Boston Scientific

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VeriFLEX™ (Liberté®)

MONORAIL®

OVER-THE-WIRE

Bare-Metal Coronary Stent System

℞ ONLY

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 premounted 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.

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

Table 1. Balloon and Stent Specifications

System Balloon Diameter (mm)	Stent Length (mm)	Nominal Pressure During Stent Deployment (atm/kPa)	Rated Burst Pressure (atm/kPa)	Minimum I.D. of Guide Catheter For Monorail Catheter (in/mm)	Minimum I.D. Guide Catheter For Over-The-Wire Catheter (in/mm)
2.75	8	9/912	18/1824	0.058/1.47	0.066/1.68
3.00	8	9/912	18/1824	0.058/1.47	0.066/1.68
3.50	8	9/912	18/1824	0.058/1.47	0.066/1.68
4.00	8	9/912	18/1824	0.058/1.47	0.066/1.68
2.75	12	9/912	18/1824	0.058/1.47	0.066/1.68
3.00	12	9/912	18/1824	0.058/1.47	0.066/1.68
3.50	12	9/912	18/1824	0.058/1.47	0.066/1.68
4.00	12	9/912	18/1824	0.058/1.47	0.066/1.68
4.50	12	9/912	16/1621	0.066/1.68	0.066/1.68
5.00	12	9/912	16/1621	0.066/1.68	0.066/1.68
2.75	16	9/912	18/1824	0.058/1.47	0.066/1.68
3.00	16	9/912	18/1824	0.058/1.47	0.066/1.68
3.50	16	9/912	18/1824	0.058/1.47	0.066/1.68
4.00	16	9/912	18/1824	0.058/1.47	0.066/1.68
4.50	16	9/912	16/1621	0.066/1.68	0.066/1.68
5.00	16	9/912	16/1621	0.066/1.68	0.066/1.68
2.75	20	9/912	18/1824	0.058/1.47	0.066/1.68
3.00	20	9/912	18/1824	0.058/1.47	0.066/1.68
3.50	20	9/912	18/1824	0.058/1.47	0.066/1.68
4.00	20	9/912	18/1824	0.058/1.47	0.066/1.68
4.50	20	9/912	16/1621	0.066/1.68	0.066/1.68
5.00	20	9/912	16/1621	0.066/1.68	0.066/1.68
2.75	24	9/912	18/1824	0.058/1.47	0.066/1.68
3.00	24	9/912	18/1824	0.058/1.47	0.066/1.68
3.50	24	9/912	18/1824	0.058/1.47	0.066/1.68
4.00	24	9/912	18/1824	0.058/1.47	0.066/1.68
4.50	24	9/912	16/1621	0.066/1.68	0.066/1.68
5.00	24	9/912	16/1621	0.066/1.68	0.066/1.68
2.75	28	9/912	18/1824	0.058/1.47	0.066/1.68
3.00	28	9/912	18/1824	0.058/1.47	0.066/1.68
3.50	28	9/912	18/1824	0.058/1.47	0.066/1.68
4.00	28	9/912	18/1824	0.058/1.47	0.066/1.68
4.50	28	9/912	16/1621	0.066/1.68	0.066/1.68
5.00	28	9/912	16/1621	0.066/1.68	0.066/1.68
2.75	32	9/912	18/1824	0.058/1.47	0.066/1.68
3.00	32	9/912	18/1824	0.058/1.47	0.066/1.68
3.50	32	9/912	18/1824	0.058/1.47	0.066/1.68
4.00	32	9/912	18/1824	0.058/1.47	0.066/1.68
4.50	32	9/912	16/1621	0.066/1.68	0.066/1.68
5.00	32	9/912	16/1621	0.066/1.68	0.066/1.68

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.
- Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon.
- Patients with known allergies to stainless steel. (See **4 WARNINGS**).

(See also **8.1 Individualization of Treatment**).

4 WARNINGS

- The device carries an associated risk of subacute thrombosis, vascular complications, and/or bleeding events. Therefore, patients should be carefully selected.
- Persons allergic to stainless steel may suffer an allergic reaction to this implant.

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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 arterial segment containing 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 delivery, 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 use if sterile barrier is damaged. If damage is found call your Boston Scientific representative.
- For single patient 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.
- 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 crimped 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 dislodgment 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.**
- Implanting 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 lesion(s). Stenting in this order alleviates the need to cross the proximal stent in placement 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 side branch patency.
- 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.
- Balloon pressures should be monitored during inflation. Do not exceed rated burst pressure as indicated on product label (see **Table 6**). Use of pressures higher than specified on product label may result in a ruptured balloon and potential intimal damage and dissection. The stent I.D. should approximate 1.1 times the reference diameter of the vessel.
- 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**).
- Do not attempt to pull an unexpanded stent back into the guiding catheter while engaged in the coronary arteries, as stent damage or stent dislodgment from the balloon may occur. (See **5.4 Stent System Removal**).
- An unexpanded stent should be introduced into the coronary arteries **one time only**. An unexpanded stent should not be subsequently moved in and out through the distal end of the guiding catheter as stent damage or stent dislodgment from the balloon may occur.
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the vascular site. Complications can include bleeding, hematoma or pseudoaneurysm.

5.4 Stent System Removal

- 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.
- Do not attempt to pull an unexpanded stent back into the guiding catheter while engaged in the coronary arteries, as stent damage or stent dislodgment from the balloon may occur.

When removing the entire Stent System and guiding catheter as a single unit:

Note: The following steps should be executed under direct visualization using fluoroscopy.

- Maintain guidewire placement across the lesion during the entire removal process. Carefully pull back the Stent System until the proximal balloon marker of the Stent System is aligned with the distal tip of the guiding catheter.
- The Stent System and the guiding catheter should be pulled back until the tip of the guiding catheter is just distal to the arterial sheath, allowing the guiding catheter to straighten. Carefully retract the Stent System into the guiding catheter and remove the Stent System and the guiding catheter from the patient **as a single unit** while leaving the guidewire across the lesion.
- Following stent placement, confirm complete balloon deflation (see **Table 2 for Deflation Time Specifications**). If unusual resistance is felt during SDS withdrawal, pay particular attention to guide catheter position. In some cases, it may be necessary to pull back slightly on the guide catheter to prevent deep seating (unplanned movement) of the guide catheter and subsequent vessel damage. In cases where unplanned guide catheter movement has occurred, angiographic assessment of the coronary tree should be undertaken to ensure that there is no damage to the coronary vasculature.

Failure to follow these steps, and/or applying excessive force to the Stent System can potentially result in stent damage, stent dislodgment from the balloon and/or damage to the Delivery System.

Table 2. System Deflation Time Specifications

	8 mm	12 mm	16 mm	20 mm	24 mm	28 mm	32 mm
2.75 mm	16 sec						
3.00 mm							
3.50 mm					21 sec		
4.00 mm							
4.50 mm	Not Offered	30 sec					
5.00 mm							

All product tested during Design Verification met a 95/95 confidence/conformance level.

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, opposition and/or geometry.

5.6 MRI Information

Non-clinical testing has demonstrated the VeriFLEX (Liberté) Stent, in single and in overlapped configurations up to 60 mm in length, is MR Conditional. It can be scanned safely under the following conditions:

- static magnetic field of 3 and 1.5 Tesla
- spatial gradient field of 700 Gauss/cm 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 60 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 60 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 minutes of MR scanning in a 3.0 Tesla Magnetom Trio®, Siemens Medical Solutions, software version Numaris/4, Syngo® MR A30 MR scanner and in a 1.5 Tesla Intera® Philips Medical Systems, software version Release 10.6.2.0, 2006-03-10, MR scanner. Stent heating was derived in computer simulation 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 9 mm from the device, both inside and outside the device lumen 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 A30 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 patients in the BSC ELECT Clinical Study completed clinical 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 200 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.

Table 3. Principal Adverse Events: In-Hospital and Out-of-Hospital to 12 Months

Event	VeriFLEX™ (Liberté®) Stent	Express® Stent Taxus® IV - SR	Express Stent Victory
In-Hospital			
MACE	0.5% (1/200) [0.0%, 2.8%]	2.1% (11/519) [1.1%, 3.8%]	2.0% (6/303) [0.7%, 4.3%]
Cardiac Death	0.0% (0/200) [0.0%, 1.8%]	0.4% (2/519) [0.0%, 1.4%]	0.0% (0/303) [0.0%, 1.2%]
Myocardial Infarction	0.5% (1/200) [0.0%, 2.8%]	2.1% (11/519) [1.1%, 3.8%]	1.7% (5/303) [0.5%, 3.8%]
Q-wave	0.0% (0/200) [0.0%, 1.8%]	0.2% (1/519) [0.0%, 1.1%]	0.0% (0/303) [0.0%, 1.2%]
Non Q-wave	0.5% (1/200) [0.0%, 2.8%]	1.9% (10/519) [0.9%, 3.5%]	1.7% (5/303) [0.5%, 3.8%]
Target Vessel Revascularization (TVR)	0.0% (0/200) [0.0%, 1.8%]	0.2% (1/519) [0.0%, 1.1%]	0.3% (1/303) [0.0%, 1.8%]
Target Lesion Revascularization (TLR)	0.0% (0/200) [0.0%, 1.8%]	0.2% (1/519) [0.0%, 1.1%]	0.3% (1/303) [0.0%, 1.8%]
TLR, PCI	0.0% (0/200) [0.0%, 1.8%]	0.2% (1/519) [0.0%, 1.1%]	0.0% (0/303) [0.0%, 1.2%]
TLR, CABG	0.0% (0/200) [0.0%, 1.8%]	0.2% (1/519) [0.0%, 1.1%]	0.3% (1/303) [0.0%, 1.8%]
Non-Target Lesion Revascularization (Non-TLR)	0.0% (0/200) [0.0%, 1.8%]	0.0% (0/519) [0.0%, 0.7%]	0.0% (0/303) [0.0%, 1.2%]
Non-TLR, PCI	0.0% (0/200) [0.0%, 1.8%]	0.0% (0/519) [0.0%, 0.7%]	0.0% (0/303) [0.0%, 1.2%]
Non-TLR, CABG	0.0% (0/200) [0.0%, 1.8%]	0.0% (0/519) [0.0%, 0.7%]	0.0% (0/303) [0.0%, 1.2%]
Serious Bleeding Events	1.0% (2/200) [0.1%, 3.6%]	0.8% (4/519) [0.2%, 2.0%]	N/A
Serious Vascular Events	1.5% (3/200) [0.3%, 4.3%]	1.3% (7/519) [0.5%, 2.8%]	N/A
[1]CVA	1.0% (2/200) [0.1%, 3.6%]	0.2% (1/519) [0.0%, 1.1%]	N/A
Stent Thrombosis	0.0% (0/200) [0.0%, 1.8%]	0.4% (2/519) [0.0%, 1.4%]	0.0% (0/303) [0.0%, 1.2%]
Out-of-Hospital to 12 Months			
MACE	18.0% (34/189) [12.8%, 24.2%]	16.8% (86/511) [13.7%, 20.4%]	12.5% (34/271) [8.8%, 17.1%]
Cardiac Death	0.0% (0/189) [0.0%, 1.9%]	1.2% (6/511) [0.4%, 2.5%]	1.1% (3/271) [0.2%, 3.2%]
Myocardial Infarction	0.0% (0/189) [0.0%, 1.9%]	1.6% (8/511) [0.7%, 3.1%]	1.5% (4/271) [0.4%, 3.7%]
Q-wave	0.0% (0/189) [0.0%, 1.9%]	0.0% (0/511) [0.0%, 0.7%]	0.7% (2/271) [0.1%, 2.6%]
Non Q-wave	0.0% (0/189) [0.0%, 1.9%]	1.6% (8/511) [0.7%, 3.1%]	1.1% (3/271) [0.2%, 3.2%]
Target Vessel Revascularization (TVR)	18.0% (34/189) [12.8%, 24.2%]	15.1% (77/511) [12.1%, 18.5%]	11.4% (31/271) [7.9%, 15.8%]
Target Lesion Revascularization (TLR)	13.8% (26/189) [9.2%, 19.5%]	12.9% (66/511) [10.1%,16.1%]	10.0% (27/271) [6.7%, 14.2%]
TLR, PCI	12.2% (23/189) [7.9%, 17.7%]	10.6% (54/511) [8.0%, 13.6%]	8.9% (24/271) [5.8%, 12.9%]
TLR, CABG	1.6% (3/189) [0.3%, 4.6%]	2.7% (14/511) [1.5%, 4.6%]	1.5% (4/271) [0.4%, 3.7%]
Non-Target Lesion Revascularization (Non-TLR)	4.2% (8/189) [1.8%, 8.2%]	3.1% (16/511) [1.8%, 5.0%]	1.5% (4/271) [0.4%, 3.7%]
Non-TLR, PCI	3.2% (6/189) [1.2%, 6.8%]	2.7% (14/511) [1.5%, 4.6%]	0.7% (2/271) [0.1%, 2.6%]
Non-TLR, CABG	1.1% (2/189) [0.1%, 3.8%]	0.4% (2/511) [0.0%, 1.4%]	0.7% (2/271) [0.1%, 2.6%]
Serious Bleeding Events	1.6% (3/189) [0.3%, 4.6%]	1.4% (7/511) [0.6%, 2.8%]	N/A
Serious Vascular Events	1.6% (3/189) [0.3%, 4.6%]	0.6% (3/511) [0.1%, 1.7%]	N/A
[1]CVA	0.0% (0/189) [0.0%, 1.9%]	0.8% (4/511) [0.2%, 2.0%]	N/A
Stent Thrombosis (sub-acute/≤30 days)	0.0% (0/200) [0.0%, 1.8%]	0.2% (1/519) [0.0%, 1.1%]	0.3% (1/300) [0.0%, 1.8%]
Stent Thrombosis (late/≥31 days)	0.0% (0/189) [0.0%, 1.9%]	0.0% (0/511) [0.0%, 0.7%]	0.7% (2/271) [0.1%, 2.6%]

Numbers are % (Count/Sample Size) [95% Confidence Interval]. 95% CIs are exact.
MACE: Major Adverse Cardiac Events, comprised of cardiac death, myocardial infarction (MI) including WHO defined Q- and non-Q-wave MI, and target vessel revascularization (TVR).
TVR: Target Vessel Revascularization, defined as ischemia-driven repeat percutaneous intervention of the target vessel or bypass surgery of the target vessel. A TVR was considered ischemia-driven if the target vessel diameter stenosis is:

- ≥50% by QCA and any of the following are present:
  - the patient had a positive functional study corresponding to the area served by the target vessel;
  - ischemic ECG changes at rest in a distribution consistent with the target vessel;
  - ischemic symptoms referable to the target lesion, or
- ≥70% by QCA in the absence of clinical or functional ischemia.

Non-Q-wave MI – Elevation of post-procedure CK levels to >2 times normal with elevated CKMB in the absence of new pathological Q-waves.
Primary endpoint of BSC ELECT was 30-Day MACE.
N/A = Not applicable.
Definitions of CVA, Serious Bleeding and Vascular Events included in the ELECT and TAXUS studies were not used in the VICTORY study.
[1]Acute neurological deficits recorded by the clinical sites that persisted for >24 hours, including transient ischemic attack (TIA) with unconfirmed duration, were reported as cerebral vascular accidents. One CVA with an incomplete onset date was conservatively reported as in-hospital.

6.2 Potential Adverse Events

Potential adverse events (in alphabetical order) which may be associated with the use of a coronary stent in native coronary arteries include but are not limited to:

- Acute Myocardial Infarction
- Allergic reaction to antiplatelet agents/contrast media
- Arrhythmias, including ventricular fibrillation (VF) and ventricular tachycardia (VT)
- Death
- Dissection
- Emboli, distal (air, tissue or thrombotic emboli)
- Emergent Coronary Artery Bypass Surgery (CABG)
- Hematoma
- Hemorrhage, requiring transfusion
- Hypotension/Hypertension
- Infection and/or pain at the access site
- Ischemia/myocardial
- Perforation or Rupture
- Pseudoaneurysm, femoral
- Restenosis of stented segment
- Spasm
- Stent embolization
- Stent thrombosis/occlusion
- Stroke/cerebrovascular accident (CVA)/transient ischemic attack (TIA)
- Total occlusion of coronary artery

7 CLINICAL STUDIES

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 multi-center, prospective, single arm registry was conducted at 20 U.S. sites enrolling 200 patients. Patients were 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. Eligible patients had visually estimated stenosis ≥50% and <100% located in a lesion ≤28mm 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.

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% are 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 (%DS) of 65% and average lesion length of 11.75 mm.

Methods: Clinical or telephone follow-up was conducted in-hospital and at 30 days, 6 months and 12 months post-procedure. Follow-up angiography was completed in 93.5% (187/200) of BSC ELECT registry patients at the 6-month clinical visit. Baseline, post-procedure and 6-month angiographic data were collected and assessed by quantitative analysis at a designated core laboratory. An independent Clinical Events Committee adjudicated major adverse clinical events and stent thrombosis.

Results: All patients enrolled in the BSC ELECT trial received a VeriFLEX™ (Liberté®) Stent. A clinical procedural success rate of 99.5% (199/200) correlates with the single reported peri-procedural MI. The technical success rate of 99.5% (199/200) reflects one initial VeriFLEX (Liberté) Stent that was attempted (2.75 mm x 16 mm) but could not cross the target lesion; however, two 2.75 mm x 8 mm VeriFLEX (Liberté) Stents were successfully implanted.

The 30-day MACE rates were 0.5% (1/200) and 2.3% (12/519) for the VeriFLEX (Liberté) Stent and TAXUS® IV Express® Stent group, respectively, for a difference of -1.8% and an exact upper one-sided 95% confidence bound of 0.7%. Since the upper 95% confidence bound of the difference is less than the pre-specified equivalence limit (delta) of 4.0%, the null hypothesis of inferiority is rejected in favor of the alternative hypothesis of non-inferiority.

Because angiographic follow-up for the TAXUS IV-SR study was required at 9 months post-index procedure, 6-month safety and efficacy measurements for the VeriFLEX (Liberté) Stent were compared to Express Stent data from the VICTORY study. These two studies both required follow-up at 6 months, including angiography for the entire VeriFLEX (Liberté) Stent intent-to-treat population (200/200) and an Express Stent angiographic subset (99/303).

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 6-month MACE rate was 15.9% (31/195) and the TLR rate was 11.8% (23/195). In the VICTORY Express Stent angiographic subset, the 6-month MACE rate was 15.3% (15/98) and the TLR rate was 13.3% (13/98).

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

	VeriFLEX (Liberté) Stent (N=200)	Express Stent VICTORY Control (N=99)
6-Month Results		
MACE	15.9% (31/195) [11.1%, 21.8%]	15.3% (15/98) [8.8%, 24.0%]
Target Vessel Revascularization	15.4% (30/195) [10.6%, 21.2%]	14.3% (14/98) [8.0%, 22.8%]
Target Lesion Revascularization	11.8% (23/195) [7.6%, 17.2%]	13.3% (13/98) [7.3%, 21.6%]
TVF to 6 Months	15.9% (31/195) [11.1%, 21.8%]	15.3% (15/98) [8.8%, 24.0%]
Stent Thrombosis to 6 months	0.0% (0/200) [0.0%, 1.8%]	2.0% (2/98) [0.2%, 7.2%]
QCA Measures		
MLD (mm), In-stent		
Post-procedure	2.75±0.45 (200) (1.70, 3.99)	2.91±0.43 (99) (2.05, 4.17)
6-Month	2.02±0.78 (187) (0.00, 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, 23.89)
6-Month	31.23±23.18 (187) (-9.65, 100.00)	30.27±20.00 (99) (-2.12, 100.00)
In-stent restenosis	21.9% (41/187) [16.2%, 28.5%]	16.2% (16/99) [9.5%, 24.9%]
Late Loss, In-stent (mm)	0.72±0.67 (187) (-0.63, 2.57)	0.82±0.59 (99) (-0.41, 2.85)

Numbers are % (Count/Sample Size) [95% Confidence Interval] or Mean±SD (N). 95% CIs are exact.
MLD = Minimum Lumen Diameter
%DS = Percent Diameter Stenosis
Target Vessel Failure (TVF): any revascularization of the target vessel, or MI (Q- and non-Q-wave), or cardiac death that cannot be clearly attributed to a vessel other than the target vessel.
6-Month MACE: the proportion of patients who experience a MACE through 210 days post-stenting out of the patients who either had an event within 210 days post-stenting and/or had clinical follow-up at least 150 days post-stenting.

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

	VeriFLEX (Liberté) Stent (N=200)	Express Stent Taxus IV-SR (N=519)
Effectiveness Measures		
Clinical Procedural Success	99.5% (199/200) [97.2%, 100.0%]	97.5% (506/519) [95.8%, 98.7%]
Technical Success	99.5% (199/200) [97.2%, 100.0%]	97.7% (507/519) [96.0%, 98.8%]
Safety Measures		
In-Hospital MACE	0.5% (1/200) [0.0%, 2.8%]	2.1% (11/519) [1.1%, 3.8%]
MACE to 30 days (Primary Endpoint)	0.5% (1/200) [0.0%, 2.8%]	2.3% (12/519) [1.2%, 4.0%]
MACE to 6 Months	15.9% (31/195) [11.1%, 21.8%]	10.9% (56/513) [8.4%, 13.9%]
MACE to 9 Months	16.9% (33/195) [11.9%, 22.9%]	16.1% (83/514) [13.1%, 19.6%]
MACE to 12 Months	18.5% (35/189) [13.3%, 24.8%]	18.6% (95/511) [15.3%, 22.2%]
TLR to 12 Months	13.8% (26/189) [9.2%, 19.5%]	13.1% (67/511) [10.3%, 16.4%]
TVF to 12 Months	18.5% (35/189) [13.3%, 24.8%]	18.0% (92/511) [14.8%, 21.6%]
Serious Bleeding Events to 12 months	2.7% (5/188) [0.9%, 6.1%]	2.0% (10/503) [1.0%, 3.6%]
Serious Vascular Events to 12 months	3.2% (6/188) [1.2%, 6.8%]	2.0% (10/504) [1.0%, 3.6%]
CVA to 12 months	1.1% (2/188) [0.1%, 3.8%]	1.0% (5/504) [0.3%, 2.3%]
Stent Thrombosis to 12 months	0.0% (0/189) [0.0%, 1.9%]	0.6% (3/511) [0.1%, 1.7%]

Numbers are % (Count/Sample Size) [95% Confidence Interval]. 95% CIs are exact.
Clinical Procedural Success: using the stent to achieve a residual diameter stenosis of <30% as visually assessed by the Investigator at the end of the stent procedure, without the occurrence of MACE as of the time of hospital discharge.
Technical Success: successful delivery and deployment of the study stent to the target lesion, without balloon rupture, embolization, or use of a device outside the treatment strategy.
30-Day MACE: the proportion of patients who experienced a MACE up to 30 days post-procedure.
6-Month MACE: the proportion of patients who experienced a MACE up to 210 days post-procedure out of the patients who either had an event within 210 days post-stenting and/or had clinical follow-up at least 150 days post-stenting.
9-Month MACE: the proportion of patients who experienced a MACE up to 284 days post-procedure out of the patients who either had an event within 284 days post-stenting and/or had clinical follow-up at least 270 days post-stenting.
12-Month MACE: the proportion of patients who experienced a MACE up to 365 days post-procedure out of the patients who either had an event within 365 days post-stenting and/or had clinical follow-up at least 335 days post-stenting.
VeriFLEX (Liberté) Stent angiographic follow-up occurred 6 months post-index procedure and Express Stent angiographic follow-up occurred 9 months post-index procedure.
CVA – Transient ischemic attack or sudden onset of vertigo, numbness, aphasia, or dysarthria due to vascular lesions of the brain such as hemorrhage, embolism, thrombosis, or rupturing aneurysm, that persisted >24 hours, including transient ischemic attack with unconfirmed duration.
Serious Bleeding Events included: hemorrhage (upper GI bleed and GI not specified) and hematuria
Serious Vascular Events included: hematoma (catheter site), hemorrhage (catheter site), and vascular pseudoaneurysm.
Stent thrombosis:
Clinical presentation of acute coronary syndrome with angiographic evidence of stent thrombosis:

- Angiographic documentation of a complete occlusion (TIMI flow 0 or 1) of a previously successfully treated artery (TIMI flow 2 to 3 immediately after stent placement and DS ≤30%), and/or angiographic documentation of a flow limiting thrombus within or adjacent to a previously successfully treated lesion
- Acute MI of the distribution of the treated vessel
- Death within first 30 days (without other obvious cause) was considered a surrogate for stent thrombosis when angiography was not available.

8 PATIENT SELECTION AND TREATMENT

8.1 Individualization of Treatment

The risks and benefits should be carefully considered for each patient before use of the VeriFLEX (Liberté) Coronary Stent System. Patient selection factors to be assessed should include a judgment regarding risk of prolonged anticoagulation. Stenting is generally avoided in those patients at heightened risk of bleeding (e.g., those patients with recently active gastritis or peptic ulcer disease, see **3 CONTRAINDICATIONS**).

Premorbid conditions that increase the risk of poor initial results or the risks of emergency referral for bypass surgery (diabetes mellitus, renal failure, and severe obesity) should be reviewed.

Thrombosis following stent implantation is affected by several baseline angiographic and procedural factors. These include vessel diameter less than 3.0 mm, vessel thrombosis, poor distal flow, and/or dissection following stent implantation. In patients undergone coronary stenting, the persistence of a thrombus or dissection is considered a marker for subsequent thrombotic occlusion. These patients should be monitored very carefully during the first month after stent implantation, because stent thrombosis may occur during this period.

8.2 Specific Patient Populations

The safety and effectiveness of the VeriFLEX (Liberté) Stent System has not been established for patients with any of the following characteristics:

- Patients with unresolved vessel thrombus at the lesion site.
- Patients with coronary artery reference vessel diameters <2.75 mm.

- 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	Inflation 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 grasping 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.
4.	With tip down, orient Stent System vertically.
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.

Step	Action
7.	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.

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**).

Step	Action
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 stenosed 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, readvance 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 Coil Clip (see **10.3 Preparation**).

10.7 In Vitro Information

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

Pressure atm (kPa)		2.75 mm Stent I.D. (mm)	3.00 mm Stent I.D. (mm)	3.50 mm Stent I.D. (mm)	4.00 mm Stent I.D. (mm)	4.50 mm Stent I.D. (mm)	5.00 mm Stent I.D. (mm)
9.0 (912)	Nominal	2.74	3.03	3.52	3.97	4.54	5.01
10.0 (1013)		2.82	3.11	3.60	4.07	4.65	5.14
11.0 (1115)		2.90	3.18	3.69	4.16	4.74	5.25
12.0 (1216)		2.96	3.24	3.76	4.24	4.82	5.35
13.0 (1317)		3.01	3.30	3.81	4.30	4.89	5.43
14.0 (1419)		3.06	3.34	3.87	4.36	4.96	5.51
15.0 (1520)		3.10	3.38	3.92	4.41	5.00	5.57
16.0 (1621)		3.14	3.41	3.96	4.45	5.06*	5.62*
17.0 (1723)		3.16	3.45	3.99	4.49		
18.0 (1824)		3.20*	3.48*	4.03*	4.54*		

*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. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

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