

FDA Approves Growth-Adjustable Pulmonary Valve for Children With Congenital Heart Disease

The US Food and Drug Administration (FDA) has approved the Autus Size-Adjustable Valve (Edwards Lifesciences) for pediatric patients with congenital heart disease requiring surgical pulmonary valve replacement.

The novel valve features polymeric leaflets and is designed to accommodate growth in children. Initially implanted at a diameter of approximately 13 mm, the valve can be expanded to an adult-sized diameter of up to 22 mm through a minimally invasive transcatheter balloon dilation procedure.

The technology may reduce the need for repeated open-heart surgeries as children grow, offering a growth-adaptable approach to long-term pulmonary valve replacement.

The Autus Size-Adjustable Valve is the first heart valve designed to be expanded after surgery to keep pace with a child's growth, and the first valve approved in the U.S. to use polymeric material rather than animal-derived tissue for its inner flaps (called leaflets).

“For far too long, children with congenital heart defects who need pulmonary valve replacement have had very limited surgical options, and those options have historically required multiple open-heart surgeries as children grow,” said Acting FDA Commissioner Kyle Diamantas, J.D. “Today’s landmark approval is a historic turning point and reflects the Trump Administration and the FDA’s commitment to help bring innovative, life-changing devices to the patients who need them most.”

Congenital heart defects are among the most common types of birth defects in the United States, affecting about 1 in every 100 births. Among these conditions are pulmonary valve abnormalities — including pulmonary valve stenosis, in which the valve is narrowed, and pulmonary valve atresia, in which the valve fails to form normally — both of which restrict blood flow from the heart to the lungs. According to the Centers for Disease Control and Prevention, pulmonary valve atresia and stenosis together affect around 4,200 babies in the United States each year.

While treatment can improve blood flow and help repair these congenital defects, some children may be left with significant pulmonary regurgitation, or leakage of blood back through the pulmonary valve. Over time, this can weaken or enlarge the right ventricle and create a need for pulmonary valve replacement as the child grows.

“For children born with congenital heart disease, valve replacement timing has always been a difficult decision — wait too long and you risk harm to the child, but intervene too early and they may need multiple open-heart surgeries as they grow,” said Michelle Tarver, M.D., Ph.D., director of the FDA’s Center for Devices and Radiological Health. “The Autus Size-Adjustable Valve gives doctors the option of far fewer trips to the operating room, which may result in better quality of life for these children and their families.”

The Autus Size-Adjustable Valve can be initially implanted as small as approximately 13 millimeters in diameter — the right size for a toddler or preschool-aged child — and later widened using a small inflatable tube (balloon catheter) as the child grows, eventually reaching up to 22 millimeters, which is comparable to an adult-sized pulmonary valve.

In addition, the Autus Size-Adjustable Valve uses polymeric material for its leaflets — the flaps inside the valve that open and close to control blood flow. Traditional valves use tissue derived from animals, which tends to harden and break down faster in children, often requiring earlier repeat surgery. One-year follow-up data suggest the Autus valve's synthetic leaflets hold up well over time. This is the first time the FDA has approved a valve that uses polymeric leaflet material for any indication.

The FDA's approval is based on data from a clinical study, which enrolled 62 pediatric patients across 12 U.S. sites. At the six-month follow-up, the first 60 patients demonstrated acceptable hemodynamic performance, meaning blood flow through the right side of the heart was within acceptable limits, and there was no more than mild leakage back through the valve. All patients in the study had a successful procedure, with no deaths, blood clots requiring additional treatment, strokes or other clot-related complications. Three patients experienced a fracture in the valve frame and two patients had reduced movement of one of the valve leaflets (the flaps that open and close), but none of these events resulted in symptoms for the patients. Additionally, valve performance began deteriorating in two patients who started to outgrow it. Both patients had their valves successfully expanded without an invasive surgical procedure, but the experience is limited. Longer-term studies are being conducted to better understand these risks, and to collect more data to show that expansion can maintain a functional valve that may lead to fewer surgical procedures for patients.

The Autus Size-Adjustable Valve is the first pediatric approval to come out of the FDA's Total Product Life Cycle Advisory Program (TAP), a voluntary program for device developers intended to spur more rapid development of high-quality, safe, effective and innovative medical devices for all patients. The FDA previously granted the Autus Size-Adjustable Valve Breakthrough Device designation, which is meant to expedite the development and review of devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

The Autus Size-Adjustable Valve was approved through the premarket approval pathway, the FDA's most stringent type of medical device marketing application. The pathway is used for certain Class III devices, which generally pose the greatest risk. Before approving a device, the FDA reviews scientific evidence, including nonclinical and clinical data, to determine whether there is reasonable assurance that the device is safe and effective for its intended use and whether the benefits outweigh the known risks.

Edwards Lifesciences received approval for the Autus Size-Adjustable Valve, developed by Autus Valve Technologies Inc.

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