

ONWARD Medical Announces First Commercial Sales of ARC-EX System

*UW Medicine and Next Steps Chicago both purchased systems
in late December 2024*

ARC-EX is the first and only FDA approved technology indicated to improve hand strength and sensation in people with spinal cord injury

ARC-EX was named a 2024 TIME Magazine Best Invention

EINDHOVEN, the Netherlands — January 9, 2025 — ONWARD Medical N.V. (Euronext: ONWD), a medical technology company creating innovative spinal cord stimulation therapies to restore movement, function, and independence in people with spinal cord injury (SCI) and other movement disabilities, today announces the first commercial sales of its ARC-EX System in the United States.

The sales mark a significant milestone in ONWARD Medical's mission, coming just days after the US Food and Drug Administration (FDA) granted de novo classification for the ARC-EX System on December 19, 2024. The first and only FDA approved technology indicated to improve hand strength and sensation in people with chronic spinal cord injury, the ARC-EX System was selected as a TIME Magazine Best Invention in 2024.

"The first commercial sales of our ARC-EX System are a pivotal moment in our mission to help people with spinal cord injury, demonstrating our ability to successfully translate scientific discovery into real-world impact for people with spinal cord injury," said Dave Marver, CEO of ONWARD Medical.

"Having witnessed the evolution of this therapy from early research in our labs to an FDA-approved technology, we are thrilled to now offer this groundbreaking treatment to patients at UW Medicine," said Chet Moritz, PhD, professor of Rehabilitation Medicine at the University of Washington School of Medicine. "This type of treatment has the potential to significantly improve hand strength, sensation, and independence for individuals living with spinal cord injury, and we are proud to be the first center to launch this treatment at Harborview Medical Center in Seattle."

In addition to UW Medicine, one of the initial ARC-EX Systems was sold to Next Steps Chicago, aligned with the Company's objective to provide access to this breakthrough technology in community rehabilitation clinics as well as major academic research centers.

"Partnering with ONWARD Medical marks a significant milestone in our mission to redefine recovery, and to innovatively provide the best possible care for those with spinal cord injuries," said Maryleen K. Jones, PT, DHS, NCS, Executive Director of Clinical Operations at Next Steps of Chicago. "This technology could change lives by offering new avenues for recovery that were previously unimaginable."

The ARC-EX System is currently authorized for clinic use in the United States, and the Company anticipates authorization for home use in 2025. ONWARD Medical plans to seek CE Mark certification in early 2025, with commercial launch in Europe expected in 2H 2025. The Company is also developing a pipeline of technologies, including its investigational implantable ARC-IM System, and its investigational ARC-BCI System, an implanted platform that uses a brain-computer interface (BCI) powered by artificial intelligence (AI).

For questions about the ARC-EX System, and its availability in the US, visit survey.onwd.com/support.

About Spinal Cord Injury (SCI)

Spinal cord injury affects approximately seven million people worldwide, including more than 300,000 in the United States. Half of injuries result in tetraplegia, affecting function of all four limbs, and making everyday tasks like eating, grooming, or using a phone extraordinarily challenging. Beyond the immediate loss of motor and sensory function, individuals with SCI face numerous secondary complications such as incontinence, poor blood pressure regulation, and loss of sexual function. The economic impact is equally significant, with lifetime treatment costs for tetraplegia exceeding \$5 million, according to the National Spinal Cord Injury Statistical Center. Historically, these injuries have been considered permanent with limited options for functional recovery, particularly for those more than one-year post-injury.

About ONWARD Medical

ONWARD Medical is a medical technology company creating therapies to restore movement, function, and independence in people with SCI and other movement disabilities. Building on more than a decade of scientific discovery, preclinical research, and clinical studies 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). In addition to the ARC-EX System, which is now cleared for commercial sale in the US, the Company is developing an implantable system called ARC-IM with and without an implanted brain-computer interface (BCI).

Headquartered in the Netherlands, the Company has a Science and Engineering Center in Switzerland and a US office in Boston, Massachusetts. The Company is listed on Euronext Paris, 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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ARC-EX Indication for Use (US): The ARC-EX System is intended to deliver programmed, transcutaneous electrical spinal cord stimulation in conjunction with functional task practice in the clinic to improve hand sensation and strength in individuals between 18 and 75 years old that present with a chronic, non-progressive neurological deficit resulting from an incomplete spinal cord injury (C2-C8 inclusive).

Other Investigational Products: All other ONWARD Medical devices and therapies including ARC-IM and ARC-BCI are investigational and not available for commercial use.

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