

# An international, multicentre prospective single arm study to investigate procedural, clinical and angiographic outcomes using the Taxus Liberte stent, with improved side branch access, following the provisional side branch T-stenting approach, in patients with complex lesions

<b>Submission date</b> 08/02/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 08/02/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 08/02/2007	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

## Study information

Scientific Title

**Acronym**

LIBERTY ONE

**Study objectives**

The purpose of the LibertÉ One study is to assess procedural, clinical and angiographic outcomes of the provisional T-stenting approach with the Taxus Liberte stent implanted in complex lesions (with side branch involvement). The Taxus Liberte stent has larger cell perimeters and as such an improved side branch access.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

International, multicentre prospective single arm study

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Coronary lesions

**Interventions**

Percutaneous Coronary Intervention (PCI), provisional side branch T-stenting.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

Target lesion revascularisation of the main branch and side branch defined by the independent core lab at nine months follow-up.

**Key secondary outcome(s)**

1. Incidence of Major Adverse Cardiac Events (MACE) defined as all cardiac deaths, Q-wave and non-Q wave myocardial infarction, target lesion revascularisation (defined as both the main and the side branch) including Percutaneous Transluminal Coronary Angioplasty (PTCA) and Coronary-Artery Bypass Grafting (CABG) at one, seven, nine and 12 months follow-up
2. Acute success rate of stent delivery, recross, and final kissing balloon dilatation, and the number of a second stent implanted on the side branch
3. Restenosis will be evaluated by compulsory nine months angiogram using the binary

definition (greater than 50% in diameter) in the main and the side branch vessel. Measure of the absolute lumen diameter will occur before, immediately after and at nine months, reflecting the net gain, difference of acute gain and late loss ratio and late loss index. Additional usual and lesion specific (main and side branch) quantitative results will be analysed

4. Target lesion and target vessel revascularisation of the main and side branch separately at seven, nine and 12 months follow-up

### **Completion date**

31/08/2008

## **Eligibility**

### **Key inclusion criteria**

1. Patients with stable angina pectoris (CCSC1234) or unstable angina and documented ischaemia or silent ischaemia
2. Patient eligible for coronary revascularisation
3. The target lesion has a major native coronary artery (more than 2.5 mm) with a stenosis more than 50% (on visual assessment) located at a side branch (more than 2 mm)
4. A de novo lesion
5. All angle severities (between branches) accepted
6. The main vessel lesion can be covered by one stent (up to 32 mm)
7. Other lesions in different vessels are successfully treated before the treatment of the target lesion (residual stenosis less than 30%, stent well deployed, no residual dissection, normal Thrombolysis in Myocardial Infarction [TIMI] flow, no chest pain, ElectroCardioGram [ECG] unchanged compared to pre-procedural ECG)
8. Only one target lesion can be included in the study
9. Signed patients informed consent

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Not Specified

### **Sex**

Not Specified

### **Key exclusion criteria**

1. Patients with in stent restenosis of target lesion
2. Severe calcifications with an undilatable lesion during balloon predilatation (Percutaneous Transluminal Renal Angioplasty [PTRA] could be considered)
3. History of bleeding diathesis
4. Untreated significant lesion greater than 50% diameter stenosis remaining proximal or distal to the target intervention
5. Patient has suffered a stroke or Transient Ischaemic Attack (TIA) within the past six months
6. Known untreatable malignancy
7. Any major surgery planned or required during the next nine months
8. Acute myocardial infarction

- 9. Allergy to contrast and/or required antiplatelet medication
- 10. Left main coronary artery

**Date of first enrolment**

01/02/2007

**Date of final enrolment**

31/08/2008

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre****Boston Scientific**

Maastricht

Netherlands

6201 BJ

## Sponsor information

**Organisation**

New Nantes Private Clinics (Nouvelles Cliniques Nantaises) (France)

**ROR**

<https://ror.org/03731ze76>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Boston Scientific (The Netherlands)

## Results and Publications

Individual participant data (IPD) sharing plan

## **IPD sharing plan summary**

Not provided at time of registration