

# SAVI TF REGISTRY

CLINICAL RESULTS EuroPCR 2016

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

ACURATE *neo*<sup>™</sup>  
TRANSFEMORAL TAVI

symetis 

# NO COMPROMISE

1000  
PATIENTS

8.2%  
PPM<sup>°</sup>

4.1%  
PVL<sup>°°</sup> ≥ 2

1.3%  
ACM<sup>°°°</sup>

<sup>°</sup> PPM : Permanent Pace-Maker

<sup>°°</sup> PVL : Para-Valvular Leak @ 7 days

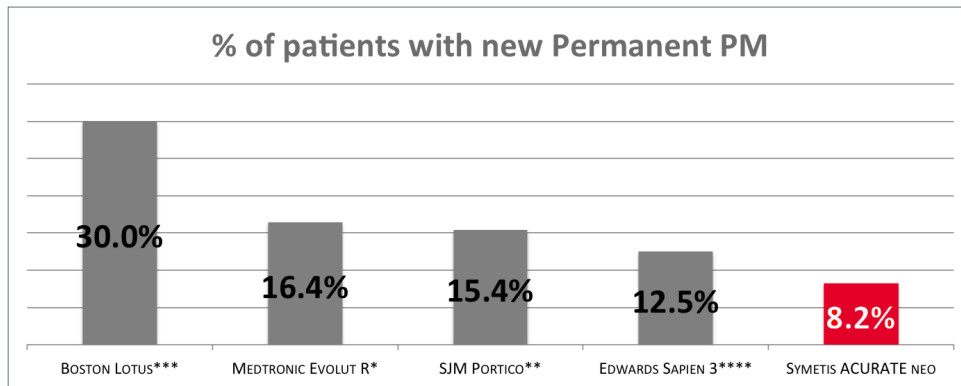
<sup>°°°</sup> ACM : All-Cause Mortality

# NEW PERMANENT PM

1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS°

# 8.2%

LOWEST NEW PPM°° RATE



euro PCR

Population [n]	994*
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

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

°° 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

# DEVICE PERFORMANCE

1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS°

# 4.1%

PVL°° ≥ GRADE 2

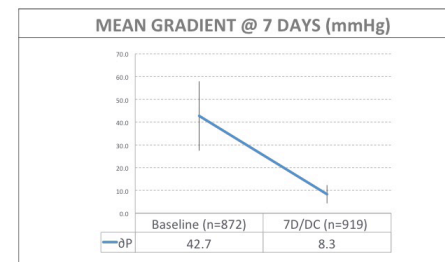
euro PCR

Population [n]	999*
Mean ΔP gradient [mmHg, mean ± SD]	8.3 ± 4.0
Mean EOA [cm <sup>2</sup> , mean ± SD]	1.81 ± 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

# 8.3

Mean gradient (mmHg)

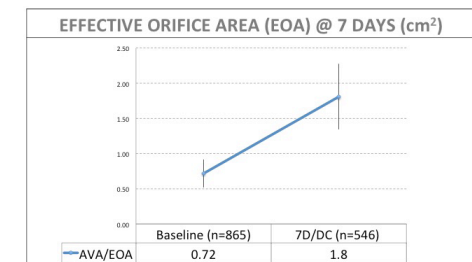
euro PCR



# 1.81

Mean EOA (cm<sup>2</sup>)

euro PCR



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°° PVL : Para-Valvular Leak @ 7 days

# ALL-CAUSE MORTALITY

1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS<sup>o</sup>

# 1.3%

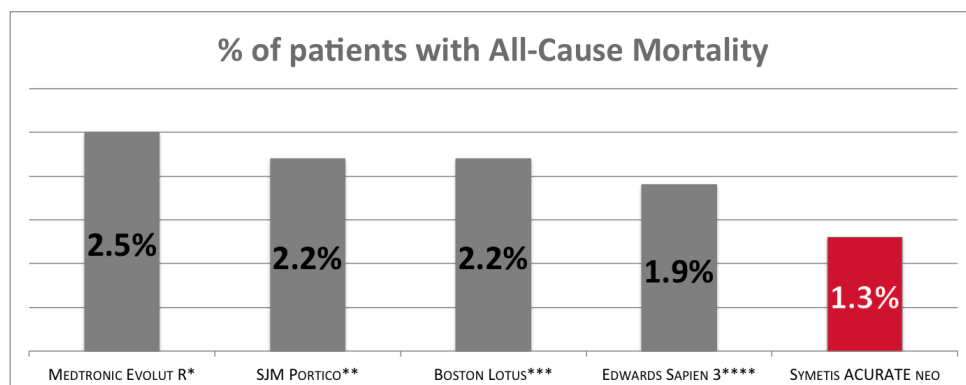
## LOWEST ACM<sup>oo</sup> RATE

# NYHA FUNCTIONAL CLASS @ 30D

1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS<sup>o</sup>

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

# 81.2% TO 9.6%



euro PCR

MACCE @ 30 DAYS	
Population [n]	994*
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

<sup>o</sup> Symetis SAVI TF registry presented by Prof. Moellmann at EuroPCR 2016, LBCT, 17 May 2016.

<sup>oo</sup> ACM : All-Cause Mortality

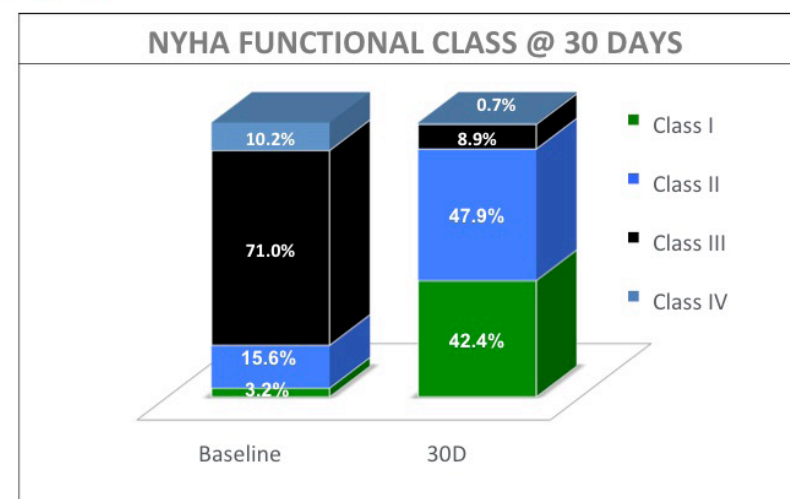
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## CONCLUSION

1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS

# NO COMPROMISE

1000

PATIENTS

8.2%

PPM<sup>°</sup>

4.1%

PVL  $\geq$  2<sup>°°</sup>

1.3%

ACM<sup>°°°</sup>

- Results show outstanding outcomes at 30 days
  - Anatomic fit of ACURATE *neo*, top-down deployment technology and stability during positioning portend to high rate of procedure success, minimal PVL & abbreviated device usage times
  - Excellent survival rates in this all-comers population
- NO COMPROMISE with the best PPM & PVL combination

<sup>°</sup> PPM : Permanent Pace-Maker

<sup>°°</sup> PVL : Para-Valvular Leak @ 7 days

<sup>°°°</sup> ACM : All-Cause Mortality

# DETAILS & ENDPOINTS

1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS<sup>°</sup>

- 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<sup>°</sup>
- 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

euro  
**PCR**

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 <sup>2</sup> , mean ± SD]	0.72 ± 0.2
NYHA Class III/IV [%]	81.2

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<sup>°°</sup> PVL : Para-Valvular Leak @ 7 days.



# intuitive at heart

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