Instructions For Use (IFU)

BARD® LIFESTAR™ Biliary Stent System
Delivery System Diagram
Information for use

Read the Bard™ LifeStyle™ Biliary Stent System IFU thoroughly. Also, thoroughly read the IFUs supplied with any other intervascular devices to be used in conjunction with the system.

• Please use the product illustration at the beginning of this booklet to guide you through the device description.

1.0 DEVICE NAME

• The brand name of the device is Bard™ LifeStyle™ Biliary Stent System.

• The Stent (Implant) is equipped with four highly visible radiopaque Tantalum Markers on both the proximal and distal end of the device.

• The Bard™ LifeStyle™ Biliary Stent System is loaded on the Bard™ LifeStyle™ Delivery System.

2.0 PRODUCT DIAGRAM

2.1 Stent (Implant): The Stent (Implant) is equipped with four highly visible radiopaque Tantalum Markers on both the proximal and distal end of the device.

2.2 Delivery System: The Bard™ LifeStyle™ Delivery System requires a minimum of guiding catheter or a minimum 6F introducer sheath.

The 6F, flexible delivery system is a dual lumen, coaxial system consisting of an Inner Catheter (B), which connects to a metal tube to the Grp (G), and a Coaxial Outer Catheter (A), which connects to the Proximal Luer Port (I).

The delivery system has a soft and Flexible Catheter Tip (G) formed from the outer catheter. The catheter tip is tapered to accommodate a 0.035" (0.89 mm) guidewire. Prior to inserting the delivery catheter over the guidewire, the system must be flushed with sterile saline at the two female Luer ports until saline drips from the distal tip of the catheter. Flushing eliminates any air bubbles from the inner catheter lumen and lubricates the surface between the inner and outer catheters. The first Luer port is located at the proximal end of the device (I) and the second is found within the Distal T-Luer Adapter (F). The Removable Safety Clip (E) presents outer sheath interaction.

2.3 Deployment Method:

The stent can be deployed by using the conventional "pin & pull-back" technique by pulling back the Distal T-Luer Adapter (F). (See Figure 1)

Figure 1: pin & pull-back Technique

The Removable Safety Clip (E) prevents accidental or premature stent release. DO NOT remove the Safety Clip (E) until the stent is ready to be deployed. Just prior to deploying the stent, the Removable Safety Clip (E) must be removed.

3.0 DEVICE DESCRIPTION

3.1 Stent (Implant):

The Bard™ LifeStyle™ Biliary Stent is a self-expanding, flexible, nitinol (nickel-titanium alloy) stent that expands to its preset diameter upon exposure to body temperature. The stent has a segmented repeating pattern and an open cell geometry with flared ends to help prevent dislocation or migration. Partial cuts around the circumference of the stent cylinder provide enhanced flexibility and allow segment-by-segment expansion. The stent is available in a wide range of diameters and lengths.

Each end of the stent has four highly visible radiopaque Tantalum Markers to facilitate accurate stent placement. Before deployment, the stent is compressed between the inner catheter and outer catheter at the distal end of the delivery system. In this compressed configuration, the stent struts lie closer together and the radiopaque markers appear as a contiguous band at each end of the stent. The stent MUST NOT be balloon expanded beyond its labeled diameter.

A single radiopaque marker on the outer catheter (D) of the delivery system is attached approximately 6 mm proximal to the distal end of the delivery system. Prior to deployment, this radiopaque marker overlaps the distal markers on the stent.

The following information regarding stent length change may assist in proper stent length selection and may facilitate proper placement in the body resulting in greater accuracy of stent placement. The information within the following table indicates the expected overall stent length change from its compressed condition within the catheters when deployed at the recommended over sizing.

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3.2 Deployment System:

The Bard™ LifeStyle™ Delivery System requires a minimum of guiding catheter or a minimum 6F introducer sheath.

4.0 INDICATIONS FOR USE

The Bard™ LifeStyle™ Biliary Stent System is indicated for the treatment of biliary structures resulting from malignancies neoplasms.

5.0 CONTRAINDICATIONS

Contraindications for the Bard™ LifeStyle™ Biliary Stent System include, but may not be limited to:

• Stenting of a perforated duct where leakage from the duct could be evacuated by the endoprosthetic.

• Severe acute preexisting a percutaneous transluminal approach.

• Extensive hepatic metastases precluding a percutaneous transluminal approach.

• Impossibility of intraductal sounding.

• Uncorrected bleeding disorders.

6.0 WARNINGS

6.1 General Warnings:

• Should unusual resistance be felt at any time during the procedure, the entire system (introducer sheath or guiding catheter and stent delivery system) should be removed as a single unit.

• Patients with known hypersensitivity to nickel-titanium may suffer an allergic reaction to this implant.

• Stenting across a major bifurcation may hinder or prevent future diagnostic or therapeutic procedures.

• Final stent placement resulting in an excessive length of stent protruding into the duodenum or displacement of the entire stent into the duodenum may damage or obstruct the intestinal tract. The distal end of the stent should protrude no more than 5 mm beyond the ampulla into the duodenum.

• The safety and effectiveness of this device for use in the vascular system have not been established.

6.2 Device Warnings:

• Visually inspect the packaging to verify that the sterile barrier is intact. DO NOT use if the sterile barrier is open or damaged.

• DO NOT use the device after the “Use By” date specified on the label.

• Visually inspect the Bard™ LifeStyle™ Biliary Stent System to verify that the device has not been damaged due to shipping or improper storage. DO NOT use damaged equipment.

• Take care to avoid unnecessary handling, which may kink or damage the delivery system. DO NOT use if device is kinked.

• If the safety clip has been removed or becomes inadvertently detached from the Grp, DO NOT use the device.

• The delivery system catheter is indicated for stent deployment only and not for any other use.

• During system flushing, DO NOT use the system if fluid is not observed exiting the catheter at the distal tip.

• If placing two overlapping stents, both stents must have identical diameters and similar metal composition.

• Once the stent is partially or fully deployed, microadjustments are no longer possible and the stent should not be dragged or repositioned in the lumen.

• Once stent deployment has been initiated, the stent cannot be recaptured using the stent delivery system.

• This product has been designed for single patient use only. DO NOT reuse. DO NOT resterilize.

• After use, the stent delivery system is a potential bioburden. Handle and dispose of this product in accordance with applicable medical practice and with applicable local, state and federal laws and regulations.

7.0 PRECAUTIONS

This device is intended for use only by physicians who are familiar with the principles, clinical applications, complications, side effects, and risks commonly associated with biliary stenting. It is strongly recommended that physician operators adhere to all applicable institutional, local, state, and federal guidelines and protocols with regard to procedural training.

7.1 System Handling Precautions:

• Non-compliance with sterility precautions may lead to infectious complications.

• An appropriate guide wire is required before introducing the stent delivery system into the body, and must remain in place during the introduction, manipulation and eventual removal of the stent delivery system.

• The Bard™ LifeStyle™ Biliary Stent System is only compatible for use with a 0.035" (0.89 mm) compatible guidewire.

• When catheters are in the body, they should be manipulated only under fluoroscopic with radiographic equipment that produces high quality images.

• Read and understand the IFU for any interventional device to be used in conjunction with the Bard™ LifeStyle™ Biliary Stent System.

• The delivery system is not designed for use with power injection systems.

• During system flushing, DO NOT use the system if fluid is not observed exiting the catheter at the distal tip.

• Faulty placement techniques could lead to stent deployment failure.

• Do not kink the delivery system.

• The delivery system will not function properly until the Removable Safety Clip (E) is removed. An occlusion against accidental stent deployment, the Safety Clip should not be removed until the stent is ready to be deployed.

• Store in a cool, dry, dark place.

7.2 Stent Placement Precautions:

• The stent experiences minimal length changes during deployment. (See Table 2).

• Appropriate diameter sizing of the stent to the target lesion is required to reduce the possibility of stent migration.

• Prior to stent deployment, remove all slack from the catheter delivery system to avoid stent displacement.

• DO NOT remove the Removable Safety Clip (E) until you are ready to deploy the stent.

• DO NOT hold the delivery system catheter during stent deployment.

• DO NOT overlap more than two stents.

• The Bard™ LifeStyle™ Biliary Stent System is a self-expanding nitinol device that MUST not protrude beyond its labeled diameter by dilatation with a PTF balloon.

• WARNING: If stent dilatation is deemed appropriate, please ensure that the selected balloon is indicated for use in the biliary tree.

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Table 1: Bard™ LifeStyle™ Biliary Stent System Component Identification Codes

<table>
<thead>
<tr>
<th>Reference</th>
<th>Lumen Diameter (mm)</th>
<th>Average Length Change at Recommended Over Sizing (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Inner Catheter</td>
<td>3.0</td>
<td></td>
</tr>
<tr>
<td>B Coaxial Catheter</td>
<td>1.5</td>
<td></td>
</tr>
<tr>
<td>C Flexible Catheter Tip</td>
<td>2.0</td>
<td></td>
</tr>
<tr>
<td>D Single radiopaque marker on the outer catheter</td>
<td>0.5</td>
<td></td>
</tr>
<tr>
<td>E Stent (Implant) with 4 Tantalum Markers at each end of the stent</td>
<td>-3.0</td>
<td></td>
</tr>
<tr>
<td>F Distal T-Luer Adapter</td>
<td>-3.0</td>
<td></td>
</tr>
<tr>
<td>G Removable Safety Clip</td>
<td>-2.0</td>
<td></td>
</tr>
<tr>
<td>H Grp</td>
<td>-2.0</td>
<td></td>
</tr>
<tr>
<td>I Proximal Luer Port</td>
<td>-3.5</td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Bard™ LifeStyle™ Biliary Stent System Length Change Information

<table>
<thead>
<tr>
<th>Unconstrained Stent Diameter (mm)</th>
<th>Reference Diameter (mm)</th>
<th>Average Length Change at Recommended Over Sizing (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>5</td>
<td>3.0</td>
</tr>
<tr>
<td>7</td>
<td>6</td>
<td>1.5</td>
</tr>
<tr>
<td>8</td>
<td>7</td>
<td>0.5</td>
</tr>
<tr>
<td>9</td>
<td>8</td>
<td>-2.0</td>
</tr>
<tr>
<td>10</td>
<td>9</td>
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<td>12</td>
<td>11</td>
<td>-2.0</td>
</tr>
<tr>
<td>14</td>
<td>13</td>
<td>-3.0</td>
</tr>
</tbody>
</table>

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As with all self-expanding nitinol stents, careful attention during stent deployment is warranted to mitigate the potential for movement of the stent.

If more than one stent is required to cover the lesion, the distal lesion, considered from point of access, should be stented first, followed by stenting of the proximal lesion. Following in this order obviates the need to cross the proximal stent for placement of the distal stents, and reduces the potential to dislodge stents that have already been placed.

To maximize stent placement accuracy, slowly and deliberately advance the distal portion of the stent until you have visual confirmation of wall apposition before steadily deploying the remaining length of the stent.

7.3 Post-Implant Precautions:

Caution should be used when crossing a deployed stent with any adjunctive device.

8. POTENTIAL COMPLICATIONS

Potential adverse events associated with the use of the Bax® LifeStar® Biliary Stent System include, but may not be limited to the usual complications reported for conventional biliary stents and transhepatic procedures such as:

• Bleeding
• Cholangitis
• Cholecystitis
• Gastrointestinal obstruction
• External biliary fistula
• Infection
• Liver abscesses
• Pain
• Pancreatitis
• Stent fractures
• Stent malposition
• Stent migration
• Stent obstruction secondary to tumor ingrowth within the stent, tumor overgrowth at the stent ends, or sludge occlusion

9. DIRECTIONS FOR USE

9.1 Procedural Access:

• Gain access to the treatment site utilizing appropriate accessory equipment compatible with the Gf® Bax® LifeStar® Biliary Stent System.

• The working lengths of the Gf Delivery System are indicated on the labels and on the device itself. In order to allow for complete stent deployment, DO NOT use an introducer sheath or guiding catheter longer than the indicated working length.

• The Gf Delivery System requires a minimum 8F introducer sheath, or a minimum 9F introducer sheath.

• Via the transhepatic route, insert a 0.035" (0.89 mm) guidewire under fluoroscopic guidance through the biliary structure and into the duodenum.

9.2 Stent Selection:

• Appropriate diameter sizing of the stent to the target lesion is required to reduce the possibility of stent migration.

• Evaluate and mark the structure. Measure the length of the structure and the diameter of the target lumen to assist in stent selection.

• Use the following guidelines for proper stent diameter selection. For target lumens ranging from 5 mm to 9 mm, select a stent with an unconstrained diameter of 1 mm larger than the target lumen. For target lumens ranging from 9 mm to 13 mm, select a stent with an unconstrained diameter of 1 to 2 mm larger than the target lumen.

• Select the appropriate length of stent to traverse the structure.

• Allow approximately 5 – 10 mm of the stent to extend beyond each end of the structure. This will allow for adequate stent coverage at either end of the stenosis.

• If placing two overlapping stents, both stents must have equal or greater diameter for similar metal composition.

• Stents should overlap by at least 5 mm to include the flared ends. DO NOT overlap more than two stents.

9.3 General Directions:

• Administration of adjunctive drug therapy before and after the procedure is left to the discretion of the treating physician.

• Pre-dilation of the structure with an appropriately sized balloon dilation catheter is left to the discretion of the treating physician.

• WARNING: Pre-dilation is deemed appropriate, please ensure that the selected balloon is indicated for use in the biliary tree.

9.4 Preparation of the Stent Delivery System:

• Visually inspect the Bax® LifeStar® Biliary Stent System to verify that the device has not been damaged due to shipping or improper storage. DO NOT use damaged equipment.

• The delivery system catheter is intended for stent deployment only and not for any other use.

• Flush the stent delivery system with sterile saline using a small volume (e.g., 5 – 10 cc) syringe. Attach the saline filled syringe to the female Luer ports, the first of which is located at the proximal end of the device (I) and the second of which is found within the T-Luer Adapter (J). Continue flushing until clear drops from the Flexible Catheter Tip (C) after flushing each Luer port.

• During system flushing, DO NOT use the system if fluid is not observed exiting the catheter at the Flexible Catheter Tip (C) after each Luer port is flushed.

• During delivery system preparation, ensure that the safety clip remains in place until the stent is ready to be deployed. If the safety clip has been removed or becomes inadvertently detached from the grip, DO NOT use the device.

9.5 Introduction of the Stent Delivery System:

• Insert the guidewire into the distal tip of the catheter until it exits the catheter at the proximal end of the device.

• Advance the delivery catheter over the guidewire into the target lumen.

• Under fluoroscopic visualization, advance the stent delivery system across the structure using the radiopaque markers to center the stent across the lesion.

• It is recommended to advance the delivery system past the structure and then pull back slightly on the entire system to achieve the correct positioning of the markers and to help insure that slack has been removed and that the delivery catheter is straight.

• Prior to stent deployment, remove all slack from the stent delivery system to avoid stent misplacement.

• DO NOT hold the delivery system catheter during stent deployment.

9.6 Stent Placement:

• During stent deployment, the entire length of the catheter system should be kept as straight as possible. Maintaining a straight catheter under slight tension during stent deployment is recommended to improve placement accuracy.

• Center the proximal stent markers and both overlapping distal marker stent markers on the outer catheter across the structure. The radiopaque markers on the stent indicate the ends of the compressed stent and the length of the expanded stent.

• By initially advancing the catheter beyond the structure, micro-adjustments of the stent can be made by pulling the entire system back toward the structure to improve placement accuracy.

• Once the stent is partially or fully deployed, micro-adjustments are no longer possible and the stent should NOT be dragged or repostioned in the lumen.

• Once stent deployment has been initiated, the stent CANNOT be recaptured using the stent delivery system.

• During stent deployment, the entire length of the catheter system should be kept as straight as possible.

• Complete stent deployment can be fluoroscopically visualized when the radiopaque markers on the proximal and distal ends of the stent are fully expanded.

9.7 Stent Deployment:

• DO NOT remove the Removable Safety Clip (G) until you are ready to deploy the stent.

• Just prior to stent deployment, remove the Safety Clip (G).

• Press the Removable Safety Clip down to remove the clip.

• Under fluoroscopic visualization, deploy the stent using the conventional “pin & pull-back” technique by slowly pulling back the Distal T-Luer Adapter (F) towards the hand that is pinned in place. Pulling back on the Distal T-Luer Adapter (F) directly refracts the outer catheter and displays a corresponding portion of the stent.

• Full stent deployment is ensured when the Distal T-Luer Adapter (F) re-enters the catheter.

• During stent deployment the moving single radio-opaque marker on the outer catheter (D) on the outer catheter moves backwards toward the proximal markers on the stent. The radiopaque markers on the stent MUST NOT move synchronously with the catheters.

• After stent deployment, carefully withdraw the delivery system from the patient over the guidewire. After removing the delivery system, visually confirm that the entire stent delivery system has been removed.

(a) Inner Catheter
(b) Outer Catheter

• Final radiographic evaluation of the implanted stent should be conducted by cholangiogram.

9.8 Post-Stent Placement:

• Post-dilation of the stent with an appropriately sized balloon dilation catheter is left to the discretion of the treating physician.

• WARNING: If post-dilation is deemed appropriate, please ensure that the selected balloon is indicated for use in the biliary tree.

• WARNING: The Bax® LifeStar® Biliary Stent is a self-expanding, nitinol stent that MUST NOT be expanded beyond its labeled diameter by dilation with a PTA balloon.

• This product has been designed for single patient use only. DO NOT reuse. DO NOT resterilize. Store in a cool, dry, dark place.

10.0 PATIENT IMPLANT INFORMATION CARDS:

A Patient IMPLANT Information Card is provided in the IFU for your convenience.

The Patient IMPLANT Information Card should be carefully folded along the perforations and removed from the IFU after the completion of the procedure.

The Patient Data, Implant Data, and Hospital Data Card should be carefully recorded on the card and given to the patient.

The patient should carry this card with them and provide to any medical personnel caring for the patient in the future.

11.0 MAGNETIC RESONANCE IMAGING (MRI) INFORMATION

Non-clinical testing demonstrated that the Bax® LifeStar® Biliary Stent is MR Conditional. A patient with the Bax® LifeStar® Biliary Stent can be scanned safely, immediately after placement of this implant, under the following conditions:

• Static magnetic field of 3.0 Tesla or less
• Spatial gradient field of 720 Gauss/cm or less
• Maximum whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of scanning for patient landmarks above the umbilicus.

In non-clinical testing, the Bax® LifeStar® Biliary Stent produced a temperature rise of less than or equal to 0.8°C at a maximum MR system-reported body whole averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of MR scanning in a 3.0 Tesla MR system (Existe, Software 6.3-D-0528, 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 Bax® LifeStar® Biliary Stent. Optimization of MR imaging parameters is recommended.

The effect of heating in the MRI environment for overlapping stents or stents with fractured struts has not been evaluated.

12.0 HOW SUPPLIED

The Bax® LifeStar® Biliary Stent System is supplied sterile by ethylene oxide gas. The package has been opened or damaged. This product has been designed for single patient use only. DO NOT reuse. DO NOT resterilize. Store in a cool, dry, dark place.

3
Symbols used on labelling

- **Consult Instructions For Use**
- **Catalogue Number**
- **Keep Away From Sunlight**
- **Lot Number**
- **Keep Dry**
- **Sterilized Using Ethylene Oxide**
- **Do Not Use If Package Is Damaged**
- **Use By**
- **Single Use**
- **Manufacturer**
- **Do Not Resterilize**
- **Minimum Introducer Size**
- **Contents: (1)**
- **Guidewire Compatibility**
- **MR Conditional**
- **Stent Length**
- **Does Not Contain Natural Rubber Latex**
- **Stent Diameter**
- **Working Length**
- **System Length**
Patient IMPLANT Information Card

Carry this card with you. Prior to any treatment, please show it to all medical personnel caring for you.

BARD® LifeStar™ Biliary Stent System

MR Conditional

Non-clinical testing has demonstrated the BARD® LifeStar™ Biliary Stent is MR Conditional. It can be scanned safely, immediately after placement of this implant, under the following conditions:

- Static magnetic field of 3.0 Tesla or less
- Spatial gradient field of 720 Gauss/cm or less
- Normal operating mode of the MR system and use of whole body transmit coil
- Maximum whole-body-averaged specific absorption rate (WB-SAR) of 2 W/kg for 15 min. of scanning for patient landmarks above the umbilicus.
- Maximum WB-SAR of 1 W/kg for 15 min. of scanning for patient landmarks below the umbilicus.

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BARD® LifeStar™ Biliary Stent System

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IN NO EVENT SHALL C. R. BARD, INC. BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS SYSTEM. C. R. BARD, INC. NEITHER ASSUMES NOR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR IT ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THIS SYSTEM.

Label Issue Date 08/2011
In the event 2 years have elapsed between this date and product use, the user should contact Bard to see if additional product information is available.
Telephone Number Inside The US: 1-800-526-4455.

Caution:
Federal (U.S.A) law restricts this device to sale by or on the order of a physician.
BARD® LIFESTAR™
Biliary Stent System

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