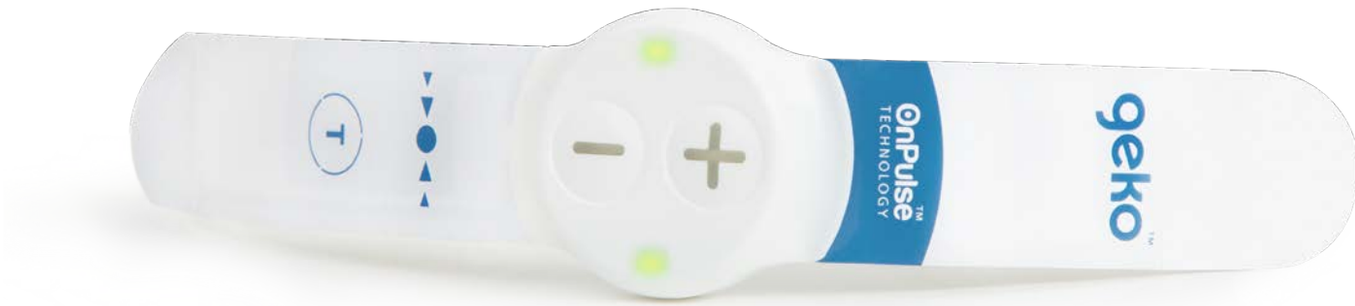
geko™
circulation support

The geko™ Device - Frequently Asked Questions



www.gekodevices.com/us

OnPulse™ TECHNOLOGY

firstkind
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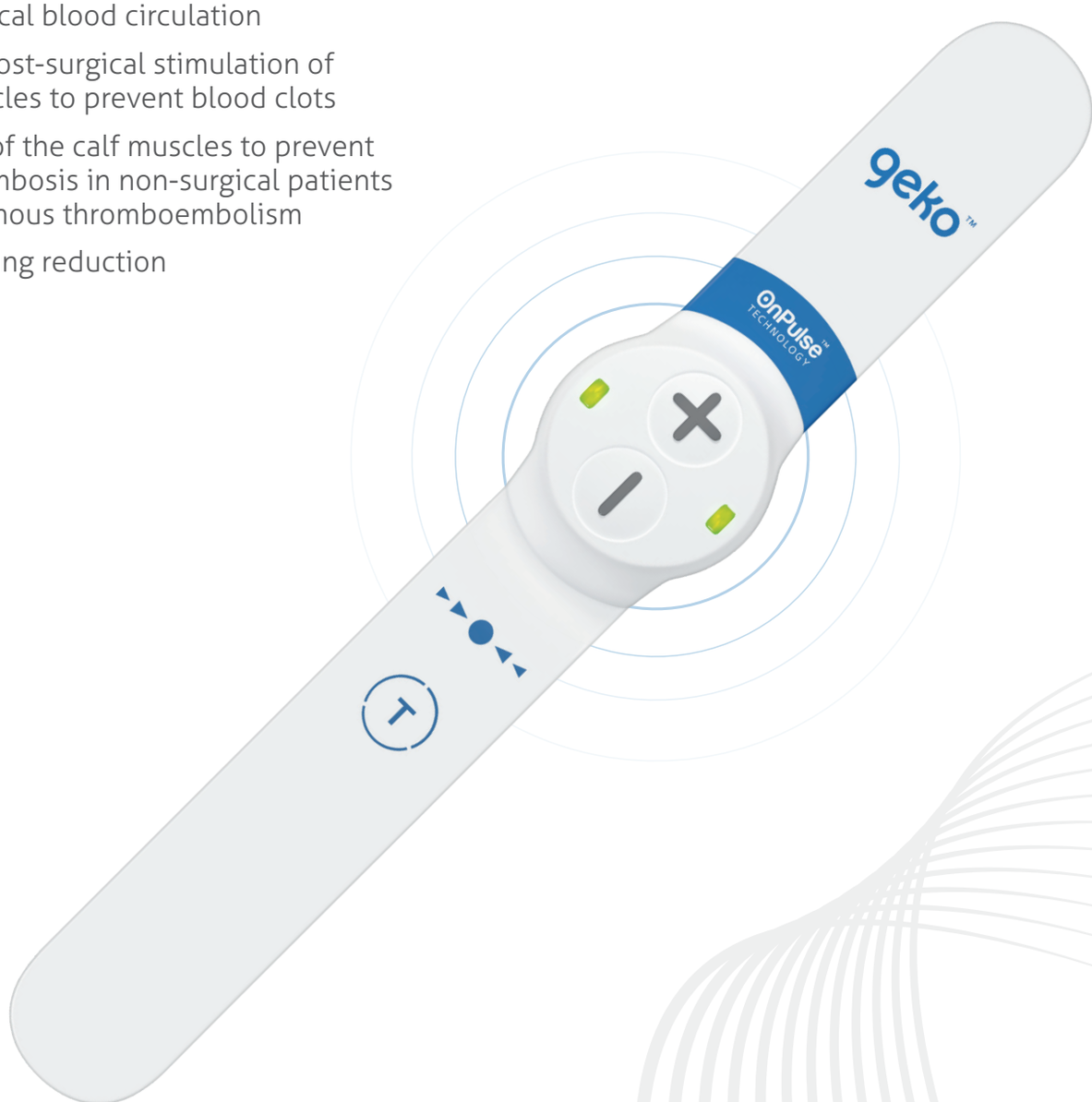
What is the geko™ device?

Powered by OnPulse™ technology, the geko™ device, is a non-invasive neuromuscular electro-stimulation device used to increase blood circulation by triggering your calf and foot muscles to contract. The disposable self-contained device is quick and easy to apply; it takes just 60 seconds to fit and is operated from two buttons.

What does the geko™ device do?

The geko™ device increases arterial, venous and microcirculatory blood flow in the lower limbs. The intended use is for:

- Increasing local blood circulation
- Immediate post-surgical stimulation of the calf muscles to prevent blood clots
- Stimulation of the calf muscles to prevent venous thrombosis in non-surgical patients at risk for venous thromboembolism
- Edema swelling reduction



How does the geko™ device work?

Worn at the knee, the geko™ device delivers painless electrical impulses to the common peroneal nerve to activate the muscle pumps of the lower leg that return blood towards the heart.

The geko™ device increases blood circulation to 60% of that normally achieved by walking without the patient having to move or exert energy and without uncomfortable muscle movements.

Powered by a wrist-watch size battery with software controlled by two buttons, the self-adhesive geko™ device shapes itself easily and comfortably to the leg.

There are two LED lights indicating when the device is switched on and which of eleven possible stimulation settings. On the underside of the strap, covered by a water-based conductive hydrogel for secure adhesion, electrodes deliver painless neuromuscular electro-stimulation to the common peroneal nerve.

Delivers painless neuromuscular electro-stimulation to the common peroneal nerve

How long do I have to wear geko™ device for?

For VTE prevention after surgery, the device should be worn on both legs right after the procedure based on your surgeon's recommendation. The short strap of the device may be placed on top of a dressing after knee surgery.

For VTE prevention , the device should be worn as long as your risk of VTE is present as determined by your physician.

For edema reduction, device can be placed on the operated leg right after the procedure between 4-10 days. Device should be worn a minimum of 6 hours but it is recommended up to 24 hours a day based on clinical studies or as recommended by your surgeon.

If device is being used pre-operatively or as a result of an injury then device should be placed on patient at the time of patient visit and be worn a minimum of 6 hours but it is recommended up to 24 hours a day based on clinical studies or as recommended by your surgeon.

You might wear it less depending on the following factors:

- Remove device if bathing and then re-apply once the leg is dry
- If device disrupts your sleep, you can reduce the setting until comfortable
  If device still bothers you then remove device and replace in the morning when you wake up

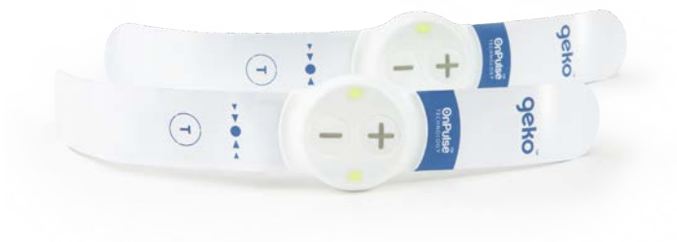
What is considered the correct level of stimulation?

When the geko™ device is fitted correctly, look for a discernible movement of the muscles in the lower leg and visible outwards and upwards movement of the foot. It is not sufficient to see only a slight movement in the muscles of the lower leg alone. The movement in both the lower leg and foot should be discernible.

Depending on the degree of swelling edema, full calf and foot muscle twitch may not be possible in the immediate post-operative period, however, at this stage, any level calf muscle activation will be beneficial. This can be confirmed by feeling the calf for activation as the stimulation level is increased, also visually seeing the calf and foot twitch as the device is turned on and stimulation setting increased.

Is the geko™ device painful to use?

No, there is no sensation of pain. There is a feeling of tapping at the side of the leg and the muscles in the lower leg contract every second which can take a few moments to adjust. Thereafter it is common to forget you are wearing the device.



Can I sleep with the geko™ device on?

There is no detrimental effect to sleeping with the devices on. However, if you are finding the devices to be disruptive then discuss this with your healthcare professional who may advise you to either lower the settings or just turn them off completely, if that is consistent with your treatment.

Is the geko™ device waterproof?

The geko™ device must be kept clean and dry. Do not bathe or shower whilst wearing the device. Prolonged exposure to water will dissolve the hydrogel and adhesion may be lost. Immersion may also affect the electronics and prevent proper operation. In the event that the device becomes wet, either by water or bodily fluid, there is no danger to the patient. The adhesive gel is water based and therefore slight dampening of the gel will remove the device from the leg once treatment is complete.

How many times can I use a single geko™ device?

The geko™ is a single-use medical device. This means that it is intended to be used on a single patient as part of a single course of treatment. The device is designed for 24 hours of operational life, with a small reserve, from the time that the device is first turned on. After 30 hours has elapsed, the device will permanently be disabled.

Can the geko™ device be used in close proximity to microwave ovens?

A microwave oven is a closed sealed unit, tested to a high standard, as such it will not interfere with the geko™ device.

Can the geko™ device be used in close proximity to open radar or transmitter sources of short wave radiation?

Do not use in proximity (i.e. within 1m) of short wave / microwave equipment as this may affect the device.

What published evidence do you have to support the geko™ claims?

We have a range of published research posted on the Clinical Studies section on the geko™ website: www.gekodevices.com/us

Are there any contraindications for using the geko™ device?

Powered muscle stimulators should not be used on patients with cardiac demand pacemakers. Powered muscle simulators should not be used on patients with recently diagnosed DVT.

See the accompanying instructions for a full list of warnings and precautions.

Why does the geko™ T device have a limited run-time?

The life time of the geko™ device is controlled by a clock that runs in the software of the device. We know through extensive testing that at the end of the expiry date the battery has sufficient capacity to operate reliably for 30 hours at the maximum setting. As the battery loses capacity its voltage falls and below a certain threshold the device may not function reliably. To maintain VTE prophylaxis the devices needs to be able to operate reliably. A 30 hour life allows for 24 hours continuous operation, with a reserve to give time in which busy staff can change the device and maintain 24 hour VTE prophylaxis or allow the patient to wear up to 30 hours at home before changing out the device.

How do I dispose of the geko™ device once I have used it?

No special measures are required for the disposal of the electronics and battery in the geko™ device. You would dispose of the devices exactly the same way you dispose of your everyday house hold waste and batteries, complying with any local legislation. Do not incinerate the devices as this may be hazardous.

Does the hydrogel in the geko™ device contain gelatin?

No. There are no materials of animal origin used in the geko™ at all. The hydrogel is hypoallergenic and acrylic-based.

I am allergic to sticking plasters. Is the geko™ device likely to cause skin irritation?

The adhesive used for the geko™ is different to that used for adhesive bandages. Skin reactions, such as rashes, are a recognized minor complication associated with electrostimulation. Some skin reactions with the geko™ device have been reported to us, but we do not yet have enough data to say whether the incidences reported are in line with other electro- stimulation devices. We do warn users of the potential for skin reactions in our Instructions for Use. In some cases skin inflammation or irritation can develop in the contact area: either remove the device or reattach in the alternative fitting location.

We are not aware of any instances where the skin reactions represent a serious risk to the health of the patient.

There may be some instances where a minor irritation is acceptable when weighed against the therapeutic benefits of the geko™. This must be discussed and agreed with your healthcare professional.

Does the geko™ contain anything that will damage the environment?

No. The geko™ device does not contain anything that is known to damage the environment.

Do we have any safety evidence for geko™ ?

We have considered the possible risks associated with using the geko™ device. To ensure its safety we have designed and manufactured the geko™ device in accordance with the International standard for the managing safety of medical devices, ISO 14971. Using this standard as a basis we have designed and manufactured the geko™ devices to be intrinsically safe.

We have conducted extensive biological safety testing, to the International biocompatibility standard, ISO 10993, and we have data that shows that the hydrogel has tested negative for cytotoxicity, sensitization and irritation, and can therefore be considered to hypoallergenic. We have also conducted extensive electrical safety testing. The key International Electrotechnical Commission standards are IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-10, the latter being the International standard for electrical safety for powered muscle stimulators.

The geko™ complies with FDA guidance for powered muscle stimulators.

Can the geko™ device be used on children over the age of 13?

The Instruction for Use states that the geko™ device must be kept out of reach from children and pets. The safety and effectiveness of the geko™ has not been tested on people under the age of 18. The geko™ device uses NMES to emulate the increase in blood flow normally achieved by walking (up to 60%), so it is unlikely to cause problems in normal adolescents. Therefore, it is a clinician's decision, exercised with caution, to prescribe the use of the geko™ device to a child between the ages of 13-18 years old, however we advise that it is used under supervision to prevent misuse.

Does spinal cord or epidural anesthesia effect how the geko™ functions?

Anesthetic agents: general anesthesia and muscle relaxants may affect the response from the geko™. A higher stimulation setting may be required for patients under anesthesia, and in some cases the neurostimulation can be blocked. The extent of the interaction will depend upon a wide range of factors, including the amount of agent itself, the time since administration, and patient related factors.

Can the geko™ device be applied to fragile or compromised skin?

Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions. This may include conditions such as phlebitis, thrombophlebitis or varicose veins where the skin is inflamed or compromised.

Who is Firstkind?

Firstkind Ltd is a wholly owned subsidiary of Sky Medical Technology Ltd, a privately owned UK company based in High Wycombe and Daresbury. Firstkind manufacture medical devices utilizing OnPulse™, Sky Medical's proprietary neuromuscular electro-stimulation technology designed to enhance the body's own circulation to increase lower limb blood circulation.

The OnPulse™ technology has been developed, manufactured and brought to market by Firstkind Ltd following a three year programme of applied research with St. Bartholomew's Hospital and Queen Mary, University of London. The OnPulse™ technology leverages a deep understanding of the anatomy and physiology of the human body, biomedical engineering and isometric neuromuscular stimulation.

Firstkind Ltd

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