

Walkasins is a prescribed wearable sensory prosthesis enabling patients with Sensory Peripheral Neuropathy to improve walking balance and subsequently decrease risk of falls.

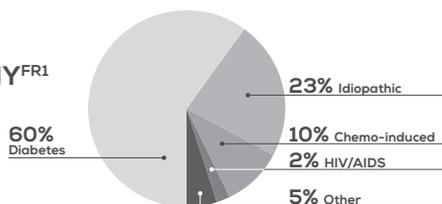
Sensory Peripheral Neuropathy and Balance

Sensory Peripheral Neuropathy (SPN) is a type of nerve damage that frequently affects sensory nerves in the soles of the feet that are responsible for signaling sense of touch, pressure and vibration, information that is crucial for our sense of balance^{1,2,3}. SPN is a common form of polyneuropathy, seen in up to 50 percent of people with diabetes⁴ and in a majority of cancer patients receiving neurotoxic anti-cancer drugs that cause chemotherapy-induced peripheral neuropathies^{5,6}. SPN may also be idiopathic, especially in the older population⁷. SPN is well documented to be associated with gait and balance impairments and a higher prevalence of falls in these categories of patients^{8,9}.



In individuals with SPN and gait and balance impairments, Walkasins replaces lost nerve function and restores important sensory information related to foot contact with the ground to the central nervous system.

LEADING CAUSES OF PERIPHERAL NEUROPATHY^{FR1}



Physiology of the Balance System

When a normally functioning adult human stands, walks, or performs balance activities, the central nervous system (CNS) relies on three principal sources of sensory information to perform movements and maintain balance in a safe and coordinated manner:



Somatosensory System

Signals position and touch information including critical pressure sensation from the soles of the feet.



Vestibular System (Inner Ear)

Signals how the head is oriented in space with respect to gravity to help with balance.



Visual System (Sight)

Helps maintain orientation and upright balance related to the environment.

Contributions to balance control from these three channels of sensory information are not “weighted” equally and may change with environmental circumstances. When standing on a firm base of support in a well-lit environment, healthy individuals typically rely about 70% on somatosensory system information, 20% on vestibular system information, and 10% on visual system information¹⁰. The CNS integrates these sources of afferent information to ensure activation of relevant muscles to maintain upright balance and avoid falling.

In normal balance control, the detection of plantar pressure occurs through cutaneous mechanoreceptors in the glabrous skin of the soles of the feet^{1,2,3}. This pressure information is signaled through cutaneous afferents to the spinal cord, brainstem, thalamic relay nuclei and onto the somatosensory cortex of the brain¹¹. An appropriate response is computed in the CNS and signaled through the body’s efferent pathways to activate appropriate muscles to control balance and avoid falling.

While normal balance function naturally declines with age, various balance abnormalities also result from diseases, conditions, or side effects from prescribed therapies. In individuals with SPN, the ability to accurately sense, measure and communicate plantar pressure information is compromised due to afferent nerve damage, often resulting in poor or staggered gait, which increases the risk of falls with the potential for serious injury. Although these patients commonly have intact efferent pathways and motor function, the inability of their afferent nerves to sense and signal plantar pressure leaves the CNS unaware of essential information for optimal balance control.

The focus for the design and development of Walkasins Sensory Prosthesis technology is on the somatosensory system and the need to replace plantar pressure sensation in patients with SPN, thereby helping to improve their balance.

Sensory Peripheral Neuropathy and Balance Impairment Research



The role of plantar cutaneous sensory afferent information for balance has been studied for more than two decades and is well-established in the peer-reviewed study literature^{2,3}. Lars Oddsson, Ph.D., a scientist and widely published investigator in topics related to balance, co-invented Walkasins[®] with PhD student Peter Meyer during his tenure at Boston University's Neuromuscular Research Center. Their early work on the role of plantar cutaneous sensation for balance control^{2,3}, combined with promising pilot data¹² led to the NIH-funded development of Walkasins for patients presenting with gait and balance impairments related to SPN.

A randomized cross-over study of short-term, in-clinic effects of Walkasins use conducted at the Minneapolis Veterans Affairs Medical Center (VAMC) published in PLOS ONE, found clinically meaningful and statistically significant improvements in gait speed and functional balance in patients with SPN using Walkasins¹³. The authors stated **"findings suggest new sensory balance cues provided to the lower limb can modulate the activity of relevant nerve afferents and become integrated into sensorimotor control of balance and gait."**

A multi-site clinical trial of long-term effects of daily Walkasins use (walk2Wellness, [ClinicalTrials.gov #NCT03538756](https://clinicaltrials.gov/ct2/show/study/NCT03538756)) was published in Frontiers In Aging Neuroscience¹⁴. The trial sites included the Minneapolis Veterans Affairs Health Care System, M Health Fairview, Baylor College of Medicine, Hebrew Senior Life (a Harvard Medical School Affiliate), and Johns Hopkins Medical Center. After 10 weeks of daily Walkasins use, this long-term study demonstrated clinically meaningful improvements in Functional Gait Assessment (FGA) and gait speed, which is associated with a lower fall risk. Authors concluded that **"a wearable sensory prosthesis may provide a new way to treat gait and balance problems and manage falls in high fall-risk patients with PN."**

In addition to the article in Frontiers in Aging Neuroscience, study data has been reported to the American Academy of Neurology, Peripheral Nerve Society, the American Congress of Rehabilitation Medicine, and the American Assembly of Physical Medicine and Rehabilitation.

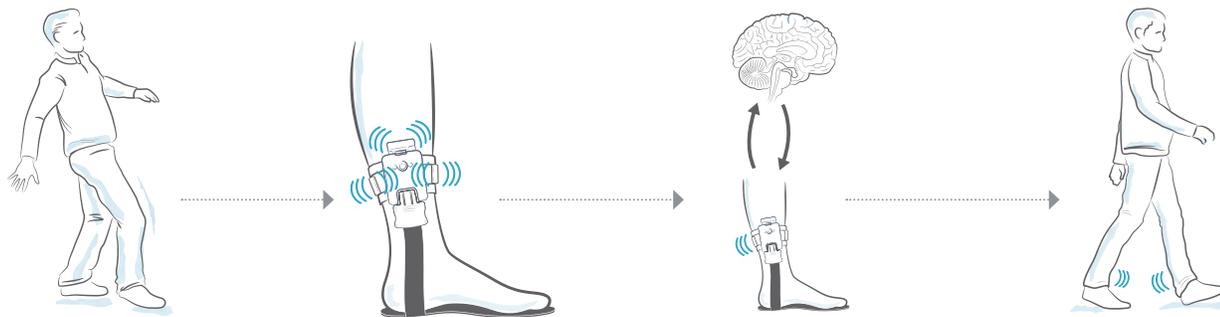
Walkasins[®] Lower Limb Sensory Prosthesis: How it Works

The Walkasins System is designed to serve as a prosthesis for the lost sensory nerve function from the plantar surface of the foot.

Walkasins Foot Pads detect plantar pressure which is analyzed and interpreted in real-time through a sophisticated proprietary software algorithm in the microprocessor within the Walkasins Leg Unit. The Leg Unit, worn on the lower leg just above the ankle, provides gentle balance stimuli administered by four tactile stimulators embedded in the Leg Unit. Walkasins replaces lost plantar sensation with tactile balance stimuli that modulate cutaneous mechanoreceptors above the ankle where sensation

remains sufficiently intact. These new balance stimuli replace lost somatosensory information necessary for the CNS to complete the sensorimotor circuit for balance control.

Minimal instruction is required for patients to benefit from this new sensory information. Following a brief 10-minute in-clinic orientation session, a majority of patients showed meaningful improvements in clinical outcomes¹³.



Lost foot sensation due to peripheral neuropathy causes unsteady walking, often leading to falls.

Walkasins evaluates balance and delivers gentle sensory signals to functioning nerves around the lower leg.

This new sensory information is integrated by the brain to help replace lost foot sensation.

Balance and gait are improved, restoring mobility and confidence.

Adopting a Care Plan for Patients with SPN Susceptible to Falls

Healthcare providers are encouraged to adopt and implement clinical practice guidelines for fall prevention, such as the STEADI^{15,16} initiative developed by the Centers for Disease Control (CDC).

The **STEADI** initiative consists of three core elements, **SCREEN**, **ASSESS**, and **INTERVENE** to help healthcare providers identify and address patients who are at risk for falling. Below is an outline of how these elements can be applied when addressing fall risk and balance impairments for patients with SPN who may benefit from Walkasins.



Screen

Regular screening of patient-reported fall history and fear of falling is an important step in identifying patients at risk of falls.

Screening questions help identify patients who are at high fall risk and may benefit from Walkasins.

Patient displays or reports:

- Numbness and reduced sensation in feet?
- Difficulty with balance?
- History of falls?
- Reduced or limited mobility?
- Low confidence, fearful, afraid, or worried about falling?¹⁷

SPN patients are 15 times more likely to experience an injurious fall⁸.



Assess

SPN is a specific fall risk factor which, along with evaluations of gait and balance, may suggest a Falls Plan of Care be developed and interventions implemented.

Assessment of risk factors and previous treatments may suggest further interventions are warranted.

Assess and evaluate the following:

- Despite previous treatments and interventions, impaired mobility continues to exist, leaving the patient at high risk for falls and injury.
- Patient has the capacity to safely use device, either independently or with a caregiver.
- Successful demonstration with use of Walkasins.

Walkasins can be considered for patients who meet these criteria.



Intervene

Interventions, devices, and treatments to address the identified risk factors should be implemented to help mitigate high fall risk and improve safety.

Prescribe and incorporate Walkasins as an intervention to reduce fall risk.

Directly targets the root cause of lost sensory nerve function:

- Other treatment interventions for balance impairment, including canes, walkers, and balance training are compensatory and do not address the reason for increased fall risk due to SPN.
- Using sensors, microprocessors, and an adaptive algorithm, Walkasins mimics the detection and signaling of sensory information thereby directly replacing critical afferent input.
- Walkasins assists individuals by actively improving their gait and balance function and reducing fall risk.



Walkasins is an evidence-based intervention, which aligns with the STEADI initiative for preventing falls.

Lars Oddsson, PhD

RxFunction Co-Founder and Walkasins Co-Inventor

Lars Oddsson, PhD, is a scientist, an inventor, a visionary leader and an entrepreneur. Dr. Oddsson has studied the physiology and science of balance for over three decades and is widely cited in the peer-reviewed scientific literature with an h-index of 41¹⁸. Oddsson teaches in the M.S. in Medical Device Innovation program at the Technological Leadership Institute at the University of Minnesota, where he also holds a position as Adjunct Professor in the Division of Rehabilitation Science. He is Visiting Professor at Reanati School of Community Health, Ben-Gurion University, Israel. Oddsson is also Co-investigator at NASA's Johnson Space Center on projects related to the development of sensorimotor countermeasures to long-term space flight. Oddsson received engineering training at Linköping University, his doctorate in Medical Sciences at the Karolinska Institute, both in Sweden, and post-doctoral training in biomedical engineering at Boston University. He has held academic appointments at Karolinska Institute, Boston University, MIT and Harvard Medical School. He is also chief technology officer and co-inventor of Walkasins, a wearable sensory prosthesis for balance.

Caution: Please review the Instructions for Use for a complete listing of indications, contraindications, warnings, and precautions prior to using this device. There are potential risks and complications with using this product including but not limited to: patients should not rely solely on Walkasins to maintain balance, this product cannot prevent falls; potential skin breakdown or injury; long-term effects of persistent low-intensity vibrations to the skin are unknown; over-tightening the strap of the Leg Unit can reduce blood flow and cause injury.

Indications for Use

Walkasins is an external lower limb sensory prosthesis intended to replace the nerve function used for detection and signaling of foot pressure sensation.

Walkasins is indicated for patients with lower limb sensory peripheral neuropathy who present with gait and balance impairments. Walkasins is indicated for patients who can feel the tactile stimuli from the Leg Unit on the lower leg.

Contraindications for Use

Walkasins is contraindicated for:

- Untreated lymphedema;
- Untreated lesion of any kind, swelling, infection, inflamed area of skin or eruptions on the lower leg near product use;
- Acute thrombophlebitis including deep vein thrombosis;
- Untreated fractures in the foot and ankle;
- Severe peripheral vascular disease.

Patient Selection Criteria

- Age: Any, as long as the Foot Pad and Leg Unit fit properly.
- Weight: 55 – 300 lbs. (25 – 136 kg).
- Health: Must be able to walk without severe impairment even when using assistive devices.
- Education: Must be able to read and understand Instructions for Use.

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