

Mission: Indigenous drug-eluting stent

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The SBIRI funding boosted the efforts of Relisys Medical Devices to develop an improved version of drug-eluting stent that is helpful in preventing fibrosis

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Hyderabad-based Relisys Medical Devices has developed an advanced version of its drug-eluting stent (DES). The previous

version was designed to eliminate the drawbacks of the currently available polymer-coated drug-eluting stent. DES is a coronary stent (a scaffold) placed into narrowed, diseased coronary arteries that slowly releases a drug to block cell

proliferation. This prevents fibrosis that, together with clots (thrombus), could otherwise block the stented artery, a process called restenosis.

The government funding from the Small Business Innovation Research Initiative (SBIRI) came as a boost to the research activities at Relisys. Prior to the fund allocation, stents were manufactured on contract basis in Europe and there was inconsistency in the quality.

The company achieved a new milestone when its new cardiac stent manufacturing facility was inaugurated by the former President of India, Dr APJ Abdul Kalam, in 2007, in Hyderabad. This stent is indeed a highly-competitive product for a great societal mission.

Equipped with an in-house laser processing facility, Relisys manufactures stents with consistent quality and better mechanical properties. This resulted in better coating quality and predictable drug release kinetics. With the better quality control equipments like SEM/ measurement microscopes, the ramp up time from R&D to pilot scale and pilot scale to production was minimized. This enabled the company to launch the base stents quickly in the market.

Industry Impact

The indigenous manufacturing of the product has provided better option for the patients. Relisys' new DES consists of a Cobalt-Chromium (CoCr) stent, coated with a porous carbon/carbon composite nano-structured matrix containing the active drug. DES sold under the brand name, COREL+C, is based on inorganic carbon coating where drug particles are homogeneously distributed inside the matrix. The coating is designed to maximum elasticity and its hardness exceeds stainless steel in terms of abrasion and scratch resistance, eliminating flaking, de-lamination or particle release. The advantages of DES are its low inflammation score, low fibrins score, 100 percent drug release, enhanced endothelialization, CoCr platform for better trackability and crossability and high radial strength.

Way Forward

With the success of this PPP initiative, an advanced DES is now available in the market at an affordable price. The company will price this product at around \$1,200 (₹55,000), which is 50 percent lesser than the market price of DES. The overall reduction in foreign exchange outflow would be around \$11 million (₹50 crore) during the life span of the product. So far, the bare metal stent that was used as the base for the DES has been commercialized. DES is expected to be commercialized by the end of 2011.

Rahul Koul in New Delhi