

Professional Expert Questionnaire

Fechnology/Procedure name & indication: IP1842 Supercapsular percutaneously assisted total hip arthroplasty for			
Your information	our information		
Name:	Mr Ashwin Kulkarni		
Job title:	Consultant Orthopaedic Surgeon		
Organisation:	University Hospitals of Leicester		
Email address:	Ashwin.kulkarni@me.com		
Professional organisation or society membership/affiliation:	(GMC)		
Nominated/ratified by (if applicable):	N/A)		
Registration number (e.g. GMC, NMC, HCPC)	GMC number: 4667788		

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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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 consent is NOT given, please state reasons I	questionnaire to be used and may be published on the NICE website as outlined above. If pelow:
	Click here to enter text.	
	se answer the following questions as for your experience.	ully as possible to provide further information about the procedure/technology
Pleas	•	to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete uced under their work programme.
4	Please describe your level of experience	Lam very familiar with Supernath Hip replacement. Letarted learning it in 2016. Lattended training

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 am very familiar with Superpath Hip replacement. I started learning it in 2016. I attended training course and cadaveric lab as well as visited other surgeon (Mr Mike Cronin) before starting the procedure myself in Jan 2017.

I audited my results after 20n cases, 80 cases and 300 cases.

The procedure is currently performed in all hospitals of Leicester. UHL, Spire and Nuffield. It went through a rigorous process of assessment and follow up through NIPAG (new interventions and procedures guidance committee).

This procedure is not practiced by surgeons other than hip surgeons, currently. It is however possible to do this procedure in treatment of hip fractures as well as hip replacement.

Patients are seen and assessed in clinic where they are provided with printed and web based information and asked to choose (after consultation). If patients wishj to go ahead with this procedure, they are booked for surgery.

Patients are selected on basis of how complex they are and their bone quality. In patients where complexity requires significant soft tissue release and/or bone loss related reconstruction Superpath is contraindicated.

	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 yes I have done research on this procedure in laboratory settings (e.g. device-related research). yes I have done clinical research on this procedure involving patients or healthy volunteers. yes I have published this research. Yes (presented in British hip society which will be abstracted in BJJ) 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?	Novel approach to standard hip replacement.
	Which of the following best describes the procedure (please choose one):	Established practice and no longer new. Yes - in my hands at nearly 5 years 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	Yes this is likely to become more popular and commonly available eventually replacing the standard procedure. (This is similar to knee arthroscopy replacing open knee procedures.)

would it be used as an addition to existing	
standard care?	

Current management

5	Please describe the current standard of care that is used in the NHS.	Posterior or Hardinge approach to the hip.
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?	Yes Anterior and DSA minimally invasive approached are competing with this procedure. These other approaches are not extensile and still involve considerably more capsular or other soft tissue release where as Superpath is extensile (it is most proximal end of the posterior approach, superpath hip is not dislocated leaving soft tissue envelope intact.

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?	Shorter length of stay in hospital, less pain early mobility and no post-surgical restrictions following hip replacement.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Majority of patients will benefit from this approach including hemiarthroplasty
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. My superpath patients average length of stay for 300 patients is 1.2 days. For standard approach it is 3 days. If this is put together with newer wound closure techniques there is no further visit for skin suture/clip removal. As there are no restrictions after surgery, there is no need to spend on equipment such as raised toilet seat etc after surgery. Being less invasive surgery patients return to walking free of walking aides early (88% in 4 weeks). Drive early (85% in 4 weeks). Return to work and sport early (3 week to 12 week based on what the patients do or play as sport). This means less time off work and more productivity.
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)	Overall the cost is less than standard procedure despite increased cost of implants and some consumables in the surgery.
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)?	It is likely to cost significantly less and it will save money in terms of staffing, equipment and ongoing care
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No special kit is required other than sterile equipment required to perform the procedure

13	Is any specific training needed in order to use the procedure/technology with respect	Yes training is essential to understand and safely use this technique in patients.
	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	This is a novel approach and currently the implants used in this technique are only manufactured by one company – Microport. The microport hip replacement implants have ODEP rating of 5* and 10* respectively for the femur and socket.
	risks (even if uncommon) and, if possible, estimate their incidence:	Potential complications include intra-operative fracture (0.5% risk), Post-operative subsidence of implants (0.5% risk). The other risks are similar to standard hip replacement except
	Adverse events reported in the literature (if possible, please cite literature)	dislocation risk is very very small. Anecdotally, I have had one patient where a piece of acetabular reamer broke inside the
	Anecdotal adverse events (known from experience)	patient without being noticed. It is likely this may have happened because of reamer basket hitting against retractor. This needed another procedure to remove the broken metal fragment.
	Theoretical adverse events	
15	Please list the key efficacy outcomes for this procedure/technology?	The procedure has been largely very successful. Oxford hip score improved similar to other hip replacements at 6 week and 6 months. The overall risks and complications are similar or less compared to other hip replacement
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Surgeon needs training before starting the procedure
17	Is there controversy, or important	Superpath procedure currently uses uncemented stem.
	uncertainty, about any aspect of the procedure/technology?	In GIRFT report cemented stem has been recommended as stem of choice for primary hip replacement.
		Cemented polished stem will be available for use with this technique in the coming year.

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 yes 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	BHS – presentations
	been recently presented / published on this procedure/technology (this can include your own work).	EARLY RESULTS AND LEARNING CURVE DATA FOR TOTAL HIP REPLACEMENT USING A NOVEL, SUPRACAPSULAR, TISSUE SPARING APPROACH "SuperPATH" (157) S Howles, M Cronin, K Sarantos, P Foguet
	Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent	University Hospital Coventry and Warwick, Warwickshire, UK
	abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a	Safety of Superpath® minimally invasive total hip replacement (THR) in a case matched comparison with THR performed with Hardinge approach
	comprehensive reference list but it will help us if you list any that you think are particularly important.	A Kulkarni, AR Brown, SL Hutchings, RU Ashford, HP Singh, JN Davison
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Currently one trial by Mr Cronin in Swansea

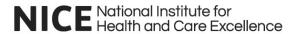
Other considerations

21	Approximately how many people each year	70% of patients undergoing hip replacement could have this procedure
	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?	No issues with technology or procedure. Every patient must be coucelled about potential to convert this to a standard posterior approach if there is difficulty doing the procedure through Superpath approach.
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?	Need for training and lack of more extensive literature.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	There is a need for comparative studies in RCT to show difference with standard approaches.
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: Early return to function or activity over 6-12 weeks Pain following procedure in early stages over 6 weeks Forgotten hip score at 6 moths Adverse outcome measures: Complications and readmissions in 6 weeks Further procedures in short term (6 months) and long term (20 years)

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	This is a very good way of doing hip replacement without compromising safety. In a surgical procedure seeing what you are doing is important to be able to do the procedure safely. That is very much possible with this procedure. I have done over 300 cases since Jan 2017 with excellent results.
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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 <u>NICE policy on declaring and managing interests</u> as a guide when declaring any interests. Further advice can be obtained from the NICE team.

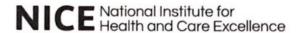
Type of interest *	interest * Description of interest		Relevant dates	
		Interest arose	Interest ceased	
Direct - financial	I am a paid consultant for Microport	May 2019	continuing	
Non-financial professional	I have support from Microport statistician for my data	May 2019	continuiong	
Choose an item.				

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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:	Mr Ashwin Kulkarni
Dated:	03/10/2021



Professional Expert Questionnaire

Technology/Procedure name & indication: IP1842 Supercapsular percutaneously assisted total hip arthroplasty for

Your information

Name:	Mr Mohammad Faisal
Job title:	Orthopaedic Consultant
Organisation:	South Warwickshire NHS Trust, Warwick Hospital
Email address:	faisaldoc67@hotmail.com
Professional organisation or society membership/affiliation:	British Orthopaedic Association, Royal college of surgeons of Edinburgh
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	General Medical Council- 4659013

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For more information about how we process your data please see our privacy notice.

	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:		
CI	ick here to enter text.		
	lease answer the following questions as fully as possible to provide further information about the procedure/technology nd/or your experience.		
PI th	ease note that questions 10 and 11 are applicable ese sections as future guidance may also be prod	e to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete duced under their work programme.	
1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the	Yes I am familiar with the technology, I have been using the Superpath technique for total hip replacement for the past 4 years and have performed more than 150 cases. I underwent cadaveric training and then performed initial cases under supervision of a experienced surgeon.	
	procedure/technology?	Since then I have used the Superpath technique for all my private patients at two private hospital sited for the past 4 years.	
	Have you used it or are you currently using it?	I am currently using the Superpath technique for total hip replacements.	
	Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?	Superpath technique at present is not widely used in the NHS, as at present very few surgeons are familiar with the technique and have the relevant training to perform the technique competently. For Superpath there is a steep learning curve before a surgeon is competent in performing total hip replacements using superpath technique. I would anticipate a reasonably quick uptake if proper training and supervision is in place.	
	 Is this procedure/technology performed/used by clinicians in specialities other than your own? 	No	
	 If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it. 	Yes, patient selection is important especially in the early stages of the learning curve as the surgeon should start with straight forward cases before attempting more complex cases to avoid comlications.	

2	Please indicate your research experience relating to this procedure (please choose one or more if relevant):	Other (please comment)- I have submitted a research proposal to do gait analysis and return of muscle function after superpath total hip replacement and the proposal has been accepted by Microport and will start the project soon. Comparison will be between standard posterior and superpath technique to compare return of normal gait and muscle function at 6 weeks post surgery.
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?	Superpath technique is a Novel approach as in this procedure as in this technique as compared to the conventional posterior and Hardinge approach none of the muscles around the hip are cut thus preserving the hip envelop, this leads to early recovery and return to daily activities and less pain.
	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?	In my opinion this procedure has the potential to replace current standard care as it will improve patient outcomes and quicker recovery in the initial 6 weeks post-surgery. More research is needed to look into patients outcomes in the UK.

5	Please describe the current standard of care that is used in the NHS.	The standard of care in the NHS is to use posterior/Hardinge approach and ODEP rated implants with good outcomes on the NJR.
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?	Superpath is a novel technique and I am aware of any other approach which is similar to this technique.
	If so, how do these differ from the procedure/technology described in the briefing?	

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?	The main benefit to the patients is early recover and return to normal activities much earlier than conventional posterior approach in the first 6 weeks, no hip restrictions post hip surgery, less analgesic requirement. Quicker return to normal function.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Younger patients in particular will benefit as they can get back to normal activities quicker and back to work within 6-8 weeks.
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?	Yes superpath technique has the potential to change the current pathway and clinical outcomes and this will benefit the healthcare system, as this technique will reduce hospital stay, fewer hospital visits post-surgery, tissue sparing technique will improve clinical outcomes Early return to full function.
	Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	
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)	Superpath technique once established will cost less than the current techniques as no special table or equipment is needed, we do not need extra staff, patients will need fewer days in hospital post-surgery, less analgesic use, fewer hospital visits.
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)?	In my experience it should cost more or less the same.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Training the surgeons and staff is needed to do this procedure safely. The only additional facility needed is one intraoperative X ray during surgery.
13	Is any specific training needed in order to	Yes surgeons and staff need to be trained.

use the procedure/technology with respect to efficacy or safety?	
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Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology?	This procedure requires a learning curve during this period surgeons should perform straightforward case, the risk factors and complications are similar to conventional technique.
	Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:	Superpath hip replacement has a longer operative time initially.
	Adverse events reported in the literature (if possible, please cite literature)	Adverse events are similar to conventional hip replacement surgery.
	Anecdotal adverse events (known from experience)	As the incision is small there is potential to miss a calcar fracture.
	Theoretical adverse events	
15	Please list the key efficacy outcomes for this procedure/technology?	Shorter incision, better HHS at 6weeks and improved VAS pain scores at 6weeks. Shorter hospital stay and quicker return to normal fucnction.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	None
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	None
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.	1) PMID: 30569673 DOI: 10.7507/1002-1892.201807011 2) Comparison of short-term outcomes between SuperPATH approach and conventional approaches in hip replacement: a systematic review and meta-analysis of randomized controlled trials Journal of Orthopaedic Surgery and Research volume 15, Article number: 420 (2020) 3) A Systematic Review and Meta-Analysis of the SuperPATH Approach in Hip Arthroplasty. PMCID: PMC8321717 PMID: 34337015
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	I am not aware of any major trials, in UK.

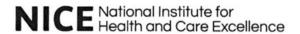
Other considerations

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)?	Depending on the number of surgeons and hospitals I would estimate 50% of the target population would easily be eligible for the technique.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	The only limiting factor would be acceptability by surgeons to the procedure and training.
23	Are you aware of any issues which would	In my NHS hospital the main problem is the hospital contract which is with a different company

	prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	and I am the only surgeon who is interested in the technique.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Research needs to be done to quantify the benefit of the procedure in real terms ie by doing studies to see return of muscle function at 6 weeks post surgery and improvement in gait in comparison to conventional technique.
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe:	Beneficial outcome measures: Harris hip score, VAS pain score, HOOS score. Operative time, blood loss and length of stay in the hospital.
	 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: 	HHS score should be done pre-operatively and at 6 weeks, and 6 months and 12 months. VAS pain score post surgery and at 6 weeks and 3 months. HOOS score done at 6 weeks, 3 months and 12 months. Adverse outcome measures: These should be done pos-operatively, at 6 weeks and 6 months.

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	In my experience superpath is a safe procedure with similar complications to conventional approaches, my operating time is now no longer than for posterior approach, the blood loss in my opinion is similar for both the approaches, VAS pain score are better for superpath and the initial 6 week recovery is much better as compared to conventional approach.	
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Declarations of interests

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	Interest arose	Interest ceased
Professional (HCP) Consultant. Providing teaching, research and	March 2020	31 December 2021
		,
	Professional (HCP) Consultant. Providing teaching, research and	Professional (HCP) Consultant. Providing teaching, research and March 2020

✓		I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations durin
	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 ar
	awa	are that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NIC
	com	mmittee.

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

Print name:	Mohammad Faisal
Dated:	04/10/2021