

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Centre for Health Technology Evaluation

### MTG Review Decision Document

#### **Review of MTG19: The geko device for reducing the risk of venous thromboembolism**

This guidance was issued in June 2014.

This topic was scheduled for early review as a result of an overlap with the partial update of the venous thromboembolism: reducing the risk for patients in hospital guideline (CG92), published in June 2015.

NICE proposes an update of the published guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance. Other factors such as price changes or newer versions of the technology will be considered relevant in the review process, but will not in individual cases always be sufficient cause to update existing guidance.

#### **1. Review decision**

Transfer the guidance to the static guidance list.

Place suitable explanatory text on the guidance landing page signposting users to the updated CG92 for recommendations on neuromuscular stimulation devices in patients admitted for a stroke.

#### **2. Original objective of guidance**

To evaluate the case for adoption of the geko device for reducing the risk of venous thromboembolism.

### **3. Current guidance**

1.1 The case for adopting the geko device is supported for use in people who have a high risk of venous thromboembolism and for whom other mechanical and pharmacological methods of prophylaxis are impractical or contraindicated. Although clinical evidence is limited, the case is supported because of the plausibility that the geko device may reduce the high risk of venous thromboembolism in patients who cannot use other forms of prophylaxis, and the low risk of the device causing harm.

1.2 In patients at high risk of venous thromboembolism who would otherwise receive no prophylaxis, using the geko device is estimated to be cost saving. The amount saved depends on the level of reduction in relative risk of deep vein thrombosis associated with geko treatment compared with no treatment. There is no direct evidence on the size of this reduction, but when values obtained with other mechanical methods of prophylaxis were used in cost modelling, the estimated cost saving for the geko device in patients at high risk of venous thromboembolism compared with no prophylaxis was £197 per patient.

### **4. Rationale**

Other than for patients admitted with a stroke, the new available evidence on geko supports the guidance recommendations. There has been no change in the availability, cost, mode of action or regulatory status. Therefore it is proposed that this guidance should be placed on the 'static list', with appropriate signposting to the updated CG92 for recommendations on patients admitted with a stroke (see Appendix 1 for explanation of options).

### **5. Implications for other guidance producing programmes**

See section 6.2 for a description of the overlap with the updated guideline on venous thromboembolism.

### **6. New evidence**

The search strategy from the original assessment report was re-run on Embase, Ovid MEDLINE, In-Process & Other Non-Indexed Citations and Ovid MEDLINE. References from January 2013 onwards were reviewed. Additional searches of clinical trials registries were also carried out and relevant guidance from NICE and other professional bodies was reviewed to determine whether there have been any changes to the care pathways. The company was asked to submit any new literature references relevant to their technology along with updated costs and details of any changes to the technology itself or the CE marked indication for use for their technology. In addition, input was sought from clinical Expert Advisers and used to inform the review proposal. The results of the literature search are discussed in the

'Summary of evidence and implications for review' section below. See Appendix 2 for further details of ongoing and unpublished studies.

## 6.1 Technology availability and changes

The geko device is still available to the NHS and during 2016 will be available to NHS in England via the NHS Supply Chain. A second generation geko device (geko device T-2) is available. This is based on the same technology as the original but has a more efficient pulse delivery to the patient. Other minor changes have been made to improve functionality. The second generation geko device has the same cost, function and mode of action and a CE certificate has not been re-issued as it was deemed by notified body, SGS United Kingdom Ltd that the scope of the certification remained unchanged.

## 6.2 Clinical practice

The NICE pathway is [venous thromboembolism](#). NICE CG92 [Venous thromboembolism: reducing the risk for patients in hospital](#) has been updated since the publication of MTG19 following the publication of new evidence on the use of intermittent pneumatic compression (IPC) as thromboprophylaxis for patients admitted with a stroke. As a result of the new evidence, the guideline recommends considering IPC for this indication after a careful explanation to the patient or family member of the risks and benefits (recommendation 1.4.5). The guideline did not consider evidence on foot impulse or neuromuscular electrical stimulation devices and states that these should not be offered for VTE prophylaxis to patients who are admitted for stroke, except in the context of research (1.4.4).

The update to CG92 considered new evidence and carried out economic modelling of relevance to MTG19. It showed that the cost and resource consequences of avoiding venous thromboembolism with mechanical prophylaxis in patients admitted with a stroke are subject to significant uncertainty. The cost modelling for geko in MTG19 included patients with a stroke in the population and assumed that savings would accrue from avoiding treatment costs associated with VTE. The cost-consequence analyses did not identify separate sub-groups of patients with stroke, or other groups for whom conventional methods of VTE prophylaxis were impractical or contraindicated. It should be assumed, therefore, that the MTG19 cost modelling is potentially subject to considerable uncertainty for patients with a stroke.

MTG19 supports the use of the geko device in patients in whom other mechanical and pharmacological methods of prophylaxis would be impractical or contraindicated.

### **6.3 NICE facilitated research**

No research has been commissioned by NICE on this technology.

### **6.4 New studies**

Nine studies published since MTG 19 involving geko were identified from literature searches or from the company of which 8 are out of scope for this review as 3 had already been included in the original evaluation (pre-publication as academic in confidence) and the remaining covered either a different population or outcomes.

The only wholly new evidence comes from a study published in 2015 which assessed the potential role of geko in augmenting the femoral vein venous blood flow following total knee replacement surgery. 30 patients were allocated randomly to receive either peroneal nerve electrostimulation plus low molecular weight heparin and below-knee compression stockings (intervention) or low molecular weight heparin and below-knee compression stockings alone (control group). The results showed that postoperative peak blood flow velocity in the femoral vein was significantly higher in the geko group compared to control group.

Six studies using geko are currently in press or preparing for submission. Four of these studies are out of scope, as they cover a different population and outcomes. One RCT (see appendix 2 - registered and unpublished trials) planned to be published in 2016, assessed DVT avoidance in 40 primary hip replacement patients performed by a single surgeon at a UK private hospital, which compared geko with thromboembolism deterrent stockings (TEDS). The company has provided copies of the manuscripts for these studies as academic and commercial in confidence.

[Commercial and academic in confidence information removed.]

## **7. Summary of new evidence and implications for review**

The limited new evidence on the geko device supports the original recommendations of MTG 19. New evidence on other mechanical devices considered during the update of CG92 means that its recommendations should be followed for people admitted for a stroke. The population covered by MTG19 is those at high risk of venous thromboembolism and for whom other mechanical and pharmacological methods of prophylaxis are impractical or contraindicated. This includes, but is not limited to, some people who have had a stroke.

## **8. Implementation**

The Company has stated that geko is being used in 6 NHS centres.

## **9. Equality issues**

In the original guidance the following equality issues were identified. The device may not be suitable for people:

- with fragile skin (for example, older patients and children) and those with burns and skin conditions within the application area of the device.
- whose common peroneal nerve or device application site is inaccessible or where the common peroneal nerve function is impaired.
- the device is unlikely to be suitable for some people considered disabled under the Equality Act 2010 such as bilateral leg amputees.

## Appendix 1 – explanation of options

If the published Medical Technologies Guidance needs updating NICE must select one of the options in the table below:

Options	Consequence	Selected – ‘Yes/No’
Standard update of the guidance	A standard update of the Medical Technologies Guidance will be planned into NICE’s work programme.	No
Update of the guidance within another piece of NICE guidance	The guidance is updated according to the processes and timetable of that programme.	No

If the published Medical Technologies Guidance does not need updating NICE must select one of the options in the table below:

Options	Consequences	Selected – ‘Yes/No’
Transfer the guidance to the ‘static guidance list’	The guidance remains valid and is designated as static guidance. Literature searches are carried out every 5 years to check whether any of the Medical Technologies Guidance on the static list should be flagged for review.	Yes
Defer the decision to review the guidance	NICE will reconsider whether a review is necessary at the specified date.	No
Withdraw the guidance	The Medical Technologies Guidance is no longer valid and is withdrawn.	No

## Appendix 2 – supporting information

### Relevant Institute work

#### *Published*

Clinical guideline 92

#### *In progress*

No appropriate guidance in progress.

### Registered and unpublished trials

Trial name and registration number	Details
NCT01935414 – Wainwright T, Middleton R. The geko™ Neuromuscular Stimulator vs Thromboembolism Deterrent Stockings (TEDS): DVT Prevention Study	RCT Publication date 2016
Griffin M, Bond D, Nicolaidis A. Measurement of blood flow in the deep veins of the lower limb using the geko™ neuromuscular electrostimulation device. Submitted to International Angiology	Publication date June 2016

### References

Yilmaz S, Calbiyi M, Yilmaz BK, Aksoy E. (2015), Potential role of electrostimulation in augmentation of venous blood flow after total knee replacement: A pilot study. *Phlebology*. p.0268355515580473.