



First 1,000 Patients enrolled in Cruz Senior Trial

Release summary

- Rapid enrolment of 1000 patients of the Cruz Senior Study in Europe
- Study aims to evaluate ultra-thin biodegradable polymer Supraflex Cruz Sirolimus-eluting Coronary Stent System in the treatment of Octo- and Nonagenarian (patients above the age of 80 yrs) all-Comer patient

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SMT, an emerging market leading company in Coronary and Structural heart is excited to announce the completion of enrolment of 1000 patients of the Cruz senior study in Europe. Cruz Senior study is a prospective, multi-centre, single-armed, non-interventional observational clinical investigation which is designed to enrol 2500 octo (>80 years) and nonagenarian (>90 years) all-comer patients with coronary artery disease. The study is recruiting patients from 47 centres from Germany, Austria, Switzerland, and France. In connection to this, the Institute for Myocardial Infarction Research (IHF GmbH) recently announced that 1,000 patients have already been enrolled in the Cruz Senior Study.

This rate of rapid enrolment mirrors the commitment of all the investigators towards research and generation of evidence in such complex community of patients. Elderly patients have high chances of additional co-morbidities like low ejection fraction, diabetes, high blood pressure, severe kidney disease, arrhythmia, aortic stenosis etc and these factors make them susceptible to complex coronary issues with challenging anatomies. Treating these anatomies needs substantial experience, outstanding technique, full proof planning and a stent with proven efficacy, safety, and ability to deliver in the most tortuous lesions.

It is very interesting to note that this study is slated to generate answers to several ambiguity encompassing the treatment paradigm of coronary artery disease occurring in patients with age greater than 80 years. Further the inclusion of patient group aged 90 years and above is very unique in its own way as it will give insights that will be novel and unexplored till such times.

Prof. Dr. David M. Leistner from the University Hospital Frankfurt is the Coordinating Investigator of the study said “This study will be a landmark study when it comes to elderly patients, 2500 patient sample size will help us with various analysis in this complex subset of patients and help us evolve the care for such complex patients. I am very happy to see the same enthusiasm in all the participating sites and I appreciate their commitment towards science.” Patients from 4 countries across Europe are participating in this study. Patients who underwent percutaneous coronary intervention (PCI) using at least one [Supraflex Cruz](#) sirolimus-eluting stent as per current practice and will be followed up for 12 months.



Supraflex Cruz stent with its best in-class features of superior deliverability, biodegradable polymers, ultra-thin struts, demonstrated rapid endothelialisation, good pharmacokinetics looks very promising in these subsets of patients treated in cathlabs across Europe

Cruz Senior will be the biggest ongoing registry in Europe which involves all-comer patients (≥ 80 years) affected by acute coronary syndrome (NSTEMI-ACS), stable angina or silent angina. These patients qualify for PCI according to ESC-treatment guidelines and physicians' clinical routine estimation.

Notably, apart from this study there are other complex patient population in which Supraflex Cruz is getting evaluated over 4 Randomised Controlled Trials (RCTs) viz Multivessel, Diabetic Multivessel, High Bleeding Risk patients and other very complex patient pool. However, Cruz Senior trial will provide evidence of Cruz stent being evaluated in the completely unique subset of very senior group of patients.

SMT has given educational grant for the Cruz Senior Study.

About Supraflex Cruz

Cruz design provides physicians an access to difficult and tortuous lesions which were very challenging in their practice. The stent retains all the benefits of the Supraflex stent or the previous "Supra" Family of stents, viz, Ultrathin strut thickness (60 microns for all diameters and lengths), blend of proprietary biodegradable polymers to release the drug, very thin layer of polymers, high radial strength, low crossing profile. The Supraflex Cruz has a very large and extensive size matrix. 1 set consist of 88 skus and covers diameters from 2.0 to 4.5 and lengths from 8 mm to 48 mm. This size matrix ensures that the physician and the patient does not need to make any compromise of accommodating a shorter or a longer stent inside the coronaries.

About SMT

SMT (Sahajanand Medical Technologies Limited) is a global developer and manufacturer of minimally invasive cardiovascular devices including coronary, structural heart and occluders devices. SMT continues to upgrade its product portfolio to cater to the healthcare needs. SMT has a global presence, and it has received recognitions from the Ministry of Health Sciences & Technologies for its contributions in the field of Coronary healthcare. SMT is committed to advance the patient care by introducing quality medical devices to serve patients. SMT has acquired Vascular Concepts Limited in the year 2020.

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