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Global Breakthrough: TruLeaf Implanted First-of-its-Kind Heart Valve via Catheter Only, Without Surgery

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TruLeaf from the AllMeD Solutions group, successfully completed the first phase of a first-in-human clinical trial of a revolutionary system for tricuspid and mitral heart valve implantation via catheter only

CAESAREA, Israel, Sept. 10, 2025 /PRNewswire/ -- [AllMeD Solutions](#) (TASE: ALMD), which holds the Israeli biomedical company [TruLeaf-Medical](#), announced the successful completion of stage 1 of the first human implantation of the innovative RoseDoc docking system for transcatheter replacement of the tricuspid valve. This is a breakthrough system that replaces diseased heart valves and is inserted via catheter, without the need for open-heart surgery.

The procedure was successfully performed for the first time ever on September 5th, 2025 in India, using compassionate care pathway, on two patients suffering from severe refractory congestive heart failure due to leaking tricuspid valve who had no alternative therapeutic options. The second phase of percutaneously (using needle stick only) implanting the implantation of the valve itself developed by the company withing the docking device, is expected to be performed in the coming months according to the trial protocol. The current step represents a major proof of concept in human for TruLeaf innovative technology aimed for transcatheter replacement of the mitral and tricuspid valves.

TruLeaf's innovative technology enables the implantation to be performed in two stages. First, a unique docking station is implanted, and subsequently the heart valve is implanted. The method, which was specifically designed to provide solutions for patients without open-heart surgery, is expected to change the future of treatment for millions of patients worldwide suffering from defective valves, who until now have not had effective medical solutions available.

"This trial is not only an important step for TruLeaf-Medical, but also a huge step for the entire medical community and a ray of hope for millions of patients," says Prof. Oz Shapira, CEO of Allmed Solutions Group. "As a heart surgeon, I deeply understand the absolute necessity of transitioning from an high-risk invasive and complex open-heart surgery to a simple, smart, safe and effective catheter-based solution. TruLeaf Medical RoseDoc platform has the potential to offer an effective treatment to millions of patients with valvular heart disease who have been deemed to be too high risk for surgery and are unsuitable to currently available catheter-based techniques. ."

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TruLeaf Medical was founded in 2017 by three Israeli entrepreneurs: Benjamin Spenser, Nathanael Benichu and the late Dr. Rosenstein, with the goal of developing a revolutionary solution for heart valve replacement. Following their previous success at PVT where they developed the Sapien3 valve – the first-ever transcatheter valve replacement device for patients with severe aortic stenosis (sold to the giant Edwards Lifesciences), they embarked now are determined to find a solution to a much more technically challenging problem - the atrioventricular valves. TruLeaf Medical continues with patient recruitment for the FIH trial in India and Uzbekistan, and plans to expand the participating sites in additional countries. The first human implantation represents a critical milestone and will accelerate the process of regulatory approval making this innovative solution available to numerous patients worldwide.