

The Texas Heart Institute Implants BiVACOR® Total Artificial Heart

First-in-human novel valveless artificial heart implanted in a patient with end-stage heart failure as a bridge to heart transplant

Houston, Texas, July 25, 2024 – [The Texas Heart Institute \(THI\)](#) and [BiVACOR®](#), a clinical-stage medical device company, announced today the successful first-in-human implantation of the BiVACOR Total Artificial Heart (TAH) as part of the [U.S. Food and Drug Administration \(FDA\) Early Feasibility Study \(EFS\) on July 9, 2024](#). BiVACOR's TAH is a titanium-constructed biventricular rotary blood pump with a single moving part that utilizes a magnetically levitated rotor that pumps the blood and replaces both ventricles of a failing heart.

The first-in-human clinical study aims to evaluate the safety and performance of the BiVACOR TAH as a bridge-to-transplant solution for patients with severe biventricular heart failure or univentricular heart failure in which left ventricular assist device support is not recommended. Following this first implantation completed at Baylor St. Luke's Medical Center in the Texas Medical Center, four additional patients are to be enrolled in the study.

"The Texas Heart Institute is enthused about the groundbreaking first implantation of BiVACOR's TAH. With heart failure remaining a leading cause of mortality globally, the BiVACOR TAH offers a beacon of hope for countless patients awaiting a heart transplant," said Dr. Joseph Rogers, President and Chief Executive Officer of The Texas Heart Institute and National Principal Investigator on the research. "We are proud to be at the forefront of this medical breakthrough, working alongside the dedicated teams at BiVACOR, Baylor College of Medicine, and Baylor St. Luke's Medical Center to transform the future of heart failure therapy for this vulnerable population."

Daniel Timms, PhD, Founder and Chief Technology Officer of BiVACOR said, "I'm incredibly proud to witness the successful first-in-human implant of our TAH. This achievement would not have been possible without the courage of our first patient and their family, the dedication of our team, and our expert collaborators at The Texas Heart Institute. Utilizing advanced MAGLEV technology, our TAH brings us one step closer to providing a desperately needed option for people with end-stage heart failure who require support while waiting for a heart transplant. I look forward to continuing the next phase of our clinical trial."

Heart failure is a global epidemic affecting at least [26 million people worldwide](#), [6.2 million adults in the U.S.](#), and is increasing in prevalence. Heart transplantations are reserved for those with severe heart failure and are limited to [fewer than 6,000 procedures per year globally](#). Consequently, the U.S. National Institutes of Health estimated that up to [100,000 patients could immediately benefit](#) from mechanical circulatory support (MCS), and the European market is similarly sized.

The successful implantation of BiVACOR's TAH highlights the potential of innovative technologies to address critical challenges in cardiac care, such as long transplantation waitlists. BiVACOR and The Texas Heart Institute remain committed to advancing the field of cardiac medicine and improving outcomes for patients worldwide.

About the BiVACOR Total Artificial Heart

The BiVACOR TAH represents a paradigm shift in artificial heart design. The size of the BiVACOR TAH is suitable for most men and women (Body Surface Area >1.4 m²). Despite its small size, the BiVACOR TAH is capable of providing enough cardiac output for an adult male undergoing exercise. Using magnetic levitation technology, the same principle used in high-speed trains, the product features a unique pump design with a single moving part: a

magnetically suspended dual-sided rotor with left and right vanes positioned within two separate pump chambers, forming a double-sided centrifugal impeller that propels blood from the respective pump chambers to the pulmonary (lung) and systemic (body) circulations. The TAH has no valves or flexing ventricle chambers, with MAGLEV making pulsatile outflow possible by rapidly cycling the pump's rotor. The non-contact suspension of the rotor via MAGLEV is designed to eliminate the potential for mechanical wear and provide large blood gaps that minimize blood trauma, offering a durable, reliable, and biocompatible heart replacement.

About BiVACOR®

[BiVACOR®](#) is a clinical-stage medical device company pioneering the development of a long-term therapy for patients with biventricular heart failure. Under the expert direction of its founder and TAH inventor, Daniel Timms, PhD, and the guidance of two luminaries in cardiovascular surgery, William E. Cohn, MD, and O.H. (Bud) Frazier, MD, the BiVACOR TAH is currently undergoing an FDA-approved first-in-human EFS. Headquartered in Huntington Beach, California, with clinical offices in Houston, Texas, and international offices in Gold Coast, Australia, BiVACOR is committed to addressing the global unmet need of patients with end-stage heart failure awaiting transplant by providing the next generation of life-extending solutions. For more information, visit bivacor.com.

About The Texas Heart Institute®

[The Texas Heart Institute](#) (THI) is an independent, nonprofit organization with the mission of improving cardiovascular health today through trailblazing research, thought leadership, education, and patient care. Located within the Texas Medical Center in Houston, Texas, and founded in 1962 by renowned cardiac surgeon Dr. Denton Cooley, THI performed the first successful heart transplant and total artificial heart implant in the United States. Since then, its physicians and surgeons have remained recognized as worldwide leaders in diagnosing and treating even the most complex cardiovascular conditions. Research programs at THI continue pushing cardiovascular science's boundaries by translating laboratory discovery into patient care. THI has been ranked among the top cardiovascular centers in the United States by US News & World Report for over 30 years. The Texas Heart Institute has an equity ownership interest in BiVACOR. www.texasheart.org [@texasheartinstitute](#)

About Baylor St. Luke's Medical Center

[Baylor St. Luke's Medical Center](#) is an 881-bed quaternary care academic medical center that is a joint venture between Baylor College of Medicine and St. Luke's Health. Located in the Texas Medical Center, the hospital is the home of the Texas Heart Institute, a cardiovascular research and education institution founded in 1962 by Denton A. Cooley, MD. The hospital was the first facility in Texas and the Southwest designated a Magnet hospital for Nursing Excellence by the American Nurses Credentialing Center, receiving the award four consecutive times. Baylor St. Luke's also has three community emergency centers offering adult and pediatric care for the Greater Houston area.

Baylor College of Medicine

[Baylor College of Medicine](#) (www.bcm.edu) in Houston is recognized as a health sciences university and is known for excellence in education, research and patient care. Baylor is a top-ranked medical school and listed 20th among all U.S. medical schools for National Institutes of Health funding and No. 1 in Texas. Located in the Texas Medical Center, Baylor has affiliations

with seven teaching hospitals and jointly owns and operates Baylor St. Luke's Medical Center, part of St. Luke's Health. Currently, Baylor has more than 3,000 trainees in medical, graduate, nurse anesthesia, physician assistant, orthotics and genetic counseling as well as residents and postdoctoral fellows. Follow Baylor College of Medicine on Facebook (<http://www.facebook.com/BaylorCollegeOfMedicine>) and Twitter (<http://twitter.com/BCMHouston>).

About Texas Medical Center

[Texas Medical Center](#) — the largest medical city globally—is at the forefront of advancing life sciences. Home to the brightest minds in medicine, TMC nurtures cross-institutional collaboration, creativity, and innovation among its 106,000-plus employees. With a campus of more than 50 million square feet, TMC annually hosts 10 million patients, performs over 180,000 surgeries, conducts over 750,000 ER visits, serves close to 14,000 heart surgeries, and delivers over 25,000 babies. Beyond patient care, TMC is pushing the boundaries of clinical research across its extensive network of partner institutions daily, pioneering effective health policy solutions to address today's complex health care issues, and cultivating cutting-edge digital health applications and medical devices.

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