

The logo for LINIC, featuring the letters 'L', 'I', 'N', and 'C' in a white, sans-serif font. The letters are arranged in a slightly curved line. Behind the letters are three overlapping, brush-stroke-like shapes in dark blue, red, and yellow, suggesting a stylized flame or a dynamic motion.

The Role of DCB in Korea Practice:

LUTONIX 035 DCB Korean Registry

1 year Data Update

Prospective, Multicenter, Post-Market Registry Assessing

The Clinical Use and Safety of the

LUTONIX 035 DCB in Fem-pop arteries

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Disclosure

Speaker name:

Jae Kyu, Kim. MD, PhD

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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)

I do not have any potential conflict of interest

Study Design

Study Design	A Prospective, Multicenter, Single Arm, Post-Market Registry
Objective	To assess the clinical use and safety of the Lutonix Drug Coated Balloon Catheter in a heterogeneous patient population in real world clinical practice.
Number of Patients/ Sites	Approximately 250 subjects at up to 16 sites. Enrollment is expected to last 12-18 months
Inclusion Criteria	Rutherford Clinical Category ≤ 4 , Stenotic or obstructive vascular lesions
Exclusion Criteria	Inadequate distal outflow
Selected Endpoint	<u>Primary Effectiveness:</u> Freedom from target lesion revascularization (TLR) at 12 months. <u>Primary Safety:</u> Freedom at 30 days from the *composite endpoint

Participating Centers (N=16)

	201	Chonnam Nat'l Univ. Hosp.	Jae-Kyu Kim
	202	Seoul Nat'l Univ. Hosp.	Hwan-Jun Jae
	203	Inha Univ. Hosp.	Yong-Sun Jeon
IR	204	Ajou Univ. Hosp.	Je-Hwan Won
	205	Seoul St. Mary's Hosp.	Ho-Jong Chun
	206	Konkuk Univ. Hosp.	Sang-Woo Park
	207	Keimyung Univ. Dongsan Hosp.	Young-Hwan Kim

	101	Asan Medical Center	Seung-Whan Lee
	102	Chungnam National University Hospital	Jae-Hwan Lee
	103	Kangbuk Samsung Hospital	Jong-Young Lee
	104	Soonchunhyang University Hospital Bucheon	Yun-Hang Cho
IC	106	Hallym University Sacred Heart Hospital	Hyun-Sook Kim
	108	Inje University Busan Paik Hospital	Han-Young Jin
	109	Myongji Hospital	Youngsung Suh
	110	YeungNam University Medical Center	Ung Kim
	111	Busan Veterans Hospital	Su-Hong Kim

Subject Disposition

	Lutonix Korea Registry (N=249)
Enrolled	249 (100.00%)
Completed 6 month (180 days)	241 (96.79%)
Completed 12 month (365 days)	187 (75.10%)
Discontinued prematurely	15 (6.02%)
Withdrawal of consent	1 (0.40%)
Death	11 (4.42%)
Investigator's decision	1 (0.40%)
Lost to follow-up	1 (0.40%)
Other	1 (0.40%)

Medical History 1

Category	Term	Lutonix Korea Registry (N=249)
Risk factors	Total	229 (92.0%)
	Diabetes	149 (59.8%)
	Type 1	10 (4.0%)
	Type 2	139 (55.8%)
	Dyslipidemia	49 (19.7%)
	Hypertension	176 (70.7%)
	Cigarette smoking	106 (42.6%)
	Current	59 (23.7%)
	Former	47 (18.9%)
	Hyperhomocysteinemia	1 (0.4%)

Medical History 2

	Total	114 (45.8%)
	Congestive heart failure (CHF)	9 (3.6%)
	NYHA class i	2 (0.8%)
	NYHA class II	1 (0.4%)
	NYHA class III	1 (0.4%)
	NYHA class unknown	5 (2.0%)
Cardiovascular disease	Stroke	38 (15.3%)
	Coronary artery disease (CAD)	48 (19.3%)
	Myocardial infarction (MI)	9 (3.6%)
	Transient ischemic attack (TIA)	2 (0.8%)
	Valvular heart disease	4 (1.6%)
	Aortic disease	2 (0.8%)
	Deep vein thrombosis (DVT)	3 (1.2%)
	Other	29 (11.6%)

Medical History 3

Category	Term	Lutonix Korea Registry (N=249)
Renal disease	Total	42 (16.9%)
	Chronic kidney disease	35 (14.1%)
	Acute renal insufficiency (serum creatinine greater than or equal to 2.5 mg/dL)	4 (1.6%)
	Other	5 (2.0%)
	Total	101 (40.6%)
Other disease	Cancer	24 (9.6%)
	Target limb amputation(s)	3 (1.2%)
	Other	90 (36.1%)

Baseline Target Lesion1

	Lutonix Korea Registry (N=249)
Type	
Stenosis	195 / 338 (57.7%)
Occlusion	143 / 338 (42.3%)
De Novo	
Yes	274 / 338 (81.1%)
No	64 / 338 (18.9%)
In-Stent Restenosis	
Yes	24 / 338 (7.1%)
No	314 / 338 (92.9%)

Baseline Target Lesion 2

Location	
Proximal 1/3 of SFA	127 / 338 (37.6%)
Mid 1/3 of SFA	160 / 338 (47.3%)
Distal 1/3 of SFA	164 / 338 (48.5%)
Popliteal P1	53 / 338 (15.7%)
Popliteal P2	23 / 338 (6.8%)
Popliteal P3	14 / 338 (4.1%)
Degree of Calcification	
None	80 / 338 (23.7%)
Mild	143 / 338 (42.3%)
Moderate	73 / 338 (21.6%)
Severe	40 / 338 (11.8%)

Baseline Target Lesion 3

Lutonix Korea Registry
(N=249)

Target Lesion Length (mm)

total		337
Mean (SD)	115.2 (79.42)	
Median	100.0	
Min - Max	5 - 450	

Reference Vessel Diameter (mm)

total		337
Mean (SD)	5.26 (0.652)	
Median	5.00	
Min - Max	2.0 - 7.0	

Initial Lesion Stenosis (%)

total		331
Mean (SD)	88.71 (14.915)	
Median	95.00	
Min - Max	26.0 - 100.0	

Summary of Pre/Post-Dilatation

	Lutonix Korea Registry (No. of Lesions=338)	95% Confidence Interval
Pre-Dilatation	305/338 (90.24%)	(86.56%, 93.18%)
Post-Dilatation	27/338 (7.99%)	(5.33%, 11.41%)

Target Limb Rutherford Classification

Lutonix Korea Registry (N=249)

Rutherford Category	Baseline	1 Month	6 Month	12 Month
0	0	48 / 101 (47.5%)	56 / 87 (64.4%)	28 / 54 (51.9%)
1	14 / 242 (5.8%)	30 / 101 (29.7%)	11 / 87 (12.6%)	10 / 54 (18.5%)
2	96 / 242 (39.7%)	12 / 101 (11.9%)	12 / 87 (13.8%)	10 / 54 (18.5%)
3	<u>100 / 242</u> <u>(41.3%)</u>	10 / 101 (9.9%)	6 / 87 (6.9%)	5 / 54 (9.3%)
4	32 / 242 (13.2%)	0	2 / 87 (2.3%)	1 / 54 (1.9%)
5	0	1 / 101 (1.0%)	0	0

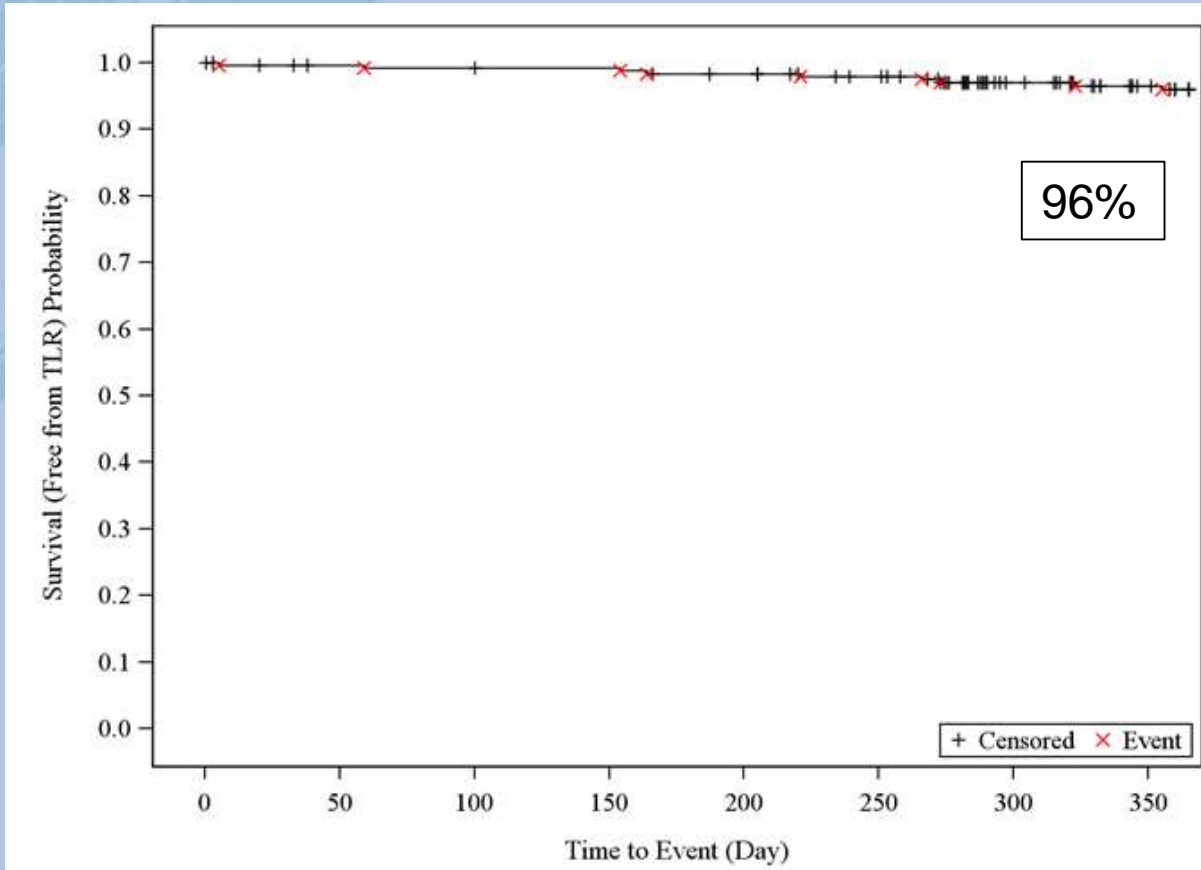
Freedom from TLR at 12 ms

	Lutonix Korea Registry (N=249)	95% Confidence Interval
Free from TLR through 12 month (365 days)	179/187 (95.2%)	[91.1%, 97.8%]

K-M Analysis of the Primary Efficacy Endpoint

Time to Event(Days)	Number of Subjects with TLR	Number of Subjects Censored	Number of Subjects Left	K-M Estimates of Subjects Free from TLR	95% Confidence Interval of Subjects Free from TLR
Day 0	0	0	249	100.0%	(100.0%,100.0%)
Day 30	1	3	245	99.6%	(97.2%,99.9%)
Day 180	4	7	238	98.4%	(95.7%,99.4%)
Day 365	9	240	0	96.0%	(92.5%,97.9%)

K-M Analysis of the Primary Efficacy Endpoint



Device Success

Lutonix Korea Registry
(Number of Devices=475)

95% Confidence Interval

Device Success

475/475 (100.00%)

(99.23%, 100%)

Procedural Success

Lutonix Korea Registry
(Number of Subjects=241)

95% Confidence Interval

Procedural
Success

232/241 (96.27%)

(93.03%, 98.28%)

Conclusion

LUTONIX Korean Registry 1 year data

shows 95.5% freedom from TLR and

96.0% K-M primary efficacy endpoint

and also shows the acceptable safety and efficacy

The LINIC logo is located in the top left corner. It features the word "LINIC" in white, uppercase letters. The letters are partially overlaid by a stylized graphic consisting of two curved, brushstroke-like shapes in dark blue and red, with a yellow and orange gradient in the center.

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