



S3V Vascular Technologies launches Nextgen Hydrophilic Coated PTCA Balloon Catheter

Bengaluru, August 7, 2018. Mysore based S3V Vascular Technologies Private Limited, a medical devices manufacturing company launched Nextgen PTCA (Percutaneous Transluminal Coronary Angioplasty) Balloon Catheters into domestic market.

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

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 by virtue of hydrophilic coating.

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. The Nextgen PTCA balloon Catheters were also launched by Dr. Bindu Dey and Sri. T. Suneel Kumar, IPS, Commissioner of Police, Bangalore.

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

Disclosing more on the present medical device industry in India, Dr Bindu Dey opined that India has a huge potential for advanced medical device products in the country. At present about 90 per cent medical devices are being imported from other countries. 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 of **Rs 13.03 crore** 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 technology at S3V. 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.

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.

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, said Mr Badari Narayan

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 Drug Eluting Stent, informed Badari Narayan.

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

After inaugurating the Hydrophilic coating division at S3V, Dr Bindu Dey congratulated the young S3V team. As a policy maker she pointed that TDB has already funded Pharma and Bio-technology sector and is now encouraging Med-tech industry that is in its nascent stage and has to be built bit by bit to build the ecosystem. She pointed that by 2025 the Indian Med-tech industry will be close to 6 to 8 billion dollars and that so much money is going out of the country due to the import of these devices and there was a need to build the device industry in India.

