DCB would be Default Strategy: Lutonix® Korean SFA registry

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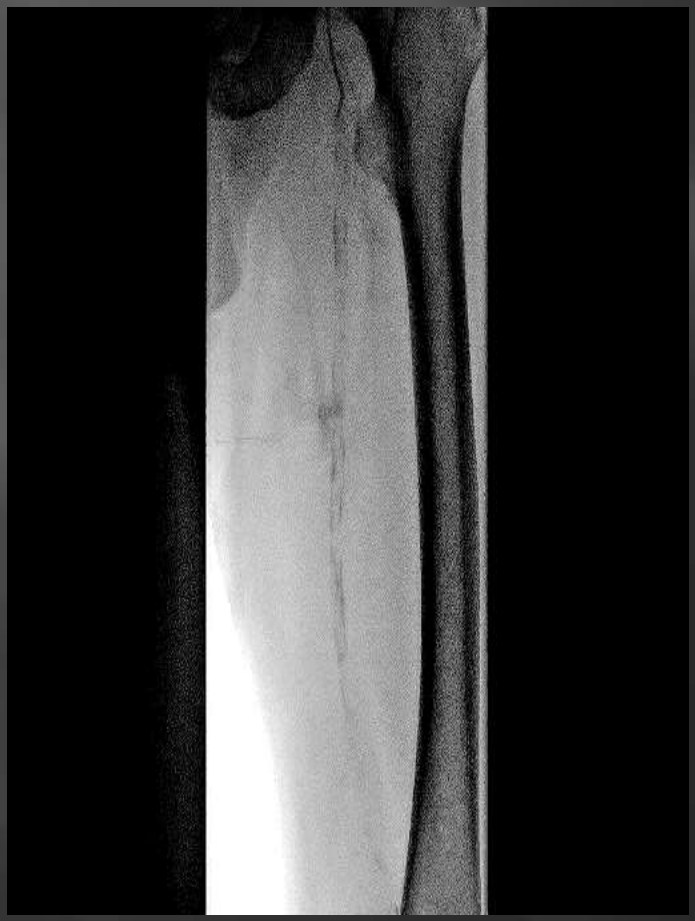
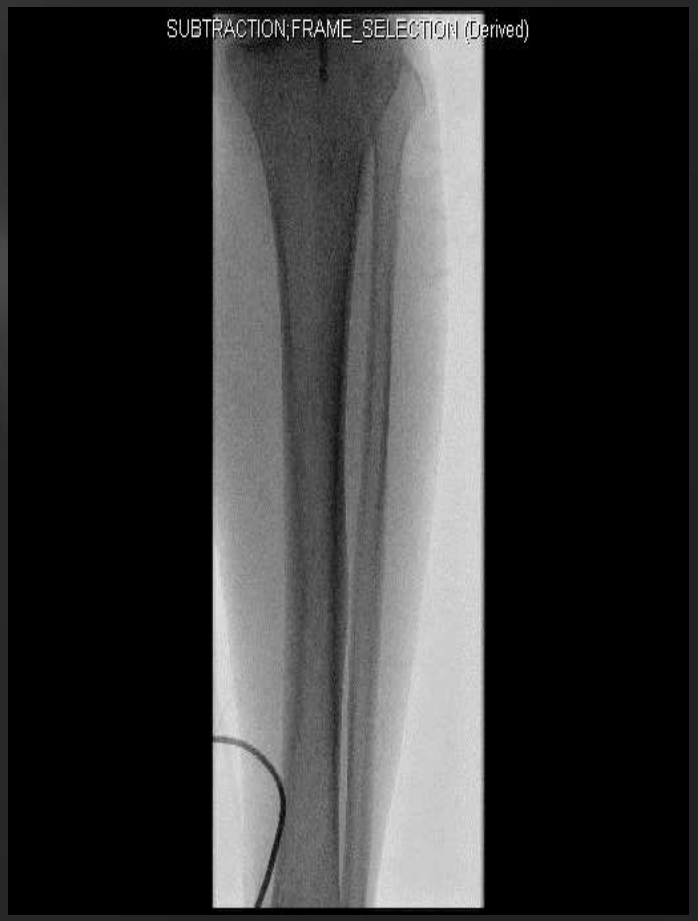
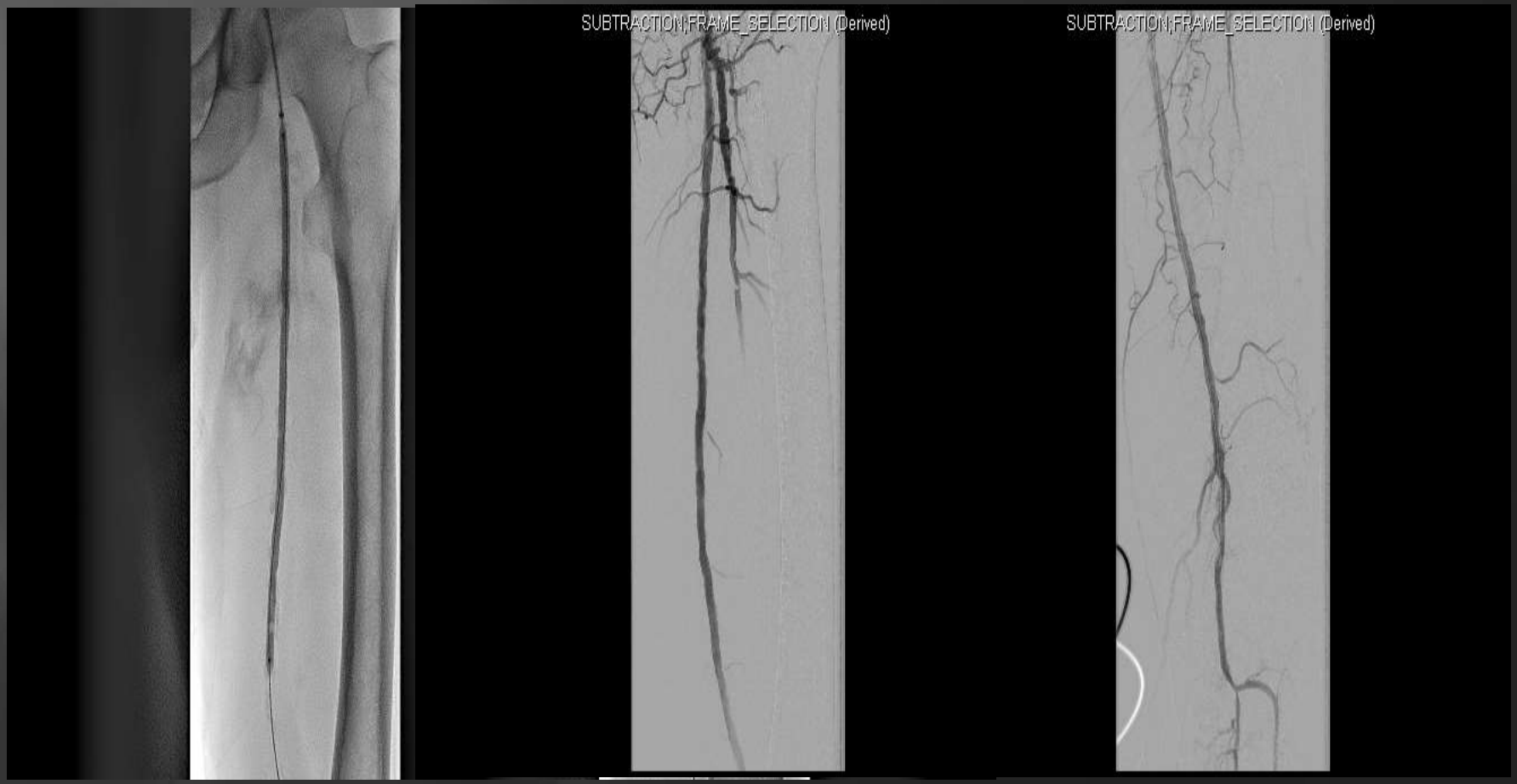
Case 1





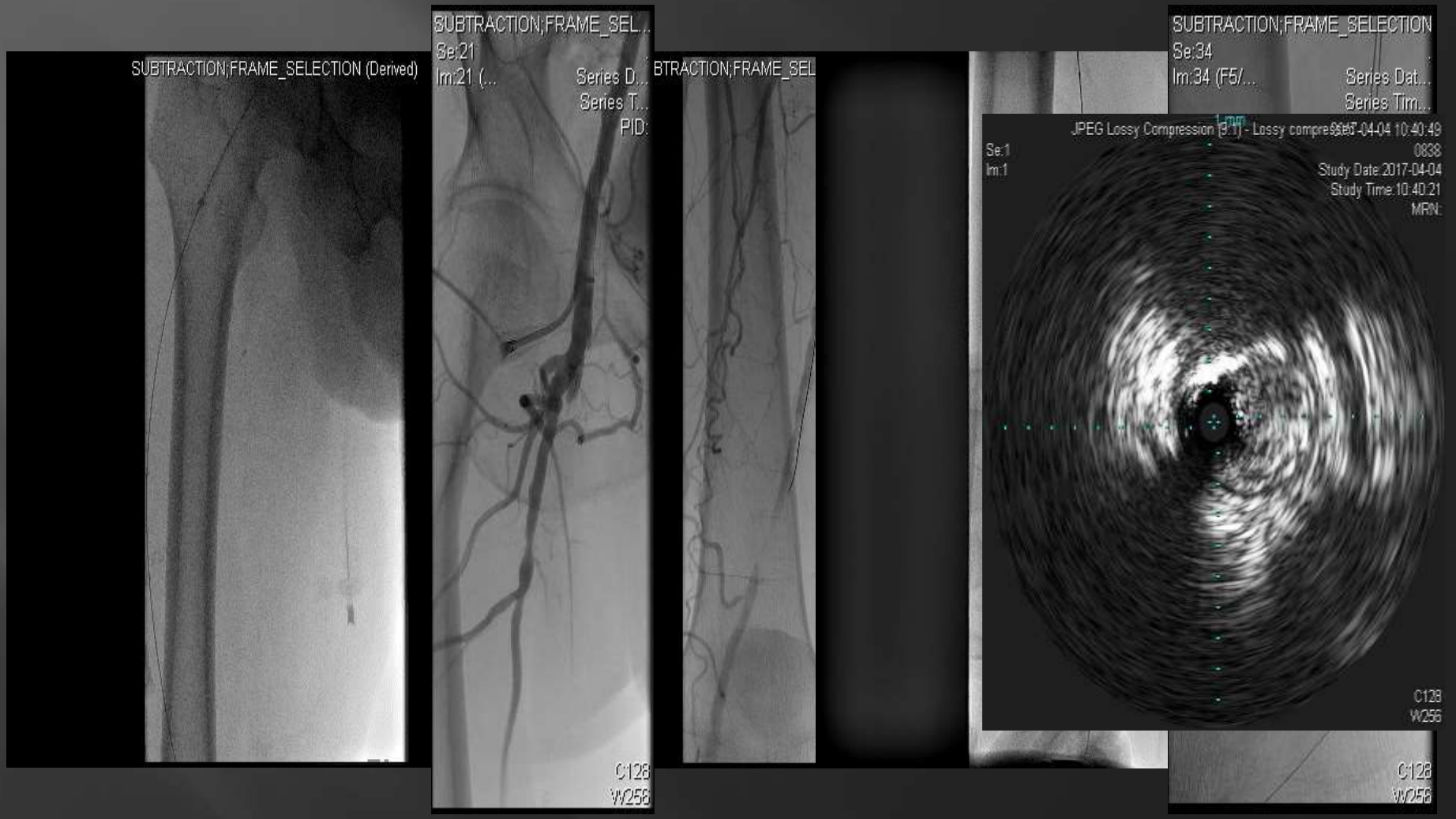
Case 1. final angiogram



NC balloon

Lutonix #2

Case 2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SUBTRACTION;FRAME_SEL...
Se:21
Im:21 (...
Series D...
Series T...
PID:
C128
W256
BTRACTION;FRAME_SEL
SUBTRACTION;FRAME_SELECTION
Se:34
Im:34 (F5/...
Series Dat...
Series Tim...
JPEG Lossy Compression (3:1) - Lossy compressed
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Im:1
0838
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Study Time:10:40:21
MRN:
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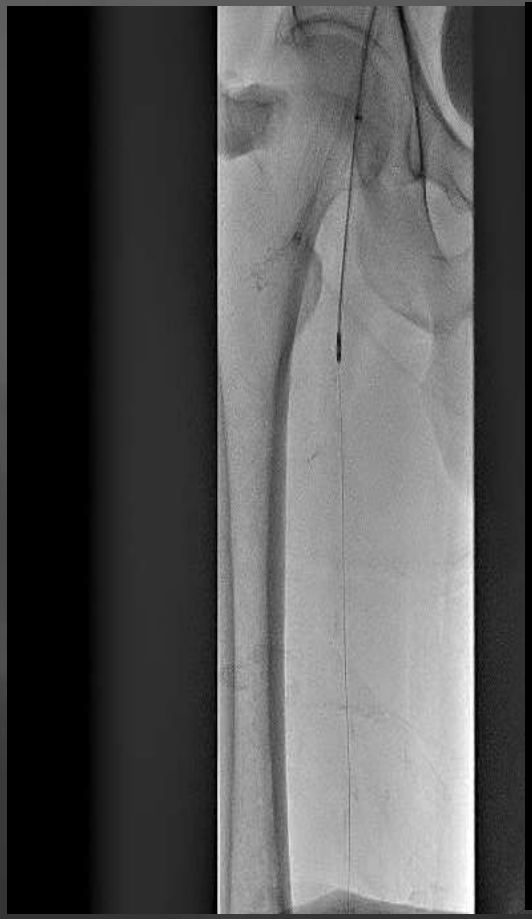
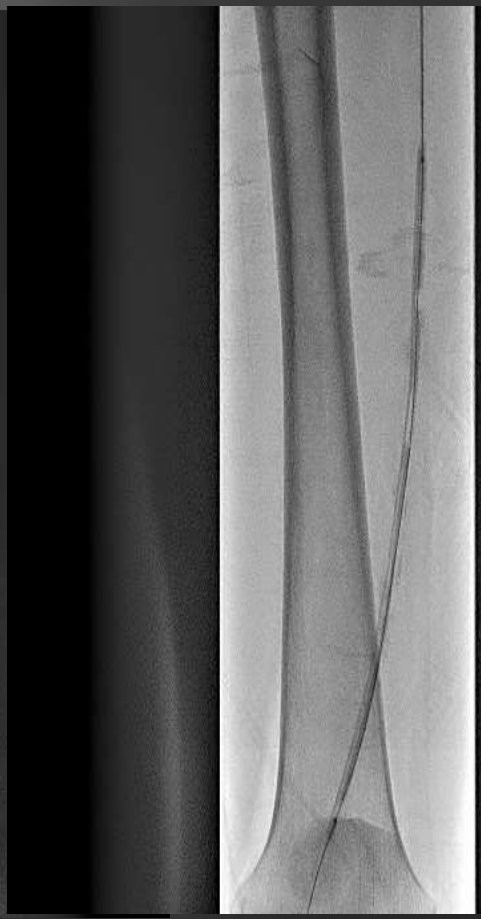
W256

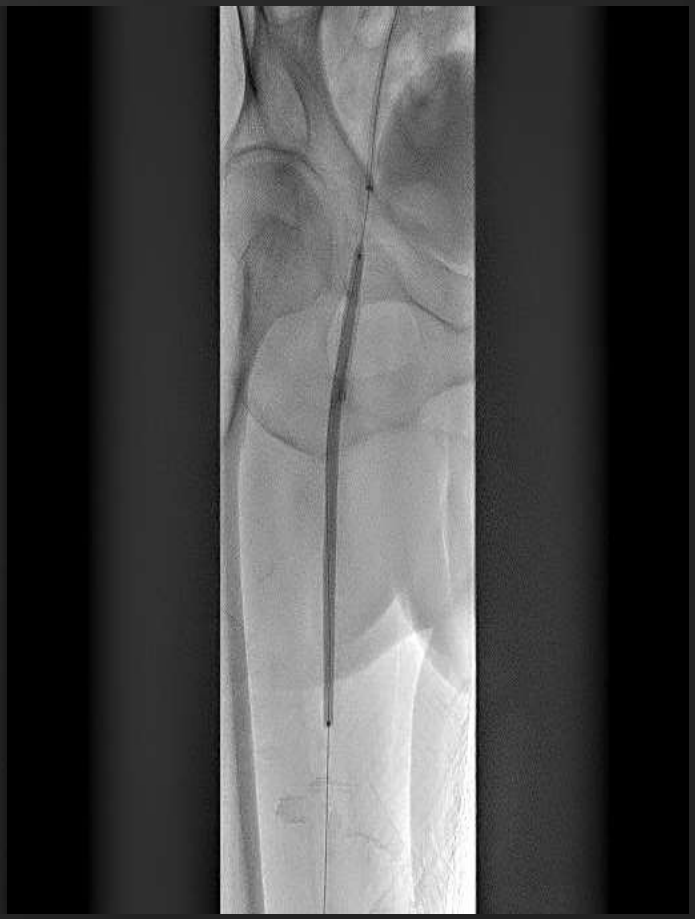
Case 2



JetStream

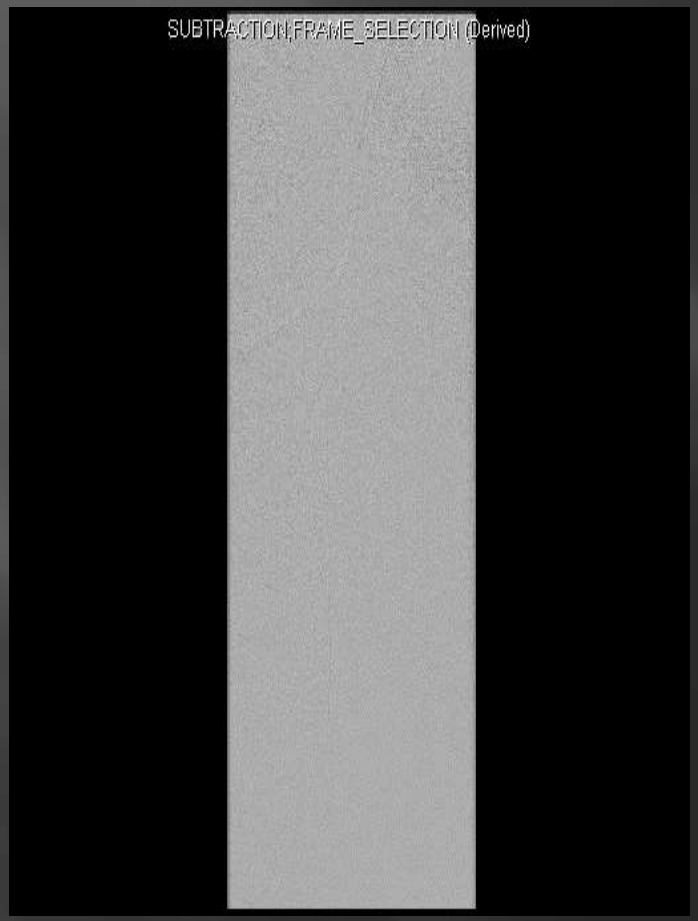


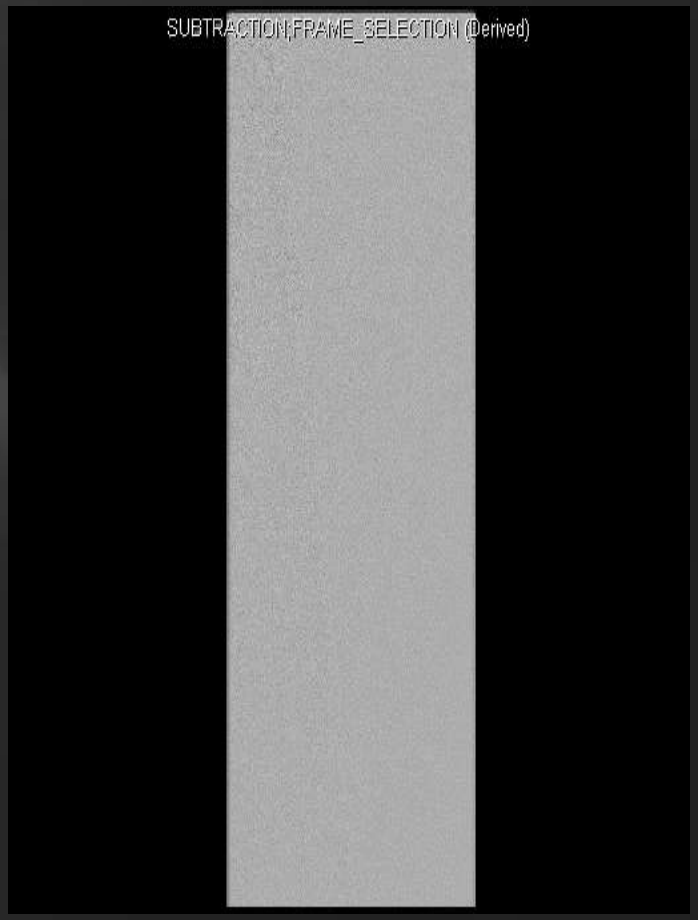
Ballooning



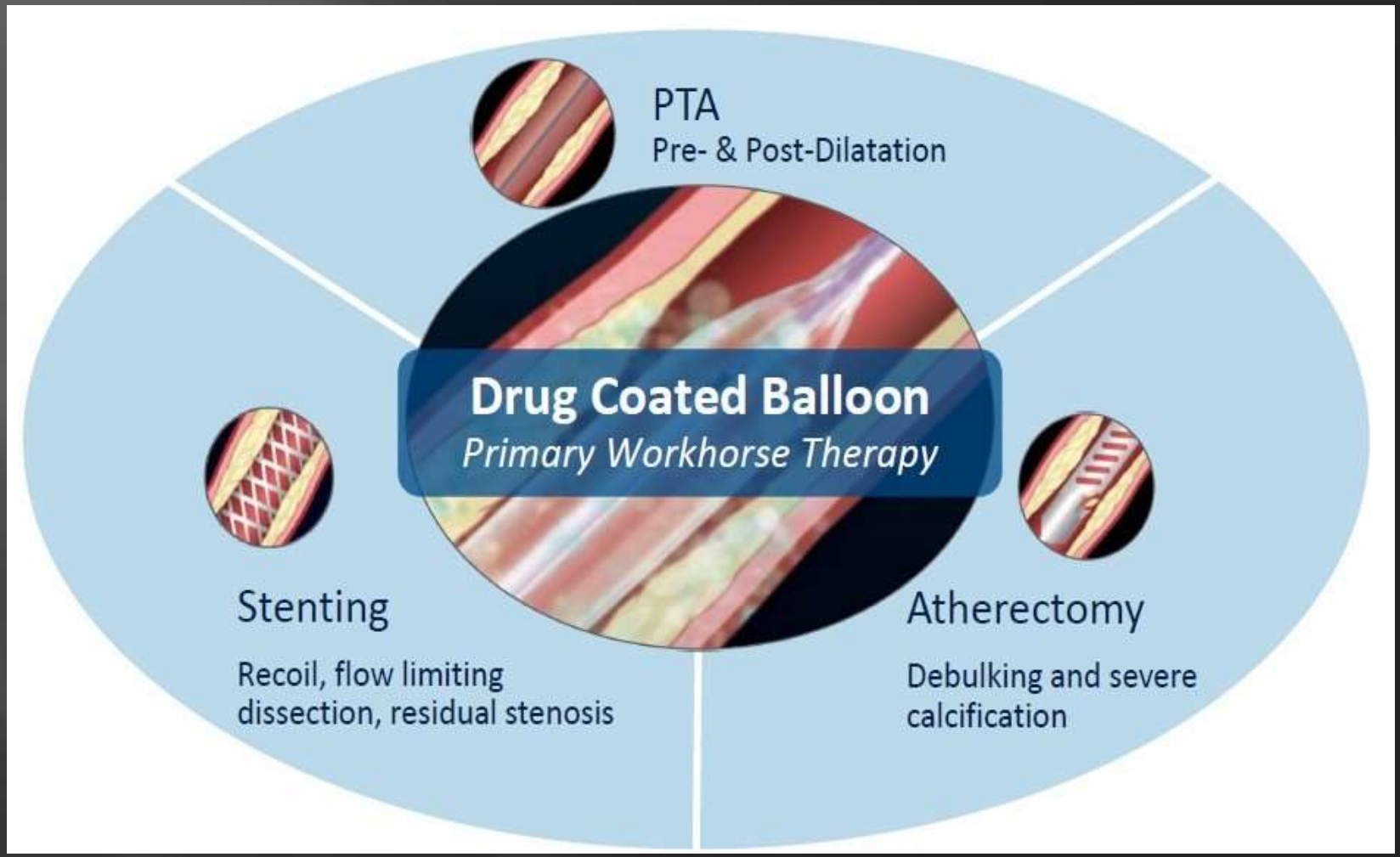
Lutonix #2

Case 2_final angiogram

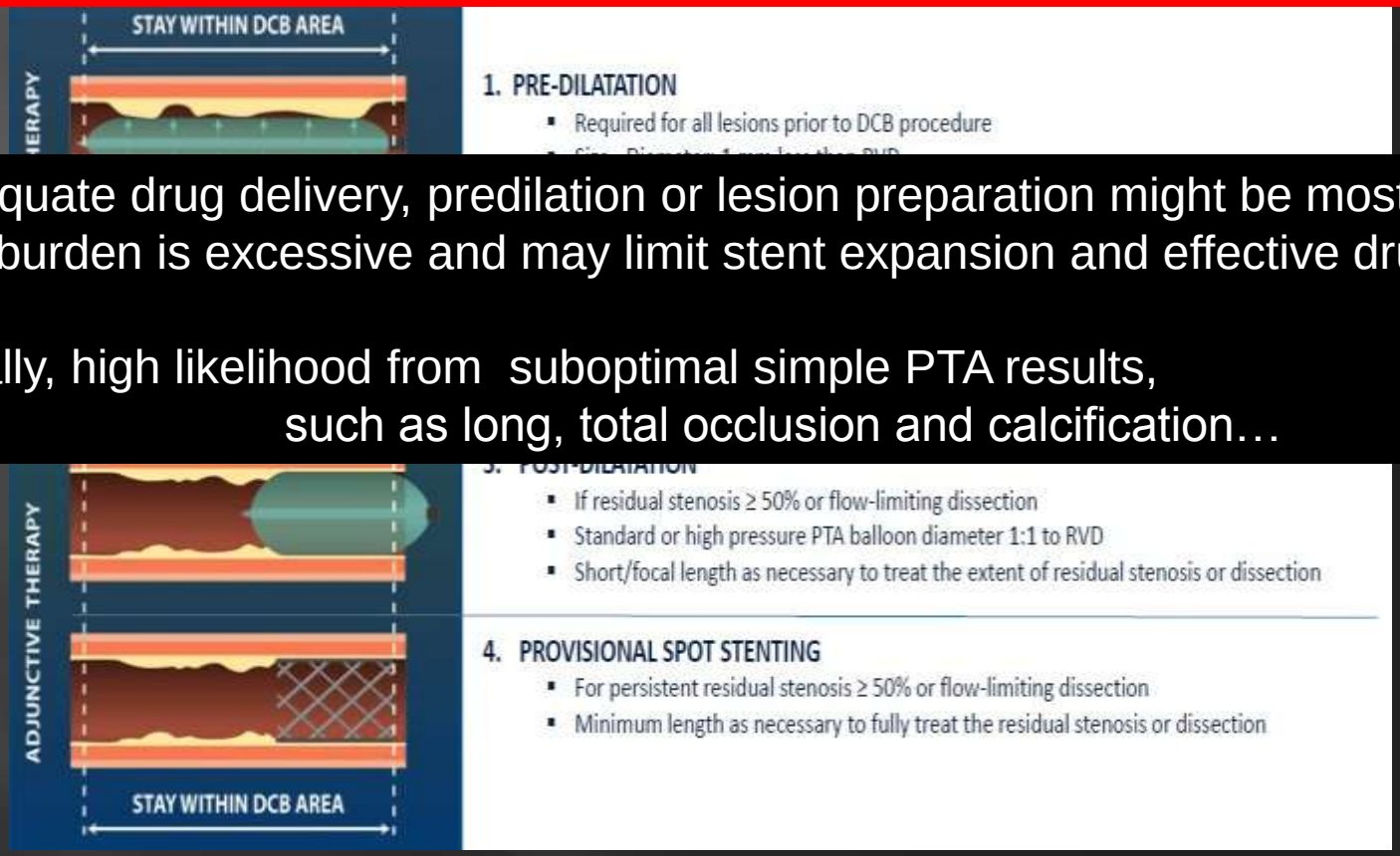




Leave nothing behind..



DCB: Complement



For adequate drug delivery, predilation or lesion preparation might be most important!
Plaque burden is excessive and may limit stent expansion and effective drug delivery.

Especially, high likelihood from suboptimal simple PTA results,
such as long, total occlusion and calcification…

Why Vessel Preparation?

- Maximize acute procedural success in complex lesions
  - Less dissection, less bailout stenting, better vessel expansion, better stent expansion
- Enhance drug elution and drug concentration into the vessel by removing barriers to drug absorption
  - Superficial and deep calcium

LUTONIX Korean SFA Registry

Prospective, Multicenter, Post-Market Registry

Assessing the Clinical Use and Safety of the

LUTONIX® 035 Drug Coated Balloon in Femoropopliteal Arteries

Background

- DCB is one of the default strategy for femoro-popliteal disease.
- LEVANT randomized trial showed reduced restenosis rate compared to conventional balloon angioplasty.
- Lutonix global registry showed excellent safety and efficacy up to 2 years.

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 in Korea
Inclusion Criteria	Rutherford Clinical Category ≤ 4, Stenotic or obstructive vascular lesions
Exclusion Criteria	Inadequate distal outflow
Selected Endpoint	Primary Effectiveness: Freedom from target lesion revascularization(TLR) at 12 months. Primary Safety: Freedom at 30 days from the *composite endpoint

*: target vessel revascularization (TVR) and target lesion revascularization (TLR), major amputation and major reintervention (new bypass graft, jump/interposition graft revision, or thrombectomy/thrombolysis) of index limb and device- and procedure-related death.

16 Participating Centers (N=249)

No.	Dept.	Site	Investigator
1	IC	Asan Medical Center	Seung-Whan Lee
2		Chungnam National University Hospital	Jae-Hwan Lee
3		Kangbuk Samsung Hospital	Jong-Young Lee
4		Soonchunhyang University Hospital Bucheon	Yun-Hang Cho
5		Hallym University Sacred Heart Hospital	Hyun-Sook Kim
6		Inje University Busan Paik Hospital	Han-Young Jin
7		Myongji Hospital	Youngsung Suh
8		YeungNam University Medical Center	Ung Kim
9		Busan Veterans Hospital	Su-Hong Kim
10	IR	Chonnam Nat'l Univ. Hosp.	Jae-Kyu Kim
11		Seoul Nat'l Univ. Hosp.	Hwan-Jun Jae
12		Inha Univ. Hosp.	Yong-Sun Jeon
13		Ajou Univ. Hosp.	Je-Hwan Won
14		Seoul St. Mary's Hosp.	Ho-Jong Chun
15		Konkuk Univ. Hosp.	Sang-Woo Park
16		Keimyung Univ. Dongsan Hosp.	Young-Hwan Kim

Subject Disposition

	Lutonix Korea registry (N=249)
Enrolled	249 (100.0%)
Completed 6 month (180 days)	241 (96.8%)
Completed 12 month (365 days)	**232 (93.2%)**
Discontinued prematurely	16 (6.4%)
Withdrawal of consent	1 (0.4%)
Death	11 (4.4%)
Lost to follow-up	2 (0.8%)

Baseline DCB Demographics

Class.	Description	Korean registry (N=249)	Global registry (N=691)
Age(Years)	Mean (SD)	69.1±10.46	68.2±9.8
Gender	Male	212 (85.1%)	67.9%
	Female	37 (14.9%)	32.1%
Risk Factor	**DM**	**149 (59.8%)**	39.5%
	Dyslipidemia	49 (19.7%)	70.0%
	Hypertension	176 (70.7%)	84.9%
	Cigarette smoking	**106 (42.6%)**	36.9%
Rutherford Grade	Class 1~2	45.5%	20.6%
	Class 3	41.3%	66.9%
	Class 4	13.2%	7.4%
	Class 5~6	-	1.6%

DCB Angiographic Demographics - I

Degree of Calcification	Lutonix Korea Registry (N=249) (Lesion N=338)
None	80 / 336 (23.8%)
Mild	143 / 336 (42.6%)
Moderate	73 / 336 (21.7%)
Severe	40 / 336 (11.9%)

		bal registry (N=691)
Target Les		101.2
Calcification	256 / 338 (75.7%)	50.2%
Chronic Total Occlusion	143 / 338 (42.3%)	31.2%
Lesion Locations		
SFA	291 / 338 (86.1%)	70.0%
Proximal Popliteal	53 / 338 (15.6%)	16.8%
Mid & Distal Popliteal	37 / 338 (10.9%)	13.1%

DCB Angiographic Demographics - II

Classification	Korean registry (N=249)	Global registry (N=691)
TASC II lesion classification		
A	26.9% (64/238)	46.8% (231/494)
B	27.7% (66/238)	33.4% (165/494)
C	**28.2% (67/238)**	13.2% (65/494)
D	**17.2% (41/238)**	6.7% (33/494)

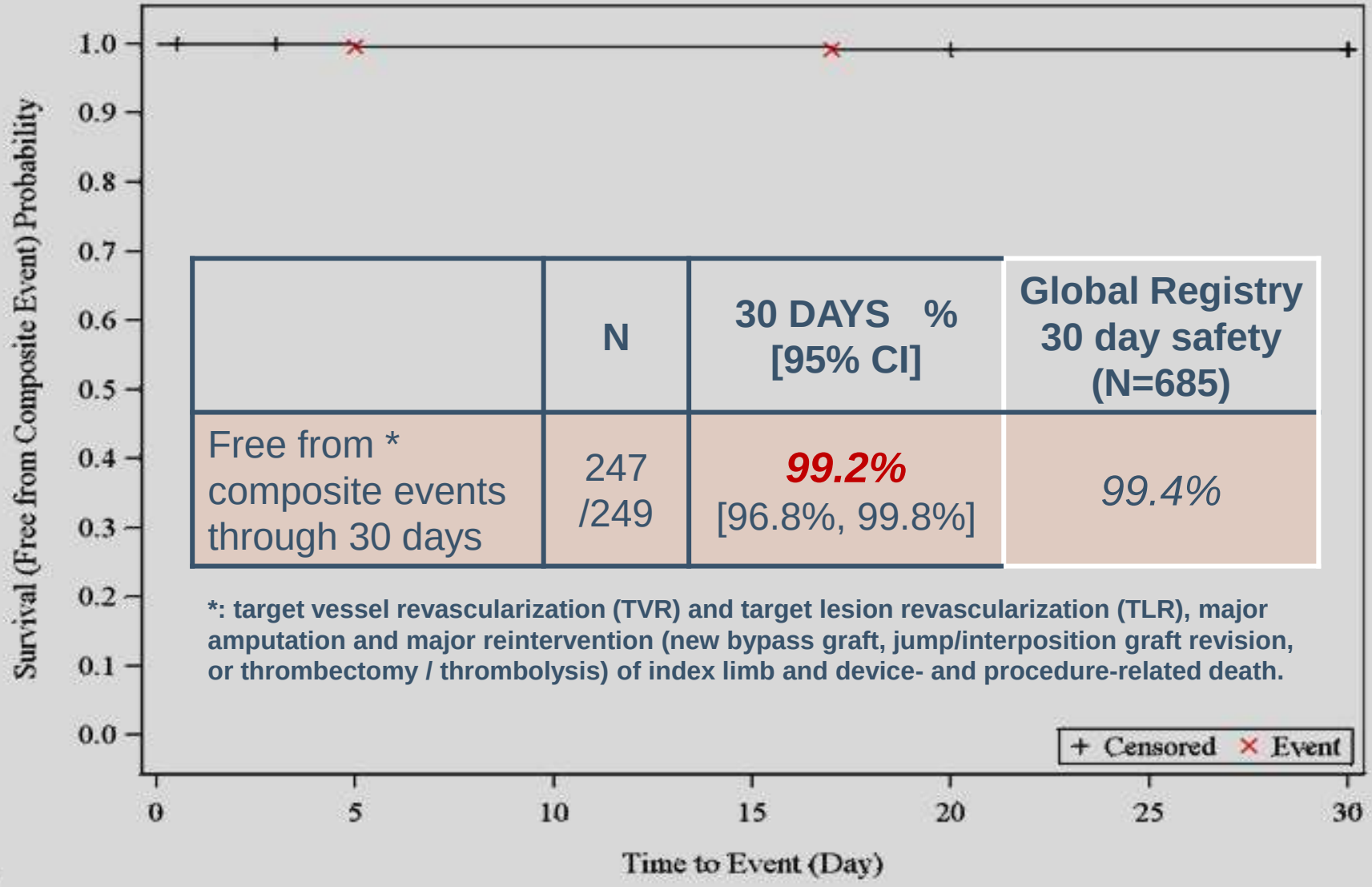
Summary of procedural data

Variables	Korean registry (N=249) Number of Lesions=338	Global registry (N=691)
Pre-dilatation performed	**90.4%** (225/249)	64.9% (448/690)
Diameter stenosis, %,		
Baseline	88.7% ± 14.91 (331)	90.0% ± 11.0 (686)
Post-procedure	12.7% ± 12.49 (326)	14.6% ± 18.69 (680)
Major Flow Limiting Dissection	2.8% (7/247)	9.5% (12/127)
Bail-out spot stenting	**8.8%** (22/249)	25.2% (174/690)

Pre & Post treatment detail

Variables	N=249	Comment
Pretreatment		
Balloon angioplasty	225 / 249 (90.4%)	
Atherectomy	15 / 249 (6.0%)	
Others	1 / 249 (0.4%)	Cutting balloon
Post-DCB treatment		
Balloon angioplasty	20 / 249 (8.0%)	
Bail-out stenting	22 / 249 (8.8%)	20 of BMS/ 2 of covered stent

Primary Safety Endpoint



	N	30 DAYS % [95% CI]	Global Registry 30 day safety (N=685)
Free from * composite events through 30 days	247 /249	***99.2%*** [96.8%, 99.8%]	*99.4%*

***: target vessel revascularization (TVR) and target lesion revascularization (TLR), major amputation and major reintervention (new bypass graft, jump/interposition graft revision, or thrombectomy / thrombolysis) of index limb and device- and procedure-related death.**

Primary safety endpoint at 1 month

Variables	N=249	Comment
TVR	**1**	Lt. SECOND TOE WOUND and 100% Stenosis
TLR	**1**	Occlusion of Lt. POPLITEAL ARTERY
Major reintervention	-	
Death	-	
Procedure-related	-	
Device-related	-	
Major index limb amputation	-	
* Minor index limb amputation *: was not in the list of primary safety endpoint	1	Lt . 4th toe ray amputation

2 composite events within 30 days

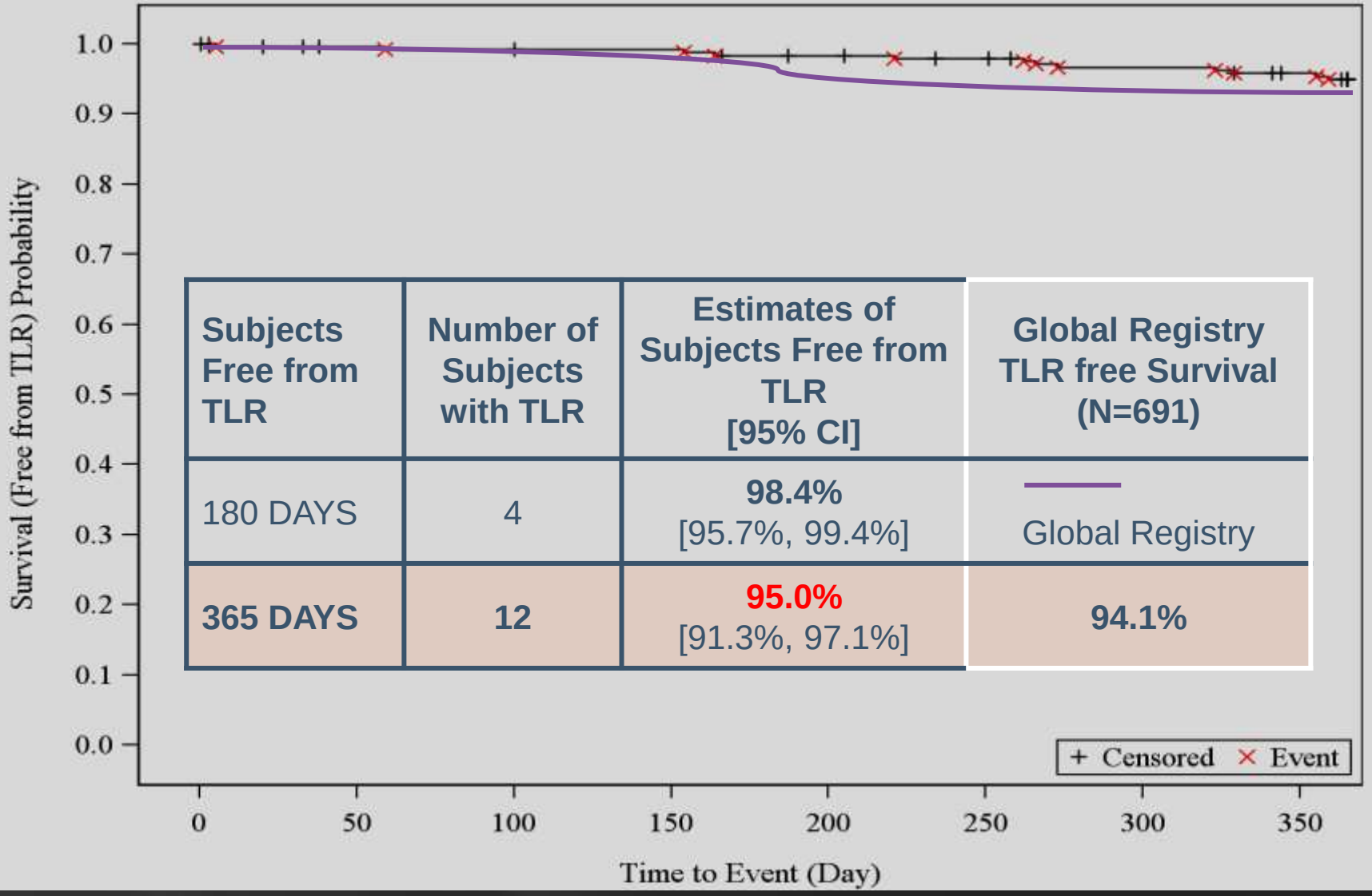
EVENT 1

- **Primary treatment: Pre-dilatation + DCB only + Post-dilatation**
  - 70% residual stenosis
- **Re-intervention @ 17 days**
  - Reason for Re-Intervention: LT SECOND TOE WOUND and 100% Stenosis
  - Location: Target vessel and non-target lesion
  - Treatment: PTA, Stenting

EVENT 2

- **Primary treatment: Pre-dilatation + DCB only**
  - 20% residual stenosis
- **Re-intervention @ 25 days**
  - Reason for Re-Intervention: Occlusion of LT POPLITEAL ARTERY
  - Location: Target lesion
  - Treatment: PTA, Stenting

Primary Efficacy Endpoint at 1 year



Subjects Free from TLR	Number of Subjects with TLR	Estimates of Subjects Free from TLR [95% CI]	Global Registry TLR free Survival (N=691)
180 DAYS	4	**98.4%** [95.7%, 99.4%]	Global Registry
365 DAYS	**12**	**95.0%** [91.3%, 97.1%]	**94.1%**

Lutonix Global SFA Real-World Registry

12 months results

MEASURE	% (n / N)
30-day Safety[1]	99.4% (681/685)
Free from TLR	**94.1% (605/648)**

[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

24 months results

MEASURE	% (n / N)
Free from TLR [1]	**90.3% (526/589)**

[1] Secondary endpoint. Clinical primary patency of the target lesion was reported by the investigator based on presenting symptoms and clinical exam.

Conclusions

- Lutonix® DCB Korean registry data shows acceptable safety at 1 month and shows 98.4% at 6 months and further 95.0% at 1 year of freedom from TLR, respectively
- The results of Lutonix® Korean registry are correspond to the results of the global registry. This study have great significance since it shows the efficacy and safety of Lutonix DCB for the large Asian population.
- Adequate vessel preparation seems to be a critical success factor for the drug delivery and the long-term result of DCB procedure
- Downstream effect should be considered when you're using multiple DCBs