

This is a First-in-Man, non-controlled long-term clinical follow-up trial to determine the clinical safety of the Stellium, DISA Vascular's Drug Eluting Stent (DES). The objective of the trial is to obtain comprehensive 30 day, 6 month, 1 year and 2 year clinical follow up data on 100 patients undergoing Percutaneous Coronary Intervention (PCI) with one or two Stellium DES in order to quantify the rate of Major Adverse Coronary Events (MACE) at these various time points.

The trial will enrol 100 patients from 8 hospital sites around South Africa. Male and female patients who are diagnosed with angina pectoris according to the Canadian Cardiovascular Society (CCS) Functional angina rating class II - IV, have resting ECG changes or a positive stress ECG test or other positive functional test and negative Troponin T test at least 6 hours after onset of symptoms will be eligible to participate in the trial. The trial will include patients who require PCI for the treatment of one or two discrete de novo native coronary artery lesion/s and who meet all required inclusion and exclusion criteria, including providing written informed consent.

Patients will attend a screening visit where their eligibility to participate in the trial will be determined. Eligible patients will be scheduled for a PCI. Final inclusion will be dependant on a Quantitative Coronary Angiography (QCA) measurement and whether the available Stellium stent sizes and diameters are appropriate for the lesion or lesions that require/s stenting. Once the Stellium has been implanted, there will be a repeat QCA measurement. All QCA analyses will be performed by an independent core laboratory. The patient will remain in hospital until discharged by the investigator. During the in-hospital visit, the patient will have a resting electrocardiogram (ECG). All patients will be given dual anti-platelet drugs, aspirin and clopidogrel, for 12 months.

The patient will return to the clinic for follow up at months 1, 6, 12 and 24. At each visit, the patient will undergo an ECG; resting ECG at screening, in-hospital and month 1, stress ECG at months 6, 12 and 24, vital signs, a physical examination and a review of adverse events and concomitant medication. There will be telephonic follow ups at months 2, 3, 5 and 9 to review dual anti platelet compliance and adverse events.

Throughout the duration of the study, the occurrence of MACE will be monitored. These safety events will be adjudicated by an independent safety monitoring board. The safety monitoring board will comprise independent cardiologists who have experience in PCI and stenting.

Intra Vascular Ultrasound (IVUS) Sub study

A sub set of at least 20 consenting patients from the trial site/s that has/have the necessary IVUS equipment will participate in the IVUS sub study at month 6. Patients who are eligible will undergo a repeat procedure at 6 months to characterise the degree of vascular healing. Participation in the sub study is voluntary. Participation in the sub study will not affect the patient's participation in the Stellium I trial.

Those patients who consent to participate in the IVUS sub study will undergo a repeat PCI with IVUS at Visit 2. This procedure will be in addition to the procedures for the Stellium I trial. The IVUS data will be analysed by an expert independent core lab.

TIME LINES FOR THE STELLIUM I CLINICAL TRIAL:

MCC Submission	December 2006
Investigator meeting	March/April 2007
MCC Approval	June 2007
Site initiation visits	Sept 2007