

# LABELING



# Liberté™

*Monorail® Coronary Stent System  
and  
Over-The-Wire Coronary Stent System*

*CAUTION: Federal law restricts this device to sale by or on  
the order of a physician.*

## **DIRECTIONS FOR USE**

**Boston  
Scientific**



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

## 1 DEVICE DESCRIPTION

The 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.

**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. of 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

Table 1. Balloon and Stent Specifications (continued from previous page)

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. of Guide Catheter For Over-The-Wire Catheter (in/mm)
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 INDICATIONS and USAGE**

The 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 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.

**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 Liberté™ Coronary Stent System has not been established in patients beyond 30 days of follow-up.

## 5.2 Stent Handling

(See also **10 Operator's 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 sterilize. Reuse, reprocessing or sterilization 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 sterilization 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 dry, dark, cool place.
- The 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, Operator's 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 **Operator's 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 5**). 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						21 sec	
3.00 mm								
3.50 mm								
4.00 mm	30 sec							
4.50 mm								
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, position and/or geometry.

#### 5.6 MRI Information

- The Liberté™ Stent has been shown to be MR safe at field strengths of 3 Tesla (T) or less, and a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MR imaging. The Liberté™ Stent should not migrate in this MR environment. MR imaging at 3T or less may be performed immediately following the implantation of the Liberté™ Stent.

In this testing, the stent experienced a maximum temperature rise of 0.65 degrees C at a maximum whole body averaged SAR of 2 W/kg for 15 minutes of MR imaging. The temperature rise was observed to be similar for comparable bare metal overlapping stents (2 to 5 mm overlap at the ends). Heating has not been determined for fractured struts. MR imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.

This stent has not been evaluated to determine if it is safe in MRI systems with field strengths greater than 3 T.

#### 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. The observed major adverse events were compared to a historical control comprised of patients who received a bare metal 3.0 or 3.5mm Express® Stent in the Taxus IV SR clinical trial.

### 6.1.1 BSC ELECT Clinical Trial Studies

Table 3. presents the major clinical events observed in the BSC ELECT Clinical Study through 30 days post-stenting procedure.

**Table 3. Principal Adverse Events: In-Hospital vs Out-of-Hospital**

Event	Liberté™ Stent to 30 days	Express® Stent to 30 days
<b>In-Hospital</b>		
MACE	0.5% (1/200)	2.1% (11/519)
Death	0.0% (0/200)	0.4% (2/519)
Myocardial Infarction <sup>†</sup>	0.5% (1/200)	2.1% (11/519)
Q-wave	0.0% (0/200)	0.2% (1/519)
Non Q-wave	0.5% (1/200)	1.9% (10/519)
Target Vessel Revascularization (TVR)	0.0% (0/200)	0.2% (1/519)
Target Lesion Revascularization (TLR)	0.0% (0/200)	0.2% (1/519)
TVR, non-target lesion	0.0% (0/200)	0.0% (0/519)
TVR, CABG	0.0% (0/200)	0.2% (1/519)
CVA	1.0% (2/200)	0.2% (1/519)
Stent Thrombosis (acute/in-hospital)	0.0% (0/200)	0.4% (2/519)
<b>Out-of-Hospital</b>		
MACE	0.0% (0/200)	0.2% (1/517)
Death	0.0% (0/200)	0.2% (1/517)
Myocardial Infarction	0.0% (0/200)	0.0% (0/517)
Q-wave	0.0% (0/200)	0.0% (0/517)
Non Q-wave	0.0% (0/200)	0.0% (0/517)
Target Vessel Revascularization (TVR)	0.0% (0/200)	0.0% (0/517)
Target Lesion Revascularization (TLR)	0.0% (0/200)	0.0% (0/517)
TVR, non-target lesion	0.0% (0/200)	0.0% (0/517)
TVR, CABG	0.0% (0/200)	0.0% (0/517)
CVA	0.0% (0/200)	0.2% (1/517)
Stent Thrombosis (sub-acute/<30 days)	0.0% (0/200)	0.2% (1/517)

Numbers are % (Count/Sample Size).

MACE: Major Adverse Cardiac Events, comprised of Cardiac Death, MI and 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 will be considered as ischemia-driven if the target vessel diameter stenosis is  $\geq 50\%$  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.

Primary endpoint of BSC ELECT registry is 30-Day MACE

### 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 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 30-Day safety and efficacy of the 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  $\geq 50\%$  and  $< 100\%$  located in a lesion  $\leq 28\text{mm}$  in length with a reference vessel  $\geq 2.75\text{mm}$  and  $\leq 4.0\text{mm}$  in diameter.

**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 into the guide catheter.

The secondary endpoints, including technical success, clinical procedural success, stent thrombosis rate, and

serious bleeding and vascular complications were also analyzed on an intent-to-treat basis.

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.

**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.

In comparison to the Express® Stent population, the Liberté™ Stent population contained smaller proportions of patients with known CHF (3.0% vs. 7.5%), CCS angina class 4 (2.5% vs. 8.3%), silent ischemia (8.5% vs. 16.4%), and known family history of CAD (40.5% vs. 58.4%). The Liberté™ Stent population had a higher proportion of patients with CCS angina class 1 (12.5% vs. 7.5%). The Liberté™ Stent group represents a lower-risk patient population.

**Methods:** Clinical follow-up was conducted in-hospital and at 30 days post-procedure. Angiographic data was 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:** In the BSC ELECT registry, the 30 Day MACE rate was 0.5% (1/200). The 30-Day MACE rates are 0.5% (1/200) and 2.3% (12/519) for the Liberté™ Stent and 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.

However, this conclusion could not be statistically adjusted for all observed differences in demographics and baseline risk characteristics between the Liberté™ Stent and Express® Stent groups due mainly to the single observed MACE in the Liberté™ Stent group. That is, if it were possible to adjust for all observed baseline differences related to risk of MACE, the alternative hypothesis of non-inferiority of the Liberté™ Stent to the Express® Stent may no longer hold. The Principal Safety and Effectiveness results are presented in the table below. The Liberté™ Stent and Express® Stent groups also had comparable rates of stent thrombosis, serious bleeding complications, serious vascular complications, and cerebral vascular events. All patients enrolled in the BSC ELECT trial received a Liberté™ Stent. A clinical procedural success rate of 99.5%

(199/200) correlates with the single reported MACE. The technical success rate of 99.5% (199/200) includes one initial Liberté™ Stent attempted (2.75mm x 16mm) that could not cross the target lesion; however, two 2.75mm x 8mm Liberté™ Stents were successfully implanted.

Table 4 summarizes principal safety and effectiveness results through 30-Days.

**Table 4. BSC Elect Principal Safety and Effectiveness Results through 30 Days**

	Liberté™ Stent (N=200)	Express® Stent (N=519)	Difference (95% CI)
<b>Effectiveness Measures</b>			
Clinical Procedural Success	99.5% (199/200)	97.5% (506/519)	2.0% [-0.7%, 3.9%]
Technical Success	99.5% (199/200)	97.7% (507/519)	1.8% [-0.7%, 3.6%]
<b>30-Day Results<sup>1</sup></b>			
30-Day MACE	0.5% (1/200)	2.3% (12/519)	-1.8% [-3.6%, 0.7%]
Cardiac Death or MI	0.5% (1/200)	2.3% (12/519)	-1.8% [-3.6%, 0.7%]
Cardiac Death	0.0% (0/200)	0.6% (3/519)	-0.6% [-1.7%, 1.4%]
MI	0.5% (1/200)	2.1% (11/519)	-1.6% [-3.4%, 1.0%]
Q-Wave MI	0.0% (0/200)	0.2% (1/519)	-0.2% [-1.1%, 1.7%]
Non-Q-Wave MI	0.5% (1/200)	1.9% (10/519)	-1.4% [-3.1%, 1.0%]
TVR, Overall	0.0% (0/200)	0.2% (1/519)	-0.2% [-1.1%, 1.7%]
TLR Overall	0.0% (0/200)	0.2% (1/519)	-0.2% [-1.1%, 1.7%]
TLR, PCI	0.0% (0/200)	0.2% (1/519)	-0.2% [-1.1%, 1.7%]
TLR, CABG	0.0% (0/200)	0.2% (1/519)	-0.2% [-1.1%, 1.7%]
Non-TLR Overall	0.0% (0/200)	0.0% (0/519)	0.0% [-0.7%, 2.0%]
Non-TLR, PCI	0.0% (0/200)	0.0% (0/519)	0.0% [-0.7%, 2.0%]
Non-TLR, CABG	0.0% (0/200)	0.0% (0/519)	0.0% [-0.7%, 2.0%]
<b>Safety Measures<sup>1</sup></b>			
In-Hospital Stent Thrombosis	0.0% (0/200)	0.4% (2/519)	-0.4% [-1.4%, 1.7%]
Out-of-Hospital Stent Thrombosis to 30 Days	0.0% (0/200)	0.2% (1/517)	-0.2% [-1.1%, 1.7%]
In-Hospital MACE	0.5% (1/200)	2.1% (11/519)	-1.6% [-3.4%, 1.0%]
Out-of-Hospital MACE to 30 Days	0.0% (0/200)	0.2% (1/517)	-0.2% [-1.1%, 1.7%]
30-Day TVF	0.5% (1/200)	2.3% (12/519)	-1.8% [-3.6%, 0.7%]
Senous Bleeding Complications to 30 Days	1.5% (3/200)	0.8% (4/517)	0.7% [-0.8%, 3.8%]
Senous Vascular Complications to 30 Days	3.0% (6/200)	1.5% (8/517)	1.5% [-0.7%, 5.0%]
CVA to 30 Days	1.0% (2/200)	0.4% (2/517)	0.6% [-0.6%, 3.2%]

Numbers are % (Count/Sample Size). CI= Confidence Interval.

Difference = Liberté™-Express®. 95% CIs of the difference in proportions are exact. 95% confidence intervals were not adjusted for observed baseline differences in risk of MACE.

Clinical Procedural Success: using the study device to achieve an in-lesion diameter stenosis of <30% of the target lesion in the average of 2 near-orthogonal projections, as visually assessed by the physician, without the occurrence of in-hospital MACE (cardiac death, MI [Q-and non-Q-wave], repeat revascularization [percutaneous or CABG] of the target vessel).

Technical Success: successful delivery and deployment of the study device to the target lesion, without balloon rupture of the study device, stent embolization, or use of the study device outside the treatment strategy.

30-Day MACE: the proportion of patients who experience MACE up to 30 days post-procedure out of the patients who have either experienced a MACE up to 30 days post-procedure or who were MACE-free with last follow-up at least 23 days post-procedure.

Target Vessel Failure (TVF): any revascularization of the target vessel, or MI (Q-and non-Q-wave), or cardiac death that can not be clearly attributed to a vessel other than the target vessel.

**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  $\leq$ 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
- 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.  
Serious Bleeding Complications included: hemorrhage (upper GI bleed and GI not specified) and hematuria.

## 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 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 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 30 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:** Liberté™ Over-The-Wire Stent System  
One (1) Liberté™ Over-The-Wire Stent System  
One (1) Electronic Directions for Use / Patient Guide Reference Card

**CONTENTS:** Liberté™ Monorail® Stent System  
One (1) 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

**STORAGE:** Store in a cool, dry dark place.

## 10 OPERATOR'S 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 <b>Table 1 - Balloon and Stent Specifications</b> )
1	20 ml (cc) syringe
1	Normal heparinized saline
1	$\leq$ 0.014 in. / 0.36 mm guidewire
1	Rotating hemostatic valve
1	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 coil clip (CLIPIT®) 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.

- 7. Advance the Stent System over the guidewire to 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**).

- 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 (stent 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 5). Balloon pressure must not exceed rated burst pressure. (see Table 5)   |
| 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. |

- 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.
- Inflate the balloon to the desired pressure while observing under fluoroscopy. Deflate the balloon. (refer to product labeling and/or Table 5 for proper stent inflation pressure.)
- 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 coil clip (CLIPIT®) (see 10.3 Preparation).  |

### 10.7 In Vitro Information

**Table 5. Typical 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 Stent 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



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