

Pediatric and Adult Interventional Cardiac Symposium

Miami Beach 2017

POCKET GUIDE SYLLABUS

Update: 12-22-16a



January 16-19, 2017 Loews Miami Beach Hotel Miami Beach, FL

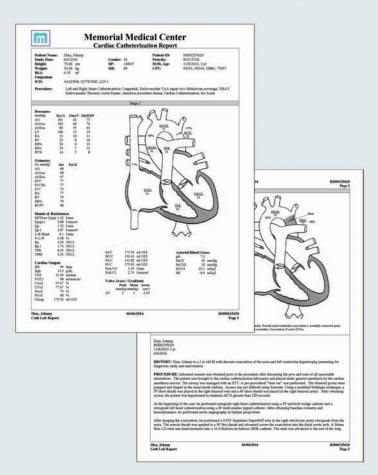
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WELCOME TO PICS~AICS

Dear Colleagues,

The Pediatric and Adult Interventional Cardiac Symposium – PICS-AICS Meeting is celebrating its 20th anniversary this year! The meeting is returning to the Loews Miami Beach Hotel, Miami, January 16th-19th, 2017, following the immense success of the meeting in 2013. This year's meeting will focus on how we can harness advances in technology to continue to grow the field of congenital and structural interventions.

Anniversaries are a time for reflection on the past and also looking to the future. It is 50 years since Rashkind's report of the first balloon atrial septostomy and over 40 years since Noel Mills and Terry King lit up the imagination of interventionalists with the first report of transcatheter ASD closure. We wanted to set the focus of this year's anniversary meeting on the evolution of congenital and structural interventions to date, and how technology will likely contribute to advancing the field over the next 50 years.

The live cases remain the focal point of the meeting. Live cases will be beamed from nine national and international venues with experienced operators that will demonstrate the latest in medical device technology using approved and investigational devices, stents and valves. The live cases this year will be transmitted live via satellite from: Riyadh, Córdoba, Santiago, Dallas, New York, Houston, Pittsburgh, Columbus, and Los Angeles.

The focus of Sunday evening's pre-symposium will transcatheter PFO closure, with an emphasis on how this procedure will evolve following recent FDA approval. The meeting proper will commence on January 16th with a TED-Style talk entitled "From Septostomies to Stem Cells -What the Next 50 Years Hold." The TED format has exploded into the public's consciousness, and has provided an extremely positive medium for sharing knowledge on all aspects of technology. This will be followed by the oral abstract presentations that allow those who continue to push the boundaries of our field with their scientific endeavors to present their work on the international stage. For each of the first three days, we will maintain the clinical focus of the meeting with lunchtime taped cases from 9 national and international centers. The afternoon of the first day will include a session dedicated to impediments to device development, and will include talks from representatives of the FDA. A simultaneous one-day Leadership seminar evaluating aspects of leadership and management in the Cath Lab will be available to those interested. The seminar will be run by a renowned leadership coach, with interactive group work focused on developing team dynamics and a positive culture within the Cath Lab.

January 17th will be the first day of Live Case Transmissions with the whole morning dedicated without any interruption to live cases. The afternoon includes a state-of-the-art session focused on ASD closure, as well as clinical cases dealing with complex structural interventions. Breakout sessions for younger interventionalists, our nursing and technologist colleagues, and how advances in Imaging will continue to develop our interventions will also take place. Later that evening we are presenting a special evening symposium on the RVOT and Transcatheter Pulmonary Valve Replacement. This continues to be one of the most exciting advances in our field over the past 15 years and updates on the ongoing clinical trials with newer valves will be presented.

On Wednesday, January 18th, live cases will be followed by an afternoon session on interventions outside the heart, as well as by a session on the left atrial appendage with wet lab anatomy demonstrations, and a session in collaboration with the CCISC on how we can measure and reduce risk in congenital cardiac catheterization. The immensely popular

PICS~AICS

breakout for our Spanish-speaking attendees will also take place later in the afternoon.

Other popular sessions, including, "My Nightmare Case in the Cath Lab," ensure opportunity for discussion and learning from each other's experiences. The final afternoon will provide a competitive feel as "Battle of the Continents," a quiz-based session on all aspects of catheterization, will return for its second year following last year's inaugural victory by North America.

Poster abstracts will be displayed throughout the meeting. We will continue to support younger interventionalists through the *PICS Young Leadership Program*, with the winner receiving faculty status and involvement in the meeting. We also wish to recognize those committed to research with The Charles S. Kleinman, MD Scientific Scholarship Award, given in memory of our dear friend Dr. Charlie Kleinman, who was so close to the *PICS* family. The winner will receive a \$5,000 grant towards his/her research endeavor. This year to celebrate our 20th anniversary, we also plan to provide sponsorship to a colleague in a developing country to ensure the meeting continues its philosophy of developing congenital and structural catheterization throughout the world.

We look forward to welcoming you to back to Miami. Please don't forget to get in shape for the 5K Run, which will take place along the backdrop of the beautiful Miami Beach. It supports a great cause: providing funds for equipment for mission trips to the developing world. Your participation is what makes the meeting the success that it is, and we look forward to learning with you and from you.

Yours truly,

Ziyad M. Hijazi & Damien Kenny on behalf of Course Directors and Co-Directors

Registration - Rotunda, Second Level			
Sunday	January 15	3-6 pm	
Monday	January 16	6:30 am-6 pm	
Tuesday	January 17	6:30 am-6 pm	
Wednesday	January 18	6:30 am-5:30 pm	
Thursday	January 19	6:30 am-5 pm	

Check at the Reception Desk for for last minute changes to the schedule.



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Important Labeling Information for United States

Indications: The Melody TPV is indicated for use as an adjunct to surgery in the management

of pediatric and adult patients with the following clinical conditions:

- Existence of a full (circumferential) RVOT conduit that was equal to or greater than 16 mm in diameter when originally implanted AND
- Dvsfunctional RVOT conduits with a clinical indication for intervention, AND
- regurgitation: ≥ moderate regurgitation, AND/OR
- stenosis: mean RVOT gradient ≥ 35 mm Hg Contraindications: None known.

Warnings/Precautions/Side Effects:

- DO NOT implant in the aortic or mitral position. Preclinical bench testing of the Melody valve suggests that valve function and durability will be extremely limited when used in these locations.
- DO NOT use if patient's anatomy precludes introduction of the valve, if the venous anatomy cannot accommodate a 22 Fr size introducer, or if there is significant obstruction of the central veins.
- DO NOT use if there are clinical or biological signs of infection including active endocarditis. Standard medical and surgical care should be strongly considered in these circumstances.
- Assessment of the coronary artery anatomy for the risk of coronary artery compression should be performed in all patients prior to deployment of the TPV.
- To minimize the risk of conduit rupture, do not use a balloon with a diameter greater than 110% of the nominal diameter (original implant size) of the conduit for pre-dilation of the intended site of deployment, or for deployment of the TPV.
- The potential for stent fracture should be considered in all patients who undergo TPV placement. Radiographic assessment of the stent with chest radiography or fluoroscopy should be included in the routine postoperative evaluation of patients who receive a TPV
- If a stent fracture is detected, continued monitoring of the stent should be performed in conjunction with clinically appropriate hemodynamic assessment. In patients with stent fracture and significant associated RVOT obstruction or regurgitation, reintervention should be considered in

accordance with usual clinical practice. Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/ sepsis, fever, hematoma, radiation-induced erythema, blistering, or peeling of skin, pain, swelling, or bruising at the catheterization site. Potential device-related adverse events that may occur following device implantation include the following: stent fracture, *stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism,

hemolysis.

*The term "stent fracture" refers to the fracturing of the Melody TPV. However, in subjects with multiple stents in the RVOT it is difficult to definitively attribute stent fractures to the Melody frame versus another stent.

For additional information, please refer to the Instructions For Use provided with the product.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Important Labeling Information for Geographies Outside of the United States

Indications: The Melody Transcatheter Pulmonary Valve is indicated for use in patients with the following clinical conditions:

- Patients with regurgitant prosthetic Right Ventricular Outflow Tract (RVOT) conduits with a clinical indication for invasive or surgical intervention, OR
- Patients with stenotic prosthetic RVOT conduits where the risk of worsening regurgitation is a relative contraindication to balloon dilation or stenting.
- Existence of a full (circumferential) RVOT conduit that was equal to or greater than 16 mm in diameter when originally implanted. The intended lifetime for the Melody device is 2 years.

Contraindications:

- Venous anatomy unable to accommodate a 22 Fr size introducer sheath; implantation in left heart.
- Unfavorable right ventricular outflow tract for good stent anchorage.
- · Severe right ventricular outflow obstruction, which cannot be dilated by balloon.
- Obstruction of the central veins.
- Clinical or biological signs of infection. Known allergy to aspirin or heparin.
- Active endocarditis.

Pregnancy. Potential Complications/Adverse Events: Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/ sepsis, fever, hematoma, radiation-induced erythema, pain at the catheterization site.

Potential device-related adverse events that may occur following device implantation include the following: stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis.

For additional information, please refer to the Instructions For Use provided with the product.

The Melody Transcatheter Pulmonary Valve and Ensemble II Transcatheter Delivery System has received CE Mark approval and is available for distribution in Europe.



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Digisonics, Inc. (Booth #26)	2	
Medtronic (Booth #5)	5, 6, 40	
NuMED (Booth #35)	11	
New York Presbyterian	15	
pfm Medical (Booth #21)	25	
Siemens (Booth #4)	31	



ACKNOWLEDGEMENTS

The PICS Foundation and PICS~AICS 2017 wish to gratefully thank the following exhibitors for their support of this year's program:

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- · St. Jude Medical Japan
- Toshiba America Medical Systems, Inc.
- · Venus Medtech

PICS~AICS Also Thanks

- Congenital Cardiology Today
- The Journal of Structural Heart Disease
- The Society for Cardiovascular Angiography and Interventions
- Wolters Kluwer
- World Congress of Pediatric Cardiology & Cardiac Surgery

2017 Live Case Centers

- Prince Sultan Cardiac Center, Riyadh, Saudi Arabia
- Private Hospital of Córdoba, Córdoba, Argentina
- Pontificia Universidad Catolica de Chile, Santiago, Chile
- New York-Presbyterian Morgan Stanley Children's Hospital, New York, NY USA
- Texas Children's Hospital, Houston, TX USA
- Children's Medical Center, Southwestern Medical Center, Dallas, TX USA
- Nationwide Children's Hospital, Columbus, OH USA
- Children's Hospital of Pittsburgh, Pittsburgh, PA USA
- Los Angeles Children's Hospital, Los Angeles, CA USA

PICS~AICS COURSE DIRECTORS & FACULTY

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Co-Directors: Clifford J. Kavinsky, MD, PhD; Ralf Holzer, MD, MSC; John D. Carroll, MD; Felix Berger, MD

Director Emeritus: William E. Hellenbrand, MD

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4th Annual PICS~AICS 5K RUN Sponsored by SIEMENS

Race: 6:00 am, Tuesday, January 17th
Loews Walking Path

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The \$30 donation includes:

- Technical T-shirt (Men's & Women's)
- · Digital chip timing
- Registration
- · Finish line and post-race refreshments

Race packets may be picked up at the Siemens booth

The race will take place rain or shine.
All fitness levels are welcome!

For more Information and Registration:

Visit the PICS-AICS Registration Desk January 16th, Monday,10:00 am-5:00 pm or the Siemens Booth #4, 6:00-8:00 pm

There will be no race-day registration

Come have some fun in the sun while doing something healthy during the PICS~AICS Symposium.

EXHIBITIONS Americana Ballroom Salon 3 & 4, 2nd Level

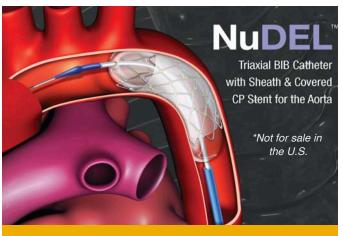
We encourage you to visit the exhibits.

Exhibitor Passport Game for a chance to win a BOSE Quiet Comfort 35 Acoustic Noise Cancelling Head Phone

The object of the game is to completely validate your passport by visiting all the booths and getting a stamp.

Turn your completed Passport in at the Registration Desk

The Exhibitor Passport Drawing will be on Thursday, January 19th at 4:45pm. The winner must be in attendance



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JANUARY 16th - PICS-AICS MONDAY Leadership Seminar

Poinciana 3 & 4 - 2nd Level

10:00 am-4:00 pm - Leadership & Management in the Cath Lab – Bob Berk, Author of "Leadership between the Sheets" Uncovering the Power of Intimacy in Business and in Life

10:00-11:30 am - Leadership, Management & Culture – Bob Berk

11:30-11:45 am - Coffee

11:45 am-12:30 pm - Leadership Track - Team Alignment

Management Track - Balancing the Books - Understanding is Key!

- Your Key Performance Indicators
- Improving Outcomes
- · Linking to Expectation

12:30-1:30 pm - Lunch

1:30-2:15 pm -

Leadership Track - Establishing a Winning Culture

Management Track - Inventory and Environment

- Deciding What You Need and How to Afford It
- Defining Priorities
- Setting and Communicating Expectations

2:15-3:00 pm -

Leadership Track - Understanding EQ in Leadership

Management Track - Effective QA/QI

- Opportunities for Staff Growth and Development
- Strategic Priorities
- Integrating Goal

3:00-4:00 pm - Bringing It All Together - Shared Learnings in Implementing Change in Your Environment



JANUARY 16th - PICS-AICS MONDAY

Morning Session

Americana Ballroom - Salon 1 & 2 - 2nd Level Moderators: Ziyad M. Hijazi; John P. Cheatham

6:45-8:15 am - Breakfast Available - Americana Foyer - 2nd Level

10:00 am-8:00 pm - Poster Abstracts - Americana Foyer - 2nd Level

8:00-8:15 am - Welcome - Ziyad M. Hijazi

8:15-8:45 am - Keynote "TED-Style" Lecture: "From Septostomies to Stem Cells – What the Next 50 Years Hold" – David Nykanen

10:00 am-4:30 pm - Leadership Seminar Presented by Bob Berk - Poinciana 1 & 2 - 2nd Level (see page 12 for detail)

8:50-10:30 am - Oral Abstract Presentations I Moderators: Michael de Moor; John Bass; Alex Javois

10:30-11:00 am - Break - Americana Foyer - 2nd Level

11:00 am-1:00 pm - Oral Abstract Presentations II – Moderators: Levent Saltik; Redmond Burke; Larry Latson

1:10-2:00 pm - Lunch Session - Taped Cases

Moderators: Brent Gordon; Terry King

- Mayo Clinic Allison Cabalka; Nathan Taggart
- Toronto Mark Osten
- Stanford Lynn Peng

Afternoon Session

Americana Ballroom - Salon 1 & 2 - 2nd Level Moderators: Thomas K. Jones; William Hellenbrand

2:00-3:30 pm - Stenting in the 21st Century – How Far Have We Come, and How Far We Have Yet to Go?

Moderators: John Rhodes; Joaquim Miro

- Use of Registries to Examine Outcomes with Stenting – Julie Vincent
- The Biomechanics of Stent Development

 Shyam Sathanandam
- Neointimal Ingrowth Can We Predict & Prevent This? – Felix Berger
- The Physiological Impacts of Stenting Measuring Flow Dynamics Aimee Armstrong
- Bioresorbable Technology Is Here, But Is It Enough for CHD Patients? – Daniel Levi
- Stents and Tissue Engineering Pie in the Sky or a Reality in the Next 20 Years? – Massimo Caputo
- Discussion

3:30-4:00 pm - Break - Americana Foyer - 2nd Level

JANUARY 16th - PICS-AICS MONDAY

4:00-5:30 pm - FDA Town Hall and Device Development (Doug Villnave Session)

Moderators: John Cheatham; Matt Gillespie; Vasum Peiris

- Introduction Allen Tower, Jr.
- Devices We Need Developing a Bioresorbable Scaffold That Works for our Population – Martin Bocks
- Devices Available Elsewhere Challenges & Progress to Achieving Availability in the US? – Evan Zahn
- Device Development: Current Challenges and How to Overcome – Thomas Forbes
- Early Feasibility Study Applicability to Pediatric Device Development – Nicole Ibrahim
- Device Approval in Different Continents Can we work together to Streamline Broader Approval Guidelines? – Experience from Japan – Teiji Akagi
- Round Table Discussion

6:00-8:00 pm - Americana Ballroom - Salon 3 & 4 - 2nd Level

- Welcome Reception
- Exhibit Hall Open

CME, CNE, AND ASRT EVALUATION / CERTIFICATE

PICS-AICS 2017 continuing education evaluations will be done online this year. After the conclusion of the meeting you will receive an email from the RUSH University Office of Interprofessional Continuing Education. To qualify for credit, you must complete a program evaluation. Once you complete this survey, you will receive your certificate of participation within one week. After successful completion of the online evaluation, you will receive a certificate of participation for a maximum of 32.25 CME or CNE credits, or 34.5 ASRT Category A credits. A certificate will be provided via email. If you have any questions please contact The Rush Office of Interprofessional Continuing Education at 312-942-7119.

CME Accreditation

Sponsored for continuing education credit by Rush University Medical Center. Rush University Medical Center is accredited by the Accreditation Council for Continuing Medical Education, the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

Rush designates this live activity for a maximum of **32.25 AMA PRA Category 1 Credit(s)™**. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CNE Accreditation

This CNE program is being presented without bias and with commercial support.

Rush University designates this live activity for thirty-two and one quarter (32.25) Continuing Education credit(s).

The American Society of Radiologic Technologists has approved this activity for a maximum of **34.5** Category A credits. This activity is approved for credit by the ASRT.

A complete list of faculty conflict of interest statements can be found in your registration packet. They are also available for viewing at the Registration Desk.



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While we treat some of the most complex cases, our outcomes are **more than 30% better** than established national benchmarks

Each year, our pediatric cardiac surgical teams perform more than

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For the years 2011-2014, our average hospital mortality was 3.0%

The Society of Thoracic Surgeons (STS) global hospital mortality for all participating pediatric cardiac centers was 3.3%

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JANUARY 17th - PICS-AICS TUESDAY

6:00 am - PICS-AICS 5K Run - Loews Walking Path

6:45-8:15 am - Breakfast Available - Americana Foyer -2nd Level

8:00 am-5:30 pm - Poster Abstracts - Americana Foyer -2nd Level

Morning Session

Americana Ballroom Salon 1 & 2 – 2nd Level

8:00-8:15 am - Update on Live Cases 2015 - Kiran Mallula

8:15 am-10:30 am - Live Cases - (Riyadh, Santiago, Córdoba) Moderators: Damien Kenny; Ziyad M. Hijazi <u>Digital Moderators</u>: Daniel Gruenstein; Alexander Javois Panelists: Carlos Zabal, Jou Kou Wang; Makram Ebeid; Alvaro Galindo

10:30-10:45 am - Break - Coffee Available - Americana Ballroom - Salon 3 & 4 - 2nd Level

10:45 am-1:00 pm - Live Cases - (Riyadh, Santiago, Córdoba) Moderators: William Hellenbrand; Daniel Levi Digital Moderators: Gareth Morgan; Kanishka Ratnayaka Panelists: Noa Holoshitz; Seong-Ho Kim; Petru Liuba; Tarek Momenah

12:45-1:15 pm - Lunch Session - Americana Ballroom -Salon 3 & 4 - 2nd Level

1:10-2:00 pm - Lunch Session - Taped Cases -Americana Ballroom - Salon 1 & 2 - 2nd Level Moderators: Richard Ringel: Jacqueline Kreutzer

- Cincinnati Bryan Goldstein
 Houston Huie Lin; John Breinholt
- Israel Elchanan Bruckheimer

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JANUARY 17th - PICS-AICS TUESDAY

Afternoon Session

Americana Ballroom - Salon 1 & 2 - 2nd Level Moderators: Ralf Holzer; Cliff Kavinsky

2:00-3:30 pm - State-of-the-Art - ASD Closure

Moderators: Horst Sievert: Worakan Promphan

- Left Atrial Disengagement Bharat Dalvi
 The Malaligned Atrial Septum Implications for Closure & Complications - David Balzer
- How Recent Erosion Data Has Changed My Practice - Zahid Amin
- Revisiting the Deficient IVC Rim Defect Which **Defects Should We Attempt?** – Masood Sadig
- ASD Closure Exclusively with TEE Why & How? Felix Berger
- ASD Closure in Children < 8Kgs Indications & Techniques - Jeremy Asnes
- Transcatheter ASD Suture-Mediated Closure **Current Status & Future Challenges** - Anthony Nobles

3:30-4:00 pm - Break - Coffee Available - Americana Ballroom - Salon 3 & 4 - 2nd Level

4:00-5:30 pm - Complex Structural Interventions (6 Case Presentations)

Moderators: Cliff Kavinsky; John Carrol; Hussam Suradi

- Mitral Valve Allison Cabalka
- TAVR with Close Coronaries Issam Moussa
- TAVR Valve-in-Valve Roberto Cubeddu
- Tricuspid Valve Reda Ibrahim
- Hybrid Case Michel Ilbawi
- Pulmonic in Native Outflow Mansour AlJufan
- Discussion





JANUARY 17th - PICS-AICS TUESDAY Breakout Session

Breakout Session Cowrie 1 & 2 - 3rd Level

2:00-3:30 pm - Nursing & Associated Professionals -

Moderators: Sharon Cheatham; Karen lacono

- Electronic Updates from the Cath Lab Karen Iacono
- Right Heart Cath Without Radiation Ileen Cronin
- Assessing Coronaries in CHD Katy Soule
- Managing PLE ... Anything New? Yoav Dori
- Mechanical Thrombectomy Karen laconno
- Ambulatory Fontan Pressure Monitoring Using An Implantable – Darren Berman
- Transcatheter Innovations Aimee Armstrong
- Discussion

Breakout Session Poinciana 1 & 2 - 2nd Level

2:00-3:30 pm - PICES Session

Moderators: Nathan Taggart; Matthew Crystal

- Call to Order; General Welcome Nathan Taggart, President
- Program Development and Negotiation

 David Nykanen (talk & discussion)
- Research Update Jeffrev Zampi, VP Research
- New/Old Business PICES Executive Committee (Gareth Morgan – Secretary; Matthew Crystal – VP Clinical; Michael Seckeler – Website Content Editor)
- Case Presentation (Interactive Session of Toughest / Most Challenging / Craziest Case)
 - Michael Hainstock





JANUARY 17th - PICS-AICS TUESDAY Breakout Session

Breakout Session Poinciana 3 & 4 - 2nd Level

4:00-5:45 pm - Advances in Imaging Modalities to Guide Interventions

Moderators: Aimee Armstrong; Shelby Kutty

- Update on Fusion Imaging Modalities Thomas Fagan
- 3-D Modeling Will Prove More Beneficial Than Holography in Guiding Congenital Interventions in the Next 10 Years
 - Pro: Colin McMahon; Con: Elchanan Bruckheimer
- Widespread Use of MRI-Guided Interventions Will Be a Reality in the Next 20 Years
 - Pro: Kanishka Ratnayaka; Con: Daniel Gruenstein
- Ultrasound for Vascular Access Should be the Gold Standard
 - · Pro: Christopher Petit; Con: Zahid Amin
- Percutaneous intervention of CASH: Alternative Non-Fluoroscopic Strategy (PAN Procedure)
- Xiangbin PanDiscussion

PICS FOUNDATION

10151 Avenue N., Chicago, IL 60617 USA The PICS Foundation is a 501(c)(3) organization.

The PICS Foundation has been organized exclusively for charitable, educational and scientific purposes.

The focus of the Foundation is to educate physicians and healthcare professionals involved in the care of children and adults with congenital and structural heart disease in the latest advances in the field of interventional therapies for congenital and structural cardiac defects. The PICS Foundation will provide educational meetings and materials to pediatric and adult cardiologists from all over the world. The PICS Foundation will also sponsor research in the area of congenital and structural heart disease.

The PICS Foundation may receive funding via individual contributions and grants from hospitals and other members of the medical community, registration fees from attendees of the annual symposium, exhibit fees from vendors attending the annual symposium and funds from individual contributors.

The primary activity of the PICS Foundation will be conducting an annual meeting for healthcare professionals. The Pediatric & Adult Interventional Cardiac Symposium is an annual meeting that is attended by approximately 1,000 healthcare professionals from all around the world. The symposium consists of 4 days of lectures and live case operations.

To support the PICS Foundation, please contact:

Ziyad M. Hijazi, MD: zhijazi@me.com
Kimberly Ray: kimberly_ray@pics-aics.com

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NIT-OCCLUD® PDA COIL SYSTEM FOR TREATMENT OF PATENT DUCTUS ARTERIOSUS





lete indications, relevant warnings, precautions, complications, and contraindications. CP Stent is a trademark of NuMED, Inc. BIB is a registered trademark of NuMED, Inc. Nit-Occlud is a registered trademark of pfm medical, Inc.

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INDICATIONS FOR USE

The CP Stent" is indicated for use in the treatment of native and/or recurrent coarctation of the aorta involving a compliant aortic isthmus or The U-S best it similates in Use in the treatment of native anoin recurrent constant on the data movining compliant anoisinities first segment of the descending potant where there is adequate size and Patency of at least one Femoral Artery and the balloon anjoiplesty is contraindicated or predicted to be ineffective. WARNINGS / PRECAUTIONS: Coarctation of the aorta involving the aortic ishmust of first segment of the descending ands should be confirmed by diagnostic imaging. The C9 stent has not been evaluated in patients weighing less than 20kg, as with any type of implant, infection secondary to contamination of the stent may lead to actifits, or abscess. Over-stretching of the artery may result in rugture or anouncym formation. Crimping the stent on a balloon catheter smaller than 12mm may cause damage to the stent. This device is intended for single use only. Do not resterilize and/or reuse it, as this can potentially result inter cause-usining to use sum. Into service is intended for single use only. Do not result in a compromised device performance and increased risk of cross-contamination. CONTRANIO(CATIONS: Patients to small to allow safe delivery of the stent without compromise to the systemic artery used for delivery. Unfavorable aortic anatomy that does not dilate with high pressure balloon angioplasty. Curred vasculative. Coclusion or obstruction of systemic artery precluding elietry of the stent. Clinical or biological signs of infection. Active endocarditis. Known allergy to aspirin, other antiplatelet agents, or heparin. Pregnancy.

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The Nit-Occlud® PDA coil is a permanently implanted prosthesis indicated for percutaneous, transcatheter closure of small to moderal size patent ductus arteriosus with a minimum angiographic diameter less than 4mm. Nit-Occlud Brief Statement. Do not implant the Nit-Occlud PDA into patients who have endocarditis, endarteritis, active infection, pulmonary hypertension (calculated PVR greater than 5 Vocod Units, thrombus in a blood vessel through which access to the PDA must be obtained, thrombus in the winning through which access to the PDA must be obtained, thrombus in the winning of the implantation is the at the time of the implantation or patients with a body weight <11 lbs (5 kg). An angiogram must be performed prior to implantation for measuring length and diameter of the PDA. Only the pfirm medical implantation delivery catheter should be used to implantation the device. Administration of 50 units of heparin per kg body weight should be injected after femoral sheaths are placed. Antibiotics should be given before (1 does) and after implantation of 20 units of heparin per kg body weight should be injected after femoral sheaths are placed. Antibiotics should be given before (1 does) and after implantation of 20 sees) in order to prevent infection during the implant procedure. Do not implant the Nit-Occiud PDA in an MR environment. Do not pull the Nit-Occiud coil through heart valves or ventricular chambers. Contrast media should not be injected through the implantation catheter. The catheter must not be connected to high pressure injectors. Patients may have an allergic response to his device due to small amounts of nicket that has been shown to be released from the device in very small amounts. If the patient experiences allergic symptoms, such as difficulty in breathing or swelling of the face or throat, the very small amounts. If the patient experiences altergic symptoms, such as difficulty in breathing or swelling of the face or throat, he's esh colud be instructed to seek medical assistance immediately. Antibiotic prophylaxis should be performed to prevent intelleve endocarditis during first 6 months after coil implantation. Potential Adverse Events: Air embolism, Altergic reaction to drug/contrast, Apnea, Arrhythmia requiring medical retertenter to period, Arteriovenous fistual, Bacterial endocarditis, Blood loss requiring transform. Chest pain, Damage to the tricuspid or pulmonary valves, Death, Embolization of the occluder, requiring percutaneous or surgical intervention, Endarteriis. False aneurysm of the feromat latery, Fever Headachehriginar, Heart falture, Hennylss after implentation of the occluder, Hypertension, Hypotension or shock, Infection, Myocardial inferction, Occluder fracture or damage, Perforation of the heart or blood vessels, Stensios of the left primonary array or descending thoraccia cants, Stroked/TA, Thrombosmic (cerebral or pulmonary), Valvular Regurgitation, Vessel damage at the site of groin puncture (loss of pulse hematoma, etc.).

MAKING A DIFFERENCE



INDICATIONS FOR USE:

INDICATIONS FOR USE:

The Covered CP Stemt* is indicated for use in the treatment of native and/or recurrent coarciation of the acrta involving the acrtic isthmus or first segment of the descending parts where there is adequate size and patency of at least one femoral artery associated with one or more of the following: Acute or chronic wall injury. Nearly attent descending parts of 3 mm or less in diameter, A non-compliant stendor across expending acrts of 3 mm or less in diameter, A non-compliant stendor across expending acrts are supported. A property of the descending parts also also across expending acrts are supported by adequate the part of the acrts involving the acrts is stimus or first segment of the descending parts should be confirmed by diagnostic imaging. The CP stem has not been evaluated in patients weighing less than 20kg. As with any type of implant, infection secondary to contamination of the stent may lead to acrtist, or abscess. Over-stretching of the artery may result in rupture or enarrays from them. Crimping the setten on a balloon catheter smaller than 12mm any cause damage to the stent. Excessive handling and manipulation of the covering while crimping the stent on potentially result in compromised device performance and increased risk of cross-contamination. CONTRAINDICATIONS: Patients too small to allow safe deliver of the setten without commonnies to the systemic artery used for delivery. Unfavorable acritic anatomy that does not dilate with delivery of the stent without compromise to the systemic artery used for delivery. Unfavorable aortic anatomy that does not dilate with high pressure balloon angioplasty. Curved vasculature. Occlusion or obstruction of systemic artery precluding delivery of the stent. Clinical or biological signs of infection. Active endocarditis. Known allergy to aspirin, other antiplatelet agents, or heparin. Pregnancy

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JANUARY 17th - PICS-AICS TUESDAY Evening Symposium

Evening Symposium

Americana Ballroom - Salon 1 & 2 - 2nd Level

Sponsored with unrestricted educational grants from:

- Edwards Lifesciences
- Medtronic
- Venus MedTech

6:00-6:30 pm - Light Dinner Buffet Available for Those Attending the Evening Symposium

6:30-9:00 pm - The RVOT – Volumes, Clinical Trials and the Future

Moderators: William Hellenbrand; Matt Gillespie; Alistair Phillips

6:30-6:45 pm - The Pulmonary Valve – The Sacrificial Lamb of Tetralogy Surgery – Is There Any Hope for Preservation in the Next 20 Years? – Emile Bacha

6:46-7:07 pm - Approach to RVOT Rehabilitation Should be Influenced by Evolving Transcatheter Technologies

- · Pro: Marc Gewillig
- · Con: Michel Ilbawi

7:08-7:23 pm - How to Deal With Complex Distal MPA, Proximal Branch PA Stenosis in Patients Undergoing tPVR – Ziyad M. Hijazi

7:25-8:10 pm - Updates on Clinical Trials for Transcatheter Pulmonary Valve Systems

- Venus Valve Shakeel Qureshi
- Edwards Valve Scott Lim: Evan Zhan
- Medtronic Valve John P. Cheatham

8:15-8:30 pm - How Evolving Imaging Modalities and 3-D Printing Will Shape tPVR Over the Next 10 Years

Mansour AlJufan

8:30-8:45 pm - Registeries – A Late Start, but an Essential Part of TPVR Outcome Assessment

- Doff McElhinnev

8:45-9:00 pm - Questions and Discussion



JANUARY 18th - PICS-AICS WEDNESDAY

6:45-8:15 am - Breakfast Available - Americana Ballroom - Salon 3 & 4 - 2nd Level

7:00 am-8:00 pm - Moderated Poster Session - Americana Foyer

Moderators:

Group 1: JV DeGiovanni; Emile Bacha

Group 2: Elchanan Bruckheimer; Mark Galantowicz

Group 3: Horst Sievert; Massimo Caputo

8:00 am-5:30 pm - Poster Abstracts - Americana Foyer

Morning Session

Americana Ballroom - Salon 1 & 2 - 2nd Level

8:00-10:15 am - Live Cases - (Dallas, Houston, New York)
Moderators: William Hellenbrand, John P. Cheatham
Digital Moderators: David Balzer; Darren Berman
Panelists: Hideshi Tomita; Abe Rothman; Raul Rossi;
Joshua Murphy

10:15-10:45 am - Break

10:45 am -1:00 pm - Live Cases - (Dallas, Houston, New York) Moderators: John Cheatham; Shakeel Qureshi Digital Moderators: Jeremy Asnes; Reda Ibrahim Panelists: Marco Papa; Charles Mullins; Wail Alkashkari; Pan Xin

12:45-1:15 pm - Lunch Available - Americana Ballroom - Salon 3 & 4 - 2nd Level

1:10-2:00 pm - Lunch Session - Taped Cases - Americana Ballroom - Salon 1 & 2 - 2nd Level

Moderators: Craig Fleishman; Lee Benson

- Los Angeles Evan Zahn
- Seattle Brian Morray
- Dublin Kevin Walsh; Damien Kenny



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JANUARY 18th - PICS-AICS WEDNESDAY

Afternoon Session

Americana Ballroom - Salon 1 & 2 - 2nd Level Moderators: Ralf Holzer; John Carroll

2:00-3:30 pm - Interventions Outside the Heart

Moderators: Elchanan Bruckheimer: Mark Galantowicz

- Airway Stenting for CHD Patients: When & How
 Gareth Morgan
- Use of Intraprocedural Broncoscopy to Assess for Airway Compression During Interventions

 Matt Gillespie
- Interventions on the Lymphatic System Early Outcomes & Longer-Term Applicability – Yoav Dori
- Interventions on the Portal System K. Sivakumar
- Renal Artery Denervation: Applicability to CHD Patients – Horst Sievert
- Interventions for Middle Aortic Syndrome A Worthy Venture or Futile Folly? – Shakeel Qureshi
- Transhepatic Liver Biopsy in TCPC Patients When & How? – Howaida El-Said
- Discussion

3:30-4:00 pm - Break - Coffee Available - American Ballroom - Salon 3 & 4 - 2nd Level

4:00-5:30 pm - Pushing the Boundaries

Moderators: Damien Kenny: Evan Zahn

- Fetal Interventions 25 Years Later
 - Doff McElhinney
 Closure of the Premature Duct How Small Is Too
 - Small? Joaquim Miro

 Assessing the Physiological Impact of our
 - Interventions How Imaging May Help Lee Benson
 The Optimal Catheter Interventions for Pulmonary
 Hypertension Where & How Big? Dietmar Schranz
 - The Future of Managing Holes...From Bioresorbable to Histerotripsy – Marc Gewillig
 - Advances in Surgical Techniques Balancing the Viewpoint of the Fabled Perils of Surgical Intervention – Sertac Cicek
 - Assessing the Physiological Outcomes of Our Interventions – Are We Underutilizing CPEX Testing? – Jonathan Rhodes
 - Discussion

6:30 pm - Motor coaches will depart from Loews Palm Court Entrance for the PICS~AICS Dinner at Nikki Beach

7:00-10:30 pm - PICS-AICS Dinner Event at Nikki Beach

This year's *PICS~AICS Dinner* will be at Nikki Beach Miami. Nikki Beach Miami is the hidden jewel of South Beach, located on One Ocean Drive along the beautiful Atlantic Ocean. Join us as we celebrate 20 years of *PICS* at Nikki Beach with dinner on the beach followed by dancing and special entertainment.

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PICS-AICS 20th Annual
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Live Surgery Case: PDA Closure

- January 17th, 2017
- ▶Private Hospital Cordoba, Cordoba, Argentina (2 case)
 - Dr. Alejandro Peirone: I am using the dedicated PDA coil: Nit-Occlud® PDA

Results of the combined U.S. Multicenter Pivotal Study

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JANUARY 18th - PICS-AICS WEDNESDAY Breakout Session

Breakout SessionPoinciana 1 & 2 - 2nd Level

2:00-3:30 pm - Left Atrial Appendage & Mitral Valve Interventions

Moderators: Roberto Cubeddu; Carlos Pedra

- Wet Lab Anatomy of the LAA Considerations for Closure – Mark Reisman
 - Operator & Institution Requirements for LAA Occlusion – Cliff Kavinsky
 - Matching the Device to the Anatomy Horst Sievert
 - The Watchman Device Is This the End of the Story for LAA Occlusion in the U.S. for the Next 10 Years?
 Saibal Kar
 - Problems with Transcatheter Mitral Valve Repair & Replacement – A Surgical Perspective – Robert March
 - Novel Approaches to the Mitral Valve for Repair & Replacement – Robert Lederman
 - Discussion

Breakout Session

Poinciana 3 & 4 - 2nd Level

4:00-5:30 pm - Measuring and Reducing Risk in Collaboration with CCISC

Moderators: Ralf Holzer; Thomas Forbes

- Data Capture and Registry Participation for QI & QA: There is No "One Shoe Fits All" Solution
 Ralf Holzer
- Use of Registry Data to Support QI & QA Efforts & How to Achieve Quality Data Entry: The CCISC
- Experience David Nykanen
 Beyond QI and QA: Use of Data for Marketing -Pitfalls & Opportunities – Thomas Forbes
- Update on IMPACT: Let's Make an Impact on Device Approval – Robert Vincent
- What Does the Future Hold: Integrating Surgical with Cath Data, Longitudinal & Multi-Center Data Capture – Jeff Jacobs
- It's Not Just about the Data: How to Achieve Transparency in Multi-Center QI Initiatives

 Lisa Bergersen
- Discussion

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JANUARY 18th - PICS-AICS WEDNESDAY Breakout Session

Breakout Session Cowrie 1 & 2 - 3rd Level

3:45-5:45 pm - Spanish Session

Moderators: Carlos Zabal (Mexico); Horatio Faella (Argentina); Daniel Aquirre (Chile)

- Computed Modeling & Simulation Role in Interventions for CHD
 - Mario Carminati (Italy)
- 3D Printing of the RVOT Practical Clinical Applications
 - José Luiz Zunzunegui (Spain)
- 3D RTA and Interventions in CHD: Imaging Overkill or Useful Technology
 - Francisco Garay (Chile)
- Preliminary Experience with the Venus P-Valve in Latin America
 - Alejandro Peirone (Argentina)
- Use of the Large V12 Advanta Stent for Coarctation of the Aorta - Early & Late Outcomes in the International Multicenter Trial
 - Carlos Pedra (Brazil)
- Experience with the ADO II AS Indications, Techniques & Results
 - Jacek Biakolwski (Poland)

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JANUARY 19th - PICS-AICS THURSDAY

6:45-8:15 am - Breakfast Available - Americana Ballroom - Salon 3 & 4 - 2nd Level

8:00 am-5:00 pm - Poster Abstracts - Americana Foyer - 2nd Level

Morning Session

Americana Ballroom - Salon 1 & 2 - 2nd Level

8:00-9:30 pm - Live Cases - (Pittsburgh, Columbus, Los Angeles) Moderators: Carlos Pedra; Thomas K Jones Digital Moderators: Wail Alkashkari; Francisco Garay Panelists: Hasri Samion, Zoltan Turi; Michael Tynan; Horacio Faella

9:30-11:00 am - Update on Structural Heart Interventions for Congenital Interventionalists

Moderators: John Carroll; Thomas Jones

- Optimizing Patient Selection & Procedure Safety for PFO Closure: Lessons Learned from Respect

 Richard Smalling
- Post-PFO Closure Medical Management Issues: Key to Long-Term Outcomes & Individualization of Medication – James Conners
- Congenital Interventionalists Have Nothing to Offer Now or in the Future with TAVR
 - Pro: Eric Horlick
 - · Con: Jamil Aboulhosn
- Interventional Options for Diastolic Heart Failure Indications, Devices & Approach – Thomas Jones
- Update on Outcomes of Transcaval TAVR
 - Robert Lederman
- Surgical Advances to Support Hybrid Interventions in Structural Heart Disease – Robert March
- Use of the MitraClip in CHD Patients Scott Lim

11:00-11:30 am - Break - Coffee Available - Americana Ballroom - Salon 3 & 4 - 2nd Level

11:30 am-1:00 pm - Live Cases - (Pittsburgh, Columbus, Los Angeles)

Moderators: Ziyad M. Hijazi; Zahid Amin Digital Moderators: Huie Lin; Lynn Peng

Panelists: Maiy El Sayed; Ali El Halabi; Jae Young Choi;

David Fulton; Jacek Bialkowski

12:45-1:15 pm - Lunch Available - Americana Ballroom - Salon 3 & 4 - 2nd Level

2:00 pm - Exhibits Close

1:10-2:30 pm - Lunch Session - My Nightmare Case In the Cath Lab

Moderators: Shakeel Qureshi; Daniel Gruenstein

JANUARY 19th - PICS-AICS THURSDAY

Afternoon Session

Americana Ballroom - Salon 1 & 2 - 2nd Level

2:30-4:00 pm - Simplifying the Complex – My Step-by-Step Approach

Moderators: Satinder Sandhu & TBD

- RVOT Stenting & Avoidance of the Pulmonary Valve in Neonates – JV de Giovanni
- VSD Closure via the Retrograde Arterial Approach

 Thomas Jones
- PDA Stenting in Tetralogy-Variant Patients

 Mazeni Alwi
- Hybrid Mitral Valve Replacement in Infants

 Emile Bacha
- Hybrid Pulmonary Valve Replacement

 Alistair Phillips
- The Hybrid Approach to HLHS Mark Galantowicz
- Modalities to Support Large Sheath Advancement in RVOT Interventions – Mario Carminati
- Discussion

3:00-3:30 am - Break - Coffee Available - Americana Foyer - 2nd Level

4:00-4:40 pm - "Battle of the Continents"

Quizmaster: Damien Kenny

4:40-5:00 pm - Prize-Giving & GoodBye!

– Ziyad M. Hijazi

Exhibitor Passport Prize is a BOSE Quiet Comfort 35 Acoustic Noise Cancelling Head Phone.

Winner must be present.

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SUMMARY LIVE CASES AND OPERATORS

TUESDAY, JANUARY 17TH

Prince Sultan Cardiac Center, Riyadh, Saudi Arabia (2 cases)

Khalid Al Najashi

Private Hospital of Córdoba, Córdoba, Argentina (2 cases)

- Alejandro Peirone

Pontificia Universidad Catolica de Chile, Santiago, Chile (2 cases)

- Francisco Garay; Carlos Pedra

WEDNESDAY, JANUARY 18TH

New York-Presbyterian Morgan Stanley Children's Hospital, New York, NY USA (2 cases)

– Alejandro Torres: Matthew Crystal: Julie Vincent

Texas Children's Hospital, Houston, TX USA (2 cases)

- Henri Justino; Athar Qureshi

Children's Medical Center at Southwestern Medical Center, Dallas, TX USA (2 Cases)

- Alan Nugent, Thomas Jones

THURSDAY, JANUARY 19TH

Nationwide Children's Hospital, Columbus, OH USA (2 cases)

- Darren Berman; Aimee Armstrong

Children's Hospital of Pittsburgh, Pittsburgh, PA USA (2 cases)

- Jaqueline Kreutzer: Sara Trucco

Los Angeles Children's Hospital, Los Angeles, CA USA (2 cases)

- Frank Ing

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EXHIBIT FLOOR MAP Americana Ballroom 3 and 4

Exhibit Overview

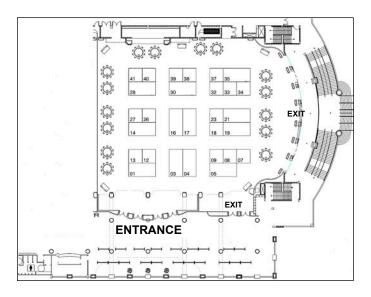
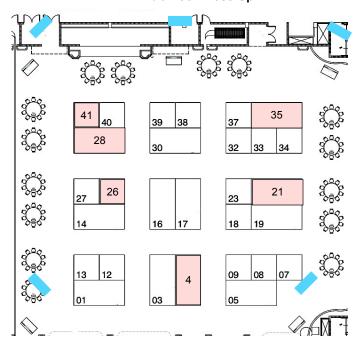


Exhibit Floor Close-Up



Color Key

- 70" Plasma Screen
- Pocket Guide Syllabus Advertiser Booths

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Edwards Lifesciences St Jude Medical

Booth: 30 Booth: 3

GORE Texas Children's Hospital
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Booth: 1 Booth: 23

Houston Methodist Hospital Toshiba

Booth: 38 Booth: 16

Lifetech Scientific Venus Medtech
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Materialise Wolters Kluwer
Booth: 39 Booth: 37

MedtronicWorld Congress of PediatricBooth: 5Cardiology & Cardiac Surgery

Nationwide Children's Hospital

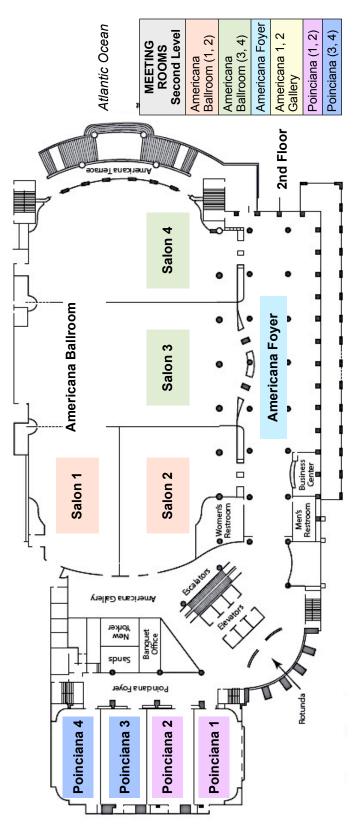
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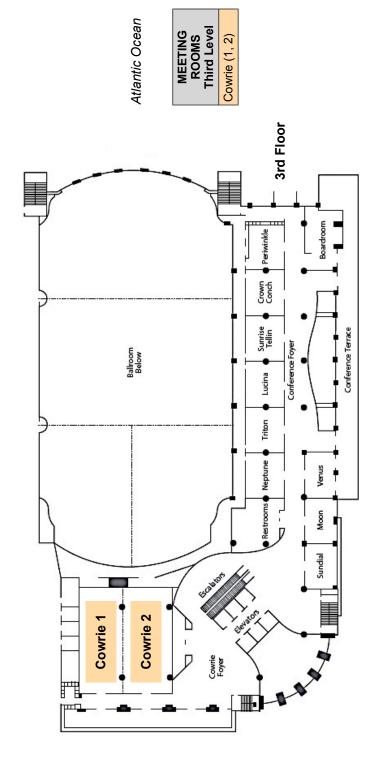
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Please go to www.chipnetwork.org and let us know more about you. It only takes two minutes. Then we'll be able to send you messages targeted to your interests.

I hope you will consider joining the CHiP Network and help foster a strong congenital heart care community.

Sincerely,

Gary Webb, MD CHiP Network 215-313-8058 garywebb6@gmail.com



The CHIP Network, the Congenital Heart Professionals Network, is designed to provide a single global list of all CHD-interested professionals.

NOTES

NOTES



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- Intervention in the Immediate Post-op Period
- The Edwards Valve
- Percutaneous Closure of the VSD Transcatheter Implant of a Melody Valve Watch VSD Closure
- Covered Stent to Eliminate
- Fontan Baffle Leak & Stenosis Native Coarctation of Aorta -Stent Implantation
- Pulmonary Artery Flow Restrictors
- Transcatheter Valve
- Intra-operative PA Stent
- Perventricular Muscular VSD Device Closure
- Closure of Septal Defect Using Real Time 3D Echo Guidance Perventricular Membranous VSD
- Hybrid Stage I Palliation for HLHS PA Bands and PSA Stent
- Intraoperative Aortic Stent for CoA
- Intraoperative LPA Stent Using Endoscopic Guidance
- Creation of ASD after PA Bands & PDA Stent for HLHS in a Preemie
- Perventricular Implant of Edwards Valve Stent in the Pulmonary Position
 Closure of Septal Defect Using
- Real Time 3D Echo Guidance High Frequency Ultrasound Creation of ASD
- PmVSD Closure

- Hybrid Stage I Palliation for Complex Single Ventricle in a 1.4 kg Neonate
- Transcatheter Implantation of Implantable Melody Valve Perimembranous VSD Closure
 - with Amplatzer Membranous VSD Occlude
 - Stent RPA. Pre-Stent Conduit & Melody Valve Implant Transeptal LHC Assessment of
 - Residual Coarctation
 - Coarctation Stenting Using a Covered CP Stent
 - Closure of ASD Under ICE
 - Guidance PFO Closure
 - Transcatheter Closure of Atrial Septal Defect (ASD) Closure of ASD under TEE
 - Guidance
 - Transcatheter Closure of
- Moderate PDA Pulmonary Angioplasty
 Hybrid Stage Palliation
 ADOI or MVSD Closure of PDA
- - VSD Closure Using a PDA Device
- Balloon Pulmonary Valvuloplasty Coil or Vascular Plug II closure of
- Coronary Fistula
 Device Closure of ASD
- Stent Placement Across Recurrent Coarctation
- Stenting RVOT on 7-day Old Newborn
- Transfemoral AVR for AS
- ASD Closure with Septal Occluder
- Stenting of Coarctation of Aorta
- Transapical AVR for Aorta Stenosis
- and more....

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