ALI**MAXX-B**®

For Endoscopic Delivery Hybrid Covered Biliary Stent Technology System

IMPORTANT PRODUCT INFORMATION

Please read this information carefully before using the ALI**MAXX-B® Biliary** Stent System. Failure to properly follow the instructions may result in serious clinical consequences.

CAUTION: Consult accompanying documents.

Single Use Only

MR Conditional

STERILE EO

Patents Pending

MERIT MEDICAL ENDOTEK™ CE 0086

Manufacturer: www.merit.com
Merit Medical Systems, Inc. South Jordan, Utah 84095 U.S.A.
1-801-253-1600
U.S.A. Customer Service 1-800-356-3748

EC REP Authorized Representative:
Merit Medical Ireland Ltd, Parkmore Business Park West,
Galway, Ireland

401943001/A ID 062210

STEP-BY-STEP ILLUSTRATIONS WHICH ARE HELPFUL FOR FOLLOWING THE DIRECTIONS FOR USE ARE LOCATED AT THE END OF THIS BOOKLET

DESCRIPTION

The ALI**MAXX-B**® Covered **Biliary** Stent System is comprised of two components: the radiopaque, self-expanding Nitinol stent and the delivery catheter. The stent comes pre-loaded on the delivery catheter.

The stent is composed of a nitinol scaffold completely covered with a biocompatible, silicone membrane. When the stent is delivered, the stent expands as a result of mechanical properties of the metal and the proprietary stent geometry. The stent is also designed to have minimal foreshortening, therefore, allowing increased stent placement accuracy. To minimize the possibility of stent migration, both ends of the stent have slightly larger diameters. Radiopaque markers are also located on both ends of the stent to facilitate stent placement (Figure 1). The stent is delivered endoscopically using the 185 cm delivery catheter working length.

The stent is deployed using a dedicated delivery system. The delivery catheter consists of an inner sheath and an outer sheath. The outer sheath constrains the stent. During stent deployment, the outer sheath is pulled back to release the expanding stent. The delivery system handle permits one-handed positioning and deployment of the stent via a trigger mechanism (Figure 8).

Once deployment is initiated, the stent cannot be reconstrained. However, prior to the point when the first deployment trigger is fully retracted, the stent can be repositioned distally (towards the duodenum) by pulling the entire delivery system toward the operator. **When the first deployment trigger has been fully retracted, this is the last point at which the operator can reposition the stent as just described.** Several radiopaque markers and bands (Figure 2) aid the operator in determining stent position and deployed stent length.

The inner sheath lumen of the delivery catheter will accommodate a 0.035" (0.89 mm) guidewire. This feature is designed to allow safe guidance of the delivery system to the intended implant site while minimizing the risk of biliary system injury from the delivery system tip.

The complete Directions for Use should be reviewed before using this system.

ALI**MAXX-B**® Hybrid Covered **Biliary** Stent System for Endoscopic Delivery

INDICATIONS

The ALI**MAXX-B**® Covered **Biliary** Stent is intended for maintaining biliary lumen patency in intrinsic and extrinsic biliary strictures.

WARNING: The safety and effectiveness of this device for use in the vascular system have not been established and can result in serious harm and/or death.

CONTRAINDICATIONS

Contraindications associated with the use of the ALI**MAXX-B**® Covered **Biliary** Stent include:

- **ALL CARDIOVASCULAR APPLICATIONS**
- Use of the device in very small intrahepatic ducts
- Stenting of a perforated duct, where leakage from the duct could be exacerbated by the prosthesis
- Strictures that cannot be safely dilated to allow passage of the delivery system.
- Patients in whom endoscopic procedures cannot be safely performed should not have stents placed via the endoscopic delivery method.
- Any use other than those specifically outlined under Indications for Use.
- Placement of the stent in biliary obstructions precluding any form of cholangiography.
- Use of the device in patients presenting with coagulopathy
- Use of the device in strictures greater than 8 cm in length.

WARNINGS

1. Placement of a stent across a branch duct or major bifurcation may result in complications due to blockage of flow from the branch duct and prevent future endoscopic access
2. Final stent placement resulting in an excessive length of the stent protruding into the duodenum or misplacement of the entire stent into the duodenum may damage or obstruct the intestinal tract.
3. The ALI**MAXX-B**® **Biliary** Stent should not be cut prior to use and should only be implanted using the catheter system supplied with the stent.
4. Physicians should carefully consider the decision to implant the ALI**MAXX-B**® **Biliary** Stent in patients with active infections or other co-morbidities involving the hepatobiliary system. Physicians should also consider the standard precautions associated with the endoscopic manipulation of a 3.3 mm (10 Fr) catheter in the biliary tract.
5. Laser ablation of lesions with a stent in place could cause patient injury.
6. Placement of a second stent within the lumen of another stent could significantly compromise the patency of the lumen.

PRECAUTIONS

- The device is intended for use by physicians who have received appropriate training.
- The device should not be resterilized.
- The sterile packaging and device should be inspected before use. If sterility or performance of the device is suspected to be compromised, it should not be used.
- The device is intended for single use only. Do not attempt to reload deployed stents onto the delivery system.
- The device should be placed under fluoroscopic monitoring.
- A complete diagnostic evaluation should be performed prior to placement to measure the stricture length and determine the proper stent length.
- Chemotherapy and irradiation may increase the risk of stent migration due to tumor shrinkage, stent erosion and/or mucosal bleeding.
- If the guidewire or delivery catheter cannot advance through the obstructed area, do not deploy the stent.
- The stent has not been evaluated for repositioning or removal after deployment in the biliary tract.

COMPLICATIONS
Complications associated with the use of the ALI**MAXX-B**® Covered **Biliary** Stent with Silicone Covering may include, but may not be limited to, the usual complications reported for conventional covered biliary stents and for endoscopic procedures such as:

- infection or fever
- stent misplacement
- stent migration
- tumor overgrowth at the stent ends
- sludge occlusion
- bleeding, hemobilia
- cholangitis
- pancreatitis
- bile duct trauma, perforation or ulceration
- stent fracture
- obstruction of branch ducts
- tumor ingrowth
- death

DIRECTIONS FOR USE
Materials Required for Stent Placement:

- ALI**MAXX-B**® Covered **Biliary** Stent of appropriate length and diameter (with **185 cm** delivery catheter working length)
- Duodenoscope system appropriately sized for the endo scopic channel (3.3 mm [10 Fr] or larger)
- Appropriate diagnostic catheters, dilators, sphincterotomes and accessories
- Radiopaque contrast solution
- 10 cc syringe filled with sterile saline
- 0.035" (0.89 mm) guidewire of at least 450 cm long (preferably stiff or extra stiff)

1. Perform Endoscopic Retrograde Cholangiopancreatography (ERCP).

1.1 Position the distal end of the endoscope in the duodenum near the major duodenal papilla (papilla of Vater) (Figure 3).
1.2 Using fluoroscopy, locate the proximal and distal ends of the stricture (Figure 4). Inject contrast solution as necessary.
1.3 Insert a 0.035" (0.89 mm) guidewire through the endoscope into the biliary system, past the biliary stricture (Figure 5).
1.4 Keep the guidewire situated through the stricture until stent deployment is complete.

NOTE: Predilatation of the biliary stricture, with a balloon catheter or appropriate dilator, may be performed prior to stent implantation at the discretion of the physician.

WARNING: Do not attempt placement of the ALI**MAXX-B**® **Biliary** Stent in patients with stenoses that cannot be dilated sufficiently to allow passage of the delivery catheter.

2. Select the Appropriate Stent Size.
Using the cholangiographic maps of the patient's biliary system as a guide, select the appropriate diameter and length ALI**MAXX-B**® Stent needed. **Allow for at least 10-20 mm of the stent to extend past both margins of the stricture.** If one stent does not sufficiently cover the stricture, the second stent should overlap at least 1 cm of the initially placed stent. (See also *Implanting More Than One Stent* following Step 9). **The stent length should NOT excessively extend into the duodenum.** Also, the ALI**MAXX-B**® **Biliary** Stent does not significantly foreshorten during deployment, therefore, stent shortening does not need to be taken into account.

NOTE: Mapping out the biliary tract cholangiographically is also necessary to determine whether a branch duct may be excluded by placement of the stent.

3. Prepare the Stent System for Insertion.

3.1. Before Opening the Sterile Package:
Check to see that the package label is consistent with the selected stent size and the appropriate delivery catheter length for the specific procedure (Endoscopic vs. Transhepatic), before opening the package. The delivery catheter working length is 185 cm.
3.2. Opening the Sterile Package:
First, carefully inspect the pouch to make sure that the sterile barrier has not been compromised. Use appropriate technique for handling the device in a sterile environment if required.
3.3. Before Using the Stent:
Check to make sure the stent (which is pre-loaded on the delivery catheter) is completely covered by the outer sheath of the delivery catheter. Only the delivery catheter tip should be exposed. Do not use the device if the stent has become exposed. Examine the entire device for any damage or defects before using the ALI**MAXX-B**® Stent. Do not use any defective materials.

3.4. Preparing the Delivery Catheter:

3.4.1 To flush the guidewire lumen, attach a 10cc syringe filled with sterile saline to the Luer port on the back of the delivery system handle (Figure 6).
3.4.2 Holding the device horizontally, flush until fluid is visible at the tip.
3.4.3 To flush the space between the inner catheter and outer sheath of the delivery catheter, attach a 10cc syringe filled with sterile saline to the Luer port on the handle shaft (Figure 6).
3.4.4 Holding the device horizontally, flush the space between the inner sheath and outer sheath until the fluid is visible at the tip.
3.4.5 After flushing the delivery catheter, remove the syringe.

4. Introduce the Delivery Catheter.

4.1 Perform ERCP if it has not already been done (Step 1) and prepare the device by flushing with saline solution (Step 3).
4.2 Keeping the guidewire positioned through the biliary stricture, remove any catheters. Make sure to replace the positioned guidewire with a 0.035" (0.89 mm) guidewire if there is not one already in place.
4.3 Holding the delivery catheter as straight as possible, carefully insert the guidewire into the tip of the delivery catheter.
4.4 Advance the delivery catheter over the guidewire and through the endoscopic channel into the biliary tract. Advance cautiously, especially if resistance is encountered.

NOTE: If significant resistance is met when advancing the delivery catheter into the endoscopic channel do not torque the device. Remove and inspect the delivery system for damage. Do not use if damaged.

NOTE: In order to ensure precise stent placement, radioscopic and endoscopic visualization of the stent itself is necessary.

NOTE: A sphincterotomy is not always essential for stent delivery, but may be performed at the option of the implanting physician.

5. Deploy the stent as described below.

Important Guidelines for Accurate Stent Placement:

- **Use the 5 radiopaque markers on the device as a guide (Figure 2 and Figure 7) when positioning the stent across the stricture.** Radioscopic visualization is required for accurate stent placement.
- **Stent is located between radiopaque marker band at distal end of the outer sheath and stent STOP (Figure 2). Center the stent at the stricture (Figure 7).** Position the ends of the loaded stent at least 10-20 mm proximal and distal to the margins of the stricture.
- Keep your elbow and upper arm close to the side of your body. This will keep the delivery handle still throughout stent deployment.
- **Keep the delivery system as straight as possible** during stent deployment.
- **Gently grab the stabilizing sheath at the entry into the working channel of the endoscope and immobilize it during deployment. This will ensure that you achieve high placement accuracy. Do not pinch or apply too much force on stabilizing sheath as it will create high deployment force and inaccurate stent placement.**
- A guidewire with radiopaque markers at known intervals may also be used to assist in stent placement.

CAUTION: Do **NOT** push forward on the delivery system with the stent partially deployed. The handle must be immobilized securely. Pushing on the delivery system may cause misalignment of the stent and possible duct damage. The stent should deploy easily. Do not deploy the stent if unusual force is required, since this may indicate a failed device.

IMPORTANT: While deploying the stent, pull back slightly on the handle to create a back tension to prevent the device from creeping forward. This action counters the tendency of the stricture to pull the expanding stent forward.

NOTE: The stent is not reconstrainable.

How to deploy the stent:

5.1 The delivery system has a handle with 2 deployment triggers enabling the user to deploy the stent in 2 steps (Figure 8). Please ensure that the two deployment triggers are ~2 inches apart. If not, slide the first trigger (Figure 8) towards the handle until you feel slight resistance.
5.2 Place the handle of the delivery system in the palm of your hand (Figure 9). Wrap your ring and little fingers around the base of the handle to form a 'pistol grip.' Then rest the tips of the index and middle fingers on the first deployment trigger. **Before you start to deploy the stent, release the elevator of the duodenoscope.**
5.3 While visualizing under fluoroscopy, slowly pull back the first deployment trigger until it touches the handle. Confirm that the positioning of the stent is correct.
5.4 If the stent is deployed more proximally than the target location, it can be repoisioned distally by slowly applying traction to the handle while not allowing the first trigger to move distally. Stop applying traction once the stent is at the correct location.
5.5 When the first deployment trigger is touching the handle, the stent will be deployed ~40-80% of its length (Figure 10).
5.6 After confirming the position of the stent, rest your index and middle fingers on the second deployment trigger (Figure 11).
5.7 Pull back the second deployment trigger until the trigger touches the handle. The stent is now fully deployed (Figure 12).

6. Confirm stent deployment, then remove the delivery system.

Confirm fluoroscopically that the stent has completely deployed and expanded. Carefully remove the delivery catheter from within the expanded stent without disturbing the position of the stent. Continue to remove the delivery catheter back over the guidewire.

7. Confirm the patency and location of the stent, using standard radiographic procedures.

8. Remove all guidewires and catheters.

9. Post-procedure management:

The patient should be observed for complications associated with ERCP, biliary dilation and stent placement.
The patient should be monitored closely for 24 hours post-implant. Patients should be routinely checked for stent patency and location within 90 days of implant, using standard radiographic procedures.

Implanting more than one stent:
Devices need to be overlapped by at least 1 cm when more than one device is placed to cover the stricture properly. 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 liver is placed first.

REPOSITIONING OF THE BILIARY STENT

WARNING: The stent has not been evaluated for repositioning after deployment in the biliary tract.

Conservative medical practice suggests that stents not be repositioned proximally (towards liver).

The repositioning of the stent may be necessary in the event that the stent is not in a desirable location or improperly sized. Position the duodenoscope so that the distal flare of the stent is visible. The ALI**MAXX-B**® **Biliary** Stent can be repositioned distally by applying gentle traction to the distal end of the stent using grasping forceps such as alligator forceps. Open the forceps and carefully pass the forceps over the distal end of the stent at the location of one of the stent connectors (Figure 13).

One jaw should be positioned outside of the stent. The other jaw should be positioned inside the stent. Close the forceps over the stent connector, grasping as much of the stent connector as possible. Do not grasp the covering of the stent alone without grasping the metal stent connector (Figure 14).

Gently apply traction to the stent connector to reposition the stent distally.

WARNING: Do not attempt repositioning by grasping the middle or proximal end of the stent.

WARNING: Do not use rat tooth or biopsy forceps to grasp the metal struts covering to reposition the stent.

WARNING: Do not rotate the stent using forceps if it is being repositioned.

REMOVAL OF THE BILIARY STENT

WARNING: Preclinical testing in animals (pigs) for stent removal was limited to 6 months post-implantation. The safety of removal in the clinical setting has not been assessed.

The removal of the stent may be necessary in the event that the stent is not in a desirable location or improperly sized. Position the endoscope so that the distal flare of the stent is visible. The ALI**MAXX-B® Biliary** stent can be removed using a snare to grasp the distal end of the stent and carefully applying traction.

Open the snare and carefully pass the lasso around the distal end of the stent (Figure 15). Close the snare and apply gentle traction to snare to remove the stent from the bile duct (Figure 16).

Once **the stent starts** to move, apply traction to snare/forceps and duodenoscope assembly. Do not allow stent to enter the working channel of duodenoscope as it may damage the scope.

WARNING: Do not attempt removal by grasping the middle or proximal end of the stent.

WARNING: Do not attempt to reload or reconstrain a deployed or partially deployed self-expanding stent. If it becomes necessary to remove a partially deployed stent the entire system should be withdrawn en bloc. Do not attempt to advance the outer sheath to recompress the stent prior to withdrawing the system.

MR Conditional

Non-clinical testing has demonstrated that the ALI**MAXX-B® Biliary** Stent is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 3-Tesla or less
- Spatial gradient field of 720 Gauss/cm or less
- Maximum specific absorportion rate (SAR) of 3 W/kg for 15 minutes of scanning.

In non-clinical testing, the ALI**MAXX-B® Biliary** Stent produced a temperature rise of less than or equal to 0.7˚C at a maximum specific absorportion rate (SAR) of 3 W/kg for 15 minutes of MR scanning in a 3-tesla MR system using a transmit/receive body coil (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI) MR scanner. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the AERO™ stent. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

STORAGE

Do not expose this device to conditions of extreme heat and humidity. Store the ALI**MAXX-B® Biliary** Stent System in a normal room temperature environment.

Store in a cool, dry place.

HOW SUPPLIED

The ALI**MAXX-B® Biliary** Stent is supplied **STERILE** by method of ethylene oxide. The ALI**MAXX-B® Biliary** Stent should not be re-sterilized.

Contact Customer Service at 1-800-356-3748 if the package has been opened or damaged.

The disposable, single-patient-use self-expanding stent is available, pre-mounted on the delivery catheter in a variety of configurations. The table below lists the lengths and diameters for the currently available stents.

The recommended guideline for choosing stent length is that the stent be long enough to extend 10-20 mm past both margins of the stricture.

Table 1. Stent Sizes

Labeled Stent Size (mm) diameter x length	Labeled Stent Diameter (mm)	Flared Diameter of Both Stent Ends (mm)
8x40 8x60 8x80	8	10
10x40 10x60 10x80	10	12

All of the Covered Biliary stents are mounted on a delivery catheter with a maximum outer diameter (OD) of 3.3 mm (10 Fr). The overall maximum length of the delivery system is 220 cm for the delivery catheter.

CAUTION: Federal law (USA) restricts this device to sale by or on order of a physician.

Each packaged unit is intended for **SINGLE-PATIENT-USE ONLY.**

For more information or to arrange for a demonstration, contact Merit Medical at the telephone number shown on the previous page.

REUSE PRECAUTION STATEMENT

Contents supplied **STERILE** using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. IF damage is found, call your Merit Medical representative.

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

WARRANTY

The manufacturer warrants that reasonable care has been used in the design and manufacture of this device. This warranty is exclusive and manufacturer makes no other representations or warranties of any kind to customers, its end users, or to any third parties with respect to the device and hereby expressly disclaims any and all other warranties, express or implied, statutory or otherwise, including, but not limited to, infringement and the implied warranties of merchantability and fitness for a particular purpose, even if manufacturer is aware of such purpose. Handling and storage of this device, as well as other factors relating to the patient, diagnosis, treatment, implant procedures, and other matters beyond the control of the manufacturer, directly affect the device and the results obtained from its use. The manufacturer's obligation under this warranty is limited to the replacement of the device. Under no circumstances shall manufacturer be liable to customer or any other person or entity for any punitive, special, incidental or consequential damages directly or indirectly arising from the use of this device. The manufacturer neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. This warranty shall not apply, and manufacturer assumes no liability with respect to, devices that have been (i) modified, changed, altered, misused, mishandled, repaired, reused, reprocessed, refurbished or resterilized; (ii) subjected to improper maintenance, testing or storage, accident, tampering, or inadequate protection against shock, vibration, excessively high or low temperatures, overpressure, or physical, environmental or electrical stress; (iii) been used outside the approved "Indications for Use" as cleared by the relevant competent authority, used contrary to the use outlined in the device specifications, or in an application or environment for which such device was not designed or contemplated; or (iv) distributed or used contrary to applicable federal, state, local or regulatory standards.

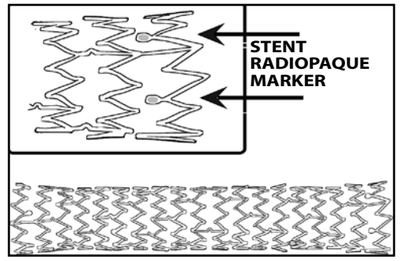

Figure 1. Radiopaque markers are located at both ends of the ALIMAXX-B® Biliary stent.

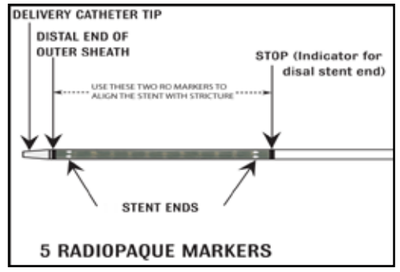

Figure 2. There are 5 radiopaque regions present on the ALI**MAXX-B**™ Biliary Stent System.

Figure 3. Position the distal end of the endoscope in the duodenum near the major duodenal papilla (papilla of Vater)

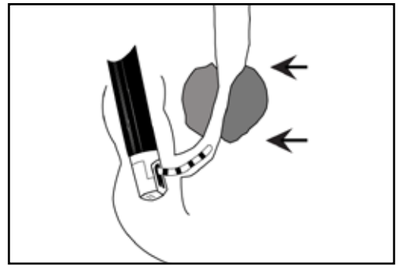

Figure 4. Using fluoroscopy, locate the proximal and distal ends of the stricture.

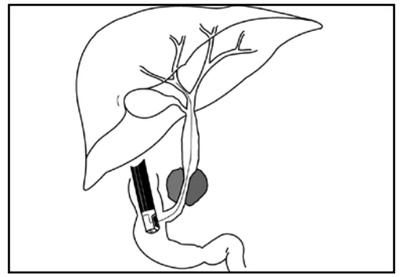

Figure 5. Insert the guidewire through the endoscope into the bile duct system and through the stricture.

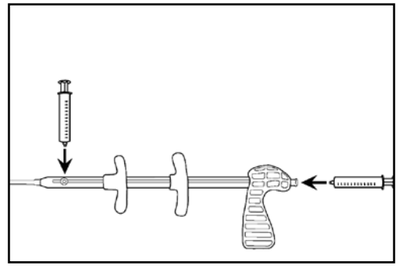

Figure 6. Flush the delivery system with saline solution through the 2 Luer ports.

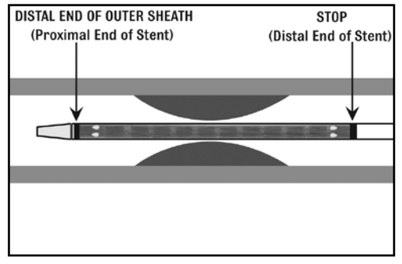

Figure 7. Using radiopaque markers as a guide, position the stent across the stricture.

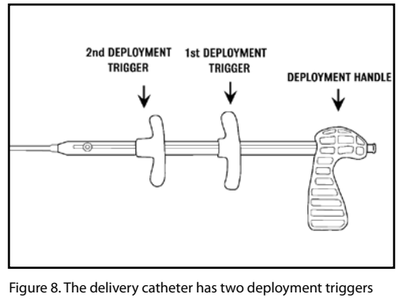

Figure 8. The delivery catheter has two deployment triggers which allow the user to deploy the stent in 2 steps.

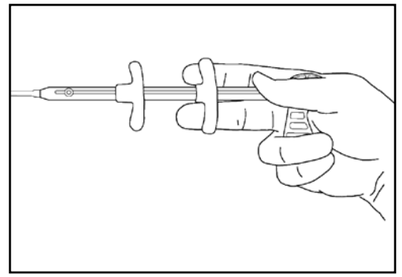

Figure 9. Hold the handle in the palm of your hand. Using the index and middle finger, grasp the first deployment trigger. Proximal End of Stent Can be Visualised Endoscopically

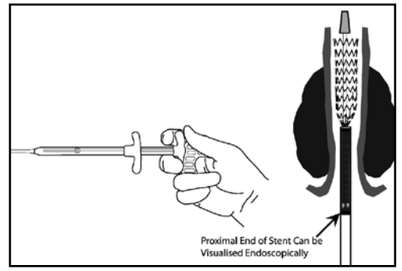

Figure 10. Slowly retract the outer sheath by pulling back on the first deployment trigger until it touches the handle.

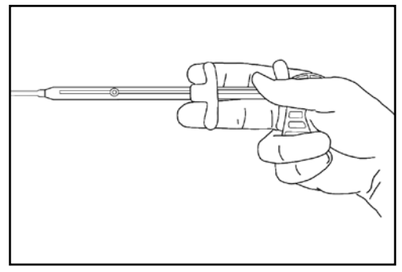

Figure 11. After confirming the stent position, use your index and middle finger to grasp the second deployment trigger.

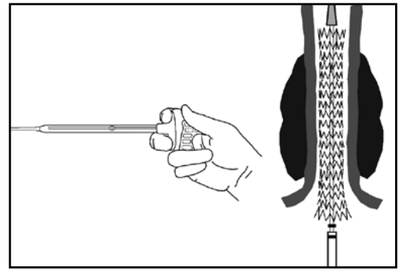

Figure 12. Pull the second deployment trigger until the trigger touches the handle. The stent is now fully deployed.

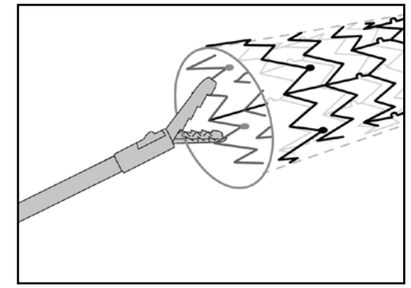

Figure 13. Open the forceps and carefully pass the forceps over the distal end of the stent at the location of one of the stent connectors.

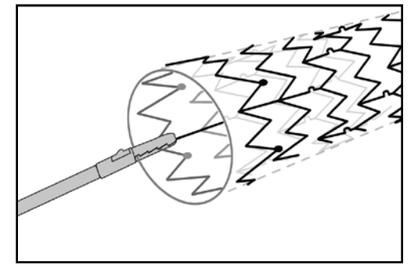

Figure 14. Close the forceps over the stent connector, grasping as much of the stent connector as possible.

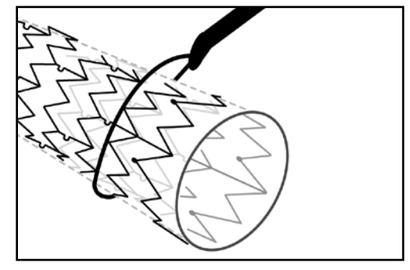

Figure 15. Open the snare and carefully pass the lasso around the distal end of the stent.

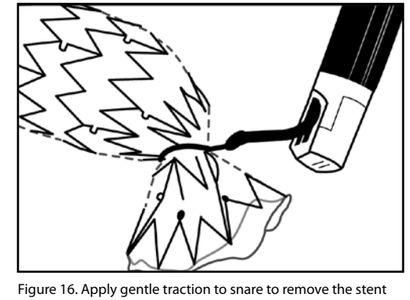

Figure 16. Apply gentle traction to snare to remove the stent from the bile duct.