

# ALIMAXX-B<sup>®</sup>

Uncovered Biliary Stent System

INSTRUCTIONS FOR USE

MODE D'EMPLOI

ISTRUZIONI PER L'USO

GEBRUIKSAANWIJZING

INSTRUCCIONES DE USO

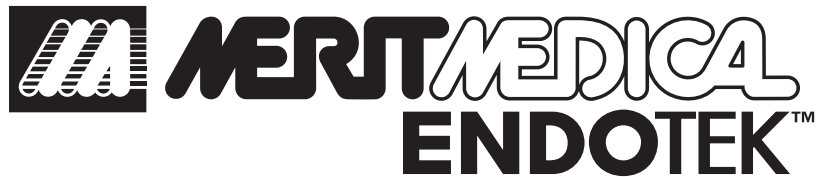
INSTRUÇÕES DE UTILIZAÇÃO

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# ALIMAXX-B® Uncovered Biliary Stent System

## DEVICE DESCRIPTION

The **MERIT ENDOTEK™ ALIMAXX-B® Uncovered Biliary Stent System** is comprised of two components: the radiopaque, self-expanding nitinol stent and the delivery system. The stent comes pre-loaded on the delivery catheter.

The stent is composed of a nitinol scaffold. 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 185cm 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 an 0.035" (0.89mm) guide wire. 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 Instructions for Use should be reviewed before using this system.

## INDICATIONS FOR USE

The **ALIMAXX-B® Uncovered Biliary Stent** is indicated for palliation of malignant strictures in the biliary tree.

**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 **ALIMAXX-B® Uncovered 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 8cm in length

## COMPLICATIONS

Complications associated with the use of the **ALIMAXX-B® Uncovered Biliary Stent** may include, but may not be limited to, the usual complications reported for conventional uncovered 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

## ADDITIONAL CAUTIONS AND WARNINGS

1. A stent placed over a bifurcation in the biliary system can prevent or complicate future access by endoscopic or other procedures.
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 **ALIMAXX-B® Uncovered Biliary Stent** must not be cut prior to use and should only be implanted using the delivery system supplied with the stent.
4. Physicians should carefully consider the decision to implant the **ALIMAXX-B® Uncovered 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 6.5F (2.2mm) 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 guide wire 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.

## INSTRUCTIONS FOR USE

### Materials Required for Stent Placement:

- **ALIMAXX-B® Uncovered Biliary Stent** of appropriate length and diameter (with 185cm delivery catheter working length)
- Duodenoscope system appropriately sized for the endoscopic channel (6.5F [2.2mm] or larger)
- Appropriate diagnostic catheters, dilators, sphincterotomes and accessories
- Radiopaque contrast solution
- 10ml syringe filled with sterile saline
- 0.035" (0.89mm) guide wire of at least 450cm 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 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" (0.89mm) guide wire through the endoscope into the biliary system, past the biliary stricture (Figure 5).
- 1.4 Keep the guide wire situated through the stricture until stent deployment is complete.

**NOTE:** Dilatation 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 **MERIT ENDOTEK™ ALIMAXX-B® Uncovered 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 **ALIMAXX® Uncovered Biliary Stent** needed. **Allow for at least 10-20mm 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 1cm of the initially placed stent. (See Implanting More Than One Stent following Step 9). **The stent length should NOT excessively extend into the duodenum.** NOTE: The **ALIMAXX-B® Uncovered 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:

Ensure 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 185cm.

### 3.2. Opening the Sterile Package:

Carefully inspect the pouch to ensure that the sterile barrier has not been compromised. Use appropriate technique for handling the device in a sterile environment.

### 3.3. Before Using the Stent:

Inspect the stent (which is pre-loaded on the delivery catheter) to ensure that the stent 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 **ALIMAXX-B® Uncovered Biliary Stent**. Do not use any defective materials.

**CAUTION:** Do not remove trigger safety until ready to deploy stent.

## 3.4. Preparing the Delivery Catheter:

- 3.4.1 **To flush the guide wire 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 until 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 guide wire positioned through the biliary stricture, remove any catheters.** Make sure to replace the positioned guide wire with a 0.035" (0.89mm) guide wire if there is not one already in place.

4.3 **Holding the delivery catheter as straight as possible, carefully insert the guide wire into the tip of the delivery catheter.**

4.4 Advance the delivery catheter over the guide wire 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 introducer sheath 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 10-20mm proximal and distal to the margins of the stricture.
- Remove the trigger safety connected at the second trigger by pulling on the tab in the direction of the red arrow and releasing the safety (Figure 8)
- To maintain stent placement, 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 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 guide wire 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. 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 device failure.

**IMPORTANT:** While deploying the stent, maintain 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 approximately 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 repositioned 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 approximately 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 guide wire.

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

#### 8. Remove all guide wires 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. NOTE: Overlapping the stents more than 1 cm may compromise the patency of the lumen.

#### MR Conditional

Non-clinical testing has demonstrated that the **ALIMAXX-B® Uncovered 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 **ALIMAXX-B® Uncovered Biliary Stent** produced a temperature rise of less than or equal to 0.8°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 (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 **ALIMAXX-B® 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 **MERIT ENDOTEK™ ALIMAXX-B® Uncovered Biliary Stent System** in a normal room temperature environment.

Store in a cool, dry place.

#### HOW SUPPLIED

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

Contact MERIT ENDOTEK™ Customer Service at **1-800-35-MERIT (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 of the currently available stents.

The recommended guideline for choosing stent length is that the stent be long enough to extend 10-20mm 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	8	10
8x60		
8x80		
10x40	10	12
10x60		
10x80		

All of the uncovered Biliary Stents are mounted on a delivery catheter with a maximum outer diameter (OD) of 6.F (2.2mm). The overall maximum length of the delivery system is 217cm.

**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**.

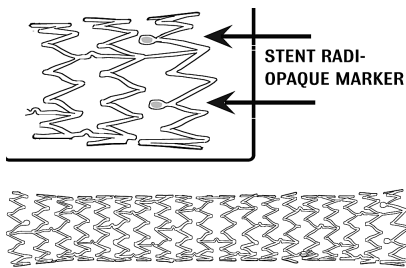
For more information or to arrange for a demonstration, contact MERIT ENDOTEK™ at the telephone number shown on the previous page.

#### REUSE PRECAUTION STATEMENT

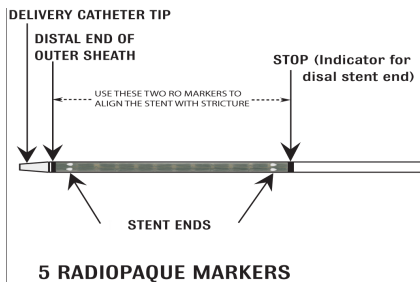
Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination 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**

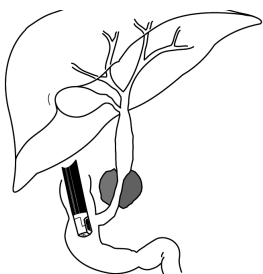
The manufacturer warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. 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 obligation under this warranty is limited to the replacement of this device; and the manufacturer shall not be liable for any incidental or consequential loss, damage, or expense 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. The manufacturer assumes no liability with respect to devices that are reused, reprocessed, or resterilized, and makes no warranties, expressed or implied, including, but not limited to, merchantability or fitness for intended use, with respect to such device.



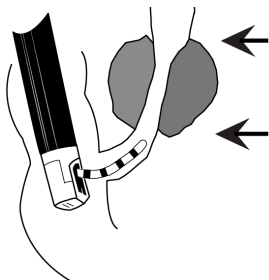
**Figure 1.** Radiopaque markers are located at both ends of the ALIMAXX-B® Uncovered Biliary Stent.



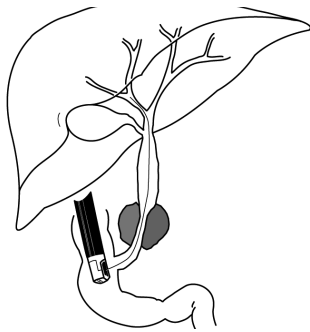
**Figure 2.** There are 5 radiopaque regions present on the ALIMAXX-B® Uncovered Biliary System.



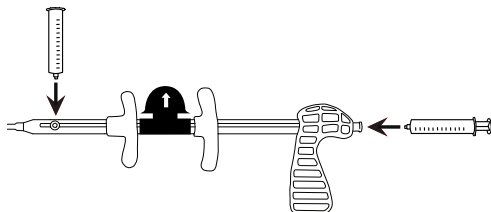
**Figure 3.** Position the distal end of the endoscope in the duodenum near the major duodenal Papilla of Vater.



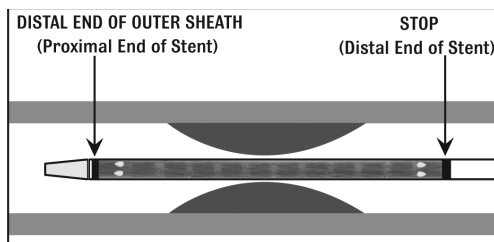
**Figure 4.** Using fluoroscopy, locate the proximal and distal ends of the stricture.



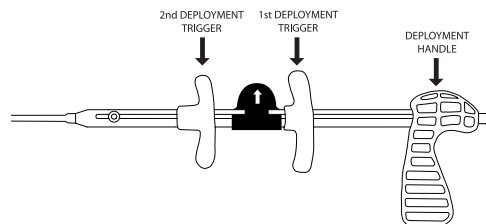
**Figure 5.** Insert the guide wire through the endoscope into the bile duct system and through the stricture.



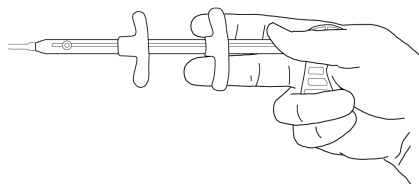
**Figure 6.** Flush the delivery system with saline solution through the 2 luer ports.



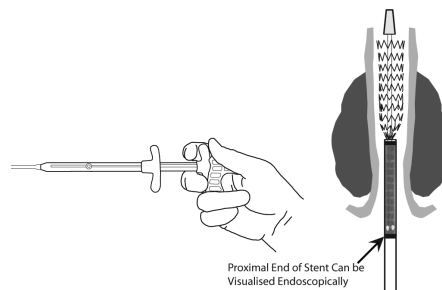
**Figure 7.** Using radiopaque markers as a guide, position the stent across the stricture.



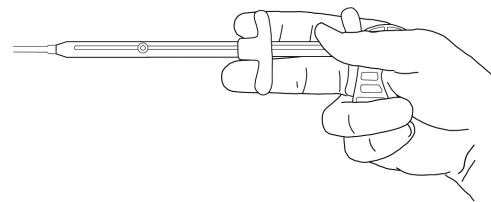
**Figure 8.** The delivery system has two deployment triggers which allow the user to deploy the stent in 2 steps.



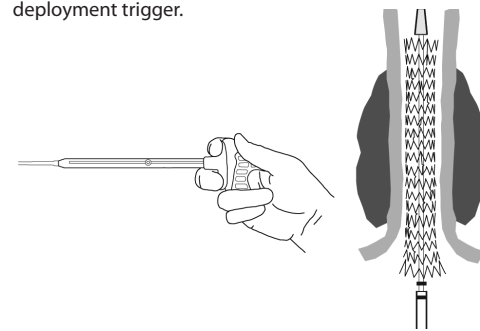
**Figure 9.** Hold the handle in the palm of your hand. Using the index and middle finger, grasp the first deployment trigger.



**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.



Single Use

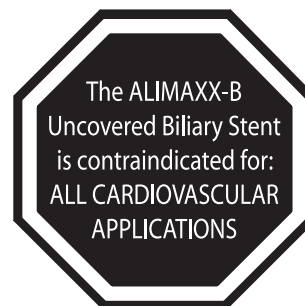


MR Conditional



Non-pyrogenic

Sterile if package is unopened or undamaged



The ALIMAXX-B Uncovered Biliary Stent is contraindicated for: ALL CARDIOVASCULAR APPLICATIONS

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

US and foreign patents issued and pending

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Germany 0800 1820871; Ireland 091 703700; Neth. 0800 0228184; U.K. 0800 973115

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