

Abbott's MitraClip Therapy Receives National Reimbursement In Japan To Treat Patients With Mitral Regurgitation

- National reimbursement adds the device into Japan's health insurance system, which enables greater access for patients
- MitraClip is a first-of-its-kind transcatheter mitral valve repair device that provides physicians with a minimally invasive way to repair leaky heart valves in people for whom surgery is too risky

ABBOTT PARK, Ill., March 19, 2018 /PRNewswire/ -- Abbott (NYSE: ABT) today announced that the Ministry of Health Labour and Welfare (MHLW) in Japan granted national reimbursement for the company's MitraClip therapy to treat people with mitral regurgitation, a serious, progressive heart disease in which the mitral valve does not close properly, allowing blood to flow backward into the heart.

Mitral regurgitation causes many life-altering symptoms and – if left untreated – can ultimately lead to heart failure and death.^{1,2,3} Most people affected are elderly because incidence increases with age.⁴

Reimbursement, which will be in effect in Japan beginning April 1, 2018, is important to local physicians and patients because it makes the therapy more accessible for people through the country's health insurance plans.

Prior to the regulatory approval of the MitraClip system in Japan in 2017, the standard-of-care treatments for patients with mitral regurgitation in Japan were open-heart surgery and medication. For some patients, surgery is not a viable option because of comorbidities or advanced age, an increasing concern in Japan. Medications typically only mask symptoms, instead of treating the underlying issue of the valve itself.

The MitraClip system is approved in Japan for the treatment of both severe degenerative mitral regurgitation (DMR) and functional mitral regurgitation (FMR) heart diseases.

"Our mission is to develop technologies and therapies that help people return to better health and quality-of-life as quickly as possible," said Michael Dale, vice president for Abbott's structural heart business. "With this reimbursement in Japan, we can help more people live better by reducing the severity of an extremely life-altering illness in a safe and predictable way."⁵

The MitraClip system is a catheter-based, minimally invasive therapy that is delivered to the heart through a blood vessel in the leg. 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.⁵

MitraClip received CE mark approval in Europe in 2008 and was approved by the U.S. Food & Drug Administration (FDA) in 2013. To date, more than 50,000 people have been treated with the MitraClip system in nearly 50 countries.

About Degenerative and Functional Mitral Regurgitation:

Degenerative mitral regurgitation (DMR) is caused by abnormality of valve structures including the valve leaflets, valve ring, and chordae tendineae. Functional mitral regurgitation (FMR) is a disease that occurs when the left ventricle of the heart dilates, leading to incomplete coaptation of the mitral valve.

For U.S. Important Safety Information, visit <https://mitraclip.com/#isi>.

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 Sep 7, 2017 at <http://www.healthline.com/health/mitral-valve-disease>.

² Patient Info. Mitral Regurgitation. 2017. Accessed Sep 7, 2017 at: <https://patient.info/health/mitral-regurgitation-leaflet>.

³ National Heart, Lung and Blood Institute. What is Heart Valve Disease? 2015. Accessed Sep 7, 2017 at: <https://www.nhlbi.nih.gov/health/health-topics/topics/hvd>.

⁴ Nkomo VT, Gardin JM, Skelton TN, Gottdiener JS, Scott CG, Enriquez-Sarano M. Burden of Valvular Heart Diseases: a Population-based Study. Lancet. 2006 Sep 16;368(9540):1005-11. <http://www.ncbi.nlm.nih.gov/pubmed/16980116>

⁵ <http://eifu.abbottvascular.com/content/dam/av/eifu-us/EL2106481%20Rev.%20A%202016-04-28.pdf>

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For further information: Abbott Media: Mary Kokkinen, (408) 845-0808; Abbott Financial: Mike Comilla, (224) 668-1872