

## UPPER EXTREMITY FES SYSTEM ON COMMERCIALIZATION PATH

Restored hand function is one of the top priorities of people living with cervical level SCI, affecting nearly 100,000 people in the U.S.

An effort by FES Center investigators to commercialize a neuroprosthesis that restores upper extremity function has received the first year of funding by the NIH's National Institute for Neurological Disorders and Stroke, for what will ultimately be a five-year, \$7M effort focused on expanding the use of the neuroprosthesis to two other centers. "We've always been driven to get our FES systems out to more people and have greater impact," said P. Hunter Peckham PhD, principal investigator on the grant. "This funding brings us much closer to our goal." Now completing their first year of the project, co-investigators P. Hunter Peckham PhD, Kevin Kilgore PhD, Megan Moynahan, MS, and their team of engineers and clinicians are focused on readying the technology for commercial production and identifying candidate trials sites.

The upper extremity FES system is built upon the Networked Neuroprosthesis (NNP) platform, a modular, implanted technology designed to provide multiple functions to the same individual. Since its conception in 2001, the NNP has been designed, prototyped, and evaluated on the bench, and is currently implanted in five participants with cervical level spinal cord injury, providing both upper extremity function and trunk stability. "In this study, we're focused on restoring upper extremity function only," said Kevin Kilgore, PhD, co-investigator on the project. "But the NNP is designed to be much more flexible and versatile, and we have plans to expand to other areas. Participants in this study may well be eligible to join other NNP-based studies in the future." One of the team's goals is to make the NNP available to other investigators interested in studying FES-based solutions to movement disorders, pain



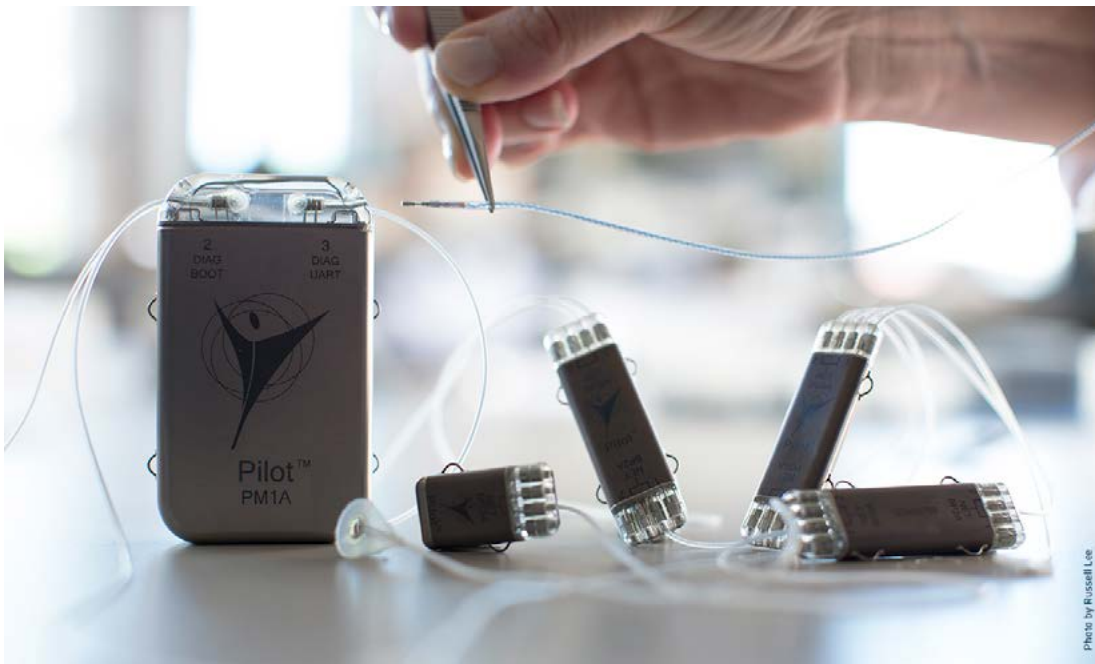
management, spasticity and autonomic functions.

The five-year project essentially creates a bridge to the completion of a multi-center pivotal clinical trial, although it will not fund the complete trial. Rather, it allows the team to test the final configuration of the technology, recruit and train two additional clinical trial sites, evaluate study outcomes, file the necessary regulatory submissions, and purchase implants for up to 13 participants. Funding from additional sources such as foundation awards and philanthropy will be necessary to complete the full study needed for FDA approval.

The effort to commercialize the system is being driven by the Institute for Functional Restoration (IFR), the mission of which is to create a sustainable commercial pathway for technologies intended for small markets. “Normally, a technology that’s been demonstrated to work this well in a small feasibility trial would be snapped up by an interested industry partner,” said Megan Moynahan, the IFR’s Executive Director. “But for products intended for a small

market, we have to de-risk more of the commercial pathway before a partner might be willing to license it.” The IFR is working to smooth the pathway to commercialization for the NNP upper extremity system. Its prior successes include securing a manufacturing partner for the NNP technology (Synapse Biomedical, Oberlin, OH), obtaining FDA approval to start studying the system in people, and negotiating with the FDA for a Class II (moderate risk) designation. In 2016, the project was accepted into FDA’s “Breakthrough Medical Devices” program.

Making FES systems available to the SCI community has been a longstanding goal of Peckham’s, whose research in this area has spanned decades, and who has facilitated numerous successful commercial endeavors. “While we’ve got a ways to go before we can claim success,” said Peckham, “I am confident we can deliver on our promise to people with spinal cord injury who have been waiting a long time for solutions.”



*For more information about FES research and programs*  
[info@FEScenter.org](mailto:info@FEScenter.org) | [www.FEScenter.org](http://www.FEScenter.org) | (216) 231-3257

#### About the Cleveland FES Center

The Cleveland FES Center is a consortium of the Louis Stokes Cleveland VA Medical Center, MetroHealth Medical Center, Case Western Reserve University, University Hospitals, and the Cleveland Clinic Neurological Institute. With their support, researchers, engineers and clinicians collaborate together to develop innovative solutions that improve the quality of life of individuals with neurological or other muscular skeletal impairments. Through the use of neurostimulation and neuromodulation research and applications, the Cleveland FES Center leads the translation of this technology into clinical deployment.

