

ULiSSES™ – the Device That Advances the State of The Art

Vascular Perfusion Solutions (VPS) has developed a new, unique, and innovative medical device that extends the timeframe for organ and limb viability — the Universal Limb/Organ Stasis System for Extended Storage, or ULiSSES™. VPS is working with a team of world-class scientists to advance ULiSSES™ through FDA clearance and into the clinic, so time doesn't run out for critically-ill patients, and limbs may be saved for both civilian and military personnel.

VPS has licensed its core technology from the Office of Technology Commercialization at UT Health San Antonio to preserve and transport limbs and vascularized tissue for both replantation, and transplantation. The company was founded by Tom DeBrooke and Professor Leonid Bunegin (Department of Anesthesiology at the UT Health Science Center, San Antonio). Tom is a serial entrepreneur and a graduate of the Harvard Business School. Professor Bunegin is the inventor and scientist behind the technology to preserve limbs and vascularized tissue, with several patents and publications in the area of vascularized tissue preservation.

The ULiSSES™ device preserves limbs and vascularized tissue using oxygenated perfusion preservation. The device can maintain severed limbs for warfighters in the field, making it possible to save and replant these limbs that would otherwise be lost. In the lab, the ULiSSES™ device has been found to preserve vascularized tissue for 24 hours, and beyond, at room temperature.

According to an article published in Nature Biotechnology, "Organ shortage is among the greatest crises facing biomedicine today" (Giwa. et al., 2017). Furthermore, estimates show that by 2050, the amputee population in the United States will reach 3.6 million people (Amputee Coalition of America). One of the main reasons for the present shortage of organs is due to organ preservation constraints. For example, current technology cannot preserve hearts for more than 4 to 6 hours, and the distance between donor and recipient becomes a significant problem. The authors of the Nature paper noted that "with all supply constraints removed, organ replacement could theoretically prevent >30% of all deaths in the United States—doubling the average person's likelihood of living to 80 years of age" (Giwa. et al., 2017).

Due to the unique design of the ULiSSES™ device, VPS is poised to revolutionize the market for limb and vascularized tissue oxygenated perfusion, preservation, resuscitation, and transport. Dr. Francisco Cigarroa, director of Pediatric Transplantation at UT Health San Antonio, stated "if we can find a way to preserve organs for longer periods of time in an efficient manner, we can give hope to millions of patients waiting for a viable organ".

In the three years since the inception of VPS, the company has been able to achieve important goals towards FDA approval. In 2018, VPS secured a DoD 'Joint Warfighter Medical Research Program' (JWMP) Grant Award for \$1MM, managed by the Congressionally Directed Medical Research Program, in collaboration with the Army's Institute for Surgical Research, the U.S. Air Force 59th Medical Wing, UTSA, and UT Health San Antonio, to test the efficacy of the device in preserving porcine limbs for 24 hours after amputation. IN the same year, VPS signed a Cooperative Research and Development Agreement (CRADA) with the U.S. Army's Institute of Surgical Research (ISR), and UT Health San Antonio to test the device for prolonged field care. In January of 2019, ULISSES™ reached the stage of an initial commercial prototype design-freeze. As of May 2019, VPS closed their initial seed round of fundraising.

VPS plans to collect additional test data and anticipates submitting a 510(k) application for clearance to the FDA in the second or third quarter of 2019. According to the latest Organ Banking Summit at Harvard Medical School "The ability to replace organs and tissues on demand could save or improve millions of lives each year globally and create public health benefits on par with curing cancer." VPS is working hard to make this statement a reality, by providing innovative solutions that improve the present state of vascularized tissue replantation and transplantation, i.e., "Saving Organs. Limbs. Lives."