TRANSCATHETER HEART VALVES GREECE 2019

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MAY 3-4, 2019 | ATHENS
ATHENS CONCERT HALL

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FREE REGISTRATION

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Under the auspices of:
Hellenic Society of Cardiology (HSC)
Working Group of Hemodynamic and Interventional Cardiology, HSC
Working Group of Heart Valve Disease, Adult Congenital Heart Disease and Pulmonary Hypertension, HSC

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JOINT SESSION

Joint Sessions also coordinated with the 4th International Conference on Cardiovascular Imaging in Clinical Practice

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Learning Objectives

Current and expanding indications for THVT
Planning and organizing THVT
Case selection and screening Imaging modalities in planning and performing THVT
THVT: Scientific workshops
THVT: Clinical workshops
Challenging cases and difficult scenarios
Avoiding and managing complications
Access site planning
New devices and future THVT

Target Attendees

Cardiologists
Cardiac Surgeons
Heart Team Members
Anesthesiologists
Vascular Surgeons
Radiologists
Intensivists
Nephrologists
Pulmonologists
Echocardiographers
Cathlab and Hybrid Room
Nurses
Researchers

Content

Lectures, Debates, Taped Cases, Live Cases

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Πάντα στη μάχη για την υγεία.

Πιστοί στο έργο μας και με κύρια προτεραιότητά μας τον άνθρωπο, προχωράμε στο μέλλον με αξιοπιστία, με πρωτοποριακές μεθόδους και πάνω από όλα με ευθύνη για τη ζωή.

Στον Όμιλο ΥΓΕΙΑ, με μία δυναμική πορεία 49 χρόνων και κυρίαρχες αξίες την αξιοπιστία, την πρωτοπορία και τον σεβασμό στον άνθρωπο και τη ζωή, πρωταγωνιστούμε στον τομέα της υγείας με 3 υπερσύγχρονα νοσοκομεία, πάνω από 2.670 εργαζομένους και περισσότερους από 4.240 συνεργάτες ιατρούς.

Καινοτομούμε και ξεχωρίζουμε, παρέχοντας **υψηλού επιπέδου υπηρεσίες υγείας** με **εξοπλισμό κορυφαίας τεχνολογικής αιχμής** και άρτια καταρτισμένο προσωπικό. Όλα τα νοσοκομεία μας έχουν αποσπάσει πολλαπλές διακρίσεις για την ποιότητα των υπηρεσιών τους, με το ΥΓΕΙΑ να είναι το μόνο νοσοκομείο στην Ελλάδα με **Χρυσή Σφραγίδα Έγκρισης του οργανισμού Joint Commission International (JCI)**.

Με ευαισθησία και αίσθηση κοινωνικής ευθύνης, υιοθετούμε **πολιτικές Βιώσιμης Ανάπτυξης**, οργανώνουμε **δράσεις αλληλεγγύης** όπως το «Ταξιδεύουμε για την Υγεία», συνεισφέρουμε στην εκπαίδευση του κοινού με **καμπάνιες ενημέρωσης και ευαισθητοποίησης** και συμμετέχουμε δυναμικά στην **προστασία του περιβάλλοντος**.

ΟΜΙΛΟΣ ΥΓΕΙΑ
Με ευθύνη για τη ζωή

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WELCOME NOTE

Dear Colleagues,

We welcome you to Transcatheter Heart Valves Greece 2019. Building on the success of prior years we have expanded the breadth and depth of the topics that will be discussed this year. A variety of innovations in transcatheter therapies have led us down a road where all valves may now be repaired or replaced percutaneously. Following in the strong footsteps of TAVR for the aortic valve we now have new and exciting therapies to discuss for the mitral, tricuspid and pulmonic valves as well. These revolutionary technologies will undoubtedly require the collaboration of all involved parties and this meeting seeks to provide a framework for these discussions to take place. The meeting is meant to be interactive so please voice your thoughts, ask questions, and give us insights learned from your own valve practice. There are multiple countries represented in our speakers and audience and the hope is that networking and collaboration will be plentiful. We have organized a variety of social events to foster these interactions and we hope that you will enjoy science, socializing and scenery! For those of you who have not visited prior, the city of Athens is a world-renowned tourist destination and we encourage you to explore and savor.

We owe a debt of gratitude to our speakers, our sponsors, all participants, and our organizing company Inventics - Medevents all of whom worked diligently for many months to bring you the program you will enjoy for the next two days. Welcome to Athens and welcome to Transcatheter Heart Valves Greece 2019!

Gregory Pattakos, MD

Stratis Pattakos, MD

Konstantinos Spargias, MD

Panos Vardas, MD

BANQUET HALL (LEVEL -2)

09.00 – 11.00 **TAVR Session I – TAVR Technology in a Rapidly-Evolving Era**

Moderators: **J. Goudevenos, I. Kanakakis, D. Sionis, P. Vardas**

1. Latest TAVR Randomized Trials **G. Pattakos**
2. High-Quality TAVR: Does a minimum volume requirement still make sense? **M. Vavuranakis**
3. The selection of SAVR devices in the TAVR era **S. Prapas**
4. Rapid deployment surgical valves with minimally invasive techniques. Can they compete with TAVR? **P. Dedeilias**
5. TAVR for low-risk patients with a self-expanding valve **N. Kleiman**
6. Live-in-a-box TAVR
7. **Discussion**

Commentators: **S. Karagiannis, G. Makos, A. Tzikas**

BANQUET HALL (LEVEL -2)

11.00 – 11.30 **WELCOME NOTES**

1. **S. Pattakos**
2. **S. Konstantinidis**
3. **I. Goudevenos**
4. **D. Tousoulis**
5. **P. Vardas**
6. **A. Kartapanis**

BANQUET HALL (LEVEL -2)

11.30 – 13.30 **TAVR Session II – TAVR on the Uprise. How do we deal with complex situations?**

Moderators: **M. Argyriou, S. Foussas, E. Pissimisis, K. Tsioufis**

1.CT Imaging of Bicuspid Aortic Valve Disease. Anatomic patterns favorable and unfavorable for TAVR and factors influencing device selection **A. Chalapas**
2. TAVR will be the treatment of choice for bicuspid aortic valve disease in the future! **N. Van Mieghem**
3. Most Bicuspid aortic valves (especially in younger low-risk patients) will remain in the surgical domain! **D. Angouras**
4. Strokes After TAVR and SAVR: Incidence in the "Modern Era" and Key Messages **S. Kodali**
5. What's Holding Back Cerebral Embolic Protection in TAVR? Data or Money? **R. Mehran**

6. TAVR in the patient with significant native or bioprosthetic mitral and/or tricuspid valve disease **A. Oto**
7. Live-in-a-box **TAVR**
8. **Discussuion**
Commentators: **K. Aznaouridis, V. Androutsopoulou, S. Makrigiannis**

13.30 – 14.00 **BREAK**

BANQUET HALL (LEVEL -2)

14.00 – 15.45 **TAVR Session III – TAVR dilemmas and complications**
Moderators: **D. Iliopoulos, G. Hahalis, V. Pyrgakis, S. Tzeis**

1. Incidence, predictors and sequelae of new LBBB and pacemaker insertion after TAVR **L. Papavasileiou**
2. Is paravalvular regurgitation after TAVR still an important consideration in 2019? **N. Kleiman**
3. A Selective versus Routine Minimalist Strategy. Is every patient eligible? **S. Kapadia**
4. Management of Coronary Disease in AS Patients: Important Treatment Considerations (When to consider CABG, timing of PCI and TAVR, and completeness of revascularization) **A. Oto**
5. To crack or not to crack? The role for fracturing bioprosthetic valves during valve-in-valve procedures **M. Kasel**
6. Live-in-a-box **TAVR**
7. Discussion
Commentators: **I. Chlorogiannis, K. Dimitriadis, A. Zacharoulis**

15.45 – 16.00 **BREAK**

TAVI with the SAPIEN 3 Valve

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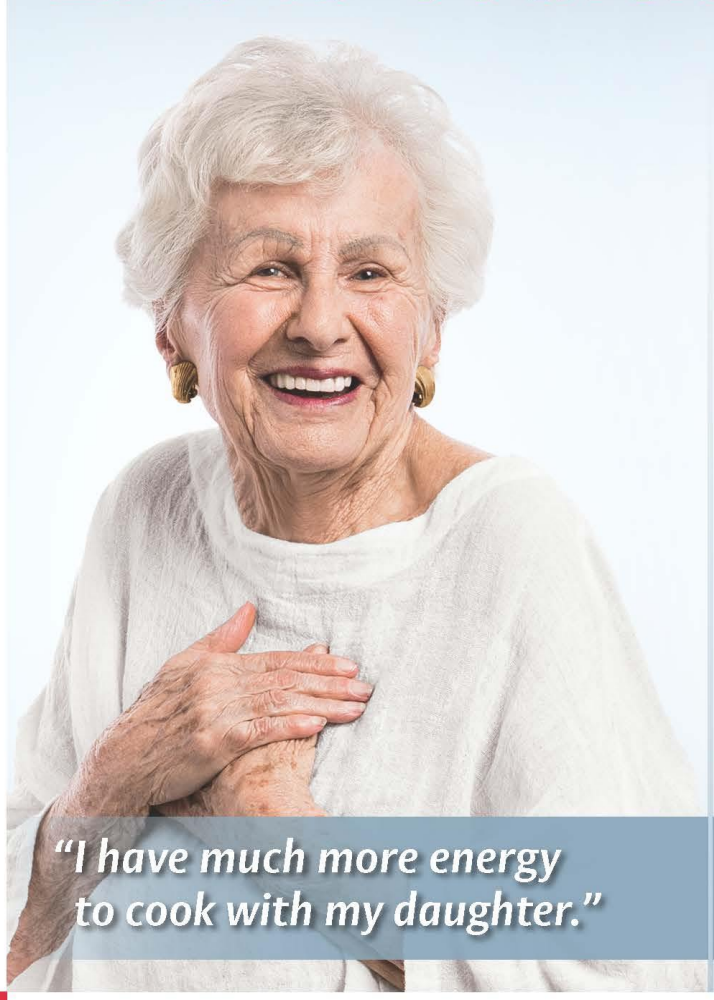
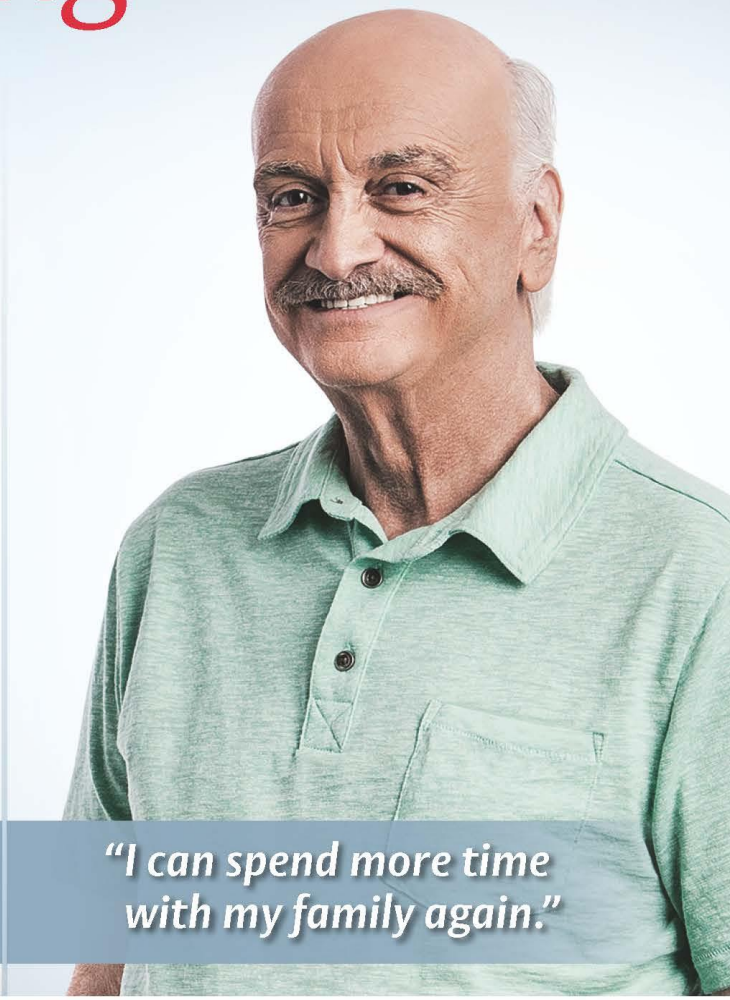


"I have much more energy to cook with my daughter."



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BANQUET HALL (LEVEL -2)

16.00 – 17.30	**JOINT SESSION I** **Aortic and Mitral Club** Moderators: **S. Adamopoulos, C. Chrysohoou, G. Filippatos** 1. In hospital mortality after TAVR. Common and uncommon causes **S. Kodali** 2. Impact of valvular heart disease on the global burden of heart failure: Can transcatheter therapies make a difference? **A. Katsaros** 3. Patient-prosthesis mismatch after transcatheter aortic valve replacement: prevalence and long-term impact **A. Patrianakos** 4. Moderate aortic stenosis with reduced ejection fraction: Can imaging guide therapy? **E. Anagnostou** 5. Minimally invasive surgery for the Mitral Valve. Hard to Beat! **G. Pattakos** 6. Can Transcatheter Edge-to-Edge, direct or indirect Mitral Rings and Chords Match or Exceed Open Surgical Procedures? **S. Kodali** Commentators: **G. Giamouzis, G. Karatasakis**
17.30 – 18.30	**JOINT KEY LECTURES** Chairmen: **P. Nihoyannopoulos, P. Vardas** 1. TAVR for All? New insights from the low-risk trials **S. Kapadia** 2. Defining Secondary Mitral Regurgitation: Get it Right! **J. Kisslo** 3. Mitraclip for Functional Mitral Regurgitation **S. Kar**
18.30 – 20.00	**JOINT SESSION II** **Mitral and Tricuspid Club** Moderators: **G. Athanassopoulos, G. Giamouzis, A. Trikas** 1. Exercise-stress echocardiography and effort intolerance in asymptomatic/symptomatic degenerative mitral regurgitation **D. Klettas** 2. Mitraclip vs. PASCAL. Similarities and differences **K. Spargias** 3. Lessons from the MITRA-FR and COAPT studies; How should we quantify MR? **K. Papadopoulos** 4. Percutaneous mitral repair after failed open surgery **S. Kar** 5. Who are the best candidates for experimental TMVR in 2019? **N. Kleiman** 6. Lessons from an International Registry on Transcatheter Tricuspid Therapies **F. Maisano**

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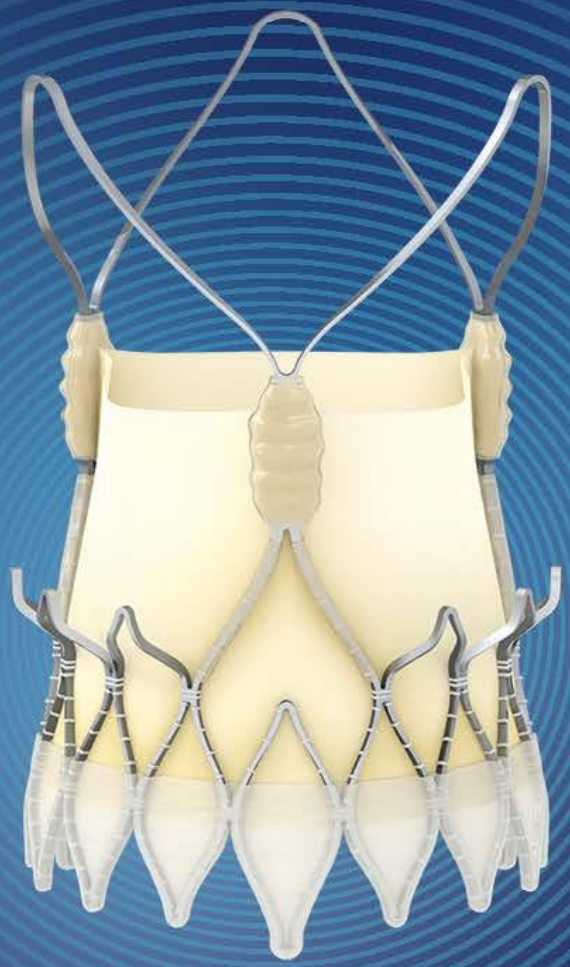
SAFETY & EFFICACY RESULTS COMPARABLE TO SAPIEN 3*[1]

MULTICENTER COMPARISON OF NOVEL SELF-EXPANDING VS. BALLOON-EXPANDABLE TRANSCATHETER HEART VALVES



-54% Observed reduced risk of elevated gradients ≥ 20 mmHg** (p=0.02)
3.2% ACURATE *neo* vs. 6.9% SAPIEN 3

-36% Observed reduced risk of in-hospital new pacemaker implantations (p=0.02)
9.9% ACURATE *neo* vs. 15.5% SAPIEN 3

Higher rates of PVL ≥2 than SAPIEN 3 (4.8% vs. 1.8%; p= 0.01)

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* Study design: observational, 1:2 propensity-matched multicenter comparison of ACURATE *neo*™ (n = 311) and SAPIEN 3 (n = 622) from 3 high volume centers in Germany. Comparable VARC-2 device failure composite endpoint with ACURATE *neo* versus SAPIEN 3 (10.9% vs. 9.6%, p=n.s.) and early safety composite endpoint (15.8% vs. 15.6%, p=n.s.).
** According to VARC-2, elevated gradients >20 mmHg are defined as mild stenosis, are assessed as Device Failure and may indicate prosthetic valve dysfunction.

1. Husser O, et al. Multicenter comparison of novel self-expanding versus balloon-expandable transcatheter heart valves. JACC Cardiovasc Interv. 2017 Oct 23;10(20):2078-2087.

BANQUET HALL (LEVEL -2)

08.45 – 11.00 **Mitral Session I – Complexities of Mitral Interventions**

Moderators: **L. Poulimenos, G. Stavridis, D. Tsiapras, M. Vavuranakis**

1. Echocardiographic evaluation of the mitral valve. A guide to decision-making for transcatheter or surgical Repair / Replacement **M. Chrissoheris**
2. Advanced Applications of CT Imaging for Transcatheter Mitral and Tricuspid Procedures **C. Mourmouris**
3. Mitral Valve-in-valve and valve-in-ring procedures. A long-needed necessity! **A. Pitsis**
4. Results of valve-in-MAC (mitral annular calcification) procedures. Assess and plan carefully! **J. Velianou**
5. Currently enrolling TMVR and TTVR FIM and CE Mark trials **S. Kar**
6. You can't beat safety and simplicity: Edge to edge therapies will be the dominant strategy for mitral repair **F. Maisano**
7. Live-in-a-box **Mitraclip**
8. **Discussion**

Commentators: **N. Baikoussis, K. Bellos, E. Petropoulou**

BANQUET HALL (LEVEL -2)

11.00 – 13.00 **TAVR Session IV – Avoiding Pitfalls**

Moderators: **D. Alexopoulos, I. Ikonomidis, A. Manginas, A. Pipilis**

1. A growing conundrum: Coronary access after TAVR. Difficulties, tips and tricks **V. Voudris**
2. Mechanisms of coronary obstruction during TAVR: prediction, prevention, and treatment **N. Van Mieghem**
3. Hybrid beating heart bypass grafting and TAVR. An excellent alternative? **N. Bouboulis**
4. Guidelines and classification of bioprothetic TAVR and SAVR dysfunction and failure. Latest data on incidence, clinical impact and valve durability **A. Manginas**
5. TAVR plus/minus AFib and/or CAD. Pharmacotherapy considerations, clinical trials and practical clinical recommendations **R. Mehran**
6. The Spectrum of Leaflet Thrombosis in Bioprosthetic Aortic Valves - Prevalence, Clinical Consequences, and Practical Management Strategies. **G. Dangas**
7. Live-in-a-box **TAVR**
8. **Discussion**

Commentators: **N. Kadoglou, A. Roubelakis, G. Tsigkas**

13.00 – 13.30 **BREAK**

BANQUET HALL (LEVEL -2)

13.30 – 15.00 **TAVR Session V – Dealing with a "gray area". Crucial questions and answers**

Moderators: **S. Konstantinidis, F. Mitropoulos, C. Olympios, K. Triantafillou**

1. How far should we push the borderline transfemoral access for TAVR? Techniques, equipment, and likelihood of glory versus gory **K. Spargias**
2. To split or not to split? The role of BASILICA and LAMPOON as adjuvant procedures during TAVR and TMVR **J. Velianou**
3. The rapid emergence of transcaval TAVR. Techniques and clinical outcomes **M. Kasel**
4. TAVR in the decompensated patient with AS. How to evaluate and treat **P. Dardas**
5. Live-in-a-box **TAVR**
6. **Discussion**

Commentators: **P. Kalyvas, D. Ketikoglou, K. Papadopoulos**

BANQUET HALL (LEVEL -2)

15.00 – 16.15 **TAVR Session VI – Looking to the future. Innovative ideas in a rapidly - evolving domain**

Moderators: **G. Bompotis, A. Dimas, Ch. Kotoulas, S. Patsilinakos**

1. Supra-annular TAVR devices. The real and possible advantages and disadvantages **K. Spargias**
2. The ACURATE Neo TAVR system. Program Update, clinical data, patient selection and future vision **BSC LECTURE TBA**
3. The PORTICO TAVR system. Program Update, clinical data, patient selection and future vision **TBA**
4. What to expect in the near future **from the market leaders**? EVOLUT **TBA**
5. What to expect in the near future **from the market leaders**? The Sapiens family and the CENTERA self-expandable valve. Program Update, clinical data and patient selection **TBA**
6. A Deep Dive into TAVR Cost-Effectiveness Studies with constantly moving goalposts **L. Michalis**
7. **Discussion**

Commentators: **D. Damaskos, K. Moldovan, L. Poulimenos**

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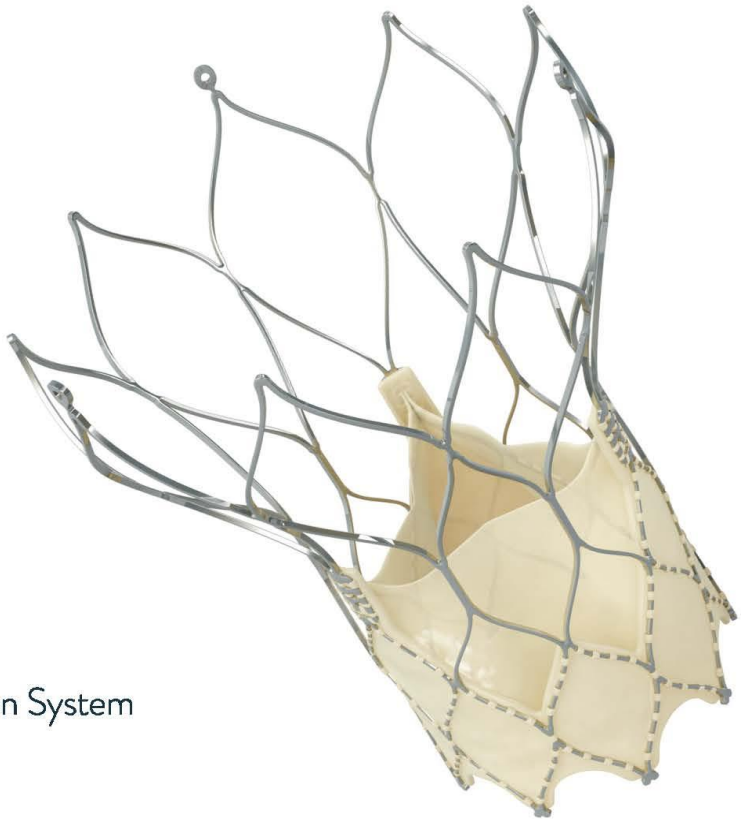

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Prior to use, appropriate Portico valve training must be completed by physician. Check the regulatory status of the device in areas where CE marking is not the regulation in force. Information contained herein is for distribution for Europe, Middle East and Africa ONLY.

16.15 – 16.30 **BREAK**

BANQUET HALL (LEVEL -2)

16.30 – 17.30 **JOINT SESSION**
SPECIAL LECTURES
Chairman: **A. Dagre**

1. TAVR device selection in the real world. Based on clinical, anatomical and device factors **M. Kasel**
2. Three-Dimensional Echocardiography is key **J. Kisslo**
3. Patient selection for transcatheter tricuspid edge-to-edge grasping and clinical outcomes **F. Maisano**

BANQUET HALL (LEVEL -2)

17.30 – 19.00 **Mitral and Tricuspid Session II – Looking to the future**
Moderators: **N. Georgakopoulos, S. Kyrzopoulos, G. Makos, A. Patrianakos**

1. Advanced echocardiography assessment of the tricuspid valve and right ventricular function and implications for transcatheter treatment **M. Chrissoheris**
2. Technical tips and tricks to successfully perform trans septal puncture for Mitraclip and TMVR procedures **K. Spargias**
3. An often Challenging MitraClip Decision: Whether to Implant a second (or third) Clip **V. Ninios**
4. Transcatheter valve-in-valve and valve-in-ring in the tricuspid position. Patient selection, tips and tricks and outcomes **A. Tzifa**
5. Minimally invasive surgery for isolated tricuspid repair **A. Pitsis**
6. The Structural Heart and Valve Center: The Roles of Cardiovascular Team Professionals **S. Pattakos**

Commentators: **Ant. Manolis, S. Kounas, G. Moustogiannis**

PROGRAM / SATURDAY, MAY 4th 2019

BANQUET HALL (LEVEL -2)

19.00 – 21.00 **My best and/or my worst Structural Procedure of the year**

Moderators: **N. Kafkas, A. Spanos, G. Triantis**

G. Katsimagklis
D. Tsikaderis
J. Zarifis
C. Arampatzis
K. Spiliotopoulos
G. Sianos
K. Perreas
D. Nikas
K. Triantafyllou
J. Iakovou
V. Lozos
Ch. Cotoulas
V. Ninios

Commentators: **N. Koutsogiannis, M. Panagiotou, S. Papaioannou**

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GENERAL INFO

CERTIFICATE OF ATTENDANCE

The certificate is marked with **16 CME/CPD credits** of continuous medical education from UEMS.
The certificates will be sent via email. Satellite symposiums are not included.

LIVE WEBCAST – VIDEO ON DEMAND

The conference will be live broadcasted via www.livemedia.gr. Videos on demand will be available after the conference.

PRESENTATIONS

Computers and slide projectors will be available for presentations. Speakers are kindly requested to give their presentation to the AV reception at least two (2) hours before the presentation.

SECRETARIAT

The secretariat would be at Level -1

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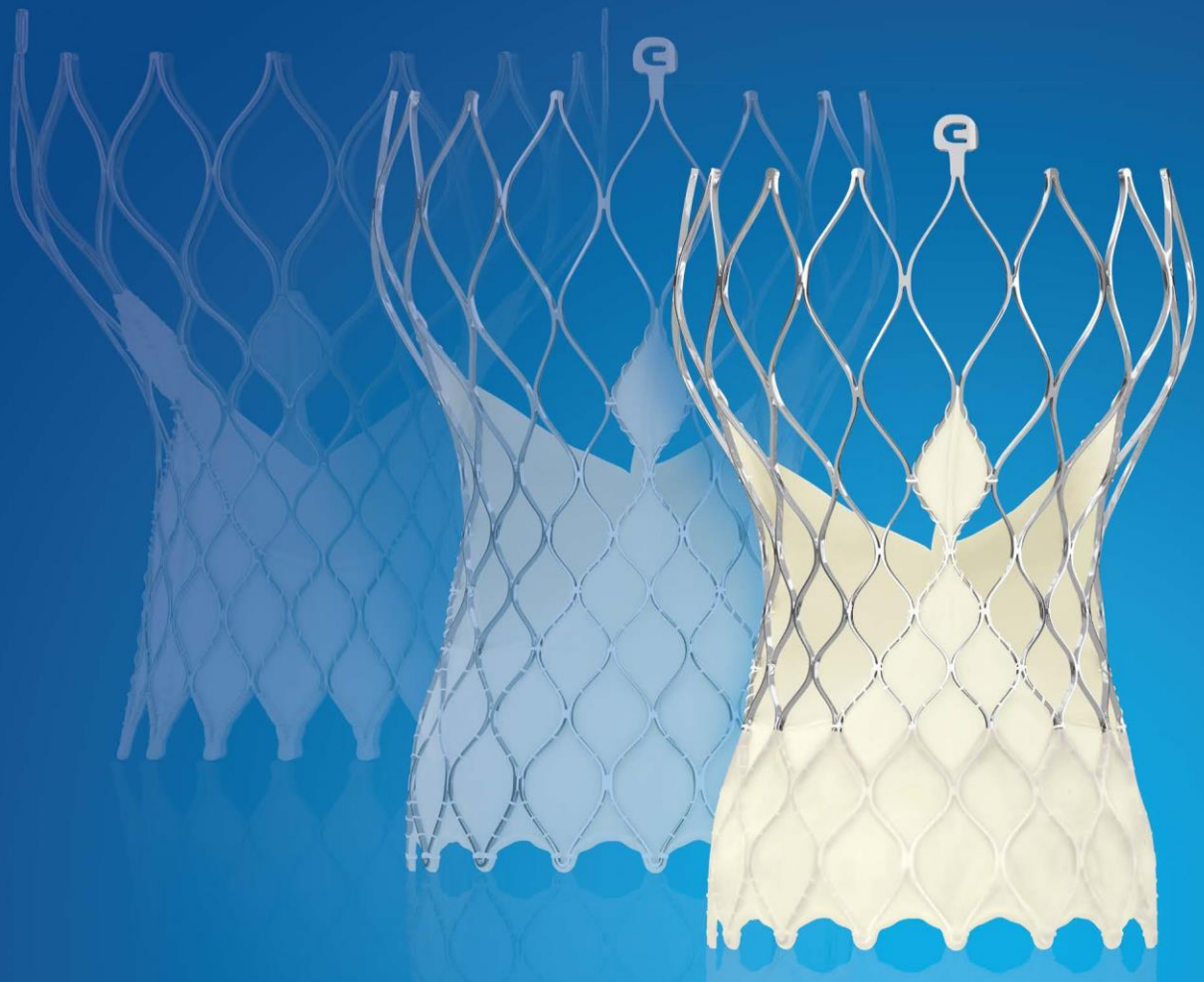

Supra-annular valve design
Unsurpassed hemodynamics

Self-expanding frame
Provides the foundation for controlled delivery

Porcine pericardial tissue
Thin and strong for low profile delivery and durability

INDICATIONS The Medtronic CoreValve™ Evolut™ R and CoreValve™ Evolut™ PRO systems are indicated for use in patients with symptomatic heart disease due to either severe native calcific aortic stenosis or failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., Society of Thoracic Surgeons predicted risk of operative mortality score ≥8% or at a ≥15% risk of mortality at 30 days).

CONTRAINDICATIONS The CoreValve™ Evolut™ R and PRO systems are contraindicated for patients presenting with any of the following conditions: known hypersensitivity or contraindication to aspirin, heparin (HIT/HITTS) and bivalirudin, ticlopidine, clopidogrel, Nitinol (Titanium or Nickel), or sensitivity to contrast media, which cannot be adequately premedicated; ongoing sepsis, including active endocarditis; preexisting mechanical heart valve in the aortic position.

WARNINGS *General* Implantation of the CoreValve™ Evolut™ R and PRO systems should be performed only by physicians who have received Medtronic CoreValve™ training. This procedure should only be performed where emergency aortic valve surgery can be performed promptly. Mechanical failure of the delivery catheter system and/or accessories may result in patient complications. Accelerated deterioration of the bioprosthesis may occur in patients presenting with an altered calcium metabolism.

PRECAUTIONS *General* The safety and effectiveness of the CoreValve™ Evolut™ R and PRO systems have not been evaluated in the pediatric population. The safety and effectiveness of the bioprosthesis for aortic valve replacement have not been evaluated in the following patient populations: patients who do not meet the criteria for symptomatic severe native aortic stenosis as defined: (1) symptomatic severe high gradient aortic stenosis — aortic valve area ≤1.0 cm^2 or aortic valve area index ≤0.6 cm^2/m^2, a mean aortic valve gradient ≥40 mm Hg; or a peak aortic-jet velocity ≥4.0 m/s, (2) symptomatic severe low-flow, low-gradient aortic stenosis — aortic valve area ≤1.0cm^2 or aortic valve area index ≤0.6 cm^2/m^2, a mean aortic valve gradient <40 mmHg; and a peak aortic-jet velocity <4.0 m/s ; who are at moderate or low surgical risk (predicted perioperative mortality risk of <15%); with untreated, clinically significant coronary artery disease requiring revascularization; with a pre-existing prosthetic heart valve with a rigid support structure in either the mitral or pulmonic position if either the pre-existing prosthetic heart valve could affect the implantation or function of the bioprosthesis or the implantation of the bioprosthesis could affect the function of the pre-existing prosthetic heart valve; with cardiogenic shock manifested by low cardiac output, vasopressor dependence, or mechanical hemodynamic support. The safety and effectiveness of a CoreValve™ Evolut™ R and PRO bioprosthesis implanted within a failed pre-existing transcatheter bioprosthesis has not been demonstrated. Implanting a CoreValve™ Evolut™ R or PRO bioprosthesis in a degenerated surgical bioprosthesis [transcatheter aortic valve in surgical aortic valve (TAV in SAV)] should be avoided in the following conditions. The degenerated surgical bioprosthesis presents with: a significant concomitant perivalvular leak (between the prosthesis and the native annulus), is not securely fixed in the native annulus, or is not structurally intact (e.g., wireform frame fracture); partially detached leaflet that in the aortic position may obstruct a coronary ostium; stent frame with a manufacturer's labeled inner diameter <17 mm. The safety and effectiveness of the bioprosthesis for aortic valve replacement have not been evaluated in patient populations presenting with the following: blood dyscrasias as defined: leukopenia (WBC <1000 cells/mm^3), thrombocytopenia (platelet count <50,000 cells/mm^3), history of bleeding diathesis or coagulopathy, or hypercoagulable states; congenital bicuspid or unicuspid valve; mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation [3-4+]); moderate to severe (3-4+) or severe (4+) mitral or severe (4+) tricuspid regurgitation; hypertrophic obstructive cardiomyopathy; new or untreated echocardiographic evidence of intracardiac mass, thrombus, or vegetation; native aortic annulus size <18 mm or >30 mm for CoreValve™ Evolut™ R and <18 mm or >26 mm for CoreValve™ Evolut™ PRO per the baseline diagnostic imaging or surgical bioprosthetic aortic annulus size <17 mm or >30 mm for CoreValve™ Evolut™ R and <17 mm or >26 mm for CoreValve™ Evolut™ PRO; transarterial access not able to accommodate an 18 Fr sheath or the 14 Fr equivalent EnVeo™ R InLine sheath when using Model ENVEOR-US or transarterial access not able to accommodate a 20 Fr introducer sheath or the 16 Fr equivalent EnVeo™ R InLine sheath when using Model ENVEOR-N-US; sinus of valsalva anatomy that would prevent adequate coronary perfusion; moderate to severe mitral stenosis; severe ventricular dysfunction with left ventricular ejection fraction (LVEF) <20%; symptomatic carotid or vertebral artery disease; severe basal septal hypertrophy with an outflow gradient.

Prior to Use Exposure to glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to the vapors. Damage may result from forceful handling of the catheter. Prevent kinking of the catheter when removing it from the packaging. This device was designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death. The bioprosthesis size must be appropriate to fit the patient's anatomy. Proper sizing of the device is the responsibility of the physician. Refer to Instructions for Use for available sizes. Failure to implant a device within the sizing matrix could lead to adverse effects such as those listed below. Patients must present with access vessel diameters of ≥5 mm when using Model ENVEOR-US or ≥5.5 mm when using Model ENVEOR-N-US, or patients must present with an ascending aortic (direct aortic) access site ≥60 mm from the basal plane for both systems. Implantation of the bioprosthesis should be avoided in patients with aortic root angulation (angle between plane of aortic valve annulus and horizontal plane/vertebrae) of >30° for right subclavian/axillary access or >70° for femoral and left subclavian/axillary access. Use caution when using the subclavian/axillary approach in patients with a patent LIMA graft or patent RIMA graft. For direct aortic access, ensure the access site and trajectory are free of patent RIMA or a pre-existing patent RIMA graft.

During Use For direct aortic and subclavian access procedures, care must be exercised when using the tip-retrieval mechanism to ensure adequate clearance to avoid advancement of the catheter tip through the bioprosthesis leaflets during device closure. For direct aortic access procedures, use a separate introducer sheath; do not use the EnVeo R InLine sheath. Adequate rinsing of the bioprosthesis with sterile saline, as described in the Instructions for Use, is mandatory before implantation. During rinsing, do not touch the leaflets or squeeze the bioprosthesis. If a misload is detected, unsheath the bioprosthesis and examine the bioprosthesis for damage (for example, permanent frame deformation, frayed sutures, or valve damage). Do not attempt to reload a damaged bioprosthesis. Do not load the bioprosthesis onto the catheter more than two times or after it has been inserted into a patient. Use the deployment knob to deploy and recapture the bioprosthesis. Do not use the trigger for deploying or recapturing because it could cause inaccurate placement of the bioprosthesis. Once the radiopaque capsule marker band reaches the distal end of the radiopaque paddle attachment (point of no recapture), retrieval of the bioprosthesis from the patient is not recommended. Retrieval after the point of no recapture may cause mechanical failure of the delivery catheter system, aortic root damage, coronary artery damage, myocardial damage, vascular complications, prosthetic valve dysfunction (including device malposition), embolization, stroke, and/or emergent surgery. During deployment, the bioprosthesis can be advanced or withdrawn as long as annular contact has not been made. Once annular contact is made, the bioprosthesis cannot be advanced in the retrograde direction; recapture until the bioprosthesis is free from annular contact, and then reposition in the retrograde direction. If necessary, and the radiopaque capsule marker band has not yet reached the distal end of the radiopaque paddle attachment, the bioprosthesis can be withdrawn (repositioned) in the antegrade direction. However, use caution when moving the bioprosthesis in the antegrade direction. While the catheter is in the patient, ensure the guidewire is extending from the tip. Do not remove the guidewire from the catheter while the catheter is inserted in the patient. Use the handle of the delivery system to reposition the bioprosthesis. Do not use the outer catheter sheath. There will be some resistance when the catheter is advanced through the vasculature. If there is a significant increase in resistance, stop advancement and investigate the cause of the resistance (for example, magnify the area of resistance) before proceeding. Do not force passage. Forcing passage could increase the risk of vascular complications (for example, vessel dissection or rupture). Persistent force on the catheter can cause the catheter to kink which could increase the risk of vascular complications (for example, vessel dissection or rupture). Once deployment is complete, repositioning of the bioprosthesis is not recommended. Repositioning of a deployed valve may cause aortic root damage, coronary artery damage, myocardial damage, vascular complications, prosthetic valve dysfunction (including device malposition), embolization, stroke, and/or emergent surgery. Do not attempt to retrieve or to recapture a bioprosthesis if any one of the outflow struts is protruding from the capsule. If any one of the outflow struts has deployed from the capsule, the bioprosthesis must be released from the catheter before the catheter can be withdrawn. Ensure the capsule is closed before catheter removal. When using a separate introducer sheath, if increased resistance is encountered when removing the catheter through the introducer sheath, do not force passage. Increased resistance may indicate a problem and forced passage may result in damage to the device and/or harm to the patient. If the cause of resistance cannot be determined or corrected, remove the catheter and introducer sheath as a single unit over the guidewire, and inspect the catheter and confirm that it is complete. Clinical long-term durability has not been established for the bioprosthesis. Evaluate bioprosthesis performance as needed during patient follow-up. Post procedure, administer appropriate antibiotic prophylaxis as needed for patients at risk for prosthetic valve infection and endocarditis. Post procedure, administer anticoagulation and/or antiplatelet therapy per physician/clinical judgment. Excessive contrast media may cause renal failure. Pre procedure, measure the patient's creatinine level. During the procedure, monitor contrast media usage. Conduct the procedure under fluoroscopy. The safety and efficacy of a CoreValve™ Evolut™ R or CoreValve™ Evolut™ PRO bioprosthesis implanted within a transcatheter bioprosthesis have not been demonstrated. However, in the event that a CoreValve™ Evolut™ R or CoreValve™ Evolut™ PRO bioprosthesis must be implanted within a transcatheter bioprosthesis to improve valve function, valve size and patient anatomy must be considered before implantation of the CoreValve™ Evolut™ R or CoreValve™ Evolut™ PRO bioprosthesis to ensure patient safety (for example, to avoid coronary obstruction). In the event that valve function or sealing is impaired due to excessive calcification or incomplete expansion, a post-implant balloon dilatation of the bioprosthesis may improve valve function and sealing. To ensure patient safety, valve size and patient anatomy must be considered when selecting the size of the balloon used for dilatation. The balloon size chosen for dilatation should not exceed the diameter of the native aortic annulus or, for surgical bioprosthetic valves, the manufacturer's labeled inner diameter. Refer to the specific balloon catheter manufacturer's labeling for proper instruction on the use of balloon catheter devices.

Note: Bench testing has only been conducted to confirm compatibility with NuMED Z-MED™ (Evolut PRO only) and Z-MED II™ Balloon Aortic Valvuloplasty catheters where CoreValve™ Evolut™ R and CoreValve™ Evolut™ PRO bioprosthesis device performance was maintained after dilation. Data on File.

POTENTIAL ADVERSE EVENTS Potential risks associated with the implantation of the CoreValve™ Evolut™ R or CoreValve™ Evolut™ PRO transcatheter aortic valve may include, but are not limited to, the following: • death • myocardial infarction, cardiac arrest, cardiogenic shock, cardiac tamponade • coronary occlusion, obstruction, or vessel spasm (including acute coronary closure) • cardiovascular injury (including rupture, perforation, tissue erosion, or dissection of vessels, ascending aorta trauma, ventricle, myocardium, or valvular structures that may require intervention) • emergent surgical or transcatheter intervention (for example, coronary artery bypass, heart valve replacement, valve explant, percutaneous coronary intervention [PCI], balloon valvuloplasty) • prosthetic valve dysfunction (regurgitation or stenosis) due to fracture; bending (out-of-round configuration) of the valve frame; underexpansion of the valve frame; calcification; pannus; leaflet wear, tear, prolapse, or retraction; poor valve coaptation; suture breaks or disruption; leaks; mal-sizing (prosthesis-patient mismatch); malposition (either too high or too low)/malplacement • prosthetic valve migration/embolization • prosthetic valve endocarditis • prosthetic valve thrombosis • delivery catheter system malfunction resulting in the need for additional re-crossing of the aortic valve and prolonged procedural time • delivery catheter system component migration/embolization • stroke (ischemic or hemorrhagic), transient ischemic attack (TIA), or other neurological deficits • heart failure • cardiac failure or low cardiac output • ancillary device embolization • individual organ (for example, cardiac, respiratory, renal [including acute kidney failure]) or multi-organ insufficiency or failure • major or minor bleeding that may require transfusion or intervention (including life-threatening or disabling bleeding) • vascular access-related complications (e.g., dissection, perforation, pain, bleeding, hematoma, pseudoaneurysm, irreversible nerve injury, compartment syndrome, arteriovenous fistula, stenosis) • mitral valve regurgitation or injury • conduction system disturbances (for example, atrioventricular node block, left-bundle branch block, asystole), which may require a permanent pacemaker • infection (including septicemia) • hypotension or hypertension • hemolysis • peripheral ischemia • bowel ischemia • abnormal lab values (including electrolyte imbalance) • allergic reaction to antiplatelet agents, contrast medium, or anesthesia • exposure to radiation through fluoroscopy and angiography • permanent disability.

Please reference the CoreValve™ Evolut™ R and CoreValve™ Evolut™ PRO Instructions for Use for more information regarding indications, warnings, precautions, and potential adverse events.

The commercial name of the device is Medtronic CoreValve™ Evolut™ PRO System.

Medtronic

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