LIFESTENT® Biliary Stent System

Recommended Guidewire Length Table	
Catheter Working Length	Recommended Guidewire Length
130 cm	300 cm
80 cm	260 cm

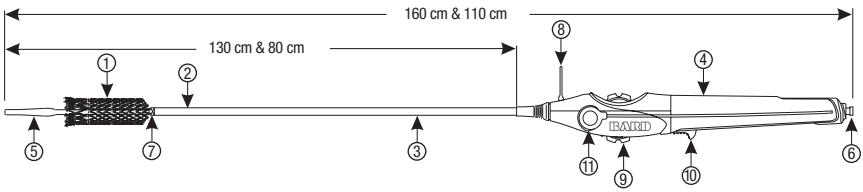


Figure 1. LIFESTENT® Biliary Delivery System

CAUTION:

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

For single use only

Device Name

The device brand name is the LIFESTENT® Biliary Stent System.

Description

The LIFESTENT® Biliary Stent System is designed to deliver a self-expanding stent to the biliary tree via a sheathed delivery system. The LIFESTENT® Biliary Stent System is comprised of the following:

- An implantable self-expanding nickel-titanium alloy (nitinol) stent **(1)**, as shown in **Figure 1** and **Figure 2**. The stent is a flexible, fine tubular mesh prosthesis, with a helical design, which achieves its unconstrained diameter upon deployment into the biliary duct. Upon deployment, the stent imparts an outward radial force on the luminal surface of the duct to establish patency. The stent has a total of 12 tantalum radiopaque markers **(1A & 1B)** located on the ends of the stent (i.e., 6 at each end).

Figure 2. LIFESTENT® Biliary Stent

- A delivery system, as shown in **Figure 1**, comprised of an inner tubing assembly that contains the guidewire lumen, a stent delivery sheath **(2)** and a system stability sheath **(3)**, which are linked together by means of a handle **(4)**. The guidewire lumen terminates distally in an atraumatic catheter tip **(5)** and originates proximally in a luer hub **(6)** designed to accept a compatible guidewire.

The self-expanding stent is constrained in the space between the guidewire lumen and stent delivery sheath. Unintended stent movement during sheath retraction is restricted by the delivery system. The stent delivery sheath has a radiopaque zone **(7)** at its distal end. Prior to deployment the shipping lock **(8)** must be removed and discarded.

Refer to "Stent Deployment Procedure, section 4. Deploy Stent" for directions on deploying the stent with the:

- Thumbwheel **(9)**
- Fast Track Deployment Lever **(10)**
- Rapid Deployment Ring **(11)**

Indications for Use

The LIFESTENT® Biliary Stent System is intended for use in the palliation of malignant strictures (neoplasms) in the biliary tree.

Contraindications

Contraindications associated with the use of trans-hepatic biliary stents include:

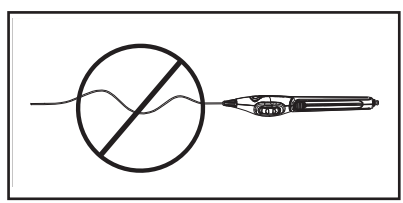
- Stenting of a perforated duct where leakage from the duct could be aggravated by the prosthesis.
- Patients with uncorrected bleeding disorders.
- Patients with severe ascites.
- Patients with extensive hepatic metastases precluding a percutaneous transhepatic approach.
- Patients with impossibility of intraductal sounding.

Warnings

- **The safety and effectiveness of this device for use in the vascular system have not been established.**
- **DO NOT** use the device after the "Use By" date specified on the label.
- **DO NOT use if the temperature exposure indicator (i.e., square label found on the pouch) is black, as the unconstrained stent diameter may have been compromised. The temperature exposure indicator label should be grey and must be clearly visible on the pouch.**
- **DO NOT** use if pouch is opened or damaged.
- **DO NOT** use with Ethiodol™ or Lipiodol contrast media.
- **DO NOT** expose the delivery system to organic solvents (e.g., alcohol).
- Persons with allergic reactions to nickel titanium (nitinol) alloy may suffer an allergic response to this implant.
- Stenting across a major bile duct branch could cause difficulties during future diagnostic or therapeutic procedures.
- The stent is not designed for repositioning or recapturing.
- The LIFESTENT® Biliary Stent System is supplied sterile and is intended for single use only. **DO NOT** resterilize and/or reuse the device.

Precautions

- The device is intended for use by physicians who have received appropriate training.
- The delivery system is not designed for use with power injection systems.
- Recrossing a partially or fully deployed stent with adjunct devices must be performed with caution.
- Prior to stent deployment, remove slack from the delivery system catheter outside the patient.



- Store in a cool, dark, dry place.
- Do not attempt to break, damage or disrupt the stent after placement.

Stent Size Selection Table: LIFESTENT® Biliary Stent System

Bile Duct Diameter	Unconstrained Stent Inner Diameter
4.0 – 4.5 mm	5.0 mm
4.5 – 5.5 mm	6.0 mm
5.5 – 6.5 mm	7.0 mm
6.0 – 7.0 mm	8.0 mm
7.0 – 8.0 mm	9.0 mm
8.0 – 9.0 mm	10.0 mm

Refer to product labeling for stent length.

Adverse Reactions

Potential complications associated with the use of transhepatic biliary stents may include, but are not limited to:

- Bile duct perforation
- Liver abscess
- Pancreatitis
- Parenchymal hemorrhage
- Sepsis / infection
- Sludge occlusion
- Stent migration
- Stent misplacement
- Stent obstruction secondary to tumor in-growth through the stent
- Tumor overgrowth at the stent ends

Directions for Use

Pre-Deployment Procedure

1. Inject Contrast Media

Perform a percutaneous transhepatic cholangiogram using standard technique.

2. Evaluate and Mark Stricture

Fluoroscopically evaluate and mark the stricture, observing the most distal level of the biliary stricture.

3. Select Stent Size

Measure the length of the target stricture to identify the appropriate length of stent required. Ensure that the stent is long enough to permit the area proximal and distal of the tumor to be covered by the stent to inhibit tumor overgrowth at the stent ends. Identify the diameter of the target bile duct (proximal and distal to the stricture). To ensure secure placement, refer to the stent size selection table for proper sizing scheme (see page 3).

4. Prepare Stent Delivery System

a) Open the box and remove the pouch containing the stent system.

b) Check the temperature exposure indicator label on the pouch to confirm that its grey background is clearly visible. See “Warnings” section.

c) Carefully inspect the pouch for damage to the sterile barrier. Then, peel open the pouch and remove the elements containing the stent system. Extract the stent system from the tray and check the following:
   i) Verify that the shipping lock is still secure in the delivery system handle.
   ii) Examine the stent and delivery system device for any damage. If it is suspected that the sterility or performance of the device has been compromised, the device should not be used.

d) Visually inspect the distal end of the delivery system catheter to ensure that the stent is contained within the sheath. Do not use if the stent is partially deployed.

e) Visually inspect the distal end of the delivery system catheter to ensure there is no gap between the delivery system catheter tip (grey colored) and the primary sheath (braided catheter with light blue colored end) such that the guidewire lumen (orange colored) is visible. Do not use the device if the orange colored guidewire lumen is visible.

f) Flush the inner lumen of the device with saline prior to use.
g) Wipe the usable length portion of the delivery system catheter with a gauze soaked with saline.

Stent Deployment Procedure

1. Insert Introducer Sheath and Guidewire

a) Gain access at the appropriate site utilizing a 6F (2.0 mm) (or larger) introducer sheath.
b) Insert a guidewire of appropriate length (see table) and diameter across the stricture to be stented via the introducer sheath.

Recommended Guidewire Length Table	
Catheter Working Length	Recommended Guidewire Length
130 cm	300 cm
80 cm	260 cm

2. Dilate Stricture

No predilation is generally performed with malignant strictures. However, if the physician deems that predilation is required, standard techniques may be used. While maintaining stricture access with a guidewire, remove the balloon catheter from the patient.

Caution: During dilation, do not expand the balloon such that dissection complication or bleeding could occur.

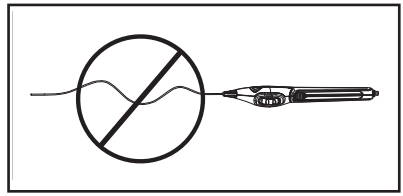
3. Introduce Stent Delivery System

a) Advance the device over the guidewire through the sheath introducer.

Note: If resistance is met during delivery system introduction, the system should be withdrawn and another system should be used.

Caution: Always use an introducer sheath for the implant procedure to protect both the liver tract and puncture site. A 6F (or larger) introducer sheath is recommended.

b) Position the tip of the delivery system past the stricture site.
c) Pull back the delivery system until the distal and proximal stent radiopaque markers are in position so that they are distal and proximal to the target stricture.
d) Remove slack from the delivery system catheter held outside the patient.



Caution: Any slack in the delivery system catheter (outside the patient) could result in inaccurate stent delivery.

4. Deploy Stent

a) Verify that the distal and proximal stent radiopaque markers are distal and proximal to the target stricture.
b) Confirm that the introducer sheath is secure and will not move during deployment.
c) Remove the shipping lock.
d) To ensure the most accurate placement, firmly hold the black system stability sheath throughout deployment

Note: Do NOT hold the silver stent delivery sheath at any time during deployment. DO NOT constrict the stent delivery sheath during stent deployment.

e) Initiate stent deployment by rotating the thumbwheel in the direction of the arrows while holding the handle in a fixed position.

Note: If excessive force is felt during stent deployment, do not force the stent system. Remove the stent system as possible, and replace with a new unit.

f) While using fluoroscopy, maintain position of the distal and proximal stent radiopaque markers relative to the targeted stricture site. Watch for the distal stent radiopaque markers to begin separating;

separation of the distal stent radiopaque markers signals that the stent is deploying. Continue turning the thumbwheel until the distal end of the stent obtains complete wall apposition.

g) With distal end of the stent apposing the duct wall, final deployment can be continued with the following methods (Fig. 3, 4, 5).

Continue to rotate the thumbwheel to achieve complete stent deployment.

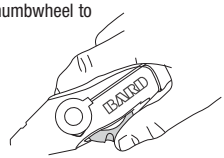


Figure 3. Thumbwheel

While maintaining a fixed handle position, place your finger in front of the deployment slide and slide it from the distal to proximal end.

Figure 4. Fast Track Deployment Lever

While maintaining a fixed handle position, peel the circular ring from the handle. Pull the rapid deployment ring towards the proximal end of the handle to achieve complete stent deployment.

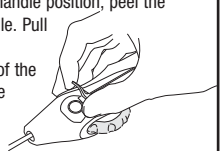


Figure 5. Rapid Deployment Ring

Note: To ensure correctly deployed stent length, fluoroscopically monitor the distal and proximal stent marker position relative to the obstruction throughout the deployment process.

h) Deployment of the stent is complete when the proximal stent radiopaque markers appose the duct wall and the sheath radiopaque zone is proximal to the proximal stent radiopaque markers.

i) Do not attempt to re-sheath catheter system prior to removal.

5. Post Stent Placement

a) Remove the delivery system from the body.

b) If additional stent-to-duct apposition is desired, select a balloon catheter that matches the size of the reference biliary duct, but that is not larger than the stent diameter itself.

c) Remove the guidewire and introducer sheath from the body.

d) Close entry wound as appropriate.

e) Discard the stent delivery system, guidewire, and introducer sheath.

Note: Physician experience and discretion will determine the appropriate drug regimen for each patient.

Magnetic Resonance Imaging (MRI) Compatibility

Conditions for All Stents

Non-clinical testing has demonstrated that the LIFESTENT® Biliary Stent is MR Conditional for biliary placement. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla.
- Spatial gradient field of 2500 Gauss/cm or less.
- Maximum whole-body-averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning per sequence.
- Normal mode operation of the MR system.

3.0 Tesla temperature Rise

Temperature rises of stents were measured according to ASTM F2182-11a in a nonclinical configuration using a GE Signa HDX Whole Body active shield MR scanner using software version 14/LX/MR and a phantom designed to simulate human tissue.

The phantom average SAR calculated using calorimetry was 2.7 W/kg. When the stent was placed in a worst-case location within the phantom, the maximal temperature rise was 2.4°C when the local SAR was scaled to 2 W/kg.

1.5 Tesla temperature Rise

Temperature rises of stents were measured according to ASTM F2182-11a in a nonclinical configuration using a GE Signa whole body coil and a phantom designed to simulate human tissue. The phantom average SAR calculated using calorimetry was 2.3 W/kg. When the stent was placed in a worst-case location within the phantom, the maximal temperature rise was 3.2°C when the local SAR was scaled to 2 W/kg.

Image Artifact

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 stent. Artifact tests were performed according to ASTM F2182-11a. Maximum artifact extended 3 mm beyond the stent for the spin echo sequence and 10 mm for the gradient echo sequence. The lumen was obscured.

Additional Information

The LIFESTENT® Biliary Stent has not been evaluated in MRI systems other than 1.5 or 3.0 Tesla. The heating effect in the MRI environment for overlapped or fractured stents is not known. The presence of other implants or the health state of the patient may require reduction of the MRI limits listed above.

How Supplied

The LIFESTENT® Biliary Stent System device is supplied sterile (by ethylene oxide gas) and is intended for **SINGLE USE ONLY.**

Symbols used on labeling

Keep away from sunlight

Keep dry

The Green Dot

Recyclable

MR Conditional

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