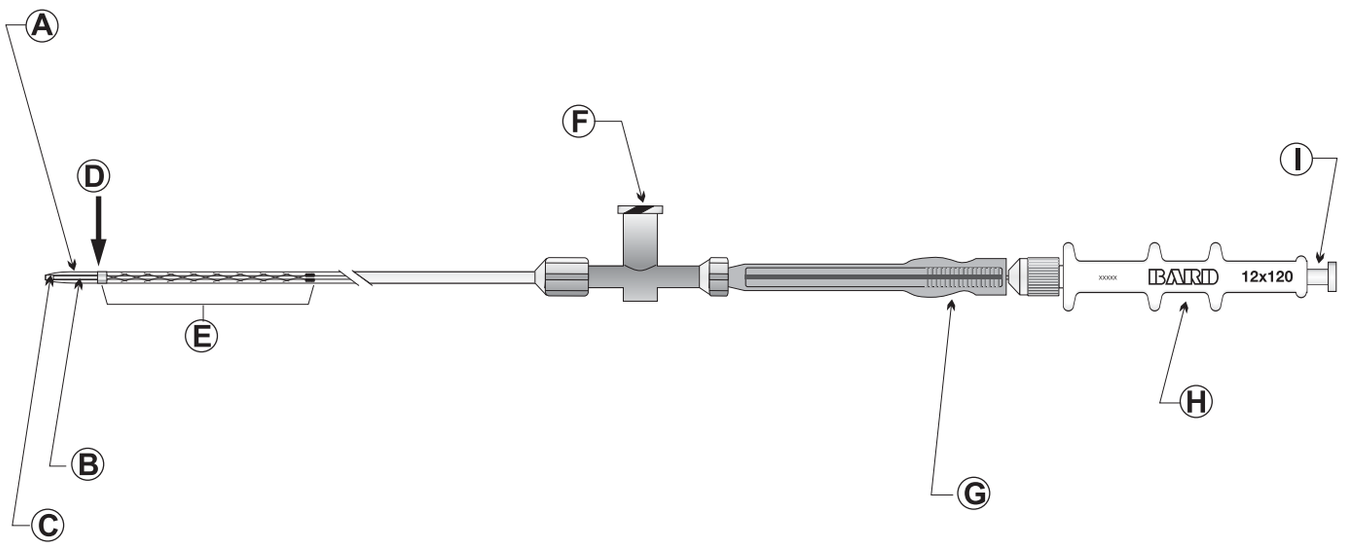
BARD® LIFESTAR™

Biliary Stent System

Instructions For Use (IFU)

BARD® LIFESTAR™ Biliary Stent System
Delivery System Diagram



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B05686 Rev.3/03-16

Information for use

Read the BARD® LIFESTAR™ Biliary Stent System IFU thoroughly.

Also, thoroughly read the IFUs supplied with any other interventional 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.*
- *Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.*

1.0 DEVICE NAME

- The brand name of the device is **BARD® LIFESTAR™ Biliary Stent System.**
- The Stent (Implant) is equipped with four highly visible radiopaque **Tantalum Markers** on both the proximal and distal end.
- The **BARD® LIFESTAR™ Biliary Stent** is loaded on the **BARD® LIFESTAR™ Delivery System.**

2.0 PRODUCT DIAGRAM (PLEASE REFER TO PAGE 1)

Table 1: BARD® LIFESTAR™ Biliary Stent System Component Identification Codes	
A	Coaxial Outer Catheter
B	Inner Catheter
C	Flexible Catheter Tip
D	A single radiopaque marker on the outer catheter
E	Stent (implant) with 4 Tantalum Markers at each end of the stent
F	Distal T-Luer Adapter
G	Removable Safety Clip
H	Grip
I	Proximal Luer Port

3.0 DEVICE DESCRIPTION

3.1 Stent (Implant):

The **BARD® LIFESTAR™ 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 segmental 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 close 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 catheter) when deployed at the recommended oversizing.

Table 2: BARD® LIFESTAR™ Biliary Stent System Length Change Information		
Unconstrained Stent Diameter (mm)	Reference Lumen Diameter (mm)	Average Length Change at Recommended Oversizing (%)
6	5	3.0
7	6	1.5
8	7	-0.5
9	8	-2.5
10	9	0.5
12	10	-3.0
12	11	-2.0
14	12	-1.5
14	13	-3.0

3.2 Delivery System:

The **BARD® LIFESTAR™ Delivery System** requires a minimum 8F guiding catheter or a minimum 6F introducer sheath.

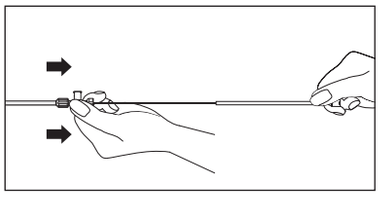
The 6F, flexible delivery system is a dual lumen, coaxial system consisting of an Inner Catheter **(B)**, which connects via a metal tube to the Grip **(H)**, and a Coaxial Outer Catheter **(A)**, which connects to the Proximal Luer Port **(I)**.

The delivery system has a soft and Flexible Catheter Tip **(C)** 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 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 **(G)** prevents outer sheath retraction.

3.3 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 **(G)** prevents accidental or premature stent release. **DO NOT** remove the Safety Clip **(G)** until you are ready to deploy the stent. Just prior to deploying the stent, the Removable Safety Clip **(G)** must be removed.

3.4 Radiopaque Markers and Verification of Positioning:

There are four radiopaque tantalum markers on each end of the stent and an additional radiopaque marker band on the outer catheter of the delivery system. In its compressed stage, the tantalum markers appear like a contiguous band at each end of the stent:

- Four radiopaque tantalum markers on each end of the stent indicate the location of the distal and proximal end of the compressed stent
- One radiopaque marker band is attached to the outer catheter and overlaps the four distal markers on the stent prior to deployment. This moving marker indicates the amount of stent deployed during the procedure.

  During stent deployment, the radiopaque markers on the stent should not move. The single radiopaque marker on the outer catheter **(D)** will retract with the outer catheter during stent deployment. When the moving marker is past the proximal stent marker by 2 cm, the stent is fully released.

4.0 INDICATIONS FOR USE

The **BARD® LIFESTAR™ Biliary Stent System** is indicated for the treatment of biliary strictures resulting from malignant neoplasms.

5.0 CONTRAINDICATIONS

Contraindications for the **BARD® LIFESTAR™ Biliary Stent System** include, but may not be limited to:

- Stenting of a perforated duct where leakage from the duct could be exacerbated by the endoprosthesis.
- Severe ascites precluding a percutaneous transhepatic approach.
- Extensive hepatic metastases precluding a percutaneous transhepatic 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 misplacement 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® LIFESTAR™ 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 Grip, **DO NOT** use the device.
- The delivery system catheter is intended 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, micro-adjustments 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 biohazard. Handle and dispose of this product in accordance with accepted 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 regarding adequate procedural training.

7.1 System Handling Precautions:

- Non-compliance with sterility precautions may lead to infectious complications.
- An appropriate guidewire 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® LIFESTAR™ Biliary Stent System** is only compatible with a 0.035“ (0.89 mm) guidewire.
- When catheters are in the body, they should be manipulated only under fluoroscopy 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® LIFESTAR™ 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 **(G)** is removed. As a precaution 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 misplacement.
- **DO NOT** remove the Removable Safety Clip **(G)** 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® LIFESTAR™ Biliary Stent** is a self-expanding nitinol stent that **MUST NOT** be expanded beyond its labeled diameter by dilatation with a PTA balloon.
- **WARNING:** If stent dilatation is deemed appropriate, please ensure that the selected balloon is indicated for use in the biliary tree.

- 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. Stenting in this order obviates the need to cross the proximal stent for placement of the distal stent, and reduces the potential to dislodge stents that have already been placed.
- To maximize stent placement accuracy, slowly and deliberately deploy 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.

8.0 POTENTIAL COMPLICATIONS

Potential adverse events associated with the use of the **Bard® 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
- Duodenal perforation
- External biliary fistula
- Infection
- Liver abscess
- Pain
- Pancreatitis
- Stent fractures
- Stent malposition
- Stent migration
- Stent obstruction secondary to tumor ingrowth through the stent, tumor overgrowth at the stent ends, or sludge occlusion

9.0 DIRECTIONS FOR USE

9.1 Procedural Access:

- Gain access to the treatment site utilizing appropriate accessory equipment compatible with the 6F **Bard® LifeStar™ Biliary Stent System**.
- The working lengths of the 6F Delivery System are indicated on the labels and on the device itself. In order to allow complete stent deployment, **DO NOT** use an introducer sheath or guiding catheter longer than the indicated working length.
- The 6F Delivery System requires a minimum 8F guiding catheter, or a minimum 6F introducer sheath.
- Via the transhepatic route, insert a 0.035" (0.89 mm) guidewire under fluoroscopic guidance through the biliary stricture 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 stricture. Measure the length of the stricture 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 stricture.
- Allow approximately 5 – 10 mm of the stent to extend beyond each end of the stricture. This will allow for adequate stent coverage at either end of the stenosis.
- If placing two overlapping stents, both stents must have identical diameters and 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-dilatation of the stricture with an appropriately sized balloon dilatation catheter is left to the discretion of the treating physician.
- **WARNING:** If pre-dilatation 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 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® 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 two 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 **(F)**. Continue flushing until saline drips 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 stricture using the radiopaque markers to center the stent across the lesion.
- It is recommended to advance the delivery system past the stricture and then to 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 catheter 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 markers stent markers and marker band on the outer catheter across the stricture. 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 stricture, micro-adjustments of the stent can be made by pulling the entire system back toward the stricture 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 repositioned in the lumen.
- Once stent deployment has been initiated, the stent **CANNOT** be recaptured using the stent delivery system.
- Once the moving marker has passed the proximal end of the stent by approximately 2 cm, the stent is completely deployed.
- Complete stent deployment can be fluoroscopically visualized when the radiopaque markers at 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 retracts the outer catheter and deploys a corresponding portion of the stent.
- Full stent deployment is ensured when the Distal T-Luer Adapter **(F)** reaches the grip.
- During stent deployment the moving single radiopaque 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 during stent deployment.
- 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 radiological evaluation of the implanted stent should be conducted by cholangiogram.

9.8 Post-Stent Placement:

- Post-dilatation of the stent with an appropriately sized balloon dilatation catheter is left to the discretion of the treating physician.
- **WARNING:** If post-dilatation is deemed appropriate, please ensure that the selected balloon is indicated for use in the biliary tree.
- **WARNING:** The **Bard® LifeStar™ Biliary Stent** is a self-expanding, nitinol stent that **MUST NOT** be expanded beyond its labeled diameter by dilatation with a PTA balloon.
- 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 biohazard. Handle and dispose of this product in accordance with accepted medical practice and with applicable local, state and federal laws and regulations.

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 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 **Bard® LifeStar™ Biliary Stent** is MR Conditional. A patient with the **Bard® 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 **Bard® LifeStar™ Biliary Stent** produced a temperature rise of less than or equal to 0.8°C at a maximum MR system-reported whole body averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of MR scanning in a 3.0 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 **Bard® LifeStar™ Biliary Stent**. Optimization of MR imaging parameters is recommended.

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

12.0 HOW SUPPLIED

The **Bard® LifeStar™ Biliary Stent System** is supplied sterile (by ethylene oxide gas) unless 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.

Symbols used on labelling

Consult Instructions For Use

Keep Away From Sunlight

Keep Dry

Do Not Use If Package Is Damaged

Single Use

Do Not Resterilize

Contents: (1)

MR Conditional

Does Not Contain Natural Rubber Latex

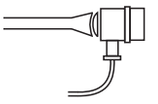
Catalogue Number

Lot Number

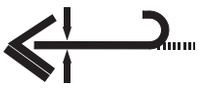
Sterilized Using Ethylene Oxide

Use By

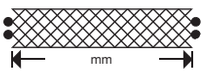
Manufacturer



Minimum Introducer Size



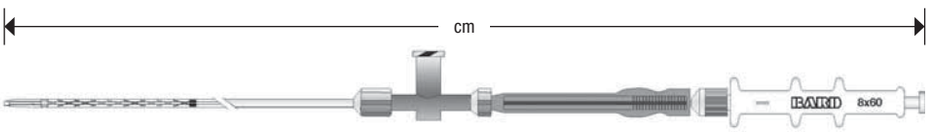
Guidewire Compatibility



Stent Length

Stent Diameter

Working Length



System Length

English

Patient **IMPLANT** Information Card

BARD® LIFESTAR™ Biliary Stent System

Patient IMPLANT Information Card

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

Manufacturer:
Angiomed GmbH & Co. Medizintechnik KG
Subsidiary of C. R. Bard, Inc.

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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
- Maximum whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 min. of scanning for patient landmarks above the umbilicus.

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BARD

Patient Data:

Name: _____

Address: _____

Date of birth: _____

Implant Data:

Product: _____ Implant Material: _____

Implantation site: _____

Date of implantation: _____

Follow up: _____

Hospital Data:

Name: _____

_____

Address: _____

_____

_____

_____

_____

Apply “Patient/Inv. chart” sticker here

Physician: _____

Phone: _____

BARD® LIFESTAR™ Biliary Stent System

For the U.S.A. only

C. R. BARD, INC. EXCLUDES ALL WARRANTIES, WHETHER EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, RELATED TO THE BARD® LIFESTAR™ BILIARY STENT SYSTEM, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

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 03/2016
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 U.S.: 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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Medizintechnik KG

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