

SMT receives India Pharma 2022 Award for DCB 'Peripherics'

5th December 2022, New Delhi, India

SMT wins India Pharma award for excellence in R&D for the development of *Peripherics'* a new-age inhouse developed Paclitaxel Drug Coated PTA Balloon. The award was given at 15th edition of E&Y powered India Pharma 2022 award at CPHI and PMEC conference in New Delhi.

Today, ever-increasing lifestyle related diseases and its related complications in cardiovascular and peripheral diseases have given rise to the treatment of restenotic lesions, small vessels, and in patients at high-bleeding risk, where the prolonged dual antiplatelet regimen should be avoided.

SMT has launched an innovative Paclitaxel Drug Eluting Balloon – Peripherics, to achieve long-term patency without leaving an implant behind to increase durable treatment options available to clinicians for in-stent restenosis and peripheral vascular disease.

Abhijeet Singhavi, Senior VP, R&D team says, "SMT has been at the forefront of innovative drug coated devices in the cardiovascular space by virtue of the domain expertise of its R&D team. Peripherics Paclitaxel drug coated balloon aimed at treating lesions in SFA and BTK is a unique culmination of hybrid excipients and paclitaxel drug, designed to maximize drug transfer and retention while ensuring efficacy and patient safety. SMT is committed to bringing innovations in the drug coated balloon arena, Peripherics is the beginning of this journey."

Speaking more about the product, R&D, Asst. Vice President Ankur Raval explains, "The "Hybrid X2" coating technology in Peripherics PTA drug coated balloon (DCB) catheter combines the best of the drug and excipient properties. Drug in both amorphous and crystalline form along with the combination of hydrophilic and lipophilic excipients provides the ideal functional requirements of DCB. Peripherics DCB is formulated to minimize the drug loss during treatment procedure, transfer maximum amount of drug within short treatment time and sustaining the drug tissue levels for longer time duration. Peripherics DCB thus ensures optimum patient safety and drug efficacy. "

Drug Coated Balloons (DCB) are semi-compliant angioplasty balloons covered with an antiproliferative drug that is rapidly released upon contact with the vessel wall. Currently DCBs which are available in the market face challenges of transferring effective therapeutic drug amount within short contact time to vessel wall. Maintaining prolonged drug concentration in arterial tissue within therapeutic range is another major limitation of available DCBs which limits the device efficacy. Such less efficacious therapeutic amount of drug and pharmacokinetic profile doesn't suffice to prevent smooth muscle cell proliferation for longer period. Considering the Indian population, who have small vessels compared to US or European population, SMT has developed the DCB which has addressed limitations of current generation DCBs, which help percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo or restenotic lesions in native infrapopliteal arteries, popliteal arteries (superficial femoral) and below to knee (BTK) arteries.

Peripherics is designed to transfer 70% of the drug in the vessel while minimizing the downstream particulate coating loss. The 2-week *in vivo* pharmacokinetics study confirms the tissue drug residence above the minimum inhibitory concentration ensuring the long-term effectiveness of the device.

Potential advantages of SMT's DCB technology include:

- 1. Homogenous drug transfer to the entire vessel wall
- 2. Short term transfer of antiproliferative drug sustained in the vessel wall
- 3. Absence of polymer helps in decreasing chronic inflammation and the trigger for late thrombosis

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4. Absence of a stent allows the artery's original anatomy to remain intact

SMT has always been at the forefront to develop cutting edge technology and innovative products considering patient safety. SMT's research & development efforts are directed to deliver innovative medical devices that aid wide treatment options with affordability.

About SMT

Sahajanand Medical Technologies Ltd is a leading medical devices company that researches, designs, develops, manufacturers and markets vascular devices globally. SMT has the leading market share in the drug eluting stent ("DES") market in India, with a market share of 31% as of March 31st, 2021 of the total DES sales volume in India. SMT is also among the top five companies in terms of market share (by sales volume of DES) in each of Germany, Netherlands, Italy and Poland, as of March 31, 2021 (Frost & Sullivan). SMT has a sales presence in more than 69 countries including direct presence in 10 countries such as Germany, Poland, Spain, France, UK and Brazil. SMT offers products that are used in: (i) interventional cardiology, i.e., devices used for the treatment of blockages in heart vessels (coronary artery disease), such as coronary stents and catheters; (ii) structural heart therapy, i.e., devices used for treatment of abnormalities in the tissues, walls, and valves of the heart, such as transcatheter aortic valve implants ("TAVI") and occluders; and (iii) peripheral intervention, i.e., devices used for treatment of blockages in the blood vessels other than those of the heart, such as renal stents.

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