

Fire Trial Shows Positive Results, Presented at ESC Congress 2023

Study Synopsis

- The findings will impact the interventional treatment of elderly patients with MI, steering physicians to physiology-guided complete revascularization.
- Data from 1445 patients across 34 centres from Italy, Spain and Poland were analyzed.

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<u>SMT</u> (Sahajanand Medical Technologies), a leading medical device company in India, focused on innovative patient care in cardiovascular segment, today announced latebreaking data of its stent <u>Supraflex Cruz</u> at the ESC Congress 2023.

The study, conducted across 34 participating sites spanning Italy, Spain, and Poland, was unveiled during the ESC Congress 2023, marking a significant step for Supraflex Cruz in the interventional cardiology space.

Principal Investigator Dr Simone Biscaglia from University Hospital of Ferrara, Italy presented primary endpoint data at one year from this study at the ESC Congress 2023. A total of 1445 older (at least 75 years of age) patients with MI (with or without ST-segment elevation) and multivessel disease were enrolled in this study from July 18, 2019, to October 25, 2021.

The study was an investigator-initiated, multicenter, prospective randomized (1:1) trial, to compare a strategy of physiology-guided complete myocardial revascularization versus a culprit-only strategy.

Speaking more on the trial, Dr Simone Biscaglia said, "Our landmark study published in the prestigious New England Journal of Medicine is an important step forward in interventional cardiology. We were extremely pleased to demonstrate that physiology-guided complete revascularization with implantation of Supraflex Cruz stents led to a highly significant 27% reduction in cardiovascular events."

The primary end point was the patient-oriented composite end point (POCE) of all-cause death, any MI, any stroke, and any revascularization at 1 year. Commenting more on the trial results, Study Chair Dr Gianluca Campo from the University Hospital of Ferrara, Italy said, "The FIRE trial addressed the lack of evidence for a revascularization strategy beyond culprit lesion treatment in older patients with a mean age of 81 years, with MI and multivessel disease. We proved our hypothesis that complete



revascularization with Supraflex Cruz, guided by coronary physiology, yielded superior results to a culprit lesion only strategy in these patients."

Chief Medical Officer at SMT, Dr Krishna Sudhir commented, "This trial is a game changer for the treatment of elderly patients with MI. At SMT we are delighted that Supraflex Cruz was chosen as the stent in the study and showed excellent results with low event rates in an extremely high risk group of patients, optimally treated with physiology-guided complete revascularization."

While complete revascularization is well documented in younger MI patients, its applicability and advantages in older patients with MI who are prone to having a higher risk of complications has been uncertain until this trial. The findings will influence the interventional treatment of elderly patients with MI, driving physicians to optimally treat with complete revascularization guided by physiology.

About SMT

SMT is a global medical device company committed to make advanced medical technologies accessible to everyone around the world. With presence in 79 countries, SMT has achieved recognitions from the Ministry of Health Sciences & Technologies for its tremendous contributions in the field of coronary healthcare. SMT also pioneered the introduction of biodegradable polymers in the cardiovascular segment. SMT will continue the journey to heal hearts around the world by creating healthcare future promising for everyone.

About Supraflex Cruz

The Cruz design provides physicians access to difficult and tortuous lesions which are very challenging in their practice. The stent retains all the benefits of Supraflex stents or the previous "Supra" family of stents, viz, thin struts, a blend of proprietary biodegradable polymers to release the drug, high radial strength, and low crossing profile. Supraflex Cruz has a very large and extensive size matrix, covering diameters from 2.0 to 4.5 and lengths from 8 mm to 48 mm. This size matrix ensures no compromises in the coronaries for either physician or patient.

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