Abbott Initiates Clinical Study To Show Outcomes For Real-World Use Of TriClip™ In Repairing Leaky Tricuspid Heart Valve

- TREAT TR study is designed to generate additional clinical data to confirm the safety and performance of TriClip for people with tricuspid regurgitation (TR)
- Abbott's TriClip offers a minimally invasive treatment option for patients in need of tricuspid valve repair but who are unable to withstand surgery

ABBOTT PARK, Ill., July 28, 2026 — Abbott announced today it has initiated the TREAT TR study, a post-market study of the company's first-of-its-kind TriClip™ transcatheter edge-to-edge repair (TEER) system that's specifically designed for the treatment of tricuspid regurgitation (TR), or a leaky tricuspid valve. The study is designed to evaluate the safety and performance of TriClip in a real-world setting and build on the body of clinical evidence that has established the system's benefits for people with TR. The first enrollment in the TREAT TR study occurred at Hospital Clínic de Barcelona in Spain, led by Xavier Freixa, M.D., and his cardiac team.

The prospective study will enroll approximately 1,000 people at up to 100 sites in the U.S., Canada and Europe. Patients will be followed for five years with check-ins at discharge, 30 days, six months and one year, and then once annually for the remaining four years. A select group of patients will also be enrolled in a sub-study that will evaluate the potential for the TriClip system to reverse cardiac remodeling, which are changes in the structure of the heart that occur when it is injured or subjected to chronic overload.

"Prior to TriClip's availability, many patients with tricuspid regurgitation had few treatment options because medical therapy didn't relieve their symptoms or they were at an increased risk for conventional open-heart surgery," said Anita Asgar, M.D., section head of interventional cardiology and medical director for the Bluhm Cardiovascular Institute, Structural Heart Program at Northwestern Medicine in Chicago, Ill. and co-principal investigator of the TREAT TR study. "Through multiple clinical studies and in working directly with patients, we've seen that TriClip can have a profound impact on the lives of people with TR, and we're excited to see additional evidence to support this minimally invasive device."

Treating tricuspid regurgitation (TR)

The tricuspid valve controls blood as it flows from the heart's right atrium to the right ventricle. TR occurs when the valve doesn't close properly, causing a leak and allowing blood to flow backward through the valve. TR can force the heart to work harder, leading to debilitating symptoms such as fatigue and shortness of breath. When left untreated, TR can lead to atrial fibrillation, heart failure, and ultimately, death. TriClip represents an option that can improve quality of life for people who continue to have symptoms of persistent TR despite medical intervention and are not considered good candidates for surgery.

TriClip's TEER technology is delivered through a vein in the leg, allowing people to avoid open-heart surgery. It works by clipping together leaflets – or flaps of tissue – to repair the tricuspid valve, helping restore proper blood flow. On average, people who receive TriClip only need one day in the hospital after the procedure before they can return home.

Data support TriClip benefits

TriClip's benefits have been evaluated in several studies, including theTRILUMINATE Pivotal trial, which showed the system safely and effectively reduced TR and heart failure hospitalization while improving quality of life. The study supported U.S. Food and Drug Administration (FDA) approval of the system.

Additional real-world data evaluating the TriClip system were presented in June 2026 at the New York Valves conference. The study, which included 3,035 patients from the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry across 278 U.S. sites, demonstrated outcomes consistent with the TRILUMINATE Pivotal trial with patients achieving significant reduction in TR while improving their quality of life.

"Clinical studies have continued to reinforce the benefits of repairing the tricuspid valve with TriClip and the significant improvements that it brings to people's daily lives, including reducing the rate of hospitalizations due to heart failure," said Lars Sondergaard, M.D., chief medical officer of Abbott's structural heart business. "We believe the TREAT TR study will further confirm TriClip's exceptional safety profile and effectiveness in reducing tricuspid regurgitation across a diverse range of patients and locations."

Frequently Asked Questions:

What is tricuspid regurgitation (TR)?

TR occurs when the tricuspid valve doesn't close properly, causing a leak and allowing blood to flow backward in the heart. TR can force the heart to work harder, leading to debilitating symptoms such as fatigue and shortness of breath. When left untreated, TR can lead to atrial fibrillation, heart failure, and ultimately, death.

How does the TriClip system help treat TR?

TriClip's TEER technology works by clipping together leaflets – or flaps of tissue – to repair the tricuspid valve and help blood flow in the right direction without the need for open-heart surgery.

What is the purpose of the TREAT TR study?

TREAT TR is a prospective, observational, single-arm, multicenter post-market study designed to evaluate the safety and performance of the TriClip system in a real-world setting. It will build on existing clinical data that has established the system's advantages for people who suffer from TR.

About TriClip:

TriClip is a non-surgical treatment option for repairing the tricuspid valve. TriClip has been approved for use in more than 50 countries, including in the U.S., Canada and Europe, since its initial CE Mark approval in 2020. The device has already been used to treat more than 15,000 people with TR.

For U.S. important safety information on TriClip, visit https://abbo.tt/TriClip_ISI.

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.

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