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## The Use of D'VILL Introducer Sheath in Congenital Cardiac Interventions

Sophia San Fui Yong MD; MI Jones; Eric Rosenthal, MD, FRCP; Shakeel Qureshi, MD

### Abstract

The importance of a kink-resistant, long delivery sheath cannot be underestimated in a congenital interventionalist's armamentarium. Most commonly used delivery sheaths include the Mullins (Cook), Flexor (Cook), Arrow-Flex (Arrow) and recently, DrySeal (Gore).<sup>1-4</sup>

We report the use of the D'Vill (NuMED) Long-Length Kink Resistant Introducer Sheath in congenital cardiac interventions. The D'VILL sheath is braided with a radiopaque marker band and has a dilator compatible with a 0.035" guidewire. It is available in 12 French and 14 French sizes with lengths of 30cm, 65cm and 85cm.

We propose the use of the 85cm D'Vill sheath as an alternative long, large-bore delivery sheath which is suitable for most congenital cardiac interventions.



Catalog Number	Introducer (FR)	Usable Length (cm)	Guide Wire (inches)
DV1230	12	30	0.035
DV1265	12	65	0.035
DV1285	12	85	0.035
DV1430	14	30	0.035
DV1465	14	65	0.035
DV1485	14	85	0.035

FIGURE 1 D'Vill Introducer sheath and specifications

### Case 1

A 31-year-old male with well controlled ulcerative colitis, was admitted with atypical chest pain. A chest radiograph revealed a widened mediastinum. The transthoracic echocardiogram and cardiac CT showed significant aortopathy (**Figure 2A**): bicuspid aortic valve with severe aortic regurgitation, dilated aortic root at 9cm and severe coarctation of aorta. At a multidisciplinary meeting discussion, the decision was to proceed with transcatheter stenting of the coarctation followed by a mechanical aortic valve and aortic root reduction surgery.

After right femoral arterial access, two Perclose Proglide sutures were applied after a check angiogram. Haemodynamic assessment revealed an invasive peak-to-peak gradient of 30mmHg across the coarctation. A 5Fr MPA1 catheter was used to cross the coarctation retrogradely with a 0.035" angled Terumo wire into the ascending aorta. After exchanging the angled Terumo wire for an 0.035" Amplatz extra-stiff wire, an 8/6 Multi-track catheter was used for angiography. An aortogram demonstrated a left aortic arch with a tight coarctation distal to left subclavian artery. Descending aorta at the level of the diaphragm measured 20mm X 17mm. Proximal transverse arch measured 20mm X 16mm (**Figure 2B**). The 8Fr right femoral arterial short sheath was then exchanged for a 14Fr 85cm D'Vill Introducer sheath, which was advanced across the coarctation into the ascending aorta. A 20mm X 48mm BeGraft aortic stent was then deployed across the coarctation. Post procedural angiogram showed a good result with no complications (**Figure 2C**). Haemostasis was achieved with the pre-applied Perclose sutures.

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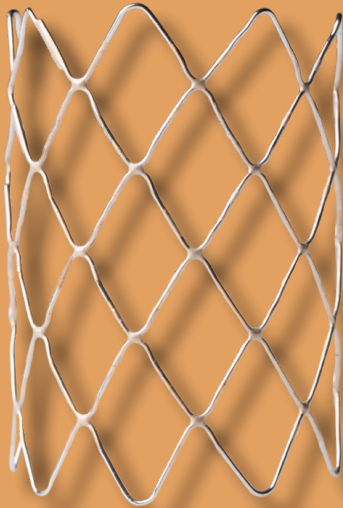
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**FIGURE 2A** CT 3D image rendering of significant dilated ascending aorta and severe coarctation of aorta

**FIGURE 2B** Measurements of distal coarctation of aorta

**FIGURE 2C** Post implantation of BeGraft Aortic stent using 14Fr D'Vill long sheath

**FIGURE 2D** CT 3D image rendering of aorta post coarctation stenting and aortic root replacement

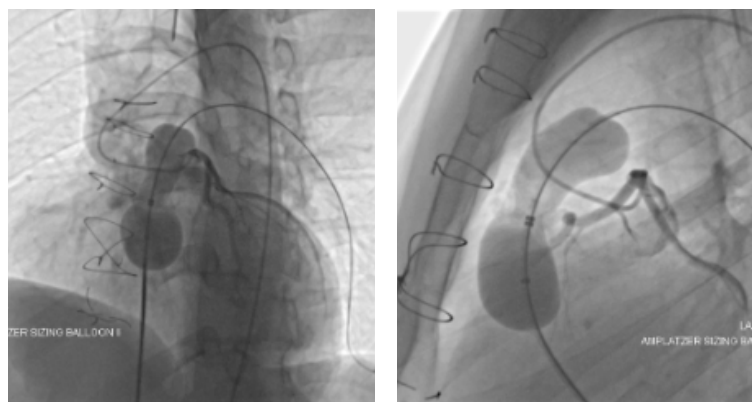
Three days later, he underwent mechanical aortic root replacement using a 27/29 On-X ascending aortic root prosthesis. He was discharged home after seven days. Six months later, a cardiac CT (**Figure 2D**) showed a good result from the coarctation stent with no complications.

## Case 2

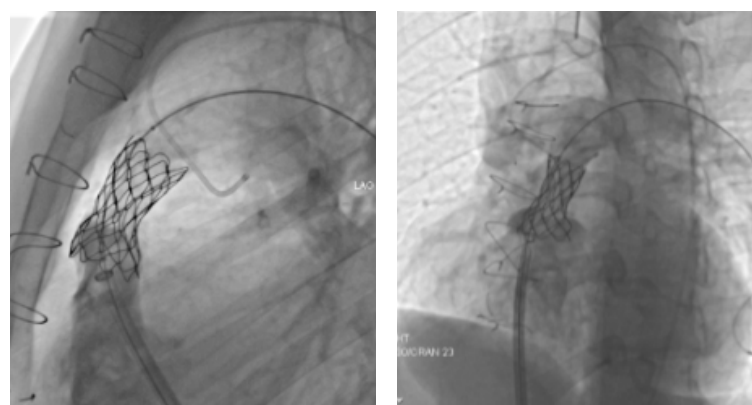
A 33-year-old male was born with critical aortic stenosis requiring balloon valvoplasty at Day Two of Life. He went on to have a Ross procedure with a 21mm pulmonary homograft at 14 years of age. Subsequently, at age 26 years, he had an episode of haemophilus influenzae infective endocarditis on the pulmonary homograft. This was treated conservatively with intravenous antibiotics. Subsequently, he had a gradual deterioration in his exercise capacity and serial cardiac imaging revealed a severely stenosed pulmonary homograft with extensive calcification.

Conduit rehabilitation was planned with a view to percutaneous pulmonary valve implantation. Right femoral venous and left femoral arterial access were obtained under ultrasound guidance and Perclose sutures were inserted in the vein. Initial haemodynamics revealed suprasystemic right ventricular pressures.

The stenotic pulmonary homograft was crossed using a 5Fr MPA1 catheter over an angled 0.035" Terumo wire. This was exchanged



**FIGURE 3A** Balloon sizing and interrogation of RVOT with simultaneous LCA selective angiography



**FIGURE 3B** Post 45mm covered Cheatham-Platinum (CCP) stent implantation using 14Fr D'Vill delivery sheath

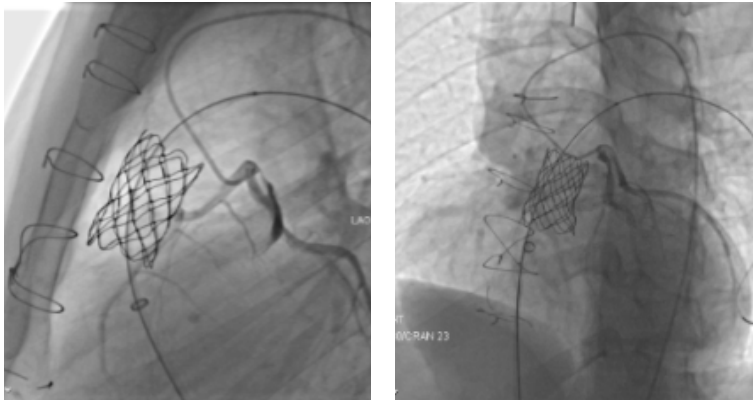
for an 0.035" Amplatzer extra-stiff wire positioned in a distal left pulmonary artery. An 8/6 Multitrack catheter was then used to perform angiograms in LAO/cranial and straight lateral positions.

Balloon sizing and interrogation of the homograft was performed using a 24mm Amplatzer sizing balloon. Simultaneous selective left coronary artery injection showed no risk of compression (**Figure 3A**).

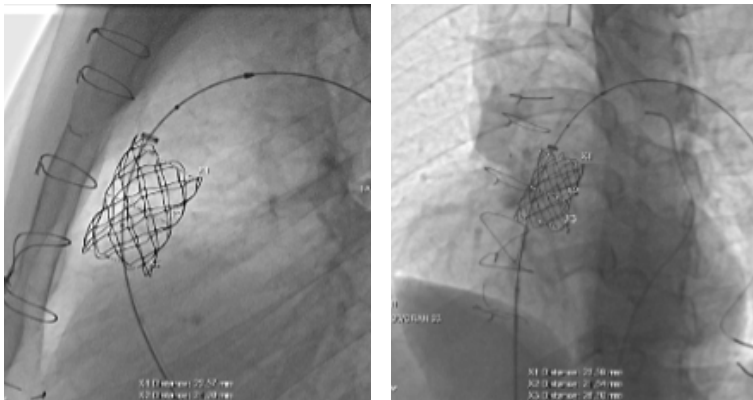
Given the extent of calcification, a decision was made to pre-stent the homograft. The 0.035" Amplatzer extra-stiff wire was exchanged for an 0.035" Lunderquist extra-stiff wire using a 6Fr JR guide catheter. The femoral venous sheath was exchanged for a 14Fr D'Vill introducer delivery sheath. A pre-mounted 45mm covered Cheatham-Platinum (CCP) stent on a 22mm X 5cm BIB balloon was deployed in the conduit, after checking the position with angiograms (**Figure 3B**).

Because of a 10mmHg residual gradient, the stent was post dilated with a 20mm X 2cm Atlas balloon followed by further check coronary angiogram (**Figure 3C**). A satisfactory landing zone was thus created with no stent recoil (**Figure 3D**). The 14Fr D'Vill sheath was then exchanged for a 24Fr DrySeal Sheath. We proceeded to implant a 23mm Edwards SAPIEN 3 valve within the newly created landing zone. Final MPA angiogram showed no pulmonary regurgitation (**Figure 3E**). There was a final 5mmHg gradient across the valve.

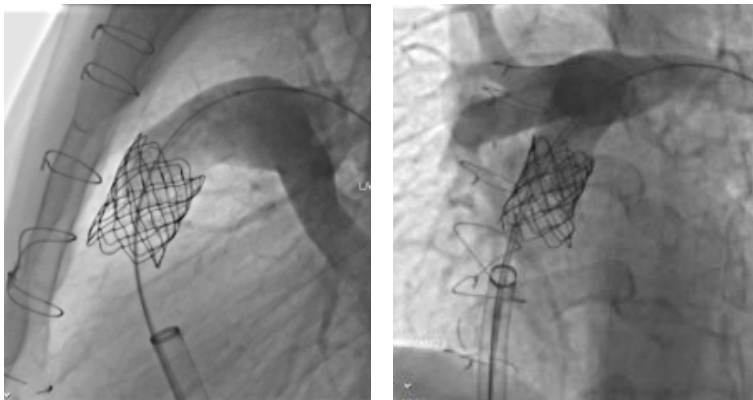




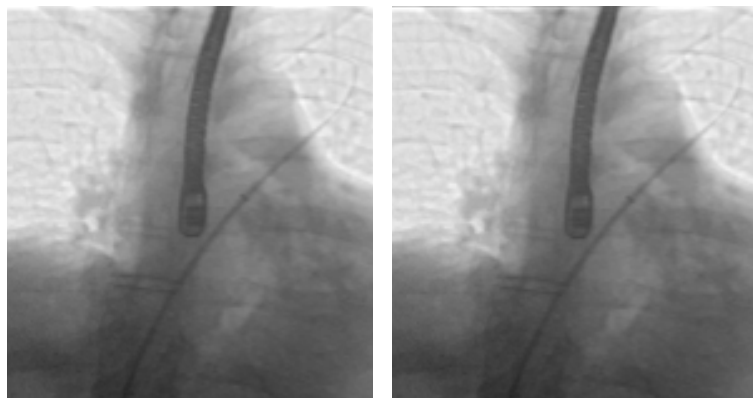
**FIGURE 3C** Selective coronary angiography post stent implantation and dilation



**FIGURE 3D** Final measurements of landing zone for valve implantation



**FIGURE 3E** Post implantation of 23mm Edwards SAPIEN 3 valve



**FIGURE 4A** 12Fr D'Vill sheath across ASD into left upper pulmonary vein

**FIGURE 4B** 24mm Occlutech Figulla Flex II device deployed using 12Fr D'Vill delivery sheath

## Case 3

A 46-year-old gentleman, previously fit and well, was referred for cardiac screening due to paternal cardiomyopathy. There was an incidental finding of a secundum atrial septal defect. Cardiac MRI demonstrated a dilated RV with RVEDVi 141ml/m<sup>2</sup> and a Qp:Qs of 1.7:1.

He was attended for a percutaneous closure of his atrial septal defect. Right femoral venous access was obtained and Perclose sutures applied. The defect was crossed using 5Fr MPA catheter into the left-upper pulmonary vein. Balloon sizing with 24mm Amplatzer sizing balloon over Amplatzer extra-stiff wire revealed a waist of 23mm. A decision was made to close the defect with 24mm ASD Occlutech Figulla Flex II device. However, the appropriate delivery sheaths were not available. Therefore, a 12Fr D'Vill delivery sheath was passed over the wire across the defect. A 24mm Occlutech ASD Figulla Flex II Occluder was then introduced into the sheath using a short 11Fr short sheath. The flexibility and stability of the D'Vill sheath allowed for the safe deployment of the device without its usual delivery sheath.

## Discussion

To have a dependable delivery sheath in the congenital cardiac catheter laboratory is paramount to procedural safety and success. At various times, all congenital interventional cardiologists may have difficulties in obtaining an optimal sheath position either due to poor trackability or kinking of delivery sheaths.

In our institution, we have utilised the D'Vill Introducer sheaths in various types of interventional procedures. The braided sheath has good trackability and is kink resistant. We have shown a selection of different types of cases here. In Case 1, the D'Vill sheath was easily passed across the coarctation of aorta with good stability. In addition, the radiopaque band at the end of the sheath is exactly at the tip – which is useful for guiding the internal dilator accurately during manipulation.

In Case 2, the D'Vill sheath maintained a stable position within the right ventricle to allow accurate balloon sizing/interrogation of the stenotic pulmonary homograft. It was also comparatively easier to advance the D'Vill sheath over the stenotic conduit into the branch pulmonary arteries. We felt that it has more predictable maneuverability and allows a safer, more precise deployment of the stent within the conduit.

In Case 3, due to a lack of the usual sheath, we used the kink resistance property of the D'Vill sheath, which allowed safe and easy deployment of an ASD device.

We have found the D'Vill sheath to be useful in most cases which require a large bore delivery sheath. It is now our first choice of delivery sheath, when appropriate. In recent years, the 65 cm long GORE DrySeal Flex Introducer sheaths have also been a great addition to the congenital cardiac catheter laboratory, especially the extra-large bore sizes ranging from 20Fr to 26Fr. However, there is a lack of long delivery sheaths in between 16Fr to 20Fr, and this needs to be addressed by the industry.

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# Program Directory 2022-2023

Published Mid-August

- Directory of Congenital & Pediatric Cardiac Care Providers in North America
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# Global Impact of the New EU MDR Regulations on Congenital Interventional Cardiology

## Part 1: The Problem

*The PICS Society Bureau of Health Policy*

“EU MDR”: Whether you work in Brussels, Bangkok, Buenos Aires or Boston, if you are a congenital interventional cardiologist the European Union Medical Device Regulations (EU MDR) impact you and your patients every day. Recent updates to these complex regulations profoundly impact congenital heart disease (CHD) patient care. Safe, effective devices you rely on are being withdrawn from the market, with incentives for new innovations dimming (notably in Europe). While much of this is due to EU regulatory developments, the impact on patient care is being felt globally.

What can you do? Get educated about these impacts. Recognize that you can influence the global regulatory environment if your community speaks with one voice and with real-world data. Regulators will listen, but there is much work ahead.

In response, The PICS Society and The Association for European Paediatric and Congenital Cardiology (AEPC Interventional Working Group) recently partnered to host a live webinar, “Global Impact of the New EU MDR Regulations on Congenital Interventional Cardiology.”

This month’s column presents highlights of that webinar’s talks by Drs. Tom Melvin and Marc Gewillig, summarizing the challenges of the new EU MDR regulations (next month’s column: webinar talks by Drs. Alan Fraser and Gearóid McGauran on the path forward). The highlights below are a fraction of these excellent presentations and the lively discussion. View the complete session on the PICS and AEPC websites. Note: organizational affiliations of all speakers are for identification purposes only.

**Dr. Bökenkamp:** This is an important step towards more collaborative efforts between both societies, and it addresses a giant practical problem for us here in Europe. My thanks go to all our speakers and to all of you who have registered for this event.

**Dr. Kenny:** I am honored to be joined by Dr. Bökenkamp, who chairs the AEPC’s Interventional Working Group. We are all uncertain and a little bit frightened as to the consequences of the new EU MDR. We all have noticed its impacts on availability of some devices. We have assembled a panel of physicians, regulators and academicians to inform you and work with regulators to improve the regulations.

Our first speaker is Dr. Tom Melvin, who previously worked on the regulatory side and is now Associate Professor, Medical Devices & Regulatory Affairs, Trinity College Dublin.

**Dr. Melvin: Where did MDR come from and why?** The first time we started to regulate medical device products in Europe was in the early 1990s, a different era where there was a need to establish a single market for trade in these types of products. Trying to sell a heart valve in Europe meant complying with different national standards and requirements. Since that time, there have been many piecemeal revisions to the regulations. In 2012, the European Commission laid out a rationale for new regulations, beginning years of protracted negotiating, leading to a revised system and regulations for medical devices applying to all EU Member States which came into effect in May 2021.

In Europe, we are now in the transition period for medical devices: the medical device regulation is applicable for all new products. BUT, for devices approved under previous directives, they can continue to be marketed under their certificate until at the very latest May 2024.

A host of matters were bolted on to the new regulations: expert panels, new transparency rules, clinical evaluations for high-risk products. Some of the challenges in implementing these new changes:

- “Significant changes”: The new regulation applies to all new products. A small design change (routine in medical devices development) may be classified as a “significant change.”
- This requires full compliance with the new regulation under tight time constraints and increased documentation rules.
- Rules concerning clinical evidence: complying with these new rules can be very hard, especially for products currently on the market.
- Under-capacity of organizations (termed “Notified Bodies”) designated to assess medical devices for conformity with the new EU MDR: Currently there are 34-35 Notified Bodies in the EU. All have to be redesignated and given power under the regulation.
- Anecdotally, when product launches are planned, it used to be de facto that all companies came to Europe, seen as much more innovation friendly. But now companies are often going through United States first. We [in the EU] have become out of line with the requirements in the United States for some pathways.

We have moved to a system that has generally increased requirements and challenges. In congenital cardiology, many companies look across their portfolio and see what products have lower volume sales and marginal profits. When costs increase, this can have a significant chilling effect in companies bringing those products into MDR compliance. So, we need to delay these rules so we can get additional time, especially regarding orphan and pediatric products. How do we protect [these products] under current legislation and what is the potential need for additional legislation? Hopefully, we’ll find a sensible solution in the coming weeks and months because it really is needed from a public health perspective.

**Dr. Bökenkamp:** Our next speaker, Dr. Marc Gewillig, is one of the most experienced and innovative pediatric cardiac interventionalists in Europe and chairs the AEPC Task force on MDR.

**Dr. Gewillig: What impact will MDR have on congenital interventional cardiology?** We are watching a shift from MDD [Medical Device Directive] to MDR. Europe wants the controls to be much more thorough-with safety first, more required data, plus more control both on production and distribution. Instead of working with a government agency (in the U.S., the FDA), the new MDR created “Notified Bodies:” private companies responsible for the safety of the products.





Because this is all very new, it is difficult to know what the required data and post-market requirements are.... Since these are private companies, it is unclear who is going to control these companies. While the Notified Bodies are responsible for safety of a product, nowhere in the MDR does it say that a Notified Body also has the obligation to certify a good product at a reasonable pace and at a reasonable price. Because the Notified Bodies are responsible only for the safety of a product, if there is ANY doubt, the Notified Bodies will block it.

Before starting a project with a device, the cost and the development time is very unpredictable, and if there is something that companies dislike enormously, it is the unpredictability of their costs.

As for required post-market surveillance, no one is against that. However, much is still unclear, such as whether retrospective data registries can be used or whether to go with a full prospective study every five years. If you ask Notified Bodies, usually the answer is given by their lawyers, not by clinicians or doctors. And as you know, when a lawyer answers, you get the most conservative answer. This means that all things together, we are now in a situation where there is an unbalanced power relationship between the Notified Bodies and manufacturers.

As an example, for some devices the costs under the previous MDD regulations (reviews, audits, testing etc.) those costs under MDR are now (or will soon be) almost tenfold higher! Companies have been confronted with excessive costs, already leading to withdrawal of some devices.

Here is a list of devices that will not survive 2023 because they will be withdrawn from the market [see archived webinar for list]. We would like to thank the companies, some of whom simply gave them to us for use in babies and children. Some of the companies have warned us that these are going to disappear soon!

**No company wants to be on this list.** Every company wants to say yes. But now that MDR is becoming a reality, they have limited time, limited personnel, limited funding. They need to think about where to invest their money.

If MDR would have been applied a couple of years ago, probably many European inventions would not have been developed. If companies and inventors would try to come on the market today, it would be likely that they wouldn't make it.

I'm afraid that there will be a shift in attitude of the interventional cardiologist. The generation working in the last couple decades was very inventive. We invented quite a few things. We took our share of responsibility. With what's going to hit us, we will be much more protocol driven. Money will become a very, very important issue.... and the progress on new devices will be very long and expensive before they get to market. If they get there at all!

In sum, I hope I have convinced you that there will be a huge major impact.

**Dr. Bökenkamp:** Thank you both! Drs. Fraser and McGauran, where do we go from here?

*In next month's issue of CCT: Part 2, Where We Go from Here...*



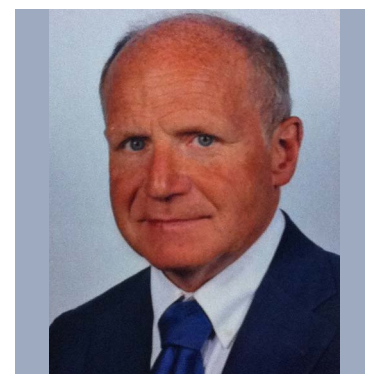
Regina Bökenkamp, MD, PhD



Damien Kenny, MD



Tom Melvin, MBBS



Marc Gewillig, MD, PhD

**View the Complete Webinar at**  
**[CHDinterventions.org](http://CHDinterventions.org) and [aepc.org](http://aepc.org)**

### Webinar Moderators:

- Damien Kenny, MD (for The PICS Society)
- Regina Bökenkamp, MD, PhD (for The AEPC Interventional Working Group)
- Eimear McGovern, MD (Digital Moderator)

### Faculty:

- Tom Melvin, MBBS, "Where did MDR come from and why?"
- Marc Gewillig, MD, PhD, "What impact will it have on congenital interventional cardiology?"
- Alan G. Fraser, MD, "Collaborative efforts to counter impact of MDR-Core MD & Beyond"
- Gearóid McGauran, MB. BCh, BAO, "The regulators' perspective from Europe"

### With thanks to:

- Burak Zengi & the Z event team (webinar support). [zevent.com.tr/en](http://zevent.com.tr/en)
- Inês Silva & Patrick Masterson at DocMatter™ (PICS/CCISC online community) [docmatter.com](http://docmatter.com)





# Call for Abstracts – The 8<sup>th</sup> World Congress of Pediatric Cardiology and Cardiac Surgery

Gil Wernovsky MD, FAAP, FACC

The 8<sup>th</sup> World Congress of Pediatric Cardiology and Cardiac Surgery (WCPCCS) will take place August 27<sup>th</sup> – September 1<sup>st</sup>, 2023, in Washington, DC, USA. Over 4,500 clinicians, scientists, administrators, and allied health professionals will gather for this once-in-a-lifetime event – held in the USA for the 1<sup>st</sup> time since 1997.

Attendees are encouraged to submit new research as abstracts for presentation at the 8<sup>th</sup> World Congress of Pediatric Cardiology and Cardiac Surgery (WCPCCS). Work that has been previously presented at other conferences, but not yet published in manuscript form, may be submitted to the 8<sup>th</sup> WCPCCS.

Abstracts received between January 17<sup>th</sup> and May 15<sup>th</sup>, 2023 will be graded in standard fashion, with final notification made by June 15<sup>th</sup>, 2023.



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## Important Dates

- Abstract Submission Opens: December 16<sup>th</sup>, 2022
- Notification of Abstract Acceptance Will Be on a Rolling Basis
- Abstracts Received After May 15<sup>th</sup>, 2023 Will Only be Considered for Poster Presentation
- Notification of Presentation Format: June 16<sup>th</sup>, 2023 by 5:00pm EST
- Final Abstracts Submission Deadline June 30<sup>th</sup>, 2023 (those received and accepted between May 15<sup>th</sup> and June 30<sup>th</sup> will be presented as posters)

Seventeen of the scientific tracks will have dedicated abstract sessions. Delegates will have the opportunity to submit their presentations to one of these 17 sessions. Most of the accepted abstracts will be presented as posters, with the “top nine” in each session given the opportunity for oral presentation (8-minute presentation, 5-minute discussion). Utilizing a live audience-response system, the audience will vote on the “Best Abstract” in each session.

## Sub-Specialty Oral Abstract Sessions

- Adult Congenital Heart Disease
- Ambulatory Cardiology
- Basic and Translational Science
- Cardiac Anesthesia
- Cardiac Catheterization
- Cardiac, Neonatal and Pediatric Intensive Care/ECMO
- Cardiac Surgery and Cardiopulmonary Bypass
- Cardiac Nursing Clinical Inquiry
- Cardiac Nursing Science
- Echocardiography
- Electrophysiology
- Fetal Cardiology
- Global Cardiac Health
- Heart Failure, Transplant and Mechanical Circulatory Support
- Multimodal Imaging
- Neurodevelopment
- Rheumatic Heart Disease

## Best Abstract of the World Congress

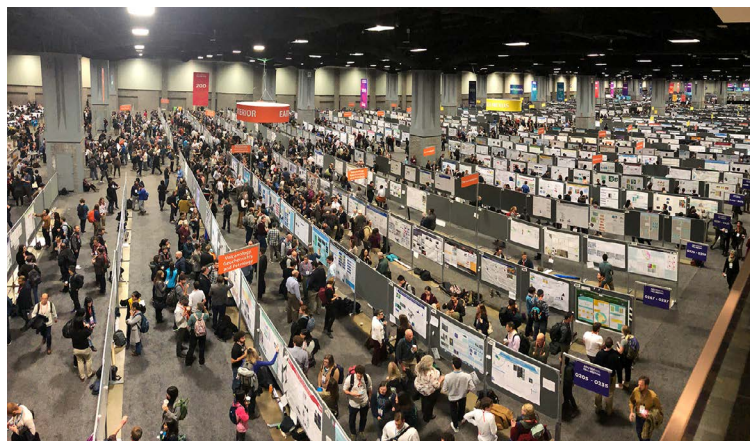
No other World Congress has offered this opportunity to young faculty and investigators. Showcasing the “Best Abstract” in each of the above sessions, a comprehensive afternoon plenary session will be held where each of the 17 “Best Subspecialty Abstracts” will be re-presented to the entire congress (8-minute presentation, no discussion), for recognition of excellence as well as ‘cross-talk’ between disciplines. Using state-of-the-art audience response systems, the large, multidisciplinary audience will select the 2023 “Best Abstract of the World Congress.”

## Embedded Societies

Fourteen Scientific Societies (below) and post-graduate courses are “embedded” within the 8<sup>th</sup> WCPCCS, including their annual competition. Fourteen Meetings in One! [wcpccs2023.org/](http://wcpccs2023.org/)







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## Embedded Meetings *and* Societal Partners







# Camp is Good Medicine

Jonathan Johnson, MD; Andrew Schneider, MD; Brian Joy, MD

Camp Odayin provides medically safe and emotionally supportive camp experiences and community building opportunities for young people with heart disease and their families. We positively impact camper lives by connecting them with friends who face similar medical challenges in the formative years when relationships, fun, and acceptance are vitally important. Our mission is based on a holistic approach to healing hearts and supporting the whole child – not just the disease.

Our goal is to improve the quality of life, mental health, and overall well-being of campers by providing a fun and adventurous environment that includes community, personal growth, and inclusion. We are committed to creating a safe space where campers, staff, and volunteers feel welcomed, respected, valued, and, we are dedicated to promoting equity in our programming and in our organization. Campers tell us that because of Camp Odayin, their mental health is better, they have more confidence, and they've met lifelong friends who "get it".

We offer year-round programs and support opportunities for the whole family! In addition to summer camps, we host Fall Family Camps, Winter Camp, online Ticker Talk, parent retreats and more!

*"Children with heart disease have unique psychosocial needs that are not often adequately addressed in the clinical care setting. Camp Odayin provides programming opportunities to support my patients and their families outside of the medical system, and moreover, invites them to join a supportive community. Through Camp Odayin, my patients identify with other kids with similar shared experiences, helping to inspire a renewed self-confidence, and cultivation of lifelong friendships!" – Dr. Andrew Schneider*

*"I always encourage my patients and their families to check out Camp Odayin. They offer such a broad range of activities. From their residential summer camps, family camps, the moms and dads retreats, and their online programming, there is something for everyone to feel engaged and connected to this very supportive community. I love seeing kids come to camp year after year and watch their camp communities and friendship circles develop. The talent show at the end of camp is an excellent example of what a week of camp can do for the campers' confidence and sense of belonging." – Dr. Brian Joy*

*"I recommend my patients go to camp because of the joy they get while there, the joy their families see watching them connect with other children, and the lifelong relationships that are made. It's a safe, fun, rewarding environment where kids can just be kids, and nobody feels 'different' because of their scars." – Dr. Jon Johnson*



## 2023 Summer Camp Dates and Locations

- **Crosslake, Minnesota**
  - June 21<sup>st</sup>-25<sup>th</sup> for grades 1-6
  - July 10<sup>th</sup>-14<sup>th</sup> for grades 6-8
  - July 17<sup>th</sup>-21<sup>st</sup> for grades 9-11
- **Elkhorn, Wisconsin**
  - July 24<sup>th</sup>-28<sup>th</sup> for grades 1-11
- **Everywhere! Virtual Camp**
  - August 18<sup>th</sup>-19<sup>th</sup>

Registration will be open from March 1<sup>st</sup> – May 1<sup>st</sup> and can be found on our website [www.campodayin.org](http://www.campodayin.org). We ask families to pay \$25 for their child to attend a week of summer overnight camp. We provide bus transportation to camp from Minneapolis, Milwaukee & Chicago, and we also offer a travel stipend to families who need financial assistance.

At Camp Odayin, campers build resilience, learn relationship skills, gain independence, and gain a sense of normalcy and restored childhood. Simply put, **Camp Odayin changes lives.**

### For more information, contact:

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## MAY

**18-20****SCAI 2023 Scientific Sessions**

Phoenix, AZ, USA

<https://scai.org/scai-2023-scientific-sessions>

## JUNE

**23-26****ASE 2023 – Foundations and the Future of  
Cardiovascular Ultrasound**

National Harbor, MD, USA

<https://www.asescientificsessions.org/>**28-1****CSI Frankfurt**

Frankfurt, Germany

[https://www.csi-congress.org/conferences-courses/  
conferences/csi-frankfurt](https://www.csi-congress.org/conferences-courses/conferences/csi-frankfurt)

## JULY

**28-29****CICT 2023 – CICT Controversies in Interventional  
Cardiovascular Therapies**

Pasadena, CA, USA

<https://cictsymposium.com/>

## AUGUST

**27-01****8th World Congress of Pediatric Cardiology and  
Cardiac Surgery**

Washington, DC, USA

<http://wcpccs2023.org/>



# Cincinnati Children's Opens First in the U.S. Heart and Mind Wellbeing Center

Terry DeMio, Cincinnati Enquirer

The distress of having a child with a congenital heart defect starts at the point of diagnosis and continues through life. Even so, specialized mental health care for the kids and their families is scarce in the United States.

As of Tuesday, Cincinnati Children's Hospital Medical Center, [www.cincinnatichildrens.org](http://www.cincinnatichildrens.org), is offering that specialized care for infants and children with congenital heart defects and for their families, including parents and siblings and even prospective parents who receive a prenatal cardiac diagnosis. The Heart and Mind Wellbeing Center at the hospital is the first of its kind in the United States, hospital officials said.



Cincinnati Children's Hospital Medical Center in Avondale, OH.  
Photo Credit: Albert Cesare/The Enquirer

Cincinnati Children's started the center as a way to provide whole care aligned with the American Heart Association's scientific statement in 2022 on an unmet need for mental health care in this population, [www.ahajournals.org/doi/full/10.1161/HCQ.0000000000000110](https://www.ahajournals.org/doi/full/10.1161/HCQ.0000000000000110).

Dr. Nadine Kasparian, a psychologist at Cincinnati Children's and director of the new center, was among experts who were

involved in research that shows that people with congenital heart defects and their families struggle with mental health.

She said the researchers charted "enormous evidence" of the need for mental health care among this population across a lifetime.

"We make a really strong argument for the need to integrate psychological services and mental health care," Kasparian said.

She said the mental health care is imperative, noting:

- About 40,000 babies a year in the United States are born with congenital heart defects.
- Congenital heart defects make up the most common birth defects in the United States.
- About 1 in 4 children with these heart defects experience "intense fear, worry and sadness."
- About 4 in 5 parents report severe psychological distress at the time of a child's discharge after cardiac surgery.
- About one-fourth undergo at least one surgery in their first year of life, but even with surgery, "there is still no cure for congenital heart disease."

Kasparian said the center will help patients from birth throughout their lives, using research-proven treatments focused on enhancing both their physical and mental health.

The American Heart Association hopes the evidence that people with congenital heart defects face a higher risk for anxiety and mood disorders will spur new standards for integrating that care into congenital heart centers, [www.heart.org/en/news/2022/07/14/people-born-with-heart-defects-need-lifetime-mental-health-care-report-says](https://www.heart.org/en/news/2022/07/14/people-born-with-heart-defects-need-lifetime-mental-health-care-report-says).

Kasparian said that by providing the care routinely to those with heart defects and their families, the new Heart and Mind Wellbeing Center normalizes mental health care, destigmatizing it.



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Funded by Cincinnati Children's Heart Institute





# IU Researchers Receive \$200,000 Grant from Department of Defense to Study Heart Defect in Infants

*IU School of Medicine Researchers have Received a Department of Defense Discovery Award of \$200,000 to Study a Common Congenital Heart Defect in Babies Called Coarctation of the Aorta*

Indiana University School of Medicine researchers have received a Department of Defense Discovery Award of \$200,000 to study a common congenital heart defect in babies called Coarctation of the Aorta.

The aorta is the main artery that carries blood away from the heart to the rest of the body. Coarctation of the aorta is a congenital heart condition where there is a narrowing of the aorta that obstructs blood flow to vital organs. It could develop by itself, or in combination with other heart defects—including along with hypoplastic left heart syndrome, one the most severe forms of congenital heart defects.

"Critical coarctation of the aorta is immediately life-threatening and treatment currently requires cardiothoracic surgery that is invasive and technically challenging," said Benjamin Landis, MD, assistant professor of pediatrics in the Division of Pediatric Cardiology. "Perioperative complications may have longstanding repercussions on the child's ability to thrive and develop normally. There is also evidence that even an excellent surgical repair does not cure the patient of long-term cardiovascular risks."

Landis and his collaborator Yunlong Liu, PhD, who is the director of the IU Center for Computational Biology & Bioinformatics, plan to use single-cell RNA sequencing of aortic tissues that are removed during cardiothoracic surgery of infants with severe coarctation of the aorta to learn more about the cells that make up the defect, which they hope could ultimately lead to new medical treatment options instead of surgery.

"Single-cell RNA sequencing is a technology that can measure gene expression levels in each individual cell," Landis said. "This process is well-suited for studying coarctation, which often has a complex geometrical structure and contains multiple different types of cells in the tissue."

Landis said defining the pathobiology early in the disease process can help them identify medical targets responsive to early interventions which could prevent later development of cardiovascular diseases or re-development of coarctation of the aorta.



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"This project will be the first of its kind to perform single-cell RNA sequencing in patients with coarctation of the aorta," Landis said. "This could be the first step toward a more complete understanding of the disease processes that are active in neonates and help us identify treatments to prevent chronic comorbidities and avoid future need for interventions. The Department of Defense Discovery Award funding is pivotal for us to be able to embark on this exciting research."

The Division of Pediatric Cardiology is one of the top-ranked pediatric cardiology programs in the country. Learn more about research, clinical care and fellowship training in the division.



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