stellarex™
Drug-coated
Angioplasty Balloon

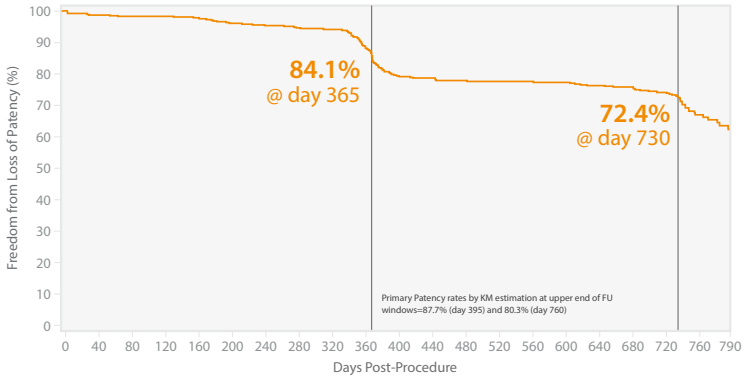
ILLUMENATE GLOBAL
2-Year Results

Global Principal Investigator: Prof. Dr. med. Thomas Zeller – Department of Angiology: University Heart Center Freiburg - Bad Krozingen; Bad Krozingen, Germany

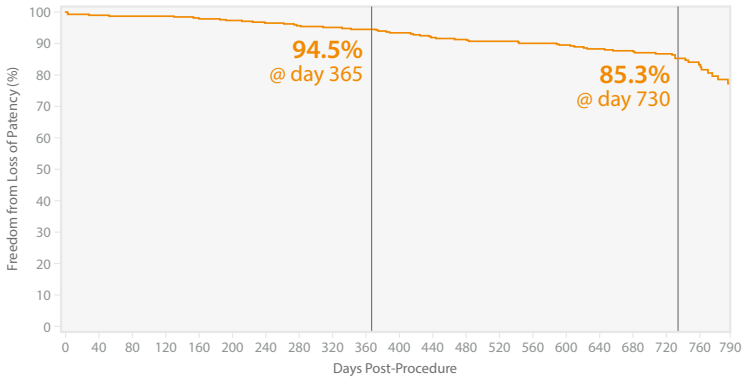
Presented by: Prof. Dr. med. Thomas Zeller, LINC 2018; Leipzig, Germany

Key Outcomes.
Independent assessment and adjudication of outcomes

Primary patency rate: 72.4% at day 730



Freedom from CD-TLR: 85.3% at day 730



Key Baseline Characteristics

Lesion (per core lab†)	Stellarex N = 417 lesions
Lesion length (cm)	7.5 ± 5.3 (413)
Total occlusions	31.3% (129/412)
Severe calcification	40.8% (164/402)
Baseline diameter stenosis (%)	80.3 ± 17.4 (412)

Demographics	Stellarex N = 371 patients
Age (yrs.)	68.2 ± 9.3 (371)
Male	73.0% (271/371)
Diabetes	33.7% (125/371)
Previous or current smoker	81.9% (304/371)
ABI	0.70 ± 0.20 (347)

Procedural	Stellarex N = 417 lesions
Pre-dilatation*	98.1% (409/417)
Post-dilatation*	28.3% (118/417)
Provisional stent*	17.3% (72/417)
Stent due to dissection*	8.4% (35/417)
Post-procedural flow-limiting dissections (Grade E or F)	0.2% (1/416)**

†Beth Israel Deaconess Medical Center, Boston, MA

*Site reported data

**Denominator is 416, because flow-limiting assessment was sometimes reported as N/A by the core lab

Objective

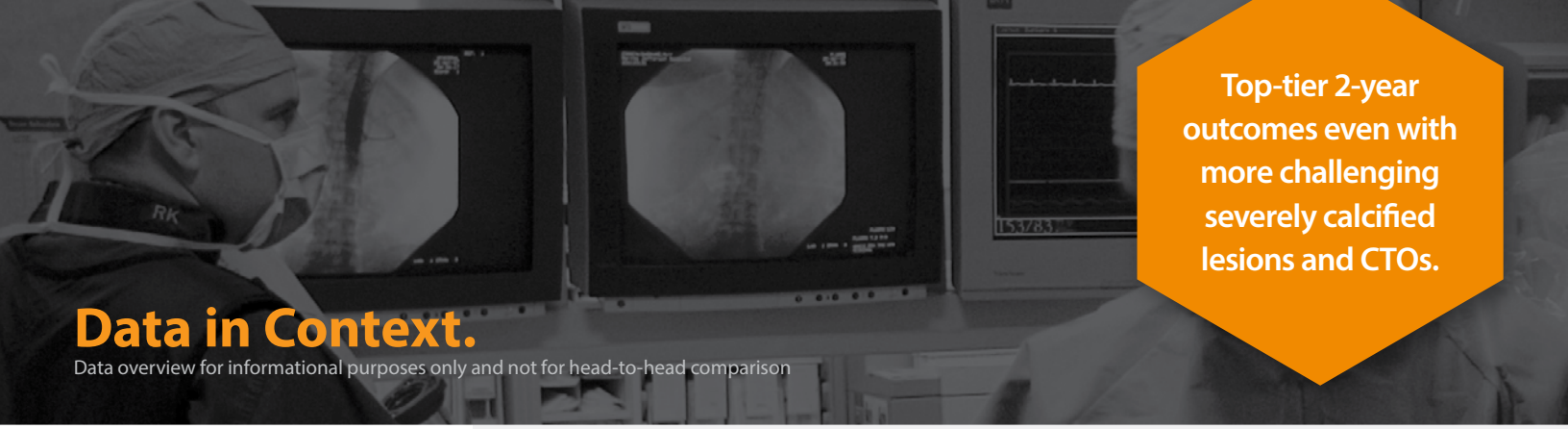
Assess the safety and performance of the Stellarex Drug-coated Angioplasty Balloon (DCB) for treatment of the superficial femoral and/or popliteal arteries

Design

- Prospective, multi-center, single-arm study
- Follow-up at pre-discharge, 1, 6, 12, 24, 36, 48 and 60 months

Methods

- Independent assessment and adjudication by Angiographic and Duplex Ultrasound Core Labs, Clinical Events Committee, and Data Safety Monitoring Board
- Data monitoring with 100% source data verification
- 371 patients enrolled at 37 sites

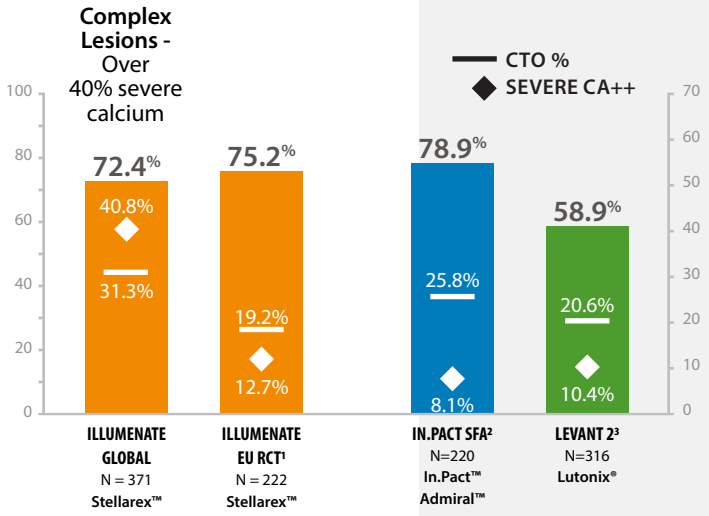


Top-tier 2-year outcomes even with more challenging severely calcified lesions and CTOs.

Data in Context.

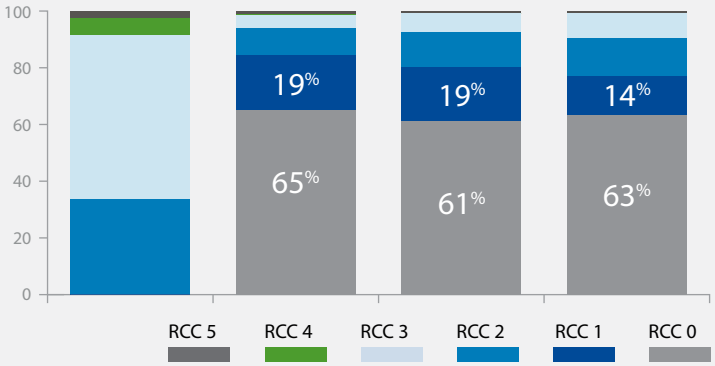
Data overview for informational purposes only and not for head-to-head comparison

Primary Patency at 2 years



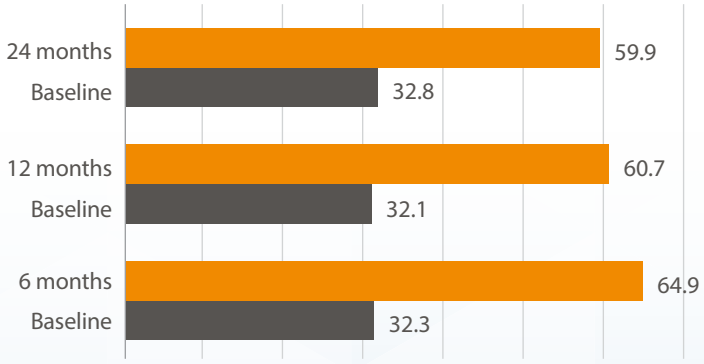
Rutherford Clinical Category thru 24 months

86.9% of patients had an improvement in their Rutherford Classification at 2 years



Mean Composite WIQ Score

Sustained patient benefit over 2 years



*For each analysis time point, only subjects with data available at both baseline and follow-up are included.

Conclusions

- ILLUMENATE Global demonstrated 2-year Primary Patency of 72.4% and CD-TLR rate of 17.8%
- Builds on the robust ILLUMENATE program with 4 trials, >1000 patients
- Confirms low-dose next-generation DCB can perform within a wide range of patient complexities

*Competitor studies are independent clinical trials with different protocols and definitions. Therefore, they are not head-to-head comparisons, and data presented cannot be directly compared. Calcium definitions may vary from study to study, and the rates presented here are based on those used and reported in each respective study. Primary patency based on Kaplan-Meier estimates.

1. M. Brodmann. ILLUMENATE EU RCT: 2-year Results; Oral Presentation. VIVA 2017, Las Vegas, NV. September 11-14, 2017.
2. Laird et al. J Am Coll Cardio 2015;66:2329-38.
3. Bard Lutonix Instructions for Use, BAW1387400r3.

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