

S3V Vascular Technologies launches Nextgen Hydrophilic Coated PTCA Balloon Catheter

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S3V initiates CE certification for Nextgen Nickel Cobalt Free Drug Eluting Stent, the first of its kind in the world.



Bangalore-based S3V Vascular Technologies Private Limited, a medical devices manufacturing company launched Nextgen PTCA (Percutaneous Transluminal Coronary Angioplasty) Balloon Catheters into the domestic market.

PTCA in layman's language is a minimally invasive procedure to open up blocked coronary arteries, allowing blood to circulate unobstructed to the heart muscle.

Talking about the S3V, medical devices market, Dr. Bindu Dey, Secretary, Technology Development Board, Ministry of Science & Technology, Government of India said, "We were good on pharma, diagnostics, but on devices front, we lag way behind. 75 percent of medical devices used in treatment of cardiovascular treatment are imported." She further said, "By the year 2025, the medical device market would grow to USD 50 billion and that Indian companies must take advantage of it."

The newly introduced device "Nextgen PTCA Balloon Catheters", according to Mr. Badari Narayan, Managing Director is the futuristic product with a future full of promises.

"Currently, these medical devices are imported at high cost. We will be shortly launching these products phase wise after obtaining necessary regulatory approvals," informed Badari Narayan.

The advantages of this are manifold such as improved trackability, pushability, low profile and higher burst pressure. It will assist to succeed even in complex anatomies due to enhanced lubricity.

The new PTCA Balloon Catheter manufacturing facility set up at Hootgalli Industrial Area, Mysore-Karnataka was just inaugurated by Padmashri Dr. C.N.Manjunath, Director, Sri Jayadeva Institute of Cardiovascular Sciences & Research, Bangalore.

Dr. Bindu Dey, Secretary, Technology Development Board, Ministry of Science & Technology, Government of India inaugurated The Hydrophilic Coating Division. This Division is capable of coating products of lengths up to 200cm. Dr. Bindu Dey and Sri T. Suneel Kumar, IPS, Commissioner of Police, Bangalore launched the Nextgen PTCA Balloon Catheters.

The state-of-the-art integrated manufacturing facility will develop futuristic medical devices and is being set up with an Investment of Rs 70 Crore.

S3V Vascular Technologies is founded by a group of enticing and thought-provoking alumni of the Indian School of Business, Hyderabad who were classmates of the founding batch of PGPMAX (Post Graduate Program in Management for Senior Executives), program of ISB which was started in the year 2010.

Disclosing more on the present medical device industry in India, Mr. Badari Narayan opined, "India has a huge potential for advanced medical device products in the country. At present, about 90 percent medical devices are being imported from other countries. The Indian medical devices market is huge. It is expected to be US \$ 8.6 billion in next two years. And industry experts say it has even greater potential to grow to US \$ 59 billion by the year 2025. The market is expected to grow 15 to 20 per cent annually, which is much higher than the global industry of 5 to 7 percent."

India with 1.3 billion population, will reach a situation by the year 2025, one million cardiovascular procedures will be done every year. The Cardiovascular disease burden, which is already high, is going to be even higher. If local entrepreneurs are encouraged by the state and central governments, India can become a leading player in the world with its existing talent pool and low manufacturing costs.

There are two major challenges to MAKE IN INDIA for class III medical devices. The first challenge is to manufacture high-quality Medical Devices at affordable prices to attract outsource of manufacturing to India. The solution for this is to set up integrated manufacturing plants. The second challenge is the regulatory brand perspective wherein MAKE IN INDIA products need to compete with globally manufactured USFDA approved products. The solution for this is that even MAKE IN INDIA products should have the highest regulatory approvals like USFDA approval or CE certification

Technology Development Board (TDB), Ministry of Science & Technology, Government of India entered into an agreement with S3V Vascular Technologies Pvt. Ltd. Under this agreement, TDB has provided financial assistance to S3V Vascular Technologies to set up an Integrated PTCA Balloon Catheter manufacturing plant and for USFDA (510 K) approval of Percutaneous Transluminal Coronary Angioplasty (PTCA) Balloon Catheter. This was done under Make in India program and to make project for Medical Devices a success.

Subsequently, S3V has entered into a non-exclusive global License and Supply Agreement with DSM Biomedical, a global solutions provider in biomedical science and regenerative medicine, for integration of their hydrophilic coating. The material master file of this coating is available with all regulatory bodies including the USFDA. Many medical devices using these coatings have received FDA approval and CE marking. The Technology Transfer from DSM Biomedical is currently being implemented.

Royal DSM is a purpose-led global science-based company in Nutrition, Health and Sustainable Living. DSM and its associated companies deliver annual net sales of about €10 billion with approximately 23,000 employees. The company is listed on Euronext Amsterdam.

S3V will be using this technology for coating Angioplasty Catheters i.e. PTCA Balloon Catheters, PTCA Guide Catheters, Intracranial Micro-catheters, Introducer Sheaths, CVC Catheters and Guide Wires, informed Badari Narayan.

Adding further, Badari Narayan said, "We are in the stage of commercialization of Current Generation Drug Eluting Stent (DES). We have initiated CE certification for the Innovative Nextgen Nickel Cobalt Free Drug Eluting Stent which will be the first of its kind in the world."

CE Certification is a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area.

"We will soon initiate animal trials for resorbable Metallic Vascular Scaffold," informed Badari Narayan.

The other products on the anvil to launch include Arterial Sheath, Coated CVC Catheters and Urology Catheters, added Badari Narayan.