

Abbott Receives FDA Approval For Next-Generation MitraClip® Device To Treat People With Leaky Heart Valves

- Innovations designed to allow doctors to treat more types of cases and anatomies
- MitraClip is the gold-standard minimally invasive alternative to open-heart surgery for people needing mitral valve repair
- Mitral regurgitation, the most common heart valve disease, affects one in 10 adults over 75

ABBOTT PARK, Ill., July 12, 2018 /PRNewswire/ -- Abbott (NYSE: ABT) today announced it received approval from the U.S. Food and Drug Administration (FDA) for a next-generation version of its leading MitraClip® heart valve repair device used to repair a leaky mitral valve without open-heart surgery. The transcatheter clip-based therapy, now on a third generation of product innovations, has been used to treat more than 65,000 patients worldwide over the last ten years.

The next-generation MitraClip system provides cardiologists with advanced steering, navigation, and positioning capabilities for the clip, making it easier to use in difficult anatomies. The enhanced system is designed to allow for more precise placement during deployment, resulting in more predictable procedures, and additionally offers a second clip size with longer arms that expands the reach of the clip-based device. The additional clip size is designed to help doctors treat patients who have more complex anatomies when repairing the mitral valve.

Abbott received CE Mark for the next-generation device earlier this year, allowing for sale of the devices in the European Union and other countries that recognize this regulatory designation.

"Physicians rely on MitraClip as an alternative to surgery for patients who aren't surgical candidates and may need treatment to relieve their symptoms or to survive," said Francesco Maisano, M.D., Prof., UniversitätsSpital Zürich, Switzerland, who was an early implanter of MitraClip. "The enhanced MitraClip design allows for even more precise navigation, accuracy, and stability during valve repairs, which may be important when treating people with more complex or advanced valve disease."

A leaking mitral valve, known as mitral regurgitation (MR) is a serious, progressive heart disease in which the flaps of the mitral valve do not close properly, allowing blood to flow backward into the heart. Incidence of mitral regurgitation increases with age, with nearly one in 10 people over the age of 75 having moderate to severe disease¹. Before MitraClip, people who were not eligible for the standard-of-care surgery to treat their MR could only manage their symptoms with medications that don't stop the progression of the disease. Left untreated, MR leads to a variety of life-altering symptoms and severe complications, and may ultimately lead to heart failure and death.^{1,2,3}

"Abbott engineers designed these enhancements based on feedback from doctors to improve device delivery and to treat more types of cases and anatomies," said Michael Dale, vice president for Abbott's structural heart business. "We're committed to helping people with mitral regurgitation return to living their best lives, and these advances will enable doctors to treat even more patients without surgery."

MitraClip treats people with degenerative mitral regurgitation and is a therapy that is delivered via a catheter to the heart through a blood vessel in the leg. MR patients are often not eligible for the standard-of-care surgery because of advanced age, frailty, multiple comorbidities or other complicating factors and the therapy offers a minimally invasive alternative. Treatment with MitraClip provides almost immediate symptom relief and patients are released from the hospital on average after two days.

Abbott recently began enrollment in the MitraClip EXPAND clinical study, a prospective study evaluating the safety and performance of the new MitraClip system in a contemporary real-world setting. Saibal Kar, M.D., director of Interventional Cardiac Research at the Smidt Heart Institute at Cedars-Sinai in Los Angeles, Calif., treated the first patient enrolled, and is the lead investigator of the study. EXPAND will enroll approximately 1,000 patients in more than 50 centers across the U.S. and Europe and interim results from the study are expected later this year.

About MitraClip

MitraClip received initial CE Mark approval in Europe in 2008 and was approved by the FDA in 2013. By securing a portion of the leaflets of the mitral valve with an implanted clip, the heart can pump blood more efficiently throughout the body, thereby relieving the symptoms of severe MR and improving patient quality of life.⁴

For U.S. Important Safety Information on MitraClip, visit <http://mitraclippossibilities.com/#isi-sec>.

About Abbott

At Abbott, we're committed to helping people live their best possible life through the power of health. For more than 125 years, we've brought new products and technologies to the world -- in nutrition, diagnostics, medical devices and branded generic pharmaceuticals -- that create more possibilities for more people at all stages of life. Today, 99,000 of us are working to help people live not just longer, but better, in the more than 150 countries we serve.

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¹ Healthline.com. Mitral Valve Disease. 2016. Accessed April 10, 2018 at: <http://www.healthline.com/health/mitral-valve-disease>.

² Patient Info. Mitral Regurgitation. 2017. Accessed April 10, 2018 at: <https://patient.info/health/mitral-regurgitation-leaflet>.

³ National Heart, Lung and Blood Institute. What is Heart Valve Disease? 2015. Accessed April 10, 2018 at: <https://www.nhlbi.nih.gov/health/health-topics/topics/hvd>.

⁴ <http://eifu.abbottvascular.com/content/dam/av/eifu-us/EL2106481%20Rev.%20A%202016-04-28.pdf>

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