Instructions for use/user manual

1.0 geko™ T-2 device

1.1 Description of geko™ T-2 device

The geko™ T-2 device is a small, disposable, internally powered, neuromuscular stimulation device that use a 1 Hz electrical frequency to stimulate muscles in the leg. It is designed for use as an aid to enhance venous return and prevent deep vein thrombosis (DVT) in the lower limbs resulting from bed rest, surgery, long-term conditions, or aging. The device is self-adhesive and can be applied to the skin without any previous preparation.

1.2 Indications for use

The geko™ T-2 device is intended for use in patients undergoing surgery or suffering from conditions that may cause DVT.

2.0 Contractions

- The geko™ T-2 device should only be used if the patient has no known contraindications.
- Ensure adequate muscle contraction has been achieved.
- The safety and effectiveness of the geko™ T-2 device has not been evaluated in patients who have undergone total hip replacement due to fracture.
- The device should not be applied over the scar tissue.
- Stimulations should not be applied over the scar tissue while the geko™ T-2 device is in use.
- Do not flex skin before applying the device.
- Ensure the device is applied over the scar tissue.
- The device is not intended for use in patients with cardiac pacemakers.

3.0 Warming

- The geko™ T-2 device should only be used if the patient is warmed and the skin is dry.
- The device should only be used if the skin is not damaged or inflamed.
- Do not use the device if the skin is irritated, or if there is a known allergic reaction to the device's adhesive or any of its components.
- Do not use the device if the skin is scratchy, rough, or tender.

4.0 Precautions

- Do not apply the device externally to the leg. It is self-adhesive and is applied internally.
- The device should not be applied over the scar tissue.
- The device is not intended for use in patients with cardiac pacemakers.

5.2 Adverse reactions

Common adhesive-related side effects include redness, itching, and skin irritation. These reactions are usually minor and resolve within 24 hours. If any reactions persist or worsen, contact your healthcare provider.

5.3 Reporting of any side effects or adverse reactions

Any adverse reactions or side effects should be reported to your healthcare provider immediately. If you are uncertain about what to do, call your local health authorities for advice.

7.0 About the geko™ T-2 device and muscle stimulation

7.1 The physiology

The body's circulatory system serves to transport blood and nutrients throughout the body. The muscles of the lower limbs play a crucial role in maintaining the circulation of blood. Contraction of the calf muscles helps to promote blood flow back to the heart, increasing venous return.

Jawad et al. 3 compared the effectiveness of neuromuscular stimulation using the geko™ T-2 device with traditional physical therapy. They found that the geko™ T-2 device was superior to the traditional method in enhancing venous and arterial blood flow measures (p<0.001) venous and arterial blood volume flow measures. The authors reported that neuromuscular stimulation using the geko™ T-2 device was effective for use in post-surgical prevention of DVT.
2.0 Contradictions

The geko™ T-2 Neuromuscular Stimulator is intended for:

Attention: Be sure to read and understand Instructions for use/user manual

- Powered muscle stimulators should not be used on
- Immediate post-surgical stimulation of the calf muscles to
- nerves, particularly in patients with a known sensitivity to
- unknown.
- not been evaluated on patients who have undergone a
- prevent venous thrombosis.

- the skin preparation method before you use the device.
- operation. Familiarize yourself with the components and
- • The geko™ T-2 device should not be switched on unless
- • No modification of this device is allowed.
- • Electrode placement and stimulation settings should be

b) following recent surgical procedures when muscle
a) when there is a tendency to haemorrhage following

• Caution should be used in the presence of the following:

- not bath or shower while wearing a geko™ T-2 device.
- afterwards. The stimulation level will need to be readjusted
- an extensive system of thin vessels
- and there is no risk of them.

7.3.3 The safety and effectiveness of the original geko™ device, the geko™ T-1, has been extensively studied. The results of this study established that at 2 Hz frequency electrical impulses applied at the common peroneal nerve resulted in a significant increase in the mean venous pressure, blood flow, and hematocrit in the calf muscles. These variables were significantly lower in the control group (no stimulation). This was due to the non-stimulated control. The changes in blood parameters were similar to those observed in rats treated with moderate diuretic (Furosipmide 25 mg/kg) in vivo, thus proving the highest angiographic condition. The geko™ device is capable of increasing blood flow and reducing the mean venous pressure by 30% to 40% in a single trial of 1 hour.

The authors reported that neuromuscular stimulation of the foot using the geko™ T-2 device results in a significant augmentation of venous flow in the calf muscles. The mean increase in the mean venous pressure was 30% to 40% in a single trial of 1 hour. The stimulation level was adjusted to achieve the optimal effect while avoiding any discomfort to the patient. The effectiveness of the geko™ device was confirmed by measuring the mean venous pressure, blood flow, and hematocrit in the calf muscles. These variables were significantly lower in the control group (no stimulation). This was due to the non-stimulated control. The changes in blood parameters were similar to those observed in rats treated with moderate diuretic (Furosipmide 25 mg/kg) in vivo, thus proving the highest angiographic condition. The geko™ device is capable of increasing blood flow and reducing the mean venous pressure by 30% to 40% in a single trial of 1 hour.

The geko™ device is safe and effective for use in the treatment of venous thrombosis prophylaxis and post-thrombotic syndrome. It is contraindicated in patients with acute trauma or fracture; pregnancy has not been established.

8.0 Operating information for healthcare professionals

Contraindications: The geko™ T-2 device has been designed to be used on the skin of the lower limb for the purpose of augmentation of venous flow and prevention of deep vein thrombosis. In order to use the geko™ T-2 device, the patient should lie comfortably on their back with the legs slightly raised. The device should be placed on the calf muscle, approximately 10 cm above the ankle. The geko™ device is a powered, neuromuscular stimulation device that is automatically turned off after 24 hours.

9.0 Disposal

The protective boot and lead set cannot be disposed of in normal domestic waste. The lead set must be disposed of in accordance with the appropriate local and national regulations. If you are unable to find the appropriate regulations for your area, please contact your local waste management authority.

10.0 Help

If you experience any problems while using the geko™ T-2 device, contact firstHealth by dialing 1-877-866-0305 or via email: info@gekodevices.com

 Specifications

- Operational time: 24 hour
- Normal operating condition: 24 hour stimulation
- Input voltage: 27 mA
- Output voltage: 5.4 V
- Maximum output power: 144 mW
- Maximum output current: 50 mA
- Input power: 100 mW
- Output power: 100 mW
- Battery capacity: 1000 mAh
- Battery life: 2 years
- Operating time: 24 hours
- Pulse width: 50 μs
- Repetition rate: 1 Hz
- Output coupling: 200 Ω to 10 kΩ
- Maximum charge: 3,000 Ω
- Indication display: green LED
- Battery: non-rechargeable
- Battery casing: terephthalate

This product is covered by granted and pending patents. The geko™ T-2 device is manufactured by firstHealth Medical Technologies Ltd. This product is intended for personal use only and is not intended for use in any clinical settings.

Manufactured by:
firstHealth Medical Technologies Ltd
6560 W. 25th Street
Cleveland, OH 44123
USA

IP22 (degree protection 20-50)

“The geko™ T-2 device is designed for use in the treatment of venous thrombosis prophylaxis and post-thrombotic syndrome. The device must be transported at a temperature between 0°C and 40°C and stored in a dry place. The device must not be exposed to vertical or horizontal shock where shocks are produced.

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