VeriFLEX™ (Liberté)®

O VER - T H E - W I R E

Bare-Metal Coronary Stent System

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

1 DEVICE DESCRIPTION

The VeriFLEX (Liberté) Coronary Stent Systems include:

- A 316L surgical grade stainless steel Liberté Stent pre-mounted on an Over-The-Wire or Monorail Balloon Catheter;
- Two radiopaque markers which aid in the accurate placement of the stent;
- A balloon enabling high pressure inflations that can be used for post-stent dilation.

Table 1. Balloon and Stent Specifications

<table>
<thead>
<tr>
<th>System Balloon Diameter (mm)</th>
<th>Stent Length (mm)</th>
<th>Nominal Pressure During Stent Deployment (atm/kPa)</th>
<th>Rated Burst Pressure (atm/kPa)</th>
<th>Minimum I.D. of Guide Catheter For Monorail Catheter (in/mm)</th>
<th>Minimum I.D. Guide Catheter For Over-The-Wire Catheter (in/mm)</th>
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<tr>
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2 INTENDED USE/INDICATIONS FOR USE

The VeriFLEX (Liberté) Over-The-Wire and Monorail Coronary Stent Systems are indicated for improving coronary luminal diameter in the following (see 8.1 Individualization of Treatment):

- Patients with symptomatic ischemic disease associated with stenotic lesions in native coronary arteries (length ≤ 28 mm) with a reference vessel diameter of 2.75 to 5.0 mm.

3 CONTRAINDICATIONS

The VeriFLEX (Liberté) Stent is contraindicated for use in:

- Patients in whom antiplatelet and/or anticoagulant therapy is contraindicated.

For further information please refer to the VeriFLEX (Liberté) Coronary Stent System Patient Information Guide.
5 PRECAUTIONS

5.1 General Precautions

• Implantation of the stent should be performed only by physicians who have received appropriate training.
• Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
• Subsequent restenosis may require repeat dilation of the atheromatous segment extending beyond the stent. The long-term outcome following repeat dilation of coronary stents is unknown at present.
• When multiple stents are required, if placement results in metal to metal contact, stent materials should be of similar composition.
• Care should be taken to control the position of the guide catheter tip during stent deployment, deployment and balloon withdrawal. Before withdrawing the stent Delivery System (SDS), visually confirm complete balloon deflation by fluoroscopy (see Table 2 for Deflation Time Specifications). Failure to do so may cause increased SDS withdrawal forces, and result in guide catheter advancement into the vessel and subsequent arterial damage.
• The safety and effectiveness of the VeriFLEX™ (Liberté) Coronary Stent System has not been established in patients beyond 365 days of follow-up.

5.2 Stent Handling

(See also 10 OPERATIONAL INSTRUCTIONS)

• Contents supplied STERILE using an ethylene oxide (EO) process. Do not reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infection of donor origin from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
• Use prior to the “Use By” date. Store in a cool, dry, dark place.
• The VeriFLEX (Liberté) Coronary Stent System is designed for use as a unit. The stent is not to be removed from its delivery balloon. The stent is not designed to be clamped onto another balloon. Removing the stent from its delivery balloon may damage the stent and/or lead to stent embolization.
• Special care must be taken not to handle or in any way disrupt the stent position on the delivery device. This is most important during catheter removal from packaging, placement over guidewire, and advancement through hemostasis valve adapter and guiding catheter hub.
• Excessive manipulation, e.g., rolling the mounted stent, may cause distortion of the stent from the delivery balloon.
• Use only the appropriate balloon inflation media (see Section 10, Operational Instructions). Do not use air or any gas medium to inflate the balloon.

5.3 Stent Placement

• Do not prepare or pre-inflate balloon prior to stent deployment other than as directed. Use balloon purging technique described in the Operational Instructions.
• Implating a stent may lead to dissection of the vessel distal and/or proximal to the stented portion, and may cause acute closure of the vessel requiring additional intervention (e.g., CABG, further dilation, placement of additional stents, or other).
• When treating multiple lesions, the distal lesion should be initially stented, followed by stenting of the more proximal lesions). Stenting in this order alleviates the need to cross the proximal lesion before deployment of the distal stent and reduces the chances for dislodging the proximal stent.
• Do not expand the stent if it is not properly positioned in the vessel. (See 5.4 Stent System Removal).
• Placement of the stent has the potential to compromise the arterial intima.
• The vessel should be pre-dilated with an appropriate sized balloon. Failure to do so may increase the risk of placement difficulty and procedural complications.

5.5 Post Implant

• Care must be exercised when crossing a newly deployed stent with an intravascular ultrasound (IVUS), a coronary guidewire, or a balloon catheter to avoid disrupting the stent placement, apposition and/or geometry.

5.6 MRI Information

Non-clinical testing has demonstrated the VeriFLEX (Liberté) Stent, in single and in overlapped configurations up to 90 mm in length, is MR Conditional. It can be scanned safely under the following conditions:

• static magnetic field of 3.0 and 1.5 Tesla
• spatial gradient field of 700 Gauss/mm or less
• normal operating mode (maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg) for 15 minutes or less of scanning.

Patients with single VeriFLEX (Liberté) Stents or VeriFLEX (Liberté) Stents at overlapped lengths up to 80 mm may safely undergo MRI in normal operating mode of 1.5T and 3T MR systems for 15 minutes or less. Non-clinical testing at other field strengths has not been performed to evaluate stent migration or heating. MRI at 1.5 or 3 Tesla may be performed immediately following the implantation of the VeriFLEX (Liberté) Stent.

In non-clinical testing, the VeriFLEX (Liberté) Stent at overlapped lengths up to 80 mm produced a maximum temperature rise of 1.4°C at a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg, as assessed by a validated calculation for 15 min of scanning in a 3.0 Tesla Magnetom Trio, Siemens Medical Solutions, software version Numaris 4, Syngo® MR A20 MR scanner and in a 1.5 Tesla Intera® Philips Medical Systems, software version Release 10.6.2, 2006-03-10, MR scanner. Stent heating was derived in computer simulations using anatomically correct human models. These calculations do not take into consideration the cooling effects of blood flow. The response of overlapped stents greater than 60 mm in length is unknown. In vivo, local SAR depends on MR field strength and may be different than the estimated whole body averaged SAR, due to body composition, stent position. The image artifact extends approximately 8 mm from the device, both inside and outside the vessel. When scanned in nonclinical testing using the sequence: Spin Echo and Gradient Echo in a 3.0 Tesla Magnetom Trio, Siemens Medical Solutions, software version Numaris 4, Syngo™ MR A40 MR system with CP head coil.

6 ADVERSE EVENTS

6.1 Observed Adverse Events

A total of 200 patients were enrolled in the BSC ELECT Clinical Study, a prospective, multi-center, single-arm registry conducted to assess the safety and effectiveness of the VeriFLEX (Liberté) Coronary Stent System. The observed major adverse events were compared to results from 519 patients randomized to receive a bare metal 3.0 or 3.5 mm Express® Stent in the TAXUS® IV SR clinical trial. The TAXUS IV SR historical control, utilized at 30 days and 12 months, completed clinical and angiographic follow-up 9 months post-index procedure. Since a stented segment was designed to be completely completed and angiographic follow-up at 6 months post-index procedure, elective stenting data for the Express Stent from the VICTORY single-arm registry was included as a comparator for the Liberté Stent 6-month clinical and angiographic data.

6.1.1 BSC ELECT Clinical Trial Study

Table 3. presents the major clinical events observed in patients who received the VeriFLEX (Liberté) Coronary Stent System in the BSC ELECT Clinical Study through 12 months post-stenting procedure, along with those who received the Express Coronary Stent System in the TAXUS IV SR and the VICTORY studies.

A total of 208 VeriFLEX (Liberté) Stents were implanted in 208 patients. Through 12 months of follow-up, there were no cardiac deaths (0.0%), no Q-wave MIs (0.0%), one non-Q-wave MI (0.5%), 26 (13.8%) target lesion revascularizations, and no stent thromboses (0.0%). Two patients who received a VeriFLEX (Liberté) Stent died during the clinical study. Both deaths were adjudicated as non-cardiac in nature: one due to colon cancer at 70 days post-index procedure and the other due to renal cancer at 353 days post-index procedure.
1.2% (6/511) [0.4%, 2.5%]

13.8% (26/189) [9.2%, 19.5%]

12.2% (23/189) [7.9%, 17.7%]

8.9% (24/271) [5.8%, 12.9%]

1.6% (4/511) [0.7%, 3.1%]

3.1% (16/511) [1.9%, 5.0%]

4.2% (8/189) [1.6%, 8.2%]

1.0% (2/200) [0.1%, 3.8%]

0.8% (4/511) [0.2%, 2.0%]

2.0% (6/303) [0.7%, 4.3%]

1.3% (7/519) [0.5%, 2.8%]

1.6% (8/511) [0.7%, 3.1%]

1.0% (2/200) [0.1%, 3.6%]

0.0% (0/303) [0.0%, 1.2%]

1.1% (3/271) [0.2%, 3.2%]

0.0% (0/200) [0.0%, 1.8%]

1.9% (10/519) [0.9%, 3.5%]

2.7% (14/511) [1.5%, 4.6%]

1.6% (8/511) [0.7%, 3.1%]

0.2% (1/519) [0.0%, 1.1%]

0.1% (1/511) [0.0%, 0.5%]

1.5% (4/271) [0.4%, 3.7%]

0.0% (0/200) [0.0%, 1.8%]

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1.4% (7/511) [0.6%, 2.8%]

1.6% (3/200) [0.3%, 4.6%]

0.0% (0/200) [0.0%, 1.8%]

0.0% (0/519) [0.0%, 0.7%]

2.1% (11/519) [1.1%, 3.8%]

2.2% (4/519) [0.4%, 4.9%]

1.6% (3/200) [0.3%, 4.6%]

0.0% (0/200) [0.0%, 1.8%]

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0.0% (0/200) [0.0%, 1.8%]

1.02 mm, average percent diameter stenosis (%DS) of 65% and characteristics included average reference vessel diameter ≤4.0 mm in diameter.

18 years of age or older with angina pectoris or functional ischemia undergoing elective treatment of a single de novo or restenotic lesion from a non-implantable percutaneous procedure in a native coronary artery.

The primary endpoint for the BSC ELECT registry was Major Adverse Cardiac Event rate defined as the composite of cardiac death, Q-wave and non-Q-wave myocardial infarction, and target vessel revascularization through 30 days. Follow-up includes a 30-day office visit (primary endpoint) followed by clinical assessments at 6 and 12 months. All patients were required to have angiographic follow-up at 6 months.

Endpoints: The primary endpoint for the BSC ELECT registry was Major Adverse Cardiac Event rate defined as the composite of cardiac death, Q-wave and non-Q-wave myocardial infarction, and target vessel revascularization through 30 days. The primary endpoint was analyzed on an intent-to-treat basis, defined as patients who had the study device introduced with the guide catheter.

BSC ELECT secondary endpoints including, but not limited to, angiographic binary restenosis, TVF, and MACE at 6 and 12 months, were also analyzed on an intent-to-treat basis; all patients were required to return for angiographic follow-up at 6 months.

Demographics: Baseline characteristics for the BSC ELECT registry indicated 67.5% were males with an average age of 62.0 years (range 35 to 90 years), 29.5% had diabetes requiring medication, 64.5% had known hyperlipidemia requiring medication, 21.0% were known current smokers and 73.5% had known hypertension requiring medication. Baseline lesion characteristics included average reference vessel diameter (RVD) of 2.89 mm, average minimum lumen diameter (MLD) of 1.02 mm, average percent diameter stenosis (%SDS) of 65% and average lesion length of 11.75 mm.

Clinical Study: 7.1 BSC ELECT Clinical Trial Objective: To evaluate the safety and efficacy of the VeriFLEX (Liberté) Coronary Stent System for the treatment of single de novo or restenotic (from a non-implantable percutaneous procedure) lesions in native coronary arteries.

Conclusion: The BSC ELECT registry demonstrated the 12-month safety and efficacy of the VeriFLEX (Liberté) Stent for treatment of patients with de novo or restenotic lesions in native coronary arteries.

Design: A multicenter, prospective, single arm registry was conducted at 20 U.S. sites enrolling 200 patients. Patients were 18 years of age or older with an angiographic or functional ischemia undergoing elective treatment of a single de novo or restenotic lesion (from a non-implantable percutaneous procedure) in a native coronary artery. Eligible patients had visually estimated stenosis ≥50% and ≥100% located in a lesion ≥28 mm in length with a reference vessel ≥2.75 mm and ≤4.0 mm in diameter.

All patients received the hospital's standard anti-coagulation regimen for coronary stent implantation. After the procedure, patients received aspirin indefinitely and clopidogrel or ticlopidine for 30 days. Follow-up includes a 30-day office visit (primary endpoint) followed by clinical assessments at 6 and 12 months. All patients were required to have angiographic follow-up at 6 months.

Endpoints: The primary endpoint for the BSC ELECT registry was Major Adverse Cardiac Event rate defined as the composite of cardiac death, Q-wave and non-Q-wave myocardial infarction, and target vessel revascularization through 30 days. The primary endpoint was analyzed on an intent-to-treat basis, defined as patients who had the study device introduced with the guide catheter.

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Table 4. 6-Month Angiographic and Relevant Clinical Results, VeriFLEX (Liberté) Stent vs. Express Stent (VICTORY Angiographic Subset)

<table>
<thead>
<tr>
<th>Effectiveness Measures</th>
<th>VeriFLEX (Liberté) Stent (N=200)</th>
<th>Express Stent VICTORY Control (N=519)</th>
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<tr>
<td>6-Month Results</td>
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<tr>
<td>MACE</td>
<td>15.9% (31/195) [11.1%, 21.6%]</td>
<td>15.3% (15/98) [9.8%, 24.0%]</td>
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<td>Target Vessel Revascularization</td>
<td>15.4% (30/195) [10.6%, 21.2%]</td>
<td>14.3% [14/98] [0.0%, 22.8%]</td>
</tr>
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<td>Target Lesion Revascularization</td>
<td>11.4% (23/195) [7.6%, 17.2%]</td>
<td>13.3% [13/98] [7.3%, 21.6%]</td>
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<tr>
<td>TVF to 6 Months</td>
<td>15.9% (31/195) [11.1%, 21.6%]</td>
<td>15.3% [15/98] [9.8%, 24.0%]</td>
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<td>Stent Thrombosis to 6 months</td>
<td>0.0% [0/200] [0.0%, 1.8%]</td>
<td>2.0% [2/98] [0.2%, 7.2%]</td>
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| QCA Measures |                                  |                                     |
|---------------|----------------------------------|                                     |
| MLD (mm), In-stent | 2.75±0.45 (300) [1.70, 3.99] | 2.91±0.42 [99] [2.05, 4.17]       |
| 6-Month        | 2.62±0.78 (187) [1.00, 3.80]     | 2.08±0.72 [99] [0.00, 3.49]        |
| %DS, In-stent |                                  |                                     |
| Post-procedure | 6.03±10.23 (200) [17-62, 36-16] | 4.73±7.37 [99] [22-32, 23-99]     |
| Late Loss, In-stent (mm) | 0.72±0.67 (187) [0.83, 2.57] | 0.82±0.59 [99] [0.41, 2.85]       |

Table 4 summarizes 6-month angiographic results for the VeriFLEX (Liberté) Stent and for the Express Stent based on data collected in the VICTORY registry. Relevant clinical results through 6 months (210 days) of follow-up are also provided. The VeriFLEX (Liberté) Stent post-6 month MACE rate was 15.9% (31/195) and the TLR rate was 11.8% (23/195). In the VICTORY angiographic subset (99/303).

Table 5 summarizes principal safety and effectiveness results through 12 months for the VeriFLEX (Liberté) Stent and for the Express Stent based on data collected in the TAXUS IV-SR study. The VeriFLEX (Liberté) Stent 12-month MACE rate was 18.5% (35/189) and the TLR rate was 13.8% (26/189). The TAXUS IV Express Stent 12-month MACE rate was 18.6% (95/511) and the TLR rate was 13.1% (67/511). Clinical outcomes achieved with the VeriFLEX (Liberté) Stent are similar to those observed for the Express Stent in the TAXUS IV-SR study.

Table 5. BSC ELECT Principal Safety and Effectiveness Results through 12 Months

<table>
<thead>
<tr>
<th>Effectiveness Measures</th>
<th>VeriFLEX (Liberté) Stent (N=200)</th>
<th>Express Stent Taxus IV-SR (N=519)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Procedural Success</td>
<td>99.5% [190/200] [97.2%, 100.0%]</td>
<td>97.5% [506/519] [95.8%, 98.7%]</td>
</tr>
<tr>
<td>Technical Success</td>
<td>99.5% [190/200] [97.2%, 100.0%]</td>
<td>97.5% [507/519] [96.0%, 98.8%]</td>
</tr>
<tr>
<td>Safety Measures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-Hospital MACE</td>
<td>0.5% [1/200] [0.0%, 2.8%]</td>
<td>2.1% [15/98] [1.1%, 3.8%]</td>
</tr>
<tr>
<td>MACE to 30 days (Primary Endpoint)</td>
<td>0.5% [1/200] [0.0%, 2.8%]</td>
<td>2.3% [12/91] [1.2%, 4.0%]</td>
</tr>
<tr>
<td>MACE to 6 Months</td>
<td>15.9% (31/195) [11.1%, 21.8%]</td>
<td>10.9% [96/913] [8.4%, 13.9%]</td>
</tr>
<tr>
<td>MACE to 9 Months</td>
<td>18.9% (33/185) [11.9%, 22.9%]</td>
<td>16.1% [83/511] [11.3%, 19.6%]</td>
</tr>
<tr>
<td>MACE to 12 Months</td>
<td>18.5% [35/189] [13.3%, 24.6%]</td>
<td>18.6% [95/511] [15.3%, 22.2%]</td>
</tr>
<tr>
<td>TLR to 12 Months</td>
<td>13.8% (26/189) [9.2%, 19.5%]</td>
<td>13.1% [67/511] [10.3%, 16.4%]</td>
</tr>
<tr>
<td>TVF to 12 Months</td>
<td>18.5% [35/189] [13.3%, 24.6%]</td>
<td>18.0% [90/511] [14.8%, 21.6%]</td>
</tr>
<tr>
<td>Serious Bleeding Events to 12 months</td>
<td>2.7% [5/180] [0.9%, 6.1%]</td>
<td>2.0% [10/503] [0.4%, 3.6%]</td>
</tr>
<tr>
<td>Serious Vascular Events to 12 months</td>
<td>3.2% [6/180] [1.2%, 6.8%]</td>
<td>2.0% [10/504] [0.4%, 3.6%]</td>
</tr>
<tr>
<td>CVA to 12 months</td>
<td>1.1% [2/180] [0.1%, 3.6%]</td>
<td>1.0% [15/504] [0.3%, 2.3%]</td>
</tr>
<tr>
<td>Stent Thrombosis to 12 months</td>
<td>0.0% [0/200] [0.0%, 1.8%]</td>
<td>0.6% [2/311] [0.1%, 1.7%]</td>
</tr>
</tbody>
</table>

Table 5 summarizes principal safety and effectiveness results through 12 months for the VeriFLEX (Liberté) Stent and the Express Stent based on data collected in the TAXUS IV-SR study. The VeriFLEX (Liberté) Stent 12-month MACE rate was 18.5% (35/189) and the TLR rate was 13.8% (26/189). The TAXUS IV Express Stent 12-month MACE rate was 18.6% (95/511) and the TLR rate was 13.1% (67/511). Clinical outcomes achieved with the VeriFLEX (Liberté) Stent are similar to those observed for the Express Stent in the TAXUS IV-SR study.

Table 5 summarizes principal safety and effectiveness results through 12 months for the VeriFLEX (Liberté) Stent and for the Express Stent based on data collected in the TAXUS IV-SR study. The VeriFLEX (Liberté) Stent 12-month MACE rate was 18.5% (35/189) and the TLR rate was 13.8% (26/189). The TAXUS IV Express Stent 12-month MACE rate was 18.6% (95/511) and the TLR rate was 13.1% (67/511). Clinical outcomes achieved with the VeriFLEX (Liberté) Stent are similar to those observed for the Express Stent in the TAXUS IV-SR study.
• Patients with lesions located in the unprotected left main coronary artery, ostial lesions, or lesions located at a bifurcation.
• Patients with diffuse disease or poor outflow distal to the identified lesions.
• Patients with a recent acute myocardial infarction where there is evidence of thrombus or poor flow.
• Patients with more than two overlapping stents due to risk of thrombus.
• Patients for longer than 365 days follow-up.

The safety and effectiveness of using mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters) or laser angioplasty catheters to treat in-stent stenosis has not been established.

9 HOW SUPPLIED
STERILE: This device is sterilized with ethylene oxide gas. It is intended for single use only. Non-pyrogenic. Do not use if package is opened or damaged.

CONTENTS: VeriFLEX™ (Liberté®) Over-The-Wire Stent System One (1) VeriFLEX (Liberté)® Over-The-Wire Stent System One (1) Electronic Directions for Use/Patient Guide Reference Card

CONTENTS: VeriFLEX (Liberté)® Monorail™ Stent System One (1) VeriFLEX (Liberté)® Monorail Stent System One (1) Electronic Directions for Use/Patient Guide Reference Card

Two (2) CLIPIT® Hypotube Clips One (1) Flushing needle with luer fitting

Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

Handling and Storage
Store in a cool, dry, dark place.

10 OPERATIONAL INSTRUCTIONS
10.1 Inspection Prior to Use
Carefully inspect the sterile package before opening. Do not use after the “Use By” date. If the integrity of the sterile package has been compromised prior to the product “Use By” date (e.g., damage of the package), contact your local Boston Scientific Representative for return information. Do not use if any defects are noted.

Note: At any time during use of the Premounted Stent System, if the stainless steel proximal shaft has been bent or kinked, do not continue to use the catheter.

10.2 Materials Required (not included in Stent System package)
Quantity
Material
1. Appropriate guiding catheter (see Table 1 - Balloon and Stent Specifications)
1. 20 ml (cc) syringe
Normal heparinized saline
1. ≤0.014 in (0.36 mm) guidewire
1. Rotating hemostatic valve
Diluted contrast medium 1:1 with normal heparinized saline
1. Infusion Device with pressure gauge
1. Torque Device
1. Pre-deployment dilation catheter
1. Three-way stopcock
1. Appropriate arterial sheath

10.3 Preparation
Packaging Removal
Step  Action
1. Carefully remove the delivery system from its protective tubing for preparation of the delivery system. When using a Monorail System, do not bend or kink hypotube during removal.

2. Remove the product mandrel and stent protector by grasp- ing the catheter just proximal to the stent (at the proximal balloon bond site), and with the other hand, grasp the stent protector and gently remove distally. If unusual resistance is felt during product mandrel and stent protector removal, do not use this product and replace with another. Follow product returns procedure for the unused device.
3. A Monorail Catheter may be coiled once and secured using the CLIPIT Coil Clip provided in the catheter package. Only the proximal shaft should be inserted into the CLIPIT Device; the clip is not intended for the distal end of the catheter.

Note: Care should be taken not to kink or bend the shaft upon application or removal of the coil clip.

Guidewire Lumen Flush
Step  Action
1. Flush Stent System guidewire lumen with normal heparinized saline. Use flushing needle supplied for the Monorail System.
2. Verify that the stent is positioned between the proximal and distal balloon markers. Check for bends, kinks and other damage. Do not use if any defects are noted.

Balloon Preparation
Step  Action
1. Rinse the stent in sterile saline.
2. Prepare inflation device/syringe with diluted contrast medium.
3. Attach inflation device/syringe to stopcock; attach to inflation port. With Monorail Systems, do not bend the hypotube when connecting to inflation device/syringe.
5. Open stopcock to Stent System; pull negative for 15 seconds; release to neutral for contrast fill.
6. Close stopcock to Stent System; purge inflation device/ syringe of all air.
7. Repeat steps 4 through 6 until all air is expelled. If bubbles persist, do not use device.
8. Remove the syringe or inflation device from the stopcock affixed to the delivery catheter.
9. Fill the stopcock port with a meniscus of contrast medium.
10. Prepare the inflation device to remove all entrapped air and fill the inflation device connector with a meniscus of contrast medium.
11. Securely couple the inflation device to the stopcock.
12. Open stopcock to stent system and leave on neutral.

10.4 Delivery Procedure
Step  Action
1. Prepare the vascular access site according to standard PTCA practice.
2. Predilate the lesion/vessel with appropriate diameter balloon.
3. Maintain neutral pressure on inflation device attached to stent system.
4. Backload Stent System onto proximal portion of guidewire while maintaining guidewire position across target lesion.
5. Fully open rotating hemostatic valve to allow for easy passage of the stent and prevent damage to the stent.
6. Carefully advance the Stent System into the hub of the guiding catheters. When using a Monorail System be sure to keep the hypotube straight. Ensure guiding catheter stability before advancing the Stent System into the coronary artery.

Note: If unusual resistance is felt before the stent exits the guiding catheter, do not force passage. Resistance may indicate a problem, and use of excessive force may result in stent damage or stent dislodgment from the balloon. Maintain guidewire placement across the lesion, and remove the Stent System and guiding catheter as a single unit. Advance the Stent System over the guidewire target lesion under direct fluoroscopic visualization. Utilize the proximal and distal radiopaque balloon markers as a reference point. If the position of the stent is not optimal, it should be carefully repositioned or removed (See 5.4 Stent System Removal). The inside edges of the marker bands indicate both the stent edges and balloon shoulders. Expansion of the stent should not be undertaken if the stent is not properly positioned in the target lesion segment of the vessel.

8. Sufficiently tighten the rotating hemostatic valve. Stent is now ready to be deployed.

10.5 Deployment Procedure
Step  Action
1. Inflate the delivery system expanding the stent to a minimum pressure of 9 atm (912 kPa) (nominal pressure). Higher pressure may be necessary to optimize stent apposition to the arterial wall. Accepted practice generally targets an initial deployment pressure that would achieve a stent ID of about 1.1 times the reference vessel diameter (see Table 6). Balloon pressure must not exceed rated burst pressure. (see Table 6)
2. Maintain inflation pressure for 15-30 seconds for full expansion of the stent.
3. Deflate balloon by pulling negative on inflation device until balloon is fully deflated.
4. Confirm stent position and deployment using standard angiographic techniques. For optimal results, the entire stented arterial segment should be covered by the stent. Fluoroscopic visualization during stent expansion should be used in order to properly judge the optimum expanded stent diameter as compared to the proximal and distal coronary artery diameter(s). Optimal expansion requires that the stent be in full contact with the artery wall. All efforts should be taken to assure that the stent is not underdilated.
5. If stent sizing/apposition requires optimization, rerotate the Stent System balloon, or another balloon catheter of the appropriate size, to the stented area using standard angioplasty techniques.
6. Inflate the balloon to the desired pressure while observing under fluoroscopy. Deflate the balloon. (refer to product labeling and/or Table 6 for proper stent inflation pressure.)
7. Reconfirm stent position and angiographic result. Repeat inflations until the desired result is achieved.

10.6 Removal Procedure
Step  Action
1. Ensure balloon is fully deflated.
2. Fully open rotating hemostatic valve.
3. While maintaining guidewire position and negative pressure on inflation device, withdraw Delivery System.
4. Monorail Catheters may be coiled once and secured using the CLIPIT Coll Clip (see 10.3 Preparation).

Note: If unusual resistance is felt at any time during lesion access before stent implantation, the Stent System and the guiding catheter should be removed as a single unit. (See 5.4 Stent System Removal)

Boston Scientific (Master Brand DFU Template 8.2677in x 1 1.6929in A4, 90105918AK), eDFU, MB, VeriFLEX (Liberté), EN, 90590772-01A
10.7 In Vitro Information

Table 6. Typical VeriFLEX™ (Liberte®) Stent and Balloon Compliance

<table>
<thead>
<tr>
<th>Pressure atm (kPa)</th>
<th>2.75 mm Stent I.D. (mm)</th>
<th>3.00 mm Stent I.D. (mm)</th>
<th>3.50 mm Stent I.D. (mm)</th>
<th>4.00 mm Stent I.D. (mm)</th>
<th>4.50 mm Stent I.D. (mm)</th>
<th>5.00 mm Stent I.D. (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.0 (912) Nominal</td>
<td>2.74</td>
<td>3.03</td>
<td>3.52</td>
<td>3.97</td>
<td>4.54</td>
<td>5.01</td>
</tr>
<tr>
<td>10.0 (1013)</td>
<td>2.82</td>
<td>3.11</td>
<td>3.60</td>
<td>4.07</td>
<td>4.65</td>
<td>5.14</td>
</tr>
<tr>
<td>11.0 (1115)</td>
<td>2.90</td>
<td>3.18</td>
<td>3.69</td>
<td>4.16</td>
<td>4.74</td>
<td>5.25</td>
</tr>
<tr>
<td>12.0 (1216)</td>
<td>2.96</td>
<td>3.24</td>
<td>3.76</td>
<td>4.24</td>
<td>4.82</td>
<td>5.35</td>
</tr>
<tr>
<td>13.0 (1317)</td>
<td>3.01</td>
<td>3.30</td>
<td>3.81</td>
<td>4.30</td>
<td>4.89</td>
<td>5.43</td>
</tr>
<tr>
<td>14.0 (1419)</td>
<td>3.06</td>
<td>3.34</td>
<td>3.87</td>
<td>4.36</td>
<td>4.96</td>
<td>5.51</td>
</tr>
<tr>
<td>15.0 (1530)</td>
<td>3.10</td>
<td>3.38</td>
<td>3.92</td>
<td>4.41</td>
<td>5.00</td>
<td>5.57</td>
</tr>
<tr>
<td>16.0 (1631)</td>
<td>3.14</td>
<td>3.41</td>
<td>3.96</td>
<td>4.45</td>
<td>5.06*</td>
<td>5.62*</td>
</tr>
<tr>
<td>17.0 (1723)</td>
<td>3.16</td>
<td>3.45</td>
<td>3.99</td>
<td>4.49</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18.0 (1824)</td>
<td>3.20*</td>
<td>3.48*</td>
<td>4.03*</td>
<td>4.54*</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Rated Burst Pressure. DO NOT EXCEED.

11 WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC’s control directly affect the instrument and the results obtained from its use.

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