

# ASX ANNOUNCEMENT

29 May 2023

## Annual General Meeting Chairman's Address and Chief Executive Officer Presentation

**BRISBANE**, 29 May 2023: Anteris Technologies Ltd (ASX: AVR) is pleased to provide the attached Chairman's Address and Chief Executive Officer Presentation to the Annual General Meeting being held today.

**ENDS**

### About Anteris Technologies Ltd (ASX: AVR)

Anteris Technologies Ltd is a structural heart company that delivers clinically superior and durable solutions through better science and better design.

Its focus is developing next-generation technologies that help healthcare professionals deliver consistent life-changing outcomes for patients.

Anteris' DurAVR™ 3D single-piece aortic heart valve replacement addresses the needs of today's younger and more active aortic stenosis patients by delivering superior performance and durability through innovations designed to last the remainder of a patient's lifetime.

The proven benefits of its patented ADAPT® tissue technology, paired with the unique design of our DurAVR™ 3D single-piece aortic heart valve, have the potential to deliver a game-changing treatment to aortic stenosis patients worldwide and provide a much-needed solution to the challenges facing doctors today.

### Authorisation and Additional information

This announcement was authorised by Mr Stephen Denaro, Company Secretary.

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Address by the Chairman Mr John Seaberg

Again, welcome on behalf of my fellow Directors, Steve Denaro, Wenyi Gu and of course our CEO, Wayne Paterson. Also, a sincere thank-you for your continued support as we continue this incredible Anteris journey together.

Before turning the meeting over to Wayne, I have a few brief comments regarding where our company stands at this moment in time and based on that assessment, why I strongly believe we are highly investable going forward. My investment thesis if you will is based not only on my 8 years as a director at Anteris but also on my 40 year experience in the cardiac space as a sales rep, marketing director, VP of Sales for a Fortune 500 medtech company, company founder and director on numerous Boards both private and public.

Here are four key questions that make up my investment thesis:

- 1. Is the company focused on high value markets?** Historically no. Wayne and I joined the board when we were focused on 2 lower value markets that required 2 different sales forces and huge volume to reach profitability. By comparison, today we're focused on arguably the highest value market in Cardiology: Structural Heart specifically TAVR.
- 2. Is the product line competitive?** Yes, extremely so. As TAVR matures as a market it needs to show viability with younger patients who exercise more and have longer life expectancies. Our DurAVR hemodynamics as shown not just in bench and animal testing but now with numerous human reports shows us to be a gamechanger. And our anti calcific tissue processing lends credibility to the fact that not only will we work better but we will also last longer!
- 3. Do the markets value new technology?** Emphatically yes! When you deal with lifesaving technologies like heart valves doctors and patients and companies want the best.
- 4. What are the value inflection points going forward?** Recently we received additional patent coverage which is always key in med tech and specifically TAVR. Our most recent human data, which was excellent by the way, was shared by one of our world class advisory board doctors at the recent EuroPCR meeting and soon we'll start enrolling patients in our FDA approved Early Feasibility Trial where we have sites in the US already ramping up readiness to do first cases. All of these and more will act as catalysts to increase our share price.

So, in summary, we are laser focused on structural heart, we have a best-in-class product line, we serve a marketplace that not only values but demands new and better technology because people's lives are on the line and there are numerous catalysts to share price growth as we confidently move forward.

Oh, and one final thought: ...none of this happens without strong, smart leadership and with that in mind, I'll turn it over to Wayne Paterson!



29 MAY 2023

ANTERIS TECHNOLOGIES LTD  
ANNUAL GENERAL MEETING





# Anteris 2022 AGM

CEO PRESENTATION

May 29<sup>th</sup> 2023



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# Agenda

- The year in review
- Financials
- Business potential
- One year patient update
- New patients
- What are the experts saying
- Valve in Valve
- What else are we up to?
- Taking the clinical discussion forward
- Collaborations that add value
- Where to from here?
- Questions



# DISCLAIMER

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This presentation contains forward looking statements. Forward-looking statements can generally be identified by use of words such as “may”, “should”, “could”, “foresee”, “plan”, “aim”, “will”, “expect”, “intend”, “project”, “estimate”, “anticipate”, “believe”, “forecast”, “target”, “outlook”, “guidance” or “continue” or similar expressions. Forward looking statements include statements about the future financial or operating performance of the Company and its related bodies corporate, statements about the Company’s current and future clinical studies, statements about the obtention and timing of regulatory approvals for the Company's products under development, statements about the Company's plans, strategies and objectives, including regarding the commercialization of its products, and statements about the industry and the markets in which the Company operates and statement about the effect of the offer described herein and proposed use of proceeds. Such statements represent the Company’s current views with respect to future events and are necessarily based upon a number of assumptions and estimates that, while considered reasonable by the Company, are inherently subject to significant technical, business, economic, competitive, political and social risks, contingencies and uncertainties.

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The financial information in this presentation is presented in an abbreviated form insofar as it does not include all the disclosures required by the AAS and other mandatory professional reporting requirements applicable to general purpose financial reports prepared in accordance with the Corporations Act.

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A Year of Achievements

# Financial report

## Balance sheet

<b>Assets</b>	<b>1,734,826</b>
Current assets	88,905
Non-current assets	1,645,921
<b>Liabilities</b>	<b>166,630</b>
Current liabilities	110,327
Non-current liabilities	56,303
<b>Equity</b>	<b>74,393</b>
Paid-in capital	72,921
Retained earnings	1,472



## Equity statement

<b>Current year</b>	<b>1,774,576</b>
Comprehensive income	15,897
Issue of share capital	88,905
Dividends	23,853
<b>Previous year</b>	<b>166,630</b>
Comprehensive income	110,327
Issue of share capital	56,303
Dividends	67,678



## Income statement

<b>Revenues</b>	<b>12,978,516</b>
Net sales	12,873,892
Investment	104,624
<b>Expenses</b>	<b>6,372,535</b>
Research and Development	1,385,395
Operating expenses	4,439,118
Marketing	548,022
<b>Net income</b>	<b>6,505,981</b>



## Cash flow statement

<b>Operations</b>	<b>12,978,516</b>
Earnings	12,873,892
Depreciation	104,624
<b>Investing</b>	<b>6,372,535</b>
Real estate	1,385,395
Equipment	4,439,118
<b>Financing</b>	<b>6,505,981</b>
Net income	6,505,981



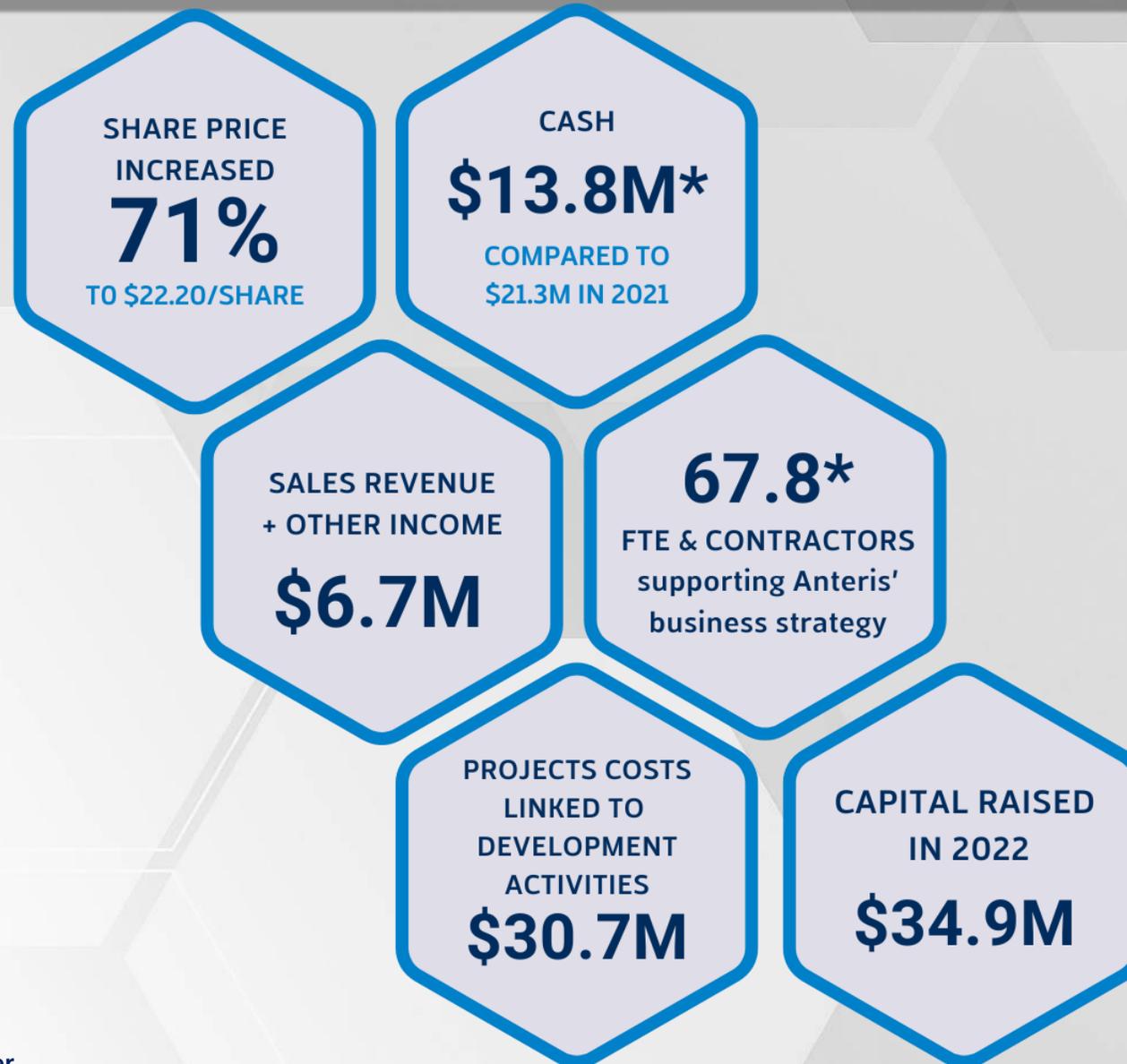
2022  
Financials



# Major milestones were achieved in 2022



# Financial highlights 2022



\* 31 December

# Financial highlights 2022



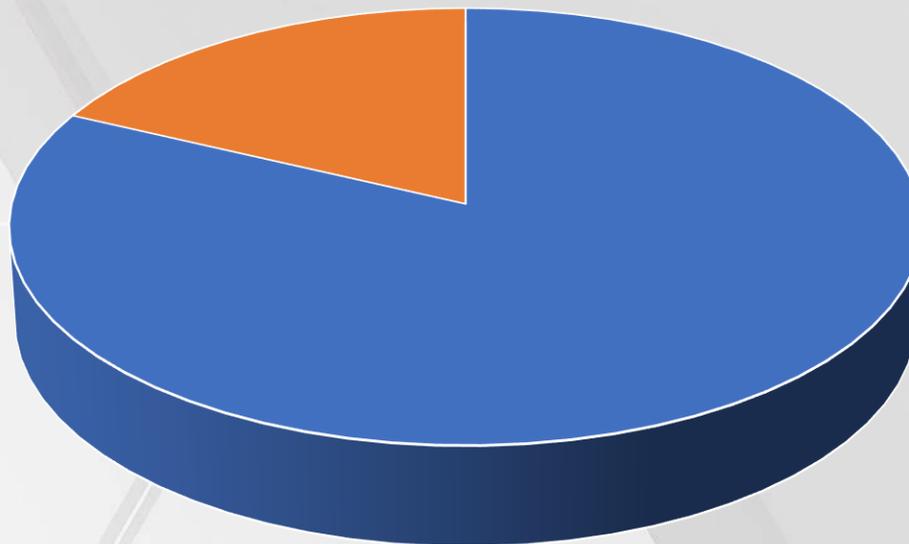
Key Financial Metrics		FY2021 Actual	FY2022 Actual
Market capitalisation (31 Dec)	(\$m)	143.8	308.6
Market capitalisation increase on prior year	(%)	516%	115%
Share price (31 Dec)	(\$/share)	12.96	22.20
Share price increase on prior year	(%)	246%	71%
Cash position (31 Dec)	(\$m)	21.3	13.8
Capital raised (gross)	(\$m)	41.8	34.9
Net loss after tax	(\$m)	22.9	44.3

- 115% increase in market capitalisation
- 71% increase in share price (246% in prior year)
- Increase in expenses primarily reflects increased R&D expenditure including costs of First-in-human and Early Feasibility Study preparations

# Focused investment in R&D has accelerated progress

## Projects \$40.1M

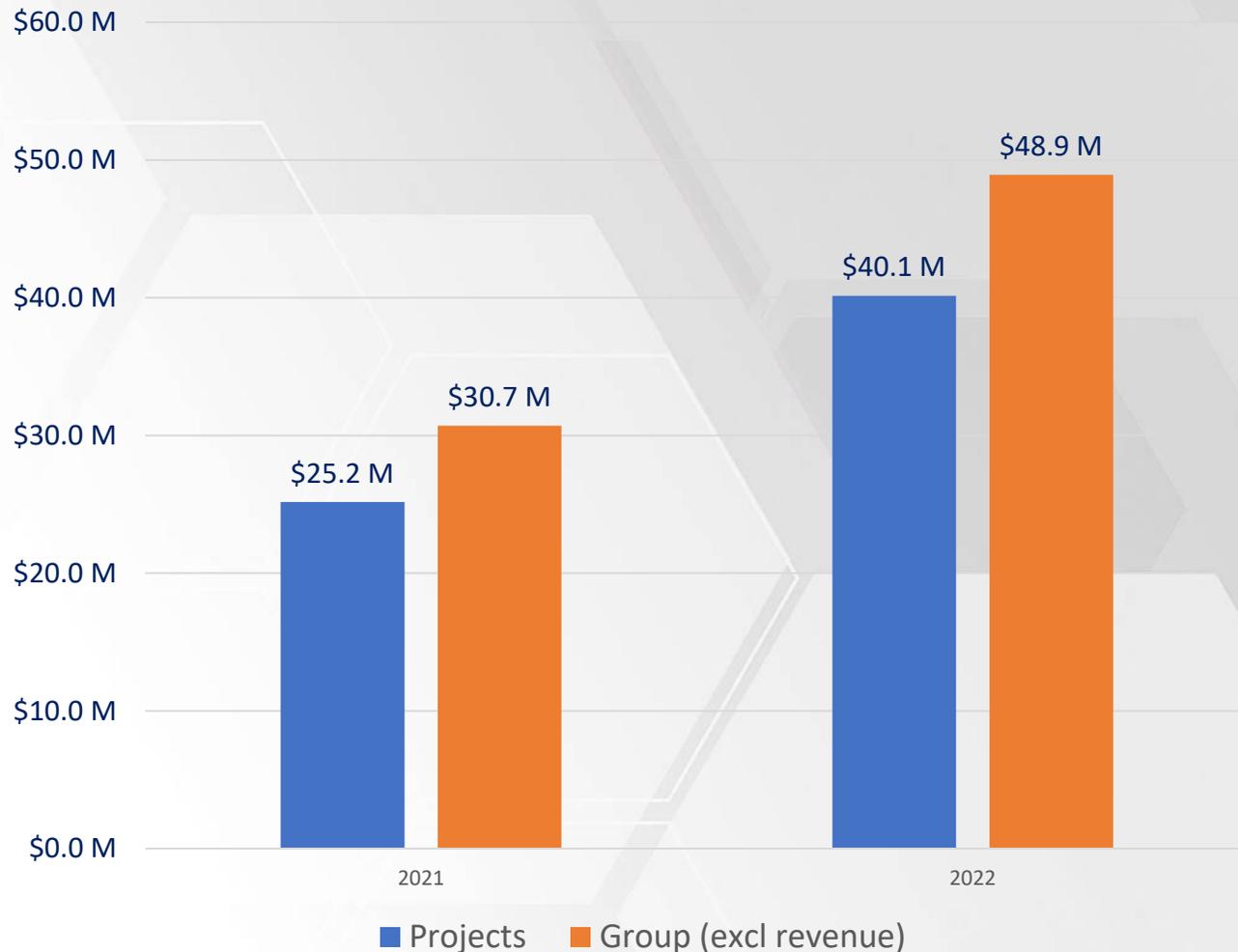
- DurAVR™ valve development program
- EFS approval
- Tbilisi first-in-human trials
- Valve science program
- Upscaling manufacturing capabilities



## Corporate \$8.8M

- Capital raising costs
- Company compliance costs
- Insurance
- Net financing costs
- Nasdaq preparations
- Office administration
- IT support
- Net of R&D tax refund and FX

# Increased project costs linked to development activities

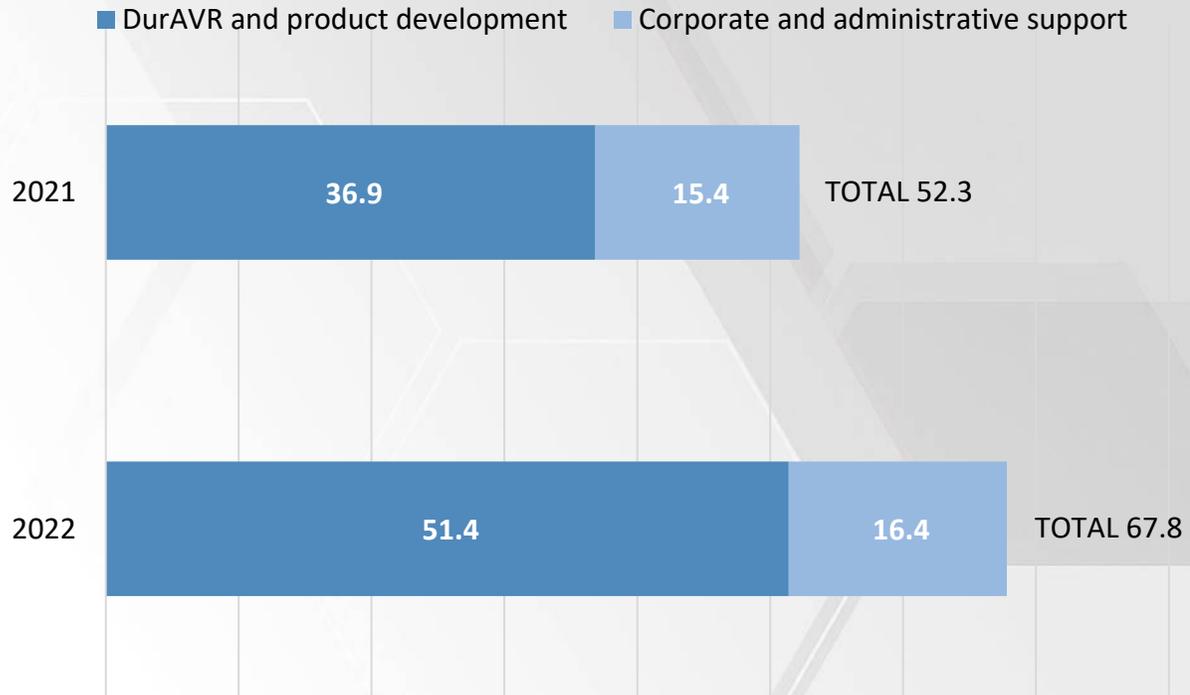


- Increased Projects costs to accelerate development activities and upscale manufacturing capabilities
- Spend linked to preparations for EFS approval and enrolment of further patients in first-in-human trials
- Corporate costs remain tightly controlled

# Highly productive, Highly diverse workforce



## FTE\* by Function



\* FTE includes contractors

## Multicultural Workforce

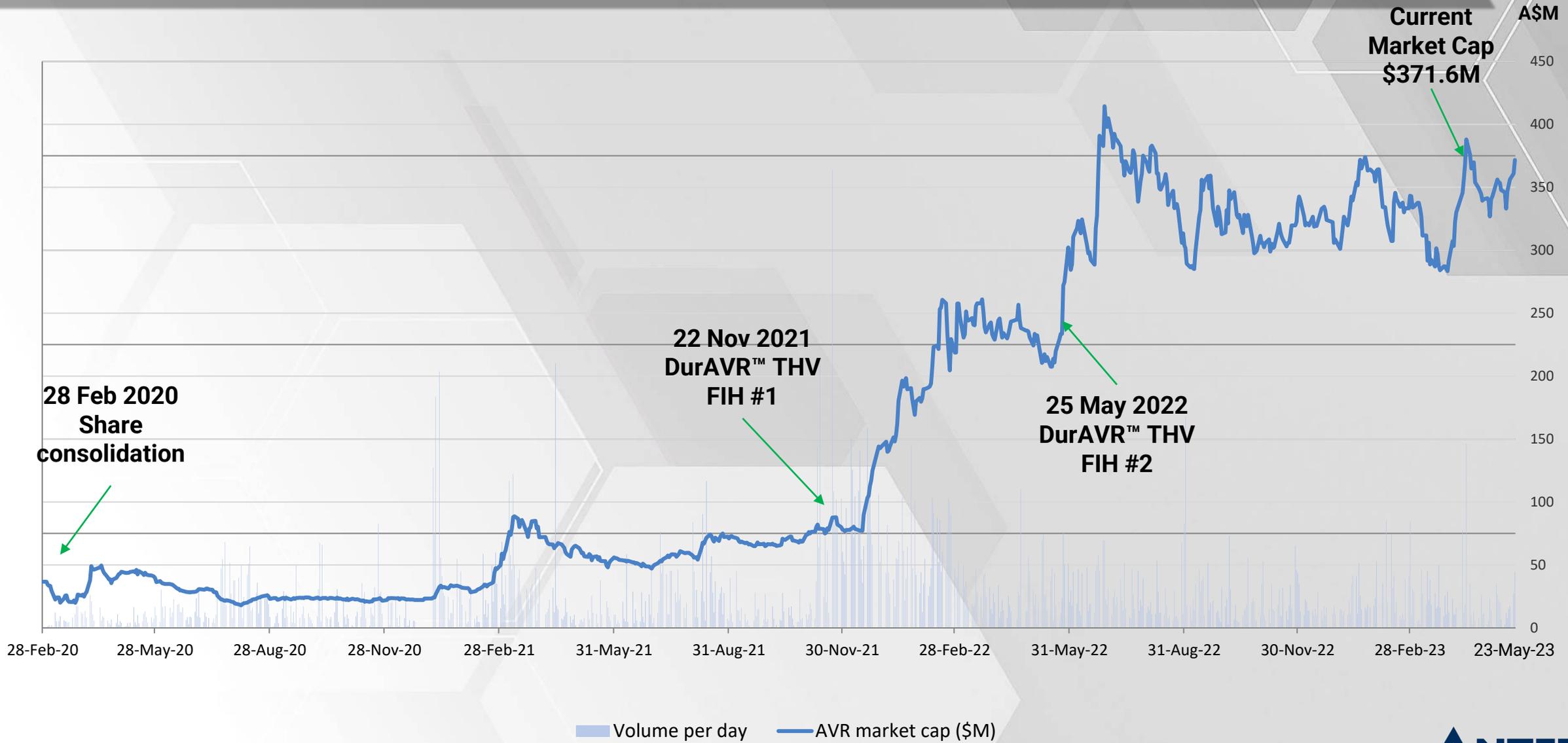


Growing team focused on the development of our innovative Anteris products

DurAVR™ and product development personnel FTE increased by 39% in 2022



# Market capitalisation post share consolidation

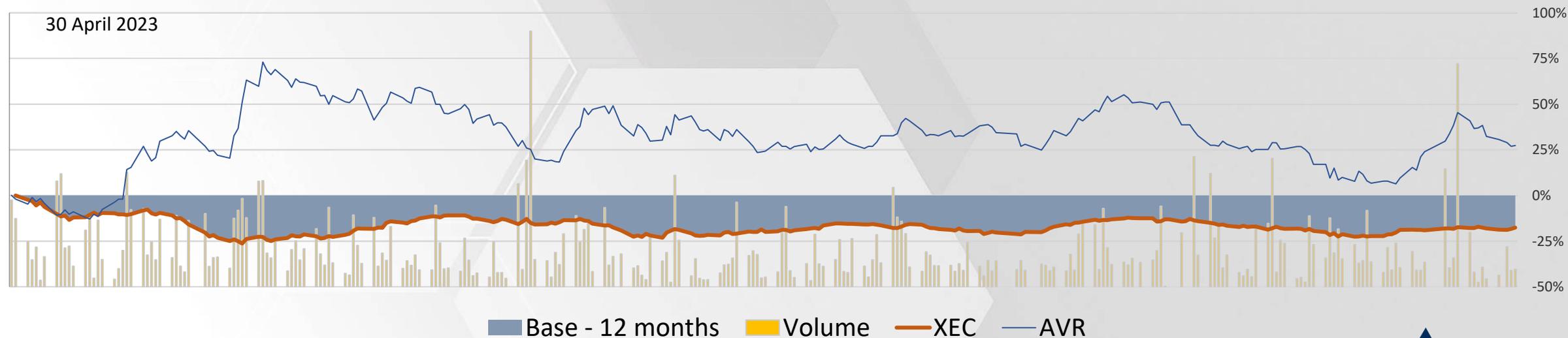


# AVR has returned 220% since the CardioCel™ divestiture

- The S&P/ASX Emerging Companies Index (XEC) is a benchmark consisting of 200 Australian microcap companies ranked anywhere between 350 to 600 by market capitalisation
- The below graph compares the performance of the AVR share price vs XEC index over a rolling 12 months

	AVR return	XEC return
Rolling 12 months	27%	-18%
Post CardioCel divestiture	220%	37%

## Rolling 12 months (incl daily trade volumes)



# Strong share price and Company valuation



**20 March 2023**  
**AVR added to the**  
**All Ordinaries**  
**Share Index**

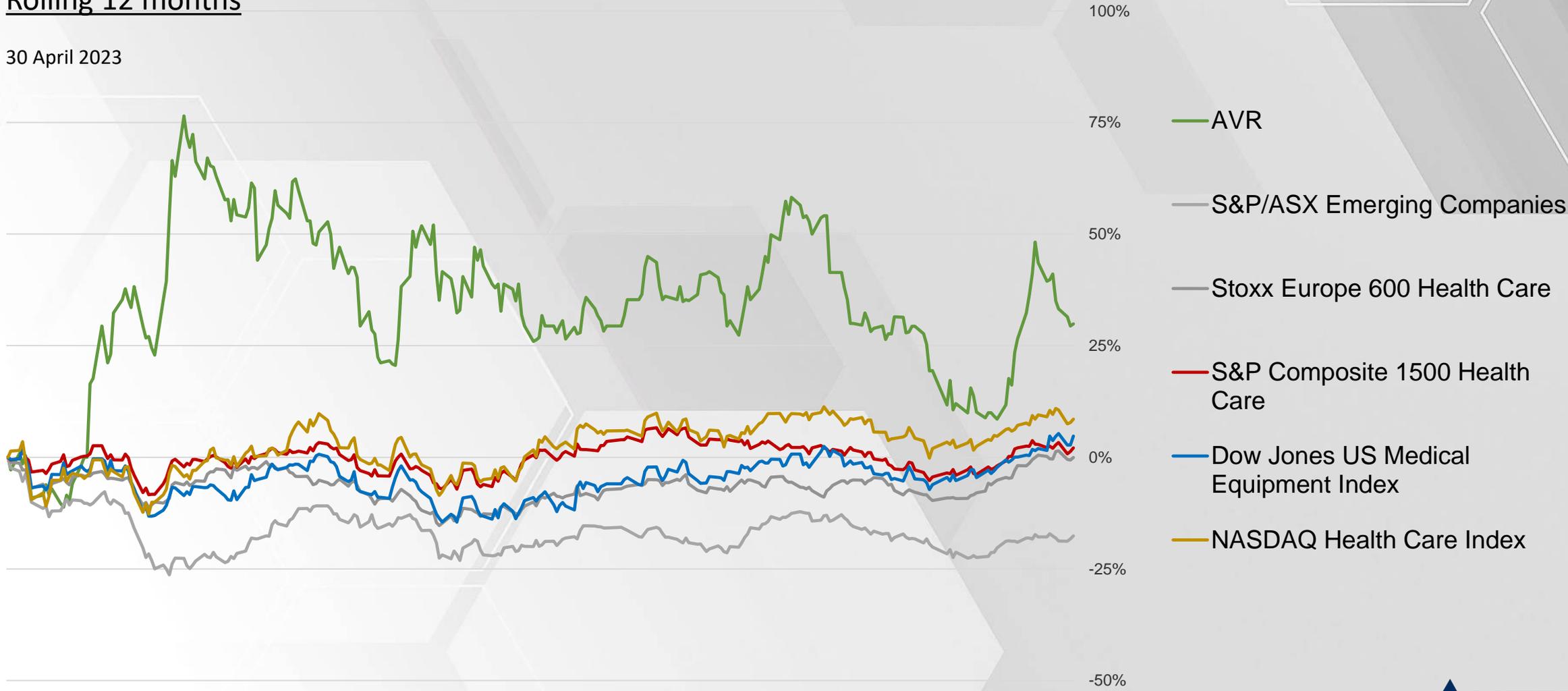


# AVR continues to outperform all major health care indices



## Rolling 12 months

30 April 2023

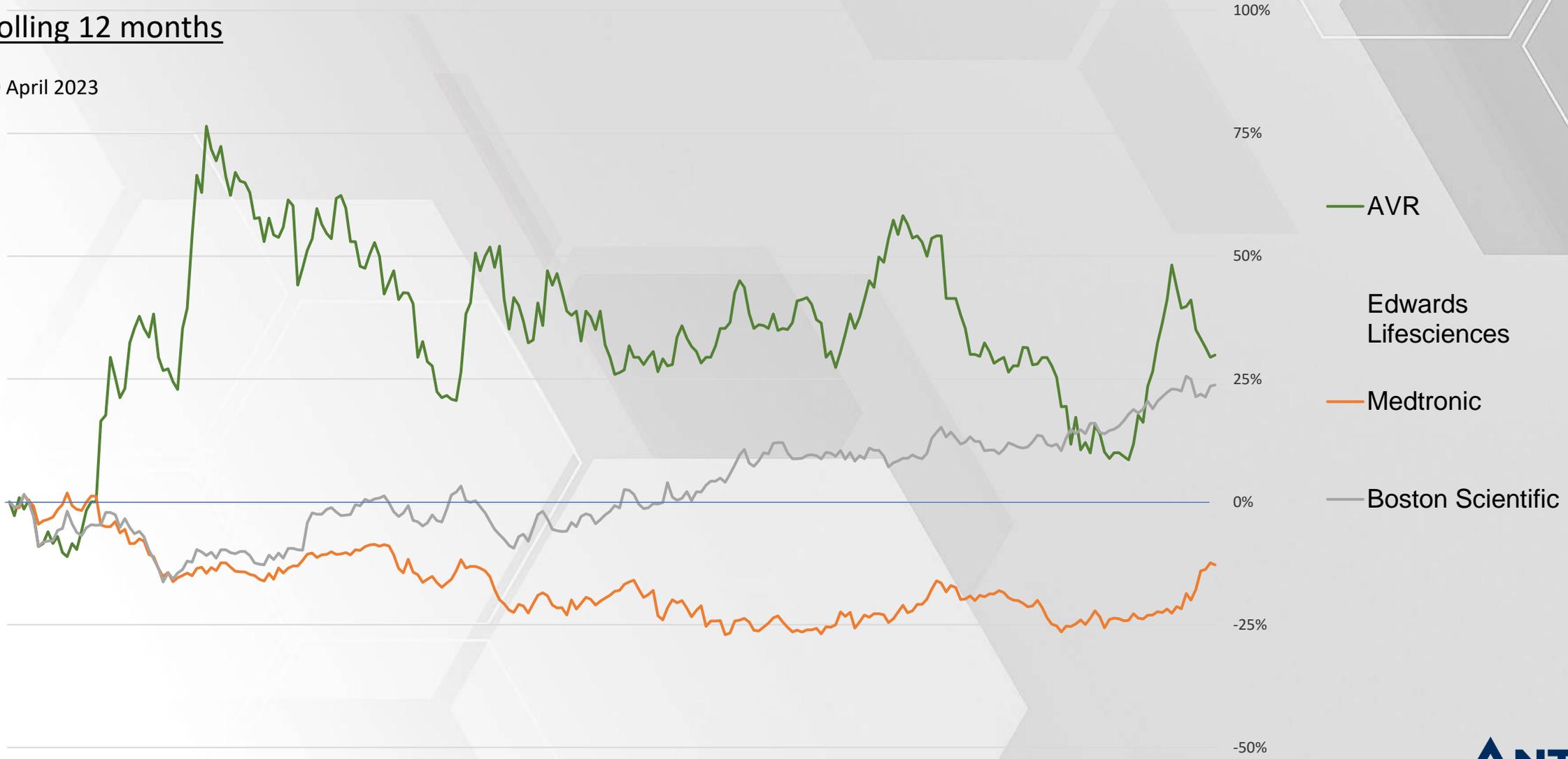


# AVR outperformed major competitors

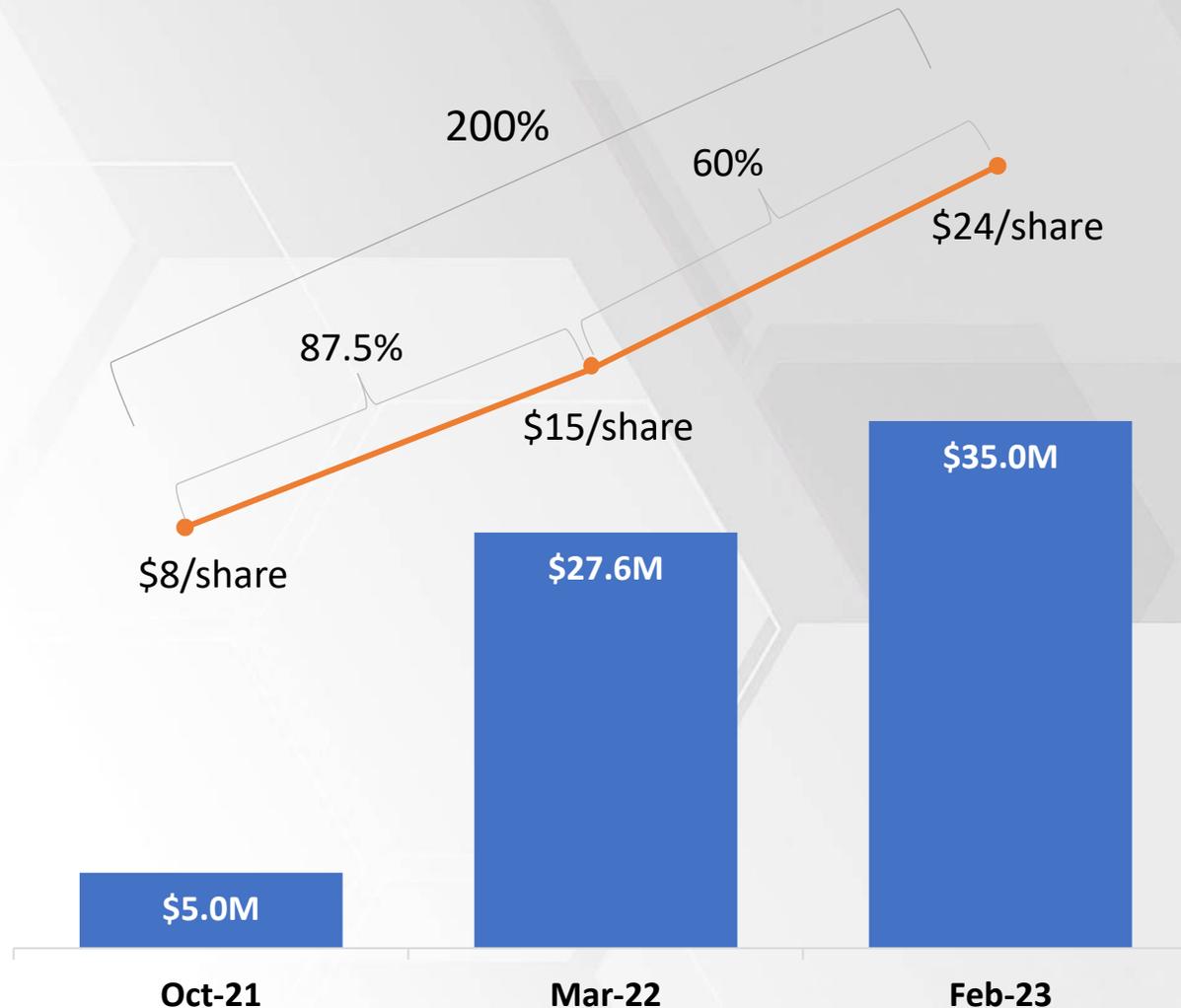


Rolling 12 months

30 April 2023



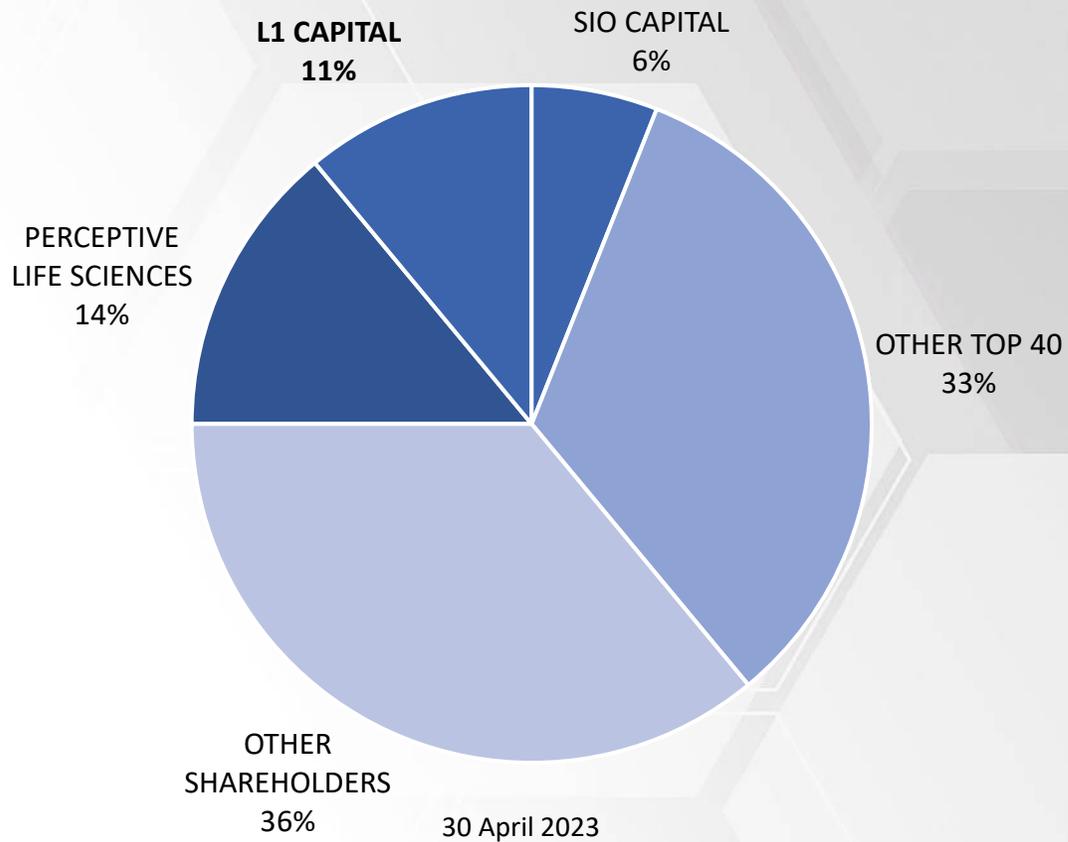
# Capital raising at ever increasing price points



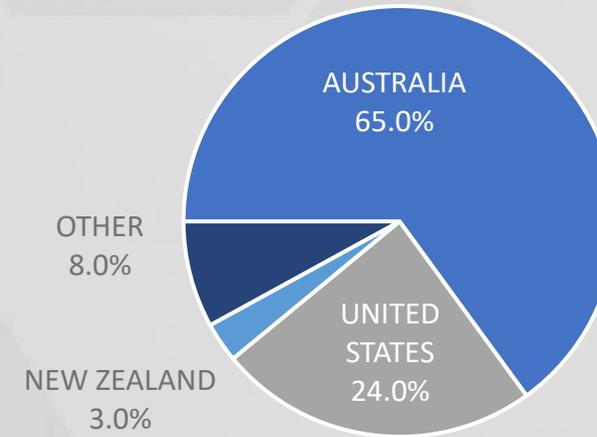
- Each capital raise has been accompanied by the achievement of significant milestones
- The value associated with those raises increased by 200% reflecting the change from \$8/share to \$24/share
- This demonstrates the increasing value proposition of Anteris to the market as it now enters into the EFS stage for DurAVR™ THV and continues to deliver on its strategy

# Top 40 investors hold 64% of the Company

## SHAREHOLDER MIX



## OWNERSHIP COUNTRY



## INVESTOR TYPE HISTORY



# Top 20 investors hold 57% of the Company



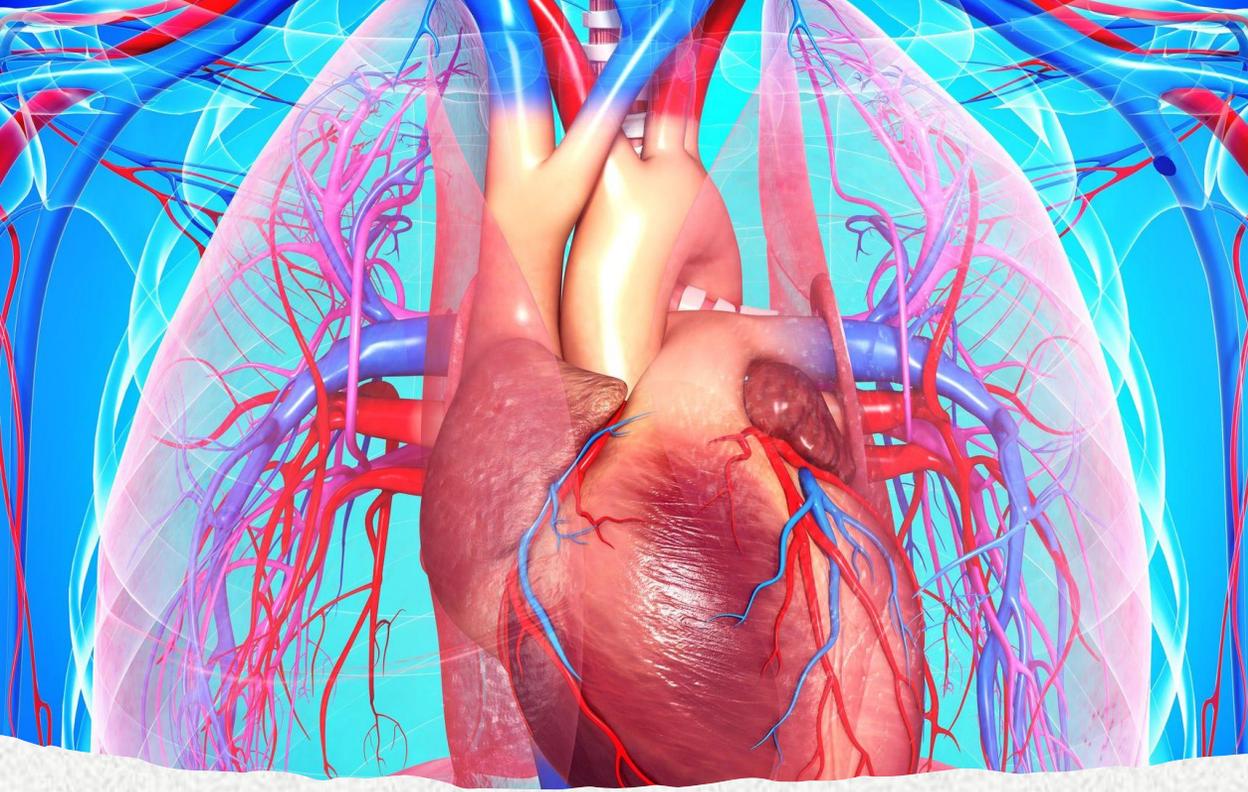
30 April 2023

Rank	Investors – beneficial interest	No. of shares	% Share of total	% Change from prior AGM	Investor Type	Country
1	Perceptive Advisors LLC	2,140,000	13.9%	16%	Institution	United States
2	L1 Capital Pty Ltd.	1,702,994	11.0%	53%	Institution	Australia
3	Sio Capital Management LLC	993,966	6.4%	-22%	Institution	United States
4	Evolution Capital Advisors	660,183	4.3%	24%	Institution	Australia
5	Chiew Family	508,861	3.3%	18%	Retail	Australia
6	Regal Funds Management Pty Ltd.	370,718	2.4%	90%	Institution	Australia
7	Neumann, Rick	359,020	2.3%	35%	Retail	Australia
8	Cameron, Janet H	335,689	2.2%	38%	Retail	Australia
9	Chew, Patrick	316,776	2.1%	10%	Retail	Australia
10	Skandinaviska Enskilda Banken AB	234,151	1.5%	100%	Broker	Sweden
11	McEwin, Iain & Dianne	231,000	1.5%	-1%	Retail	Australia
12	Lamm, David	125,000	0.8%	100%	Retail	Israel
13	Silver, Stephen	124,805	0.8%	105%	Retail	Australia
14	Amzalak, Menachem	119,210	0.8%	16%	Retail	Australia
15	Rooke, Gary	119,000	0.8%	6%	Retail	Australia
16	Morgan Stanley & Co. International Plc	112,431	0.7%	100%	Lending / Borrowing	United Kingdom
17	Clough, Daniel	100,000	0.6%	0%	Retail	Australia
18	Kumova, Tolga	98,175	0.6%	11%	Retail	Australia
19	Barrett, Sean	96,000	0.6%	4%	Retail	Australia
20	Affinity Asset Advisors, LLC	90,000	0.6%	100%	Institution	United States

800 million  
people are  
over 65

# GLOBAL POPULATION HITS **EIGHT BILLION**





2% - 5% of people over 65  
have aortic stenosis

This increases to 12% - 15%  
over 75

point of view.

# Diagnosis

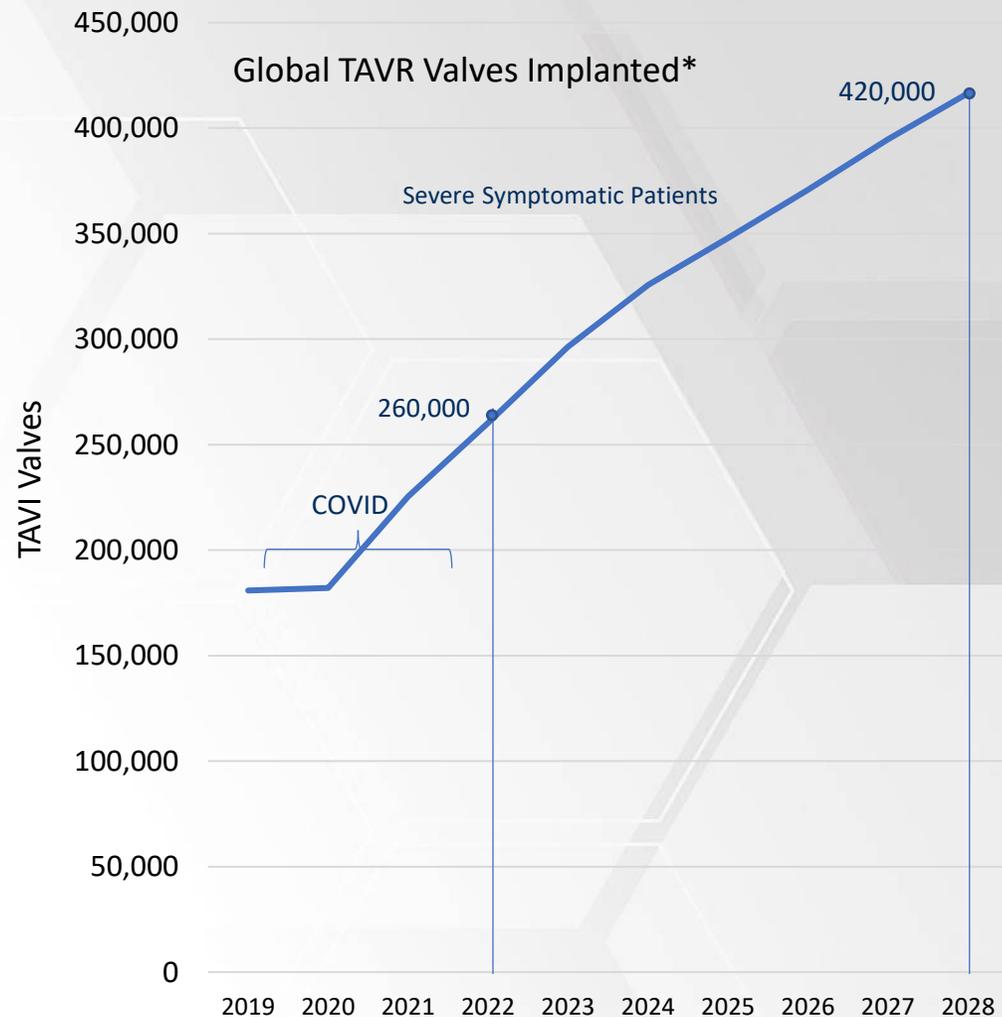
identifying or de

## Aortic stenosis is under treated

- The population above 65 globally is 10% or 800 million people (according to world bank)
- The world population continues to age rapidly and the incidence of aortic stenosis and severe aortic stenosis is growing with the population
- The available global patient pool is 10-20 million people
- At today's value 1% of this market is 3,500,000,000 -7,000,000,000
- 10% is 35-70 billion

# TAVR Global Market out to 2028 (15 billion AUD)

Significant Organic Growth, with A LOT of Upside with Expanded Indications



TAVR Market has the Potential to grow even more

3 Trials Currently in Progress

Evolut™ EXPAND TAVR



- Asymptomatic patients who still have severe AS
- Currently enrolling



- Patients with moderate AS who have not yet progressed to severe
- Enrollment has begun

These 3 Trials focus on Asymptomatic and Moderate Aortic Stenosis.

Once completed in approx. 2025 time frame, they have the potential to increase 2x the TAVR Market size.

2028 Market Potential over 800,000  
TAVR Globally

A photograph of an iceberg floating in the ocean. The top part of the iceberg is visible above the water, while a much larger, submerged part is visible below the surface. The water is a deep blue, and the sky is a lighter blue with some clouds.

Today we are only  
scratching the  
surface

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Scratching  
the Surface



21 patients now  
implanted with DurAVR™



**Clinical study update**

1-Year Interim Analysis

# Cohort 1 & 2 are difficult to treat small annulus patients

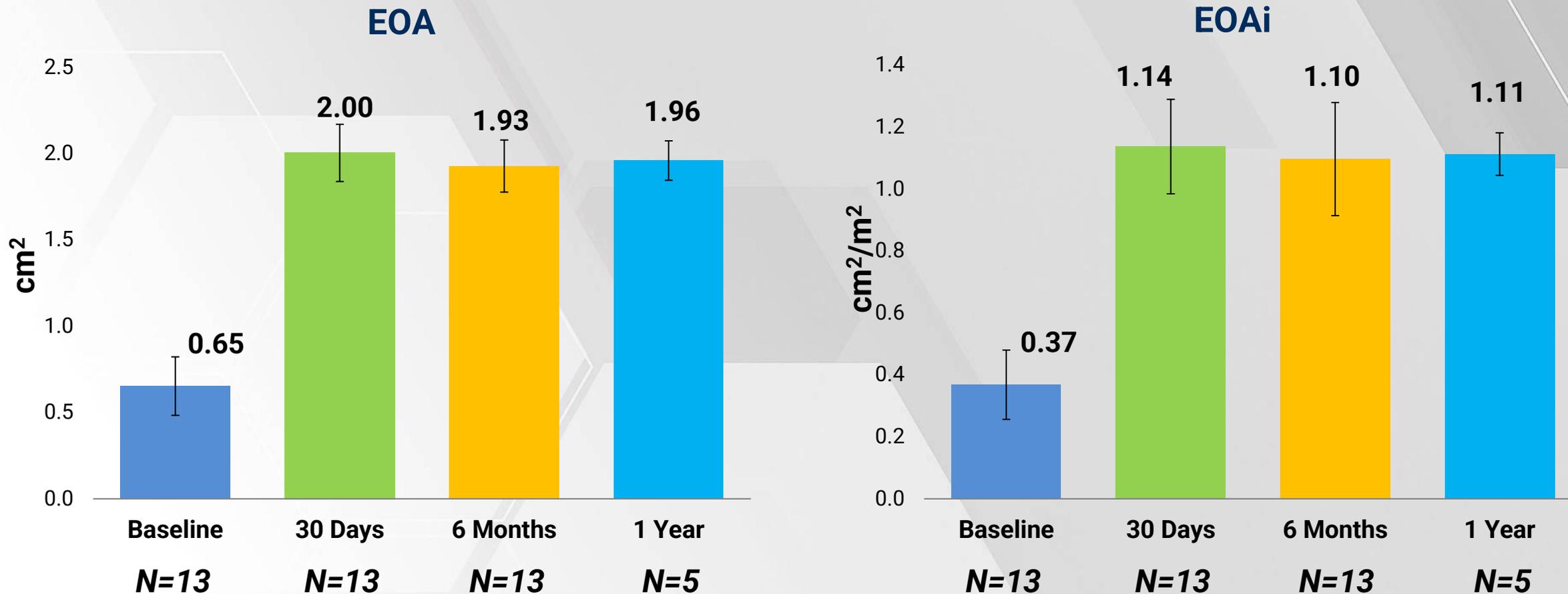
## Cohort 1 and 2

Baseline characteristics	n = 13
Age (years)	73.92 ± 6.4
Gender (female)	77%
STS Prom (%)	2.34 ± 1.07
Area-derived annulus diameter (mm)	22.95 ± 1.09
NYHA Class	
II	85%
III	15%
Implant timeframe	Nov-2021 and May-2022

# Excellent results maintained over 1 year

Cohort 1 & 2

Mean annulus size: 22.95 mm  
(N=13)



1-year transthoracic echocardiogram (TTE) available only for the first 5 subjects at the time of this analysis

EOA: Effective Orifice Area | EOAI: Effective Orifice Area indexed

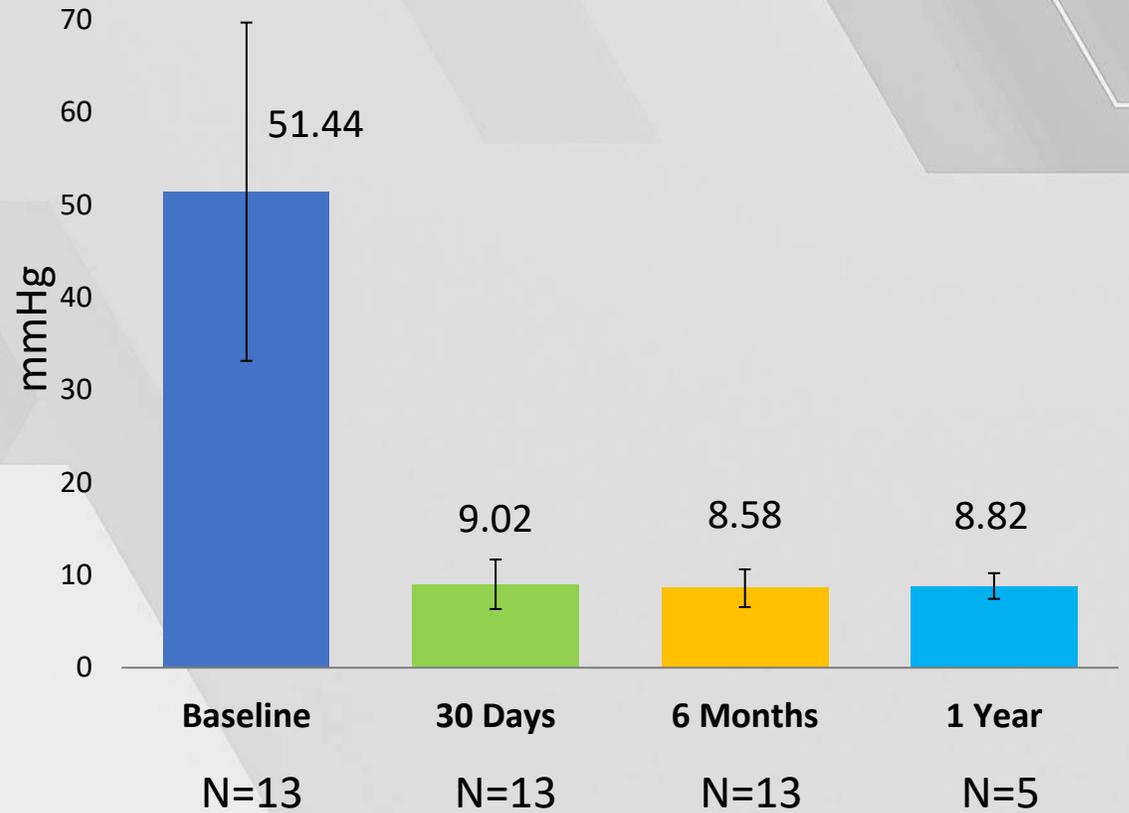
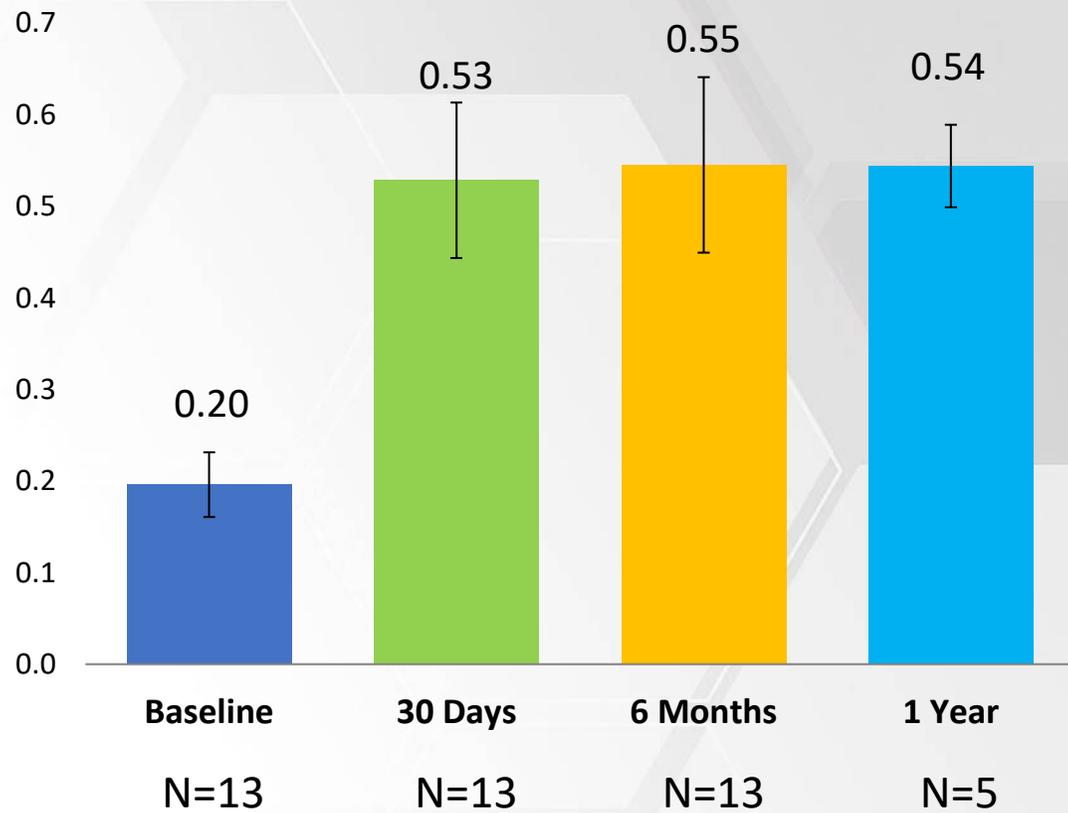
# Outstanding 1-Year Haemodynamics

## Cohort 1 & 2

Mean annulus size: 22.95 mm  
(N=13)

DVI

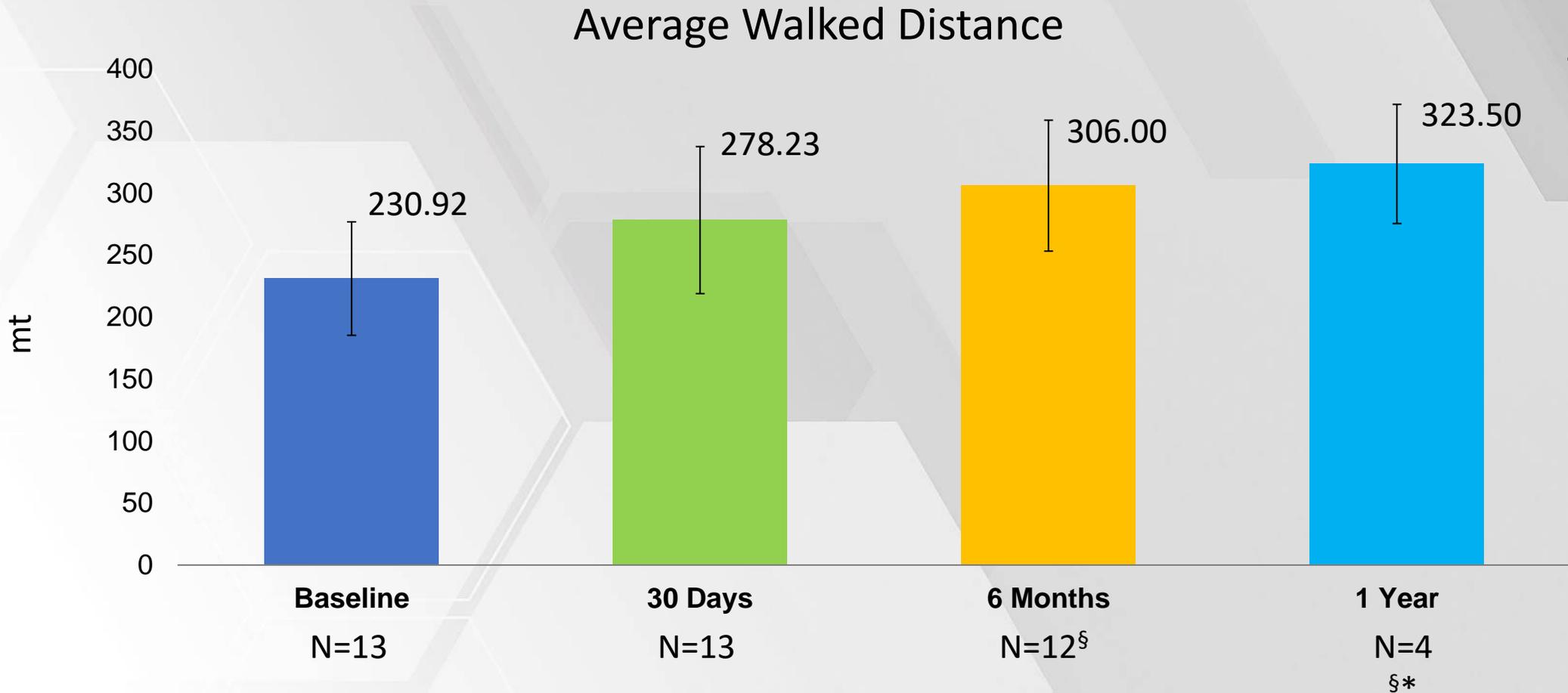
MPG



1-year transthoracic echocardiogram (TTE) available only for the first 5 subjects at the time of this analysis

DVI: Doppler Velocity Index | MPG: Mean Pressure Gradient

# Huge improvements in exercise capacity



40%  
increase  
from  
baseline

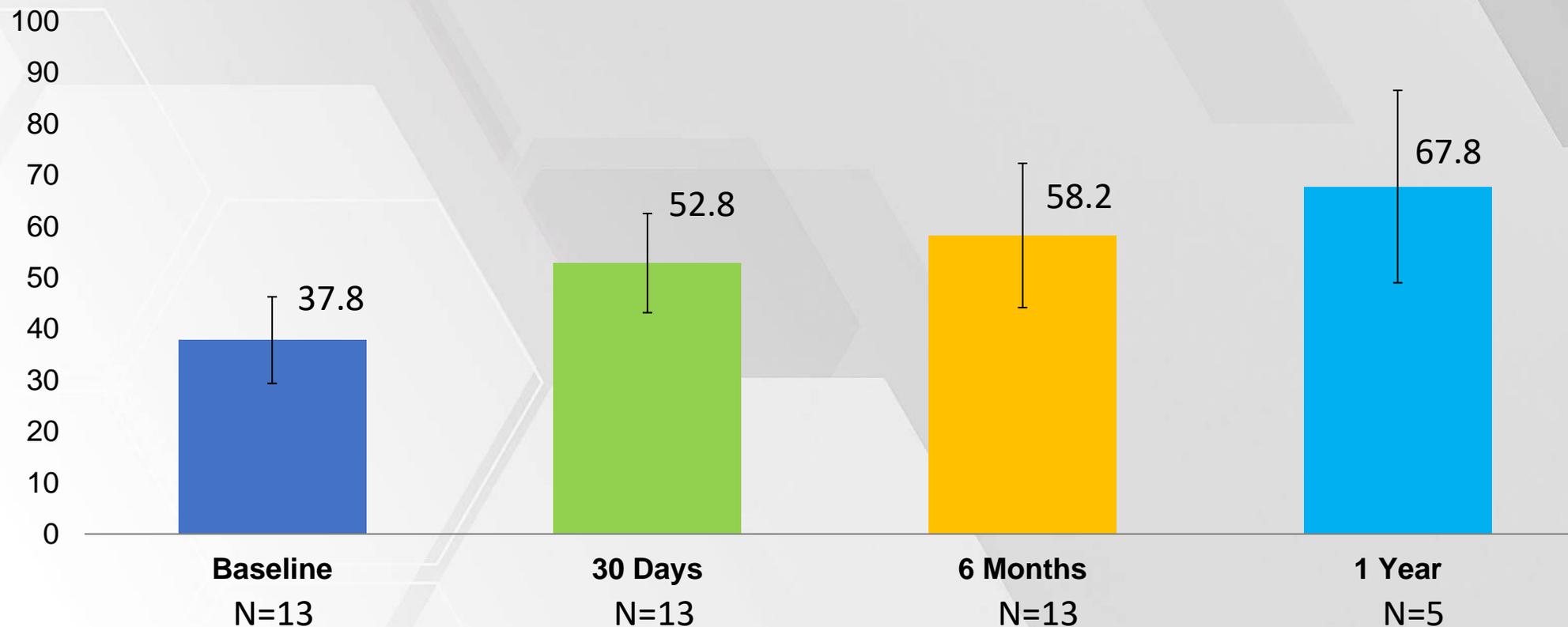
<sup>§</sup> One subject performed the baseline and 30-day 6MWT with the support of an assistive device and was unable to complete the assessment at 6-month and 1-year follow-up due to hip replacement.

\* 1-year 6MWT available only for the first 4 subjects at the time of this analysis

# Significant improvements in QOL score over 12 months

## Cohort 1 & 2

### KCCQ Overall Summary Score



1-year KCCQ available only for the first 5 subjects at the time of this analysis



## Cohort 3

7 new patients + 1 compassionate use patient

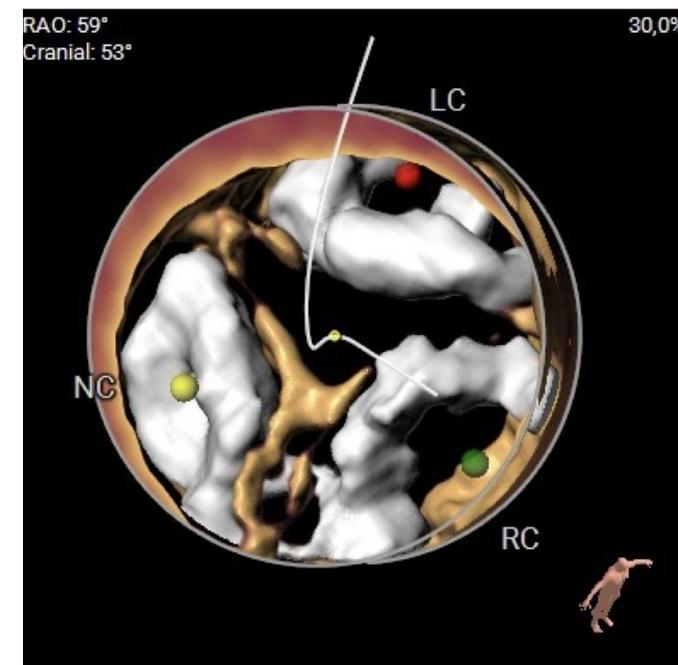
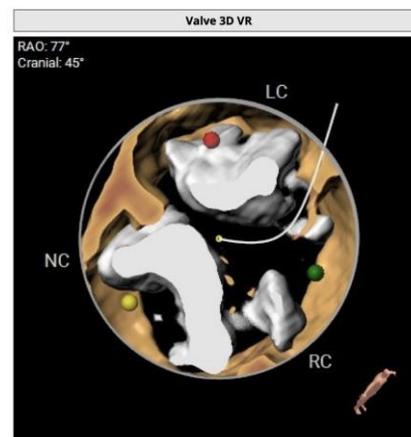
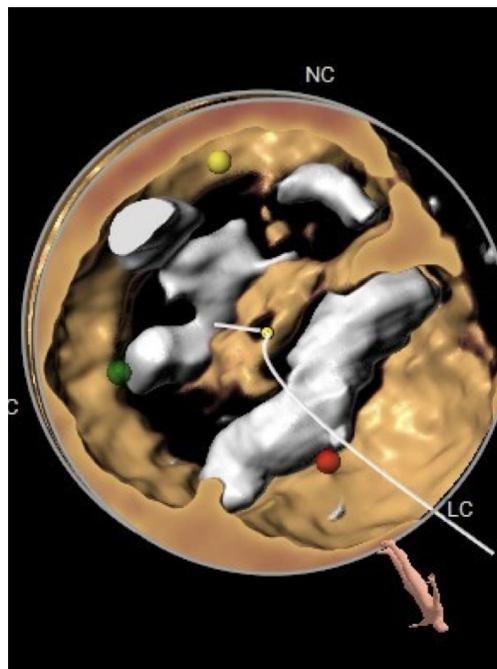
# Cohort 3 Objectives

## Great clinical results while defining device limitations in prep for EFS

- Verify improvements in balloon function
- Clinical experience for EFS
- Push the upper and lower bounds of the valve sizing range
- Depth of implant optimization
- Volume based sizing
- Test Crimper



# Difficult to treat anatomies



# Baseline Characteristics

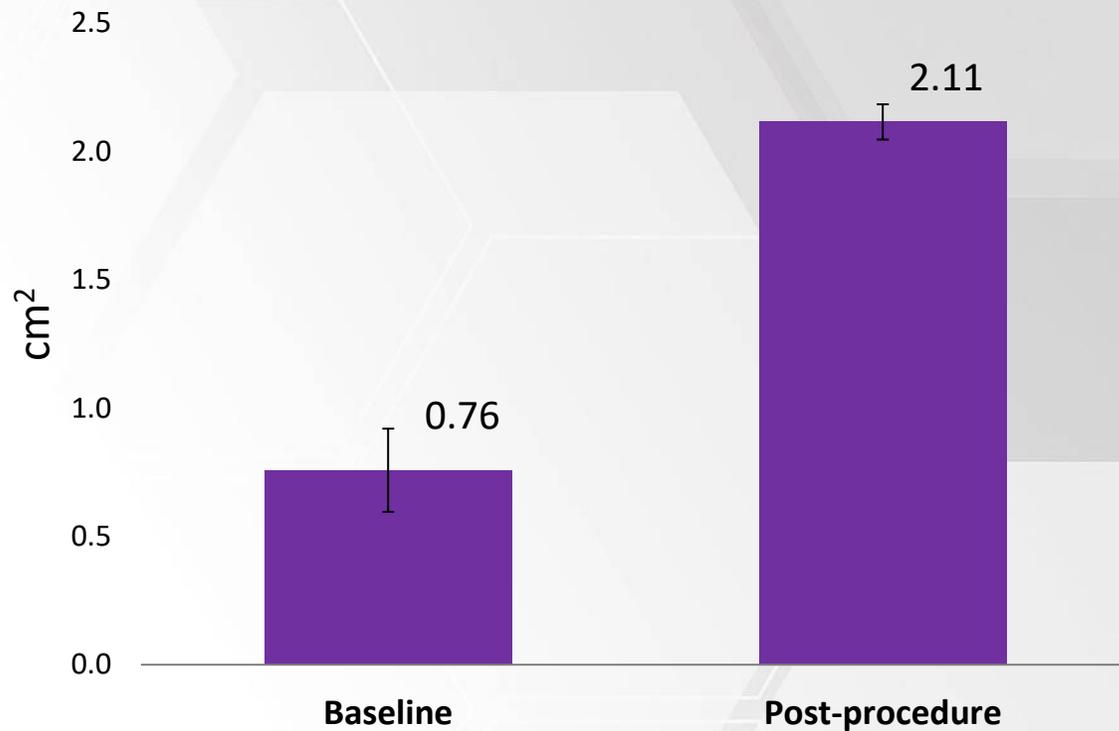
Baseline characteristics	n = 7
Age (years)	74.86 ± 4.60
Gender (female)	86%
STS Prom (%)	2.07 ± 0.47
Area-derived annulus diameter (mm)	22.33 ± 1.51
NYHA Class	
II	71%
III	29%
Implant timeframe	April 2023

# Post-procedure (48h) Haemodynamics

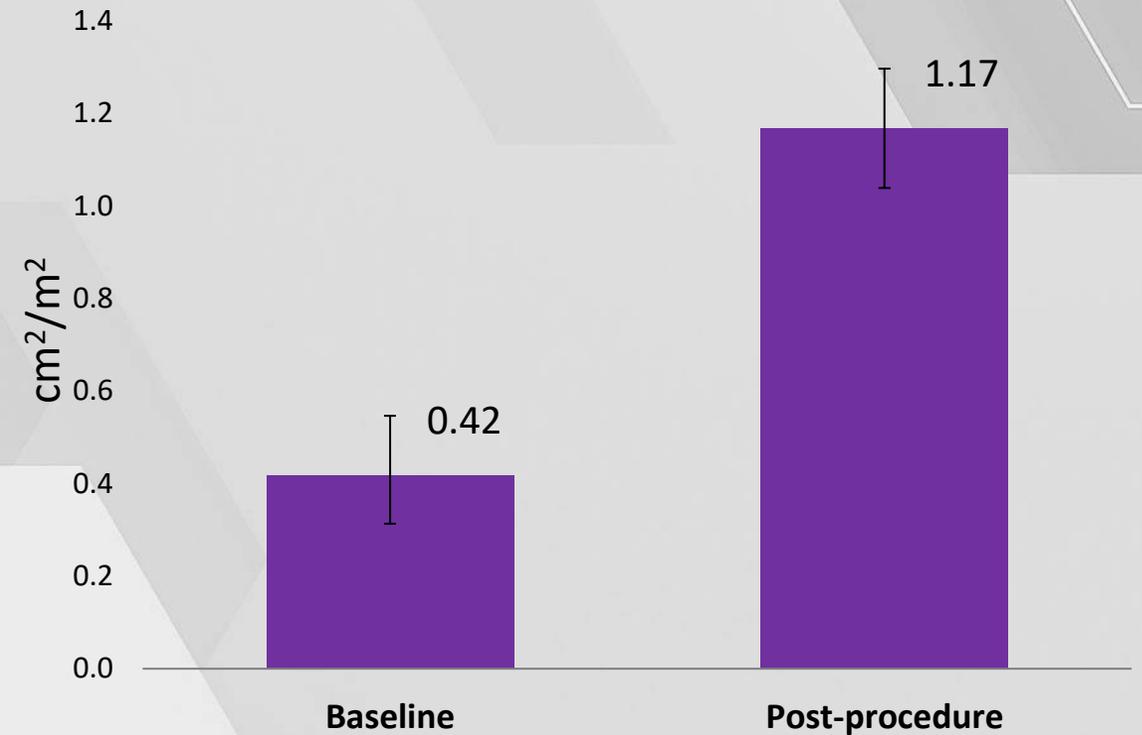
## Cohort 3

Mean annulus size: 22.33 mm

EOA



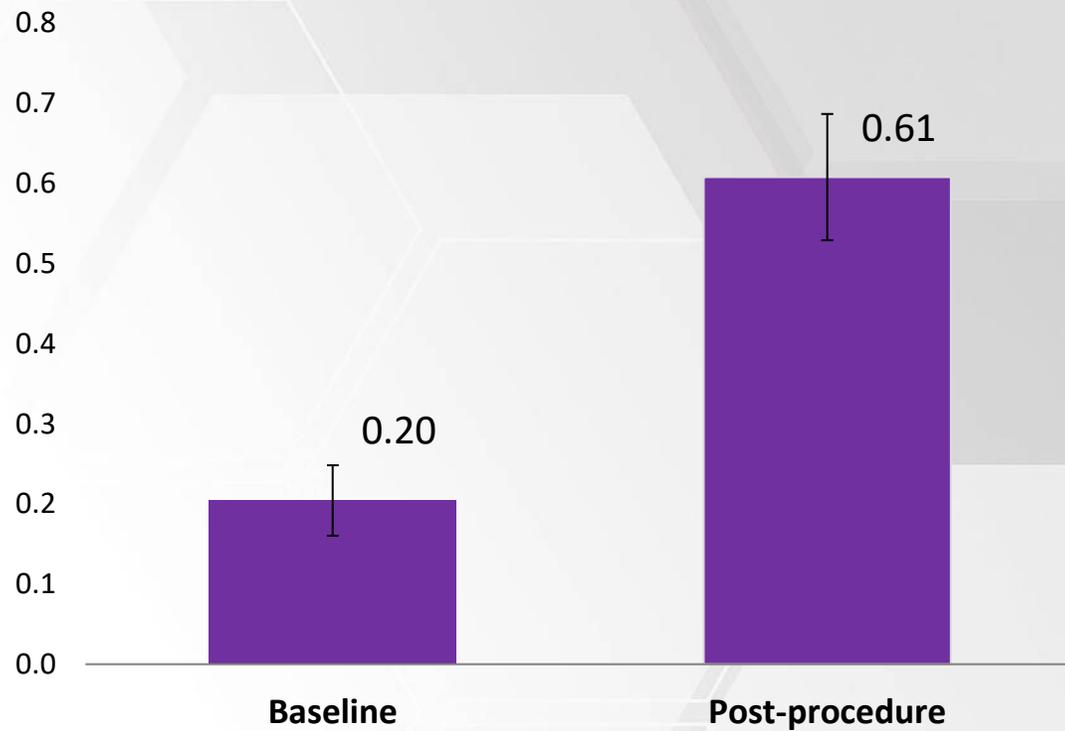
EOAi



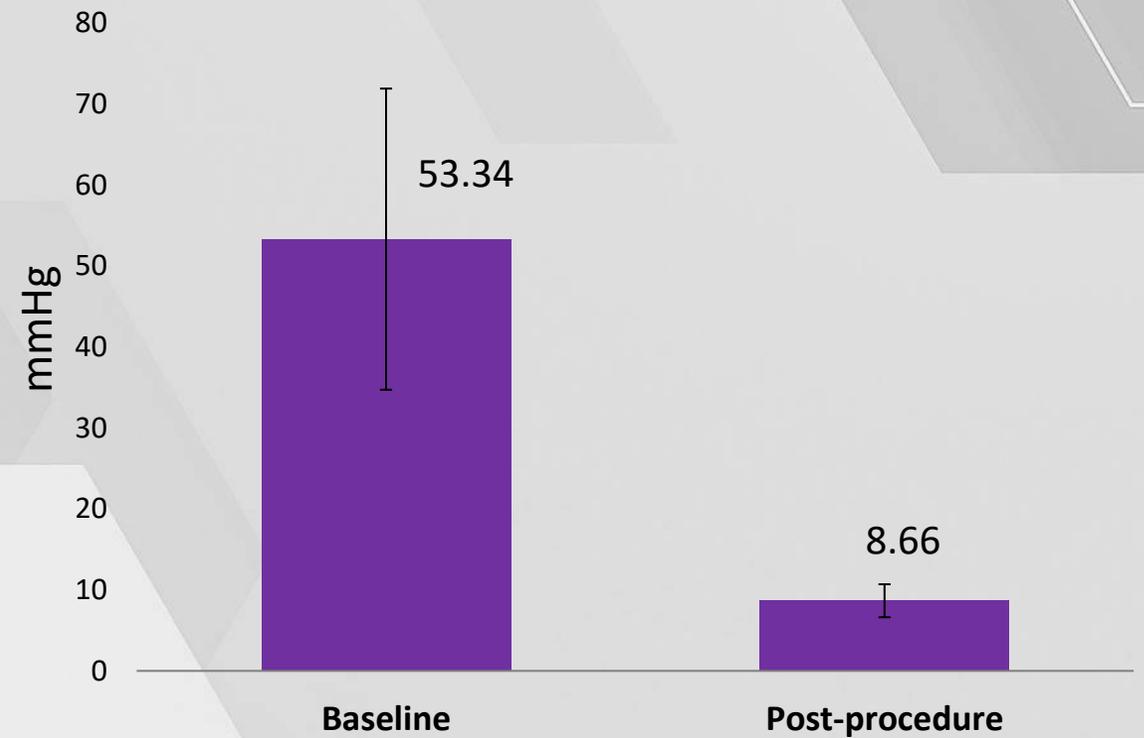
# Post-procedure (48h) Haemodynamics all patients

Mean annulus size: 22.73 mm

DVI

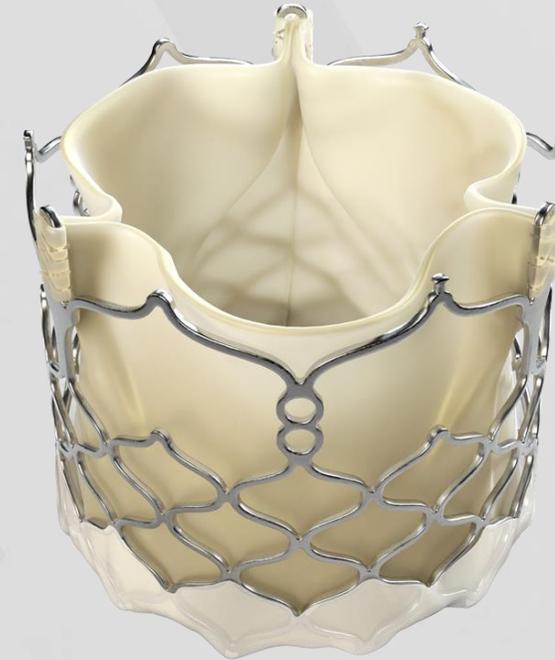


MPG



## 8/8 Successful Cases

- 7 FIH, 1 Compassionate Use
- Mean annulus 22.3
- Percutaneous Closure in all
- Intraop TEE- 7 trace/zero, 1 mild PVL
- ZERO Central leak
- No pacer at d/c





Compassionate  
use case

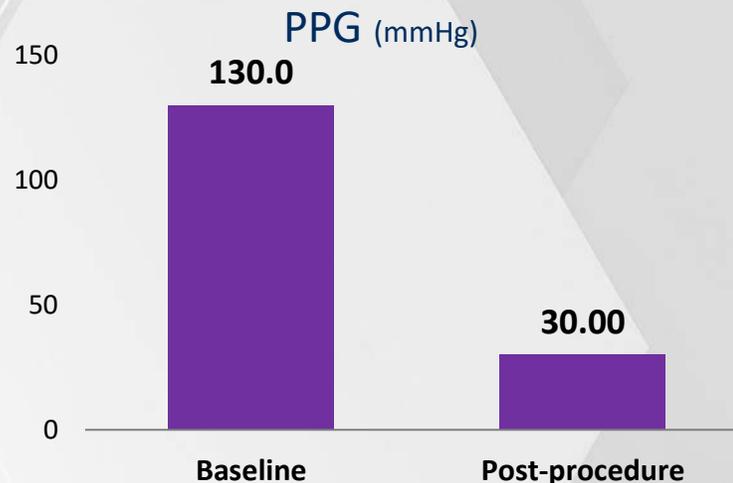
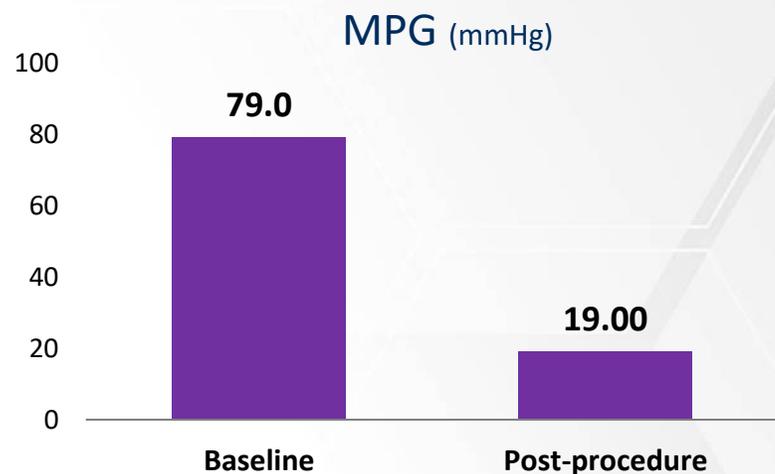
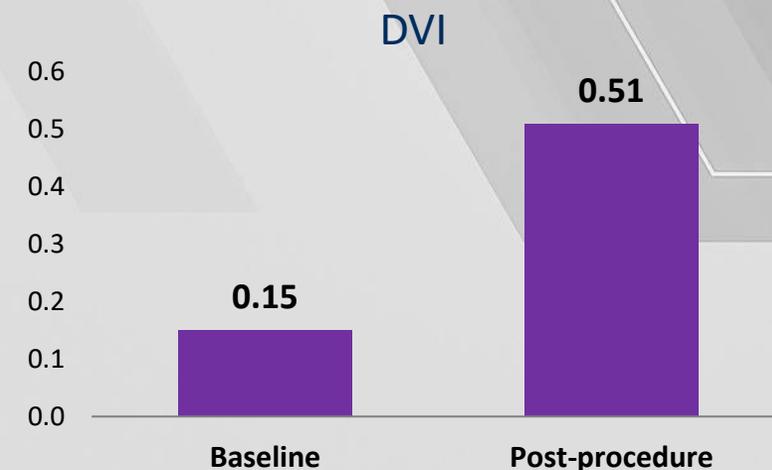
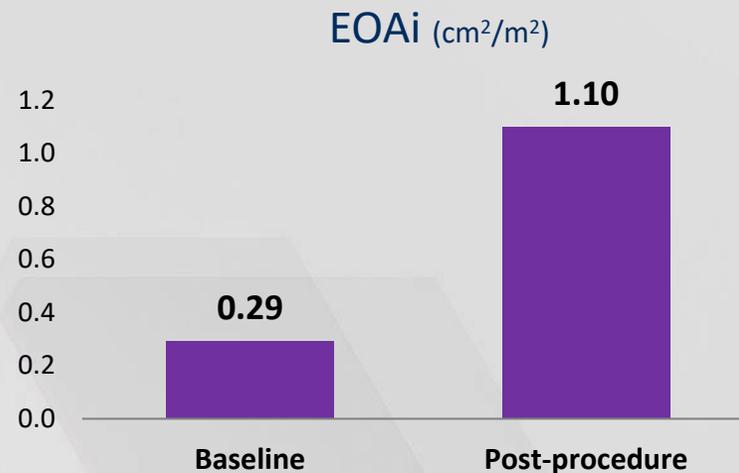
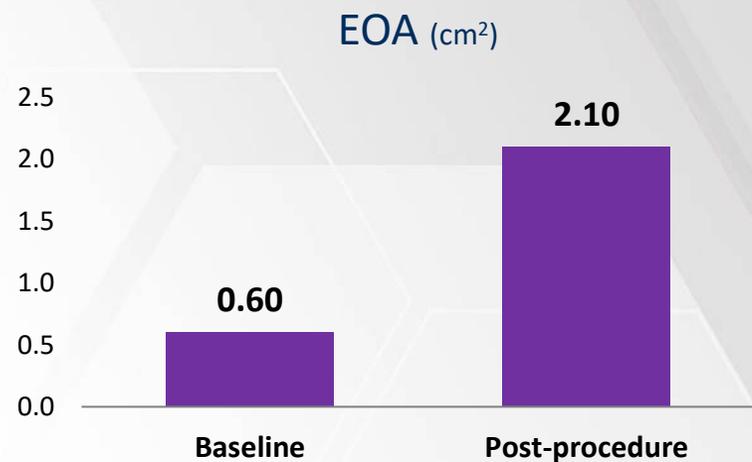
# Baseline Characteristics

Compassionate case – 24 April 2023

Baseline characteristics	
Age (years)	66
Gender	Female
STS Prom	1.12 %
Area-derived annulus diameter	24 mm
NYHA Class	3
AV morphology	Bicuspid
LV Ejection Fraction	33 %
Comorbidities and risk factors	systemic hypertension, mild-moderate mitral insufficiency, low LV EF, risk of coronary obstruction.

# Excellent haemodynamics results in severe bicuspid anatomy

Compassionate case – 24 April 2023







All Subjects  
Post-procedure (48h) Interim  
Analysis

# Baseline Characteristics

## All Subjects

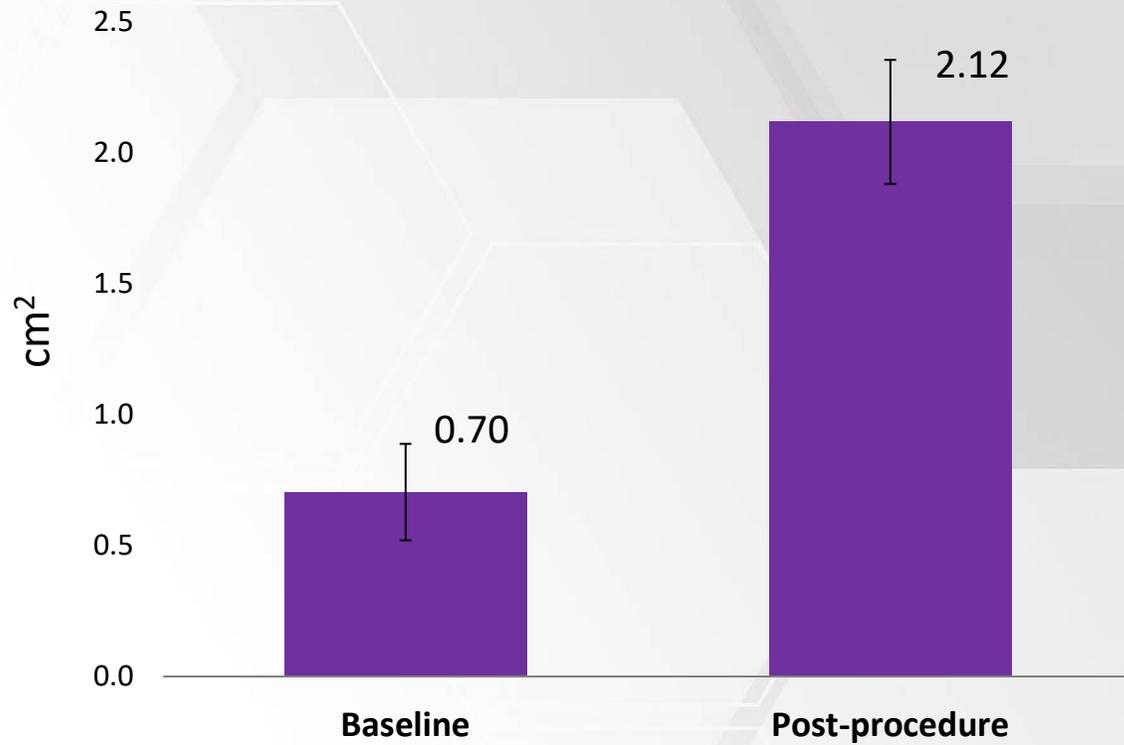
Baseline characteristics	n = 20
Age (years)	74.25 ± 5.72
Gender (female)	80%
STS Prom (%)	2.25 ± 0.90
Area-derived annulus diameter (mm)	22.73 ± 1.25
NYHA Class	
II	80%
III	20%
Implant timeframe	Nov-2021, May-2022, Apr-2023

# Post-procedure (48h) Haemodynamics

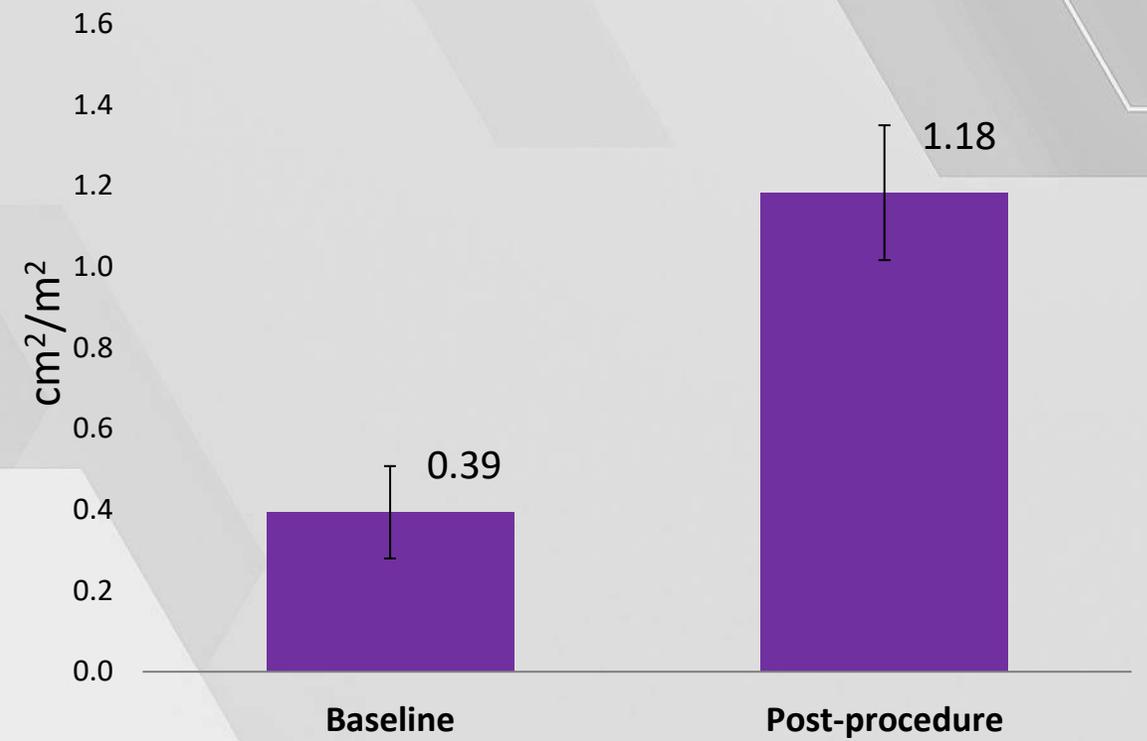
## All Subjects

Mean annulus size: 22.73 mm

EOA



EOAi



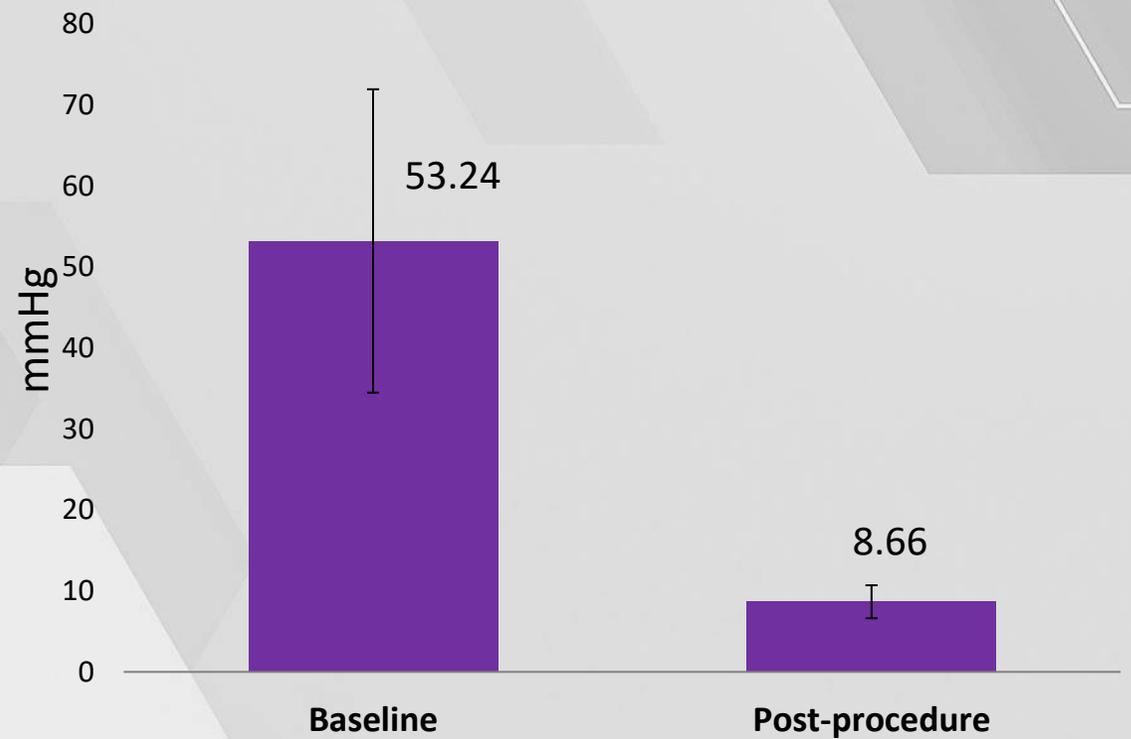
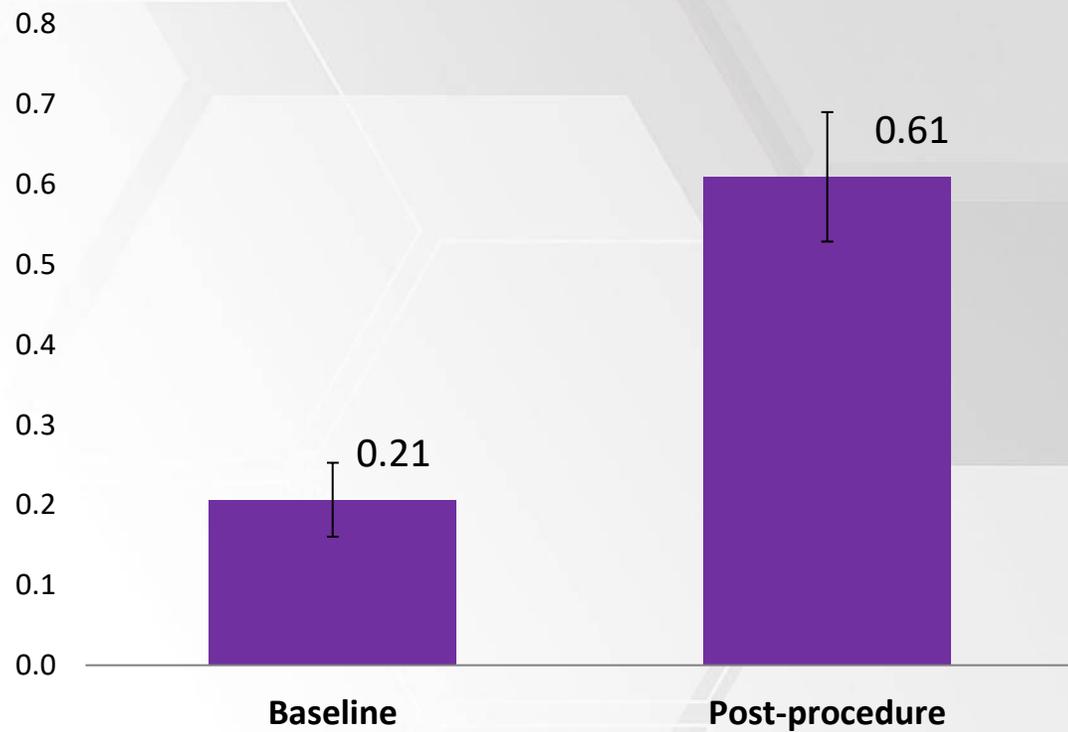
# Post-procedure (48h) Haemodynamics

## All Subjects

Mean annulus size: 22.73 mm

DVI

MPG



What are the experts saying about DurAVR™ ?

### INTEGRATION Example: Biomimetic THV to Restore Normal Ao Flow

DurAVR™ THV: A biomimetic design shaped for native performance

- Native-like shape and valve
- Single-piece leaflet design
- Large open cells for coronary access
- ADAPT™ Aortic Calcification Tissue Engineering Process
- Balloon-expandable delivery with commissure alignment

Native shape and coaptation length enable native-like performance

First in Human study shows sustained hemodynamic performance

Parameter	Baseline	30 Days	6 Months	1 Year
EOA (cm <sup>2</sup> )	0,65	9,02	8,58	8,82
MPG (mmHg)	51,44	2,00	1,93	1,96

Mean aortic diameter: 22.95 mm (n=20)

DurAVR™: AVR that restores normal Aortic Flow

Condition	FD	FRR	n
Healthy Aortic Valve	10mm	1%	(n=5)
DurAVR™	14cm	4%	(n=5)

2025 EUPCR  
EuroPCR  
EAPCI



EXPERT INTERVIEW WITH

**CEO WAYNE PATERSON**

AND

**REBECCA T. HAHN, MD**



2 products , 2 indications 2 pathways

---

- Aortic Stenosis (at the current rate will be AUD 15 billion by 2028)
- Valve in Valve (up to 30% of existing patients)

2n

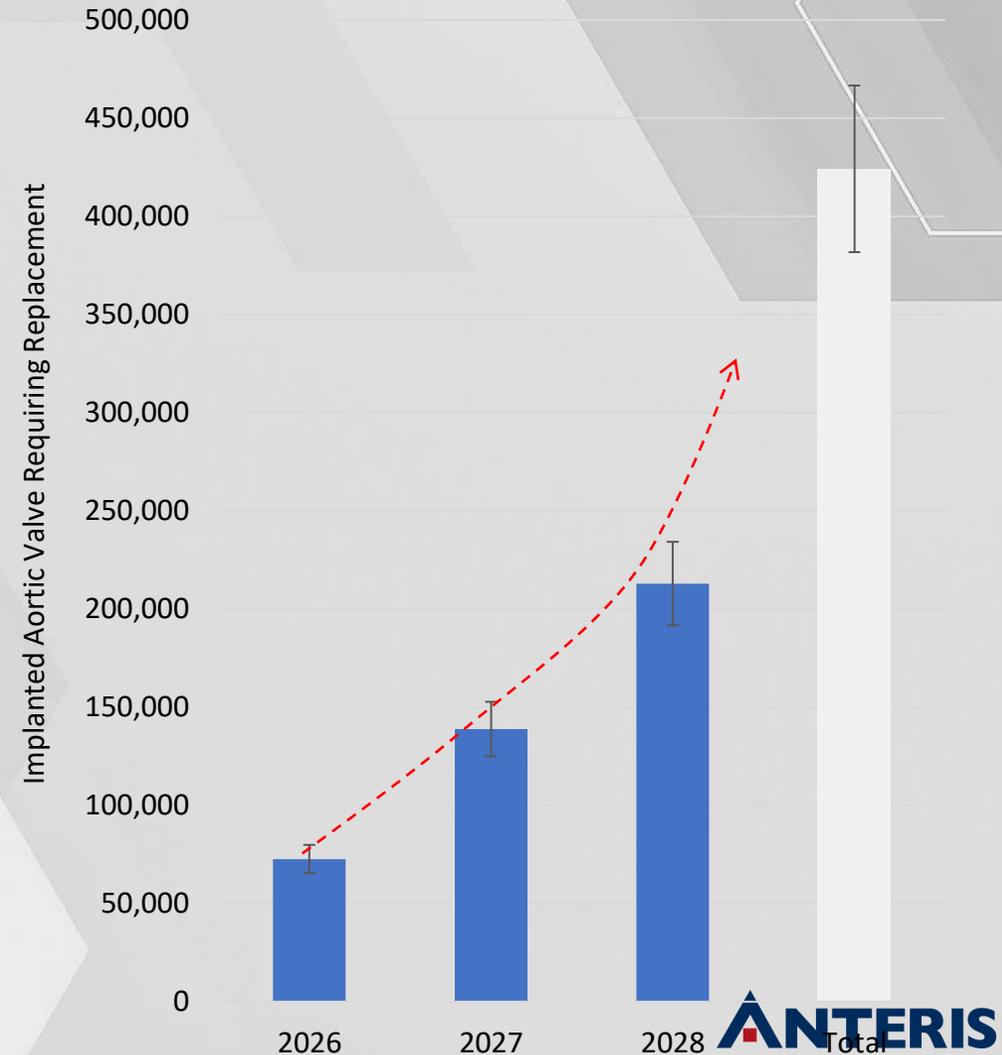
POWER OF TV

## An Evolving New Market for Repeat SAVR & TAVI Procedures

### Valve-in-Valve Represents a Large Growing Market for DurAVR™ THV

- Between 5 to 7 years after implantation of a bioprosthetic heart valve - they begin to fail
- 5% of current TAVR Procedures are ViV, projected to be 20% by 2026
- Younger and more active patients are now being treated, who will require several repeat valve procedures over their lifetime
- Growing demand by physicians & patients to have a Valve for Life the first time and if a replace of a failed first TAVI/SAVR

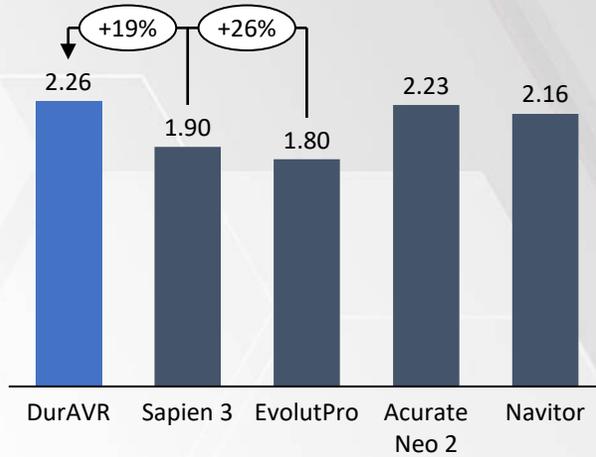
### Global Aortic Valve-in-Valve



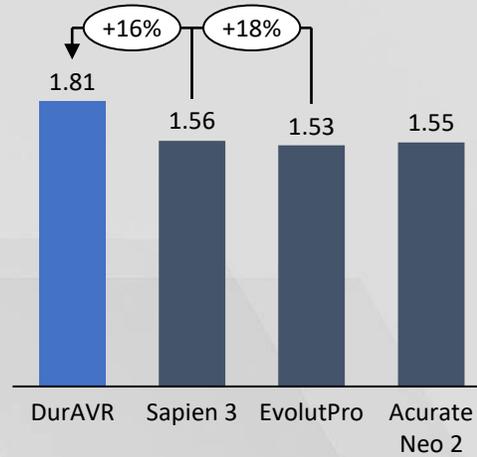
# TAV in 21mm SAV hydrodynamic results

## Magna Ease 21mm

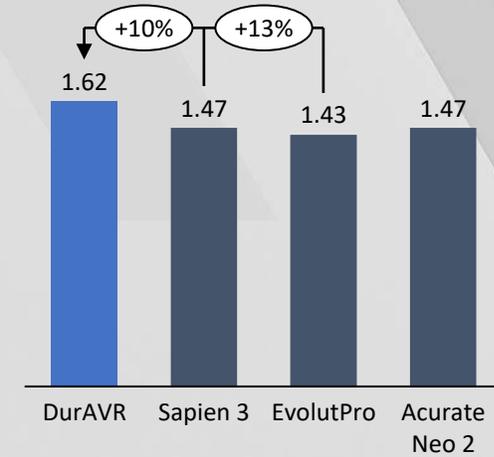
EOA  
(cm<sup>2</sup>)



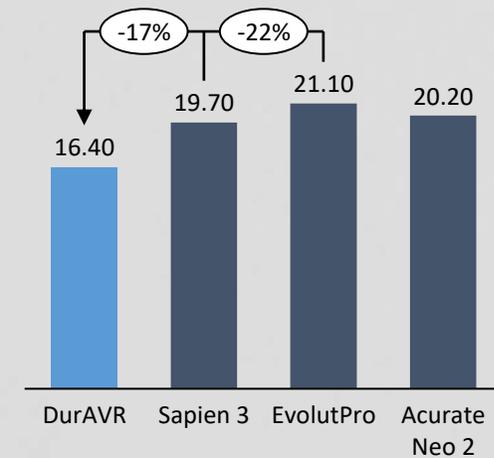
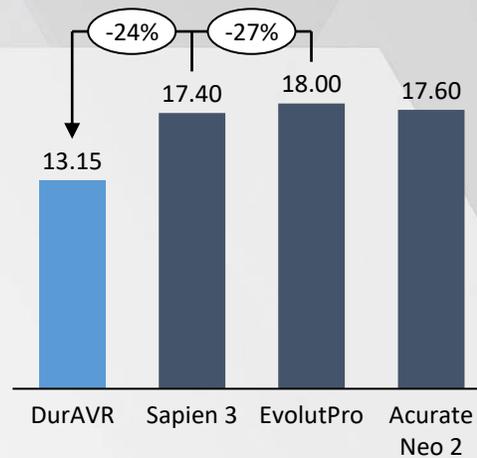
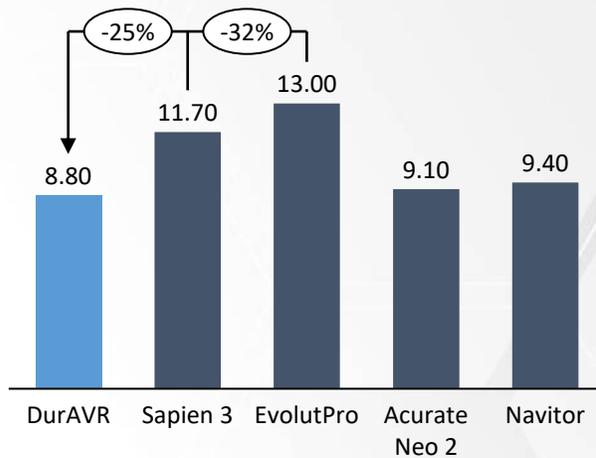
## Mosaic AV 21mm



## Hancock AV 21mm



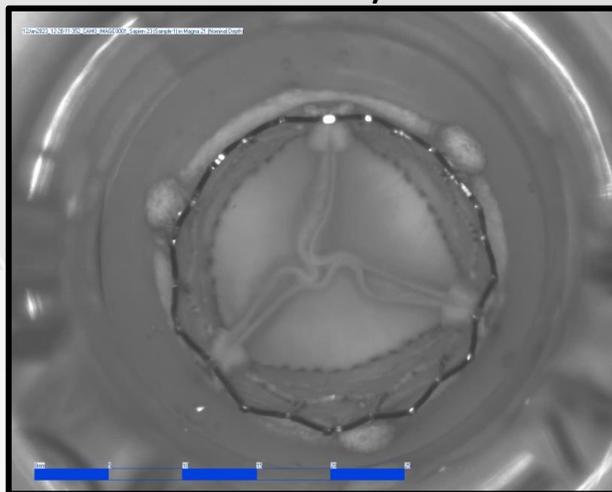
MPG  
(mmHG)



Note: Navitor too large according to ViV sizing app for Mosaic 21 and Hancock 21

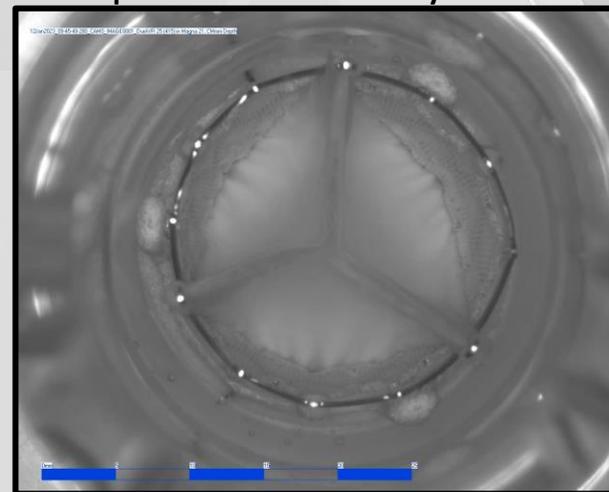
# DurAVR™ can address current challenges

### Poor Haemodynamics



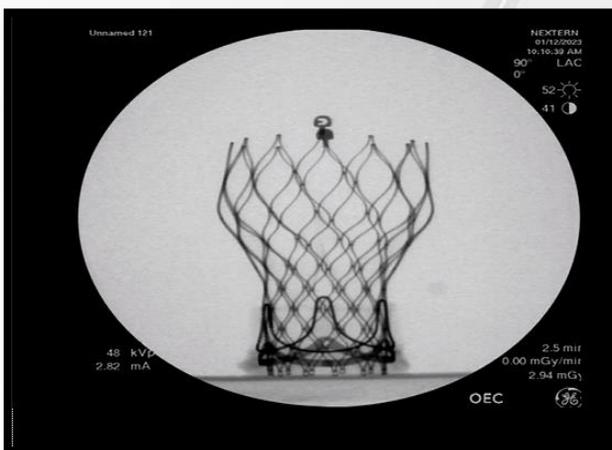
Sapien 23  
EOA 1.9  
MG 11.7  
Moderate pinwheeling

### Improved Haemodynamics



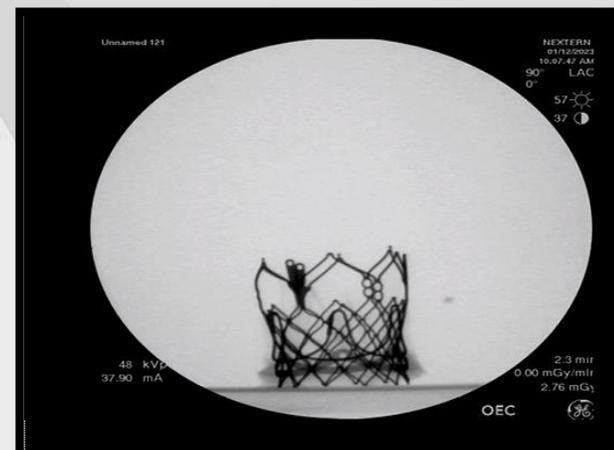
DurAVR™  
EOA 2.26 (+19%)  
MG 8.8 (-25%)  
No pinwheeling

### Poor Coronary Access



Evolut 23  
Tall frame prevents  
coronary access

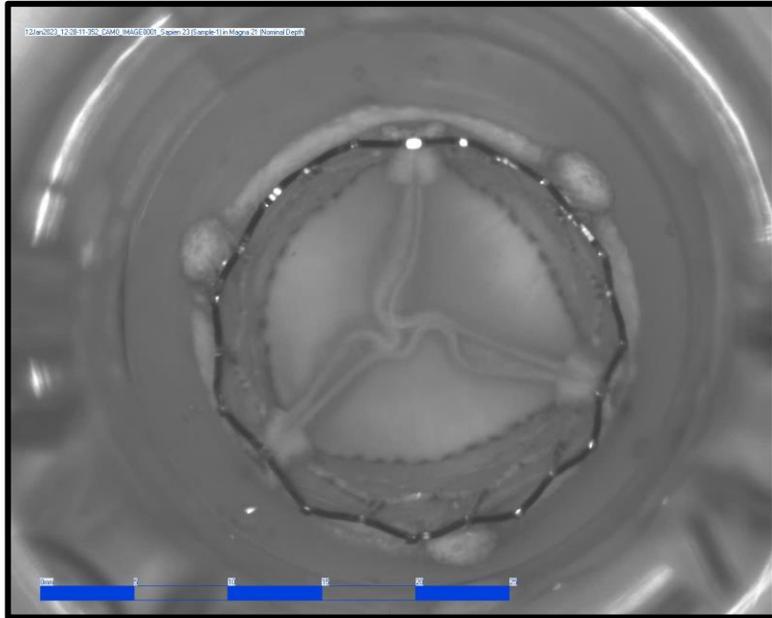
### Ease of Coronary Access



DurAVR™  
Short frame  
Large open cells  
Easy coronary access

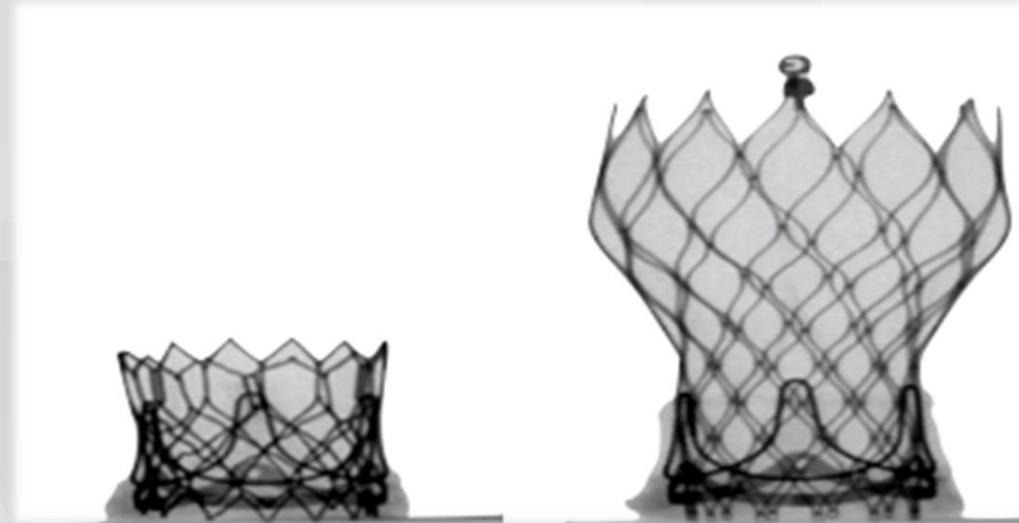
# Current valves: Result in clinical compromises

- Poor Haemodynamics



Sapien 23  
64% severe PPM

## Coronary Access Issues



ViV - in 21 mm Magna Ease SAVR

Evolut 23:  
Tall frame prevents  
coronary access

## Current valves do not address all these challenges

- Balloon expandable (BE) TAVR have poor haemodynamics in small SAVR
- Self expanding (SE) TAVR have moderate haemodynamics, but higher rates of limited future coronary access
- Physicians most often trade off coronary access for haemodynamics

# Yesterday's TAVR's Were Not Imagined For Today's Patients

1st and 2nd Generation TAVR's designed to solve different problems for today's patients

"Patients need a safe alternative to open heart surgery"

1<sup>st</sup> and 2<sup>nd</sup>  
Generation TAVRs

~85yrs



2011 – 2013 average patient age was 84<sup>(1)</sup>

"Patients need a valve that restores an active lifestyle for the rest of their life"

3<sup>rd</sup> Generation  
DurAVR™

~65yrs



From 2019 the average patient age is 73 and declining<sup>(2)</sup>

DurAVR™ was designed for younger and more active patients

Sources:  
(1) STS-ACCTVT Registry of Transcatheter Aortic Valve Replacement. J Am Coll Cardiol (2020);76:2492-2516.  
(2) N Engl J Med 2019; 380:1695-1705.

DurAVR™ THV IS NOT AVAILABLE FOR SALE, FOR CLINICAL INVESTIGATIONAL USE ONLY.

# Patients Need New Solutions that Last Longer and Work Better

## Valve Science Must Progress Beyond 3 Piece Designs

Younger patients  
now eligible



Guidelines  
TAVR as class for ages 65-80



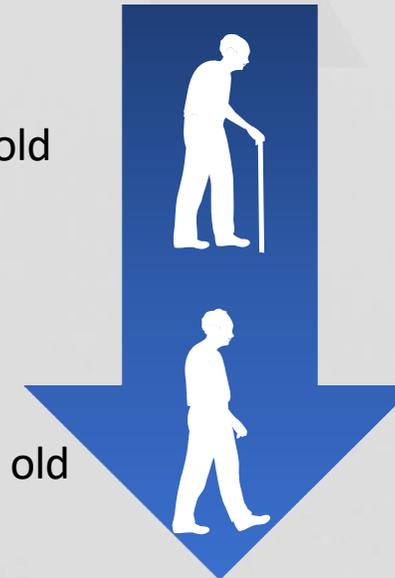
- Indications:
- Moderate
  - Asymptomatic



What Does  
this Mean?

~85 years old

PATIENT AGE



~65 years old

KEY CONSIDERATIONS

Life  
Expectancy

Exercise  
Capacity

Need to Avoid  
Valve-in-Valve

Need More "Normal"  
Haemodynamics



What else are we up to ?

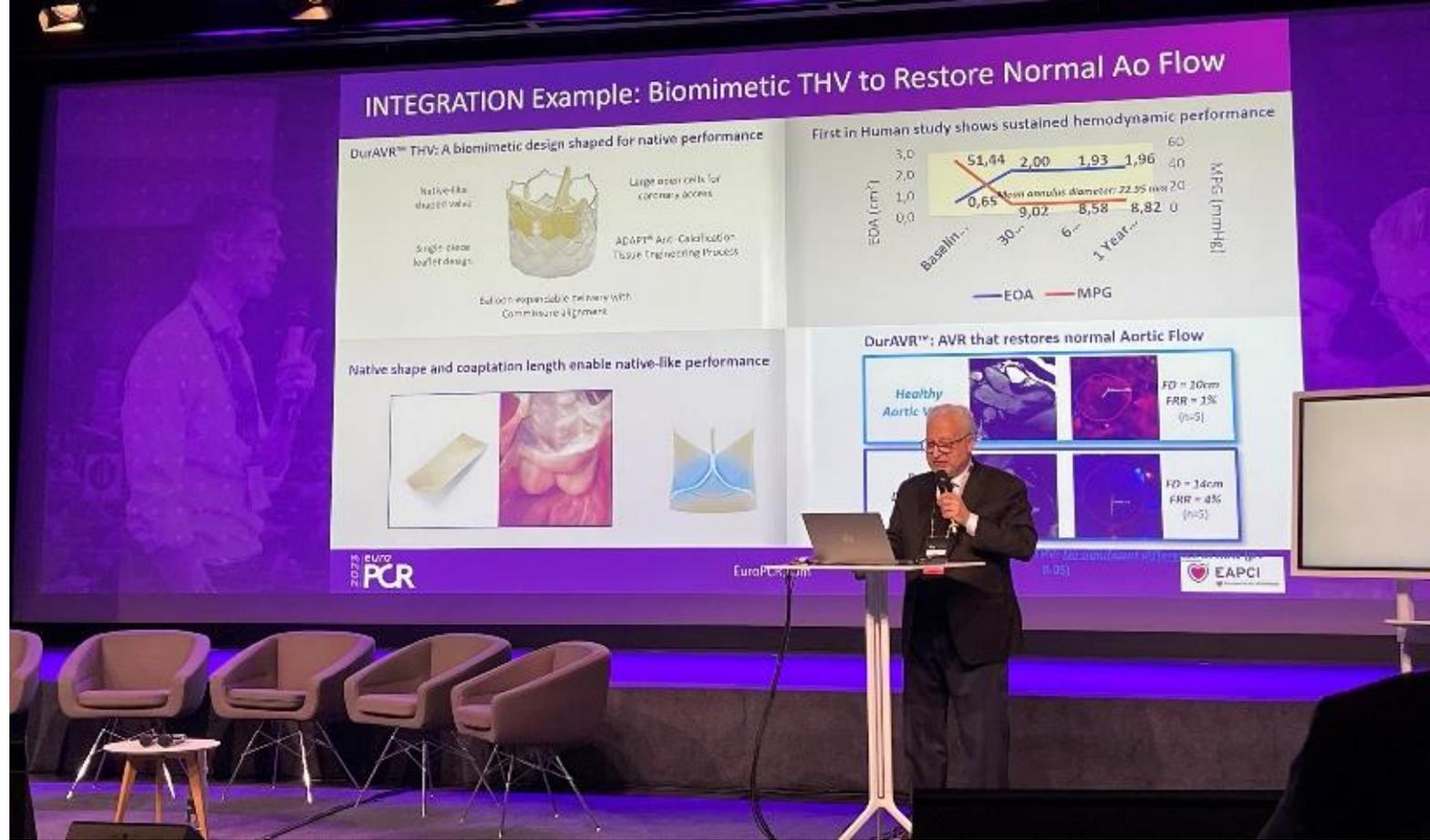


### DurAVR™: A First-in-class Biomimetic Transcatheter Aortic Valve

**DurAVR™ THV System**

- DurAVR™ THV Biomimetic valve**
  - Native-like shaped valve
  - Balloon-expandable large cells
  - ADAPT™ Anti-Calcification Tissue Engineering Process
  - Commissure alignment
  - Single piece leaflet design
  - PVI skirt
- ComASUR™ TF Delivery System**

Logos: EuroPCR.com, EAPCI



### INTEGRATION Example: Biomimetic THV to Restore Normal Ao Flow

**DurAVR™ THV: A biomimetic design shaped for native performance**

- Native-like shaped valve
- Large open cells for coronary access
- Single piece leaflet design
- ADAPT™ Anti-Calcification Tissue Engineering Process
- Balloon-expandable networks with commissure alignment

**First in Human study shows sustained hemodynamic performance**

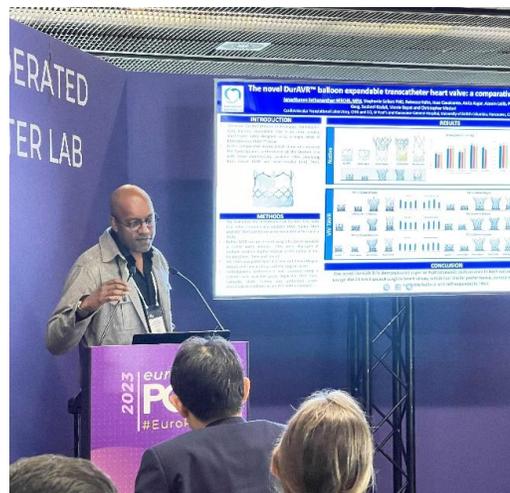
Parameter	Baseline	30 min	6 min	1 Year
EOA (cm <sup>2</sup> )	51.44	2.00	1.93	1.96
MPG (mmHg)	0.65	9.02	8.58	8.82

Legend: EOA (blue line), MPG (red line)

**DurAVR™: AVR that restores normal Aortic Flow**

Flow State	FD (cm)	FRR (%)	n
Healthy Aortic Valve	30	3%	5
DurAVR™	14	4%	5

Logos: EuroPCR, EAPCI



#### The novel DurAVR™ balloon expandable transcatheter heart valve: a comparative...

**INTRODUCTION**

**RESULTS**

**CONCLUSION**



### Performance Comparison

Parameter	n=5	Baseline
EOA (cm <sup>2</sup> )	0.5	51.44
MPG (mmHg)	58.0	0.65

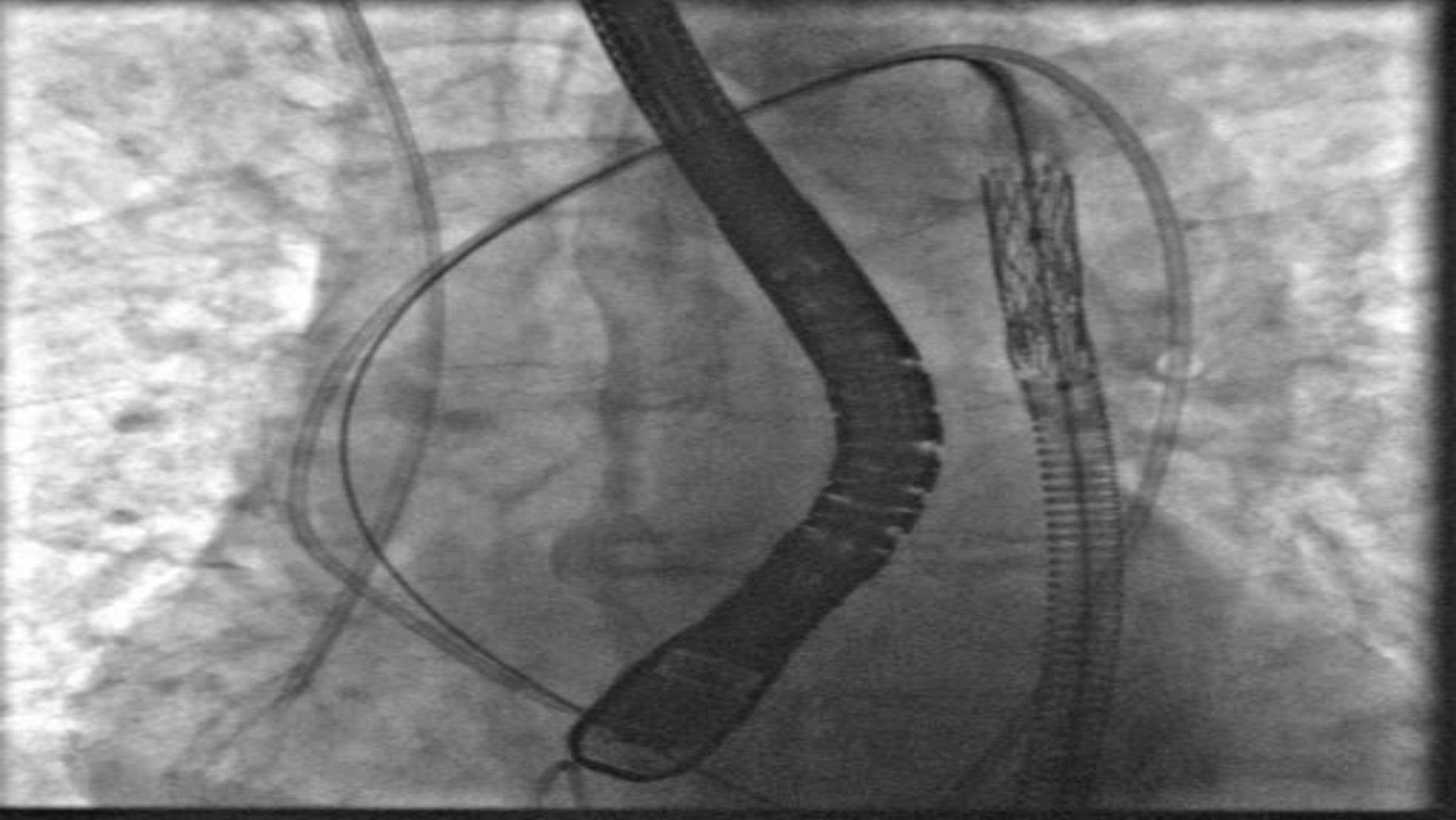
**DurAVR™ First-in-Class Clinical Study**

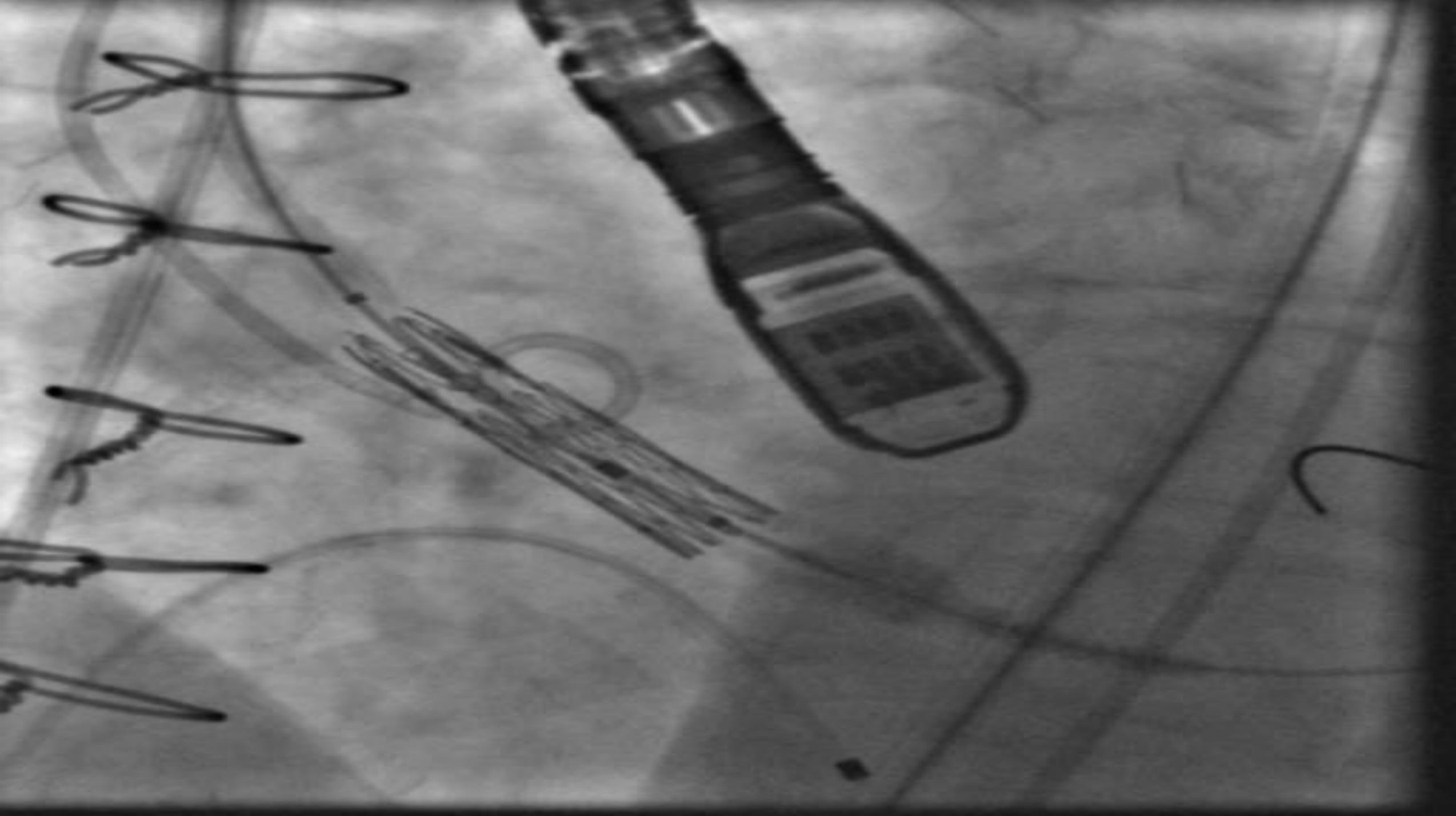




**ComASUR™**  
TRANSFEMORAL DELIVERY SYSTEM







United States of America

To Promote the Progress of Science and Useful Arts

The Director of the United States Patent and Trademark Office has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this United States

# Patent

grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America, and if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States of America, products made by that process, for the term set forth in 35 U.S.C. 354(a)(2) or (c)(1), subject to the payment of maintenance fees as provided by 35 U.S.C. 41(b). See the Maintenance Fee Notice on the inside of the cover.

Katherine Kelly Vidal  
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

**(12) United States Patent**  
Quill et al.

(10) Patent No.: **US 11,622,853 B1**  
(45) Date of Patent: **Apr. 11, 2023**

(54) **PROSTHETIC HEART VALVES**

(71) Applicant: **Anteris Technologies Corporation**, Eagan, MN (US)

(72) Inventors: **Jason Quill**, Forest Lake, MN (US); **William Leon Neethling**, Booragoon (AU); **Christopher B. Brodeur**, Plymouth, MN (US); **Ramji Iyer**, Plymouth, MN (US); **Kathya Roth**, Plymouth, MN (US)

(73) Assignee: **Anteris Technologies Corporation**, Eagan, MN (US)

(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **17957,675**

(22) Filed: **Sep. 30, 2022**

(51) Int. Cl. **A61F 2/24** (2006.01)

(52) U.S. Cl. **A61F 2/2418** (2013.01); **A61F 2/2412** (2013.01); **A61F 2/2415** (2013.01)

(57) **Field of Classification Search**  
CPC — A61F 2/2412; A61F 2/2415; A61F 2/2418  
See application file for complete search history.

(56) **References Cited**  
U.S. PATENT DOCUMENTS

4,624,822	A	11/1986	Arn et al.
5,855,401	A	1/1999	Basler et al.
6,491,511	B1	12/2002	Doran et al.
6,682,559	B2	1/2004	Myers et al.
7,025,780	B2	4/2006	Gabbay
7,087,079	B2	8/2006	Navia et al.

8,778,018 B2 7/2014 Iobbi  
8,992,599 B2 3/2015 Thabrizar et al.  
9,011,523 B2 4/2015 Chalhoub, III et al.  
9,095,430 B2 8/2015 Cunanan et al.  
9,162,470 B2 11/2015 Cai et al.  
9,205,172 B2 12/2015 Leonard Neethling et al.  
9,259,313 B2 2/2016 Wheatley  
9,301,853 B2 4/2016 Campbell et al. (Continued)

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EP	2777618	9/2014

(Continued)

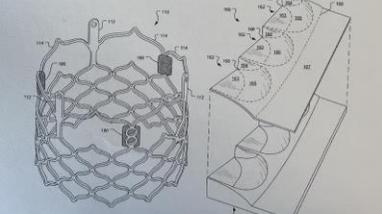
**OTHER PUBLICATIONS**

International Search Report and Written Opinion in International Applica. No. PCT/US2018/030669, dated Nov. 26, 2018, 10 pages. (Continued)

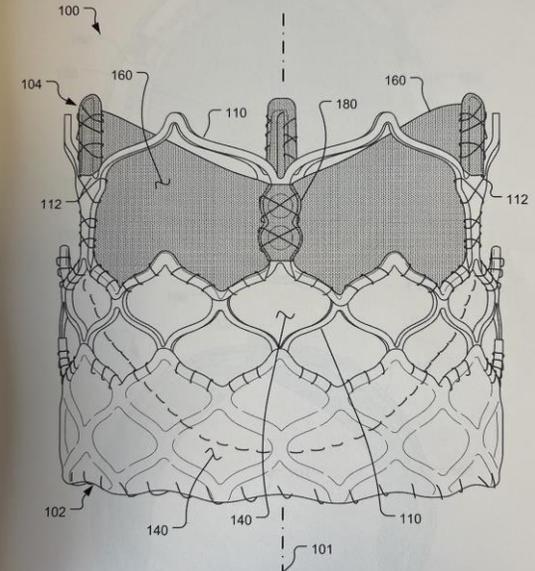
**Primary Examiner** — Subh Ganesan  
(74) Attorney, Agent, or Firm — Fish & Richardson P.C.

(57) **ABSTRACT**  
This document provides devices and methods for the treatment of heart conditions. For example, this document provides prosthetic heart valves and transcatheter heart valve replacement methods. The prosthetic heart valves can be configured into a low-profile configuration for containment within a small diameter delivery sheath. The prosthetic heart valves include can include a valve member attached to a stent frame. In some embodiments, the valve member is a molded biomaterial with a novel shape and resulting performance characteristics. Localized protective covering members can be attached to the stent frame to prevent the valve member from contacting the stent frame as the valve member cycles between its open and closed configurations.

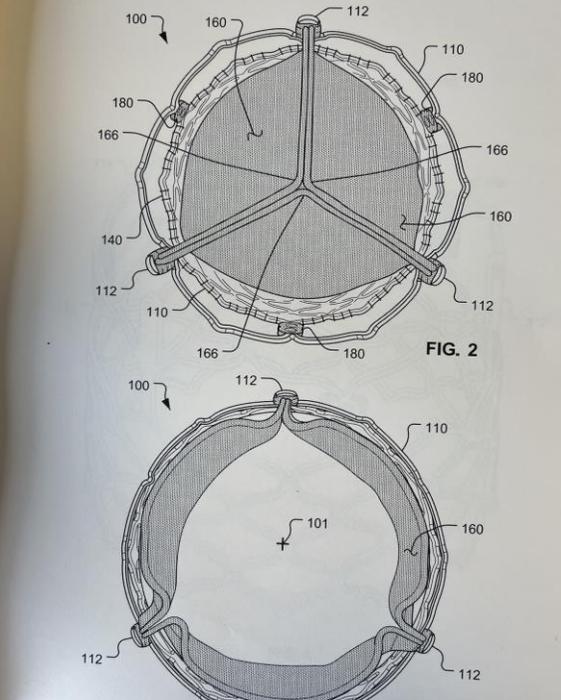
**20 Claims, 6 Drawing Sheets**



U.S. Patent Apr. 11, 2023 Sheet 1 of 6 US 11,622,853 B1



U.S. Patent Apr. 11, 2023 Sheet 2 of 6 US 11,622,853 B1



New Patents issued that change the landscape

# Patents that change the landscape

US Patent 11,648,107 provides Anteris with exclusivity to protect the following key features of the DurAVR™ THV:

- The single-piece 3-dimensionally molded biomimetic valve for high performance and fatigue resistance

US Patent 11,622,853 provides Anteris with exclusivity to protect the following key features of the DurAVR™ THV:

- The specific geometry of the biomimetic valve's molded shape for superior haemodynamics
- The structure of the stent framework with large cells and smaller cells
- The protective materials on the stent framework in locations that eliminate direct contact between the valve and stent for enhanced durability

## United States Patent Durl et al.

### PROSTHETIC HEART VALVES

Applicant: **Anteris Technologies Corporation**,  
Eagan, MN (US)

Inventors: **Jason Quill**, Forest Lake, MN (US);  
**William Leon Neethling**, Booragoon  
(WA); **Christopher B. Brodeur**,  
Plymouth, MN (US); **Ramji Iyer**,  
Plymouth, MN (US); **Kaitlyn Roth**,  
Plymouth, MN (US)

Assignee: **Anteris Technologies Corporation**,  
Eagan, MN (US)

Subject to any disclaimer, the term of this  
patent is extended or adjusted under 35  
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(52) **U.S. Cl.**  
CPC ..... **A61F 2/2418** (2013.01); **A61F 2/2412**  
(2013.01); **A61F 2220/0075** (2013.01)

(58) **Field of Classification Search**  
CPC ..... **A61F 2/2412**; **A61F 2/2415**; **A61F 2/2418**  
See application file for complete search history.

(56) **References Cited**

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4,624,822 A	11/1986	Arru et al.
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6,682,559 B2	1/2004	Myers et al.
7,025,780 B2	4/2006	Gabbay
7,087,079 B2	8/2006	Navia et al.

(10) **Patent No.:** **US 11,622,853 B1**  
(45) **Date of Patent:** **Apr. 11, 2023**

8,778,018 B2	7/2014	Iobbi
8,992,599 B2	3/2015	Thubrikar et al.
9,011,525 B2	4/2015	Claiborne, III et al.
9,095,430 B2	8/2015	Cunanan et al.
9,192,470 B2	11/2015	Cai et al.
9,205,172 B2	12/2015	Leonard Neethling et al.
9,259,313 B2	2/2016	Wheatley
9,301,835 B2	4/2016	Campbell et al.

(Continued)

#### FOREIGN PATENT DOCUMENTS

CN	203736349	7/2014
EP	2777618	9/2014

(Continued)

#### OTHER PUBLICATIONS

International Search Report and Written Opinion in International  
Appl. No. PCT/US2018/050669, dated Nov. 26, 2018, 10 pages.

(Continued)

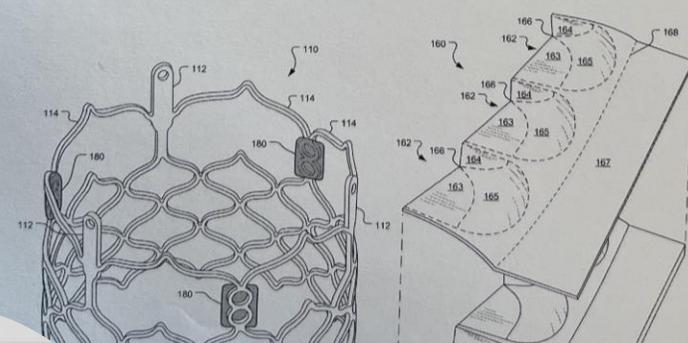
*Primary Examiner* — Suba Ganesan

(74) *Attorney, Agent, or Firm* — Fish & Richardson P.C.

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This document provides devices and methods for the treatment of heart conditions. For example, this document provides prosthetic heart valves and transcatheter heart valve replacement methods. The prosthetic heart valves can be configured into a low-profile configuration for containment within a small diameter delivery sheath. The prosthetic heart valves include can include a valve member attached to a stent frame. In some embodiments, the valve member is a molded biomaterial with a novel shape and resulting performance characteristics. Localized protective covering members can be attached to the stent frame to prevent the valve member from contacting the stent frame as the valve member cycles between its open and closed configurations.

**20 Claims, 6 Drawing Sheets**





US facilities validated and online

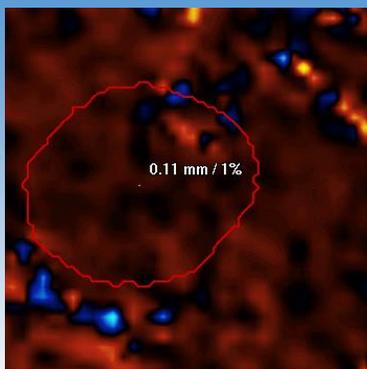
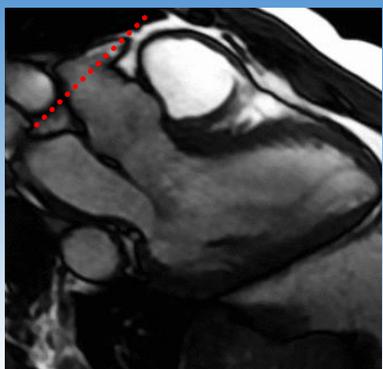


Taking the clinical discussion forward

# DurAVR™: First AVR Shown to Restore Normal Aortic Flow

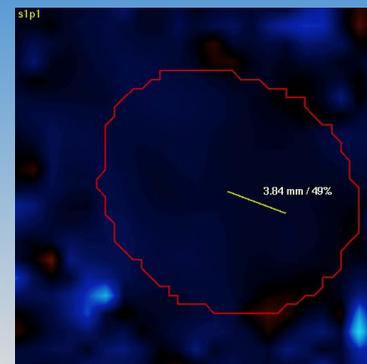
Normal Valve Flow vs DurAVR™ : No Significant Difference in Flow (p=0.45)

## Healthy Aortic Valve



Flow Displacement (FD) = 12%  
Flow Reversal Ratio (FRR) = 0%

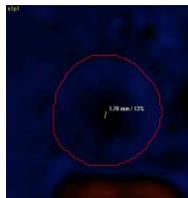
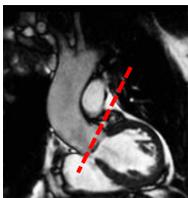
## Post DurAVR™ HV



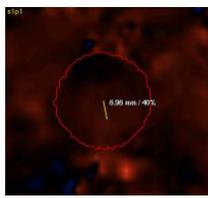
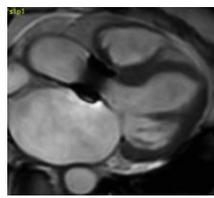
Flow Displacement (FD) = 14%  
Flow Reversal Ratio (FRR) = 4%

## Impaired Aortic Flow

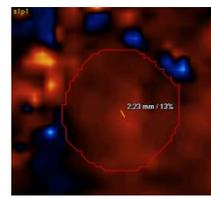
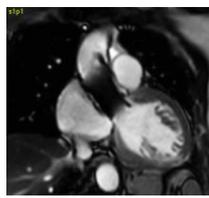
Severe AS  
FD = 46%  
FRR = 23%



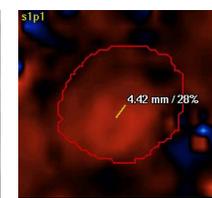
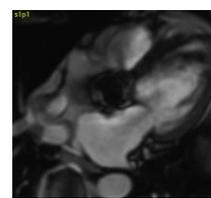
Edwards' Sapien 3  
FD = 48%  
FRR = 35%



Medtronic's Evolut R  
FD = 25%  
FRR = 4%



Edward's CEP Magna Ease  
FD = 27%  
FRR = 30%

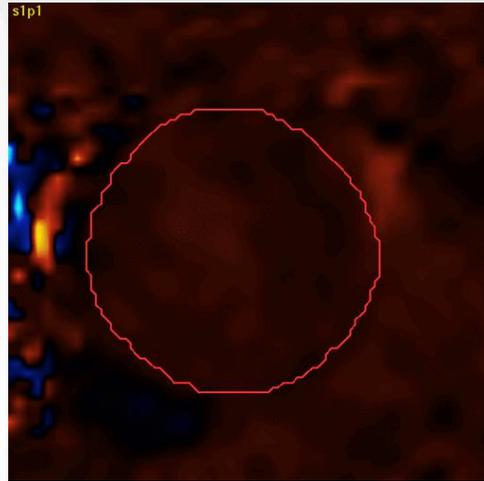


Severe AS

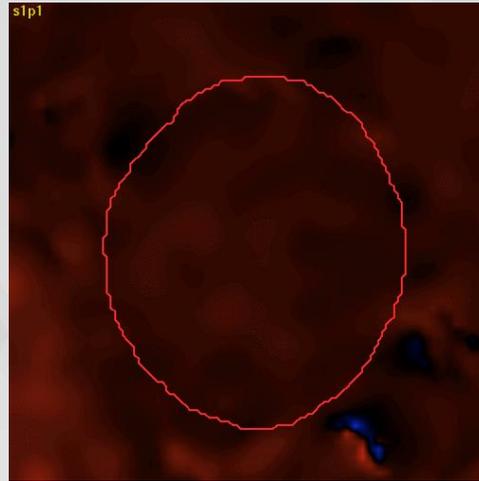
Normal Valve Flow vs TAVR:  
p<0.05

Normal Valve Flow vs SAVR:  
p<0.001

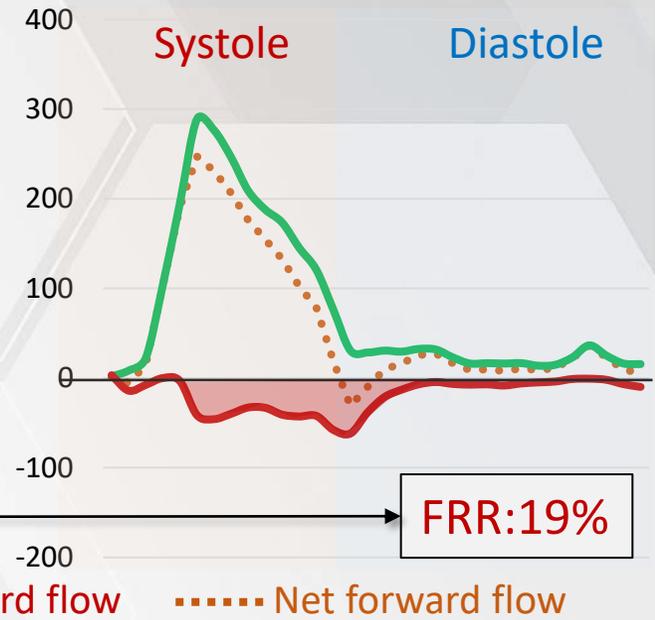
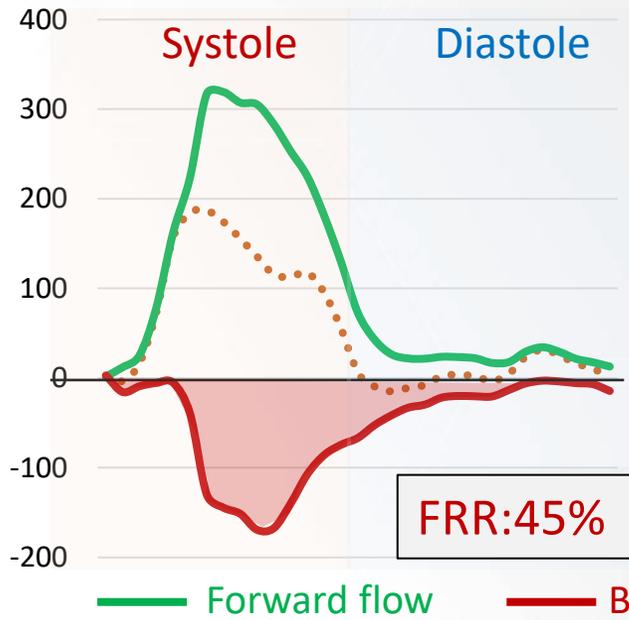
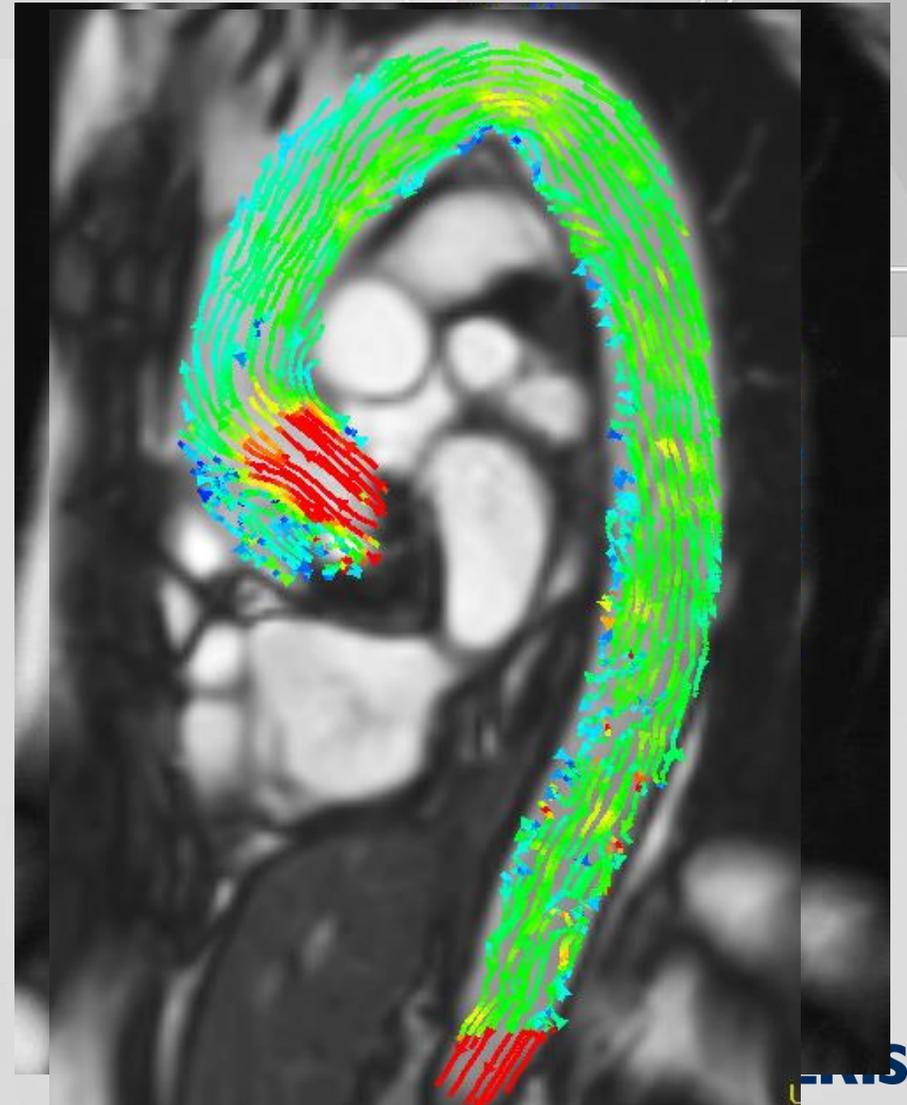
Pre-intervention



Post DurAVR™  
implantation at 12  
months

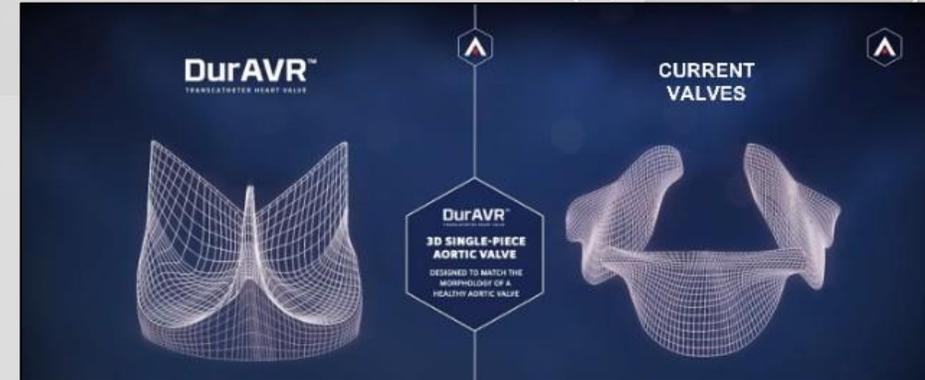


Flow streamlines at peak systole  
demonstrating restoration of normal flow  
patterns



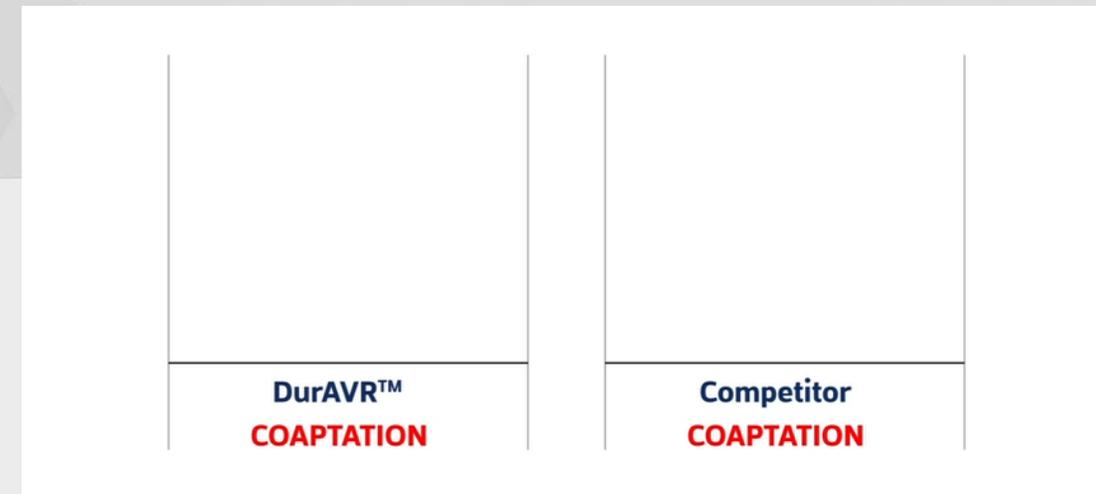
# DurAVR™ Shaped to Perform like Native Aortic Valve

Optimizes flow dynamics, restoring haemodynamic performance



Single Piece

Three Piece



Graphical representation of the 3D single-piece geometry of DurAVR™ THV (left), and standard balloon-expandable TAVI devices (right).



Collaborations that drive value



# Research Collaboration

## Anteris – Ear Science Institute



[anteristech.com](https://www.anteristech.com)

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# Next Gen DurAVR™ that can be injection molded



Anteris

- Novel Protein + Polyurethane/Glycerol Scaffold
- Scaffold development
- Prototype manufacturing & optimization

- Scaffold testing
- Valve Design & Engineering Concepts
- Prototype - performance testing

First Single Piece Heart Valve Prototype - POC





## V2V Medtech

The next big thing in  
mitral valve repair



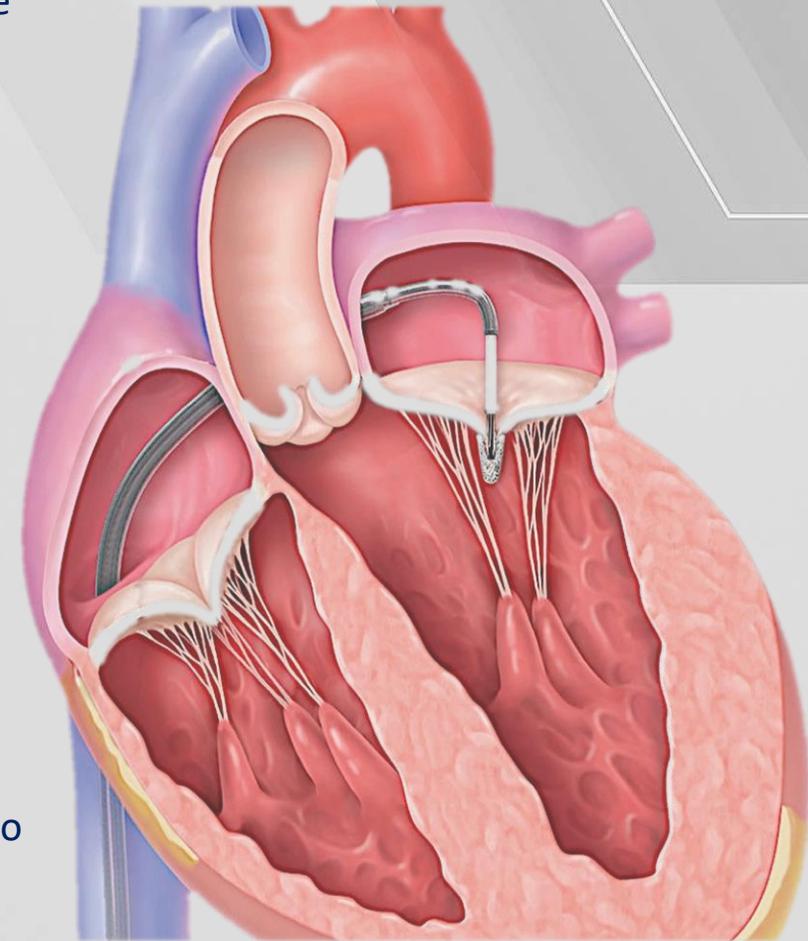
[anteristech.com](https://www.anteristech.com)

Follow us @anteristech



# V2Vmedtech – Innovative mitral valve TEER device

- Development of a minimally invasive device for the treatment of mitral and tricuspid valve regurgitation
- Anteris will partner with leading physicians including Dr. Vinayak Bapat (v2v CMO and primary developer)
- Market is expected to be A\$4.1B by 2028<sup>1</sup>
- Adjacent to the DurAVR™ TAVR market
- Anteris will contribute cash and in-kind contributions providing engineering, clinical, regulatory, marketing and executive management resources
- Anteris holds two of three Board positions in addition to CEO / CFO
- Ownership interest of 30%. Potential to increase to between 58% and 60% linked to contributions and milestones. Upon achievement of FIH, Anteris can potentially increase to 100%



# Capitalizing on a culture of Dr driven innovation

“Fixed” TEER devices lack the ability to treat a range of mitral anatomies

V-Clip is a versatile TEER device that can address anatomical configurations – uniquely expanding TEER therapy to more patients that otherwise would be sent to surgery

## Fixed Clip

MitraClip

Pascal

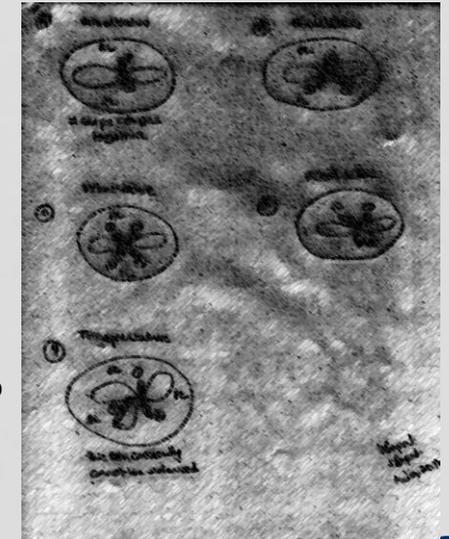


## Versatile Clip

V-Clip

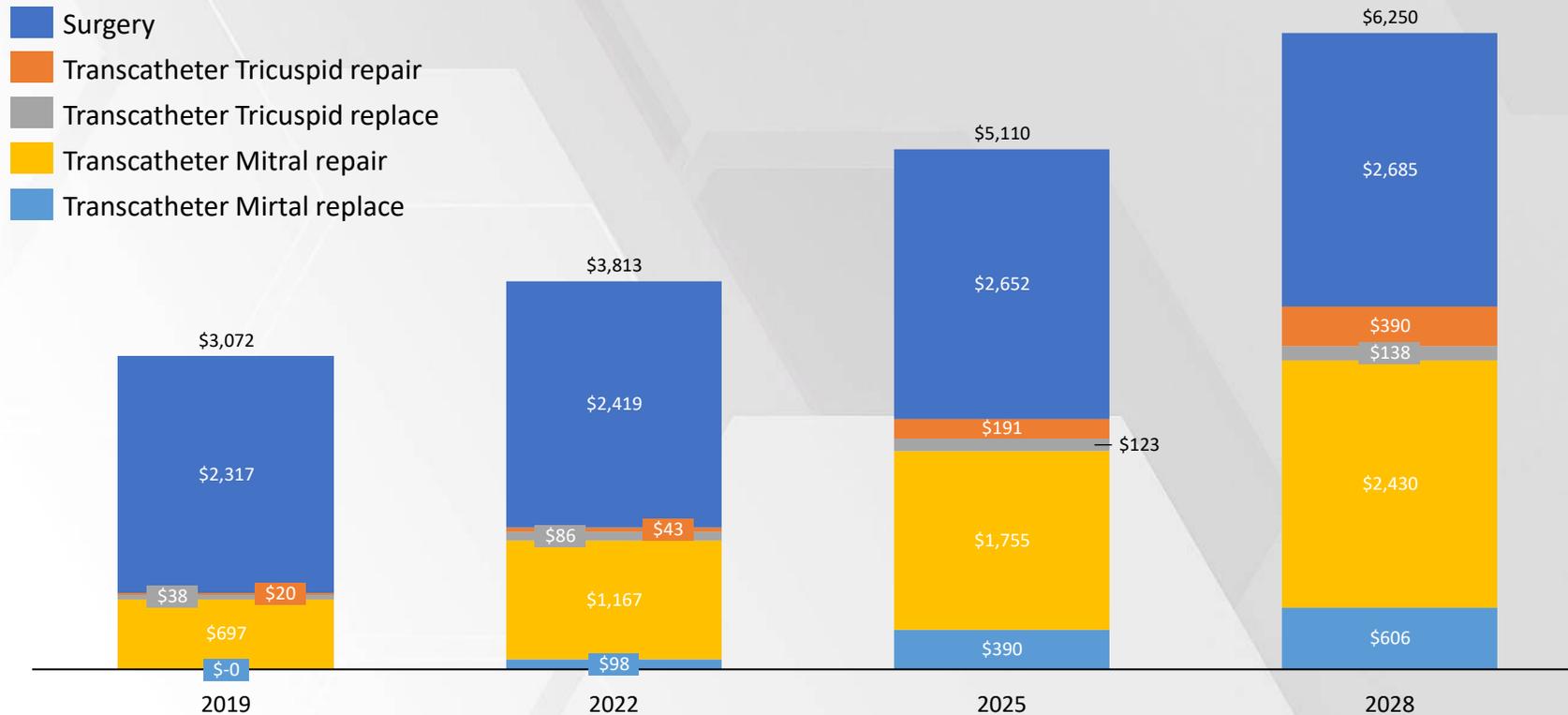
Independent clips to individually clasp the anterior and posterior leaflets

Clips are cinched together to complete the anterior and posterior leaflet coaptation



# 13.9% CAGR resulting in 2028 Market of ~US\$2.8B

## TMTT Market Revenue (\$M)



In 2022 Surgery is the Gold Standard Treatment for Mitral valve disease.

By 2028 Surgery is still the prevalent treatment for TMV and TTV Repair.

But TMV and TTV Repair with ASP of US\$25k makes up 45% of revenue share.

\* Clarivate Market Data 2021

Assume TMV/TTV Repair ~ASP US\$25,000

# Anteris Institutional Partnerships



Partnering to Define a New Paradigm in Aortic Valve Science



COLUMBIA UNIVERSITY  
MEDICAL CENTER



MINNEAPOLIS  
HEART  
INSTITUTE

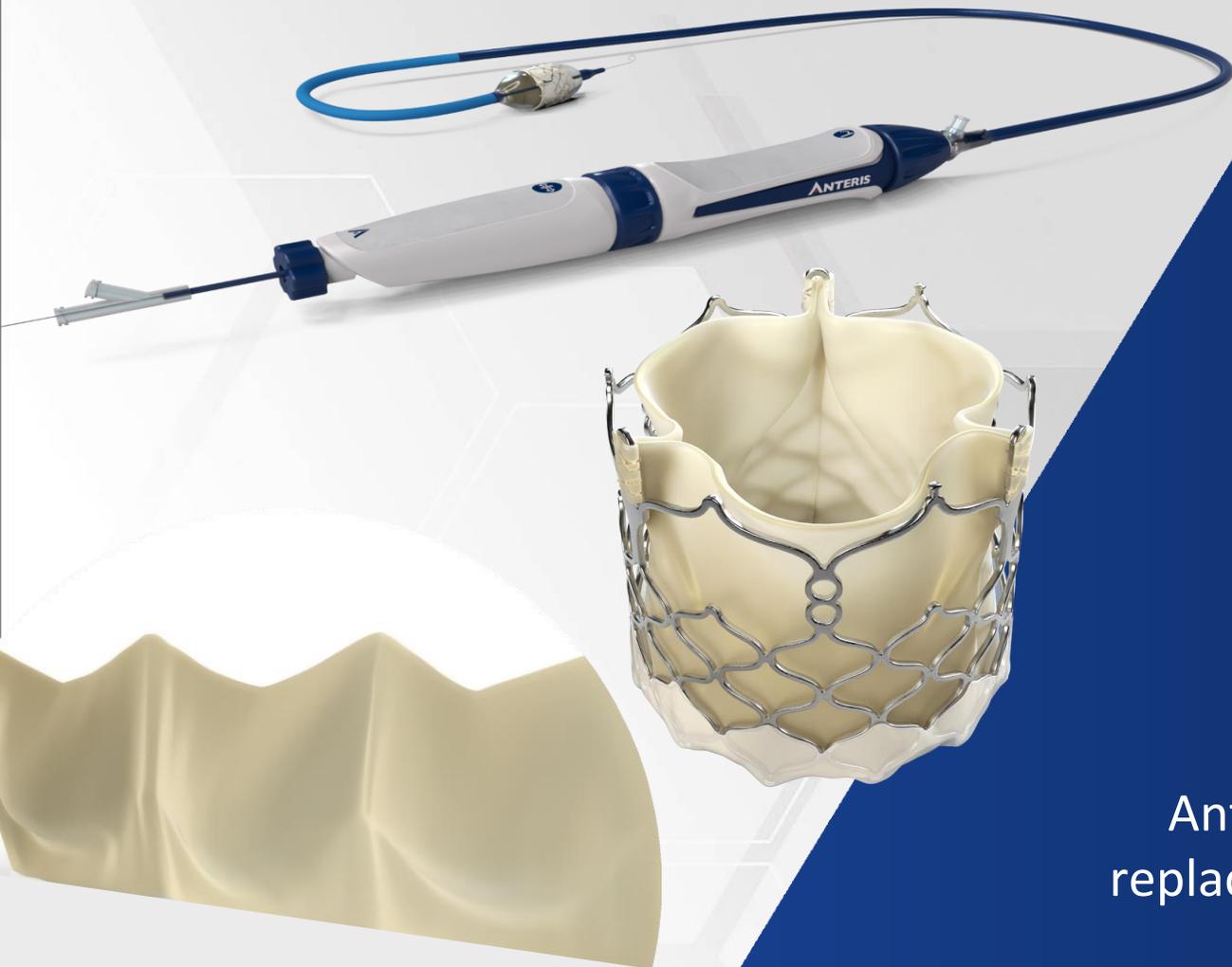


A person is standing on a tall, black ladder that extends from the bottom of the frame towards the top. The person is wearing a light-colored t-shirt and dark shorts, and is reaching up with their right hand towards the text. The background is a bright blue sky with scattered white clouds. The text 'WHERE DO WE GO FROM HERE?' is written in a large, light blue, sans-serif font across the middle of the image.

WHERE DO WE GO FROM HERE?

The sky really is the limit

# Anteris Has Addressed Unmet Medical Needs With A New Class Of Product



By combining....

- Tissue science (ADAPT®)
- Valve design (DurAVR™)
- Physician developed delivery system (ComASUR™)

Anteris has created a more “human like” aortic valve replacement with results that reflect pre-disease states

# Milestones

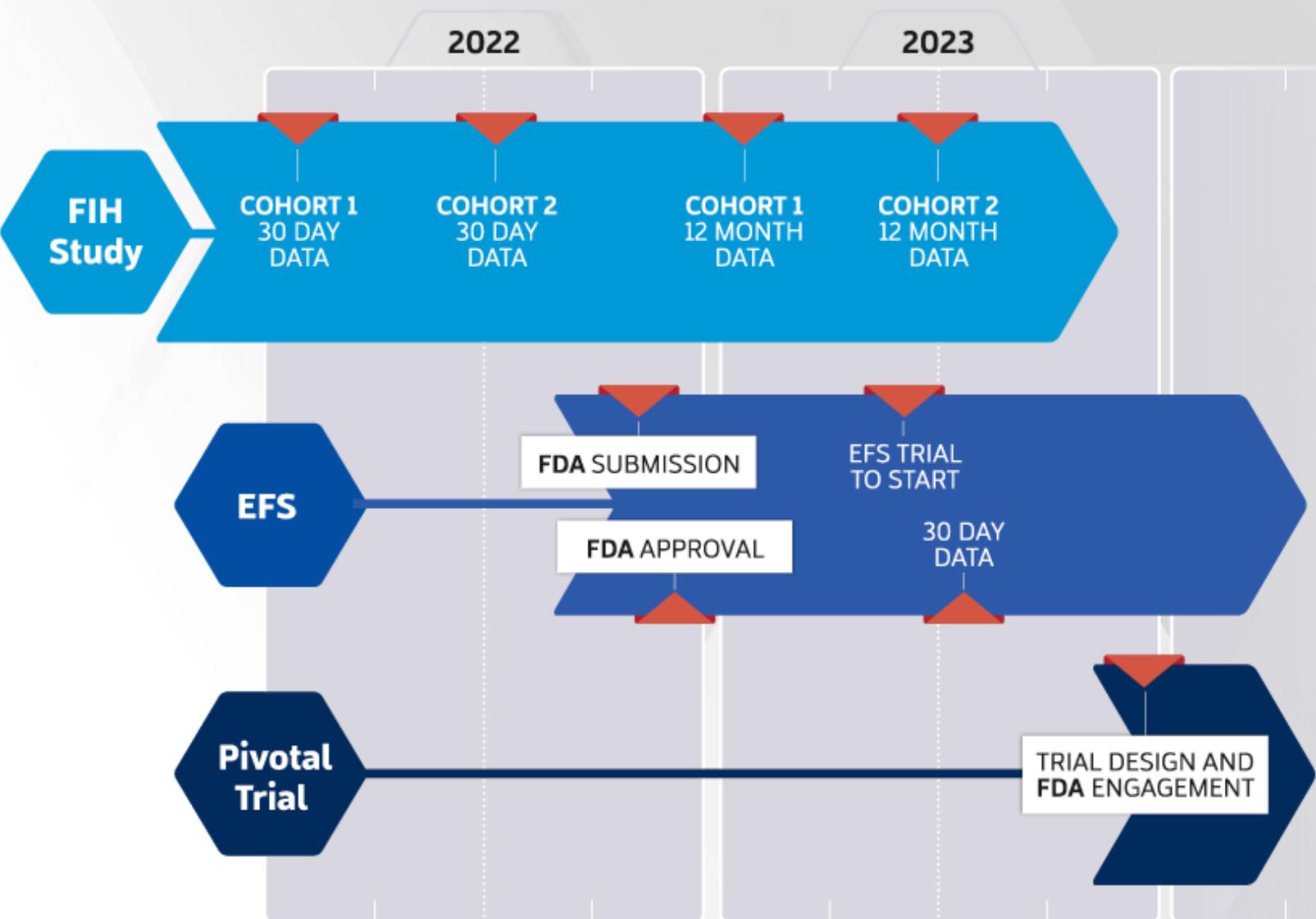


- ✓ ADAPT® Commercial Use - Global
- ✓ ADAPT® vs. AOA Anti-Calcification Study
- ✓ DurAVR™ THV Design Validation
- ✓ ComASUR™ Design Validation
- ✓ Bench and Pre-clinical Studies
- ✓ DurAVR™ THV FIH Valve Study - Ethics Submission
- ✓ Patent Grant (ComASUR™ Transcatheter System)
- ✓ Key Partnerships with IQVIA & CRF
- ✓ DurAVR™ THV First in Human Trial - Cohort 1 (5 pats)
- ✓ ComASUR™ Alignment used in DurAVR Patients
- ✓ DurAVR™ THV First in Human Trial - Cohort 2 (8 pats)
- ✓ US FDA EFS Approval
- ✓ DurAVR™ THV First in Human Trial - Cohort 3 (8 pats)

We are past the POC stage !

- ✓ Early Feasibility Study (USA)
- Global Pivotal Study
- US Regulatory Approval

# Path to Commercialisation



M&A

Go  
alone

Partnership



# Anteris investment thesis

Anteris has introduced the first new valve design in over 20 years

- Anteris has demonstrated significant clinical benefits for patients and therefore commercial viability and potential market leadership (>51%) in a USD \$10bn market
- Anteris is supported by Global Tier 1 Physicians, Scientists and Institutions
- Anteris' key investors are mostly physician led and based between New York and Australia
- Due to its clinical results, Anteris is a potential acquisition target as it will disrupt current incumbents' market share
- Anteris also has the ability to commercialize alone and is therefore a credible threat to established players in a USD \$10bn market by 2028



# Key account focus enables self funding commercial rollout upon launch

- Anteris anticipates >5% (USD 250-300 million) market share in the first 12 months post launch based on currently proven clinical results (best in class)
- TAVR procedures continue to be concentrated in high volume centers.
- 65% volume comes from top 20% of centers
- Anteris is well covered in these centers currently via its Medical Advisory Board physicians.
- Regulatory approval (clinical trials) and early commercialization costs are within the scope of our capital management strategy.
- 5% share in US = 50% share in top 10 centers or 25% share in top 35 centers

