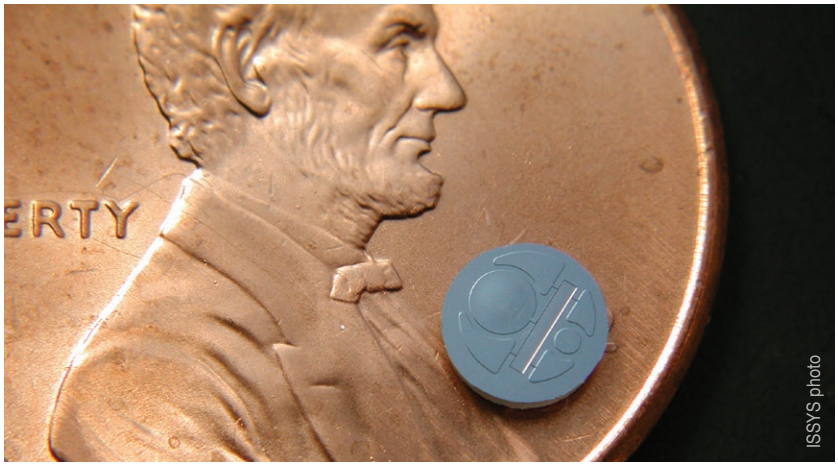
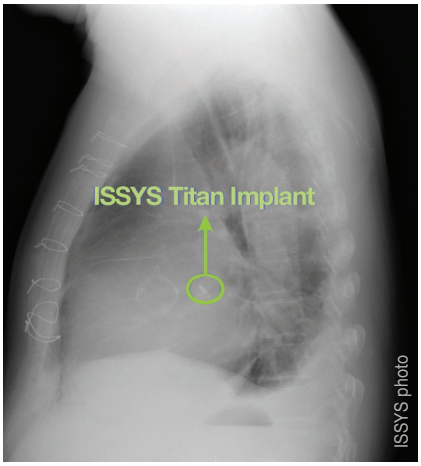
National Aeronautics and Space Administration

Technology Originating in NASA's SBIR Program Undergoes Clinical Trials for Cardiovascular Monitoring

Implantable devices show promise for management of chronic diseases



The ISSYS MEMS pressure sensor is extremely small, designed to fit easily into its miniaturized implantable devices.



The ISSYS Titan Implant, shown in a patient's left ventricle.

Wireless, implantable cardiovascular system sensors developed to help NASA Glenn Research Center (GRC) better understand blood flow in astronauts during spaceflight are now finding success in clinical trials as a key device to help monitor patients with congestive heart failure (CHF) and to manage their condition. Developed by Integrated Sensing Systems, Inc. (ISSYS), the Titan Wireless Implantable Hemodynamic Monitor (WIHM) uniquely measures the pressure of the left side of the heart (both left atrium and left ventricle), as well as any location in the cardiovascular system, including the pulmonary artery. ISSYS WIHM has also been used with left ventricular assist devices (LVAD). Based on microelectromechanical system (MEMS) technology, these devices provide cardiac wave pressure measurements and ventricle filling pressure—significant parameters for the management of CHF. Data is provided on demand via a remote monitoring feature that enables home monitoring and remote healthcare provider management, allowing providers to adjust medications as needed, and assisting with real and false emergencies.

Benefits of Technology Transfer

- **Non-invasive disease management:** Once implanted, the devices enable both remote home and healthcare provider monitoring of many chronic diseases involving the cardiovascular system or other fluidic systems, eliminating the need for multiple surgeries or invasive procedures to continually manage these conditions.
- **Cost efficiency:** Because chronic conditions can be monitored remotely, fewer visits to healthcare providers may be required, false emergencies can be filtered, and medication levels can be tailored optimally, lowering the overall costs of managing chronic disease.
- **Early disease detection:** Related conditions that may appear alongside the condition being monitored and managed may be detected earlier, improving patient care and overall health outcomes.

success

On the Record

"ISSYS has been remarkably successful in developing very small sensors to do a very specific job in a very harsh environment—inside the human body." — *Dr. Jerry Myers, Technical Director, NASA Integrated Medical Model and Technical Lead, NASA GRC Human Research Program Office*

"Our interaction with NASA has been very helpful in allowing us to overcome many challenges early on, including technical, timeframe, and funding challenges. We are very grateful for the support we received from NASA and other organizations that helped to advance this research." —*Dr. Nader Najafi, President and CEO, ISSYS, Inc.*

About Integrated Sensing Systems, Inc.

ISSYS is a leader in advanced MEMS technologies for design and manufacturing of industrial, medical, microfluidic, and scientific analytical sensing applications. Founded in 1995, ISSYS is one of the oldest independent MEMS companies in the United States. The company operates a comprehensive, state-of-the-art MEMS fabrication facility located near Ann Arbor, MI.

Technology Origins

GRC researchers were looking for tools that would enable better understanding of fluid shifts and redistribution of fluid in the human body during spaceflight, as well as macro- and micro-scale biofluid mechanics of the vascular system in various environments, including microgravity. A solicitation for proposals led to a 2002 Small Business Innovation Research (SBIR) contract with ISSYS. The company aimed to both deliver on GRC's research goals as well as develop a device that would ultimately enable management of chronic disease in patients on Earth.

The Transfer Process

The Phase I SBIR contract enabled development of the first implantable sensor, with advantages including small size (just 0.4 grams); safety (biocompatible and nonthrombogenic); wireless and battery-less operation; real-time and continuous measurement of bodily fluid flow and pressure; long implant lifetime (more than 10 years); speed (produces 200+ data samples per second); and intelligence (electronics located inside the device). A Phase II SBIR contract enabled further development of the device, along with a small, wireless handheld remote monitor for home use, and a custom-made Internet database that allows patients to submit home-monitored cardio waveforms to medical staff who can access the data, on demand, from anywhere in the world.

Clinical Trials

ISSYS's devices have been performing successfully in clinical trials in Europe where an implant is placed (upon a surgeon's decision) either in the left atrium or left ventricle for long-term management of CHF patients. The Linköping Hospital in Sweden requested and received approval to use ISSYS implants in a different study with patients who receive an LVAD. Three LVAD patients have successfully received an ISSYS implant. Notably, the most significant cardio pressure waveform to be monitored for treatment of chronic CHF is the left side of the heart, and ISSYS's devices represent the only currently available option for miniature implants to monitor pressures in the left atrium or left ventricle.

Looking Ahead

With the success of clinical trials in adults, next year ISSYS will also begin the first clinical trials in pediatric patients suffering from single functional ventricle (SFV) defect. Using the ISSYS implantable devices to manage care in SFV patients may help to improve care and lower the costs of care.

Moving forward, the company also has plans for clinical testing of the devices for use in patients suffering from intracranial pressure (ICP) conditions, either as a result of traumatic brain injuries or hydrocephalus disease (excessive accumulation of cerebrospinal fluid in the brain), one of the most common birth defects in the United States.

For More Information

If you would like additional information about GRC's technology transfer opportunities, please contact:

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