



RxFunction Announces Plans for Long-Term Clinical Trial for walkasins®

The walk2Wellness study is designed to assess longer-term mobility and quality of life benefits for people living with peripheral neuropathy

For Immediate Release

Eden Prairie, MN - (May 9, 2018) – RxFunction, Inc., a medical device company that created **walkasins® – the first Wearable Sensory Prosthesis (WSP™)** – has announced plans to conduct its first long-term clinical trial of **walkasins®**, the **walk2Wellness** study. The announcement was made in conjunction with Peripheral Neuropathy Awareness Week, (May 6 – 12), sponsored by [The Foundation for Peripheral Neuropathy®](#). Peripheral neuropathy, commonly a consequence of diabetes or chemotherapy, and widely present in the elderly population is estimated to affect 20 million Americans, according to the [National Institutes of Health](#). Peripheral neuropathy, a disorder in which the nerves in the feet are damaged, can cause numbness and pain, and lead to loss of balance function and increase the risk of falls.

The walk2Wellness clinical trial will evaluate **walkasins** use on 100 patients from multiple sites across the country for up to one year. The randomized, cross-over trial will involve patients with sensory peripheral neuropathy experiencing gait and balance problems who are at high risk of falling. Plans call for participants to be tested for gait function, balance confidence and social participation measures immediately and after 10, 26 and 52 weeks, with 10 weeks being the primary end-point of the study. Recruitment of patients for the **walk2Wellness** study is expected to begin this summer and will be handled by the participating sites.

The **walk2Wellness** trial will build upon a recent study of **walkasins** at the **Veterans Administration Medical Center in Minneapolis** that demonstrated short-term immediate improvement of **walkasins** on functional balance and walking speed resulting in reduced fall-risk in a majority of patients.

“Already we have seen remarkable results with individual patients showing significant improvements in gait outcomes, reducing fall risks and walking more confidently using **walkasins**, said Dr. Lars Oddsson, who co-invented and developed the patented technology while a research professor at **Boston University’s Neuromuscular Research Center**. “We now hope to determine that **walkasins** can provide sustained longer-term improvement in clinical and patient reported outcomes. In addition, we expect to identify which patients receive the most significant benefits from our technology. The data we collect in the **walk2Wellness** study will help us address insurance and Medicare reimbursement for walkasins.”

Nationally recognized in balance research and clinical application, Dr. Diane Wrisley, Professor and Director of Post-Professional Programs, **Wingate University Department of Physical Therapy in North Carolina**, has conducted a long-term case-study on a patient who has used **walkasins** on a daily basis for over a year. “The patient has shown dramatic and sustained improvement in several clinical outcome measures, demonstrating normal performance on several of these measures,” she said. “He is more active while using **walkasins**.”

Walkasins consists of a thin sensor-instrumented Foot Pad placed in the shoe that measures changes in foot pressure reflecting the patient’s state of balance. The Foot Pad connects to a Leg Unit that contains a micro-processor and a proprietary algorithm that activates vibrator motors placed around the leg to provide new tactile balance cues to the patient. Leaning too far in any one direction triggers a vibration on that side of the leg signaling to the brain to correct balance. Patients can then better sense where their feet are on the ground helping them to improve balance and mobility.

About RxFunction, Inc. RxFunction is a medical device company with an initial focus on developing and leading a new business segment within the U.S. medical grade assistive technology marketplace. The company’s vision is to improve physical ability and quality of life for patients with sensory peripheral neuropathy at high risk of falling. Privately held and headquartered in Eden Prairie, MN, RxFunction created walkasins® building upon patented technology developed by co-founder Dr. Lars Oddsson as a research professor at Boston University’s Neuromuscular Research Center. Walkasins® has not been submitted to the FDA for review and is not available for sale at this time. Walkasins® is manufactured in Minnesota.

RxFunction website: www.rxfuction.com

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