Next Generation Drug-coated Balloon: Clinical Results in Common to Complex Patients

Prakash Krishnan, MD
Mount Sinai Medical Center, NY

innovation you

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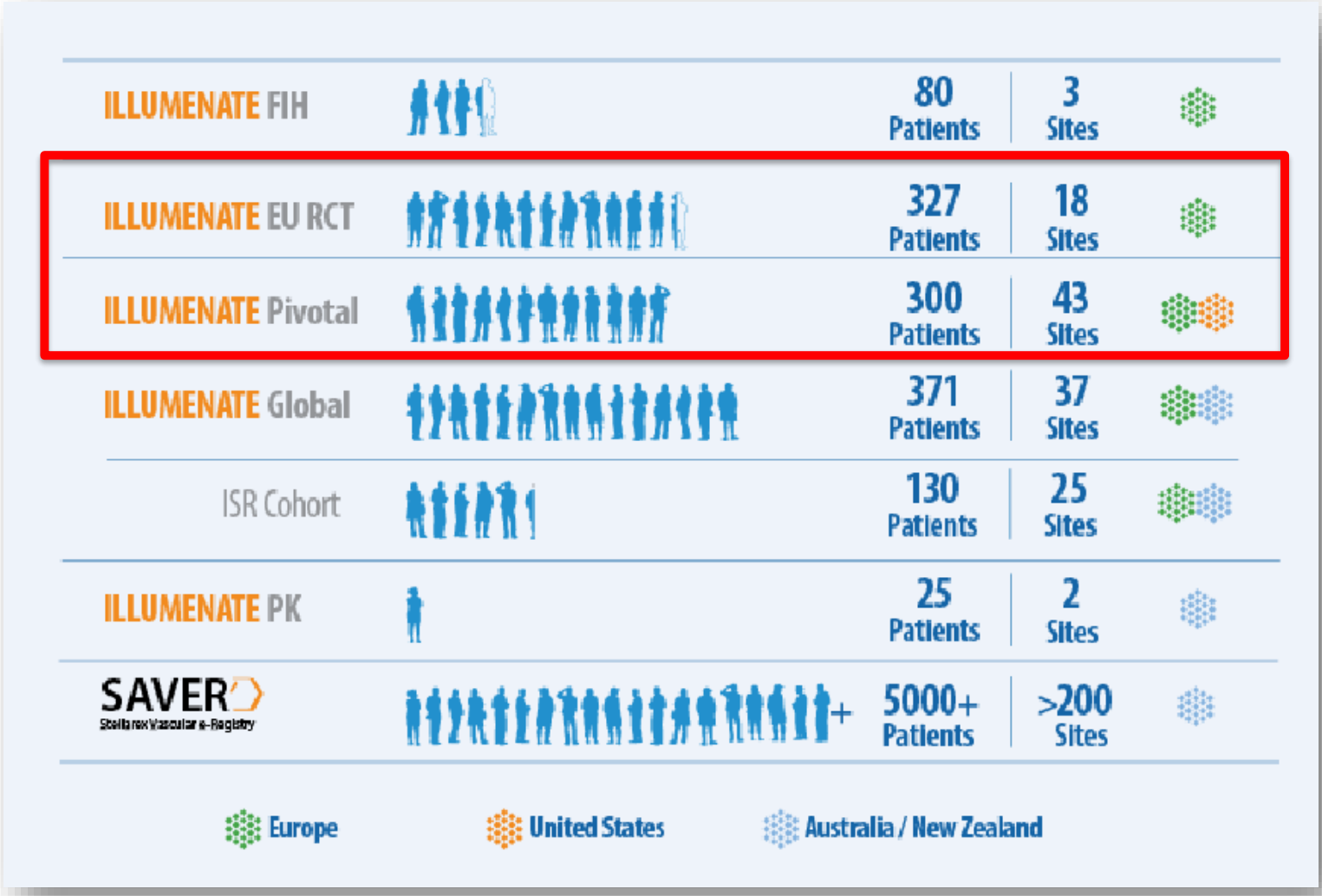
Robust Clinical Program Underway



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ILLUMENATE RCTs

2 Trials, 628 Patients

	ILLUMENATE EU RCT	ILLUMENATE PIVOTAL
Prinicipal Investigators	H. Schröder (Berlin, Germany)	S. Lyden (Cleveland, OH, US) P. Krishnan (New York, NY, US)
N Patients	**328**	**300**
N Sites	**18**	**43**
Patient Population	Claudication and Rest pain	
Objectives	Demonstrate safety and efficacy of the Stellarex DCB vs. standard PTA for the treatment of fem-pop arterial disease	
Primary Safety Endpoint	Freedom from 30-day device- and procedure-related death and freedom from 12-month target limb major amputation and clinically-driven TLR	
Primary Effectiveness Endpoint	Primary patency at 12 months defined as freedom from restenosis (determined by duplex ultrasound PSVR ≤ 2.5) and freedom from clinically-driven TLR	

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ILLUMENATE RCTs

2 Trials, Same Rigor

ILLUMENATE EU RCT	ILLUMENATE US Pivotal
Angiographic Core laboratory *	
Duplex Core laboratory *	
Clinical Event Committee *	
External Monitoring with 100% source data verification	

* blinded to the assigned treatment

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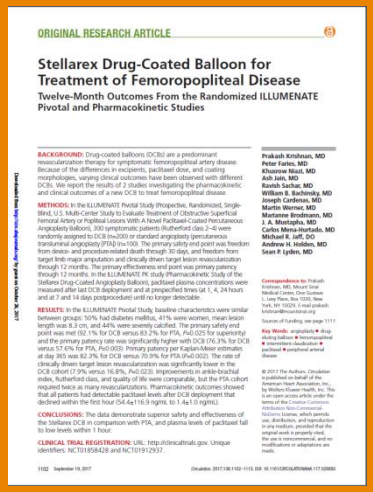

ORIGINAL RESEARCH ARTICLE

Stellarex Drug-Coated Balloon for Treatment of Femoropopliteal Disease

Twelve-Month Outcomes From the Randomized ILLUMENATE Pivotal and Pharmacokinetic Studies

Prakash Krishnan, MD
Peter Faries, MD
Khusrow Niazi, MD
Ash Jain, MD
Ravish Sachar, MD
William B. Bachinsky, MD
Joseph Cardenas, MD
Martin Werner, MD
Marianne Brodmann, MD
J. A. Mustapha, MD
Carlos Mena-Hurtado, MD
Michael R. Jaff, DO
Andrew H. Holden, MD
Sean P. Lyden, MD

BACKGROUND: Drug-coated balloons (DCBs) are a predominant revascularization therapy for symptomatic femoropopliteal artery disease. Because of the differences in excipients, paclitaxel dose, and coating morphologies, varying clinical outcomes have been observed with different DCBs. We report the results of 2 studies investigating the pharmacokinetic and clinical outcomes of a new DCB to treat femoropopliteal disease.

METHODS: In the ILLUMENATE Pivotal Study (Prospective, Randomized, Single-Blind, U.S. Multi-Center Study to Evaluate Treatment of Obstructive Superficial Femoral Artery or Popliteal Lesions With A Novel Paclitaxel-Coated Percutaneous Angioplasty Balloon), 300 symptomatic patients (Rutherford class 2–4) were randomly assigned to DCB (n=200) or standard angioplasty (percutaneous transluminal angioplasty [PTA]) (n=100). The primary safety end point was freedom from device- and procedure-related death through 30 days, and freedom from target limb major amputation and clinically driven target lesion revascularization through 12 months. The primary effectiveness end point was primary patency through 12 months. In the ILLUMENATE PK study (Pharmacokinetic Study of the Stellarex Drug-Coated Angioplasty Balloon), paclitaxel plasma concentrations were measured after last DCB deployment and at prespecified times (at 1, 4, 24 hours and at 7 and 14 days postprocedure) until no longer detectable.

RESULTS: In the ILLUMENATE Pivotal Study, baseline characteristics were similar between groups: 50% had diabetes mellitus, 41% were women, mean lesion length was 8.3 cm, and 44% were severely calcified. The primary safety end point was met (92.1% for DCB versus 83.2% for PTA, P<0.025 for superiority) and the primary patency rate was significantly higher with DCB (76.3% for DCB versus 57.6% for PTA, P<0.003). Primary patency per Kaplan-Meier estimates at day 365 was 82.3% for DCB versus 70.9% for PTA (P<0.022). The rate of clinically driven target lesion revascularization was significantly lower in the DCB cohort (7.9% versus 16.8%, P<0.023). Improvements in ankle-brachial index, Rutherford class, and quality of life were comparable, but the PTA cohort required twice as many revascularizations. Pharmacokinetic outcomes showed that all patients had detectable paclitaxel levels after DCB deployment that declined within the first hour (54.4±116.9 ng/mL to 1.4±1.9 ng/mL).

CONCLUSIONS: The data demonstrate superior safety and effectiveness of the Stellarex DCB in comparison with PTA, and plasma levels of paclitaxel fall to low levels within 1 hour.

CLINICAL TRIAL REGISTRATION: URL: http://clinicaltrials.gov. Unique identifiers: NCT01858428 and NCT01912937.

ILLUMENATE Pivotal

Krishnan P, Faries P, Niazi K, Jain A, Sachar R, Bachinsky WB, Cardenas J, Werner M, Brodmann M, Mustapha JA, Mena-Hurtado C, Jaff MR, Holden AH and Lyden SP. Stellarex Drug-Coated Balloon for Treatment of Femoropopliteal Disease: Twelve-Month Outcomes From the Randomized ILLUMENATE Pivotal and Pharmacokinetic Studies. *Circulation*. 2017;136:1102-1113.

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ILLUMENATE Pivotal
Baseline Patient Characteristics

	Stellarex	PTA	p
Age (years)	68.3 ± 10.3 (200)	69.8 ± 9.8 (100)	0.225
Rutherford Clinical Category			0.735
2	31.5% (63/200)	35.0% (35/100)	
3	64.5% (129/200)	60.0% (60/100)	
4	4.0% (8/200)	5.0% (5/100)	
ABI	0.75±0.21 (193)	0.76± 0.2 (100)	0.508
Hypertension	93.5% (187/200)	94.0% (94/100)	0.867
Hyperlipidemia	88.0% (176/200)	90.0% (90/100)	0.606
Coronary Artery Disease	45.0% (90/200)	48.0% (48/100)	0.623
Previous or Current Smoker	84.0% (168/200)	75.0% (75/100)	0.061

Krishnan P, Faries P, Niazi K, et al. Stellarex Drug-Coated Balloon for Treatment of Femoropopliteal Disease: 12-Month Outcomes from the Randomized ILLUMENATE Pivotal and Pharmacokinetic Studies. *Circulation.* 2017.

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ILLUMENATE Pivotal
Baseline Patient Characteristics

	Stellarex	PTA	p
Female	44% (88/200)	36% (36/100)	0.185
Diabetes	49.5% (99/200)	52.0% (52/100)	0.683
Renal Insufficiency	18.0% (36/200)	16.0% (16/100)	0.666
BMI ≥ 30	39.5% (79 /200)	30.0% (30/100)	0.107

- Particularly high rate of females enrolled and patients with co-morbidities that are challenging to treat

Krishnan P, Faries P, Niazi K, et al. Stellarex Drug-Coated Balloon for Treatment of Femoropopliteal Disease: 12-Month Outcomes from the Randomized ILLUMENATE Pivotal and Pharmacokinetic Studies. *Circulation.* 2017.

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ILLUMENATE Pivotal
Baseline Angiographic Data: Per Core Lab

	Stellarex	PTA	p
Lesion Length (cm)	8.0 ± 4.5 (199)	8.9 ± 4.6 (100)	0.105
Restenotic [1]	9.5% (19/200)	18.0% (18/100)	0.035
Total Occlusion	19.0% (38/200)	18.0% (18/100)	0.834
Severe Calcification	43.9% (87/198)	43.0% (43/100)	0.877
Diameter Stenosis (%)	73.9 ± 16.9 (200)	74.8 ± 17.0 (100)	0.673
Reference Vessel Diameter (mm)	4.86 ± 0.92 (200)	5.15 ± 1.05 (100)	0.017
0-1 Patent Run-off Vessels	32.5% (54/166)	30.5% (25/82)	0.745

1. Site-reported data

Krishnan P, Faries P, Niazi K, et al. Stellarex Drug-Coated Balloon for Treatment of Femoropopliteal Disease: 12-Month Outcomes from the Randomized ILLUMENATE Pivotal and Pharmacokinetic Studies. *Circulation.* 2017.

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ILLUMENATE Pivotal
Procedure Characteristics

	Stellarex	PTA	p
Pre-dilatation Performed[1]	100% (200/200)	100% (100/100)	N/A
Study Device Inflation Time[1] (min/lesion)	3.9 ± 2.0 (200)	3.7 ± 2.3 (100)	0.557
Post-DCB/PTA Dissection Grades[2]			
Grade D	20.0% (40/200)	12.0% (12/100)	0.084
Flow-limiting Dissection (Grade E or F)	0.0% (0/193)	0.0% (0/98)	N/A
Bail-out Stent Placement[1]	6.0% (12/200)	6.0% (6/100)	1.000
Post-procedure Diameter Stenosis (%)[2]	25.2 ± 11.7 (199)	27.4 ± 10.1 (100)	0.107

1. Site-reported data
2. Per Angiographic Core Lab

Krishnan P, Faries P, Niazi K, et al. Stellarex Drug-Coated Balloon for Treatment of Femoropopliteal Disease: 12-Month Outcomes from the Randomized ILLUMENATE Pivotal and Pharmacokinetic Studies. *Circulation.* 2017.

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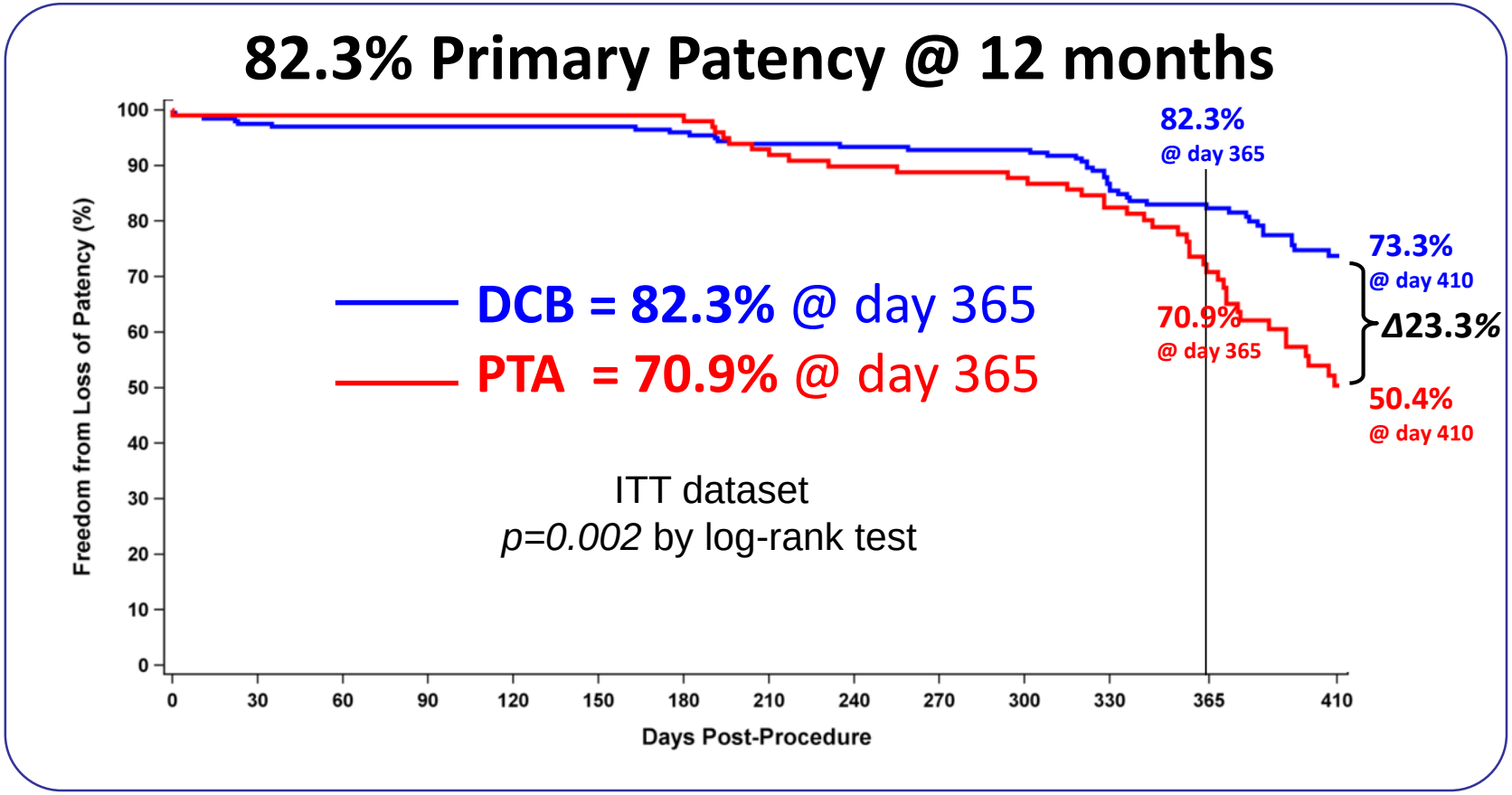
ILLUMENATE US Pivotal



Primary patency defined as freedom from restenosis determined by duplex ultrasound PSVR ≤2.5 and freedom from clinically-driven TLR at 12 months. Assessed per lesion. KM estimates reported at day 410 to capture all patients and events within the full 320-410 follow-up window. Rates from the middle of the protocol visit window (365 days) reported for consistency and comparative purposes with other trials.

Krishnan P, Faries P, Niazi K, et al. Stellarex Drug-Coated Balloon for Treatment of Femoropopliteal Disease: 12-Month Outcomes from the Randomized ILLUMENATE Pivotal and Pharmacokinetic Studies. *Circulation.* 2017.

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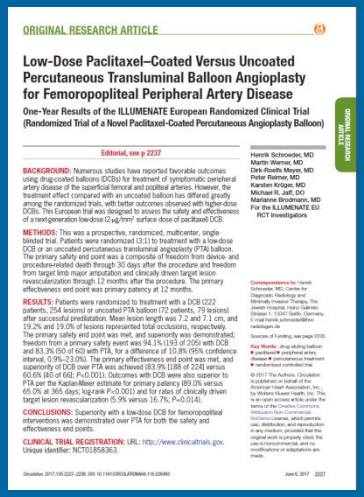

ORIGINAL RESEARCH ARTICLE

Low-Dose Paclitaxel–Coated Versus Uncoated Percutaneous Transluminal Balloon Angioplasty for Femoropopliteal Peripheral Artery Disease

One-Year Results of the ILLUMENATE European Randomized Clinical Trial (Randomized Trial of a Novel Paclitaxel-Coated Percutaneous Angioplasty Balloon)

Editorial, see p 2237

Henrik Schroeder, MD; Martin Werner, MD; Dirk-Roelfs Meyer, MD; Peter Reimer, MD; Karsten Krüger, MD; Michael R. Jaff, DO; Marianne Brodmann, MD; For the ILLUMENATE EU RCT Investigators

BACKGROUND: Numerous studies have reported favorable outcomes using drug-coated balloons (DCBs) for treatment of symptomatic peripheral artery disease of the superficial femoral and popliteal arteries. However, the treatment effect compared with an uncoated balloon has differed greatly among the randomized trials, with better outcomes observed with higher-dose DCBs. This European trial was designed to assess the safety and effectiveness of a next-generation low-dose (2 μg/mm² surface dose of paclitaxel) DCB.

METHODS: This was a prospective, randomized, multicenter, single-blinded trial. Patients were randomized (3:1) to treatment with a low-dose DCB or an uncoated percutaneous transluminal angioplasty (PTA) balloon. The primary safety end point was a composite of freedom from device- and procedure-related death through 30 days after the procedure and freedom from target limb major amputation and clinically driven target lesion revascularization through 12 months after the procedure. The primary effectiveness end point was primary patency at 12 months.

RESULTS: Patients were randomized to treatment with a DCB (222 patients, 254 lesions) or uncoated PTA balloon (72 patients, 79 lesions) after successful predilatation. Mean lesion length was 7.2 and 7.1 cm, and 19.2% and 19.0% of lesions represented total occlusions, respectively. The primary safety end point was met, and superiority was demonstrated; freedom from a primary safety event was 94.1% (193 of 205) with DCB and 83.3% (50 of 60) with PTA, for a difference of 10.8% (95% confidence interval, 0.9%–23.0%). The primary effectiveness end point was met, and superiority of DCB over PTA was achieved (83.9% (188 of 224) versus 60.6% (40 of 66); P<0.001). Outcomes with DCB were also superior to PTA per the Kaplan-Meier estimate for primary patency (89.0% versus 65.0% at 365 days; log-rank P<0.001) and for rates of clinically driven target lesion revascularization (5.9% versus 16.7%; P=0.014).

CONCLUSIONS: Superiority with a low-dose DCB for femoropopliteal interventions was demonstrated over PTA for both the safety and effectiveness end points.

CLINICAL TRIAL REGISTRATION: URL: http://www.clinicaltrials.gov. Unique identifier: NCT01858363.

ILLUMENATE EU RCT

Schroeder H, Werner M, Meyer DR, Reimer P, Kruger K, Jaff MR, Brodmann M and Investigators IER. Low-Dose Paclitaxel-Coated Versus Uncoated Percutaneous Transluminal Balloon Angioplasty for Femoropopliteal Peripheral Artery Disease: One-Year Results of the ILLUMENATE European Randomized Clinical Trial (Randomized Trial of a Novel Paclitaxel-Coated Percutaneous Angioplasty Balloon). *Circulation*. 2017;135:2227-2236

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ILLUMENATE EU RCT

Baseline Patient Characteristics

	Stellarex	PTA	p
Age (years)	66.8 ± 9.2 (222)	69.0 ± 8.6 (72)	0.079
Male	72.1% (160/222)	68.1% (49/72)	0.514
Rutherford Clinical Category			0.525
2	15.4% (34/221)	21.1% (15/71)	
3	82.8% (183/221)	77.5% (55/71)	
4	1.8% (4/221)	1.4% (1/71)	
Diabetes	37.4% (83/222)	36.1% (26/72)	0.846
Hypertension	77.9% (173/222)	83.3% (60/72)	0.326
Hyperlipidemia	61.7% (137/222)	68.1% (49/72)	0.332
Smoking Status			0.188
Never Smoked	10.8% (24/222)	16.7% (12/72)	
Previous or Current	89.2% (198/222)	83.3% (60/72)	
ABI	0.72 ± 0.21 (212)	0.69 ± 0.26 (68)	0.250

Schroeder H, Werner M, Meyer DR, et al. Low-Dose Paclitaxel-Coated vs. Uncoated PTA for Femoropopliteal Peripheral Artery Disease: One-Year Results of the ILLUMENATE European Randomized Clinical Trial. *Circulation.* 2017;135(23):2227-2236.

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ILLUMENATE EU RCT

Baseline Angiographic Data

	Stellarex	PTA	p
Lesion Length (cm)	7.2± 5.2 (250)	7.1 ± 5.3 (79)	0.878
Lesion Type[1]			
De Novo	92.1% (234/254)	89.9% (71/79)	0.529
Restenotic	7.9% (20/254)	10.1% (8/79)	
Total Occlusion	19.2% (48/250)	19.0% (15/79)	0.967
Calcification			
None/Mild	55.8% (140/251)	59.5% (47/79)	0.775
Moderate	31.5% (79/251)	30.4% (24/79)	
Severe	12.7% (32/251)	10.1% (8/79)	
Diameter Stenosis (%)	78.7 ± 16.0 (250)	80.8 ± 15.7 (79)	0.297
Reference Vessel Diameter (mm)	5.02 ± 0.79 (250)	4.77 ± 0.69 (79)	0.012
# of Patent Run-off Vessels			
0	8.5% (18/211)	5.9% (4/68)	0.229
1	19.0% (40/211)	13.2% (9/68)	
2	32.2% (68/211)	45.6% (31/68)	
3	40.3% (85/211)	35.3% (24/68)	

Per Core Lab Adjudication

* Per Site Assessment

Schroeder H, Werner M, Meyer DR, et al. Low-Dose Paclitaxel-Coated vs. Uncoated PTA for Femoropopliteal Peripheral Artery Disease: One-Year Results of the ILLUMENATE European Randomized Clinical Trial. *Circulation.* 2017;135(23):2227-2236.

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ILLUMENATE EU RCT

Procedural Characteristics

	Stellarex	PTA	p
Pre-dilatation Performed[1]	100% (254/254)	98.7% (78/79)	0.237
Post-DCB Dissection Grades **Grade A-C** **Grade D-F**	 61.1% (151/247) 1.2% (3/247)	 74.0% (57/77) 0.0% (0/77)	0.095
Flow-limiting Dissection	0.4% (1/247)	0.0% (0/77)	1.000
Bail-out Stent Placement[1]	15.4% (39/254)	11.4% (9/79)	0.381
Post-procedure Diameter Stenosis (%)	23.6 ± 11.4 (251)	23.1 ± 10.3 (78)	0.724

1. Site-reported data

Schroeder H, Werner M, Meyer DR, et al. Low-Dose Paclitaxel-Coated vs. Uncoated PTA for Femoropopliteal Peripheral Artery Disease: One-Year Results of the ILLUMENATE European Randomized Clinical Trial. *Circulation.* 2017;135(23):2227-2236.

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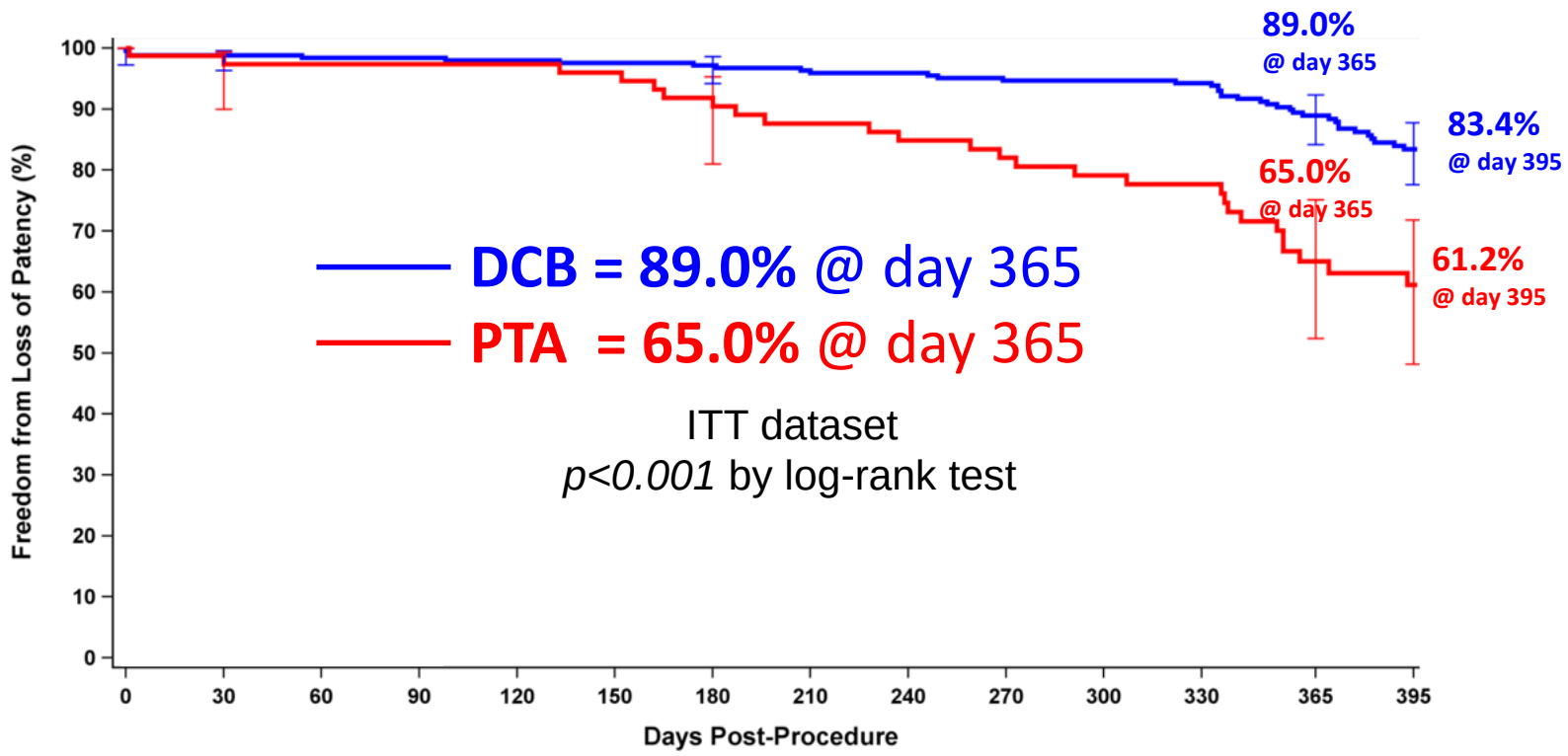
ILLUMENATE EU RCT

89% Primary Patency @ 12 Months



Primary patency defined as freedom from restenosis (determined by duplex ultrasound with PSVR ≤2.5) and freedom from clinically-driven TLR at 12 months. Assessed per lesion. KM estimates reported at day 395 to capture all patients and events within the full (and legitimate) 335-395 follow-up window. Rates from the middle of the protocol visit window (365 days) reported for consistency and comparative purposes with other trials.

Schroeder H, Werner M, Meyer DR, et al. Low-Dose Paclitaxel-Coated vs. Uncoated PTA for Femoropopliteal Peripheral Artery Disease: One-Year Results of the ILLUMENATE European Randomized Clinical Trial. *Circulation.* 2017;135(23):2227-2236.

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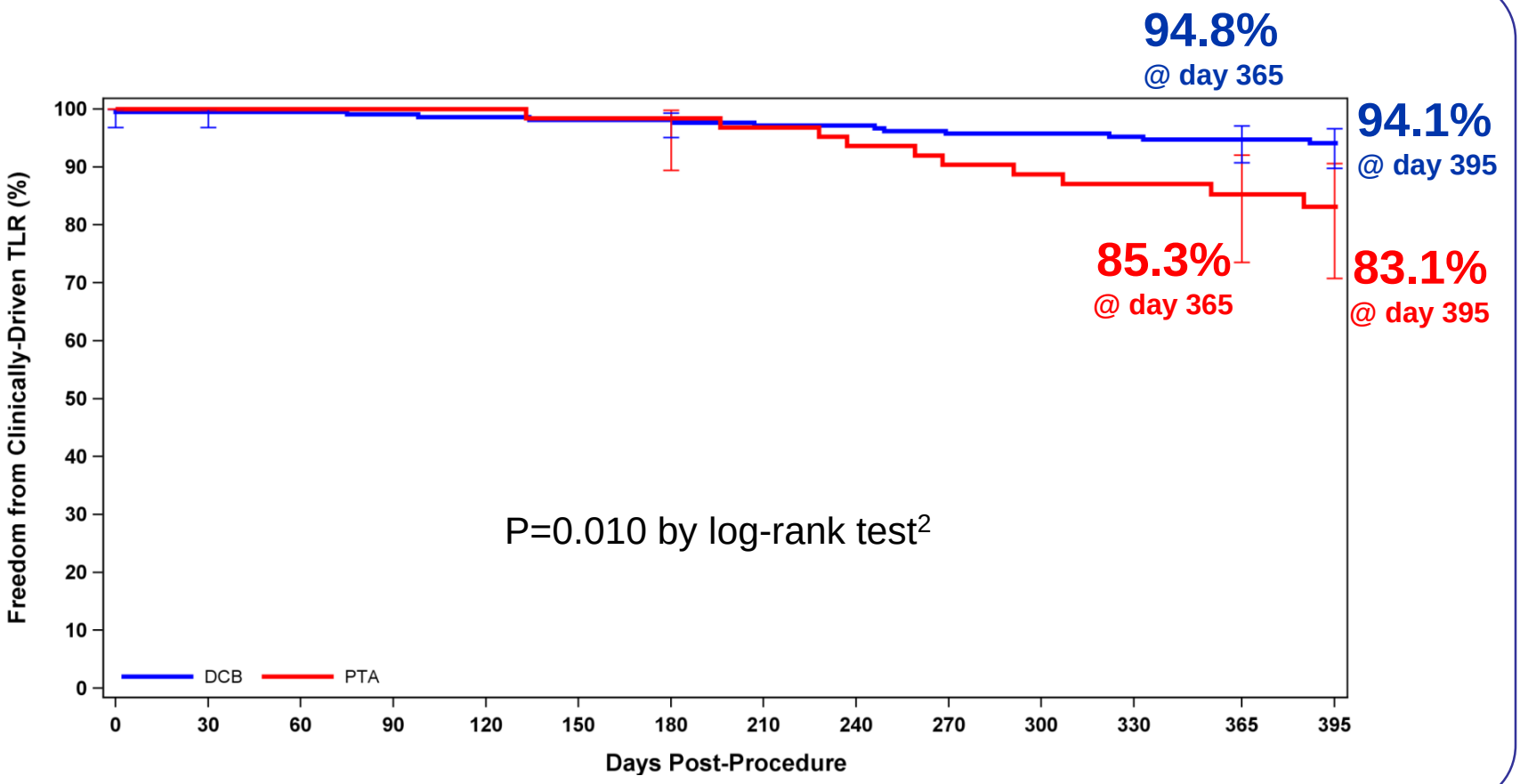
ILLUMENATE EU RCT

CD-TLR[1] Free at 12 Months: 94.8%



1. Clinically-driven TLR defined as reintervention due to PSVR≥2.5 (or >50% stenosis via angio) due to an increase in the RCC >1 category or deterioration in the ABI by >0.15 compared to maximum early post-procedural level. Per subject analysis.
2. Descriptive, post-hoc analyses; Hypothesis testing was not pre-specified. Log-rank p-value is post-hoc.
3. As-treated data set is considered the primary data set for the endpoint

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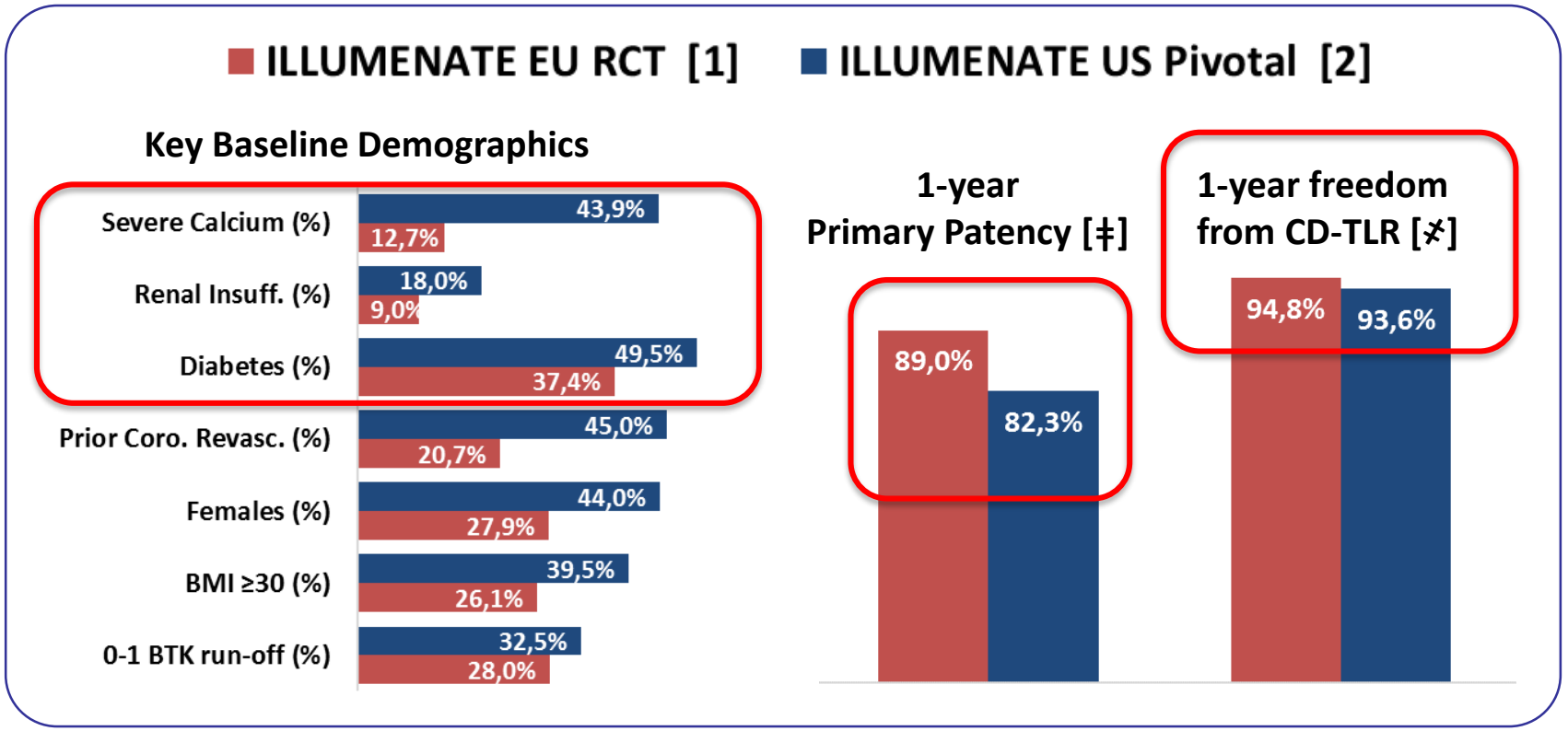
ILLUMENATE RCTs in context

Top Tier Outcomes across different patient complexities



[‡] Core-lab adjudicated (VascCore Core laboratory - Boston, MA, USA) Duplex derived Primary Patency based on PSVR ≤2.5 . KM survival estimates at 365 days

[✗] freedom from CEC adjudicated clinically driven TLR by KM survival estimates at 365 days

1. Schroeder H. et al. Low-Dose Paclitaxel-Coated vs. Uncoated PTA for Femoropopliteal Peripheral Artery Disease: One-Year Results of the ILLUMENATE European Randomized Clinical Trial. *Circulation.* 2017;135(23):2227-2236.

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Level 1 Evidence: DCB Pivotal RCTs in context

Similar patient characteristics across 3 of 4 Trials

	IN.PACT SFA [1]	LEVANT 2 [2]	ILLUMENATE EU RCT [3]	ILLUMENATE US Pivotal [4]
Females	35.0%	38.9%	27.9%	**44.0%**
Diabetes	40.5%	43.4%	37.4%	**49.5%**
Renal Insuff.	8.3%	NA	9.0%	**18.0%**
RC≥3	62.3%	70.6%	**84.6%**	68.5%
Lesion length	8.9 cm	6.3 cm	7.2 cm	8.0 cm
Severe Calcium*	8.1%	10.4%	12.7%	**43.9%**
CTOs	**25.8%**	20.6%	19.2%	19.0%

* different Ca++ definitions may apply across trials

1. Tepe G et al. Drug-coated balloon versus standard percutaneous transluminal angioplasty for the treatment of superficial femoral and popliteal peripheral artery disease: 12-month results from the IN.PACT SFA randomized trial. Circulation. 2015 Feb 3;131(5):495-502
2. K.Rosenfield et al. Trial of a Paclitaxel-Coated Balloon for Femoropopliteal Artery Disease. N Engl J Med 2015
3. Schroeder H, Werner M, Meyer DR, et al. *Circulation.* 2017;135(23):2227-2236.
4. Krishnan P, Faries P, Niazi K, et al. *Circulation.* Published online July 2017. https://doi.org/10.1161/CIRCULATIONAHA.117.028893

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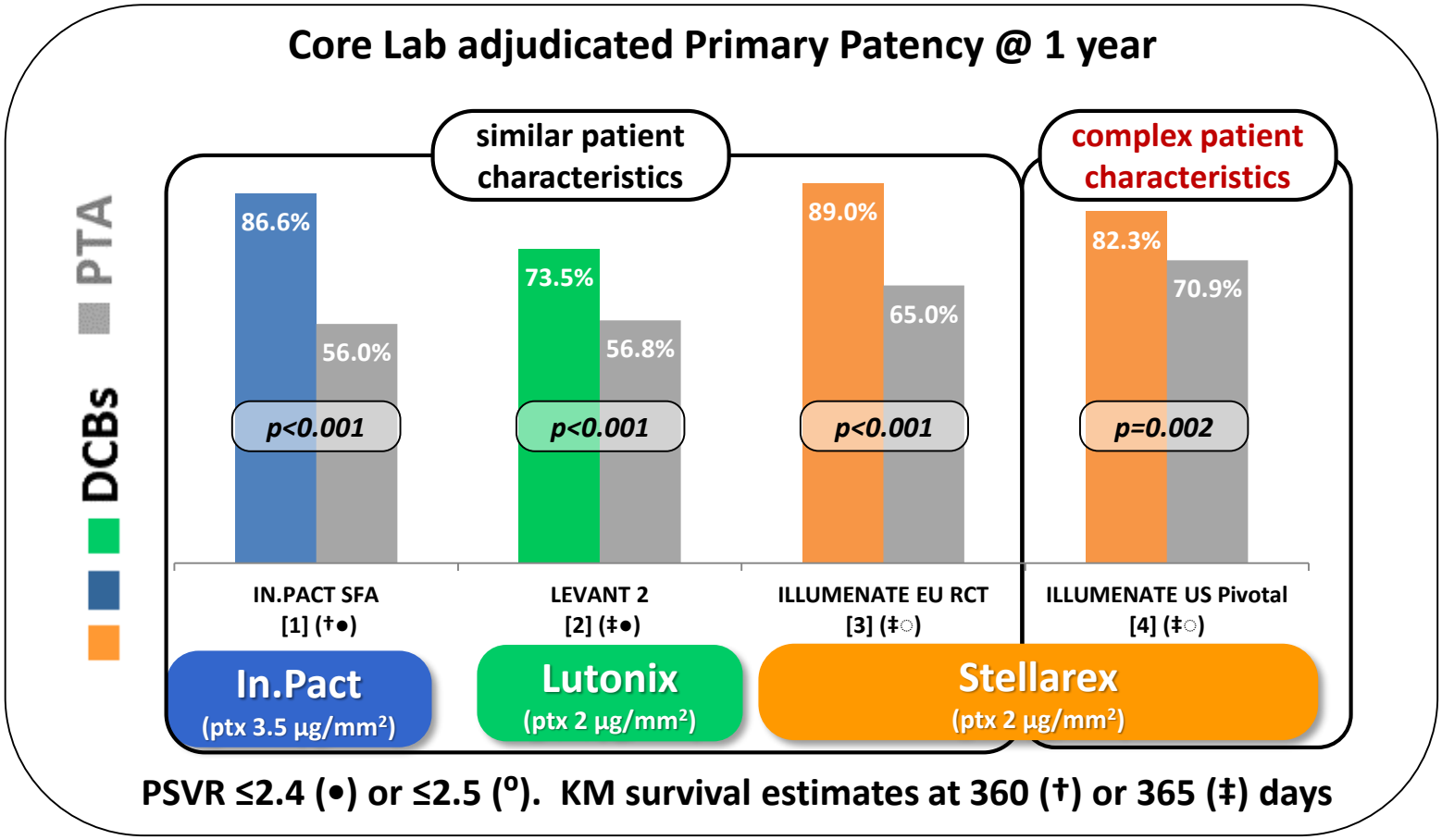
Level 1 Evidence: DCB Pivotal RCTs in context

ILLUMENATE EU RCT: 1st trial showing highest rates of Primary Patency vs. DCB Pivotal RCTs of similar design and patient profiles



1. Tepe G et al. IN.PACT SFA Trial Investigators Circulation 2015 + G.Tepe, Charing Cross 2014 oral presentation + Jaff M. Drug-coated Balloon Treatment for Patients with Intermittent Claudication: Insights from the IN.PACT Global Full Clinical Cohort. (Updated data from IN.PACT SFA presented on slide 12) Oral Presentation, VIVA 2016
2. K.Rosenfield et al. Trial of a Paclitaxel-Coated Balloon for Femoropopliteal Artery Disease. N Engl J Med 2015
3. Schroeder H, Werner M, Meyer DR, et al. *Circulation.* 2017;135(23):2227-2236.
4. Krishnan P, Faries P, Niazi K, et al. *Circulation.* Published online July 2017. https://doi.org/10.1161/CIRCULATIONAHA.117.028893

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ILLUMENATE EU RCT
2-Year Outcomes

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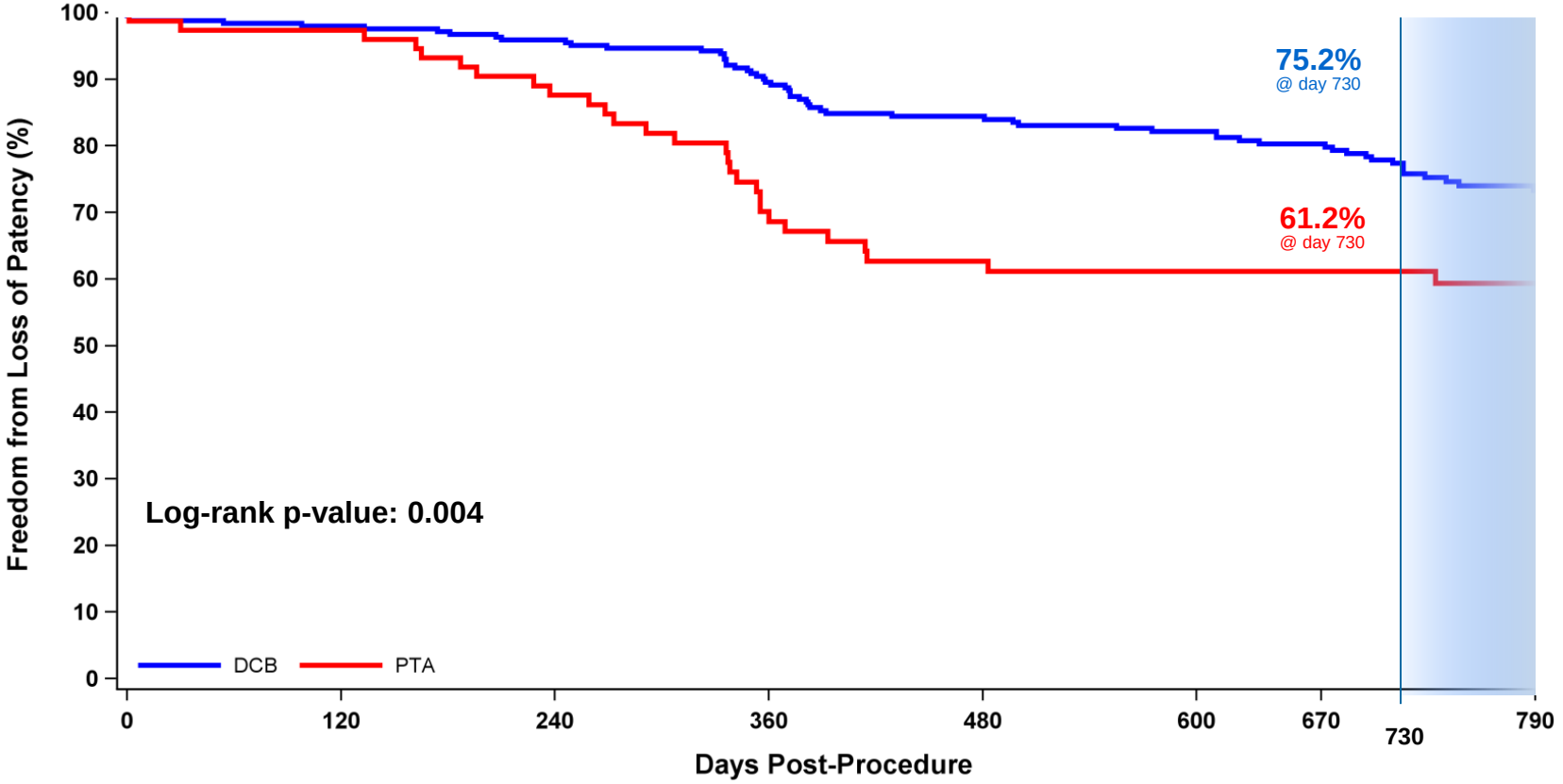
2-year Primary Patency
ILLUMENATE EU RCT Study



Days	365	730	790
DCB Event Free	89.2%	75.2%	73.3%
PTA Event Free	68.7%	61.2%	59.3%

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2-year Primary Patency

(exact rate through 790 days)

Primary Efficacy Endpoint[1]	DCB	PTA	Difference [95% CI][3]	p-value[3]
Patency at 24 Months	75.9% (145/191)	61.0% (36/59)[2]	14.9% [1.1%, 28.7%]	0.025

1.Patency is defined as absence of target lesion restenosis (as assessed by the duplex ultrasound core laboratory based on PSVR ≤ 2.5) and freedom from clinically-driven target lesion revascularization (CD-TLR) through 790 days.

2. The original 12 month patency rate for the PTA arm was 60.6% (40/66). When 3 additional subjects are included as success carried backwards due to newly available 2 year data, the post-hoc 12 month rate is 64.2% (43/67).

3. Confidence interval of the difference is asymptotic. p-value was based on the chi-square test.

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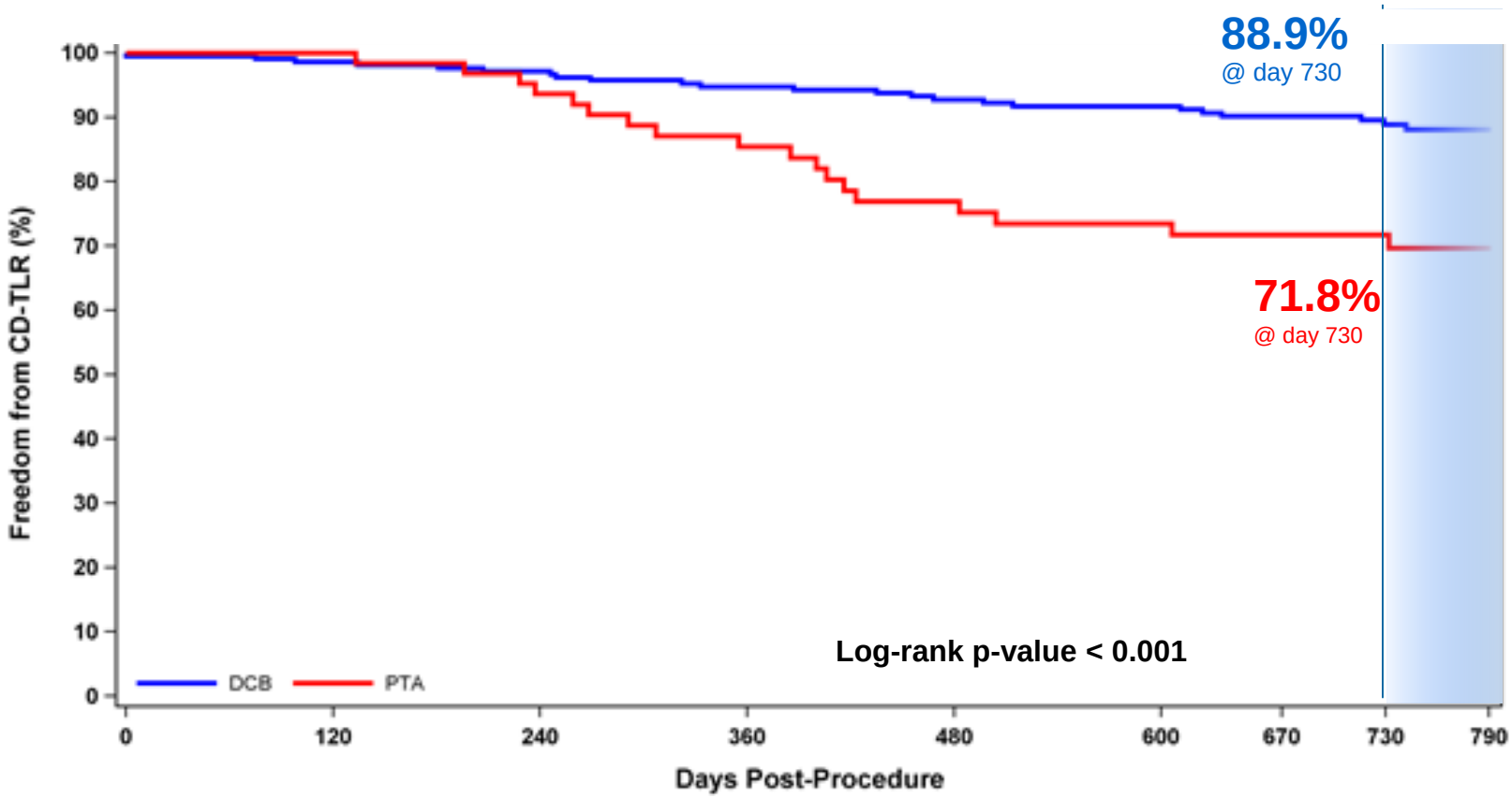
2-year Freedom from CD-TLR

ILLUMENATE EU RCT Study



Days	365	730	790
DCB Event Free	94.8%	88.9%	88.1%
PTA Event Free	85.4%	71.8%	69.7%

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Key Safety Endpoints at 2 Years*

ILLUMENATE EU RCT Study

	DCB	PTA	P-value
All-Cause Death	**6.5% (13/199)**	**5.1% (3/59)**	**1.000**
Major Adverse Events[1]	**14.0% (27/193)**	**31.7% (19/60)**	**0.002**
Cardiovascular Death	1.6% (3/191)	1.7% (1/59)	1.000
Target Limb Amputation	1.1% (2/188)	0.0% (0/58)	1.000
Clinically-driven TLR	12.1% (23/190)	30.5% (18/59)	<0.001

*Includes all MAEs reported through 790 days post-procedure

1. Sum of the components may not add up to the overall rate as some subjects may experience more than one event type. Numbers are % (n/N) The numerator is the number of subjects with an event prior to the close of the visit window. The denominator includes subjects with an event or those without an event having follow-up on or past the opening of the visit window.

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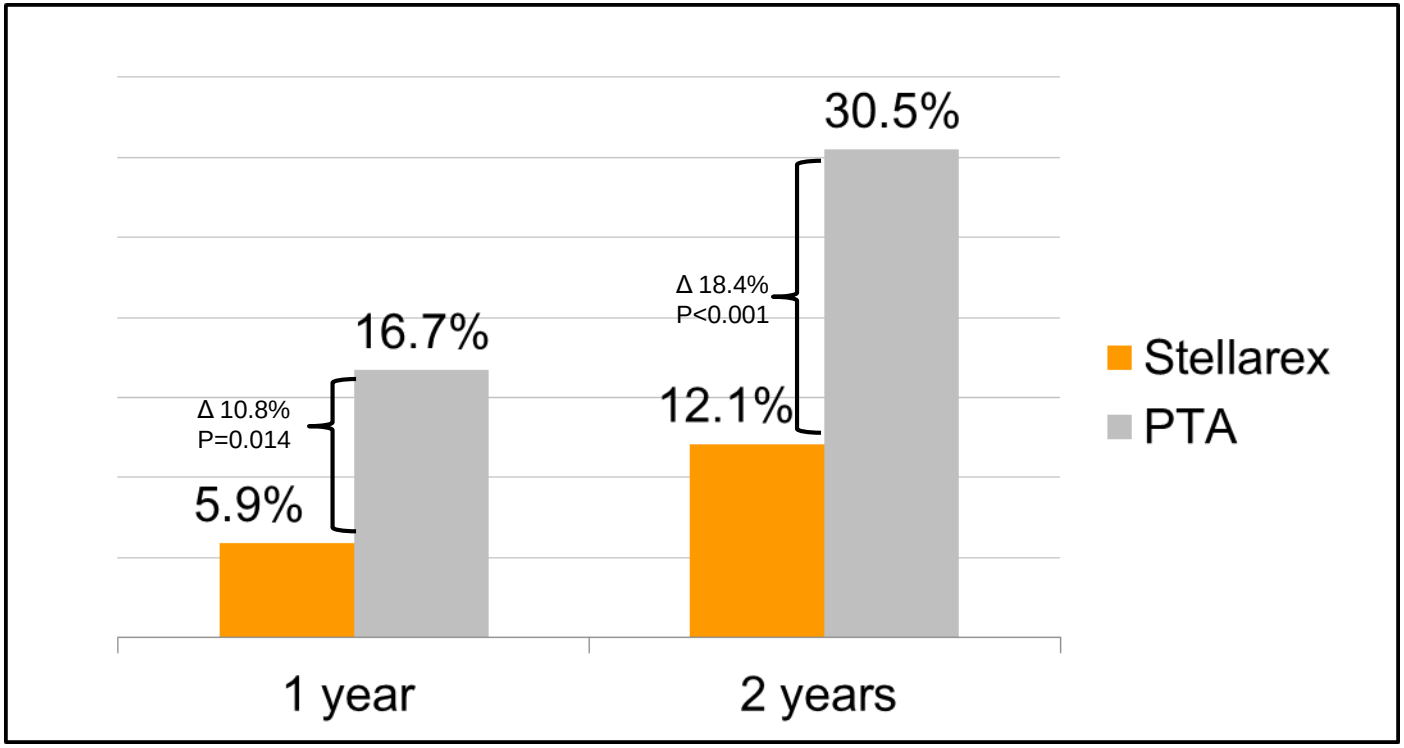
Clinically-driven TLR

ILLUMENATE EU RCT Study

- Significant treatment effect observed out to 2 years
- Treatment effect increased from 1 to 2 years



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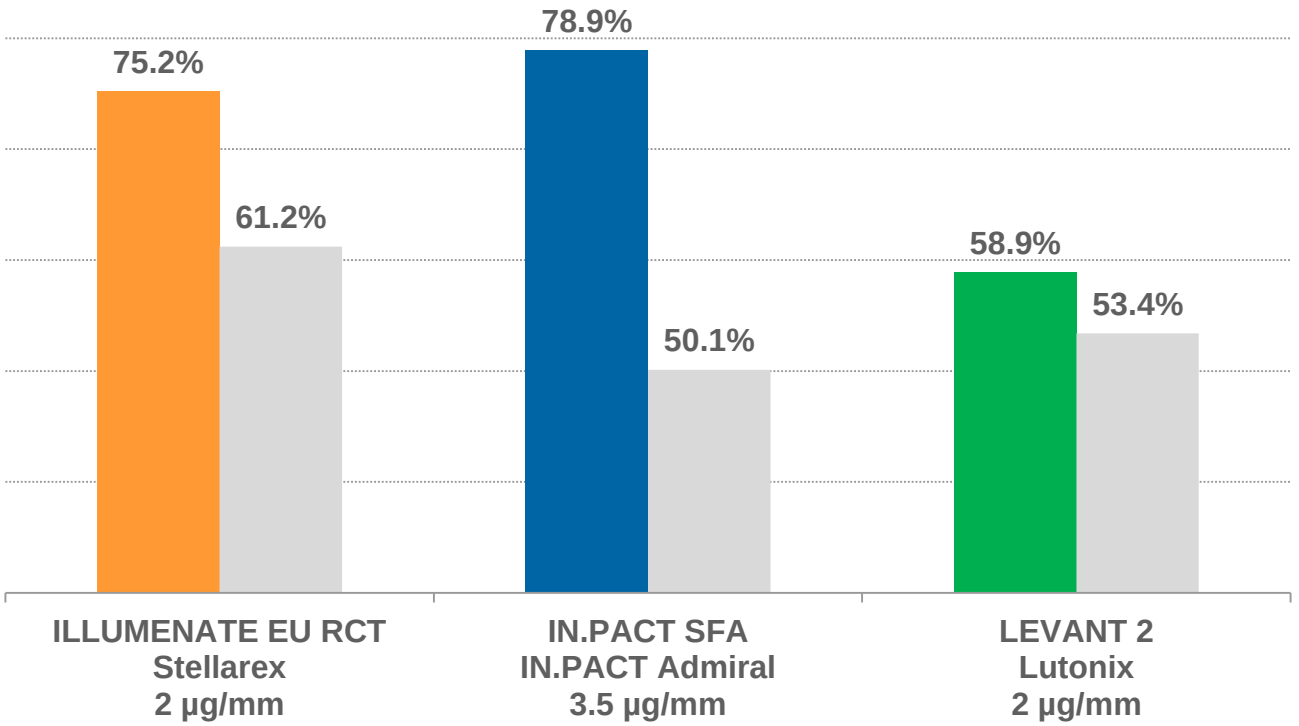
Data in Context
DCB Primary Patency Rates at 2 Years

Core lab adjudicated patency, KM estimates



Laird et al. J Am Coll Cardio 2015;66:2329-38
Laurich C. Oral Presentation. *SVS*. 2015

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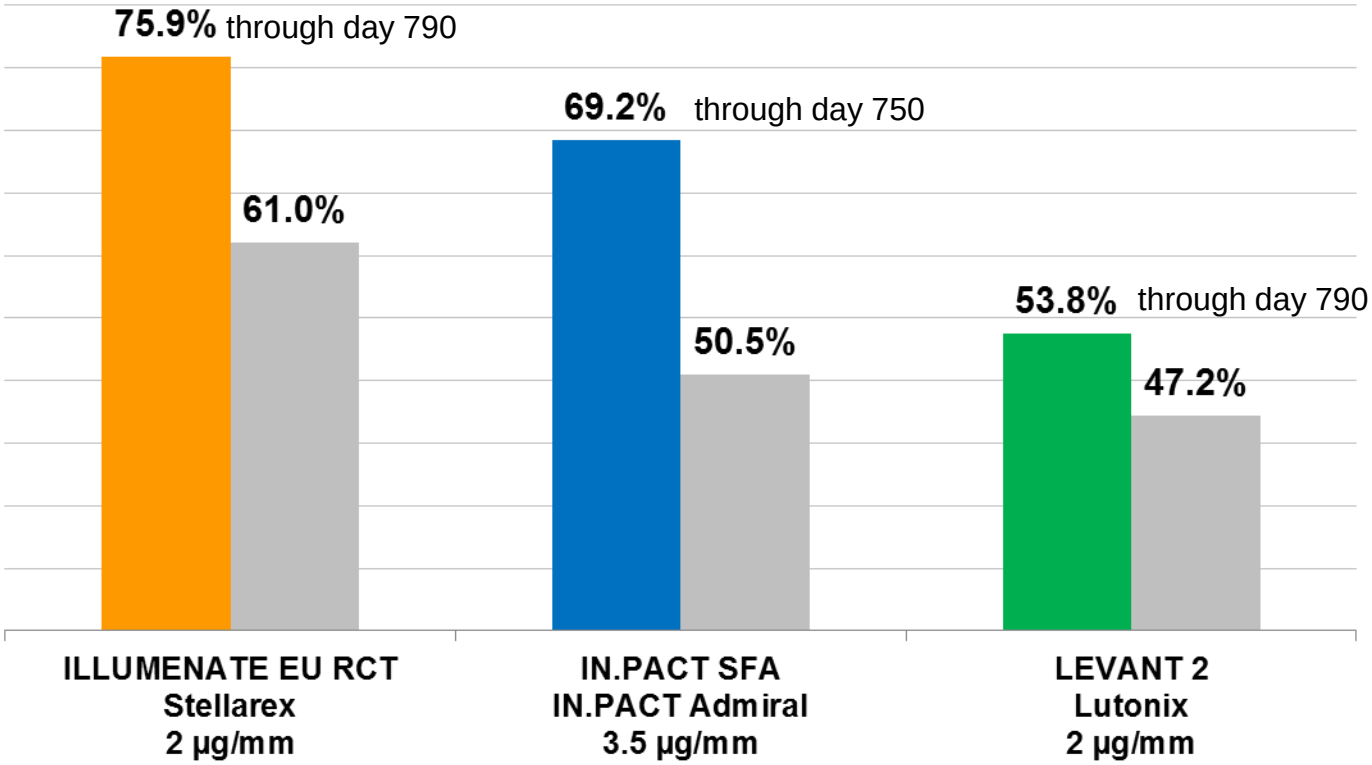
Data in Context
DCB Primary Patency Rates at 2 Years

Core lab adjudicated patency, exact rates



Medtronic IN.PACT Admiral Instructions for Use, Rev. 1F

http://www.bardpv.com/wp-content/uploads/2017/02/BAW1387400r3-Lutonix-DCB-IFU-with-GeoAlign-5F.pdf

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Key Take-Aways

- Stellarex is backed by solid and broad level 1 evidence based on 2 randomized trials
- Durable treatment effect was demonstrated, with no indication of late catch-up at 2 years
- Stellarex is the first low-dose DCB to demonstrate a significant treatment effect at 2 years

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