Dear Colleagues,

The Pediatric and Adult Interventional Cardiac Symposium – PICS~AICS 2015, is being held at the Aria Hotel, Las Vegas from September 18th-21st, 2015. The focus of this year’s meeting is on how we can overcome greater complexity through collaboration. Hence, we have focused sessions outlining opportunities for greater integration with adult structural heart disease specialists and congenital surgeons. As well as integrating the new, we have endeavored to ensure the meeting continues to support open dialogue, as well as visual learning, along with updates from all the relevant trials and societies, with real opportunities for networking and sharing global clinical and research experience. We will continue to provide a professional but relaxed atmosphere to support this fantastic learning opportunity with social gatherings to ensure friends can meet and enjoy catching up.

We really wanted to focus in this year’s meeting on ways we can work together to rise to the challenges of the next 40 years. This year sees the celebration of great innovations in CHD with the first report of the use of prostaglandin to maintain ductal patency, as well as the true beginning of device closure with the first report of ASD closure from Terry King and Noel Mills. We are honored to have Dr. King talk at the meeting, and give us his perspective on the evolution of ASD closure and part of our prerogative is to challenge the new generation to build on Dr. King’s platform to push the boundaries of interventional therapies for congenital and structural patients.

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/valves/stents, etc. The live cases this year will be transmitted live via satellite from: Riyadh, Córdoba, São Paolo, Mumbai, Las Vegas, Seattle, Columbus, Houston and San Diego.

This year’s meeting will be preceded by an imaging symposium on Thursday evening with discussions concentrated on advanced imaging platforms and radiation reduction constitute one of the great new horizons of catheterization, and we urge you to attend as we will have state-of-the-art talks from all the major imaging devices. The images will be transmitted live via satellite from: Riyadh, Córdoba, São Paolo, Mumbai, Las Vegas, Seattle, Columbus, Houston and San Diego.

By Ziyad M. Hijazi, MD; Damien Kenny, MD on behalf of Course Directors and Co-Directors
At Toshiba, we go beyond listening and give you a voice. Because understanding your business is our business, your challenges become our challenges, and together, we find creative ways to solve them. With decades of experience and groundbreaking technology built into all of our products, you can see you’re actually being heard. It’s not just lip service.
platform vendors so that you may bring this evolving technology to your patients.

On Friday, September 18th, the morning will begin with Live Case Transmissions. We will continue with the popular Taped Case Sessions over lunchtime with three taped cases presented and discussed on both Friday and Saturday. The afternoon sessions will include a session focused on QA/QI issues for the Cath Lab, and also discuss new accreditation benchmarks that are evolving, as well as how registries can meaningfully help us to improve the service we provide. Friday will finish with Oral Abstract Presentations with the best abstracts going forward to an abstract final presentation on Sunday lunchtime. We have had over 180 abstract submissions from all over the globe, and we are committed to ensuring that the scientific efforts of our colleagues are given the attention they deserve so that we may all learn from their innovation.

On Saturday, September, 19th, live cases will be followed by a special collaborative joint session with the Congenital Surgeons discussing opportunities and obstacles for development of hybrid techniques. This is a pivotal opportunity for us to discuss the benefits and challenges of hybrid therapies, and we are hopeful that this session will provide a platform for a working document on hybrid therapies for congenital and structural heart disease. We are honored this year to have a number of world-renowned surgeons as part of our faculty including Professor Sir Magdi Yacoub, one of the pioneers of congenital heart surgery and cardiac transplantation. There will be a Structural Heart Breakout session entitled “Innovations in Structural Heart Disease.” There will be further breakout sessions for nurses and technologists and younger interventionalists who are establishing their practice, as well as continuation of the special breakout for our Spanish-speaking attendees.

Other popular sessions, including “My Nightmare Case in the Cath Lab” and “Meet the Experts” ensure opportunity for discussion and learning from each other’s experiences. The final afternoon will provide a competitive feel as the girls will challenge the boys to a “Best Case” lunchtime session followed by a “Battle of the Continents,” a quiz-based session on all aspects of catheterization with the winner claiming global victory and dominance!

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.

We look forward to welcoming you back to Las Vegas. Please don’t forget to get in shape for the 5K Run, which promises to be memorable this year! 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 and from you.

Yours truly,
Ziyad M. Hijazi and Damien Kenny
on behalf of Course Directors and Co-Directors

The PICS Foundation in collaboration with the Rush University Medical Center.
SEPTEMBER 17th - THURSDAY SESSION
Collaboration to Counter Complexity: The Future of Congenital and Structural Interventions
Special One Day Industry-Sponsored Symposium at PICS~AICS

Moderators: John Cheatham, Ziyad M. Hijazi

6:00-8:30 pm - Innovations in Imaging for Congenital and Structural Heart Disease Interventions - Just How Far Can They Take Us?
- Siemens
- Toshiba
- Philips

Sponsored for CME Credit by Rush University Medical Center

Rush University Medical Center is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. Rush University Medical Center designates this live activity for a maximum of (35) AMA PRA Category 1 Credit(s)™. Physicians should claim only credit commensurate with the extent of their participation in the activity.

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This activity is being presented without bias and with commercial support.
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Pulse Oximetry Monitoring for CCHD Screening
Transcatheter and Surgical Heart Valves
Cerebral/Somatic Monitoring
Oxygenators and Filters
Ablation Technologies
RVOT Conduits
Pacemakers
Cannulæ
ICDs

PLEASE VISIT OUR BOOTH AT PICS/AICS 2015!

Two leaders committed to the lifetime management of patients with congenital heart disease.
EVERY STEP OF THE WAY.
## SEPTEMBER 18th - PICS FRIDAY SESSION

**8:00-8:10 am - Welcome** - Ziyad M. Hijazi

**8:10-8:20 am - Live Case 2014 Update** – Kiran Mallula

**8:25-10:30 am - Live Cases - (Riyadh, Córdoba, São Paolo)** -
- **Moderators:** Ziyad M. Hijazi, John Cheatham
- **Digital Moderators:** Damien Kenny, Bryan Goldstein
- **Panelists:** BG Alekyan, Carlos Zabal, Daniel Gruenstein, Alexander Javois, Seong-Ho Kim, Ali El-Halabi

**10:30-10:45 am - Coffee Break**

**10:45-12:45 pm - Live Cases - (Riyadh, Córdoba, São Paolo)** -
- **Moderators:** John Carroll, Thomas Jones
- **Digital Moderators:** Alexander Javois, Reda Ibrahim
- **Panelists:** Francisco Garay, Thomas Fagan, Makram Ebeid, Roberto Cubeddu, Maiy El Sayed, Nguyen Lan Hieu

**12:45 - Lunch Available**

**1:00-2:00 pm - Lunchtime Session - Taped Cases**
- **Moderators:** Dave Balzer, Aimee Armstrong
  - Brent Gordon
  - Bryan Goldstein
  - Jeremy Asnes

**2:00-3:30 pm - Congenital and Structural Interventions - What We Can Learn from Each Other** -
- **Moderators:** John Carroll, Neil Wilson, Ziyad M. Hijazi
  - **Imaging:** Transesophageal Echocardiography - What the Congenital Guys Showed Me – Rebecca Hahn
  - **Technique:** General Anesthesia, Blood Preservation, Hemostasis Devices, Transseptal Puncture, Dual Antiplatelet Therapy – Clifford Kavinsky
  - **Physiology:** Measuring Shunts, Flows, or Just Taking the Path of Least Resistance? When and Why Make the Effort? – Jamil Aboulhosn
  - **Devices:** Necessity as the Mother of Invention, From PDA Devices to the Ventricular Septum, the Left Atrial Appendage and Paravalvar Leaks – Horst Sievert
  - **Stents / Advanced angioplasty:** Thanks for Showing Us the Way – Felix Berger
  - **Evolution:** Bonhoeffer to Cribrier, Why Everyone Wins. Our Shared Property Encourages Industry to Listen and Maintain R&D – Thomas Jones

**2:00-3:30 pm - Breakout Session - QA/QI and Accreditation for the Cath Lab** -
- **Moderators:** Alexander Javois, Larry Latson, Ralf Holzer
  - What Is Quality? Strategies for Quality Improvement and Assurance, National and International (One Shoe Does Not Fit All) – Ralf Holzer
  - Accreditation for Congenital Cardiac Catheterization Laboratories- Will it Improve Quality? – Larry Latson
  - IMPACT – We Are Listening!! – Robert Vincent
  - C3PO – QI: Why Multicenter QI Initiatives Are Important – Lisa Bergersen
  - QA in Developing Countries; How to Achieve High Quality with Limited Resources – Francisco Garay
  - Putting It Together Locally: Real Patient Impact of QA/QI – Andrew Glatz
  - Discussion

**2:00-3:30 pm - PICES Breakout Session**

**3:15-3:45 pm - Coffee Break / Visit Exhibits**

**3:45-5:45 pm - Abstract Presentations**
- **Room 1:** Moderators: John Bass, Girish Shirali, Marco Papa
- **Room 2:** Moderators: Teiji Akagi, Michael de Moor, JV DeGiovanni

**5:50-6:00 pm - PICS Award**

**6:00-8:00 pm - Welcome Reception**
SEPTEMBER 19th - PICS SATURDAY SESSION

8:00-8:15 am - Special Lecture: Transcatheter ASD Closure – 40 Years Old - Terry King

8:20-10:20 am - Live Cases - (Mumbai, San Diego, Las Vegas) -
Moderators: Giacomo Pongiglione, Eric Horlick, William Hellenbrand
Digital Moderators: Henri Justino, Daniel Gruenstein
Panelists: Mazeni Alwi, Jacek Bialkowski, Sertac Cicek Thomas Forbes, Jacqueline Kreutzer, Levent Saltik

10:20-10:45 am - Coffee Break

10:45-12:45 pm - Live Cases (Mumbai, San Diego, Las Vegas) -
Moderators: Shakeel Qureshi, Mario Carminati, Damien Kenny
Digital Moderators: Daniel Levi, Lynn Peng
Panelists: Wei Gao, Worokan Promphan, Kanishka Ratnayaka, Mark Reisman, Raul Rossi, Shyam Sathanandam

1:00-2:00 pm - Lunch Session - Taped Cases
Moderators: David Nykanen, Julie Vincent, John Cheatham
• Mark Osten
• Christopher Petit
• Frank Ing

2:00-5:30 pm - Joint Session with the Congenital Heart Surgeons – Building a Successful Hybrid Program – The Collaborative Approach -
Moderators: Michel Ilbawi, Damien Kenny
• Hybrid Approaches in CHD – A Slow Starter or Past Its Prime?
  • The Interventionalist's Viewpoint: Dietmar Schranz
  • The Surgeon’s Viewpoint: Christopher Caldarone
• Cardiopulmonary Bypass – Myths and Truths
  – Massimo Caputo
• “I Just Don’t Like the Hybrid Room” – Lessons for the Future – Mark Galantowicz
• No Way In – Hybrid Approaches to Access the Heart in Neonates with Critical Outflow Tract Obstruction
  – Darren Berman
• Perventricular VSD Closure – Pushing the Boundary
  – Zahid Amin
• Working Together – Are There Lessons to be Learnt from the Heart Team Concept in Structural Heart Disease?
  – Roberto Cubeddu
• Exit Angiography – Is it Worth the Hassle? – Ralf Holzer
• Discussion and Break
• Pulmonary Valve Replacement – An Opportunity to Build
  • Interventional Perspective: Frank Ing
  • Surgical Perspective: Alistair Phillips
• Cases and Discussion:
  • Carotid Cutdown for Ductal Stenting in a Neonate with Duct-Dependent Circulation – Mazeni Alwi
  • Perventricular Closure of Perimembranous Defects
    – Alexander Y. Omelchenko
• Hybrid Interventions on the Pulmonary Arteries – When Can We Stent and When Should We Patch? – Sertac Cicek
• Optimizing Decision-Making in Planning a Hybrid Procedure – Julie Vincent
• Debate: The Hybrid Approach to HLHS Should Remain on the Reserves Bench – A Data Driven Debate and Discussion
  • Pro: Michel Ilbawi
  • Con: Lee Benson
• Discussion
SEPTEMBER 19th - PICS SATURDAY SESSION

2:00-5:30 pm - Breakout Session - Innovations in Structural Heart Disease - Moderators: Robert March, Clifford Kavinsky, Ziyad M. Hijazi

- Mitral Valve and the Left Atrial Appendage
- Anatomy Wet Lab Demonstrations – Mark Reisman
- Approval of the WATCHMAN...Are There Still Unanswered Questions? – Zoltan Turi
- Next Generation Devices....Will Another Device Achieve FDA Approval Within 10 Years? – Saibal Kar
- The Changing Landscape of Percutaneous Mitral Valve Repair – Horst Sievert
- Percutaneous Mitral Valve Replacement: Where Will We Be in 5 Years? – Matt Gillespie

- Tricuspid Valve Disease
- Anatomy Wet Lab Demonstrations – Mark Reisman
- Case Presentation – John Carroll
- Heterotopic Valve Replacement for Severe TR – Doomed to Fail or a Niche Market? – Hans Figulla
- Percutaneous Tricuspid Valve Repair for Chronic Tricuspid Regurgitation: The Mitralign Device – Scott Lim
- Trans-Atrial Intrapercardial Tricuspid Annuloplasty – Robert Lederman
- The Current State of Valve-in-Valve Tricuspid Technology for Failed Bioprostheses – Doff McElhinney

3:45-4:00 pm - Break

- Aortic Valve Disease
- Anatomy Wet Lab Demonstrations – Mark Reisman
- Case Presentation – Adam Greenbaum
- Prevention of Catastrophic Complications During TAVR Procedures – Robert March
- Emerging Transcatheter Aortic Valve Technologies – Hans Figulla
- TAVR for Aortic Regurgitation – Steve Bailey
- Predictors for Early Discharge after TAVR – Christian Spies
- Patent Foramen Ovale/Paravalvular Leaks
- Case Presentation – Ziyad M. Hijazi
- FDA Approval: Is There Enough Evidence to Appeal for Limited Approval for PFO Closure in High-Risk Patient Subsets – Mark Reisman
- Where Do We Stand with Percutaneous Treatment of Paravalvular Leaks? – Zoltan Turi

3:00-3:30 pm - Break

- MRI-Guided Transcatheter Therapy – Kanishka Ratnayaka
- Percutaneous Transcatheter Valve in Valve Replacement – Matt Gillespie
- CT Surgeon’s Role in Intervention in the Modern Day Cath Lab – Mark Galantowicz
- “Analyze This” – Interactive Session (An interactive session with audience participation and prizes) – Kathleen Nolan, Jason Swinning

5:35-6:35 pm - Meet the Experts

- Room 1 – Michael Tynan, Mario Carminati
- Room 2 – Charles Mullins, Horacio Faella
The Nit-Occlud® coil system for PDA closure is designed to match individual morphologies and sizes. The delivery system facilitates optimal device positioning. The Nit-Occlud® PDA coil is repositionable and retrievable prior to release. Tight and compact windings ensure efficient occlusion. The Nit-Occlud® PDA coil was determined to be MRI conditional. Radiopaque material ensures optimal device positioning and repositionability.

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SUMMARY LIVE CASES AND OPERATORS

FRIDAY, SEPTEMBER 18TH

KFSH&RC
Riyadh, Saudi Arabia
(2 cases)
Mansour Al-Jufan, MD; Fadel AlFadley, MD

Private Hospital of Córdoba
Córdoba, Argentina
(2 cases)
Alejandro Peirone, MD

Instituto Dante Pazzanese de Cardiologia
São Paulo, Brazil
(2 cases)
Carlos Pedra, MD

SATURDAY, SEPTEMBER 19TH

Nanavati Superspeciality Hospital
Mumbai, India
(2 cases)
Bharat Dalvi, MD; Prafulla Kerkar, MD

Rady Children’s Hospital
San Diego, CA USA
(2 cases)
John W. Moore, Howaida El-Said

Sunrise Children’s Hospital
Las Vegas, NV
(2 cases)
Alvaro Galindo, MD; Abraham Rothman, MD

MONDAY, SEPTEMBER 21ST

Nationwide Children’s Hospital
Columbus, OH USA
(2 cases)
Darren Berman, MD; Aimee Armstrong, MD

Seattle Children’s Hospital
Seattle, WA USA
(2 cases)
Thomas Jones, MD

Texas Children’s Hospital
Houston, TX USA
(2 cases)
Henri Justino, MD
SEPTEMBER 20th - PICS SUNDAY SESSION

1:00-2:00 pm - Lunch Session - Abstract Finals
Moderators: Michael de Moor, John Bass, Alexander Javois

2:00-3:30 pm - Current Controversies in Congenital Heart Interventions
Moderators: Giacomo Pongiglione, Roberto Cubeddu, William Hellenbrand
- Palliation In Newborns with Tetralogy of Fallot: Infundibular vs. Ductal Stenting – JV DeGiovanni
- Complex Aortic Arch Narrowing: Stent vs. Surgical Treatment – Thomas Forbes
- Transcatheter ASD Closure – The Risk of Erosion with Some Devices Is Just Too High
  • Pro: John Rhodes
  • Con: Joachim Miro
- There is a Place for Transcatheter Closure of Perimembranous and Subarterial VSD’s – Kevin Walsh
- When Should We Close Aorto-pulmonary Collaterals In Patients with a Single Ventricle? – Mark Fogel

4:00-5:30 pm - Update on Valve Interventions in Congenital Heart Disease
Moderators: William Hellenbrand, Reda Ibrahim
- The Melody Valve Reaches Adolescence. What Lessons Have We Learned and Where Do We Go from Here?
  – John Cheatham
- Endocarditis – Is it Valve-, Substrate- or Operator-Driven? – Julie Vincent
- Update on Next Generation “Native” RVOT Valve Studies
  – Ziyad M. Hijazi
- Transcatheter Valve-in-Valve Interventions, Beyond the RVOT – Doff McElhinney
- Transcatheter Aortic Valve Therapy: A Primer for the Congenital Interventional Cardiologist – Eric Horlick
- MitraClip in Congenital Heart Disease – TBD

2:00-5:00 pm - Spanish Breakout Session
SEPTEMBER 21st - PICS MONDAY SESSION

8:20-9:45 am - Live Cases - (Columbus, Houston, Seattle) -
Moderators: Carlos Pedra, Ziyad M. Hijazi
Digital Moderators: Matthew Gillespie, Michael de Moor
Panelists: Masood Sadiq, Tarek Momenah, Bryan Goldstein,
Jou-Kou Wang, Hideshi Tomita, Jae Young Choi

9:50-11:10 pm - New Interventions in the Extremely Premature Infant - The Next Frontier -
Moderators: Neil Wilson, Felix Berger, Evan Zahn
- Cardiac Catheterization in Premature and Low Birth Weight Infants: Tips, Techniques, Complications and Results: Experiences-to-Date – Lee Benson
- A New Method for Transcatheter PDA Closure in Premature Infants Using Commercially Available Technology:
  - The Cedars Sinai Approach – Evan Zahn
  - The St. Justine Approach – Joachim Miro
- Experience with Hybrid Treatment of HLHS in Low Birth Weight Newborns – Alistair Phillips
- Imaging in Small Infants – Transthoracic Echocardiography Guided Interventions
  – Craig Fleishman
- Transcatheter Treatment of the Atretic RVOT in Low Birth Weight Newborns – Marc Gewillig
- When Things Go Awry…Cardiopulmonary Bypass Issues Specific to Premature and Low Birth Weight Newborns
  – Vincent Olshove

11:15 am -12:55 pm - Live Cases - (Columbus, Houston, Seattle)
Moderators: William Hellenbrand, Ralf Holzer
Digital Moderators: Julie Vincent, Shyam Sathanandam
Panelists: Yun-Ching Fu, Nathaniel Taggart, Wail Alkashkari,
Thomas Doyle, Noa Holoshitz

1:00-2:00 pm - Lunchtime Session - The Girls “vs” The Boys - Most Innovative Approach -
Moderators: Cliff Kavinsky, Sharon Cheatham
- Closing a Hole: Lynn Peng vs. John Bass
- Opening a Stenosis: Howaida El Said vs. David Balzer
- Replacing a Valve: Jacqueline Kreutzer vs. Mario Carminati

2:00-3:30 pm - My Nightmare Case in the Cath Lab
Moderators: Shakeel Qureshi, Neil Wilson

3:45-5 pm - Battle of the Continents - Best Case and Who Knows the Most!
Moderator: Damien Kenny
- Each Continent Will Have 4 Competitors – One Case and GK Questions
  - Europe – Captain: Shakeel Qureshi
  - North America – Captain: Lee Benson
  - South America – Captain: Carlos Pedra
  - Africa, Australia and Asia – Captain: Masood Sadiq

5:00pm - Closing Remarks – Ziyad M. Hijazi
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The 2015 PICS Award will be given on Friday, September 18th, 2015. The Committee (Mike Tynan, Charles Mullins, Shak Qureshi and Lee Benson) chose this year someone special who dedicated his/her life to medicine and interventional therapies.

What distinguishes the PICS Award from other awards, is the amount of work that goes in choosing the winner, then in contacting their family members without their own knowledge to collect their photos and memorabilia, and the element of surprise. Please join us in Las Vegas and share the joy with the winner!

The 2015 PICS Achievement Award will be given on Friday, September 18th, 2015.

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<td>2011 - Charles S. Kleinman</td>
<td>2011 - Ziyad M. Hijazi</td>
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<th>Distinguished Service Award</th>
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<td>2013 - Sharon L. Cheatham</td>
<td>2014 - Qi-Ling Cao</td>
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“The 2015 PICS Achievement Award will be given on Friday, September 18th, 2015.”

Please visit www.PICSymposium.com for up-to-date program changes.
Sign-up Now for the 3rd Annual PICS~AICS 5K RUN

The 3rd Annual PICS~AICS 5K RUN is sponsored by Siemens, and will take place Sunday, September 20th at 6 am, rain or shine. All fitness levels are welcome!

You'll be making a difference, and supporting CHIMS (Congenital Heart Intervention Mission Support) - http://chimsupport.com.

The donation includes:
- Technical T-shirt (Men and Women)
- Digital chip timing
- Registration
- Finish line and post-race refreshments.

All race packets and maps may be picked up at the Siemens booth #408, Saturday, September 19th, between 8:00 am-5:00 pm. The course map will be available to view after August 1st.

How to Register

Pre-Registration: $25.00 till August 1st, then $30.00 until Saturday, September 19th at 6:00 pm. *There will be no race-day registration*

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

To Register for the Run, go to: www.seashorestriders.com/race-schedule/3rd-annual-pics-aics-5k-run

SAVE THE DATE FOR PICS 2016 - Jan. 16-19, 2016; Lowes Miami Beach, FL USA
**PICS~AICS REGISTRATION INFORMATION**

Online Registration for Attendees:

Registration & Hotel Questions:
For further information, please contact Colene Diodati at:
pics@candsmeetings.com

Registration for Faculty and Exhibitors:
For further information, please contact Kimberly Ray at:
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Sir Magdi Yacoub: Keynote Lecture: Innovations at What Price...

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“Who will be 2015’s PICS~AICS Achievement Award winner?”
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<td>William E. Hellenbrand, MD</td>
<td>Yale University Medical Center, New Haven, CT USA</td>
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Offering children and adults a proven option for managing pulmonary valve conduit failure without open heart surgery.

**Data from US IDE Study**

**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 (circular) RVOT conduit that was equal to or greater than 16 mm in diameter when originally implanted AND
- Dysfunctional RVOT conduits with a clinical indication for intervention, AND:
  - regurgitation: > moderate regurgitation, AND/OR
  - stenosis: mean RVOT gradient ≥ 35 mm Hg

**Contraindications:** None known

- 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.

**Potential device-related adverse events that may occur following device implantation include the following:**

- Stent fracture, *stent fracture* refers to the fracturing of the Melody frame versus another stent.

**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/infection, fever, hematoma, radiation-induced erythema, blistering, or peeling of skin, pain, swelling, or bruising at the catheterization site.

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.
When Precise Sizing is the Heart of the Matter

Tyshak NuCLEUS™ PTV Catheters

PTS–X™ Sizing Balloon Catheters

Rx only

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The Tyshak NuCLEUS™ PTV Balloon Dilatation Catheters are recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve in the following:

A patient with isolated pulmonary stenosis. A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.

The PTS–X™ Sizing Balloon Catheters are recommended for use in those patients with cardiovascular defects wherein accurate measurement of the defect is important to select the appropriately sized occluder device. Refer to the Instructions for Use for relevant warnings, precautions, complications, and contraindications.

Manufactured for:

B. Braun Interventional Systems Inc.

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