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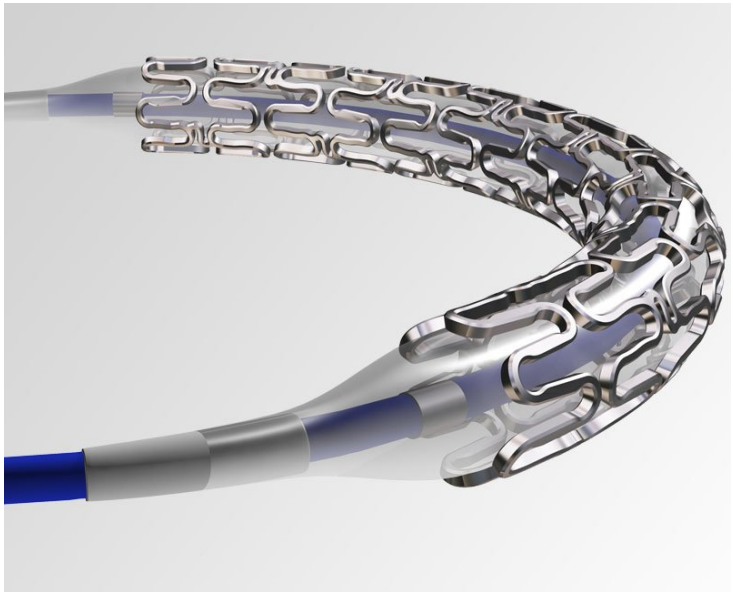
Made in India Supraflex stent clinically at par with global standards

24 September 2018 | News

The findings of the TALENT trial presented at the Transcatheter Cardiovascular Therapeutics 2018 (TCT) conference in San Diego, USA establishes India's largest stent manufacturer SMT's Supraflex stent clinically at par with Abbott's Xience family, with a numerically better outcome.



Supraflex, a cardiac drug eluting stent designed and manufactured in India has been confirmed to be at par with Abbott's Xience through an investigators-driven study called 'TALENT'. **Dr Patrick Serruys** a globally renowned cardiology researcher was the chair for the TALENT trial. The findings of the TALENT trial were presented at the 'late breaking trial session' at Transcatheter Cardiovascular Therapeutics 2018 (TCT), the largest global conference of cardiologist currently underway in San Diego, USA. This study was conducted in 7 countries - United Kingdom, Netherlands, Poland, Spain, Italy, Hungary and Bulgaria - across 23 renowned centres with a sample size of 1435 patients. Xience is regarded as global standard in safety and efficacy for drug eluting stents.

Over 5,00,000 stents are used in India every year. A cardiac stent is a device used to unblock clogged arteries. Drug eluting stents are coated with medicines that help lower recurrence chances of an artery narrowing after corrective surgery.

Presenting the findings of TALENT trial, **Dr Patrick Serruys**, said, "Safety and efficacy of Supraflex SES with ultra thin struts and biodegradable polymer were compared with Xience EES in all comers-population. Supraflex was found to be non-inferior to the Xience for DOCE (device oriented end points) at 12 months in an all comer-population* with a lower rate of CI-TLR** in the per protocol analysis."

Padma Shri **Dr Upendra Kaul,** one of the leading cardiologist from India was the co-chair of the TALENT Study. Commenting on the study, **Dr Kaul** said, "There remained a perception that stents produced outside of India were superior to homegrown devices. There were demands from Indian manufacturers to prove that their devices are comparable to those made elsewhere in robust clinical trials. TALENT is the first such trial to yield positive results and stands out with a far better

efficacy compared to the competitors."

Prof. R. de Winter, MD, Academisch Medisch Centrum, Amsterdam, The Netherlands; and A. Zaman, MD, Cardiac Catheter Laboratories, Royal Freeman, Newcastle, UK, were the Principal Investigators for the TALENT trial.

The TALENT trial included mean patient age of 65 years, and about three-quarters were men, with about 40% of patients presenting with stable angina and 60% with Acute Coronary Syndromes (ACS). The rate of a device-oriented composite endpoint of cardiac death, target-vessel MI, and clinically indicated TLR at 12 months was 4.9% with Supraflex and 5.3% with Xience, a difference that met criteria for non-inferiority (P< 0.001).

In a per protocol analysis Supraflex had better efficacy as compared to Xience. The rate of clinically driven re procedure rate was 1.2% vs 3.1% which was also statistically significant. The lower the re procedure rate the better it is.

Supraflex is available in 65 countries across the world and is the largest selling drug eluting stent of SMT (Sahajanand Medical Technologies), India's largest stent manufacturer. Supraflex has advanced features like biodegradable polymer and ultrathin strut* (60µm) thickness compared to 81 µm strut thickness and biostable polymer coating of Xience. The TALENT clinical study results matches with the published meta-analysis, highlighting benefits of lower strut thickness.

Mr Ganesh Sabat CEO, SMT said, "The result of the TALENT study is significant for the coronary stent industry. The success of this study resonates well with make in India. We are proud to establish India name in such a complicated and high end life-saving technology industry. We now have strong credentials to achieve our dream of becoming a leading global player in coronary stent industry."