PoNS®

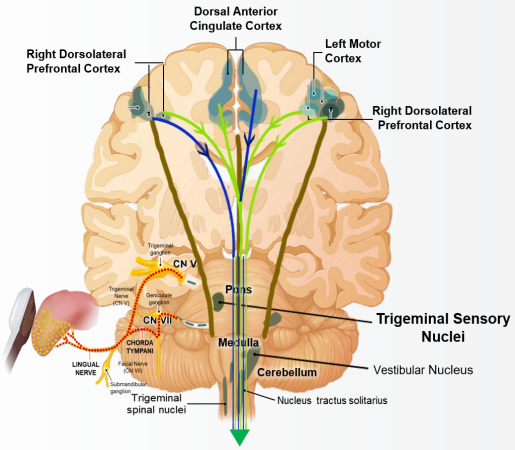
Portable Neuromodulation Stimulator

What is PoNS?

PoNS is an innovative, non-invasive neuromodulation system that delivers a mild electrical stimulation to the surface of the tongue.

PoNS is indicated as a prescription-only therapy for adults 22+ as an adjunct to a supervised therapeutic exercise program, for the treatment of gait deficits due to mild-to-moderate multiple sclerosis or chronic stroke symptoms.

The Science Behind PoNS[3,4]



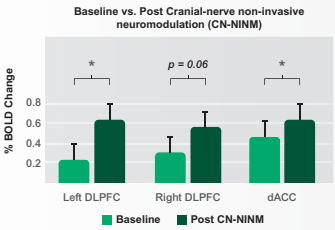
Translingual Neurostimulation (TLNS): When the PoNS device is on, the electrodes on the mouthpiece send mild electrical impulses to the cranial nerves on the surface of the tongue. This electrical stimulation creates a flow of neural impulses into the brainstem and cerebellum— the body's movement control center.

Brain & Neuroplasticity: From the brainstem, these impulses travel throughout the brain and activate a neural network involved in regulating motor function and initiate a cascade of changes in multiple brain regions resulting, with consistent use, in neuroplasticity.

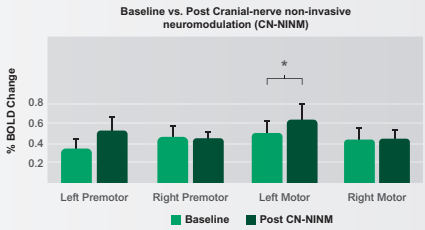
Leonard et al.[6]

Working memory and gait imagery activity during fMRI scans revealed brain activation in the dorsolateral prefrontal cortex, anterior cingulate cortex, and left motor cortex, after 14 weeks of PoNS therapy, while the control group only showed increased activation in premotor cortex from baseline.

WORKING MEMORY



GAIT IMAGERY



How PoNS is Applied

PoNS is to be used in conjunction with supervised therapeutic exercise, referred to as PoNS Therapy.

PoNS Therapy is a comprehensive 12-week program for patients with chronic stroke symptoms or 14-week program for patients with MS which combines in-clinic and in-home use of the PoNS device guided by a PoNS Trainer to focus on targeted therapeutic exercises.

The Benefit of PoNS

Portable device to induce neuroplasticity

Individualized exercise plan to fit patient's needs

State-of-the-art technology to track compliance

Treatment primarily done at home

Non-pharmaceutical treatment

Learn More:
855.918.1582
PonsTherapy.com

bioness®

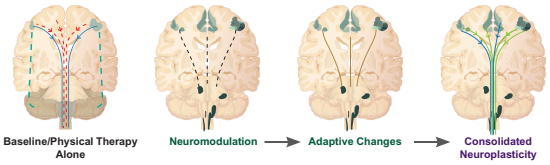
The Studies Behind PoNS

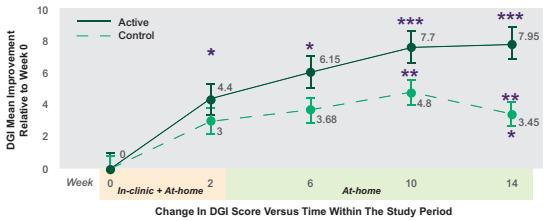
MULTIPLE SCLEROSIS

Tyler et al.[5]

100% improvement in the DGI* scores
All 10 subjects in the active **PoNS + PT group** experienced at least a 4-point improvement from baseline to week 14 in the Dynamic Gait Index.

Only 3 subjects in the Placebo **PoNS + PT group** experienced at least a 4-point improvement from baseline to week 14 in the Dynamic Gait Index.

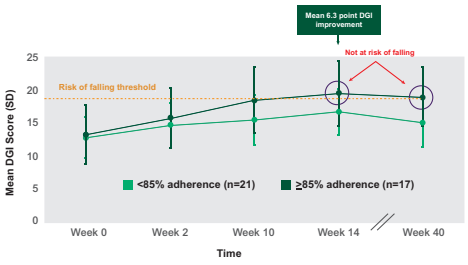




Change In DGI Score Versus Time Within The Study Period

PoNSTEP

Adherence (≥70%) to PoNS treatment is associated with a statistically significant and clinically meaningful improvement in gait deficit over 14 weeks. Participants with ≥85% adherence were fall risk free (60%) and maintained improvement at 6-m after end of treatment.

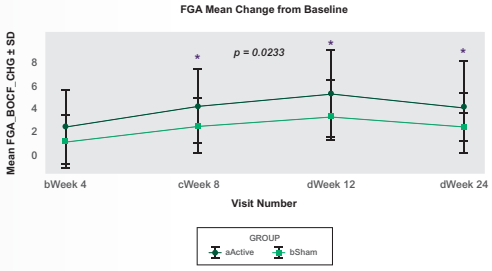


*DGI = Dynamic Gait Index, a measure of the ability to walk. Tyler et al. Journal of NeuroEngineering and Rehabilitation 2014, 11:79

STROKE

Stroke Registrational Program

Treatment with PoNS transitions standard physical rehabilitation therapy from a non-clinically significant (PT) to a clinically significant outcome (PoNS + PT). PoNS Therapy led to a clinically meaningful (MCID >4) adjusted mean change in FGA of 5.37 points (95% CI: 4.23 to 6.52) from baseline to Week 12, while the sham group experienced a non-clinically meaningful change of 3.31 points (95% CI: 1.96 to 4.66).



Responder Rate

45% more subjects achieved a Clinically Meaningful (CM) response in the PoNS group using a 6-point threshold (56.1% vs 11.1%) and at least 30% more subjects achieved response in the PoNS group at a ≥4-point improvement threshold (63.1% vs 33.3%) than in the sham group.

Real World Evidence[7,8]

58%
of the people with MS had at least a 4 point improvement in their FGA (Functional Gait Assessment)[7]

70%
of those with Stroke experienced at least a 5 point improvement in FGA[8]

In all clinical studies and the real-world utilization, no one experienced any serious or persistent side effects associated with the device.

References: 1. Wallin et al. (2019); Neurology; DOI: 10.1212/WNL.0000000000007035 **2.** Williams et al. (2014); Multiple Sclerosis International; DOI: 10.1155/2014/203183 **3.** Ptito et al. (2019); Presented at 9th Annual Traumatic Brain Injury Conference (Arlington, VA) **4.** Danilov et al. (2015); in Brain Neurotrauma: Molecular, Neuropsychological, and Rehabilitation Aspects (CRC Press) **5.** Tyler et al. (2014); Journal of NeuroEngineering and Rehabilitation **6.** Leonard et al. (2017); Multiple Sclerosis Journal – Experimental, Translational and Clinical **7.** Helius Medical Inc. (2020); Real World Evidence Study (Data on file, August 2, 2020) **8.** Helius Medical Inc. (2023); Statistical Analysis Report (Data on file, January 26, 2023)

Indication for Use: The PoNS device is indicated for use as a short term treatment of gait deficit due to mild to moderate symptoms from multiple sclerosis and is to be used as an adjunct to a supervised therapeutic exercise program for adults 22 years of age and over by prescription only. The PoNS device is indicated for use as a treatment of dynamic gait deficits due to chronic symptoms from stroke and is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only.

The PoNS device delivers electrical stimulation directly to the surface of the tongue. Precautions for use are similar to those for wearable electrical stimulation medical devices. Electrical stimulation should not be used: if there is an active or suspected malignant tumor, in areas of recent bleeding or open wounds, and in areas that lack normal sensation. The PoNS has not been tested on, and thus should not be used by individuals who are pregnant. Do not use the PoNS if you are sensitive to nickel, gold or copper.

Full prescribing information can be found in product labeling or at https://bionessmedical.com/pons/safety-information/.

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