

Concept Medical Inc. Granted 'Breakthrough Device Designation' From the FDA for Its MagicTouch AVF Sirolimus Coated Balloon

Concept Medical Inc. (CMI) has been granted "Breakthrough Device Designation" from the U.S. Food and Drug Administration (FDA) for MagicTouch AVF, its Sirolimus drug-coated balloon (DCB) catheter, for the treatment of stenotic lesions of Arteriovenous Fistulae or Arteriovenous graft in hemodialysis treatment of renal failure.

TAMPA, Fla., August 29, 2019 (Newswire.com) - The FDA received Concept Medical Inc. (CMI) request to designate MagicTouch AVF as a Breakthrough Device in July 2019. The proposed indications for the Breakthrough Device Designation for "The MagicTouch Sirolimus Coated Balloon Catheter is indicated for use in percutaneous transluminal angioplasty (PTA), after appropriate vessel preparation for treatment of stenotic lesions of dysfunctional native arteriovenous dialysis fistula or graft with 4 mm to 12 mm diameter and up to 100 mm in length." CMI on Aug. 28 was informed by the FDA that "your combination product and proposed indication for use meet the criteria and have been granted designation as a Breakthrough Device".

The logo for Concept Medical, featuring the company name in white serif font on a dark blue square background.

Hemodialysis is a procedure used to manage kidney failure, using a machine to send the patient's blood through a filter, called a dialyzer, outside of the body. The procedure requires access to blood vessels, which is surgically created to gain entry into a blood vessel ("vascular access"), usually in the forearm.

Two types of vascular access designed for long-term use include the arteriovenous fistula (AVF) and the arteriovenous graft (AVG).

- An arteriovenous fistula (AVF) is a connection created surgically (also called as a native fistula) between an artery and a vein so as to expand the bore of the vein. An AV fistula causes extra pressure and extra blood to flow into the vein, making it grow large and strong (maturing of the AVF). The larger vein provides easy, reliable access to blood vessels. Without this kind of access, regular hemodialysis sessions would not be possible. Untreated veins cannot withstand repeated needle insertions, because they would collapse the way a straw collapses under strong suction.

- Arteriovenous graft (AVG), is another method for connecting an artery and a vein and is made by surgically suturing an external tube, made of a biomaterial, between the two vessels.

Common complications of AVF and AVG are infection, stenosis of the fistula, thrombosis, aneurysm, and limb ischemia. PTA tackles the complications of AVF and AVG.

PTA is a procedure that can open a blocked blood vessel using a small catheter, with a "balloon" at one end. Current technology uses drug delivery devices to deliver drugs that inhibit the inflammatory and proliferative pathways that lead to restenosis. Sirolimus is widely accepted as a drug of choice for such purpose.

[Concept Medical Inc.](#) has pioneered the development of Sirolimus delivery platform technology used in Magic Touch AVF balloons for the treatment of stenotic lesions in AVF and AVG.

The world's first pilot study to investigate the safety and efficacy of [Magic Touch PTA](#) Sirolimus balloon in vascular access interventions was started in Singapore in 2018. Led by Principal Investigator, Dr. Tan Chieh Suai, a multi-disciplinary team of doctors consisting of interventional nephrologists, vascular surgeons and interventional radiologists, is conducting the study entitled "Sirolimus coated angioplasty balloon in the salvage of thrombosed arteriovenous graft" in Singapore General Hospital.

In response to the breakthrough designation for [Magic Touch AVF](#), Adjunct Assistant Professor Tan Chieh Suai, Senior Consultant and Director for the Interventional Nephrology Program in the Department of Renal Medicine in Singapore General Hospital and Duke-NUS Medical School, said, "The award of the breakthrough Device Designation for the use of sirolimus coated balloons in dialysis access is fantastic news for patients on hemodialysis, as there is an urgent need for effective and durable treatment for narrowing (stenosis) within the dialysis circuit. We are very encouraged by the early results of our pilot study in Singapore and grateful to all patients who had participated in the study. In particular, I am most touched by feedback given by one of the patients: 'So far so good. This new study helped me a lot, saved me from repeated procedures in which I used to need intervention every three months; Now, I can have more time at home, rather than in a hospital.' We look forward to the launch of a larger multi-center randomized study to confirm our results."

Dr. Tjun Yip Tang, Associate Professor and Consultant Vascular and Endovascular Surgeon, Singapore General Hospital, Singapore has highly appreciated the success of Concept Medical Inc. and said, "We are still in the early stage in the clinical study of drug-coated balloons for hemodialysis access patients. The Paclitaxel -based technology study results have certainly been encouraging, but more research is required to determine if other devices may prove to be more effective or uniquely beneficial for specific anatomical or clinical subtype presentations. Our preliminary data using the [Magic Touch](#) sirolimus coated balloon (SCB) at the graft-vein junction of blocked AV grafts, and within native AV fistulas, have been promising to date, with an excellent safety profile and patient acceptability. Technical and procedural success has been 100%. We have yet to repeat intervention in those who have had SCB elution to their native fistula, but the follow-up is still early, but we are

highly encouraged by this initial pilot data.”

The breakthrough device designation granted to [Magic Touch AVF](#) offers [Concept Medical Inc.](#) an opportunity to interact with the FDA’s experts. Under the program, FDA will provide CMI with priority review and interactive communication regarding device development and clinical trial protocols through to commercialization decisions.

Additional **Links**

- [Website](#)
- [MagicTouch AVF](#)

Additional **Images**

