NICE National Institute for Health and Care Excellence

NICE guidance

The geko device for reducing the risk of venous thromboembolism

Medical technologies guidance
Published: 25 June 2014

www.nice.org.uk/guidance/mtg19

Contents

1 Recommendations

NICE medical technologies guidance addresses specific technologies notified to NICE by sponsors. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

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.

2 The technology

Description of the technology

2.1 The geko device (FirstKind Ltd) is a battery powered, disposable neuromuscular electrostimulation device that is designed to increase venous blood flow, with the aim of reducing the risk of venous thromboembolism.

2.2 The geko device is portable, compact and resembles a small wristwatch. It is applied to the skin over the fibular head (or other application site) and held in position wrapped around the leg, below the crease of the knee. The device uses a patented electrical impulse delivery system. The impulses stimulate the common peroneal nerve, which causes muscular contractions in the lower leg and foot. The muscular action drives the venous muscle pump of the lower leg, facilitating the emptying of veins and increasing the return of blood to the heart. This is designed to imitate the process normally achieved by walking, without the person having to move.

2.3 The geko device is applied by a healthcare worker to 1 or both legs as needed. The device is non-invasive, small (149 mm × 42 mm × 11 mm) and lightweight (16 g), and does not restrict movement of the knee. The device is self-adhesive but an extra adhesive overlay is provided and used if necessary. The small contact area (35 cm^2) of the device is designed to minimise skin irritation and sweating. This device is available in a single size which is claimed to be suitable for most people. The device is disposable and must be replaced every 24 hours.

2.4 The geko device received a CE mark as a class IIa medical device in October 2010, to increase blood circulation and for the prevention of venous thrombosis.

2.5 The list price stated in the sponsor's submission is £22 (excluding VAT) per pair of geko devices.

2.6 The claimed benefits of the geko device in the case for adoption presented by the sponsor are:

- The geko device reduces the risk of venous thromboembolism via the prevention and reduction of venous stasis.
- Good patient adherence due to ease of application, which could help with a faster recovery.
- Discreet and comfortable to wear, allowing the person to retain their independence and mobility. This may help maintain patient wellbeing and ensure self-sufficiency.
- Minimal skin contact and therefore avoidance of skin irritation, skin breakdown and sweating.
- The geko device addresses an unmet need by delivering venous thromboembolism prophylaxis to patient groups who cannot use standard venous thromboembolism prophylaxis.
- The potential to improve speed of patient recovery and therefore reduce the length of hospital stay.

Current management

2.7 Venous thromboembolism – reducing the risk (NICE clinical guideline 92, currently being partially updated in the light of new evidence on mechanical prophylaxis in patients who have had a stroke) recommends that all people admitted to hospital should have an assessment of their risk of venous thromboembolism. They should also have their risk of bleeding assessed before pharmacological prophylaxis is offered, and treatment should be determined by the balance of the risks of venous thromboembolism and bleeding occurring.

2.8 The choice of mechanical venous thromboembolism prophylaxis should be based on individual patient factors including clinical condition, surgical procedure and patient preference. Recommended methods of mechanical venous thromboembolism prophylaxis include anti-embolism stockings (thigh or knee length), foot impulse devices and intermittent

pneumatic compression devices (thigh or knee length).

2.9 NICE clinical guideline 92 makes special reference to anti-embolism stockings and recommends that they should not be offered to people who have suspected or proven peripheral arterial disease, peripheral arterial bypass grafting, peripheral neuropathy or other causes of sensory impairment, cardiac failure, severe leg oedema or pulmonary oedema from congestive heart failure, major limb deformity preventing correct fit, local conditions in which stockings may cause damage (for example, 'tissue paper' skin, dermatitis, gangrene or recent skin graft) and unusual leg size or shape.

2.10 The guideline recommends offering combined venous thromboembolism prophylaxis with mechanical and pharmacological prophylaxis to people with major trauma or spinal injury, and to those having elective hip or knee replacement and hip fracture surgery. It also recommends consideration of combined venous thromboembolism prophylaxis for other orthopaedic surgery, based on assessment of risks and discussion with the patient, and for women who are pregnant or who have given birth during the previous 6 weeks who are having surgery, including caesarean section.

3 Clinical evidence

Summary of clinical evidence

3.1 Full details of all clinical outcomes considered by the Committee are available in the assessment report overview.

3.2 The key clinical outcomes for the geko device presented in the decision problem were:

- venous transit time, blood flow and blood velocity
- incidence of deep vein thrombosis
- incidence of pulmonary embolism/venous thromboembolism
- patient adherence.

3.3 In its evidence submission, the sponsor presented 7 studies, an interim report (Khanbhai et al. 2013) and some post-marketing surveillance data about the geko device. Two of the 7 studies were published reports (Tucker et al. 2010 and Warwick et al. 2013) and 3 were unpublished studies (Jawad [cardiac], Jawad [coagulation] and Jawad [versus intermittent pneumatic compression]) based on a PhD thesis by Jawad (2012). The other 2 papers reported results from a study by Williams (a published poster [Williams published, 2013] and an unpublished manuscript [Williams unpublished, 2013]).

3.4 The External Assessment Centre considered that 3 of the 7 sponsor-submitted geko studies provided relevant evidence in line with the comparators and outcomes defined in the scope. The 4 studies excluded from further consideration by the External Assessment Centre were: Tucker et al. (2010), because the comparators were baseline measures and voluntary muscle action (dorsiflexions); Warwick et al. (2013), because of the lack of a proper control arm; Jawad (cardiac) (2012), because of the use of cardiac outcomes not defined in the scope; and Williams (published 2013), because it did not provide sufficient details of

how baseline measurements were obtained.

3.5 Jawad (coagulation; 2012) described measurements taken in 10 healthy people using the THRIVE device (a predecessor of the geko device). Participants were placed in airline-style seating for 4 hours with the device activated for 5 minutes, every 15 minutes. All measurements were repeated in a second visit without the device to provide baseline values. Measurements of arterial and venous blood flow were made using colour flow duplex ultrasound and laser doppler flowmetry. A statistically significant increase was observed in mean venous blood flow ($p \leq 0.001$) and mean venous peak velocity ($p \leq 0.001$) with the device when compared against baseline values in the same leg. The highest increase was found after 3 hours in both measures (+326% and +181% respectively) during the 4-hour session. No statistically significant difference from baseline was observed in mean arterial velocity, although mean arterial volume increased significantly ($p \leq 0.05$). The majority of people reported only mild discomfort with the device. During public consultation, the sponsor presented additional results from this study on the changes in the adjusted mean tissue plasminogen activator antigen concentration.

3.6 Jawad (versus intermittent pneumatic compression; 2012) compared the efficacy of the geko device in enhancing lower limb blood perfusion against 2 intermittent pneumatic compression devices (Huntleigh Flowtron Universal and Kendall SCD Express) in 10 healthy people. Measurements were made using colour flow duplex ultrasound and laser doppler fluximetry. The median (and inter-quartile range) values for the venous blood volume flow were 123.5 ml/min (73.4) at baseline, 163 ml/min (105.3) for the geko device at a normal clinical use setting, 129 ml/min (42.7) for the geko device at a threshold setting (the minimum setting to elicit a minor muscular contraction in both the calf and the foot) and 118 ml/min (72.7) and 115 ml/min (60.2) for the 2 intermittent pneumatic compression devices. Therefore, the geko device increased venous blood volume flow by approximately 30% more than intermittent pneumatic compression devices ($p \leq 0.001$). The geko device also increased arterial blood volume flow by approximately 30% ($p \leq 0.001$), arterial blood velocity by 24% ($p \leq 0.001$) and total microcirculatory blood velocity by approximately 370% ($p \leq 0.001$). When using a visual analogue

scale, no statistically significant differences in discomfort were found between the geko device and the intermittent pneumatic compression devices ($p \geq 0.05$).

3.7 A study by Williams et al. (2014) compared the geko device against an intermittent pneumatic compression device in 10 healthy volunteers. The study found that venous blood flow was statistically significantly increased with the geko device (101%) compared against the intermittent pneumatic compression device (3%) (p=0.002) and peak venous velocity was statistically significantly increased with the geko device (103%) compared against the intermittent pneumatic compression device (51%) (p=0.002).

3.8 The sponsor presented post-market surveillance data based on self-completed questionnaires from 216 people who had used the geko device in the UK after either vascular or orthopaedic surgery or non-surgical treatment. The data showed that in general the device adhered well to the leg, was easy to apply and use, and was comfortable to wear. At consultation, further data were presented. In response to a question asking how many days the device was worn, 98% (121/123) of patients wore the geko device for 1 or more days. The question was amended during data collection to ask how long the device was worn and 44% (41/93) of patients responded that they wore the device for 24 hours or more.

3.9 As part of its response to consultation, the sponsor also submitted interim unpublished results from 2 ongoing studies. One study was designed to compare lower limb circulation during intermittent pneumatic compression of the foot with the geko device after elective total hip replacement. The study is a single-centre, randomised, intra-patient comparison involving 10 patients in a UK centre. Blood flow is measured using duplex ultrasound, and patient tolerability is measured using a questionnaire. Interim results on 7 patients were submitted as commercial-in-confidence data. The second study, which is described as a pilot involving a planned total of 40 patients, is a multicentre, randomised, open-label investigation comparing the incidence of asymptomatic and symptomatic deep vein thrombosis with the geko device against thromboembolic deterrent stockings after elective total

hip replacement. Asymptomatic deep vein thrombosis and blood flow measurements are carried out using duplex ultrasound at baseline, day 2, at discharge and 6 weeks after surgery. Interim results on 16 patients were submitted on a commercial-in-confidence basis.

3.10 A meeting abstract (Barnes et al. 2014) became available after the medical technologies consultation document was issued. This described a study in which blood flow in people with peripheral arterial disease wearing the geko device for 40 minutes was compared with baseline values. Results for 16 patients showed a statistically significant increase in arterial, venous and microcirculatory flow.

3.11 The External Assessment Centre noted a number of limitations of the clinical evidence presented in the sponsor's original evidence submission:

- All the geko studies included only healthy people: there were no studies on patients or in clinical settings.
- In some of the studies, people were positioned in economy-style airline seating, which is not representative of a typical hospital setting.
- In the submitted evidence, the longest period of time for which the device was continuously active was 30 minutes.

3.12 The External Assessment Centre critically appraised all of the additional evidence and information submitted during consultation. It concluded that, although relevant to the scope, it did not provide conclusive evidence for the clinical effectiveness of the geko device, or for its mechanism of action. The External Assessment Centre considered that the new evidence submitted during consultation was promising because the studies were conducted in a patient population with an activated geko device. However, it noted significant limitations in the study methodology and the level of information provided. In particular, the External Assessment Centre judged that the additional information contained conflicting information and was inconclusive about the effect of shear stress on the endothelium. It noted that the Barnes et al. (2014) abstract contained very few details of the study, that it was not on people at risk of deep vein thrombosis, and that it showed an increase in

venous blood flow comparable to that demonstrated in existing studies. The External Assessment Centre also reviewed the additional post-market surveillance information presented during consultation. It considered that these data did not provide a sufficiently detailed description of either how long the geko device was activated, or if acceptability and tolerability for patients were related to the period for which the geko device was activated. The External Assessment Centre also noted that the number of patients who stopped using the geko device, or the rationale for stopping use, were not reported in the post-market surveillance report.

Evidence on other neuromuscular stimulation devices

3.13 In its submission, the sponsor presented evidence on other mechanical venous thromboembolism prophylaxis methods including neuromuscular electrostimulation and intermittent pneumatic compression studies. Using the sponsor's search strategy, the External Assessment Centre identified a total of 22 studies (15 neuromuscular electrostimulation and 7 intermittent pneumatic compression). It excluded 10 of these (4 neuromuscular electrostimulation and 6 intermittent pneumatic compression) and identified, from its own literature search, 5 further studies. Of the resulting 17 studies, 6 presented evidence on the effect of neuromuscular electrostimulation on the incidence of deep vein thrombosis with all but 1 (Moloney et al. [1972]) showing a reduction.

3.14 The External Assessment Centre judged that the efficacy demonstrated by other neuromuscular electrostimulation or intermittent pneumatic compression devices currently in use could not be generalised to the geko device. It noted that other devices use different methodologies that introduce uncertainties related to the type of muscle contractions caused by the geko device.

Committee considerations

3.15 The Committee noted that most of the studies on the geko device involved healthy people, but acknowledged that there were some relevant data on patients (see sections 3.8–3.10). The Committee was advised by clinical experts that it is likely that the blood flow results from

healthy people are generalisable to patients at high risk of venous thromboembolism. The Committee judged that, on balance, the generalisability of the blood flow results to patients was plausible and concluded that the increased blood flow benefits of geko should be realisable in patients who are unable to receive other methods of mechanical prophylaxis.

3.16 The Committee debated at length whether evidence of increased blood flow during use of the geko device could be used as a surrogate for effectiveness in reducing the risk of venous thromboembolism. The Committee heard a range of expert opinions, a majority of which advised that this assumption was reasonable. It therefore accepted that the available data on measurements of blood flow provide some support for the claim that the device reduces the risk of venous thromboembolism. However, further research is needed to confirm that the geko device reduces the incidence of venous thromboembolism in clinical practice, and to demonstrate conclusively the size of the risk reduction associated with its use.

3.17 The Committee noted no evidence of harm to patients from the geko device. It heard expert advice that the risk of harm is very low and the expert advisers had no concerns about possible side effects. The Committee considered that this was particularly important in the context of the population in the scope, who might otherwise not be offered prophylaxis.

3.18 The Committee was mindful that the population in the decision problem included only people who have a high risk of venous thromboembolism and for whom other mechanical and pharmacological methods of prophylaxis are impractical or contraindicated. It considered that the incidence of venous thromboembolism in this population, without any prophylaxis, is likely to be high and that the geko device offers plausible benefit with a low risk of harm.

3.19 The Committee discussed other potential benefits of the geko device for patients. It noted the post-market surveillance data and heard expert advice that the geko device is simple to use and offers advantages in terms of mobility and comfort, which may help improve adherence to its

use. The Committee judged that the geko device may offer an acceptable alternative means of prophylaxis to those who are unable to use current methods. It noted that the benefits to patients of this device should become clearer as the evidence base in hospitalised patients matures.

3.20 The Committee noted that there were a number of ongoing studies and considered that further research on the geko device, in clinical settings, would be useful in resolving the uncertainties about how much it reduces the risk of venous thromboembolism. The Committee recognised the practical difficulties of conducting studies in people who cannot receive existing methods of venous thromboembolism prophylaxis because of the small numbers and particular circumstances of such people. However, data on its use could be collected and audited, and could contribute to the evidence base. If research demonstrated that the geko device is as effective as other mechanical methods of prophylaxis, particularly intermittent pneumatic compression, then its use might be supported in a broader population. The Committee wished to give strong encouragement to both research and data collection.

4 NHS considerations

System impact

4.1 The sponsor claimed that the geko device addresses unmet need by delivering venous thromboembolism prophylaxis to patient groups who cannot currently use the standard mechanical means of venous thromboembolism prophylaxis.

4.2 The sponsor proposed that use of the geko device would only be initiated in a hospital setting and would not result in changes to the current pathway or involve additional system resources. The External Assessment Centre agreed with these assumptions.

Committee considerations

4.3 The Committee considered the size of the population described in the decision problem of the scope. It heard differing estimates from expert advisers, the External Assessment Centre and the sponsors, ranging from a 'small' population to around 50,000 patients per year. The Committee concluded that there is a population with an unmet need but that it is not possible to accurately estimate this population.

5 Cost considerations

Cost evidence

5.1 No existing studies were identified on the cost impact of the geko device.

5.2 The sponsor submitted a de novo cost analysis using a decision tree model that estimated the cost associated with the geko device compared with no mechanical prophylaxis. The model population was patients for whom current mechanical methods of prophylaxis are impractical or contraindicated.

5.3 The decision tree structure was an amended version of the model from the NICE clinical guideline on venous thromboembolism. The model assumed that patients treated with the geko device experienced a reduction in their baseline risk of deep vein thrombosis. Of the patients who went on to experience deep vein thrombosis, most would have either symptomatic or asymptomatic deep vein thrombosis but some would progress to pulmonary embolism. A proportion of patients with deep vein thrombosis also experienced post-thrombotic syndrome, a permanent comorbidity that could generate costs over the patient's lifetime. Further, it was assumed that the patients who had a pulmonary embolism also had a risk of death. The time horizon for the decision tree was 1 year but the model also included the lifetime (15 years) cost of post-thrombotic syndrome. The External Assessment Centre stated that it believed the model structure captured the clinical pathway of care, assumptions and health states in an appropriate manner for the evaluation.

5.4 Most of the clinical parameters were based on the NICE clinical guideline on venous thromboembolism. The key assumptions for clinical parameters used in the model were:

- The underlying risk of deep vein thrombosis was 29.1% with no prophylaxis (this was based on the average risk of deep vein thrombosis for all surgical-related patients according to the NICE clinical guideline on venous thromboembolism).
- The proportion of deep vein thrombosis progressing to a pulmonary embolism was 10.5%.
- There was a 6% chance of pulmonary embolism causing death. No other mortality cause was considered.
- The relative risk of a deep vein thrombosis after treatment with the geko device was 0.39.
- Post-thrombotic syndrome occurred in 25% of patients with symptomatic deep vein thrombosis or a pulmonary embolism and 15% of patients with asymptomatic deep vein thrombosis.

5.5 No evidence was available for the reduction in relative risk of deep vein thrombosis associated with the use of the geko device. The sponsor's assumption of a relative risk of 0.39 was based on the incidence of subclinical deep vein thrombosis after the use of neuromuscular electrostimulation as reported in Browse & Negus (1970). The sponsor stated that this was a conservative assumption and further justified this because the value fell within the range (0.31–0.58) identified for intermittent pneumatic compression in the NICE clinical guideline on venous thromboembolism. The External Assessment Centre disagreed with this assumption.

5.6 The cost of the geko device was £22 per pair exclusive of VAT. The cost of purchasing the device per course of 6 days, to treat both legs, was therefore £132.

5.7 In the sponsor's model, the cost per patient estimated for the geko device was £359 and for the comparator (no prophylaxis) it was £565, resulting in a cost saving for the geko device of £206 per patient. After correcting for an error in the hourly nursing cost, the External Assessment Centre calculated the cost saving per patient to be £197.

5.8 The sponsor conducted univariate, 2-way and probabilistic sensitivity

analyses. The 3 factors that affected the cost analysis the most were the cost associated with post-thrombotic syndrome, the relative risk of deep vein thrombosis associated with the geko device as a form of prophylaxis, and the proportion of deep vein thromboses that are symptomatic. The probabilistic sensitivity analysis showed that the geko device remained cost saving in 99% of simulations performed, with a mean cost saving of about £200 per patient. The sponsor concluded that the geko device was cost saving compared with no prophylaxis. The External Assessment Centre, stated that, although it believed the underlying assumption on risk reduction to be flawed, the sensitivity analysis covered all the uncertain variables, was well performed and that the results supported the conclusions about cost savings from the submitted model.

5.9 The sponsor performed subgroup analysis in people for whom pharmacological prophylaxis is indicated and prescribed. An economic model was developed using values for the relative risk of deep vein thrombosis with pharmacological prophylaxis alone and with pharmacological prophylaxis plus the geko device of 0.14 and 0.02, respectively. Compared with pharmacological prophylaxis alone, the geko device in combination with pharmacological prophylaxis was cost saving for the first 2 days and cost neutral if used for 3 days. It was not estimated to be cost saving after more than 3 days of treatment, with an incremental cost of £69 after 6 days of treatment.

Committee considerations

5.10 The Committee considered that the cost model structure was appropriate and that the sponsor had addressed some of the uncertainties in the cost model through sensitivity analyses.

5.11 The Committee discussed the relevance of studies (some conducted many years ago) that demonstrated the efficacy of neuromuscular electrostimulation in reducing deep vein thrombosis. It noted that the reduction in relative risk in deep vein thrombosis used for the geko device (0.39) in the base case was taken from a neuromuscular electrostimulation study in 1970 by Browse and Negus, and was further justified by falling within the range identified in the NICE clinical guideline

on venous thromboembolism (0.34–0.58) for intermittent pneumatic compression. The Committee heard from the External Assessment Centre that the unique mode of action of the geko device introduces uncertainty about the association between the type of muscle contractions generated and a reduction in the incidence of deep vein thrombosis compared with those generated by using either neuromuscular electrostimulation or intermittent pneumatic compression.

5.12 The majority of experts advised the Committee that the increase in venous blood flow shown by other mechanical prophylaxis devices was comparable to that demonstrated for the geko device. The Committee heard a range of expert opinions about the generalisability to the geko device of the reduction in risk observed in neuromuscular electrostimulation studies. It judged, on balance, that a reduction in risk for people who are unable to receive any other means of prophylaxis was plausible. The Committee therefore considered that the assumption in the cost model that the geko device reduces the risk of venous thromboembolism compared against no prophylaxis was reasonable. The Committee noted that in the model a relative risk of 0.39 was used and so the baseline risk of deep vein thrombosis with no prophylaxis of 29% was reduced to 11% with the use of geko. This base case gave an estimated cost saving of £197 per patient for geko compared with no prophylaxis. The Committee was also aware that the geko device continued to be cost saving up to a relative risk of deep vein thrombosis of 0.76, meaning that for a baseline risk of 29%, using geko would be cost saving as long as it reduced the risk to less than 22%. The Committee concluded that even if the risk reduction associated with geko was less than that associated with intermittent pneumatic compression devices, it was unlikely that the reduction in risk would be so small that the geko device would incur costs, especially for patients who are unable to receive alternative means of prophylaxis.

6 Conclusions

6.1 The Committee was mindful of the circumstances of the patient population included in the evaluation, who are at high risk of venous thromboembolism and unable to receive either any other mechanical or pharmacological method of prophylaxis. It considered that it is plausible that the geko device would reduce the risk of venous thromboembolism in these patients, despite the lack of direct evidence from clinical studies. It also took account of the low risk of harm from the device. Taking these considerations into account, the Committee judged that the case for adoption of the geko device in this population of patients was supported.

6.2 The Committee considered that further research on the geko device in clinical settings could focus on reducing the current uncertainties about the reduction in relative risk in the defined patient population, and allow investigation into its use in broader patient populations.

Sir Andrew Dillon
Chief Executive
June 2014

7 Committee members and NICE lead team

Medical Technologies Advisory Committee members

The Medical Technologies Advisory Committee is a standing advisory committee of NICE. A list of the Committee members who took part in the discussions for this guidance appears below.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each Medical Technologies Advisory Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Professor Bruce Campbell (Chair)
Consultant Vascular Surgeon, Exeter

Dr Peter Groves (Vice Chair)
Consultant Cardiologist, Cardiff and Vale NHS Trust

Professor Dilly Anumba
Chair of Obstetrics and Gynaecology/Honorary Consultant Obstetrician and Gynaecologist, University of Sheffield

Ms Susan Bennett
Lay member

Dr Keith Blanshard
Consultant Interventional Radiologist, University Hospitals of Leicester NHS Trust

Prof Nigel Brunskill

Professor of Renal Medicine, University of Leicester

Mr Matthew Campbell-Hill
Lay member

Mr Andrew Chukwuemeka
Consultant Cardiothoracic Surgeon, Imperial College Healthcare NHS Trust

Professor Daniel Clark
Head of Clinical Engineering, Nottingham University Hospitals NHS Trust

Professor Tony Freemont
Professor of Osteoarticular Pathology, University of Manchester

Professor Peter Gaines
Consultant Vascular Interventional Radiologist, Sheffield, Vascular Institute and Sheffield Hallam University

Professor Shaheen Hamdy
Professor of Neurogastroenterology, University of Manchester

Dr Jerry Hutchinson
Independent Medical Technology Adviser

Dr Cynthia Iglesias
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Professor Mohammad Ilyas
Professor of Pathology, University of Nottingham

Dr Greg Irving
General Practitioner, University of Liverpool

Dr Eva Kaltenthaler
Reader in Health Technology Assessment, ScHARR, University of Sheffield

Dr Paul Knox
Reader in Vision Science, University of Liverpool

Mrs Jacqui Nettleton
Programme Director, Commissioning, Western Sussex Hospitals NHS Trust

Mrs Karen Partington
Chief Executive, Lancashire Teaching Hospitals NHS Foundation Trust

Professor Brian J Pollard
Professor of Anaesthesia, University of Manchester. Consultant Anaesthetist, Central Manchester University Hospitals

Mr Brian Selman
Managing Director, Selman and Co

Professor Wendy Tindale
Scientific Director, Sheffield Teaching Hospitals NHS Foundation Trust

Professor Allan Wailoo
Professor of Health Economics, School of Health and Related Research (ScHARR), University of Sheffield

Mr John Wilkinson
Director of Devices, Medicines and Healthcare Products Regulatory Agency

Dr Janelle Yorke
Lecturer and Researcher in Nursing, University of Manchester

NICE lead team

Each medical technology assessment is assigned a lead team of a NICE technical analyst and technical adviser, an expert adviser, a technical expert, a patient expert, a non-expert member of the Medical Technologies Advisory Committee and a representative of the External Assessment Centre.

Paul Dimmock
Technical Analyst

Bernice Dillon
Technical Adviser

Sameh Dimitri
Lead Expert Adviser

Gerard Stansby
Lead Expert Adviser

David Warwick
Lead Expert Adviser

Brian Selman
Non-Expert MTAC Member

James Clinch
External Assessment Centre Representative

Jennifer Summers
External Assessment Centre Representative

8 Sources of evidence considered by the Committee

The External Assessment Centre report for this assessment was prepared by King's Imaging Technology Evaluation Centre (KITEC):

- Clinch J, Healey A, Keevil S et al. (2013) The geko™ electro-stimulation device for venous thromboembolism prophylaxis (September, 2013)

Submissions from the following sponsor:

- FirstKind Limited

The following individuals gave their expert personal view on the geko device by providing their expert comments on the draft scope and assessment report:

- Mr Sameh Dimitri, nominated/ratified by The Vascular Society – clinical expert
- Professor Gerard Stansby, nominated/ratified by The Vascular Society – clinical expert
- Mr David Warwick, ratified by The Vascular Society – clinical expert
- Professor Andrew Nicolaides, ratified by The Vascular Society – clinical expert
- Mr John Scurr, nominated by The Vascular Society – clinical expert
- Professor Charles McCollum, nominated by The Vascular Society – clinical expert
- Mr John Mosley, nominated by The Vascular Society – clinical expert

The following individuals gave their expert personal view on the geko device in writing by completing a patient questionnaire or expert adviser questionnaire provided to the Committee.

- Mr Sameh Dimitri, nominated/ratified by The Vascular Society – clinical expert
- Professor Gerard Stansby, nominated/ratified by The Vascular Society – clinical expert
- Mr David Warwick, ratified by The Vascular Society – clinical expert

- Mr George Geroulakos, nominated by The Vascular Society – clinical expert
- Mr John Scurr, nominated by The Vascular Society – clinical expert
- Dr Mohideen Jameel, ratified by Association of Surgeons of Great Britain and Ireland – clinical expert
- Mr Frank Smith, nominated by The Vascular Society – clinical expert
- Dr Irfan Akhtar, nominated by The Vascular Society – clinical expert
- Ms Lynda Bonner, ratified by Royal College of Nursing – clinical expert
- Professor Andrew Nicolaides, ratified by The Vascular Society – clinical expert
- Mr Bankole Akomolafe, nominated by The Vascular Society – clinical expert
- Anticoagulation Europe – patient organisation group

About this guidance

This guidance was developed using the NICE medical technologies guidance process.

It has been incorporated into the NICE pathway on venous thromboembolism, along with other related guidance and products.

We have produced a summary of this guidance for the public. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Related NICE guidance

For related NICE guidance, please see the NICE website.

Changes after publication

April 2015: Minor maintenance

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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