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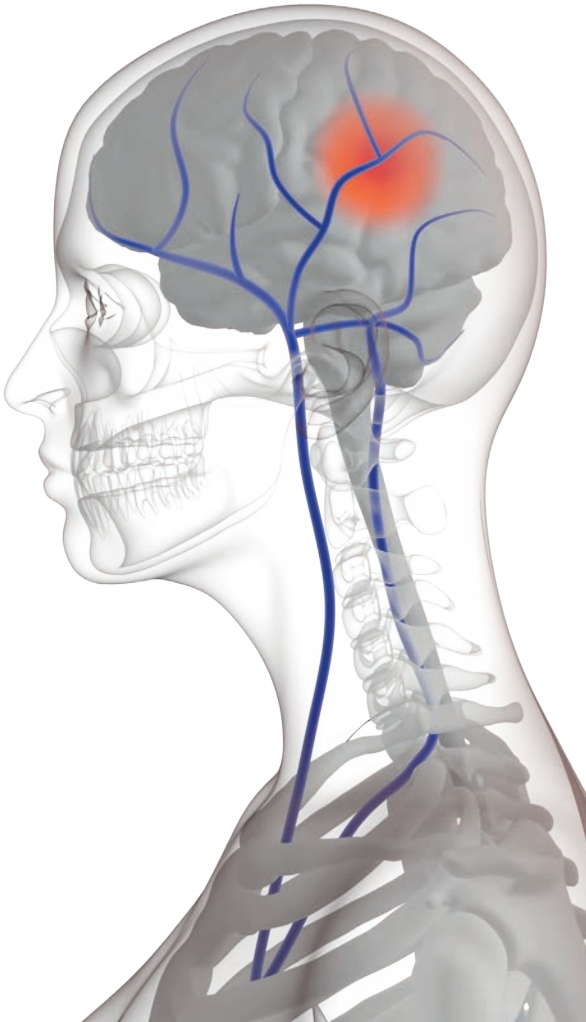
VTE Prophylaxis

Serving an unmet need in high-risk acute stroke patients



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Providing venous thromboembolism (VTE) prophylaxis to at-risk stroke patients

The risk of venous thromboembolism (VTE) after stroke is increased in patients with restricted mobility and associated increase in venous stasis[1].

The alteration in blood flow in weakened limbs may lead to vessel wall injury, whilst there is also an abnormal tendency for the blood to clot more after stroke[9].

The definition of Venous Thrombo-Embolism (VTE) includes deep vein thrombosis (DVT) and Pulmonary embolism (PE) caused by a DVT.

Current recommendations for reducing VTE risk in immobile stroke patients:

- Intermittent Pneumatic Compression (IPC).
- Prophylactic-dose LMWH when bleed risk reduces.
- Anti-embolism stockings are not recommended.

VTE prophylaxis in stroke-potential challenges:

- Patients with fragile or broken skin contraindicated for IPC.
- Patients with peripheral arterial disease contraindicated for IPC.
- Patients may develop an intolerance to IPC in the acute phase.
- Patients with a high bleed risk contraindicated for chemical VTE prophylaxis.

Patients are at risk because they are often highly immobile resulting in temporary paralysis of the calf and foot muscle pumps. It is reported that the loss of gastrocnemius muscle pump results in a 47% reduction in venous flow velocity[3] thereby increasing the risk of VTE.

The geko™ device

Easy to use, geko™ is a battery powered, disposable, **neuromuscular electrostimulation device** designed to increase blood flow in the deep veins of the leg[4].

The geko device™ gently stimulates the common peroneal nerve **activating the calf and foot muscle pumps** resulting in increased blood flow[5], and the reduction of oedema[6].

60%

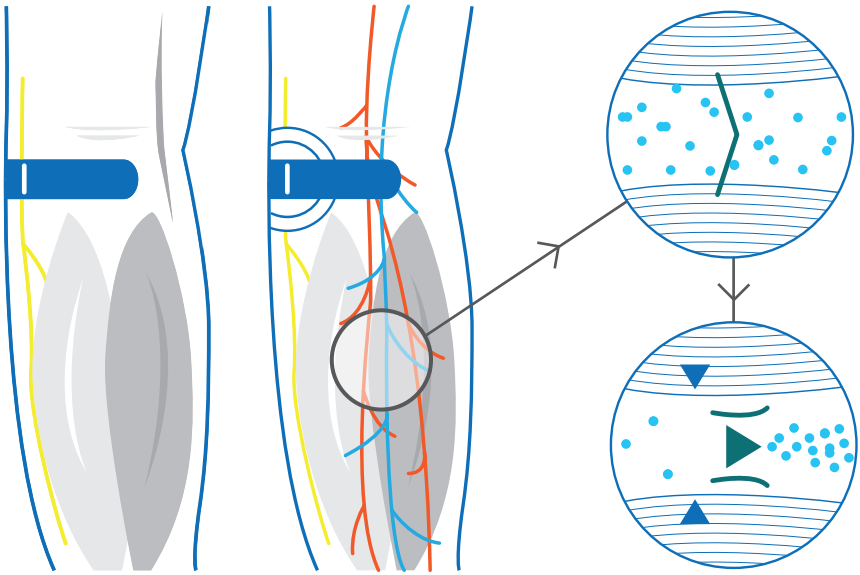
The increase in blood flow is equal to 60%[5] of walking without a patient having to move.

Zero

No wires or leads. Small, light and comfortable to wear. Silent in operation.

10g

Weighs just 10g. Quick and easy to fit.



The unmet need

Providing VTE prophylaxis to at-risk stroke patients.

In current practice, standard of care + IPC is often the recommended primary VTE prophylaxis intervention and is supported by the CLOTS 3 study[2,7,8].

CLOTS 3 reported that non adherence of IPC was up to 73.7%[8], with patient refusal of continuous wear being the leading reason for non-compliance.

This resulting unmet DVT prophylactic need in acute stroke patients is high with an associated symptomatic DVT risk of 6.3%.

CLOTS 3 study summary[8]

Key outcomes	Standard of care with no IPC	Standard of care with IPC
Incidence of any DVT *(proximal or calf)*	21.1%	16.2%
Incidence of symptomatic DVT *(proximal or calf)*	6.3%	4.6%
Incidence of PE	2.4%	2.0%
Non adherence to IPC*	N/A	up to 73.7%

The University Hospital of North Midlands NHS Trust

*Defined as wearing IPC continuously until patient regained mobility, discharge or death or until 30 days.

A new approach[13]

The CLOTS 3 health technology assessment acknowledges that IPC reduces DVT incidence in stroke patients via a reduction in venous stasis of the lower limb.

The assessment also reports that stroke patient adherence rates to IPC would leave a large population of these patients in need of an alternative anti-stasis intervention.

The geko™ device is approved by NICE as an anti-stasis therapy to reduce the risk of VTE and is positioned as an alternative to IPC when IPC is contraindicated or cannot be tolerated. NICE cite that DVT in stroke patients form most commonly in the deep veins of the calf muscles.[2]

The prevention of stasis in the deep veins of the calf is therefore of clinical relevance and the geko™ device is proven to increase blood flow velocity (and thereby prevent venous stasis) within the deep veins of calf[4].

In response to the above clinical need, Firstkind has worked with the University Hospital of North Midlands NHS Trust to introduce the geko™ device into their stroke pathway for patients who cannot be prescribed IPC[13]. Real world data collected from a 581 patient clinical audit suggests that 36% of patients needed the geko™ device as an alternative form of VTE prophylaxis.

The clinical audit suggests that the geko™ device is as effective as IPC with the device being well tolerated by stroke patients; the device offers an alternative VTE prophylaxis strategy to patients who would otherwise only have standard of care treatment available to them.

Clinically proven

The geko™ device is proven to prevent stasis in the deep veins of the calf.

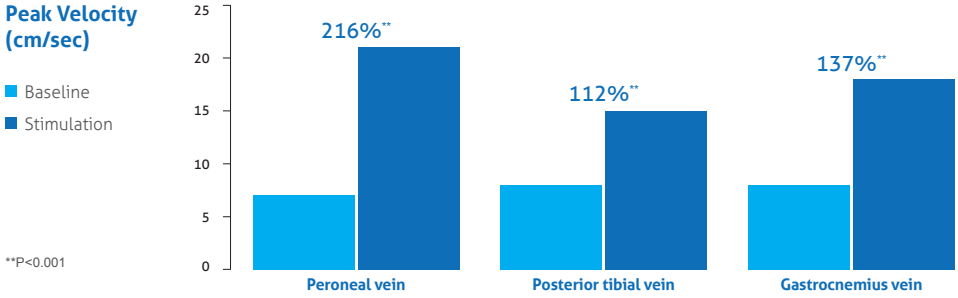
A DVT is a blood clot that forms mostcommonly in the deep veins of the calf muscles[9]. Blood stasis in the deep veins of the calf is a critical factor in the formation of a DVT[2].

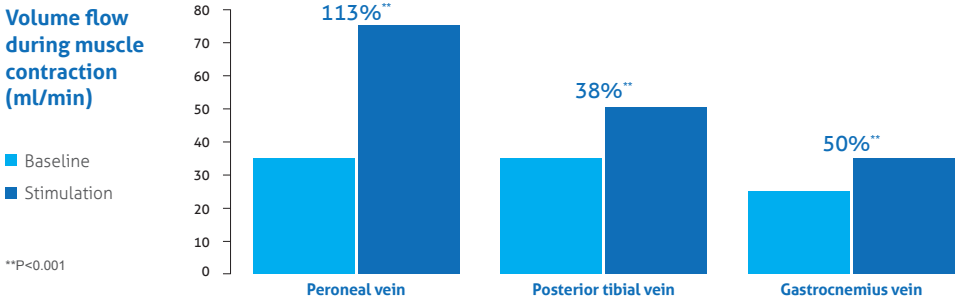
A study that clearly highlighted this was performed by Labropoulos et al. They demonstrated that isolated calf DVT was detected in 282 limbs of 251 patients examined.

The peroneal veins were most frequently involvedwith 115 limbs (41%) affected. Posterior tibial and gastrocnemius vein involvement accounted for 37% and 29% respectively[12].

The study summary below shows statistical significance, increases in blood flow within the gastrocnemius, peroneal and posterior tibial veins[4] (P<0.05-0.001).

The anti-stasis capability of the geko™ device within these deep veins of the calf is of clinical relevance in managing VTE risk in stroke patients when IPC is contraindicated or not tolerated.





Other studies report that geko™ delivers superior augmentation of lower limb blood flow and is a leading device for the prevention of stasis[5].

Addressing the unmet VTE prophylactic need in acute stroke patients

Immobilised acute stroke patients, especially in the circumstance of calf pump paralysis, suffer from stasis of venous blood in the deep veins of the calf and an increased risk of DVT[10].

The geko™ device is proven[3,4] to create conditions where this risk will be reduced:

Real world and CLOTS 3 clinical data confirm high unmet need of up to 73.7%[8].

IPC reduces VTE risk in stroke patients by reducing venous stasis in the lower limb*.

The geko™ device increases blood flow velocity (and thereby prevents venous stasis) within the deep veins of the calf (P<0.05-0.001)[4].

Real world clinical audit data suggests that the geko™ device is well tolerated by stroke patients and is as effective as IPC[13].

Without any mechanical anti-stasis intervention being prescribed alongside standard of care the symptomatic DVT risk in stroke is 6.3%.[4].

NICE recommend the use of the geko™ device when other prophylactic methods can't be used and its intervention would save £197 per patient[14].

It is recognised that when compared to IPC, the proven superior anti-stasis capability of the geko™ device will result in at least an equivalent reduction of DVT incidence[12].

In this scenario and when compared to no treatment, the use of the geko™ device for 5 days **will save £36 per patient**[13] and provides VTE prophylaxis to patients who would have no other form of prevention.

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