

First Report of the 12-Month Results from the SELUTION4SFA RCT:

Comparison of a Sirolimus-Eluting Balloon vs. Balloon Angioplasty
for Treatment of Femoropopliteal Artery Lesions

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Background

- **Peripheral Artery Disease (PAD)** affects almost 12% of the general population and is associated with an **increased risk of limb amputation, myocardial infarction, stroke and death.**
- **Paclitaxel drug-coated balloons are routinely used** as the standard of care for treatment of femoropopliteal lesions for patients with PAD.
- **In the US to date, no sirolimus-eluting balloon alternatives are approved.**
- Contrary to paclitaxel, which exerts a cytotoxic effect, **sirolimus drug is cytostatic** and carries potent anti-inflammatory properties.
- Historically, sirolimus on a balloon has **presented technical challenges** in terms of tissue transfer and retention but is the **predominate drug used on coronary drug-eluting stents.**

SELUTION SLR™ Drug Eluting Balloon (DEB) Clinical Overview

Extensive clinical program spanning across **CORONARY** and **PERIPHERAL** spaces

EU DeNovo

SELUTIONDENOVO

Pis S Eccleshall, C Spaulding



RCT

N=3,323, m-center
DEB v. DES strategy

**12M Primary
Endpoint
Completed**

2 US IDE RCTs (ISR and DeNovo)

SELUTION4ISR

Pls D Cutlip, R Mehran



RCT, IDE

N=418, m-center
ISR

**12M Primary
Endpoint
Completed**

SELUTION4 DeNovo

PI R Waksman



RCT, IDE

N=960, m-center
De Novo

**Enrollment
Completed**

2 IDE RCTs (SFA and BTK)

SELUTION4SFA

Pls S J Mathews, T Zeller



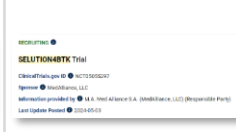
RCT, IDE

N=300, m-center
Fem-Pop

**12M Primary
Endpoint
Completed**

SELUTION4BTK

Pls E Armstrong, M Brodmann



RCT, IDE

N=376, m-center
BTK

Enrolling

3 Complex CLTI

PRESTIGE

T. Tang, - VIVA 2022



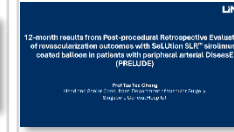
PRISTINE

T. Tang - Cardio. Interv.
Radiol. 2024



PRELUDE

T. Chong - LINC 2026



SFA/BTK Real World

SUCCESS

M.Lichtenberg - CX 2026
M.Lichtenberg - CX 2025



2 Proof-of-Concept

SELUTION FIM

T.Zeller - J Endovasc Ther. 2020



LIMUS FLOW

C.Ramos - LINC 2024



2 Complex SFA

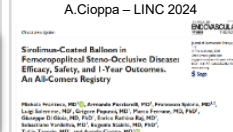
SELUTION SFA Japan

O. Iida - JET 2025
O.Iida - JACC CI 2024



SELUTION SFA IT

M.Franzese - J Endovasc Ther. 2023
A.Cioppa - LINC 2024



SELUTION SLR™ PTCA DEB now
approved for ISR use in U.S.

Study Device: SELUTION SLR SUSTANE™ DEB

2 Key Features Define the Unique Performance of SELUTION SLR DEB Technology



Cordis 2023 Data on file.
SELUTION SLR™ PTA DEB is approved in the United States for Investigational Use Only. Not available for Commercial Sale in the US.

MicroReservoirs

- ~4 μm spheres of **sirolimus** mixed with biodegradable polymer
- **Controlled release of sirolimus**

Proprietary Phospholipid Blend Coating

- Phospholipid blend containing and protecting MicroReservoirs at 1 $\mu\text{g}/\text{mm}^2$ sirolimus dose
- **Enhances drug transfer efficiency**

Study Design at a Glance

PIs: S J Mathews (US), T Zeller (EU)

KEY STUDY FACTS



Prospective



Single-Blinded



Randomized

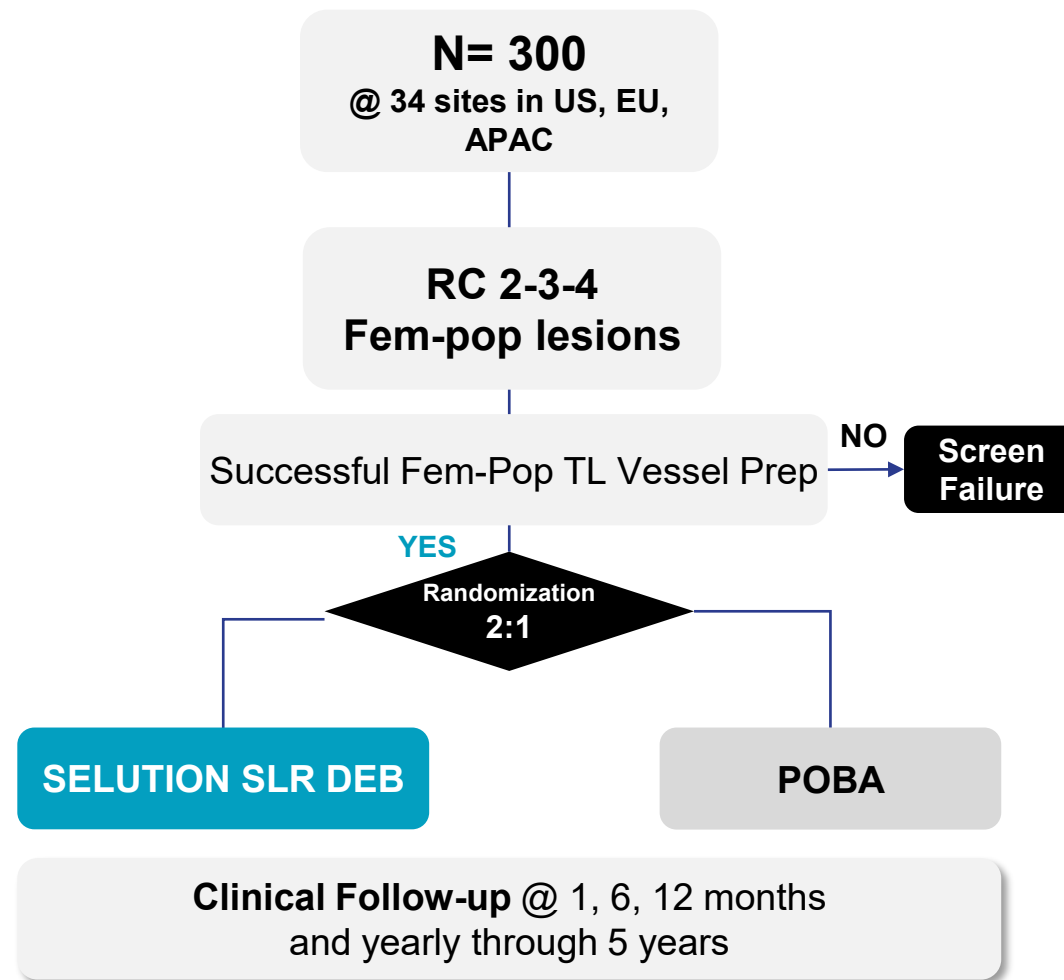


Multicenter



Full Independent Adjudication

ClinicalTrials.gov ID: NCT05132361



Key Inclusion and Exclusion Criteria



Major Inclusion Criteria

- ✓ Symptomatic PAD, **Rutherford Class 2-4**
- ✓ Adequate in/outflow
- ✓ De Novo or non-stented restenotic lesions
- ✓ $\geq 70\%$ stenosis
- ✓ CTOs allowed ($\leq 10\text{cm}$)
- ✓ Treatment length (3-30 cm)
- ✓ **SFA or popliteal (P1/P2)**
- ✓ Reference vessel diameter (4-7 mm)



Major Exclusion Criteria

- × **Rutherford Class 5-6**
- × Prior target vessel stent
- × **Lesions that could not be pre-treated successfully**
- × Target limb procedure within 14 days before or 30 days after index procedure
- × Target limb iliac or common femoral artery bypass within 6 weeks of index procedure
- × Immunocompromised or active cancer treatment
- × Chronic renal insufficiency

34 Participating Sites Across 4 Countries



United States

- NC Heart and Vascular Research, LLC (Pasi)
- St. Helena Hospital (Clavijo)
- Palm Vascular Center (Beasley)
- Mission Cardiovascular Research Institute (Jain)
- Cardiac and Vascular Institute Research Foundation (Lee)
- Cardiovascular Consultants of South Georgia (Sizemore)
- Holy Name Medical Center (Herman)
- Vascular Care Group (Arous)
- James J. Peters VA Medical Center (Chander)
- Cardiovascular Institute of the South (Walker)
- Baylor College of Medicine (Chung)
- Mercy Hospital (Thomas)
- MedStar (Bernardo)
- Manatee Memorial Hospital (Mathews)
- Advocate Lutheran General Hospital (Schwartz)
- Tennessee Center for Clinical Trials (D. Gupta)
- First Coast Cardiovascular Institute (Ali)
- Memorial Healthcare System (Roberts)
- Guardian Research Organization, LLC (A. Gupta)
- ClinRé (Armstrong)
- Heart Hospital Baylor Plano (Sayfo)
- Arkansas Heart (Lendel)
- Miriam Hospital (Soukas)
- El Paso Cardiology (Raja)
- Emory University Hospital (Niazi)



Germany

- Universitäts-Herzzentrum Freiburg – Bad Krozingen (Zeller)
- RoMed Rosenheim (Tepe)
- Universitätsklinikum Leipzig, Germany (Scheinert)
- Sana Kliniken Oberfranken Coburg (Thieme)
- Krankenhaus Buchholz (Herttig)
- University Clinic Tübingen (Schmehl)
- Alexianer Klinikum Hochsauerland (Lichtenberg)



Austria

- LKH-Universitätsklinikum Graz (Brodmann)



Hong Kong

- Queen Mary Hospital (Chan)
- The Chinese University of Hong Kong (Yan)

Primary Endpoints: SELUTION SLR DEB v. POBA



Primary Safety Endpoint (Testing *Non-Inferiority* to POBA)

Major Adverse Events defined as:

- 30-day freedom from all-cause death
- Freedom from 12-Mo target limb above-ankle amputation
- Freedom from 12-Mo clinically-driven target lesion revascularization (CD-TLR)

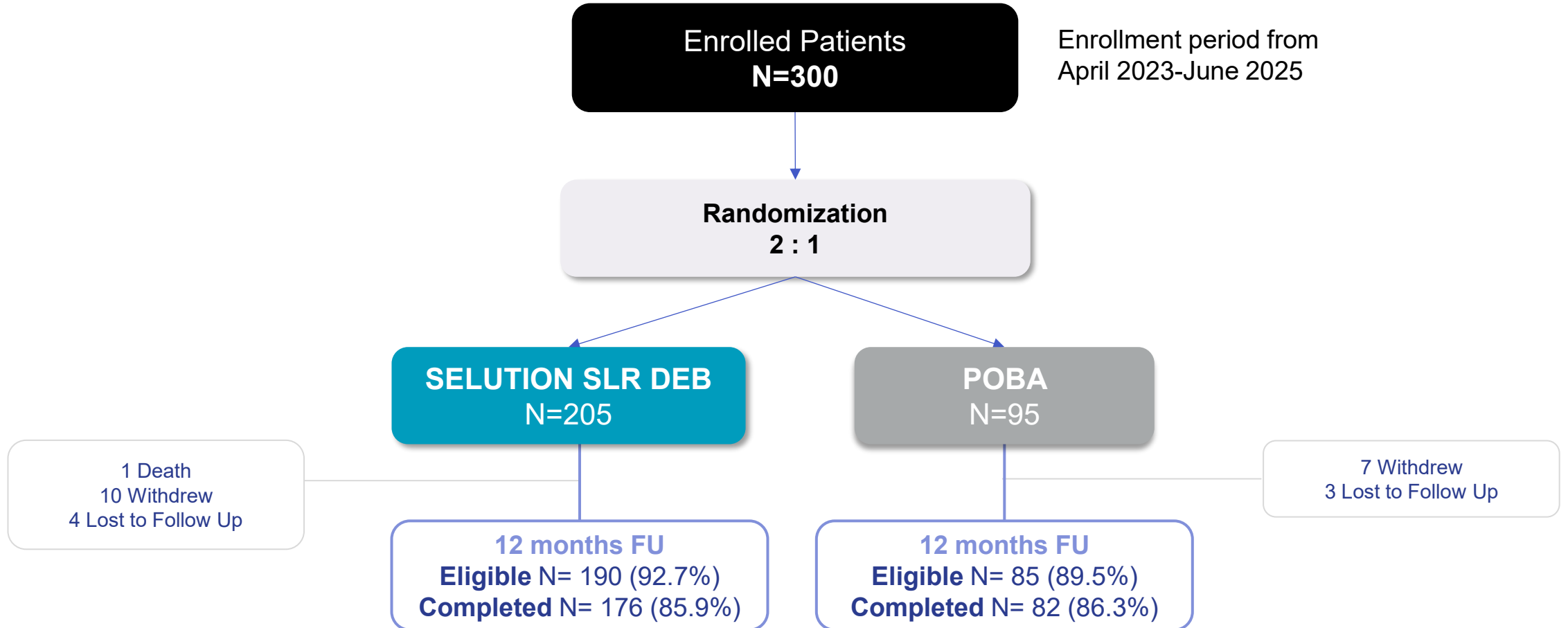


Primary Efficacy Endpoint (Testing *Superiority* to POBA)

Primary Patency defined as:

- Freedom from 12-Mo CD-TLR
- Freedom from 12-Mo occlusion or restenosis (Core lab adjudicated DUS PSVR > 2.4) of TL

Study Flow – Patient Consort Diagram



Patients were considered eligible if they had not previously withdrawn or died. Patient visits were considered completed if they had a recorded visit in person or remotely within the required time frame.

Baseline Patient Characteristics

	SELUTION SLR DEB N = 205	POBA N = 95	p-value
Age (years)	70.8 ± 9.4	70.5 ± 9.1	0.78
Female	37.1%	49.5 %	0.05
Diabetes Mellitus	41.5%	40.0%	0.90
Current Smoker	32.2%	29.5%	0.84
Hypertension	87.3%	80.0%	0.12
Dyslipidemia	81.0%	78.9%	0.76
Cerebral Stroke	6.8%	10.5%	0.36
Myocardial Infarction	14.6%	15.8%	0.86
Chronic Kidney Disease	9.3%	9.5%	1.00
Rutherford Class			0.68
2	12.2%	15.8%	
3	76.6%	72.6%	
4	11.2%	11.6%	
Ankle Brachial Index (ABI)	0.8 ± 0.2	0.8 ± 0.2	0.83

All data is core lab adjudicated. Data are presented as percentages % (n/N) or mean (±SD). Values represent total n unless otherwise specified.
p-value calculated using ANOVA for continuous variables and Fisher's exact test for categorical variables.

Baseline Lesion Characteristics

	SELTION SLR DEB	POBA	p-value
RVD (mm)	5.5 ± 0.8	5.3 ± 0.7	0.13
Lesion Length (mm)¹	92.9 ± 57.6	72.4 ± 49.8	0.002
Lesion Type			0.83
De novo	91.5% (204/223)	93.1% (94/101)	
Restenotic	8.5% (19/223)	6.9% (7/101)	
Pre-Procedure Diameter Stenosis (%) ¹	76.5 ± 18.4	80.4 ± 19.1	0.08
Lesion Location¹			0.58
Superficial Femoral Artery (SFA)	56.7% (122/215)	65.6% (63/96)	
Proximal Popliteal Artery (PPA)	7.4% (16/215)	6.3% (6/96)	
SFA-PPA	34.0% (73/215)	27.1% (26/96)	
Other ²	1.9% (4/215)	1.0% (1/96)	
Total Occlusions¹	24.1% (49/203)	38.0% (35/92)	0.02
Calcification (PACCS) ¹			0.82
None (Grade 0)	24.8% (51/206)	23.9% (22/92)	
Non-Severe (Grade 1 or 2)	24.8% (51/206)	28.3% (26/92)	
Severe (Grade 3 or 4)	50.5% (104/206)	47.8% (44/92)	

Data are presented as percentages % (n/N) or mean (±SD). Values represent total n unless otherwise specified.

p-value calculated using ANOVA for continuous variables and Fisher's exact test for categorical variables.

¹Core-lab adjudicated.

²Other lesion locations included external iliac artery

Baseline Procedural Characteristics

	SELTION SLR DEB	POBA	p-value
IVUS Used	31.5% (70/222)	30.7% (31/101)	0.90
Lesion Preparation ¹			0.41
Atherectomy (+/- POBA)	43.9% (90/205)	42.1% (40/95)	
Specialty Balloon Only	0.5% (1/205)	0.0% (0/95)	
Intravascular Lithotripsy Only	1.5% (3/205)	1.1% (1/95)	
POBA Only	50.2% (103/205)	49.5% (47/95)	
Combination of Other Devices	3.9% (8/205)	7.4% (7/95)	
Inflation Time (sec)	176.9 ± 50.0	157.9 ± 65.2	0.04
Inflation Pressure (ATM)	8.1 ± 2.2	9.0 ± 3.6	0.03
Provisional Stenting	5.0% (11/222)	10.0% (10/100)	0.14
Reason for Provisional Stenting ²			
Residual Stenosis	28.6% (4/14)	10.0% (1/10)	1.00
Flow Limiting Dissection	42.9% (6/14)	70.0% (7/10)	0.12
Other ³	28.6% (4/14)	20.0% (2/10)	1.00
Final Residual Stenosis (%) ⁴	25.9 ± 12.6	26.8 ± 13.9	0.57
Procedure Success [†]	98.5% (198/201)	97.8% (90/92)	

Data are presented as percentages % (n/N) or mean (±SD). Values represent total n unless otherwise specified.

p-value calculated using ANOVA for continuous variables and Fisher's exact test for categorical variables.

¹A lesion may have had more than one type of pre-treatment device used, so pre-treatment devices may sum to more than the total number of lesions treated.

²More than one reason for bailout stenting may be used, so number of reasons may sum to more than the total number of stented lesions.

³Other reasons for provisional stenting included grade B dissection, persistent recoil or venous AV fistula

⁴Core lab adjudicated.

[†] Procedure success is defined as residual diameter stenosis ≤ 50% on completion angiography by core lab assessment (evaluated post-procedure), or residual diameter stenosis ≤ 30% if bailout stenting was used

12 Mo Primary Endpoint by Proportional Event Rate

Primary Safety Endpoint^{1,2}

(Composite of freedom from perioperative death at 30 days, 12 Mo major target limb amp & CD-TLR)

- SELUTION SLR DEB: 92.8%
- POBA: 84.2%
 - p-value<0.0001
 - Difference = 8.6%
 - 95% Confidence Interval (0.3%, 16.8%)

1. In the case of missing data, imputation for missing primary endpoint data will be based on multiple imputation via fully conditional specific regression, using 100 imputed data sets, combining the imputed data sets for inference via 'Rubin's rules.'

2. Analysis based on a Farrington-Manning test with alpha = 0.025.

3. Analysis is based on a likelihood ratio test with a one-sided 0.025 alpha level.

Primary Efficacy Endpoint^{1,3}

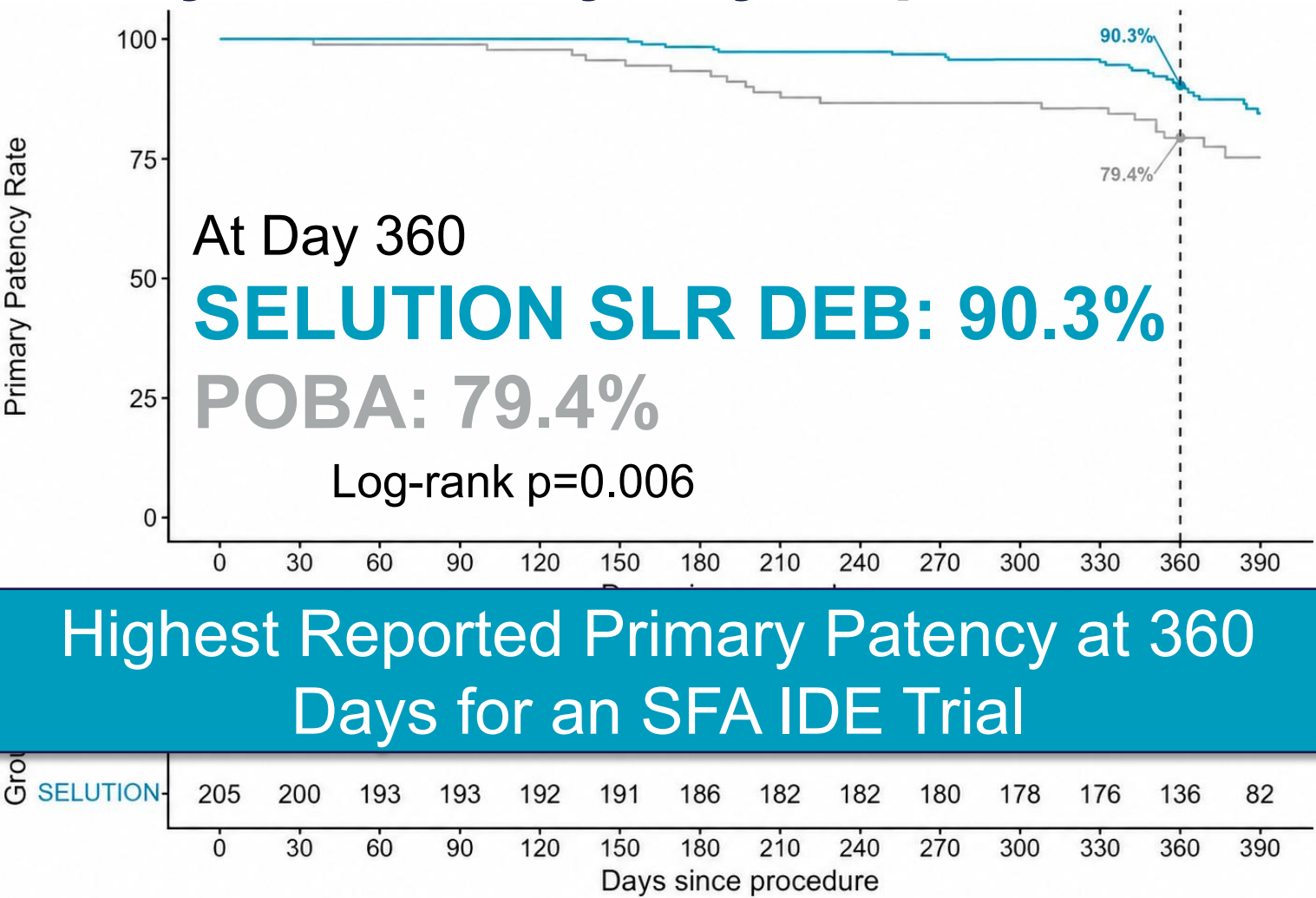
(Primary Patency⁴ defined as a composite of 12 Mo freedom from CD-TLR & restenosis)

- SELUTION SLR DEB: 78.6%
- POBA: 65.2%
 - p-value=0.019
 - Difference = 13.4%
 - 95% Confidence Interval (0.8%, 25.9%)

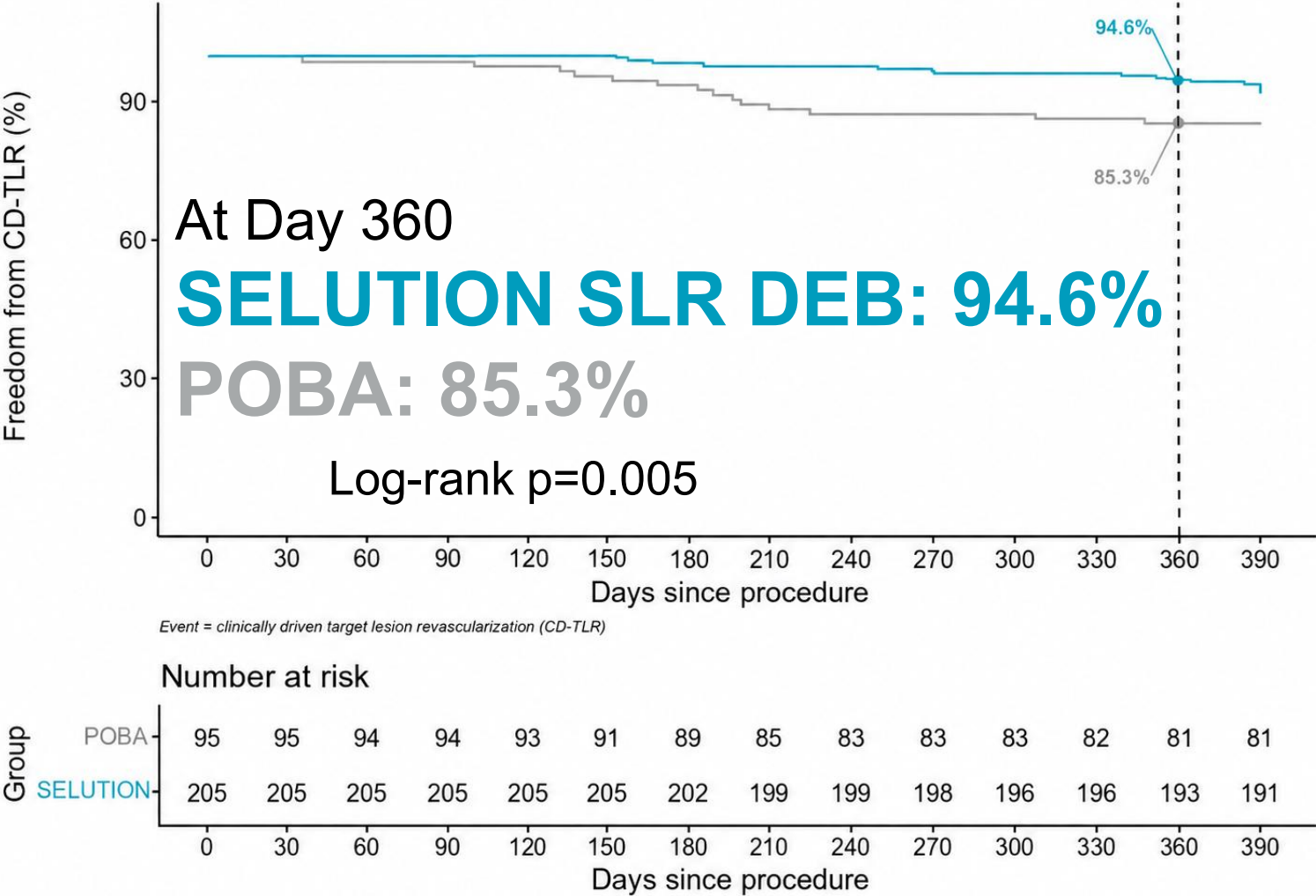
4. Primary patency is defined as freedom from ALL of the following adverse events evaluated at 12 months post procedure: clinically driven target lesion revascularization (CD-TLR, defined as re-intervention of target lesion(s) due to recurrent, persistent, or worsening symptoms and angiographic restenosis (≥50% diameter stenosis) of target lesion by ACL measurement) and restenosis as determined by core lab adjudicated duplex ultrasound peak systolic velocity ratio of >2.4 or occlusion of the target lesion.

**SELUTION SLR DEB is non-inferior to POBA for safety (p<0.0001)
and superior for effectiveness (p=0.019)**

Primary Patency at 360 Days by Kaplan-Meier Estimate



Freedom from CD-TLR at 360 Days by Kaplan-Meier Estimate



Safety Outcomes at 360 Days

	SELUTION SLR DEB	POBA	p-value
CD-TLR¹	6.4% (13/202)	15.2% (14/92)	0.02
MALE ²	1.0% (2/201)	2.2% (2/93)	0.43
Major (above-the-ankle) Amputation	0.5% (1/201) ³	0.0% (0/93)	0.50
Major Reintervention of the Target Limb ⁴	1.0% (2/201)	2.2% (2/93)	0.43
Major Cardiovascular Events	2.0% (4/201)	4.3% (4/93)	0.26
Cardiovascular Death	0.0% (0/201)	0.0% (0/93)	n/a
Myocardial Infarction (MI)	1.5% (3/201)	2.2% (2/93)	0.69
Stroke	0.5% (1/201)	3.2% (3/93)	0.06
All-cause Mortality	0.5% (1/201)	0.0% (0/93)	0.50
Target Lesion Thrombosis ⁵	0.0% (0/201)	0.0% (0/93)	n/a

Data are presented as percentages % (n/N) or mean (±SD). Values represent total n unless otherwise specified.

p-values calculated using the Z-test.

1. Defined as re-intervention of target lesion(s) due to recurrent/persistent/worsening symptoms and the angiographic finding of ≥ 50% restenosis of target lesion by ACL measurement.

2. Major Adverse Limb Events (MALE): Composite rate of above ankle amputation of the index limb or major reintervention.

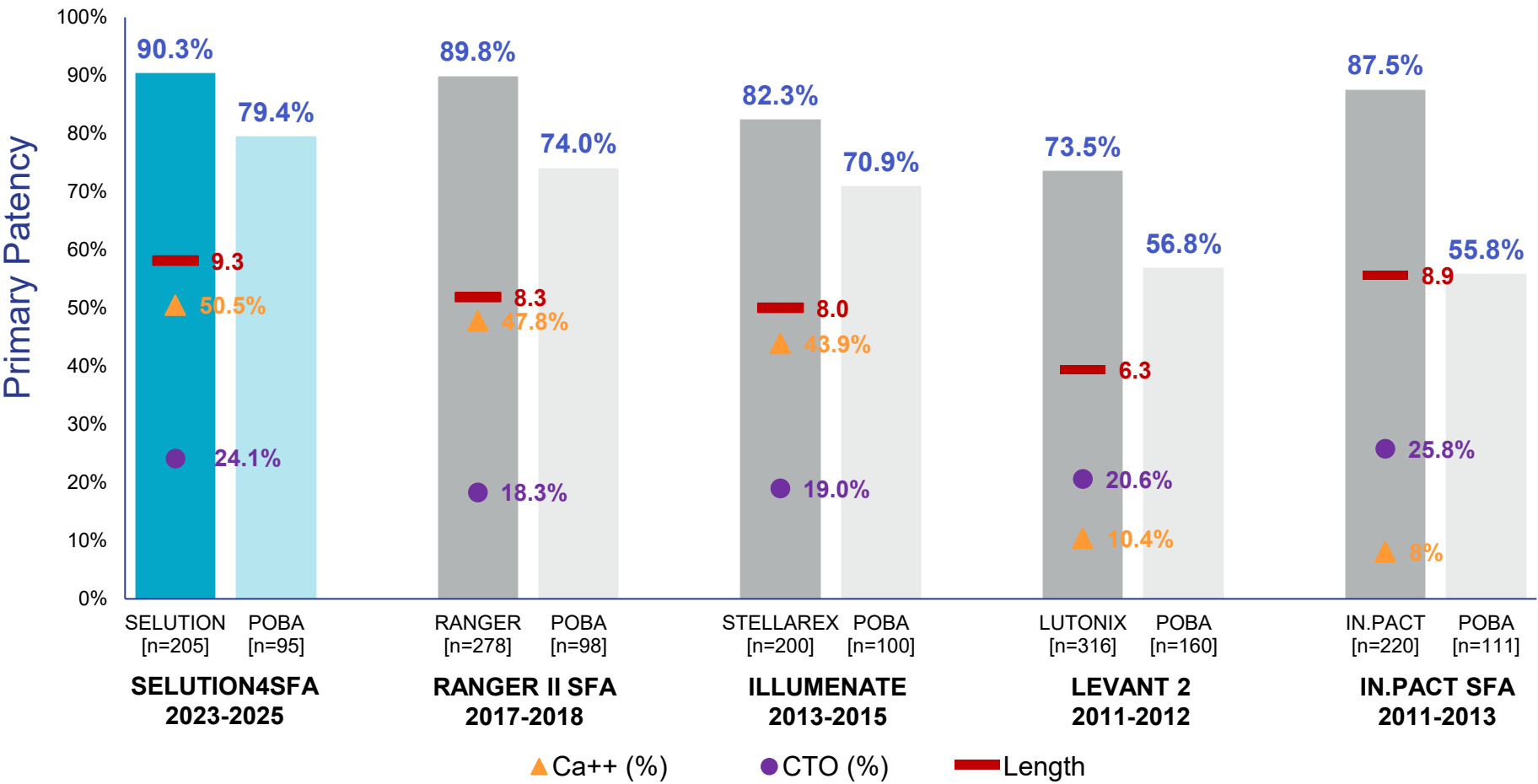
3. Amputation was not device or procedure-related

4. New bypass graft, jump/interposition graft revision, or thrombectomy/thrombolysis.

5. Assessed via angiographic or DUS core lab adjudication.

SFA IDE Trials - Data in Context

(12 Mo Primary Patency by KM Estimate)



Conclusions

- Despite treating long (9cm+) and heavily calcified lesions, SELUTION SLR SUSTANE DEB achieved **patency results (90.3%) in-line with best-in-class PTX** and the **highest reported KM rate** in SFA IDE trials to date
- The SELUTION4SFA trial **successfully met** the statistical threshold for **superiority to POBA (p=0.019)**
- SELUTION SLR SUSTANE DEB demonstrates **clinical efficacy** for a sirolimus eluting balloon equaling that of approved PTX devices with a **proven safety profile** for SFA disease
- **Consistency of results** across SELUTION trials (SFA Japan, SUCCESS registry) and vessel beds (coronary [ISR, De Novo]; peripheral [ATK, BTK, Claudicant, CLTI]; AVF)

Thank You for Your Attention