NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP742 Synthetic cartilage implant insertion for first metatarsophalangeal joint osteoarthritis (hallux rigidus)

Your information

Name:	Heath Taylor
Job title:	Consultant Orthopaedic Surgeon
Organisation:	University Hospitals, Dorset
Email address:	heathtaylor@me.com
Professional organisation or society membership/affiliation:	BOFAS
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	4114046

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NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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:

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 procedure/technology, please indicate your experience with it.	Yes, I am familiar with the procedure. It is used reasonably widely in the NHS, with increasing uptake.
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	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):	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?	Yes - may become the standard for select patients

Current management

5	Please describe the current standard of care that is used in the NHS.	C h e i l e c t o m y o r f u

		s i o n , o r p o s s i b l y o t h e r m o r e i n v a s i v e f o r m s

		of joint replacement
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?	There are other joint replacements, but they are more invasive, or made of different materials.

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?	Joint preserving surgery, retaining range of movement
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Mild to moderate OA of 1st MTPJ
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 - by avoiding the need for fusion in mild to moderate OA cases
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
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)?	about the same

12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	usual theatre equipment
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	yes, but training in the technique is quick and simple

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	Usual risk of any procedure, plus risk of failure, loosening, ongoing pain
15	Please list the key efficacy outcomes for this procedure/technology?	pain, range of movement, function
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	longevity of implant

17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	yes - depends who you ask!
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.

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.	Other people better placed to advise
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Yes - Mark Davies can advise

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)?	Not sure
22	Are there any issues with the usability or practical aspects of the procedure/technology?	no
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

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:

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
Choose an item.			
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:	**HeathT Taylor**
Dated:	**10 September 2021**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP742 Synthetic cartilage implant insertion for first metatarsophalangeal joint osteoarthritis (hallux rigidus)**

Your information

Name:	Maneesh Bhatia
Job title:	Consultant Orthopaedic Foot Ankle Surgeon
Organisation:	University Hospitals Leicester
Email address:	maneeshbhatia@yahoo.com
Professional organisation or society membership/affiliation:	GMC, BOFAS
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	5198567 GMC

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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 been using Cartiva since 2015. I have registered this with NIPAG in my Trust and I duly report back the outcome to NIPAG. As per my logbook I have performed 20 procedures so far. Out of these I have revised 3 cases to fusion.

	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 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.
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 is used as an addition to existing standard care

Current management

5	Please describe the current standard of care that is used in the NHS.	The current management of hallux rigidus involves – orthotics, steroid injections, cheilectomy & 1st MTP joint fusion. In addition Cartiva and 1st MTP joint arthroplasty are used for patients who would not like for their toe joint to be fused.

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?	Sialistic arthroplasty is an alternative to Cartiva as an alternative to joint fusion.

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?	It is a simple technique and in my experience it is successful for 80-85% patients at a follow up of up to 5-6 years. It preserves movements of the big toe joint. If it fails it can easily be revised to joint fusion.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with significant arthritis of the big toe joint who do not like the idea of joint fusion (mostly females).
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?	It is performed as day case procedure. The surgical time is 30-45 minutes. Patients are able to weight bear immediately and the rehab is quicker as compared to joint fusion. It avoids the complication of non union (seen in about 10% patients following fusion).
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
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)?	About the same
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Nothing extra other than the Cartiva implant.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	It is an easy procedure to perform & does not require specific training. There might be a small learning curve in order to attain better outcomes (as with any other surgery).

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	Failure of the procedure (15-20% chance). However, this can be easily revised to joint fusion.
15	Please list the key efficacy outcomes for this procedure/technology?	The biggest advantage is to preserve movements of the big toe joint
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Failure of the procedure (15-20% chance in my experience).
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):	Most or all district general hospitals.

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.	Daniels TR, Younger AS, Penner MJ, Wing KJ, Miniaci-Coxhead SL, Pinsker E, Glazebrook M. Midterm Outcomes of Polyvinyl Alcohol Hydrogel Hemiarthroplasty of the First Metatarsophalangeal Joint in Advanced Hallux Rigidus. Foot Ankle Int. 2017 Mar;38(3):243-247. doi: 10.1177/1071100716679979. Epub 2016 Dec 7. PMID: 27909032. Goldberg A, Singh D, Glazebrook M, Blundell CM, De Vries G, Le ILD, Nielsen D, Pedersen ME, Sakellariou A, Solan M, Younger ASE, Daniels TR, Baumhauer JF; Cartiva MOTION Study Group. Association Between Patient Factors and Outcome of Synthetic Cartilage Implant Hemiarthroplasty vs First Metatarsophalangeal Joint Arthrodesis in Advanced Hallux Rigidus. Foot Ankle Int. 2017 Nov;38(11):1199-1206. doi: 10.1177/1071100717723334. Epub 2017 Aug 18. PMID: 28820949.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	I am not aware

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)?	Hallux rigidus affects 20% of population over the age of 40 years. Of these 10-20% of this subgroup might be benefitted by this procedure (as an estimate)
22	Are there any issues with the usability or practical aspects of the procedure/technology?	No
23	Are you aware of any issues which would prevent (or have prevented) this	No

	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?	A multi-centre RCT comparing Cartiva to Sialistic implants or Cheilectomy would be useful
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: VAS Range of movements MOXFQ Patient satiscation Adverse outcome measures: Complications, failure, revision

Further comments

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

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Choose an item.			
Choose an item.			

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Print name:	**Maneesh Bhatia**
Dated:	**08/01/21**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP742 Synthetic cartilage implant insertion for first metatarsophalangeal joint osteoarthritis (hallux rigidus)**

Your information

Name:	Mr Chris Blundell
Job title:	Consultant Orthopaedic Surgeon
Organisation:	Sheffield Teaching Hospital NHS Trust
Email address:	chris.blundell@nhs.net
Professional organisation or society membership/affiliation:	BOFAS
Nominated/ratified by (if applicable):	Mr Mark B Davies
Registration number (e.g. GMC, NMC, HCPC)	3563546

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YES ☐ 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 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 familiar with the device. I was a recruiter to the original pivotal trial. I have implanted the device more than 50 times
	Have you used it or are you currently using it?	Yes I am
	− Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?	Not exactly
	− Is this procedure/technology performed/used by clinicians in specialities other than your own?	Yes by Podiatrists Practicing Surgery
	− If your specialty is involved in patient selection or referral to another specialty for this	No

	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 involvement in research on this procedure.
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):	It was a novel approach 10 years ago when we started the PRCT on this device, though widely practiced and published now Established practice and no longer new.
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 additional to current care techniques or as an alternative

Current management

5	Please describe the current standard of care that is used in the NHS.	Most often this is a fusion of the 1st MTPJ rather than a replacement, but on occasions it may be that a cheilectomy is more appropriate
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?	Silastic replacement, similar performance but historic risks about were debris were of concern

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?	Preservation of motion
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Females more often due to the desire to vary heel height
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 improved outcomes and patient satisfaction
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 as a fusion
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)?	Similar
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?	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	It has been clinically proven to be safe
15	Please list the key efficacy outcomes for this procedure/technology?	Improved range of motion, pain relief and restoration of function
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?	Yes use in osteoporosis is uncertain
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all teaching hospitals with a dedicated foot and ankle orthopaedic consultant hospitals.

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.	Baker MI, Walsh SP, Schwartz Z, Boyan BD. A review of polyvinyl alcohol and its uses in cartilage and orthopedic applications. *J Biomed Mater Res B Appl Biomater.* 2012 Jul;100(5):1451-7. Baumhauer JF, Marcolongo M. The Science Behind Wear Testing for Great Toe Implants for Hallux Rigidus. *Foot Ankle Clin*. 2016 Dec; 21(4):891-902. Daniels TR, Younger SE, Penner MJ, et al. Midterm outcomes of polyvinyl alcohol hydrogel hemiarthroplasty of the first metatarsophalangeal joint in advanced hallux rigidus. *Foot Ankle Int.* 2017;38(3):243-247. Glazebrook M, Baumhauer J, Davies MB. Revision of Implant to Great Toe Fusion: Did We "Burn a Bridge" With a Synthetic Implant Hemiarthroplasty? *Foot & Ankle Orthopaedics.* 2017 Sep 11;2(3):2473011417S000044. Younger ASE, Baumhauer JF. Polyvinyl Alcohol Hydrogel Hemiarthroplasty of the Great Toe: Technique and Indications. *Techniques in Foot and Ankle Surgery.* 2013;12(3):164-169. Younger AS, Baumhauer JF, Glazebrook M. Polyvinyl alcohol hemiarthroplasty for first metatarsophalangeal joint arthritis. *Curr Orthop Pract*. 2013;24(5):493-497. Goldberg A, Singh D, Glazebrook M, **Blundell CM**, De Vries G, Le ILD, Nielsen D, Pedersen ME, Sakellariou A, Solan M, Younger ASE, Daniels TR, Baumhauer JF. Association between patient factors and outcome of synthetic cartilage implant hemiarthroplasty versus first metatarsophalangeal joint arthrodesis in advanced hallux rigidus. Foot and Ankle International. 2017;38 (11):1199-1206 Baumhauer JF, Singh D, Glazebrook M, **Blundell CM**, Nielsen D, Pedersen ME, Sakellariou A, Solan M, Wansbrough G, Younger ASE, Daniels TR. Correlation of hallux rigidus grade with motion, VAS pain, intraoperative cartilage loss, and treatment success for first MTP joint arthodesis and synthetic cartilage implant. Foot Ankle Int. 2017 Nov; 38(11):1175-1182.

		Glazebrook MA, Younger ASE, Daniels TR, Singh D, **Blundell C**, De Vries G, Le ILD, Nielsen D, Pedersen ME, Sakellariou A, Solan M, Wansbrough G, Baumhauer JF. Treatment of first metacarpophalangeal joint arthritis using hemiarthroplasty with a synthetic cartilage implant or arthrodesis: A comparison of operative and recovery time. Foot Ankle Surg. Accepted 2017-May-19. Baumhauer J, Singh D, Glazebrook M, **Blundell CM**, et al. Prospective, randomised, multicentred clinical trial assessing safety and efficacy of a synthetic cartilage implant versus first metatarsophalangeal arthrodesis in advanced hallux rigidis. Foot and Ankle Int. 2016; 37(5): 457-69 Glazebrook M, Younger ASE, Daniels TR, Singh D, **Blundell CM**, et al; Treatment of first metatarsophalangeal joint arthritis using hemiarthroplasty with a synthetic cartilage implant or arthrodesis. Submitted to FAI October 2016.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	None – they have been completed

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)?	I don't know
22	Are there any issues with the usability or practical aspects of the procedure/technology?	No not once trained
23	Are you aware of any issues which would prevent (or have prevented) this	No

	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?	No
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: FAAM MOxFQ SF12 All proven to be improved after Cartiva Adverse outcome measures:

Further comments

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

NICE National Institute for Health and Care Excellence

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.	Nil in the last 12 months or the future		
Choose an item.			
Choose an item.			

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Print name:	**Mr Chris Blundell**
Dated:	**09/09/2021**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP742 Synthetic cartilage implant insertion for first metatarsophalangeal joint osteoarthritis (hallux rigidus)**

Your information

Name:	James Davis
Job title:	Consultant Orthopaedic Surgeon
Organisation:	South Devon healthcare Trust
Email address:	James.davis@nhs.net
Professional organisation or society membership/affiliation:	GMC
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	3484294

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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?	I have been using the Cartiva implant since being a principal investigator in the trial performed in the UK. I have implanted it in appropriate patients since this time. The time period of usage is approximately 10 years.
	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 currently using this implant in the appropriate patients. It is not an implant used for all cases of hallux rigidus in my practice and is anecdotally successful in the patients treated by me. It is used in a judicious manner for certain patients with hallux rigidus excluding those who have: poor bone stock/osteoporosis, exsisting hallux valgus that is uncorrected and significantly stiff hallux rigidus, in my practice those who have less than 15 degrees of dorsiflexion not impeded by a large dorsal impinging osteophyte. It may be performed by a small amount of non specialist foot and ankle surgeons but I am unaware of any that do. All the patients selected appropriate for this procedure have the procedure cariied out by a foot and ankle specialist and have pre and post PROMS scores.

	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. I have published this research. I was named on the paper published in the foot and ankle journal and on the prize winning presentation at the American Academy of orthopaedic surgeons for the paper following 500 implantations in comparison to big toe fusions over a 2 year follow up period that was performed prospectively and given the American Academy prize for the quality of the research. 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):	It is a new material and design for a replacement. Many of the previous replacements have been significantly more distant from the norm. This replacement has the advantage that there seems to be little loss of bone and if a revision to a fusion is required this is no more difficult than a primary fusion and there has been no loss of length of the metatarsal and therefore minimal compromise in the post revisional function. In my opinion it is a far better option than ones where segments of bone have to be removed. Established practice and no longer new.
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 is an additional option available for a small group of patients with hallux valgus. In a normal year I would perform approximately 40-50 fusions of the big toe joint and perhaps 2-5 Cartiva replacements making it between 2-5% of the patients treated for big toe arthritis.

Current management

5	Please describe the current standard of care that is used in the NHS.	Standard care is either non-operative or operative and operative treatment in my practice is divided into: Fusion, cheilectomy, Cartiva replacement, shortening and corrective osteotomies and arthroscopy.
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 there are numerous joint replacements and hemi joint replacements on the market and in my opinion a number of these have significantly more problems than the Cartiva. Many of these alternatives require excision of a section of bone to replace it with the implant making revisional surgery significantly more challenging. Cartiva is a less intrusive method of achieving, in my view a better result than many of the competitors, the study showed that it was only mildly inferior in terms of pain relief to a fusion. Fusion is one of the most dependable and predictable operations performed in foot and ankle surgery.

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?	Prevents the need for fusion in a select group of individuals and if it eventually fails, which all joint replacements do, the salvage operation is less involved and more predictable than most other replacements.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with a pre operative good range of motion with a well aligned toe without Hallus valgusand no significant osteoporosis.
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 in a small group of patients appropriately selected. It is not a panacea for the treatment of big toe arthritis.
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)	The current trend to use expensive implants to fuse the big toe joint makes its cost similar if not slightly less.
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)?	No increased net cost
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?	The company supports new surgeons in their cases. This is not a difficult operation to perform, requires no jigs, joint balancing or bony corrections. It in my practice is one of the easier operations.

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	Infection, less than 1%, as with any joint replacement, failure and requirement for revision, which is easier than other joint replacements, subsidence 1-5% in my practice. Pain from the replacement up to 20%.
15	Please list the key efficacy outcomes for this procedure/technology?	PROMS scores and EQ-5D ratings.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Appropriate surgical use. There are strict indications in my practice for its use as outlined above.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	There is always controversy generated between joint replacements with advocates of other procedures finding fault. The original study was beautifully designed and performed generating truthful and robust supportive data.
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.

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.	
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	There are cases entered on the BOFAS registry. If the NICE guidance persists we had decided as BOFAS council to release a statement in our support of the procedure and a necessity for those continuing to implant to input the data on the BOFAS registry for surveillance.

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)?	2-5 in my practice.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	none
23	Are you aware of any issues which would prevent (or have prevented) this	The recent NICE guidance which appears to have been based on the advice from a retired hip surgeon without communication to the specialist society. I am the immediate past president of BOFAS and know that we as a body were not consulted before the guidance was published. We

	procedure/technology being adopted in your organisation or across the wider NHS?	as a society are focussed on appropriate and high standard treatments for the foot and ankle patients of the UK and would not support any operation that was deemed worse than the alternatives. We are not able to police our members activities but are able to define and do, acceptable standards of foot and ankle surgical care.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	If there are genuine concerns then, as all foot and ankle procedures should, validated PROMS outcome submission to the national BOFAS registry.
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: MOXFQ and EQ-5D score pre and post op will establish the success of this operative intervention. Adverse outcome measures: Failure rates over 10 years. Time to revision surgery and reasons. This operation takes 6 months to reach fully effect and in the Americas revisions have been performed early for pain before the critical time for pain relief was reached. The original paper documents this improvement with time.

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	I have been using it over the last 10 years at the rate of 2-5 per year and have had to revise 2 in total. One for subsidence in osteoporotic bone that was unrecognised by me prior to the operation and one for post operative stiffness and pain. The rest are surveilled by our surgical care practitioner on an annual basis and are continuing to perform in a predictable and reasonable way. Not all patients have perfect pain relief but all are better than they were before.

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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
Choose an item.			
Choose an item.			
Choose an item.			

x ☐ 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:	**James Davis**
Dated:	**10/9/21**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP742 Synthetic cartilage implant insertion for first metatarsophalangeal joint osteoarthritis (hallux rigidus)**

Your information

Name:	Mr Rajeshkumar Kakwani
Job title:	Consultant Orthopaedic Surgeon
Organisation:	Northumbria Healthcare NHS Trust
Email address:	Rajesh.kakwani@nhct.nhs.uk
Professional organisation or society membership/affiliation:	BOFAS Scientific Committee member
Nominated/ratified by (if applicable):	BOFAS
Registration number (e.g. GMC, NMC, HCPC)	GMC 5205151

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.

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:

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	Familiar Used widely in NHS/Privately Used by Foot & Ankle Surgeons

	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 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.
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?	Yes For great toe metatarso-phalangeal arthritis

Current management

5	Please describe the current standard of care that is used in the NHS.	Fusion surgery, silastic arthroplasty

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?	silastic arthroplasty, but silastic have a high risk of transfer metatarsalgia and silicon synovitis

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?	Pain improvement with low complication rate
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Early/moderate arthritis of the great toe metatarso-phalangeal joint
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, for Early/moderate arthritis of the great toe metatarso-phalangeal joint
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)	No, the implant is costlier than silastic arthoplasty
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)?	no
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	no

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	no

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	Residual pain needing revision surgery
15	Please list the key efficacy outcomes for this procedure/technology?	Bone preserving compared to silastic
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	No
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):	Most or all district general hospitals.

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.	Bernasconi A, De Franco C, Iorio P, Smeraglia F, Rizzo M, Balato G. Use of synthetic cartilage implant (Cartiva®) for degeneration of the first and second metatarsophalangeal joint: what is the current evidence? J Biol Regul Homeost Agents. 2020 May-Jun;34(3 Suppl. 2):15-21. ADVANCES IN MUSCULOSKELETAL DISEASES AND INFECTIONS - SOTIMI 2019. PMID: 32856435. Smyth NA, Murawski CD, Hannon CP, Kaplan JR, Aiyer AA. The Use of a Synthetic Cartilage Implant for Hallux Rigidus: A Systematic Review. Foot Ankle Spec. 2020 Jul 3:1938640020937160. doi: 10.1177/1938640020937160. Epub ahead of print. PMID: 32618201.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	BOFAS

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?	NO
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?	COST

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	NO
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: Numerous short term results available in peer reviewed publications Adverse outcome measures: None

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
Choose an item.	None		
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:	**Rajeshkumar Kakwani**
Dated:	**10/09/21**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP742 Synthetic cartilage implant insertion for first metatarsophalangeal joint osteoarthritis (hallux rigidus)**

Your information

Name:	Click here to enter text. Robert Clayton
Job title:	Click here to enter text. Consultant Orthopaedic Surgeon;
Organisation:	Click here to enter text. NHS Fife
Email address:	Click here to enter text. Raeclayton@me.com
Professional organisation or society membership/affiliation:	Click here to enter text. GMC member British Orthopaedic Foot and Ankle Society (Full member, council member and Director of Media and Communications)
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	Click here to enter text. GMC no 4697600

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.

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

YES 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?	I am a specialist foot and ankle surgeon. I have been implanting Cartiva since early 2016 and was the first user in Scotland. I have implanted about 50 to date. I have attended users group meetings. I have been to numerous professional subspecialist meetings where the Cartiva has been discussed and research evaluated.
	Have you used it or are you currently using it?	Yes, I am currently using it in private practice only
	− Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?	I can only speak for NHS Scotland. There are a few low volume users. Uptake is likely to increase fast as there is a clear demand and clinical indication for this type of implant
	− 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	No

	specialty for this 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):	It is a minor variation. The implant is used for first metatarsophalngeal joint partial replacement (hemiarthroplasty). Numerous implants for this indication have been used over several decades. **Established practice and no longer new.** This implant was introduced over ten years ago and a lot of clinical data are available regarding safety and efficacy 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	Rather than replace the current standard of care, it is a supplement and another option. For patients who have advanced arthritis in the first metatarsophalangeal joint, the standard of care

	would it be used as an addition to existing standard care?	remains fusion. However not all patients will accept the loss of movement in the great toe that results from fusion and for some patient groups, particularly women, this loss of movement can cause significant limitations. Cartiva provides a further treatment option for these patients, allowing preservation and restoration of some of the joint movement while relieving pain. As with all prosthetic joints, there are some limitations and potential risks but if the treating surgeon is aware of these and is able to discuss these in detail with their patient then the patients can make an informed decision about which treatment option is better for them.

Current management

5	Please describe the current standard of care that is used in the NHS.	For hallux rigidus, in early arthritis the standard of care is dorsal cheilectomy. For more advanced arthritis the standard is first metatarsophalangeal fusion.
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. Several implants exist. These include the silastic replacement, which has largely fallen out of favour due to concerns about silicosis but has contemporary supporting evidence from some centres. The Townley Biopro hemiarthroplasty is widely used in southern Scotland and has some long term data to support its use. There are many other implants. Most other devices are metal and problems have been reported with implant loosening. The MOJE ceramic implant was popular in the mid 2000s but also fell out of favour within a few years due to concerns about loosening. With around ten years of clinical data this does not currently appear to be a major problem with the Cartiva.

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?	Pain relief from hallux rigidus (arthritis of the great toe) along with preservation of movement (where the gold standard treatment of fusion by definition abolishes this movement)
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Women. Also those who undertake sports and activities in which dorsiflexion (upward bending) of the great toe is important; these include yoga, Pilates, curling, and dancing
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?	The Cartiva procedure is no less invasive than fusion but does carry a quicker recovery for ht patient, with a shorter period of immobilisation and protection of load bearing on the toe being required. This can allow patients to return to work or physical activity faster.
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)	I suspect this is cost neutral. The cost of the implant has to be considered against the cost of fixation devices for fusion, where there is a trend towards ever more expensive locking plate fixation devices.
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)?	Cost neutral. Both require an anaesthetic as a day case. Operating time is shorter for the Cartiva
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No changes to existing facilities. This is performed under general (or regional) anaesthetic as a day case.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes but for any properly trained and experienced foot and ankle surgeon this is straight forward. It is not a technically demanding operation and the necessary skill can be taught in a dry lab.

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	About 10% of patients will have pain and some of these will elect to convert to a fusion. This is comparable to the rates in other established joint replacement surgery including total knee replacement. There is a risk of implant subsidence and loosening, I cannot provide a precise figure of this but I put this at around 1-2%. It should be expected that this figure will rise with longer time periods post surgery.
15	Please list the key efficacy outcomes for this procedure/technology?	Pain relief and range of movement in the joint. The MOX-FQ is a good patient centred PROM scoring system for implants such as this.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Data exist to ten years but not beyond. With any implant there is always a risk that failure rates could increase with time.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Some surgeons natural tendency is to stick with fusion as this is the gold standard and provides excellent pain relief for most patients. Other surgeons favour other implants as above.
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**. Any foot and ankle specialist Orthopaedic surgeon will have the skill set required to carry out this procedure. 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.	I am not aware of anything that will not show up in a full literature search. Due to the pandemic restrictions on meetings and conferences there has been a lot less “hot off the press” research presented since early 2020.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	The BOFAS Registry monitors fusion and has the potential to monitor Cartiva. There are no registries that I am aware of in the UK. There was a large international RCT published in 2015 and follow up studies from that patient group are released periodically.

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 know, but in my own practice covering a population of 350,000 I could potentially offer ten to twenty a year so extrapolating across the UK would make about 2-4000

22	Are there any issues with the usability or practical aspects of the procedure/technology?	No. It is easy to use.
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 general inertia and resistance which is always seen in the NHS in introducing new treatments
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Large volume long term follow up studies are always valuable, but there is already quite a lot out there, including the lands=mark level 1 RCT
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: Pain scores, MOX-FQ score, EQ-5D quality of life scores. Should be measured at 1 year and then ideally every 5 years thereafter Adverse outcome measures: Revision, implant subsidence, pain scores and overall patient dissatisfaction.

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	As I was the first surgeon in Scotland to offer this, I was implanting a lot in 2016-18. Since. Then other surgeons have taken it up so my own volumes have fallen. Overall numbers in Scotland have, I suspect, risen

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Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.	I am a paid consultant for Stryker for their education I programme. I took on this role in 2019. In 2020 Stryker took ownership of the Cartiva through their takeover of Wright Medical	**2020**	**Ongoing**
Choose an item.			
Choose an item.			

YES 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.Robert Clayton**
Dated:	**Click here to enter text.7 September 2021**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP742 Synthetic cartilage implant insertion for first metatarsophalangeal joint osteoarthritis (hallux rigidus)**

Your information

Name:	Solan MC
Job title:	Consultant Foot and Ankle Orthopaedic Surgeon
Organisation:	Royal surrey Hospital
Email address:	matthewsolan@nhs.net
Professional organisation or society membership/affiliation:	BOFAS / BOA
Nominated/ratified by (if applicable):	BOFAS
Registration number (e.g. GMC, NMC, HCPC)	3665163

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

x☐ 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?	Extensive first hand experience and knowledge of associated literature. Contributor to the original Motion Study comparing CARTIVA with MTPJ Fusion
	Have you used it or are you currently using it?	Yes
	− Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?	Widely, but not frequently. The criteria for use are relatively narrow.
	− Is this procedure/technology performed/used by clinicians in specialities other than your own?	Maybe some podiatric surgeons
	− If your specialty is involved in patient selection or referral to another specialty for this	N/A

	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. All of the above. 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):	Innovative, and useful in carefully selected cases Established practice and no longer new. NO A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. NOT REALLY, BUT HAS NOT BEEN FORMALLY RANDOMISED AGAINST CHEILECTOMY Definitely novel and of uncertain safety and efficacy. – NOVEL – AND SHOWN TO BE SAFE AND EFFECTIVE The first in a new class of procedure. - YES
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?	AS AN ALTERNATIVE in some but not all cases

Current management

5	Please describe the current standard of care that is used in the NHS.	Joint fusion or cheilectomy are the most frequently used procedures for big toe arthritis. More complex “replacement” options exist but are largely still experimental or have become disused. Revising a CARTIVA is straightforward. Revision after larger implants can be a major challenge. This is one of the strengths of the CARTIVA
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?	Hemicap metal implant; Sialastic joint replacement; Moje Joint replacement – and there are others. All of these are “larger” joint replacements and, should outcomes be poor, are difficult to salvage.There are no Level 1 studies of these devices. The Level 1 Cartiva Motion study showed results equivalent to fusion. No study comparing Cartiva with cheilectomy has been undertaken. Some of the unfavorable literature about Cartiva is from North America, and the device has often ben used as an alternative to cheilectomy (for which there is no good evidence) and not as an alternative to fusion (which the Motion study showed equivalence)

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?	Avoiding fusion, in carefully selected cases. Faster recovery and preservation of joint movement. Fusion produces permanent stiffness which is a problem for some patients
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Those who prefer not to undergo joint fusion – younger and more active. In my own experience post-menopausal women are not well suited to cartiva
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 Potential for improved outcomes. Fewer post-op visits than a fusion requires. No less invasive though
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
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)?	Same
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Implant availability only

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

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	None – beyond occasional need for revision surgery Reports of poor outcomes, in my opinion through “indiscriminate use” In older women the device may subside – presumed to be bone-health related – compromising outcomes.
15	Please list the key efficacy outcomes for this procedure/technology?	Proven to be an alternative to joint fusion.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Not always a suitable alternative to cheilectomy
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Not always a suitable alternative to cheilectomy
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 BY FOOT AND ANKLE SPECIALISTS TRAINED IN USE 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.	Nothing that a LitSearch will not reveal. Local PhD study showing theoretical stresses in bone around CARTIVA – not clinically relevant.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Sadly no registry

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)?	Approx 50% of all patients having MTP fusion currently would be eligible.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	None

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?	Cartiva vs Cheilectomy (stratified by age and gender)
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: Pain score, patient satisfaction and range of motion MOXFQ and SF-12 scores Adverse outcome measures: Early complications; revision (or poor results that might justify revision); especially looking at problem rates in women >50yrs

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	There are good reasons and sufficient evidence to have this device available to the discerning clinician. A trial vs cheilectomy would be welcome

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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	Co-author of study (reputational interest only) - ongoing		
Choose an item.			
Choose an item.			

☐ **X** 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:	**Solan MC**
Dated:	**7/9/2021**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP742 Synthetic cartilage implant insertion for first metatarsophalangeal joint osteoarthritis (hallux rigidus)**

Your information

Name:	Steve Hepple
Job title:	Consultant Orthopaedic Surgeon
Organisation:	North Bristol NHS Trust
Email address:	Steve.hepple@nbt.nhs.uk
Professional organisation or society membership/affiliation:	British Orthopaedic Foot and Ankle Society
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 3475384

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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	Have used the technology regularly both NHS and privately. Have performed at least 30 cases in last 5 years Technique is well known amongst foot and ankle surgeons. In my experience those using it are familiar with its limitations and accept that it may not give perfect results but in selected patients it is a reasonable intervention that can provide symptom relief and avoid the negative effects of the main alternative procedure (fusion) Procedure should be limited to use by bone fide foot and ankle orthopaedic surgeons in selected cases.

	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
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):	Variation of approach. Interposition arthroplasty has been used for many years but this technique uses a specific implant. The uniqueness is that implantation does not compromise other options in the future which is the case in many other types of interposition arthroplasty. Provides a useful option A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy and in many units has now become established practice and no longer new.
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?	Additional option

Current management

5	Please describe the current standard of care that is used in the NHS.	Options of joint replacement surgery or fusion. The former is complex and difficult to salvage if it fails. The latter results in complete joint stiffness which is unacceptable to some patients. The technology in question provides a useful middle option.

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?	Many other implants available but most require much more bone resection which creates issues when it comes to revision surgery

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?	Able to resolve pain but preserve movement in the joint.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Select group of patients suffering hallux rigidus without substantial deformity and who are unable to tolerate fusion
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?	Marginal effect – just a different option. It does represent less invasive/restrictive treatment and if successful shorter follow up needed
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)	Approximately the same
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)?	No major change in cost. Procedure is slightly shorter (few minutes) than the main alternative
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	None apart from supply

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Minimal training for surgeon – no extra resourse

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	No obvious device specific harm. Main risk is that it may fail and require revision but the revision surgery to fusion is no more difficult than primary fusion surgery
15	Please list the key efficacy outcomes for this procedure/technology?	Prosthesis survival, PROMS
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?	Some surgeons feel that the benefits have not yet been proven in comparison to current treatment but no concerns over actual safety
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.

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.	
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)?	I estimate approximately 1 in 5 patients with hallux rigidus might consider this option
22	Are there any issues with the usability or practical aspects of the procedure/technology?	none
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?	none

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	no
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: PROM eg Manchester foot and ankle questionnaire Prosthesis survival rates Adverse outcome measures: As above

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
Choose an item.			
Choose an item.			
Choose an item.			

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Print name:	**Steve Hepple**
Dated:	**6/9/21**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP742 Synthetic cartilage implant insertion for first metatarsophalangeal joint osteoarthritis (hallux rigidus)**

Your information

Name:	David Townshend
Job title:	Consultant Orthopaedic Surgeon
Organisation:	Northumbria NHS Healthcare Trust
Email address:	David.townshend@nhct.nhs.uk
Professional organisation or society membership/affiliation:	British Orthopaedic Association, British Orthopaedic Foot and Ankle Society
Nominated/ratified by (if applicable):	Mark Davies
Registration number (e.g. GMC, NMC, HCPC)	GMC 440086

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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?	Consultant Orthopaedic Surgeon with a specialist interest in Foot and Ankle Surgery since 2010. I am familiar with the Cartiva **Synthetic cartilage implant insertion for first metatarsophalangeal joint osteoarthritis.**
	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 used this as a fellow in Vancouver, Canada as part of the FDA trial. I have not used in my own Consultant practice. I am aware of it's use elsewhere in the UK. I am aware that some podiatric surgeons also use this implant. We do not refer patients for this procedure. Patients with 1st MTP arthritis in our practice are offerd cheilectomy, fusion or silastic joint replacement.

	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 had no involvement in research on this procedure.
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):	It is a novel design of implant but the concept of 1st MTP arthroplasty is not novel. A minor variation on an existing procedure, which is unlikely to alter the procedure's 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?	Addition to standard care as an arthroplasty implant option.

Current management

5	Please describe the current standard of care that is used in the NHS.	Cheilectomy, Fusion or other arthroplasty.

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?	We use the Wright Medical (now part of Stryker) Swanson silastic implant. There are numerous other 1st MTP implants on the market. The silastic replacement is essentially a hinged spacer which is inserted into the medullary canals either side if the joint. The Cartiva implant is a hemiarthoplasty inserted into the metatarsal side of the joint to effectively provide cushioning to the central part of the joint.

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?	More bone preservation.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients who have relatively early arthritis.
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?	May lead to improved outcomes. Less invasive (bone conserving)
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 will cost more.
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)?	Implant costs more than current standard or care.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No additional facilties.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Surgeon should be familiar with procedure and ideally have attended training.

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	Failure of procedure to relieve symptoms, early failure of implant. Large well designed FDA study showed equivalence to MTP fusion with acceptable safety profile. I am aware of some smaller studies suggesting lower satisfaction rates and higher re-operation rates.
15	Please list the key efficacy outcomes for this procedure/technology?	Reduction in pain, improvement in function, maintenance of range of movement.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	The conflicting reports in the current literature suggest that the procedure may not be suitable for all patients with 1st MTP OA and that patient selection is important.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	As above
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.

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.	Numerous poster and podium presentations at BOFAS and AOFAS last few years.
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)?	unknown
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?	Cost

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Improved outcomes compared tocheilectomy and current implants, specifically silastic.
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: MOXFQ, EQ5D Adverse outcome measures: Revision, re-operation, complications

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
Direct - financial	Consultant Stryker – Total Ankle Replacement (research, teaching)	**2014**	**current**
Choose an item.			
Choose an item.			

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

Print name:	**David Townshend**
Dated:	**10th September 2021**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP742 Synthetic cartilage implant insertion for first metatarsophalangeal joint osteoarthritis (hallux rigidus)

Your information

Name:	Tim Clough
Job title:	Consultant Orthopaedic Foot&Ankle Surgeon
Organisation:	Wrightington Wigan Leigh NHS Foundation Trust
Email address:	tim.clough@doctors.org.uk
Professional organisation or society membership/affiliation:	BOFAS, BOA, RCS England, GMC
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	3680155

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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 procedure/technology, please indicate your experience with it.	I operate on all foot and ankle pathology including 1st MTPJ arthritis. I am familiar with the Cartiva procedure. This procedure is performed at a number of NHS Trust in limited indications.

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 also assessed its clinical outcome (performed by other surgeons). 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):	It is a novel approach Novel. Efficacy is part of ongoing clinical outcome study for the last 7-8 years. There have been a number of studies so far published.
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 to existing care

Current management

5	Please describe the current standard of care that is used in the NHS.	Conservative strategies +/- insoles, injection therapy, cheilectomy or surgical treatment for end stage disease.
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?	Cheilectomy

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?	Longer efficacy/survival/action than cheilectomy
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	(Young patients) with early arthrosis
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?	It is an augment (extra) treatment option, rather than replacing
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)	Slightly more (due to the implant costs)
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)?	See above
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Needs a non designer clinical outcome study
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	It may fail (sinkage, pain or stiffness) requiring revision/further surgery
15	Please list the key efficacy outcomes for this procedure/technology?	Pain relief
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Ongoing pain, stiffness, sinkage, leading to revision
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	See above
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	(Once approved) Most or all district general hospitals.

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.	Clinical Trial > Foot Ankle Int. 2019 Apr;40(4):374-383. doi: 10.1177/1071100718815469. Epub 2018 Dec 3. **Midterm Outcomes of a Synthetic Cartilage Implant for the First Metatarsophalangeal Joint in Advanced Hallux Rigidus** Mark Glazebrook [1], Chris M Blundell [2], Dominic O'Dowd [2], Dishan Singh [3], Gwyneth de Vries [4], Ian L D Le [5], Dominic Nielsen [6], M Elizabeth Pedersen [7], Anthony Sakellariou [8], Matthew Solan Randomized Controlled Trial > Foot Ankle Int. 2016 May;37(5):457-69. doi: 10.1177/1071100716635560. Epub 2016 Feb 27. **Prospective, Randomized, Multi-centered Clinical Trial Assessing Safety and Efficacy of a Synthetic Cartilage Implant Versus First Metatarsophalangeal Arthrodesis in Advanced Hallux Rigidus** Judith F Baumhauer [1], Dishan Singh [2], Mark Glazebrook [3], Chris Blundell [4], Gwyneth De Vries [5], Ian L D Le [6], Dominic Nielsen [7], M Elizabeth Pedersen [8], Anthony Sakellariou [9], Matthew Solan > Foot Ankle Int. 2019 Oct;40(10):1140-1148. doi: 10.1177/1071100719855049. Epub 2019 Jun 13. **Early Outcomes and Complications of Synthetic Cartilage Implant for Treatment of Hallux Rigidus in the United States** Spenser J Cassinelli [1], Stephanie Chen [1], Timothy P Charlton [1], David B Thordarson [1]
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Cartiva Motion study 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)?	?100/year
22	Are there any issues with the usability or practical aspects of the procedure/technology?	No
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?	See 12,14,16,17 above.
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: MOXFQ, EQ5D5L, VAS, Adverse outcome measures: Complications, Pain, stiffness, revision rates

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	Have extensively researched the clinical outcome of alternative surgical management strategies

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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
Choose an item.			
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.**
Dated:	**Click here to enter text.**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP742 Synthetic cartilage implant insertion for first metatarsophalangeal joint osteoarthritis (hallux rigidus)

Your information

Name:	Mr Jitendra Mangwani
Job title:	Consultant Orthopaedic Foot and Ankle Surgeon
Organisation:	University Hospitals of Leicester NHS Trust
Email address:	Jitendra.mangwani@uhl-tr.nhs.uk
Professional organisation or society membership/affiliation:	General Medical Council
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	5205970

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.

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:

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?	Yes, I have performed this particular procedure (CARTIVA) on NHS patients.
	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?	As far as I understand this particular procedure is used by specialist foot and ankle surgeons in many NHS trusts.
	– Is this procedure/technology performed/used by clinicians in specialities other than your own?	To the best of my knowledge this procedure is used by clinicians in the speciality of foot and ankle surgery.
	– If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please	Yes, the patient selection is done by the specialist foot and ankle surgeons.

	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). 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 has a place in the treatment pathway of first metatarso-phalangeal arthritis.

Current management

5	Please describe the current standard of care that is used in the NHS.	Fusion of the first MTP joint.
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?	Not to my knowledge.

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?	Maintaining the range of movement in 1st MTP joint.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients who would like to keep movement in their 1st MTP joint.
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?	I don't think so, but can provide an alternative treatment option for patients who are keen to keep the movement in the 1st MTP joint.
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)	Implant (CARTIVA) may cost more than the standard 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)?	If there is widespread use of this prosthesis in the NHS, it may cost more for the treatment of 1st MTP joint arthritis.
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	None.

	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	10-20% of patients may need another procedure such as fusion of the 1st MTP joint due to ongoing symptoms in spite of having CARTIVA procedures.
15	Please list the key efficacy outcomes for this procedure/technology?	Maintaining range of movement and function in the 1st MTP joint.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	The safety has been demonstrated in previous medical trials.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Only in the way of need for revision surgery and some ongoing pain, discomfort and swelling.
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.	There are several papers published on CARTIVA in the last 5-7 years.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Previously published and as far as I am aware there are no major trials underway.

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)?	10-15 patients per year may be eligible in my practice.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	None significant.
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your	Early revision to 1st MTP fusion in 10-20% of patients as per previous publications.

	organisation or across the wider NHS?	
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Research is already published on this topic.
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: Manchester and Oxford Foot Score (MOXFQ) and EQ5D-3L Adverse outcome measures: Revision rates

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
Choose an item.	No conflicts of interest to declare		
Choose an item.			
Choose an item.			

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Print name:	**Mr Jitendra Mangwani**
Dated:	**10th September 2021**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP742 Synthetic cartilage implant insertion for first metatarsophalangeal joint osteoarthritis (hallux rigidus)**

Your information

Name:	Click here to enter text. Ms Julie Kohls
Job title:	Click here to enter text. Consultant
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Email address:	Click here to enter text. juliekg6@gmail.com
Professional organisation or society membership/affiliation:	Click here to enter text. BOFAS
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	Click here to enter text. GMC 5201452

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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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?	I have done 30-35 Cartiva implantations
	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 will now only use the procedure for patients with a large central cyst as part of their pathology as the cartiva then gives me the opportunity to fill the cyst

	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 and the 5 year results were very promising
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):	It cn be a very good option for some patients 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?	If the Cartiva would stay where it is placed during surgery, it should offer significant benefits. It can work but in some patients the cartiva either breaks or the bone underneath it subsides

Current management

5	Please describe the current standard of care that is used in the NHS.	I mostly have reverted to offering Cheilectomies or fusions and reserve the Cartiva for patients with a large cyst and strong bone

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?	Not that I would use but there are surgeons who use silastic implant

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?	If the problems with the cartiva can be understood and corrected it will be a very good operation for patients with arthritis who want to maintain movement
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Yes
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 A cartiva is much cheaper than a fusion with a plate and the recovery is quicker
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 is only less expensive if patients do not need a fusion at a later date ie within the first few years
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 less expensive than a plate for a fusion but more expensive than a cheilectomy. However there are patients out there who have had a cartiva and who are in pain but who don't want a fusion. This number of patients is not insignificant -
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	We need to understand why the cartiva works for some but not all patients perhaps there is an optimum implant depth. Certainly many surgoens talk about measuring boen density

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	There are patient facebook groups against cartiva or supporting other patients in pain
15	Please list the key efficacy outcomes for this procedure/technology?	Range of motion, pain levels, level of function
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Patient weight, activity level, bone quality perhaps leading to subsidence
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.

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.	I have been more influenced by the number of patients seeking 2nd opinions from me about their cartiva – they are female. I have had three of my own Cartiva's go on to fusion that I am aware of. I also have another 4 patients who regularly come to see me in clinic but who don't want to progress to a fusion
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	I kept my own records as best as I could

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)?	I do a lot of first ray surgery but I have only done cheilectomies and first MTPJ fusions in the past 2 years
22	Are there any issues with the usability or practical aspects of the procedure/technology?	It was quite straightforward I thought
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?	Not for this

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	They measured the Cartiva against a fusion and found it to be superior. It should be measured against a chilectomy
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:

Further comments

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

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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.Julie Kohls**
Dated:	**Click here to enter text.10 Sept 2021**