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Restoring the sense of touch

A Minneapolis firm's device is designed to help people sidelined with nerve damage regain the ability to walk.

Imagine trying to walk without being able to feel your feet. For 20 million Americans with peripheral neuropathy, this is not a hypothetical situation. The condition, in which nerve damage steals the sense of touch from the lower limbs, causes millions of falls and trips to the emergency room every year.

Neuropathy has more than 100 different known causes, but advanced diabetes is one of the most common.

Now a nascent Twin Cities company called RxFunction is closing in on commercial sales of a medical device that it bills as the first "wearable sensory prosthesis" that can address the patient's lack of foot sensation to prevent falls and get users off the couch.

"It has this dramatic impact on daily activities," said company president and co-founder Lars Oddsson, who helped develop the technology while at Boston University. Patients with the device "can now be involved in daily life again."

The device, called the Walkasins, consists of two wearable components that work together to detect when a person is off-balance and about to fall.

That information normally comes from nerves in the bottom of a person's foot, whether or not they realize it; but with neuropathy, that signal is missing. Walkasins are designed to address that sensory gap and transform a wobbly gait into a confident stride.

The device has been validated in early clinical testing funded in part by federal grants and is now being tested in a larger clinical setting at the Minneapolis VA Health Care System.

The device is not yet for general sale. Company CEO and co-founder Dan Leach said the device will eventually be registered with the FDA as a 510(k)-exempt device. Although that designation means the device is considered low risk, companies still have to follow detailed quality manufacturing rules to sell FDA-registered devices.

Unlike with many medical devices, surgery is not required for using Walkasins. Rather, the device includes a semi-durable foot pad worn inside a regular shoe that has sensors reading the varying level of pressure in key locations on the sole of the foot. The footpad is intended to be swapped out every three months or so.

That foot-pressure data is captured and analyzed by an algorithm inside a tiny computer strapped to the patient's ankle. The ankle unit also includes a series of four vibrating motors that read the algorithm outputs and trigger the vibratory signals, telling the wearers when and where to adjust their balance or gait based on hundreds of foot-pressure readings per second.

Although it may not sound intuitive, Oddsson and Leach say wearers report being able to understand the signals and walk normally again with almost no instruction. "They're not

thinking about it. The brain just knows how to assimilate the information,” Leach said. “The skin is a marvelous way to transmit information.”

Though not yet on the market, the product has had several votes of confidence. RxFunction was a finalist in the 2013 Minnesota Cup competition for innovative start-ups and has received two rounds of funding through the National Institute of Health’s Institute on Aging.

Leach noted that the small-business innovation grants came through during the infamous “fiscal cliff” period in 2012-13, in which funding for such programs was slashed but not cut off entirely. “Our financial discipline of the company was set during the fiscal cliff,” Leach said.

The privately held company is headquartered in Minneapolis and has accepted an undisclosed amount of funding for Minnesota Investment Bank and Cedar Point Capital and about \$1.3 million from the NIH.

Once the device is on the market, likely before year’s end, Walkasins will be available by prescription after a medical assessment for neuropathy, clinical need and potential physical benefits. The manufacturer’s list price for the device will be \$4,400 though Leach noted that the price may come down as sales rise.

So far, only a handful of the devices have been sold, but the buyers are notable: the U.S. Department of Veterans Affairs, which runs VA healthcare facilities and sees potential in the veteran population, who have higher rates of neuropathy than the general populace.

And the other buyer? “We sold one unit to NASA,” Leach said. The U.S. space agency is exploring the idea of using the technology for Mars-bound astronauts, who will have plenty of options to maintain strength and cardiovascular health, but may find it difficult to maintain their ability to balance over a long mission, he said.

