SELUTION SLR™ DEB

DRUG ELUTION DONE BETTER

SUMMARY OF

SELUTION DENOVO TRIAL

A prospective, multi-center, randomized, open-label, non-inferiority clinical trial to compare a SELUTION SLR DEB strategy vs. systematic DES strategy in de novo lesions.

3323 PATIENTS IN **62** SITES LOCATED ACROSS EUROPE AND ASIA

1:1 RANDOMIZATION

DEB STRATEGY
1661 PATIENTS
Provisional stenting when needed

DES STRATEGY
1662 PATIENTS

FOLLOW-UP AT
30 DAYS **12** MONTHS TO **5** YEARS

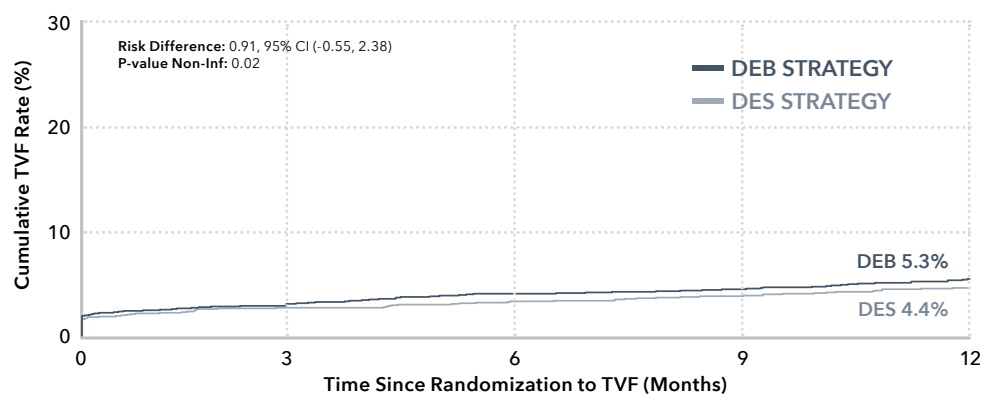
Co-primary endpoints = non-inferiority of TVF at 12 months and 5 years.

Conditional superiority analysis if non-inferiority established at 5 years.

STUDY RESULTS

SELUTION SLR DEB ACHIEVES DES-LIKE OUTCOMES WHILE PRESERVING FUTURE OPTIONS[1]

PRIMARY ENDPOINT MET: TVF AT 12 MONTHS*



5.3%
TARGET VESSEL FAILURE
DEB STRATEGY

VS

4.4%
TARGET VESSEL FAILURE
DES STRATEGY

* Intention to Treat

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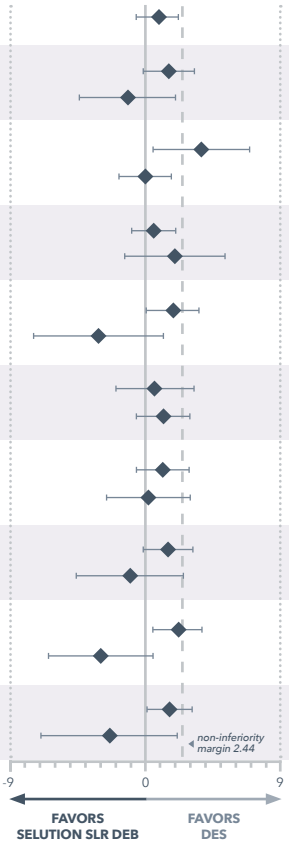
SELUTION SLR DEB

IS AN ALTERNATIVE TO DES STRATEGY ACROSS BROAD SUBGROUPS

SUBGROUP ANALYSIS OF THE PRIMARY ENDPOINT: TVF AT 12 MONTHS[1]

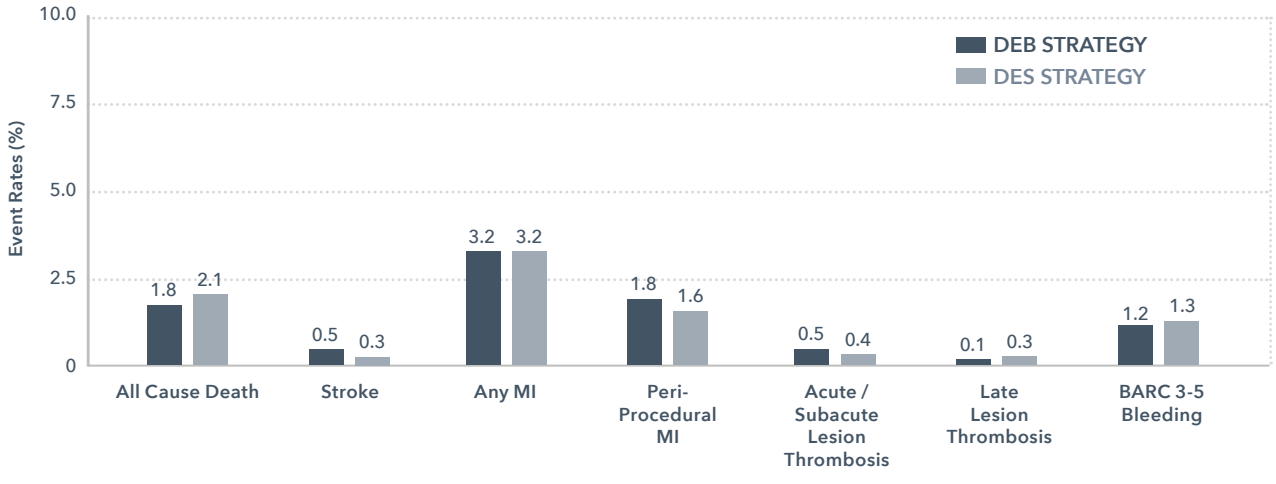
Subgroup		SELUTION DEB Strategy (%)	DES Strategy (%)	Absolute Risk Difference	AR (95% CI)	Interaction p-value
Overall		5.3%	4.4%		0.91 (-0.55, 2.38)	
Age ≥ 75 yrs	No (N = 2,525) Yes (N = 798)	5.4% 5.0%	3.9% 6.1%		1.58 (-0.06, 3.23) -1.15 (-4.33, 2.03)	0.13
Sex	Female (N = 842) Male (N = 2,481)	7.4% 4.7%	3.7% 4.7%		3.65 (0.54, 6.75) 0.00 (-1.66, 1.67)	0.04
Diabetes	No (N = 2,464) Yes (N = 859)	4.6% 7.3%	4.1% 5.3%		0.56 (-1.06, 2.18) 1.96 (-1.30, 5.23)	0.45
High bleeding risk	No (N = 2,542) Yes (N = 522)	5.7% 4.9%	4.0% 7.9%		1.79 (0.12, 3.47) -3.05 (-7.27, 1.17)	0.04
Any device size ≥ 3.0mm	No (N = 897) Yes (N = 2,403)	4.2% 5.6%	3.5% 4.4%		0.64 (-1.9, 3.2) 1.17 (-0.6, 2.9)	0.74
Any bifurcation lesions	No (N = 2,064) Yes (N = 1,246)	4.5% 6.5%	3.4% 6.2%		1.16 (-0.53, 2.86) 0.23 (-2.49, 2.94)	0.57
Any long lesion (≥ 25mm)	No (N = 2,542) Yes (N = 759)	5.0% 6.0%	3.5% 6.9%		1.50 (-0.07, 3.06) -0.97 (-4.47, 2.53)	0.21
Any severe or moderate calcification	No (N = 2,454) Yes (N = 865)	5.3% 5.5%	3.1% 8.4%		2.14 (0.54, 3.73) -2.87 (-6.29, 0.54)	0.01
Multivessel procedure	No (N = 2,776) Yes (N = 547)	5.1% 6.5%	3.5% 8.8%		1.60 (0.09, 3.12) -2.31 (-6.76, 2.14)	0.10



SELUTION SLR DEB

STRATEGY IS AS SAFE AS DES STRATEGY

SAFETY ENDPOINTS: DEB STRATEGY VS DES STRATEGY



1. Selution DeNovo Trial, Oral Presentation, TCT 2025

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For Healthcare Professionals Only.

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