

Patient Brochure	
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Title Page Page 1	Pediatric Pulmonary Valve Replacement <i>A guide for parents and caregivers</i> The AUTUS size-adjustable valve Offering an alternative therapeutic option for children with pulmonary valve disease
Inside Your Heart Page 2	If your child has congenital heart disease and has been diagnosed with a pulmonary valve defect, you likely have a lot of questions. This brochure is here to help. Inside, you will find information about what pulmonary valve disease means for your child and what therapy options are available, including a new treatment for the pulmonary valve designed specifically for pediatric patients. This booklet does not include everything you need to know about pulmonary heart valves, pulmonary heart valve replacement surgery, or about related medical care. Regular check-ups by your child's heart doctor are important. Call or see your child's doctor whenever you have questions or concerns about your child's health, especially if any unusual symptoms or changes in overall health occur. As always, your child's care team is your most important resource. Pulmonary valve disease (PVD) is more common than many people realize. Today, in the United States: Over 100,000 children may be living with PVD, estimates suggest^{1,2} ~7,000 babies are born in the US each year with PVD³
Table of Contents Page 3	How the Heart Works 4 What is Pulmonary Valve Disease? 5 Treatment Options for PVD 6 How Does the Care Team Decide Treatment? 7 Introducing the AUTUS valve 8 What to Expect: The Procedure 10 Life After Surgery 11 Clinical Studies 12 Pulmonary Valve Replacement Risk Information 13 Implant Patient Registry 14 Contact Information 15 Notes 15
How the Heart Works Page 4	Understanding how the heart and its valves work is a helpful place to start Your child's heart has four chambers and four valves — the tricuspid, pulmonary, mitral, and aortic valves — each acting as a one-way door to keep blood moving in the right direction. Blood from the body enters the right side of the heart, travels to the lungs to pick up oxygen, returns to the left side, and is then sent out to the rest of the body.

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	It is a carefully coordinated loop, and every valve plays a role in keeping it on track. The Pulmonary Valve The pulmonary valve sits between the right ventricle and the pulmonary arteries, which carry blood from the heart to the lungs. With each heartbeat, the valve opens to let blood through, then closes to keep it from flowing back into the heart.
When the Pulmonary Valve Doesn't Work the Way It Should Page 5	What Is Pulmonary Valve Disease? Congenital heart disease (CHD) means a child is born with a heart condition. Pulmonary valve disease (PVD) can be one of these conditions or part of a larger condition. When a child has PVD, their pulmonary valve is not formed or working the way it should be. Common Diagnoses³ • Tetralogy of Fallot: A congenital heart condition that includes four distinct differences; a narrowing located between the heart and the lungs (often includes the heart valve), thickening of the right heart muscle, a hole between the two lower chambers of the heart, and the major blood vessel to the body shifted in a position that is abnormal. • Pulmonary atresia: A congenital heart condition in which the valve between the right lower heart chamber and lungs does not develop properly preventing blood flow from heart to lungs. • Congenital pulmonary stenosis: A congenital heart condition in which there is narrowing between the right lower heart chamber and the lungs, most commonly the valve, making it harder for the blood to flow from the heart to the lungs. • Double outlet right ventricle: A congenital heart condition in which the major blood vessel leaving the heart to the body connects mainly from the right lower heart chamber instead of the left, either partially or completely. There is also often a hole between the two lower chambers of the heart. These diagnoses can include pulmonary valve dysfunction, such as obstruction of blood flow across the valve and blood leaking through the valve. Common Symptoms of PVD Some children with PVD have no symptoms at all. When symptoms do appear, they can include:^{4,5} Heart murmur an unusual sound heard through a stethoscope, often the first sign Fatigue tiring easily during everyday play or activity, unable to keep up with peers Breathing problems fast or labored breathing, even at rest Blue or purple skin tone a bluish tint to the lips, nails, or skin, signaling low oxygen Other signs

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	poor feeding in infants, poor weight gain, chest pain, or fainting
Current Treatment Options for PVD Page 6	Pulmonary Valve Replacement, or PVR Patients who have pulmonary valve disease may require pulmonary valve replacement. During the procedure, the valve is removed and replaced with a new one.¹ PVR can be done in two ways, depending on your child's specific situation: • Surgical replacement — an open-heart procedure in which the surgeon removes the diseased valve and places a new one. The new valve may be biological (from human or animal tissue) or synthetic.¹ • Transcatheter replacement — a less invasive approach where the new valve is delivered through a tube inserted into a blood vessel, without opening the chest. This option is generally used in older children and adolescents, depending on their anatomy and the size of the available devices.^{6,7,8}
Current Treatment Options for PVD Page 6	Today's pediatric options for PVD Surgeons do their best with the tools available, but most surgical non-conduit* pulmonary valves were developed for other purposes and were not designed with children in mind. That has left families and care teams with limited choices. Conduits including homografts Most frequently used in: Specific anatomies and younger children Key consideration: Limited availability; fixed size, deteriorates over time, often requiring early reoperation^{9,10} Bioprosthetic valve Most frequently used in: Older children and teens Key consideration: Smallest available size is too large for young children; limited durability, often requires early reoperation^{9,11} Transcatheter valve Most frequently used in: Teens and adults Key consideration: Less invasive, but devices are too large for young children^{6,7,8} <i>*A conduit is a tube that surgeons place to create or restore the pathway that carries blood from the heart to the lungs. The conduit often includes a valve that helps blood flow in the correct direction. A homograft is a type of conduit from donated human heart that includes both a valve and a blood vessel.</i>
How Does the Care Team	Every child is different. The right treatment depends on several factors that your child's care team will weigh carefully. Factors to be considered, include:^{11,12} • The type and severity of the valve problem

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Decide Treatment? Page 7	• Your child's age and body size • The anatomy of your child's heart and surrounding structures • Your child's overall health Your care team will walk you through the options and help you understand what is right for your child. Many children with pulmonary valve disease need more than one open-heart surgery during childhood. A journey that spans childhood Each time an implanted valve is outgrown or does not function properly, another procedure is considered. For many, adult-sized valves become available as a treatment option in teenage year but have limited durability when implanted during adolescence compared to older adults.
A New Kind of Therapy, Designed for Children Page 8	Introducing the AUTUS valve The AUTUS size-adjustable valve was created specifically for children and is an alternative therapeutic option designed to support a patient from early childhood onwards. This approach to care is designed to reduce the number of open-heart surgeries your child needs over their lifetime, while protecting heart function.
A New Kind of Therapy, Designed for Children Page 8	Why might this new therapy pathway be an option for your child? A valve designed specifically for the small anatomy of children with a path that extends from early childhood onwards¹³ Enables individualized treatment based on child's size with custom sizing at the time of surgery based on your child's body size¹⁴ Designed to reduce open-heart surgeries over the course of the lifetime with the ability to expand the valve size as your child grows Long term clinical studies are ongoing to evaluate these benefits.
Built for a Child's Heart Page 9	The AUTUS valve is the first and only surgically implanted pulmonary replacement valve that is designed to be enlarged over time as a child grows. When the valve is placed, your child's doctor selects the right size for your child's heart at that moment. Using a less invasive, catheter-based procedure, the valve may be gently enlarged to accommodate your child's growth, as recommended by your care team.

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	The AUTUS valve is created around the following ideas that together make a new kind of care possible: Created specifically for children The AUTUS valve is the only surgical pulmonary replacement valve created for small anatomy—appropriate for children as small as 10 kg, or 22 lbs. Custom-sized to your child at the time of surgery With a correctly sized valve, treatment can begin before lasting changes to heart function take hold. During the procedure, the surgeon adjusts the valve size to match your child's body size to allow for optimal blood flow. The diagram illustrates the expansion process of the AUTUS valve in three stages, connected by arrows. The first stage shows the valve 'initially sized at implantation' as a small, folded device. A red arrow points to the second stage, 'AUTUS valve partially expanded (as needed)', where the valve is more open. A purple arrow points to the third stage, 'AUTUS valve expanded (as needed)', where the valve is fully open and larger. Each stage includes a 3D rendering of the valve's structure. Designed for expansion as your child grows The AUTUS valve is designed to be gently enlarged as your child grows, without another open-heart surgery.^{13, 14} Not all children will need future adjustment. Your care team will guide follow-up decisions.
What to Expect: The Procedure Page 10	Determining if the AUTUS size-adjustable valve is right for your child Your care team will provide guidance on whether your child is a candidate for the AUTUS size-adjustable valve. Children receiving the AUTUS valve may have any of the following diagnoses: • The area in the heart where the pulmonary valve is located or the size of the pulmonary valve is too small for the patient • The pulmonary valve leaks, meaning blood flows backwards into the heart through the pulmonary valve • A combination of the above Your care team will use certain criteria such as the dimensions of the heart chamber and valve, how high the pressures are, and how much blood flows backwards to determine if your child fits within the criteria.

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	The AUTUS valve should not be implanted when the patient has an active infection in the heart or the body or when the patient cannot tolerate blood thinning medication, including aspirin. Every child's surgery is unique. What follows is a general overview of what the procedure typically involves. Before Surgery Your child will be given general anesthesia before the procedure begins. They will be fully asleep and will not feel anything. Accessing the Heart Once your child is under anesthesia, the surgical team will make an incision down the center of the chest. The breastbone (sternum) is carefully divided to allow the team to reach the heart. A small tool called a retractor holds the sternum open during the procedure. Implanting the AUTUS valve The surgeon will place the valve where your child's pulmonary valve sits. The valve is secured using standard surgical techniques, with the exact procedure being determined by the surgeon based on your child's anatomy. Closing Once the valve is in place and the surgical team has confirmed everything is working as expected, the sternum is closed and secured with small wires. The chest tissues and skin are then closed in layers. Recovery Right after surgery, your child will be closely watched as they wake up. Your care team will help you know what to expect in the hospital and at home.
Life After Surgery Page 11	Going home Your child will gradually build back their strength and energy over the weeks that follow. Talk to your care team about when your child can return to school, physical activity, and the routines they enjoy. Your child's strength and energy will return in the weeks ahead Ask your care team when your child can go back to school and normal activities Every child's recovery is different — your care team is your best resource Follow-up care Children who receive a pulmonary valve replacement need ongoing cardiology care throughout their lives. Regular visits allow the care team to monitor valve function, track your child's growth, and plan ahead for any future needs.¹⁵

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	• Lifelong cardiology care is part of the journey and regular visits will help your care team keep a close eye on the valve. • Your team will track your child's growth and plan ahead together with you. • Blood thinning medication, such as aspirin will be started when the AUTUS valve is implanted, which they may need to take for the rest of their life. Your care team will provide details specific to your child's needs. • Additional recommendations may include, but are not limited to: - Other medication for prevention of potential infection - Routine dental hygiene practices Ongoing Support You may find additional support beneficial during the process of receiving AUTUS valve therapy. Edwards Lifesciences is here to help.  Contact our patient support center by scanning the QR code or at this website: https://www.edwards.com/patients-care-partners/patient-support-center. There may also be local support services available to you in your area. Talk with your child's care team to learn more.								
Clinical Studies Page 12	The AUTUS valve is currently being evaluated in a clinical study approved by the United States Food and Drug Administration (FDA). The study is designed to evaluate how safe the valve is and how well it works in children between 18 months and 16 years old who are undergoing pulmonary valve replacement. Sixty-two total patients have been enrolled in this study. Results from the patients in the study were collected immediately following surgery, one month after surgery (62 patients), six months after surgery (60 patients) and one year after surgery (51 patients). These results can be found below. Ongoing follow-up will continue to assess the long-term durability of the AUTUS valve and the results of non-surgical post implant size adjustments.¹⁴ Successful valve surgery, measured immediately after the AUTUS valve implant <table border="1"> <thead> <tr> <th></th><th>Risk per 100 patients</th></tr> </thead> <tbody> <tr> <td>No more than mild narrowing across valve</td><td>0 out of 100</td></tr> <tr> <td>No or very small amount of blood leaking through valve</td><td>0 out of 100</td></tr> <tr> <td>No blood leaking around valve</td><td>0 out of 100</td></tr> </tbody> </table> Safety of the Valve 30 Days After Surgery (reviewed by an independent group of doctors)		Risk per 100 patients	No more than mild narrowing across valve	0 out of 100	No or very small amount of blood leaking through valve	0 out of 100	No blood leaking around valve	0 out of 100
	Risk per 100 patients								
No more than mild narrowing across valve	0 out of 100								
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No blood leaking around valve	0 out of 100								

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		Risk per 100 patients	
	Death	0 out of 100	
	Blood clot on valve which needs surgery or other treatment	0 out of 100	
	Blood clot in the body blocking blood flow and creating symptoms	0 out of 100	
	Valve Function Concerns 6 months and 1 year After Surgery (reviewed by an independent group of doctors)		
		Risk per 100 patients at 6 months	Risk per 100 patients at 1 year
	More than mild narrowing across valve	0 out of 100	0 out of 100
	More than small amount of blood leaking through valve	0 out of 100	0 out of 100
	Valve needing surgery or treatment in catheterization lab for reason other than the patient growing	0 out of 100	0 out of 100
	Other valve related concerns In three patients (4.8%), the frame structure of the AUTUS valve had breaks but was still working normally and still had the same shape. In all three patients, this was seen on x-ray during a routine visit one year after the valve was implanted. None of the patients had any symptoms because of the frame breaking and the valves and patients will continue to be monitored by their doctors. In two patients (3.9%), one of the two leaflets in the AUTUS valve had reduced movement. This was seen during a routine visit six months after the valve was implanted in one patient, and one year after the valve was implanted in the other patient. Testing of blood flow across the valve done in the doctor's office showed the valve was working properly but with a small amount of blood leaking through the valve. Neither patient had any symptoms because of the reduced movement in the leaflet and the valves and patients will continue to be monitored by their doctors.		

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	Other Serious Complications at 30 days, 6 months and 1 year related to the AUTUS valve were reviewed by an independent group of doctors and the results are shown below.			
		Risk per 100 patients at 30 days	Risk per 100 patients at 6 months	Risk per 100 patients at 1 year
	Death	0 out of 100	0 out of 100	0 out of 100
	Blood clot on valve	0 out of 100	0 out of 100	0 out of 100
	Blood clot in the body blocking blood flow	0 out of 100	0 out of 100	0 out of 100
	Other heart surgery or heart procedure needed (aside from related to the AUTUS valve)	0 out of 100	0 out of 100	3.8/100 (3.8%)
	Major bleeding	0 out of 100	0 out of 100	0 out of 100
	Infection of the valve	0 out of 100	0 out of 100	0 out of 100
	Damage to the red blood cells resulting in low blood count	0 out of 100	0 out of 100	0 out of 100
	Removal of the valve after surgery	0 out of 100	0 out of 100	1.9/100 (1.9%)*
	*for reasons not related to the valve			
Potential Adverse Events Page 13	As with any surgery, there are risks with the AUTUS valve and/or the implant procedure which vary in severity. The most serious risks, although rare, include heart attack, the shutting down of multiple organs and death. Other possible risks are listed below. The severity of these risks and how likely they are to. individual patients depend on several factors and should be discussed with your doctor. • Compression or clot in an artery that supplies the heart muscle • Bleeding: - surrounding the heart, lung, or another closed space - including at the time of or after procedure - medication-related • Damage to major blood vessels including separation of layers, creation of a hole, or tearing • Blood clot in artery or a deep vein such as in the leg that disrupts flow, including clot that started in a different location and traveled through the bloodstream • Allergic reaction • New heart valve not functioning properly - Leaking through the valve - Narrowing across the valve - Leaking around the valve - Damage to the valve components including the frame breaking - Reduced movement of the valve leaflets • Abnormal heart rhythms (slow or fast) • Blood pressure changes including very low or very high			

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	• Tear or hole created in esophagus which connects the mouth to the stomach • Stroke or brief, stroke-like symptoms • Kidney failure or kidneys not working as well after surgery • Infection of the / in the: - Heart valve - Blood - Lungs - Wound • Blood clot on or in the valve • Fluid or air surrounding lungs or heart preventing them from working properly • Fluid in lungs	
Potential Adverse Events Page 13	In addition to the risks above, the following list includes risks from the expansion of the AUTUS valve after it is first implanted. Similar to surgery, the severity of these risks and how likely they are to occur for individual patients depend on several factors and should be discussed with your doctor. • Creating a hole or tear in a major blood vessel or a heart chamber including the pathway between the right sided chamber and the blood vessel to the lungs • Kidney failure or kidneys not working as well immediately after the procedure including from the dye used • Allergic reaction to the dye used in the procedure This information is not a substitute for talking with your doctor.	
Implant Patient Registry	Implant patient registry	

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Page 14	Edwards Lifesciences maintains a registry of patients who have received Edwards implantable devices. Once you are enrolled in the registry, you will receive an identification card that should be kept with you at all times. The card includes information that may be helpful to medical team members when you seek care. It is important that the confidential information in the registry be kept up-to-date. If you have received Edwards implantable products, you should notify the registry if you move or change doctors. There is no charge for enrollment or updates to the registry. How to enroll or update your records To register with the Edwards implant patient registry or update your enrollment, please send an email with your name, address, phone number, and Edwards product information, including serial number, model number, implant date, implanting surgeon's name, hospital name, and city. The registry can be reached by: Phone Toll-free phone in the USA and Canada: 1.888.713.1564 Phone from outside the USA: 1.949.250. 2012 Mail Implant Patient Registry Edwards Lifesciences LLC P.O. Box 11150 Santa Ana, CA 92711-1150 USA Email patient_registry@edwards.com
Contact Information Page 15	Phone Toll-free phone in the USA and Canada: 1.888.713.1564 Phone from outside the USA: 1.949.250. 2012 Mail Edwards Lifesciences 1 Edwards Way Irvine, CA 92614 USA Email patient_support@edwards.com Online www.edwards.com Notes

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Important Risk Information Page 16	Important Risk Information AUTUS Size-Adjustable Valve Indications: The AUTUS valve is indicated for the management of pediatric patients weighing ≥ 10 kg who require surgical pulmonary valve replacement for dysfunctional native or surgically-repaired right ventricular outflow tract (RVOT), as determined by echocardiography to meet the following criteria: (1) severe pulmonary stenosis (i.e., right ventricle (RV) to pulmonary artery (PA) peak instantaneous gradient ≥ 60 mmHg); (2) $\geq$ moderate pulmonary regurgitation; or (3) $\geq$ moderate pulmonary stenosis (i.e., RV to PA peak instantaneous gradient ≥ 40 mmHg) and $\geq$ moderate pulmonary regurgitation. Contraindications (Who should not receive): The AUTUS valve should not be implanted in patients who have an active bacterial infection, any other active infection in the heart or body, or cannot tolerate anticoagulant or antiplatelet drugs (including aspirin). Potential Adverse Events: Allergic reaction; infection including the heart valve; blood cell rupture; blood clot in lung vessels; valve not functioning properly; leaking through the valve, narrowing across the valve, leaking around the valve, damage to the valve components including the frame breaking, reduced movement of valve leaflets; clotting of/around valve; bleeding; low blood count, abnormal clotting of blood, heart attack; heart rhythm disturbance; very low blood pressure; heart vessel narrowing; heart muscle not getting enough oxygen; clot or bleeding in brain; procedure site pain, swelling, or bruising; perforation or damage of a major blood vessel or a heart chamber; fluid around the heart; fluid around a lung; infection in a portion of the lung; kidneys not working normally or requiring dialysis; blood clot in an artery; perforation of a major blood vessel or heart chamber; radiation-induced skin redness, tearing of heart tissue. CAUTION: US law restricts this device to sale by or on the order of a physician.
References Page 16	1. Bauser-Heaton H, Barry OM, Hofferberth SC, et al. Challenges and priorities for children with congenital valvar heart disease. <i>JACC Adv.</i> 2024;3(10):101191. 2. Parker SE, Mai CT, Canfield MA, et al. Updated national birth prevalence estimates for selected birth defects in the United States, 2004–2006. <i>Birth Defects Res A Clin Mol Teratol.</i> 2010;88(12):1008-1016. doi:10.1002/bdra.20735 3. Mai CT, Isenburg JL, Canfield MA, et al. National population-based estimates for major birth defects, 2010–2014. <i>Birth Defects Research.</i> 2019;111(18):1420-1435. doi:10.1002/bdr2.1589 4. Pavlicek J, Klaskova E, Kapralova S, et al. Major heart defects: the diagnostic evaluations of first-year-olds. <i>BMC Pediatr.</i> 2021;21:528. doi:10.1186/s12887-021-02997-2

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Commercial Patient Implant Card - Draft

This person has an Autus Size-Adjustable Valve, pulmonary heart valve replacement.	
Autus Valve Technologies, Inc. 75 Arlington Street, 5th Floor, Boston, MA 02116 www.autusvalve.com	
Patient Name (First, Middle, Last) _____	
Implanting Facility Name _____	Implant Date _____
Implanting Physician _____	Physician Phone # _____
Place label sticker here	

MRI Safety Information	
 A patient with the Autus Size-Adjustable Valve may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.	
Name/Identification of the Device	Autus Size-Adjustable Valve
Nominal Value(s) of Static Magnetic Field [T]	3.0 T or 1.5 T
Maximum Spatial Field Gradient	20 T/m (2000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil or Extremity RF transmit-receive coil
Maximum Whole Body SAR [W/kg]	2 W/kg (Normal Operating Mode)
Limits on Scan Duration	60 Minutes
MR Image Artifact	The presence of this implant may produce an image artifact. In non-clinical testing, the image artifact caused by the device extends approximately 45 mm from the Autus Size-Adjustable Valve when imaged with a gradient echo pulse sequence and a 3.0 T MR system.
If information about a specific parameter is not included, there are no conditions associated with parameter	