

RANGERTM

Paclitaxel-Coated PTA Balloon Catheter

Clinically Proven in both randomized and real-world trials





RANGER™ DCB has been studied in over 250 patients, in both randomized and real-world clinical trials

RANGER SFA RANDOMIZED CONTROLLED TRIAL



RANGER ALL COMERS* REGISTRY

N = 149

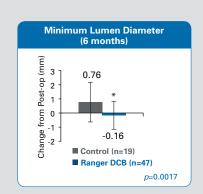
Avg Lesion Length

135 mm



The Ranger SFA-Trial has achieved among the highest FTLR of 94.4% at 6 months, with significantly less late lumen loss vs. PTA

94.4%
Freedom from
TLR vs.
88% PTA



The Ranger All-Comers Registry confirms benefit of an efficient drug coating technology in challenging, real-world lesions

91.9% Freedom from TLR*

91.1% Primary Patency**





^{*}Interim analysis at 6 months of 149 patients

^{**}Kaplan Meier Estimate

RANGER™ Clinically Proven in both randomized and real-world trials

6 months

RANGER SFA TRIAL



Design

Level 1 evidence trial:

- Randomized, controlled trial
- Multicenter, 10 centers in Europe
- External, blinded core lab adjudication

Baseline Characteristics Average lesion length: 68 mm

Diabetes: 39 %

Moderate & Severely Calcified: 60 %

Total occlusion: 34%

Percent diameter stenosis: 85 %

Efficacy Results

Late Lumen Loss was significantly less for Ranger DCB than for

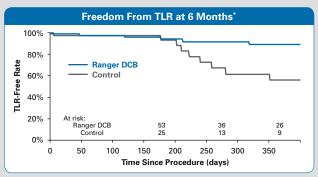
control (P = 0.0017) → Primary endpoint was met

Safety Results

Similar Adverse Event and Serious Adverse Event rates between groups

- No target limb amputations
- 1 death within 6 months (control group)

Freedom from TLR rate through 6 months: 88 % control vs 94.4 % Ranger (P = 0.47)



*Kaplan-Meier analysis

RANGER REGISTRY

N = 149

 Avg Lesion Length 135 mm

Design

Multicenter registry, with planned enrollment of 180 patients

Baseline

Characteristics

Diabetes: 34 %

Rutherford: 80 % Class III & higher

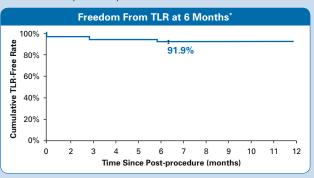
Average lesion length: 135 mm

TASC C&D: 59 %

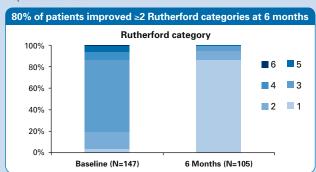
Percent diameter stenosis: 91 %

Safety & Efficacy results at 6 months

91.9% Freedom from TLR 91.1 % Primary Patency



*Kaplan-Meier estimate







CONCLUSION

The Ranger DCB has been studied in over 250 patients, in both randomized and real-world clinical trials.

The Ranger SFA-RCT has achieved among the **highest FTLR of 94.4% at 6 months**, with significantly less late lumen loss vs. PTA.

The Ranger All-Comers Registry confirms benefit of an efficient drug coating technology in challenging, real-world lesions with FTLR of 91.9%* and Primary Patency of 91.1%*.

*Kaplan-Meier estimate

Ranger All-Comers Registry, Interim analysis at 6 months of 149 patients.
Sponsored by Klinikum Arnsberg, M. Lichtenberg and the SFA Registry Investigators, CIRSE 2016.
Ranger SFA RCT presented at CIRSE 2016 by Prof Scheinert, Principal Investigator.
Ranger™ Paclitaxel-Coated PTA Balloon Catheter is manufactured by Hemoteq AG and distributed by Boston Scientific Corporation.

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