

Abbott Receives FDA Approval For First And Only Device In The U.S. To Treat Leaks After Heart Valve Replacement Without Additional Surgery

- Amplatzer™ Paraclose PVL Occluder is a minimally invasive device for paravalvular leak (PVL) closure that offers patients an alternative to repeat open-heart surgery
- PVL is a backflow of blood that can commonly occur around a replacement heart valve

ABBOTT PARK, Ill., Oct. 28, 2026 — Abbott, the global healthcare leader, announced today it has received U.S. Food and Drug Administration (FDA) approval for the Amplatzer™ Paraclose PVL Occluder, the first and only transcatheter device approved in the U.S. that is specifically designed to treat paravalvular leak (PVL), a backflow of blood around a surgical heart valve.

When diseased or damaged heart valves can't be repaired, they may be replaced with either mechanical or tissue valves in an open-heart surgical procedure. Following heart surgery, sometimes a small gap between the native heart tissue and replacement valve can remain or develop over time and lead to PVL. These blood leaks occur in 7% to 17% of mitral valve replacements and 5% to 10% of aortic valve replacements.¹ PVL can lead to symptoms associated with heart failure, including shortness of breath, fatigue and swelling of the legs and feet. It can also result in hemolysis, a condition where red blood cells are damaged, causing severe anemia. Implanted through a catheter that is inserted through an artery or vein in the leg, the Amplatzer Paraclose device offers patients a minimally invasive treatment option to address PVL without requiring another surgery.

"The U.S. approval of the Amplatzer Paraclose PVL Occluder addresses a significant treatment gap for people suffering from a paravalvular leak," said Amar Krishnaswamy, M.D., section head of Invasive & Interventional Cardiology in the Robert and Suzanne Tomisch Department of Cardiovascular Medicine, Sydell and Arnold Miller Family Heart, Vascular & Thoracic Institute at the Cleveland Clinic. "Its unique elliptical shape is specifically designed to effectively close a wide range of PVL shapes and sizes that allows many patients to avoid another cardiac surgery."

Designed for the unique challenges of PVL closure

Delivered through an artery or vein in the leg, the Amplatzer Paraclose device has an oblong shape and unique design features to enable effective closure across diverse PVL anatomies.

PARADIGM study data reinforces Paraclose's safety and effectiveness

FDA approval for the Amplatzer Paraclose PVL Occluder was supported by positive clinical data from the PARADIGM study, a prospective, multicenter, single arm study that includes 200 patients, demonstrating that Amplatzer Paraclose provides an effective, minimally invasive alternative to open-heart reoperation.

"Offering this purpose-built device fills a critical unmet need as physicians treating PVL in the U.S. previously didn't have an approved alternative to repeat open-heart surgery," said Sandra Lesenfants, senior vice president of Abbott's structural heart business. "The Amplatzer Paraclose PVL Occluder builds upon Abbott's minimally invasive portfolio of structural heart devices that allows people with cardiovascular conditions to be effectively treated without the risk of surgical complications."

Frequently Asked Questions:

What is the Amplatzer Paraclose PVL Occluder?

The Amplatzer Paraclose PVL Occluder is the first and only minimally invasive device approved in the U.S. that is designed to close PVL around surgical replacement heart valves.

What is a paravalvular leak (PVL)?

After heart valve replacement surgery, sometimes a small gap can remain or develop between the natural heart tissue and replacement valve. Blood leaking through this gap is known as a PVL.

How does the Amplatzer Paraclose PVL Occluder work?

The Amplatzer Paraclose PVL Occluder is implanted through a catheter that is inserted through an artery or vein in the leg. The device is positioned within the PVL to close the leak.

How is the Amplatzer Paraclose PVL Occluder different from other Amplatzer devices?

The Amplatzer portfolio of devices, including the Amplatzer Piccolo™ Occluder and Amplatzer Talisman™ PFO Occluder, provides minimally invasive treatment options for the closure of congenital heart defects and for stroke risk reduction. The Amplatzer Paraclose PVL Occluder is designed to treat PVL, a backflow of blood around a surgical heart valve. Outside of the U.S., the Amplatzer Paraclose PVL Occluder is known as the Amplatzer Valvular Plug III, which has been approved to treat PVL in Europe since 2020.

For U.S. important safety information on the Amplatzer Paraclose PVL Occluder, visit <https://abbo.tt/ParacloseISI>.

For U.S. important safety information on the Amplatzer Piccolo Occluder, visit <https://abbo.tt/PiccoloISI>.

For U.S. important safety information on the Amplatzer Talisman PFO Occluder, visit <https://abbo.tt/AmplatzerTalismanISI>.

About Abbott:

Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing

technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 122,000 colleagues serve people in more than 160 countries.

Connect with us at www.abbott.com and on [LinkedIn](#), [Facebook](#), [Instagram](#), [X](#) and [YouTube](#).

¹Davidavicius G, Rucinskas K, Drasutiene A, et al. Hybrid approach for transcatheter paravalvular leak closure of mitral prosthesis in high-risk patients through transapical access. J Thorac Cardiovasc Surg. 2014;148(5):1965-1969.

For further information: Abbott Media: Cynthia Kong, (669) 400-6879, Abbott Financial: Mike Comilla, (224) 668-1872
