



Bridge to Life® Secures FDA De Novo Clearance for VitaSmart® Hypothermic Oxygenated Perfusion (HOPE) System, the First Ever U.S. Approval for Cold Machine Perfusion in Liver Transplant Preservation

Descrizione

COMUNICATO STAMPA - CONTENUTO PROMOZIONALE

Updated Press Release: An earlier version of this announcement was inadvertently distributed in error. This release supersedes all prior versions and reflects the Company's accurate and complete disclosure.

VitaSmart Commercial Launch Expected 1Q26

FDA-cleared labeling supports broad clinical applicability, including Donation after Circulatory Death (DCD) donors, and positions VitaSmart® as a scalable and economically compelling platform for U.S. transplant centers

DULUTH, Ga., Jan. 20, 2026 /PRNewswire/ - Bridge to Life® Ltd., a global innovator in organ preservation and perfusion technologies, today announced that the U.S. Food and Drug Administration (FDA) has granted De Novo clearance for the VitaSmart® Hypothermic Oxygenated Perfusion (HOPE) System, establishing a new regulatory classification for hypothermic oxygenated perfusion in liver transplantation in the United States.

The FDA clearance enables the commercial use of VitaSmart® for hypothermic oxygenated perfusion of donor livers following static cold storage and prior to transplantation, providing a clear, regulated pathway for U.S. transplant centers to incorporate HOPE protocols into clinical practice.

"This clearance represents a transformational milestone for Bridge to Life and an important advancement for liver transplantation in the United States," said Don Webber, CEO and President of Bridge to Life® Ltd. "VitaSmart® is the first FDA-cleared hypothermic oxygenated perfusion system for liver transplantation, and the labeling reflects FDA's determination of safety and effectiveness, aligned with real-world transplant practice. We believe this will support adoption, contribute to improved organ utilization, and offer meaningful clinical and significant economic value to

transplant programs.â?•

Expanding the Opportunity for DCD Liver Utilization

Donation after Circulatory Death (DCD) grafts represent an important donor category in contemporary liver transplantation. Inclusion of DCD grafts within the FDA-cleared labeling reflects clinical interest in preservation strategies intended to support graft management prior to implantation.

â??Having an FDA-cleared hypothermic oxygenated perfusion system commercially available represents an important development for transplant programs,â?• said Kristopher Croome, MD, Professor of Surgery and Transplant and Hepatobiliary Surgeon at Mayo Clinic Florida. â??The availability of VitaSmartâ??s HOPE technology under FDA-cleared labeling, supports ongoing efforts to optimize preservation strategies, particularly with DCD liver grafts. Without a fixed perfusion duration limitation this represents an important advancement and underscores the FDAâ??s recognition of hypothermic oxygenated perfusion as a safe and clinically meaningful approach to liver preservation, empowering transplant teams with greater flexibility to deliver the best possible care to patients in need,â?• Dr. Croome further commented.

Labeling Designed to Support Real-World Clinical Practice

The FDA-cleared labeling for VitaSmartâ?¢ supports hypothermic oxygenated perfusion of donor livers prior to transplantation in both Donation after Brain Death (DBD) and Donation after Circulatory Death (DCD) donors, within defined donor criteria.

Importantly, the cleared indication does not specify a maximum machine perfusion duration, allowing clinicians to apply hypothermic oxygenated perfusion within the scope of the indication using clinical judgment and established protocols. Extended HOPE duration provides operational and patient safety advantages, including improved coordination of transplantation logistics, avoidance of rushed implantation, and reduced risk of re-exposure to static cold ischemia. These factors directly impact intraoperative stability and post-transplant outcomes.

Clinical Evidence Supporting De Novo Clearance

FDA clearance was supported by data from the Bridge to HOPE pivotal clinical trial, a multicenter, randomized controlled study conducted in the United States evaluating end-ischemic portal venous hypothermic oxygenated perfusion in adult liver transplantation.

The study enrolled 219 recipients across 15 U.S. transplant centers, including extended-criteria donor populations in both DBD and DCD grafts. The statistically significant clinical results of the trial formed the basis for FDAâ??s De Novo determination and demonstrated improvements in early graft function with a strong safety profile.

Economic and Operational Considerations for Transplant Centers

Within the scope of its cleared use, VitaSmartâ?¢ is designed to support:

These considerations are increasingly important as transplant programs balance clinical outcomes, operational complexity, and resource constraints. Potential economic and operational benefits may vary by center and clinical practice.

Launch PlansAs previously announced, Bridge to Life has appointed David Castiglioni as Chief Commercial Officer to lead the U.S. commercialization of VitaSmart and support continued growth across the company's proprietary solutions portfolio. Mr. Castiglioni brings extensive experience in the transplantation sector and in working with healthcare providers to implement clinically integrated solutions.

Bridge to Life plans to initiate the U.S. commercial launch of VitaSmart during the first quarter of 2026. The launch will build on the company's existing commercial infrastructure and longstanding relationships across the transplantation community.

Purpose-Built HOPE Technology for U.S. Adoption

VitaSmart® delivers hypothermic oxygenated perfusion by cooling donor livers to controlled hypothermic temperatures while providing oxygenated perfusate prior to transplantation. The system is engineered for reliability, simplicity, and ease of use, supporting adoption across a wide range of transplant center environments under its FDA-cleared indication.

Acknowledgment of Investigators and Team

"I want to personally thank the investigators, transplant teams, and clinical staff at the 15 transplant centers in the US who participated in the Bridge to HOPE study, as well as the Bridge to Life team whose dedication and scientific rigor made this milestone possible," added Webber. "This clearance reflects years of disciplined clinical execution and collaboration, and we are deeply grateful to everyone who contributed."

About Bridge to Life® Ltd. Bridge to Life® Ltd. is a global leader in organ preservation solutions, offering a comprehensive portfolio that includes Belzer UW®, EasiSlush®, and the VitaSmart® Hypothermic Oxygenated Perfusion System. Bridge to Life partners with transplant centers and organ procurement organizations worldwide to advance preservation science and support life-saving transplantation.

For more information, visit www.bridgetolife.com.

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