

- The study demonstrated that VitalStim Therapy is a safe application treatment approach. Over 4,500 stimulations were administered to nearly 900 patients without negative side effects like laryngospasms or changes in heart rhythms or blood pressure; no problems were observed in patients who had pacemakers.
- The lasting effectiveness of VitalStim Therapy was demonstrated in a 3-year follow-up study (submitted to the FDA), which showed that the improvement in swallow function achieved by this therapy persisted for up to 3 years after treatment.

### About Empi

Empi is a leading manufacturer and provider of non-invasive medical products for pain management and physical rehabilitation. Headquartered in St. Paul, Minnesota, Empi is committed to delivering positive patient outcomes and providing innovative products specifically designed to meet the needs of the patient, medical professional and payor. More information about Empi and its wide range of products and services can be found on the company's Web site, [www.empi.com](http://www.empi.com).

### About the VitalStim Therapy Team at Empi

A dedicated team of professionals actively supports the clinicians in the field, providing tangible clinical solutions and generating significant cost benefit for the healthcare facilities. Through its infrastructure and its people, Empi stands behind its products and guarantees ongoing quality and reliability.



For more information on VitalStim Therapy, call us at **1-800-506-1130** or visit [www.vitalstimtherapy.com](http://www.vitalstimtherapy.com)



VitalStim® Therapy is a breakthrough therapy approach to treat dysphagia (difficulty with swallowing).

Since its introduction in 2003 its adoption has quickly grown and is now in use by a majority of dysphagia treatment professionals.

## About Dysphagia

- Dysphagia is a neglected medical disorder that impacts as many as 15 million Americans, with approximately one million people annually receiving a new diagnosis of the condition.
- One in 17 people will develop some form of dysphagia in his or her lifetime, including 50 to 75 percent of stroke patients and 60 to 70 percent of patients who undergo radiation therapy for head and neck cancer. Estimates of dysphagia's prevalence in such neurological diseases as Parkinson's Disease and ALS run as high as 90 percent..

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Dysphagia, or difficulty swallowing, impacts as many as 15 million Americans...  
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- Dysphagia is especially prevalent among the elderly; for instance, studies suggest that up to 75 percent of nursing home residents experience some degree of dysphagia. As many as half of all Americans over 60 will experience dysphagia at some point after that age.
- According to the Agency for Health Care Policy and Research (AHCPR), it is estimated that over 60,000 people a year die from cases of aspiration pneumonia just in the United States, with a large proportion of these cases due to dysphagia arising from a variety of causes: primarily stroke, degenerative neurological diseases, and head and neck cancer
- If not properly managed, dysphagia can lead to aspiration pneumonia, choking, chronic malnutrition, severe life-threatening dehydration, an increased rate of infection, longer hospital stays, or long-term institutional care.

- Dysphagic patients experience personal discomfort and a drastic reduction in the quality of their lifestyles due to the inconvenience of feeding tubes. The loss of swallowing can also lead to severe depression due to the interruption of patients' normal ways of life.

## About VitalStim® Therapy

- VitalStim Therapy is a breakthrough therapeutic intervention for use in the treatment of dysphagia. It is a specialized form of neuromuscular electrical stimulation (NMES), specifically designed to treat dysphagia. NMES has a long-term track-record in a wide variety of therapeutic and rehabilitative settings.
- Cleared to market by the FDA in December 2002, VitalStim Therapy is a non-invasive external electrical stimulation therapy that re-educates the throat muscles needed for swallowing. The device is a portable, dualchannel electrotherapy system that is used with electrodes specifically designed for application to the muscles of the throat to promote swallowing.
- VitalStim Therapy is delivered using custom designed surface electrodes placed over the target swallowing muscles. The electrodes have been specifically designed to accommodate the anatomy of the neck and to perform to the specifications of the VitalStim Therapy protocol.
- Dysphagia is traditionally treated by speech-language pathologists, whose main focus is prevention of aspiration and its complications; until VitalStim Therapy, few curative therapeutic techniques had been available.
- Following the referral by a physician, VitalStim Therapy is typically administered by a clinician who has been certified in the use of the technique, based on a 2-week online learning curriculum followed by a 2-day onsite certification course. VitalStim Therapy can only be administered by those who have passed the certification process.
- Once the patient's dysphagia has been medically evaluated, the treatment sessions begin with the electrodes placed on the skin at specific points on the patient's throat, and feeding practice and other exercises are performed. Therapy sessions are repeated, until the patient's swallowing patterns have been restored to the optimum level.
- Patients frequently see dramatic improvement in six to 20 daily sessions.
- Since it became available in 2003, over 12,000 clinical professionals have been certified to use VitalStim Therapy. To date, VitalStim Therapy has been utilized in more than 10,000 facilities throughout the world; more than 800,000 patients have been helped by this therapy.

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...VitalStim Therapy represents a significant savings,... by reducing the burden of feeding tubes and improving patient outcomes.  
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- Compared to the cost of managing a patient with a feeding tube, VitalStim Therapy represents a significant savings. Feeding tube costs are reported to average over \$31,000 per patient per year. The total annual cost to Medicare just for enteral feeding supplies for outpatients was more than \$670 million in 2003. This figure is almost 6% of the total Medicare budget for that year. Including the monies spent in hospitals, the total cost of dysphagia to the health care system is well over \$1 billion dollars and rising rapidly. The prevalence of feeding tube usage, according to a recent study, is also rising steadily.

## About the Evidence: Efficacy & Safety

- Over 30 peer reviewed studies have been presented and/or published on the safety and efficacy of VitalStim Therapy
- The studies demonstrate that VitalStim Therapy is safe, that professionals and patients are satisfied, and that the therapy increases patient outcomes.
- VitalStim Therapy's clearance by the FDA was based on a long-term study of nearly 900 patients, both in-patient and outpatient, which included direct comparison of electrical stimulation using VitalStim Therapy with thermotactile stimulation.
- Electrical stimulation proved to be significantly more effective in restoring swallowing function.
- In patients with severe dysphagia, VitalStim Therapy's success rate in restoring patients' swallowing function past the point of their requiring a feeding tube (Percutaneous Endoscopic Gastrostomy or PEG) was 97.5%, versus 39% for thermal application.
- Further, in well over one-third of these severe dysphagia cases, VitalStim Therapy was able to restore the patient's swallowing function completely
- VitalStim Therapy proved effective across the full spectrum of age groups and in both sexes.
- VitalStim Therapy's effectiveness was independent of the time between the onset of dysphagia and treatment.

