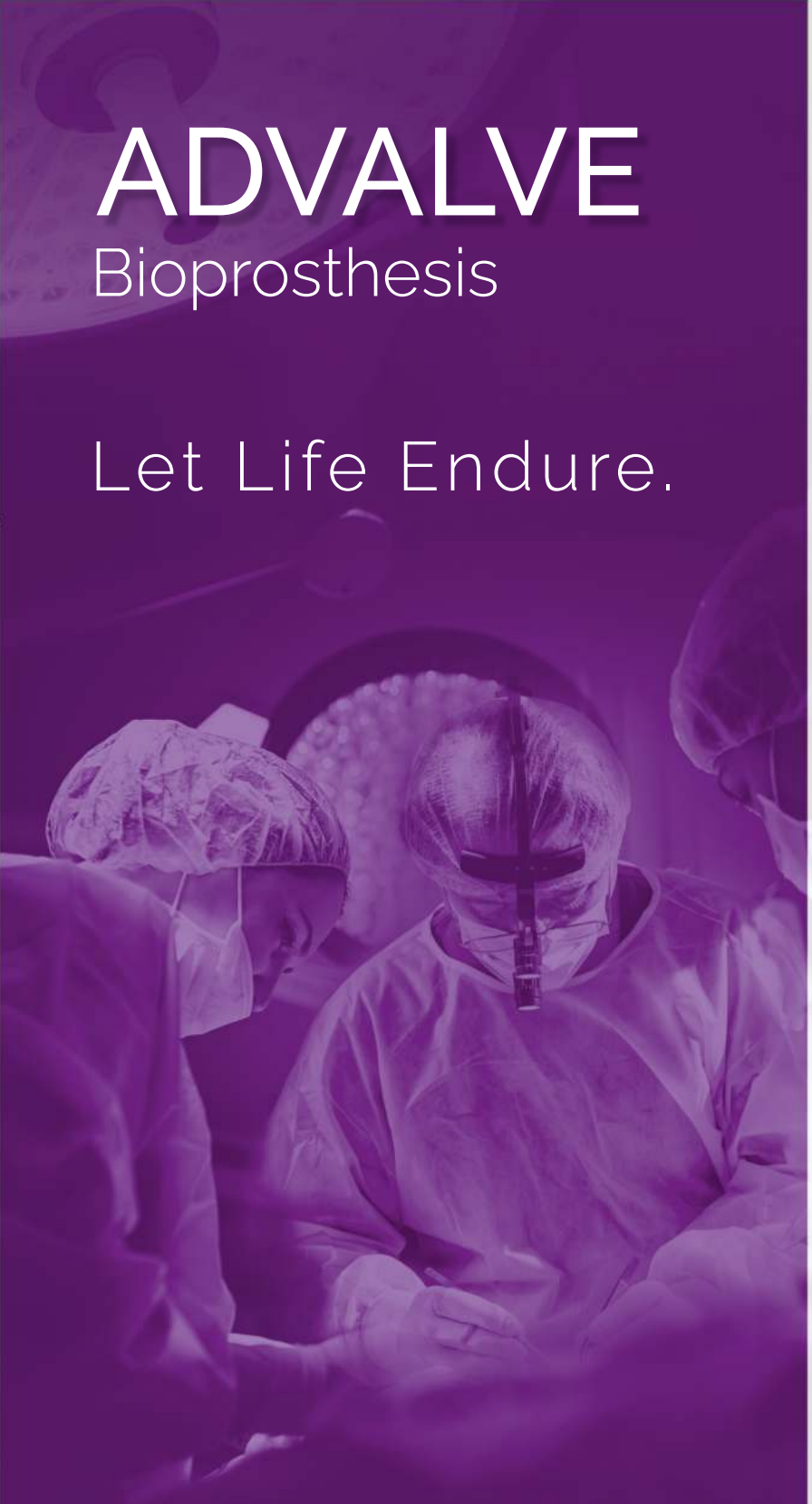
ADVALVE
Bioprosthesis

Technical Brochure

Let Life Endure.



Advanced Cardiac Surgery

advancing the science of cardiothoracic surgery

AMS
Advanced MedTech Solutions

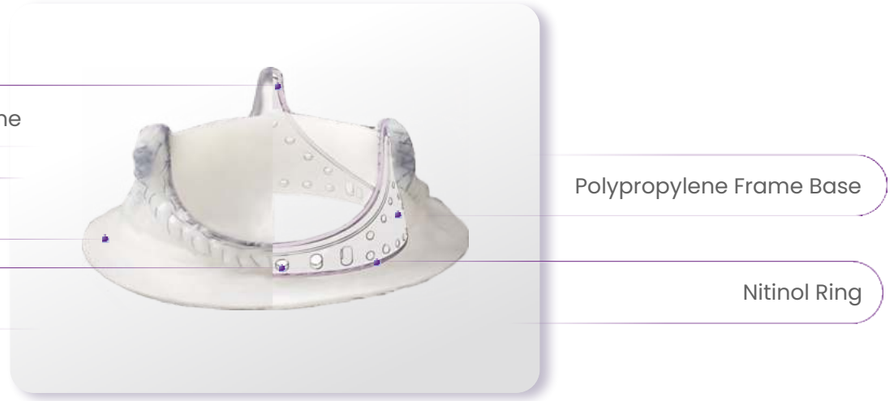
Beyond Endurance, Beyond Excellence.

Spatial Modeling Technology

Composite Metal Polymer Stent [1,2]

Redistributes significant load to the polymer frame.

The Nitinol wire circuit acts as a vibration dampener.



Advanced Leaflet Technology

Advanced Digital Fabrication

Pericardial thickness detection ensures uniform prosthesis quality.

Even stress distribution across leaflet surface.

eGDGe
Ethylene Glycol Diglycidyl Ether

Tissue Fixation Technology

eGDGe Cross-Linking Minimizes Calcification.

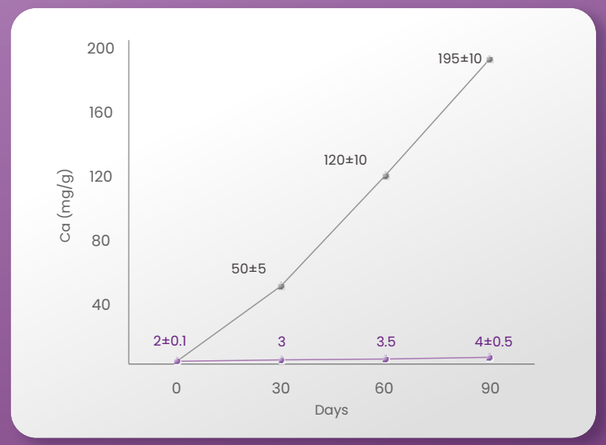
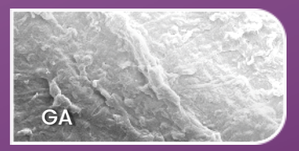


Fig.1 - Accumulation of calcium in biomaterial implanted in animals (accelerated calcification model). Next to the name of the fixative is a diagram of its molecule, where the hydrocarbon chain; ●— reaction groups —◄ ►— . At point "0" is the amount of calcium in the non-implanted biomaterial.[3]

Lower Calcification Risk: eGDGe vs GA

Experimental models show a pronounced inhibition of calcification with eGDGe .[4]



Biomechanical Characteristics[3] :

Enhanced Elasticity and Durability, Resistant to Long-Term Degradation.

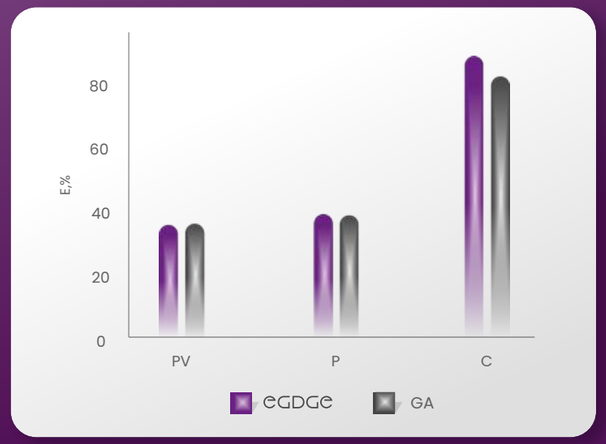
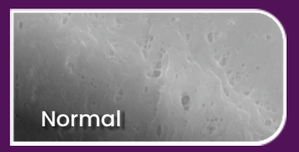
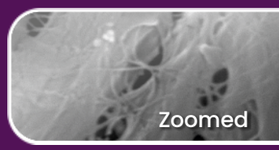


Fig.2 - PV - Porcine Aortic Valve Leaflets, P - Pericardium, C- Cattle Arteries[3]

Anti-Bacterial Treatment:

Fibrous film of chlorhexidine bigluconate on the surface of an eGDGe-treated prosthesis.





Transprothesis Gradient

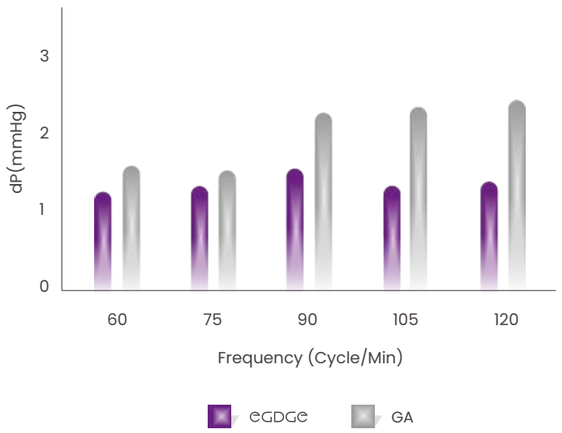
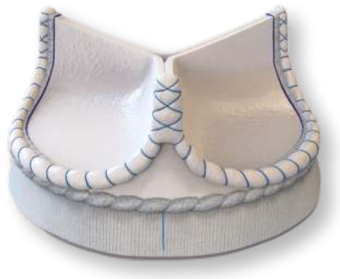


Fig.3 - Transprothesis gradient of ADVALVE prostheses treated with diepoxy compound (eGDGe) or glutaraldehyde (GA) during bench tests in the mitral position. *- significant differences ($p<0.05$) between the groups of GA and EGDGE bioprostheses.[3]



Minute Volume

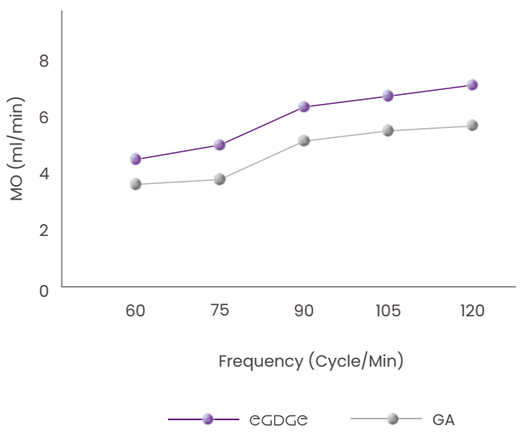


Fig.5 - Minute volume of ADVALVE prostheses treated with diepoxide (eGDGe) or glutaraldehyde (GA), mitral position, bench tests.[3]

Clinical Outcomes[2]

Absence of Primary Tissue Failure (PTF)

eGDGe-treated bioprostheses vs GA-treated counterparts.

30.59% Lower PTF Rate — Compared to GA treated ones.

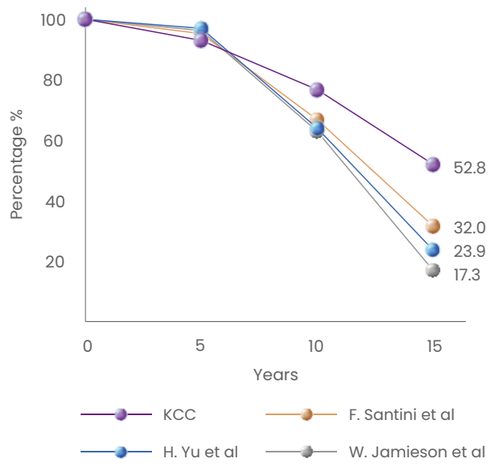


Fig.4 -Actuarial results of primary tissue failure (PTF) absence of bioprostheses in patients younger than 50 years old (according to various studies). KCC is a group of patients with epoxy-treated bioprostheses (own data) compared to Santini F. et al. , Yu H. et al. Jamieson W. et al.[2]

Lower Immunogenicity[2,3]

Compared to GA, eGDGe-treated tissues lower immune response and deterioration risk.

Compatibility with Advanced Modifications[2,3]

The absence of excessive free aldehyde groups in eGDGe-treated biomaterials allow antithrombotic and antibacterial coatings without compromising integrity.

Advanced Anti-Calcification[2]

Effective Inhibition of Calcification

Diphosphonates inhibit calcium phosphate and hydroxyapatite crystallization.

Long-Term Protection

Prolonged Anti-calcification due to covalent binding of diphosphonates with eGDGe - treated groups, beneficial for paediatric & young patients.

Antibacterial Protection

Chlorhexidine immobilization resists gram-negative and gram-positive microbes & Improves valve replacement outcomes in Infectious endocarditis.

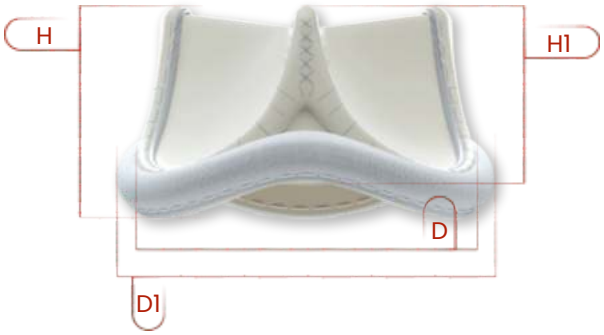
References

1. Karaskov, A. M., et al. "*Uniline Next-Generation Russian Biological Prosthesis for Mitral Valve Replacement: First Experience.*" Paper presented at: **Russian Journal of Thoracic and Cardiovascular Surgery Conference**, 1–6 Feb. 2017, Russia.
2. Barbarash, L. S., and I. Y. Zhuravleva. "*Evolution of Heart Valve Bioprostheses: Achievements and Challenges of Two Decades.*" Paper presented at: **Scientific Research Institute of Complex Problems of Cardiovascular Diseases**, 2012, Kemerovo, Russia .
3. Data on file.

** ADVALVE is manufactured by AMS under a technology license from Neocor for Uniline.

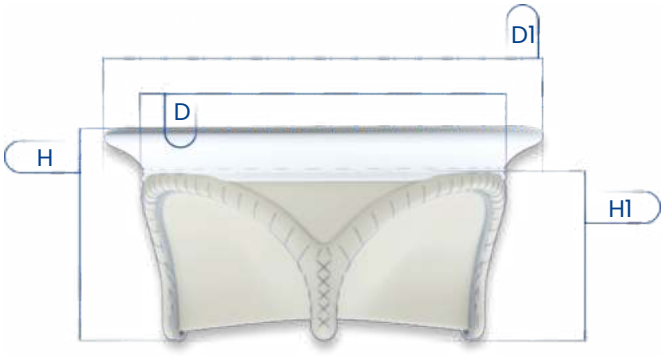
Technical Specifications

ADVALVE Aortic



Nominal Specifications (mm)	AVA19s	AVA21s	AVA23s	AVA25s
D - Stent Diameter	19	21	23	25
D1 - External Sewing Ring Diameter	24.5	27	28	30
H - Total Height	16	16.5	17.0	17.5
H1 - Aortic Protrusion	13	13.5	14.5	15.0

ADVALVE Mitral



Nominal Specifications (mm)	AVM26s	AVM28s	AVM30s	AVM32s
D - Stent Diameter	26	28	30	32
D1 - External Sewing Ring Diameter	38.0	40.0	42.0	43.5
H - Total Height	15.0	16.0	16.5	17.5
H1 - Ventricular Protrusion	12	13.5	15	15

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