LUTONIX AV Clinical Trial

A Prospective, Global, Multicenter, Randomized, Controlled Study Comparing LUTONIX® 035 AV Drug Coated Balloon PTA Catheter vs. Standard Balloon PTA Catheter for the Treatment of Dysfunctional AV Fistulae

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AV IDE Protocol CL0023-01

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Disclosure

Speaker name:

Scott O. Trerotola, MD

I have the following potential conflicts of interest to report:

- [X] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [X] Other(s)

- [ ] I do not have any potential conflict of interest

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Conflicts of Interest

- Paid consultant for the following companies:
  - Bard Peripheral Vascular
  - LUTONIX
  - WL Gore
  - B Braun
  - Teleflex
  - Medcomp
  - Cook
- Royalties
  - Cook
  - Teleflex

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Study Design	Prospective, Global, Multicenter, Randomized, Safety and Effectiveness
Objective	To assess the safety and effectiveness of the LUTONIX® 035 AV Drug Coated Balloon PTA Catheter in the treatment of dysfunctional AV fistulae
Number of patients/sites	285 randomized subjects at 23 clinical sites
Primary effectiveness endpoint	Target Lesion Primary Patency (TLPP) - 6 months
Primary safety endpoint	Freedom from any serious adverse event(s) involving the AV access circuit through 30 days
Follow up	1, 3, 6, 9, 12, 18, 24 month visits
Status	First Subject: June 2015 Enrollment Completion: March 2016

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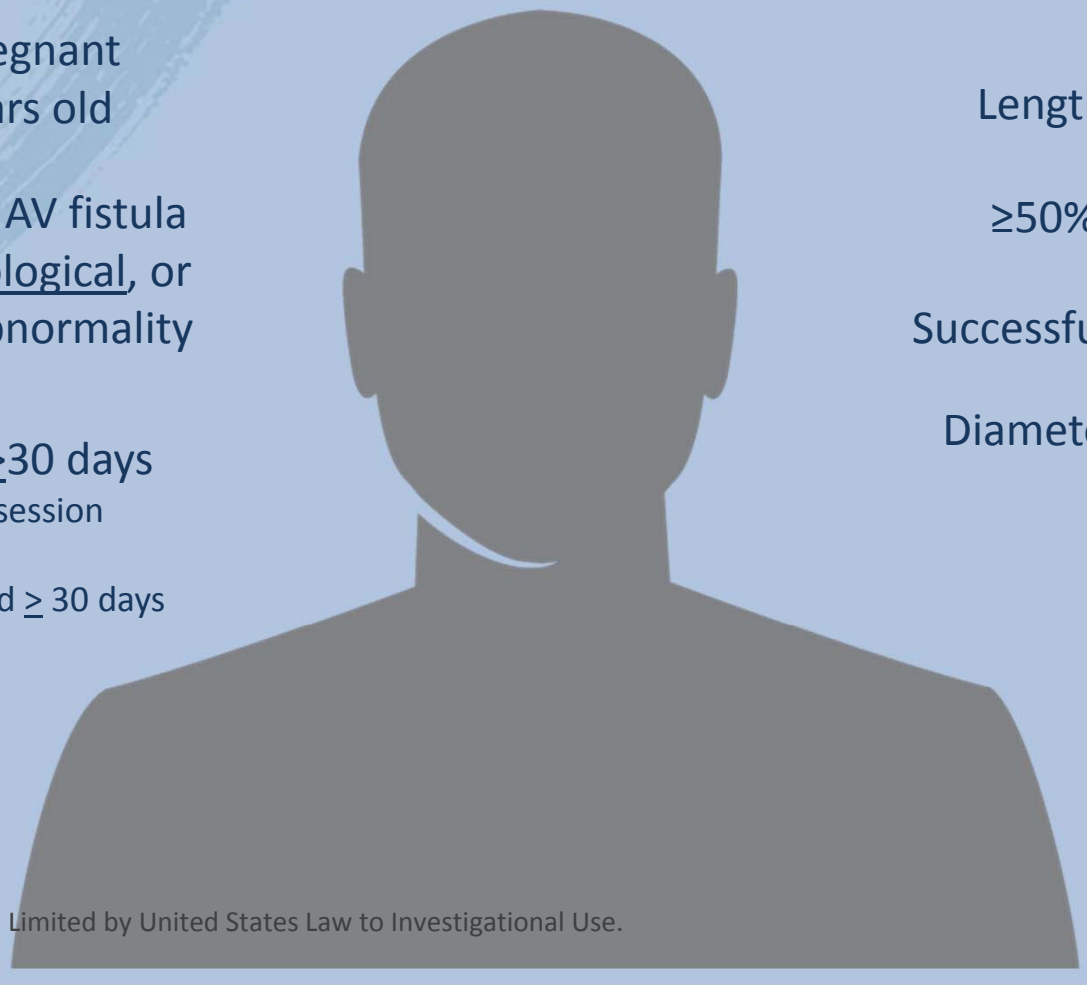
Key Inclusion Criteria

CLINICAL

Male or non-pregnant female ≥21 years old

Upper extremity AV fistula w/clinical, physiological, or hemodynamic abnormality

Fistula created ≥30 days
- 1+ hemodialysis session
- 2 needles
- Catheter removed ≥ 30 days



ANGIOGRAPHIC

Length ≤10 cm

≥50% stenosis

Successful pre-dilation

Diameter 4-12 mm

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Key Exclusion Criteria

CLINICAL

Lower extremity access

Central veins

Thrombosed access

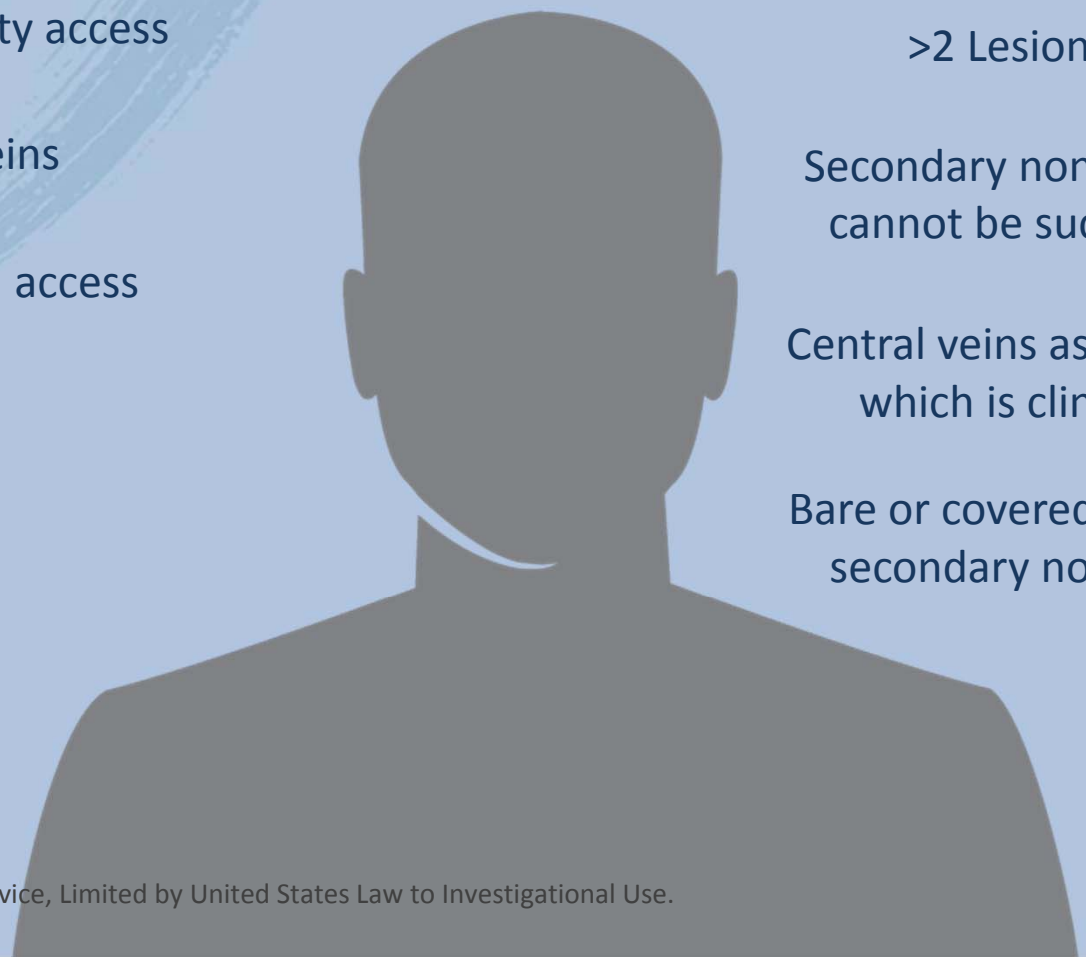
ANGIOGRAPHIC

>2 Lesions in circuit

Secondary non-target lesion that cannot be successfully treated

Central veins as a secondary lesion, which is clinically significant

Bare or covered stent in target or secondary non-target lesions



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Inclusion Criteria

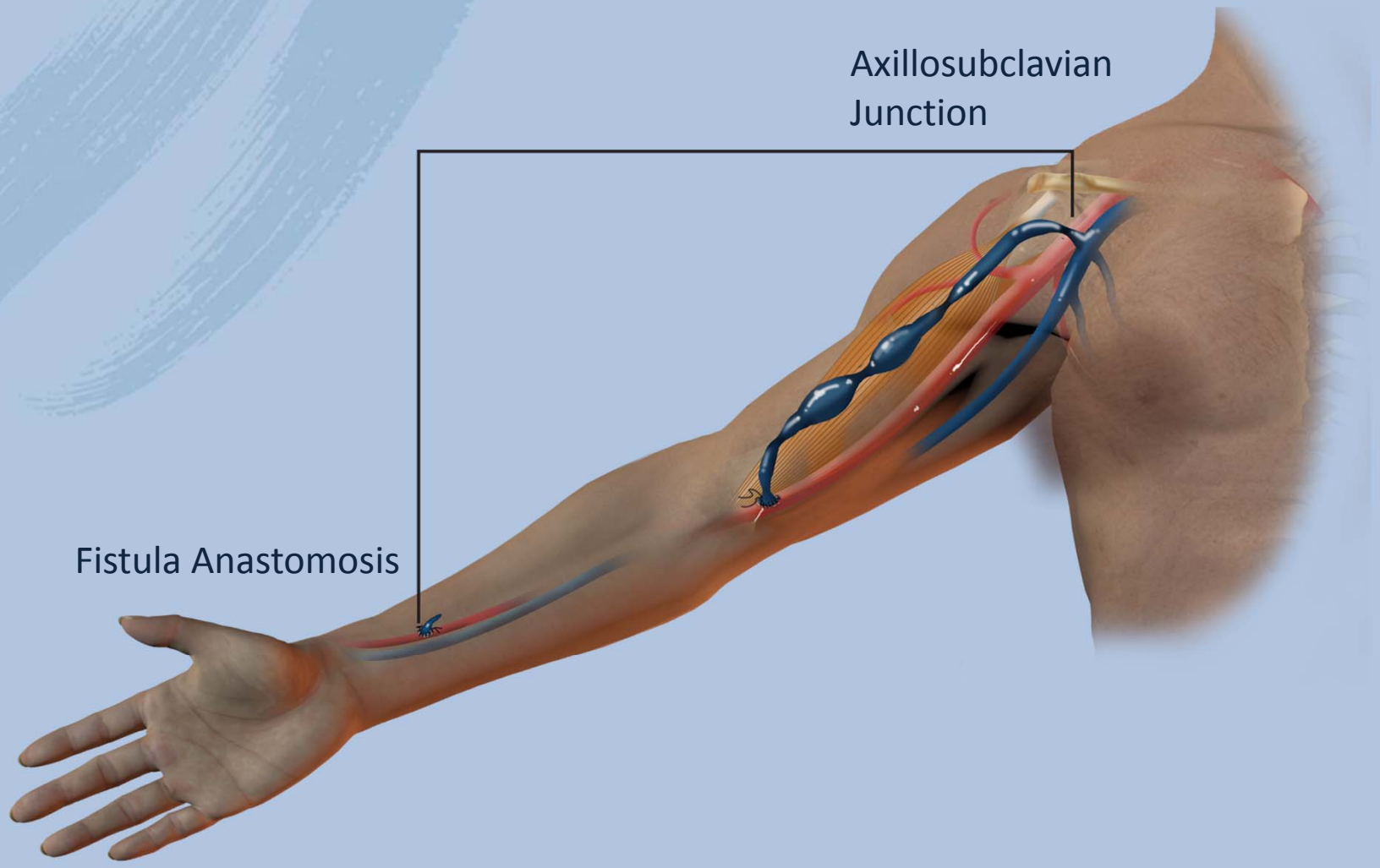

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Image courtesy of Bard: illustration by Paul Schiffmacher

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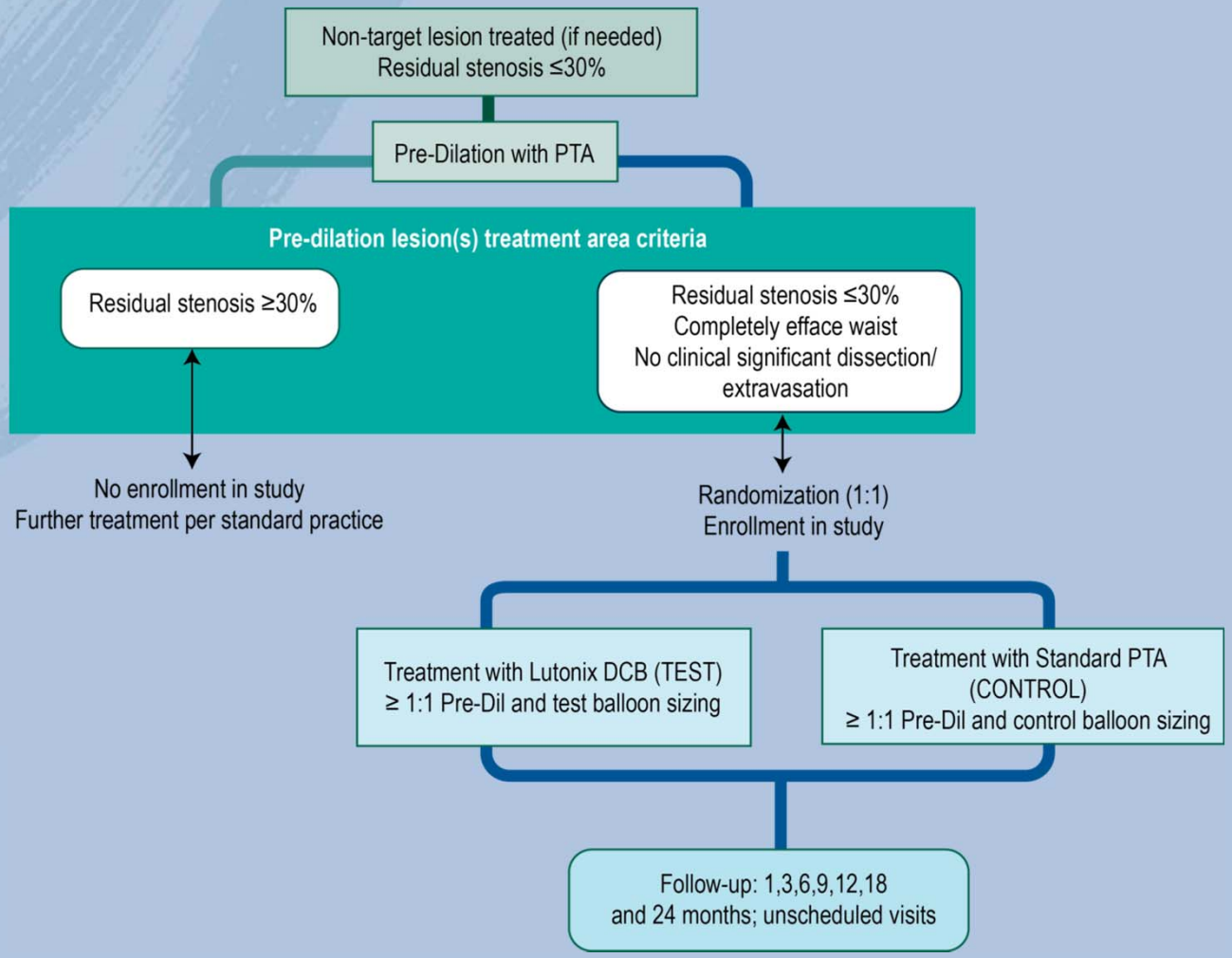
Study Design



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Demographics

	DCB (n=141)	PTA (n=144)
Mean Age	63.6	61.0
Male (%)	61.7%	59.0%
Hypertension (%)	94.3%	98.6%
Diabetes mellitus (%)	58.2%	65.3%
Dyslipidemia (%)	60.3%	58.3%
Current smoking (%)	13.5%	14.6%
Peripheral arterial disease (%)	9.9%	18.1%
Coronary artery disease (%)	30.5%	27.8%

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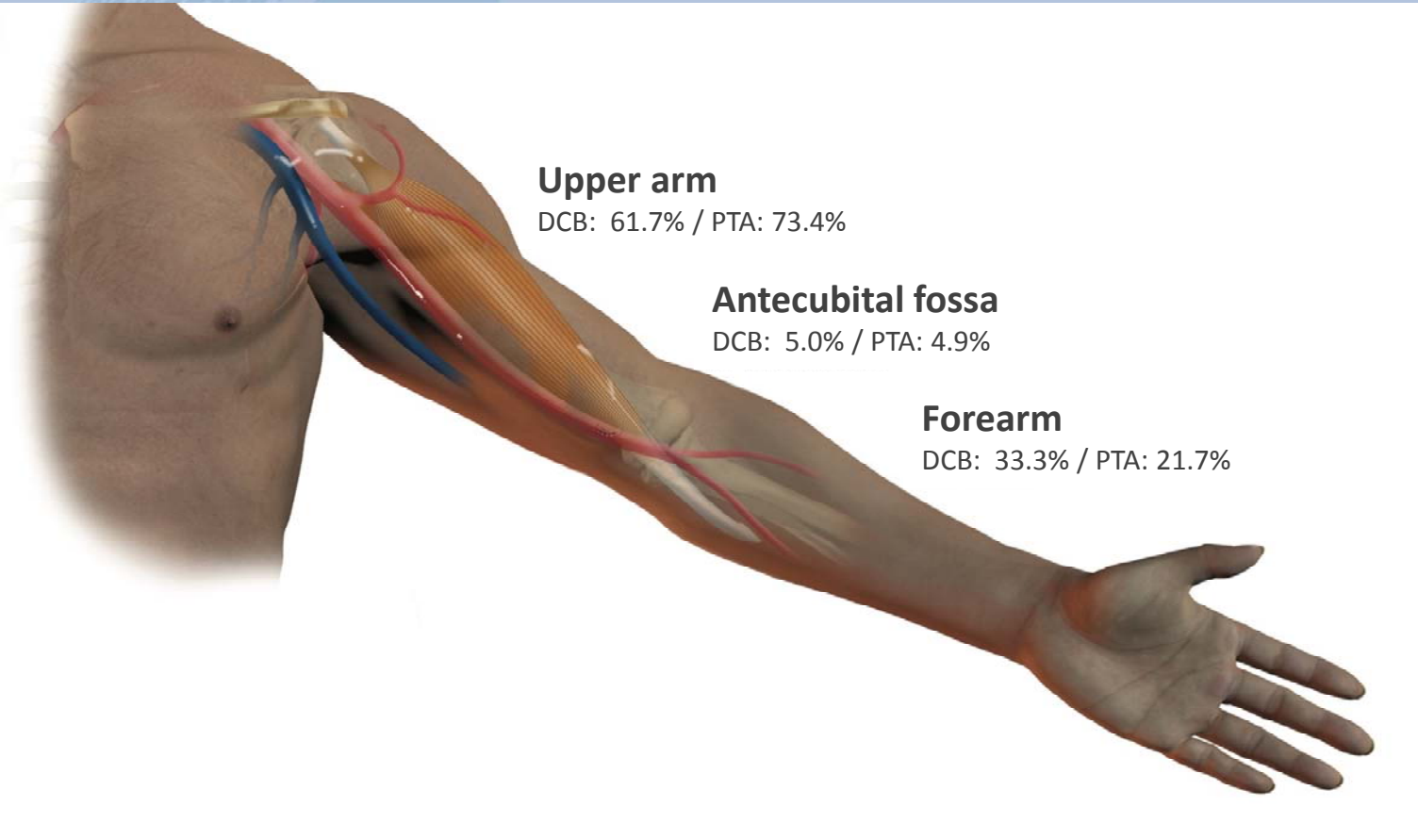
Treated Fistula Locations



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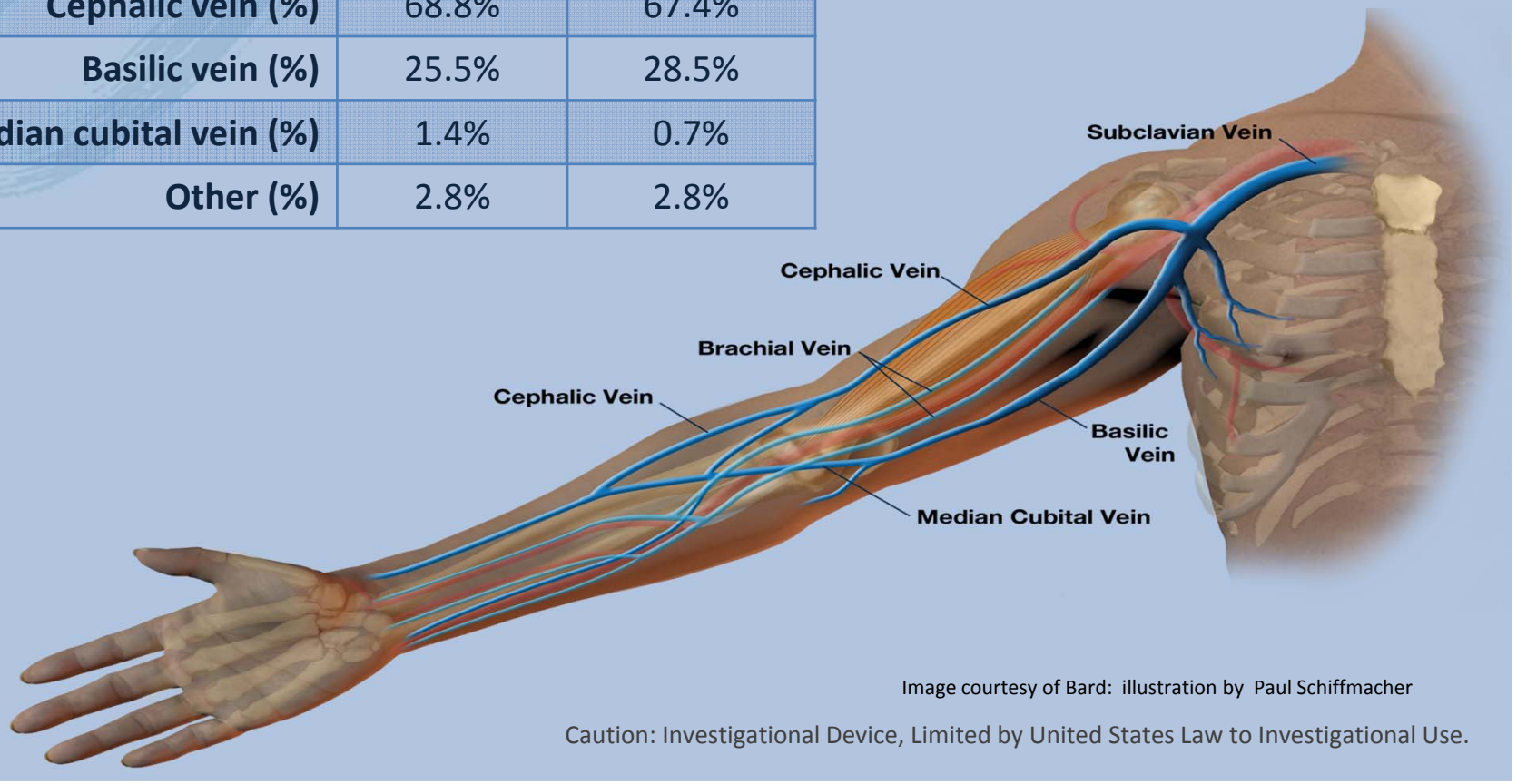
Treated Vessel Locations

	DCB (n=141)	PTA (n=144)
Subclavian vein (%)	0.7%	0.0%
Brachial vein (%)	0.7%	0.7%
Cephalic vein (%)	68.8%	67.4%
Basilic vein (%)	25.5%	28.5%
Median cubital vein (%)	1.4%	0.7%
Other (%)	2.8%	2.8%



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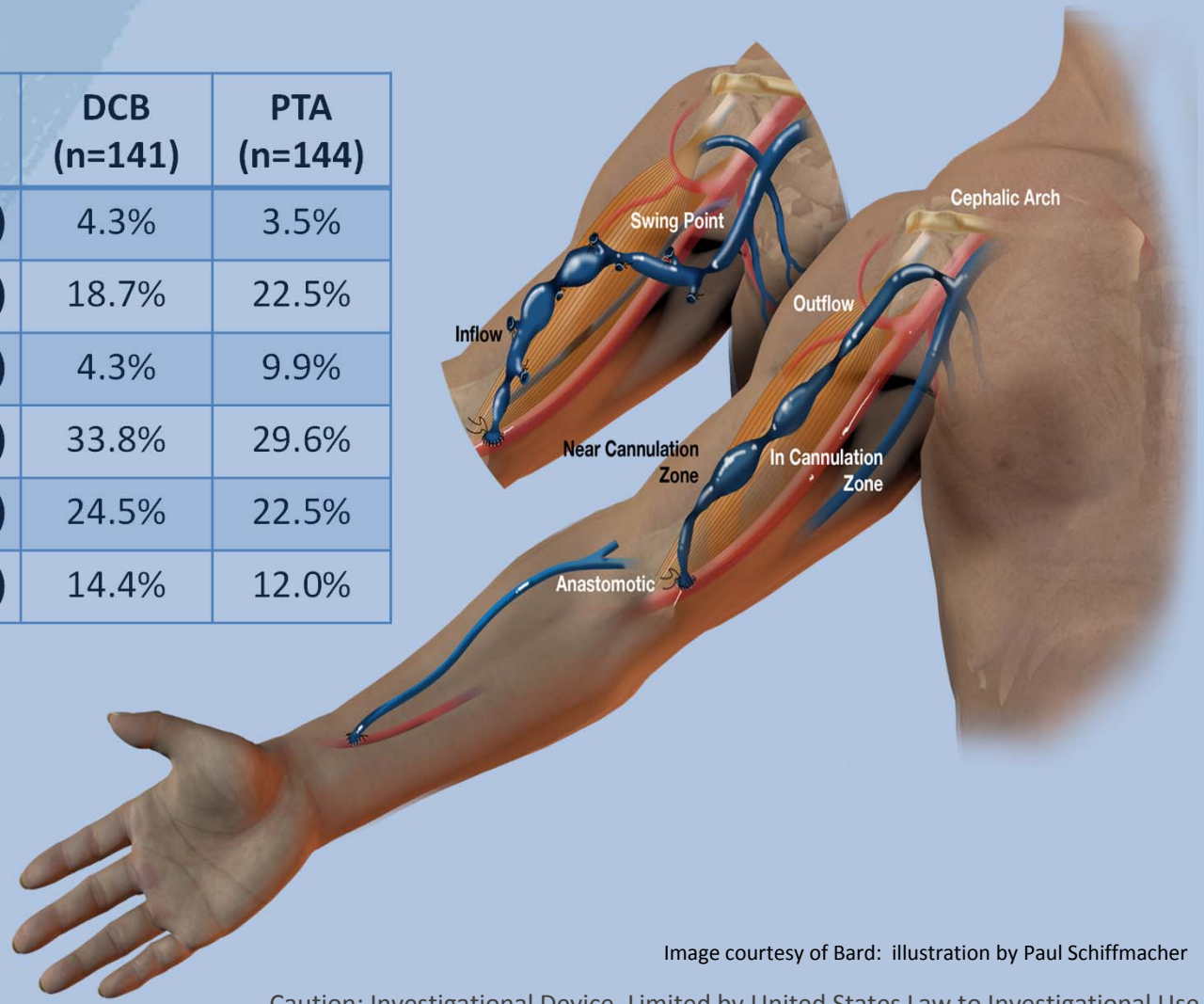
Target Lesion Locations

	DCB (n=141)	PTA (n=144)
Anastomotic (%)	4.3%	3.5%
Cephalic arch (%)	18.7%	22.5%
In cannulation zone (%)	4.3%	9.9%
Inflow (%)	33.8%	29.6%
Outflow (%)	24.5%	22.5%
Swing point (%)	14.4%	12.0%



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Lesion Characteristics

	DCB (n=141)	PTA (n=144)
De novo, (%)	30.5%	27.1%
Tandem, (%)	2.8%	7.0%
Target lesion length, mm (mean ± SD)	28.4 ± 15.09	29.5 ± 18.69

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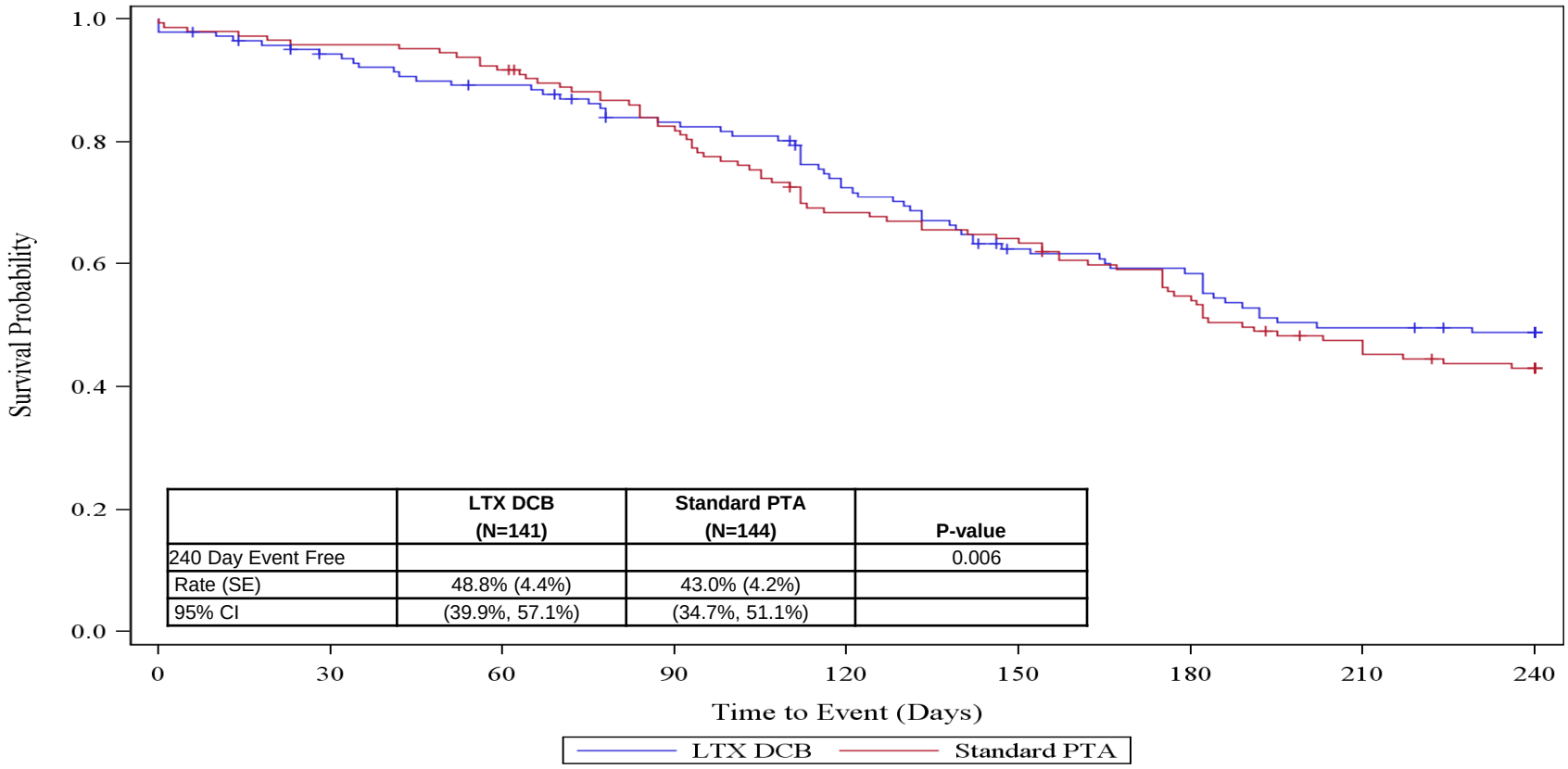
Primary Safety at 240 Days



	LTX DCB (N=141)	Standard PTA (N=144)	P-value
240 Day Event Free			0.006
Rate (SE)	48.8% (4.4%)	43.0% (4.2%)	
95% CI	(39.9%, 57.1%)	(34.7%, 51.1%)	

95% CI of the rate and the rate difference at each time point were calculated based on normal approximation and one-sided p-value is from test for non-inferiority, with 10% as non-inferiority margin.

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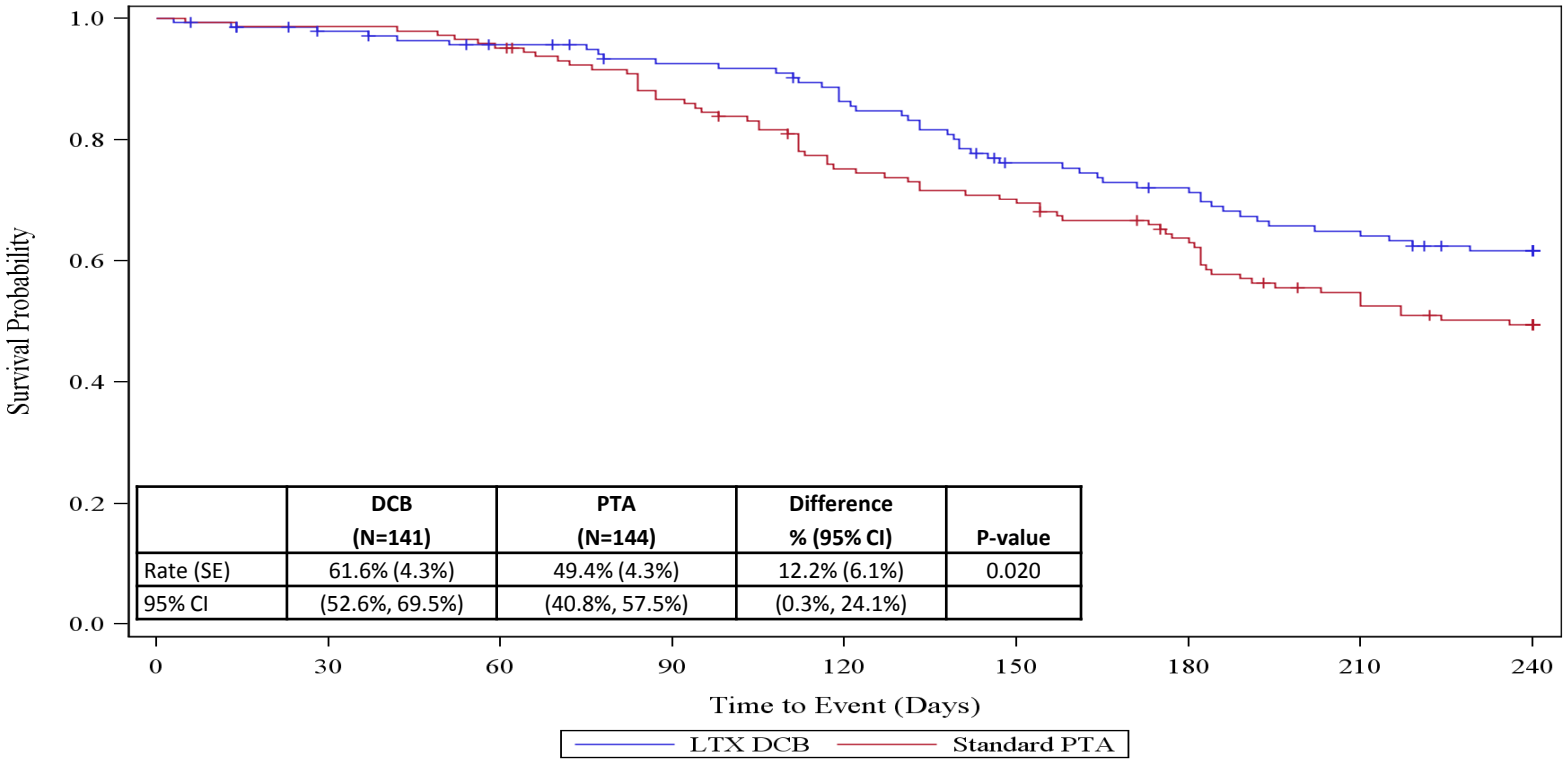
Data shown are interim, site reported and subject to change

Target Lesion Primary Patency at 240 Days



	DCB (N=141)	PTA (N=144)	Difference % (95% CI)	P-value
Rate (SE)	61.6% (4.3%)	49.4% (4.3%)	12.2% (6.1%)	0.020
95% CI	(52.6%, 69.5%)	(40.8%, 57.5%)	(0.3%, 24.1%)	

Target Lesion Primary Patency (TLPP) ends with a clinically driven re-intervention of the target lesion or access thrombosis.
95% CI of the rate and rate difference at each time point were calculated based on normal approximation using Greenwood formula variance estimators. Log-Rank Test was used to compare the two treatment curves between Day 0-240 and one-sided p-value was provided.

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Number of Interventions Required to Maintain TLP at 240 Days

	LTX DCB (n=141)	Standard PTA (n=144)	P-value*
Number of interventions	66	94	0.024
n	141	144	
Mean (SD)	0.47 (0.732)	0.65 (0.805)	
Median	0	0	
Min – Max	0 - 3	0 - 4	

*Two-sided P-value

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Summary

- First in fistula trial designed to incorporate a wide variety of lesions/fistula types

- 240 day results demonstrated:
  - Safety outcomes non-inferior to PTA
  - Target lesion primary patency
    - 61.6% DCB vs. 49.4% PTA (Δ 12.2% p = 0.02)*
  - 29.8% fewer interventions required to maintain TLP in DCB arm

*one-sided P-value

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