

# ONWARD® Medical Announces Third Implant of Brain-Computer Interface (BCI) System to Restore Movement after Spinal Cord Injury

*Company continues pioneering research on BCI-enabled system to restore mobility after spinal cord injury*

EINDHOVEN, the Netherlands — September 19, 2024 — 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), announces another successful implant of its investigational ARC-BCI™ System to restore lower limb mobility after SCI.

The ARC-BCI System combines the investigational ONWARD ARC-IM® System (an implanted technology that delivers targeted stimulation to the spinal cord) with the investigational WIMAGINE® BCI from [CEA-Clinatec](#) to create a DigitalBridge™ across the injured spinal cord. The implant procedure was performed on September 12, 2024, by Jocelyne Bloch, MD, head of functional neurosurgery at Centre Hospitalier Universitaire Vaudois (CHUV) in Lausanne, Switzerland.

“The procedure went smoothly, and early signs are encouraging,” said neurosurgeon Dr. Jocelyne Bloch. “We look forward to sharing more information in the coming months as the participant progresses in their rehabilitation and we publish observations from the study.”

This implant is part of an ongoing clinical feasibility study supported by a grant from the European Innovation Council under the [Reverse Paralysis](#) project and coordinated by .NeuroRestore, a Swiss neuroscience research institute. The researchers are also exploring use of the ONWARD ARC-BCI System to address upper limb movement challenges after SCI in a separate early feasibility clinical study funded by the [Christopher & Dana Reeve Foundation](#).

The WIMAGINE BCI from CEA-Clinatec is an epidurally-implanted device with 7 years of human safety data; ONWARD ARC-IM Therapy has now been applied in more than 30 study participants.

“While other companies race to develop BCIs to communicate with and control computers, ONWARD Medical stands alone in our commitment to exploring the potential for this promising technology to restore movement of the human body after paralysis,” said Dave Marver, CEO of ONWARD Medical. “We salute our brilliant partners at CEA-Clinatec and .NeuroRestore for their important contributions to this research.”

This latest news marks the third human implant of the WIMAGINE BCI paired with ARC-IM Therapy to restore thought-enabled movement after SCI and the second for lower limb mobility. The first human use of ARC-BCI Therapy for lower limb mobility occurred in 2021, with results describing the individual’s augmented control over when and how he moved his paralyzed legs published in [Nature](#) in May 2023. In the fall of 2023, an individual was implanted to explore the potential for ARC-BCI Therapy to restore upper extremity function after SCI.

Earlier this year, the Company announced that it has been accepted into the US FDA's new Total Product Lifecycle Advisory Program (TAP) for its ARC-BCI platform. Prior to the acceptance, the Company announced its ARC-BCI System was awarded FDA Breakthrough Device Designation (BDD), a requirement for TAP consideration. This is the Company's 10<sup>th</sup> such award.

To learn more about ONWARD Medical's commitment to partnering with the SCI Community to develop innovative solutions for restoring movement, function, and independence after spinal cord injury, please visit [ONWD.com](https://onwd.com).

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

### **About ONWARD Medical**

ONWARD® Medical 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 scientific discovery, preclinical, and clinical research conducted at leading hospitals, rehabilitation clinics, and neuroscience laboratories, the Company has developed ARC Therapy™, which has been awarded ten Breakthrough Device Designations from the US Food and Drug Administration (FDA).

ONWARD ARC Therapy is targeted, programmed spinal cord stimulation designed to be delivered by the Company's external ARC-EX® or implantable ARC-IM® platforms. ARC Therapy can also be delivered by the Company's ARC-BCI™ platform, which pairs the ARC-IM System with brain-computer interface (BCI) technology to restore movement after SCI with thought-driven control.

Use of non-invasive ARC-EX Therapy significantly improved upper limb function after SCI in the global pivotal Up-LIFT trial, with results published by *Nature Medicine* in May 2024. The Company has submitted its regulatory application to the FDA for clearance of the ARC-EX System in the US and is preparing for regulatory submission in Europe. In parallel, the Company is conducting clinical studies with its ARC-IM Therapy, which demonstrated positive interim clinical outcomes for improved blood pressure regulation following SCI. Other ongoing clinical studies focus on using ARC-IM Therapy to address mobility after SCI and gait challenges in Parkinson's disease as well as using the ARC-BCI platform to restore thought-driven movement of both upper and lower limbs after SCI.

Headquartered in Eindhoven, the Netherlands, ONWARD Medical has a Science and Engineering Center in Lausanne, Switzerland and a US office in Boston, Massachusetts. The Company is listed on Euronext Brussels and Amsterdam (ticker: ONWD).

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

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