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Reliability of Echocardiographic Estimation of Angiographic Minimal Ductal Diameter

By P. Syamasundar Rao, MD and U. Subramaniam, MD

Introduction

Since the description by Gross and Hubbard in 1938,[1] surgical closure has been the conventional treatment of choice for management of Patent Ductus Arteriosus (PDA) and remained so until wider application of the trans-catheter techniques described in 1960s and 1970s by Porstmann, Rashkind and their associates,[2-5] respectively, became clinically relevant.[6] A number of devices have been used for percutaneous occlusion of the PDA, as reviewed extensively elsewhere.[7-11] With all the devices used for trans-catheter closure of PDA, the size and shape of the ductus are germane in the selection of the type and size of the device to be implanted.[6,12-15] Minimal ductal diameter (MDD), measured on aortic arch angiography, forms the basis for categorizing the ductal size (Table 1)[15] and is utilized in the selection of device size.[6,12-15] However, the selection of the patients for trans-catheter occlusion of PDA is largely based on the results of echo-Doppler studies performed during the evaluation of these patients. The objective of this study is to examine the reliability of echocardiography in estimating the angiographic MDD. While the data were collected, analyzed, and presented nearly a decade ago,[16] we have not formally published these data at that time, but believe the data are still valid and useful today, leading us to complete the paper at this time.

Type	Description
Silent PDA	Less than 1.5mm and no murmur
Very small PDA	≤ 1.5 mm with audible murmur
Small PDA	1.5 to 3 mm with audible murmur
Moderate PDA	3 to 5 mm with audible murmur
Large PDA	> 5mm with audible

Table 1. Classification of Sizes of the Patent Ductus Arteriosus (PDA). Reproduced from Rao PS. J Invasive Cardiol 2011; 23:517-20.[15]

Study Subjects and Methods

Study Subjects

During a four-year period ending June 2006, 83 patients were brought to the cardiac catheterization laboratory with intent to close the PDA. An Amplatzer Duct Occluder was implanted across the PDA in 53 patients and Gianturco coil occlusion was performed in 15 patients. No transcatheter intervention was performed in six patients, two because of very high pulmonary vascular resistance, three because the PDAs were too large to safely trans-catheter occlude and one because the PDA was tiny. The selection of the type and size of device used was based on the principles outlined by the senior author (PSR) in prior publications.[6,12-14] Adequate two-dimensional and color Doppler echocardiographic and angiographic MDD measurement data for comparison were available in 47 of these patients. These 47 patients form the subjects for this investigation.

Methods

Echocardiograms

Two-dimensional (2-D), M-mode and Doppler (pulsed, continuous wave and color flow imaging) examination was performed in parasternal long and short axis, apical four- and two-chamber, subcostal and suprasternal notch views in a conventional manner, as described elsewhere,[17,18] with particular attention to define the size of the PDA. Parasternal short-axis or ductal views were used to measure 2-D and color Doppler MDDs. Examples of 2-D (Figures 1 and 2) and color Doppler (Figures 3 and 4) imaging of the PDAs are illustrated in Figures 1 thru 4. Measurements were recorded as shown in these figures. These echo-Doppler studies were performed two weeks to four months prior to cardiac catheterization and trans-catheter closure of PDA.

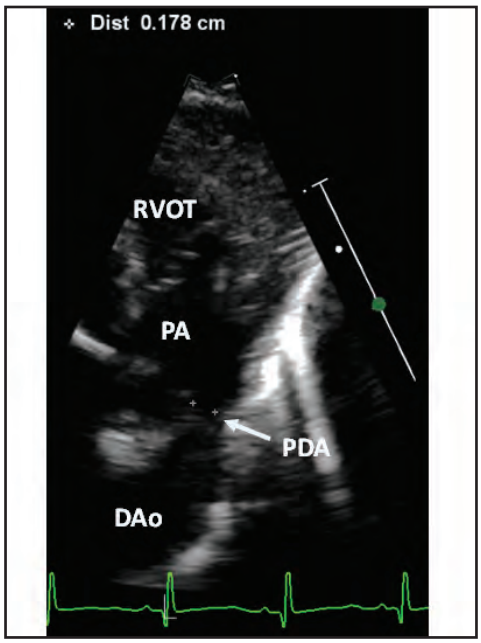

*Figure 1. Selected video frame from modified parasternal short axis view (ductal view) demonstrating a Patent Ductus Arteriosus (PDA); 2-D measurement of the minimal ductal diameter (*Dist) is shown. DAo, descending aorta; PA, pulmonary artery; RVOT, right ventricular outflow tract.*

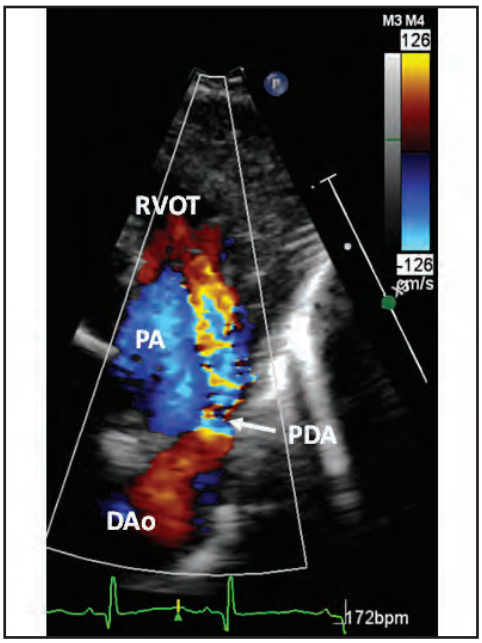

Figure 3. Selected video frame from modified parasternal short axis view (ductal view) demonstrating a patent ductus arteriosus (PDA) with left to right shunt; color Doppler appearance of the minimal ductal diameter (arrow) is shown. DAo, descending aorta; PA, pulmonary artery; RVOT, right ventricular outflow tract.

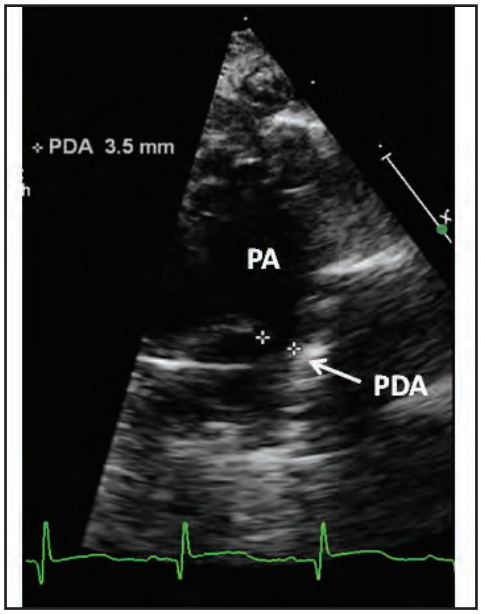

*Figure 2. Selected video frame from precordial short axis views demonstrating 2-D measurement (*3.5 mm) of the minimal ductal diameter of patent ductus arteriosus (PDA).*

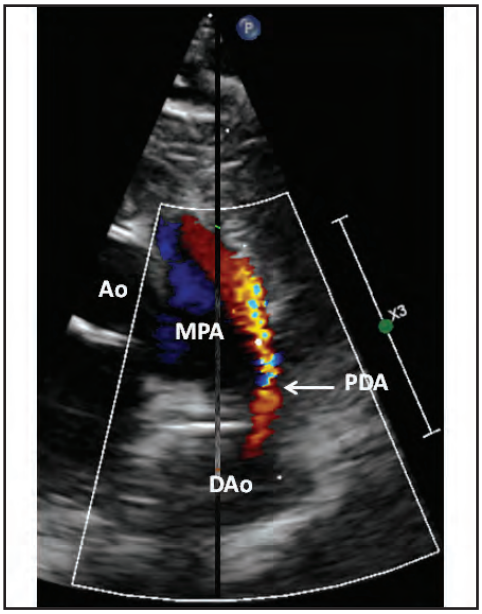

Figure 4. Selected video frame from precordial short axis view demonstrating a patent ductus arteriosus (PDA) with left to right shunt by color Doppler (arrow). Ao, aorta; DAo, descending aorta; MPA, main pulmonary artery.

Angiocardiograms

After securing hemodynamic data during right- and left-heart catheterization in a conventional manner, selective aortic arch cine-angiograms with contrast injection via marker pigtail catheters were performed in 30^{o} right anterior oblique and straight lateral projections. The MDD, length, and diameter of the ampulla of PDA were obtained by measuring digitally, comparing with the distance between the radiopaque markers on the catheter (Figures 5 and 6). While the MDD, length, and diameter of the ampulla of PDA were used in deciding on the type and size of the device selected for occlusion of PDA, the MDD is used for analysis in this study.

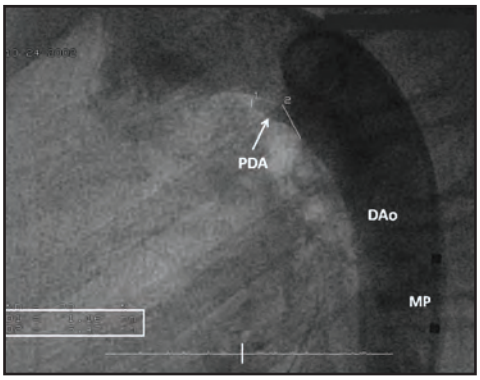

Figure 5. Selected frame from aortic arch cineangiogram in lateral view demonstrating measurements in a patient with small patent ductus arteriosus (PDA) (arrow). Measurements of minimal ductal diameter and ductal ampulla are shown. Catheter with markers (MP) is seen in the descending aorta (DAo). Measured values are shown at the bottom left corner.

Statistical Analysis

The data are expressed as mean ± standard deviation (SD). Age and weight ranges, apart from mean, were also given to comprehend the spread of these values. Comparison between groups was made by independent sample t test. Linear regression analysis comparing the echocardiographic and angiographic measurements was performed and the correlation coefficients calculated. Statistical significance was set at $p < 0.05$. Bonferroni correction was applied when multiple comparisons were made.

Results

Study Subjects

The ages of the 47 patients who had both echocardiographic and angiographic measurements of MDD ranged between four months and 303 months with a mean of 55.4 months. Their weights were between 3.5 kg and 77 kg with a mean of 17.9 kg.

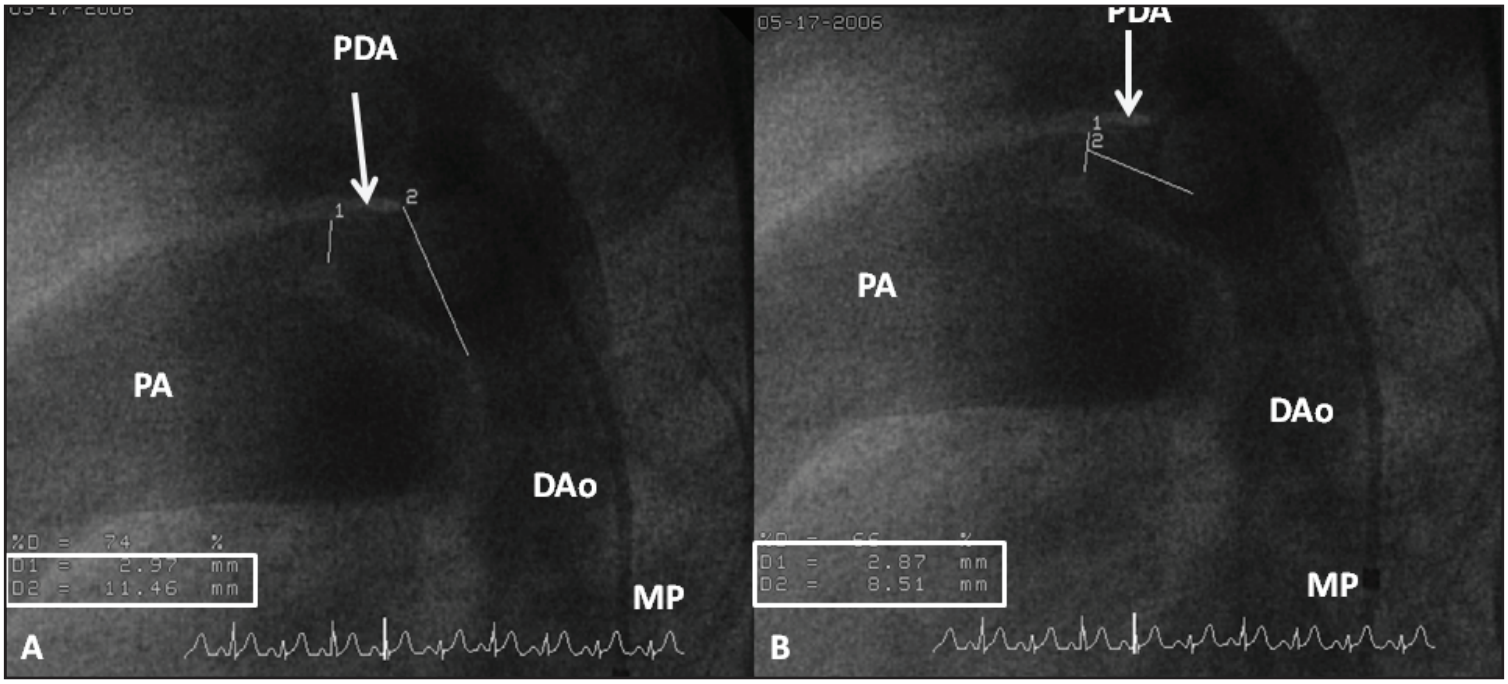

Figure 6. Selected cine frames from aortic arch angiogram in lateral views demonstrating measurements of moderate to large patent ductus arteriosus (PDA) (arrow). Measurements of minimal ductal diameter and ductal ampulla in A and minimal ductal diameter and length of the ductus in B are shown. Catheter with markers (MP) is partly seen in the descending aorta (DAo). The measurements are marked in a rectangular insert in both A and B. PA, main pulmonary artery.

Transcatheter closure of their PDAs was performed as described previously.[6,19-21] The selection of the type and size of the device implanted is based on the shape and MDD of the PDA as described elsewhere.[13-15] Thirty-one of these patients underwent Amplatzer duct occluder closure of their PDAs and 13 patients had Gianturco coil occlusion. Three patients did not undergo closure because of large size (N = 2) or pulmonary vascular obstructive disease (N = 1).

Comparison of PDA diameters

The MDD by color Doppler was 4.26 ± 1.57 mm (Mean ± SD), slightly larger (p = 0.007) than that obtained on 2-D (3.99 ± 1.37 mm). Both of these were larger (p < 0.01) than angiographic MDD (2.28 ± 1.25 mm) (Table 2). The patients were divided into six age groups as well as into Krichenko types; the echo vs. angiographic difference continues to persist (p < 0.05 to <0.001) for all age groups (Table 2) and for all PDA types. Linear regression analysis revealed poor correlation between 2-D and angiographic (r= 0.288) and color Doppler vs. angiographic (r= 0.344) minimal ductal diameters, while an excellent correlation (r=0.889) was seen between 2-D and color Doppler MDDs.

Discussion

The above presented data indicate that both 2-D and color Doppler echocardiographic MDDs of PDA consistently overestimate angiographic MDDs. Consequently, the angiographic MDD should be used in selection of the size of the device for implantation across the PDA. In the current clinical practice, angiographic MDD is used in the choice of device size and our data support such clinical practice. However, echo-Doppler studies, in addition to giving an estimate of MDD, provide information on size of the left atrium (including left atrium to aortic root [LA:Ao] ratio), left ventricular dimension and left ventricular function.[17,18] The echo-Doppler studies are also useful in excluding other cardiac defects, particularly coarctation of the aorta. Thus, echo -Doppler studies are extremely useful in clinical evaluation of patients with PDA and selection of patients for PDA occlusion.

The causes for the discrepancy between the echocardiographic and angiographic MDDs are not clearly understood. The echocardiographic and angiographic MDD data were not simultaneously recorded in this study. As mentioned in the above section on "Methods," the echo-Doppler measurements were secured two weeks to four months prior

Age In Months	Two-Dimensional MDD	Color Doppler MDD	Angiographic MDD*
All patients - 4 to 303 months	3.99 ± 1.37	4.26 ± 1.57	2.28 ± 1.25
4 to 15 months	4.27 ± 1.36	5.23 ± 1.80	2.91 ± 1.50
16 to 30 months	3.49 ± 1.06	4.17 ± 1.61	1.89 ± 0.97
31 to 45 months	4.03 ± 2.04	4.07 ± 1.72	1.90 ± 1.19
46 to 60 months	3.76 ± 1.85	3.23 ± 1.22	1.46 ± 0.65
61 to 75 months	3.98 ± 1.36	3.83 ± 1.29	3.26 ± 1.69
76 to 303 months	4.12 ± 1.25	4.14 ± 1.34	2.05 ± 0.83

*Table 2. Comparison of Echocardiographic and Angiographic Minimal Ductal Diameters in Different Age Groups. MDD, Minimal ductal diameter. Mean ± Standard deviations are shown. *Angiographic MDDs were smaller (p < 0.05 to < 0.01) than two-dimensional and color Doppler echocardiographic MDDs for the entire cohort and for all six age groups.*

to cardiac catheterization and transcatheter occlusion of PDA. While it is possible that non-simultaneous recording of the echocardiographic and angiographic data may be responsible for this discrepancy, one must postulate that the ductus got constricted in each of these patients between echocardiographic and angiographic studies. However, since there is no evidence for clinical improvement from the time of echocardiography to the time of angiography, this explanation is unlikely. Another potential cause is ductal constriction secondary to catheter stimulation of the ductus during cardiac catheterization and angiography. The angiography was performed after recording the hemodynamic data in each case. This does entail manipulation of the catheter in the region of PDA. One might, therefore, postulate that the ductus was stimulated by the catheter manipulation causing constriction. Indeed, we observed an infant whose PDA was very small (Figure 7) on angiography, but it was larger (Figure 8) on prior echocardiographic study.[22] However, this would require postulating that the ductus got slightly constricted in each and every case and this is unlikely. Other causes of ductal constriction were explored in our review,[22] and include: relative calmness (reopened by excitement),[23] former prematurity,[24-26] kinking of the ductus in upright position,[27] and a large proximal shunt.[28] Each of these were explored, but could not explain the discrepancy for entire group. Finally, several drugs and pharmacologic agents (for example, oxygen, catecholamines, bradykinin, acetylcholine, 5-hydroxytryptamine, bradykinin, cimetidine [a selective H2 blocker], diphenhydramine, and nonsteroidal anti-inflammatory drugs such as indomethacin and ibuprofen) may produce ductal constriction,[22,29] but none of these drugs or pharmacologic agents were used during catheterization in our study subjects and therefore, cannot be blamed for producing ductal constriction. As per our protocol, we did not administer oxygen to the patients until after O_2 saturation data and angiograms were secured. Consequently, O_2 is also an unlikely explanation for the discrepancy. The most likely explanation is the degree of sensitivity of these two methods is different in indicating the true size of the PDA.

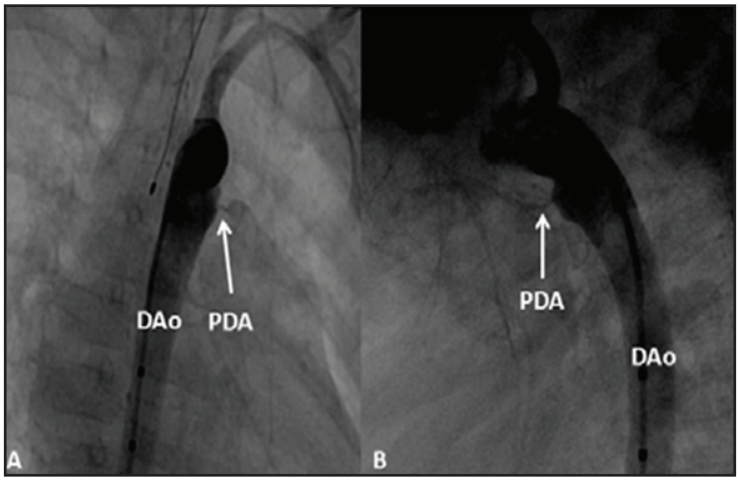

Figure 7. Selected aortic arch cineangiographic frames in right anterior oblique (A) and straight lateral (B) views demonstrating an extremely small (arrows in A and B) patent ductus arteriosus (PDA). DAo, descending aorta. Reproduced from Yates MC, Gautam NK, Rao PS. Congenital Cardiology Today 2015; 13(5):1-7.

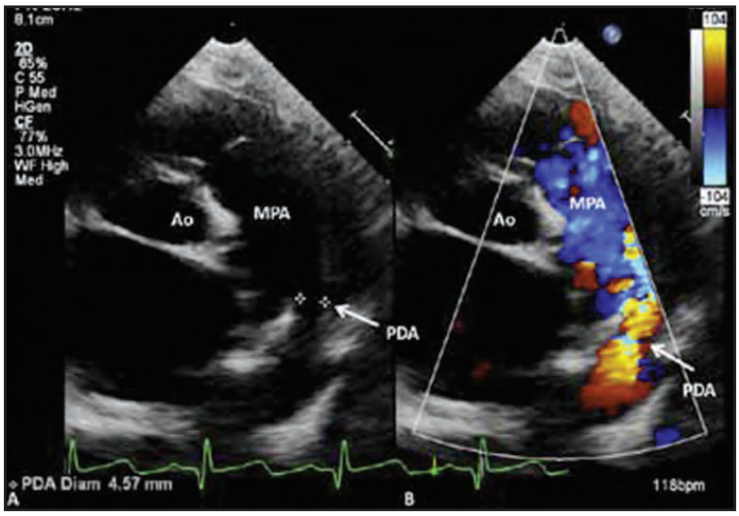

Figure 8. Selected video frames from parasternal short axis views demonstrating a patent ductus arteriosus (PDA); 2D measurement of the minimal ductal diameter (A) with left to right shunt by color Doppler (B) are shown. Ao, aorta; MPA, main pulmonary artery. Reproduced from Yates MC, Gautam NK, Rao PS. Congenital Cardiology Today 2015; 13(5):1-7.

Conclusion

The above data indicate that the echocardiographic (both 2-D and color Doppler) PDA diameters consistently overestimate angiographic MDDs of PDA. The echo-Doppler studies provide information on left ventricular volume overloading in addition to the ductal diameter and are helpful in clinical evaluation of PDA patients and in selection of patients for transcatheter occlusion. The angiographic MDD is useful and essential for the selection of the size of the device used to occlude the PDA. The echocardiographic MDDs should not be used for the selection of the size of the device to be implanted for closure of PDA.

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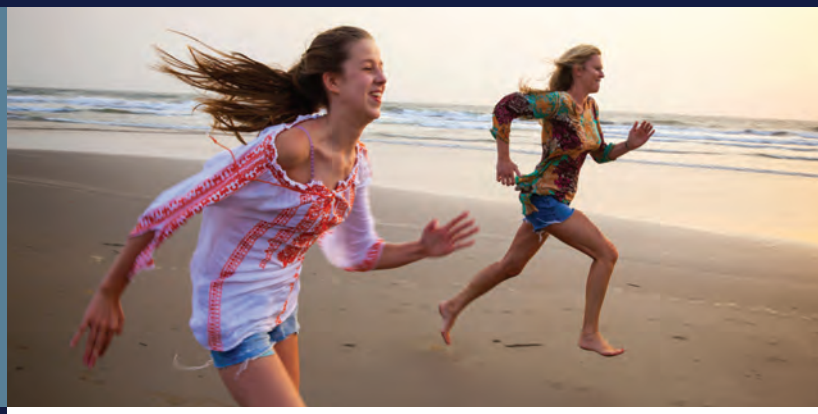

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- **DO NOT implant in the aortic or mitral position. Pre-clinical bench testing of the Melody valve suggests that valve function and durability will be extremely limited when used in these locations.**
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- Assessment of the coronary artery anatomy for the risk of coronary artery compression should be performed in all patients prior to deployment of the TPV.
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- The potential for stent fracture should be considered in all patients who undergo TPV placement. Radiographic assessment of the stent with chest radiography or fluoroscopy should be included in the routine postoperative evaluation of patients who receive a TPV.
- If a stent fracture is detected, continued monitoring of the stent should be performed in conjunction with clinically appropriate hemodynamic assessment. In patients with stent fracture and significant associated RVOT obstruction or regurgitation, reintervention should be considered in accordance with usual clinical practice.

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

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

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

For additional information, please refer to the Instructions for Use provided with the product or available on http://manuals.medtronic.com.

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

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- Implantation of the TPV in the left heart
- RVOT unfavorable for good stent anchorage
- Severe RVOT obstruction, which cannot be dilated by balloon
- Obstruction of the central veins
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- Active endocarditis
- Known allergy to aspirin or heparin
- Pregnancy

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

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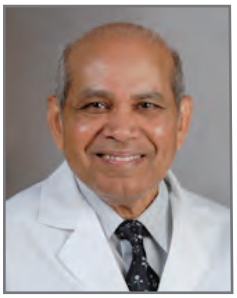

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Five Good Reasons to Attend SCAI 2019

By John Moore, MD, MPH, FSCAI;
Lee Benson MD, FRCPC, FACC, MSCAI;
Daniel Gruenstein, MD, FSCAI

SCAI 2019 Annual Scientific Sessions are coming soon! If you are an interventional cardiologist or other professional involved in the care of pediatric or congenital heart patients, and you have not registered, please keep reading. Here are five very good reasons to attend:

1. *SCAI 2019* has a discrete and comprehensive Learning Track totally devoted to interventional procedures in children and in patients with Congenital Heart Disease.
2. The Congenital (and Pediatric) Track is large enough to provide an extensive curriculum presented by experts and thought leaders in the field.
3. The Congenital Tract is small enough to feel comfortable and friendly. It is easy to ask questions and to participate in the Sessions, and it is intimate enough to "corner" experts for more extensive individual discussions.
4. In addition to the Congenital Track, there are four other Learning Tracks, which provide comprehensive programs in Structural, Peripheral, and Coronary Interventions, and in Catheterization Laboratory Issues in general. Selectively visiting these Tracks can provide numerous opportunities for terrific crossover learning.
5. This year's *SCAI* meeting is at The Cosmopolitan in Las Vegas, May 19th-22nd. This is a great venue in a city which has unlimited culinary and entertainment options, and you can plan on warm sunny days!

Just a few words about the Congenital Heart Disease Track Program. The organization of the Track this year is by patient age:

- On Monday, we will deal mostly with interventions in newborns and infants.
- On Tuesday, we will discuss procedures in children.
- On Wednesday, we will present an adolescent and adult congenital-oriented program.

The Congenital Track will cover the newest techniques and technologies as well as new aspects of older more established procedures using case-oriented approaches. There will be more "case in a box" presentations than in previous years and more in-depth workshops. There will also be Sessions this year, which have never before been presented in the *SCAI* Congenital Track: one on Interventional Radiology for Pediatric Cardiologists and another on Simulation in Congenital Interventional Cardiology. Dr. Neil Wilson, a wonderful humorist and authoritative speaker will give the Mullins Lecture, and there are "fun" Sessions like "Cath Lab Jeopardy" and "I Blew It." On Wednesday, there will also be a combined Session with the Structural Track focusing on how interventions in Adult Congenital Heart Disease differ from the same procedures in children.

As always, there will be many opportunities to reunite and network with colleagues and friends while we discuss the most important and the newest techniques and technologies in interventional congenital cardiology.

We have tried very hard to put together a truly outstanding program. We hope you will join us in Las Vegas!

Register and download the advance program at www.scai.org.

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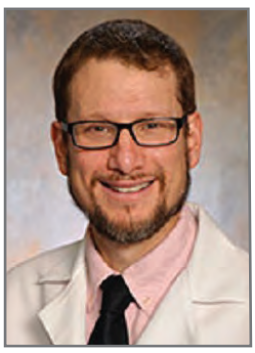

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Medical News, Products & Information

Compiled and Reviewed by Kate Baldwin

Edwards' SAPIEN 3 Ultra Transcatheter Heart Valve Receives FDA Approval

PRNewswire - IRVINE, Calif., Dec. 28, 2018/PRNewswire/ – Edwards Lifesciences Corporation (NYSE: EW), the global leader in patient-focused innovations for structural heart disease and critical care monitoring, today announced that the SAPIEN 3 Ultra system has received U.S. Food and Drug Administration (FDA) approval for transcatheter aortic valve replacement in severe, symptomatic aortic stenosis patients who are determined to be at intermediate or greater risk of open-heart surgery.

"The advanced SAPIEN 3 Ultra system features enhancements on the valve and a new delivery system to address the needs of both patients and clinicians, building on our best-in-class performance of SAPIEN 3 to further advance and improve patient care," said Larry L. Wood, Edwards' Corporate Vice President, Transcatheter Heart Valves. "We look forward to introducing the SAPIEN 3 Ultra system to U.S. patients."

The SAPIEN 3 Ultra system builds on Edwards' decades of engineering and experience in the development of tissue heart valves, and the proven benefits of the Edwards SAPIEN valves.

"The Edwards SAPIEN 3 Ultra system provides meaningful technology improvements that help further optimize the transcatheter aortic valve replacement procedure, adding simplicity and advancing patient care," said John Webb, MD, Director of Interventional Cardiology and Cardiac Catheterization Laboratories at St. Paul's Hospital, Vancouver, and Professor of Cardiology at the University of British Columbia.

Dr. Webb is a consultant to Edwards Lifesciences.

For more information, visit www.Edwards.com

First-in-Man Clinical Trial: 24-Day-Old Baby Receives BeGrow Stent

- Successful first-in-man implantation of BeGrow stent in a 24-day old baby
- After placement in newborn/infant and dilations >11,5 mm; BeGrow breaks open in a controlled way and grows with the patient to adult age
- Bentley is the first company to develop a stent specifically for pulmonary artery stenosis in infants

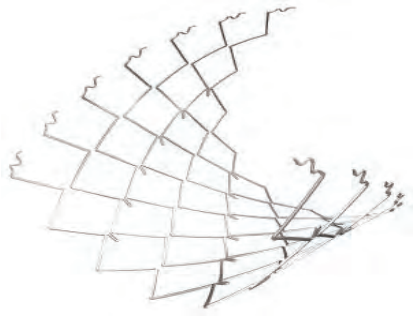
A 24-day-old infant has received the first-in-man placement of BeGrow, a novel stent system that grows with the child, to alleviate pulmonary artery stenosis.

BeGrow is small enough to fit a newborn's 6 mm diameter pulmonary artery, yet can be post-dilated to a vessel diameter of 11.5 m, as a child grows up (around 8-10 years of age). Beyond this diameter, the stent breaks open at pre-determined points in a controlled way. This feature makes the stent unique, and particularly suitable for when young patients transition to adulthood without having to experience open-heart surgery and the associated risks.

The first-in-man procedure marks the start of the BeGrow clinical trial performed by principal investigator and interventional pediatric cardiologist, Professor Oliver Kretschmar from the Kinderspital Zurich, Switzerland.

"We have been looking for something to fulfill the need for a stent that can grow with the vessel from infant to child to adult," remarked Professor Kretschmar. "With BeGrow, the stent 'breaks open in a controlled way' when it has been dilated to a diameter >11.5 mm, after which point it is designed to grow with the child's vessel, as pig studies have shown. If needed, we could place an adult-width stent in the pulmonary artery, while BeGrow remains in situ," he continued, noting that the clinical trial results would determine the preferred course of action in the long term.

"The benefit of the BeGrow is that the stent can stay in the patient for the rest of their life," he added. "Even if we add-in another stent of adult size, it is certain that we will not have to surgically remove the BeGrow, like we do with other current off-label solutions, inherently carrying a risk of vessel damage," he said.



The BeGrow stent system should be indicated for intraluminal placement in the pulmonary arteries of newborns and infants for the treatment of pulmonary artery stenosis, an indication that meets an unmet medical need. BeGrow is balloon-expandable with a low crimped profile that can be inserted and dilated at minimal pressure via the 4 French (F) compatible catheter to 6 mm expanded diameter, the width of a newborn pulmonary artery. The stent is available in lengths of 10, 13, 17, 20, and 24 mm.

The novel stent system, developed by leading vascular technology company, Bentley (Hechingen, Germany), is aimed at treating babies with congenital heart disorders, which have a prevalence of approximately one in 100 newborns in Europe. Few medical device companies have developed devices for pediatric cardiology because the market is so small.

Christian Bader is BeGrow product manager and former research and development (R&D) project leader for Bentley. "Due to the extremely small diameter of an infant's blood vessels, there is currently only one option for these patients, which is a coronary stent," he explained. "However, these stents can't grow to an adult vessel diameter, hence surgical removal is required. At Bentley we have focused our research and development [R&D] on finding a solution to meet this need for pediatric cardiologists to improve the clinical outcome and quality of life for the patient."

Chief of Pediatric Cardiology
Orlando, Florida

The Walt Disney Pavilion at AdventHealth for Children (AHFC) - formerly Florida Hospital for Children - and AdventHealth Medical Group (AHMG) - formerly Florida Hospital Medical Group - are looking for a dynamic and experienced Chief in Pediatric Cardiology to lead our growing program. The group is open to both noninvasive and interventional cardiology backgrounds. The new leader will also have experience with both inpatient and outpatient settings, including outreach strategies. The position will involve clinical responsibilities with protected administrative time.

The pediatric cardiology division is part of a full-service program including six cardiologists (with plans to continue to grow), two world class cardiothoracic surgeons, a robust intensive care group, top cardiac anesthesia and surgical results rivaling any program in the country. Our state of the art hybrid catherization laboratory see over 150 diagnostic/interventional procedures and over 125 electrophysiology procedures annually. We also performed over 200 surgeries in 2018. There is a robust adult congenital cardiology population and we have a board certified adult congenital cardiologist in the group. The group has seven outpatient locations in six counties covering a population of 2.75 million people.

Working with an expanding and committed children's hospital, a strong employed physician multispecialty group, a family-centered practice atmosphere, and a competitive benefits/compensation package are just a few of the many reasons why this is an excellent career opportunity to consider.

Requirements of the position include:

- Experience with inpatient and outpatient settings
- At least 7-10 years of experience post fellowship
- Board certification in Pediatric Cardiology through ABP
- Prior group leadership experience is preferred

Our Walt Disney Pavilion at AdventHealth for Children is a full service, tertiary children's hospital with over 200 dedicated pediatric beds, more than 30 peds ICU beds with a dedicated peds CICU, a 102 bed NICU, 17 bed pediatric emergency department and statewide pediatric network and transport system. We started our comprehensive pediatric open heart program in 2012 and have a strong track record of positive outcomes. We also have several key destination programs including our level IV Epilepsy program, and we increased Orlando area NICU beds to 150 total in 2017. Our unparalleled network consists of 27 hospitals across the state with one children's hospital at the center totals over 20,000 births and several extremely successful pediatric subspecialty programs including outreach clinics. These 27 hospitals refer patients for tertiary and quaternary services to our main location near downtown Orlando. Our newest program has brought pediatric liver transplant services to Central Florida.

For more information or to submit your CV directly:
Jason Junker, Director, Provider Recruitment
phone: (407) 200-2538
Jason.Junker@AdventHealth.com

AdventHealth
for Children

BeGrow Clinical Study

Research into BeGrow began in 2012, and was conceptualized and designed by Bentley's co-founder, Miko Obradovic. Technical development was complete in 2017 and the clinical trial began that year at the Kinderspital Zurich, with two sites in Germany and one in Austria to be added soon.

The BeGrow clinical study is a prospective, multi-center, explorative, open label single-arm study to assess the safety and performance of the BeGrow Stent System for newborns and infants in pulmonary artery stenosis. The primary outcome measures are vessel enlargement directly after procedure, and during follow-up to 12 months. A total of 18 infants will be included.

"Bentley will submit for CE immediately after the 12-month results [primary outcome measures] and will continue to gather long term results of efficacy and safety up to 8-10 years of age," said Natasa Mitrovic, clinical affairs manager for BeGrow.

Expert Opinion – a Novel Option for Newborns

"Currently, standard of care in infants comprises stents neither made nor indicated for infants. They are only designed for adults," reflected Professor Kretschmar. "With children, especially the very young, we have to customize adult products, but the diameter of these stents is restricted, and with over-dilation we lose function. We then need to add-in an adult stent, but because the size of the original stent is restricted, the vessel can remain narrowed." The continued growth of BeGrow within the vessel wall, after 11.5 mm, is designed to overcome these issues.

A further advantage of BeGrow, Professor Kretschmar added, is the possibility of using a very small 4F vessel sheath to enter the vessel as opposed to a standard large sheath that can damage a vessel upon insertion. "The result in the first case was excellent," he reported.

"We hope that this development means we can implant a stent at a very early age and this can grow with, and stay with, the patient for the rest of their life, but of course, long-term results need to be shown in trials," added Professor Kretschmar.

About Bentley

Bentley was founded in 2009 by medical entrepreneurs Lars Sunnanväder and Miko Obradovic. The company has seen substantial growth since the launch of its first product in 2012 and today operates a global sales and distribution network in more than 70 countries.

The six top-line products in Bentley's portfolio are:

- BeGraft coronary, launched in 2012.
- BeGraft peripheral: first generation, launched in 2013; second generation, launched in 2015.
- BeSmooth peripheral, launched in 2014.
- BeGraft aortic, launched in 2016.
- BeGraft peripheral PLUS, launched in 2017.
- BeGrow, clinical trial started in 2018.

Image Diagnostics' ilex55: The Recipient of the 2018 Excellence in Surgical Products Award

The ilex55 by Image Diagnostics is this year's winner of the Excellence in Surgical Products Award for the category of OR Visualization. A revolutionary mobile imaging system, the ilex55 has onboard multi-modality video integration on a 55-inch screen and offers options to display four images simultaneously. With its split-screen capability, images from C Arms, cameras, ultrasounds, PACS, or hemodynamics can all be seen on one monitor with remote control video formatting. The 4K imaging displays clearer images than ever before with calibrated surgical color. Ilex55's mobility and 20-inch vertical adjustability allows for it to be configured to any room or procedural need, providing budgetary and ergonomic advantages with no downtime during installation and maximum flexibility.

"The ilex55 is a testament to IDI's commitment to product development and underscores our ability to uniquely apply new technology to existing applications in this industry," said Remo Rossi, President of Image Diagnostics Inc. "IDI is honored to receive this award and proud to be part of the constant innovation occurring in the healthcare industry."

A large part of what distinguishes ilex55 from other options are its features, designed for optimal imaging capabilities, ergonomic flexibility and functionality. Below are features and advantages of the innovative mobile monitor system:

ilex55 Imaging Features:

- 55" UHD 4K monitor on an easy to move mobile platform with 20" vertical travel
- Display one 4K image, two side-by-side images or up to four 26" HD images at one time
- Remote control screen layout and sourcing selection
- Calibrated surgical color
- Integrated speaker and USB charging station
- Displays analog and digital signals from multiple sources including: C-Arm, ultrasound, echocardiogram, hemodynamics, cameras, image guidance, & PACS

ilex55 Key 4K Ultra High Definition Advantages

- Expanded Color Pallet - 4K systems have the capacity to produce more shades of color and greyscale with or without a 4K input source. Naturally this expanded color pallet allows higher accuracy and visibility than current HD technology.
- Dose Reduction - ilex55 customers observe and state they will use the C-Arm Mag function less, as the image quality is improved and so much larger.
- Image Clarity – ilex55 provides an increase in sharpness and clarity. More pixels and colors make a cleaner picture.

To see the full article about the award, please visit the following link: https://bit.ly/2rOQeol.

For more information about Image Diagnostics, please visit www.imagediagnostics.com.

MaineHealth
Physician
Recruitment Center

PEDIATRIC CARDIOLOGIST

Congenital Heart has been the premier Congenital Cardiology Practice in the state of Maine for over 50 years. We are excited to announce that Congenital Heart is partnering with Maine Medical Partners and MaineHealth. This partnership will form the new Division of Pediatric Cardiology and Congenital Heart Care at Maine Medical Center. Commensurate with this partnership is the opportunity to expand with the addition of three Pediatric Cardiologists:

1) **BC Pediatric Electrophysiologist** with expertise in the management of pediatric and adult-congenital electrophysiology . The applicant should be technically proficient in radiofrequency/cryoablation, pacemaker/AICD insertion and management, and ventricular tachycardia ablation. The applicant will work closely with a large group of busy adult electrophysiologists but function as the director of the Pediatric and Adult-Congenital EP program.
2) **BC non-invasive Pediatric Cardiologist** with at least 6-8 years of clinical experience in a busy clinical/academic center with expertise and advanced training in echocardiography (fetal, TTE and TEE) with the ability to provide imaging and related consultation in the operating room and catheterization laboratory. This individual should possess leadership skills and desire to advance into leadership positions within the division. A research interest is encouraged with opportunities for collaboration with established research institutes like the Maine Medical Cardiovascular Research Institute (MMCRI).
3) **BE/BC non-invasive Pediatric Cardiologist** with expertise and advanced training in echocardiography (fetal, TTE and TEE) with the ability to provide imaging and related consultation in the operating room and catheterization laboratory. The candidate would ideally have clinical interest and experience in the management of Heart Failure and Cardiomyopathy. A research interest is encouraged with opportunities for collaboration with established research institutes like the Maine Medical Cardiovascular Research Institute (MMCRI).

General Pediatric Cardiology call responsibilities will be shared with the other members of the division.

These candidates will join 4 other Pediatric Cardiologists, who have established the only comprehensive Congenital Heart program in the state of Maine. The program has recently hired an experienced surgeon to serve as the Director of Congenital Cardiac Surgery. Comprehensive catheter-based interventional services and state-of-the-art imaging are performed.

Inpatient responsibilities are at The Barbara Bush Children's Hospital, a 96-bed hospital within Maine Medical Center - the tertiary medical center for children serving the state of Maine and southern and eastern New Hampshire. The Children's Hospital medical staff represents all of the pediatric medical and surgical subspecialties that provide comprehensive services for children. Maine Medical Center (MMC) has a full complement of Residencies and Fellowships and functions as an integral part of Tufts University Medical School.

Situated on the Maine coast, Portland offers the best of urban sophistication combined with seaside charm. It receives tourists from around the world with nationally recognized restaurants, breweries, and hotels. The area has an active outdoor community providing four-season recreational opportunities such as skiing, hiking, sailing, and miles of beautiful beaches. Just two hours north of Boston, this is an exceptionally diverse and vibrant community.

For more information, please contact Gina Mallozzi, Physician Recruiter, at (207) 661-2092 or gmallozzi@mmc.org.

PICS-AICS

Pediatric and Adult Interventional Cardiac Symposium

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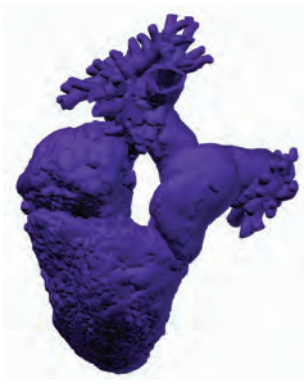
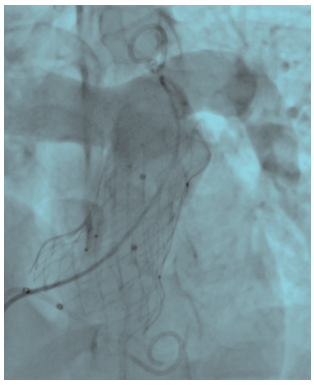
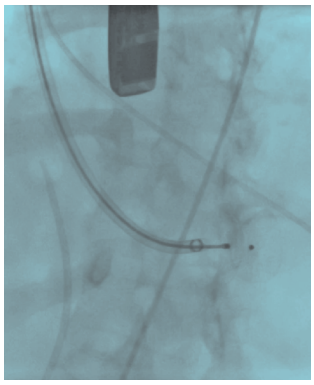


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Interventional Systems
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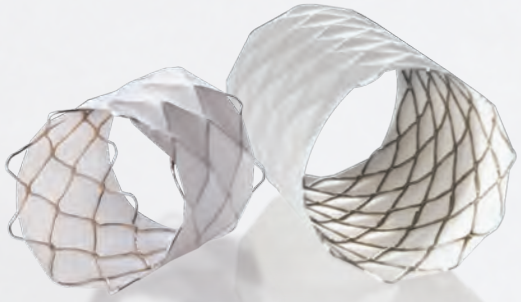
CP STENT™

Large Diameter, Balloon Expandable Stent

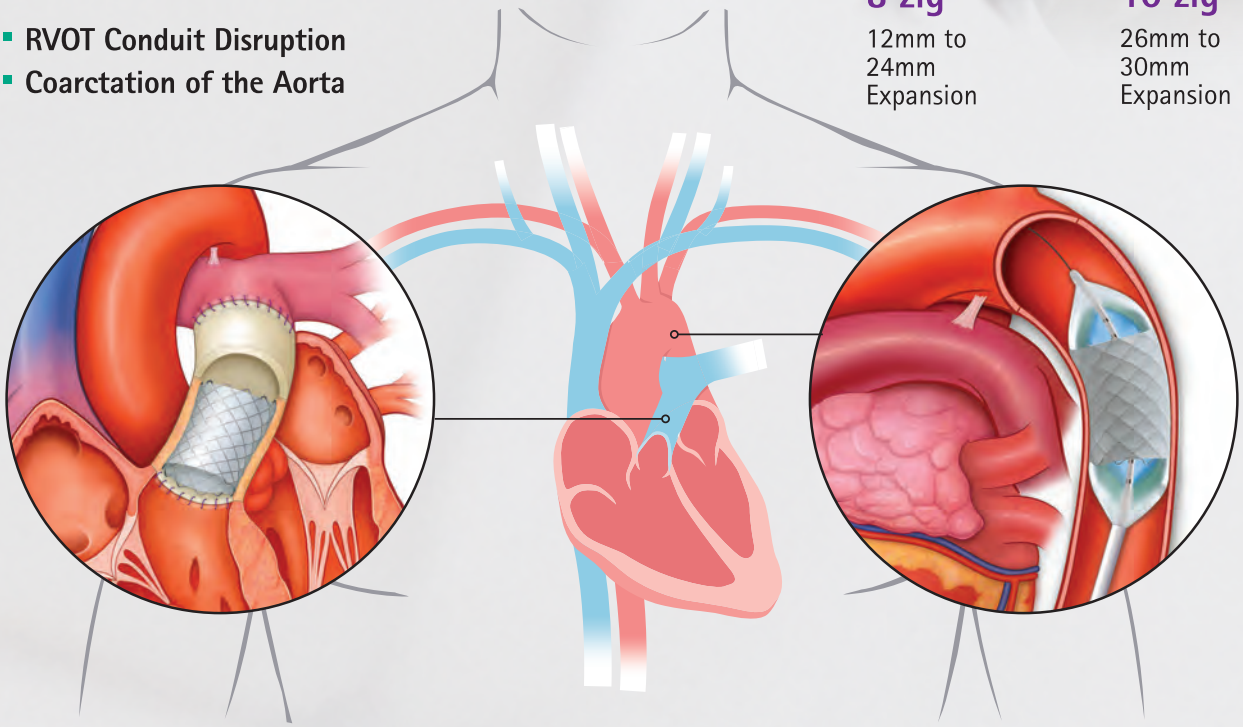


8 zig
12mm to 24mm Expansion

10 zig
26mm to 30mm Expansion

For Treatment Of:

- RVOT Conduit Disruption
- Coarctation of the Aorta



Indications for Use:

The CP Stent is indicated for use in the treatment of native and/or recurrent coarctation of the aorta involving a compliant aortic isthmus or 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 Covered CP 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 Covered CP 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 pre-dilatation procedures performed in preparation for transcatheter pulmonary valve replacement.

Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician. **Contraindications:** Clinical or biological signs of infection. Active endocarditis. Pregnancy. **Contraindications (CoA only):** Patients too small to allow safe delivery of the stent without compromise to the systemic artery used for delivery. Unfavorable aortic anatomy that does not dilate with high pressure balloon angioplasty. Curved vasculature. Occlusion or obstruction of systemic artery precluding delivery or the stent. Known allergy to aspirin, other antiplatelet agents, or heparin. **Contraindications (RVOT only):** Patients too small to allow safe delivery of the stent without injury to a systemic vein or to the right side of the heart. **Warnings / Precautions:** Radiofrequency heating during MRI scans on overlapped, 10 zig CP Stents has not been evaluated. Excessive force while crimping may weaken welds of the stent. Crimping the 8 zig stent on a balloon catheter smaller than 12mm, and the 10 zig on a balloon catheter smaller than 26mm, may cause damage to the stent. The stent is rigid and may make negotiation through vessels difficult. **Warnings / Precautions (CoA only):** Coarctation of the aorta involving the aortic isthmus or first segment of the descending aorta should be confirmed by diagnostic imaging. The NuMED CP Stent has not been evaluated in patients weighing less than 20kg. As with any type of implant, infection secondary to contamination of the stent may lead to aortitis, or abscess. Over-stretching of the artery may result in rupture or aneurysm formation. **Warnings / Precautions (Covered CP Stent only):** Excessive handling and manipulation of the covering while crimping the stent may cause the covering to tear off of the stent. Crimping the device in the opposite direction of the folds in the covering may cause the covering to catch while inserting into the hemostasis tool and introducer. This could cause the covering to tear off the stent. Pulling the Covered stent back through the introducer and/or hemostasis valve may cause the covering to catch and tear off of the stent. **Warnings / Precautions (RVOT only):** During the Premarket Approval study the Medtronic Melody valve was used for valve restoration. The safety and effectiveness of the Covered CP Stent for pre-stenting of the right ventricular outflow tract (RVOT) landing zone (i.e. prophylaxis or prevention of either RVOT conduit rupture or TPVR fracture; use as a primary RVOT conduit) in preparation of a transcatheter pulmonary valve replacement (TPVR) has not been evaluated. As with any type of implant, infection secondary to contamination of the stent might lead to endocarditis, or abscess formation. The Covered Stent can migrate from the site of implant potentially causing obstruction to pulmonary artery flow. Over-stretching of the RVOT may result in rupture or aneurysm of the RV-PA conduit or the native pulmonary artery. The inflated diameter of the stent should at least equal the diameter of the intended implant site. **Reference the IFU for a complete listing of indications, contraindications, warnings and precautions. www.bisusa.org**

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