

SAVI TF REGISTRY

CLINICAL RESULTS **EuroPCR 2016**

LATEST RESULTS AT EuroPCR 2016.
1000 PATIENTS ENROLLED @ 30 DAYS.

ACURATE *neo*[™]
TRANSFEMORAL TAVI

symetis 

NO COMPROMISE

1000
PATIENTS

8.2%
PPM[°]

4.1%
PVL^{°°} ≥ 2

1.3%
ACM^{°°°}

[°] PPM : Permanent Pace-Maker

^{°°} PVL : Para-Valvular Leak @ 7 days

^{°°°} ACM : All-Cause Mortality

NEW PERMANENT PM

1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS^o

DEVICE PERFORMANCE

1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS^o

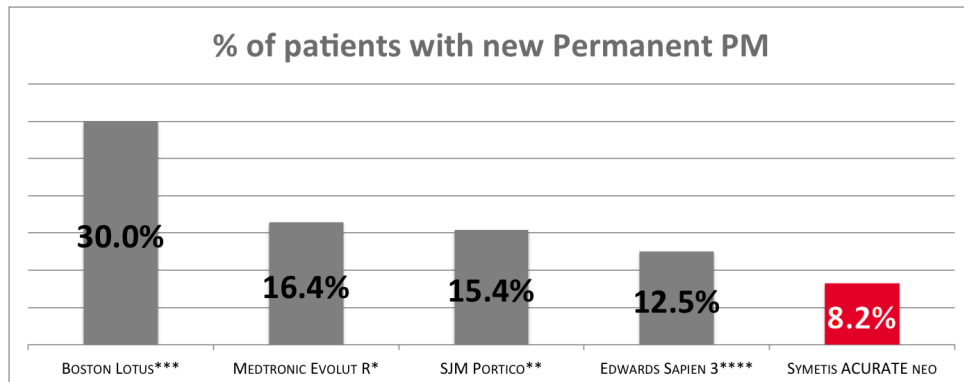
8.2%

**NO NEED
TO COMPROMISE
PPM & PVL**

4.1%

LOWEST NEW PPM^{oo} RATE

PVL^{oo} ≥ GRADE 2



Data presented side by side for illustration

Population [n]	999 ¹
Mean Δ P gradient [mmHg, mean \pm SD]	8.3 \pm 4.0
Mean EOA [cm ² , mean \pm SD]	1.81 \pm 0.5
PVL Grade	
≤ Grade 1 (none to mild) [n/%]	926 / 95.9
Grade 2 (moderate) [n/%]	39 / 4.0
> Grade 2 [n/%]	1 / 0.1

¹ one patient withdrew consent after treatment

Population [n]	994 ¹
All-cause mortality [n/%]	13 / 1.3
Stroke [n/%]	19 / 1.9
MI [n/%]	3 / 0.3
Re-intervention post-DC [n/%]	0 / 0.0
Freedom from MACCE [n/%]	959 / 96.5
New pacemaker implantation [n/%]	82 / 8.2

¹ one patient withdrew consent after treatment, 5 patients lost to follow-up

^o Symetis SAVI TF registry presented by Prof. Moellmann at EuroPCR 2016, LBCT, 17 May 2016.

^{oo} PPM : Permanent Pace-Maker

* Medtronic Evolut R data from the IDE trial presented at ACC 2016

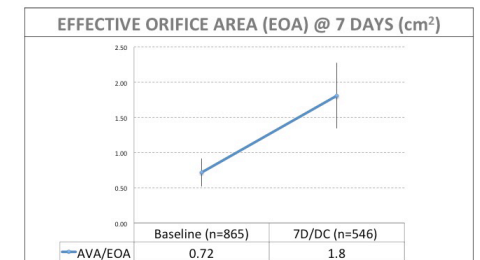
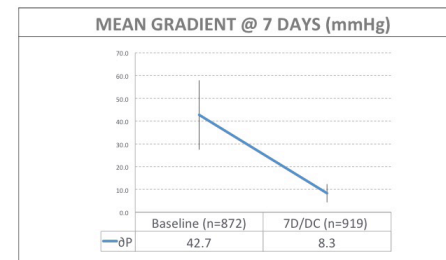
** SJM PORTICO data from the PORTICO I registry presented at EuroPCR 2016

*** Boston Lotus data from the RESPOND registry presented at EuroPCR 2016

**** EDW. SAPIEN 3 data from the European SOURCE 3 registry presented at EuroPCR 2016

8.3
Mean gradient
(mmHg)

1.81
Mean EOA
(cm²)



^o Symetis SAVI TF registry presented by Prof. Moellmann at EuroPCR 2016, LBCT, 17 May 2016.

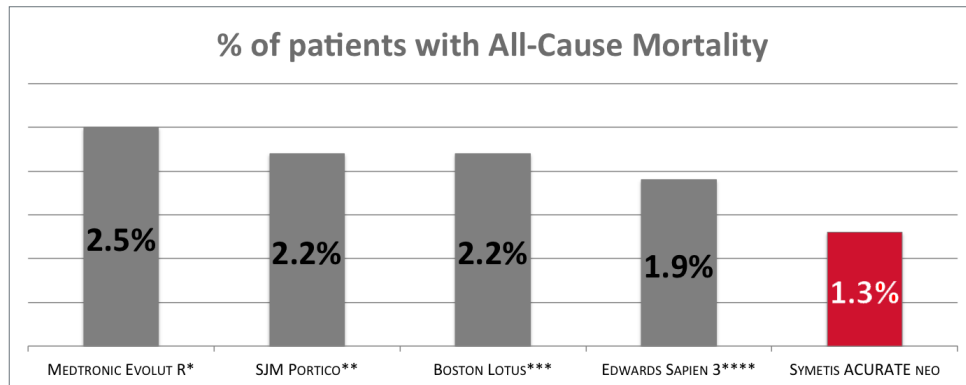
^{oo} PVL : Para-Valvular Leak @ 7 days

ALL-CAUSE MORTALITY

1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS*

1.3%

LOWEST ACM^{oo} RATE



Data presented side by side for illustration

MACCE @ 30 DAYS	
Population [n]	994 ¹
All-cause mortality [n/%]	13 / 1.3
Stroke [n/%]	19 / 1.9
MI [n/%]	3 / 0.3
Re-intervention post-DC [n/%]	0 / 0.0
Freedom from MACCE [n/%]	959 / 96.5
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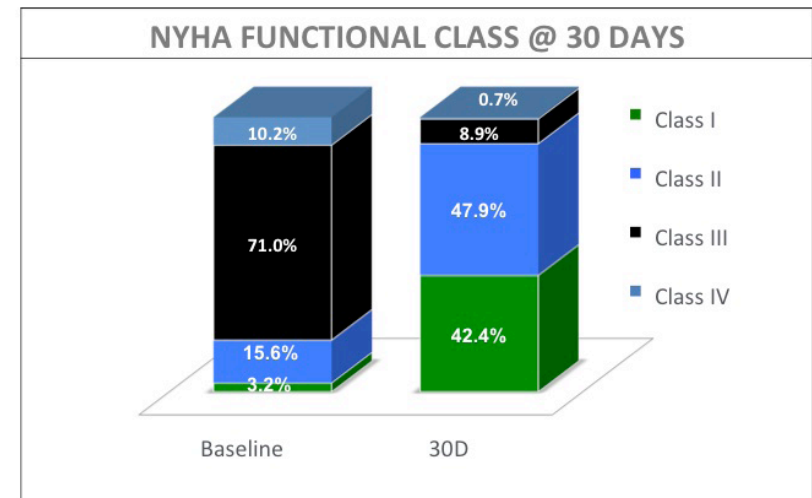
**** EDW. SAPIEN 3 data from the European SOURCE 3 registry presented at EuroPCR 2016

NYHA FUNCTIONAL CLASS @ 30D

1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS*

SIGNIFICANT REDUCTION OF THE NYHA FUNCTIONAL CLASS BETWEEN BASELINE & 30D

81.2% TO 9.6%



* Symetis SAVI TF registry presented by Prof. Moellmann at EuroPCR 2016, LBCT, 17 May 2016.

CONCLUSION

1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS

NO COMPROMISE

1000
PATIENTS

8.2%
PPM[°]

4.1%
PVL \geq 2^{°°}

1.3%
ACM^{°°°}

- Results show outstanding outcomes at 30 days
 - Anatomic fit of ACURATE *neo*, top-down deployment technology and stability during positioning promise a high rate of procedure success, a minimal PVL & abbreviated device usage times

- Excellent survival rates in this all-comers population
- NO COMPROMISE with the best PPM & PVL combination

[°] PPM : Permanent Pace-Maker

^{°°} PVL : Para-Valvular Leak @ 7 days

^{°°°} ACM : All-Cause Mortality

DETAILS & ENDPOINTS

1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS[°]

- European Post-Market Registry to collect safety and performance data after CE mark was obtained in June 2014
- Symetis ACURATE neo™ Valve Implantation using TransFemoral Access (SAVI TF) Registry
 - Recruitment performed in 25 sites in 6 EU countries
 - 1000 patients enrolled between Oct. 2014 and Apr. 2016 up to 30 days^{°°}
- Primary Endpoints
 - All-Cause Mortality (ACM) @ 30 days
- Secondary Endpoints
 - Procedure success post-implant
 - Device performance @ 7 days and 12 months
 - VARC 2 safety @ 30 days and 12 months
 - NYHA class @ 30 days and 12 months

BASELINE CHARACTERISTICS (n=1000)	
Age [years, mean±SD]	81.1 ± 5.2
Female [n/%]	612 / 61.2
Log. EuroSCORE I [%, mean ± SD]	18.1 ± 12.5
Log. EuroSCORE II [%, mean ± SD]	6.6 ± 7.5
STS Score [%, mean ± SD]	6.0 ± 5.6
∂P [n/mmHg, mean ± SD]	42.7 ± 15.2
AVA [n/cm ² , mean ± SD]	0.72 ± 0.2
NYHA Class III/IV [%]	81.2

[°] Symetis SAVI TF registry presented by Prof. Moellmann at EuroPCR 2016, LBCT, 17 May 2016

^{°°} PVL : Para-Valvular Leak @ 7 days.



intuitive at heart

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