BARD® LIFESTAR™
Vascular Stent System

Instructions For Use (IFU)

BARD® LIFESTAR™ Vascular Stent System Delivery System Diagram
Instructions for use
Read the Bard® LifeStar™ Vascular 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.
• The device is supplied in a sterile condition. All materials included in the sterile package are individually packaged in an outer carton. The outer carton as well as the carrier labels are sterile. The external surface of the sterile pouch and the product carton should be considered sterile.
• 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™ Vascular Stent System.
• The Stent (implant) is equipped with four highly visible radiopaque Tantalum Markers on both the proximal and distal end.
• The Bard® LifeStar™ Vascular Stent is loaded on the Bard® LifeStar™ Delivery System.

2.0 PRODUCT DIAGRAM
(Please refer to page 1)

2.1 GENERIC DESCRIPTION
The Bard® LifeStar™ Vascular Stent System is a self-expanding, flexible, nitinol (nickel-titanium) alloy stent that expands to a 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.

The Bard® LifeStar™ Vascular Stent System is available in the sizes indicated as follows, listing all item codes for 80 cm and 135 cm long stent delivery system.

<table>
<thead>
<tr>
<th>Stent Length</th>
<th>Diameter</th>
<th>Reference Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>80 cm Delivery System</td>
<td>20 mm</td>
<td>VUL01020</td>
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<td>30 mm</td>
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3.0 DEVICE DESCRIPTION

3.1 Stent (Implant)
The Bard® LifeStar™ Vascular Stent is a self-expanding, flexible, nitinol (nickel-titanium) alloy stent that expands to a 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.

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3.2 Delivery System:
The Bard® LifeStar™ Delivery System has catheter working lengths of 80 cm and 135 cm and 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 can slide via a metal tube to the Grp. (G), and a Coaxial Outer Catheter (A), which connects to the Proximal Luer Port (P).

4.0 INDICATIONS FOR USE
The Bard® LifeStar™ Vascular Stent System is indicated for the treatment of iliac occlusive disease in patients with symptomatic vascular disease of the common and/or iliac arteries up to 12.6 mm in length with a reference vessel diameter of 5 to 9 mm.

5.0 CONTRAINDICATIONS
There are no known contraindications.

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.
• Sterilizing across a major bifurcation may hinder or prevent future diagnostic or therapeutic procedures.
• In patients requiring the use of antacids and/or H2-antagonists before or immediately after stent placement, oral absorption of antagonists (e.g., aspirin) may be adversely affected.
• Overshrinking the artery may result in spasm, dissection, and/or perforation that may result in serious complications.
• Longterm outcomes following repeated dilatation of endothelialized stents are unknown.
• A limited subset of patients received overlapped stents in the clinical study; therefore, data regarding overlapped stents is limited.

6.2 Device Warnings:
• DO NOT use the device if the sterile barrier is open or damaged.
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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 iliac stenting. It is strongly recommended that physician operators adhere to all applicable institutional, local, state, and federal guidelines, and protocols regarding appropriate procedural training.

7.1 System Handling Precautions:
• 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 printed on the label.

7.2 System Operation Precautions:
• Visually inspect the Bard® LifeStar™ Vascular 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 leak or damage the delivery system. DO NOT use if device is kinked.
• Non-compliance with sterility precautions may lead to increased procedure times.
• 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.

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8.1 Study Endpoints and additional data: The rate of Major Adverse Clinical Events (MACE) was the primary safety and effectiveness endpoint for the study. MACE was defined as peri-procedural death (death during the procedure or prior to hospital discharge), target lesion revascularization (any treatment to bypass or dilate the stenotic lesion), and all-cause death.

8.2 Patient Population: The protocol allowed for a broad spectrum of patients with iliac artery occlusive disease to be treated with the LifeStar® Iliac Stent, including patients with poor distal runoff, concurrent lesions or recent distal bypass surgery, and/or restenotic lesions. The intent was to test the device in a non-selective population that would more closely represent the clinical population following device commercialization. Patients diagnosed with preoperative coagulation disorders, contraindications to antiplatelet therapy, or who demonstrated the presence of soft, thrombotic, or embolic material within or adjacent to the lesion(s) being treated with the stent device were excluded. Characteristics of patients enrolled in the study included age, gender, medical history, and previous vascular procedures are presented in Table 4.

7.3 Post-Implant Precautions: Caution should be taken when using a crossed stent deployment with any adjunctive device.

7.4 In the event of thrombosis of the expanded stent, thrombolytics and PTA may be attempted.

7.5 In the event of complications such as infection, pseudotumor, or fistulization, surgical removal of the stent may be required.

8.0 SUMMARY OF CLINICAL INVESTIGATIONS

The purpose of the clinical study was to provide the human clinical trial experience to support the safety and effectiveness of the LifeStar® Iliac Stent System. The U.S. clinical trial protocol described the device to be safe and effective for its intended use. Data gathered from the clinical study were collected on both the Bard® LifeStar® Iliac Stent and the Bard® LifeStar® Iliac Stent System. The U.S. clinical trial protocol described the device to be safe and effective for its intended use. Data gathered from the clinical study were collected on both the Bard® LifeStar® Iliac Stent and the Bard® LifeStar® Iliac Stent System. The U.S. clinical trial protocol described the device to be safe and effective for its intended use.

Table 4: Baseline Medical History / Demographics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Summary Statistics</th>
<th>95% Confidence Interval (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>67.31 ± 10.31</td>
<td>65.55% to 69.07%</td>
</tr>
<tr>
<td>Percent Male</td>
<td>54.48%</td>
<td>60/116 (95% CI: 46.54% to 62.42%)</td>
</tr>
<tr>
<td>History of Myocardial Infarction (MI)</td>
<td>23.13% (111/477)</td>
<td>16.80% to 30.96%</td>
</tr>
<tr>
<td>History of Periprosthetic Transluminal Urinary Arteriography (PTA)</td>
<td>40.30% (49/122)</td>
<td>32.38% to 48.76%</td>
</tr>
<tr>
<td>History of Coronary Artery By-pass Graft (CABG)</td>
<td>25.37% (25/100)</td>
<td>18.76% to 33.36%</td>
</tr>
<tr>
<td>History of Cardiovascular Accident (CVA) or Transient Ischemic Attack (TIA)</td>
<td>14.18% (19/134)</td>
<td>9.27% to 21.09%</td>
</tr>
<tr>
<td>History of Diabetes Mellitus</td>
<td>26.87% (35/132)</td>
<td>20.08% to 34.54%</td>
</tr>
<tr>
<td>History of Hypertension</td>
<td>73.66% (90/122)</td>
<td>65.61% to 80.43%</td>
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<tr>
<td>History of Peripheral Vascular Disease (PVD)/Claudication</td>
<td>89.50% (201/224)</td>
<td>83.23% to 94.77%</td>
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<tr>
<td>History of Peripheral Arterial Occlusive Disease</td>
<td>94.06% (214/228)</td>
<td>90.41% to 96.71%</td>
</tr>
</tbody>
</table>

All tables: Mean ± Standard Deviation for all quantitative variables, Percent (95% confidence interval / sample size)

Table 5: The LifeStar® Iliac Stent System

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Summary Statistics</th>
<th>95% Confidence Interval (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limb to be Treated</td>
<td>Left</td>
<td>42.54% (50/116)</td>
</tr>
<tr>
<td></td>
<td>Right</td>
<td>57.46% (66/116)</td>
</tr>
<tr>
<td>Reference Lumen Diameter (RDL)</td>
<td>6.95 ± 0.15 (95% CI: 6.77 to 7.13)</td>
<td></td>
</tr>
<tr>
<td>Percent Stenosis</td>
<td>60.00% ± 4.88%</td>
<td>56.81% to 63.19%</td>
</tr>
<tr>
<td>Lesion Length</td>
<td>25.72 ± 18.76% (95% CI: 22.84 to 28.50)</td>
<td></td>
</tr>
</tbody>
</table>

8.4 Results: The results of the LifeStar® Iliac Clinical Study are presented in Table 5. Nine-month post-procedure follow-up was complete in 89 subjects (96.94% of the total sample size of 92 patients). The number of follow-up patients was determined based on the number of patients available at study completion. Patients who did not complete the nine-month follow-up were considered to be lost to follow-up. All available clinical and ultrasound data were included in the analysis. The rate of MACE was less than 25%. The rate of the primary combined safety and effectiveness endpoint (i.e., nine-month MACE rate less than 25%) was determined to be safe and effective for its intended use.

9.0 Protocol requirements: (Table 5 provides post-treatment lesion characteristics. Antiplatelet/anticoagulation therapy and dual antiplatelet therapy were left to physician discretion. Overstenting stent placement was noted, and twelve stents in six lesions were placed in an overlapping configuration.

Table 5: Baseline Lesion Study Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Summary Statistics</th>
<th>95% Confidence Interval (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum Lumen Diameter (MLD) (mm)</td>
<td>2.16 ± 0.16 (95% CI: 1.97 to 2.31)</td>
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</tr>
<tr>
<td>Maximum Lumen Diameter (MLD) (mm)</td>
<td>6.95 ± 0.15 (95% CI: 6.77 to 7.13)</td>
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9.1 Methods: Baseline patient assessments included a clinical examination, and clinical history targeting the extent of peripheral vascular disease, a clinical category determination, and a high/brachial index measurement. At the time of the procedure, lesions were assessed angiographically to determine whether they fit the protocol requirements. Table 5 provides pre-treatment lesion characteristics. Antiplatelet/anticoagulation therapy and dual antiplatelet therapy were left to physician discretion. Overstenting stent placement was noted, and twelve stents in six lesions were placed in an overlapping configuration.
9.0 SUMMARY OF ADVERSE EVENTS

All adverse events through the nine-month follow-up window were submitted for adjudication by an independent Clinical Monitor. The incidence of adverse events was presented descriptively as a percentage of events (i.e., patients who could have more than one event per the total patient population with (95% CI). No unreported adverse device effects (SAEs) were reported in the Luminexx® Clinical Study. Adverse events were summarized as serious or non-serious and attributed to the stent, procedure, or pre-existing or concurrent condition. Seven patients died through the nine-month follow-up interval (5.2%). None of the deaths occurred within the peri-procedure (≤3 days post-indication procedure) timeframe. One patient death (0.75%) was related to complications of thrombectomy of the target lesion and a subsequent chain of revascularization procedures and systemic events. The remaining deaths were the result of pre-existing and/or concurrent conditions, and were not related to the study procedure or the study device.

Table 8 provides a summary of in-hospital serious adverse events (SAEs) and Table 9 provides a cumulative summary of all reported SAEs < nine months through the nine-month follow-up interval (≤365 days). Most prevalent SAEs observed through the nine-month follow-up interval are summarized below:

- **Target Limb Revascularization:** Target limb revascularizations were defined as a revascularization procedure outside the margins of the treatment area (i.e., >5 mm from the proximal or distal end of the stent, but in the same limb). Target limb revascularization was noted in 15 patients (11.19%) through the nine-month follow-up interval. Procedural complications of the target lesion and a subsequent chain of revascularization procedures and systemic events were reported.

- **Non-Target Limb Revascularization:** Non-target limb revascularizations were noted in 12 patients (8.96%) through the nine-month follow-up period. As with target limb revascularization, these non-target limb procedures represent a progression of the peripheral disease process.

10.0 POTENTIAL COMPLICATIONS

Potential adverse events associated with the use of the Bard® LifeStar™ Vascular System include, but may not be limited to:

- **Aortic dissection**
- **Aneurysm**
- **Arterial thrombosis**
- **Arterial aneurysm**
- **Arterial occlusion/thrombus, near the puncture site**
- **Arterial occlusion/thrombus, remote from puncture site**
- **Arterial occlusion/reatenosis of the treated vessel**
- **Arterial rupture**
- **Arteriovenous fistula**
- **Arthroplasty**
- **Atherosclerosis**
- **Death related to procedure**
- **Death unrelated to procedure**
- **Embolization, arterial**
- **Embolization, venous**
- **Febrile**
- **Hematoma bled, remote site**
- **Hematoma bled at needle, device path: nonvascular procedure**
- **Hypersensitivity reactions**
- **Hypertension**
- **Hypotension**
- **Infection**
- **Infections requiring intervention (bypass or amputation, or foot or leg)**
- **Local infection**
- **Malposition (failure to deliver the stent to the intended site)**
- **Myocardial infarction**
- **Pseudoaneurysm formation**
- **Pulmonary embolism**
- **Renal failure**
- **Restenosis of the stented artery**
- **Septicemia/bacteremia**
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™ Vascular Stent System

Non-clinical testing has demonstrated the Bard® LifeStar™ Vascular Stent System 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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Manufactured by:
Angiomed GmbH & Co.
Medizintechnik MS
Subsidiary of C.R. Bard, Inc.

Distributed in the U.S.A. by:
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Subsidiary of C.R. Bard, Inc.
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1-900-321-4954
FAX: 1-480-966-7362
1-800-440-5376
www.bardpv.com

MR Conditional
11.2 Stent Selection:

- Under fluoroscopic visualization, advance the stent through
- Via the femoral route, insert a 0.035” (0.89 mm)
- Allow approximately 5–10 mm of the stent to extend
- Flush the stent delivery system with sterile saline

**WARNING:**

- Select the appropriate length of stent to traverse the stricture.
- The patient should carry this card with them and
- The Patient Data, Implant Data, and Hospital Data

11.6 Stent Placement:

- During stent deployment, the entire length of the stent should be kept as straight as possible. Maintaining a straight stent reduces stent migration during 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 structure, micro-adjustments of the stent can be made by pulling the entire system back toward the structure to improve placement accuracy.
- **WARNING:** 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.
- **WARNING:** 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.

11.7 Stent Deployment

**PRECAUTION:** **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).
- 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 placed in place. Pulling back on the Distal T-Luer Adapter (F) directly retracts the outer catheter and displays a corresponding portion of the stent.
- Full stent deployment is ensured when the Distal T-Luer Adapter (F) firmly touches the Grip.
- During stent deployment the moving single radio-opaque marker on the outer catheter (D) on the outer catheter moves backward 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.
  1. Inner Catheter
  2. Coaxial Outer Catheter
- Final radiographic evaluation of the implanted stent should be conducted by angiogram.

11.8 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:** The Balloon LifeStar™ Vascular Stent System is a self-expanding, nitinol stent that MUST NOT be expanded beyond its labeled diameter by dilation with a PTA balloon.
- **PRECAUTION:** This product has been designed for single patient use. DO NOT re-use. DO NOT resterilize.
- **PRECAUTION:** 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.
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**

**Symbols and Their Meanings:**

- **REF**: Catalogue Number
- **LOT**: Lot Number
- **STERILE EO**: Sterilized Using Ethylene Oxide
- **Use By**: Use By
- **Manufacturer**: Manufacturer
- **Minimum Introducer Size**: Minimum Introducer Size
- **NON PYROGENIC**: Non Pyrogenic
- **Guidewire Compatibility**: Guidewire Compatibility
- **Stent Length**: Stent Length
- **Stent Diameter**: Stent Diameter
- **Working Length**: Working Length
- **System Length**: System Length
C. R. BARD, INC. EXCLUDES ALL WARRANTIES, WHETHER EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, RELATED TO THE BARD® LIFESTAR™ VASCULAR 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 12/2011
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 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.