

# FDA approves mechanical heart valve for newborns

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approved for years, there is an unmet need in young pediatric patients, especially newborns and infants, with congenital [valve](#) defects who may be too small to use currently-marketed [heart](#) valves," Jeff Shuren, M.D., director of the FDA's Center for Devices and Radiological Health, said in a statement.

The Masters Series Mechanical Heart Valve is made by St. Jude Medical, based in St. Paul, Minn.

**More information:** [More Information](#)

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(HealthDay)—The U.S. Food and Drug Administration has approved the world's smallest mechanical heart valve, designed to be used in newborns and other young infants with heart defects.

In a news release Tuesday, the agency said it approved a 15-mm version of the Masters Series Mechanical Heart Valve with Hemodynamic Plus Sewing Cuff. This mechanical heart valve was first approved in 1995 for patients with diseased, damaged, or malfunctioning aortic or mitral [heart valves](#). Approval of the smaller size valve was based on a clinical study of 20 infants ranging in age from 1.5 weeks to 27 months.

Potential valve-related adverse reactions could include blood clots in the device and bleeding in the brain. The valve should not be used in patients who cannot tolerate anticoagulation therapy, the FDA said.

"While larger replacement heart valves have been

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