Allium Endoscopic Biliary Stent (BIS)

Instructions For Use

Manufactured by

***Allium Ltd*.**

DEVICE NAME

"ALLIUM Endoscopic Biliary Stent" (BIS)

DEVICE DESCRIPTION

Allium's BIS stent is to be inserted into the Common Bile Duct to allow free flow of bile from the gall bladder and liver to the duodenum by supporting the obstructed area of the bile duct lumen, keep it open and prevent its re-stenosis.

Allium's BIS stent is intended for endoscopic retrograde insertion into the common bile duct of patients diagnosed with malignant obstruction of the common bile duct in order to drain the occluded biliary ducts. It is intended to remain in place up to 1 year**.**

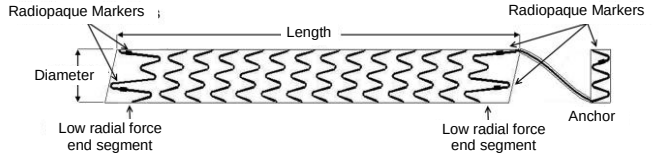
Allium's BIS stent comes in a configuration to best fit the anatomy of the segment of the bile duct where it will be deployed. The tubular shaped stent has a high radial force body to keep open the stenosed segment, as well as low radial force ends designed to reduce the friction between the stent extremities and the surrounding tissue in order to reduce the reactive proliferative tissue development.

The BIS stent has a metal structure with self-radial-expanding design. The caliber of the stent when fully opened is 8 or 10 mm in diameter and is covered with a thin layer of polymeric material and is easy to remove. Once inserted and positioned into the occluded common bile duct, it is released from its specially designed 10 Fr delivery device.

ALLIUM Endoscopic Biliary Stent comes in two configurations to best fit the occluded segment of the bile duct where it will be deployed:

1. Endoscopic System with anchor (BIS-A-E)

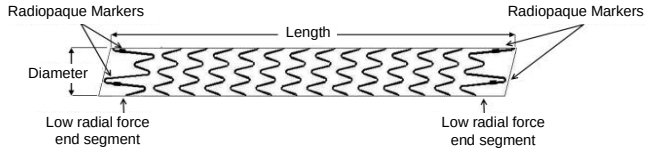
***The ALLIUM Endoscopic Biliary Stent* with anchor** has an anchoring segment to prevent upward migration of the stent. It is intended to keep the papilla of Vater intact in order to prevent reflux from the duodenum toward the biliary tract. In these patients the body of the stent is in the common bile duct while the trans-spincteric single wire segment passes through the sphincter and the anchor is in the duodenum. Each end of the body has 3 radiopaque markers with an additional one at the anchor.



***Allium Endoscopic Biliary Stent with anchor (BIS-A-E*)**

2. Endoscopic System without anchor (BIS-O-E)

***The ALLIUM Endoscopic Biliary Stent* without anchor** is intended for use in cases intended to leave its downstream end protruding into the duodenum. Each end of the body has 3 radiopaque markers.



Allium Endoscopic Biliary Stent without anchor (BIS-O-E)

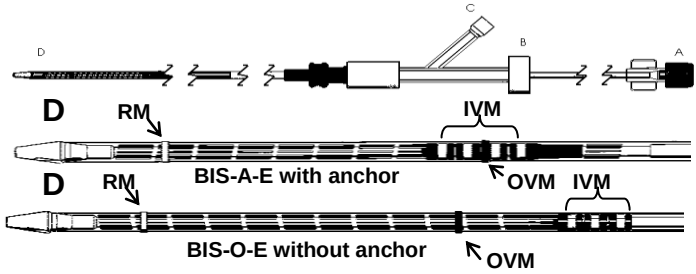
The device is composed of 2 main elements:

1. The stent
2. Deployment system

BIS Insertion system

The deployment device has a ***black outer visual marker* (OVM)** on the overtube and beneath it **4 yellow *inner visual markers*** (**IVM**) on the inner tube, both indicating the place of the wire connecting the anchor to the body of the stent.

ALLIUM Endoscopic Biliary Stent delivery device



Biliary Stent Ordering Information:

Endoscopic System with Anchor		
Order Number	**Stent Diameter**	**Stent Body Length**
BIS-A-E-8-60	8 mm	60 mm
BIS-A-E-8-80	8 mm	80 mm
BIS-A-E-8-100	8 mm	100 mm
BIS-A-E-8-120	8 mm	120 mm
BIS-A-E-10-60	10 mm	60 mm
BIS-A-E-10-80	10 mm	80 mm
BIS-A-E-10-100	10 mm	100 mm
BIS-A-E-10-120	10 mm	120 mm

Endoscopic System without Anchor		
Order Number	**Stent Diameter**	**Stent Body Length**
BIS-O-E-8-60	8 mm	60 mm
BIS-O-E-8-80	8 mm	80 mm
BIS-O-E-8-100	8 mm	100 mm
BIS-O-E-8-120	8 mm	120 mm
BIS-O-E-10-60	10 mm	60 mm
BIS-O-E-10-80	10 mm	80 mm
BIS-O-E-10-100	10 mm	100 mm
BIS-O-E-10-120	10 mm	120 mm

INDICATIONS FOR USE

ALLIUM Endoscopic Biliary Stents *(BIS) are indicated for obstructive jaundice caused by malignant bile duct obstruction.*

Do not use the Anchored BIS design if the obstructing lesion involves the papilla or is situated less than 2 cm from the papilla.

CONTRAINDICATIONS
The insertion of BIS is contraindicated in patients who:

- Have jaundice that was not been previously evaluated.
- Cannot tolerate any form of antibiotic treatment.
- Have a post-surgical anatomy that precludes the performance of ERCP.
- Have bleeding disorders or are on anticoagulation therapy.
- Have a history of illness, medication, or surgery that may affect the efficacy of the stent.
- Have a history of allergy to iodine preparations.
- Have renal failure.

POTENTIAL COMPLICATIONS
Potential complications associated with insertion of the ***"ALLIUM Endoscopic Biliary Stent"*** are similar to all other biliary stents and **may include:**
Pain/discomfort, bleeding, perforation of the bile duct, infection, sepsis, liver abscess, pancreatitis, stent misplacement or migration, stent obstruction by tumor tissue or sludge, allergic reactions to the nickel-titanium alloy

PRECAUTION
Checking the device: The device should be inspected for any damage before insertion. **In case damage is observed THE DEVICE SHOULD NOT BE USED.**
Training: Proper training for positioning and deploying the ***"ALLIUM Endoscopic Biliary Stent"*** is required. The device can be used only by physicians who underwent appropriate training for its use. Prior to use, the technical information supporting this device should be carefully reviewed.

Stent positioning: Manipulation of the delivery device and stent positioning should be done using high quality endoscopy and fluoroscopy systems.

WARNINGS
General

- The ***"ALLIUM Endoscopic Biliary Stent"*** is not intended for definitive treatment of the biliary tract pathology.
- The ***"ALLIUM Endoscopic Biliary Stent"*** or its delivery mechanism should not come in contact with organic solvents at anytime before its use.
- The safety and effectiveness of the ***"Allium Trans-hepatic Biliary Stent"*** for use in the vascular system have not been established and should not be used in blood vessels.

Device Related:

- **Single use device:** The ***"ALLIUM Endoscopic Biliary Stent"*** is intended for Single Use Only-**DO NOT RESTERILIZE**.
  Reuse, reprocessing, resterilization or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient.
  Reuse, reprocessing, resterilization or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient or end user.
- The device should not be used if the package is open or damaged or if the device has been contaminated prior to insertion.
- The constricted stent and delivery system should be visually inspected for damage prior to use.
- Remounting an expanded stent into the delivery system and its reuse should not be attempted. This can seriously damage the patient's health.
- The stent should only be placed under direct endoscopic and fluoroscopic visualization.
- Longitudinal compression of the stent by instrumentation could dislodge the stent.
- Should stent migration occur, the stent can be removed and replaced with a new one.

DIRECTIONS FOR USE
Pre-procedural preparation
The antibiotic prophylaxis for each patient is a broad spectrum oral antibiotic to be started at least 3 hours before the procedure and to be continued according to protocols used for endoscopic stent insertion procedures.
Identifying, measuring and dilation of the common bile duct obstruction

- Perform a cholangiogram to visualize the biliary tract.
- Use fluoroscopy imaging to identify the obstructed area.
- Measure the length of the occlusion.
- Insert through the occlusion a 0.035" guide wire.
- Consider dilatation of the strictured segment (Recommended).
- Choose the appropriate stent length.

MRI INFO– BIS

MRI Information

MR Conditional

The Biliary Stent was determined to be MR-conditional.
Non-clinical testing demonstrated that the Biliary Stent is MR Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:

Static Magnetic Field
-Static magnetic field of 3-Tesla or less
-Maximum spatial gradient magnetic field of 720-Gauss/cm or less

MRI-Related Heating
In non-clinical testing, the Biliary Stent produced the following temperature rises during MRI performed for 15-min of scanning (i.e., per pulse sequence) in 1.5-Tesla/64-MHz (Magnetom, Siemens Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MR 2002B DHHS Active-shielded, horizontal field scanner) and 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR systems:

	1.5-Tesla	3-Tesla
MR system reported, whole body averaged SAR	2.9-W/kg	2.9-W/kg
Calorimetry measured values, whole body averaged SAR	2.1-W/kg	2.7-W/kg
Highest temperature change	+2.7°C	+3.5°C

These temperature changes will not pose a hazard to a human subject under the conditions indicated above.

Artifact Information
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 Biliary Stent. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 5-mm relative to the size and shape of this implant.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	1,263-mm2	68-mm2	1 660-mm2	116-mm2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

System preparation
Prior to insertion of the device and as a part of its preparation the delivery system should be flushed as follows:

- Ensure that the hemostasis valve (B) is closed tightly.
- Fill a syringe with 10 ml irrigation water or isotonic saline solution.
- Connect the syringe to the delivery system's hemostasis valve luer connector (C).
- Flush the delivery system while making sure that the water is coming out of the outer tube near the tip (D). Flushing the system is a **must** for an easy and smooth release of the stent.

After irrigation ensure that the hemostasis valve (B) is opened before proceeding.

Stent Insertion Steps:
Insertion of the ***"ALLIUM Endoscopic Biliary Stent"*** is done under sedation and under direct vision (ERCP) and fluoroscopy.

- Insert a 0.035" guide wire through the duodenoscope into the papilla of Vater and through the occlusion (ERCP).
- Performing a sphincterotomy is at the physician discretion. Sphincterotomy is recommended if a stent without an anchor is used.
- The BIS delivery system is 10 Fr in diameter. In order to ensure optimal stent release, the minimal ductal lumen diameter should not be less than 15 Fr.
- Insert the stent delivery system over a guide wire into the strictured area until the *radiopaque marker* (**RM**) and the 3 radiopaque markers at the tip of the stent pass over the upstream limit of the stenosis. Follow advancement of the stent by fluoroscopy. Note that the 3 radiopaque markers at the tip of the stent are very near to each-other (squeezed together) before expansion of the stent.
- If an **anchored device** is used, the delivery system should be inserted until the *black outer visual marker* (**OVM**) reaches the orifice of the papilla. This position enables to

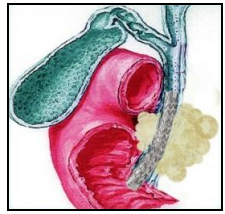
position the entire stent body into the common bile duct and the anchoring segment in the duodenum.

- If a sent **without an anchor** is used, the delivery system should be inserted until the *black outer visual marker* (**OVM**) reaches the orifice of the papilla. This will position about 10 mm of the downstream end of the stent to protrude from the papilla.

> **Note:** Keeping the yellow **inner visual marker** (**IVM**) fixed in place during stent release is a key factor for accurate stent positioning.

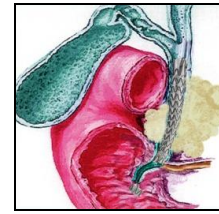
- Holding the stent in position, ensure that the hemostasis valve (**B**) is unlocked by turning the valve cover in a counter-clock-wise direction
- The nurse stabilizes the delivery system by putting its rear Luer (**A**) to her/his sternum and starts to pull carefully the Y-connector (over-tube) a few centimeters using a constant force towards the rear and stops, without releasing the Y-connector. This will pull the over-tube covering the stent backward together with the black visual marker. *Since the black outer visual marker (***OVM***) will disappear from the field of view*, when positioning an anchored BUS it is very important to continue seei*ng the* ***yellow inner visual markers*** **(IVM)** *which is on the inner tube at the level of the orifice to ensure proper positioning of the stent.*
- **When a stent without an anchor is used the IVM should be 1 cm far from the papilla, near the endoscope, to leave 1 cm of the stent into the duodenum.**
- Under fluoroscopy follow the expansion of the upstream end of the stent by seeing the 3 radiopaque markers separate from each other.
- The stent cannot be retracted into the delivery mechanism but it can be repositioned if up to 40% of it is expanded.
- The nurse continues to pull the Y-connector slowly all the way toward the rear Luer (**A**) with the endoscopist keeping the **yellow inner visual marker** (**IVM**) at the orifice.
- After complete expansion of the stent, verify that stent has been completely released from the delivery system by gently pushing it in and out of the stent. If the delivery system (**D**) can move without moving the stent, this proves complete separation of the stent from the delivery system.
- Check the accuracy of the deployment by injecting contrast into the common bile duct through the back Luer (**A**).
- Under fluoroscopic control carefully remove the delivery system, taking care not to dislodge the stent.

See the anchoring segment in the duodenum and the connecting wire entering into the papilla.



Allium Endoscopic Biliary Stent without anchor

Note the tip of the stent protruding from the Vater Papilla



Allium Endoscopic Biliary Stent with anchor

anchoring segment in the duodenum and the connecting wire along the papilla

Removing the Stent

- After its deployment the ***"ALLIUM Endoscopic Biliary Stent"*** can be removed from the common bile duct under vision (ERCP) if its distal end or the anchoring segment is in the duodenum.
- The removal procedure should be done by a physician trained to perform ERCP.
- Removal of stent should be done under sedation.
- Removal of the stent is done using an endoscopic snare or forceps.
- Under vision insert a duodenoscope until the down-stream end of the stent is seen in the duodenum.

- Approach and engage the distal end of the stent or the anchor.
- Start pulling the stent outward. This may initiate tearing the polymeric cover. Continue to pull the stent **together with the endoscope outward**.
- If the entire stent is in the common bile duct, under fluoroscopy insert a guide wire through the Vater papilla and through the stent. Insert a balloon (10 mm balloon for a 8 mm stent and a 12 mm balloon for a 10 mm stent) over the guide wire. Inflate the balloon and gently pull it outward. If a sphincterotomy was done at the insertion of the stent, the stent and the balloon will come out into the duodenum. Then pull the endoscope together with the stent. If a sphincterotomy was not done and the balloon cannot pass the papilla with the stent either the sphincter is dilated by inflating the balloon before engaging the stent or a sphincterotomy can be done before stent removal.
- After its removal, verify that the entire stent came out. Check that the small loops at both ends of the stent are out.

DISCLAIMER OF WARRANTIES

Allium, Ltd. warrants that reasonable care has been used in the manufacture of this device. This warranty is exclusive and in lieu of all other warranties whether expressed, implied, written or oral, including but not limited to any warranties of merchantability of fitness for a particular purpose. As a result of biological differences in individuals, no product is 100% effective under all circumstances. Because of this fact, and since Allium, Ltd. has no control over the conditions under which the device is used, diagnosis of the patient, methods of administration or its handling after the device leaves our possession, Allium, Ltd. does not warrant either a good effect or against any ill effect following its use. Allium, Ltd. shall not be liable for any incidental or consequential loss, damage, or expense arising directly or indirectly from the use of this device. Allium, Ltd. will replace any device that we feel was defective at the time of shipment. No representative of Allium, Ltd. may change any of the foregoing or assume any additional liability or responsibility with this device.

Labeling Information

Symbol	This Symbol Means
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	Use By
	Batch Code
	Sterilization Using Ethylene Oxide
	Catalog Number
	Caution, Consult Accompanying Documents
	Manufacturer
	Authorized Representative in the European Committee
	Consult Instructions for Use
	Store in Dry Place at Room Temperature
	Do Not Use if Package is Damaged

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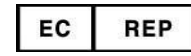

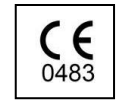

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