A single radiopaque marker on the outer catheter (B) of the delivery system is attached approximately 6 mm proximal to the distal end of the delivery system. Prior to deployment, this radiopaque marker overlays 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 lists the expected overall stent length change (from its compressed condition within the catheter) when deployed at the recommended oversizing.

### Table 2: Bard® LifeStar™ Vascular Stent System Length Change Information

<table>
<thead>
<tr>
<th>Unconstrained Stent Diameter (mm)</th>
<th>Reference Vessel Diameter (mm)</th>
<th>Average Length Change at Recommended Oversizing (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>7</td>
<td>0.5</td>
</tr>
<tr>
<td>7</td>
<td>8</td>
<td>0.5</td>
</tr>
<tr>
<td>8</td>
<td>9</td>
<td>2.5</td>
</tr>
<tr>
<td>9</td>
<td>10</td>
<td>0.5</td>
</tr>
<tr>
<td>10</td>
<td>11</td>
<td>0.5</td>
</tr>
</tbody>
</table>

### Instructions for use

#### 1.0 DEVICE NAME
- The brand name of the device is Bard® LifeStar™ Vascular Stent System.
- The Stent (implant) is supplied 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

**A**
- Coaxial Outer Catheter
- Inner Catheter
- Flexible Catheter Tip
- A single radiopaque marker on the outer catheter
- (implanted) with 4 Tantalum Markers at each end of the stent
- Distal T-Luer Adapter
- Removable Safety Clip
- Grip
- Proximal Luer Port

**B**
- 80 cm Delivery System
- Stent Length
- Diameter
- 20 mm
- 30 mm
- 40 mm
- Thickness
- 8 mm
- 9 mm
- 10 mm
- Length
- 60 mm
- 90 mm
- 120 mm
- 150 mm
- 180 mm
- 210 mm
- 240 mm
- 270 mm
- 300 mm
- 330 mm
- 360 mm
- 390 mm
- 420 mm
- 450 mm
- 480 mm
- 510 mm
- 540 mm
- 570 mm
- 600 mm
- 630 mm
- 660 mm
- 690 mm
- 720 mm
- 750 mm
- 780 mm
- 810 mm
- 840 mm
- 870 mm
- 900 mm
- 930 mm
- 960 mm
- 990 mm
- 1020 mm
- 1050 mm
- 1080 mm
- 1110 mm
- 1140 mm
- 1170 mm
- 1200 mm
- 1230 mm
- 1260 mm
- 1290 mm
- 1320 mm
- 1350 mm

**C**
- 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

### 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 its nominal inner diameter upon 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.

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

<table>
<thead>
<tr>
<th>Diameter</th>
<th>Length</th>
<th>Reference Vessel Diameter</th>
<th>Average Length Change at Recommended Oversizing</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 mm</td>
<td>60 mm</td>
<td>7</td>
<td>0.5</td>
</tr>
<tr>
<td>9 mm</td>
<td>60 mm</td>
<td>8</td>
<td>0.5</td>
</tr>
<tr>
<td>10 mm</td>
<td>60 mm</td>
<td>9</td>
<td>2.5</td>
</tr>
<tr>
<td>11 mm</td>
<td>60 mm</td>
<td>10</td>
<td>0.5</td>
</tr>
<tr>
<td>12 mm</td>
<td>60 mm</td>
<td>11</td>
<td>0.5</td>
</tr>
</tbody>
</table>

#### 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 delivery system is a dual lumen, coaxial system consisting of an Inner Catheter (B), which can slide over a metal guide to the Grip (G), and a Coaxial Outer Catheter (A), which connects to the Proximal Luer Port (F).

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 (F) and the second is found within the Distal T-Luer Adapter (F). The Removable Safety Clip (G) prevents outer sheath retraction. Press the safety clip down to remove the clip.

#### 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.

### 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 external iliac arteries up to 126 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:
- If the safety clip has been removed or becomes inadvertently detached from the Grip (G), **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 or 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 grabbed or repolished in the lumen.
- Once stent deployment has been initiated, the stent cannot be recaputured using the stent delivery system.

### 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 indicated on the label.
- **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 infection**.
- **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.**
8.1 Study Endpoints and additional data:
The rate of Major Adverse Clinical Events (MACE) was the primary combined safety and effectiveness endpoint for the study. MACE for the device was defined as periprocedural death (death during the procedure or prior to hospital discharge), target lesion revascularization (any treatment to bypass the lesion), significant lumen diameter within the stented segment or within 5 mm of its margins, or stented segment >50% stenosis as determined by duplex ultrasound at nine months post-procedure. Bayesian statistical models, using non-informative prior probabilities for the parameters of interest, were used to evaluate whether there was a 96% probability that the MACE rate would be less than a maximum threshold of 25% at nine months post-procedure.

Additionally for informational purposes, including anatomic success (i.e., achievement of ≤30% final residual diameter stenosis) and primary patency (continuous flow through the treated segment without revascularization at nine months post-procedure) were also evaluated.

Evaluations and definitions were adapted from standards established by the Society for Interventional Radiology (SIR), the Society for Vascular Surgery (SVS), the International Society of Cardiovascular (ISCVS), and described by the SIR Technology Assessment Committee.

To ensure impartiality, all adverse events were submitted for review by an independent Medical Monitor (i.e., a physician independent of the Luminexx Clinical Study and Sponsor). All available information, either from the source documents or summarized on the case report forms was used to adjudicate an event.

8.2 Patient Population:
The protocol allowed for a broad spectrum of patients with iliac artery occlusive disease to be treated with the Luminexx Stent, including patients with poor distal runoff, non-compliant or recent distal bypass surgery, and restless medical 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 angioplasty therapy, or who demonstrated the presence of soft, thrombotic, or erectile material within or adjacent to the lesion(s) being treated with the study device were excluded. Characteristics of patients enrolled in the study including age, gender, medical history, and previous vascular procedures are presented in Table 4.

8.3 Post-Implant Precautions:
Caution should be taken when crossing a deployed stent with any adjunctive device.

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

In the event of complications such as infection, pseudoaneurysm, or dislodgment, surgical removal of the stent may be required.

The safety and effectiveness of the Luminexx Vascular Stent System has not been established in patients beyond 9 months of follow-up.

8.8 SUMMARY OF CLINICAL INVESTIGATIONS
The purpose of the clinical study was to provide the human clinical experience to support the safety and effectiveness of the Luminexx Vascular Stent System. The U.S. clinical trial proved the device to be safe and effective for its intended use.

Data gathered from the clinical study were collected on both the Luminexx® Iliac Stent and the Luminexx® 3 Stent. If the Luminexx® 3 Stent and the Luminexx® Iliac Stent were included collectively as the Luminexx® Stent, the stent in each of these devices was the same, however, the delivery systems were different. The Luminexx® Iliac Stent had a 7F profile and the Luminexx® 3 Stent had a 6F profile. The commercial device, the Luminexx® Vascular Stent System, uses essentially an electropolished version of the Luminexx® Stent and includes a grip on the 6F delivery system. The clinical data collected with both the Luminexx® Iliac Stent and the Luminexx® 3 Stent were analyzed individually.

For the purpose of the clinical trial, lesions were assessed angiographically to determine whether they fit the protocol requirements. Table 5 provides pre-treatment lesion characteristics. Antiplatlet/anticoagulant therapy and antiplatelet/diabetes was left to physician discretion. Overlapping stent placement was avoided and twelve stents in six lesions were placed in an overlapping configuration.

Table 6: The Luminexx Clinical Study are presented in Table 6.

8.4 Results:
Thirty-day post-procedure compliance was 97.76% (131/134 patients). The percentage of in-office follow-up at nine months post-procedure was 82.00% (109/134 patients). Three additional patients were contacted by telephone and one patient’s medical chart was reviewed. Ninety-seven of 134 patients had evaluable ultrasonography that were included in the nine-month assessment interval.

Primary Effectiveness and Safety Endpoint: Using Bayesian statistical models, the study was considered a success if there was at least a 96% probability that the nine-month MACE rate was less than a maximum threshold of 25%. The model was developed on a time-to-event basis within various subintervals of the follow-up period. At final analysis, the prior probability was 99.24%. The nine-month MACE rate was less than 25%. Therefore, the Luminexx Clinical Study successfully achieved the primary endpoint outlined in the protocol and demonstrated that the Luminexx® Stent was 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 ± 10.35</td>
<td>65.55% to 69.07%</td>
</tr>
<tr>
<td>Percent Male</td>
<td>54.48%</td>
<td>46.04% to 62.67%</td>
</tr>
<tr>
<td>History of Myocardial Infarction (MI)</td>
<td>23.13% (131/564)</td>
<td>16.80% to 30.96%</td>
</tr>
<tr>
<td>History of Perforant Trans-luminal Coronary Angioplasty (PTCA)</td>
<td>40.30% (564/131)</td>
<td>32.38% to 48.76%</td>
</tr>
<tr>
<td>History of Coronary Artery Bypass Graft (CABG)</td>
<td>25.37% (564/221)</td>
<td>18.76% to 33.36%</td>
</tr>
<tr>
<td>History of Carotid-vascular Accident (CVA) or Trans-cranial Ischemic Attack (TIA)</td>
<td>14.18% (131/929)</td>
<td>9.27% to 21.09%</td>
</tr>
<tr>
<td>History of Diabetes Mellitus</td>
<td>26.87% (131/500)</td>
<td>20.08% to 34.54%</td>
</tr>
<tr>
<td>History of Hypertension</td>
<td>73.66% (80/331)</td>
<td>65.61% to 80.43%</td>
</tr>
<tr>
<td>History of Hyperlipidemia</td>
<td>89.50% (131/145)</td>
<td>83.23% to 95.77%</td>
</tr>
<tr>
<td>History of Peripheral Vascular Disease (PVD)/Clutching (Clutching)</td>
<td>10.76% (131/145)</td>
<td>9.42% to 12.10%</td>
</tr>
</tbody>
</table>

All tables: Mean ± Standard Deviation for all quantitative variables, Percent (95% confidence interval / sample size)
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 unanticipated 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 concomitant condition. Seven patients died through the nine-month follow-up interval (5.2%). None of the deaths occurred within the peri-procedural period (≤ 30 days post procedure) timeframe. One patient death (0.75%) was related to complications of thromboembolism 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 concomitant 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 follow-up (< 365 days) 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 concomitant condition. Seven patients died through the nine-month follow-up interval (5.2%). None of the deaths occurred within the peri-procedural period (≤ 30 days post procedure) timeframe. One patient death (0.75%) was related to complications of thromboembolism 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 concomitant conditions, and were not related to the study procedure or the study device.

Table 8: In-Hospital Serious Adverse Events per Total Patient Population

<table>
<thead>
<tr>
<th>Event</th>
<th>Summary Statistics</th>
<th>95% Confidence Interval (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distant Revascularization (Target Limb)</td>
<td>11.19% (10/134)</td>
<td>6.90% to 17.65%</td>
</tr>
<tr>
<td>Revascularization (Non-target Limb)</td>
<td>8.96% (12/134)</td>
<td>5.2% to 13.75%</td>
</tr>
<tr>
<td>Major Bleed</td>
<td>5.73% (8/134)</td>
<td>3.05% to 11.34%</td>
</tr>
<tr>
<td>Death</td>
<td>5.22% (7/134)</td>
<td>2.55% to 10.39%</td>
</tr>
<tr>
<td>Sepsis/Infection</td>
<td>4.11% (6/134)</td>
<td>2.79%</td>
</tr>
<tr>
<td>Arterial Thrombosis</td>
<td>3.73% (5/134)</td>
<td>1.65% to 7.44%</td>
</tr>
<tr>
<td>False Anemia</td>
<td>2.99% (4/134)</td>
<td>1.17% to 7.42%</td>
</tr>
<tr>
<td>Arterial Hypertrophy</td>
<td>2.24% (5/134)</td>
<td>0.76% to 6.38%</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>2.24% (5/134)</td>
<td>0.76% to 6.38%</td>
</tr>
<tr>
<td>Carotid Artery Disease</td>
<td>2.24% (5/134)</td>
<td>0.76% to 6.38%</td>
</tr>
<tr>
<td>Congestive Heart Failure</td>
<td>1.49% (2/134)</td>
<td>0.41% to 5.28%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1.49% (2/134)</td>
<td>0.41% to 5.28%</td>
</tr>
<tr>
<td>Respiratory Failure</td>
<td>1.49% (2/134)</td>
<td>0.41% to 5.28%</td>
</tr>
<tr>
<td>All Fistula Stereol</td>
<td>1.49% (2/134)</td>
<td>0.41% to 5.28%</td>
</tr>
<tr>
<td>Wound Infection</td>
<td>1.49% (2/134)</td>
<td>0.41% to 5.28%</td>
</tr>
<tr>
<td>Claudication/Rest Pain (Non-target Limb)</td>
<td>0.75% (1/134)</td>
<td>0.13% to 4.11%</td>
</tr>
<tr>
<td>Claudication/Rest Pain (Target Limb)</td>
<td>0.75% (1/134)</td>
<td>0.13% to 4.11%</td>
</tr>
<tr>
<td>Dissection</td>
<td>0.75% (1/134)</td>
<td>0.13% to 4.11%</td>
</tr>
<tr>
<td>Critical Limb ischemia</td>
<td>0.75% (1/134)</td>
<td>0.13% to 4.11%</td>
</tr>
<tr>
<td>Lumbar Spinal Stenosis</td>
<td>0.75% (1/134)</td>
<td>0.13% to 4.11%</td>
</tr>
<tr>
<td>Colon Cancer</td>
<td>0.75% (1/134)</td>
<td>0.13% to 4.11%</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>0.75% (1/134)</td>
<td>0.13% to 4.11%</td>
</tr>
<tr>
<td>Fever</td>
<td>0.75% (1/134)</td>
<td>0.13% to 4.11%</td>
</tr>
<tr>
<td>Hematuria</td>
<td>0.75% (1/134)</td>
<td>0.13% to 4.11%</td>
</tr>
<tr>
<td>Ischemic Collits</td>
<td>0.75% (1/134)</td>
<td>0.13% to 4.11%</td>
</tr>
<tr>
<td>Lumbar Spinal Stenosis</td>
<td>0.75% (1/134)</td>
<td>0.13% to 4.11%</td>
</tr>
<tr>
<td>Prostatic Hypertrophy</td>
<td>0.75% (1/134)</td>
<td>0.13% to 4.11%</td>
</tr>
<tr>
<td>Shortness of Breath</td>
<td>0.75% (1/134)</td>
<td>0.13% to 4.11%</td>
</tr>
<tr>
<td>Small Bowel Obstruction</td>
<td>0.75% (1/134)</td>
<td>0.13% to 4.11%</td>
</tr>
<tr>
<td>Gudrun Cancer</td>
<td>0.75% (1/134)</td>
<td>0.13% to 4.11%</td>
</tr>
<tr>
<td>Urinary Retention</td>
<td>0.75% (1/134)</td>
<td>0.13% to 4.11%</td>
</tr>
<tr>
<td>Carotid Artery Disease</td>
<td>0.75% (1/134)</td>
<td>0.13% to 4.11%</td>
</tr>
</tbody>
</table>

10.0 POTENTIAL COMPLICATIONS

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

- Abrupt stent closure
- Acute thrombosis
- Thrombus formation in native vessel
- Embolization
- Ischemic injury/infarction
- Thrombosis
- Arterial occlusion/thrombus
- Arterial occlusion/thrombus, remote from puncture site
- Arterial occlusion/restenosis of the treated vessel
- Arterial rupture
- Arteriovenous fistula
- Arterial hypotrophy
- Atheroembolization
- Death related to procedure
- Death unrelated to procedure
- Embolization, arterial
- Renal embolization, stent
- Fever
- Hematoma bled, remote site
- Hematoma bled at needle, device path: nonvascular procedure
- Hematoma bled, puncture site: vascular procedure
- Hypersensitivity reactions
- Hypertension/hypotension
- Internal injury/dissection
- Ischemia/infarction of tissue/organ
- Ischemia requiring intervention (by-pass or amputation or the heart or legs)
- 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.

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

### MR Conditional

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 mins. of scanning for patient landmarks above the umbilicus.
- Maximum WB-SAR of 1 W/kg for 15 mins. of scanning for patient landmarks below the umbilicus.

Bard and LifeStar are trademarks and/or registered trademarks of C.R. Bard, Inc.
11.1 DIRECTIONS FOR USE

11.0 DIRECTIONS FOR USE

• It is recommended to advance the delivery system to avoid stent misplacement.

PRECAUTION: DO NOT hold the delivery system catheter during stent deployment.

11.6 Stent Placement:

• During stent deployment, the entire length of the stent delivery system may be placed 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 markers band on the outer catheter across the structure. The radioopaque 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, minor 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 retracted or repopulated in the lumen.

• WARNING: Once stent deployment has been initiated, the stent CANNOT be recapacitated 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 radioopaque 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 planted in place. Pulling back on the Distal T-Luer Adapter (F) directs retract the outer catheter and deploy 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 radio- opaque marker on the outer catheter (D) on the outer catheter moves backwards toward the proximal markers on the stent. The radioopaque markers on the stent MUST NOT move during stent deployment.

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

(a) Inner Catheter
(b) Coaxial Outer Catheter

Final radiological 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 Bard LifeStar™ Vascular Stent System is a self-expanding, nitinol stent that MUST NOT be expanded beyond its labeled diameter by dilation with a PI-T balloon.

• PRECAUTION: This product has been designed for single patient use only. 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.

12.0 PATIENT IMPLANT INFORMATION CARDS:

• A Patient Implant Information Card is provided in the IU for your convenience.

• The Patient Implant Information Card should be carefully folded along the perforations and removed from the IU 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.

13.0 MAGNETIC RESONANCE IMAGING (MRI) INFORMATION

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

• Static magnetic field of 3.0 Tesla or less

Non-contrasted mode of the MR system and use of whole body transmit coil.

• Spatial gradient field of 720 Gauss/cm or less

Maximum whole-body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes 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.

3.0 Tesla Temperature Rise

Non-clinical testing of RF-induced heating was performed at 128 MHz in a GE Signa HDx 3.0 T MR system software version 4.5.1 13B. The testing was according to ASTM F2182 and the stents were in a location and orientation in the phantom that produced the worst case heating. RF power was applied for 15 minutes and the conductivity of the phantom material was about 0.5 S/m. The phantom average SAR calculated using calorimetry was 2.6 W/kg. For scans performed on landmarks above the umbilicus, the maximal temperature rise was 2.3°C when the local SAR was scaled to 2 W/kg for a stent length of 80 mm. The maximal temperature rise was 1.15°C when the local SAR was scaled to 1 W/kg for a stent length of 80 mm. Other stent lengths exhibited a lower rise.

Predicted in-vivo based on these non-clinical tests and computer simulation of the patient exposure to the electromagnetic fields in MRI yielded a maximal in-vivo rise of 5°C for the maximal SAR values specified above and a scan time of 15 minutes. The actual in-vivo rise is expected to be less than 1°C. This calculation did not include the cooling due to blood flow in the lumen of the stent and blood perfusion in the tissue outside the stent.

1.5 Tesla Temperature Rise

Non-clinical testing of RF-induced heating was performed at 64 MHz in a GE Signa 1.5 Tesla coil. The testing was according to ASTM F2182 and the stents were in a location and orientation in the phantom that produced the worst case heating. RF power was applied for 15 minutes and the conductivity of the phantom materials was about 0.5 S/m. The phantom average SAR calculated using calorimetry was 1.8 W/kg. For scans performed on landmarks above the umbilicus, the maximal temperature rise was 3.4°C when the local SAR was scaled to 2 W/kg for a stent length of 150 mm. The maximal temperature rise was 1.7°C when the local SAR was scaled to 1 W/kg for a stent length of 150 mm. Other stent lengths exhibited a lower rise.

Predicted in-vivo based on these non-clinical tests and computer simulation of the patient exposure to the electromagnetic fields in MRI yielded a maximal in-vivo rise of 6.1°C for the maximal SAR values specified above and a scan time of 15 minutes. The actual in-vivo rise is expected to be less than 1°C. This calculation did not include the cooling due to blood flow in the lumen of the stent and blood perfusion in the tissue outside the stent.

Image Artifact

The image artifacts appear as localized signal loss and extend approximately 1.7 mm from the device in the parallel direction and 1.2 mm perpendicular to the stent's longitudinal axis, both inside and outside the stent lumen when scanned in non-clinical testing using a Gradient echo (GRE) pulse sequence with 100 msec repetition time, 15 msec echo time, 30 degrees flip angle, 256 x 256 matrix size, 10 mm section thickness, 22 cm field of view, number of excitations of 2 and 16 kix bandwidth, in a 3 T Excite General Electric Healthcare (Milwaukee, WI). Software GE 6.0- 0528, with whole body send/receive RF coil.

14.0 HOW SUPPLIED

The Bard LifeStar™ Vascular 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 re-use. 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
- Non Pyrogenic
- Guidewire Compatibility
- Stent Length
- Stent Diameter
- Working 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.