

# VitalStim<sup>®</sup> Therapy

## Fact Sheet



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ysphagia, or difficulty with swallowing, is a sorely 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 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.
- Indeed, 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. Based on CDC data, more people

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die annually from dysphagia-related causes than from all forms of liver disease, kidney disease, and HIV-AIDS combined – and nearly as many die from diabetes, the #6 killer of Americans.

- 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 – and possibly death.
- Dysphagic patients experience personal discomfort and a drastic reduction in the quality of their lifestyles due to the inconvenience and pain of feeding tubes, which for many has been the primary treatment option for this

condition. 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 completely new, 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 proven, 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, dual-channel 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 uniquely designed external skin electrodes, placed on specific neck muscles in a pattern that has been fully validated. Because the electrical current emitted by the device has been carefully selected to elicit a contraction in the muscles responsible for a normal swallow response, use of VitalStim Therapy leads to improved quality of the muscle contraction, and thereby to improved swallow function.
- Dysphagia is traditionally treated by speech-language pathologists, whose main focus is prevention of aspiration and its complications; until VitalStim Therapy, little or no 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-day training seminar. VitalStim Therapy can only be administered by those who have passed the certification process.

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*...VitalStim  
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- Once the patient's dysphagia has been medically evaluated, the 60-minute 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 daily (or almost every day), until the patient's swallowing patterns have been restored to the optimum level.
- Patients frequently see dramatic improvement in six to 20 daily sessions – sometimes in as little as three days.
- Since it became available in 2003, over 5,000 clinical professionals have been certified to use VitalStim Therapy. To date, VitalStim Therapy has been utilized in more than 4,000 facilities throughout the world; more than 100,000 patients have been helped by this therapy.
- Compared to the cost of managing a patient with a feeding tube, VitalStim Therapy represents a significant savings, even including the cost of all treatment sessions and all special supplies (such as electrodes). 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.
- VitalStim Therapy is actively facilitating scientific research, providing outcome data for peer-review analysis – more than 20 such studies are currently underway or being submitted for publication.

## **About the VitalStim Therapy FDA Study: Efficacy & Safety**

- 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 thermal stimulation, a common approach to treating dysphagia.
- Based on this direct comparison study, electrical stimulation proved to be significantly more effective in restoring swallowing function. Measurable improvement was noted in over 98% of patients studied, compared with less than 33% of the patients receiving thermal stimulation.

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- 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, while not a single patient was restored to full function by means of thermal application.
  - VitalStim Therapy was effective independently of the cause of a patient's dysphagia, including such common causes as stroke, head or neck cancer, degenerative neurological conditions (e.g., Parkinson's Disease, Multiple Sclerosis), and respiratory conditions.
  - VitalStim Therapy proved effective across the full spectrum of age groups and in both sexes. The success rate in patients over 80 years old was comparable to that in patients 51-80 years old, as was the success rate in children aged 1-4, and even in infants.
  - VitalStim Therapy was also effective independently of any other health problems that were unrelated to patients' dysphagia, such as diabetes, hypertension, coronary artery disease or chronic obstructive pulmonary disease (COPD).
  - VitalStim Therapy's effectiveness was independent of the time between the onset of dysphagia and treatment. It was just as effective in patients who had suffered from dysphagia for over 6 months as in those who had only recently developed the condition.
  - In fact, VitalStim Therapy even worked in patients who had endured swallowing impairment for as long as 40 years. Long-term sufferers (over 6 months) required more treatments than short-term sufferers: an average of over 8 treatments versus an average of 5 respectively.



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- The study also showed that VitalStim Therapy is a safe application of electrical stimulation. 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, and that the superior results of electrical stimulation over thermal stimulation are maintained long-term.

## About Chattanooga Group

VitalStim Therapy is a product of Chattanooga Group, which has been a worldwide leader in providing medical products for over 50 years, with a track record of providing technology to the rehabilitation market, particularly in the area of electrotherapy. Chattanooga Group is headquartered in Hixson, TN, just outside Chattanooga.



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