ALIMAXX-B® for Endoscopic Delivery Hybrid Covered Biliary Stent Technology System

**CAUTION:** Consult accompanying documents.

**WARNINGS**

1. Placement of a stent across a branch duct or major biliary bifurcation may be complicated due to blocking of flow from the branch duct and prevent future endoscopic access.

2. Final stent placement resulting in an excessive length of overlap into the duodenum may damage pancreatic tissue.

3. The ALIMAXX-B® Stent System should not be cut prior to use and should only be implanted using the system supplied with the stent.

4. Patients should carefully follow the decision to implant the ALIMAXX-B® Stent in patients with active infections or other contraindications involving the hepatobiliary system. Physicians should also consider the potential for repositioning associated with the endoscopic manipulation of a 3.1 mm (10 Fr) catheter in the biliary system.

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**

1. The device is intended for use by physicians who have received appropriate training.

2. The device should not be sterilized.

3. The device should be placed under fluoroscopic monitoring.

4. The device is intended for single use only. Do not attempt to reload deployed stents into the delivery system.

5. The device is not reconstraining.

6. Chemotherapy and irradiation may increase the risk of stent migration due to tumor shrinkage, stent erosion or mucosal bleeding.

If the guide wire or delivery catheter cannot advance through the obstruction, the stricture should not be dilated with a balloon catheter even though the stricture (Figure 5).

**How to deploy the stent:**

1. Before Opening the Sterile Package: Check the package to ensure that the selected stent size and the appropriate delivery catheter length are included. Use the package to confirm that the sterile barrier has not been compromised. Use the sterile barrier to facilitate placement.

2. Place the endoscope into the duodenum (Figure 7) and begin the procedure as described below.

3. After confirming the position of the stent, rest your index and middle fingers on the second deployment trigger (Figure 11).

4. Introduce the Delivery Catheter.

5. Perform Endoscopic Retrograde Cholangiopancreatography (ERCP).

6. Position the distal end of the endoscope in the duodenum near the major duodenal papilla (papilla of Vater) using standard radiographic procedures.

7. Using fluoroscopy, locate the proximal and distal end of the stent to be deployed. Confirm that the stricture is dilatable as necessary.

8. Using a 0.035” (0.89 mm) guidewire through the endobiliary system into the biliary stricture, pull the guidewire immediately into the stricture.

9. Guide the guidewire through the vascular structure using the guidewire as a guide, select the appropriate diameter and length of delivery catheter, working length 185 cm.

1.1 Position the distal end of the endoscope in the duodenum near the major duodenal papilla (papilla of Vater) using standard radiographic procedures.

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1.3 Insert a 0.035” (0.89 mm) guidewire through the endobiliary system into the biliary stricture, pull the guidewire immediately into the stricture.

1.4 Keep the delivery catheter as straight as possible, carefully insert the guidewire into the tip of the delivery catheter.

1.5 Advance the delivery catheter over the guidewire and carefully deploy the endobiliary system into the biliary tract. Advance cautiously, especially if resistance is encountered.

**WARNING:** Note: If sufficient resistance is met when advancing the delivery catheter into the endobiliary channel do not torque the catheter. The delivery system is for deployment only. Do not use if damaged.

**NOTE:** In order to ensure smooth stent placement, radiographic and endoscopic visualization of the stent itself is necessary. A stent's appearance is not always characteristic of stent delivery, and may be performed at the option of the implanting physician.

**5. Deploy the stent as described below.**

**Important Guidelines for Accurate Stent Placement:**

1. Use the 5 radiopaque markers on the device as a guide (Figure 3 and Figure 7) when determining the stent from the stricture. Radiographic visualization is required for accurate stent placement.

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REMOVAL OF THE BILIARY STENT

WARNING: Prediscal testing in animals (goats) 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® Biliary stent may 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/feneces 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 reconstraining 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® 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 absorption rate (SAR) of 3 W/kg for 15 minutes of scanning.

In non-clinical testing, the ALI® Biliary Stent produced a temperature rise of less than or equal to 0.7˚C at a maximum specific absorption rate (SAR) of 3 W/kg for 15 minutes of MR scanning in a 3-Tesla MR system using a transmit/receive body coil (Brach, Stryker G6, 30-9286, Donner 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 AEROS™ stent. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

Storage

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

Store in a cool, dry place.

How Supplied

The ALI® Biliary Stent is supplied STERILE by method of ethylene oxide. The ALI® 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.

Table 1. Stent Sizes

<table>
<thead>
<tr>
<th>Size (mm)</th>
<th>Diameter (mm)</th>
<th>ENDPOINTS TIP</th>
<th>DELIVERY CATHETER TIP</th>
<th>INDEX MARKER</th>
<th>MARKER</th>
<th>STENT ENDS</th>
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The recommended guideline for choosing stent length is based on the margins of the stricture.

REQUISITE PRECISION STATEMENT

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

For single-patient use only. Do not reuse 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 infection diseases 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, in end users, or to any third parties with respect to the device and hereby expressly disclaims all of any and all warranties, express or implied, statutory or other, 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 or 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 effect the device and the results obtained from its use. The manufacturer’s obligation under this warranty is limited to the replacement of the device. Limitation 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, reused, modified, repaired, reused, repaired 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 electrostatic stress; (iii) been used outside the approved “Indication for Use” as assigned by the relevant competent authorities, used contrary to the use outlined in the device specifications, or in an environment or application for which such device was not designed or contemplated or felt distributed or used contrary to applicable federal, state, local or regulatory standards.

REUSE PRECAUTION STATEMENT

Do not attempt to reload or reconstraining 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.

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