NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1934 Percutaneous deep venous arterialisation for chronic limb-threatening ischaemia

Your information

Name:	Hosaam Nasr
Job title:	Consultant Vascular and Endovascular Surgeon
Organisation:	University Hospitals Birmingham
Email address:	[redacted]
Professional organisation or society membership/affiliation:	MBChB – University of Liverpool MD(Res) – University of London FRCS (England)
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	6028596

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☒ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

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Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I am currently the Critical Limb Ischaemia lead for the unit and in charge of the lower limb complex endovascular interventions. I am very familiar with the technology. However, as a unit, we have not introduces it to our unit yet.
	Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this	I know that the technology is used in selected centres only. The LimbFlow team came to our unit and there is general agreement to introduce it in carefully selected patients.

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. I have done research on this procedure in laboratory settings (e.g. device-related research). I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research. I have had no involvement in research on this procedure. Other (please comment)
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Established practice and no longer new. A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. Definitely novel and of uncertain safety and efficacy. The first in a new class of procedure.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	It wouldn't replace the current standard of care. It might be an additional salvage solution for a small group of patients with who have CLTI and no revascularisation option.

Current management

5	Please describe the current standard of care that is used in the NHS.	We aim to revascularise with open surgical repair (bypass) if possible. If the patient is not a candidate for open surgery either physiologically or anatomically, they would be considered for endovascular intervention. Most patients will be treated with POBA and drug eluting technology is only used within the confines of research.
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	NO

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Potential limb salvage in CLTI patients with no revascularisation option.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with good inflow vessels (up to the below knee popliteal) with crural vessel disease and good pedal and deep veins.
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Yes Not sure
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	It would definitely cost more than the standard revascularisation procedure (open or endo).
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	This procedure has the potential to be cost effective, if there is evidence that it improves amputation free survival in CLTI patients.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	None

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	I don't think so. However, it has to be performed by and experienced / skilled endovascular specialist.

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	• Venous congestion. • Pain in the initial few days/weeks post intervention. • Rapid progression of foot infection (if it was subtle and not identified prior to intervention) • Need for re intervention (both arterial and venous) Schmidt A, et al. Midterm Outcomes of Percutaneous Deep Venous Arterialization With a Dedicated System for Patients With No-Option Chronic Limb-Threatening Ischemia: The ALPS Multicenter Study. JEVT 2020; 1-8 I also had access to the data from LimbFlow to prepare a business case for the introduction of DVA in our department at UHB.
15	Please list the key efficacy outcomes for this procedure/technology?	
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	No long term data available yet.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	

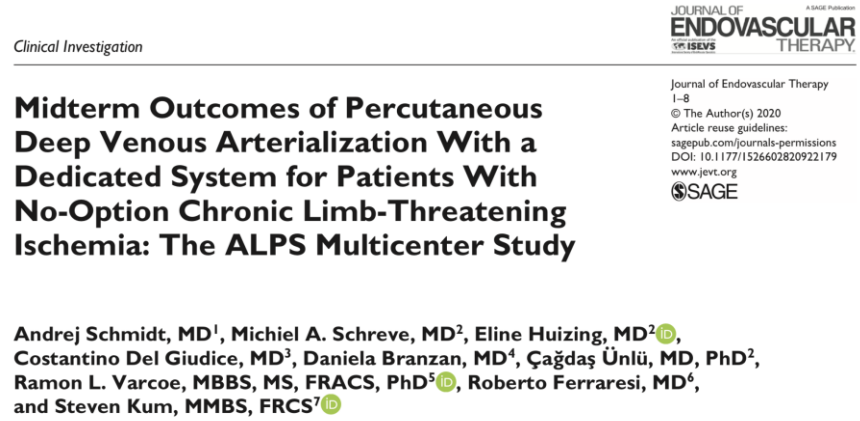
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK. Cannot predict at present.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	Most of the results are from the PROMISE I and PROMISE II studies. I am also attending the PROMISE UK investigators meeting on the 11th of November 2022.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	PROMISE I PROMISE II PROMISE UK

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	Less than 20% of the total CLTI patients will be suitable.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Technically, this procedure is simpler than complex tibial and pedal revascularisation, a technique that is not currently mastered by endovascular specialists in all the units across the UK. My concern with DVA, is that more units will offered this procedure as an alternative to complex arterial revascularisation.
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	• Lack of evidence. • Cost. • This is a resource intensive procedure throughout the patients' treatment journey, from pre-op assessment, technicality of the procedure and post procedural surveillance. More recently, it had been noted that the majority of patients required re-intervention to embolise the foot venous tributaries in order to encourage more flow to the distal foot.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	There is ongoing research at the moment. Ultimately, we will need an RCT the compares DVA Vs conservative treatment in CLTI patients with no revascularisation option.
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: – Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.	Beneficial outcome measures: QoL Amputation free survival (At least 2 year follow up) Adverse outcome measures: Technical failure rate Re-intervention rate (Target lesion revascularisation TLR)

	– Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Pain and quality of recovery following the procedure. Radiation exposure to patient and health care professionals. Mortality
26	Is there any other data (published or otherwise) that you would like to share with the committee?	PROMISE I and PROMISE II trial results.  *Clinical Investigation* JOURNAL OF ENDOVASCULAR THERAPY Journal of Endovascular Therapy 1–8 © The Author(s) 2020 Article reuse guidelines: sagepub.com/journals-permissions DOI: 10.1177/1526602820922179 www.jevt.org SAGE **Midterm Outcomes of Percutaneous Deep Venous Arterialization With a Dedicated System for Patients With No-Option Chronic Limb-Threatening Ischemia: The ALPS Multicenter Study** Andrej Schmidt, MD[1], Michiel A. Schreve, MD[2], Eline Huizing, MD[2], Costantino Del Giudice, MD[3], Daniela Branzan, MD[4], Çağdaş Ünlü, MD, PhD[2], Ramon L. Varcoe, MBBS, MS, FRACS, PhD[5], Roberto Ferraresi, MD[6], and Steven Kum, MMBS, FRCS[7]

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	

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Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Non-financial professional			
Non-financial personal			
Choose an item.			

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Hosaam Nasr**
Dated:	**27/10/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1934 Percutaneous deep venous arterialisation for chronic limb-threatening ischaemia**

Your information

Name:	Ian Hunter
Job title:	Consultant vascular surgeon
Organisation:	Somerset & North Devon Regional Vascular Service
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Vascular Society of Great Britain & Ireland
Nominated/ratified by (if applicable):	Vascular Society of Great Britain & Ireland
Registration number (e.g. GMC, NMC, HCPC)	GMC 4637017

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Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this	I do not have first hand experience of the technique but have treated patients with critical limb ischaemia for the whole of my surgical career. I am therefore very familiar with the disease and patient population. I have read the existing literature regarding the technique and attended presentations on the subject

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. ✓ I have done research on this procedure in laboratory settings (e.g. device-related research). I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research. I have had no involvement in research on this procedure. ✓ Other (please comment)
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Established practice and no longer new. A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. Definitely novel and of uncertain safety and efficacy. ✓ The first in a new class of procedure.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	ADDITION TO EXISTING CARE.

Current management

5	Please describe the current standard of care that is used in the NHS.	Combination of bypass surgery / arterial angioplasty.
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	No.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Potential limb salvage where other options not viable.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Diabetic patients / critical limb ischaemia.
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Possibly.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	About the same / ? slightly more initially.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	More.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Minimal - should be able to use existing facilities

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes.

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	
15	Please list the key efficacy outcomes for this procedure/technology?	
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK.

		Cannot predict at present.

Abstracts and ongoing studies

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20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	
22	Are there any issues with the usability or practical aspects of the procedure/technology?	

23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: – Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Adverse outcome measures:
26	Is there any other data (published or otherwise) that you would like to share with the committee?	

Further comments Questions 14-26 left blank as I am currently not best placed to answer these questions accurately.

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	I have specialist knowledge in the disease area but not the technology - yet.

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Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
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Choose an item.			
Choose an item.			
Choose an item.			

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Print name:	Click here to enter text. IAN HUNTER
Dated:	Click here to enter text. 14th November 2022

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1934 Percutaneous deep venous arterialisation for chronic limb-threatening ischaemia

Your information

Name:	Narayanan Thulasidasan
Job title:	Consultant Interventional Radiologist
Organisation:	Guy's & St Thomas' NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	General Medical Council
Nominated/ratified by (if applicable):	British Society of Interventional Radiology
Registration number (e.g. GMC, NMC, HCPC)	GMC No. 6164087

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1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	I am familiar with the percutaneous deep venous arterialization (pDVA) procedure and the Limflow technology used to perform the procedure, having to date performed 10 pDVA procedures using the Limflow technology as part of the PROMISE-UK trial, and a further Limflow pDVA as a commercial case (authorised at local trust level on a compassionate basis). I have also performed the vast majority of follow-up angiograms and re-interventions (stealing collateral embolization, angioplasty/stenting of lateral plantar vein stenosis) for this series of patients, and am part of the multidisciplinary team responsible for their ongoing clinical and imaging follow-up. Within the NHS, this procedure has almost exclusively been performed only in the research setting (i.e. recruitment to the PROMISE-UK trial) to date. However, with emerging data from the US/European trials testifying to the utility of the procedure in a specific group of patients who have exhausted all other treatment options, and once the 1-year data from the PROMISE-UK trial is available, I expect a significant and rapid increase in interest from UK clinicians. The procedure is performed by vascular surgeons and interventional radiologists, and best practice is that the primary procedure itself and the clinical/imaging follow-up and any reinterventions necessary are done by a multidisciplinary team comprising the above two specialties along with podiatry. Correct patient selection and timing of intervention is crucial to successful outcome, and therefore these decisions are best taken by a multidisciplinary team familiar with both performance of the procedure itself and the nuances regarding follow-up (timing of any minor amputations/debridements and need for any specific reinterventions to modulate the blood flow at the appropriate moments). An interventional radiologist and vascular surgeon working together provide the optimum combination of expertise for this.

2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. I have done clinical research on this procedure involving patients or healthy volunteers.
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	The current standard of care for peripheral arterial disease causing chronic limb-threatening ischaemia is revascularisation via angioplasty or bypass surgery along with debridement of non-viable tissue, however there is a subset of patients in whom neither of these approaches are feasible or are attempted but unsuccessfully. This group of patients have been termed “no-option CLTI” patients, and it is to this group that pDVA is currently being offered. The concept of arterialising veins in the foot for patients in whom the distal arterial circulation is not reconstructable by either of the above methods is not new, but was only performed successfully by a handful of clinicians worldwide, with a generalisable protocol for patient selection, procedural technique and follow-up never defined (both open surgical, endovascular and hybrid techniques were used). However, in the last 5 years the concept of pDVA has been introduced, with two major pathways for the procedure: the Limflow system (which contains all the equipment required to perform the procedural steps, including some novel technologies, along with ongoing research by the company to formalize patient selection, procedural technique and follow-up), and the “off-the-shelf” pDVA technique which uses equipment already widely available to perform the procedure, but given variation between individual practitioners and some limitations imposed by the equipment used, is not a completely homogenous method with similarly divergent outcomes and less formalised research structures. Definitely novel and of uncertain safety and efficacy.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	This procedure would primarily be used as an addition to existing standard of care in the “no-option CLTI” group of patients described above, however my feeling is that in the future with further research about patient selection and timing of procedure in relation to outcomes, there may be a role for, if not prophylactic, but at least very early pDVA in a small subset of patients (diabetic patients with renal failure and severely calcified foot arteries to prevent them

		experiencing the devastating complications of wet gangrene and subsequent amputation at an earlier stage in their disease process.

Current management

5	Please describe the current standard of care that is used in the NHS.	The current standard of care for peripheral arterial disease causing chronic limb-threatening ischaemia is revascularisation via angioplasty or bypass surgery along with debridement of non-viable tissue, however for patients in whom these approaches for revascularisation are either not feasible or unsuccessful the usual result is a major lower limb amputation, which in itself can herald major morbidity, loss of quality of life and indeed earlier mortality.
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	Other than the “off-the-shelf” pDVA techniques mentioned above, and a tiny amount of open surgical venous arterialisation procedures performed usually as a last resort and with minimal success, there is no alternative procedure or technology with similar function/mode of action to this.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	From my experience thus far, in correctly-selected patients and with close early follow-up, this procedure has a high success rate in saving patients from lower limb amputation and thus maintaining quality of life, independence, freedom from chronic pain and burden of multiple hospital/clinic attendances to manage chronic wounds.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Diabetic and renal failure patients with concomitant peripheral arterial disease. The procedure is of particular benefit from patients with both of these comorbidities, who are especially difficult to treat by conventional angioplasty/bypass surgery.
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	By preventing the need for major lower limb amputation, this procedure would provide a lifeline to patients not treatable by conventional means, and after the early intensive follow-up period of 4-6 months would reduce hospital visits significantly and prevent the morbidity associated with major amputation.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	In-hospital costs for the primary pDVA procedure and early follow-up, when compared against a “simple” below-knee amputation, are likely to be somewhat higher. However, I anticipate that by 6 months post-procedure, the cost savings per patient from performing pDVA will be apparent when balanced against the additional cost of amputation rehabilitation, prosthesis/mobility aids and potentially requirement for a social care package.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	The initial outlay for this procedure is likely to be more expensive than standard care, mainly due to the equipment to perform the pDVA, additional angiography suite time and need for a few ultrasound follow-up visits (as would be expected if the patient had underwent successful revascularization). However, as mentioned above, the cost savings will become apparent over the next few months when limb salvage is achieved, and those cost savings will likely be sustained over the patient’s lifetime.

12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	The procedure can be performed in any angiography suite (including hybrid operating theatre or cath lab). These will be present already in any centre looking to perform this procedure.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Centres new to the procedure should have input from clinicians from other centres experienced a performing the procedure during the patient selection phase, and then proctoring for their first 5-10 cases. This will ensure the right patients receive the procedure to allow it to demonstrate maximum efficacy and mitigate any complications.

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	The main potential harm of the technology is the hastening of limb ischaemia caused by the early arterial steal and venous hypertension resulting in early amputation, however these are mostly mitigated by careful patient selection, and must be weighed against the fact that these "no-option CLTI" patients are on the road to major amputation in any case. With respect to the Limflow pDVA system, the PROMISE trial had a 30% amputation rate[1], most of which occurred during the first three months following the procedure, supporting the view that careful patient selection (avoiding patients where severe infection is driving the necrosis or where the level of necrosis is too proximal) coupled with judicious early pDVA is the key to avoiding this complication. The ALPS registry showed a similar rate of early amputation[2] (again mostly within the first 3-6 months), with both studies recording similar amputation-free survival rates. There are have been anecdotal reports of arterial injury and sudden stent thrombosis with the "off-the-shelf" pDVA procedures, however the lack of standardised procedure technique and patchy reporting of these cases make meaningful comparisons with the published Limflow literature difficult. The remaining adverse events/risks remain the same for any endovascular revascularisation procedure (access site bleeding, infection, thrombosis, vessel dissection, distal embolisation, contrast nephropathy, circuit stenosis or occlusion). There was some consideration given to the potential for high-output cardiac failure given the creation of an A-V fistula, but these have not materialised, even in patients who have had bilateral pDVAs performed (personal communications from other PROMISE-2 investigators) [1] https://doi.org/10.1016/j.jvs.2021.04.057

		[2] https://doi.org/10.1177/1526602820922179
15	Please list the key efficacy outcomes for this procedure/technology?	The efficacy outcome for this procedure at the most basic level is limb salvage i.e. freedom from major amputation. However, other important efficacy outcomes include speed and completeness of wound healing, resolution of ischaemic rest pain and functional outcomes (patient quality of life and preservation of independence measures).
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	When deployed in correctly-selected patients who have failed or are unsuitable for traditional revascularisation techniques, there are no concerns regarding efficacy and safety of this procedure. However, when pDVA is performed too late in the clinical trajectory in patients with rapidly progressive wet gangrene the venous hypertension
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	The main uncertainty has been what truly defines a "no-option CLTI" patient, and then what the true limb salvage outcomes for these patients are – there is a dearth of data on this topic because trials in this area are mainly interventional so nobody truly has any idea what happens to untreated patients. To their credit, the Limflow company have funded a US trial (CLariTI, https://clinicaltrials.gov/ct2/show/NCT04304105) to investigate this, and 3-month results presented at the Leipzig Interventional Course this year show that by three months a third of "no-option CLTI" patients had undergone a major amputation (1 year results awaited, the trial has just completed enrolment).
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	A minority of hospitals, but at least 10 in the UK. (realistic aim would be that eventually any vascular surgery hub site would have expertise to provide it)

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).	VIVA 2022 Late-breaking clinical trials: 6-Month Results from the PROMISE II US Pivotal Trial of the LimFlow System - Daniel Clair LINC 2022 Natural progression of high-risk chronic limb-threatening ischemia: The CLariTI study - Anahita Dua

	Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	Otherwise, results from the PROMISE trial and ALPS registry are referenced above, and there are several easily-searchable “off-the-shelf” DVA case series.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Regarding the Limflow pDVA system: PROMISE-2 has completed recruitment and 6-month results were presented at VIVA 2022 earlier this month. PROMISE-UK completed enrolment this month and one year follow-up will be completed by November 2023.

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	Extrapolating from our screening for trial recruitment at Guy’s & St Thomas (around 20 patients over two years) and potential for expanded indication after the PROMISE-2 and PROMISE-UK trial results, allied with the increasing prevalence of type 2 diabetes and its associated complications in the UK, I would expect 200-500 cases to be performed per year in the UK.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	To avoid inappropriate use of the procedure, it would be advised that a committee experienced in pDVA “vets” cases proposed by new sites and proctors the first several cases. There is a learning curve to both case selection and performance, and therefore a dedicated team is advised to concentrate the expertise in the first instance.
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	The major issues are the nuances surrounding patient selection and the high initial upfront cost.

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Completion of the PROMISE-2, PROMISE-UK and CLariTI studies should address initial uncertainties in the research base. Beyond that, I would suggest enrolling all non-trial patients in a registry to stratify outcomes by WiFi classification and pre-procedure anatomical variations.
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: – Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: - Primary procedure technical success - Number, type and impact of reinterventions to maintain pDVA circuit patency (if required) - Time to debridement/minor amputation (if required) – usually within first 3 months - Wound healing speed over 6-9 months - Functional outcomes (physiotherapy assessment) and QoL assessment pre-pDVA and post-complete wound healing (usually within 6 months) - An adaptation of the “WIWI” (was it worth it) questionnaire recently developed to assess cancer patients perceptions of treatment Adverse outcome measures: - Procedural technical failure - Early pDVA circuit occlusion (within first 6 months) - Major amputation (within first 6 months)
26	Is there any other data (published or otherwise) that you would like to share with the committee?	No

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	Treatment of peripheral arterial disease has been undergoing several small incremental improvements over the last decade, but effective pDVA is the first genuine paradigm shift I have seen in my career which will help the most difficult-to-treat patients.

NICE National Institute for Health and Care Excellence

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Non-financial professional	Sub-investigator in the PROMISE-UK trial of Limflow pDVA	March 2020	November 2022
Direct - financial	Have proctored one case Limflow pDVA case at a different hospital and was remunerated with a one-off fee by Limflow SA for this	20/5/2021	20/5/2021
Non-financial professional	Short trip with overnight stay to Paris to attend Limflow investigators meeting, funded by Limflow SA	9/2/2022	10/2/2022

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Narayanan Thulasidasan**
Dated:	**13/11/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1934 Percutaneous deep venous arterialisation for chronic limb-threatening ischaemia

Your information

Name:	Click here to enter text. Paul Moxey
Job title:	Click here to enter text. Consultant Vascular Surgeon
Organisation:	Click here to enter text. St George's Hospital, Tooting, London
Email address:	Click here to enter text. [redacted]
Professional organisation or society membership/affiliation:	Click here to enter text. GMC Full Licence to Practice, Council BSET, Member Vascular Society of GB and I.
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	Click here to enter text. GMC 6057022

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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☒ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this	I have performed 6 of these new procedures at St George's Hospital and been in close communication with the 3 other UK centres that have performed this procedure so far. It is performed by vascular surgeons and interventional radiologists usually in partnership in the UK. It is not performed by any other specialties. Patients will have critical limb ischaemia and will likely have had multiple previous procedures prior to be considered for deep venous arterialisation. Patients will be discussed in an MDT before being put forward for the procedure. I am PI at St George's for the PROMISE trial of this procedure in the UK. This is across 4 different sites and is a post market registry study.

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. I have done clinical research on this procedure involving patients or healthy volunteers.
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Open deep venous arterialisation has been around for 20+ years and NICE recently published guidance. This assessment is for the percutaneous or keyhole method of creating the fistula using novel technology Definitely novel and of uncertain safety and efficacy.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	In addition for patients with 'no option limb ischaemia' in whom there is no bypass or standard angioplasty option and other option would be palliation or amputation

Current management

5	Please describe the current standard of care that is used in the NHS.	Mostly done as part of clinical trial currently but should become standard of care for this small group of patients

6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	No

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	To avoid amputation or palliation in patients with no other option to revascularize a critically ischaemic limb
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Yes, patients with critical limb ischaemia
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Yes, could reduce the number of amputations performed in UK thus reducing burden on patients, amputee rehab, and social care.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	There is no current standard of care to compare to. Certainly the cost of the treatment to avoid a potential amputation is considerably less than the cost of amputee rehab, prosthesis and long term social care.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Nothing to compare to in terms of treatment as this is a modality where currently there is no option apart from major amputation or palliation. The up front costs are expensive (approx. £10k) for the equipment but the comparative costs of major amputation and its social impact are considerably higher.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	A hybrid operating theatre or modern interventional radiology suite. Usually 2 consultant operators to perform the procedure. Nil change in facilities for the units already performing the procedure, suspect will remain a tertiary referral centre procedure.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, there is a learning curve and it is a complex procedure. Proctoring and support from industry for team training will be essential for safe delivery.

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	It is essentially a long peripheral angioplasty/venoplasty technique done under GA. Risks of bleeding, infection, thrombosis etc immediately during or after the procedure 3-5% if based on standard angioplasty data. Fistula occlusion ie blockage of the stent is the main concern. If stent occluded maybe possible to reopen the fistula and restore flow but if unable to reopen the procedure will fail.
15	Please list the key efficacy outcomes for this procedure/technology?	Amputation free survival, wound healing, quality of life
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Graft patency and if maintain graft patency equates to better QoL and wound healing
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Biggest clinical question is does deep venous arterialisation lead to improved tissue oxygenation and in turn does this lead to wound healing? The procedure has been proven to be technically possible but it's the AFS/QoL/wound healing outcomes that need to be shown to improve.
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Fewer than 10 specialist centres in the UK.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	Promise 2 US trial just been presented at VIVA meeting in USA UK Promise Trial just completed and data awaited Promise 1 trial published previously
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	UK Promise has just concluded having recruited 26 pts, results awaited Promise 1 and 2 US trials published

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	Hard to give an exact estimate as majority of 'no option CLI' pts end up with a major amputation. Not every pt is suitable for the treatment. Likely applicable in 10-20% of pts with critical limb ischaemia
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Technically challenging procedure to puncture vein and artery and create and internal fistula. Definite learning curve.

23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	No
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	No RCT but that is not possible as the control arm would be major amputation. A funded registry for these cases to be followed up in would be safest and most robust way to assess long term efficacy and safety of the procedure going forward.
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Amputation free survival QoL Wound healing Readmission rate Adverse outcome measures: Bleeding, infection, graft occlusion
26	Is there any other data (published or otherwise) that you would like to share with the committee?	

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	Published trial data does look positive with 75% AFS at 6 months in a very comorbid and frail cohort of patients. Patient selection is key and the ability to follow up closely and re-intervene if needed (lysis/angioplasty etc) is vital to the success of the procedure. Up front cost will be an issue unless the devices go onto the high cost device tariff

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Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Non-financial professional	Sub PI for the UK Promise Trial – I did not receive any financial payment for this	**April 2018**	**Ongoing**
Choose an item.			
Choose an item.			

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Click here to enter text. Paul Moxey**
Dated:	**Click here to enter text. 11/11/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1934 Percutaneous deep venous arterialisation for chronic limb-threatening ischaemia

Your information

Name:	Athanasios Saratzis
Job title:	Associate Professor of Vascular Surgery
Organisation:	University of Leicester
Email address:	[redacted]
Professional organisation or society membership/affiliation:	BSET, VSGBI, RCS
Nominated/ratified by (if applicable):	BSET, VSGBI
Registration number (e.g. GMC, NMC, HCPC)	GMC: 7024328

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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☒ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Not applicable - consent given.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this	I have performed this procedure 4 times. I was a local principal investigator for their UK-wide cohort study. I have advanced endovascular expertise regarding revascularisation in patients with peripheral arterial disease. I am very familiar with the use of the technology and its adoption in the UK, including all relevant specialties.

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done clinical research on this procedure involving patients or healthy volunteers.
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	The first in a new class of procedure. This is a very difficult question to answer. Clinicians have previously performed deep venous arterialisation but NOT using percutaneous approaches exclusively. This is the first fully percutaneous endovascular deep venous arterialisation procedure.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	The current standard of care is amputation. It has the potential to replace the current standard of care.

Current management

5	Please describe the current standard of care that is used in the NHS.	Amputation.

6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	No.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Save patients from losing their leg.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with no revascularisation options to save their leg from amputation.
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Yes.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	About the same. Amputation is very costly to the NHS (but not the secondary care institution). I think this technology can change the way we treat these patients and save the NHS money (but not the hospitals).
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Training of staff.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Already in place.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Leg pain and swelling.
15	Please list the key efficacy outcomes for this procedure/technology?	Limb salvage.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Issues re- training of staff.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No.
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	A minority of hospitals, but at least 10 in the UK.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	No abstracts that I am aware of. Please look up the PROMISE study.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	PROMISE cohort study

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	500
22	Are there any issues with the usability or practical aspects of the procedure/technology?	It requires a lot of training.
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	No.

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Lim salvage Adverse outcome measures: Pain.
26	Is there any other data (published or otherwise) that you would like to share with the committee?	No.

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	

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Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Non-financial professional	I have attended a dinner funded by the company where they presented their technology in 2021.	**10/02/2021**	**10/02/2021**
Choose an item.			
Choose an item.			

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

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Print name:	**Athanasios Saratzis**
Dated:	**27/10/2022**