MagicTouch PTA is Non-Inferior to Paclitaxel DCB in The World's Only RCT for SFA

SIRONA

World's only RCT comparing Sirolimus vs Paclitaxel head-to-head to evaluate the primary patency at 1 year in the treatment of SFA.

482 Patients

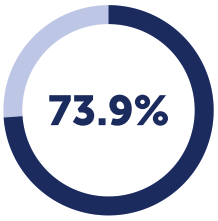
Patients treated with Sirolimus Coated Balloon		Patients treated with Paclitaxel Drug Coated Balloon
238	MagicTouch PTA	Paclitaxel DCB 244

COMPLEX PATIENT COHORT

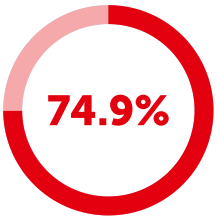
Rutherford Becker (3)	Diabetes Mellitus	Lesion Length (mm)
72.7% vs 68.9%	34% vs 33.2%	84.3 ± 61.7 vs 84.1 ± 60.1

PRINCIPAL INVESTIGATOR : PROF. ULF TEICHGRÄBER

Primary Patency - 1 year*



MagicTouch PTA (150/203)

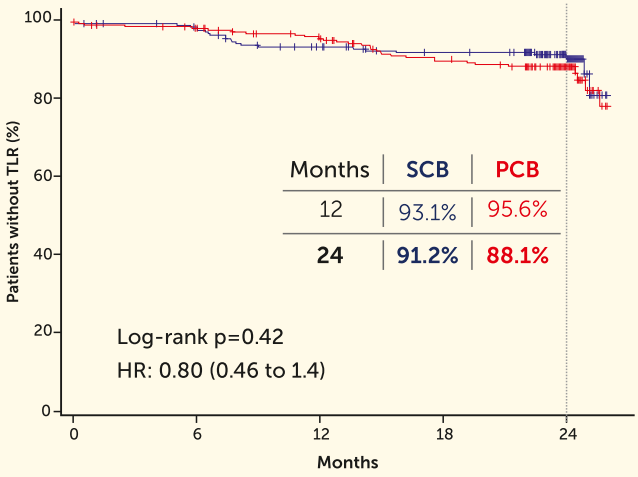


Paclitaxel DCB (149/199)

Rate difference: -1.0% (95% CI: -9.6% to 7.6%)

P = 0.019 (non-inferiority)

Freedom from cd-TLR - 1 & 2 years**



Improvement by ≥ 1 Rutherford Category - 1 Year
88.8% vs 90.0%

P = 0.75 | Rate Difference = -1.2% (95% CI: -7.3 to 4.9)

Freedom from Primary Composite Safety Outcome - 1 Year
90.5% vs 92.7%

P = 0.003 (non-inferiority) | Rate difference: -2.2% (95%CI: -7.7 to 3.2)

Key Takeaways

SIRONA is the only RCT proving non-inferiority of Sirolimus DCB – MagicTouch PTA against a direct comparison with 7 PCBs at 1 year primary patency. At 2 years, there were no significant differences in primary patency, major target limb amputation, and all-cause mortality between the groups with improvement in the vascular quality of life. Additionally, at 2 years Freedom from cd-TLR in Sirolimus DCB shows clear tendency towards better outcomes against Paclitaxel DCBs.

*Presented by Prof. Ulf Teichgräber at TCT USA 2025 | **Presented by Prof. Dr. Dierk Schienert at LINC 2026.

Concept Medical

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MagicTouch PTA SIROLIMUS COATED PTA BALLOON CATHETER

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