

Abbott gets FDA consent for Next-Gen MitraClip Device

13 July 2018 | News

MitraClip is the gold-standard minimally invasive alternative to open-heart surgery for people needing mitral valve repair



Abbott has 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 the 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.

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. 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.