NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1192/2 Leadless cardiac pacemaker implantation for bradyarrhythmias**

Your information

Name:	Archana RAo
Job title:	Consultant Cardiologist
Organisation:	Liverpool Heart and Chest Hospital
Email address:	[redacted]
Professional organisation or society membership/affiliation:	BHRS/ EHRA
Nominated/ratified by (if applicable):	N/A
Registration number (e.g. GMC, NMC, HCPC)	4781875

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

☐ Please tick this box if you would like to receive information about other NICE topics.

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with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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

yes

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

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 am familiar with the technology and an early adopter of leadless pacing in the UK having done my first case in 2015. I use is regularly (perhaps on a weekly basis) on patient who are eligible and deemed to benefit from it including those who have undergone lead extraction procedures. No I do not believe this is done by clinicians in other specialities. I frequently receive referrals from renal physicians with patients on dialysis to be offered this trechnology.

	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 but have recruited into registries for this procedure and have published case reports on the novel uses of this procedure.
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. Does this have a multi-indication? 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):	yes I think with a dual chamber device, it is more nuanced than that and often folks may adopt a modular approach with implanting one and adding another if needed in the future. A minor variation on an existing procedure, which is unlikely to alter the procedure's 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 is likely to be used as an addition to existing standard care

5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	No substantial changes to procedure technique although alternative routes are being explored (Jugular) and data on this is being gathered. Evidence base continues to expand on the safety and efficacy of the procedure.

Current management

6	Please describe the current standard of care that is used in the NHS.	Transvenous single and dual chamber pacing
7	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 in the bradycardia platform

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	Mitigation of the long-term impact of leads with in the vasculature. In the short-term device related complications and in the medium to long term risks of infection and subsequent lead extraction
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patient deemed at higher risk of CIED infection. Young patients (consequences of transvenous leads in the medium and long term) Patients with issues with vascular access
10	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?	Remains unclear at this stage
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	The experience and training of the operators is really important as is careful patient selection re: patient characteristics as well as mode of pacing. Experience with large bore sheaths and vascular access is key for safe delivery.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	As above

Safety and efficacy of the procedure/technology

13	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:	Expense .the short term cost is significant when compared to an equivalent transvenous system. Adverse events include vascular access complications, embolization of the device and lack of availability on medium to long term for extraction of device

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Duray GZ, Ritter P, El-Chami M, et al. Micra Long-term performance of a transcatheter pacing system: 12-Month results from the Micra Transcatheter Pacing Study. *Heart Rhythm* (2017), doi: 10.1016/j.hrthm.2017.01.035. Cantillon DJ, Exner DV, Badie N, et al. Complications and Health Care Costs Associated with Transvenous Cardiac Pacemaker in a Nationwide Assessment, *JACC: Clinical Electrophysiology* (2017), DOI: 10.1016/j.jacep.2017.05.007 Boersma et al. Position paper. Europace (2022) 24, 1691–1708
14	Please list the key efficacy outcomes for this procedure/technology?	Success of procedure. Pacing parameters 30 day/ 12 month re intervention Pacing performance and battery longevity
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	As above
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	
17	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

18	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.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Pan Surveillance Registry (PSR run by Medtronic)
20	Please list any other data (published and/or unpublished) that you would like to share.	

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 % of the total pacemaker population
22	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	Beneficial outcome measures: Cost per QALY Annual complication rates

	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:	Adverse outcome measures: Already discussed

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	None

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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 receive honoraria for teaching and training (not on leadless) but other aspects of CIED from BSci/ Abbott/ Medtronic	**Ongoing since 2018**	
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:	**Archie Rao**
Dated:	**19/02/2025**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1192/2 Leadless cardiac pacemaker implantation for bradyarrhythmias**

Your information

Name:	Iain Matthews
Job title:	Consultant Cardiologist
Organisation:	Northumbria Healthcare NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Member of the British Heart Rhythm Society
Nominated/ratified by (if applicable):	Dr Honey Thomas of the British Heart Rhythm Society
Registration number (e.g. GMC, NMC, HCPC)	GMC 6073504

How NICE will use this information:

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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.

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 am familiar with the principles of the technology and understand the rationale for using it but have no practical experience of using it.

	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	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. Does this have a multi-indication? 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 title adequately reflects the procedure. There is no multi-indication option. This is a novel approach/design compared to current pacing systems that require leads. 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?	It will be used as an addition to standard care.

5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	Not to knowledge.

Current management

6	Please describe the current standard of care that is used in the NHS.	Current standard of care is a pacing system that use leads that run within an upper limb vein (cephalic or axillary/subclavian) to the heart and attach to a pulse generator that sits subcutaneously in the infraclavicular region.
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	No similar/competing technology

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	This novel technology has a reduced risk of infection and vascular access complications
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Those at high risk of infection or vascular access complications.
10	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?	This technology could lead to improved outcomes in appropriately selected patients.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	None
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	The delivery kit for the technology is novel and new operator will require proctoring/mentoring.

Safety and efficacy of the procedure/technology

13	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:	Vascular trauma Cardiac tamponade Damage to tricuspid valvular apparatus Death

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	
14	Please list the key efficacy outcomes for this procedure/technology?	Medium to long term pacing parameters Battery longevity Ease of extraction (if required)
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Safety of implantation in the hands of new operators
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Not to my knowledge
17	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

18	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	Nil specific

	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.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Uncertain
20	Please list any other data (published and/or unpublished) that you would like to share.	

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 all PPM implants in the UK
22	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: Survival at 30 days post implant Survival at 12 months post implant Need for early re-intervention i.e. device not at ERI Adverse outcome measures: Procedural death and bleeding/vascular trauma requiring intervention

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	

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

Print name:	**Iain Matthews**
Dated:	**03/03/2025**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1192/2 Leadless cardiac pacemaker implantation for bradyarrhythmias

Your information

Name:	Riyaz Somani
Job title:	Consultant Cardiologist & Electrophysiologist
Organisation:	Glenfield Hospital, University Hospitals of Leicester.
Email address:	[redacted]
Professional organisation or society membership/affiliation:	FESC, FRCP, FACC
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	4518107

How NICE will use this information:

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X☐ Please tick this box if you would like to receive information about other NICE topics.

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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.

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 implanting leadless pacemakers since 2016 and have implanted over 100 devices since then. I have received training in the implantation of Medtronic's Micra device and implanted their first Micra AV device in the UK in 2020. I have also received training in the implantation of Abbott's Aveir device. I have recently received training in implanting leadless devices via the jugular (neck) vein. Over the course of the last 12 years, the implantation numbers have steadily increased throughout the UK. I think there has been an appropriate cautious uptake but with time and experience the technology has emerged as a very useful treatment option for some patients with bradyarrhythmias and a vital option for device implanters. Cardiologists are appropriately best positioned to assess patients for suitability of leadless device implantation. With the limited number of centres and implanters currently offering leadless devices in the UK, it is common practice for patients to be referred to tertiary centres (such as Glenfield Hospital) for consideration of these devices. Patients are usually discussed in a MDT setting before discussing the option with patients as part of a shared-decision making process. Based on the evidence base (which has expanded significantly over the last few years) patients in whom a leadless device is often favoured include:

	procedure/technology, please indicate your experience with it.	Patients with previous cardiac device infection Patients on haemodialysis. Young patients with low levels of pacing expected. Immunocompromised patients. Patients receiving thoracic radiotherapy. Patients with certain types of congenital heart disease. Patient in whom upper limb/chest venous anatomy would preclude the use of a conventional device.
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research.
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. Does this have a multi-indication? How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?	I think the title is appropriate. The indication is for the treatment of bradyarrhythmia. Twelve years ago, when the technology was first introduced, the technology was seen as revolutionary and a complete change in the way device therapy for bradyarrhythmia could be offered. Twelve years on, the technology and implantation technique remains transformative and continues to evolve with different manufacturers bringing to production their variations (in device and implantation tecniques) with a continued appropriate cautious uptake within the NHS. Nonetheless, with the wealth of experience gained in the UK/NHS, with increasing publication and registry data now available, the level of confidence with these devices, in terms of safety and efficacy has significantly increased.

	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?	In its current state of evolution, leadless pacemakers remain an adjunct to conventional pacemakers and have not reached 'prime-time' status as the default implantation strategy. Leadless pacemakers are currently unable to offer conduction system pacing and only the Abbott's Aveir device is currently able to allow both atrial and ventricular pacing. This will likely change in time.
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	Since the publication of the previous NICE guidance, Medtronic have launched an 'AV' option in addition to their 'VR' option. This is designed to 'sense' atrial activity and consequently pace the RV in a synchronised fashion. There are limitations in the 'synchronisation' which is limited to heart rates below 110bpm and does allow for atrial pacing. Furthermore, Medtronic have launched their second generation with improved battery longevity and greater automaticity in AV synchrony. There has also been an increasing number of implants reported via the jugular vein, which may provide a more direct route to the septum and reported data thus far suggests a potentially safe option for implantation. Abbott have also launched their Aveir system, initially a single RV device and more recently an additional RA device which can communicate with the RV device to allow true DDD functionality. There is also a suggestion that these devices may be extractable at the time of battery depletion, although data on this is limited. Boston Scientific have also launched their EMPOWER modular pacing system which may work in concert with their EMBLEM subcut ICD, thereby providing both tachy and brady therapies with leadless technology. I have not had exposure to this system. Given the number of years since the last NICE publication, there is a wealth of publications (national and international) relating to leadless pacemakers. These comprise of randomised and non-randomised patient related studies, registry data and case reports. From my personal experience and from the evidence base that has been published, I believe there is a clear and

		vital role for leadless pacemakers to be available to the appropriate patient group and should no longer be looked upon as a research related option.

Current management

6	Please describe the current standard of care that is used in the NHS.	There is likely underutilisation of this technology within the NHS. That's certainy my perception. At present, leadless devices are offered in a select number of hospitals in the UK, The majority of these are tertiary centres with cardiothoracic back-up available, although a small number of secondary care centres without cardiothoracic services are emerging as implanting centres with a clear 'SOP' in place to ensure the safe and standardised transfer of patients in the event of complications. Training in implantation of leadless pacemakers remains prescriptive with the manufacturers strictly controlling the number of implanters and ensuring that they are all exposed to a structured training program with the deployment of proctors for the first few implants for all new implanters. This is likely to have helped with the safe role out of the technology and the relatively few complications seen in published data. Patient selection continues to involve MDT discussions and a joint decision making process with the patient. Follow-up can be offered remotely to minimise patient inconvenience.

7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	No. The competing technology is conventional pacing with pacing leads. These remain the mainstay for the majority of patients. They allow for conduction system pacing and the ability to upgrade devices to CRT (if LV function subsequently develops) which may be more challenging with leadless devices.

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	Published data suggests leadless technology to be safe and effective in the right patient group. The procedure itself is as quick an=s conventional device implantation and usually very well tolerated under local anaesthetic and light sedation. Early mobilisation and safe same day discharges are increasing being seen with the use of this technology. The availability of remote follow-up is also beneficial.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with previous cardiac device infection Patients on haemodialysis or with ESRF. Young patients (below 40) with low levels of pacing expected. Immunocompromised patients. Patints receiving immunosuppessants/steroids. Patients receiving thoracic radiotherapy. Patients with certain types of congenital heart disease. Patient in whom upper limb/chest venous anatomy would preclude the use of a conventional device. Patients with AF and bradyarrhythmia.
10	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 availability of this technology within the NHS is vital. There remains a cohort of patients with pacing requirements where a conventional pacemaker would either not be an option or would be a sub-optimal option. Broadening the use of this technology through national guidance has the potential to ensure more patients are considered for this technology. There is strong evidence that this technology is likely to be beneficial in patients with previous device infection, indwelling catheters and in those that are immunocompromised, with lower rates of infection likely. Having appropriate guidance and pathways in place is likely to lead to improved longer-term outcomes and the need for fewer future procedures.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	As above, appropriate training provided by the manufacturers, proctoring of ne implanters and ensuring the number of implants per operator remains at a level to ensure competence is maintained, is important. Centres delivering this could be broadened and not simply limited to cardio-thoracic centres is viable as long as strong governance and ‘SOPS’ are in place.

12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	As above with on-going longer term data collection both locally (audit) and nationally (registry) to ensure safety and efficacy remains optimum.

Safety and efficacy of the procedure/technology

13	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	Groin complications (haematoma/bleeding/false aneurysm) with published data confirming a marked reduction if using ultrasound guidance (1.2%) to gain access compared with an anatomic approach (3.2%). Cardiac perforation requiring surgical intervention (0.1%). Infection – significantly lower (<1%) compared to conventional pacing (7-12%). Device migration – 1 in 700 cases.
14	Please list the key efficacy outcomes for this procedure/technology?	Percentage of patients with an appropriate pacing capture threshold (eg < 2.0 V) at implantation with nominal pulse width. Stable pacing parameters persisting at follow-up visit. Electrical performance (sensing, impedence) during longer-term follow-up.
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Having implanted these for several years (and having a good understanding of the literature), I have no concerns about these devices. In the appropriate patient cohort, with appropriately trained implanters and clear pathways in place, the availability of this technology isvital and can be delivered safely and effectively.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Management of devices at time of battery depletion. The suggestion is that certainly for the Micra devices, these are unlikely to be possible to remove. The manufacturers suggest implanting a new device or switching over to a conventional device at the time of battery depletion remain viable options.

		Abbott's Aveir device has been reported to be extractable even several years post-implant. Data on this is limited but if this is the case then would help minimise the amount of 'hardware' left insitu.
17	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

18	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	1. Paul Roberts, Mohamed Hassan ElRefai, Paul Foley, Archana Rao, David Sharman, Riyaz Somani, Simon Sporton, Gary Wright, Amir Zaidi, Chris Pepper, **UK Expert Consensus Statement for the Optimal Use and Clinical Utility of Leadless Pacing Systems on Behalf of the British Heart Rhythm Society**, Arrhythmia & Electrophysiology Review 2022;11:e19. 2. El-Chami MF, Bonner M, Holbrook R, et al. Leadless pacemakers reduce risk of device-related infection: review of the potential mechanisms. Heart Rhythm 2020;17:1393–7. Crossref| PubMed 3. Steinwender C, Lercher P, Schukro C, et al. State of the art: leadless ventricular pacing: a national expert consensus of the Austrian Society of Cardiology. J Interv Card Electrophysiol 2020;57:27–37. Crossref| PubMed 4. El-Chami MF, Al-Samadi F, Clementy N, et al. Updated performance of the Micra transcatheter pacemaker in the real-world setting: a comparison to the investigational study and a transvenous historical control. Heart Rhythm 2018;15:1800–7. Crossref| PubMed 5. Chintz L, Ritter P, Khelae SK, et al. Accelerometer-based atrioventricular synchronous pacing with a ventricular leadless pacemaker: results from the Micra atrioventricular feasibility studies. Heart Rhythm 2018;15:1363–71. Crossref| PubMed 6. El-Chami MF, Clementy N, Garweg C, et al. Leadless pacemaker implantation in haemodialysis patients: experience with the Micra transcatheter pacemaker. JACC Clin Electrophysiol 2019;5:162–70. Crossref| PubMed 7. El-Chami MF, Johanse JB, Zaidi A, et al. Leadless pacemaker implants in patients with pre-existing infections: results from the Mircra postapproval registry. J Cardiovasc

		Electrophysiol 2019;30:569–74. Crossref| PubMed 8. Roberts PR, Pepper C, Rinaldi CA, et al. The use of a single chamber leadless pacemaker for the treatment of cardioinhibitory vasovagal syncope. Int J Cardiol Heart Vasc 2019;23:100349. Crossref| PubMed 9. Turagam MK, Gopinathannair R, Park PH, et al. Safety and efficacy of leadless pacemaker for cardioinhibitory vasovagal syncope. Heart Rhythm 2020;17:1575–81. Crossref| PubMed 10. Glikson M, Nielsen JC, Kronborg MB, et al. 2021 ESC guidelines on cardiac pacing and cardiac resynchronization therapy. Eur Heart J 2021;42:3427–520. Crossref| PubMed 11. Kempa M, Mitkowski P, Kowalski O, et al. Expert opinion of a Working Group on Leadless Pacing appointed by the National Consultant in Cardiology and the Board of the Heart Rhythm Section of the Polish Cardiac Society. Kardiol Pol 2021;79:604–8. Crossref| PubMed 12. Triantafyllou K, Karkos CD, Fragakis N, et al. Ultrasound-guided versus anatomic landmark-guided vascular access in cardiac electrophysiology procedures: a systemic review and meta-analysis. Indian Pacing Electrophysiol J 2022;22:145–53. Crossref| PubMed
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	As above.
20	Please list any other data (published and/or unpublished) that you would like to share.	I have recently submitted a manuscript relating to 'Expert opinion on safe same day discharge following leadless pacemaker implantation'. Awaiting response. There is emerging data on safe jugular approach for leadless pacemaker implantation.

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)?	The number of leadless devices implanted increases year-to-year, but the overall number of implants in the UK remains relatively low (415). Whilst leadless devices remain an option for a niche group of patients, there is little doubt that there is under-utilisation, particularly when comparing to other health care systems. This may partly be driven by previous National guidance, Whilst it is difficult to be sure what percentage of implantations should be considered and ultimately receive a leadless device, I would expect the annual number to be in the

		thousands (not hundreds). Removing the requirement for research from the guidance and having a broader list of indications based on the evidence (above) would ensure increased uptake, which ultimately would lead to improved outcomes.
22	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:** Procedure time. Fluoroscopy time. Time to discharge post-implant. Quality of life using prescribed questionnaire. **Adverse outcome measures:** Infection rates. Complication rates. Need for re-intervention. Need for cardiac surgery. Mortality. Deterioration in pacing parameters. Need for upgrade of pacing system. (1 month, 6 months, 12 months).

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	

NICE National Institute for Health and Care Excellence

Declarations of interests

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

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Non-financial professional	I have worked with Medtronic in compiling a group of experts to help gauge opinion and to author a manuscript in relation to same day discharges post leadless pacemaker implantation.	**2023**	**On-going**
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:	**Riyaz Somani**
Dated:	**02/03/2025**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1192/2 Leadless cardiac pacemaker implantation for bradyarrhythmia's**

Your information

Name:	Aldo Rinaldi
Job title:	Cardiologist, Electrophysiology Lead
Organisation:	Guy's &St Thomas' hospitals
Email address:	[redacted]
Professional organisation or society membership/affiliation:	British Cardiac Society, BHRS
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	3497830

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

X☐ Please tick this box if you would like to receive information about other NICE topics.

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 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.

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.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	YES, use the technology regularly in my clinical practice
	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	Yes Recent NICOR data suggested a low implant rate of approx 300 procedures Uptake may increase with newer technologies 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. yes I have done research on this procedure in laboratory settings (e.g. device-related research). yes I have done clinical research on this procedure involving patients or healthy volunteers. yes I have published this research. yes Other (please comment)
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. 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):	Yes yes Established practice and no longer new. The first in a new class of procedure.
4	Does this procedure/technology have the potential to replace current standard care or	Addition

	would it be used as an addition to existing standard care?	
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	Yes Dual chamber technology has been introduced and is now in use for patients requiring dual chamber pacing Yes-large amount of data on implants No RCT

Current management

6	Please describe the current standard of care that is used in the NHS.	LCP for patients who cannot receive standard transvenous pacing
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	no

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	Allows pacing in patients who cannot receive standard transvenous pacing
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Device infection, limited vascular access, congenital heart disease, renal failure
10	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
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Currently being used in nhs
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes-training as per company recommendations

Safety and efficacy of the procedure/technology

13	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:	Tamponade/perforation <1% Device embolization <1%

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	
14	Please list the key efficacy outcomes for this procedure/technology?	Implant safety, long tem efficacy and battery longevity
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	End of life device management-abandonment vs extraction
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	End of life device management-abandonment vs extraction
17	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

18	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.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	
20	Please list any other data (published and/or unpublished) that you would like to share.	

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 10% of pacemaker patients
22	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: efficacy, battery longevity Adverse outcome measures: implant complications

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	

NICE National Institute for Health and Care Excellence

Declarations of interests

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

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Non-financial professional	Research funding from Abbott and Medtronic		
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:	**Aldo Rinaldi**
Dated:	**15/4/2024**

View results

Respondent

69 Anonymous

48:41
Time to complete

1. Project Number and Name - (Can be found on email) *

Leadless cardiac pacemaker implantation for bradyarrhythmias (IP1192/2)

Your information

2. Name: *

Andrew Turley

3. Job title: *

Consultant cardiologist with specialist interest in cardiac implantable electronic devices

4. Organisation: *

British cardiovascular society, South Tees NHS foundation trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

British cardiovascular society

7. Nominated/ratified by (if applicable):

British cardiovascular society clinical standards committee

8. Registration number (e.g. GMC, NMC, HCPC) *

4523099

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, as communicated by the coordinator/administrator.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

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 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: https://www.nice.org.uk/privacy-notice

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

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

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

Consultant since 2010, immediate past chair Northeast cardiovascular network cardiac rhythm management group. Experience implanting pacemakers, ICD, CRT, EBR, subcutaneous ICD (Performed over 3500 device implant). Our unit implants leadless devices (Medtronic, Abbott) both single chamber and dual chamber. I do not personally implant leadless brady devices but have over seen the implementation and governance.

12. 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.

South Tees NHS foundation trust is the only acute trust in the Northeast cardiovascular network currently implanting leadless devices. We have been implanting leadless device for approximately 5 years in highly selected patients where transvenous systems are not feasible. We have taken external referrals from within the cardiac network footprint. Regional guidance on indications has been developed. Our unit is a large cancer unit and renal dialysis unit. I have referred patients for leadless pacing

13. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [x] 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.
- [x] I have visited company research and development labs to review the technology

14. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

yes

16. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

Leadless pacemakers almost certainly will become the standard of care in the future. At present the single biggest limiting step is the cost of the device which is approximately 10 times more than a transvenous lead system. Evidence shows that leadless devices have lower infection rates than devices with leads. Device extraction of transvenous systems is highly complex with significant morbidity and at times mortality. This is the single biggest positive feature of leadless systems. Training programmes for registrars would need to be altered as implant techniques are different to conventional transvenous systems. Technology for dual chamber functionality remains in its infancy and is not yet ready for wide-spread clinical use in my opinion. Approximately 50% of single lead pacemakers in the US are now leadless devices and I imagine UK practice will follow this in the next 5-10 years or so

17. Which of the following best describes the procedure:

- ( ) 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.

18. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

Please see above. In my opinion the future of pacing for bradycardia indications will become heavily reliant on leadless devices. This is likely to happen over the next 5-10 years. At present the technology is used in regional centres only but there is no reason why this should not be rolled out to all hospital's providing bradycardia treatment in the future once cost implications can be addressed. At present there will still need to be a role for transvenous systems such as cardiac resynchronisation therapy pacing systems.

19. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

The 1st generation leadless pacemakers were a VVIR system. They would work as a single-chamber system designed for implant in the ventricle only. Medtronic have a single chamber system that does provide a degree of AV synchrony by a software and technology upgrade. The device however still has some issues on its ability to track the atrium and in my opinion is not as reliable as a dual chamber lead ed transvenous system. Abbott have a dual chamber dual device system with a leadless device designed for the atrium as well as the ventricle. The use of this system in the UK market is very limited although we have used this system at South Tees NHS foundation trust. Again the technology has some teething issues regarding software. Other leadless device is unlikely to come to market in the near future (next 1-2 years) from other manufacturer's.

20. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

Yes. Since the initial guidance was introduced on leadless devices we now have significant post marketing real world experience of leadless devices from both Europe and America which has shown both their safety in terms of implant procedure as well as their long term complication rates which have been consistently shown to be lower than transvenous systems in relation to infection which is the most serious long term complication. What we do not have at present is long term data on the ability to extract these devices. Short-term data is available. Thought does need to be given to patients selection and what happens at the time of generator replacement. since the initial guidance was released we also now have the option of a dual chamber system which was not previously available.

21. Do you think the guidance needs updating?

Yes the old guidelines as significantly out of date and do not reflect the current evidence base

Current management

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

The current standard of care within the UK is a transvenous/leaded system. This has been the standard of care for decades. It is a reliable and effective way at treating bradycardia. The cost implications of this system are minimal. The problem of any transvenous system is the long term problems of transvenous leads and the subsequent risk of infection

23. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

No. All device manufacturers are developing lea less pacemakers for the treatment of bradycardia. Within the UK the current commercially available systems are via Medtronic and Abbott. The initial device released by Abbott was removed from the market due to significant safety concerns and has been significantly redesigned. The EBR leadless system allows left ventricular pacing via a leadless device this is currently awaiting formal approval via the FDA and currently only available within UK markets as part of research or registry studies and must have a coexisting device implant to work and cannot be used as this stand-alone unit

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

Reduced infection risk. No need for venous access which is a significant benefit in patients such as renal dialysis patients Also patients requiring radiotherapy to the chest area. Transvenous leads have a life expectancy of 10-15 years. Pacing young patients under the age of 50 years of age leads to potential issues in the future due to lead management which leadless devices may avoid

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Leadless pacing - Reasons to consider.
Previous device infection or endocarditis
Vascular access issues e.g. prior (BUT NOT ACTIVE) radiotherapy/blocked subclavian/multiple leads in SVC.
Planned radiotherapy where device may cause issues.
Dialysis patient (infection risk and access issues)
Congenital CHB / young patient age (avoid potential lead-related long term issues)
High infection risk (e.g. PADIT>6 / immunosuppression, ESRF)
Other erosion risk (e.g. low BMI, tissue coverage, mental health + palpable device risk)
Severe TR +/- PHT where sheath can help with implant.
Desire to avoid pacing leads across TV.
Commitment to potent anti-thrombotics (e.g. Starr Edwards or DAPT for recent PCI)
Urgent 'pace and ablate' indication with follow-on AVN via access sheath.

26. 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. Cardiac implantable electronic device infections are both costly in terms of financial cost for management as well as significant cost in terms of bed days and also the cost of morbidity and mortality to the patient (a wealth of literature exists on this). Appropriate use of leadless devices in appropriately selected patients will have a positive outcome. Device extraction is incredibly costly.

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

The procedure needs to be undertaken in a cardiac catheterisation laboratory. These facilities already exist for transvenous bradycardia device implants. The team, both cardiologists and physiologists who implant these devices need to be appropriately trained as the devices are typically implanted via the femoral route. There is some literature suggesting jugular access may be feasible. Both of these access routes are different to normal transvenous pacing access sites. There is a learning curve as there is in any new procedure.

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

Yes see above. The device is typically implanted via the femoral route. Involves a large bore catheter. The procedure has much more in common with electrophysiology procedures e.g. EP studies and ablation than it does with transvenous lead implants. The majority of device implanters in the UK will not be trained in EP procedures. there is also implications in training registrars i.e. the future work force.

Safety and efficacy of the procedure/technology

29. 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

Conflicting data exists
EP Europace, Volume 25, Issue 9, September 2023, euad269, https://doi.org/10.1093/europace/euad269:
This study looked at implants between 2016 and 2019 in the US. Complications were higher in the leadless pacemaker group in US population, this included pericardial complications, device thrombus, thromboembolic complications and vascular complications.

Other studies estimate for micra leadless pacemaker implantation complications such as vascular perforations and tears resulting in cardiac tamponade to be low with an incidence of less than 1%. It does comment that rescue surgery should be on hand to repair perforations. This would limit the rollout to all district hospitals.(Heart Rhythm 2021;18:1132–1139)

EP Europace, Volume 25, Issue 1, January 2023, Pages 112–120, https://doi.org/10.1093/europace/euac112
A review from Italy in a multicentre study shown complication rates from leadless pacemakers to be low. And overall lower than transvenous pacemakers. Specifically, the risk of late complications is significantly lower in leadless devices.

PMID: 38869811 DOI: 10.1007/s11886-024-02079-6
A 2024 meta analysis on the effectiveness and safety of leadless pacemakers included 21 studies involving over 47,000 patients suggesting that leadless pacing is associated with lower overall complication rates and similar effectiveness to transvenous pacemakers but the study does recommend that further randomised controlled trials are warranted to validate the results. Complications included dislodgement, pneumothorax, mortality, pericardial effusion, cardiac tamponade, pacing thresholds and pacing impedance

30. Please list the key efficacy outcomes for this procedure/technology?

Reduced infection risk, no risk of pneumothorax,

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

long-term uncertainties about the ability to extract devices that have been implanted for 10+ years. Management of patients at generator change. Dual chamber functionality remains uncertain at present. uncertainty about the ability to implant at a district general hospital given the risk of cardiac perforation

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

as above

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ○ 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

34. 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.

    Unaware other than via pub med. Both EHRA and heart rhythm society meetings due in the next 2-3 months where there are likely to be abstracts presented on leadless devices

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

    All companies have ongoing registries. Data from these registries are not readily available at present. There are 33 trials listed on clinical trials.Gov looking at leadless pacemaker implantation. some are regulatory studies ie IDE studies from America. Others are multicentre.
    https://clinicaltrials.gov/search?cond=leadless%20pacemakers

36. Please list any other data (published and/or unpublished) that you would like to share.

    Nil

Other considerations

37. 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)?

    As stated previously up to 50% of the VVIR market in America get a leadless device accepting that this is driven by insurance. Within the UK estimates for demand on current indications would be less than 10% (current restrictions on leadless device is may be too restrictive)

38. 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.

    Acute procedural complications. Long term efficacy of the device in terms of pacing thresholds and measurements. Time to generator change. Infection risk both short-term within 1 year, and long term greater than 1 year.

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Adverse outcome measures.

    These should include early and late complications. Please state the post procedure timescales over which these should be measured:

    as per clinical trials.
    Acute Vascular injury. Device embolisation. Suboptimal device measurements (impedance, threshold, sensing) pericardial effusion, cardiac tamponade requiring intervention, need for cardiothoracic surgical intervention, death, clinically significant thromboembolic events
    chronic issues > 30 days vascular injury AV malformations. Device embolisation late. Suboptimal device measurements (impedance threshold sensing) thromboembolic complications. Tricuspid regurgitation due to device interference with valve apparatus

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

nil

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.

41. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [x] Indirect
- [ ] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

I am also a trustee for the patient charity arrhythmia alliance. I do not view this as a direct conflict.

43. 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. *

- (•) I agree
- ( ) I disagree

Signature

44. Name: *

Andrew Turley

45. Date: *

03/02/2025

View results

Respondent

73 Anonymous

99:26
Time to complete

1. Project Number and Name - (Can be found on email) *

Leadless cardiac pacemaker implantation for bradyarrhythmias (IP1192/2)

Your information

2. Name: *

Dr Chris Pepper

3. Job title: *

Consultant Cardiologist

4. Organisation: *

Leeds Teaching Hospitals NHS Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

FRCP, Member: British Cardiac Society, Member: British Heart Rhythm Society

7. Nominated/ratified by (if applicable):

N/A

8. Registration number (e.g. GMC, NMC, HCPC) *

GMC 3309922

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, as communicated by the coordinator/administrator.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

(●) I agree

( ) I do not agree

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

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 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: https://www.nice.org.uk/privacy-notice

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

(●) I agree

( ) I disagree

The procedure/technology

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

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

Yes
I have experience of implanting and following up the Medtronic Micra device since market release in 2015.
I was local PI for the BSCI MODUAR ATP study of their EMPOWER device and have been implanting the Abbott Aveir device since 2024
I have provided training for Cardiologists in the implantation of the Micra device and and am part of the Medtronic educational faculty.
I have spoken at national and international professional meetings around the use of leadless pacemakers

12. 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 currently use both e the Medtronic Micra and Abbott Aveir devices.
I have some knowledge of the national and international use of leadless pacing devices such as is in the public domain.
The technology is not used in other fields other than my own.
Please see the above with regard to my experience.

13. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [x] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [x] I have done clinical research on this procedure involving patients or healthy volunteers.
- [x] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

14. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

Yes largely (Intracardiac echocardiography is not required and rarely if ever used it he UK, however X-ray contrast is required)

16. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

It is an entirely novel means of delivering permanent cardiac pacing compared to previously existing technology (although leadless pacing technology has now been around for approaching 15 years, is internationally established and covered by international clinical expert guidelines, and as such is arguably no longer novel)

17. Which of the following best describes the procedure:

- (●) 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.

18. 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 will add to and complement the existing standard of care

19. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

The answer to this depends on your comparison. There are two separate devices currently clinically available. They have important differences in the device technology and implant technique. In my view these differences are sufficient that they should be addressed separately.
The Medtronic Micra is essentially unchanged from its original launch other than some battery improvements and software developments.
The Abbott Aveir is a development of the previously withdrawn Nanostim device and has undergone several improvements from that device, including new battery technology and a redesigned retrieval button, plus development of a bespoke retrieval system.

20. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

No. It has however been strengthened. There is progressively increasing data based on clinical experience to support the initial data that preceded their launch. No new concerns have arisen.

21. Do you think the guidance needs updating?

Yes without question. Current guidance is outdated, out of line with international established practice and is restricting patient access to important technology.

Current management

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

Established standard of care is the trans-venous pacemaker consisting of a subcutaneously placed generator connected to the heart via 3 pacemaker wires passing through the venous system. Most of the acute and long term complications of pacing relate to the need to implant these wires and their long term presence within the vasculature.

23. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

If so, how do these differ from the procedure/technology described in the briefing?

No

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

Most acute and long term complications of trans-venous pacing relate to the need to connect a device placed in the subcutaneous environment to the blood pool and endocardium. These include complications of implantation such as pneumothorax, and longer term issues such as pacing lead conductor or insulation fracture, or device infection. In addition some patients are unable to receive a conventional device due to occlusion or absence of central veins.
Long term data supports the concept that the leadless technology reduces the risk of implant related complications, reduces the risk of long term infection and provides an option for patients unable to receive a conventional device or who are at increased risk of complications from it.
In addition, patients benefit psychologically from the absence of a palpable device or implant scar. This is particularly marked in those who have previously experienced complications from a trans-venous device.

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

A BHRS endorsed Consensus Document describes this well. (Roberts...Pepper Arrhythm Electrophysiol Rev. 2022 Apr;11:e19. doi: 10.15420/aer.2022.17)
They include:
- those lacking central venous access
- those at increased of infection including:
- those who have previously experienced device infection
(those on haemodialysis
those on immunosuppressive drugs
those at high risk of wound or device pocket infection)
- those who are at high risk of implant related complications from a transvenous device

26. 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?

In terms of eligibility for a pacemaker, the leadless technology is identical and does not change the patient pathway up to the point of implantation.
For those receiving a device, in appropriately selected patients the devices can reduce the risk of future device complication such as infection or the need for lead extraction due to lead failure (a highly costly and resource intensive procedure: see published literature, eg Gould...Rinaldi Heart 2020 https://doi.org/10.1136/heartjnl-2019-315839). This should reduce the future healthcare burden imposed by and and experienced by these individuals
The implant procedure is different from a transvenous device and requires a different operative set up and operator skillset.

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

These devices can be implanted in any existing cardiac catheter laboratory. Established pathways to emergency cardiac surgical support require to be in place but in my view these do not need to be in the same institution.

28. 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

29. 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

These are well described in the existing literature. (e.g.: Mikhael F El-Chami, Lindsay Bockstedt, Colleen Longacre, Lucas Higuera, Kurt Stromberg, George Crossley, Robert C Kowal, Jonathan P Piccini
European Heart Journal, Volume 43, Issue 12, 21 March 2022, Pages 1207–1215, https://doi.org/10.1093/eurheartj/ehab767)

The key ones specific to leadless pacing include:
Cardiac injury and perforation potentially requiring emergency cardiac surgery: approx 0.5%
Vascular injury: 0.5-1%
Device dislodgement: very rare
Device infection: very rare

These compare favourably to historical comparative and prospective registry data for transvenous implants.

(In addition there are risks that are similar for both leadless and transvenous technologies, including pacing induced cardiomyopathy, pacemaker syndrome, device failure)

30. Please list the key efficacy outcomes for this procedure/technology?

- Safety of the implant procedure
- Short, medium and long term electrical performance
- Short, medium and long term freedom from complications
- Clinical outcome data at least comparable to transvenous devices, including mortality, heart failure, freedom from re-intervention, freedom from heart failure
- Comparable cost-efficacy when used in clinical identical circumstances to transvenous devices

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

For Micra VR concerns are now minimal to none
For Aveir VR: medium to long term follow up data is lacking
For Micra AV: what is the clinical impact of the atrial sensing and how does it compare in terms of quality of life and other outcomes to conventional dual chamber pacing?
For Aveir AR: What is the acute implant safety in a real world setting after full market release?
For Aveir DR: Long term data is lacking on maintenance of dual chamber pacing, impact on device battery longevity and consequent cost efficacy compared to Micra AV

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

See above (31). It is important (a) that these devices are regarded as separate and different rather than lumping togetheras 'leadless technology' There are meaningful difference in terms of the nature of the different technologies and (b) that it is recogised these devices are complementary to and not intended to replace existing transvenous technology.

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) 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

34. 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.

N/A

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

Micra PAR registry is ongoing
Abbott are setting up a registry for Aveir which is not yet fully up and running

36. Please list any other data (published and/or unpublished) that you would like to share.

N/A

Other considerations

37. 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)?

This is unanswerable as it is contingent on clinical practice and NHS organisational reimbursement criteria.
In principle any patient requiring a single chamber pacemaker could be eligible for a leadless device. In the US, where Micra is fully reimbursed, more that 50% of single chamber pacemaker implants are leadless. This is unlikely to be replicated in the UK due to training requirements and absence of financial incentivisation.
About a quarter of the 40,000 pacemaker implants in the UK are single chamber, theoretically suggesting up to 10,000 potential implants per year. In practice only a small minority of these will be leadless in the absence of a major change in practice. Leadless pacemaker recipients will remain a small minority of pacemaker patients, it is however likely that there will (and should) be a significant increase over the 400 implants performed in 22-23 (NICOR data: https://www.nicor.org.uk/interactive-reports/national-audit-of-cardiac-rhythm-management-nacrm)
The numbers receiving dual chamber devices are harder to predict but I would not anticipate major short term expansion.

38. 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.

Much of this is described in the literature and above. It should be device specific and compared to equivalent transvenous technology:

-Reintervention / device upgrade rates (1-5 years)
-Rehospitalisation rates (1-5 years)
-Patient QoL (1-6 months)
-Psychological wellbeing (1-6 months)

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

As above, this should be device specific and compared to equivalent transvenous technology:
- Implant success (acute)
- Implant complication (acute)
- Need for reintervention
- Device failure rate / need for extraction or removal

This data exists and is within the published literature

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

1. As noted above, it is important to recognise the significant differences between different device technologies. I believe these differences are sufficient that the devices need to be considered separately rather than as 'leadless pacing' as a single entity.
2. It should be recognised that leadless technology complements rather than replaces existing transvenous devices and adds significantly to the therapeutic repertoire of the pacing cardiologist.
3. Specific training is required for individuals performing leadless pacing and a requirement for this should be built in to any recommendation or guideline. It should not be assumed that a cardiologist trained in transvenous pacing or other forms of interventional cardiology can perform leadless implantation safely without specific instruction.
4. It remains important, as with all devices, to prospectively monitor outcomes and device performance across the whole lifetime of the patient.

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.

41. Type of interest: *

- [x] Direct: financial
- [x] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [ ] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

I am a member of the Medtronic training faculty for leadless pacing
I have received financial reimbursement for the provision of training in the use of the Medtronic Micra device. I deliver training courses and have proctored consultant colleagues in their early implant experience and have received professional fees for this activity.
I have received financial reimbursement for attending advisory boards in the development of training for leadless pacemaker implantation.
I have received travel expenses and support from Abbott and BSCI to attend training in the implantation of the Aveir and EMPOWER devices respectively.
I have provided lectures at national and international meetings on the place of leadless pacing in modern cardiology practice, but have not received financial reimbursement for this.
I am a believer in the value of leadless pacemakers and use them in my day to day clinical practice in accordance with existing NICE guidelines!

43. 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. *

- (•) I agree
- ( ) I disagree

Signature

44. Name: *

Dr Chris Pepper

45. Date: *

02/03/2025

View results

Respondent

72 Anonymous

53:25
Time to complete

1. Project Number and Name - (Can be found on email) *

Interventional Procedures Programme Invitation to act as a professional expert Leadless cardiac pacemaker implantation for bradyarrhythmias (IP1192/2)

Your information

2. Name: *

David Sharman

3. Job title: *

Consultant Cardiologist

4. Organisation: *

Northampton General Hospital NHS trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

GMC

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

4524966

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, as communicated by the coordinator/administrator.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

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 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: https://www.nice.org.uk/privacy-notice

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

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

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

Yes - we have implanted 200 leafless Micra Pacemakers to date over the past 7 years, and I have proctored and trained other centres and Consultant implanters. We are publishing a complete data set of non surgical leadless pacemaker insertion.

12. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

I am very familiar with Leadless uptake in the UK and the barriers. This technology is only used by Cardiology.

13. 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).
- [x] 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.
- [x] Complete dataset registry now trying to publish as a non surgical centre experience.

14. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

Yes but additionally should be considered for use with SICD for ATP therapy given Empower entering the market.

16. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

This is a very different and novel technology compared to standard transvenous pacemaker systems. It is however now established and accelerating on a worldwide basis with over 250,000 implants.

17. Which of the following best describes the procedure:

- (•) 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.

18. 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 the potential to replace some current standard of care for bradycardia pacing as evidenced by Japan use now circa 30%, however will not replace the majority of standard transvenous pacemaker implants given the battery longevity and lack of atrial pacing with Micra, and new Aveir atrial leadless unit that is in trials.

19. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

For micra, the jugular approach is increasingly being adopted as a vascular approach. Aveir has now RV and RA units and Empower is to enter the market for independent use or with the SICD.

20. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

Yes. The ongoing audit data attests to safety and longevity plus battery utilisation has been optimised with Micra to extend its longevity. Non surgical centre implantation is proven to be safe (happy to submit our data directly while waiting for publication).

21. Do you think the guidance needs updating?

Yes

Current management

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

Most hospitals the current standard of care is a transvenous system and if an old one is failing, further lead implantation thus increasing the surface area of intravascular foreign material and complications.

23. 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 three on the market now:
Micra (VR2 and AV2)
Empower
Aveir (RV and RA)
The first two are a similar platform and implantation whereas Aveir is designed to be removable with a helix fixation and limited to RV apical placement, increasing perforation risk.

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

Reduced infection risk for those with high risk or prosthetic intracranial material or in extraction of infected pacing systems
Recused Vascular damage
Pacemaker implant in compromised vascular access (eg stenosis/ occlusion)
For those patients at risk of wound compromise (psychiatric)

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Infected extracted pacing systems
High infection risk (dialysis/ ulcers/ immunosuppressants etc)
Prosthetic intracranial material (eg valves)
Undergoing radiotherapy
Psychiatric indications
Occluded or compromised venous access
Potential young patients with malignant vasovagal syndrome as destination therapy
Middle age patients to reduce vascular complications and preserve access
Those requiring an other operative procedure requiring heavy arm use for rehab (eg hip fracture)

26. 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. Reduced complications by 53%.

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

Can be done safely in a non surgical centre with the correct protocols - we are happy to share our non surgical data while waiting publication. Links to a surgical centre for transfer. Yes

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

Yes - online course and in person training with Sim plus proctoring in place already for Micra implantation.

Safety and efficacy of the procedure/technology

29. 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

Upgrade to transvenous system
Displacement during implantation - recapture required
Cardiac perforation. Micra is 0.4% currently form the literature.
Rapid battery depletion due to high output requirement due to exit block.
These are all evidenced and I have anecdotal personal experience

30. Please list the key efficacy outcomes for this procedure/technology?

Safety
Infection and lead complications reduction
Re-Intervention
System longevity

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

Longevity in high pacing burden
Battery longevity with Aveir RA and RV units combined
Battery longevity Empower with SICD
Number of devices possible to implant in RV (max 3 Micra) in lifetime
Potential for SSS or RA pacing need if only RV pacing unit

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

Discussed above

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- (●) 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

34. 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.

We are now trying to publish our complete series for Micra implant in a non surgical centre over the past 7 years. This data can be shared directly while waiting publication.

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

Currently in progress: Aveir and Empower systems are in trials.

36. Please list any other data (published and/or unpublished) that you would like to share.

Northampton hospital non surgical centre data for leadless implant

Other considerations

37. 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)?

NGH has a population of 450,000 and we implant roughly 30 a year maximally. This could increase to double potentially.

38. 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.

QOL questionnaire - short and medium term
Reduced infection
Reduced vascular complications (medium- long term)
Reduced lead and pacemaker pocket complications

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Immediate:
Dislodgement
Cardiac perforation
Death
Vascular complications
Failure to implant

Medium:
Pacemaker syndrome

Late:
Reintervention
System upgrade
Infection

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

There is a distinction between Micra/ Empower and Aveir: they are different fixation systems and Aveir is designed to be extracted. They should potentially be distinguished between.

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.

41. Type of interest: *

- [x] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [ ] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

I have a talk on Micra leadless pacing - funded by Medtronic at the ESC in London 31.8.2024

43. 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. *

- (●) I agree
- ( ) I disagree

Signature

44. Name: *

David Sharman

45. Date: *

28/02/2025

View results

Respondent

71 Anonymous

22:47
Time to complete

1. Project Number and Name - (Can be found on email) *

IP1192/2

Your information

2. Name: *

Manav Sohal

3. Job title: *

Consultant Cardiologist and Electrophysiologist

4. Organisation: *

St. George's University Hospitals NHS Foundation Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

GMC

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

6053147

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, as communicated by the coordinator/administrator.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

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 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: https://www.nice.org.uk/privacy-notice

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

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

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

I am familiar with the technology and regularly implant both commercially available leadless pacing systems.

12. 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 routinely implant these devices and they are solely implanted by cardiologists. The use of the technology is limited at present (to centres with cardiac surgical support).

13. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [x] 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

14. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

Yes

16. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

Highly innovative. Pacing leads are the weak link in any pacing system and it does seem that leadless pacing will become the standard during my working lifetime.

17. Which of the following best describes the procedure:

- (•) 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.

18. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

Currently it is an addition but I suspect it will become the standard in the next 10-20 years.

19. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

20. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

Yes

21. Do you think the guidance needs updating?

Yes

Current management

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

Transvenous pacemakers. Leadless pacing is currently used when vascular access from the subclavian veins is not possible and for other select indications.

23. 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 two types of leadless pacing device.

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

Less risk of infection. Best option for patients with occluded subclavian vessels.

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Renal patients on dialysis. Patients with occluded subclavian vessels. Patients at high risk of device infection.

26. 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 can certainly lead to less pacing related morbidity in a select group of patients.

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

The technology can only be delivered in sites with cardiac surgery on site.

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

Yes. This is all administered by the vendors of each commercially available device.

Safety and efficacy of the procedure/technology

29. 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

Vascular access complications (1-2%)
Cardiac tamponade (<1%)

30. Please list the key efficacy outcomes for this procedure/technology?

They pace well.

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

Quality of AV synchrony

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

No

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) 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

34. 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.

    Everything is in the public domain and will be found in a literature search.

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

36. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

37. 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 am not sure.

38. 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.

    Stability of pacing parameters over time
    Robustness of AV synchrony

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Adverse outcome measures.

    These should include early and late complications. Please state the post procedure timescales over which these should be measured:

    Access site complications (early)
    Tamponade (early)
    Device migration (early or late)
    Infection (late)
    Device failure (late)

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

No

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.

41. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

N/A

43. 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. *

- (•) I agree
- ( ) I disagree

Signature

44. Name: *

Manav Sohal

45. Date: *

17/02/2025

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1192/2 Leadless cardiac pacemaker implantation for bradyarrhythmias**

Your information

Name:	Matthew Geoffrey David BATES
Job title:	Consultant Cardiologist / Electrophysiologist
Organisation:	South Tees Hospitals NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Fellow of the Royal College of Physicians of Edinburgh; Member of the British Medical Association (BMA); Member of the Medical and Dental Defence Union of Scotland (MDDUS); Member of the British Heart Rhythm Society; Member of the European Society of Cardiology / European Heart Rhythm Association; Member of the Heart Rhythm Society
Nominated/ratified by (if applicable):	BCS Committee (Neil Swanson)
Registration number (e.g. GMC, NMC, HCPC)	6048706

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

☒ Please tick this box if you would like to receive information about other NICE topics.

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 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.

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?	**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?** Yes, I am very familiar with leadless pacemakers for bradyarrhythmia. Following compliance with all required training (including both simulators and laboratory experience), proctoring, local new technology / clinical procedures governance structures and national registry participation, I have been implanting Medtronic Micra leadless pacemakers in selected, clinically-indicated patient populations since 2017. All patients were appropriately entered in the contemporary Medtronic PRS registry and I have published our work in a variety of formats including a regional case series combined with atrio-ventricular node (AVN) ablation and nationally with UK colleagues in the context of specific patient indications. As first (and now solo) operator, I have implanted > 100 Medtronic Micra leadless devices with full data compliance nationally (NICOR) and regionally. Since mid-2024, with worldwide approvals for Abbott Aveir leadless pacemakers, we have again complied with all required training (including both simulators and laboratory experience), proctoring, local new technology / clinical procedures governance structures and national registry participation. I have now undertaken 20 implants as either first or second operator to maximise institutional experience of this new technology. Our centre was the first in the UK centre (and potentially worldwide) to implant the recently launched dual chamber Aveir leadless pacemaker with follow-on AVN ablation.

	− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	**Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?** Yes, leadless pacemaker implantation is widely used across the UK in 2025 – the Medtronic Micra system dominates the national experience as these devices have been implanted in UK for > 10 years. There has been relatively brisk growth in the number of leadless pacemakers implanted per year in the UK according to NICOR data but the overall number of implants still remains small (e.g. 49 de novo implants in 2015-16 versus 318 in 2022-23 from **annual figures)**. These number remains particularly small in comparison to conventional leaded pacemaker for bradyarrhythmia for which there are ~ 2500 de novo implants **per month** in the UK and numbers have been relatively status for many years **Is this procedure/technology performed/used by clinicians in specialities other than your own?** In the UK (and in contrast to other parts of the world), Cardiologists are responsible for transvenous pacemaker implantation. In the UK, while microbiologists, cardiac surgeons, renal physicians, cardiac physiologists and intensivists etc may be closely involved in the management of patients who have a strong indication for consideration of leadless pacemaker implantation for bradyarrhythmia, the procedure of leadless pacemaker implantation will be exclusively performed by cardiologists. **If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.** N/A
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 previously trained in this procedure in laboratory setting **YES** I have done clinical research on this procedure involving patients or healthy volunteers.**YES** I have published this research **YES** Roberts PR, Pepper C, Rinaldi CA, **Bates MGD**, Thornley A, Somani R, Abozguia K, Harris S, Rao A, Pedersen M, McComb JM, Shepherd E, Moore P, Segal OR, Schilling RJ, Zaidi A. The use of a single chamber leadless pacemaker for the treatment of cardioinhibitory vasovagal

		syncope. Int J Cardiol Heart Vasc 2019; 23: 100349. doi: 10.1016/j.ijcha.2019.100349. eCollection 2019 Jun.PMID: 30976654 Other (please comment)
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. Does this have a multi-indication? 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):	**Does the title adequately reflect the procedure?** Yes, although bradyarrhythmia (singular) could be used **Is the proposed indication appropriate? If not, please explain.** Yes, although bradyarrhythmia (singular could be used) **Does this have a multi-indication?** No, although the Boston Scientific Empower leadless pacemaker has primarily been designed to function in a modular Cardiac Rhythm Management (CRM) system when paired with a subcutaneous Implantable Cardioverter Defibrillator (ICD) to enable delivery of anti-tachycardia pacing (ATP) in patients with a subcutaneous ICD who would not otherwise be able to benefit from this form of therapy for ventricular tachyarrhythmia (VA). **How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?** Subjectively, I would suggest that leadless pacemaker technology for bradyarrhythmia is genuinely innovative with some disruptive potential. Whilst the intrinsic concept of pacemaker implantation for bradyarrhythmia (in terms of indications, risks / benefits, patient populations etc) is clearly many decades old, leadless pacemakers have been commercially available and approved in the UK for only ~10 years and de novo implantation numbers have increased by a factor of 6 over that period albeit absolute numbers remain very small. Leadless pacemaker implantation via the femoral vein using dedicated delivery catheters is certainly a “novel approach/concept/design” when compared to conventional trans-venous leaded pacemaker implantation. Industry representatives suggest that in certain non-UK territories, up to 70% of single chamber (VVIR) pacemaker for bradyarrhythmia are now leadless

		Which of the following best describes the procedure (please choose one): **X 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. I'd argue that leadless pacemaker implantation has been performed in the UK for > 10 years so cannot claim to be "new". With > 300 de novo implants in 2022-23, it may be regarded as an "established practice" - the Medtronic Micra was certainly the "first in a new class of procedure" several years ago and the procedure is "definitely novel" albeit the global data to support safety and efficacy does exist so this statement cannot be chose.
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 reported by industrial partners that in fee-paying / insurance-based healthcare systems (e.g. territories in the United States of America) and for certain indications (e.g. VVIR single chamber pacemaker implantation for symptomatic bradyarrhythmia in atrial fibrillation), leadless pacemakers now outnumber de novo leaded devices. Currently in the UK, leadless pacemakers are implanted largely in specific patient populations with an indication for a pacemaker for bradyarrhythmia (e.g. limited vascular access, at higher risk of infection / erosion, post-device extraction etc) but it is clearly possible that "softer" indications (including patient preference) may play a role in the future expansion of leadless pacemaker implantation. For the majority of patients with an indication for pacing for bradyarrhythmia, leaded device may arguably remain "standard of care" for the foreseeable future but it is also perhaps inevitable that the longer term future of in particularly single chamber pacemaker implantation will be leadless.
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?	**Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?** Yes, since the prior IPG626 (leadless cardiac pacemaker implantation for bradyarrhythmias) for IP1192 (2018) there have been iterative developments associated with the Medtronic Micra system (e.g. approval for the Micra AV device with an effective VDD pacing ability for a single

	Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	chamber pacemaker then development of the Micra VR2 and AV2 devices with updated software) and more recent approvals of both the Abbott Aveir and the Boston Scientific Empower. The Abbott Aveir system has potential for a leadless dual chamber pacing system (DDDR) with dedicated right atrial and right ventricular implants whereas the Boston Scientific system has focussed on the modular CRM approach to enable a right ventricular leadless pacemaker to deliver anti-tachycardia pacing (ATP) in patients implanted with a subcutaneous ICD too. The Abbott delivery system has also been subject to minor modifications enabling repeated use of the same delivery catheter for right trail and right ventricular implants. **Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?** Yes, worldwide 'real-world' data regarding safety and efficacy of the Medtronic Micra trans-catheter pacing system (TPS) has expanded significantly in volume and, as stated above, two other manufacturers have published safety and efficacy data to support their successful applications for implantation approvals.

Current management

6	Please describe the current standard of care that is used in the NHS.	Leaded pacemaker implantation (for those patients able to undergo conventional transvenous pacemaker implantation). Leadless pacemaker implantation is arguably already 'standard of care' for patients **unable** to undergo conventional transvenous pacemaker implantation (e.g. patients with a bradyarrhythmia pacing indication and SVC occlusion or unilateral axillary occlusion and contra-lateral AV fistula for intermittent haemodialysis etc)

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

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	Lower risk of all complications associated with leaded pacing systems (e.g. vein thrombosis, cardiac implantable electronic device-related infection, lead fracture, lead displacement etc); lower risk of all complications / issues associated with pocket formation for pacing generator placement (e.g. CIED-related infection, unsatisfactory cosmetic appearance, interactions with clothing / lifestyle); ease of combination of the procedure with concomitant AV node ablation (due to lower risk of displacement and similar access route); avoidance of potential impact of leaded systems on tricuspid valve function; avoidance of potential impact of conventional generator on external beam radiotherapy delivery.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Yes, patient specific patient groups that might benefit from consideration of a leadless pacemaker for symptomatic bradyarrhythmia include: patients with previous device infection or endocarditis; patients with vascular access issues e.g. prior radiotherapy / blocked subclavian(s) / multiple leads in superior vena cava (SVC); planned radiotherapy where device generator may cause issues; haemodialysis patients (infection risk and access issues); congenital complete heart block / young patient age (i.e. to avoid potential lead-related long-term issues); patent at high infection risk (e.g. PADIT>6 / immunosuppression, ESRF); patient with other erosion risk (e.g. low BMI, poor tissue coverage at shoulder, mental health issues with palpable device generator risk); severe tricuspid regurgitation +/- pulmonary hypertension where steerable delivery catheter may assist with implant and desire to avoid pacing leads across tricuspid valve; pacing indication in patient with fixed commitment to potent anti-thrombotics (e.g. Starr Edwards or dual anti-platelet therapy for recent MI/PCI to avoid pocket bleeding risk); urgent ‘pace and ablate’ indication with follow-on AVN via leadless catheter delivery sheath.
10	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, if reduced long-term risk of CIED-related infection, other lead- and pocket-related complications and a reduced need for re-attendance for elective AV node ablation translate to predicted reduced heart care usage then there may be improved outcomes, fewer hospitals visits and less invasive treatments. Leadless pacemakers for bradyarrhythmia are generally replaced with an additional device rather than ‘box change’ on battery depletion so reduced re-instrumentation of a pocket will result in reduced CIED-related infection too. These predicted health economic benefits would need to be balanced against known and predicated device longevity and relevant safety and efficacy data clearly.

11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	None, a conventional catheter laboratory (with all allied health professional staff) and Cardiac Rhythm Management (CRM) consultant cardiologist operator are still required for leadless pacemaker implantation. Currently (due to the use of steerable delivery sheaths and femoral venous access) many UK leadless pacemaker implanters are Consultant Electrophysiologists (EP) rather than Consultant Cardiologists with an interest in Devices but both groups do implant leadless pacemakers and there are training programmes / transposable skills.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, all currently approved leadless pacemaker companies in the UK provide bespoke training in their technology to all relevant NHS staff including the use of various combinations of simulators, animal models and proctorship.

Safety and efficacy of the procedure/technology

13	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	Hauser RG et al state in their 5-year outcomes study that the Major Adverse Cardiac Events (MACE) for Medtronic Micra and associated 30-day event rates include **Thrombosis 0.11%** • Deep vein thrombosis 0.06% • Pulmonary embolism 0.06% **Events at groin puncture site 0.55%** • Arteriovenous fistula 0.17% • Incision site haemorrhage 0.11% • Lymphatic fistula 0.06% • Vascular pseudoaneurysm 0.11% • Vessel puncture site haematoma 0.11% **Cardiac effusion/perforation 0.44%** • Cardiac perforation 0.06% • Cardiac tamponade 0.33% • Pericardial effusion 0.06% **Pacing issues 0.88%** • Device capturing issue/elevated thresholds 0.72% • Device dislocation without embolization 0.11%

		• Device embolization during implant 0.06% • Undersensing 0.06% **Cardiac rhythm disorder 0.06%** • Cardiac arrest 0.06% • Extrasystoles 0.0% • Ventricular dyssynchrony 0/0% **Infection 0.22%** • Abdominal wall infection 0.06% • Catheter site infection 0.06% • Device-related infection 0.0% • Haematoma infection 0.06% • Sepsis 0.06% 5-year cumulative incidences in the Hauser RG et al study are similarly low. These do however remain estimates based on original 1809 patient implantation cohort. The true incidence of MACE for Medtronic Micra is not known but can be estimated. Following the original trans-catheter pacing system (TPS) post-approval registry, Medtronic did not specifically included Micra implantation data as a separate category in its product survey reports (PSR). El-Chami MF et al (2024) estimated that 70,000–75,000 Micra pacemakers were implanted worldwide in 2020. As 126 MACE occurred in 2020, the estimated Micra MACE incidence for that year was 0.2%. Even if MACE were underreported by a factor of 5, the estimated incidence would still be <1%. The Abbott Aveir data is also published including from the original n=1225 patient cohort for Aveir VR with similarly low MACE 30-day rates including: • Cardiac effusion / perforation 0.4% • Device dislodgment 0.4% • Infection 0.2% • Device malfunction 1.2% El-Chami MF et al. Leadless pacemakers at 5-year follow-up: the Micra transcatheter pacing system post-approval registry. Eur Heart J 2024; 45: 1241–1251.

		Hauser RG et al. Major adverse clinical events associated with implantation of a leadless intracardiac pacemaker. Heart Rhythm 2021; 18: 1132-1139.doi: 10.1016/j.hrthm.2021.03.015. Epub 2021 Mar 11. Knops R et al. One year safety and performance outcomes from a clinical study of a dual-chamber leadless pacemaker system. Heart Rhythm. 2024;21:1199-1200 https://doi.org/10.1016/j.hrthm.2024.04.026
14	Please list the key efficacy outcomes for this procedure/technology?	Consistent sensing / pacing parameters (e.g. sensitivity / threshold) Prevention of symptomatic bradyarrhythmia Device longevity
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Real-world device longevity Real-world extraction data for current generation devices Real-world consequences of multiple right ventricular devices
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Differential cost over conventional leaded pacemakers for bradyarrhythmia Relative cost-effectiveness analysis in at risk and general patient populations given costs
17	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. **X A minority of hospitals, but at least 10 in the UK** Fewer than 10 specialist centres in the UK. Cannot predict at present. Pacemaker implantation for bradyarrhythmia is not currently undertaken in “the majority of district general hospitals” in the UK such that it is not likely that leadless pacemaker implantation will even reach this level (even if all pacemakers for bradyarrhythmia were leadless in the future).

Abstracts and ongoing studies

18	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.	All major publication for the Medtronic Micra, Abbott Aveir and Boston Scientific Empower will be detected in a formal NICE literature review so I have highlighted only some recent (i.e. 2023 / 2024) abstracts: Ip J, Brady P, et al. Leadless vs. Transvenous Single-Chamber Ventricular Pacemakers: Real-World Evidence from AVEIR™ VR Coverage with Evidence Development Study. Poster presented at: HRS 2024; May 17, 2024, Boston, MA. Reddy V, et al. How Safe is Aveir? Data Summary from Aveir DR IDE and VR Real-World Evidence Studies. Abstract Presented at: HRS 2024; May 18, 2024, Boston, MA. Knops R. Tachycardia Therapy and Trial Endpoint Results of the First Modular, Intra-body, Communicating Subcutaneous Defibrillator-Leadless Pacemaker System: MODULAR ATP Interim Cohort. Heart Rhythm Society Late Breaking Clinical Trials. May 18th, 2024 LB-469805-03 Leong D DH, Mondesert BA et al. Effects of Implantable Cardioverter-Defibrillator Leads on the Tricuspid Valve and Right Ventricle: A Randomized Comparison of Transvenous versus Subcutaneous Leads. Heart Rhythm Society Late Breaking Clinical Trials. May 19th 2023;LB-456090-02 Mont L. et al. Pacing Performance of the First Leadless Pacemaker Communicating with an S-ICD from the full cohort of the MODULAR ATP study. European Society of Cardiology Late Breaking Clinical Trials and Science, September 2, 2024. Schuger C, Joung, B., Ando, KI, et al. Assessment of Primary Prevention Patients Receiving An ICD- Systematic Evaluation of ATP: APPRAISE ATP. Heart Rhythm Society Late Breaking Clinical Trials. May 17th, 2024 LB-469803-02
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Abbott Aveir Registry (UK CI Prof Tom Wong, we are actively participating in JCUH, Middlesbrough with local PI Dr Simon James)
20	Please list any other data (published and/or unpublished) that you would like to share.	All published data will be available on formal literature review

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)?	NICOR data in 2022-23 would suggest that ~25,000 de novo pacemaker implants for bradyarrhythmia are undertake in the UK annually. In this financial year there were only 318 de novo leadless pacemaker implants but even with a conservative future prediction of 10% of de novo pacemaker implants being leadless, this could account for 2000 – 3000 procedures annually.
22	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: As above, efficacy measures (i.e. pacing parameters acute and chronic, impact on patient symptoms attributable to prior bradyarrhythmia, battery longevity and avoidance of re-intervention) Adverse outcome measures: As above, all safety parameters should be assessed over time including those (above) related to infection, need for re-intervention, thrombosis, cardiac rhythm and pacing related complications, heart failure, upgrade indication

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	Formal clinical and cost effective analysis versus conventional leaded pacemaker implantation Patient-reported outcome measures Specific patient populations e.g. post-extraction (including avoidance of externalised temporary permanent systems in those with pacing dependence post-extraction) and renal dialysis

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:	**Matthew Bates**
Dated:	**2 February 2025**