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# How can new TAVI Valves Reduce Complications

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# **Financial Disclosure**

I, Eberhard Grube have the following financial interest/arrangement that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation

**Speaker Bureau/ SAB:** Medtronic, Boston Scientific, HighLife, Jena Valve, Protembis, Anteris, Valve Medical

<u>Equity Interest:</u> Cardiovalve, Claret, Shockwave, Valve medical, CardioMech, Millipede, Imperative Care, Pi-Cardia, Ancora, Laminar, ReNiva Medical

## The Ideal Transcatheter Aortic Valve



Next Generation THV design with a focus on Lifetime Management of Aortic Stenosis *Priorities for the Future* 

	Optimize index procedure	Safety, reproducibility, low access profile, personalized valve sizing, PVL solution
Patient ifetime	Extend valve longevity	Novel tissue technology, valve design
	Maintain coronary access	Short frame height, commissural alignment
	Plan for	Control of valve orientation relative to anatomy

## Device Technology *Alternative Materials*

New tissue processes and novel materials are actively being researched, and this research may address shortcomings of current bioprosthetic valves.



# New TAVI Valves in 2023

Clinical trial and real-world data show that the new TAVI systems are producing excellent clinical outcomes.

They are improving and addressing further: Conduction-, PVL-, Coronary - and Peripheral Access issues ("Lifetime Management")

## Improve Deployment Accuracy, Ease of Use



# **Ensure Durability**





Tissue engineering

FEA Modeling

Animal Testing

# What are the current Challenges for TAVI devices?



#### AR and PVL

Vascular Complications

Stroke

Conduction Disturbances

# Associated with mortality







#### STS National Database Trusted, Transformed, Real-Time.

In-Hospital, 30 Day, and One Year Stroke







2%

1.4%

2022 Q1

1.5%

# So many TAVI choices...how do we optimize outcomes with each? And which Device is Best for which Patient?







#### • Acurate Neo 2

- Portico/Navitor
- My Val

Increasing Clinical Use/Next in Line



- Jena Valv/J Valve
- Venus A Valve







### Others!

- VitaFlow
- Taurus One
- Trinity
- Colibri
- Inovare
- Thubrikar
- HLT Meridian
- NVT
- Xeltis
- Zurich TEHV

- Direct Flow
- Engager
- Centera

### So many Choices



#### Distill the Essentials



No matter the Device, there are two Keys to optimizing TAVR Outcomes and reducing Complications

> Patient Evaluation and Sizing utilizing 3D Measurements for both Access and Valve, consider specific risk factors

Correct Implant Technique to get the device in the right location with minimal complications

Each device has its own nuances for sizing and for implant technique – you must understand the specifics for the device you are choosing!

## Optimizing outcomes begins with the patient

#### Anatomical Risk Factors for PVL, Vascular Complications, & Stroke

- Highly calcified:
  - Iliac arteries
  - Aorta
  - Femoral arteries
  - Annulus
- Highly tortuous:
  - Iliac arteries
  - Aorta
  - Femoral arteries



#### Patients with the above risk factors should be given a device: designed to minimize PVL, vascular complication, and stroke

# Evolut<sup>™</sup> FX TAVI System New Technology





### **Evolut FX Design Features**

- Nosecone redesign
- More flexible capsule
- Single spine shaft
- Optimized stability layer
- Three inflow markers

# Aortic Valve Therapies: New Technologies Improving Bioprosthesis Durability Profiles







It's all about the leaflets and material science innovation!

#### • Edwards X4 RESILIA tissue valve

- Anti-calcification treatment
- Anteris DurAVR transcatheter valve
  - Single piece 3D shape

#### • Foldax TRIA heart valve

• Polymer Leaflets & Robotic Manufactoring

# "Rebooting" or Increasing Momentum



## **VENUS Aortic Heart Valves**

#### Venus-Vitae<sup>®</sup> Valve



- Balloon expandable
- Anti Calcification treated Dry Tissue
- PET skirt embedded with PU foam
- Valve sizes: 20-23-26-29



#### Venus PowerX Valve



- Self expanding, supra annular
- Anti Calcification treated
  Dry Tissue
- Adaptive Foam PU foam for sealing
- Preloaded
- Short Valve Frame
- Large Celle for Cotonary Access
- •

# **Transfemoral J-Valve**





# Transfemoral Jena Trilogy<sup>R</sup> Valve



MANADEC

#### JENAVALVE

JenaValve Technology Receives CE Mark for its Trilogy<sup>™</sup> TAVI System for the Treatment of Aortic Regurgitation and Aortic Stenosis

IRVINE, Calif., May 25th, 2021 (GLOBE NEWSWIRE) -





 $\equiv$ 

# Jena Trilogy<sup>R</sup> Valve for Aortic Regurgitation



• LOCATORS: 1. Anatomic correct positioning, 2. Control implant depth 3. Eliminate PVL 4. Secure anchoring

Transfemoral Jena Valve Case Example



51 bpm

# German Registry – Multicenter Study -Summary

#### PVR at 30 days Patient characteristics: • 95 patients: 30.6% mean age: 76y Female: 36% \_ EuroSCORE: 6.7% 96% None or Trace *Outcome:* • Technical success (VARC-3): 100% 65.3% • Device success (VARC 3): 96.8% • 2<sup>nd</sup> valve required: 0% • 30-day mortality: 1.7% • Moderate or severe AR: 0% ■None ■Trace ■Mild ■≥ Moderate

	Overall, N = 85 <sup>1</sup>	Aortic stenosis, N = 35 <sup>1</sup>	Aortic regurgitation, N = 50 <sup>1</sup>
New pacemaker	10 / 85 (12%)	1 / 35 (2.9%)	9 / 50 (18%)

## Valve Medical Ultra-Low Profile TAVR System Geminus Valve & System Design – (Gen I and II)



# Docking of two modules

Docking **Fully Assembled Valve** 1/3/1938 3/3/ Instituto Dante Pazzanese de Cardiol Instituto Dante Pazzanese de Card Coro HD Coro HDR L: 118 WW: 105 [D] 118 WW: 105 [D] LAO: 19 CAU: 4 8/4/2016 9:33:40 AN LAO: 15 CAU: 1 8/4/2016 9:15:11 AN

1<sup>o</sup> Successful case in São Paulo, Instituto Dante Pazzanese, August 4 2016 A. Abizaid, E. Grube, MB. Leon

# **Final Thoughts**



- The risk for each complication will vary on a case by case basis, and all available information should be weighed to come up with an individualized plan for each patient.
- The key to mitigating most complications is proper valve size selection and proper placement.
- Recapture technology should be exploited whenever necessary to ensure the patient leaves the room with the valve in the right location.

# TAVR Newcomers *Caveats to Consider...*

- There is no single "perfect" TAVR system design optimization involves tradeoffs and compromises (e.g. external cuff to reduce PVR adds profile)
- Strong subjective opinions regarding features which is more important... PVR prevention, ultra-low profile, low PPM rate, retrievable and repositionable, BE vs. SE, etc.
- Significant operator experience necessary to formulate thoughtful impressions – difficult to be an expert with more than ~3 TAVR systems
- Future TAVR systems should be expected to treat <u>ALL</u> patients with AS (esp. lower risk and BAV)!

# TAVR Newcomers & New Techniques *What's Hot?*

- The industry leaders continue to iterate and innovate!
- Rapid emergence of other TAVR systems approved in EU and coming to US (AcurateNeo2, and Natvitor)
- New TAVR systems from CHINA are entering the clinical marketplace (Venus A+ and J-Valve)
- TAVR newcomers are developing novel device designs (dry leaflet technology, PVL prevention, ultra-low profiles)
- Tissue engineering concepts are quickly evolving and may *spark a future round of improved valve leaflet designs*
- New Techniques for Lifetime Managament and AV Remodeling are increasingly being used