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INFORMATICS

Stimel-03 & SSMD: FDA Indications for Use



Procedures that Fit Within the FDA (K 130424): Indications for Use of the Stimel-03 and SSMD

This document presents a comprehensive list of potential therapeutic procedures that can be performed using the Stimel-03 and SSMD, innovative tools with FDA clearance for a variety of indications. The procedures illustrated within this document offer broad applications, demonstrating the devices' exceptional versatility. From the management of muscle spasms – providing much-needed relaxation and alleviation from discomfort – to the prevention or retardation of disuse atrophy, the **Stimel-03 and SSMD** play a crucial role in the preservation of muscle health and the enhancement of physical resilience.

The devices' use extends to fostering improved local blood circulation, aiding in the promotion of optimal nutrient delivery and waste removal at the cellular level, thus contributing to overall health and tissue recovery. Moreover, the Stimel-03 and SSMD are instrumental in stroke rehabilitation, facilitating muscle re-education and the re-establishment of coordination and strength, which is often disrupted in the aftermath of a stroke.

The unique BioRhythmIQ™ technology embedded in the Stimel-03 and SSMD promotes a personalized approach to treating each indication for use. By interpreting and replicating patient-specific neural signals that the brain sends to muscle fibers, the **Stimel-03 and SSMD** activates and trains the affected muscle groups optimally for each patient. Additionally, the biofeedback feature of the Stimel-03 and SSMD enhances patient engagement and adapts the treatment process to individual needs. These features collectively enhance efficacy across all therapeutic applications.

The following are the indications for use of the FDA-cleared Stimel-03 and SSMD:

- **Relaxation of muscle spasms.**
- **Prevention or retardation of disuse atrophy**
- **Increasing local blood circulation**
- **Stroke Rehabilitation by muscle re-education**
- **Maintaining or increasing range of motion.**
- **Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis**

Relaxation of Muscle Spasms

Muscle spasms can occur due to various conditions, including musculoskeletal disorders, nerve injuries, neurological conditions, or even stress. Use of the Stimel-03 and SSMD can be combined with other therapeutic interventions like massage, myofascial release, heat or cold therapy, and gentle stretching to alleviate these spasms. The devices might be used in clinic settings, or the patient may be trained to use them at home, integrating them into their daily routine to manage chronic spasms. Patient education about the underlying cause of spasms, possible triggers to avoid, and self-management techniques can be an important part of this treatment strategy.

Prevention or Retardation of Disuse Atrophy

The prevention or retardation of disuse atrophy is crucial in maintaining muscle integrity during periods of inactivity or immobilization. The Stimel-03 and SSMD are instrumental in this regard, as they help prevent the weakening and shrinking of muscles that are not actively being used. By delivering electrical stimulation to induce muscle contractions, this therapy aids in preserving muscle mass and promoting metabolic activity within the muscle tissues. This application is especially beneficial for patients recovering from surgery or those unable to engage in traditional forms of physical activity.

Increasing Local Blood Circulation

The Stimel-03 and SSMD can stimulate muscle contractions, enhancing local blood flow in the targeted area. This can aid in wound healing and tissue repair, especially beneficial for post-operative patients or patients with circulatory issues. Complementary therapies such as massage, compression therapy, thermal therapy, and light exercises could be incorporated into the treatment plan. Patient education about the importance of regular movement and lifestyle modifications like smoking cessation and healthy diet might also be an integral part of this therapy.

Stroke Rehabilitation by Muscle Re-Education

After a stroke, muscle control often gets impaired due to neurological damage. The Stimel-03 and SSMD can be used to stimulate the affected muscles and help the brain re-learn to control these muscles. This would typically be a part of a larger rehabilitation plan involving gait training, balance exercises, occupational therapy for improving daily living skills, and cognitive therapy if needed. Involvement of the patient's family in understanding the recovery process, adapting the home environment, and providing support and encouragement can also play a critical role in this therapeutic approach.

Maintaining or Increasing Range of Motion (ROM)

Joint mobility can be affected by various factors such as injury, surgery, arthritis, or other degenerative joint diseases. The Stimel-03 and SSMD can stimulate the muscles supporting the affected joints, helping maintain or improve flexibility and movement. This can be combined with other manual therapy techniques, stretching exercises, strength training, and use of appropriate assistive devices. Patient education about the importance of regular exercise and joint protection strategies might also be part of this therapy.

Post-Surgical Stimulation of Calf Muscles to Prevent Venous Thrombosis

After surgeries requiring extended bed rest, especially orthopedic surgeries like hip or knee replacements, there is a risk of developing deep vein thrombosis. The Stimel-03 and SSMD can be used to promote muscle contractions in the calf muscles, enhancing blood flow and preventing clot formation. This could be combined with the use of compression stockings, regular monitoring for signs of venous thrombosis, and as soon as the patient is able, gentle mobilization exercises.