Review of LEVANT 2 Outcomes and Latest Results from the LEVANT Global SFA Registry

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

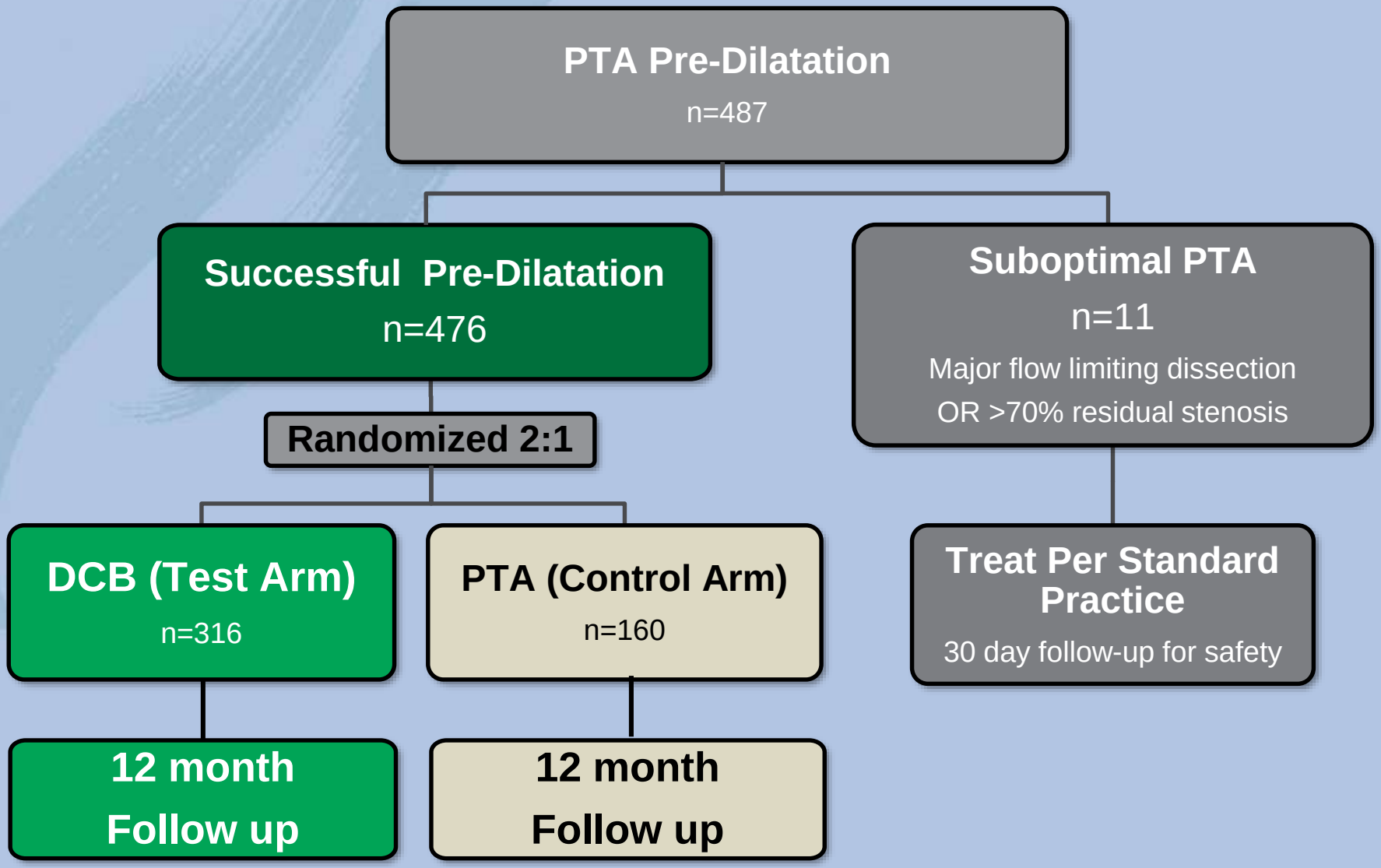
- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☒ Other(s) Cook, Termo, BSJ,

☐ I do not have any potential conflict of interest

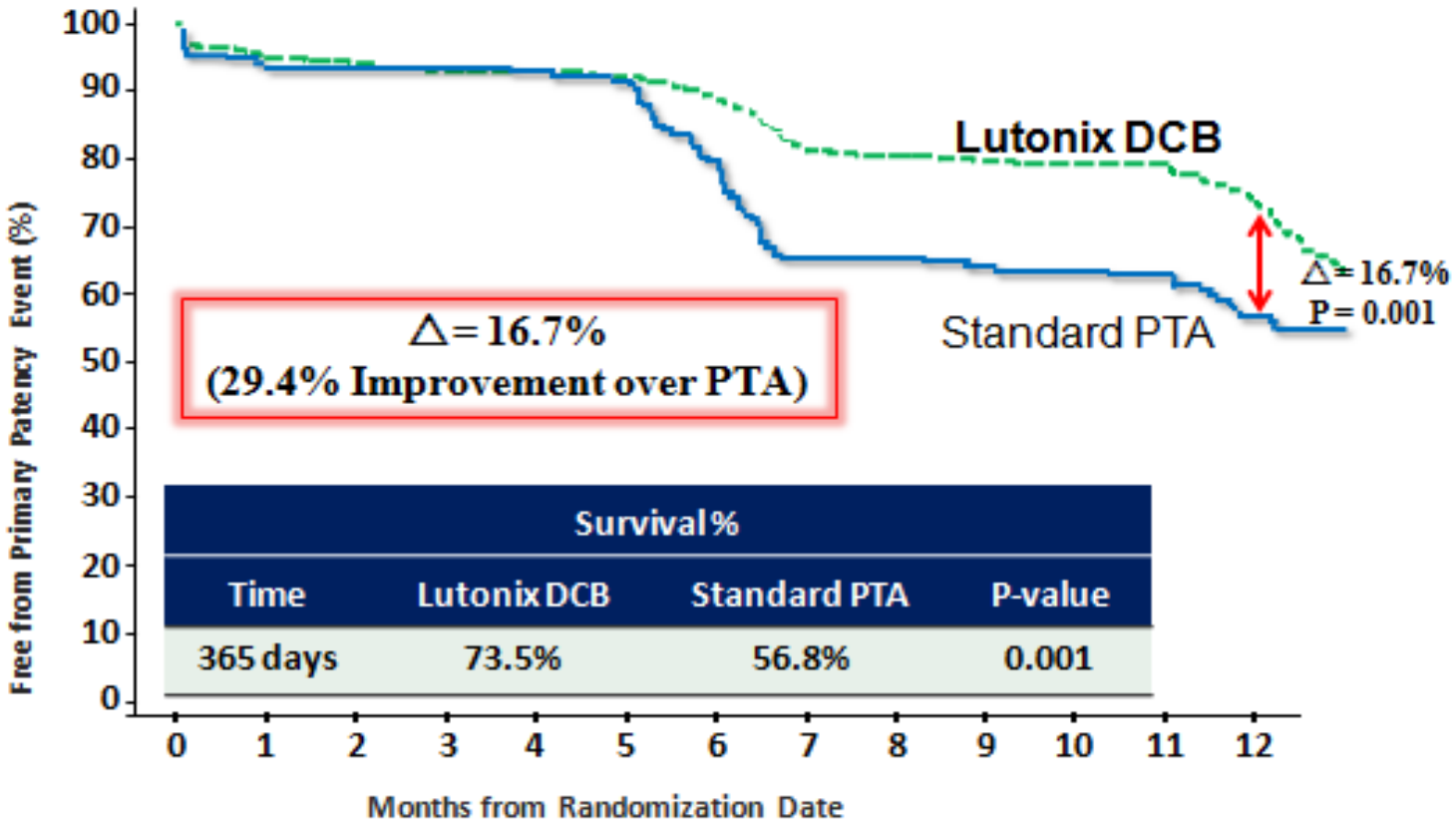
Levant 2 Primary Endpoints

Safety	Efficacy
Freedom from all-cause peri-operative death AND Freedom at 1 YEAR in the index limb from: • Amputation (above or below the ankle) • Re-intervention • Index-limb-related death	Primary patency of the target lesion at 1 YEAR: Absence of restenosis defined by DUS PSVR ≥2.5 AND Freedom from target lesion revascularization (TLR)

LEVANT 2 Randomized Study Flow

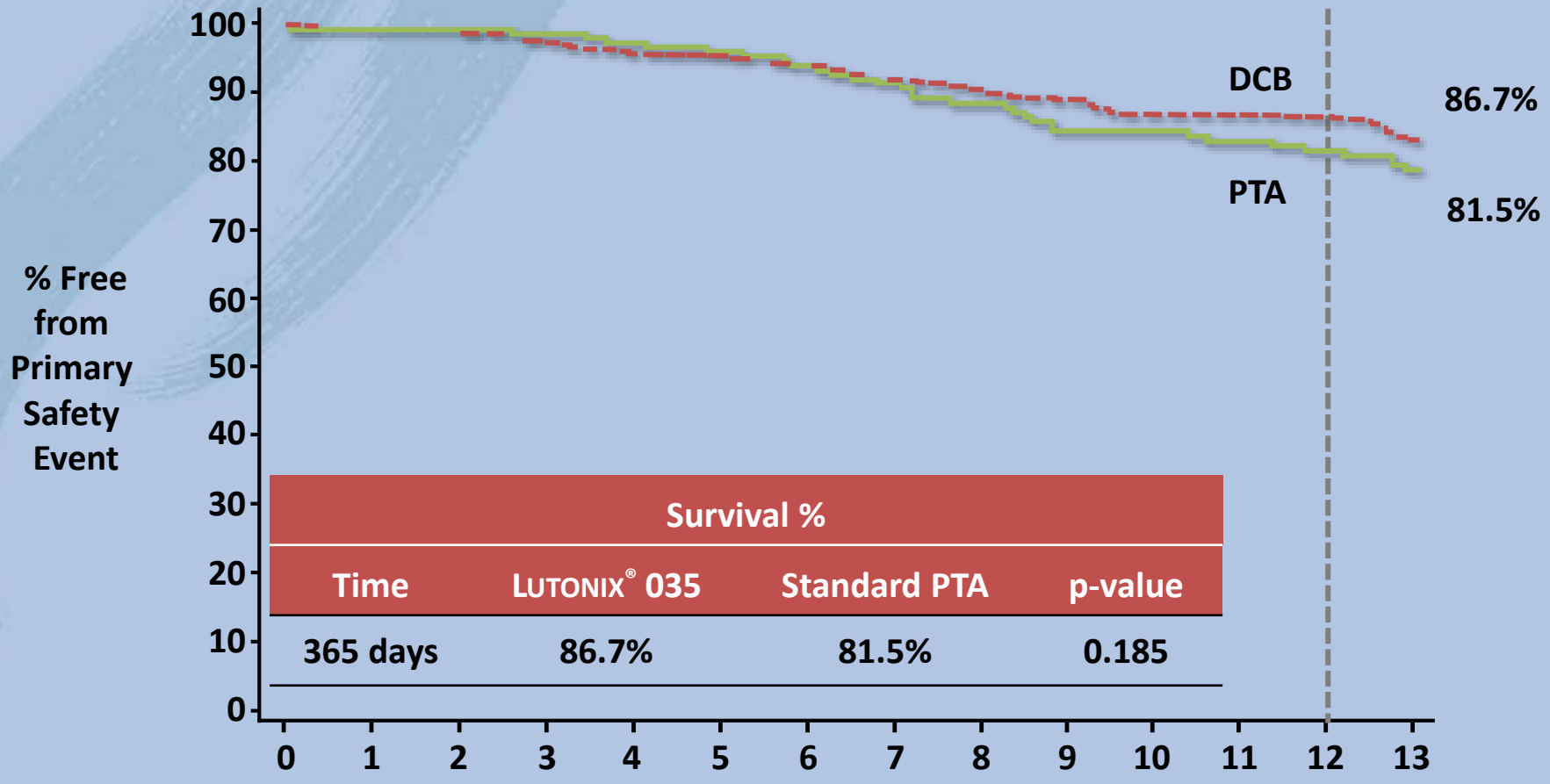


LEVANT 2 Primary Patency



Survival %			
Time	Lutonix DCB	Standard PTA	P-value
365 days	73.5%	56.8%	0.001

Freedom from Primary Safety Event (KM)



Survival %			
Time	LUTONIX® 035	Standard PTA	p-value
365 days	86.7%	81.5%	0.185

Additional Kaplan-Meier Analysis performed as part of sensitivity analysis, not primary endpoint analysis

LUTONIX® DCB Global SFA Registry Study

LUTONIX® DCB Global SFA Registry Study Synopsis

OBJECTIVE	To demonstrate safety and assess the clinical use and outcomes of the LUTONIX® Drug Coated PTA Dilatation Catheter in a heterogeneous patient population in real world clinical practice.
STUDY DESIGN	Prospective, Global Multicenter, Single Arm Registry
STUDY DEVICE	LUTONIX® 035 Drug Coated PTA Dilatation Catheter
PRIMARY ENDPOINT	*Efficacy*: Freedom from TLR at 12 months *Safety*: Freedom at 30 days from TVR, major index limb amputation, and device- and procedure-related death.
NUMBER OF SUBJECTS/SITES	691 subjects 38 global sites/10 countries
FOLLOW-UP	1, 6, 12, & 24 months

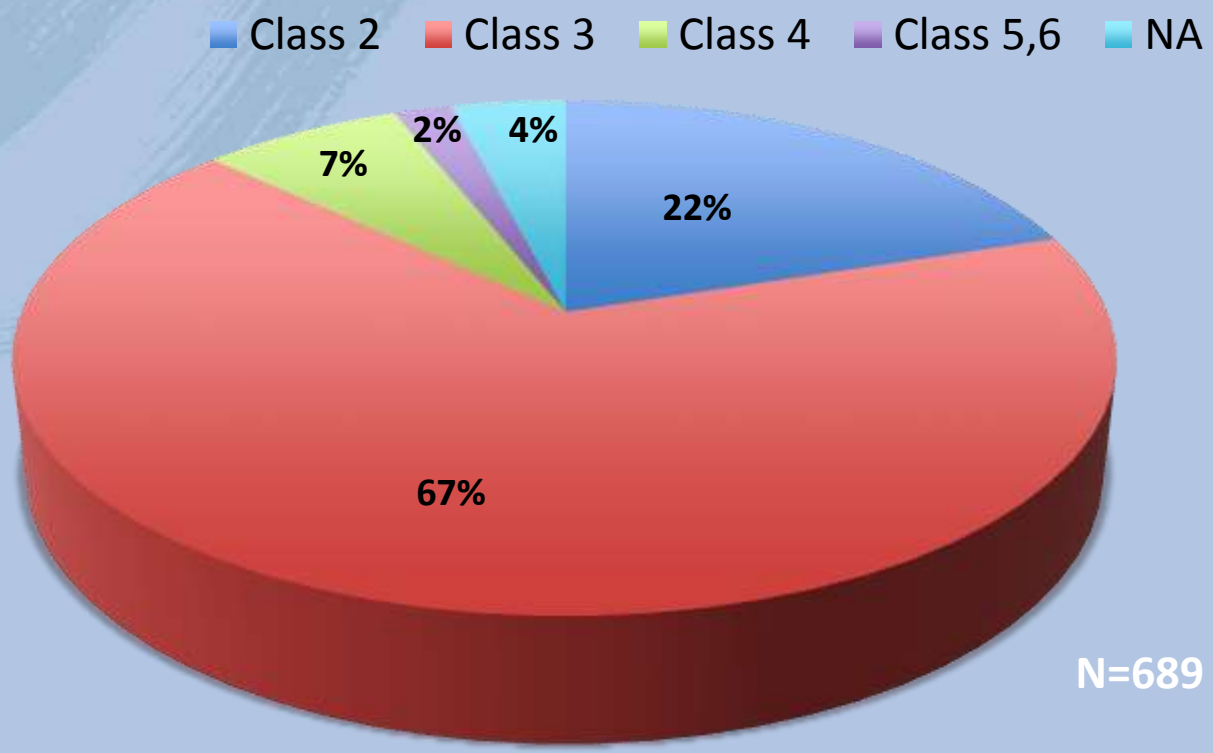
Baseline DCB Demographics

Lutonix Global Real World SFA Registry

	Global SFA Registry (N=691)
Age, Mean ± SD (n)	68.2 ± 9.9 (691)
Male gender, % (n/N)	67.9% (469/691)
Obesity	24.7% (164/665)
Current Smoker	36.9% (254/689)
Dyslipidemia	70.0% (484/691)
Diabetes	39.5% (273/691)
Hypertension	84.9% (587/691)

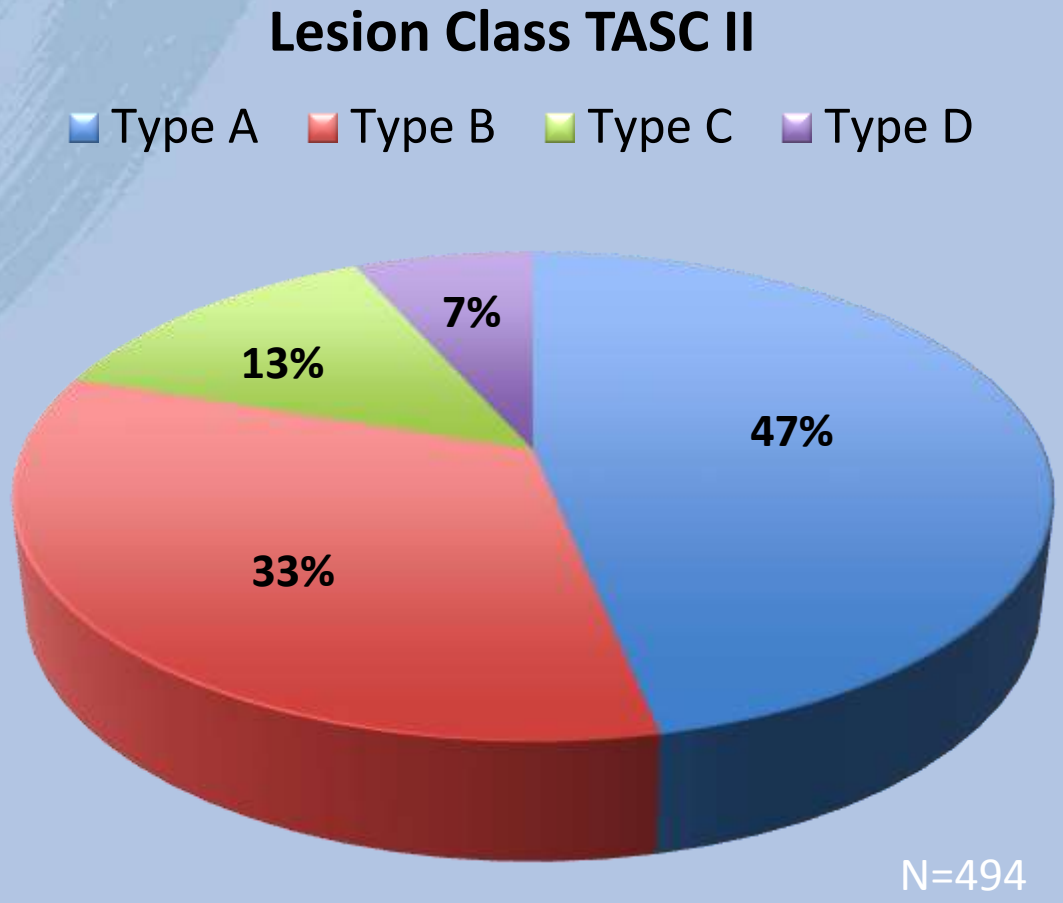
Lutonix Global SFA Real-World Registry

Baseline Rutherford Category



Lutonix Global SFA Real-World Registry

Lesion Characteristics



DCB Angiographic Demographics

Lutonix Global Real World SFA Registry

	Global SFA Registry (N=691)
Two or more lesions treated	15.6% (108/691)
Total Lesion Length (mm)	101.2 ± 84.2 (685)
Treated Length (mm)	136.6 ± 89.7 (689)
Calcification	50.2% (238/474)*
Chronic Total Occlusion	31.2% (214/686)
Lesion Locations	
SFA	70.0% (483/690)
Proximal Popliteal	16.8% (116/690)
Mid & Distal Popliteal	13.1% (91/690)
Final %Diameter Stenosis	14.6 ± 18.6 (680)
Bail-out Stenting	25.2% (174/690)
Dissection	18.4% (127/690)

* Data not initially collected. Data collected after approximately 200 patients enrolled.

Lutonix Global SFA Real-World Registry

30-Day Safety

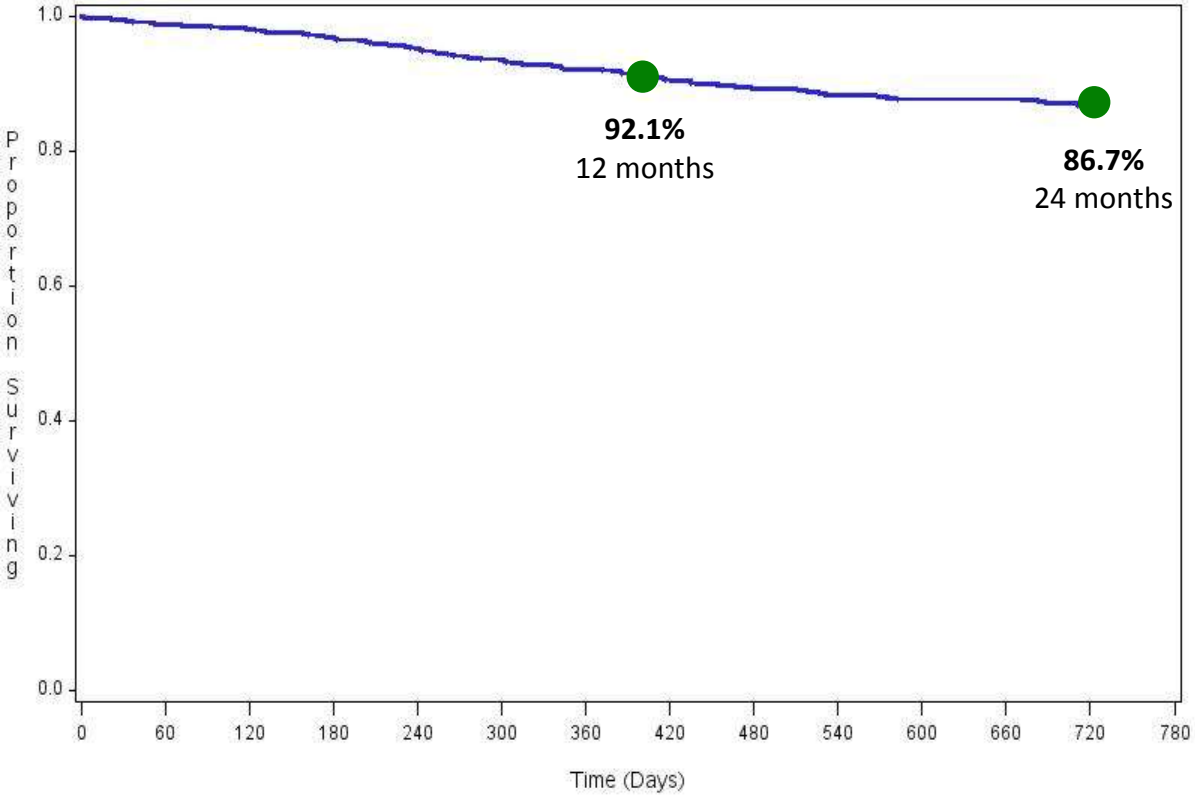
	% (n/N)
30-Day Safety[1]	99.4% (681/685)

1 Freedom at 30 days from TVR, major index limb amputation, and device and procedure-related death.
All SAEs adjudicated. Study monitored.

Lutonix Global SFA Real-World Registry

Primary Safety Endpoint

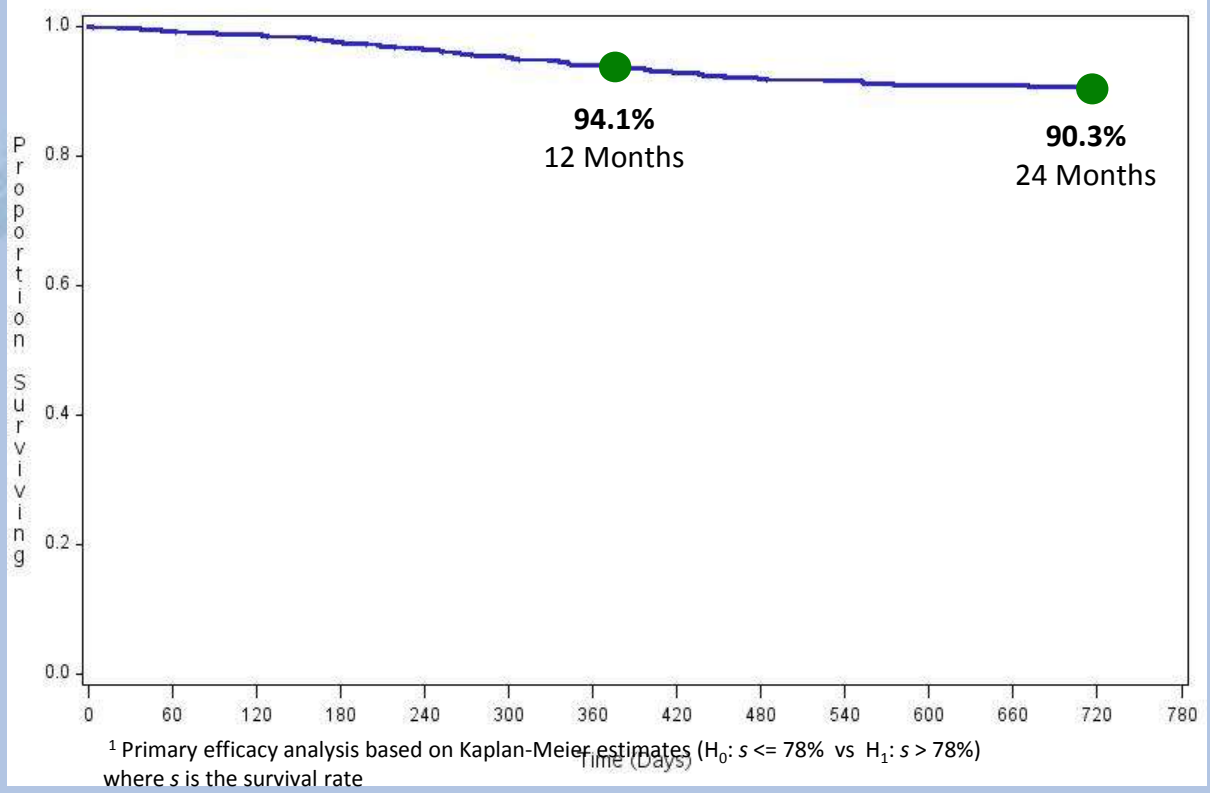
Time	N	Survival % [95% CI]	Subjects with Events	Subjects Censored	Subjects at Risk
Month 12 (365 Days)	616	92.1% [89.8%, 93.9%]	53	31	605
Month 24 (730 Days)	508	86.7% [83.9%, 89.1%]	86	306	297



Lutonix Global SFA Real-World Registry

TLR Free Survival

Time	N	Survival % [95% CI]	P-value[1]	Subjects with Events	Subjects Censored	Subjects at Risk
Month 12 (365 Days)	628	94.1% [92.0%, 95.6%]	<.001	40	34	617
Month 24 (730 Days)	527	90.3% [87.7%, 92.3%]		63	318	310



[1] Primary efficacy analysis based on Kaplan-Meier estimates (H_0: s <= 78% vs H_1: s > 78%) where s is the survival rate

Lutonix Global SFA Real-World Registry

24 Month Secondary Endpoints

All Cause Death, % (n/N)	5.9% (36/615)
Major Index Limb Amputation, % (n/N)	0.9% (5/582)
Minor Index Limb Amputation, % (n/N)	0.7% (4/580)
Reintervention for Treatment of Embolization to the Distal Vasculature, % (n/N)	0.7% (4/580)
Reintervention for treatment of thrombosis of the target vessel, % (n/N)	2.7% (16/583)

Lutonix Global SFA Real-World Registry

24 Month Sub-group Analysis

Sub-group	Freedom from TLR % (n/N)
Calcification	88.3% (174/197)
Chronic Total Occlusion	89.5% (162/181)
Diabetics	91.0% (141/155)

All SAEs adjudicated. Study monitored.

LUTONIX Global SFA Real-World Registry ISR Sub-group Analysis

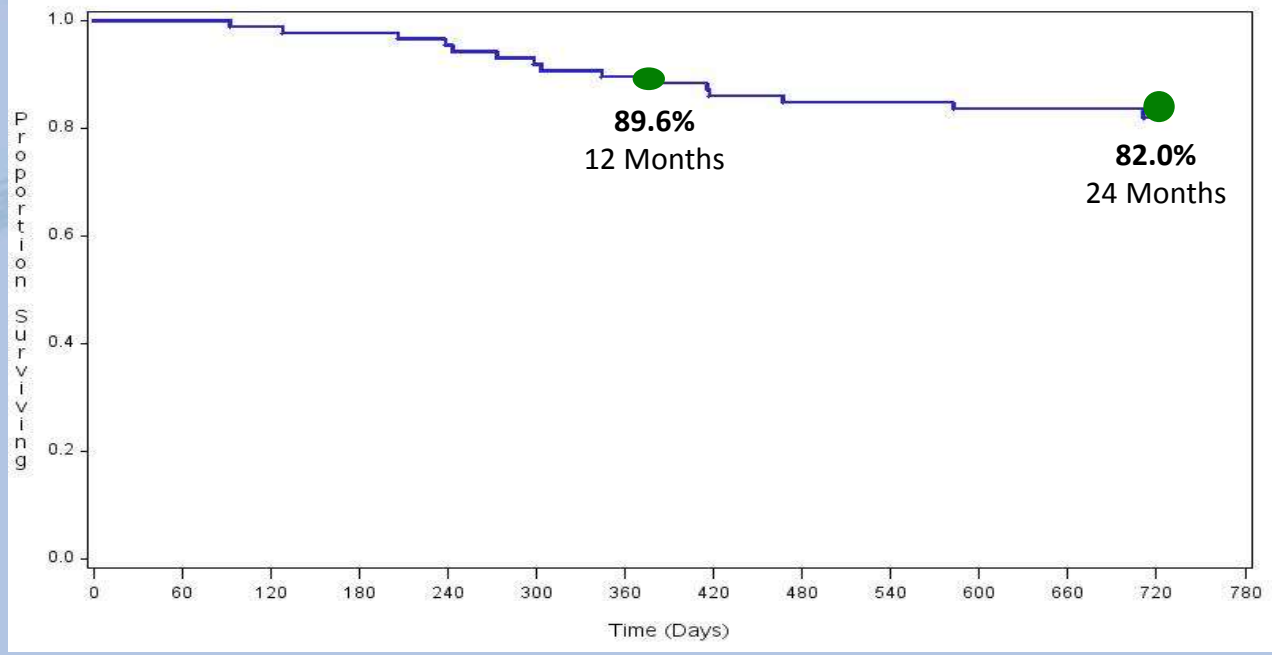
All Subjects vs. ISR
Baseline Lesion Characteristics

	All Subjects (23 – 500 mm)	ISR
Total Lesion Length (mm)	101.2 ± 84.2 (685)	154.4 ± 97.1 (89)
Treated Length (mm)	136.6 ± 89.7 (689)	182.1 ± 90.5 (89)
Calcification, % (n/N)	50.2% (238/474)	37.7% (26/69)
Chronic Total Occlusion, % (n/N)	31.2% (214/686)	28.1% (25/89)
Lesion Locations, % (n/N)		
SFA, % (n/N)	70.0% (483/690)	70.8% (63/89)
Proximal Popliteal, % (n/N)	16.8% (116/690)	18.0% (16/89)
Mid & Distal Popliteal, % (n/N)	13.1% (91/690)	11.2% (10/89)
Final % Diameter Stenosis, %	14.6 ± 18.6 (680)	13.2 ± 17.65 (89)
Bail-out Stenting, % (n/N)	25.2% (174/690)	33.7% (30/89)
Dissection, % (n/N)	18.4% (127/690)	13.5% (12/89)

Lutonix Global SFA Real-World Registry

ISR - Primary Safety Endpoint

Time	N	Survival[2] % [95% CI]	Subjects with Events	Subjects Censored	Subjects at Risk
Month 12 (365 Days)	78	89.6% [80.9%, 94.4%]	9	4	76
Month 24 (730 Days)	67	82.0% [71.8%, 88.8%]	15	33	41



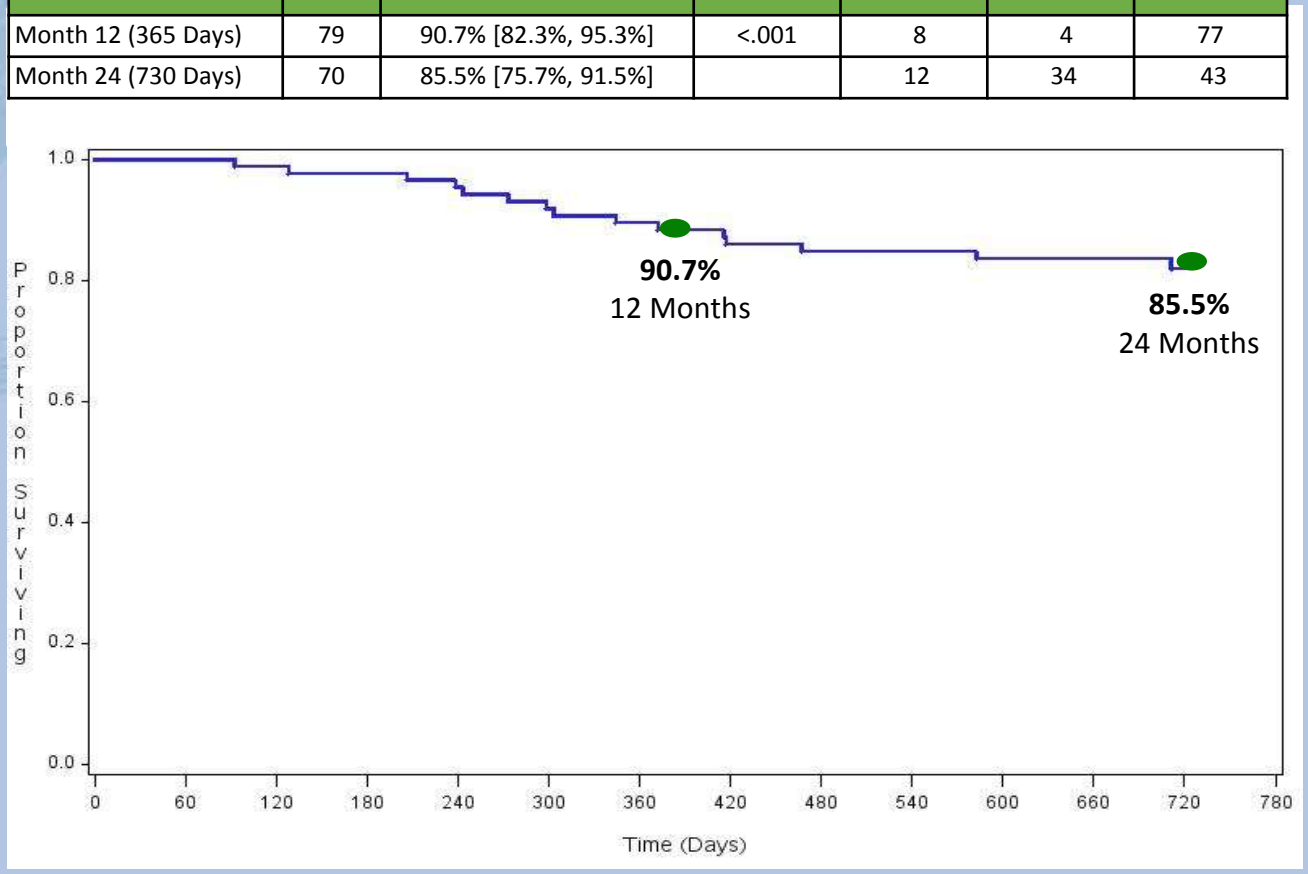
[1] Additional key safety analysis based on Kaplan-Meier estimates

Note: Primary safety event is device- or procedure related death, TVR, or major amputation within 30 days.

Lutonix Global SFA Real-World Registry

ISR - TLR Free Survival

Time	N	Survival % [95% CI]	P-value[1]	Subjects with Events	Subjects Censored	Subjects at Risk
Month 12 (365 Days)	79	90.7% [82.3%, 95.3%]	<.001	8	4	77
Month 24 (730 Days)	70	85.5% [75.7%, 91.5%]		12	34	43



[1] Primary efficacy analysis based on Kaplan-Meier estimates (H_0: s <= 78% vs H_1: s > 78%) where s is the survival rate

LUTONIX Global SFA Real-World Registry Long Lesions Sub-group Analysis (140–500mm)

All Lesions vs. Long Lesions (140–500mm)

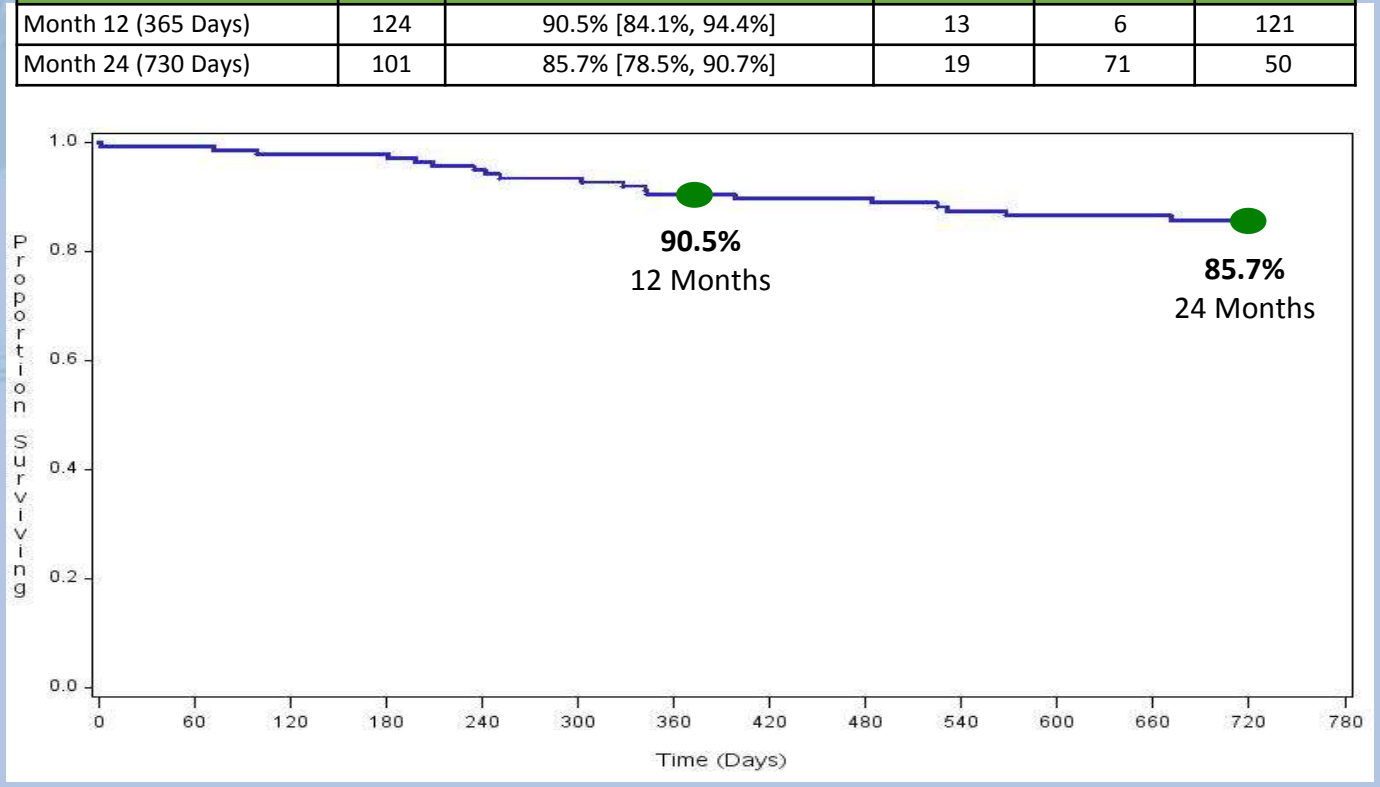
Baseline Lesion Characteristics

	All Lesions (23 – 500 mm)	Long Lesions (140 – 500 mm)
Total Lesion Length (mm)	101.2 ± 84.2 (685)	212.3 ± 65.3 (140)
Treated Length (mm)	136.6 ± 89.7 (689)	242.5 ± 83.3 (140)
Calcification, % (n/N)	50.2% (238/474)	57.5% (46/80)
Chronic Total Occlusion, % (n/N)	31.2% (214/686)	42.1% (59/140)
Lesion Locations, % (n/N)		
SFA, % (n/N)	70.0% (483/690)	66.5% (93/140)
Proximal Popliteal, % (n/N)	16.8% (116/690)	15.7% (22/140)
Mid & Distal Popliteal, % (n/N)	13.1% (91/690)	17.9% (25/140)
Final % Diameter Stenosis, %	14.6 ± 18.6 (680)	19.0 ± 21.0 (140)
Bail-out Stenting, % (n/N)	25.2% (174/690)	35.7% (50/140)
Dissection, % (n/N)	18.4% (127/690)	34.3% (48/140)

Lutonix Global SFA Real-World Registry

Long Lesion - Primary Safety Endpoint

Time	N	Survival[2] % [95% CI]	Subjects with Events	Subjects Censored	Subjects at Risk
Month 12 (365 Days)	124	90.5% [84.1%, 94.4%]	13	6	121
Month 24 (730 Days)	101	85.7% [78.5%, 90.7%]	19	71	50



[1] Additional key safety analysis based on Kaplan-Meier estimates

Note: Primary safety event is device- or procedure related death, TVR, or major amputation within 30 days.

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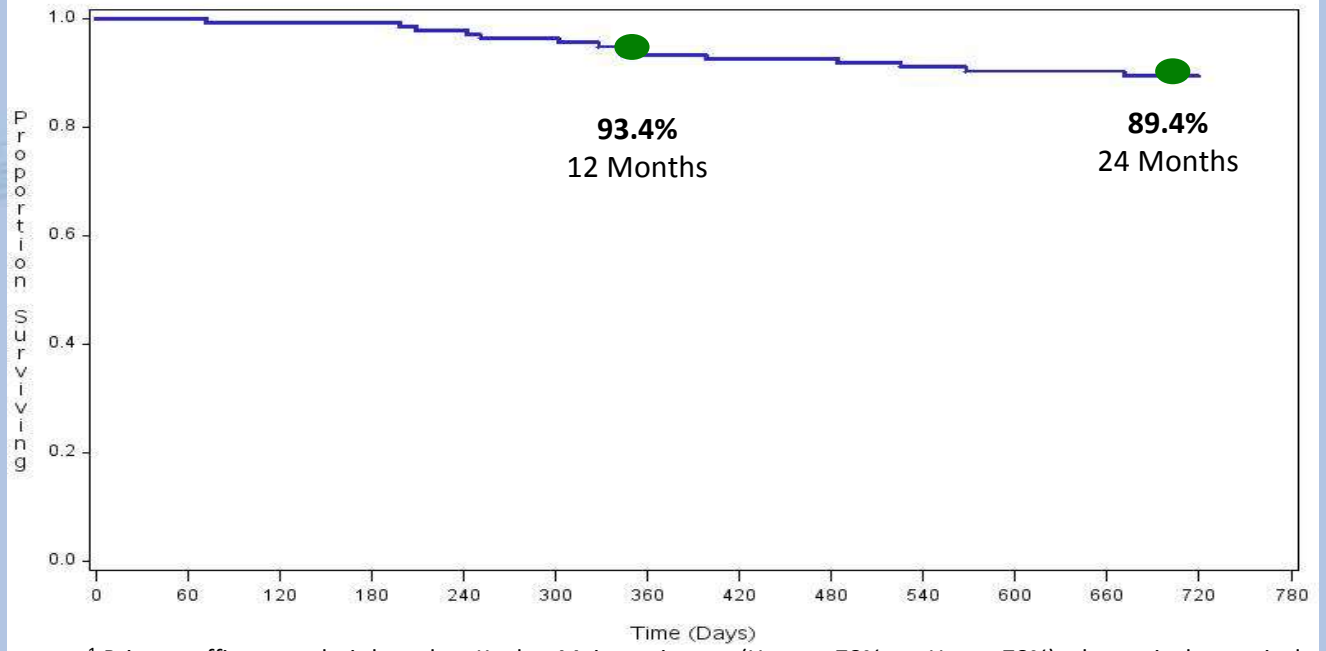
Lutonix Global SFA Real-World Registry

Long Lesion - TLR Free Survival

Time	N	Survival % [95% CI]	P-value[1]	Subjects with Events	Subjects Censored	Subjects at Risk
Month 12 (365 Days)	128	93.4% [87.7%, 96.5%]	<.001	9	6	125
Month 24 (730 Days)	106	89.4% [82.8%, 93.6%]		14	74	52



[1] Primary efficacy analysis based on Kaplan-Meier estimates (H_0: s <= 78% vs H_1: s > 78%) where s is the survival rate

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LEVANT Japan Clinical Study Design

Study Objective	Evaluate safety and efficacy of Lutonix Drug Coated PTA Dilatation Catheter for treating femoropopliteal stenosis and/or occluded lesions in Japanese patient population
Study type	Prospective, Japanese Multicenter, Single Blind, Randomized Study
Primary endpoints	➢ Safety Composite of freedom from all-cause peri-operative (≤30 day) death and freedom at 6 months from the following: index limb amputation (above or below the ankle), index limb re-intervention, and index-limb-related death. ➢ Efficacy Primary Patency of the target lesion at 6 months. ＜Primary Patency is defined as the absence of target lesion restenosis (defined by DUS peak systolic velocity ratio (PSVR) >2.5) and freedom from target lesion revascularization (TLR).
# of subjects	# of randomized patients：109 DCB 71 : PTA 38 (2:1)
Core lab	DUS：VasCore Angiographic： Synvacor PK： BASi

Summary

- LUTONIX LEVANT 2 demonstrated superior patency for DCB vs. PTA
- LUTONIX LEVANT 2 demonstrated non-inferior safety DCB vs. PTA
- LUTONIX Global SFA Registry demonstrated durable benefits at 24 months and re-enforced the safety for the LUTONIX® 035 DCB in real-world patients
- LUTONIX Global SFA Registry showed favorable and sustainable Freedom from TLR at 24 months, in complex lesions (calcified, CTOs) and Diabetics
- LUTONIX Global SFA Registry showed the LUTONIX® 035 DCB is effective and sustainable at 24 months in ISR and long lesions (>140mm)

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