



# **Real-world experience using a 2<sup>nd</sup> generation self-expanding prosthesis**

1-year outcomes of 1000 patients  
enrolled in the SAVI-TF registry



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- ✓ **I have the following potential conflicts of interest to report:**
  - Proctor for Symetis and St. Jude Medical

# Post-market Registry

- Symetis ACURATE *neo*<sup>™</sup> Valve Implantation using TransFemoral Access (SAVI TF) Registry
- Multicentre, all-comers registry
- Treatment according to standard of care
- EC approval of post-market registry in SEP 2014
  - 1<sup>st</sup> 1000 consented patients
  - Recruitment performed at 25 centers in EU from Oct 2014 to Apr 2016

## ■ Primary

- All-cause mortality @30 days

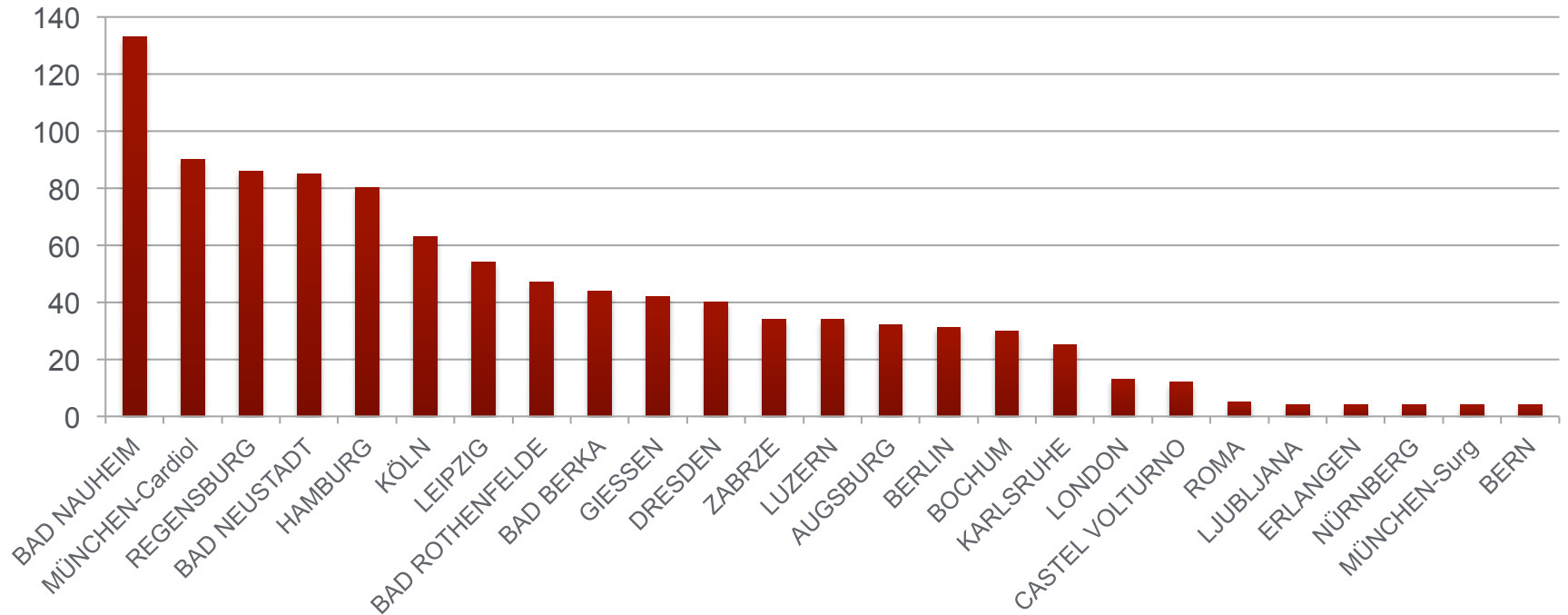
## ■ Secondary

- Procedure success
- Device performance @ 7 days and 12 months
- VARC 2 safety @ 30 days and 12 months
- NYHA class @ 30 days and 12 months

# SAVI TF – Enrolment

25 sites in Europe (CH, DE, IT, PL, SL & UK)

Enrolment (n=1000)



# SAVI TF – Baseline Characteristics

## Baseline Characteristics (n=1000)

Age [years, mean $\pm$ SD] (n=1000)	81.1 $\pm$ 5.2
Female [n/%]	612 / 61.2
Log. EuroSCORE I [%, mean $\pm$ SD] (n=872)	18.1 $\pm$ 12.5
Log. EuroSCORE II [%, mean $\pm$ SD] (n=720)	6.6 $\pm$ 7.5
STS Score [%, mean $\pm$ SD] (n=630)	6.0 $\pm$ 5.6
$\Delta$ P [mmHg, mean $\pm$ SD] (n=872)	42.7 $\pm$ 15.2
AVA [cm <sup>2</sup> , mean $\pm$ SD] (n=865)	0.72 $\pm$ 0.2
NYHA Class III/IV [n/%] (n=963)	782 / 81.2

# SAVI TF – Acute Outcomes

Acute Outcomes	
Population [n]	1000
Procedural success [n/%]	987 / 98.7
VinV [n/%]	9 / 0.9
Conversion to surgery [n/%]	3 / 0.3
Aborted procedure [n/%]	1 / 0.1
*Device usage time [min:sec, mean $\pm$ SD]	6:34 $\pm$ 6:0
Deployed with rapid pacing [n/%]	487 / 48.7

\*Delivery system into sheath to delivery system removal post-implant

# SAVI TF – Performance

Performance	7 DAYS n=999*	12 MONTHS n=604*
Mean $\Delta$ P gradient [mmHg, mean $\pm$ SD]	8.3 $\pm$ 4.0	7.3 $\pm$ 3.7 (484)
Mean EOA [cm <sup>2</sup> , mean $\pm$ SD]	1.81 $\pm$ 0.5	1.8 $\pm$ 0.4 (257)
PVL Grade	n=966	n=587
$\leq$ Grade 1 (none to mild) [n/%]	926 / 95.9	566 / 96.4
Grade 2 (moderate) [n/%]	39 / 4.0	20 / 3.4
$>$ Grade 2 [n/%]	1 / 0.1	1 / 0.2

\* One patient withdrew consent after treatment. At 12 months echo data were available for 604 patients



## SAVI TF – MACCE

MACCE	30 DAYS	12 MONTHS
Population [n]	994*	983*
All-cause mortality [n/%]	13 / 1.3	83 / 8.4
Stroke [n/%]	19 / 1.9	35 / 3.6
MI [n/%]	3 / 0.3	13 / 1.3
Re-intervention post-DC [n/%]	0 / 0.0	5 / 0.5
<b>Freedom from MACCE [n/%]</b>	<b>959 / 96.5</b>	<b>863 / 87.8</b>
New pacemaker implantation [n/%]	82 / 8.2	98 / 10.0

\* 30 days: One patient withdrew consent, 3 patients lost to follow-up, 2 did not return for 30D visit. 12 months: 4 patients withdrew consent, 13 patients lost- to follow-up

# SAVI TF – VARC 2

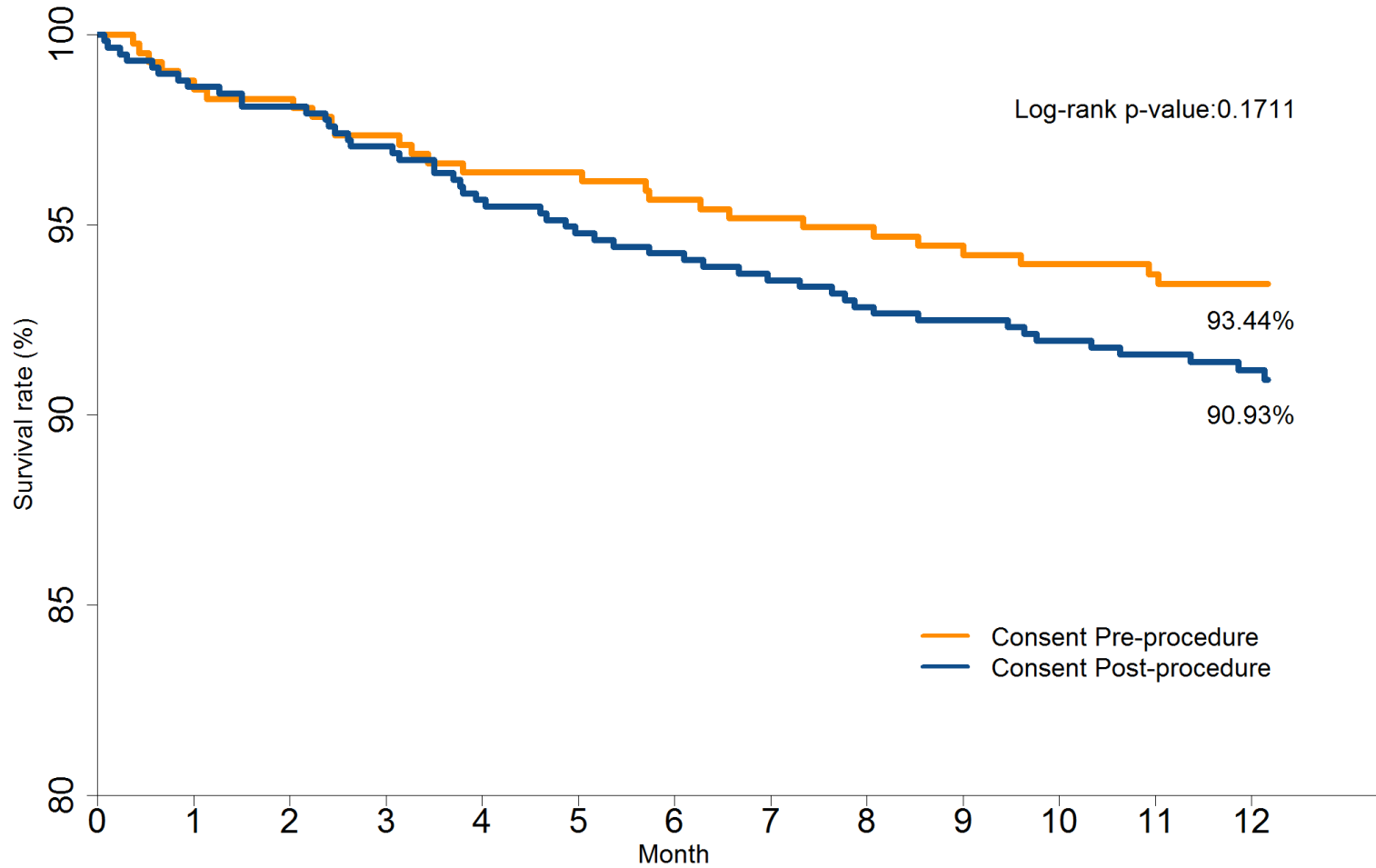
VARC 2 Combined Safety	30 DAYS	12 MONTHS
Population [n/%]	994*	983*
All-cause mortality [n/%]	13 / 1.3	83 / 8.4
Stroke [n/%]	19 / 1.9	35 / 3.6
Life-threatening bleeding [n/%]	15 / 1.5	21 / 2.1
Coronary artery obstruction requiring intervention [n/%]	0 / 0.0	1 / 0.1
Major vascular complications [n/%]	38 / 3.8	41 / 4.2
**AKI stage 2 or 3 [n/%]	15 / 1.5	32 / 3.3
***Repeat procedure for valve-related dysfunction [n/%]	12 / 1.2	17*** / 1.7
Patients with at least one VARC 2 event [n/%]	86 / 8.7	168 / 17.1
<b>Freedom from VARC 2 events [n/%]</b>	<b>908 / 91.3</b>	<b>815 / 82.9</b>

\* 30 days: One patient withdrew consent, 3 patients lost to follow-up, 2 did not return for 30D visit. 12 months: 4 patients withdrew consent, 13 patients lost- to follow-up

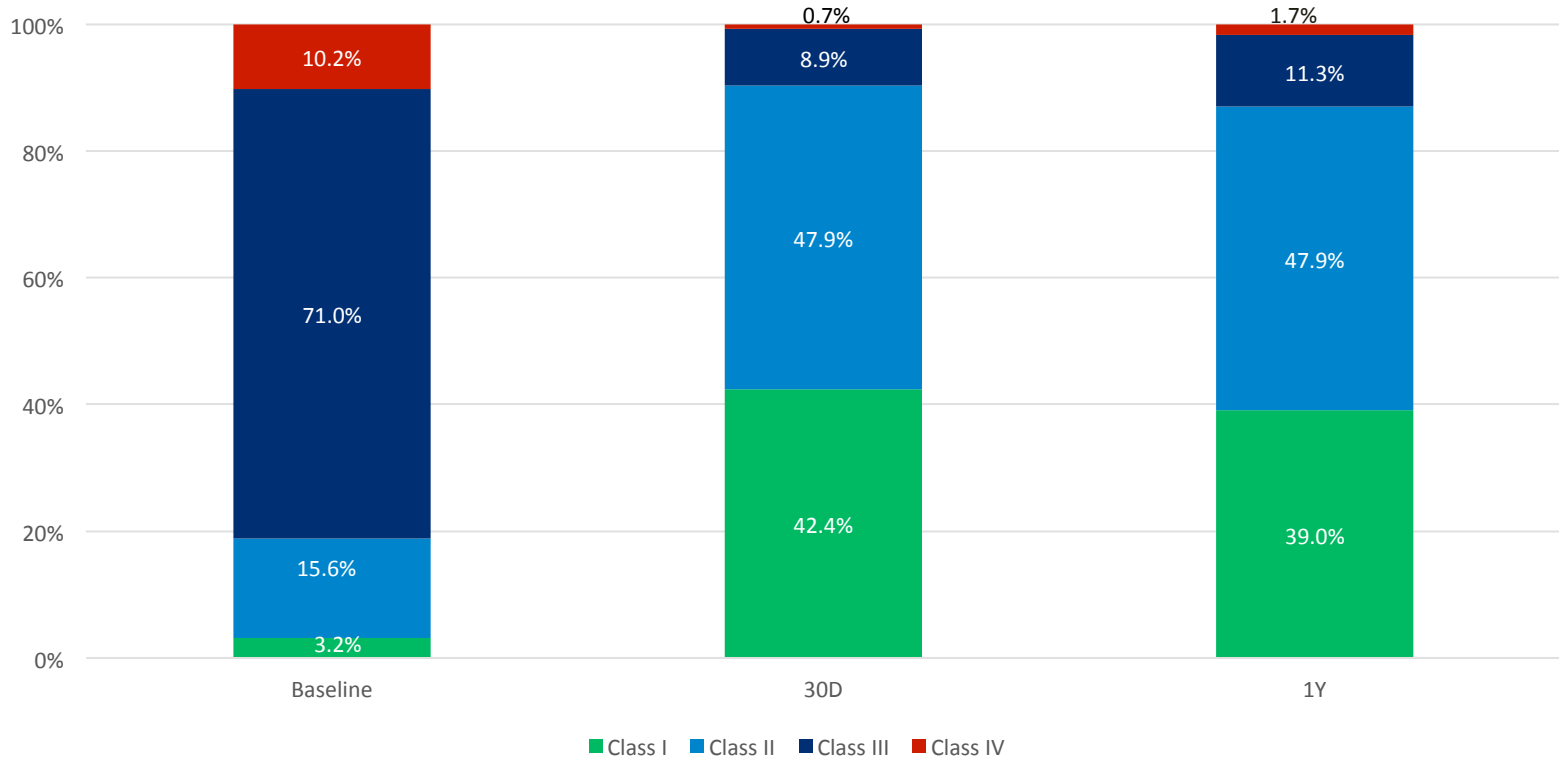
\*\* AKI stage unknown for one patient

\*\*\* 12 VinV, 5 SAVR

# SAVI TF – 1-year Survival



## SAVI TF – NYHA



# SAVI TF – Conclusions

- 1-year outcomes of the all-comers SAVI-TF registry confirmed the safety and efficacy of the ACURATE *neo* transcatheter heart valve system
  - Single digit mortality
  - Single digit mean gradient
  - Minimal PVL
  - Lowest new PPM rates in TAVI

# Supplemental slide

# SAVI TF – Valve Size

