Global Chronic Total Occlusion Analysis of All Lutonix® DCB SFA Combined Trials

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Disclosure

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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

Meta-Analysis

Purpose of this meta-analysis including the Levant 2, Levant 2 Continued Access, Global Registry and Long Lesion Studies were to compare the efficacy and safety of

LUTONIX DCB

between the Chronic Total Occlusion and Non-Chronic Total Occlusion subject

Study Population

Total Subjects

(n=1800)

CTO

(n=486)

Levant 2 –13.4% (65/486)

Levant 2 CA – 30.0% (146/486)

Global Registry – 44.0% (214/486)

Long Lesion – 12.6% (61/486)

Non-CTO

(n=1314)

Levant 2 –19.1% (251/1314)

Levant 2 CA – 40.3% (529/1314)

Global Registry – 36.3% (477/1314)

Long Lesion – 4.3% (57/1314)

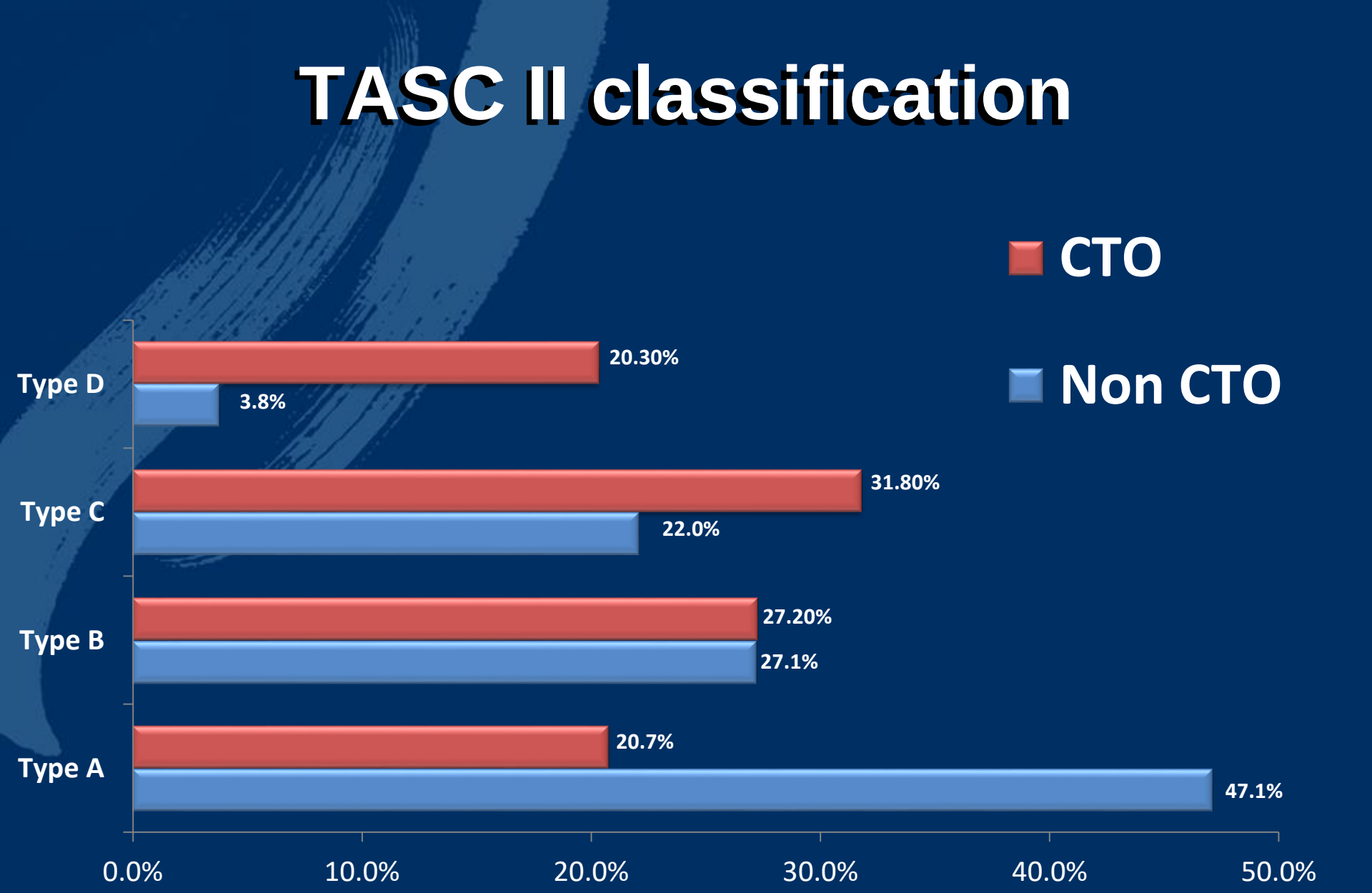
Demographics

	CTO (N=486)	No CTO (N=1314)
Age, Mean ± SD (n)	67.5 ± 10.05 (486)	68.6 ± 9.3 (1314)
Gender, n (%)		
Male	332 / 486 (68.3%)	848 / 1314 (64.5%)
Female	154 / 486 (31.7%)	466 / 1314 (35.5%)
Race, n (%)*		
American Indian / Alaska Native	0/272 (0.0%)	1/837 (0.1%)
Asian	1/272 (0.4%)	5/837 (0.6%)
Black / African American	9/272 (3.3%)	37/837 (4.4%)
Native Hawaiian / Other Pacific Islander	0/272 (0.0%)	1/837 (0.1%)
Other	0/272 (0.0%)	1/837 (0.1%)
Unknown	4/272 (1.5%)	16/837 (1.9%)
White	258/272 (94.9%)	776/837 (92.7%)
BMI (kg/m2), n	477	1293
Mean (SD)	27.4 (4.89)	27.9 (4.79)
Min - Max	15 - 53	13 - 49
Long Lesion Subject, n/N (%)	125/486 (25.7%)	158/1314 (12.0%)
Bailout Stent Subject, n/N (%)	128/486 (26.3%)	147/1314 (11.2%)

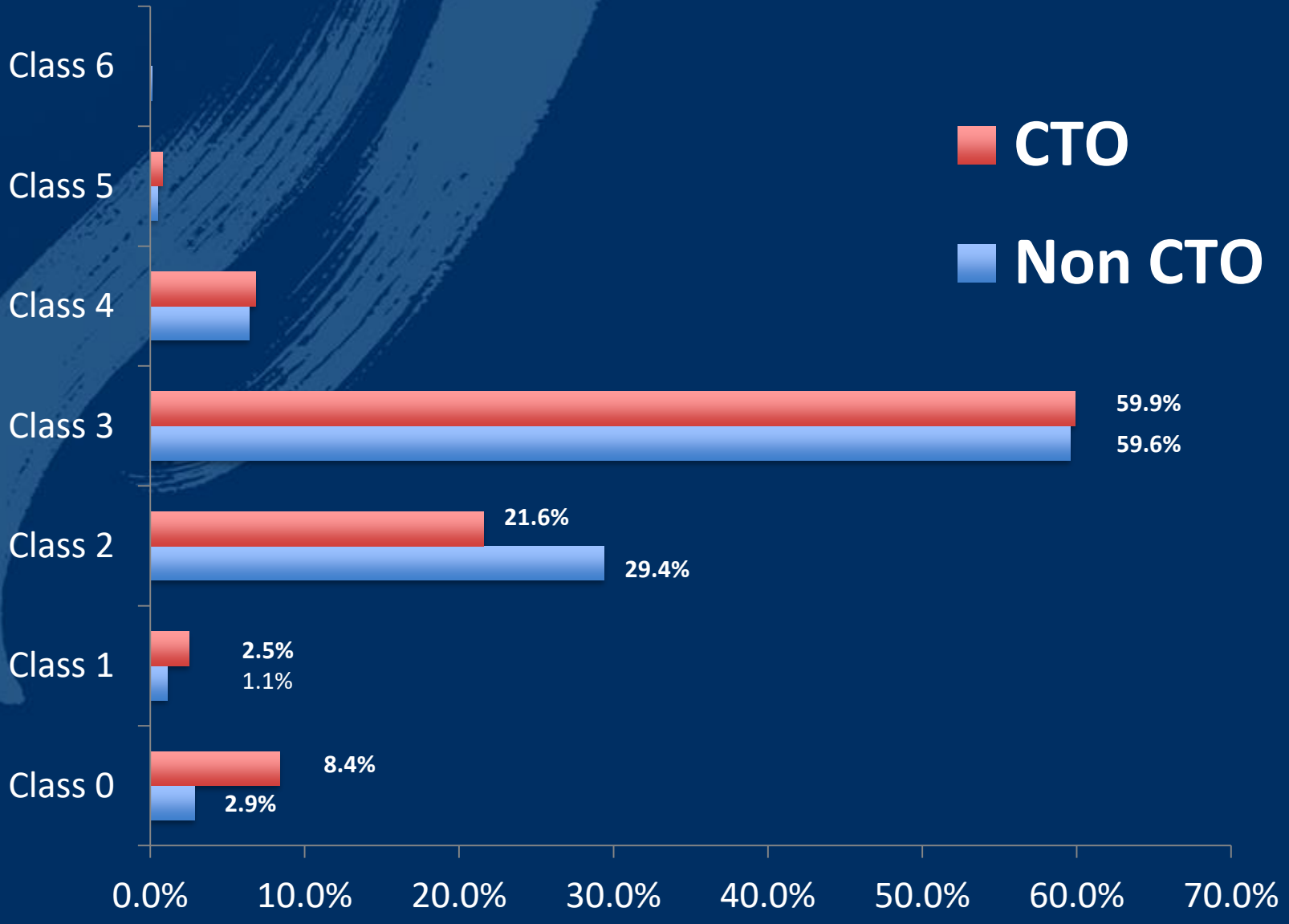
Lesion Characteristics

	CTO (N=486)	Non-CTO (N=1314)
Number of Treated Lesions, n/N (%)	458/486 (94.2%)	1158/1287 (90.0%)
1	26/486 (5.3%)	119/1287 (9.2%)
2	2/486 (0.4%)	9/1287 (0.7%)
3	0/486 (0.0%)	1/1287 (0.1%)
4		
Mean Lesion Length, (mm,SD)	117.2 (83.06)	72.8 (67.03)
Min - Max	3.0 - 450.0	2.3 - 500.0
Baseline RVD Average (mm), n	485	1277
Mean (SD)	4.9 (0.74)	4.9 (0.76)
Min - Max	3.0 - 7.0	2.0 - 7.5
Calcification, n/N (%)	272/428 (63.6%)	686/1128 (60.8%)
Baseline Stenosis (%), n	486	1281
Mean (SD)	100.0 (0.00)	80.1 (11.93)
Min - Max	100 – 100	6.0 - 99
Final Stenosis (%), n	251	359
Mean (SD)	31.9 (24.79)	32.6 (24.35)
Min - Max	0.0 - 150	0.0 - 150
Lesion Locations, n/N (%)		
SFA	435/486 (89.5%)	1139/1314 (86.7%)
Popliteal	93/486 (19.1%)	246/1314 (18.7%)
Dissection, n/N (%)	273/483 (56.5%)	572/1281 (44.7%)

TASC II classification

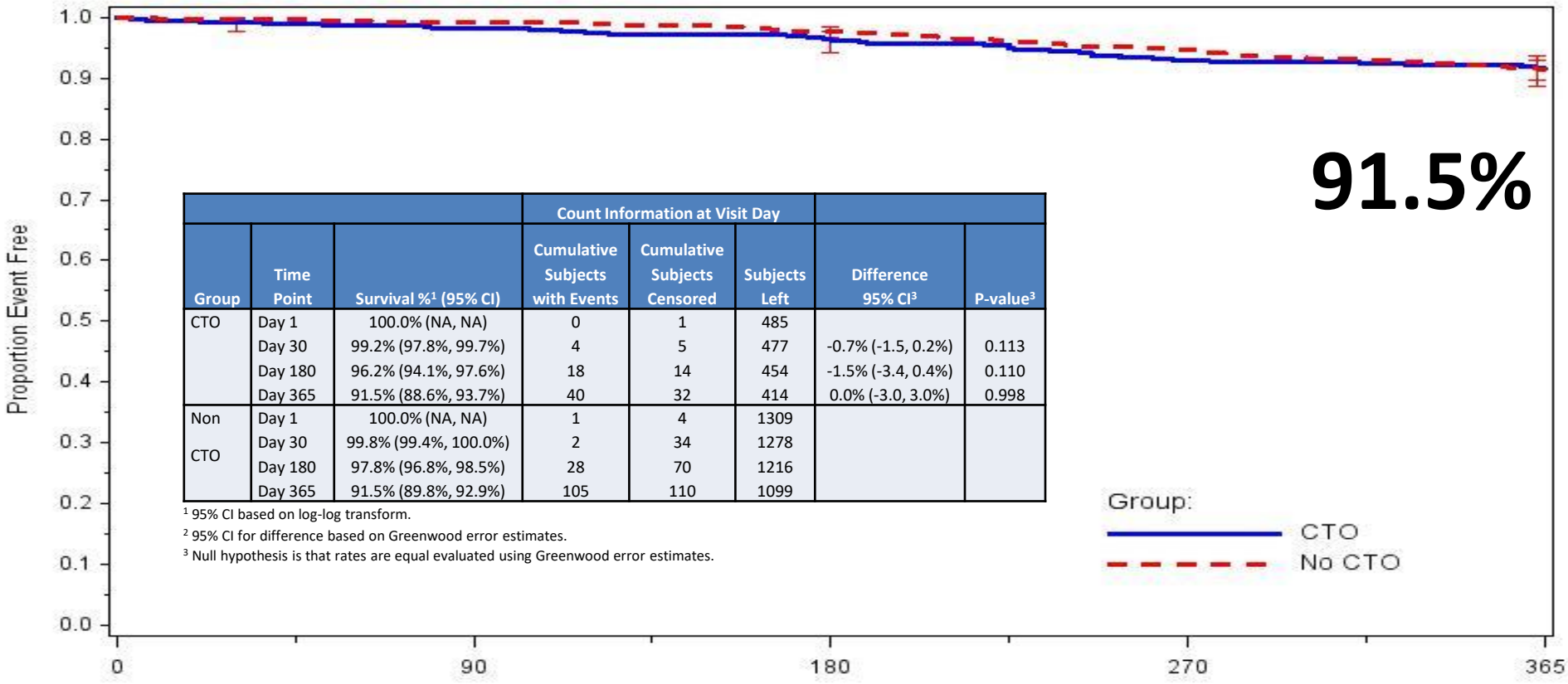


Baseline Rutherford Category



Freedom from Clinically-Driven TLR

Lutonix



			Count Information at Visit Day				
Group	Time Point	Survival %[1] (95% CI)	Cumulative Subjects with Events	Cumulative Subjects Censored	Subjects Left	Difference 95% CI[3]	P-value[3]
CTO	Day 1	100.0% (NA, NA)	0	1	485		
	Day 30	99.2% (97.8%, 99.7%)	4	5	477	-0.7% (-1.5, 0.2%)	0.113
	Day 180	96.2% (94.1%, 97.6%)	18	14	454	-1.5% (-3.4, 0.4%)	0.110
	Day 365	91.5% (88.6%, 93.7%)	40	32	414	0.0% (-3.0, 3.0%)	0.998
Non CTO	Day 1	100.0% (NA, NA)	1	4	1309		
	Day 30	99.8% (99.4%, 100.0%)	2	34	1278		
	Day 180	97.8% (96.8%, 98.5%)	28	70	1216		
	Day 365	91.5% (89.8%, 92.9%)	105	110	1099		

[1] 95% CI based on log-log transform.

[2] 95% CI for difference based on Greenwood error estimates.

[3] Null hypothesis is that rates are equal evaluated using Greenwood error estimates.

Major Amputation

	CTO (N=486)	No CTO (N=1314)	P-Value*
30 Days	0 / 481 (0.0%)	1 / 1285 (0.1%)	0.317
6 Months	1 / 476 (0.2%)	3 / 1252 (0.2%)	0.906
12 Months	1 / 461 (0.2%)	4 / 1217 (0.3%)	0.681

*Null hypothesis is that rates are equal evaluated using normal approximation

Minor Amputation

	CTO (N=486)	No CTO (N=1314)	P-Value*
30 Days	2 / 481 (0.4%)	2 / 1285 (0.2%)	0.406
6 Months	2 / 476 (0.4%)	2 / 1250 (0.2%)	0.412
12 Months	2 / 460 (0.4%)	4 / 1214 (0.3%)	0.762

*Null hypothesis is that rates are equal evaluated using normal approximation

Rutherford Change

Summary	CTO (N=486)	Non CTO (N=1314)
Rutherford Class at Baseline		
n	485	1311
Mean (SD)	2.8 (0.64)	2.7 (0.64)
Min - Max	0.0 – 5.0	0.0 – 6.0
Rutherford Class at 12 Months		
n	345	932
Mean (SD)	0.8 (1.14)	0.9 (1.11)
Min - Max	0.0 - 5.0	0.0 - 6.0
12 Months Change from Baseline		
n	344	932
Mean (SD)	-2.0 (1.25)	-1.9 (1.20)
Min - Max	-5.0 – 2.0	-5.0 - 3.0

Summary

- CTO / Non-CTO demographics and lesion characteristic of this combined meta analysis was well matched

- Study outcomes – 1 Year
  - TLR Free: 91.5% CTO / 91.5% Non-CTO
  - Major Amputation: 0.2% CTO / 0.3% Non-CTO
  - Minor Amputation: 0.4% CTO / 0.3% Non-CTO

Lutonix DCB has **EQUALLY EFFECTIVE and SAFETY**
In Subjects with CTO and Non-CTO lesion

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