

# CONGENITAL CARDIOLOGY TODAY

Timely News & Information for Congenital/Structural Cardiologists & Cardiothoracic Surgeons Worldwide

North American Edition Vol. 20 - Issue 9

September 2022

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# The Bioresorbable reSept™ ASD Occluder: Moving Closer to the Ideal

Thomas K. Jones, MD, FAAP, FACC, FPICS, MSCAI

Secundum Atrial Septal Defect (ASD) is a common condition and accounts for about 10% of all Congenital Heart Disease at birth. Excluding bicuspid aortic valve, ASD is the most common congenital heart defect diagnosed in adulthood. For many years open-heart surgical repair was the only option to treat these individuals. Indeed, the very first successful open-heart operation performed in 1954 on a young child, and using her father's circulation to support the patient, was to close an ASD. The first transcatheter ASD occlusion was performed in the mid-1970s by King and Mills. In the decades following, transcatheter ASD occluder and delivery system technology has progressed considerably with over a dozen different ASD occluders approved and commercially available around the world. In addition to congenital ASD, clinically significant iatrogenic secundum ASD has emerged as an important clinical entity occurring in 10 - 24% of patients undergoing adult structural interventional procedures where access to the left atrium with large diameter sheaths is gained via transseptal puncture.

Regulatory and other long-term studies of percutaneous ASD closure have consistently demonstrated improved morbidity and mortality compared with contemporary surgical experience. Complete closure rates following transcatheter closure approach 96% with low procedural adverse event rates. The significant favorable differences in overall morbidity and mortality, length of stay, cost, and psychological impact has made percutaneous ASD closure for patients with suitable atrial septal anatomy the treatment of choice and standard of care at most health care institutions around the world.

An important design feature of all commercially available ASD occluders is the presence of a metallic framework that supports some amount of synthetic fabric responsible for closing the defect. Following release, the occluder is held in place within the atrial septum by clamping forces generated by the metallic framework. The healing response incited by the occluder results in the eventual incorporation of the occluder into the atrial septal that is covered by endothelium. The metallic framework of the occluder no longer contributes to the structural integrity of the repair. However, this metallic framework left behind becomes a lifetime intracardiac foreign body. It is important to note these lifelong implants are overwhelmingly used in a young patient population creating many decades of exposure to potential late risks. Clinical events following implant, either directly or indirectly attributable to these metallic frame occluders, are fortunately uncommon, but can be serious or life-threatening: including cardiac wall erosion with perforation and tamponade, thrombus formation, valve disruption and arrhythmia.

The lifetime risk of a permanent implant on the atrial septum is an unknown. Clinicians and biomedical engineers have speculated that changes in blood flow patterns, rigidity of the atrial septum, physical stresses on the support of AV valves, and the type of endothelial tissue resulting from current septal occlusion devices may contribute to very late complications and may take many years to manifest as clinical conditions.

The advent of successful transcatheter treatments for atrial fibrillation, left atrial appendage occlusion, mitral valve repair or replacement and emerging heart failure treatments has also emphasized the importance of maintaining percutaneous transseptal access to the left heart. The presence of metallic framework ASD occluders creates a barrier to perform the precise transseptal access these increasingly sophisticated structural heart procedures require.

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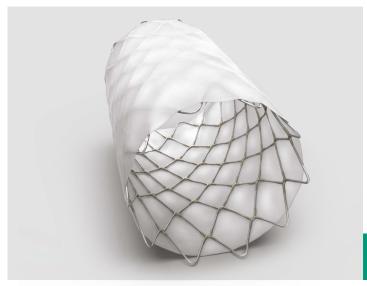
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#### INTRODUCING THE

### **G-ARMOR STENT® PORTFOLIO**

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The G-ARMOR Stent® maintains a greater than 13% longer stent length after expansion¹

Indications for Use: G-ARMOR Stent®, G-ARMOR Covered Stent™, G-ARMOR Mounted Stent™, G-ARMOR Covered Mounted Stent™

The G-Armor Stent® is indicated for use in the treatment of native and/or recurrent coarctation of the aorta involving a compliant aortic isthmus or first segment of the descending aorta where there is adequate size and patency of at least one femoral artery and balloon angioplasty is contraindicated or predicted to be ineffective. The G-ARMOR Covered Stent™ is indicated for use in the treatment of native and/or recurrent coarctation of the aorta involving the aortic isthmus or first segment of the descending aorta 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 atretic descending aorta of 3 mm or less in diameter; a non-compliant stenotic aortic segment found on pre-stent balloon dilation; a genetic or congenital syndrome associated with aortic wall weakening or ascending aortic aneurysm. The G-ARMOR Covered Stent™ is indicated for use in the treatment of right ventricle to pulmonary artery (right ventricular outflow tract) conduit disruptions that are identified during conduit procedures performed in preparation for transcatheter pulmonary valve replacement.

Please see the Instructions for Use for a full prescribing information including a warnings, precautions and contraindications at www.bisusa.com/garmorifu

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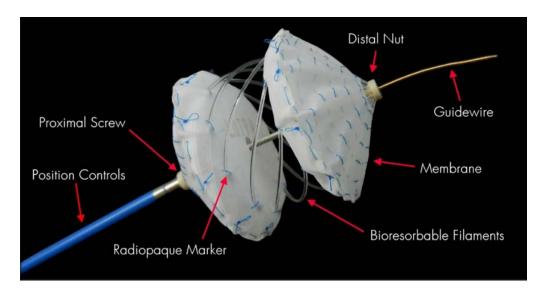


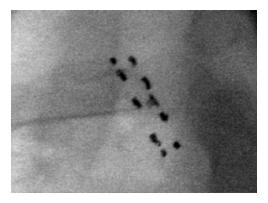
FIGURE 1 The reSept ASD Occluder attached to the delivery system.

For these reasons interventional cardiologists have expressed a need for ASD occluders to be bioresorbable. The ability of the rigid framework of an occluder to be gradually reabsorbed during the healing response was identified as a highly desirable attribute by key opinion leaders and the pioneers of transcatheter ASD occlusion since 1990. Such a device framework would remain intact during the process of endothelial incorporation but eventually resorbed, resulting in a fully 'healed' intact septum within several years. After this, the device would no longer be present, eliminating the risk of late sequelae and leaving the atrial septum free from any barriers to future transseptal puncture should the need arise.

An early attempt at a bioresorbable occluder, the BioSTAR™ (NMT Medical) was introduced in Europe in 2005. A major engineering accomplishment at the time, this device incorporated a bioresorbable membrane composed of collagen-rich porcine intestinal submucosa supported by a metallic frame. While effective in closing septal defects with appropriate resorption of the occluding biological membrane, safety and procedural flexibility issues limited its acceptance. A major drawback to this design was the rigid metal framework that would remain behind - in essence, still a permanent implant. This experience highlighted the key challenge in developing a fully bioresorbable occluder: making a device framework that will perform as needed to position and secure the device to the septum while also making it resorbable. Without overcoming this key challenge, the true potential of bioresorbable atrial septal occluders would never be realized, until now. The  $reSept^{TM}$ ASD Occluder was designed to achieve this key engineering requirement of replacing the metal framework of a septal occluder with resorbable material while retaining all the major functional attributes of a metallic framed device.

The reSept™ ASD Occluder (formerly known as the Carag™ Bioresorbable Septal Occluder (CBSO) was based upon an earlier, nonbioresorbable, device, the Solysafe™ Septal Occluder. Following CE Mark approval, the device was implanted in over 1,000 patients in Europe and South America. The Solysafe™ Septal Occluder contained a metal framework supporting two opposing polyester patches. The delivery system for the Solysafe™ occluder has been retained for use with the reSept™ occluder with minor changes to simplify operation. Despite good clinical results and low rates of procedural complications, the company voluntarily withdrew the Solysafe™ occluder from the market secondary to fractures of the metal framework, recognizing that these events represented a risk to patients and weakened the marketability and competitiveness of their design. Following the withdrawal, the company initiated the development of a bioresorbable framework version of this occluder, now known as the  $reSept^{TM}$  ASD Occluder.

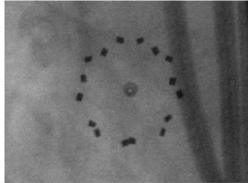
The reSept<sup>™</sup> ASD Occluder is a self-centering device with two opposing foldable polyester covers which are attached to a framework



consisting of PLGA (poly lactic-co-glycolic acid) monofilaments. (Figure 1). The polyester fabric is secured to the monofilaments by Pt-Ir-Markers and a suture. There are 8 or 10 filaments comprising the entire framework, depending on device size (8 filaments in device Types S and M, or 10 filaments in type L). Deployment of the occluder allows the two opposing polyester covers to come together on either side of the atrial septum. The coaxial proximal and distal position controls of the delivery system are used to position each cover independently. When brought together, the two hubs that are the filament holders lock together providing the necessary counterforce to keep the disks opposed to one another and closing the defect. The occluder is retrievable and repositionable at all stages of delivery even after initial deployment. The delivery system is intended for transfemoral delivery through a 12 French Mullins sheath.

Within a few months following implantation, the reSept ASD Occluder is covered by neo endothelium. The non-resorbable, woven polyester material, which covers the implant, provides an additional level of protection from embolism of the resorbable filaments and the non-resorbable radiopaque markers. Resorption of the PLGA framework begins after six to eight months and is complete by about 24 months.

A First in Human (FIH) study of the reSept ASD Occluder began at the Cardiovascular Center, Frankfurt, Germany, in 2014. The study included 15 adult patients, nine with ASD and six with patent foramen ovale (PFO). There were no significant procedural or early post-procedural complications. One subject was noted to have thrombus adherent to the occluder discovered at 17 months that resolved following a course of oral anticoagulation. CE Mark approval was granted in 2017. Six additional patients were treated in a European post-market registry between March 2020 February 2021 including six children and two adults. atHeart Medical, the study sponsor discontinued commercial sales in Europe to focus on clinical investigations in



**FIGURE 2** Fluoroscopic images of an implanted reSept Occluder in LAO cranial and RAO caudal views. Note the radiopaque markers arrayed on each membrane confirming appropriate coplanar apposition of the occluder on either side of the atrial septum.



#### Seeking pediatric cardiologists in Denver

Pediatrix® Cardiology of the Rocky Mountains is seeking a board-certified/eligible pediatric cardiologist skilled in non-invasive imaging, including transthoracic echo and TEE, to join our practice. Experience in fetal and/or adult congenital heart disease is desirable but not required. We also have an opening for a general pediatric cardiologist.

- Established practice that's been in the market for more than 35 years.
- Two offices are in the Denver metro area, with outreach clinics in Colorado, Nebraska and Wyoming.
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- · Postoperative cardiac surgery care.
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- Services include general pediatric cardiology, interventional and diagnostic catheterizations, fetal cardiology, preventive cardiology, telecardiology, electrophysiology and cardiopulmonary exercise stress testing.



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For more than 30 years, Pediatrix® Cardiology of the Rocky Mountains has been a trusted provider of pediatric cardiology services to patients, families, hospitals and physicians across the Rocky Mountain region. Our board-certified pediatric cardiologists specialize in cardiac care of unborn babies, infants, children and adolescents. They also provide care to adults with congenital heart disease.

Pediatrix Cardiology of the Rocky Mountains is proud to partner with the Congenital Heart Center at Rocky Mountain Hospital for Children. The heart center offers full-service cardiac care for pediatric patients, as well as adult patients with congenital heart disease, including diagnostic cardiac catheterization, catheter-based septal device closure, transcatheter valve replacement, electrophysiology studies with complex arrhythmia ablations and full-spectrum cardiothoracic surgery.

For more information, contact: Travis Weeks Regional Clinical Recruiter Pediatrix Medical Group 602.649.2857 Travis.weeks@pediatrix.com



#### THE BIORESORBABLE RESEPT™ ASD OCCLUDER: MOVING CLOSER TO THE IDEAL



support of U.S. FDA approval. There are no plans for additional enrollment in the European post-market registry initiated in 2020.

The U.S. FDA issued an Investigational Device Exemption (IDE) for the reSept ASD occluder in late 2020 allowing the sponsor, at Heart Medical to initiate a Pre-Market Approval Clinical Study. The study is a prospective, three-staged, single-arm, multicenter, clinical investigation evaluating the safety and efficacy of the reSept™ ASD Occluder in subjects with clinically significant secundum ASD. Outcomes and study endpoints of this study will be compared with established Performance Goals of current FDA-approved transcatheter secundum ASD occluders (Amplatzer™ Septal occluder; Gore Cardioform™ Occluders). Inclusion and Exclusion criteria are presented below and are consistent with criteria used in the regulatory studies of currently approved devices.

#### Inclusion Criteria

All answers must be YES to be eligible.

- 1. Age < 85 years.
- 2. Weight  $\geq$  15 kg.
- 3. Male or Female.
- 4. Clinically significant, isolated secundum ASD associated with a L-R shunt and signs of RV volume overload.
- 5. ASD diameter of 4 to 19 mm on screening diagnostic echocardiogram.
- 6. Isolated secundum ASD of size 4 to 22 mm on stop-flow balloon diameter, based upon echocardiographic and fluoroscopic evidence obtained during the procedure.
- 7. Ability to take low dose Aspirin from 24 hours pre implant to six months following.
- 8. Adequate septal rim/defect margins to support the device. The rim is considered adequate unless it measures less than 5mm over a 45° segment of the defect.
- 9. Capable of giving informed consent or, for minors, consent of the parent or legal guardian, and willingness to comply with the clinical investigation requirements.

#### **Exclusion Criteria**

All answers must be NO to be eligible.

- 1. Pregnancy.
- 2. Significant valve dysfunction or increased pulmonary vascular resistance/severe pulmonary hypertension.
- 3. Acquired pathological or congenital

- abnormalities of the cardiovascular system (other than isolated secundum ASD) that would interfere with the conduct of the clinical investigation.
- 4. Subjects having undergone leftsided structural heart interventions performed via transseptal access (Mitraclip, LAAO, percutaneous mitral valve replacement).
- 5. Evidence of thrombus in the left atrium, left atrial appendage, other cardiac chamber, or the inferior vena
- 6. Sepsis or any other infection not successfully treated at least 30 days prior to device placement.
- 7. Active endocarditis or other infection(s) producing bacteremia.
- 8. History of atrial tachycardia, atrial fibrillation or flutter, AV block, or ventricular arrhythmia requiring antiarrhythmic medication, pacemaker or AICD.
- 9. Vasculature is of inadequate size to accommodate all procedural instrumentation.
- 10. Known allergy to investigational device components or medications, or other contraindication to clinical

- investigation medications (aspirin, heparin), including a documented history of bleeding, clotting or coagulation disorders, untreated ulcer or any other contraindication to aspirin.
- 11. Known hypercoagulable state.
- 12. Any disorder in the investigator's opinion that could interfere with compliance of safety evaluation, as well as any severe concurrent illness that would limit life expectancy.
- 13. Currently active subject in an investigational drug or device study that could confound the results of this study.
- 14. Patients who, in the opinion of the investigator, are inappropriate for inclusion into this clinical investigation or will not comply with requirements of the clinical investigation.
- 15. Patients known to abuse drugs or alcohol.
- 16. Patients with the diagnosis of Patent Foramen Ovale (PFO).

Follow-up evaluations of treated subjects include physical examination, ECG and transthoracic echocardiograms (TTE)

**TABLE 1** ASCENT ASD Study Sites and Principal Investigators

Site	Principal Investigator
Children's Hospital of Los Angeles	Darren Berman, MD
Los Robles Regional Medical Center	Saibal Kar, MD
Yale University Medical Center	Jeremy Asnes, MD
Joe DiMaggio Children's Hospital/Memorial Healthcare	Larry Latson, MD
Advocate Children's Hospital	Alexander Javois, MD
Boston Children's Hospital	Diego Porras, MD
University of Michigan Medical Center	Jeffrey Zampi, MD
Mount Sinai Medical Center	Barry Love, MD
Columbia University Medical Center/NYPH	Robert Sommer, MD
Cincinnati Children's Hospital	Shabana Shahanavaz, MD
Children's Hospital of Philadelphia	Matthew Gillespie, MD
UPMC Children's Hospital of Pittsburgh	Bryan Goldstein, MD
Medical University of South Carolina	John Rhodes, MD
Medical City Dallas Hospital	Vivian Dimas, MD
Primary Children's Hospital	Robert Gray, MD
University of Virginia Medical Center	Scott Lim, MD
Seattle Children's Hospital	Thomas Jones, MD
Hôpital cardiologique Haut-Leveque (CHU Bordeaux)	Jean-Benoit Thambo, MD
Hôpital des Enfants (CHU Toulouse)	Clément Karsenty, MD

#### THE BIORESORBABLE RESEPT™ ASD OCCLUDER: MOVING CLOSER TO THE IDEAL



performed prior to discharge and at 1, 6 and 12 months. Extended follow-up evaluations with TTE are performed at 18, 24-, 36-, 48- and 60-months post implant.

Given the novel nature of this device, the sponsor and FDA have agreed to a stepwise enrollment strategy. This approach allows for a thorough assessment of engineering assumptions about device and delivery system performance and sizing guidelines to be incorporated into subsequent stages of the trial.

The study design includes three stages as outlined below:

- Stage 1: 25 subjects at up to 10 investigational sites.
- Stage 2: 25 subjects at up to 15 (5 additional) investigational sites.
- Stage 3: Up to 200 subjects at up to 35 (20 additional) investigational sites for a total of up to 250 subjects.

Study outcome measures of interest are summarized below:

The Primary Efficacy Endpoint is the composite clinical success of subjects evaluated at 12-months post implantation and defined as:

- Clinically effective ASD closure, defined as no residual ASD or clinically insignificant residual ASD as determined by core laboratory review; and
- 2. No re-intervention to treat the defect; and
- 3. No device or procedure related serious adverse event.

The Primary Safety Endpoint is the incidence of subjects experiencing one or more serious device or procedure related adverse events through the 12-month follow up visit.

Secondary Efficacy Endpoints to assess device performance include:

- Technical success defined as successful placement and release of the occluder within the ASD.
- Procedural success, defined as technical success with residual ASD ≤ 4mm as measured immediately following the procedure and at discharge without occurrence of a serious adverse
- Closure success, among subjects that were a technical success, defined as no residual ASD or clinically insignificant residual ASD. Assessment of closure success is performed at each follow up through the 12 months.

An independent core lab will adjudicate all echocardiogram studies from screening through the 12-month follow-up visit. An independent Data Safety Monitoring Board (DSMB) will be responsible for advising the sponsor in case the clinical investigation needs to be suspended or stopped due to safety concerns. A separate, independent Clinical Events Committee (CEC) will pass on judicially the relationship of all adverse events to the investigational device and the implant procedure.

Enrollment in Stage 1 of the trial began in the Spring of 2021 under the leadership of Co-National Principal Investigators, Drs. Larry Latson and Saibal Kar. Based upon the results demonstrated in Stage 1, the FDA approved moving forward with Stage 2 of the study in February 2022. This will permit enrollment of an additional 25 subjects at up to 15 investigational sites. Participating sites and Principal Investigators are listed in **Table 1**. Additional information can be found at: <a href="https://atheartmedical.com/patients/">https://atheartmedical.com/patients/</a> or <a href="https://clinicaltrials.gov/ct2/show/NCT04591392">https://clinicaltrials.gov/ct2/show/NCT04591392</a>.





### THOMAS K. JONES, MD, FAAP, FACC, FPICS, MSCAI

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# Hospital Directory 2022-2023

**Published Mid-August** 

- Hard copies are available at CCT's booth at PICS 2022
- Hospitals that Offer Open Heart Surgery for Children in North America
- Contact information at each hospital for Chief of Pediatric Cardiology & Fellowship Director
- Lists each hospital's Pediatric Cardiologists & Cardiothoracic Surgeons
- Lists Pediatric Cardiology Fellowships
- Distributed to Division Chiefs by mail
- Electronic version available on CCT's website:
   CongenitalCardiologyToday.com





## **Pediatric Cardiologist**

The Congenital Heart Center at the University of Florida is recruiting a Pediatric Cardiologist to care for infants, children, and adolescents in our Tallahassee area clinic. You will be a part of the University of Florida Congenital Heart Center, based in nearby Gainesville.

The pediatric cardiology and heart surgery program at **UF** Health Shands Children's Hospital is the highest ranked program in Florida by U.S. News & World Report. We are one of the largest centers in the state of Florida, with equal distribution of both surgical and medical patients. You will also provide pediatric cardiology education to residents, fellows, medical students, and other health care professionals within the Congenital Heart Center. There are exceptional opportunities for clinical research. Please see <a href="https://chc.med.ufl.edu">https://chc.med.ufl.edu</a> for more information.

Tallahassee is a vibrant community that is the state capital and home to Florida State University. There are outstanding opportunities for education, recreation, and entertainment. For additional information, please see the following hyperlink:

https://imsva91-ctp.trendmicro. com:443/wis/clicktime/v1/ query?url=https%3a%2f%2fvisittallahassee. com&umid=DA12054E-D76F-6605-9648-E92C7F93D 7D7&auth=5ab06289d9c3b14f9a77f69d29e7a2587 0e86301-aba2063c61f8ceffa48ed27cd16cdc0f42d4a f<sub>1</sub>d

The candidate should be board certified with an interest in outpatient cardiology. The position includes a faculty appointment at the University of Florida in the College of Medicine, Gainesville, Interested candidates could have clinical activities at both locations. Academic rank will be awarded based upon the career stage and development of the candidate.

Please apply online at:

https://explore.jobs.ufl.edu/en-us/job/520018/ pediatric-cardiologist-physician



### **Division Chief of** Health Pediatric Cardiology

The Congenital Heart Center, at the University of Florida is recruiting a tenure or non-tenure track faculty position at the Associate or Professor level to serve as Division Chief for Pediatric Cardiology. Rank and/or Tenure status will be commensurate with qualifications.

#### The Opportunity

The Division Chief will work with the Congenital Heart Center Director to create the strategic, clinical and operational priorities for Pediatric Cardiology. This person acts as a key liaison with internal and external partners and provides oversight of academic, clinical and research missions.

#### Strategic Development

- Assists with key recruitments for Division and Department Leadership positions
- Develops, implements, and manages a strategic plan that ensures consistent growth and success across all missions
- Works to ensure that the University of Florida College of Medicine (COM), Congenital Heart Center (CHC), and UF Shands goals are integrated and aligned
- Understands and reacts to departmental, organizational, and external business drivers, opportunities, and threats
- Sets priorities and key metrics to ensure aggressive growth goals across clinical missions
- Strengthens current clinical programs necessary to achieve the CHC and COM vision and goals
- Increases external funding for Division
- Strengthens existing educational programs and help develop new ones
- Serve as a role model and lead the training of the next generation of physician scientists
- Creates and implements new clinical programs to achieve the CHC vision and goals
- Ensures alignment between all units by meeting with the faculty
- Work closely with the Center leadership to ensure a united vision and shared priorities

#### Leadership

- Represent the department with internal and external clinical partners as the Chief of Pediatric Cardiology
- Responsible for developing strong relationships with University of Florida Health partners
- Develop relationships that further the CHC vision and goals
- Work with the Clinical Divisions to understand their unique challenges and identify opportunities within their units
- Provide leadership in developing off-campus clinical programs
- Provide leadership in developing Pediatric Cardiology specific research programs
- Support the Center leadership in all strategic initiatives

#### **Operational Oversight**

- Serve as trusted partner and advisor to CHC Director and
- Manage and mentor the Pediatric Cardiology faculty
- Participate in annual clinical Division reviews and set key success metrics for the missions
- Integrate and balance the CHC's missions across the department
- Ensure CHC clinical vision and goals are met by clinical faculty

This position will be located at the University of Florida in Gainesville, FL and will occasionally travel to our regional UF Health locations.

Please apply online at <a href="https://explore.jobs.ufl.edu/en-us/">https://explore.jobs.ufl.edu/en-us/</a> job/522028/chief-aso-prof



# PICS Society Membership Benefits: What is the Value Proposition?

Ziyad M. Hijazi, MD, MPH, FPICS; Damien Kenny, MD, FPICS; Norm Linsky, MPA, MA

Two years ago, in announcing its vision for the new PICS Society, the Founding Board of Directors laid down a bold challenge: the vision of the PICS Society will be—MUST be—a world where anyone who can benefit from minimally invasive techniques to treat Congenital Heart Disease (CHD) can access safe, effective care. Since day one of your new Society, it is through that prism that the Society's many programs have been identified, chosen and pursued.

Achieving this vision will not be easy, but it is hard to think of anything more important to us all and to the patients we are honored to serve. Now, as we approach two exciting milestones—welcoming member number 500, with members in over 50 countries—this is the right time to step back and consider an important metric: What are the benefits of joining the PICS Society? When you join, pay the modest dues and invest your scarce time in Society activities, what do you get back in return? What can you give back? How should your society represent your interests? These are fair questions to ask.

The answer is three-fold:

- You receive tangible membership benefits, such as our journal, DocMatter enrollment, educational discounts and more.
- 2. You receive intangible benefits, most critically by building a stronger, effective voice that speaks collectively about the economic and social issues that impact us all.
- 3. Fundamentally, we have the obligation to demonstrate to you the PICS Society's "value proposition." What demonstrates why the PICS Society is uniquely poised to serve you, represent you and provide opportunities for your professional growth?

#### **Tangible Membership Benefits**

Annual PICS Symposium & Fellows/Early Career Course: This September's meeting in Chicago marks the 25<sup>th</sup> anniversary of our flagship event. Building on our foundation of live and taped cases, lectures, hands-on workshops, industry sessions, a Latin American track, abstracts presentations and an exposition hall, the meeting focuses on "news you can use" plus what is on the horizon. While all are welcome, of course, PICS members receive a significant registration discount.

DocMatter Community: New this year is member-only access to the DocMatter online professional community, your global online platform for peer-to-peer collaboration. PICS is grateful for the partnership of the Congenital Cardiovascular Interventional Study Consortium (CCISC, Founder Dr. Tom Forbes and President Dr. Lee Benson) in what quickly has become the worldwide forum for



Pediatric and Congenital Interventional Cardiovascular Society

interchange of clinical discussion. PICS (and/or CCISC) members receive free "read/write" access to the Community, participating in scores of discussions every week. PICS/CCISC would like to thank B. Braun Interventional Systems Inc. and NuMED for Children for their generous support.

Pediatric Cardiology Journal complimentary subscription: This year PICS began a long-term partnership with Springer Publishing to provide every PICS member with FREE access to this leading journal (published eight times annually). As the Society's new official journal, Pediatric Cardiology (Editor-in-Chief Karim Diab, MD, FPICS) offers many opportunities to submit articles, abstracts, case reports and other items to this respected peer-reviewed journal. We encourage you to take advantage of this important membership benefit, both to stay current with the latest research and practices, as well as to share your own research/techniques with your colleagues globally.

Professional education year-round: While the annual PICS Symposium is our field's must-attend event, our educational portfolio is about to grow dramatically. Coming soon: webinar series focused on best practices and emerging technologies, PICS/Istanbul meeting in collaboration with the Turkish Society of Cardiology (watch for "save the date" announcement), online archived and on-demand educational content on CHDinterventions.org (launching this fall), PICS 2023 Symposium (Washington DC) in parallel with the 2023 World Congress of Pediatric Cardiology and much more. As always, PICS members receive registration discounts.

Congenital Cardiology Today (CCT): The newsletter you are reading now is the foundation of the PICS – CCT partnership. CCT is the official news and information source for PICS, a relationship that has enabled both organizations to communicate even more effectively with the pediatric/congenital interventional cardiology community. All PICS members receive CCT at no charge. CCT's Hospital Directory of Congenital Cardiac Care Providers in North America Offering Open Heart Surgery for Children is a valuable professional resource tool that provides the CHD community with detailed information to better serve your patients and to facilitate communication between hospitals and programs. The updated Hospital Directory is available electronically on CCT's homepage: CongenitalCardiologyToday.com.





### **Congenital Heart Surgeon**

#### Primary Purpose of Organizational Unit

The UNC School of Medicine has a rich tradition of excellence and care. Our mission is to improve the health and wellbeing of North Carolinians, and others whom we serve. We accomplish this by providing leadership and excellence in the interrelated areas of patient care, education, and research. We strive to promote faculty, staff, and learner development in a diverse, respectful environment where our colleagues demonstrate professionalism, enhance learning, and create personal and professional sustainability. We optimize our partnership with the UNC Health System through close collaboration and commitment to service.

#### **OUR VISION**

Our vision is to be the nation's leading public school of medicine. We are ranked 2nd in primary care education among all US schools of medicine and 5th among public peers in NIH research funding. Our Allied Health Department is home to five top-ranked divisions, and we are home to 18 top-ranked clinical and basic science departments in NIH research funding.

#### **OUR MISSION**

Our mission is to improve the health and well-being of North Carolinians and others whom we serve. We accomplish this by providing leadership and excellence in the interrelated areas of patient care, education, and research.

Patient Care: We will promote health and provide superb clinical care while maintaining our strong tradition of reaching underserved populations and reducing health disparities across North Carolina and beyond.

Education: We will prepare tomorrow's health care professionals and biomedical researchers by facilitating learning within innovative curricula and team-oriented interprofessional education. We will cultivate outstanding teaching and research faculty, and we will recruit outstanding students and trainees from highly diverse backgrounds to create a socially responsible, highly skilled workforce.

Research: We will develop and support a rich array of outstanding health sciences research programs, centers, and resources. We will provide infrastructure and opportunities for collaboration among disciplines throughout and beyond our University to support outstanding research. We will foster programs in the areas of basic, translational, mechanistic, and population research.

#### **Position Summary**

The Department of Surgery at The University of North Carolina is seeking applications for a full-time academic congenital heart surgeon to join our Division of Cardiothoracic Surgery. The Division of Cardiothoracic Surgery is among 9 clinical Divisions in the Department of Surgery. The Division currently includes 7 faculty members that provide exceptional care to patients from across the state of North Carolina. Academic appointment will be commensurate with the candidate's experience.

The ideal candidate will be mid to late career with a proven track record and requisite experience in all aspects of congenital cardiac surgery. The chosen candidate will be expected to work closely with the current Section Chief of Congenital Cardiac Surgery. The breadth of responsibilities will include neonatal cardiac surgery, pediatric heart failure, transplantation, ECMO, and adult congenital surgery. Preference will be given to individuals who bring unique skills, interests or qualifications to the current faculty in a complementary fashion. Individuals with a strong interest in research are encouraged to apply. Faculty members within the Division of Cardiothoracic Surgery must possess a desire to commit to all three mission of the department and school of medicine, including the clinical, education, and research missions. Regarding the education mission, faculty members are expected to regularly participate in the education of medical students, residents, and fellows. Regarding research, a commitment to any one of a broad array of research interests is desirable, including but not limited to clinical, outcomes, health services, basic science, translational, ethics, education, or global surgery research. Regarding the clinical mission, faculty members must be committed to delivering high quality clinical care that is of value to the patients of UNC. Selected candidate must be team-oriented and have the ability to interact well with colleagues inside and out of the Division.

#### Minimum Education and Experience Requirements

Prospective candidates must be Board Certified/Board Eligible or Equivalent in Thoracic Surgery and in Congenital Cardiac Surgery.

#### Preferred Qualifications, Competencies, and Experience

Completion of an ACGME approved Cardiothoracic Surgery Residency and Congenital Cardiac Surgery fellowship is preferred. Chosen candidate should either have a current North Carolina Medical License or be eligible for application.

Please apply online at <a href="https://unc.peopleadmin.com/postings/234256">https://unc.peopleadmin.com/postings/234256</a>

The University of North Carolina at Chapel Hill is an equal opportunity and affirmative action employer. All qualified applicants will receive consideration for employment without regard to age, color, disability, gender, gender expression, gender identity, genetic information, national origin, race, religion, sex, sexual orientation, or status as a protected veteran.



#### **Intangible Membership Benefits**

"The more the members, the louder our voice!": You've heard this before, and of course it is about much more than decibels. Rather, it is about speaking effectively with one voice to address the many challenges—economic, regulatory, social, access, MOC, credentialing, etc.—that interfere with our ability to provide the best possible care to the widest number of patients.

One of our members sent us an eloquent note: "As a participant in other important medical professional societies, I believe creation of a society dedicated solely to the pediatric & congenital interventional cardiology field is greatly needed. Thank you! I am happy PICS has taken this bold step to create such a groundbreaking society that will work towards advancement of our field, as our field tends to be globally overlooked, undersupported and too often ignored. We are modest in numbers, but so incredibly important to that parent to whom her child's health is the most important thing in the world!"

There has never been a more important time for our voice to be stronger, united and put to use. In the U.S., after decades of effort (PICS Advocacy Chair John Cheatham is one example among many), we now have a strong and positive dialogue with the FDA, a major step forward. As the Federal Government's lead regulator for medical device approval, the FDA understands that the relatively small numbers of CHD patients make large scale clinical trials virtually impossible. Through our dialogue with the FDA, our profession's voice is now having real impact in developing equally effective pathways to ensuring the safe, effective and TIMELY introduction of tools we need. We have much work ahead to continue the momentum.

In other parts of the world, there are growing challenges in the policy and regulatory arenas. We are engaged with national societies accordingly. In the European Community, recent modifications to the EU Medical Device Regulation (EU MDR) framework poses serious disincentives to development of new devices in our field. Even more troubling,

devices we have relied on for years to treat our patients are being withdrawn from the market for non-medical reasons, due to the onerous requirements of the EU MDR.

The impacts of both of these trends—a more understanding FDA and a difficult EU MDR framework—are not confined to individual national borders. Much as the adage that "a butterfly near the equator can lead to a hurricane in Canada," these trends have the potential to impact every single one of us, whether we work in Miami, Manila, Madrid or Mumbai.

In the areas of Continuing Medical Education (CME) and Maintenance of Certification (MOC) rules, updated requirements in both of these areas (including some that are controversial) mandate that we speak with one voice to improve those programs.

"I believe creation of a society dedicated solely to the pediatric and congenital interventional cardiology field is greatly needed. Thank you! ... We are modest in numbers, but so incredibly important to that parent to whom her child's health is the most important thing in the world!"

PICS Society Member

As other professional medical societies have long known (and as we have addressed in previous CCT columns), the impact of our collective voice is arguably the single most vital—if intangible—benefit of becoming a PICS Society member!

Early Career and Leadership Training: In our first two years, PICS has placed strategic importance on opportunities by and for early career members. This year we are holding our second annual Fellows/ Early Career Course (Drs. Darren Berman and Vivian Dimas, Co-Directors) preceding the Chicago Symposium. Our Early Career Committee (Dr. Aimee Armstrong, Chair, Drs. Gianfranco Butera and Dan Gruenstein, Co-Chairs) is one of our most

active, with an expanding educational and research agenda led by its members. Opportunities for involvement abound.

A Big Table: Since its inception, the PICS Society has warmly welcomed nurses, technologists and other medical professionals who work closely with pediatric/congenital interventionalists. In addition to programming at the annual Symposium, our Nurses/Allied Professionals Committee has become more active and welcomes new members. Similarly, at all levels of PICS, we recognize that we are not alone and have formed close working partnerships with national societies throughout the world to develop guidelines, educational programs and advocacy efforts.

Other Intangible Benefits: These include networking, the FPICS (Fellow of the PICS Society) designation and certificate signifying the highest level of achievement in our profession, as well as volunteer opportunities in our many committees and projects.

#### Conclusion

The Value Proposition: As noted above, every professional society must demonstrate value to its current and prospective members: Why invest your scarce funds and even scarcer time in a professional society? We hope this column helps answer that question by highlighting the tangible benefits of joining, and arguably the even more important intangible reasons.

In large part, it all comes back to the reason you dedicated your professional life to this field, and in fact is our "value proposition" to you: We offer you the opportunity to help achieve the vision of pursuing a world where anyone who can benefit from minimally invasive techniques to treat CHD can access safe and effective care.

#### Not a Current PICS Member?

Download the application form at CHDinterventions.org and click on "PICS Society."









#### Pediatric Cardiologist Opportunities – Northeast Ohio

Ohio-based Akron Children's Hospital seeks *Pediatric Clinical Cardiologists* to join its expanding Heart Center. Akron Children's Hospital is the largest pediatric healthcare system in Northeast Ohio and is ranked among the best children's hospitals by *US News and World Report*.

This integrated healthcare delivery system includes:

- Two free-standing children's hospitals
- More than 800 providers, who manage over 1.1 million patient visits annually
- A network of more than 50 primary and specialty care locations
- Robust research and innovation endeavors

The successful candidates will join a well-established group: Sixteen pediatric cardiologists, 7 advanced practice providers and 2 cardiothoracic surgeons who provide cardiac care to over 10,000 patients annually. Services include: Congenital cardiac surgery, interventional and diagnostic cardiac catheterizations, electrophysiology testing and ablation, pacemaker/ICD implantation, a robust fetal echocardiography program, adult congenital cardiac program and a cardiac advanced imaging. Affiliation with Northeast Ohio Medical University leads to academic appointment and teaching opportunities.

Two positions are available: Youngstown campus and Akron campus.

#### Youngstown position offers:

- Full or Part-time employment as outpatient pediatric cardiologist, joining 2 full time cardiologists.
- Outpatient clinic
- No cardiac ICU nor inpatient call (no weekend rounding). Outpatient call only for Youngstown.
- Opportunities for subspecialty interests
- Competitive compensation package with options for annual bonus.
- Equidistant (1.5 hour) between Cleveland and Pittsburgh.

#### Akron position offers:

- Full time employment as clinical pediatric cardiologist
- Outpatient clinic
- Inpatient call rotation.
- Opportunities for subspecialty interests.
- An attractive compensation plan that includes bonus compensation

Requirements include board eligibility/certification in Pediatric Cardiology and the ability to obtain an active medical license in the state of Ohio.

Akron Children's Hospital is set in the beautiful Cuyahoga Valley, just minutes south of Cleveland. This four-season community offers outdoor enthusiasts more than 40,000 acres of parks for year-round enjoyment. Excellent public and private secondary schools offer top-notch education.

Interested candidates may contact Jane Hensley, Physician Recruiter at 330-543-3015 or jhensley@akronchildrens.org. To learn more, visit our website at www.akronchildrens.org.

One Perkins Square | Akron, OH 44308 | akronchildrens.org



# Philips EchoNavigator Helps Interventional Teams Treat Structural Heart Disease with Greater Ease and Efficiency

- EchoNavigator 4.0 empowers heart teams with greater control of live fusion imaging plus new anatomical modeling and transseptal puncture guidance during minimally-invasive procedures
- Seamless integration and communication between Philips Ultrasound System EPIQ CVxi and Philips Image Guided Therapy System - Azurion - supports efficient fusion-imaging workflow for minimally-invasive treatment of structural heart disease

Royal Philips, a global leader in health technology, announced at EuroPCR (May 2022, Paris, France) the international launch of EchoNavigator 4.0¹, the new release of its advanced image-guided therapy solution for the treatment of structural heart disease. EchoNavigator 4.0 gives users of Philips' EPIQ CVXi interventional cardiology ultrasound system greater control of live fusion-imaging on the company's Image Guided Therapy System - Azurion - platform.

By integrating real-time transesophageal echocardiography (TEE), which places the ultrasound transducer close to the heart, and X-ray fluoroscopy, EchoNavigator 4.0 helps interventional teams to decide, guide, treat, and confirm complex structural heart disease therapy, such as heart valve repair or replacement. The solution also includes extended anatomical intelligence models, transseptal puncture guidance to help access the left atrium and mitral valve from the right atrium, and new 3D live image fusion capabilities, including Philips' TrueVue photo-realistic rendering and GlassVue volumetric imaging modes. It also features automatic selection of an appropriate set of multiplanar reconstruction planes (sections taken from the 3D echo heart model), with presets for common views of the aortic and mitral valves and left atrial appendage.

The latest EchoNavigator release gives us unique peri-interventional possibilities by offering a comprehensive set of automated views based on advanced 3D heart models in combination with live fusion imaging.

"The latest EchoNavigator release gives us unique peri-interventional possibilities by

offering a comprehensive set of automated views based on advanced 3D heart models in combination with live fusion imaging," said Dr. Patric Biaggi, Head of Cardiac Imaging at Heart Clinic Hirslanden in Zurich, Switzerland. "This allows us to treat our patients with greater confidence and precision during every stage of the procedure."

Largely due to lifestyle choices and the aging population, structural heart disease is now commonplace in older individuals. In the USA, for example, as many as 1 in 10 people over the age of 75-years are affected by a condition known as mitral regurgitation<sup>2</sup>, which means the mitral valve in their heart does not close properly, adversely affecting the amount of oxygenated blood that can be pumped round their body. Worldwide, around 156 million people are estimated to suffer from the condition<sup>3</sup>. Fortunately, in many cases treating structural heart disease can now be performed via image-guided, minimallyinvasive, catheter-based procedures that impose far less trauma than open-heart surgery.

# Improved Communication and Teamwork

Philips EchoNavigator helps improve communication and teamwork between echocardiographers and interventionists during image-guided therapy by automatically fusing together echocardiography ultrasound and X-ray images, while also enhancing understanding of the relationship between X-ray and ultrasound in an intuitive way that

helps interventional teams to complete procedures with greater safety, confidence, and clarity.

"Cardiology teams across the world are facing increasing numbers of complex structural heart disease cases and are seeking new ways to deliver effective high-quality care despite staffing shortages," said Karim Boussebaa, General Manager of Image Guided Therapy Systems at Philips. "By helping echocardiographers and interventionists to work together in even more highly coordinated ways, this new release of EchoNavigator is an important step forward in boosting patient throughput, making more efficient use of time and resources, and achieving positive cardiovascular care outcomes."

# Greater Control for Echocardiographers

EchoNavigator 4.0 puts greater control of imaging in the hands of the echocardiographer via the EPIQ ultrasound platform's touch screen, including the ability to fuse and annotate echocardiography and X-ray fluoroscopy images. Anatomical features can be identified either manually or automatically, with anatomical markers and annotations applied to one modality automatically transposed to the other. Live fusion images, markers, and annotations are immediately visible to interventional cardiologists via the Azurion platform's FlexVision Pro monitor to help guide catheterization and therapy device deployment.





### Pediatric Cardiology (General/Inpatient, Fetal and Advanced Imaging, Heart Failure/Transplant)

Join the University of Maryland School of Medicine, Department of Pediatrics, Division of Pediatric Cardiology. As we grow our nationally ranked pediatric heart program, we are seeking Assistant, Associate and Professor level candidates in the following areas: fetal and advanced imaging, heart failure/transplant, and general/inpatient cardiology.

#### Position Highlights:

- Superb working environment including seven (7) Pediatric Cardiologists, two (2) Pediatric Congenital Heart Surgeons and a commensurate group of Nurse Practitioners focused on general and specialized clinical inpatient and outpatient cardiology care
- Strong inpatient and outpatient cardiology practice that includes eleven (11) outpatient practice sites across the State of Maryland, to include two (2) collegiate sports medicine practices
- Integration with the thirteen (13) hospitals of the University of Maryland Health System, and with other regional health systems
- Collaborate with skilled and recognized experts, including pediatric cardiac surgeons, pediatric cardiac intensivists, genetics, behavioral pediatrics and
  pediatric neurology, maternal-fetal medicine specialists, and board certified adult congenital cardiologists
- Excellent opportunities for collaborative research, quality initiatives, academic instruction and leadership

#### Features:

- U.S. News & World Report Top 50 Pediatric Cardiology and Heart Surgery Center!
- Full spectrum of care from prenatal to adulthood, all in one hospital
- Expanded critical care, neurology, and neonatology services providing opportunities for career development.
- Nineteen (19) bed PICU with nine (9) dedicated PCICU beds, faculty and leadership
- ECMO and VAD program
- State of the art 52-bed Level IV NICU
- Six (6) bed IMC, Twenty-nine (29) general pediatric beds
- Twenty (20) bed Pediatric Emergency Department
- Home to a pioneering artificial blood clinical research program

#### Benefits/Perks:

- Very generous leave package
- Dependent tuition remission for any school within the University of Maryland system
- Excellent pension/retirement plans
- Liability, life and disability insurance coverage
- Very competitive salary with bonus opportunities
- Full spectrum of academic citizenship opportunities germane to large academic institution, with extensive and varied avenues for growth and promotion

#### Qualifications:

- The successful applicant must have:
  - MD or equivalent
  - Clinical training in pediatrics and pediatric cardiology
    - Completed fellowship and be board eligible or board certified
- · Preference will be given to candidates who have expertise in either fetal imaging and heart failure/transplant

The University of Maryland Children's Hospital (UMCH) has a renowned Children's Heart Program. We are located near the downtown Inner Harbor area, just one of Baltimore's many outstanding attractions. From fine arts and orchestras to professional sports teams, first-class dining and shopping to a wealth of historical sites, our city offers a full range of recreational and cultural opportunities. The area provides suburban and urban living options, both containing an abundance of family friendly neighborhoods and outstanding educational institutions. Another benefit of living and working in the Mid-Atlantic Region is the moderate weather, with four distinct seasons. The central location enables easy access to beaches to the east and mountains to the west.

To learn more about your opportunity to join a dynamic and innovative team of cardiologists meeting the complex needs of Maryland's fetal, pediatric, and adult congenital heart patients, visit:

https://umb.taleo.net/careersection/som\_faculty\_and\_post\_docs/jobsearch.ftl?lang=en (Job Number: 210000VL)

Applicants should apply through the Taleo link and job number provided above, as well as submit their curriculum vitae to:

Michael Bridges, <a href="mailto:mbridges@som.umaryland.edu">mbridges@som.umaryland.edu</a>, 410.328.5752

UMB is an equal opportunity/affirmative action employer. All qualified applicants will receive consideration for employment without regard to sex, gender identity, sexual orientation, race, color, religion, national origin, disability, protected Veteran status, age, or any other characteristic protected by law or policy.



#### **MEDICAL NEWS**

# Extended Automatic Modeling and Transseptal Puncture Guidance

Additional context and guidance are provided by EchoNavigator's automated 3D anatomical modeling capabilities. These include models for the mitral valve and its leaflets, and transseptal area models to help identify the optimum zone in the wall separating the right and left atrium where the septum can be punctured to catheterize the left atrium and mitral valve. These 3D modeling capabilities also allow EchoNavigator 4.0 to automatically select an optimal set of multiplanar reconstruction planes, with presets for optimally viewing the aortic and mitral valves and left atrial appendage.

# Enhanced Fusion Imaging with Cardiac TrueVue and TrueVue Glass Rendering

EchoNavigator 4.0's fusion imaging capabilities have been further enhanced

by the ability to fuse live X-ray fluoroscopy images with live TrueVue and TrueVue Glass rendered echocardiography images to more easily visualize positioning and device-tissue interactions. Philips TrueVue 3D echo rendering improves visualization of anatomical structures and devices, while TrueVue Glass with Color allows interventionists to view the location of regurgitant blood flow across a heart valve.

With its long history of leadership in cardiology innovation, informed by continuous collaboration with leading clinical partners, Philips is uniquely positioned to deliver integrated solutions that span the care pathway to help solve cardiology's daily challenges and provide better heart care with greater efficiency.

- update: a report from the American Heart Association https://pubmed.ncbi.nlm.nih.gov/20019324/.
- 3. Dziadzko V, Clavel MA, Dziadzko M, et al. Outcome and undertreatment of mitral regurgitation: a community cohort study. Lancet. 2018;391(10124):960-969. doi:10.1016/S0140-6736(18)30473-2 https://pubmed.ncbi.nlm.nih. gov/29536860/.



#### References

- 1. Philips EchoNavigator 4.0 is not yet available in all markets, e.g not available in USA or China.
- 2. Lloyd-Jones D, Adams RJ, et al. Heart disease and stroke statistics--2010

# **G-ARMOR STENT® PORTFOLIO**

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NOW AVAILABLE IN THE U.S. & CANADA



# Treat a broaders range of patients

with longer stent length after expansion, lower foreshortening rate, and compatibility with 13-18F introducers







## Non-Invasive Imaging Pediatric & Fetal Cardiologist

The Heart Center at Phoenix Children's Hospital is seeking application for the position of a full-time non-invasive imaging pediatric and fetal cardiologist to join this nationally ranked, high volume, tertiary referral cardiology program with an IAC Fetal, pediatric and adult congenital Echo certified lab. The ideal candidate will join a team of experienced and advanced trained team of echo faculty and sonographers; and will participate in interpreting transthoracic echocardiograms, performing intraoperative and periprocedural transesophageal studies, interpreting fetal echocardiograms, supervision of fellows and sonographers while participating in departmental quality audits and research projects. Phoenix Children's Hospital has a large volume Fetal Cardiology Program integrated with all delivery hospital systems throughout the Phoenix metropolitan area. There are multiple opportunities to participate in pediatric and fetal echo research. Phoenix Children's also hosts the annual, internationally renowned Phoenix Children's Fetal Cardiology Symposium.

#### Desirable candidate should have:

- Advanced echocardiography and fetal cardiology 4th year imaging fellowship training or equivalent clinical experience
- Experience providing cardiovascular evaluation in a fetal treatment center preferred
- At least 3-5 years clinical experience preferred
- Experience in interpretation of 3D echocardiogram preferred
- Experience with teaching residents and fellows
- Experience in conducting clinical research and mentoring trainees

The staff physician shall provide patient care services and will support the PCH mission of providing hope, healing and the best health care for children and their families.

For more information and to apply for the position, click on the link below.

<u>Open Position - Non-Invasive Imaging Pediatric and Fetal Cardiologist - Career Opportunities @ Phoenix Children's Hospital (phoenixchildrens.com)</u>

#### Phoenix Children's Values

- Family-Centered care that focuses on the need of the child first and values the family as an important member of the care team
- Excellence in clinical care, service and communication
- Collaborative within our institution and with others who share our mission and goals
- Leadership that set the standard for pediatric health care today and innovations of the future
- Accountability to our patients, community and each other for providing the best in the most cost-effective way.



# Flexible Health Care Monitoring Solutions Needed for All Levels of Patient Acuity

Providing a mobile and modular telemetry platform from hospital to home represents the future of health care. InfoBionic unveils a solution with their launch of a new suite of virtual telemetry solutions as part of their recently announced MoMe<sup>(TM)</sup> ARC Platform.

- The virtual care boom continues across the United States.
- Providers continue to struggle with outdated technologies that provide limited data and continue to be plagued with report delays.
- Remote cardiac monitoring devices provide essential data.
- As patients move from the hospital to the home, health care providers are left looking for a flexible and modular solution that can work well for all levels of patient acuity.

Stuart Long, CEO of InfoBionic, a Massachusetts-based digital health company, finds that the new products can be fully configured to nearly any virtual cardiovascular monitoring use case, making them the ideal solution in the new era of remote and virtual patient care.

InfoBionic's MoMe<sup>(TM)</sup> ARC Platform is an innovative new cloud platform that allows for a flexible and modular suite of products to work in concert to capture data in from real-time to near real-time. InfoBionic is pleased to introduce its 3rd generation of products, including the new MoMe<sup>(TM)</sup> Gateway and a suite of innovative Bluetooth® lead sets that will allow for greater quality, precision and flexibility from low acuity to high acuity in both inpatient and outpatient care settings.

The Gateway is designed to collect information from three different InfoBionic developed modular Bluetooth lead set systems:

 The K1, a 5-in-1 pod with a disposable electrode that provides a

- 1-lead view, 1-channel capability.
- The K3, a 5-in-1 device featuring 3 electrodes providing a 6-lead view, 2-channel capability.
- The K7, a 5-in-1 device using 5 electrodes which provides a 7-lead, 3-channel capability.

"We must keep pace with the changing demands brought on by remote patient care. We've focused on advancing our technology to provide from remote near real-time monitoring and now to in hospital real-time telemetry for a variety of patients with varying levels of medical complexity. Providing a mobile and modular telemetry platform from hospital to home is part of the future of health care, and our solution will help manage the everincreasing demand on our health care system."

Stuart Long, CEO of InfoBionic, a Massachusetts-based digital health company

The MoMe Now is designed specifically for inhospital telemetry to provide step-down level of telemetry for any bed or location that would need an easy to deploy mobile telemetry monitor.







# Pediatric Electrophysiologist Faculty Position

The Department of Pediatrics of the University Of Illinois College Of Medicine at Peoria (UICOMP) seeks Pediatric Cardiac Electrophysiology candidates for a pediatric cardiology faculty position. This cardiologist will work primarily at OSF Healthcare Children's Hospital of Illinois.

The candidate must hold an MD/DO degree, be board certified or board-eligible in pediatric cardiology, and hold or be eligible for an Illinois physician license. Candidates must have completed residency & fellowship training. Additional training and/or extensive experience in pediatric and congenital cardiac electrophysiology, invasive and non-invasive, is required. This faculty member will be at the full time assistant/associate/professor rank based on the experience of the candidate.

The candidate will join a well-established team of 10 pediatric cardiologists, 2 pediatric cardiovascular surgeons, 4 advanced practice providers, and EP nursing. Professional efforts will be bolstered by state-of-the-art facilities, including EP lab.

#### Responsibilities:

- Patient care duties including inpatient, outpatient and interventional.
- Satellite clinics in the region.
- Device checks both in person and remote.
- On-call duties for pediatric cardiology and electrophysiology.
- Teaching of medical students, residents, and fellows.
- Academic efforts including original research and QI.
- Administrative efforts related to EP program.

The University of Illinois at Chicago is an affirmative action, equal opportunity employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, gender identity, sexual orientation, national origin, protected veteran status, or status as an individual with a disability.

For fullest consideration, please apply at: https://uic.csod.com/ux/ats/careersite/1/home/requisition/41?c=uic

For more information please contact: Marc Knepp, MD; Division Head, Pediatric Cardiology; mknepp1@uic.edu; 309.624.3901







# Pediatric Cardiology Faculty Opportunity

The Department of Pediatrics at Rainbow Babies & Children's Hospital (RBC) and The Congenital Heart Collaborative (TCHC) are conducting a national search to identify candidates at any academic rank, including 2023 fellows for two additional Pediatric Cardiologists to join their robust and expanding program. While the primary focus of these positions is ambulatory care, opportunities exist for noninvasive imaging and inpatient service based on the interests of the candidates.

#### **Opportunity Highlights:**

- Opportunities currently include serving as primary representative with MetroHealth, an
  existing partnership and innovative affiliation between RBC and the MetroHealth System to
  provide world class pediatric cardiology care in downtown Cleveland, with options to serve
  additional clinics at the main RBC campus and other ambulatory locations across Northeast
  Ohio.
- Alternatively, opportunity exists to exclusively provide ambulatory care at main RBC campus and other ambulatory locations.
- The RBC Heart Center provides comprehensive services across all cardiac subspecialties and includes 21 faculty (12 cardiologists, 5 cardiac intensivists, 2 cardiothoracic surgeons, and 2 cardiac anesthesiologists) along with a full complement of interdisciplinary team members.
- The RBC Heart Center and Nationwide Children's Hospital Heart Center in Columbus, OH have partnered to form The Congenital Heart Collaborative (TCHC). TCHC is a dedicated service line with a common executive administration and functions as one program on two campuses with the commitment to expand access to high-quality comprehensive cardiac care regardless of patient age to the communities served while equally embracing a scholarly and educational mission.
- RBC Heart Center has an ACGME accredited Pediatric Cardiology fellowship with 2 fellows per year.
- The facilities at the RBC Heart Center include a recently opened, state-of-the-art
  Interventional Cath/EP/Hybrid OR suite and a beautiful, dedicated cardiac stepdown unit.
  Planning is underway for a new state-of-the-art Pediatric Cardiac Intensive Care Unit that
  will be immediately adjacent to the Hybrid Cath/EP suites and stepdown unit with plans for
  opening in 2023.

For more details about this opportunity, please contact Karis Beasley at <a href="mailto:karis@careerphysician.com">karis@careerphysician.com</a>

University Hospitals is an AA/EOE/ADA employer committed to excellence through diversity.



# Children's Hospital Colorado First in the World to Implant Recently FDA-Approved G-Armor Stent for Treatment of Congenital Heart Disease

Custom Stent was Designed and Developed by Gareth Morgan, MD, Interventional Cardiologist at Children's Hospital Colorado, in Conjunction with NuMED for Children, and Implanted in Father of Two

Children's Hospital Colorado (Children's Colorado) is the first hospital in the world to implant the newly FDA-approved G-Armor Stent, <a href="www.numedforchildren.com/product/g-armor-stentr-and-g-armor-mounted-stenttm">www.numedforchildren.com/product/g-armor-stentr-and-g-armor-mounted-stenttm</a>. Although the stent is designed to be used in the smallest of patients, it was first implanted in a Colorado father of two. The stent was developed by interventional cardiologist, Gareth Morgan, MD, who oversees the Interventional Congenital Cardiology program at Children's Colorado in conjunction with NuMed for Children.

Unlike many other stents, the G-Armor is hand-manufactured with considerable capacity for expansion and minimal shortening during implantation. The result is a stent that can be dilated to accommodate a patient's natural growth, potentially reducing the need for additional stent implantation – a key benefit to growing pediatric patients. The high expansion range also provides cardiac interventionalists the ability to treat a broader range of patients.

"I am proud to have led the development of the first custom stent approved by the FDA in a decade to treat congenital heart disease," says Morgan, who is also an associate professor at the University of Colorado School of Medicine. "This new stent, in combination with our unmatched imaging technologies, removes significant surgical uncertainties, and is expected to result in improved outcomes for patients of all ages."

The first patient was Randy Welch, who was told as a child that the small hole in his heart would close. But as a new dad working at the National Institutes of Health in Maryland, Welch learned the hole had expanded significantly and was causing his heart to pump extremely hard, which could ultimately result in heart failure. After moving back to Colorado and seeking cardiology care, Welch was quickly referred to Joseph Kay, MD, program director for the Children's Colorado / UCHealth Adult Congenital Heart Disease program. This unique program on the Anschutz Medical Campus specializes in treating adults, like Welch, who were born with congenital heart defects. <a href="www.childrenscolorado.org/doctors-and-departments/departments/heart/programs-and-clinics/adult-congenital-heart-disease/">www.childrenscolorado.org/doctors-and-departments/departments/heart/programs-and-clinics/adult-congenital-heart-disease/</a>.

Welch's two options were either open heart surgery or implanting this new stent in the Children's Colorado heart catheterization lab, <a href="www.childrenscolorado.org/doctors-and-departments/departments/heart/programs-and-clinics/cardiac-catheterization/">www.childrenscolorado.org/doctors-and-departments/heart/programs-and-clinics/cardiac-catheterization/</a>. With a second child on

the way, Welch wanted the procedure with the lowest risk and quickest recovery time. Working with his colleague Jenny Zablah, MD, who leads the innovative interventional imaging team, Dr. Morgan created a 3D model of Welch's heart and determined that Welch was a good candidate for the new stent.

As is the case of many young adults with Congenital Heart Disease, Dr. Kay and Dr. Morgan deemed that Welch's procedure and recovery would be best managed by the congenital cardiac team at Children's Colorado to take advantage of the hospital's highend imaging technologies, virtual-reality planning and the extensive experience of the entire catheterization lab team.

"Working in the medical field, I understood I needed to repair my heart, but I kept putting it off. The thought of having open-heart surgery with two babies at home wasn't very appealing," said Welch. "But Dr. Morgan and Dr. Kay explained how left untreated, I could go into heart failure or have a stroke. The new stent was a perfect option for me."

Six months after surgery, Randy is feeling good, his heart looks great and his future is bright.

#### About Children's Hospital Colorado

Children's Hospital Colorado is one of the nation's leading and most expansive nonprofit pediatric healthcare systems with a mission to improve the health of children through patient care, education, research and advocacy. Founded in 1908 and recognized as a top 10 children's hospital by U.S. News & World Report, Children's Colorado has established itself as a pioneer in the discovery of innovative and groundbreaking treatments that are shaping the future of pediatric healthcare worldwide. Children's Colorado offers a full spectrum of family-centered care at its urgent, emergency and specialty care locations throughout Colorado, including an academic medical center on the Anschutz Medical Campus in Aurora, hospitals in Colorado Springs, Highlands Ranch and Broomfield, and outreach clinics across the region. For more information, visit www.childrenscolorado.org or connect with us on Facebook, Twitter, Instagram and YouTube.



# **NEONATOLOGY TODAY**





# **Pediatric Cardiologist**

#### Division of Pediatric Cardiology, Department of Pediatrics University of Utah School of Medicine

This is an excellent opportunity to join a vibrant and collegial academic environment. The Division of Pediatric Cardiology at the University of Utah School of Medicine has immediate openings for full-time, pediatric cardiologists with expertise and interest in general cardiology. Clinical responsibilities will be carried out at SCL Health - St. Vincent Hospital in Billings, Montana, outreach sites in Bozeman and Missoula, Montana, and Intermountain Primary Children's Hospital in Salt Lake City, Utah. Inpatient responsibilities include work in Neonatal Intensive Care, Pediatric Intensive Care, and consulting in other units throughout both hospitals. Inpatient work is supported by advanced practice providers (NPs and PAs), cardiology fellows, and pediatric residents. Academic productivity in quality improvement, research, teaching, and advocacy is expected and supported by the division.

The Division has a very active research program with a strong support infrastructure and supporting team. The Division has been a core site of the Pediatric Heart Network of the National Institutes of Health (NIH) since inception and participates in the NPC-QIC and all the major registries including PC4, PAC3, and IMPACT. In addition, the Division is a core site for the Scientific Focus Research Network of the American Heart Association (AHA). Numerous opportunities for collaborative research exist within the Division, as well as throughout the Department, School of Medicine, and University.

Qualified candidates must be Board Eligible/Board Certified in Pediatric Cardiology with expertise in General Pediatric Cardiology. Selected candidates will receive a faculty appointment in the Department of Pediatrics on the Clinical Track at the academic rank commensurate with experience and qualifications.

The Department and University offers a competitive salary and an unmatched benefits program, including non-contributory retirement contributions of 20.2% of annual salary that vest immediately. The Department offers a faculty development and mentoring program designed to help faculty succeed in translational or basic research.

Located in the south-central portion of Montana, Billings is the seat of Yellowstone county and the largest city in the state. Billings offers easy access to everything from fabulous restaurants to quintessential mountain hiking. Billings is a family-friendly community with a variety of school options including Montessori schools, parochial schools, and a praiseworthy public school system. Billings is proud to boast a traveler friendly international airport in a safe city with very little traffic. With 300 plus days of sunshine and 12 different ski hills, it's a wonderful place to live and work. Montana offers amazing views, adventure, and landscape that are incomparable to anything in the U.S.

Interested individuals can apply for the position at https://utah.peopleadmin.com/postings/138167. Cover letter and curriculum vitae are required. For additional information about the position, please contact: Antonio Cabrera, MD, Division Chief, at antonio.cabrera@hsc.utah.edu.

The University of Utah Health (U of U Health) is a patient focused center distinguished by collaboration, excellence, leadership, and respect. The U of U Health values candidates who are committed to fostering and furthering the culture of compassion, collaboration, innovation, accountability, diversity, integrity, quality, and trust that is integral to our mission.

The University of Utah values candidates who have experience working in settings with students, staff, faculty and patients from diverse backgrounds and possess a strong commitment to improving access to higher education, employment opportunities, and quality healthcare for historically underrepresented groups.

Individuals from historically underrepresented groups, such as minorities, women, qualified persons with disabilities and protected veterans are encouraged to apply. Veterans' preference is extended to qualified applicants, upon request and consistent with University policy and Utah state law. Upon request, reasonable accommodations in the application process will be provided to individuals with disabilities.

The University of Utah is an Affirmative Action/Equal Opportunity employer and does not discriminate based upon race, ethnicity, color, religion, national origin, age, disability, sex, sexual orientation, gender, gender identity, gender expression, pregnancy, pregnancy-related conditions, genetic information, or protected veteran's status. The University does not discriminate on the basis of sex in the education program or activity that it operates, as required by Title IX and 34 CFR part 106. The requirement not to discriminate in education programs or activities extends to admission and employment. Inquiries about the application of Title IX and its regulations may be referred to the Title IX Coordinator, to the Department of Education, Office for Civil Rights, or both.



# A First for the United States: Norton Children's Heart Institute Physicians Implant Tiny Pacemaker, Saving Infant's Life

Patient Born at 28 Weeks with Slow Heart Rate and Congenital Heart Disease Receives Never Before Used Pacemaker Implant

A multidisciplinary team within Norton Children's Heart Institute, affiliated with the UofL School of Medicine, worked together to save the life of an infant born with congenital structural heart defects and complete atrioventricular block (CCAVB) that led to a slow heart rate. The patient was too small for the traditional path of care, driving the innovative team to perform the first known human implantation of a novelly-designed tiny pacemaker in a premature infant.

"It is remarkable how our team of pediatric specialists came together with the device company to offer a resolution for such a small patient weighing less than three pounds at the time of implant," said Soham Dasgupta, MD, pediatric electrophysiologist, Norton Children's Heart Institute and U of L Assistant Professor of Pediatric Cardiology. "This unique case is unlike any other and we are so pleased to see this patient thriving as a result of the innovative approach."

Approximately 1 in 22,000 infants are born with CCAVB. Untreated, the condition has a high incidence of pro-longed illness or death. The usual treatment involves implantation of a pacemaker once the patient meets a minimum body size, typically 4 1/2 to 5 1/2 pounds, to accommodate the implantable device. Taking time for the baby to grow while being otherwise treated is strongly preferred for this situation. With this patient, however, the traditional plan was not working.

"In this instance, the patient was not of the optimal size and medical/conservative management was unsuccessful, so a specially modified pediatricsized pacemaker also known as an implantable pulse generator (IPG) created by Medtronic was used," Dr. Dasgupta said.

Dr. Dasgupta and his colleague, Christopher L. Johnsrude, MD, Director of Pediatric and Adult Congenital Electrophysiology and U of L Associate Professor of Pediatric Cardiology, reviewed the relevant preclinical data from a procedure where a similar tiny pediatric IPG had been implanted in an adult Yucatan miniature pig, an animal with a heart that resembles a child's heart.

Once it was determined the pediatric IPG was potentially compatible with the patient at Norton Children's, Dr. Dasgupta worked with Norton Children's Research Institute, affiliated with the U of L School of Medicine, and the manufacturer, to obtain local Institutional Review Board approval and emergency authorization from the U.S. Food and Drug Administration.

Once the device was in hand, the procedure to place the implant was completed over the course of a two-hour open-heart surgery. The tiny device measures 1.16 by 0.65 by 0.38 inches and weighs 0.18 ounces.

"While the operative steps might be comparable to the usual pacemaker implantation surgery, this surgery was especially delicate due to the very small size of the baby," said Bahaaldin Alsoufi, MD, Chief of Pediatric Cardiothoracic Surgery, Co-Director of Norton Children's Heart Institute and U of L Professor of Cardiothoracic Surgery. "This tiny pacemaker generator was positioned in the abdominal wall on the right side and was connected to the usual leads that were attached to the heart. This novel device will provide the necessary support that the baby currently needs. At time of repair of the patient's congenital heart defect in the future, we will be able to utilize these same leads and likely connect them then to a traditional larger pacemaker generator."

To date, the patient is doing well and continues to be cared for by cardiac and neonatal specialists across Norton Children's Heart Institute.

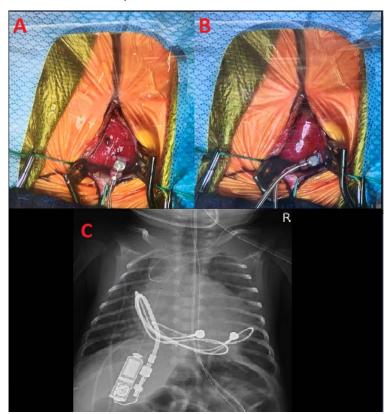


FIGURE 1 Sternotomy at the time of implantation of an epicardial single chamber pacemaker in a premature infant with CCAVB (head at the top). (A) Implantation of the cathode of the epicardial Medtronic CapSure™ EPI Model 4968 pacing lead on the left ventricular apex, and (B) anode implanted on the right ventricular free wall. (C) Postoperative chest radiograph demonstrating a bipolar ventricular epicardial lead connected to the abdominal Pediatric IPG pacemaker.



### **OCTOBER**

#### 01

12<sup>th</sup> Annual UCLA Fetal Cardiac Imaging and Evaluation Symposium

Virtual

https://www.cme.ucla.edu/courses/event-description?registration\_id=941697&client\_view\_p=f

### **NOVEMBER-DECEMBER**

27-01

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# UIC ILLINOIS CHICAGO

#### Asst/Assoc/Professor of Pediatric Cardiology

The Department of Pediatrics of the University Of Illinois College Of Medicine at Peoria (UICOMP) seeks Pediatric Cardiac Electrophysiology candidates for a pediatric cardiology faculty position. This cardiologist will work primarily at OSF Healthcare Children's Hospital of Illinois. The candidate must hold an MD/DO degree, be board-certified or board-eligible in pediatric cardiology, and hold or be eligible for an Illinois physician license. Candidates must have completed residency & fellowship training. Additional training and/or extensive experience in pediatric and congenital cardiac electrophysiology, invasive and non-invasive, is required.

The candidate will join a well-established team of 10 pediatric cardiologists, 2 pediatric cardiovascular surgeons, 4 advanced practice providers, and EP nursing. Professional efforts will be bolstered by state of the art facilities, including EP lab. Excellent collaboration exists among pediatric subspecialists as well as adult cardiology colleagues. UICOMP supports a thriving education program with medical students, residents, and fellows.

Clinical activities will include outpatient clinics, inpatient rotation, and procedural time. Travel to outreach clinics located in surrounding community cities is required. Inpatient and procedural care is provided at OSF Healthcare Children's Hospital of Illinois (CHOI). Clinical activities of this faculty member will be at the full time assistant/associate/professor rank based on the experience of the candidate

#### **Duties & Responsibilities:**

- Patient care duties including inpatient, outpatient and interventional.
- Satellite clinics in the region.
- Device checks both in person and remote.
- On-call duties for pediatric cardiology and electrophysiology.
- Teaching of medical students, residents, and fellow.
- Academic efforts including original research and QI.
- Administrative efforts related EP program

#### **Minimum Qualifications:**

- MD/DO or foreign equivalent.
- Eligible for licensure in Illinois.
- BC/BE in Pediatric Cardiology.
- 3 years pediatric residency/3years pediatric cardiology fellowship or equivalent.
- Significant experience or formal training in Pediatric Cardiac Electrophysiology (invasive and non-invasive).

For fullest consideration submit your application to: https://uic.csod.com/ux/ats/careersite/1/home/requisition/41?c=uic

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Request an Accommodation







# Pediatric Cardiologist Noninvasive Cardiac Imaging

The Heart Center at Nationwide Children's Hospital (NCH) seeks a Noninvasive Cardiac Imaging specialist, at any academic rank, to join its growing and dynamic program.

Candidates should be board-certified or eligible in pediatric cardiology, with advanced training and expertise in performing and interpreting echocardiography and/or advanced cardiac imaging (MRI/CT expertise preferred) along with a strong interest in clinical/translational research. Clinical and research leadership opportunities are available, commensurate with the experience of the applicant.

The successful applicant will join our IAC-accredited NCH Noninvasive Cardiac Imaging team which currently includes 11 attending physicians and 20 sonographers, and performs more than 20,000 echocardiographic studies annually, including more than 1300 fetal, transesophageal, intracardiac, intravascular, and 3-D echocardiograms. Our growing Heart Center cardiac MRI/CT program includes 8 attending physicians from Cardiology and Radiology, and performs over 1000 annual studies. Academic productivity is an expectation as is mentoring junior faculty and fellows. The program includes a 4th year Advanced Noninvasive Cardiac Imaging fellowship to complement the core pediatric and combined pediatric-adult cardiology fellowship programs.

The Heart Center embraces a culture of patient safety and quality, transparency, value-based care, public health awareness, excellence in education and engagement in translational/outcomes research. Our program is closely partnered with the Center for Cardiovascular Research at the NCH-Research Institute which provides infrastructure to support the clinical research enterprise. Research opportunities include engaging in basic science research, clinical research, translational research, population based studies, and research-based education or quality improvement initiatives.

The Heart Center is also part of the Congenital Heart Collaborative between the University Rainbow Babies & Children's Hospital (Cleveland, OH) and Nationwide Children's Hospital heart programs which provides additional opportunity for collaborative research.

Named to the Top 10 Honor Roll on U.S. News & World Report's 2021-22 list of "Best Children's Hospitals," Nationwide Children's Hospital is one of America's largest not-for-profit free-standing pediatric health care systems providing unique expertise in pediatric population health, behavioral health, genomics and health equity as the next frontiers in pediatric medicine, leading to best outcomes for the health of the whole child. Integrated clinical and research programs, as well as prioritizing quality and safety, are part of what allows Nationwide Children's to advance its unique model of care. Nationwide Children's has a staff of more than 13,000 that provides state-of-the-art wellness, preventive and rehabilitative care and diagnostic treatment during more than 1.6 million patient visits annually. As home to the Department of Pediatrics of The Ohio State University College of Medicine, Nationwide Children's physicians train the next generation of pediatricians and pediatric specialists. The Abigail Wexner Research Institute at Nationwide Children's Hospital is one of the Top 10 National Institutes of Health-funded free-standing pediatric research facilities. More information is available at NationwideChildrens.org.

To learn more about Nationwide Children's or apply for this position visit us at: NationwideChildrens.org/physician-careers

Candidates may submit their curriculum vitae by email to:

John Kovalchin, MD
Director, Non-Invasive Imaging
John.Kovalchin@NationwideChildrens.org or

Robert Gajarski, MD, MHSA Section Chief, Pediatric Cardiology The Heart Center at Nationwide Children's Hospital Robert.Gajarski@NationwideChildrens.org

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