Allium Biliary Stent
for Trans-hepatic Insertion

Instructions For Use

Manufactured by

***Allium Ltd*.**

DEVICE NAME

Allium Trans-hepatic Biliary Stent (BIS)

DEVICE DESCRIPTION

The **Trans-hepatic BIS** is to be inserted into the Common Bile Duct **(CBD)** to allow free flow of bile to the duodenum by supporting the obstructed area of the bile duct lumen, keeping it open, and preventing its re-stenosis.

*The **Trans-hepatic BIS*** device *is intended for transhepatic, percutaneous, antegrade insertion into the CBD of patients diagnosed with an obstruction caused by malignancies. The stent will drain the occluded biliary duct and ensure its patency. It is intended to remain in place for up to 1 year.*

The **Trans-hepatic BIS** comes in 2 configurations to best fit the anatomy of the segment of the bile duct where it will be deployed: Self-anchoring design and anchored design. The two designs are tubular shaped, with 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 anchored design has an additional segment to protrude into the duodenum and is attached to the main body.

The BIS System is composed of 2 main elements:

1. The Stent

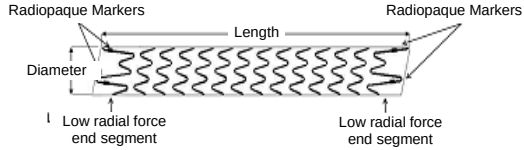
2. The Delivery Device

The Insertion Device has a radiopaque marker **(RM)** on the distal part of the over tube, 1 cm proximal to the end of the mounted stent. This marker is for the initial positioning of the un-expanded stent. The **RM** moves back during deployment of the stent.

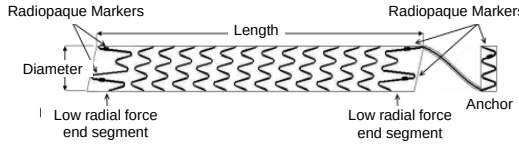
The **Trans-hepatic BIS** has a metal structure with self-radial-expanding design. It has a large caliber structure (8 or 10 mm in diameter), is completely covered with a thin layer of polymeric material, and is easy to remove. Once inserted into the occluded common bile duct using the specially designed 10 Fr delivery device, the stent is released to self-expand in the occluded part of the duct. Following the deployment process the delivery device is carefully removed from the body.

Visualization of the System: The stent has 3 radiopaque markers at each end (the anchored design has an additional one at the anchor) to enhance its fluoroscopic visualization.

Self-anchoring Design



Anchored Design



The **Trans-hepatic BIS Delivery Device**

The Delivery Device for Trans-hepatic insertion of the *Self-anchoring stent* has a *Radiopaque Marker* (**RM**) on the overtube to indicate the distal 1 cm end of the stent. The **RM** moves back during stent release.

The Delivery Device for Trans-hepatic insertion of the *Anchored stent* has a *Radiopaque Marker* (**RM**) on the overtube to indicate the place of the wire connecting the anchor to the body of the stent. When positioning the stent, the **RM** should be at the level of the papilla. The **RM** moves back during stent release.

Trans-hepatic BIS Ordering Information:

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

Transhepatic Self-anchoring System		
Order Number	**Stent Diameter**	**Stent Body Length**
BIS-O-T-8-60	8 mm	60 mm
BIS-O-T-8-80	8 mm	80 mm
BIS-O-T-8-100	8 mm	100 mm
BIS-O-T-8-120	8 mm	120 mm
BIS-O-T-10-60	10 mm	60 mm
BIS-O-T-10-80	10 mm	80 mm
BIS-O-T-10-100	10 mm	100 mm
BIS-O-T-10-120	10 mm	120 mm

INDICATIONS FOR USE

The **Trans-hepatic BIS** stents are indicated for palliation of malignant bile duct obstructions causing obstructive jaundice. The Anchored Design is indicated in obstructions more than 2 cm above the papilla.

CONTRAINDICATIONS

The insertion of the **Trans-hepatic BIS is contraindicated in patients who:**

- Have jaundice that has not been previously evaluated and treated.
- Cannot tolerate any form of antibiotic treatment.
- 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.

Do not use the Anchored BIS design if the obstructing lesion involves the papilla or is situated less than 2 cm from the papilla. Patients should be advised that the Allium stent is offered instead of an external-internal drainage or a small caliber biliary stent.

POTENTIAL COMPLICATIONS

Irritation may occur and may be related to device insertion, particularly during the first few days after insertion. If the symptoms persist, patients should be instructed to contact their physician.

Potential complications and risks associated with insertion of the **Trans-hepatic BIS** are those associated with performing a percutaneous transhepatic bile drainage procedure, or the routine insertion of a Biliary Stent or other instrumentation.

Potential complications with the use of the **Trans-hepatic BIS** may include, but are not limited to, the following:

Failure to reach the obstructed site, pain/discomfort, perforation of the bile duct, bleeding, infection/sepsis/liver abscess, pancreatitis, Stent migration or misplacement, stent obstruction by tumor tissue compression or sludge, growth of tumor tissue into the stent lumen through its ends, allergic reactions to the nickel-titanium alloy.

If the stent is not well tolerated, removal of the stent usually resolves the discomfort and other complications.

PRECAUTIONS

Checking the device: The entire 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 **Trans-hepatic BIS** is required. The device can be used only by physicians who underwent appropriate training for its use. Prior to its use, the technical information supported this device should be carefully reviewed.

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

WARNINGS

General

- The **Trans-hepatic BIS** is not intended for the definitive treatment of the obstructive biliary tract disease or of the complications of biliary tract diseases.
- The safety and effectiveness of the **Trans-hepatic BIS** for use in the vascular system have not been established and **should not be used in blood vessels**.
- The **Trans-hepatic BIS** or its delivery mechanism should not come in contact with organic solvents anytime before their use.

Device Related:

- **Single use device:** The **Trans-hepatic BIS** 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 of an expanded stent into the delivery system or reuse of a stent should not be attempted. These can seriously damage the patient's health.
- Catheterization through an implanted stent is not recommended. Introduction and passage of a catheter through the stented biliary tract may dislodge the stent and/ or damage the cover.
- The stent should only be placed under direct fluoroscopic visualization.
- Longitudinal compression of the stent by instrumentation could dislodge the stent.
- The stent may migrate during or after placement: If this occurs, the stent should be removed and a new one may be considered for insertion instead.

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 percutaneous stent insertion procedures.

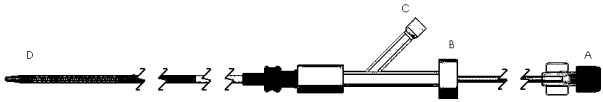
Identifying, measuring, and dilating the common bile duct obstruction

- Use fluoroscopy imaging to perform a percutaneous cholangiogram to visualize the biliary tract, the papilla and duodenum.
- Identify the obstructed area and mark the target area for the stent using external radiopaque markers applied to the beginning and the end of the obstruction.
- Measure the occlusion and its distance to the papilla.

- 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.
- Choose the appropriate length of stent.

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 5-10 ml of sterile irrigation water or isotonic saline solution.
- Connect the syringe to the delivery system's hemostasis valve luer connector (C)
- Slowly flush the delivery system while making sure that water comes out of the outer tube at the distal tip (D). It is normal to encounter resistance while depressing the syringe plunger.
- Flushing the system is a must to facilitate release of the stent.
- Ensure that the hemostasis valve (B) is opened completely before proceeding.



The **Trans-hepatic BIS** delivery device

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

Percutaneous Trans-hepatic Insertion

Percutaneous insertion of the **Trans-hepatic BIS** is performed under local anesthesia and/or sedation and under fluoroscopic visualization. When using an anchored design an endoscopic guidance can be combined.

1. As performed during a drainage procedure, insert a long, fine needle until one of the bile ducts is reached.
2. Perform a percutaneous cholangiogram to visualize the biliary tract, the papilla and the duodenum.
3. Pass a guide wire into the biliary tract, passing through the obstruction, the papilla into the duodenum.
4. Insert the delivery device under fluoroscopic visualization until the obstruction site is crossed.
5. If an anchored BIS is used, the delivery device is carefully pushed forward until the radiopaque marker (RM) just crosses the papilla.
6. If an anchored design is used and the procedure is combined with endoscopic guiding, push slowly the delivery device until the RM passes the papilla and appears at the orifice and the endoscopist sees it.
7. Holding the delivery device in position, ensure that the hemostasis valve (**B**) is opened by turning the valve cover counter-clockwise.
8. Release the stent in the following manner:

While holding the rear luer connector (A) firmly fixed, carefully pull backward the over tube of the device connected to the hemostasis valve body using a constant force.

IMPORTANT: Holding the delivery device fixed in place during stent release is a key factor for accurate stent positioning.

9. Follow expansion of the stent fluoroscopically. The 3 radiopaque markers at the ends of the body of the stent will separate from each other, indicating expansion of the stent.
10. Check the accuracy of the deployment by injecting contrast into the common bile duct.
11. After complete expansion of the stent, verify that stent has been completely released from the delivery system by gently pushing the delivery system into and out of the stent.
12. Under fluoroscopic control carefully remove the delivery system, taking care not to dislodge the stent.

Removing the Stent

- Removal of stent should be performed under sedation.
- The removal procedure should be done by a physician trained to perform ERCP.
- The tip of the stent protruding into the duodenum (in anchored design - the anchor) of the **Trans-hepatic BIS** is engaged using a snare or flexible endoscopic foreign body forceps:

- Start pulling the stent outward. This may initiate tearing the polymeric cover and unraveling of the stent. Continue to pull the metal wire **together with the endoscope outward**.

- If the entire stent is in the CBD, removal of the stent can be tried as following:

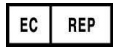
- Since a sphincterotomy was not done at the insertion of the stent, perform a sphincterotomy or balloon dilates the papilla.
- Under fluoroscopy insert a guide wire through the Vater Papilla and through the stent.
- Insert a dilating balloon (10 mm balloon for a 8 mm stent, 12 mm balloon for a 10 mm stent) over the guide wire. Inflate the balloon in the stent and pull it outward.
- When the stent appears from the orifice, either pull the endoscope together with the stent or deflate the balloon and remove the stent using a snare or an endoscopic forceps.

Verify that the entire stent came out by checking that the second small loop at the up-stream end of the stent came 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
	Do Not Reuse
	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

For further questions or information, please contact the manufacturer:

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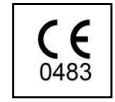

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