

# ACURATE TA™ Post-Market Registry - SAVI 250

## Trial overview

- Post-market surveillance conducted of the 1<sup>st</sup> 250 commercial patients treated: Symetis ACURATE TA™ Valve Implantation Registry (SAVI)
- SAVI was launched in November 2011 and closed recruitment in November 2012.
- 17 centers in Argentina, Germany, Italy and Switzerland represents “real-world” use of ACURATE TA™ in clinical practice
- Outcomes confirm high procedure success rate, superior safety profile and minimal PV leak in commercial use
- Follow-up at 30D complete and 12M follow-up to close by year’s end.

## Baseline patient characteristics

	SAVI 250
n=	250
Age [years]	80.9 ± 6.3
Logistic EuroSCORE [%]	22.3 ± 12.7
STS Score [%]	8.0 ± 5.9
NYHA Class III/IV [%]	92.7
Female [%]	49.2
Mean aortic gradient [mmHg]	43.2 ± 17.4
Mean effective orifice area (cm2)	0.7 ± 0.2

## Procedure success

	Post-Implant
Implant procedures [n]	250
Procedural success [n/%]	
■ 2 VnV*	245 / 98.0
■ 3 Conversion to SAVR**	

\*VnV due to too low placement

\*VnV due to too high placement

\*\*Conversion to SAVR after bioprosthesis pulled into LV during DS retrieval

\*\*Conversion to SAVR due to too low placement of bioprosthesis

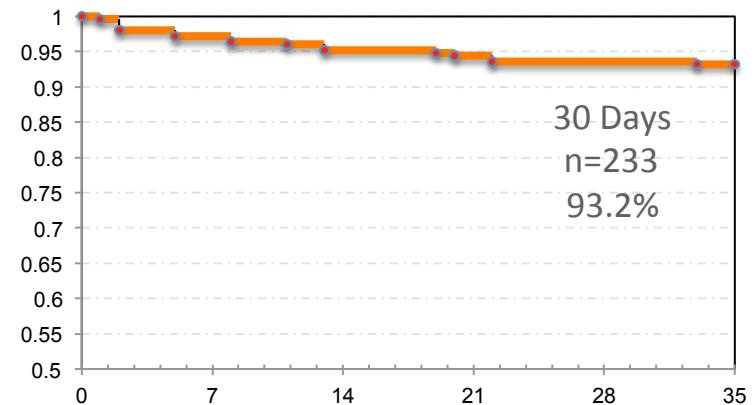
\*\*Conversion to SAVR 7 days post-procedure due to severe AR secondary to valve malposition at deployment

# ACURATE TA™ Post-Market Registry - SAVI 250

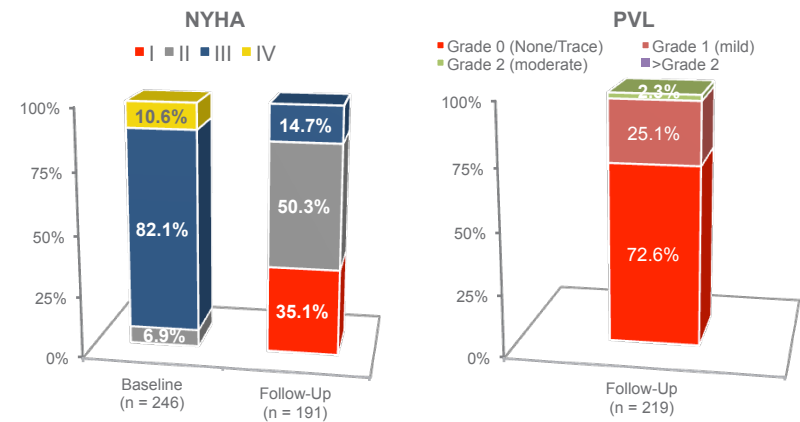
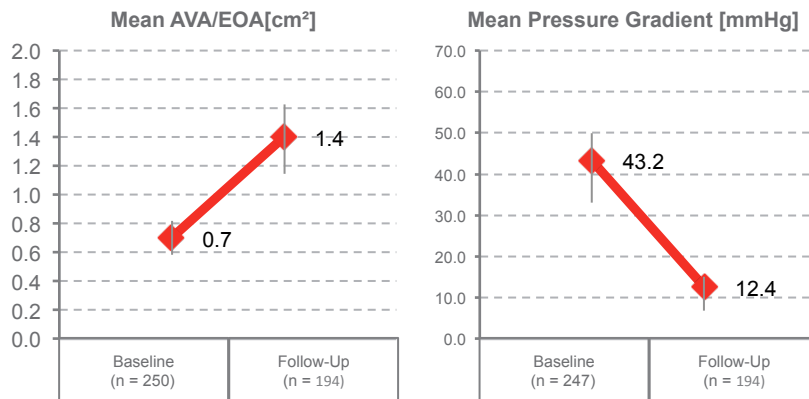
## Safety

	30D
Procedures performed [n]	250
All-cause mortality [n/%]	17 / 6.8
Stroke [n/%]	7 / 2.8
MI [n/%]	2 / 0.8
New pacemaker required [n/%]	25 / 10.0

## Survival



## SAVI Efficacy at Follow-Up



# Participating centres

1. Bad Nauheim/Kerckhoff Klinik: Prof. Walther & Dr. Kempfert (n=42)
2. Leipzig/Herzzentrum: Dr. Holzhey (n=35)
3. Bad Rothenfelde/Schüchtermann-Schillersche Kliniken; Dr. Hofmann (n=28)
4. Bad Berka/Zentralklinik: Dr. Girdauskas (n=27)
5. Hamburg/Universitäres Herzzentrum Hamburg: Dr. Treede (n=22)
6. Karlsruhe/Klinik für Herzchirurgie: Dr. Schröfel & Dr. Helmeshoff (n=19)
7. Essen/Universitätsklinikum Essen: Dr. Thielmann (n=18)
8. Aachen/Universitätsklinikum: Prof. Autschbach, Dr. Lotfi & Dr. Haushofer (n=11)
9. Bern/Inselspital Bern: Prof. Carrel & Dr. Huber (n=10)
10. Regensburg/ Universitätsklinikum Regensburg: Prof. Hilker (n=8)
11. Stuttgart/Sana Herzchirurgie Stuttgart: Prof. Doll & Dr. Czesla (n=6)
12. Köln/ Uniklinik Köln: Prof. Wahlers & Dr. Madershahian: (n=5)
13. Dresden/ Herzzentrum Dresden Universitätsklinik: Prof. Matschke & Dr. Kappert (n=5)
14. Bad Neustadt/ Herz- und Gefäß-Klinik: Prof. Diegeler (n=4)
15. Bologna/Hospitale S.Orsola-Malpighi: Prof. Di Bartolomeo & Dr. Savini (n=4)
16. Mainz/Universitätsmedizin: Dr. Schnelle & Dr. Wohlhoefer (n=3)
17. Buenos Aires/ Hospital Italiano Buenos Aires: Dr. Agatiello (n=3)