deployed and repositioning attempts are not recommended. While keeping slight tension on the delivery system to prevent shortening of the deployed endoprosthesis, slowly pull back on the remainder of the outer sheath until the deployment is complete. Note: To fully deploy the device to its labeled length, pull gently backward on the stiff portion of the inner catheter during deployment. Note that pushing forward on the stiff portion during deployment may result in a device length shorter than the labeled length. Note: The device will not be longer or a larger diameter than what is labeled.

9. While maintaining position of the guidewire across the stricture, carefully withdraw the delivery catheter through the lumen of the endoprosthesis and remove it via the introducer sheath. Moderate resistance may be felt when the tapered tip exits through the introducer sheath valve. Note: Should difficulty be encountered in pulling the tapered tip back through the deployed endoprosthesis, the outer sheath may be carefully pushed forward until the leading end of the outer sheath rejoins the inner catheter at the tapered tip. The rejoined catheter can then be withdrawn through the lumen of the deployed endoprosthesis.
10. Using standard cholangiographic procedures, the position and patency of the endoprosthesis should be verified. If the stricture does not allow the endoprosthesis to immediately expand to its full diameter, it is possible that it will further expand over the course of several days. Balloon inflations may be used at the discretion of the implanting physician to expand the endoprosthesis. The balloon diameter selected for this purpose should be less than the nominal diameter of the GORE VIABIL® Biliary Endoprosthesis used (refer to Table 1).
11. It is acceptable to place multiple devices to tailor the overall device lengths to achieve complete coverage beyond a stricture (i.e., greater than or equal to 2 cm). Devices need to be overlapped by at least 1 cm. It is recommended that only devices of the same diameter be overlapped. Even though the order of placement may be dependent on the patient's anatomy and physician's judgment, it is recommended that the device closest to the duodenum or most downstream device is placed first.
12. When clinically appropriate, remove any guidewires or catheters and then the introducer sheath. Use standard techniques to achieve hemostasis.

DIRECTIONS FOR USE — II. ENDOSCOPIC DELIVERY (200 cm CATHETER)

Materials Required for Endoprosthesis Placement

- GORE VIABIL® Biliary Endoprosthesis
- Sterile syringe
- Duodenoscope system appropriately sized for instrument channel (8.5 Fr or larger)
- 0.035" (0.89 mm) guidewire at least 450 cm long (preferably stiff or extra stiff)
- Appropriate diagnostic catheters, dilators, sphincterotomes and accessories
- Saline solution
- Radiopaque contrast solution

A. Endoscopic Retrograde Cholangiopancreatography (ERCP)

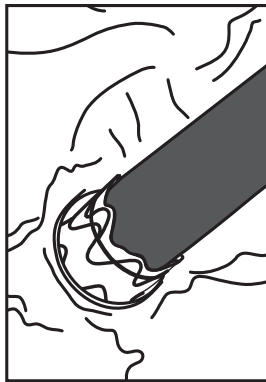
1. The distal end of the endoscope is positioned in the duodenum near the location of the major duodenal papilla (papilla of Vater), and the common bile duct (CBD) is cannulated. A sphincterotomy is not always necessary for delivery of the endoprosthesis, but may be performed at the discretion of the implanting physician.
2. Through the injection of contrast solution, define the anatomy of the patient's biliary tract.
3. Through the use of various guidewires, catheters and dilators, place a 0.035" (0.89 mm) guidewire across the biliary stricture. Pre-dilatation of the stricture may be performed at the discretion of the implanting physician.
4. Using the cholangiographic maps of the biliary system, select the appropriate length and diameter GORE VIABIL® Biliary Endoprosthesis to use. An endoprosthesis with transmural drainage holes may be selected if it is necessary to place the endoprosthesis across branch ducts or a bifurcation.

B. Preparation of Endoprosthesis and Deployment Catheter

1. Prior to Opening Sterile Package:
Check that the endoprosthesis diameter, endoprosthesis length and catheter length are appropriate for the specific procedure before removing it from the packaging. It is recommended that the endoprosthesis extend at least 2 cm past the margins of stricture and that the diameter is slightly oversized (see Table 1). However, if the stricture is located in close proximity to the major duodenal papilla (papilla of Vater), care should be taken to prevent excessive endoprosthesis length from extending into the duodenum. Ensure that the selected endoprosthesis does not have transmural drainage holes in the lining component unless they are specifically desired.
2. Opening the Sterile Package:
Carefully inspect the packaging for damage to the sterile barrier. Peel back the outer pouch and remove the coil. Gently pull the hub from the coil and remove the delivery catheter containing the pre-mounted endoprosthesis.
3. Inspection Prior to Use:
Prior to using the GORE VIABIL® Biliary Endoprosthesis, all materials to be used for the procedure should be carefully examined for bends, kinks, breaks or other damage. Do not use any defective materials.
4. Preparation of the Delivery Catheter:
 - a. Flush the delivery catheter by attaching a syringe of saline to the flushing port on the catheter hub assembly (Figure 3a). Continue flushing until a steady stream of fluid exits the tip of the catheter and the deployment lumen at the proximal end of the device.
 - b. After flushing the catheter, remove the syringe.

C. Introduction of the Delivery System and Deployment of the Endoprosthesis

1. With the endoscope appropriately positioned in the duodenum, ensure that an 0.035" (0.889 mm) diameter "stiff" guidewire with a length at least twice that of the delivery catheter is in place.
Note: Never attempt to endoscopically deploy a GORE VIABIL® Biliary Endoprosthesis unless placed over an appropriate guidewire.
2. With the delivery catheter as straight as possible, insert the guidewire into the tip of the delivery catheter while supporting the delivery catheter and the compressed endoprosthesis. Carefully advance the endoprosthesis in small increments (approximately 0.5 cm) over the guidewire, through the endoscope working channel, and into the biliary papilla. **Note:** If excessive resistance is felt as the GORE VIABIL® Endoprosthesis is introduced into the endoscope, remove and inspect the delivery system for damage. Do not reuse the GORE VIABIL® Endoprosthesis if damaged. Ensure a compatible endoscope working channel size (Table 1), and that the guidewire is free of kinks.
3. Using fluoroscopic and endoscopic guidance, advance the delivery catheter over the guidewire. Advance cautiously, especially if resistance is felt. If excessive resistance is felt, at the physician's discretion, remove the delivery catheter and endoscope together.
4. Position the GORE VIABIL® Endoprosthesis across the target stricture using the radiopaque markers on the stent. These markers identify the proximal and distal ends of the loaded endoprosthesis. **The GORE VIABIL® Biliary Endoprosthesis should extend at least 2 cm proximal and distal to the margins of the stricture. Positioning should not result in excessive length into the duodenum.** If an endoprosthesis with transmural drainage holes is selected, the middle and hepatic end radiopaque rings demarcate the boundaries of the holed region. If transpapillary stent placement is desired, advance the catheter until the white edge of the distal end of the covered stent / containment line is visible just outside the papilla. This orientation must be maintained throughout the entire line-pull process of endoprosthesis delivery.



5. Once optimal endoprosthesis position is verified fluoroscopically and endoscopically, the endoprosthesis is ready to be deployed.

Note: Should it become necessary to remove the GORE VIABIL® Endoprosthesis from the duct prior to deployment, you may withdraw the catheter with loaded endoprosthesis back into the endoscope working channel after the catheter is fully advanced into the bile duct.

6. Ensure the delivery catheter is as straight as possible coming out of the endoscope working channel.
7. Stabilize the delivery catheter at the entrance of the working channel of the endoscope. It is also important to stabilize the endoscope relative to the patient. This will minimize catheter movement during deployment and ensure accurate endoprosthesis positioning.
8. Untwist the screw-connector at the base of the deployment knob. Relax the elevator. While keeping the segment of the catheter outside the endoscope working channel as straight as possible, slowly pull the deployment knob away from the hub. The deployment line incorporates a double layer of line over the constrained endoprosthesis. Approximately 10-25 cm (depending on endoprosthesis length) of initial deployment line pull ("pre-deployment pull") is necessary to release the first layer of line from the catheter (hub to tip) constraining the endoprosthesis and before deployment release of the endoprosthesis from the delivery catheter begins. **Deployment of the endoprosthesis will occur from the tip of the delivery catheter toward the hub (hilar to duodenal).** Approximately 25-65 cm (depending on endoprosthesis length) of total deployment line pull is necessary for complete deployment of the endoprosthesis. Continue to pull deployment line until it exits the deployment catheter. If deployed as instructed, the endoprosthesis will not foreshorten.

Note: Once deployment has started, repositioning of the endoprosthesis should not be attempted.

Note: To fully deploy the device to its labeled length, maintain constant position of the delivery catheter during deployment. Note that pushing forward on the catheter during deployment may result in a device length shorter than the labeled length.

Note: The device will not be longer or a larger diameter than what is labeled.

9. Following deployment of the endoprosthesis, 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. Moderate resistance may be felt when the distal tip is withdrawn into the endoscope working channel. Excessive or abrupt force during catheter removal may damage the endoprosthesis, or delivery catheter.
10. Using standard cholangiographic procedures, the position and patency of the endoprosthesis should be verified. If the stricture does not allow the endoprosthesis to immediately expand to its full diameter, it is possible that it will further expand over the course of several days. Balloon inflations may be used to expand the endoprosthesis. The balloon diameter selected for this purpose should be less than the nominal diameter of the GORE VIABIL® Biliary Endoprosthesis used.
11. It is acceptable to place multiple devices to achieve complete coverage beyond a stricture (i.e., greater than or equal to 2 cm). Devices need to be overlapped by at least 1 cm. It is recommended that only devices of the same diameter be overlapped. Even though the order of placement may be dependent on the patient's anatomy and physician's judgment, it is recommended that the device closest to the duodenum or most downstream device is placed first.

D. Post-Deployment

1. When clinically appropriate, remove any guidewires or catheters and then the endoscope.

STERILIZATION

The GORE VIABIL® Biliary Endoprosthesis is supplied STERILE. The GORE VIABIL® Biliary Endoprosthesis should not be re-sterilized.

DEFINITIONS



Use By



Attention, See Instructions for Use



Do Not Re-Use



Catalogue Number



Batch Code



European Authorized Representative



Contents sterile unless package has been opened or damaged.



Contents sterile unless enclosed package has been opened or damaged. Sterilized by ethylene oxide.



Diameter



Do Not Resterilize



Guidewire Compatibility



MR Conditional



AM0119-ML2



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