

IP1192-2 Leadless cardiac pacemaker implantation for bradyarrhythmias

IPAC date: 11/09/2025

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1.	Consultee 5 Medtronic	Lay description	We recommend that further description is added to this section, otherwise this has the potential to be misleading for the patient as it does not fully describe the complete procedure. We suggest the following edit: "The procedure is done by inserting a tube (catheter) through a large blood vessel (vein) in leg or neck, through which the leadless pacemaker is delivered into the heart chamber".	Thank you for your comment. The description has been changed.
2.	Consultee 1 Boston Scientific	1	We are supportive of the recommendations made by the NICE committee.	Thank you for your comment.
3.	Consultee 3 Individual	1 General comment	I am a consultant cardiologist running the leadless pacemaker, extraction and complex device service at Freeman hospital, Newcastle. We deliver adult and congenital cardiac care and transplant, oncology, dialysis and lead extraction services, covering a relatively isolated but broad geographic area. We often have patients with complex/long-term device needs in whom leadless pacing is a valuable treatment option. The majority of our patients being offered leadless pacing fall under the remit covered in this document so we do not feel any edits are required and	Thank you for your comment. Consultee agrees with the draft recommendations.

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			agree with the contents. We agree that dual leadless pacing is still a novel strategy with data required to confirm safety and longer term clinical effectiveness before being utilised more widely.	
4.	Consultee 6 Abbott Medical	1	General Observation It is unclear across the proposed guidance whether the term 'pacing' refers to the devices which are implanted by the procedure, or the clinical therapy provided. We request that the guidance explicitly distinguish between the different pacing indications, as these are clinically and mechanistically defined and are related as such in literature and regulatory submissions. Specifically, leadless pacing encompasses a range of single-chamber and dual-chamber use cases, and it is important that the guidance reflect these differences to support appropriate patient selection. We recommend the following delineations be made in the guidance: - (a) Single-chamber ventricular pacing VVI(R): For patients with atrioventricular (AV) block and atrial fibrillation. - (b) Single-chamber atrial pacing AAI(R): For patients with sinus node disease without AV conduction disease. - (c) Single-chamber ventricular pacing and atrial sensing VDD(R): For patients with AV block and intact sinus node	Thank you for your comment. The committee updated the draft guidance, including separate recommendations for right ventricular pacing, dual-chamber pacing and atrial pacing.

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			function. - (d) Dual-chamber pacing DDD(R): For patients with sinus node dysfunction and/or AV block. We request that the proposed guidance be updated to clearly differentiate these delineations, including the relevant evidence assessment sections. Doing so will ensure the guidance reflects the full scope of clinical applications and informs appropriate use of the leadless pacing systems.	
5.	Consultee 2 NHS England	1	2. "Single" versus "dual chamber" We welcome the approach made in the draft guidance to differentiate between single and dual chamber pacing, the latter being currently recommended only in a research setting. However, the dual chamber system consists of two separate pacemakers, and while the dual chamber functionality (i.e. communication between the two components) is recognised as new and insufficiently established to be routinely recommended, we feel that the same caution should be expressed regarding the atrial component per se. The atrial leadless pacemaker has been, and will be, implanted as a stand-alone device (i.e. single chamber) in patients with sinus node dysfunction (e.g. Von Felten, E. Europace 2025 https://doi.org/10.1093/europace/euaf085.542 and Ip,J.	Thank you for your comment. The committee updated the draft guidance, including separate recommendations for right ventricular pacing, dual-chamber pacing and atrial pacing.

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			PACE 2025 https://doi.org/10.1111/pace.15138). This has the attraction of a reasonable predicted battery life (12 years versus 6 years as part of a dual chamber system), and may prove to be an excellent option for some patients, but as yet there is very little clinical data to support single chamber atrial leadless pacing. For this reason we would suggest that the committee consider changing the wording in the recommendation from "single chamber pacing" to "right ventricular pacing" and throughout from "dual chamber pacing" to "atrial or dual chamber pacing". This might also help in avoiding any confusion relating to certain other systems, such as the investigational WiCS left ventricular pacemaker (a leadless ultrasound transducer, driven by a subcutaneous ultrasound emitter and functioning in concert with a conventional pacing system), and future devices aiming to provide leadless conduction system pacing.	

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6.	Consultee 2 NHS England	1	The comments below have been collated from feedback given by six consultant clinician members of the Device Working Group of NHS England. The proposed update to guidance on leadless cardiac pacemakers (LCPs) is welcome: since the previous guidance was issued, considerable clinical evidence has accumulated, as well as international guidelines for their use and British Heart Rhythm Society guidance. Leadless pacemakers now have an established role in the treatment of bradycardias and have been a great improvement in therapy for certain groups of patients. As ever, we are impressed with the thoroughness of the committee's work in collating the evidence base. We would raise the following points: 1. Generalisability of outcomes from one manufacturer to all. The draft recommendations relate to the use of LCPs generically. The overwhelming majority of clinical evidence regarding the acute and (especially) chronic safety and performance comes from a single family of devices (Medtronic Micra® VR, and subsequent iterations), first implanted in 2014 and market released in 2016. The St Jude (now Abbott)	Thank you for your comment. The draft guidance recommends that 'clinicians doing this procedure should collect data on safety and outcomes of the procedure. Enter details about everyone having leadless cardiac pacemaker implantation for bradyarrhythmias into the National Institute for Cardiovascular Outcomes Research (NICOR) National Audit of Cardiac Rhythm Management and regularly review the data on outcomes and safety.' The draft guidance states 'Leadless cardiac pacemaker technology is evolving. There are several devices available, not all offer dual-chamber leadless pacing.'

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			Nanostim® was withdrawn in 2016 on safety grounds: after a number of modifications to hardware, software and training a new version, the Aveir® VR (ventricular) pacemaker, was approved for market release in 2022 and the Aveir AR (the other part of the Aveir DR dual chamber system) in 2023. The Boston Scientific Empower® ventricular LCP is not yet approved. While early results from the newer devices are promising, as are their predicted battery longevities, pacemakers are almost always permanent implants so large-scale real-world results will be important as will the chronic (>5 year) performance of these devices. There are important hardware and software differences between the three families of devices. In particular, the Abbott devices use a helix (screw) for active fixation while the Medtronic and Boston devices use virtually identical tines, so the implant procedures differ in many respects.	
7.	Consultee 2 NHS England	1	Furthermore, the atrial component of the Abbott dual chamber system requires a different procedure from the ventricular devices: this is more technically challenging and (because of the thinness of many parts of the atrium), there is an increased potential for complications including dislodgement and cardiac perforation, both of which have been seen. It will therefore be important to closely monitor outcomes from implants of the atrial device as they become	Thank you for your comment. The committee updated the draft guidance, including separate recommendations for right ventricular pacing, dual-chamber pacing and atrial pacing.

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			devolved from super-specialised research centres to more general use. Thus, while we have not seen evidence of significant safety or performance shortcomings from the newer devices, we share the slight concern expressed in one of the Specialist submissions (that of [REDACTED]) that the track record of the “established” Medtronic device has been generalised to all leadless pacemakers.	
8.	Consultee 7 NHS professional	1	NICE Leadless Guidance Consultation response IPG 10340 For the attention of the NICE Committee: I have been a consultant cardiologist and electrophysiologist for over 20 years, and I’m a current clinical end user for medical devices including pacemakers to treat bradycardia. I work in a tertiary referral centre providing care across a broad range of pathologies including patients with congenital heart disease, heart transplantation, chronic renal failure and infection of conventional lead-based pacemakers that require extraction. I welcome this NICE HealthTech evaluation of leadless pacemakers - the recommendation for single chamber leadless pacemaker is comprehensive and appropriate. However, whilst I’m supportive of the committee’s proposed guidance on Single Chamber pacing, I encourage	Thank you for your comment. The committee considered additional evidence published since the original recommendations were drafted and updated the draft guidance. Section 3.9 of the draft guidance includes an updated list of people for whom the procedure may be particularly beneficial.

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			the NICE committee to re consider the proposed guidance around Dual Chamber Leadless pacing for the following reasons: Dual chamber leadless pacemakers are currently being implanted into patients in our Trust and more than 10 other tertiary NHS hospitals across the four nations of the UK. Dual Chamber Leadless pacing is being used in patients who require atrial pacing, benefit from AV synchrony and the conventional lead based permanent pacing approach is either undesirable or impossible. Relevant evidence The clinical evidence of Safety and Efficacy for leadless pacing is accumulating at a rapid pace as this technology is being used clinically in Europe, US and other parts of the world. I would like to highlight the following studies supporting the safety and Efficacy of Dual Chamber Leadless pacing for committee review as part of the consultation: <u>1. Safety and Efficacy</u> • One-Year Safety and Performance of a Dual-Chamber Leadless Pacemaker (Doshi 2025), https://www.ahajournals.org/doi/10.1161/CIRCEP.124.013619 • Dual-chamber leadless pacemaker implant procedural	

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			outcomes: Insights from the AVEIR DR i2i study (Doshi 2025), https://www.heartrhythmjournal.com/article/S1547-5271(25)02176-9/fulltext • Commercial Implant Experience of a Helix-Fixation Dual-Chamber Leadless Pacemaker (Hadadi 2025), https://onlinelibrary.wiley.com/doi/10.1111/jce.16688 • Atrial helix-fixation leadless pacemaker:real-world single-chamber implant experience (Nair 2025),https://link.springer.com/article/10.1007/s10840-025-02041-8 • First European Experience with a Leadless Atrial Pacemaker (Felten 2025), https://www.heartrhythmopen.com/article/S2666-5018(25)00161-8/fulltext Article in press • Modular Leadless Pacing: A case series of leadless pacemaker upgrades (Mouawad 2025), https://www.jacc.org/doi/10.1016/j.jacep.2024.11.006 • Chronic retrieval outcomes for an atrial leadless pacemaker (Doshi 2025), https://www.heartrhythmjournal.com/article/S1547-5271(24)03446-5/fulltext • Leadless vs. transvenous atrial pacemakers: real world evidence from Aveir AR coverage with evidence development study (Nilsson 2025), https://www.heartrhythmjournal.com/article/S1547-	

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			5271(25)01773-4/fulltext (Abstract only) • Leadless vs. transvenous single-chamber ventricular pacemakers: Real-World evidence from AVEIR VR Coverage with evidence development study (Ip JE 2024), https://www.heartrhythmjournal.com/article/S1547-5271(24)01359-6/fulltext (Abstract only) • A Dual-Chamber Leadless Pacemaker (Knops 2023), https://www.nejm.org/doi/full/10.1056/NEJMoa2300080 <u>2. Dual-chamber leadless pacemaker performance</u> • Battery longevity of a helix-fixation dual-chamber leadless pacemaker: results from the AVEIR DR i2i Study (Reddy 2025), https://academic.oup.com/europace/article/27/6/euaf074/8157530 • Six-month electrical performance of the first dual-chamber leadless pacemaker (Hindricks 2025), https://www.heartrhythmjournal.com/article/S1547-5271(24)02525-6/fulltext • Atrioventricular Synchrony Delivered by a Dual-Chamber Leadless Pacemaker System (Ip JE 2024), https://www.ahajournals.org/doi/10.1161/CIRCULATIONAH.A.124.069006 • Temperature-based rate response in a leadless pacemaker system (Rashitan 2025), https://www.heartrhythmjournal.com/article/S1547-	

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			5271(24)03615-4/fulltext <u>3. Implantation procedure</u> • Implantation techniques for a helix-fixation dual-chamber leadless pacemaker (Neuzil 2024), https://www.heartrhythmjournal.com/article/S1547-5271(24)03384-8/fulltext <u>4. Patient preference / Quality of life</u> • Patient preferences for features associated with leadless versus conventional transvenous cardiac pacemakers (Reed 2024), https://www.ahajournals.org/doi/10.1161/CIRCOUTCOMES.124.011168 <u>Interpretation of evidence</u> The clinical evidence supports the use of Dual Chamber Leadless pacing in humans. Conventional lead-based pacemakers remain the mainstream therapy in treating patients with patient bradycardia, however in patients who require a Dual Chamber pacemaker but the conventional lead-based pacing arrangement is undesirable or impossible, the technological advancements that Dual Chamber leadless pacing provides, is an excellent option. <u>Particular considerations of vulnerable patient groups</u> There are a number of vulnerable patient groups who are	

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			severely disadvantaged by not being able to access Dual Chamber Leadless technology in the UK through the NHS, including patients who have congenital heart disease, on haemodialysis or have vascular access issues which remove the option of conventional lead-based pacemakers. <u>Suitability of recommendation to the NHS</u> Currently leadless Dual Chamber pacemakers are being used clinically in the UK, Europe, the US and many other parts of the world. Given all of the above, and the extensive Clinical evidence which has become available even since NICE first began this work and data collection on Leadless pacemakers - I would support the NICE recommendation level for Dual Chamber leadless pacemaker being changed by the NICE committee to: "Can be used during the evidence generation period (previously special arrangements)".	
9.	Consultee 2 NHS England	1.1 Single-chamber pacing	Suggest: "..as an option for right ventricular pacing...."	Thank you for your comment. The committee updated the draft guidance, including separate recommendations for right ventricular pacing, dual-chamber pacing and atrial pacing.

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10.	Consultee 5 Medtronic	1 Single- chamber pacing	Title should be amended to: "Single-chamber right ventricular pacing" to align with the specific pacing location being evaluated (also see related comment on 1.1)	Thank you for your comment. The committee updated the draft guidance, including separate recommendations for right ventricular pacing, dual-chamber pacing and atrial pacing.
11.	Consultee 5 Medtronic	1.1 Single- chamber pacing	We agree with this recommendation, however, more clarity in the wording is essential to ensure that this relates to right ventricular pacing, as per the scope and evidence base of the guidance. If this is not explicitly stated, there is a risk that this could be misconstrued to include single chamber right atrial pacing, which has not been evaluated in this IPG. We therefore request that the wording of 1.1. should be amended to: "Leadless cardiac pacemaker implantation can be used as an option for single-chamber right ventricular pacing in people with bradyarrhythmias." This also aligns with the description given in 2.1.	Thank you for your comment. The committee updated the draft guidance, including separate recommendations for right ventricular pacing, dual-chamber pacing and atrial pacing.
12.	Consultee 2 NHS England	1.2, 1.3 Dual- chamber pacing	Suggest "...for people who need atrial or dual-chamber pacing..."	Thank you for your comment. The committee updated the draft guidance, including separate recommendations for right ventricular pacing, dual-chamber pacing and atrial pacing.

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13.	Consultee 5 Medtronic	1.2, 1.3Dual-chamber pacing	We agree with this recommendation, but suggest that further clarity is provided to ensure this is well-understood by all users of this guidance. Given the current variety of leadless pacemakers available and the different uses, we suggest that the following addition to the recommendation is included, to ensure absolute clarity and that the recommendation remains contemporary on publication in this rapidly evolving field: "More research is needed on leadless pacemakers for bradyarrhythmias for people who need dual-chamber pacing requiring two devices before it can be used in the NHS." This also aligns with the description in 2.4.	Thank you for your comment. The committee updated the draft guidance, including separate recommendations for right ventricular pacing, dual-chamber pacing and atrial pacing.
14.	Consultee 6 Abbott Medical	1.2, 1.3 Dual-chamber pacing	We respectfully disagree with the proposed recommendation. This description does not reflect the state of the rapidly growing clinical evidence, which is demonstrating that dual-chamber leadless pacing DDD(R) is safe, effective, and appropriate for use in well-defined patient populations. We request this section is revised to an alternative recommendation statement NICE has, which reads: "There are uncertainties around the long-term [safety and/or efficacy] of this procedure. It can be used if needed while more evidence is generated to check if it is safe and/or clinically effective. This guidance will be reviewed within [X]"	Thank you for your comment. The committee considered additional evidence published since the original recommendations were drafted and updated the draft guidance.

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			years and the recommendations may change." This better reflects the evidence situation with dual-chamber leadless pacing, as per below. <Safety and Efficacy> - One-Year Safety and Performance of a Dual-Chamber Leadless Pacemaker (Knops 2025), https://www.ahajournals.org/doi/10.1161/CIRCEP.124.013619 - Dual-chamber leadless pacemaker implant procedural outcomes: Insights from the AVEIR DR i2i study (Doshi 2025), https://www.heartrhythmjournal.com/article/S1547-5271(25)02176-9/fulltext - Commercial Implant Experience of a Helix-Fixation Dual-Chamber Leadless Pacemaker (Hadadi 2025), https://onlinelibrary.wiley.com/doi/10.1111/jce.16688 - Atrial helix-fixation leadless pacemaker:real-world single-chamber implant experience (Nair 2025), https://link.springer.com/article/10.1007/s10840-025-02041-8 - First European Experience with a Leadless Atrial Pacemaker (Felten 2025), https://www.heartrhythmopen.com/article/S2666-5018(25)00161-8/fulltext (Article in press) - Modular Leadless Pacing: A case series of leadless	

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			pacemaker upgrades (Ip JE 2025), https://www.jacc.org/doi/10.1016/j.jacep.2024.11.006 - Chronic retrieval outcomes for an atrial leadless pacemaker (Doshi 2025), https://www.heartrhythmjournal.com/article/S1547-5271(24)03446-5/fulltext - Leadless vs. transvenous atrial pacemakers: real world evidence from Aveir AR coverage with evidence development study (Nilsson 2025), https://www.heartrhythmjournal.com/article/S1547-5271(25)01773-4/fulltext (Abstract only) - Leadless vs. transvenous single-chamber ventricular pacemakers: Real-World evidence from AVEIR VR Coverage with evidence development study (Ip JE 2024), https://www.heartrhythmjournal.com/article/S1547-5271(24)01359-6/fulltext (abstract only) - A Dual-Chamber Leadless Pacemaker (Knops 2023), https://www.nejm.org/doi/full/10.1056/NEJMoa2300080 <Dual-chamber leadless pacemaker performance> - Battery longevity of a helix-fixation dual-chamber leadless pacemaker: results from the AVEIR DR i2i Study (Reddy 2025), https://academic.oup.com/europace/article/27/6/57530	

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			- Six-month electrical performance of the first dual-chamber leadless pacemaker (Hindricks 2025), https://www.heartrhythmjournal.com/article/S1547-5271(24)02525-6/fulltext - Atrioventricular Synchrony Delivered by a Dual-Chamber Leadless Pacemaker System (Ip JE 2024), https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.124.069006 - Temperature-based rate response in a leadless pacemaker system (Rashtian 2025), https://www.heartrhythmjournal.com/article/S1547-5271(24)03615-4/fulltext <Implantation procedure> - Implantation techniques for a helix-fixation dual-chamber leadless pacemaker (Neuzil 2024), https://www.heartrhythmjournal.com/article/S1547-5271(24)03384-8/fulltext <Patient preference / QoL> - Patient preferences for features associated with leadless versus conventional transvenous cardiac pacemakers (Reed 2024), https://www.ahajournals.org/doi/10.1161/CIRCOUTCOMES.124.011168	

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15.	Consultee 2 NHS England	1.2, 1.3 Dual- chamber pacing	Suggest "...for people who need atrial or dual-chamber pacing..."	Thank you for your comment. The committee updated the draft guidance, including separate recommendations for right ventricular pacing, dual-chamber pacing and atrial pacing.
16.	Consultee 4 Individual	1.3 Dual- chamber pacing	Whilst I agree with the need for further research into dual chamber leadless devices, this appears to make no provision for it's use in selected high risk cases where there is a paucity of other options? As written, this appears to have been excluded and potentially creates a clinical risk.	Thank you for your comment. The committee updated the draft guidance, including separate recommendations for right ventricular pacing, dual-chamber pacing and atrial pacing.
17.	Consultee 2 NHS England	Why the committee made these recommend ations	Suggest "For right ventricular pacing,..." and "...for atrial or dual-chamber pacing.."	Thank you for your comment. The committee updated the draft guidance, including separate recommendations for right ventricular pacing, dual-chamber pacing and atrial pacing.
18.	Consultee 6 Abbott Medical	1 and 2	In connection with our prior comment regarding the need to distinguish between pacing indications, we note that the	Thank you for your comment.

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			proposed guidance does not appear to fully account for the range of clinical indications for leadless pacemakers. Specifically, there is a disconnect between Sections 1 (1.1 and 1.2), which provide simplified overview of the procedure, and Sections 2 (2.1 and 2.2), where the discussion appears to focus predominantly on VVI(R) pacing for AV block and does not explicitly reference other clinically validated pacing modes. Notably, single chamber atrial pacing AAI(R) for sinus node dysfunction and ventricular pacing with atrial sensing VDD(R) for AV block in patients with intact sinus node function are absent from the current description. These modalities are recognized in clinical guidelines, and are supported by research as listed below. We therefore recommend that Section 1 of the guidance be updated to explicitly reference these additional pacing indications, including AAI(R) and VDD(R). <u><AAI(R) pacing></u> - Long-term follow up of single-chamber atrial pacing—system upgrade and Wenckebach block point behavior: potential implications for leadless AAI pacing? (Badertscher 2025), https://link.springer.com/article/10.1007/s10840-025-	Section 2 is a simple summary of the procedure description. Section 2.2 mainly focuses on right ventricular leadless pacemaker implantation as most of the evidence available is around this and this is not brand specific. Section 2 of the draft guidance has been updated.

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			02061-4 - Effect of PR interval and pacing mode on persistent atrial fibrillation incidence in dual chamber pacemaker patients: a sub-study of the international randomized MINERVA trial (Boriani G 2019), https://academic.oup.com/europace/article/21/4/636/5285479 <Leadless AAI(R) pacing> - Atrial helix-fixation leadless pacemaker:real-world single-chamber implant experience (Nair 2025), https://link.springer.com/article/10.1007/s10840-025-02041-8 - Modular Leadless Pacing: A case series of leadless pacemaker upgrades (Ip JE 2025), https://www.jacc.org/doi/10.1016/j.jacep.2024.11.006 - Chronic retrieval outcomes for an atrial leadless pacemaker (Ip JE 2025), https://www.heartrhythmjournal.com/article/S1547-5271(24)03446-5/fulltext - First European Experience with a Leadless Atrial Pacemaker (Felten 2025), https://www.heartrhythmopen.com/article/S2666-5018(25)00161-8/fulltext (Article still in press) - Leadless vs. transvenous atrial pacemakers: real world	

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			evidence from Aveir AR coverage with evidence development study (Nilsson 2025), https://www.heartrhythmjournal.com/article/S1547-5271(25)01773-4/fulltext (Abstract only)	
19.	Consultee 5 Medtronic	2.1 Information about the procedure	Due to the various types of leadless pacemakers (as noted in 2.5), we strongly recommend that this section includes additional detail to ensure clarity. The Micra AV device is a single chamber leadless pacemaker that uses atrial sensing and ventricular pacing, As such, this has the potential to be confused with the dual chamber (two device) systems with the current definition. We request that the following amendment is made for statement 2.1 to rectify this: "Most leadless pacemakers deliver single-chamber right ventricular pacing (with or without atrial sensing), but DC systems that deliver atrial or AV pacing using two devices are also available".	Thank you for your comment. Section 2.1 of the draft guidance has been updated.
20.	Consultee 6 Abbott Medical	2.1 Information about the procedure	We recommend that Section 2.1 be updated to reflect the current clinical practice and therapy capabilities, while ensuring precise description of pacing modalities. In particular, the second sentence of 2.1 should be revised and read: "Most currently available leadless pacemakers deliver single-chamber right ventricular pacing, typically in	Thank you for your comment. Section 2.1 of the draft guidance has been updated.

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			patients with AV block and atrial fibrillation (VVI(R)). Moreover, other leadless pacemakers are available according to the patient's indication, including leadless single-chamber right atrial pacing (AAI(R)), leadless single-chamber right ventricular pacing with right atrial sensing (VDD(R)), and leadless dual-chamber pacing (DDD(R))." We believe these updates are essential to ensure the guidance accurately reflects the evolving landscape of leadless pacing technologies and the diversity of patient populations they are intended to serve.	
21.	Consultee 2 NHS England	2.2 Information about the procedure	A minor point, but this describes the positioning of a ventricular leadless pacemaker. An atrial device does not cross the tricuspid valve into the right ventricle	Thank you for your comment. Section 2.2 of the draft guidance has been updated.
22.	Consultee 6 Abbott Medical	2.2 Information about the procedure	We recommend section 2.2 be updated since it currently only refers to leadless single-chamber ventricular pacing and the description of the procedure tends to be brand-specific. It does not explain the other leadless single-chamber or leadless dual-chamber modalities as commented previously, or take into account other steps in the implantation procedure.	Thank you for your comment. Section 2.2 of the draft guidance has been updated.

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			We suggest referring to the manuscript listed below in order to enable a comprehensive description of the implantation procedure of leadless pacemakers in the right ventricle and right atrium. - Implantation techniques for a helix-fixation dual-chamber leadless pacemaker (Neuzil 2024), https://www.heartrhythmjournal.com/article/S1547-5271(24)03384-8/fulltext	
23.	Consultee 5 Medtronic	2.4 Information about the procedure	The description of 'single procedure' is not factually accurate as a dual chamber system can also be implanted in two separate procedures in a modular approach i.e. one device is placed in the right atrium in a first procedure, and a second device placed in the right ventricle in a subsequent procedure. In order to reflect this accurately, we suggest that 2.4 is amended to: "A dual-chamber leadless pacemaker system consists of two devices implanted percutaneously, either in a single procedure or over multiple procedures, into the target chambers: one in the right atrium and another in the right ventricle".	Thank you for your comment. Section 2.4 of the draft guidance has been updated.
24.	Consultee 6 Abbott Medical	3.8 The evidence	Increasing numbers of operators are using leadless pacemaker devices in people with dementia. One of the main benefits of using leadless pacemakers in these individuals is the removal of complications due to "twiddlers	Thank you for your comment.

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			syndrome", which is typically associated with transvenous pacemakers. Another vulnerable group of people are those with congenital heart disease. These individuals are prone to Bradycardia, and AV Synchrony is often important to maintain the heart function. In these individuals, access to the heart chambers can be challenging due to multiple prior surgeries and interventions, making leadless dual-chamber pacing highly valuable in this cohort of people - as highlighted in the following recent case report. - Dual-chamber leadless pacemaker in complex adult congenital heart disease: a case report (Ngan HTA 2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC11489873/ As a result of the above, we request NICE considers adding people with Dementia and people with Congenital Heart Disease to the list section 3.8.	Section 3.9 of the draft guidance includes an updated list of people for whom the procedure may be particularly beneficial.
25.	Consultee 2 NHS England	General	Cost implications Finally, we appreciate that cost-effectiveness is not within the remit of this IP guidance. However, the committee will be aware that leadless pacemakers come with an acquisition cost considerably higher than that of their conventional counterparts. Furthermore, the dual chamber	Thank you for your comments. Costs considerations are not within the remit of IP guidance.

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			leadless system requires two pacemaker units, both with significantly limited lifespans when used in dual chamber mode, so that the cost/year of treatment would be many times higher. Unrestricted, widespread uptake of leadless pacing (as is already happening in countries where it is fully reimbursed) would be a considerable cost pressure on the NHS.	The committee discussed this comment but decided not to change the guidance.

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."