NICE National Institute for Health and Care Excellence

NICE guidance

Leadless cardiac pacemaker implantation for bradyarrhythmias

HealthTech guidance
Published: 29 August 2018

www.nice.org.uk/guidance/htg484

© NICE 2026. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

© NICE 2026. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

Contents

© NICE 2026. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

This guidance replaces IPG626.

1 Recommendations

1.1 Evidence on the safety of leadless cardiac pacemaker implantation for bradyarrhythmias shows that there are serious but well-recognised complications. The evidence on efficacy is inadequate in quantity and quality:

- For people who can have conventional cardiac pacemaker implantation, leadless pacemakers should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.
- For people in whom a conventional cardiac pacemaker implantation is contraindicated following a careful risk assessment by a multidisciplinary team, leadless cardiac pacemakers should only be used with special arrangements for clinical governance, consent and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.

1.2 Clinicians wishing to do leadless cardiac pacemaker implantation for bradyarrhythmias in people who cannot have conventional cardiac pacemaker implantation should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy compared with conventional pacemaker implantation, and provide them with clear written information. In addition, the use of NICE's information for the public on leadless cardiac pacemaker implantation for bradyarrhythmias is recommended.

1.3 Further research in people who could have conventional cardiac pacemaker implantation should report the patient selection criteria and compare leadless pacemakers with conventional pacemakers. Follow-up should be for at least 5 years and outcomes should include adverse events, symptom relief, quality of

© NICE 2026. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

life and device durability in the long-term.

1.4 Clinicians should enter details about all patients having leadless cardiac pacemaker implantation for bradyarrhythmias onto the National Institute for Cardiovascular Outcomes Research database and review local clinical outcomes.

1.5 The procedure should only be done in specialist centres by clinicians with specific training on, and supervised experience in, inserting the device. Centres where this procedure is done should have both cardiac and vascular surgical support for emergency treatment of complications.

1.6 NICE advises clinicians to follow the Medicines and Healthcare products Regulatory Agency's (MHRA) Expert Advisory Group recommendations on leadless cardiac pacemaker therapy.

1.7 NICE may review this procedure on publication of further evidence.

© NICE 2026. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

2 The condition, current treatments and procedure

The condition

2.1 Bradyarrhythmias are abnormal heart rhythms that can result in a slow heart rate (bradycardia), usually defined as less than 60 beats per minute. There are a range of causes including diseases such as sick sinus syndrome or atrioventricular block. The most common causes are the natural ageing process, ischaemic heart disease, heart valve disorders and heart failure. If untreated, bradycardia may lead to fatigue, fainting, palpitations, dizziness, heart failure and an increased risk of death.

Current treatments

2.2 Bradyarrhythmias are managed with pacemakers, as described in NICE technology appraisal guidance on dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block and dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome without atrioventricular block. Dual-chamber pacing is recommended for symptomatic bradycardia caused by sick sinus syndrome, atrioventricular block, or a combination of sick sinus syndrome and/or atrioventricular block, and also for sick sinus syndrome in people without atrioventricular block. Single-chamber ventricular pacemakers may be used for atrioventricular block alone or with sick sinus syndrome in people with continuous atrial fibrillation, or people who have specific factors such as frailty or comorbidities that influence the balance of risks and benefits in favour of single-chamber pacing.

The procedure

2.3 The aim of implanting a leadless cardiac pacemaker is to detect cardiac

© NICE 2026. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

bradyarrhythmias and deliver electric pulses to the heart to increase the heart rate. The leadless pacemaker has a built-in pulse generator, battery and electrodes. The procedure is done under local anaesthesia, with or without sedation, in a cardiac catheterisation laboratory. Under fluoroscopic guidance, the proximal end of the pacemaker is attached to a deflectable bespoke delivery catheter system and inserted percutaneously through the femoral vein using a dedicated introducer sheath. It is then advanced into the right atrium through the tricuspid valve, into the right ventricle and positioned near the apex or lower septum. Contrast may be injected into the right ventricle to visualise the desired location. Once positioned, the pacemaker is deployed and securely implanted into the endocardial wall using a fixation mechanism (a screw-in helix or nitinol tines). An electrode at the distal end of the pacemaker delivers electrical impulses that pace the heart. Electrical measurements are taken and, if satisfactory, the pacemaker is released from the catheter and the catheter is removed. If the position is suboptimal, the pacemaker can be detached from the endocardium and repositioned prior to final release of the delivery catheter.

2.4 The pacemaker is programmed using an external programmer that transmits signals to it. The pacemaker can be retrieved using a catheter retrieval system, if device dislodgement is discovered at follow-up.

2.5 The device can only detect and pace the right ventricle (single chamber) in contrast to some conventional pacemakers that can provide dual-chamber (right atrium and right ventricle) detection and pacing. It is therefore suitable for people who only need single-chamber ventricular pacing.

© NICE 2026. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

3 Committee considerations

The evidence

3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 8 sources, which was discussed by the committee. The evidence included 6 case series and 2 retrospective matched case-control studies and is presented in table 2 of the interventional procedures overview. There is an overlap of patients in the included studies. Other relevant literature is in the appendix of the overview.

3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: adequate pacing performance and quality of life.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: cardiac perforation, cardiac tamponade, pericardial effusion, device dislodgement, battery failure, revision rates and duration of device function.

3.4 Three submissions were received from patient organisations and were discussed by the committee.

Committee comments

3.5 The leadless cardiac pacemakers currently available are only used for right ventricular pacing, and are not suitable for people who need sequential pacing or dual-chamber pacing.

3.6 Problems related to battery life have been reported for 1 device.

3.7 Different devices are available or in development for use in this procedure, and the technology and their attachment mechanisms are evolving. There is limited evidence on efficacy and safety for some of these devices.

© NICE 2026. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

3.8 The committee was informed that different manufacturers offer different types of training programmes.

© NICE 2026. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

Update information

Minor changes after publication

January 2026: Interventional procedures guidance 626 has been migrated to HealthTech guidance 484. The recommendations and accompanying content remain unchanged.

ISBN: 978-1-4731-8716-0

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

© NICE 2026. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).