VitalStim® Therapy vs. Non-FDA Cleared NMES Devices in the Treatment of Dysphagia:

Problems and Risks in Perspective

Neuromuscular electrical stimulation (NMES) is a treatment modality that has a long and proven track record in many areas of rehabilitation. However, special care must be taken when employing this modality in the treatment of dysphagia.

For example, the use of non-FDA cleared devices and/or electrodes in the application of electrical stimulation to the muscles of the throat for the treatment of dysphagia may put a patient at risk for unintended medical complications, such as laryngeal spasms, aspiration, or trismus.

In addition, such use exposes the provider to risks attendant upon the application of a medical device for a condition for which it does not carry an indication.

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To date, *only one* NMES product has been cleared by the FDA for use on throat muscles in the treatment of dysphagia, VitalStim® Therapy. According to published FDA clearance indications, *The VitalStim® Therapy Treatment Device is intended for muscle re-education and for the creation of functional muscle use patterns in the throat muscles necessary for correct and functional swallowing. The device is indicated for treatment of dysphagia from any etiology other than mechanical causes requiring surgery.*

Development of VitalStim® Therapy

Based on a formal request from the Chattanooga Group, the FDA in late 2001 cleared a new application for electrotherapy for the medical management of dysphagia. The product, VitalStim® Therapy, was the subject of a clinical trial submitted to the FDA that lasted more than five years and involved over 800 patients. Two reasons for the large volume of patients in the study were to thoroughly assess safety issues involving the use of electrical current on throat muscles, and to determine the ***effectiveness*** of treatment.

Careful protocol planning was established and adjustments were made to both the electrotherapy system and the electrode delivery system to minimize the occurrence of any adverse effects. In addition, a three-year follow-up study was conducted, which determined that the results achieved in the original study were sustained.

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Among the most critical factors in the development of this unique medical device were placing limitations on the electrical current output of the device, as well as consideration of VitalStim-specific electrode design and electrode placement. Even now, the manufacturer continues to make a significant investment in an ongoing program of technology improvement and modifications to maintain the high quality, and ensure the safety of the custom-designed VitalStim® Therapy electrodes used in the sensitive application for treatment of dysphagia.

The Safety of VitalStim® Therapy

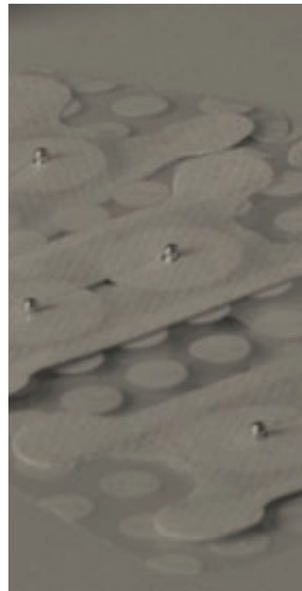
In over 4,500 applications of electrical stimulation during the clinical trial, no adverse effects occurred with VitalStim® Therapy. Further, in the four years since the device was cleared by the FDA, Chattanooga Group, the product manufacturer, reports there have been an estimated 300,000 separate treatment sessions – *without a single documented adverse event being reported* to either the FDA or the manufacturer.

These treatments were administered to over 25,000 patients by 3,000 certified practitioners in more than 2,000 facilities in 40 states and 10 other countries, and across all care settings.

The Risks of Off-Label Use

When the FDA cleared the VitalStim® Therapy application, it included the electrodes as an integral component of the modality. The use of the VitalStim® Therapy device with the custom-developed electrodes is therefore considered to be the only proper use of FDA-cleared electrotherapy equipment and supplies in the treatment of dysphagia. Conversely, the use of any other devices and/or electrodes for the medical treatment of dysphagia is considered to be off-label, and such practice carries certain risks of increased liability, as well as business risks.

Since the FDA clearance of VitalStim®, Chattanooga Group has received calls and requests about the use of alternative electrotherapy systems and/or electrodes in the treatment of dysphagia. Some providers do not feel they need to be educated in electrotherapy, and



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merely want a general protocol provided to them by the manufacturer. From a professional and industry point of view this is a major concern, since such an approach carries a potential liability if patients suffer injuries or other harm because the provider was not properly trained and/or used improper protocol, equipment, or electrodes.

In addition, Medicare prohibits payment for the use of medical devices for the treatment of conditions for which they have not been cleared to market – that is, for which they lack an indication. The following statement is from *Medicare's Intermediary Manual, Part 3, Chapter II – Coverage of Services*:

3151.1 Devices Not Approved by FDA.

> "... the use of any other devices and/or electrodes for the medical treatment of dysphagia is considered to be off-label, and such practice carries certain risks of increased liability, as well as business risks."

-- Medical devices which have not been approved for marketing by the FDA are considered investigational by Medicare and are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Program payment, therefore, may not be made for medical procedures or services performed using devices which have not been approved for marketing by the FDA.

Thus, in addition to increasing its risk exposure, any facility that allows its practitioners to utilize non-FDA cleared electro-stimulation devices and/or electrodes for the medical treatment of dysphagia, will be denied reimbursement for a claim for the treatment session.

VITALSTIM® THERAPY
BY CHATTANOOGA GROUP

For more information about VitalStim Therapy, call 1-800-506-1130 + 1-423-870-7200 or visit our website at vitalstimtherapy.com.

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