



DurAVR™ built with ADAPT® technology

Creating the world's most
durable valve



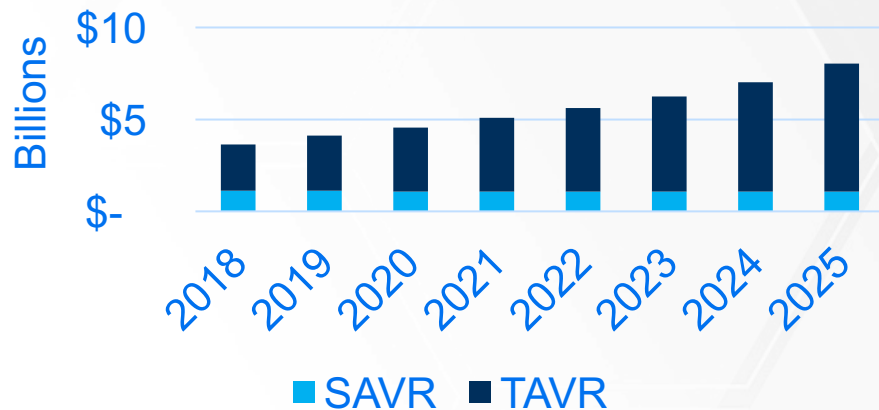
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The TAVR market is growing significantly

Market Potential of AVR as Treatment of Severe Aortic Stenosis(SAS)

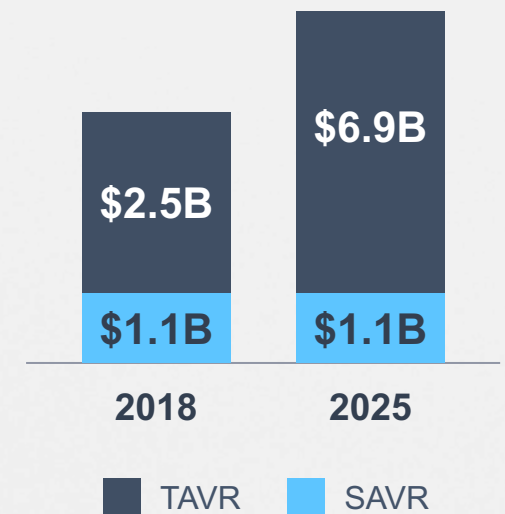


By 2025, Global Aortic Valve Replacement to reach

\$8B USD*

TAVR is expected to be 62% of procedure volume and 87% of market revenue.

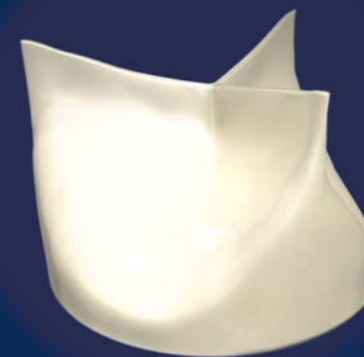
TAVR CAGR **15.6%**



*Includes Tier 1 markets (US,EU) and China; data on file

DurAVR™

A unique 3D single-
piece Aortic Valve
Replacement



DurAVR™ Designed to Last Longer⁽³⁾ and Work Better^(4,5)



DurAVR™ (an ADAPT® product)



Lasts Longer⁽³⁾

Works Better

Durability = full function over time

(a)+(b) =

Better hemodynamics = Better outcomes

(a) No calcification

(b) Less mechanical stress

Lower mean gradient*

Larger EOA's*

ADAPT® Tissue Science

DurAVR™
3D Valve Design

No DNA⁽¹⁾
Most extensive⁽²⁾
long-term data

Unique 3D single-piece valve
Zero leaflet wear
and no diminished
EOA at 12 years⁽³⁾

	ΔP (mmHg)	EOA (cm ²)
Normal	4.0-5.0	3.5-4.00
DurAVR	3.86-5.34	3.04-3.28
Corevalve ⁽⁴⁾	7.76-10.27	1.44-1.66
Sapien ⁽⁵⁾	11.66	1.35

1) Neethling et al data on file, 2) Neethling et al data on file, multiple publications, 3) Neethling et al data on file
4) Midha et. al. 2016 JACC. 9 (15): 1618-28 5) * Hahn et. al. 2019 JACC. 12 (1): 25-34



ADAPT[®] TISSUE SCIENCE

First and only anti-calcification
treatment demonstrating **zero**
calcification in humans beyond 10
years



ADAPT[®] is widely studied and has been used in over 20,000 patients worldwide



Multi-Centre Experience with 500 CardioCel[®] Implants Used for the Repair of Congenital Heart Defects

Key I'camba

- ADAPT[®] has good durability in the repair of CHD.
- Multi-centre study (2 centres, 100 patients, 277 patients).
- ADAPT[®] has good durability in the repair of CHD.
- No evidence of calcification (biological or non-biological).
- ADAPT[®] performs comparably to the synthetic and polymeric substitutes in the ovine, rat, and porcine models.

OBJECTIVE

To assess the performance of CardioCel[®] in the repair of congenital heart defects.

RESULTS

- ADAPT[®] has good durability in the repair of CHD.
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CONCLUSIONS

- ADAPT[®] has good durability in the repair of CHD.
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- ✓ >20,000 implants in young patients with congenital heart disease
- ✓ 10-year clinical data with no calcification in pediatric patients
- ✓ Largest series is 500 patients



DurAVR™ shows zero wear in accelerated testing equivalent to 12 years



ACCELERATED WEAR TESTING

Anteris Valve shows no wear at 550 million cycles

Day 1



200 million



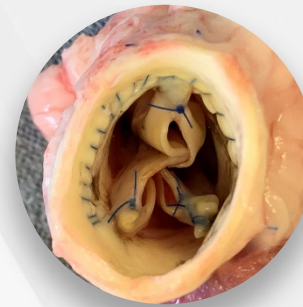
500 million



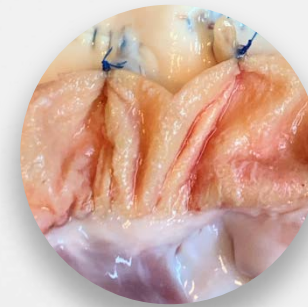
Competitor Valves demonstrate wear and may breakdown at 250 million cycles

SHEEP CALCIFICATION MODEL

Well Anchored Sutures



Supple Cusps



Clean Margins (Annulus)





Valves implanted in juvenile sheep and assessed at 6 months:

- ADAPT® aortic valves show no calcification



DurAVR™ promises best in class hemodynamics



Design Option	Inner Diameter of Annulus or Surgical Valve(mm)	ΔP_{mean} (mmHg)	EOA (cm ²)
 DurAVR™ (25MM)	23	4.89	3.07
	21	5.17	3.04
 DurAVR™ (25 MM)	23	5.34	3.26
	21	3.86	3.28
COREVALVE* (26MM)	21 (True ID of 23mm Perimount)	7.76 ± 0.14	1.66 ± 0.05
COREVALVE* (23MM)		10.27 ± 0.18	1.44 ± 0.05
SAPIEN * (23MM)		11.66 ± 0.22	1.35 ± 0.02

SUPERIOR HEMODYNAMICS OF $\Delta P_{\text{mean}} \leq 6$ mmHg and EOA ≥ 2.9 cm²



* Midha et. al. 2016 JACC. 9 (15): 1618-28



DurAVR™ First in Human study patient #1

“I have not seen these kind of results with commercially available valves” - Prof Bart Meuris

	Patients with other surgical valves* (N>1400)	DurAVR™ Patient 1
Peak Gradient mmHg	23	11
Mean Gradient mmHg	11	5
EOA cm ²	1.9	2.9



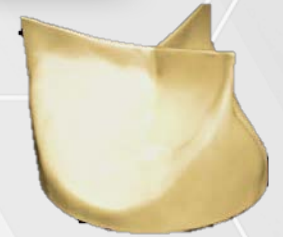
Post Operative Trans Esophageal Echo (TEE)
of DurAVR™ Heart Valve

* Average of 1400 patients implanted with commercially available surgical valves at Leuven University Hospitals

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Developing the world's most durable heart valve



The right science

- ADAPT® anti-calcification treatment is proven over 10 years in humans, with zero calcification in published studies.
- Zero DNA
- Zero residual glutaraldehyde

The right design

- The DurAVR™ 3D single-piece valve is proven to have less wear at the leaflets than conventional valves.
- Current tests suggest superior hemodynamic profile based on design benefits
- Significantly less sutures to manufacture than conventional valves

The right time

- The FDA approved the use of TAVR in “low risk” (younger) patients in 2019. Replacement valves need to last longer.

