BARD® LIFESTAR™
Vascular Stent System

Instructions For Use (IFU)

BARD® LIFESTAR™ Vascular Stent System
Delivery System Diagram

BARD® LIFESTAR™ Vascular Stent System

BARD | PERIPHERAL VASCULAR
Instructions for use
Read the Baus® 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 sterile condition. All materials inside the sterile barrier pouch (the delivery system and stent as well as the carrier tubes) are sterile. The external surface of the sterile pouch and the product carton should not be considered sterile. 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 Baus® LifeStar™ Vascular Stent System.
• The Stent (implant) is equipped with four highly visible radiopaque tantalum markers on both the proximal and distal end.
• The Baus® LifeStar™ Vascular Stent is loaded on the Baus® LifeStar™ Delivery System.

2.0 PRODUCT DIAGRAM

(please refer to page 1)

2.0 DEVICE DESCRIPTION

3.1 Stent (implant):
The Baus® LifeStar™ Vascular Stent is a self-expanding, flexible, nitinol (nickel-titanium alloy) stent that is supplied in a compressed condition 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.
The Baus® LifeStar™ Vascular Stent System is available in the sizes indicated as follows, listing all item codes for 60 mm and 135 mm long stent delivery system:

3.2 Diameter: The Baus® LifeStar™ Delivery System has catheter working lengths of 80 cm and 135 cm and requires a minimum 8 F introducer sheath or a minimum 6 F delivery sheath. The 6 F delivery system is a dual lumen, coaxial system consisting of an inner Catheter (B), which connects via a metal tube to the Grasp (G), and a coaxial Outer Catheter (A), which connects to the Proximal Luer Port (L).
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. The flushing eliminates air bubbles from the inner lumen and lubricates the surface between the inner and outer catheters. The first Luer port is located at the proximal end of the device (I) and the second is found within the Distal Luer Adapter (F). The Removable Safety Clip (G) prevents outer sheath retraction. Press until safety clip is removed to open the clip.

3.3 Deployment Method:
The stent can be deployed by using the conventional “pin and pull-back” technique by pulling back the Distal Luer Adapter (F). (See Figure 1)

“pin and pull-back” Technique

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

3.4 Radiopaque Markers and Verification of Positioning:
There are four radiopaque tantalum markers on each end of the stent and an additional radiopaque marker band on the outer catheter of the deployment system. In its compressed stage, the tantalum markers appear like a contiguous band at each end of the stent. The stent MUST NOT be balloon expanded beyond its labeled diameter.

A single radiopaque marker on the outer catheter (B) 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 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 target location.
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: Baus® LifeStar™ Vascular Stent System Length Change Information

<table>
<thead>
<tr>
<th>Uncompressed Diameter (mm)</th>
<th>Reference Vessel Diameter (mm)</th>
<th>Average Length Change at 1.1mm Oversizing (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>8</td>
<td>0.5</td>
</tr>
<tr>
<td>7</td>
<td>9</td>
<td>0.5</td>
</tr>
<tr>
<td>10</td>
<td>12</td>
<td>0.5</td>
</tr>
</tbody>
</table>

One radiopaque marker band is attached to the outer catheter and overlaps the four distal markers on the stent prior to deployment. This moving marker indicates the amount of stent deployment during the procedure.

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

4.0 INDICATIONS FOR USE
The Baus® LifeStar™ Vascular Stent System is indicated for the treatment of iliac occlusive disease in patients with symptomatic iliac disease or stenosis 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:
• Should no 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.
• In patients requiring the use of antacids and/or H2-antagonists before or immediately after stent placement, oral absorption of antipasitive agents (e.g., aspirin) may be adversely affected.
• Oversizing the artery may result in spasm, dissection, and/or perforation which may result in serious complications.
• Long-term outcomes following repeated dilatation of endohelalized stents are unknown.
• A limited subset of patients received overlapped stents in the clinical study; therefore, data regarding overlapped stents is limited.
• Appropriate diameter sizing of the stent to the target lesion is required to reduce the possibility of stent migration.
• The Baus® LifeStar™ Vascular Stent is a self-expanding stent and MUST NOT be expanded beyond its labeled diameter by dilatation with a 0.035” balloon.

6.2 Device Warnings:
• If the safety clip has been removed or becomes inadvertently detached from the Grasp, 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 pressure is observed exiting either catheter at the distal end.
• 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.

7.0 PRECAUTIONS
This device is intended for use only by physicians who are familiar with the clinical, pathological, 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 Baus® 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 dinked.
• 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 safety and effectiveness endpoint for the study. MACE was defined as periprocedural death during the procedure or prior to hospital discharge, target lesion revascularization (any treatment to bypass or increase lumen diameter within the stented segment or within 5 mm of its margins), or stented segment occlusion (>50% stenosis as determined by duplex ultrasound) at nine months post-procedure. Bayesian statistical models, using non-informative prior probability distributions for the parameters of interest, were used to evaluate whether the target rate of MACE 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 Cardiovascular Angiography and Interventions (SCAI), the Society for Vascular Surgery (SVS), the International Society of Cardiovascular Surgery (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 Lumix® 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 Lumix® Stent, including patients with poor distal runoff, commotant or recent distal bypass surgery, and/or restenotic lesions. The intent was to test the device in a non-select patient-set that would more closely represent the clinical patient 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 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 used 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 formation, or dissection, surgical removal of the stent may be required.
• The safety and effectiveness of the Lumix® Vascular Stent System has not been established in patients beyond nine months of follow-up.

8.4 Results:

Thirty-day follow-up compliance was 97.76% (93/134 patients). The percentage of in-office follow-up at nine months post-procedure was 82.08% (110/134 patients); three additional patients were contacted by telephone and one patient’s medical chart was reviewed. Ninety-seven of 134 patients had evaluable ultrasounds 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 the 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 95% posterior probability was 99.24%. The nine-month MACE rate was less than 25%. Therefore, the Lumix® Clinical Study successfully met its primary endpoint outlined in the protocol and demonstrated that the Lumix® Stent was safe and effective for its intended use.

Table 4: Baseline Medical History / Demographics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Summary Statistics 1</th>
<th>95% Confidence Interval (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Years) 2</td>
<td>67.31 ± 10.3t</td>
<td>65.55% to 69.07%</td>
</tr>
<tr>
<td>Percent Male</td>
<td>54.48%</td>
<td>46.04% to 62.90%</td>
</tr>
<tr>
<td>History of Myocardial Infarction (MI)</td>
<td>23.13%</td>
<td>16.80% to 30.96%</td>
</tr>
<tr>
<td>History of Periarterial Transmural Coronary Angioplasty (PTCA)</td>
<td>40.30%</td>
<td>32.38% to 48.76%</td>
</tr>
<tr>
<td>History of Coronary Artery Bypass Graft (CABG)</td>
<td>25.37%</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%</td>
<td>9.93% to 21.09%</td>
</tr>
<tr>
<td>History of Diabetes Mellitus</td>
<td>26.87%</td>
<td>20.08% to 34.54%</td>
</tr>
<tr>
<td>History of Hypertension</td>
<td>73.66%</td>
<td>65.61% to 80.43%</td>
</tr>
<tr>
<td>History of Hyperlipidemia</td>
<td>89.55%</td>
<td>83.23% to 92.86%</td>
</tr>
<tr>
<td>History of Peripheral Vascular Disease (PVD)/Calcification</td>
<td>97.76%</td>
<td>93.62% to 99.24%</td>
</tr>
<tr>
<td>All tables: Mean ± Standard Deviation for all quantitave variables, Percent (95% confidence interval / sample size)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

All tables: The Score Interval Method was used for confidence interval percentages

Number of patients reporting < 134

One patient did not have a value recorded for History of Hyperlipidemia.

8.5 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. Antithrombotic/anticoagulant therapy and monitoring were left to the discretion of the physician discretion. Overlapping stent placement was allowed, and twelve stents in six lesions were placed in an overlapping configuration.

Table 5: Baseline Lesion Characteristics

<table>
<thead>
<tr>
<th>Minimum Lumen Diameter (mm)</th>
<th>Maximum Lumen Diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.16 ± 1.0 (n=156)</td>
<td>3.95 ± 1.15 (n=156)</td>
</tr>
<tr>
<td>2.57 ± 1.18 (n=156)</td>
<td>52.80</td>
</tr>
</tbody>
</table>

* Lesion length was not reported by the core lab or the site for one patient.

At 30 days post-procedure, a telephone call was made to assess patient status and complications since the time of the procedure. At nine months post-procedure, a clinic visit was required and the primary and secondary endpoints were assessed. The nine-month follow-up evaluation included clinical examination, an assessment of adverse events, and a duplex ultrasound evaluation.
8.5 Gender Bias:
Males accounted for 54.48% of patients in the study. A comparison between gender and MACE demonstrated a slightly higher incidence of MACE in males than females, but the difference was not significant (Fisher’s Exact Test, P = 0.184).

8.6 Clinical Study Conclusions:
The U.S. multi-center study of the Luminexx® Stent achieved its primary safety and effectiveness endpoint. The posterior probability was 99.24% that the MACS rate was less than 25% at nine months post-procedure. This probability along with observed rates for other clinical outcomes demonstrated that the Luminexx® Stent is safe and effective for use in the treatment of iliac artery occlusive disease.

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 concurrent condition. Seven patients died through the nine-month follow-up interval (5.2%). No deaths occurred within the peri-procedure interval (< 30 days post-invasive 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 condition, and were not related to the study procedure or the study device.

Table 7 provides a summary of in-hospital serious adverse events (SAEs) and Table 8 provides a cumulative summary of all reported SAEs < nine months follow-up (≤< 365 days). The more prevalent SAEs observed through the nine-month follow-up interval are summarized below:

- **Target Limb Revascularization:** Target limb revascularization was 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 timeframe. The revascularization procedures were performed to treat progression of disease or conditions that were not present or did not need treatment at baseline. None of the revascularization events were attributed to either the Luminexx® Stent or the study procedure.

- **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.

- **Amputation:** Four amputations were reported (2.24%) through the nine-month interval. All four amputations were performed on the study-limb and were associated with distal-disease progression. Two amputations were performed below-the-knee, one above-the-knee, and one amputation involved a toe.

- **Major Blending Event:** Eight patients (5.97%) experienced major bleeding events throughout the course of the study. Six of these events were unrelated to the study device or procedure. Two patients experienced major bleeding events attributed to the index procedure (1.49%).

- **Sepsis:** Six patients (night incideneces) experienced sepsis during the course of the study; five patients (3.73%) experienced sepsis that peaked in number during the nine-month follow-up interval (<365 days). No incidents of sepsis were attributable to either the device or the ilac stenting procedure.

### Table 7: In-Hospital Serious Adverse Events through ‘9 Months’ (<365 days) 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>Distent Revascularization (Target Limb)</td>
<td>11.19%</td>
<td>9.00% to 13.65%</td>
</tr>
<tr>
<td>Revascularization (Non-target Limb)</td>
<td>8.96%</td>
<td>7.21% to 10.71%</td>
</tr>
<tr>
<td>Major bleed</td>
<td>5.07%</td>
<td>3.65% to 6.49%</td>
</tr>
<tr>
<td>Sepsis (Target Vessel)</td>
<td>0%</td>
<td>(&lt; 0.13%)</td>
</tr>
<tr>
<td>Sepsis (Non-target Limb)</td>
<td>0%</td>
<td>(&lt; 0.13%)</td>
</tr>
<tr>
<td>Death</td>
<td>1.17%</td>
<td>0.41% to 2.94%</td>
</tr>
<tr>
<td>Stroke</td>
<td>2.24%</td>
<td>1.07% to 3.28%</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>2.24%</td>
<td>1.07% to 3.28%</td>
</tr>
<tr>
<td>Target Lesion Revascularization</td>
<td>1.73%</td>
<td>0.65% to 2.81%</td>
</tr>
<tr>
<td>False Anxeny</td>
<td>1.49%</td>
<td>0.41% to 2.58%</td>
</tr>
<tr>
<td>Amputation on Study Site Delay</td>
<td>1.49%</td>
<td>0.41% to 2.58%</td>
</tr>
<tr>
<td>Arthymia</td>
<td>1.49%</td>
<td>0.41% to 2.58%</td>
</tr>
<tr>
<td>All Fistulas Stereos</td>
<td>1.49%</td>
<td>0.41% to 2.58%</td>
</tr>
</tbody>
</table>

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

- **Abruption stent closure**
- **Dissection**
- **Amputation**
- **Anxemy**
- **Angina/coronary ischemia**
- **Arterial aneurysm**
- **Arterial occlusion/thrombus, near the puncture site**
- **Arterial occlusion/thrombus, remote from puncture site**
- **Arterial occlusion/restenosis of the treated vessel**
- **Arterial rupture**
- **Arteriovenous fistula**
- **Arthymia**
- **Atheroembolization**
- **Death related to procedure**
- **Death unrelated to procedure**
- **Embolization, arterial**
- **Embolization, venous**
- **Hypertension/hypertension**
- **Hypersensitivity reactions**
- **Hypertrophy**
- **Ischemia**
- **Ischemia/reperfusion injury**
- **Renal failure**
- **Restenosis of the stented artery**
- **Septicaemia/bacteraemia**
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 T 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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<table>
<thead>
<tr>
<th><strong>Patient Data:</strong></th>
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<td><strong>Address:</strong></td>
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<table>
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<tr>
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<td><strong>Implantation site:</strong></td>
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<td><strong>Follow up:</strong></td>
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<table>
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<td><strong>Phone:</strong></td>
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</table>

Apply "Patient/Inv. chart" sticker here
11.1 Introduction of the Stent Delivery System:

11.2 Stent Selection:

• via the femoral route, insert a 0.035” (0.89 mm) guidewire.

• Insert the guidewire into the distal tip of the catheter.

• The 6F Delivery System requires a minimum 8F guidewire or 6F catheter catheter.

• Via the femoral route, insert a 0.035” (0.89 mm) guidewire under fluoroscopic guidance through the appropriate introducer sheath or guiding catheter and pass the lesion.

11.3 Direct General Directions:

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

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

11.4 Preparation of the Stent Delivery System:

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

• PRECAUTION: DO NOT use the device after the "Use By" date specified on the label.

• PRECAUTION: Visually inspect the LifeStar™ Vascular Stent System to verify that the device has not been damaged due to shipping or improper storage. DO NOT use damaged equipment.

• WARNING: 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 (B) and the second of which is found within the Distal T-Luer Adapter (F). Continue flushing until saline drops from the distal tip of the Flexifit catheter Tip 1 (C) after flushing each Luer port.

• PRECAUTION: During system flushing, DO NOT use the system if fluid is not observed exiting the catheter at the visible Luer Adapter Tip (G) after each Luer port is flushed.

• During delivery system preparation, ensure that the safety clip remains in place until the stent is ready to be deployed.

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

11.5 Introduction of the Stent Delivery System:

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

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

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

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

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

11.6 Stent Placement:

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

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

• By initially advancing the catheter beyond the 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 proximal end has passed the stent end 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: PRECAUTION: DO NOT remove the Removable Safety Clip (G) until you are ready to deploy the stent.

• APTO: 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 deploys a corresponding portion of the stent.

• Full stent deployment is ensured when the Distal T-Luer Adapter (F) reaches the Grips.

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

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

11.8 Stent Post-Placement:

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

12.0 PATIENT IMPLANT INFORMATION CARDS:

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

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

13.0 MAGNETIC RESONANCE IMAGING (MRI) INFORMATION

13.1 Non-clinical testing demonstrated that the LifeStar™ Vascular Stent System is MR Conditional. A patient with the 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-operating 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.

13.2 Tesla Temperature Rise

Non-clinical testing of RF-induced heating was performed at 128 MHz in a GE Sigma HDx 3.0T MR system software version 46.0.1. 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 temperature rise was 2.3°C when the local SAR was scaled to 2 W/kg for a stent length of 80 mm. The maximum temperature rise was 1.15°C when the local SAR was scaled to 1 W/kg for a stent length of 80 mm. If the stent length exhibited a lower rise.

Predicted in-vivo heating 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 in temperature was expected to be less than expected as 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 Sigma white body 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 temperature rise was 3.4°C when the local SAR was scaled to 2 W/kg for a stent length of 150 mm. The maximum 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 heating 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 in temperature was expected to be less than expected as 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.

14.0 HOW SUPPLIED

The LifeStar™ Vascular Stent System is supplied sterile by ethylene oxide gas unless the package has been opened or damaged. This product has been designed to open and remove only one time use. DO NOT reuse. DO NOT resterilize. Store in a cool, dry, dark place.
Symbols used on labelling

- Consult Instructions For Use
- Keep Away From Sunlight
- Keep Dry
- Do Not Use If Package Is Damaged
- Single Use
- Do Not Resterilize
- Contents: (1)
- MR Conditional
- Does Not Contain Natural Rubber Latex

- Catalogue Number
- Lot Number
- Sterilized Using Ethylene Oxide
- Use By
- Manufacturer
- Minimum Introducer Size
- Non Pyrogenic
- Guidewire Compatibility
- Stent Length
- Stent Diameter
- Working Length
- System Length
BARD® LIFESTAR™ Vascular Stent System

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

Caution:
Federal (U.S.A) law restricts this device to sale by or on the order of a physician.