

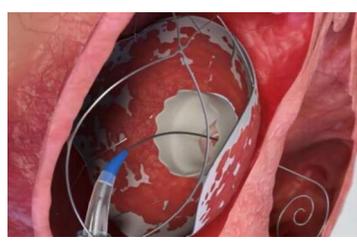
Allmed Solutions Achieves Landmark 'Needle-Stick' Heart Valve Replacement

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PR Newswire

OR AKIVA, Israel, Dec. 9, 2025

OR AKIVA, Israel, Dec. 9, 2025 /PRNewswire/ – Allmed Solutions (TASE: ALMD), an Israeli biomedical company, has announced a dramatic success in a first-in-human trial, achieving the full replacement of a major heart valve in critically ill patients via a minimally invasive catheterization procedure, entirely eliminating the need for high-risk open-chest surgery.



Allmed Solutions and its subsidiary, TruLeaf Medical, have completed the final stage of a trial for their innovative RoseDoc system. The new technology allows for a diseased heart valve to be fully replaced with a new, functional one, performed solely through a needle stick access point.

The groundbreaking procedure was carried out on two patients suffering from severe heart failure caused by a massive leak in their tricuspid valve (the three-leaflet valve on the right side of the heart). For both patients, conventional medical and surgical options had been exhausted, and their condition was considered too severe to undergo standard open-heart surgery. The investigational treatment was therefore provided under a compassionate care pathway.

The replacement was completed in two stages. Approximately three months prior, a novel proprietary docking system was implanted in the patients' hearts. The final procedure, completed recently, involved the implantation of the valve itself - the RoseDoc system.

Restoring normal valve function resulted in immediate and dramatic clinical improvement. Both patients reported a substantial change in their functional capacity and were discharged home within five days of the final valve implantation.

Prof. Oz Shapira, CEO of Allmed Solutions and an Emeritus Professor of Heart Surgery, emphasized the significance of the achievement.

"The success recorded in recent days is a defining moment. The ability to fully replace heart valves via needle stick only, with no incisions and no opening of the chest, is an extraordinary breakthrough," Prof. Shapira said. "We are entering a new and safer era for patients."

Prof. Shapira highlighted that the uniqueness of this Israeli development lies in its innovative docking system. This system is the only one in the world that enables the catheter-based replacement of two different types of heart valves, both the tricuspid valve on the right side and valves on the left side of the heart.

This breakthrough offers significant hope for millions of patients worldwide who are currently considered too high-risk for conventional surgery, leaving them without an adequate medical solution.

TruLeaf Medical was founded in 2017 by three experienced Israeli entrepreneurs: Benjamin Spenser, Nathanael Benichu, and the late Dr. Rosenstein. The team had previously achieved major success developing the world's first-ever transcatheter valve replacement, the Sapien 3 valve, which was part of PVT, a company later acquired by the global medical-device giant Edwards Lifesciences.

Following the successful early trial, the company is continuing to recruit patients in India and plans to expand the trial to sites in Israel, South Africa, and Uzbekistan as it advances toward global regulatory approval and commercialization.

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