The Parastep® I System

Indications, Contraindications, Warnings, Precautions and Adverse Effects

INDICATIONS FOR USE

The Parastep® I System enables appropriately selected skeletally mature spinal cord injured persons (levels C6-T12) to stand and to attain limited ambulation and/or take steps, with assistance if required, following a prescribed period of physical therapy training in conjunction with rehabilitation management of spinal cord injury.

Effective use of the Parastep® I System requires the user to demonstrate (1) adequate trunk control and balance to maintain up right posture while standing and ambulating, and (2) intact flexion withdrawal reflexes in the lower extremities to shorten adequately the limb to initiate taking a step.

For safe use of the Parastep® I System, a patient must be able to stand with the assistance of a walker and safely lower himself/herself to the ground without the system operating or have assistance available in the event of device failure.

Physicians prescribing the Parastep® I System should be experienced in the rehabilitation management of spinal cord injured patients.

In addition, the clinician training the patient is required to complete the Parastep® I System training provided by the manufacturer, Sigmedics, Inc.

The effective use of the Parastep® I System to stand and take steps was found to be significantly improved for the 61% of the patients in the preapproval clinical trials who practiced standing and taking steps with the device at home during the period of time they were also enrolled in the physical therapy training sessions.

Caution: Federal law restricts this device to sale by or on the order of a licensed physician.

CONTRAINDICATIONS

1. Cardiac demand pacemaker
2. Cancer in the area of electrode placement
3. Severe scoliosis
4. Severe osteoporosis
5. Skin disease at stimulation sites or over swollen, infected, or inflamed areas or skin eruptions, e.g. phlebitis, thrombo phlebitis, varicose veins
6. Irreversible contracture
7. Autonomic dysreflexia

WARNINGS

1. Adequate safety measures should be taken in the case of persons with suspected heart or pulmonary problems.
2. Persons known to have or suspected of having heart disease should not receive electrical stimulation without medical evaluation of cardiac status and appropriateness for functional neuromuscular stimulation (FNS).
3. Caution should be used in the transthoracic application of FNS devices, in that the introduction of electrical current into the heart may cause dysrhythmias.
4. Caution should be used in treating persons with suspected epilepsy.
5. Safety has **not** been established for the use of FNS devices during pregnancy.
6. Patients with sensation may find stimulation to be uncomfortable.
7. The use of electrodes or cables other than those obtained from Sigmedics, Inc. may cause unpleasant or even painful sensations, skin irritations, burns, or cause the device to be ineffective.
8. Do **not** carry the rechargeable battery in a pocket, purse or place where the battery terminals could be short circuited, or deliberately short circuit these terminals, as intense heat can be generated and fire or injury may result.
9. Do **not** attempt to recharge any battery other than the original Sigmedics, Inc. system or rechargeable battery that was obtained from Sigmedics, Inc., as alkaline or other non-rechargeable batteries may explode and/or burn when charging is attempted.
10. Never submerge the battery charger in water or any other liquid, or plug the charger into the wall outlet if it has been accidentally submerged or wet by water or other fluid. Allow the charger and system components to dry completely before using or plugging the charger back into the AC wall outlet.
11. Do **not** stimulate over the carotid sinus nerves, especially in patients with a known sensitivity to the carotid sinus reflex.
12. Do **not** position electrodes over neck or mouth as severe spasm of the laryngeal and pharyngeal muscles may occur. The contractions may be strong enough to close the airway or cause difficulty in breathing.
13. Do **not** apply stimulation to the head.
14. Keep the Parastep® I System out of the reach of children.
15. Caution should be observed in treating patients with vision or hearing impairments which interfere with training.

PRECAUTIONS

1. Precaution should be observed in the presence of the following:
   a. Use in individuals with underlying bleeding diathesis.
   b. Use in individuals who have recently undergone surgical procedures when muscle contraction may disrupt the healing process.
   c. Placement of electrodes over the lower abdomen in women who are menstruating.
2. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced and/or prevented by proper preparation and daily cleaning of the skin at the electrode application site, use of an alternative conductive medium, or alternate electrode placement.
3. A user can expect a reduction of ambulatory ability if the use of the Parastep® I System is interrupted for several months. Under such circumstances, the user should return to the prescribing clinician for reevaluation and/or retraining prior to reuse.
4. The long-term effects of chronic electrical stimulation are unknown.
5. The long-term effects of use of the Parastep® I System on the growth and development of children are unknown.

ADVERSE EFFECTS

1. Skin irritation may occur at the electrode application site.
2. Improper use of electrodes may result in skin burns at the electrode application site.
3. Use of the Parastep® I System by persons with severe osteoporosis may result in fracture.
4. Use of the Parastep® I System by spinal cord injured persons may result in bruises sustained as a result of a fall(s).
5. Use of the Parastep® I System by persons with impaired sensation may result in soft tissue injury.
6. Use of the Parastep® I System may result in bone fracture(s).