

TriClip™ G4 System

Category:

Best Medical Technology

Company Name:

Abbott

Product/Solution Name:

TriClip™ G4 System

Compound/Tech Name:

TriClip™ G4 System

Trade Name:

TriClip™ G4 System

Corporate Name:

Abbott

Date of Approval:

2024-04-02

Indications:

Abbott's TriClip™ transcatheter edge-to-edge repair system is a first-of-its-kind, minimally invasive clip-based device that is specifically designed for the tricuspid valve, which has long been considered the forgotten valve with limited treatment options outside of open-heart surgery.

A leaky tricuspid valve, or tricuspid regurgitation (TR), is a condition in which the valve between the two right heart chambers (right ventricle and right atrium) doesn't close properly, resulting in blood flowing backward into the right atrium of the heart, which can reduce the amount of blood reaching the lungs and lead to heart failure. This progressive and often-debilitating condition can lead to symptoms such as fatigue, shortness of breath and abdominal discomfort - all of which can impair daily activities and overall quality of life.

People with TR are typically older individuals with multiple comorbidities who are considered high risk for traditional surgical repair (open-heart surgery) or valve replacement. With comorbidities and the tricuspid valve's complex anatomy front of mind, Abbott created TriClip to serve as an additional non-surgical treatment option that works by clipping together a portion of the leaflets of the tricuspid valve to reduce the backflow of blood.

Through its FDA approval in April 2024, TriClip represents the first and only non-surgical repair option for patients with severe TR who are not responding to traditional medical therapies and are not surgical candidates - a distinction that earned it a breakthrough device designation from the U.S. FDA in November 2020.

Therapeutic Areas:

Globally, TR affects over 70 million people, with more than 1.6 million of those people living in the U.S. Despite its prevalence, TR is still undertreated. If left untreated, there can be substantial consequences, such as developing other conditions like atrial fibrillation and heart failure that can ultimately, result in death.

TriClip redefines the treatment landscape by serving as a non-surgical option for people who may have once thought there wasn't a path forward for them following their diagnosis. With this device, patients experience reduced regurgitation and improved blood flow, helping them achieve meaningful improvements in their symptoms, mobility and quality of life.

The proven and scalable platform of TriClip represents a significant step forward in improving outcomes for this patient population who may have been overlooked in the past due to their age and/or comorbidities.

General Information File Document upload:

[**IFU TriClip G4 System_FDA.pdf**](#)
[**TriClipG4ISI.pdf**](#)

Background information and need for drug / device:

Tricuspid regurgitation is one of the most common manifestations of valvular heart disease, yet it remains one of the most underdiagnosed and undertreated. While often secondary to mitral regurgitation and atrial fibrillation, the burden of TR is substantial, affecting up to 85% of individuals over the age of 50 and approximately 1 in 30 people over the age of 65 suffering from significant TR. Before TriClip the options were medical therapy and surgical treatment, both of which had substantial issues. Surgery was often considered too high risk for patients, so medical therapy had long been used as the go-to treatment option. Long-term findings, though, showed medical therapy offered

little efficacy in reducing TR severity, with over 90% of patients experiencing no meaningful improvements at one year.

Abbott saw there was a critical unmet need for a safe, effective and minimally invasive therapy for people with TR who were not candidates for surgery and weren't finding success with medical therapy. TriClip fills that void by offering a catheter-based therapy that directly addresses the root cause of TR and is backed by clinical evidence demonstrating significant reductions in regurgitation, improved quality of life and a favorable safety profile. By transforming care for this patient population, TriClip has redefined what's possible in the disease management of TR.

Background File Document upload:

[**TriClipG4ISI.pdf**](#)

[**IFU TriClip G4 System_FDA.pdf**](#)

History of the development of the solution/product:

The development of Abbott's TriClip system builds on the success of the company's MitraClip™ clip-based repair system for mitral regurgitation (also known as MR, a leaky mitral valve on the left side of the heart), a recipient of the Prix Galien USA Award for Best Medical Technology in 2020. Abbott saw how MitraClip transformed the treatment of MR globally, and wanted to apply key learnings from the device to address the unmet needs in TR.

Early off-label use of MitraClip in the tricuspid position suggested feasibility, but there were still some challenges given the complex anatomy and three-leaflet design of the tricuspid valve. With these insights in hand, Abbott designed TriClip with specific modifications for navigating the right side of the heart and precise leaflet grasping, ultimately changing the course for how physicians approached TR treatment.

The approval of TriClip was supported by robust clinical findings primarily from the TRILUMINATE™ Pivotal trial, the world's first randomized, controlled clinical study evaluating the safety and effectiveness of TEER with the TriClip system compared to medical therapy in people with severe TR. Results demonstrated that Abbott's TriClip offers people with severe or higher TR considerable benefits, including significant and sustained improvements in the severity of their TR and their quality of life with a positive safety profile - all of which help secure FDA approval for the device in April 2024.

TriClip reflects the evolution of Abbott's pioneering platform with multiple clip sizes, enhanced steerability and optimized delivery for precision placement and underscores the power of clinician collaboration, innovative engineering, and rigorous clinical studies in finding life-changing treatment options.

To learn and see more about Abbott's TriClip approval, please visit <https://www.multivu.com/players/English/9255151-abbott-receives-fda-approval-for-triclip-device-to-repair-leaky-tricuspid-heart-valve/>

Development File Document upload:

[FINAL_Abbott SH TRILUMINATE 2year outcomes Press Release.pdf](#)

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

TriClip is the first and only minimally invasive device specifically designed for tricuspid valve repair offering an important alternative to open-heart surgery for patients with TR. Until recently, people with TR who weren't considered candidates for open-heart surgery were left with only symptom-focused medical therapy, which couldn't address their underlying valve dysfunction. By offering a tailored, catheter-based solution for the complex anatomy of the tricuspid valve, TriClip represents a new standard of care for a patient population that had long been underserved.

The patient impact that TriClip has had can be seen through the journey of Gregory, a Vietnam veteran and retired member of the U.S. Air Force. Once debilitated by TR, Gregory experienced symptoms that turned everyday tasks into challenges. He wasn't able to walk across the room, tie his shoe or even enjoy a meal without being reminded of the discomfort of his condition. And like so many other people, open-heart surgery wasn't an option for him, leaving him with no clear path forward.

After receiving TriClip and spending one day in the hospital, Gregory was able to return home and resume the activities he loved. He was back to practicing Tai Chi, playing golf and traveling with his family - all the things that made him feel like he got his life back. His story is just one of many that show TriClip doesn't just repair the tricuspid valve, it restores quality of life, independence and dignity.

The broader implications of TriClip's success are equally meaningful and shed light on how one device can change the course of treatment for people all over the world and redefines what's possible and structural heart therapy.

Innovation File Document upload:

N/A

Please provide appropriate references (PubMed, Abstract, Website):

References:

- Kolte, Dhaval & Elmariah, Sammy. (2020). Current state of transcatheter tricuspid valve repair. Cardiovascular Diagnosis and Therapy. 10. 89-97. 10.21037/cdt.2019.09.11.
- Sorajja, P. et al. (2023). Transcatheter repair for patients with tricuspid regurgitation. New England Journal of Medicine, 388(20), 1833-1842. doi: 10.1056/NEJMoa2300525
- Kar, S., Makkar, R. R. et al. Two-year outcomes of transcatheter edge-to-edge repair for severe tricuspid regurgitation: The Triluminate Pivotal Randomized Controlled Trial. Circulation, 151(23), 1630-1638. <https://doi.org/10.1161/circulationaha.125.074536>

Additional Resources:

- (Multichannel News Release) Abbott Receives FDA Approval for TriClip™, First-Of-Its-Kind Device to Repair Leaky Tricuspid Heart Valve (<https://www.multivu.com/players/English/9255151-abbott-receives-fda-approval-for-triclip-device-to-repair-leaky-tricuspid-heart-valve/>)
- (Press Release) FDA Advisory Committee Votes in Favor of Abbott's First-Of-Its-Kind TriClip™ System to Treat People with a Leaky Tricuspid Heart Valve (<http://abbott.mediaroom.com/2024-02-13-FDA-Advisory-Committee-Votes-in-Favor-of-Abbotts-First-of-Its-Kind-TriClip-TM-System-to-Treat-People-With-a-Leaky-Tricuspid-Heart-Valve>)
- (Press Release) New Late-Breaking Data Reinforce Benefits of Abbott's TriClip for People with Leaky Tricuspid Heart Valve (<https://abbott.mediaroom.com/2025-03-31-New-Late-Breaking-Data-Reinforce-Benefits-of-Abbotts-TriClip-TM-for-People-With-Leaky-Tricuspid-Heart-Valve>)

Videos:

- (Gregory Media Interview with NBC Bay Area) A New Technology for Americans with Heart Defect (<https://www.nbcbayarea.com/news/health/new-technology-americans-heart-defect/3655841/>)
- (TriClip Video) TriClip G4 TEER: Tricuspid Valve Repair for Improved Patient Outcomes (https://www.youtube.com/watch?v=_Non_xG1Rkw)

References File Document upload:

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