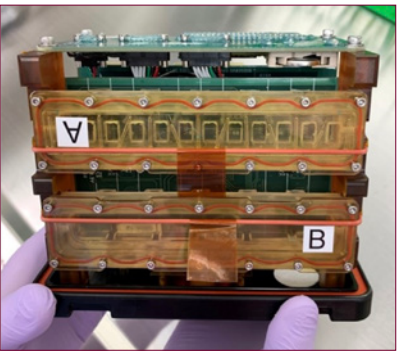
Heart tissue sent to International Space Station in March returns, under analysis

MARY KORR
RIMJ MANAGING EDITOR

Johns Hopkins Medicine researchers and a Brown physician researcher are part of a multi-institution team that collaborated with NASA to send human heart "tissue-on-a-chip" specimens into space in March. The tissue samples were launched aboard SpaceX CRS-27, a resupply mission to the International Space Station (ISS), from NASA's Kennedy Space Center in Florida.



Tissue chambers loaded into a plate habitat designed for research aboard the International Space Station. [DEOK-HO KIM AND DEVIN MAIR, JOHNS HOPKINS MEDICINE]

The heart tissue samples returned to Earth in mid-April and are being processed and analyzed for further study by Johns Hopkins researchers in laboratories at Johns Hopkins All Children's Hospital in St. Petersburg, Florida.

The project was designed to monitor the tissue for changes in heart muscle cells' mitochondria and ability to contract in low-gravity conditions. Astronauts on board during the mission introduced three FDA-approved medicines to the samples in efforts to prevent heart cell changes known or suspected to occur in those undertaking long-duration spaceflights.

"It's possible that what we learn from these experiments in space could also inform how we treat age-related cardiac problems," said **DEOK-HO KIM, PhD**, professor of biomedical engineering at the Johns Hopkins University School of Medicine, "because many heart cellular changes already detected in space explorers mimic changes linked to heart muscle aging in general."

A SpaceX Dragon resupply ship approaches the International Space Station carrying more than 6,200 pounds of science experiments, crew supplies, and other cargo on March 16, 2023. [NASA]

Science Experiments Summary

Among the science experiments the unmanned cargo ship Dragon delivered to the space station for NASA and its partners were:

3D Heart Cells, Tissue

The first **Cardinal Heart** investigation conducted aboard the space station showed that four weeks of microgravity exposure can cause significant changes in heart cell function and gene expression. Researchers concluded that these changes could lead to long-term medical issues. The **Cardinal Heart 2.0** experiment builds on these results, using heart organoids, 3D structures made up of all the different types of cells, to test whether clinically approved drugs reduce these microgravity-induced changes in heart cell function. Results could support the development of effective drug combinations to improve the health of astronauts and patients on Earth.

Astronaut **Sultan AlNeyadi** posted this photo on Twitter, which shows the Minus Eighty-Degree Laboratory Freezer (MELFI), that can reach temperatures as low as –100°C, to preserve some of the research samples.

The **Engineered Heart Tissues-2** study continues work with 3D cultured cardiac muscle tissue to assess human cardiac function in microgravity. Previous work with 3D cultures in space detected changes at the cellular and tissue level that could provide early indication of the development of cardiac disease. This investigation tests whether new therapies prevent these adverse spaceflight effects from occurring. The model used in this study has potential use in drug development and other applications related to diagnosing and treating cardiac dysfunction on Earth.

Cardinal Heart 2.0 and Engineered Heart Tissues-2 are the final two experiments comprising the National Institutes for Health and International Space Station National Lab's Tissue Chips in Space initiative. Researchers hope to learn more about the impact of microgravity on human health and disease, and translate that understanding to improved human health on Earth. ❖

In Fall River, MA, Southcoast Health cardiothoracic surgeon and Brown University Assistant Professor of Pathology and Laboratory Medicine (Research) **PETER H.U. LEE, MD, PhD**, who has served on the Science Subcommittee of the ISS National Laboratory, was a participant in the study. RIMJ posed a few questions to Dr. Lee, who was in Houston last week giving a talk at the NASA Johnson Space Center.

Peter H.U. Lee, MD, PhD [SOUTHCOAST HEALTH]

RIMJ: Were you involved as a collaborator with the researchers at Johns Hopkins, NASA, and the NIH with this particular science experiment and is it a continuation of earlier ones sent to the space station?

DR. LEE: For this project, I have been a co-investigator with Dr. Deok-Ho Kim at JHU being the Principal Investigator. At the time of the application, I was the only team member with experience doing spaceflight experiments. The original grant began with our 2020 space station experiment and this last one was a follow-up to the first one.

RIMJ: Post-splashdown, the experiment is now under analysis. When can the results be expected and what is your expectation?

DR. LEE: Typically, it should take 3-6 months for the samples to be processed and analyzed. Hopefully, we will be able to publish our results within about a year from now, ideally sooner.

Research with these beating 3D engineered heart tissues allows us to study the effects of spaceflight on the heart in a culture dish, thereby reducing the reliance on animal studies. As a cardiac surgeon, I am hopeful that these studies will also help address heart disease for patients on Earth.

RIMJ: Did you watch the lift-off and splashdown? That must be very exciting for an investigator to see.

DR. LEE: This was my fourth International Space Station experiment but unfortunately, also the first one I wasn't able to see the launch for. In additional to the 4 ISS experiments, I had an experiment launch with Blue Origin in the past 10 years. Prior to that, I have been part of numerous experiments with the space shuttle, parabolic (zero gravity) flights, and Russian biosatellites. ❖

A SpaceX Falcon 9 rocket soars upward after its liftoff from Launch Complex 39A at NASA's Kennedy Space Center in Florida on March 14, 2023, on the company's 27th Commercial Resupply Services mission for the agency to the International Space Station. Liftoff was at 8:30 p.m. EDT. The Dragon spacecraft delivered more than 6,000 pounds of science and research, supplies, and equipment to the crew aboard the space station, including the final two experiments comprising the National Institutes for Health and International Space Station National Laboratory's Tissue Chips in Space initiative, Cardinal Heart 2.0 and Engineered Heart Tissues-2. [NASA]

FDA authorizes changes to simplify use of bivalent mRNA COVID-19 vaccines

WASHINGTON, DC – On April 18, the U.S. Food and Drug Administration amended the emergency use authorizations (EUAs) of the Moderna and Pfizer-BioNTech COVID-19 bivalent mRNA vaccines to simplify the vaccination schedule for most individuals. This action includes authorizing the current bivalent vaccines (original and omicron BA.4/BA.5 strains) to be used for all doses administered to individuals 6 months of age and older, including for an additional dose or doses for certain populations. The monovalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States.

Changes

- Most individuals, depending on age, previously vaccinated with a monovalent COVID-19 vaccine who have not yet received a dose of a bivalent vaccine may receive a single dose of a bivalent vaccine.
- Most individuals who have already received a single dose of the bivalent vaccine are not currently eligible for another dose. The FDA intends to make decisions about future vaccination after receiving recommendations on the fall strain composition at an FDA advisory committee in June.
- Individuals 65 years of age and older who have received a single dose of a bivalent vaccine may receive one additional dose at least four months following their initial bivalent dose.
- Most individuals with certain kinds of immunocompromise who have received a bivalent COVID-19 vaccine may receive a single additional dose of a bivalent COVID-19 vaccine at least 2 months following a dose of a bivalent COVID-19 vaccine, and additional doses may be administered at the discretion of, and at intervals determined by, their healthcare provider. However, for immunocompromised individuals 6 months through 4 years of age, eligibility for additional doses will depend on the vaccine previously received.
- Most unvaccinated individuals may receive a single dose of a bivalent vaccine, rather than multiple doses of the original monovalent mRNA vaccines.
- Children 6 months through 5 years of age who are unvaccinated may receive a two-dose series of the Moderna bivalent vaccine (6 months through 5 years of age) OR a three-dose series of the Pfizer-BioNTech bivalent vaccine (6 months through 4 years of age). Children who are 5 years of age may receive two doses of the Moderna bivalent vaccine or a single dose of the Pfizer-BioNTech bivalent vaccine.
- Children 6 months through 5 years of age who have received one, two or three doses of a monovalent COVID-19 vaccine may receive a bivalent vaccine, but the number of doses that they receive will depend on the vaccine and their vaccination history.

Available data show that almost all of the U.S. population 5 years of age and older now have antibodies as a result of either vaccination or infection against SARS-CoV-2. The use of bivalent COVID-19 vaccines for all doses administered to individuals 6 months of age and older is supported by the data described below, as well as post-marketing data, including real-world data, with the monovalent and bivalent mRNA COVID-19 vaccines, which have been administered to millions of people, including young children. A second bivalent dose for individuals 65 years of age and older is supported by data showing the waning of immunity in this population over time and its restoration by an additional dose. Additionally, based on evidence from studies conducted previously, immunocompromised individuals may require additional doses.

Vaccines and Related Biological Products Advisory Committee

The latest authorizations follow discussions that occurred during a meeting with the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) on Jan. 26. At that time, by a unanimous vote, the committee recommended harmonizing the strain composition of COVID-19 vaccines used in the U.S. There was also support for simplifying the vaccine dosing schedule.

In June, the FDA will hold a meeting of its VRBPAC to discuss the strain composition of the COVID-19 vaccines for fall of 2023. Much like the FDA does yearly with the influenza vaccines, the agency will seek input from the committee on which SARS-CoV-2 variants and lineages are most likely to circulate in the upcoming year. Once the specific strains are selected for the COVID-19 vaccines, the FDA expects manufacturers to make updated formulations of the vaccines for availability this fall.

The amendments to the EUAs were issued to ModernaTX Inc. and Pfizer Inc. ❖

American Lung Association releases 2023 State of the Air report

PROVIDENCE – Providence's air quality has seen improved levels of ozone pollution since last year's report, according to the American Lung Association's 2023 State of the Air report, which was released in April. For the first time, the metro area received a passing grade for ozone pollution, under the current standard. The report also found several counties throughout the state of Rhode Island received improved grades for ozone pollution, while receiving worsened grades for particle pollution.

The Lung Association's 24th annual report grades Americans' exposure to unhealthy levels of ground-level ozone air pollution, annual particle pollution and short-term spikes in particle pollution over a three-year period. This year's report covers 2019–2021.

"Here in Rhode Island and across the nation, we are seeing ozone pollution improving, thanks in big part to the success of the Clean Air Act. But there is more work to do," said **DAN FITZGERALD**, Director of Advocacy for the Lung Association. "Even one poor air quality day is one too many for our residents at highest risk, such as children, older adults, individuals who are pregnant, and those living with chronic disease. That's why we are calling on Governor McKee and the General Assembly to continue to take action to ensure that everyone has clean air to breathe. The Lung Association calls on Rhode Island lawmakers to meet the benchmarks set forth by the Act on Climate, reduce greenhouse gas emissions, and ensure a transition to zero-emission transportation."

Nationally, the report found that ozone pollution has generally improved across the nation, thanks in large part to the success of the Clean Air Act. However, more work remains to fully clean up harmful pollution, and short-term particle pollution continues to get worse. In addition, some communities bear a greater burden of air pollution. Out of the nearly 120 million people who live in areas with unhealthy air quality, a disproportionate number – more than 64 million (54%) – are people of color. In fact, people of color were 64% more likely than white people to live in a county with a failing grade for at least one measure, and 3.7 times as likely to live in a county with a failing grade for all three measures.

Ground-level ozone pollution

Compared to the 2022 report, the Providence metro area experienced fewer unhealthy days of high ozone in this year's report. "State of the Air" ranked Providence as the 52nd most polluted city for ozone pollution, which is better compared to its ranking of 47 in last year's report. Several counties also saw grades improve for ozone pollution, including Kent (from a D to a C), and Providence (from an F to a C),

Particle pollution

The report also tracked short-term spikes in particle pollution, which can be extremely dangerous and even deadly. Providence's short-term particle pollution worsened in this year's report, which means there were more unhealthy days. The area is tied for 95th most polluted for short-term particle pollution. Ten out of twelve counties in the metro area received B grades for short-term particle pollution this year after receiving A grades last year.

See the full report results at Lung.org/SOTA. ❖

Populations at Risk

County	Total Pop	Under 18	65 & Over	Pediatric Asthma	Adult Asthma	COPD	Lung Cancer	Cardio-vascular Disease	Pregnancy	Poverty Estimate	Non White
Bristol	50,818	9,202	10,488	607	5,253	2,533	33	3,299	451	3,611	4,889
Kent	170,715	31,451	33,783	2,075	17,602	8,375	109	10,812	1,501	13,635	23,984
Newport	85,264	13,820	20,151	912	8,981	4,463	55	5,964	707	7,899	12,664
Providence	658,221	133,834	105,211	8,828	66,630	29,103	422	35,998	6,572	90,405	270,169
Washington	130,592	20,520	29,158	1,354	13,869	6,743	84	8,882	1,160	11,421	12,499
TOTAL:	**1,095,610**	**208,827**	**198,791**	**13,776**	**112,335**	**51,217**	**703**	**64,955**	**10,391**	**126,971**	**324,205**

Country's first state-regulated overdose prevention center slated to open in early 2024

PROVIDENCE – Project Weber/RENEW, in partnership with CODAC Behavioral Healthcare, recently announced that it will open the country's first state-regulated overdose prevention center in early 2024. The center, which will be located in Providence, will prevent overdose deaths and provide critically needed services, including the ability to use pre-obtained drugs under the supervision of trained staff. The surging overdose epidemic claimed a record high 435 lives in Rhode Island in 2021.

Funding for the center's first year of operations comes from opioid settlement funds distributed to Rhode Island, totaling $2.6 million. Project Weber/RENEW and clinical partners CODAC were selected for the project by the state's Executive Office of Health and Human Services.

"This is a historic and humane step forward in the fight against the epidemic of overdose deaths," Project Weber/RENEW Executive Director **COLLEEN DALEY NDOYE** says. "With more than 100,000 people dying in this country every year – and hundreds in Rhode Island alone – it is time for us to take action to keep more people from dying. No one can make the decision to ask for support and help, let alone decide to enter treatment or recovery if they are dead. We have many years of experience as a peer-led organization, and we're ready to make Rhode Island a leader in a new era of harm reduction."

Overdose prevention centers (sometimes referred to as "safe consumption sites" or "harm reduction centers") offer an array of services under one roof – almost all of which are already offered at Project Weber/RENEW's current drop-in centers in Providence and Pawtucket. These include: access to basic needs such as food, water, and hygiene products; safer use supplies and Narcan/naloxone; case-management services, HIV and hepatitis C testing and linkage to care; housing support; peer recovery coaching; and support groups; among others.

Additionally, the overdose prevention center will also allow people to use pre-obtained substances under the supervision of trained professionals. Staff will make sure every individual has the opportunity to test their drugs for fentanyl and other substances and will also be on hand to make sure someone does not overdose or to help reverse an overdose. When a potential overdose is spotted early, it can be quickly and effectively reversed.

Legislation that authorized the creation of an overdose prevention center in Rhode Island was recently amended and passed by the state legislature. These vital bills were sponsored by Rhode Island State Senator **JOSH MILLER** and State Representative **JAY EDWARDS**. That law will now sunset in March 2026, allowing for the time needed to get the facility open, operating, and evaluated.

Data has shown that no one has ever died at an overdose prevention center anywhere in the world in the many decades they've existed. Recent data from the two overdose prevention centers operating in New York City show that they reversed more than 600 overdoses in their first year of operation, with only a handful needing EMS services.

Regulation, evaluation

The Rhode Island Department of Health will regulate the overdose prevention center through a comprehensive set of requirements. A rigorous evaluation will be conducted by The People, Place & Health Collective at Brown University's School of Public Health to measure the program's individual and community outcomes. Researchers at the Collective have combined decades of experience evaluating harm reduction interventions, including overdose prevention centers in other countries. Project Weber/RENEW Deputy Director **ASHLEY PERRY** and Overdose Prevention Program Director **DENNIS BAILER**, both people with lived experience, will be co-directors of the space.

"It's impossible to overstate how important an overdose prevention center is. It will help save so many lives!" says Bailer. "People die when they use alone, and they don't have to be alone. More people are dying now than ever before because the entire illicit drug supply is contaminated with fentanyl and other drugs. Overdoses are also now skyrocketing in our Black and Brown communities. It's imperative that we do what we can to help keep people alive, and right now that starts by opening spaces like this overdose prevention center."

The proposed location for the center is on Huntington Avenue in Providence, which is an overdose hotspot with no direct residential neighbors. The center, which will be open on weekdays, will be staffed by Project Weber/RENEW and CODAC, the state's largest provider of nonprofit outpatient services for opioid use disorder. Staff will include experts with lived experience, including peer recovery specialists, nurse practitioners, and doctors who can prescribe suboxone and methadone.

Project Weber/RENEW and CODAC have begun reaching out to residents and stakeholders directly about the project. Both organizations are committed to working closely with state, local and community leaders ahead of and during the center's operation.

"CODAC is excited and honored to partner with Project Weber/RENEW on this initiative," CODAC CEO **LINDA HURLEY** says. "The work of the overdose prevention center is evidence-based, proven to save lives. It is a critical piece of the continuum of care needed to assist and protect our community members who are suffering from substance use disorders." ❖

Governor McKee update on access to Mifepristone in Rhode Island

PROVIDENCE – Governor Dan McKee issued the following update about access to Mifepristone in Rhode Island on April 17th:

"The State of Rhode Island is fortunate to have strong protections in place for reproductive freedom that other states may not have. Despite the federal court ruling in Texas, access to safe reproductive health care like Mifepristone remains legal in Rhode Island. Here in Rhode Island, our Administration is working to ensure continued access to care, which is available through ample supply of medication and surgical means.

Last week, I directed the Rhode Island Department of Health (RIDOH) to conduct outreach to health care facilities in Rhode Island to ensure sufficient inventory and that Mifepristone continues to remain accessible. There is a sufficient amount of Mifepristone in Rhode Island at this time. However, RIDOH remains in regular contact with our health care facilities to ensure that patients do not experience any challenges accessing medication and care.

RIDOH has also issued a formal advisory to Rhode Island providers reiterating that there should be no changes in clinical practice for the prescribing, dispensing, and administration of Mifepristone, or any other reproductive health medication, in Rhode Island at this time.

Our Executive Office of Health and Human Services (EOHHS) has conducted outreach to our three contracted Medicaid Managed Care Organizations (Neighborhood Health Plan of Rhode Island, UnitedHealthcare of New England and Tufts Health Public Plans) that currently serve one out of every three Rhode Islanders, to ensure continued access to Mifepristone under current rules and regulations allowed under the Medicaid Program. Additionally, EOHHS is continuing to share important updates with community partners and advocates to ease concerns or confusion given the various federal court rulings related to Mifepristone access.

My team will continue to stay connected with the Biden Administration and the coalition of Governors focused on protecting these rights. I've directed my legal team to monitor the progress of both the Washington and Texas cases closely. We will also continue working with providers like Planned Parenthood of Southern New England, who have been strong partners in navigating this effort and ensuring continued access in our state." ❖

RIDOH, CDC highlight STI data

Rates of STIs are increasing

PROVIDENCE – The Centers for Disease Control and Prevention (CDC) recently released their 2021 Sexually Transmitted Disease (STD) Surveillance. The annual report shows STI rates continued to increase, with more than 2.5 million new cases of chlamydia, gonorrhea, and syphilis identified in the United States in 2021. RIDOH released its annual 2021 Rhode Island HIV, Sexually Transmitted Infections, Viral Hepatitis, and Tuberculosis Surveillance Report in February.

"While there is no one reason why rates of STIs are increasing, some factors may be sexual activity with larger networks of partners, substance abuse, and social and economic disparities that limit access to healthcare. In addition, biomedical interventions to prevent HIV and pregnancy may create the incorrect perception that condoms are not needed as much as they were in the past," said **UTPALA BANDY, MD, MPH**, RIDOH Interim Director. "Long-acting injectable contraceptives and pre-exposure medications to reduce your chances of getting HIV (also known as pre-exposure prophylaxis, or PrEP) do not protect against STIs. Fortunately, Rhode Island is a national leader in launching innovative programs to increase access to condoms and testing. These programs can help Rhode Islanders stay health and safe during this time of rapidly increasing STI rates."

The RIDOH and CDC STI surveillance reports indicate:

- From 2012–2021, there has been a 21% increase in chlamydia cases in Rhode Island, from 4,313 cases in 2012 to 5,199 cases in 2021. Nationwide, 1.6 million chlamydia infections were reported in 2021. Most chlamydia cases in the last 10 years have been diagnosed in females. In 2021, nearly twice as many cases were diagnosed in females than in males in Rhode Island. This difference is likely due to two factors. First, women generally access routine healthcare and subsequent screening more frequently than men and are screened for chlamydia more often. Second, men who have chlamydia often do not have symptoms and do not seek healthcare for screening and treatment. From 2017-2021, the highest rates of chlamydia were in people in their 20s, followed by people ages 30–39 and those age 19 or younger.
- From 2012–2021, there has been a 232% increase in gonorrhea cases in Rhode Island, from 507 cases in 2012 to 1681 cases in 2021. More than 700,000 gonorrhea cases were reported nationwide in 2021. In the last 10 years, more gonorrhea cases have been observed in males than in females. In the last five years, case rates for gonorrhea have been consistently highest among people in their 20s, followed by people in their 30s.
- From 2012–2021, there has been a 382% increase in infectious syphilis cases in Rhode Island, from 68 cases in 2012 to 328 cases in 2021. Reported cases of syphilis (all stages) totaled more than 176,000 cases nationwide in 2021. These data represent diagnosed cases based on positive test results and history. In 2021, more cases of infectious syphilis were observed among females compared to prior years; however, males still account for the majority of the reported cases reported. Gay, bisexual, and other men who have sex with men (GBMSM) are disproportionately affected by STIs, including infectious syphilis in Rhode Island, a trend that is also observed nationally.
- In the last two years, RIDOH received its first reports of congenital syphilis in over 10 years. Congenital syphilis continued to surge nationwide in 2021, increasing 203 percent since 2017. In 2021, 38 jurisdictions, including 37 states and the District of Columbia, reported an increase in congenital syphilis cases. ❖

W&I researchers present clinical trial results at Society of Gynecologic Oncology annual meeting

PROVIDENCE – The results of two clinical trials that now define the new standard of care for women with advanced-stage or recurrent endometrial cancer were presented at the recent Society of Gynecologic Oncology annual meeting.

These trials demonstrated that adding immunotherapy to standard cytotoxic chemotherapy improved progression-free survival until cancer recurred, and early results suggested a long-term survival benefit.

"Treatment options for women with advanced endometrial cancer represent a true unmet need in our discipline. The ability to participate in these efforts is part of our commitment to improving outcomes for these patients," said **DR. ASHLEY STUCKEY**. She is an Associate Professor in the Division of Gynecologic Oncology and the Department of Obstetrics and Gynecology at Women and Infants Hospital, The Warren Alpert Medical School of Brown University, and a faculty member at the Legorreta Cancer Center as well as a co-author on Dostarlimab for Primary Advanced or Recurrent Endometrial Cancer, recently published in the *New England Journal of Medicine* on March 27.

DR. CARA MATHEWS said, "There has been a great deal of enthusiasm for newer treatment options in cancer, such as immunotherapy, although positive trial results have been lacking in gynecologic cancer." Dr. Mathews is a co-author of Pembrolizumab plus Chemotherapy in Advanced Endometrial Cancer, also published in the *New England Journal of Medicine*. She is an Associate Professor in the Division of Gynecologic Oncology and the Department of Obstetrics and Gynecology at Women and Infants Hospital and a faculty member at the Legorreta Cancer Center at Brown University.

Dr. Mathews also provided an encore presentation of Overall Survival with Maintenance Olaparib at a 7-year Follow-Up in Patients with Newly Diagnosed Advanced Ovarian Cancer and a BRCA Mutation: The SOLO1/GOG 3004 Trial. These results were initially presented by **DR. PAUL DISILVESTRO**, the Director of the Program in Women's Oncology and a Professor in the Division of Gynecologic Oncology and the Department of Obstetrics and Gynecology at Women and Infants Hospital and a member of the Legorreta Cancer Center at Brown University at the European Society of Medical Oncology Annual Meeting in Paris, France, in September 2022.

Dr. DiSilvestro, the primary author of this manuscript which was published in the *Journal of Clinical Oncology* in September 2022 said, "This trial previously demonstrated that the use of olaparib for these patients dramatically lengthened remission. The long-term results now indicate that this treatment likely cures a substantial portion of women with advanced ovarian cancer and a BRCA mutation. This is groundbreaking for our discipline." ❖

University Orthopedics' Dr. Derek Jenkins to introduce hip implant to region

EAST PROVIDENCE – University Orthopedics adult reconstruction surgeon **DR. DEREK JENKINS** recently became the first in New England to use EMPHASYS™ for a total hip replacement surgery.

"I'm honored that Depuy-Synthes and Johnson & Johnson, a global leader in hip and knee replacement technology, would choose our practice to showcase their newest innovations," said Dr. Jenkins, a senior member of the surgical staff involved in joint replacement research. "Our reputation at University Orthopedics, Brown University, Rhode Island Hospital, and The Miriam Hospital is being noticed on the national level. We may be the smallest state but we are doing big things here in Rhode Island."

The EMPHASYS™ stem by DePuy Synthes, the orthopaedics company of Johnson & Johnson, builds on the long and distinguished track record of the CORAIL™ hip stem, with which Dr. Jenkins has had success in more than 2000 hip replacements over the span of 10 years.

"Our preliminary survey of our total hip replacement results with the CORAIL™ shows a 0% dislocation rate which is really exceptional. We are currently studying outcomes of these newer stem designs, and are excited to be part of the innovation process and what it could mean for our patients," he said.

Keeping many of the same design features that have made the CORAIL™ system a success, Depuy-Synthes called EMPHASYS™ Hip Solutions the next evolution. Some of the improvements the company highlights include:

- A wider variety of stem sizes to accommodate different-sized femurs
- Better fit and surgical preparation for a variety of femur types, including narrow canals
- Better bone preservation due to its intraosseus and extra-osseus design design
- Reduction of the number of implants, instruments, and trays, creating a streamlined workflow specific to a surgeon's preferred surgical approach, including Anterior Approach
- Better recreation of the femoral head center which can lead to ideal positioning of the acetabulum and femur to achieve desired patient leg length outcomes ❖

Center for Innovative Neurotechnology for Neural Repair present groundbreaking research to U.S. Congress

PROVIDENCE – Intelligent Spine Interface (ISI) researchers **DAVID BORTON, PhD**, principle investigator and associate professor of engineering and brain science at Brown University, associate professor of neurosurgery at Lifespan, and Biomedical Engineer at the Providence VA Health care Center for Neurotechnology and Neurorestoration (CfNN), and **JARED FRIDLEY, MD**, associate professor of neurosurgery at The Warren Alpert Medical School at Brown University and a neurosurgeon at Lifespan's Norman Prince Spine Institute (NPSI), were invited to present their research to the U.S. Congress at the Defense Advanced Research Projects Agency's (DARPA) 2023 Demo Day. They are one of less than ten teams chosen to share their work. The clinical trial designed to test the ISI is sponsored by Rhode Island Hospital, with both DARPA and the Veterans Affairs Medical Center (VAMC) collaborating.

The Intelligent Spine Interface (ISI) is a groundbreaking clinical trial aimed at restoring limb movement, sensation and bladder control in individuals who have suffered spinal cord injuries using an implant developed by the Center for Innovative Neurotechnology for Neural Repair (CINNR), a one-of-a-kind lab space in Providence. Borton and Fridley are testing whether the implanted ISI device can be seamlessly integrated into the body's nervous system, helping to bridge the gap in neural circuitry resulting from a spinal injury.

David Borton, PhD

Jared Fridley, MD

"Our hope is that by using machine learning, while restoring the two-way signal flow from limbs to brain and bridging the gap of injury, we can gain a life-changing understanding and a real clinical tool to aid patients with spinal cord injury," said Dr. Fridley. "Better understanding these neural networks would be a groundbreaking step."

"We know that circuits around a spinal lesion often remain active and functional," said Dr. Borton. "We're taking the signals out of the body from those functional circuits, translating them through advanced neural networks, then sending them to the other side of the lesion, in a bi-directional way."

Researchers presented their work in Washington, D.C. on April 18 to the U.S. Senate and on April 19 to the U.S. House of Representatives. ❖

Fatima Hospital now offering Inspire sleep apnea treatment

NORTH PROVIDENCE – Fatima Hospital is now offering Inspire therapy, a breakthrough obstructive sleep apnea (OSA) treatment option for those who cannot use Continuous Positive Airway Pressure (CPAP) therapy.

DR. JOHN TARRO, an otolaryngologist, performed the first case at Fatima. **DR. ZACHARY QUAY-DE-LA VALLEE** and **DR. C. IAN NEWBERRY**, all of RI ENT Physicians in Providence, are also trained in the procedure.

Inspire works inside the body with a patient's natural breathing process to treat sleep apnea. Mild stimulation opens the airway during sleep, allowing oxygen to flow naturally. The patient uses a small handheld remote to turn Inspire on before bed and off when they wake up.

The safety and efficacy of Inspire was evaluated during the STAR clinical trial. Five-year STAR trial outcomes show patients using Inspire experience significant reductions in sleep apnea events and significant improvements in quality-of-life measures. There have been over 150 peer-reviewed publications on Inspire. These publications show results consistent with those seen in the STAR trial.

To learn more about Inspire, visit InspireSleep.com or www.fatimahospital.com ❖

Normal Pressure Hydrocephalus Multidisciplinary Center opens at RIH APC

PROVIDENCE – The Norman Prince Neurosciences Institute has opened the Normal Pressure Hydrocephalus (NPH) Multidisciplinary Center at the Rhode Island Hospital Ambulatory Patient Center (APC).

"Symptoms of NPH are complex and can be like other memory and movement disorders. Our team will evaluate patients in a comprehensive one-day visit to our center and provide a diagnosis and discuss treatment options," said **PETRA KLINGE, MD, PhD**, director, CSF Disorders of the Brain and Spine, Rhode Island Hospital.

Symptoms of NPH may include memory and cognitive impairment, problems with walking or a sensation that one's feet feel "stuck," and impaired bladder control. Because NPH is a chronic condition, its symptoms can develop slowly over months to years. The cause of NPH is currently unknown.

For more information, visit
https://www.lifespan.org/locations/normal-pressure-hydrocephalus-multidisciplinary-clinic ❖