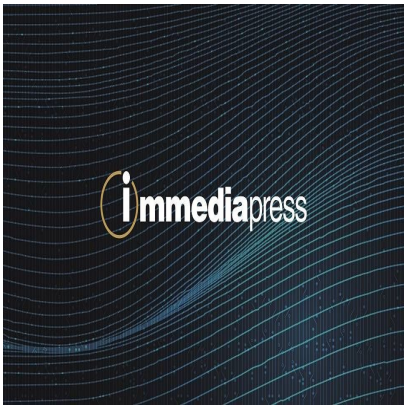


SIRONA 3-Year Results: Sirolimus-Coated Balloon Shows Higher Freedom From Repeat Revascularization Than Paclitaxel-Coated Balloons in Femoropopliteal Disease

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Descrizione

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

Late-breaking data presented at TCT 2026 and published simultaneously in JACC: Cardiovascular Interventions show durable benefit with MagicTouch PTA, with similar walking capacity, quality of life and safety in both groups

TAMPA, Fla., Nov. 3, 2026 /PRNewswire/ â?? Three-year results from the randomized SIRONA trial show that patients with femoropopliteal artery disease treated with the MagicTouch PTA (Concept Medical) sirolimus-coated balloon (SCB) were more often free from clinically driven target lesion revascularization (cdTLR) than those treated with paclitaxel-coated balloons (PCB). There were no between-group differences in walking capacity, quality of life or clinical safety.

Principal Investigator Prof. Ulf TeichgrÃ¤ber, Jena University Hospital, Germany, presented the results as a late-breaking clinical science presentation at TCT 2026, with simultaneous publication in JACC: Cardiovascular Interventions. It is the first randomized comparison of the two technologies to report beyond two years.

SIRONA is an investigator-initiated, multicenter randomized trial at 25 centers in Germany and Austria. A total of 482 patients with symptomatic femoropopliteal disease (96.3% with intermittent claudication) were randomized 1:1 to SCB or PCB angioplasty after successful lesion predilation. It previously met its 12-month non-inferiority primary endpoints for patency and safety.

At three years, freedom from cdTLR was 88.2% with SCB and 80.2% with PCB, an absolute difference of 8.0 points (95% CI 1.0â??14.8; P=0.01; hazard ratio 0.60, 95% CI 0.36â??0.97; log-rank P=0.03). Curves separated after year one.

Patient-reported walking distance and quality of life improved in both groups and were sustained through three years, with no between-group differences. Safety outcomes were similar: all-cause mortality was 7.4% in both groups (HR 1.16, 95% CI 0.59â??2.28), major amputation was rare (one vs two patients), and amputation-free survival was 92.1% with SCB and 92.2% with PCB. Freedom from clinically driven target vessel revascularization did not differ significantly (83.8% vs 79.1%; P=0.27).

The findings come amid renewed scrutiny of paclitaxel-coated devices after the SWEDEPAD 2 trial, which led the 2026 European Society for Vascular Surgery guideline update to recommend a more cautious approach to their use in claudication.

As SIRONA was powered for its 12-month endpoints, the investigators noted that three-year analyses are exploratory and the cdTLR finding requires confirmation. Follow-up will continue to five years.

Prof. Ulf TeichgrÃ¤ber, Principal Investigator, said: â??Patients in both groups did well; those treated with the sirolimus-coated balloon needed fewer repeat procedures at the target lesion, with the difference emerging after the first year. Five-year follow-up will tell us whether this benefit holds.â?•

Dr. Manish Doshi, Founder and Managing Director, Concept Medical, added: â??We thank the SIRONA investigators and patients. These results add to the randomized evidence for MagicTouch PTA which is more validation of product and technology and we remain committed to rigorous long-term data for sirolimus-coated balloons in peripheral artery diseaseâ?•

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Source: SIRONA randomized controlled trial (NCT04475783), presented as a late-breaking clinical science presentation at TCT 2026 by Prof. Ulf TeichgrÃ¤ber on November 2, 2026, and simultaneously published in JACC: Cardiovascular Interventions (DOI: 10.1016/j.jcin.2026.10.020). The trial was funded by Concept Medical Inc., which had no role in data analysis, interpretation, or manuscript preparation.

About MagicTouch PTA

MagicTouch PTA, developed by Concept Medical Inc., uses proprietary NanolutÃ© technology to deliver sub-micron particles of sirolimus encapsulated in a biocompatible carrier, ensuring deep penetration into the vessel wall. The device has received CE Mark approval in Europe and Breakthrough Device Designation from the U.S. FDA for the treatment of below-the-knee disease, as well as IDE approvals for both SFA and BTK treatment with ongoing trials.

About Concept Medical Inc.

Concept Medical Inc., headquartered in Tampa, Florida, has a global presence and is dedicated to enhancing patient care through cutting-edge research and development of drug-delivery technologies. Its proprietary platforms are designed to deliver pharmaceutical agents across vascular luminal surfaces with unparalleled precision. Concept Medical is the developer of the MagicTouch family of sirolimus-coated balloons (SCB) â?? the worldâ??s first and most utilized SCB technology â?? well recognized for its versatility and efficacy in treating coronary and peripheral artery disease. The MagicTouch and Abluminus product lines have been used to treat over a million patients globally.

For more information, please visit www.conceptmedical.com.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device. Product availability is subject to regulatory approval in respective countries. MagicTouch PTA is an investigational device in the United States and is approved for use in clinical trials only.

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