Lutonix AV Global Registry

6 Month Results

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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)

- ☐ I do not have any potential conflict of interest

Lutonix AV Global Registry

Study Design

Study Design	A Prospective, Multicenter, Single Arm Real-World Registry Investigating the Clinical Use and Safety of the Lutonix® Drug Coated Balloon PTA Catheter for Treatment of Dysfunctional Native and Synthetic AV Fistulae
Objective	To demonstrate safety and assess the clinical use and outcomes of the Lutonix® DCB for treatment of dysfunctional AV fistulae located in the arm in a heterogeneous patient population in real world clinical practice
Number of Subjects/Sites	324 subjects enrolled at 25 international sites
Primary Endpoints	Efficacy: Target Lesion Primary Patency (TLPP) through 6 months. Safety: Freedom from any serious adverse event(s) involving the AV access circuit through 30 days
Follow-up	Clinical assessment at 6 months. Clinical or telephone assessment at 3 and 12 months
Global PI	Dimitrios Karnabatidis, MD- Patras, Greece

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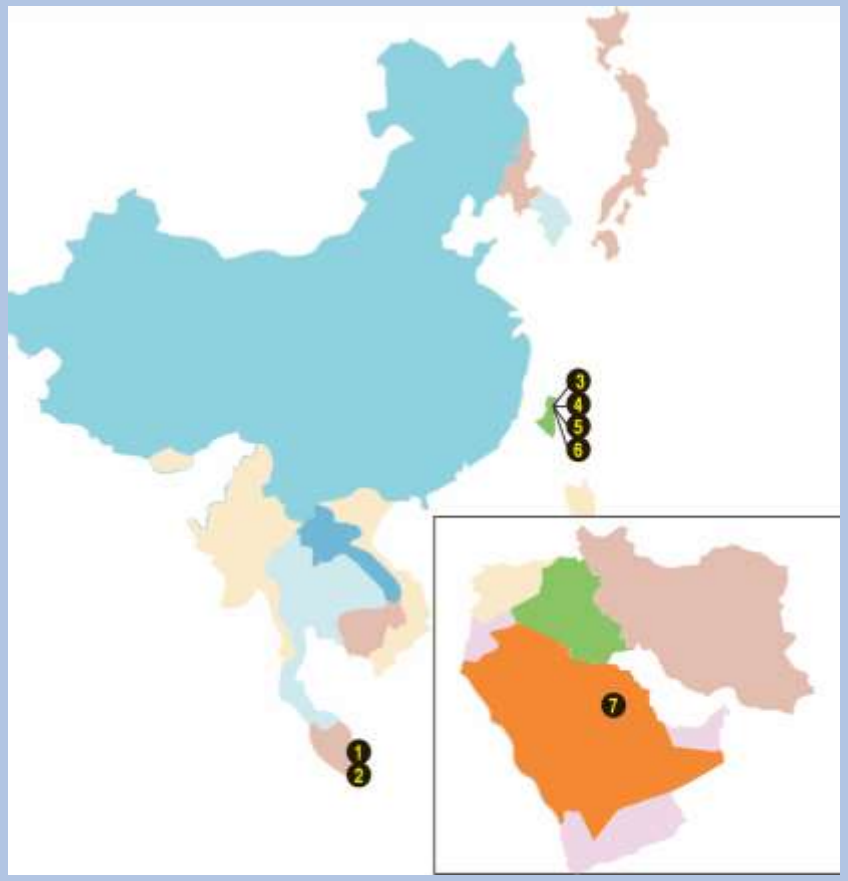

Prof. Karnabatidis
Dr. Ponce
Dr. Chong
Dr. Pietura
Dr. Ko

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Dr. Pegis
Prof. Tozzi
Dr. Jaffer
Prof. Deutschmann

Dr. Chang
Dr. Lucas
Dr. Saracino
Dr. Ferrario
Dr. Steiner

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Dr. Boura
Dr. Ahmad
Prof. Teichgraeber

Dr. Mishunin
Dr. Cioni
Dr. Huang
Dr. Savio
Dr. Arabi

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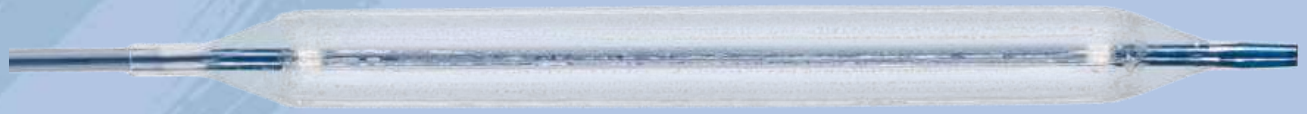
Study Device: LUTONIX® 035 DCB



- Low dose, 2 µg/mm^2 paclitaxel + polysorbate and sorbitol excipients
- 4-12 mm diameters, 40-100 mm lengths
- .035” guidewire compatible, nylon, semi-compliant balloon
- Over the wire, co-axial shaft, 75 cm, 100cm
- Nominal 6atm, RBP up to 12atm

BD

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Key Patient Demographics

Diabetes	Hypertension	Dyslipidemia
41.9%	73.4%	26.9%
Mean Age 67.3 ±12.8		

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AVF vs. AVG

Synthetic Graft – 25%

Native Fistula- 75%

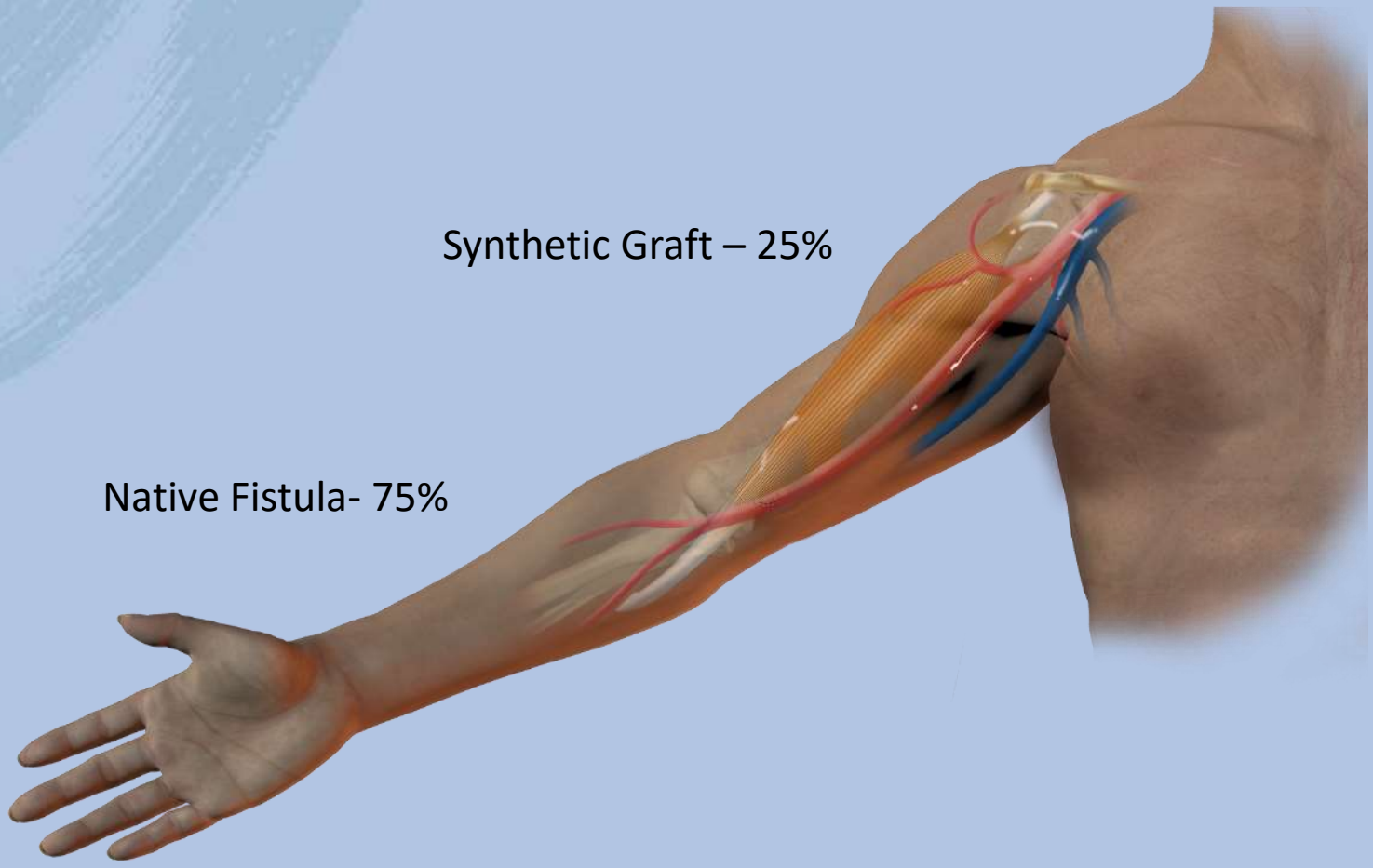

Image courtesy of BD : illustration by Paul Schiffmacher

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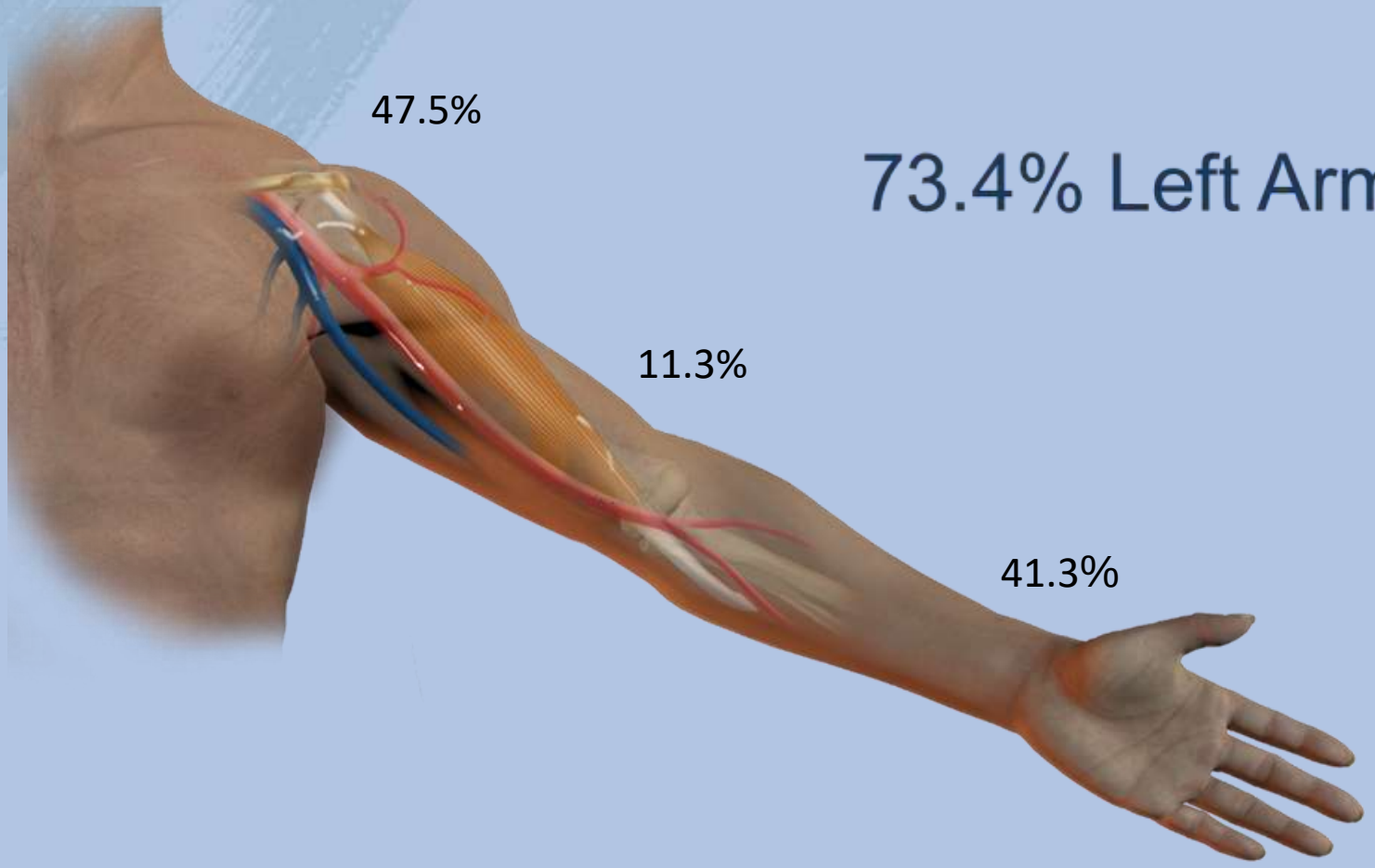
Access Location



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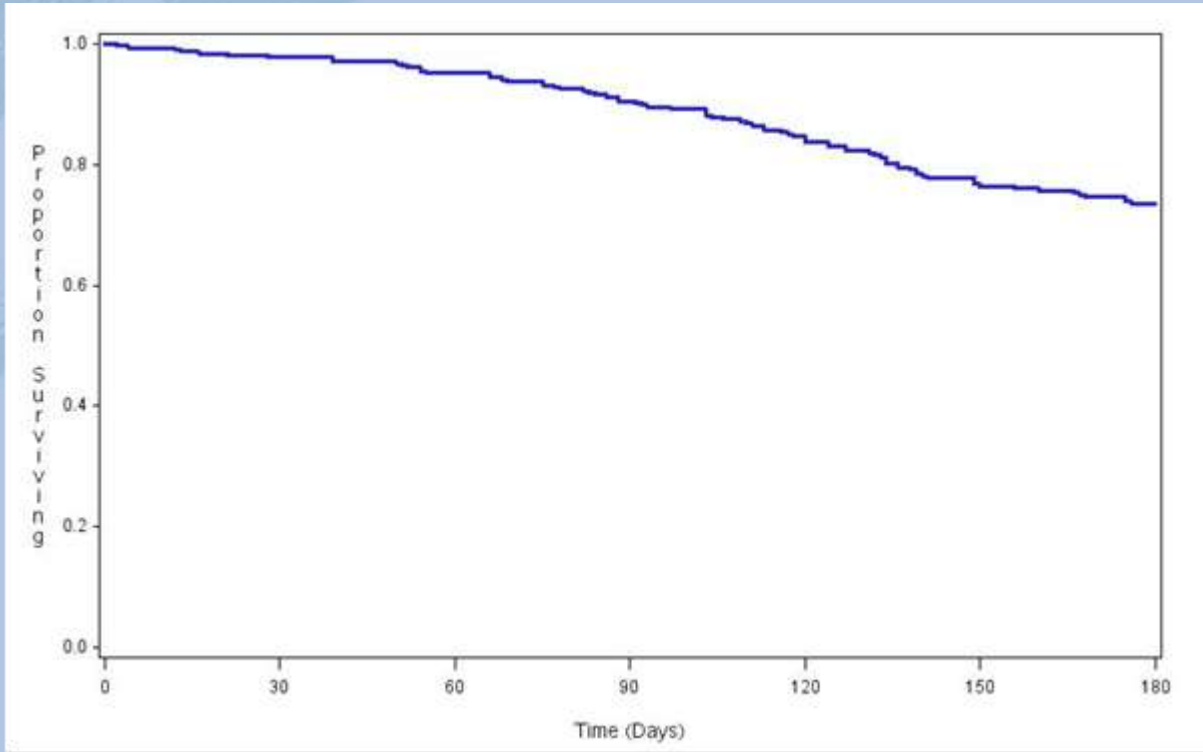
73.5% TLPP at 6 Months



Real World treated lesions; Central vein, ISR, AVG/AVF, Cephalic Arch, Restenotic, etc.

Kaplan-Meier Method, ITT subjects
Data shown is interim, site reported, and subject to change.

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6 Month Similar TLPP

LTX AV Global Registry	LTX AV Global Registry (With CVS)	Trerotola et. al[1]	Kitrou et. al[2]
75.0%	73.5%	71.4%	72.2%

1. Trerotola et al. Drug Coated Balloon Angioplasty in Failing AV Fistulas: A Randomized Controlled Trial Clin J Am Nephrol 2018 Aug 7;13(8):1215-1224

2. Kitrou et al. Paclitaxel-Coated Balloons for the Treatment of Dysfuntional Dialysis Access. Results from a Single-Center, Retrospective Analysis Cardiovasc. Intervent Radiol DOI 10.1007/s00270-016-1479-y

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Key Lesion Characteristics

Restenotic	ISR	Central Vein
52.9%	11.1%	11.6%

Mean Target Lesion Length 32.0 mm ± 20.86mm

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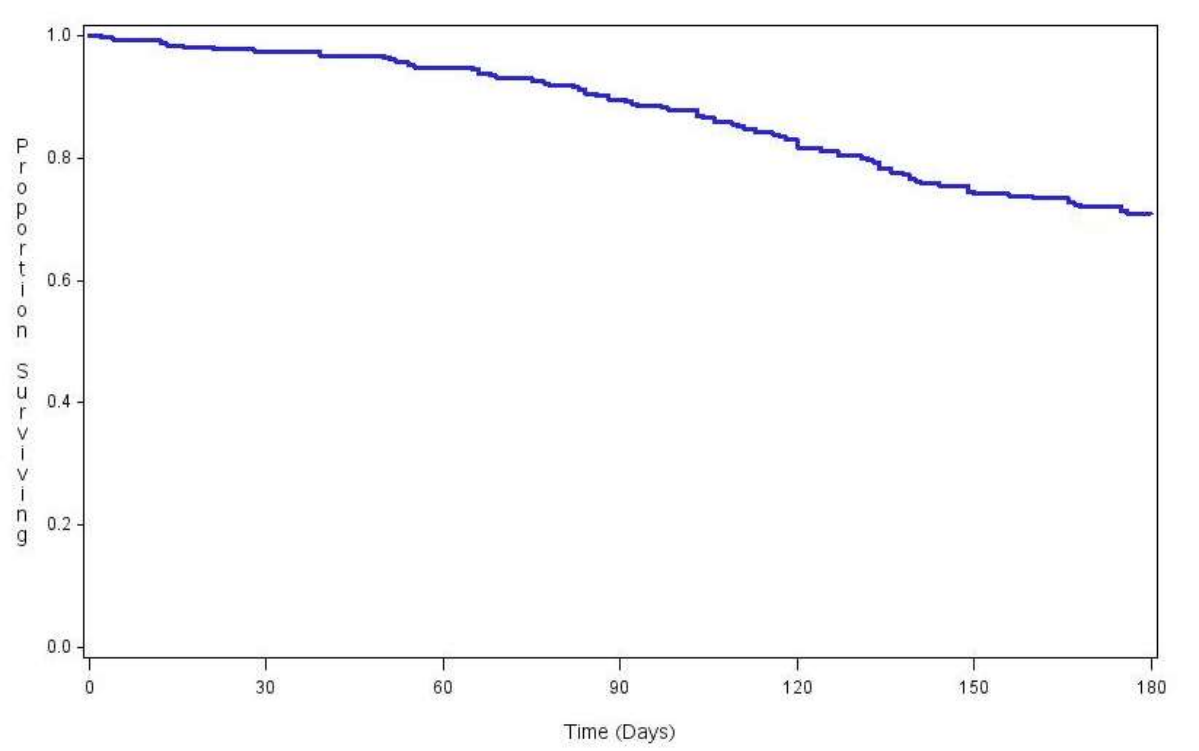
70.9% ACPP at 6 Months



Kaplan-Meier Method, ITT subjects
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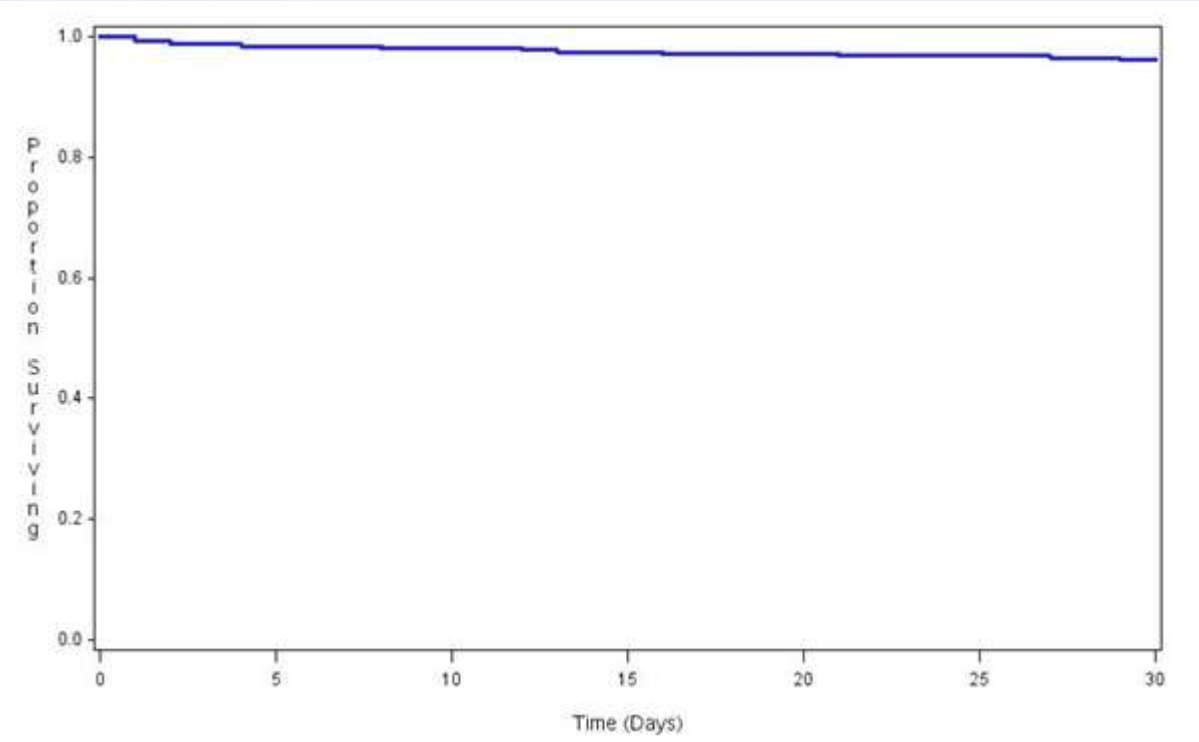
96.1% Freedom from Primary Safety Events



Kaplan-Meier Method, ITT subjects
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Largest DCB Arm

Title	Device	DCB	Control
Lutonix AV Global Registry	Lutonix®	**N=324**	
Trerotola 2018	Lutonix®	N=141	N=144
Lucev 2018	In.Pact™	N=31	N=31
Patane 2018	Lutonix®, In.Pact™	N=60	N=86
Zheng 2018	Lutonix®	N=23	
Bjorkman 2018	In.Pact™	N=19	N=20
Swinnen 2018	In.Pact™	N=70	N=62
Irani 2018	In.Pact™	N=59	N=60
Maleux 2018	In.Pact™	N=33	N=31
Kitrou 2017	Lutonix®	N=20	N=20
Troisi 2017	Freeway™, In.Pact™	N=38	
Kitrou 2016	Lutonix®	N=39	
Verbeek 2016	In.Pact™	N=41	
Swinnen 2015	In.Pact™	N=37	
Massmann 2015	Elutax	N=15	
Lai 2014	Sequent®	N=10	N=10
Patane 2014	In.Pact™	N=26	
Kitrou 2014	In.Pact™	N=20	N=20
Katsanos 2012	In.Pact™	N=20	N=20

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Exploratory Subgroup Analyses

Vessel Prep Performed?	
No	Yes
15 / 37 (40.5%)	174 / 251 (69.3%)
p=0.0009	

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Exploratory Subgroup Analyses

DCB Inflation Time		
50-120 seconds	120-180 seconds	180-240 seconds
92 / 156 (59.0%)	95 / 129 (73.6%)	3 / 4 (75.0%)
P=0.0019		

Lutonix AV Global Registry

75.0% TLPP (73.5% including Central Veins)

AVF/AVG, ISR, Restenotic lesions Included

324 pts (Largest DCB Recruitment)

96.1% Primary Safety Endpoint

Procedural Variables Matter

Recommend pre-dilation and >2 min inflation time

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