



# DurAVR™ built with ADAPT® technology

Creating the world's most  
durable valve



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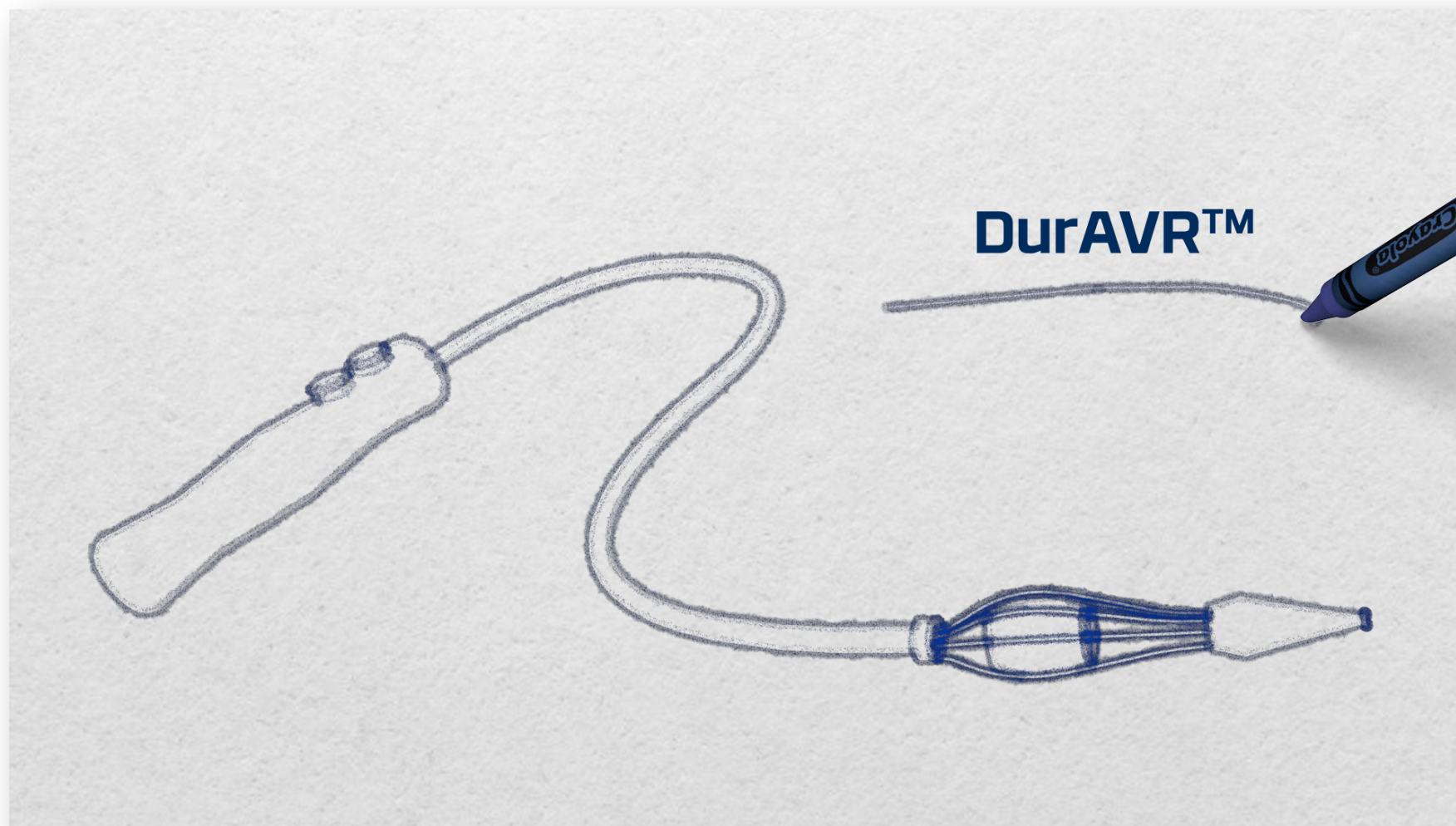
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# Agenda



- Anteris company overview
- ADAPT® The world's best anti-calcification treatment
- DurAVR™ 3D single-piece valve

# Anteris developing the world's most durable heart valve

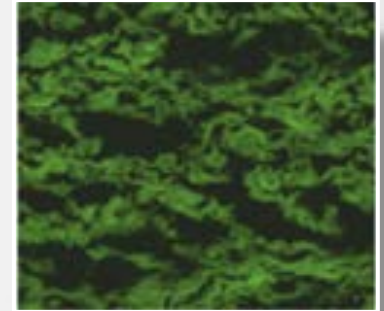




# Creating the world's most durable and hemodynamically superior heart valve

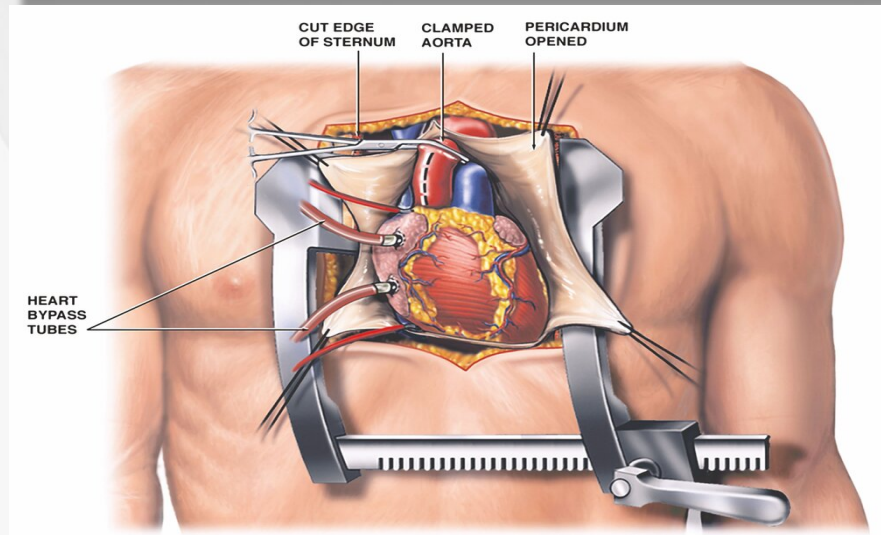
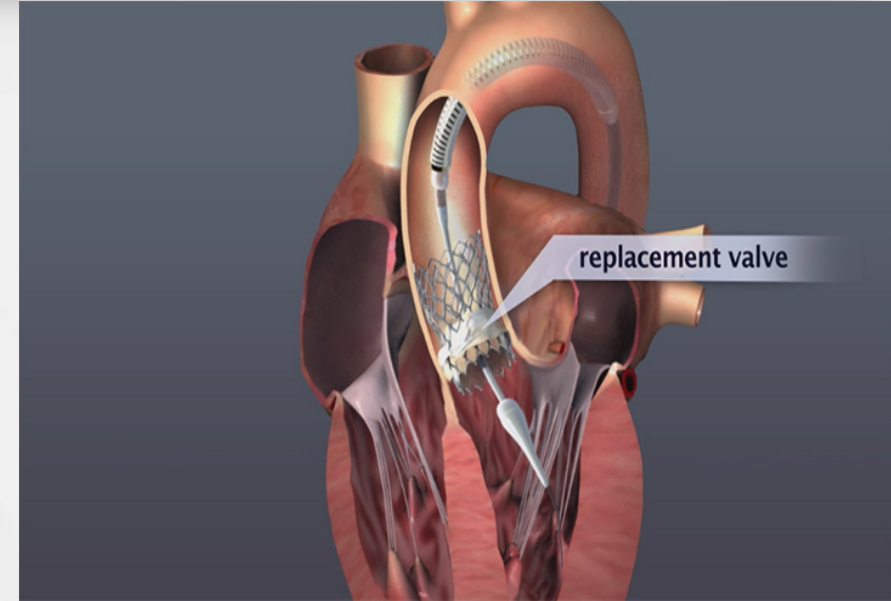
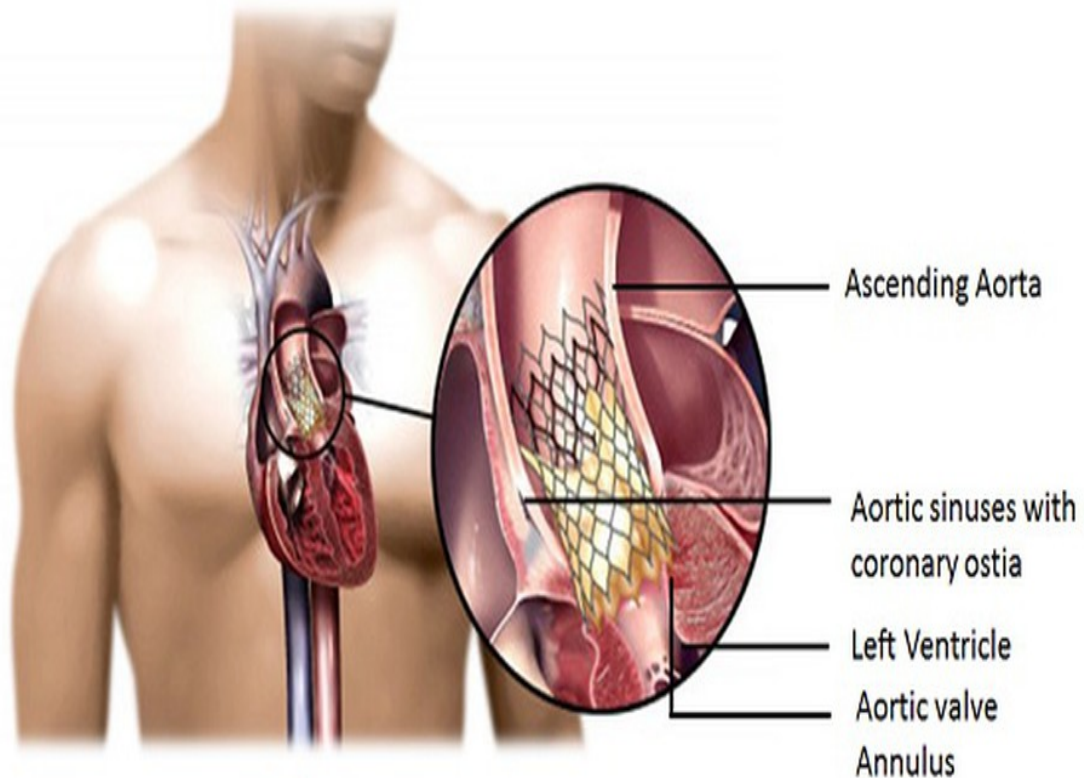


- Anteris is a structural heart company with unique technology (ADAPT<sup>®</sup> and DurAVR<sup>™</sup>) that solves critical issues with currently marketed heart valves.
- Anteris is competing in a potential **USD \$8 BN market**.
- ADAPT<sup>®</sup> is the unique anti-calcification treatment platform technology on which our structural heart products are built.
- ADAPT<sup>®</sup> has unique properties that are critical to longer lasting aortic valves and has been used in over **20,000** patients globally.
- DurAVR<sup>™</sup>, built with ADAPT<sup>®</sup> technology, is a novel and highly durable 3D single-piece aortic valve for the treatment of aortic stenosis.
- DurAVR<sup>™</sup> has unique properties that are critical to longer lasting valves and is now in human clinical trials following successful preclinical studies.

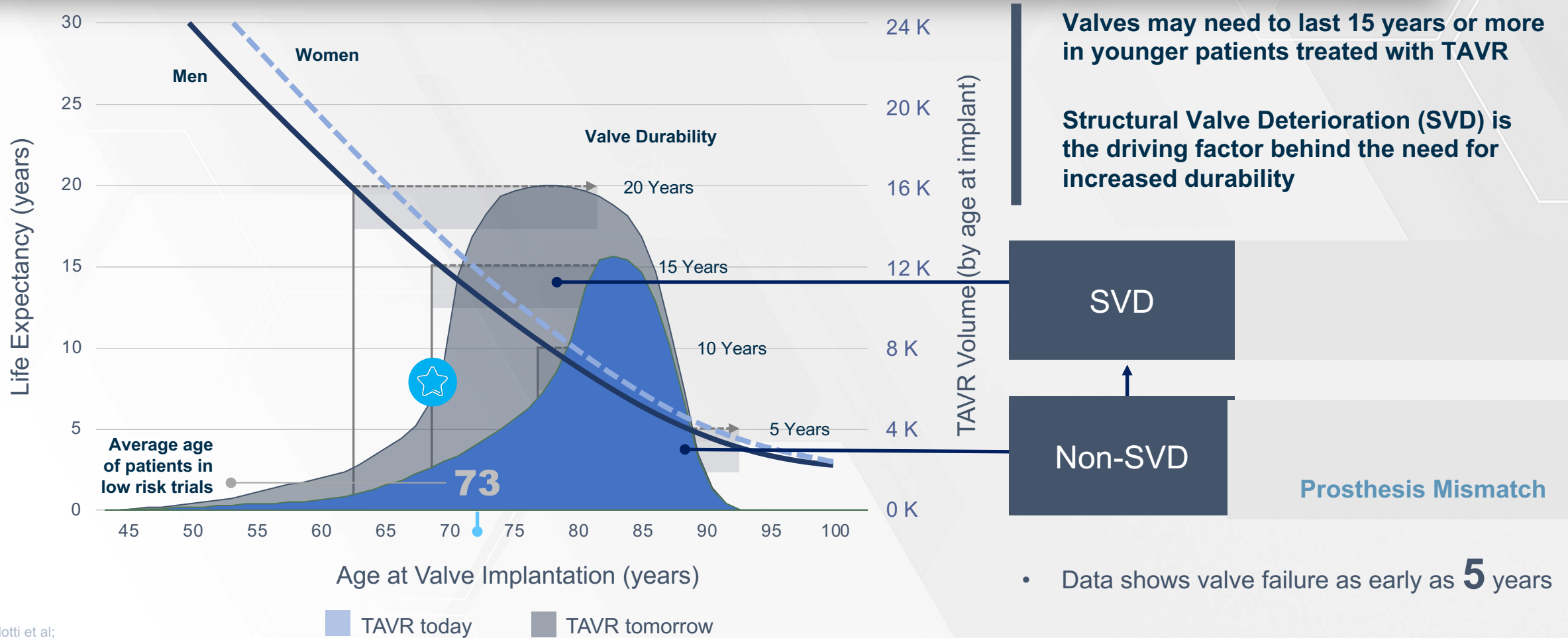


# Transfemoral Aortic Valve Replacement (TAVR) is much less invasive than surgery

## TAVR PROCEDURE



# The 2019 FDA approval for low-risk (younger patients) is driving market expansion



Lancalotti et al;  
Courtesy of Windecker S. TCT 2019  
Barbanti et al; J AM HeartAssoc 2018

\*Popma FF, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. N Engl J Med. 2019;380(18):1706-1715.

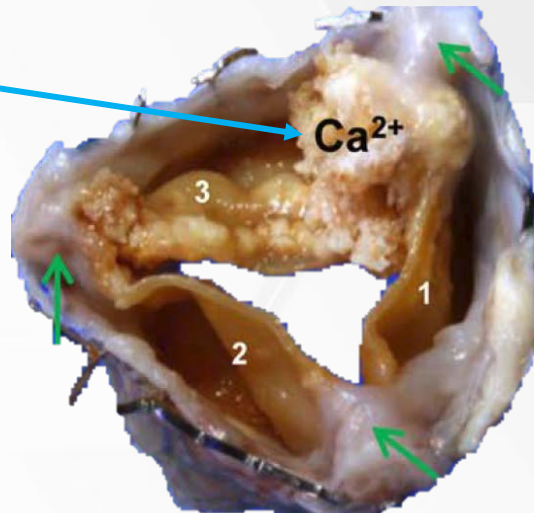
\*Mack, MJ, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. N Engl J Med. 2019;380(18):1695-1705



# Why a durable heart valve matters

- The FDA approved the use of TAVR in “low-risk” (younger) patients in 2019.
- As a result replacement valves need to be durable and long lasting.

Currently marketed  
TAVR valve showing  
significant calcification



## LONG-TERM DURABILITY OF TAVR

FDA

- Our current understanding of the long-term durability of TAVR is limited.
- Recent assessment of PARTNER 2A 5-year outcomes suggests SAPIEN XT is associated with a higher rate of structural valve deterioration compared to SAVR.
  - Although a similar mid-term trend has not been observed for SAPIEN 3, long-term follow up data are not available.

## TAVR DURABILITY IS A LONG-TERM ASSESSMENT

FDA

- The question of long-term durability is not feasible to address premarket
  - Durability is largely a function of structural valve deterioration, and biological responses cannot be accurately modeled in non-clinical testing
  - A premarket requirement for clinical studies to evaluate long-term durability would have prevented TAVR availability to patients in need
- To address long-term durability, FDA has mandated post-approval studies and surveillance for all TAVR devices (consistent with an appropriate balance of premarket and postmarket data requirements)

	Continued follow-up of pivotal trial subjects	TVTR/CMS-linked surveillance of commercial use
Extreme Risk	5 years	5 years
High Risk	5 years	5 years
Intermediate Risk	10 years	5 years
Low Risk	10 years	10 years

www.fda.gov

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# The Transcatheter Aortic Valve Replacement (TAVR) market is growing significantly

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

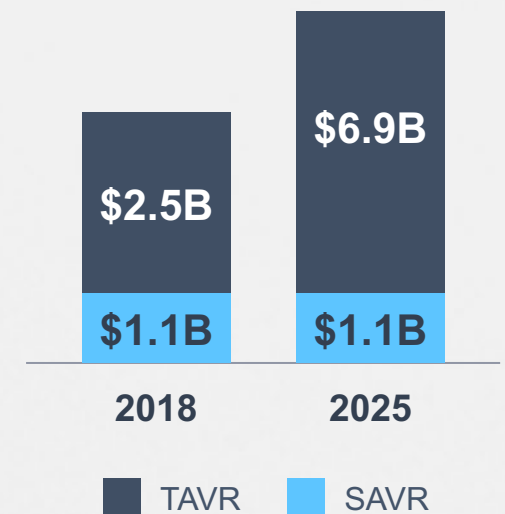


By 2025, Global Aortic Valve Replacement to reach

**\$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

# ADAPT<sup>®</sup> TISSUE SCIENCE

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



# ADAPT<sup>®</sup> is widely studied and has been used in over 20,000 patients worldwide



- ✓ >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™ addresses the key areas that lead AVR degradation

$\text{Ca}^{+2}$

Only DurAVR™ is made from ADAPT® treated tissue with superior anti calcification properties

DurAVR™ is made from one piece of tissue resulting in 35% less stress on the leaflets

Other valves are constructed from tissue that has residual DNA which promotes inflammation and immune response that leads to calcification



Other valves are constructed of three separate pieces of tissue resulting in greater stress and sub-optimal coaptation



DurAVR™ has no residual glutaraldehyde



Other valves have residual glutaraldehyde which is toxic and requires manual rinsing pre-implantation

DurAVR™ has 20-30 sutures = lower manufacturing costs



Other valves require 100's of sutures per valve during manufacturing

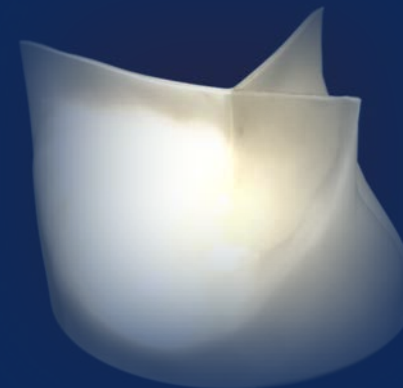


Addressing even one of these could be a significant competitive advantage... The DurAVR™ 3D single-piece heart valve addresses all of these.



# DurAVR™

A unique 3D single-  
piece Aortic Valve  
Replacement



# DurAVR™ Lasts Longer<sup>(3)</sup> Works Better<sup>(4,5)</sup>



DurAVR™ (an ADAPT® product)

**Lasts Longer<sup>(1)</sup>**



**Durability**

(#1 unmet medical need)



**No calcification**

**Less mechanical stress**

**Works Better**



**Better outcomes**

(#1 treatment objective)



**Lower mean gradient\***

**Larger EOA's\***

*ADAPT® Tissue Science*

*DurAVR™  
3D Valve Design*



1) Neethling et al data on file  
\* Hahn et. al. 2019 JACC. 12 (1): 25-34

# DurAVR™ shows zero wear over 12 years



## ACCELERATED WEAR TESTING

Anteris Valve shows no wear at 550 million cycles

**Day 1**



**200 million**



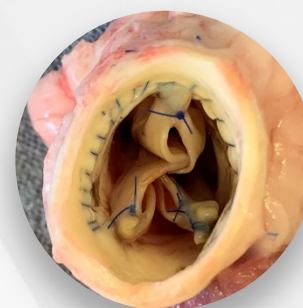
**500 million**



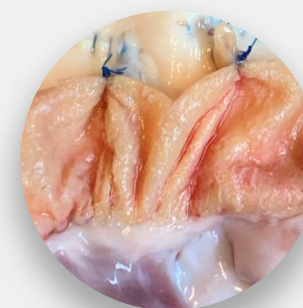
Competitor Valves demonstrate wear and may breakdown at 250 million cycles

## 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

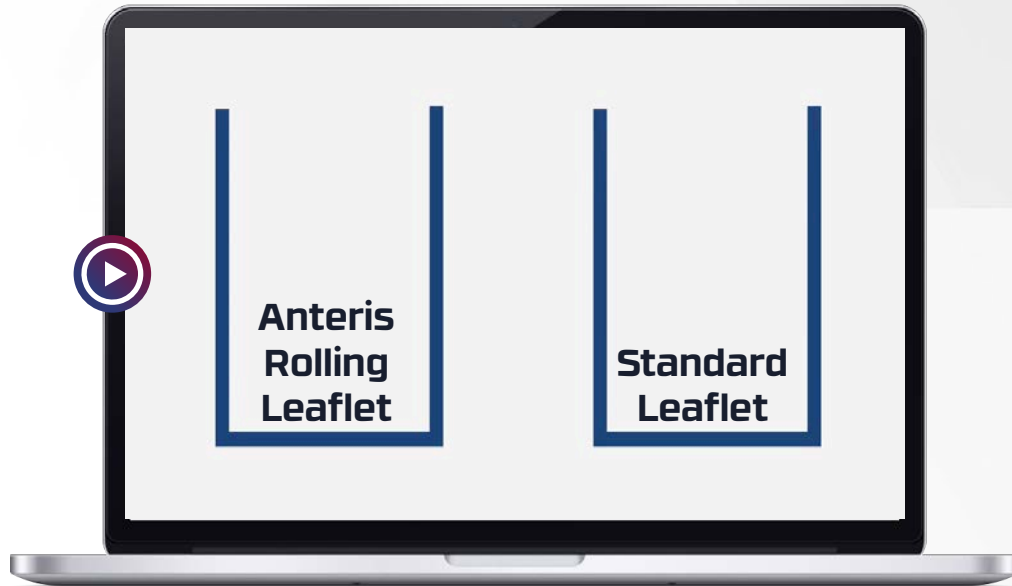


# DurAVR™ is a unique 3D single-piece valve made from ADAPT®



Rolling leaflets mimic natural coaptation and reduces stress

- 01.** Anatomically Correct
- 02.** 3D Aortic Valve Demonstrates More Natural Leaflet Motion



- 01.** Zero suture tears up to 400 million cycles
- 02.** Zero visible tissue fatigue up to 400 million cycles
- 03.** Zero visible change in GOA/EOA (0 to 400 million cycles)





# 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 <sup>2</sup>	1.9	2.9

\* Average of 1,400 patients implanted with commercially available surgical valves at Leuven University Hospitals.

Proprietary Material of Anteris Technologies Ltd.





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



# DurAVR™ promises best in class hemodynamics



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

SUPERIOR HEMODYNAMICS OF  $\Delta P_{\text{mean}} \leq 6$  mmHg and EOA  $\geq 2.9$  cm<sup>2</sup>



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

# DurAVR™ Lasts Longer<sup>(3)</sup> Works Better<sup>(4,5)</sup>



## DurAVR™ (an ADAPT® product)

**Lasts Longer<sup>(3)</sup>**

**Works Better**

**Durability = full function over time**

**Better hemodynamics = Better outcomes**

**No calcification**

**Less mechanical stress**

**Lower mean gradient\***

**Larger EOA's\***

### ADAPT® Tissue Science

No DNA<sup>(1)</sup>  
Most extensive<sup>(2)</sup>  
long-term data

**Unique 3D single-piece valve**  
Zero leaflet wear and no diminished EOA at 12 years<sup>(3)</sup>

### DurAVR™ 3D Valve Design

	$\Delta P$ (mmHg)	EOA (cm <sup>2</sup> )
Normal	4.0-5.0	3.5-4.00
DurAVR™	3.86-5.34	3.04-3.28
Corevalve <sup>(4)</sup>	7.76-10.27	1.44-1.66
Sapien <sup>(5)</sup>	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



# Developing the world's most durable heart valve



## The right science

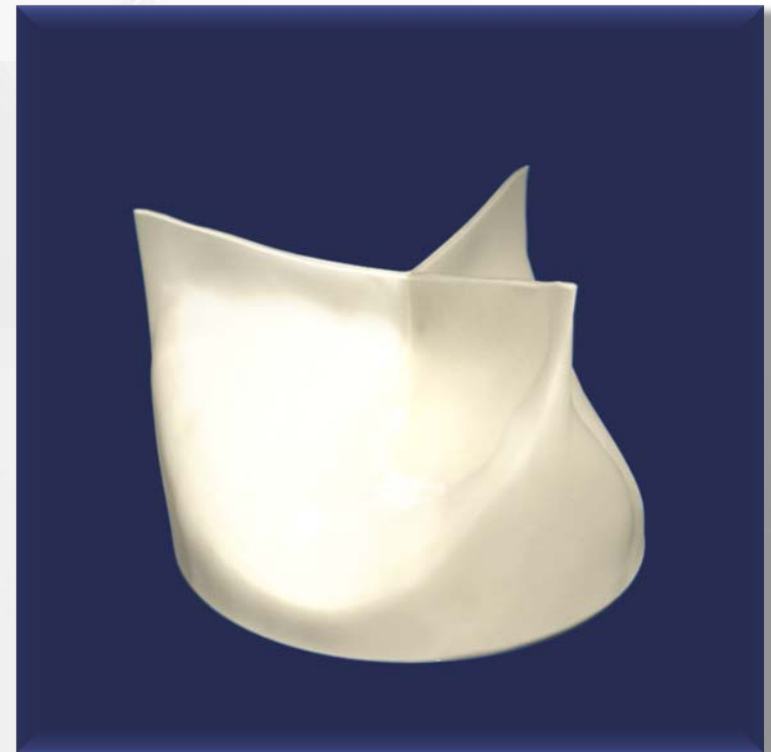
- ADAPT® anti-calcification treatment is proven over 10 years in humans, with zero calcification in published studies.
- Zero DNA.
- Zero residual glutaraldehyde.

## 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.





# Anteris™ is supported by a world class TAVR focused advisory board



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A large, glowing blue wireframe globe is centered in the background, composed of numerous interconnected points and lines, giving it a digital or network-like appearance.

*Innovation to support life's journey  
is at the heart of our story...*

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