BiVACOR Total Artificial Heart Successfully Implanted in First Patient in Australia; TAH in Place Over 100 Days

Australia's first TAH implant was an unmitigated clinical success. The first patient in the world discharged with the BiVACOR TAH, supporting the longest in-patient use as a bridge to heart transplant.

Huntington Beach, CA / Gold Coast, Australia (March 12, 2025) – BiVACOR, a clinical-stage medical device company, announced today the first successful implantation of the BiVACOR Total Artificial Heart (TAH) in Australia. The implant occurred at St.Vincent's Hospital Sydney on November 22, 2024. Following weeks of in-hospital monitoring, the patient was the first in the world to be discharged from the hospital with the BiVACOR TAH as he awaited a heart transplant. After having the device for 105 days, a donor heart became available, and the patient received a heart transplant on March 6, 2025.

This study evaluates the safety and performance of the BiVACOR TAH System in patients as a bridge to donor heart transplant. It was the first implantation to occur outside of the US and is the first in a series planned in Australia as part of the Artificial Heart Frontiers Program. This initiative received a $50 million grant from the Australia Medical Research Future Fund in 2024, aimed at developing and commercializing devices to treat the most common forms of severe heart failure and provide new solutions for patients who are poorly served.

"It is incredibly rewarding to see our device provide extended support to the first Australian patient. The unique design and features of the BiVACOR TAH translate into an unparalleled safety profile, and it's exhilarating to witness decades of work come to fruition, " said Daniel Timms, PhD, Founder and CTO of BiVACOR. "The Australian patient is the longest to be supported by the BiVACOR TAH implant while waiting for a heart transplant, allowing him to celebrate another birthday, Christmas, and New Year with friends and family, free from the symptoms of heart failure."

Continued Timms, "The entire BiVACOR team is deeply grateful to the patient and his family for placing their trust in our Total Artificial Heart. Their bravery will pave the way for countless more patients to receive this lifesaving technology."

The study in Australia follows a five-patient FDA Early Feasibility Study in the US. Last year, the patients were successfully implanted with the TAH, received a heart transplant, and were subsequently discharged from the hospital. The FDA has greenlighted the expansion of the EFS study in the United States to an additional fifteen patients beginning in Q2 2025.

The BiVACOR TAH represents a paradigm shift in the design of artificial hearts. Its size is suitable for most men and women. Despite its compact dimensions, the BiVACOR TAH can deliver sufficient cardiac output for an adult male during exercise. Utilizing magnetic levitation technology, the same principle employed in high-speed trains, this product features a distinctive pump design with a single moving part: a magnetically suspended dual-sided rotor with left and right vanes located 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 contains no valves or flexible ventricle chambers, yet *pulsatile outflow is efficiently achieved by transiently increasing the rotor speed each second*. The non-contact suspension of the rotor via MAGLEV is designed to eliminate potential mechanical wear while providing large blood gaps that minimize blood trauma, resulting in a durable, reliable, and biocompatible heart replacement.

The BiVACOR Total Artificial Heart is available for investigational use only and has not been approved for use outside of clinical studies.

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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.

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