

ONWARD® Announces First-in-Human Implant of ARC-IM™ Stimulator with Brain-Computer Interface (BCI) to Restore Arm, Hand, and Finger Function after Spinal Cord Injury

Pioneering procedure pairs Company's investigational ARC-IM implantable spinal cord stimulator with an investigational brain-computer interface

EINDHOVEN, the Netherlands — September 27, 2023 — ONWARD Medical N.V. (Euronext: ONWD), the medical technology company creating innovative spinal cord stimulation therapies to restore movement, function, and independence in people with spinal cord injury (SCI), today announces the successful first-in-human implant of its ARC-IM Stimulator*, to restore upper extremity function after SCI. The patient also received a wireless brain-computer interface (BCI), designed to initiate thought-driven movement when paired with ARC-IM.

ONWARD ARC-IM delivers targeted, programmed ARC-IM Therapy to the spinal cord to restore movement and other functions after spinal cord injury. ARC-IM Therapy has been applied across multiple clinical feasibility studies to restore mobility and stabilize blood pressure after SCI. For the first time, ARC-IM Therapy has now also been used to restore upper extremity movement and function.

Two procedures were performed last month by neurosurgeon Jocelyne Bloch, MD, at Centre Hospitalier Universitaire Vaudois (CHUV) in Lausanne, Switzerland. The ARC-IM implant procedure took place on August 14, 2023, and nine days later the BCI WIMAGINE® from CEA-Clinattec was implanted.

Working in concert with ARC-IM, the BCI is engineered to capture the intention of a paralyzed individual to move their upper extremities and uses artificial intelligence to decode those thoughts. ARC-IM then converts the decoded information into ARC-IM Therapy - precise stimulation of the spinal cord - resulting in thought-driven movement.

“The implant procedures involving the ONWARD ARC-IM and Clinattec BCI went smoothly,” said Dr. Jocelyne Bloch. “We are now working with the patient to use this cutting-edge innovation to recover movement of his arms, hands, and fingers. We look forward to sharing more information in due course.”

This latest breakthrough is part of an ongoing clinical study investigating the safety and effectiveness of thought-initiated spinal cord stimulation after SCI. It builds on the ONWARD announcement from May 2023 that pairing its ARC Therapy with a BCI implant resulted in an individual gaining augmented control over movement of his paralyzed legs. The study is supported by a grant from the European Innovation Council (Reverse Paralysis project) and is coordinated by .NeuroRestore co-Directors – Professor Grégoire Courtine and Dr. Jocelyne Bloch – as well as Guillaume Charvet, head of the Medical Device Development Lab at CEA-Clinattec.

“This is another impressive piece of research from our partners at .NeuroRestore. We are excited to learn how ARC-IM Therapy may restore upper extremity function after SCI, and we are eager to see how the addition of a BCI might augment our therapy,” said Dave Marver, CEO of ONWARD. “Congratulations to the teams at EPFL, CHUV, and CEA-Clinattec for this breakthrough. We feel privileged that our technology is part of this research.”

The Company expects to share more information about this pioneering research in the coming months, concurrent with a peer-reviewed publication describing the procedure and results.



**All ONWARD devices and therapies, including but not limited to ARC-IM™, ARC-EX™, and ARC Therapy™, alone or in combination with a BCI, are investigational and not available for commercial use.*

About ONWARD Medical

ONWARD is a medical technology company creating therapies to restore movement, function, and independence in people with spinal cord injury (SCI) and movement disabilities. Building on more than a decade of science and preclinical research conducted at leading neuroscience laboratories, the Company has received nine Breakthrough Device Designations from the US Food and Drug Administration for its ARC Therapy™ platform.

ONWARD® ARC Therapy, which can be delivered by external ARC-EX™ or implantable ARC-IM™ systems, is designed to deliver targeted, programmed spinal cord stimulation. Positive results were presented in 2023 from the Company's pivotal study, called Up-LIFT, evaluating the ability for transcutaneous ARC Therapy to improve upper extremity strength and function. The Company is now preparing regulatory approval submissions for ARC-EX for the US and Europe. In parallel, the Company is conducting studies with its implantable ARC-IM platform, which demonstrated positive interim clinical outcomes for improved blood pressure regulation following

SCI. Other ongoing studies include combination use of ARC-IM with a brain-computer interface (BCI).

Headquartered in Eindhoven, the Netherlands, ONWARD has a Science and Engineering Center in Lausanne, Switzerland and a US office in Boston, Massachusetts. The Company also has an academic partnership with .NeuroRestore, a collaboration between the Swiss Federal Institute of Technology (EPFL), and Lausanne University Hospital (CHUV).

For more information, visit [ONWD.com](https://onwd.com), and connect with us on [LinkedIn](#) and [YouTube](#).

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