



CONCEPT MEDICAL ANNOUNCES PRELIMINARY 3-YEAR SIRONA DATA AT CHARING CROSS SYMPOSIUM 2026

Descrizione

COMUNICATO STAMPA - CONTENUTO PROMOZIONALE

LONDON, April 27, 2026 /PRNewswire/ - Concept Medical Inc., today announced the presentation of preliminary 3-year follow-up data from the SIRONA randomised trial at the Charing Cross (CX) Symposium 2026, reinforcing its leadership in drug-delivery technologies for peripheral interventions.

The data were presented by Principal Investigator Prof. Ulf Teichgraber during a podium first session on 3-year results from the SIRONA randomised trial.

SIRONA is a randomised controlled trial evaluating sirolimus-coated versus paclitaxel-coated balloon angioplasty in femoropopliteal artery disease, designed to generate robust head-to-head comparative evidence in a field historically dominated by paclitaxel-based therapies. Previously in JACC published 12-month results demonstrated non-inferiority across the trial's primary efficacy and safety endpoints.

In the current 3-year analysis, MagicTouch PTA, a sirolimus-coated balloon, showed higher freedom from clinically driven target lesion revascularization (cdTLR) compared with the paclitaxel-coated balloon group (88.2% vs 80.2%; HR 0.60; 95% CI 0.36-0.97; log-rank $p=0.03$). The results are pending Clinical Events Committee (CEC) adjudication. Taken together, these preliminary findings suggest that sirolimus-coated balloon angioplasty may provide more durable long-term outcomes than paclitaxel-coated balloon angioplasty.

At 3 years, Freedom of all-cause mortality remained comparable between treatment groups (92.6% vs 92.6%; HR 1.12; $p=0.67$), supporting a balanced long-term safety profile. Rates of Freedom of major amputation were low, with no statistically significant difference observed between groups (99.6% vs 99.6%; HR 0.54; $p=0.61$).

Prof. Ulf Teichgraber, Principal Investigator, said, "The preliminary 3-year SIRONA data are very exciting. Seeing a sustained reduced reduction in cdTLR with MagicTouch PTA over such a long follow-

up period is highly encouraging and speaks to the durability of sirolimus-based drug delivery in femoropopliteal interventions. These findings add important long-term randomized evidence to the field and, pending final CEC adjudication, represent a very promising signal for the future role of sirolimus-coated balloons in peripheral artery disease. Importantly, these findings should not be interpreted as a class effect, but rather highlight the need to evaluate individual sirolimus-coated balloon technologies based on robust clinical evidence.â?•

Dr Manish Doshi, Founder and Managing Director, Concept Medical, added, â??For us, SIRONA represents the discipline of long-term clinical science, going beyond early outcomes to truly understand durability. These 3-year findings continue to strengthen the comparative evidence for sirolimus-coated balloon therapy. As we scale globally, our focus remains on generating high-quality, long-term data that clinicians can rely on with confidence.â?•

About Concept Medical

Concept Medical Inc. is a global pioneer in drug-delivery technologies for vascular interventions. The company is headquartered in Florida, USA, with manufacturing operations in India. Its proprietary Nanoluteâ?¢ technology platform is designed to enable controlled and sustained delivery of sirolimus across coronary and peripheral applications. The companyâ??s flagship product, MagicTouch, is among the most clinically studied sirolimus-coated balloon platforms worldwide.

Source: Data from the SIRONA randomised trial, presented by Prof. Ulf Teichgraber at the Charing Cross (CX) Symposium 2026, London, UK. Preliminary results prior to Clinical Events Committee (CEC) adjudication.

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