



PRESS RELEASE

August 11, 2026
Gothenburg

CAUTION—Investigational device in the US. Limited by Federal (United States) law to investigational use. The safety and effectiveness of this device have not been established. The XVIVO heart technology is not commercially available in the US.

XVIVO receives CE certificates for its groundbreaking heart preservation technology, transforming access to life-saving transplants across Europe

XVIVO is proud to announce that its innovative heart preservation technology, XVIVO Heart Assist Transport system, has received CE certificates, making it available to any heart transplant center throughout Europe. This regulatory milestone marks a significant advancement both for XVIVO and for the broader field of heart transplantation.

Today, only three out of ten donated hearts are used for transplantation, often due to the limited time a donor heart can be preserved outside of the body. Additionally, early complications after transplantation often hinder long-term success. XVIVO Heart Assist Transport system directly addresses both challenges by safely extending preservation time and improving clinical results, enabling better donor-recipient matching, enhancing the efficiency of transplant programs, and ultimately improving patient outcomes.

Powered by hypothermic oxygenated perfusion (HOPE) — a novel method that actively preserves the heart in a controlled, oxygen-rich environment — the XVIVO Heart Assist Transport system is the first heart technology of its kind to demonstrate superiority in clinical trials over traditional ice storage, the current standard of care for preservation of donor hearts.

The randomized controlled trial (NIHP2019), published in The Lancet, showed a 76 percent risk reduction in severe primary graft dysfunction (PGD) — a critical early predictor of long-term transplant success when HOPE was used. Additionally, 12-month follow-up data revealed a 38 percent risk reduction in severe complications, with a one-year survival rate of 92 percent in the XVIVO group compared to only 86 percent in the control group.

“This is a proud and defining moment for everyone at XVIVO”, says Christoffer Rosenblad, CEO of XVIVO. “Receiving CE certificates for our heart technology brings us one step closer to changing the paradigm of heart preservation. We are deeply grateful to the patients, clinicians, transplant teams and partners across Europe whose dedication helped make this possible. XVIVO Heart Assist Transport system is not just a technological breakthrough — it’s a symbol of hope for the thousands of patients waiting for a new heart”.

With CE certificates now in place, the XVIVO Heart Assist Transport system is immediately available for clinical use across Europe. This reinforces XVIVO's commitment to advancing transplant medicine through science, innovation, and collaboration.

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About Us

Founded in 1998, XVIVO is the only medical technology company dedicated to extending the life of all major organs - so transplant teams around the world can save more lives. Our solutions allow leading clinicians and researchers to push the boundaries of transplantation medicine. XVIVO is headquartered in Gothenburg, Sweden, and has offices and research sites on two continents. The company is listed on Nasdaq Stockholm under the ticker symbol XVIVO. More information can be found on the website www.xvivogroup.com.

This information is information that XVIVO Perfusion AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2026-08-11 13:32 CEST.

Attachments

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