NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1925 Minimally invasive deformity correction system for the treatment of adolescent idiopathic scoliosis

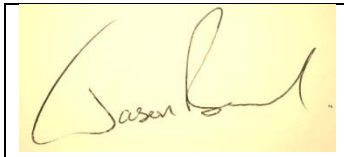
Your information

Name:	Jason Bernard
Job title:	Consultant Orthopaedic Spinal Surgeon
Organisation:	St George's Hospital, London
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Scoliosis Research Society, British Scoliosis Society, British Association of Spinal Surgeons
Nominated/ratified by (if applicable):	SRS 72362
Registration number (e.g. GMC, NMC, HCPC)	GMC 3475669

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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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



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?	As part of paediatric scoliosis management, non fusion spinal correction techniques are valuable especially for the juvenile patient who may have substantial growth remaining, but also for those patients and families whose primary goal is to avoid fusion surgery. I routinely treat these patients. I have used “traditional growth rods” and Magec rods. I have implanted one Apifix system at the patient’s and family’s considered request. I have used Vertebral Body Tethering and have published a success rate over 90% with this technique.
	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.	Exact data would be available from HES, but I estimate that 50 to 100 growth rod and non-fusion systems are implanted for scoliosis each year in England. It is recognised that all growing systems have a high complication rate (such as breakage, loosening and infection) and a high reoperation rate. Any new system which has an improvement to offer on existing systems should be evaluated. These implants are purely for use in paediatric spinal deformity treatment.

2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	Regarding “Apifix”; I have had no involvement in research on this procedure. Other : I was heavily involved in 2015/16 in an attempt to open a cohort follow up study of Apifix for 10 to 20 patients at St George’s Hospital. I had Ethical approval and Research office approval but the funding offer was withdrawn when the manufacturer was procured by a new owner and management team. The study was unable to find alternative funding and therefore never began recruitment.
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 concept of a lengthening rod attached to the spine by screws or hooks to control scoliosis is a well established one. The Apifix offers a novel self lengthening ratchet mechanism, and a polyaxial bearing system to allow some movement of the spine. This reduces the mechanical loading of the screws and the ratchet mechanism to theoretically reduce breakage. It also allows some ongoing movement to the joints of the spine which will theoretically reduce the occurrence of “spontaneous” fusion after more rigid systems. Published data support the safety and efficacy of the Apifix system. 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?	It may replace existing growing rod systems, both traditional and magnetically driven. The manufacturer intends that its main use however should be as an internal brace to control moderate scoliosis in the adolescent growth spurt. This would potentially be suitable for 10 to 20% of all adolescent scoliosis patients and for them would aim to replace, or be available instead of traditional fusion methods.

Current management

5	Please describe the current standard of care that is used in the NHS.	Current care is to provide an orthotic brace for moderate curves of the spine during growth until such time that the brace no longer controls the progression of the curve. At that point, if there is substantial expected growth, then a growth friendly non fusion system is preferred. If the patient is of a reasonable height already and near the end of growth then a fusion is preferred. It should be stated that other than VBT and Apifix – which are not supported by the NHS at present- growth “friendly” systems (traditional and magnet driven growth rods) are intended to have a second operation to revise the fixation to a fusion device (and therefore have a 100% revision rate), as well as a 50% unexpected revision rate during use.
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?	VBT has a similar intent and works by restricting curve growth anteriorly on the convex side by compression with a “tethering” cable. The Apifix works by applying a distracting force to the spine posteriorly and on the concave side of the curve.

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?	1. Avoid fusion 2. Avoid repeat surgeries and visits for rod lengthening 3. Enjoy continuous lengthening rather than sporadic 4. Reduce revision surgeries and revision surgery to fusion
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Adolescents with moderate scoliosis who are in the growth spurt. Typically aged 8 to 14 years.
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 as outlined in Q7.
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 procedure has similar hospital costs and time requirements as growth rod insertion. 2 hours of theatre time and one night hospital stay is sufficient. If implant cost is similar to Magec for example and no visits are required for lengthening and there are reduced visits for breakage related revision then this represents a saving. In addition, if even 50% were successful in avoiding fusion, then the savings from avoiding a 4 hour revision with ITU stay and fusion implant expense would be considerable. This should be subject to a formal economic model. Current data would suggest a much higher success rate, perhaps 80% allowing for breakage and infection.
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)?	Economic modelling will reveal the “break even” point based upon initial cost and revision rate. As existing systems have around a 150% revision rate, and a high initial cost, then I expect that substantial savings could be made with even a modest success rate in avoiding final fusion.

12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No change. In fact it reduces HDU/ITU use.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Training is minimal for any experienced spinal deformity surgeon.

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	As distinct from existing growing rod systems there are no additional harms. The known complications include: 1. Infection 2. Breakage 3. Loosening 4. Revision 5. Proximal kyphosis 6. Potential for final fusion 7. Spinal cord injury
15	Please list the key efficacy outcomes for this procedure/technology?	Infection rate, unplanned revision for breakage or loosening, rate of revision to fusion at skeletal maturity.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	None in addition to existing systems.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No

18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	A minority of hospitals, but at least 10 in the UK.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	FDA Executive Summary Prepared for the Spring 2021, Meeting of the FDA's Pediatric Advisory Committee H170001 Minimally Invasive Deformity Correction (MID-C) System https://www.fda.gov/media/147901/download Surgical management of moderate adolescent idiopathic scoliosis with a fusionless posterior dynamic deformity correction device: interim results with bridging 5–6 disc levels at 2 or more years of follow-up Yizhar Floman MD1, Ron El-Hawary MD, MS2, Michael A. Millgram MD1, Baron S. Lonner MD3, and Randal R. Betz MD4 Publication Date:10 Jan 2020 Page Range:748–754 Volume 32: Issue 5 DOI link https://doi.org/10.3171/2019.11.SPINE19827 High Failure Rates of a Unilateral Posterior Peri-Apical Distraction Device (ApiFix) for Fusionless Treatment of Adolescent Idiopathic Scoliosis Stadhouder, Agnita MD1,a; Holewijn, Roderick M. MD, PhD2; Haanstra, Tsjitske M. PhD3; van Royen, Barend J. MD, PhD1; Kruyt, Moyo C. MD, PhD4; de Kleuver, Marinus MD, PhD5 The Journal of Bone and Joint Surgery: October 6, 2021 - Volume 103 - Issue 19 - p 1834-1843 doi: 10.2106/JBJS.20.02176

		Multicenter Study Spine Deform. 2021 Jan;9(1):149-153. doi: 10.1007/s43390-020-00189-z. Epub 2020 Aug 21. Vertebral growth modulation by posterior dynamic deformity correction device in skeletally immature patients with moderate adolescent idiopathic scoliosis Yizhar Floman 1 , Ron El-Hawary 2 , Baron S Lonner 3 , Randal R Betz 4 , Uri Arni
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Yizhar Floman 1 , Ron El-Hawary 2 , Baron S Lonner 3 , Randal R Betz 4 , Uri Arni

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)?	50 to 100 per year is my estimate.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	The procedure is less complex than existing techniques.
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?	Uncertainty regarding the eventual revision rate in general use outside of a study. In other words this may be no better and no worse than existing devices in general use. Audit of outcomes by registry would be recommended.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Audit by registry will provide the necessary data.
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe:	Beneficial outcome measures: 1. Unplanned revision rate. 2. Success rate in avoiding final fusion. 3 final curve magnitude and

	- 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:	4 patient functional outcomes Adverse outcome measures: Infection rate Breakage rate Revision to fusion rate.
26	Is there any other data (published or otherwise) that you would like to share with the committee?	no

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	Simple operative technique. Undemanding follow up in clinic. Good patient tolerance.

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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
Indirect	I am paid for educational services by several implant companies including Globus, Stryker and Zimmer/Zimvie.		
Indirect	I am the recipient of an educational grant from "Wimbledon Clinics" for attending the Scoliosis Research Society annual meeting 2022.		
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:	**Jason Bernard**
Dated:	**1 Nov 2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1925 Minimally invasive deformity correction system for the treatment of adolescent idiopathic scoliosis**

Your information

Name:	Julian Leong
Job title:	Consultant Spinal Surgeon
Organisation:	Royal National Orthopaedic Hospital
Email address:	[redacted]
Professional organisation or society membership/affiliation:	GMC
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	4743958

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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?	Yes
	Have you used it or are you currently using it?	No
	− Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?	Rarely used in the NHS
	− Is this procedure/technology performed/used by clinicians in specialities other than your own?	I don't believe so
	− If your specialty is involved in patient selection or referral to another specialty for this	I have not referred anyone for this procedure

	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):	Completely novel 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?	Could replace growth rod or fusion

Current management

5	Please describe the current standard of care that is used in the NHS.	Spinal fusion or Spinal growing rods

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?	Growing rods – Magnetically driven or Manually distracted Vertebral body tethering – anterior non-fusion surgery of the spine

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?	Preserve spinal motion and avoid fusion
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Flexible scoliosis in skeletally immature patients
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 fewer hospital visits or less invasive treatment, remain flexible
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)	Depends how much they charge for the implant, and the revision rate.
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)?	As above
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Same as spinal fusion or growing rod insertions

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	Metallosis Metalwork failure Revision Under or Over correction
15	Please list the key efficacy outcomes for this procedure/technology?	Avoiding fusion or further operation
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	As 14
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	As 14
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Fewer than 10 specialist centres in the UK.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	
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)?	5-10% of scoliosis operations
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Should require similar skills as spinal fusion
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?	As 14

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Amount of Metallosis
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: SRS-22r Radiographic outcomes Pain score (until skeletal maturity) Adverse outcome measures: Metallosis, Complications, reoperation, pain, metalwork failure
26	Is there any other data (published or otherwise) that you would like to share with the committee?	

Further comments

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

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Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Indirect	Depuy Synthes paying into hospital research fund	**10/2022**	**Ongoing**
Indirect	Globus paying into hospital research fund	**10/2022**	**Ongoing**
Indirect	**Globus funding research project (REFLECT Trial)**	**6/2020**	**Ongoing**
Indirect	**Biedermann funding PhD student**	**10/2019**	**10/2022**

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

Print name:	**Julian Leong**
Dated:	**27th October 2022**