



SMT receives National reimbursement for Supraflex Cruz heart stent in France to treat people with coronary heart disease

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SMT (Sahajanand Medical Technologies Pvt Ltd), the Indian market leader in coronary heart stent announced that it has received the full reimbursement confirmation for its Supraflex and Supraflex Cruz from the Ministry of Health and Public Affairs of France (*Le ministre des solidarités et de la santé*). Both the products have received price approval at par with the other advanced drug eluting stents in the world.

France government appointed committee (*CNEDiMTS*) conducts a rigorous scientific review process for reimbursement. During this two-step process, the clinical data of the product is evaluated rigorously for the safety and its applicability to the population of France. This approval is based on the positive clinical data from the Talent All-Comers trial, a prospective, multi-center, randomized controlled clinical trial consisting of entirely European-based patients with ischemic coronary artery disease. The result was published in the world leading medical journal the Lancet. This is the first time that clinical data from an Indian manufactured drug eluting stent has been published in the Lancet.

“We have been honored and happy to be the first center to implant the new ultrathin (60 microns) Supraflex Cruz coronary stent in France recently. The initial experience with Cruz has been good with 100% procedure success. We have tested it in 20 patients, some were complex tortuous lesions and we found the product at par with others with excellent deliverability. The stent was challenged with lot of direct stenting with very promising performance even with long stents (48 mm in a RCA). The stents implantation and deployment were easy and perfectly apposed without any recoil or foreshortening. This new technology is a good addition for the French physicians and patients will benefit with the latest technology now getting available, approved, and reimbursed by the French health authority. I am very happy to have the first stent coming from India in France as I personally often visited and liked this country very much. We are looking forward to adapting this technology in a major way going forward.” Said Dr Marc Silvestri, Interventional cardiologist from *Aix en Provence-France*.

Adding more on the new development SMTs VP of Regulatory Projects, Ammad Shorabji said, “We are happy to receive the approval from the French authorities. Success of Supraflex and Supraflex Cruz reimbursement is the validation of robustness of the quality standards and the clinical data of SMT products which are at par with the global standards.”

“Our 20 years of experience and more than one million stent implants worldwide will provide the French physicians lots of confidence. The stent has unmatched capability in deliverability and trackability. Since its launch in Europe one year back, we have received overwhelming response. We look forward to saving more lives in France by enabling access to arteries and



lesions which were difficult to access in the past.,” said Gaurav Goel, Head of Western Europe at SMT.

This announcement was made public and appeared in France’s **Title III of the reimbursable products and services list (LPPR)**. SMT has also done an acquisition of Vascular Concepts Ltd recently to enter the structural heart space.

*Supraflex Cruz is a trademark of Sahajanand Medical Technologies Pvt. Ltd. or its affiliates. Specifications are subject to modification, revision and improvement.

*The CE Mark indicates that the product satisfies requirements of EU Directives (EU : The European Union) and all products need to be CE certified to be sold in Europe.

About SMT (Sahajanand Medical Technologies)

SMT is a global medical device company committed to making advance medical technologies accessible to everyone around the world. With a presence in over 75 countries, SMT has achieved recognition from the Government of India for its tremendous contributions in the field of Cardiovascular healthcare. SMT has also led the development of innovative biodegradable polymer coating technology in coronary stent system. SMT will continue the journey to healing hearts around the world by creating a healthcare future promising for everyone.

About HAS (Haute Autorité de Santé)

HAS is tasked with the evaluation of health products from a medical and economic perspective. It issues appraisal recommendations that aid public authorities in reimbursement and pricing decision-making with regards to the national health fund. HAS evaluates the clinical benefit of drugs, medical devices, procedures, and other health technologies, assessing added benefit over existing therapeutic strategies.

When innovation is claimed and potentially associated with a significant impact on health spending, health products and technologies are required to undergo a health economic evaluation. HAS offers early dialogues on evidence generation plans for new pharmaceuticals, medical device, or diagnostic/interventional procedure. The objective of these early dialogues (ED) is to provide companies with recommendations on the last development phase (pivotal study/studies) and support generation of good quality evidence for proper Health Technology Assessment (HTA). (Source: https://www.has-sante.fr/jcms/c_415958/en/about)

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