

LifeStent Balloon Expandable Biliary Stent System

For single use only

1.0 Device Description

The LifeStent balloon expandable biliary stent systems are balloon expandable stents which are provided mounted onto a balloon catheter which acts as the delivery system. The stent is a permanently implanted device used to maintain patency of a major bile duct obstructed by tissue of an impinging tumor. This flexible, balloon expandable stent is made by laser cutting an open lattice design into a 316L stainless steel tube. The stent is supplied mounted onto a balloon catheter and expanded by balloon inflation.

2.0 Condition

2.1 Contents

One LifeStent balloon expandable biliary stent system (LifeStent mounted on a balloon catheter).

2.2 Sterile

Sterilized with ethylene oxide gas.
Do not autoclave.

2.3 Storage

Store in a cool, dark, and dry place.

3.0 Indications

- The LifeStent balloon expandable biliary stent system is intended for use in the palliation of malignant strictures (neoplasms) in the biliary tree.

4.0 Contraindications

- Stenting of a perforated duct where leakage from the duct could be exacerbated by the prosthesis.
- Patients with bleeding disorders.
- Severe ascites.

5.0 Warnings

- The safety and effectiveness of this device for use in the vascular system have not been established.
- This device is designed and intended for ONE TIME USE ONLY. DO NOT RESTERILIZE AND/OR REUSE.

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- Use the device prior to the USE BY date specified on the package.
- Do not use the device if the package is open or damaged.
- Should unusual resistance be felt at any time during the insertion process, do not force passage.
- If resistance occurs during movement through the sheath, the stent/catheter should be withdrawn carefully.
- During implantation, if resistance occurs after the stent has exited the sheath or if the stent cannot be delivered to the target location, attempts to retract the stent/catheter into the sheath may result in stent dislodgement. The stent/catheter/sheath should be removed as a single unit.
- The maximum balloon inflation pressure used to deploy the stent must not exceed the rated burst pressure (RBP) specified on the label. The use of a pressure monitoring device is recommended to prevent over pressurization.
- Use only the recommended balloon inflation medium. Do not use air or any gaseous medium to inflate the balloon as this may cause uneven expansion and difficulty in deployment of the stent.
- The stent cannot be re-positioned after it is fully deployed.
- Stenting across a bifurcation could compromise future diagnostic or therapeutic procedures.
- Do not retract the balloon catheter until the balloon is fully deflated under vacuum.

6.0 Precautions

- Only physicians familiar with the potential complications, side effects, and hazards commonly associated with biliary stent placement should use this device.
- Inspect the LifeStent balloon expandable biliary stent and delivery system prior to use to verify that the stent has not been damaged during shipment or handling and that the device dimensions are suitable for the specific procedure. Do not attempt to remove or adjust the stent on the delivery system.
- The inflated diameter of the balloon used during stent expansion should approximate the diameter of the bile duct. To ensure full expansion of the stent, the balloon should be inflated to a minimum of the nominal pressure. Over-expansion of the stent can result in a ruptured bile duct.
- Recrossing a partially or fully deployed stent with adjunct devices must be performed with caution to avoid damage to the stent architecture.
- The minimal acceptable sheath French size is printed on the package label. Do not attempt to pass the stent/delivery system through a smaller size sheath introducer than indicated on the label.

- When catheters are in the body, they should be manipulated only under fluoroscopy. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum.
- To prevent the possibility of galvanic corrosion, it is **not recommended** that stents manufactured of different materials be implanted where overlapping may occur.
- Refer to the instructions for use supplied with any interventional devices to be used in conjunction with the LifeStent balloon expandable biliary stent system for their intended uses, contraindications, and potential complications.

7.0 Potential Complications

- Sepsis/infection
- Cholangiitis
- Hemobilia
 - Peritonitis
 - Pancreatitis
 - Abscess
 - Parenchymal hemorrhage
 - Stent migration
 - Stent obstruction secondary to tumor growth through the stent
 - Tumor overgrowth at the stent ends
 - Bile duct occlusion/obstruction
 - Bile duct perforation
 - Bile duct rupture due to overstretching of the duct
 - Persons with allergic reactions to stainless steel may suffer an allergic response to this implant.

8.0 Procedure

8.1 Recommended Materials

- GUIDEWIRE with compatible diameter and length
- SHEATH in the appropriate size and configuration
- BALLOON CATHETER (for pre-dilation)
- INFLATION DEVICE (with pressure monitoring capability)
- Three-way STOPCOCK
- NORMAL SALINE
- CONTRAST MEDIUM diluted 1:1 with NORMAL SALINE

8.2 Site Access and Preparation

1. Perform a percutaneous cholangiogram using standard technique and identify the location and length of the stricture.
2. Access the biliary tree through a routine transhepatic approach. Ensure that the entry site into the bile duct is peripheral enough to place the stent and safely complete the procedure.

3. Insert a SHEATH of appropriate diameter and sufficient length to cross the stricture.
4. Obtain access to the stricture by negotiating a GUIDEWIRE into the bile duct and across the stricture.
5. Pre-dilate the stricture with a BALLOON CATHETER.
6. Withdraw the BALLOON CATHETER, leaving the GUIDEWIRE in place.
7. Re-position the SHEATH across the stricture.

8.3 Stent/Delivery System Preparation

1. Select the appropriate configuration (length and diameter) LifeStent balloon expandable biliary stent system to ensure that the stent will extend slightly proximal and distal to the stricture and approximate the diameter of the obstructed duct at the implant site following expansion.
2. Remove the stent/delivery system from its packaging [and remove the transport mandrel and balloon sheath from the distal end of the catheter if present].
3. Inspect the stent for adherence to the balloon and centered placement in relation to the balloon marker bands. Do not reposition the stent or hand crimp.
4. Flush the delivery system guidewire lumen with NORMAL SALINE.
5. Prepare an INFLATION DEVICE with CONTRAST MEDIUM diluted 1:1 with NORMAL SALINE.
6. Attach the INFLATION DEVICE to the inflation port of the delivery system using a STOPCOCK.
7. Induce a negative pressure to remove any air from the balloon and inflation lumen. Repeat until all air is expelled.
8. Allow the inflation lumen to fill with the diluted CONTRAST MEDIUM and maintain at neutral pressure.

8.4 Stent Delivery

1. Wipe the exposed GUIDEWIRE with NORMAL SALINE to remove residual tissue or contrast medium.
2. Advance the stent/delivery system over the GUIDEWIRE to the treatment site, position the stent across the stricture within the SHEATH, and verify that the stent is still centered within the balloon marker bands.
3. Retract the SHEATH while maintaining the position of the stent.
4. Slowly inflate the delivery system balloon to nominal pressure, expanding the stent to optimize strut apposition against the bile duct wall, and confirm complete expansion fluoroscopically. **Do not exceed the Rated Burst Pressure of the delivery system.**
5. After stent deployment, apply negative pressure to the balloon until it is fully deflated. Carefully rotate the delivery system catheter to ensure that it is free of the stent and withdraw it at ambient pressure with the GUIDEWIRE remaining across the stricture.
6. Confirm optimal stent apposition using standard techniques.

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

This product is manufactured and sold under one or more of the following US patent(s): US Patent No. 6,117,165.

International and U.S.A. patents pending.

9.0 Magnetic Resonance Imaging (MRI)

 MR Conditional

Non-clinical testing demonstrated that the LifeStent balloon expandable stent is MR Conditional. Patients with this implant can be scanned safely, immediately after placement, 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 LifeStent balloon expandable stent produced a temperature rise of less than or equal to 0.6°C at a maximum absorption rate (SAR) of 3-W/kg for 15-minutes of scanning in a 3-Tesla MR system (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI).

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the LifeStent balloon expandable stent. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

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