NICE National Institute for Health and Care Excellence

IP1192/2 Leadless cardiac pacemaker implantation for bradyarrhythmias

IPAC date: 11/12/2025

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1.	Consultee 1 Medtronic Company	**1**	Thank you for the opportunity to comment. We agree with the draft recommendations and welcome the clarification around the type of pacing for each recommendation.	Thank you for your comments and agreeing with the recommendations.
2.	Consultee 2 NHS professional	**1**	"The Freeman hospital Newcastle is a large tertiary cardiology centre providing a wide range of heart rhythm services including device extraction and management of arrhythmia in patients with congenital heart disease. There is a newly developed service implanting leadless pacemakers and this guidance is relevant to our practice. Overall we support the guidance as it is currently written, and that all of the relevant currently published evidence has been considered. We agree that there is sufficient evidence to support right ventricular leadless pacing.	Thank you for your comments and agreeing with the recommendations.

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
			We agree that there is not enough evidence to comment on long term outcomes on dual chamber leadless pacing. We agree that there is insufficient evidence to comment on the long term outcomes and efficacy and safety of atrial-only pacing at present.	
3.	Consultee 3 NHS professional	**1.1 to 1.4**	I have been a consultant cardiologist and electrophysiologist for over 20 years, and I'am 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 evidence review is comprehensive, and the recommendations are just.	Thank you for your comments and agreeing with recommendations on right ventricular pacing and dual chamber pacing.
4.	Consultee 4 Abbott Company	**1**	Abbott welcomes the majority of revisions made following the initial consultation and appreciates NICE's consideration of the feedback provided. However, we believe there are outstanding points that warrant further attention and addressing, particularly regarding the	Thank you for your comments and agreeing with recommendations on right ventricular pacing and dual chamber pacing.

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
			inconsistent approach to the recommendation level for leadless atrial pacing.	IPAC considered your comments on atrial pacing and amended the recommendations in line with dual chamber pacing. The committee noted that the right atrial pacing component is identical in both single-atrial and dual-chamber pacing systems currently available, its performance is assumed to be the same and it would be impractical to have different recommendations.
5.	Consultee 2 NHS professional	**1.2**	In sections 1.2-1.4 the phrase 'not an option' is used. This is open to interpretation. We take 'transvenous pacing is not an option' to mean that the balance of risks and benefits is such that the patient and the clinical team would not undertake a transvenous pacemaker. There are patients, with prior infection, venous acess issues and so forth, where transvenous pacing might be technically possible, but carries such high risk that the patient and clinical team would not want to proceed with transvenous pacing. We would consider that for these patients transvenous pacing is not an option, despite technical feasibility."	Thank you for your comment. IPAC considered your comment and amended section 1.2 as follows: *'When transvenous pacing is unsuitable, leadless cardiac pacemaker implantation can be used during the evidence generation period for dual-chamber pacing or right atrial pacing alone for bradyarrhythmias. There must be enhanced informed consent and auditing of outcomes'.*

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
6.	Consultee 4 Abbott Company	**1.5**	Abbott recommends "Atrial Pacing" is reworded as "Right atrial pacing" to provide consistency with Section 1.2.	Thank you for your comments. IPAC considered your comments and amended 'atrial pacing' as 'right atrial pacing'.
7.	Consultee 3 NHS professional	**1.5 to 1.6**	However, I would support a further change to the proposed guidance in section **1.5** & **1.6** to "***Atrial leadless pacemakers can be used when transvenous pacing is not an option during the evidence generation period with an enhanced informed consent and auditing of outcomes".*** The current proposed Guidance around Leadless Dual Chamber and Leadless Atrial Pacing creates a significant risk of unnecessary implantation of an additional ventricular leadless device in patients who only require an atrial leadless pacemaker in patients who have SA nodal dysfunction without AV node pathology is not uncommon and transvenous pacing system is not an option. My above suggested change and alignment of Atrial pacing guidance to be consistent with Dual chamber guidance mitigates this risk.	Thank you for your comments. IPAC considered your comments on atrial pacing and amended the recommendations in line with dual chamber pacing. The committee noted that the right atrial pacing component is identical in both single-atrial and dual-chamber pacing systems currently available, its performance is assumed to be the same and it would be impractical to have different recommendations.
8.	Consultee 3	**1.5 and 1.6**	**Particular considerations of vulnerable patient groups**	Thank you for your comments.

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
	NHS professional		There are a number of vulnerable patient groups who require an atrial leadless pacemaker only, and may be forced to have an additional ventricular leadless pacemaker unnecessarily if the stand alone atrial leadless pacemaker is not available for clinical use in the UK. Furthermore, access to the ventricular chambers may be possible in patients with previous cardiac surgeries such as Fontan and mechanical tricuspid valve. Patient access to Atrial leadless pacemakers will be essential to avoid higher risk surgical lead placement when pacing the atrium is necessary and transvenous pacing is not an option. **Suitability of recommendation to the NHS** Atrial leadless pacemakers are safe and effective as part of the dual chamber leadless platform and as a stand-alone procedure. I would support a revised NICE recommendation for Atrial leadless pacemakers to: "**can be used *when transvenous pacing is not an option during the evidence generation period with an enhanced informed consent and auditing of outcomes"***.	Please see response to comment above.

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
9.	Consultee 2 NHS professional	**1.5**	T is out view that atrial-only pacing will become an increasingly important use of leadless pacing, particularly in young patients where battery longevity and preserved vascular access is of concern and AV conduction disturbance is less common.	Thank you for your comments. IPAC considered your comments on atrial pacing and amended the recommendations in line with dual chamber pacing. The committee noted that the right atrial pacing component is identical in both single-atrial and dual-chamber pacing systems currently available, its performance is assumed to be the same and it would be impractical to have different recommendations. Section 3.10 lists patients who might be beneficial from leadless pacing.
10	Consultee 4 Abbott Company	**1.4, 1.5, 1.6**	Abbott supports NICE's recommendations for Dual-Chamber Leadless pacing and respectfully requests that the same recommendation be applied to Atrial Leadless pacing within the same modular platform. Both Atrial (AR) and Dual-Chamber (DR) configurations are integral components of the same modular platform, sharing an identical delivery system, fixation helix, device electronics, and i2i communication protocol. Furthermore, the procedural steps, implantation environment, and operator training requirements are identical across both configurations (reference image	Thank you for your comments and agreeing with recommendations on dual chamber pacing. IPAC considered your comments on atrial pacing and amended the recommendations in line with dual chamber pacing. The committee noted that the right atrial pacing component is identical in both single-atrial and dual-chamber pacing systems currently available, its performance is assumed to be the same and it

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
			provided separately). If NICE maintains the "more research is needed" recommendation for Atrial Leadless pacing, when transvenous pacing is a not option, it creates an artificial and illogical distinction within a single technology family that has already been deemed appropriate to be "used during the evidence generation period" in its Dual-Chamber configuration. The evidence base for Leadless Atrial pacing now comprises of multiple peer-reviewed studies, and NICE's own dataset demonstrates the safety, efficacy, and programmability comparable to that of Leadless Dual-Chamber pacing.	would be impractical to have different recommendations.
11	Consultee 4 Abbott Company	1.5 Atrial pacing	NICE's own compiled data on Atrial Leadless pacing demonstrates safety and performance outcomes that meet or exceeds those used to support the current dual-chamber pacing recommendation of "When transvenous pacing is not an option, leadless cardiac pacemaker implantation can be used during the evidence generation period". Consequently, maintaining the recommendation of "more research is needed" for Atrial Leadless pacing under the same clinical circumstances is inconsistent with the demonstrated performance and available evidence.	Thank you for your comments. IPAC considered your comments on atrial pacing and amended the recommendations in line with dual chamber pacing. The committee noted that the right atrial pacing component is identical in both single-atrial and dual-chamber pacing systems currently available, its performance is assumed to be the same and it would be impractical to have different recommendations.

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
			NICE's own compiled data demonstrates: • Leadless Atrial capture success > 90 % and complication-free rate > 88 %. • > 95 % Leadless Atrial implant success, major complications < 4 %, threshold normalization to ≈ 0.8 V by 24 h, and battery longevity ≈ 11 years with optimized programming. • Atrial capture threshold success 92.8 % at 12 months, mean threshold 0.83 V @ 0.4 ms, AV synchrony 97 %, and 12-month complication-free rate 88.6 %. Mekary et al., J Cardiovasc Electrophysiol 2025 – "A Modular Approach for Leadless Pacing" demonstrates: • Among 89 implants (37 Atrial -only cases) - major complications 3.4 %, minor 1.1 %, > 95 % stable electrical parameters, and i2i communication adequate in 94 % of dual-node implants. • This study highlights AVEIR Leadless pacemakers as a modular system in which components share identical hardware and governance. This supports Abbott's position that AVEIR Atrial and AVEIR Dual-Chamber configurations should not be evaluated as separate procedures, but rather as elements of a single, validated platform.	Evidence from 2 studies was considered by the committee. Mekary 2025, reporting on 89 implants with short term follow-up (mean 4.7 months) was identified in our update searches and included in appendix B (table 5) of the overview because it represents a heterogenous cohort comprising atrial, ventricular and dual chamber pacing. Another retrospective cohort study on atrial leadless pacing by the same author (Mekary 2025) involving 53 patients with 1 month follow-up, is currently in press and was not identified in our update searches. This study has been added to appendix B (table 5) because pacing thresholds has already been reported in included studies, and it shows that *'all patients had improved pacing thresholds after 24 hours (0.8V at 0.4 ms), which remained stable during follow-up'.*

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
			Mekary et al., Heart Rhythm 2025 – "Elevated Pacing Thresholds During Atrial LP Implantation" demonstrates: • In 53 patients, ~70 % had initial PT ≥ 3 V from helix micro-injury; thresholds normalized by 24 h to ≈ 0.8 V, with no dislodgements or persistent issues. • Acute elevated thresholds reflect transient inflammatory response and resolve within 24 h with adequate COI ≥ 1 mV, showing predictable and safe procedural behaviour. • This study supports the "can be used during the evidence generation period" recommendation for Atrial Leadless pacing, when transvenous pacing is not an option. In addition to the substantial evidence supporting Dual-Chamber and Atrial Leadless pacing previously submitted by Abbott during the initial consultation period, the evidence presented herein demonstrates an equivalent level of evidentiary maturity to that which underpinned NICE's "can be used during the evidence generation period" recommendation for Dual-Chamber	

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
			Leadless pacing when transvenous pacing is not an option.	
12	Consultee 4 Abbott Company	1.5 to 1.6	NICE's interventional procedures framework is designed to enable evidence-based adoption where safety and feasibility have been established, but long-term data is still accruing. Atrial Leadless pacing clearly meets this definition. Retaining the "more research is needed" recommendation for Atrial Leadless pacing (when transvenous pacing is not an option) would be disproportionate to the available evidence and inconsistent with the Committee's approach to facilitating patient access to appropriate technologies. Accordingly, Abbott recommends that Atrial Leadless pacing be assigned the same recommendations currently applied to Dual-Chamber Leadless pacing in Sections 1.2, 1.3, and 1.4.	Thank you for your comments. IPAC considered your comments on atrial pacing and amended the recommendations in line with dual chamber pacing. The committee noted that the right atrial pacing component is identical in both single-atrial and dual-chamber pacing systems currently available, its performance is assumed to be the same and it would be impractical to have different recommendations.
13	Consultee 4 Abbott Company	**1.5 to 1.6**	The proposed recommendation for Leadless Atrial pacing ("This procedure should only be done as part of formal research"), creates a scenario in which patients contraindicated for Transvenous Atrial pacing, and for whom Leadless Atrial pacing is the only clinically appropriate option, may be compelled to receive a Dual-Chamber Leadless system to ensure access to	Thank you for your comments. IPAC considered your comments on atrial pacing and amended the recommendations in line with dual chamber pacing. The committee noted that the right atrial pacing component is identical in both single-atrial and dual-chamber pacing systems currently available,

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
			the Atrial device. This unnecessary implantation of an additional Ventricular device would increase procedural time as well as cost for the NHS system. As outlined in previous comments, the application of different recommendation levels to Dual-Chamber and Atrial Leadless devices, despite both being components of the same technology platform, creates this risk. Abbott therefore recommend that NICE mitigate this by changing the recommendation for Atrial Leadless pacing to be consistent with the recommendation already applied to Dual-Chamber Leadless pacing in Sections 1.2, 1.3, and 1.4.	its performance is assumed to be the same and it would be impractical to have different recommendations.
14	Consultee 3 NHS professional	**3.1**	**Relevant Atrial Leadless pacing evidence:** The clinical evidence of Safety and Efficacy for atrial leadless pacing is accumulating as a stand-alone procedure or as part of the dual chamber leadless platform. 1. Maximizing Battery Longevity of Leadless Pacemaker Systems by Optimizing Individualized Programming – https://www.heartrhythmjournal.com/article/S1547-5271(25)02974-1/abstract	Thank you for your comments and sharing relevant evidence on atrial pacing. Five references have been considered and included in the overview. • Nair 2025, Felten 2025 (table 2) • Doshi 2024, Mekary 2025, Ip 2025 (table 5). 2 studies are not included in the overview:

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
			2. Atrial helix-fixation leadless pacemaker:real-world single-chamber implant experience (2025), https://link.springer.com/article/10.1007/s10840-025-02041-8 3. Modular Leadless Pacing: A case series of leadless pacemaker upgrades (2025), https://www.jacc.org/doi/10.1016/j.jacep.2024.11.006 4. Chronic retrieval outcomes for an atrial leadless pacemaker (2025), https://www.heartrhythmjournal.com/article/S1547-5271(24)03446-5/fulltext 5. First European Experience with a Leadless Atrial Pacemaker (2025), https://www.heartrhythmopen.com/article/S2666-5018(25)00161-8/fulltext 6. Leadless vs. transvenous atrial pacemakers: real world evidence from Aveir AR coverage with evidence development study (2025), https://www.heartrhythmjournal.com/article/S1547-5271(25)01773-4/fulltext 7. A Modular Approach for Leadless Pacing - Mekary - 2025 - Journal of Cardiovascular Electrophysiology	• Nilsson 2025, is a conference abstract with limited detail and • Ip 2025, is a case series involving only 3 people. Conference abstracts which typically provide limited detail are not considered adequate to support decision making and are therefore not included in this overview. In addition, case series with less than 30 patients have been excluded due to the large volume of published literature.

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
			https://onlinelibrary.wiley.com/doi/10.1111/jce.16740	
15	Consultee 2 NHS professional	**3.10**	We agree with the list of patients with higher risk of complication from transvenous pacing in section 3.10.	Thank you for your comments.
16	Consultee 4 Abbott Company	**3.13**	"For consideration of the committee linked to current wording in section 3.13 on ""slightly reduced battery life"": Recently published: (Ip et al., Heart Rhythm 2025 – Maximizing Battery Longevity by Optimizing Programming) demonstrated the following longevity characteristics of Atrial Leadless pacing: • Across 217 AVEIR implants (17 Atrial only), single-chamber Atrial devices achieved 11.6 [9.2–13.0] years median longevity, even with >80 % pacing burden. • Switching to IDR mode raised Dual-Chamber Atrial longevity from ~6.8 to ~9.9 years."	Thank you for your comments and sharing details about a recent article currently in press (Ip 2025). This study (on first generation leadless pacing systems in only 17 atrial implants) reported increased total projected longevity. These findings can be attributable to performance and patient specific programming. Similar findings have been reported in studies included in the overview. So, this study has been added to appendix B (table 5) in the overview.
17	Consultee 4 Abbott Company	**3.13**	The description "Dual-chamber pacing system with atrial sensing" should be reworded to "Dual-chamber pacing system with atrial sensing & pacing ".	Thank you for your comments. 3.13 has been amended as follows: *'The dual-chamber pacing system with atrial sensing and pacing has been associated with slightly reduced*

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
				battery life compared with single chamber pacing, in common with other pacemakers'.

"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."