

LIBERTE'

Principal Investigator:

William Felten, MD (MidMichigan)

Sub-Investigators:

Rodney Diehl, DO

Sponsor:

Boston Scientific Corporation

Study Purpose:

TAXUS Liberté Post-Approval Study; A U.S. Post-Approval Study of the TAXUS® Liberté® Paclitaxel-Eluting Coronary Stent System

Objective:

To compile real-world clinical outcomes data for the TAXUS Liberté Paclitaxel-Eluting Coronary Stent System in routine clinical practice in conjunction with the use of dual antiplatelet therapy (DAPT).

Inclusion Criteria

- Patient is > 18 years of age.
- Consecutive patients who are eligible to receive a TAXUS Liberté Stent and the study-required DAPT will be evaluated for enrollment in this study.
- The TAXUS Liberté Paclitaxel-Eluting Coronary Stent System is currently indicated for improving luminal diameter for the treatment of de novo lesions in native coronary arteries > or equal to 2.25 mm to < or equal to 4.00 mm in diameter in lesions < or equal to 34 mm in length.
- All patients who have a TAXUS Liberté Stent implant procedure attempted and who have signed the Informed Consent Form will be included until enrollment objectives have been reached.
- Patients in whom the treating physician has determined that the TAXUS Liberté Stent is the most appropriate device even if outside of the approved indication, should also be asked to participate in the study.

Exclusion Criteria

- Patient with known hypersensitivity to paclitaxel or structurally related compounds.
- Patient with known hypersensitivity to the polymer or any of its individual components.
- Patient judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or delivery device.

LIBERTE'

- Patient who cannot receive the protocol required dual antiplatelet therapy.
- Patient on warfarin or similar anticoagulant therapy.
- Patient with known pregnancy.
- Planned surgery necessitating discontinuation of antiplatelet therapy within the 30-months following enrollment.
- Current medical condition with a life expectancy of less than 3 years.
- Patient currently enrolled in another device or drug study whose protocol specifically excludes concurrent enrollment or that involves blinded placement of a drug-eluting stent other than the TAXUS Liberté Stent.
- Patient judged unable to cooperate with prolonged DAPT.
- Patient unable to give informed consent.
- Patient judged inappropriate for randomization due to other condition requiring chronic thienopyridine use.
- Patient treated with both a drug-eluting stent and a bare-metal stent during the index procedure.
- Patient who experienced a prior transient ischemic attack (TIA) or a prior stroke.
- Patient requiring chronic daily use (greater than 2 consecutive weeks) of non-steroidal anti-inflammatory drugs (NSAIDs) with the exception of aspirin. Occasional use of NSAIDs on an as needed or "prn" schedule is not exclusionary.
- Patient with active pathological bleeding (such as peptic ulcer or intracranial hemorrhage).

Randomization Inclusion Criteria (12-months):

- Patient is "12-Month Clear," which is defined as patients enrolled in the study who are free from all death, MI, stroke, repeat coronary revascularization, stent thrombosis and major bleeding (severe or moderate by GUSTO classification) 12 months after stent implantation and who are compliant with 12 months of DAPT following stent implantation. Exceptions to this rule are: Patients who experience repeat PCI and/or peri-procedural myocardial infarction occurring during or within 6 weeks after the index procedure will not be excluded from the definition of 12-Month Clear.

Randomization Exclusion Criteria (12-months):

- Known pregnancy.
- Patient switched from prasugrel to other thienopyridine after discharge from index hospitalization.

LIBERTE'

- Patient switched maintenance dose of prasugrel (such as 10mg to 5mg; or 5mg to 10mg) within 6-months prior to randomization.
- Percutaneous coronary intervention or cardiac surgery between 6 weeks post index procedure and randomization.
- Planned surgery necessitating discontinuation of antiplatelet therapy within the 21 months following randomization.
- Patients on warfarin or similar anticoagulant therapy.
- Current medical condition with life expectancy of less than 3 years.

Status:

Active enrollment

If you have any questions, please feel free to contact the coordinators, and they will be happy to answer any questions you have regarding this study.