

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.



COMPLEX PATIENT COHORT

Rutherford Becker (3)

72.7% vs 68.9%

Diabetes Mellitus

34% vs 33.2%

Lesion Length (mm)

84.3 \pm 61.7 vs 84.1 \pm 60.1

PRINCIPAL INVESTIGATOR : ULF TEICHGRÄBER

1 Year Clinical Outcomes

Primary Patency



MagicTouch PTA
(150/203)



Paclitaxel DCB
(149/199)

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

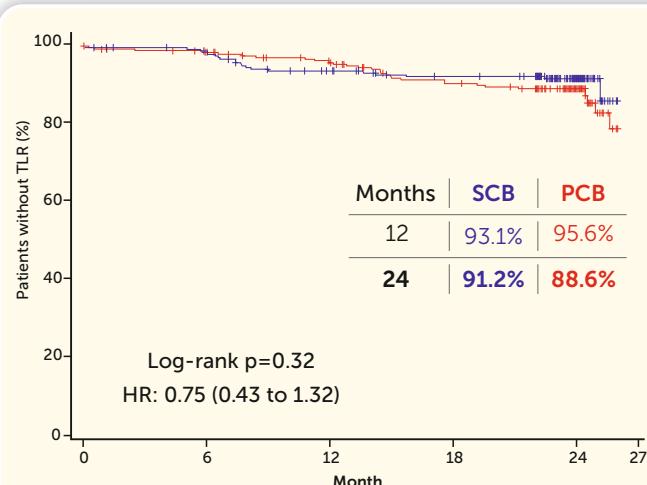
P = 0.019 (non-inferiority)

Improvement by \geq 1 Rutherford Category - 1 Year

88.8% vs 90.0%

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

2 Year Clinical Outcomes*



Freedom from Composite Safety Outcome - 1 Year

90.5% vs 92.7%

P = 0.003 (non-inferiority)

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 two years, there were no significant differences in primary patency, improvement in the vascular quality of life, freedom from cd-TLR, major target limb amputation, and all-cause mortality between the groups.

*Presented by Prof. Ulf Teichgräber at ASVS 2025. | Preliminary result before CEC adjudication



**Concept
Medical**



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MagicTouch PTA
SIROLIMUS COATED PTA BALLOON CATHETER