CONGENITAL CARDIOLOGY TODAY
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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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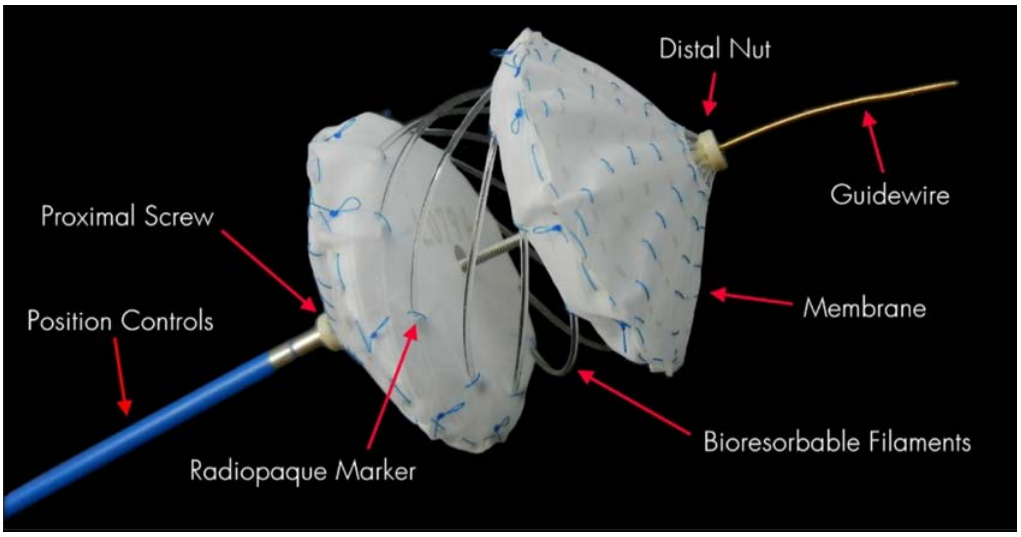


FIGURE 1 *The reSept ASD Occluder attached to the delivery system.*

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.

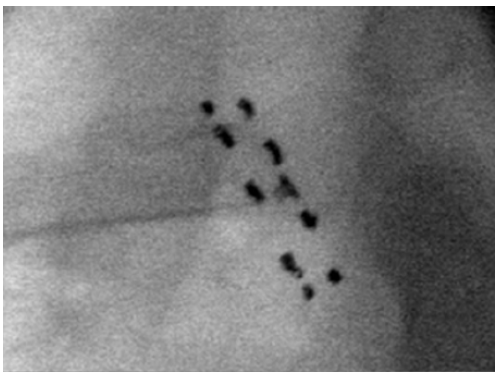
An early attempt at a bioresorbable occluder, the BioSTAR™ (NMT Medical) was introduced in Europe in 2005. A major engineering accomplishment at the time, this device incorporated a bioresorbable membrane composed of collagen-rich porcine intestinal submucosa supported by a metallic frame. While effective 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™ 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, non-bioresorbable, 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™ ASD Occluder.

The reSept™ 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



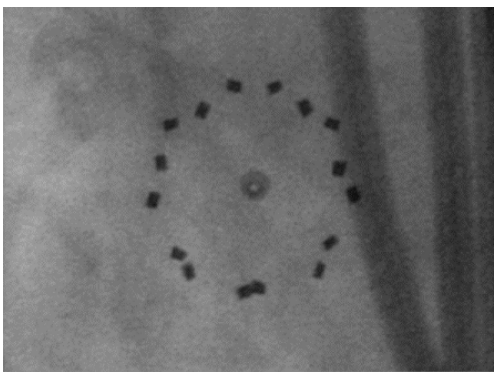


FIGURE 2 *Fluoroscopic images of an implanted reSept Occluder in LAO cranial and RAO caudal views. Note the radiopaque markers arrayed on each membrane confirming appropriate coplanar apposition of the occluder on either side of the atrial septum.*

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, atHeart 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 ≥ 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 to19 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 left-sided 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 cava.
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 anti-arrhythmic 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

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:

1. 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.

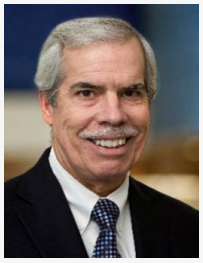
The Primary Safety Endpoint is the incidence of subjects experiencing one or more serious device or procedure related adverse events through the 12-month follow up visit.

Secondary Efficacy Endpoints to assess device performance include:

1. Technical success defined as successful placement and release of the occluder within the ASD.
2. 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 event.
3. 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: https://atheartmedical.com/patients/ or https://clinicaltrials.gov/ct2/show/NCT04591392.



THOMAS K. JONES, MD, FAAP, FACC, FPICS, MSCAI
Senior Congenital Interventional Cardiologist
Seattle Children's Hospital
Professor, Pediatrics
University of Washington School of Medicine
Seattle, Washington, USA
thomas.jones@seattlechildrens.org
206.987.2266

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:

1. 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 25th 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 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.

PICS Society

Pediatric *and Congenital* Interventional Cardiovascular Society

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.

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 ground-breaking society that will work towards advancement of our field, as our field tends to be globally overlooked, under-supported 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."

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 4.0[1], 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[2], 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[3]. Fortunately, in many cases treating structural heart disease can now be performed via image-guided, minimally-invasive, 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.

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.

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 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/.

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(TM) 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(TM) 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(TM) 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 ever-increasing demand on our health care system."

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

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

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, www.numedforchildren.com/product/g-armor-stentr-and-g-armor-mounted-stenttm. 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. www.childrenscolorado.org/doctors-and-departments/departments/heart/programs-and-clinics/adult-congenital-heart-disease/.

Welch's two options were either open heart surgery or implanting this new stent in the Children's Colorado heart catheterization lab, www.childrenscolorado.org/doctors-and-departments/departments/heart/programs-and-clinics/cardiac-catheterization/. 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 high-end 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

The Children's Hospital

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.

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.

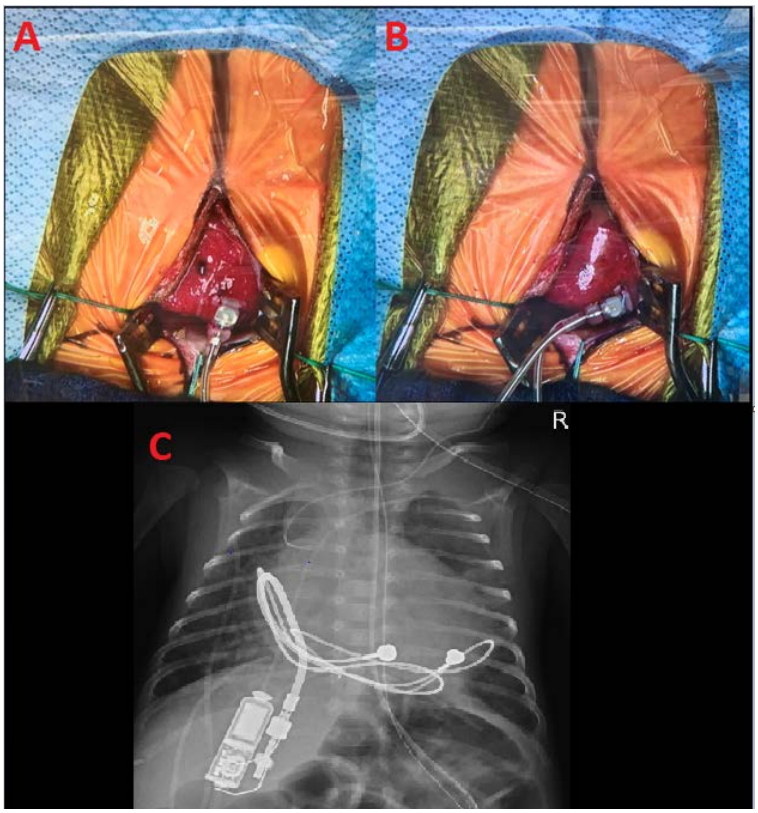


FIGURE 1 *Sternotomy at the time of implantation of an epicardial single chamber pacemaker in a premature infant with CCAVB (head at the top).* ***(A)*** *Implantation of the cathode of the epicardial Medtronic CapSure™ EPI Model 4968 pacing lead on the left ventricular apex, and* ***(B)*** *anode implanted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

OCTOBER

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12th Annual UCLA Fetal Cardiac Imaging and Evaluation Symposium
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