Update on the LUTONIX BTK Global Registry: First look at 300 patient interim follow up data

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Disclosure

Dierk Scheinert, MD

Advisory Board /Consultant:

Abbott, Biotronik, Boston Scientific, Cook Medical, Cordis, CR Bard, Gardia Medical/Allium, Medtronic, TriReme Medical, Trivascular, Upstream Peripheral Technologies

Study Design

Study Design	Prospective, Multicenter, Single Arm Registry
Objective	To demonstrate safety and assess the clinical use and outcomes of the Lutonix DCB for treatment of stenosis or occlusion of native below-the-knee arteries in a heterogeneous patient population in real world clinical practice
Number of patients/sites	371 subjects enrolled from 26 international sites
Inclusion Criteria	Rutherford Class: 3-5, ≥ 70% stenosis lesion, target vessel(s) reconstitute(s) at or above the ankle with inline flow to at least one patent
Exclusion Criteria	Neurotrophic ulcer or heel pressure ulcer or ulcer potentially involving calcaneus (index limb)
Primary Endpoints	Safety: Freedom from BTK MALE+POD at 30-days Efficacy: Freedom from TLR at 6 months
Follow-up	1, 6, 12 and 24 Months

Study Centers

PI Name
Prof. Willfort-Ehringer
Dr. Loewe
Prof. Brodmann
Prof. Hausegger
Dr. Lerut
Dr. Lansink
Dr. Clemens
Dr. Zech
Dr. Giménez-Gaibar
Dr. Alves
Prof. Sapoval
Dr. Lichtenberg – Study Co-PI
Dr. Thieme

PI Name
Prof. Scheinert – Study Co-PI
Prof. Eckstein
Dr. Sunderdiek
Prof. Tepe
Dr. Perez Delgado
Prof. Zeller
Prof. Karnabatidis
Prof. Brountzos
Dr. Rossato
Dr. Cioppa
Dr. Tolva
Dr. Butterfield
Dr. Alaeddin

Patient Follow-up

EVENT	Pre-Procedure	Procedure	Post-Procedure	30 Day	6 Month	12 Month	24 Month
Visit Window				±2 Weeks	±1 Month	±1 Month	±2 Months
Inclusion/Exclusion Criteria	√	√					
Informed Consent	√						
Medical History	√						
Routine Physical Exam	√		√	√[1]	√	√	√[1]
Current Medication	√			√	√	√	√
Rutherford Classification	√			√[1]	√	√	√[1]
Adverse Event Monitoring		√	√	√	√	√	√
Wound Healing Assessment	√			√[1]	√	√	√[1]

[1]Required only if clinical visit occurs

Demographics / Baseline Characteristics

Description	BTK Study Registry (N=364)
Age (Years), Mean ± SD (n)	73.6 ± 9.5 (364)
Gender, % (n/N)	
Female	28.0% (102/364)
Male	72.0% (262/364)
BMI ≥30 kg/m², % (n/N)	23.7% (85/358)
Hypertension, % (n/N)	86.8% (316/364)
Dyslipidemia, % (n/N)	62.4% (227/364)
Current/Previous Smoker, % (n/N)	50.5% (184/364)
Diabetes	64.0% (233/364)
Rutherford Category	
3	23.7% (86/363)
4	10.5% (38/363)
5	*65.8% (239/363)*

RCC 5

65.8%

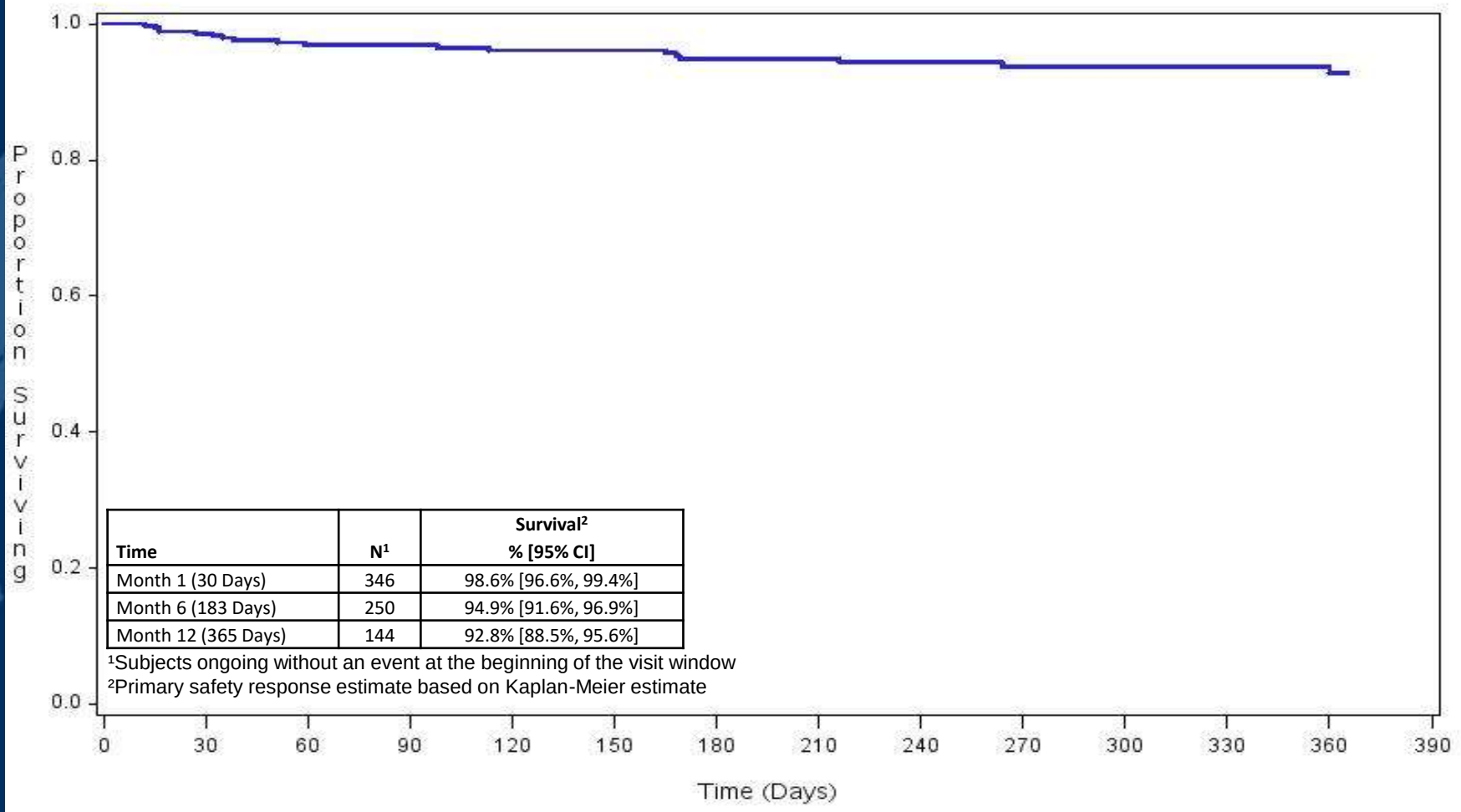
(239/363)

Lesion Characteristics

Description	BTK Study Registry (N=364)
Lesion Location[1]	
Popliteal	6.9% (25/364)
Tibioperoneal Trunk	20.6% (75/364)
Anterior Tibial	51.1% (186/364)
Posterior Tibial	22.3% (81/364)
Peroneal	22.8% (83/364)
Total Target Length (mm), Mean ± SD (n)	121 ± 97.9 (364)
Average RVD (mm), Mean ± SD (n)	2.7 ± 0.52 (361)
(min, max)	(1.7, 4.5)
Calcification, % (n/N)	64.3% (279/434)
Severe Calcification, % (n/N)	23.9% (83/348)
TASC	
A	25.3% (92/363)
B	26.2% (95/363)
C	16.8% (61/363)
D	14.3% (52/363)
Unknown	17.4% (63/363)

[1]Subjects may be in more than one category.

Freedom from Primary Safety Events



Time	N[1]	Survival[2] % [95% CI]
Month 1 (30 Days)	346	98.6% [96.6%, 99.4%]
Month 6 (183 Days)	250	94.9% [91.6%, 96.9%]
Month 12 (365 Days)	144	92.8% [88.5%, 95.6%]

[1]Subjects ongoing without an event at the beginning of the visit window
[2]Primary safety response estimate based on Kaplan-Meier estimate

Freedom at 30-Days from the composite of all-cause death, above-ankle amputation or major re-intervention, i.e., new bypass graft, jump/interposition graft revision, or thrombectomy/thrombolysis of the index limb involving a below-the-knee artery.

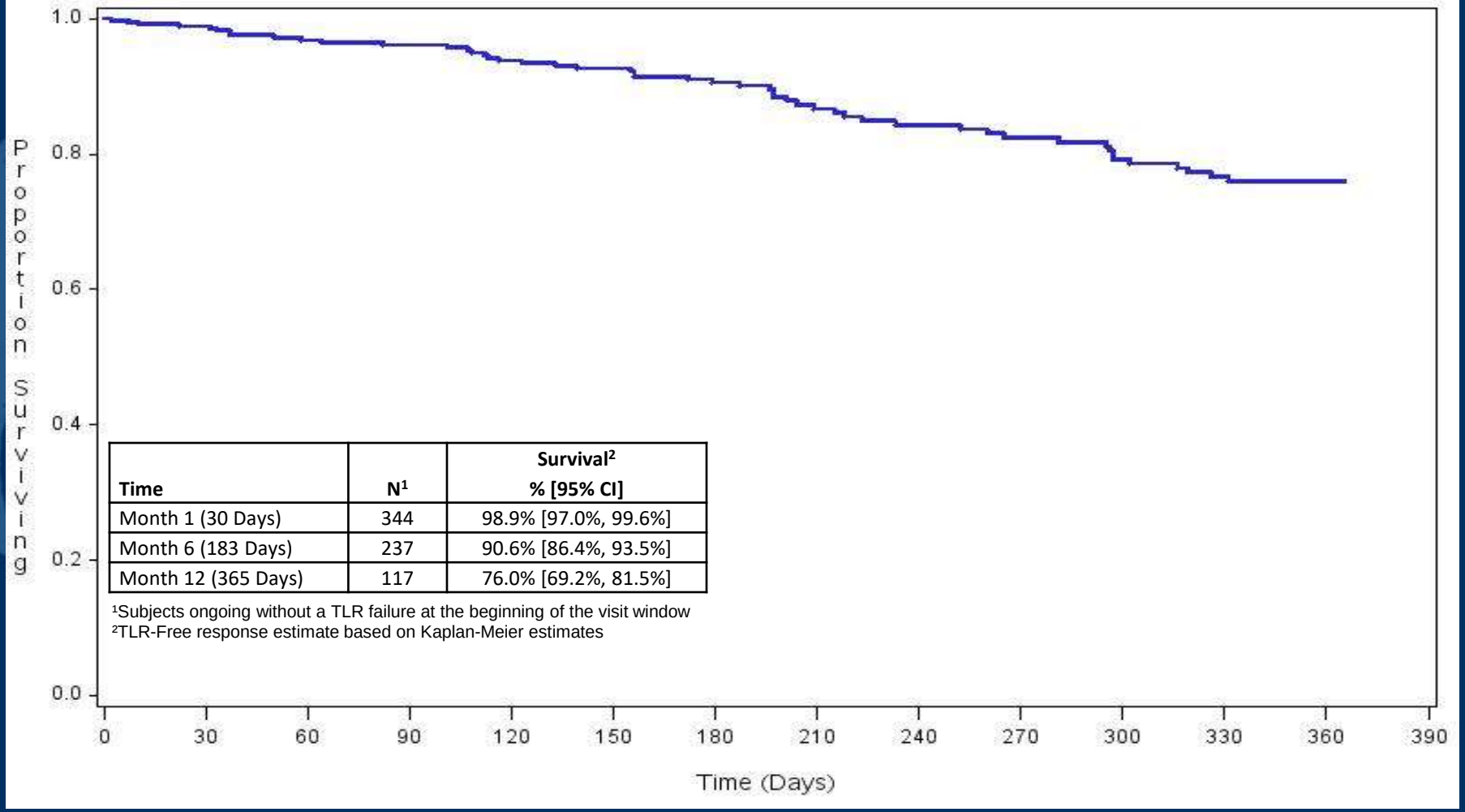
Additional Safety Profile - 12 months

Freedom From	N[1]	Survival[2] % [95% CI]
All Cause Death Survival	150	86.5% [81.2%, 90.4%]
Major Amputation	145	94.8% [91.0%, 97.0%]
Re-inte		
Re-intervention For Distal Embolization	150	100.0% [NA, NA]
TVR	117	75.0% [68.1%, 80.6%]
Unexpected Device or Drug Related Event	150	99.6% [97.2%, 99.9%]

Amputation free rate – 94.8%

[1]Subjects ongoing without a failure at the beginning of the visit window
[2]Survivor rate based on Kaplan-Meier Estimate

Freedom from TLR



Time	N[1]	Survival[2] % [95% CI]
Month 1 (30 Days)	344	98.9% [97.0%, 99.6%]
Month 6 (183 Days)	237	90.6% [86.4%, 93.5%]
Month 12 (365 Days)	117	76.0% [69.2%, 81.5%]

[1]Subjects ongoing without a TLR failure at the beginning of the visit window
[2]TLR-Free response estimate based on Kaplan-Meier estimates

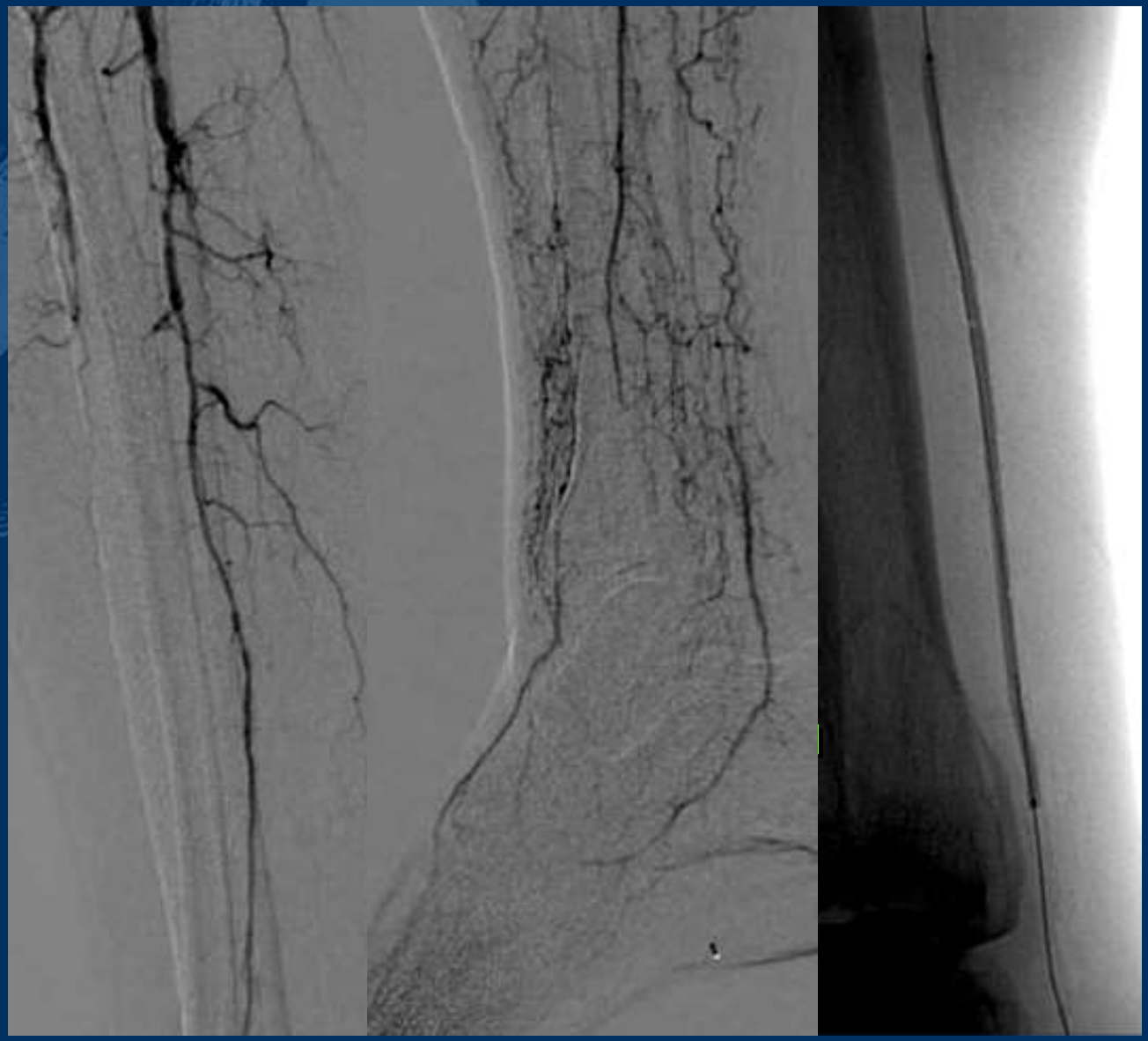
Rutherford Category Shift – 12 Month

Description	BTK Study Registry (N=144)
Improved by 5 Levels	[illegible]
Improved by 4 Levels	[illegible]
Improved by 3 Levels	[illegible]
Improved by 2 Levels	[illegible]
Improved by 1 Levels	[illegible]
No Change	[illegible]
Worsened by 1 Levels	2.8% (4/144)

77% Improved by ≥1 RCC

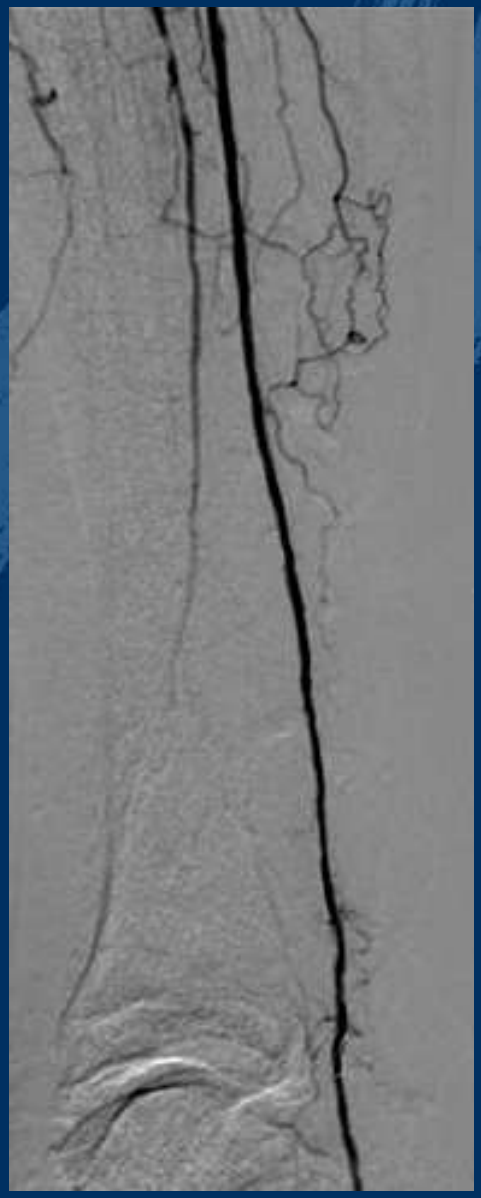
60% Improved by ≥3 RCC

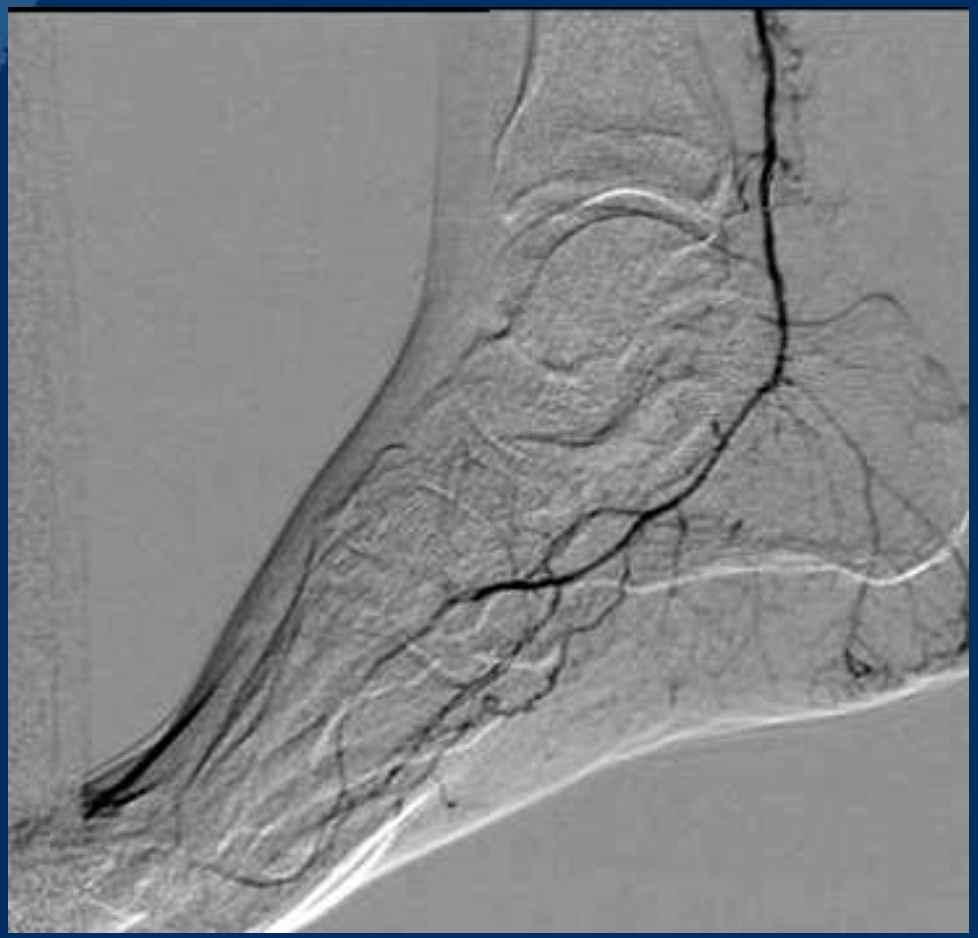
Male, 74, Diabetes, CKI, Diabetets



Case performed by Dr. Lichtenberg, Klinikum Arnsberg

After Lutonix DCB 2.5 x 120 mm





Case performed by Dr. Lichtenberg, Klinikum Arnsberg

12 Month Conclusions

- Only BTK Registry Multi Center On-going Study
- Promising Treatment Effect in Below-the–Knee Arteries
- Safety Consistent with the Strong Safety Profile of the Lutonix DCB in PAD
- Freedom from TLR 76.0% at 12 months
- Low Amputation Rate – 5.2% at 12 months
- ~60% Improvement by ≥3 Rutherford Classifications at 12 months
- **ZERO** Re-interventions for Distal Embolization at 12 months

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