E·LUMINEXX®

Biliary Stent

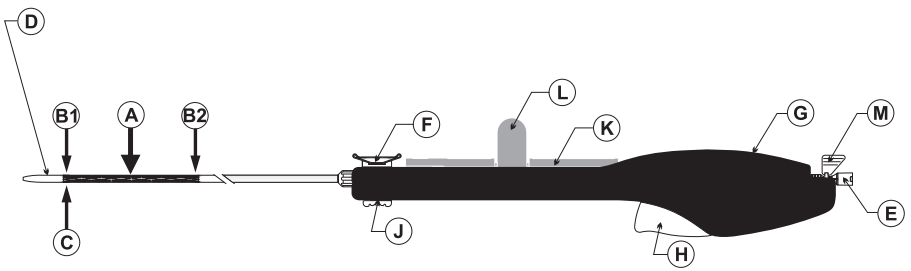
INSTRUCTIONS FOR USE (IFU)

BARD | PERIPHERAL VASCULAR

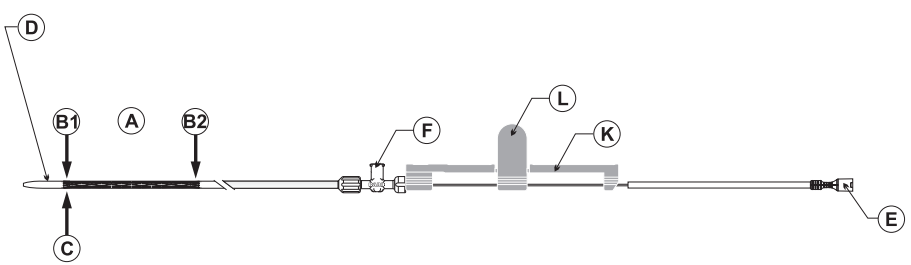
B05691 Vers.6/11-09

BARD® E•LUMINEXX® Biliary Stent Delivery System Diagrams

BARD S.A.F.E.®♦ Delivery System with the PERFORMAXX® Grip



BARD S.A.F.E.® Delivery System after removal of the PERFORMAXX® Grip



♦ **S.A.F.E.** = Secure Adhesive Free Tip Design

INFORMATION FOR USE

Read the BARD® E•LUMINEXX® Biliary Stent 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.*

1.0 DEVICE NAME

- The brand name of the device is **BARD® E•LUMINEXX® Biliary Stent**.
- The Stent (Implant) is equipped with four highly visible radiopaque **PUZZLE® Tantalum Markers** on both the proximal and distal end.
- The **BARD® E•LUMINEXX® Biliary Stent** is loaded on the **BARD S.A.F.E.® Delivery System** with the **PERFORMAXX® Grip**.

2.0 PRODUCT DIAGRAMS (PLEASE REFER TO PAGE 2 AND 3)

Table 1: BARD® E•LUMINEXX® Biliary Stent Component Identification Codes

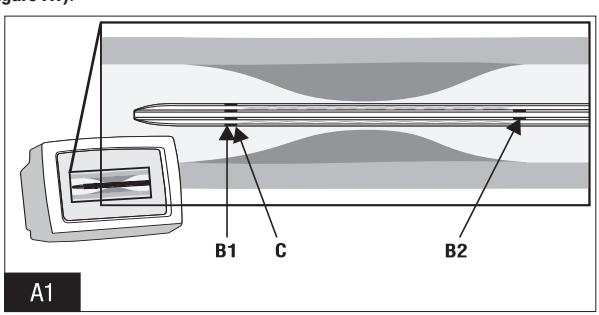
A	Stent (implant)	E	Proximal Luer port	K	Safety clip
B1	4 Distal PUZZLE® Tantalum Markers	F	Distal T-Luer adapter	L	Safety clip tabs
B2	4 Proximal PUZZLE® Tantalum Markers	G	PERFORMAXX® Grip	M	Conversion tab
C	A single radiopaque marker on the outer catheter	H	Trigger		
D	Flexible catheter tip	J	Slide mechanism		

3.0 DEVICE DESCRIPTION

3.1 Stent (Implant):

The **BARD® E•LUMINEXX® 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.

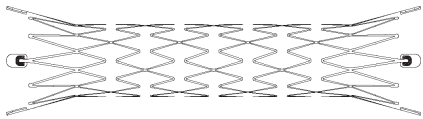
Each end of the stent has four highly visible radiopaque **PUZZLE® Tantalum Markers** to facilitate accurate stent placement **(see Figure A1)**.



A1

Before deployment, the stent **(A)** 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 **(B1 and B2)**. The stent **MUST NOT** be balloon expanded beyond its labeled diameter.



A single radiopaque marker **(C)** on the outer catheter 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 **(B1)** 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® E•LUMINEXX® Biliary Stent Length Change Information

Unconstrained Stent Diameter (mm)	Reference Lumen Diameter (mm)	Average Length Change at Recommended Oversizing (%)
4	3	0.0
5	4	0.0
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 S.A.F.E.® 6F Delivery System** requires a minimum 8F guiding catheter or a minimum 6F introducer sheath. The delivery system has a soft and flexible catheter tip **(D)** formed from the outer catheter. The catheter tip is tapered to accommodate a 0.035“ (0.89 mm) guidewire. The guidewire exit port is located at the proximal end of the delivery system. 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 lubricates the surface between the inner and outer catheters. The first Luer port is located at the proximal end of the device **(E)** and the second is found within the T-Luer adapter **(F)**. The **BARD S.A.F.E.® Delivery System** also features a next generation **STENTLOC® Mechanism** that uses compression along the entire length of the stent to prevent unintentional movement or misplacement during deployment.

3.3 Deployment Methods:

The **BARD S.A.F.E.® Delivery System** with the **PERFORMAXX® Grip (G)** is a multifunctional stent deployment system that offers four different stent deployment options:

- “The Trigger Method”
- “The Slide Method”
- “The Combination Method (Trigger/Slide)”
- “The Conventional Method”

3.3.1 The Trigger Method

Stent deployment can be accomplished using "The Trigger Method" by pumping the trigger **(H)** of the handle. "The Trigger Method" offers micro-clicks for ultimate control 2 mm at a time or full pumps for rapid, one-handed stent deployment. **(See Figure 1)**

3.3.2 The Slide Method

Using "The Slide Method", the stent can be deployed by pulling back the slide mechanism **(J)**. **(See Figure 2)**

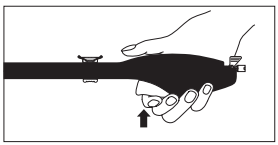
3.3.3 The Combination (Trigger/Slide) Method

"The Combination Method" utilizes "The Trigger Method" until the stent has achieved wall apposition and then switches to "The Slide Method" to complete the deployment. **(See Figures 1 & 2)**

3.3.4 The Conventional Method

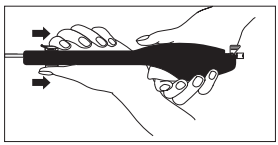
"The Conventional Method" requires the user to remove the white conversion tab **(M)** before snapping the catheter out of the **PERFORMAXX® Grip**. The stent can then be deployed by using the conventional "pin & pull-back" technique by pulling back the T-Luer adapter **(F)**. **(See Figure 3)**

Figure 1:



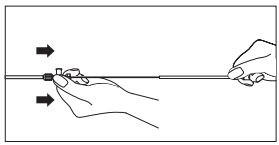
Trigger Method

Figure 2:



Slide Method

Figure 3:



Conventional Method

A removable red Safety Clip **(K)** prevents accidental or premature stent release. **DO NOT** remove the Safety Clip **(K)** until you are ready to deploy the stent. Just prior to deploying the stent, the Safety Clip **(K)** must be removed by pressing the two red tabs **(L)** together and removing the clip from the grip.

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 deployment 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 **(B1)** and proximal end of the compressed stent **(B2)**
- One radiopaque marker band is attached to the outer catheter **(C, same position as B1)** 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 **(B1 and B2)** should not move. The marker band **(C)** on the outer catheter will retract with the outer catheter during stent deployment. When the moving marker is past the proximal marker **(B2)** by 2 cm, the stent is fully released.

4.0 INDICATIONS FOR USE

The **BARD® E•LUMINEXX® Biliary Stent** is indicated for the treatment of biliary strictures resulting from malignant neoplasms.

5.0 CONTRAINDICATIONS

Contraindications for the **BARD® E•LUMINEXX® Biliary Stent** 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:

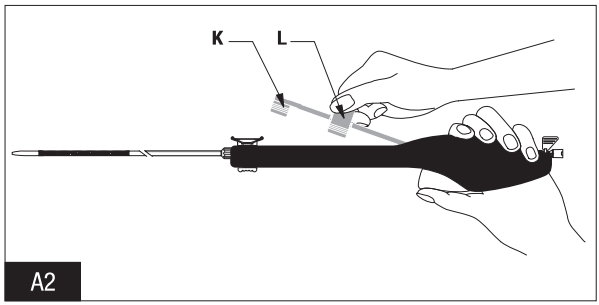
- Visually inspect the packaging to verify that the sterile barrier is intact. **DO NOT** use if the sterile barrier is open or damaged.
- **DO NOT** use the device after the "Use By" date specified on the label.
- Visually inspect the **BARD® E•LUMINEXX® Biliary Stent** to verify that the device has 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 red 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.
- If the **PERFORMAXX® Grip** is removed from the stent delivery system, it **MUST NOT** be reattached. In this event, the stent **MUST** be deployed using "The Conventional Method" of deployment. (See instructions for "The Conventional Method".)
- 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.

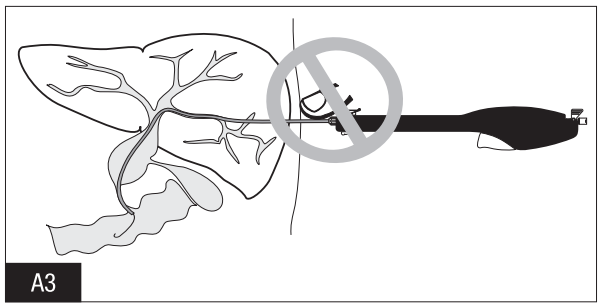
7.1 System Handling Precautions:

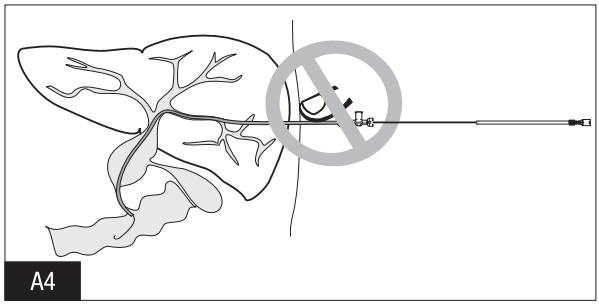
- Non-compliance with sterility precautions may lead to infectious complications.
- An appropriate guidewire is required before introducing the stent deployment system into the body, and must remain in place during the introduction, manipulation and eventual removal of the stent deployment system.
- The **BARD® E•LUMINEXX® Biliary Stent** 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® E•LUMINEXX® Biliary Stent**.
- The delivery system is not designed for use with power injection systems.
- Faulty placement techniques could lead to stent deployment failure.
- Do not kink the delivery system.
- The delivery system will not function properly until the Safety Clip **(K)** is removed **(See Figure A2)**. 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 white conversion tab unless you have selected "The Conventional Method" for stent deployment.
- **DO NOT** remove the Safety Clip **(K)** until you are ready to deploy the stent.
- **DO NOT** hold the delivery system catheter during stent deployment. **(See Figure A3/A4)**





- **DO NOT** overlap more than two stents.
- The **BARD® E•LUMINEXX® Biliary Stent** is a self-expanding nitinol stent that **MUST NOT** be expanded beyond its labeled diameter by balloon dilatation.
- 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 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

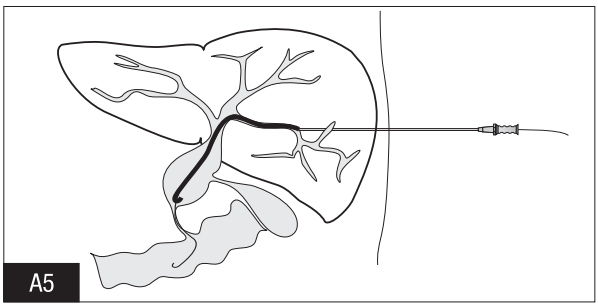
Potential adverse events associated with the use of the **BARD® E•LUMINEXX® Biliary Stent** include, but may not be limited to the usual complications reported for conventional biliary stents and transhepatic procedures such as:

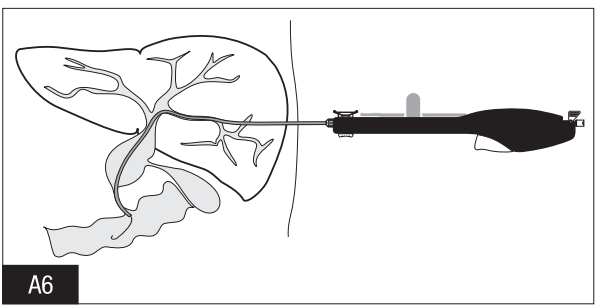
- Bleeding
- Cholangitis
- Cholecystitis
- Duodenal perforation
- External biliary fistula
- Infection
- Liver abscess
- Pain
- Pancreatitis
- Stent fractures
- Stent malposition
- Stent migration
- Stent obstruction secondary to tumor ingrowth through the stent, tumor overgrowth at the stent ends, or sludge occlusion

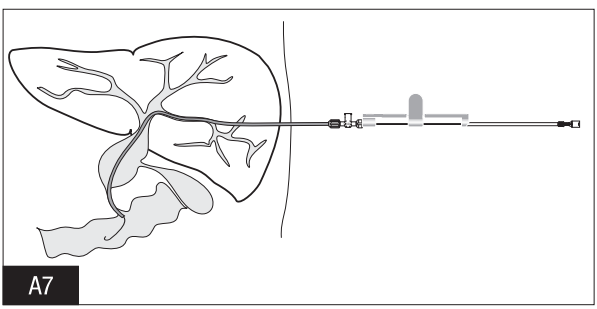
9.0 DIRECTIONS FOR USE

9.1 Procedural Access:

- Gain access to the treatment site utilizing appropriate accessory equipment compatible with the 6F **BARD® E•LUMINEXX® Biliary Stent** System.
- The working lengths of the **BARD S.A.F.E.® 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 **BARD S.A.F.E.® 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. **(See Figure A5, A6 and A7)**







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 3 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 and impede tumor overgrowth at the ends of the stent.
- If placing two overlapping stents, both stents must have identical diameters.
- Stents should overlap by at least 5 mm to include the flared ends. **DO NOT** overlap more than two stents.

9.3 General Directions:

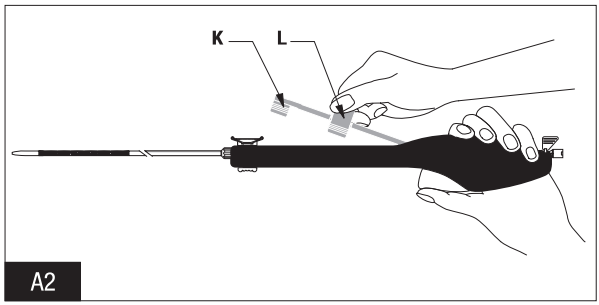
- Administration of adjunctive drug therapy before and after the procedure is left to the discretion of the treating physician.
- Pre-dilatation of the stricture with an appropriately sized balloon dilatation catheter is left to the discretion of the treating physician.
- Warning: If pre-dilatation is 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® E•LUMINEXX® 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 **(E)** and the second of which is found within the T-Luer adapter **(F)**. Continue flushing until saline drips from the distal tip of the catheter **(D)** after flushing each Luer port.
- During system flushing, **DO NOT** use the system if fluid is not observed exiting the catheter at the distal tip **(D)** after each Luer port is flushed.
- During delivery system preparation, ensure that the red safety clip remains in place until the stent is ready to be deployed. If the red safety clip has been removed or becomes inadvertently detached from the grip, **DO NOT** use the device.

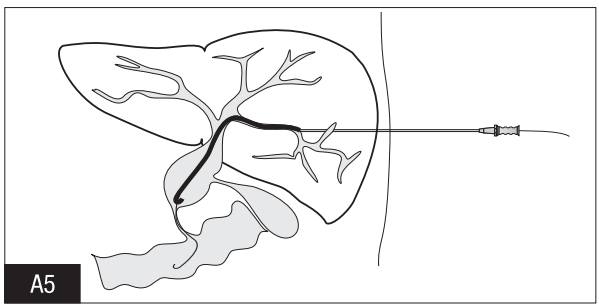
9.5 Selection of Deployment Method:

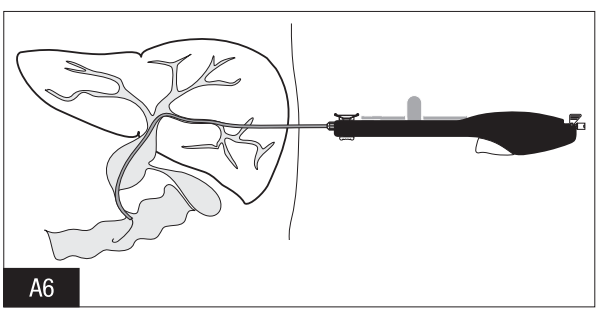
- Determine whether you will use the **PERFORMAXX® Grip** for stent deployment. (See instructions for "Stent Deployment with the PERFORMAXX® Grip", Section 9.8.)
- If selecting "The Conventional Method" of stent deployment, this option must be selected at the beginning of the procedure. (See instructions for "The Conventional Method", Section 9.9.)
- If the **PERFORMAXX® Grip** is removed from the stent delivery system, it **MUST NOT** be reattached. In this event, the stent **MUST** be deployed using "The Conventional Method" of deployment.
- A removable red Safety Clip **(K)** prevents accidental or premature stent release.
- **DO NOT** remove the Safety Clip **(K)** until you are ready to deploy the stent.
- Just prior to deploying the stent, the Safety Clip **(K)** must be removed by pressing the two red tabs **(L)** together and removing the clip from the grip. **(See Figure A2)**

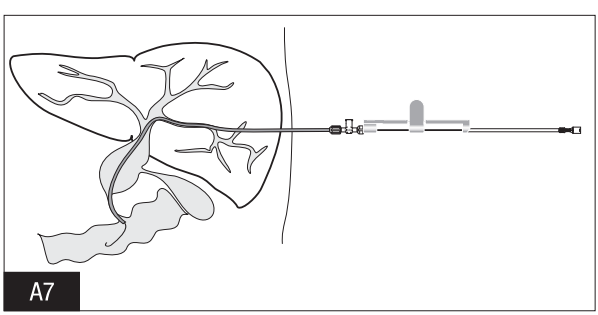


9.6 Introduction of the Stent Delivery System:

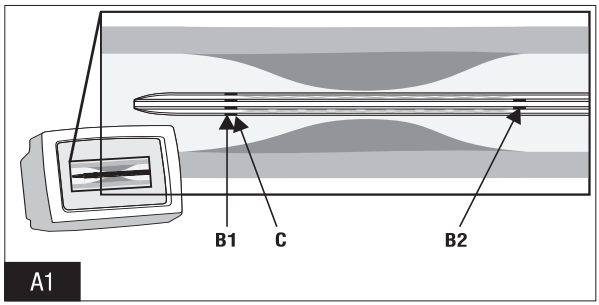
- Insert the guidewire into the distal tip of the catheter until it exits the catheter at the proximal end of the device.
- Advance the delivery catheter over the guidewire into the target lumen. **(See Figure A5, A6 and A7)**



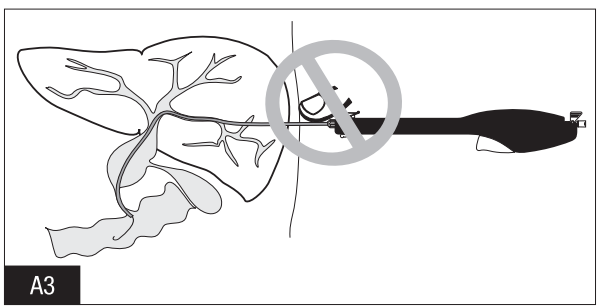


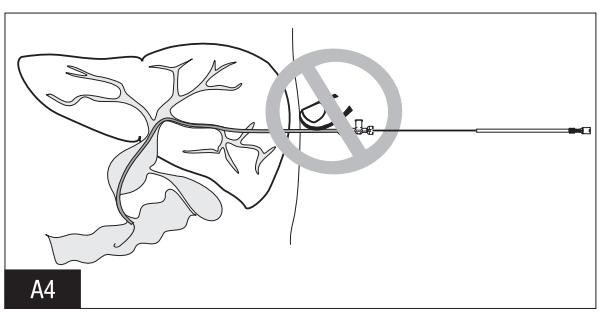


- Under fluoroscopic visualization, advance the stent delivery system across the stricture using the radiopaque markers to center the stent across the lesion. **(See Figure A1)**



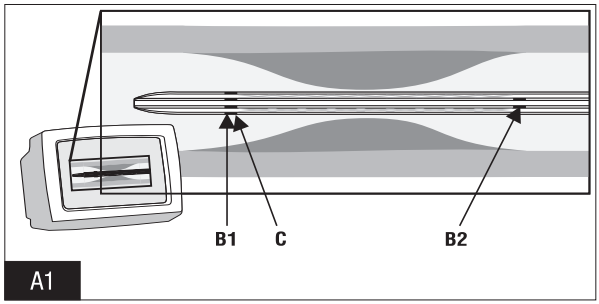
- It is recommended to advance the delivery system past the stricture and then to pull back slightly on the entire system to achieve the correct positioning of the markers and to help insure that slack has been removed and that the delivery catheter is straight.
- Prior to stent deployment, remove all slack from the catheter delivery system to avoid stent misplacement.
- **DO NOT** hold the delivery system catheter during stent deployment. **(See Figure A3/A4)**





9.7 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 (**See Figure A1**, "B2") and both overlapping distal markers (**See Figure A1**, stent markers "B1" and marker band on the outer catheter "C") across the stricture. The radiopaque markers on the stent indicate the ends of the compressed stent and the length of the expanded stent.

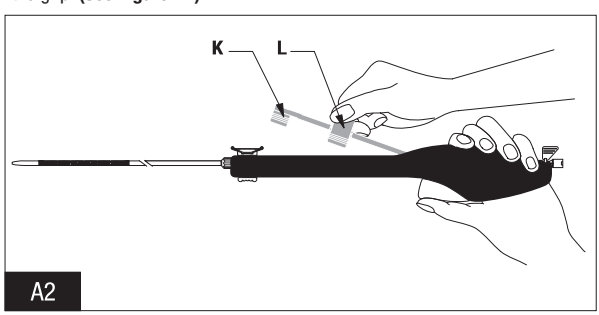


A1

- 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.

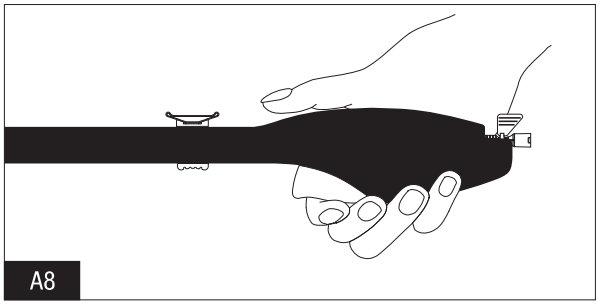
9.8 Stent Deployment With the PERFORMAXX® Grip:

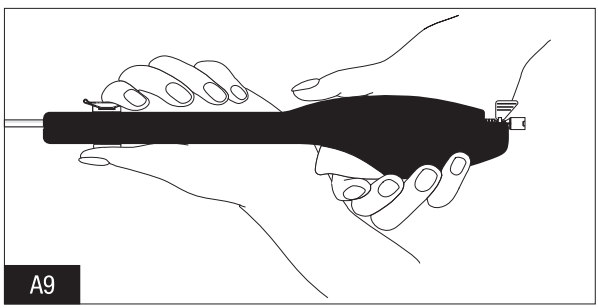
- There are three different stent deployment options with the **PERFORMAXX® Grip**:
  - "The Trigger Method" (See Section 3.3, Figure 1)
  - "The Slide Method" (See Section 3.3, Figure 2)
  - "The Combination Method (Trigger/Slide)"
- Switching from "The Trigger Method" to "The Slide Method" can be done at any time during stent deployment; however, switching from "The Slide Method" to "The Trigger Method" **MUST** be avoided.
- **DO NOT** remove the Safety Clip **(K)** until you are ready to deploy the stent.
- Just prior to stent deployment, remove the red Safety Clip **(K)** by pressing the two red tabs **(L)** together and removing the clip from the grip. **(See Figure A2)**

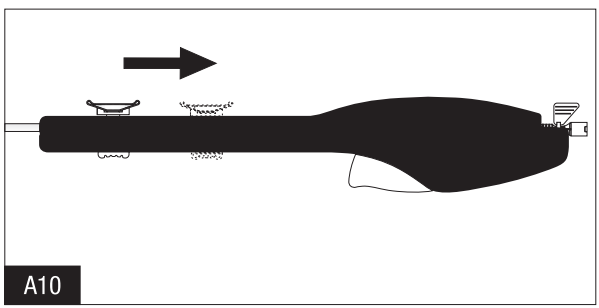


A2

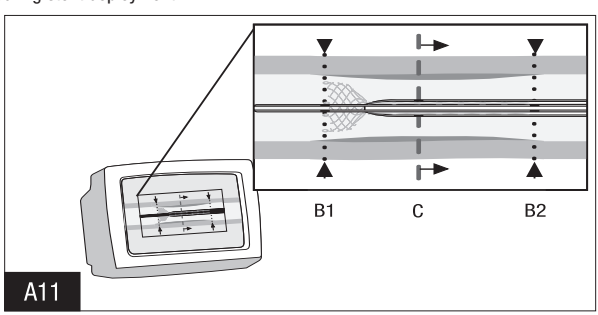
- Under fluoroscopic visualization, deploy the stent utilizing your chosen method of deployment until the stent is fully deployed and the slide mechanism has reached the proximal end of the handle. **(See Figure A8 – A10)**



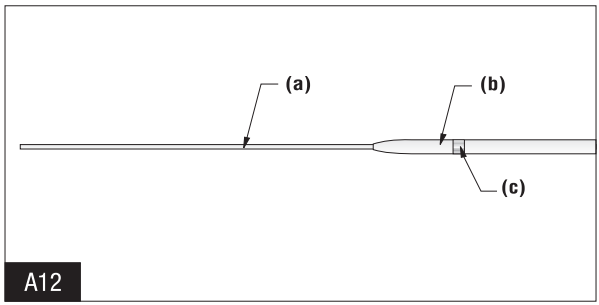




- During stent deployment **(See Figure A11)**, the moving radiopaque marker (C) on the outer catheter moves backwards toward the proximal markers on the stent (B2). The radiopaque markers on the stent (B1, B2) **MUST NOT** move during stent deployment.



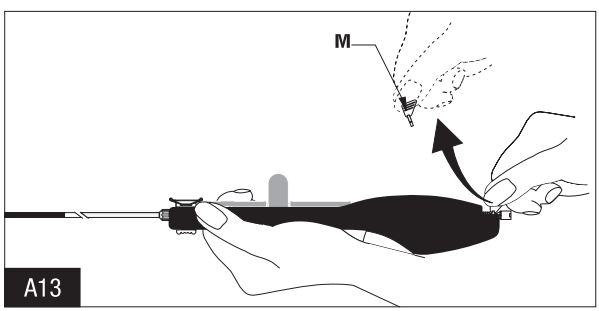
- After stent deployment, carefully withdraw the delivery system from the patient over the guidewire. After removing the delivery system, visually confirm that the entire stent delivery system has been removed. **(See Figure A12)**
  (a) inner catheter
  (b) outer catheter
  (c) moving distal marker (C) on outer catheter



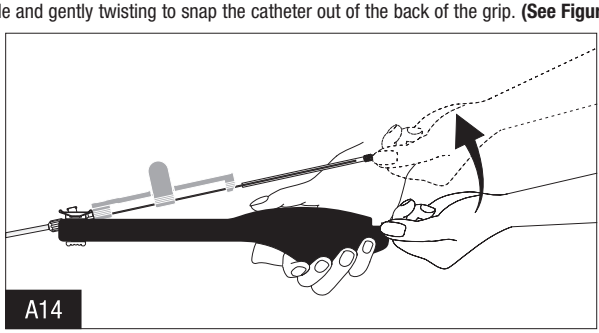
- Final radiological evaluation of the implanted stent should be conducted by cholangiogram.

9.9 Stent Deployment Using The Conventional Method:

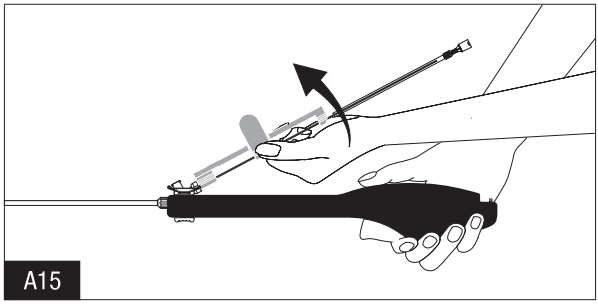
- In addition to the three deployment options outlined in Section 9.8 there is also an option to release the stent **WITHOUT** the **PERFORMAXX® Grip**:
  - "The Conventional Method" (See Section 3.3, Figure 3)
- To allow "The Conventional Method" of deployment, remove the white conversion tab **(M)** from the back of the grip. **(See Figure A13)**



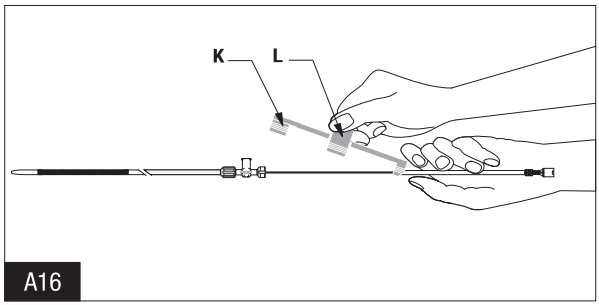
- Separate the **PERFORMAXX® Grip** from the delivery system catheter by grasping the Luer lock **(E)** at the back end of the handle and gently twisting to snap the catheter out of the back of the grip. **(See Figure A14)**



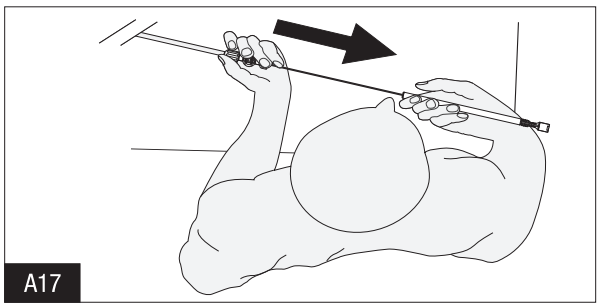
- Then grasp the deployment system at the front T-Luer adapter **(F)** and snap the deployment system completely out of the grip. **(See Figure A15)** Use caution not to bend the metal portion of the catheter during removal from the grip.



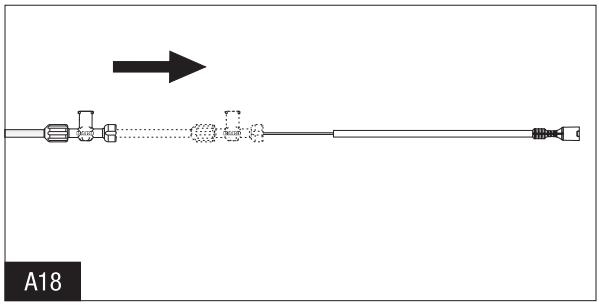
- **DO NOT** remove the Safety Clip **(K)** until you are ready to deploy the stent.
- Just prior to stent deployment, remove the red Safety Clip **(K)** by pressing the two red tabs **(L)** together and removing the clip from the grip. **(See Figure A16)**



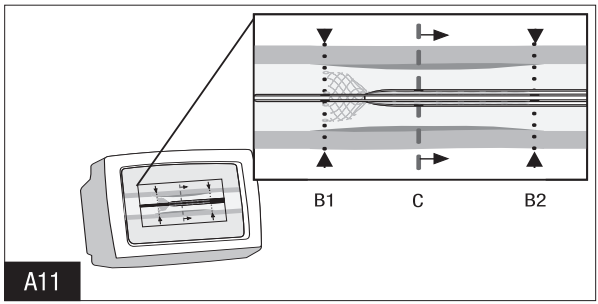
- Under fluoroscopic visualization, deploy the stent using the conventional "pin & pull-back" technique by slowly pulling back the T-Luer adapter **(F)** towards the hand that is pinned in place. Pulling back on the T-Luer adapter **(F)** directly retracts the outer catheter and deploys a corresponding portion of the stent. **(See Figure A17)**



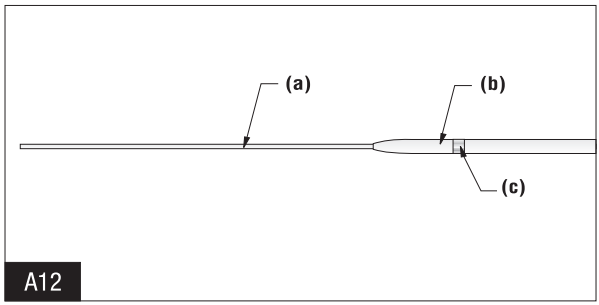
- Full stent deployment is ensured when the T-Luer adapter **(F)** reaches the metal handle. **(See Figure A18)**



- During stent deployment **(See Figure A11)**, the moving radiopaque marker (C) on the outer catheter moves backwards toward the proximal markers on the stent (B2). The radiopaque markers on the stent (B1, B2) **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. **(See Figure A12)**
  (a) inner catheter
  (b) outer catheter
  (c) moving distal marker (C) on outer catheter



- Final radiological evaluation of the implanted stent should be conducted by cholangiogram.

9.10 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.
- The **BARD® E•LUMINEXX® Biliary Stent** is a self-expanding, nitinol stent that **MUST NOT** be expanded beyond its labeled diameter by balloon dilatation.
- 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 back of 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.
- Apply one of the peel-off stickers found in the IFU to the indicated area on the Patient IMPLANT Information Card. This peel-off sticker contains important information about the patient's stent implant.
- 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® E•LUMINEXX® Biliary Stent** is MR Conditional. A patient with the **BARD® E•LUMINEXX® 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 MR system reported whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of scanning.

In non-clinical testing, the **BARD® E•LUMINEXX® 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® E•LUMINEXX® 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® E•LUMINEXX® Biliary Stent** 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 labeling

Consult instructions for use

Keep away from sunlight

Keep dry

Do not use if package is damaged

The Green Dot

Recyclable

Single use

Do not resterilize

Symbols used on labeling

Caution, consult accompanying documents

MR Conditional

Units

Manufacturer

Date of manufacture

Sterilized using ethylene oxide

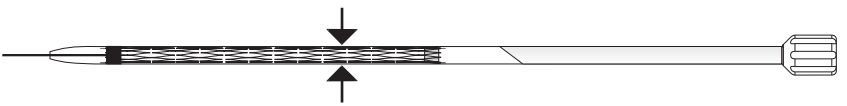
Use by

Catalogue number

Symbols used on labeling

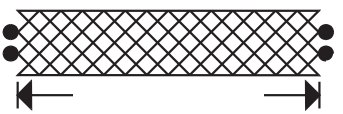
Lot number

Guidewire Compatibility

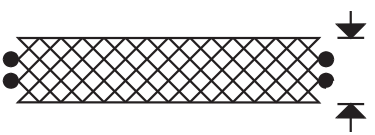


Deployment System

Working Length



Stent Length



Stent Diameter

BARD® E•LUMINEXX® Biliary Stent

For the USA only

C. R. BARD, INC. EXCLUDES ALL WARRANTIES, WHETHER EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, RELATED TO THE BARD® E•LUMINEXX® STENT, 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.

U.S. Patent Nos.: **5,707,386**
5,716,393
5,860,999
6,053,941
6,572,647
other patents pending

Label Issue Date 11/2009
In the event 3 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® E•LUMINEXX® Biliary Stent

Patient IMPLANT Information Card

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

MR Conditional

This Device is classified as MR Conditional. For further details on MR compatibility, please refer to product's IFU available on www.bardpv.com or call 1-800-562-0027.

BARD | PERIPHERAL VASCULAR

Manufacturer:

Angiomed GmbH & Co.
Medizintechnik KG
Subsidiary of C. R. Bard, Inc.
Wachhausstraße 6
76227 Karlsruhe
Germany

Tel: ++ 49 721 9445 - 0
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Distributed in the USA by:

Bard Peripheral Vascular, Inc.
Subsidiary of C. R. Bard, Inc.
1625 West 3rd Street
Tempe, AZ 85281
USA
TEL: 1-480-894-9515
1-800-321-4254
FAX: 1-480-966-7062
1-800-440-5376
www.bardpv.com

BARD

Patient Data:

Name: _____

Address: _____

Date of birth: _____

Implant Data:

Product: _____ Implant Material: _____

Implantation site: _____

Date of implantation: _____

Follow up: _____

Apply “Patient/Inv. chart” sticker here

Hospital Data:

Name: _____

Address: _____

_____

Physician: _____

Phone: _____

English

Physician's Record

REMOVE THESE LABELS TO COMPLETE YOUR PATIENT FILE

BARD | PERIPHERAL VASCULAR

Product Data

apply "Patient/Inv. chart" sticker here

Patient Data:

Name: _____

Date of implantation: _____

Implantation site: _____

Follow up: _____

Manufacturer: **Angiomed GmbH & Co. Medizintechnik KG • Wachhausstraße 6 • 76227 Karlsruhe • Germany**

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Product Data

apply "Patient/Inv. chart" sticker here

Patient Data:

Name: _____

Date of implantation: _____

Implantation site: _____

Follow up: _____

Manufacturer: **Angiomed GmbH & Co. Medizintechnik KG • Wachhausstraße 6 • 76227 Karlsruhe • Germany**

BARD® E•LUMINEXX® Biliary Stent

Manufacturer:

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Medizintechnik KG

Subsidiary of C. R. Bard, Inc.

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