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US hearts to be treated by made-in-India Sirolimus coated balloon

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India based Concept Medical receives worldâ??s first IDE approval from the US FDA



Concept Medical has announced receiving US Food and Drug Administration (FDA)’s Investigational Device Exemption (IDE) approval for the world’s first & made in India Sirolimus coated balloon- MagicTouch for coronary artery diseases.

The Indian company has developed the world's first Sirolimus-drug Coated Balloon (SCB) and now has IDE approval for the device. US FDA's IDE approval allows the investigational device to be used in a clinical study to prove the safety and effectiveness of the device.

These clinical studies are conducted to support a pre-marketing authorization (PMA) by the USFDA. As of today, no company has IDE approval for a Drug-Coated Balloon in the USA.

US currently follows conventional percutaneous coronary intervention (PCI), which uses stents, and since the newer generation of interventionalists and modern-day PCI are leaning towards Drug-Coated Balloons, considering neither the operator nor the patient would prefer having a permanent metal implant, this moment will be a gamechanger for the fraternity as well as for the company.

Surat-based Concept Medical raised funds for the IDE in 2018, and the SCB has so far received two breakthrough device designations and the IDE title to add to it. The IDE approval has been granted for In-Stent Restenosis (ISR), which will help the company to study the device in this indication in the US population.

Concept Medical's MagicTouch SCB is currently the most clinically studied SCB, with more than 7000 patients. Concept Medical has also designed two clinical studies which will soon start enrolling patients in the USA, apart from the already submitted strong pre-clinical and clinical evidence from multiple studies to the FDA.