



TECHNOLOGIES

Bringing the latest in Cardiac Rhythm Management Technology to patients across all of India



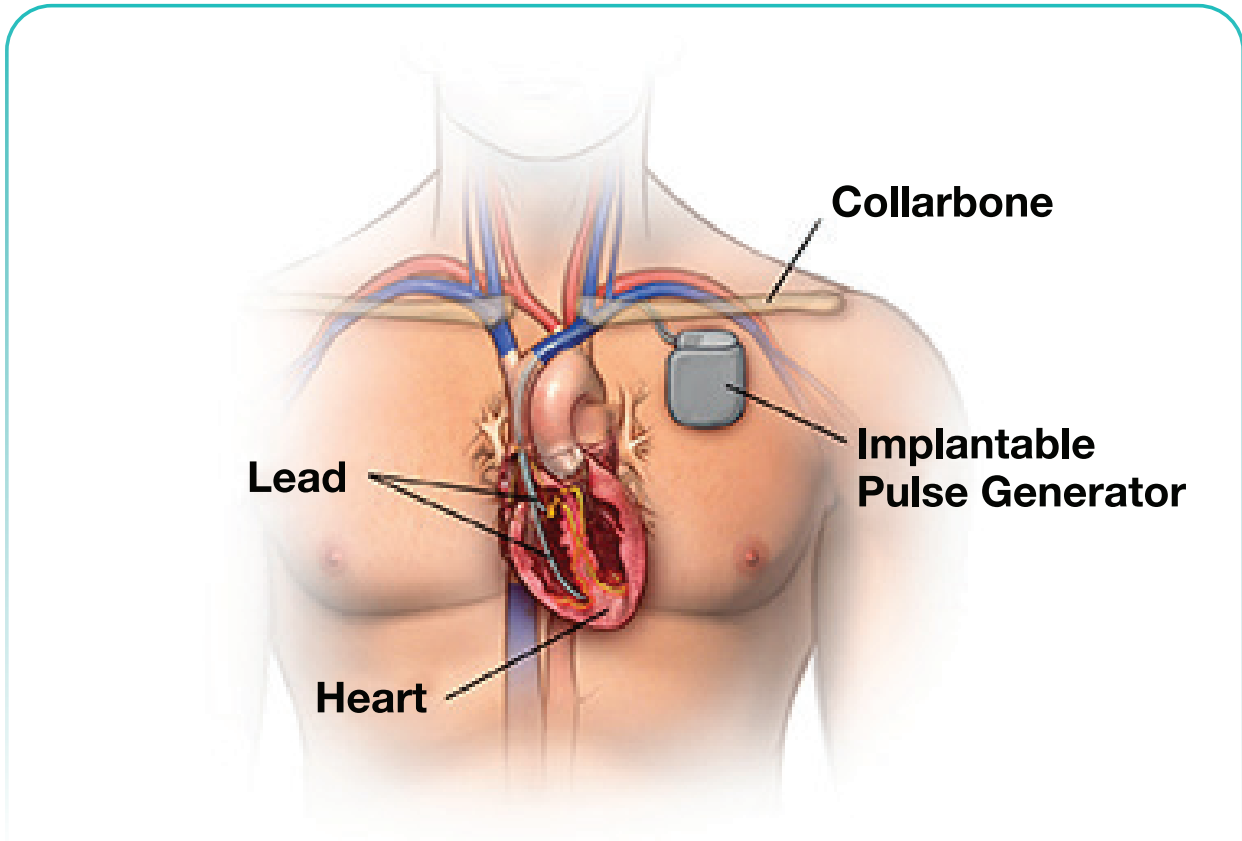
Eligibility: Class I or IIa indication for implantation of a single chamber ventricular pacemaker - according to ACC/AHA/HRS guidelines.

Caution: Investigational device, limited to investigational use only.

To explore the possibilities offered by this innovative leadless device, Reach out to your healthcare provider today & discuss the potential benefits of enrolling in the clinical trial.



What Are Pacemakers?



- It is a small implanted device used to treat a slow heart beat, otherwise known as bradycardia.
- When you have bradycardia, your body and vital organs could not be getting the blood supply it needs.
- Pacemakers send electrical pulses to help your heart beat at a normal rate, so that the body and organs can get the blood supply needed to function.



Limitations and long-term complications associated with current pacemakers



Leads¹

- Leads can become fractured, dislodged, and are a frequent cause of infection.
- Leads are often abandoned in the body, leaving wires in the patients bloodstream indefinitely.
- Leads are screwed into the heart, a high invasive process.



Highly Invasive

- The implant procedure is highly invasive, being a blood contacting device that requires vascular access.
- The device traverses the venous blood stream and actually touches the inside of the heart.



Surgical procedures

- Lengthy procedure that utilizes highly specialized equipment, resulting in increased cost to patient and hospital.
- More time under anesthesia and longer recovery period associated with increased surgical time.



Physical Appearance^{2,3}

- Obvious visual physical appearance of device and many post-implant physical activity restrictions.



Device size and its placement

- Large size can cause discomfort during various activities, especially sleep.

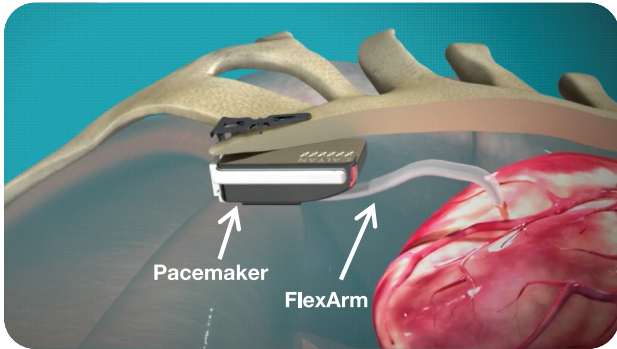


Risk of infection¹

- Infection at surgical sites or along the leads.




Calyan's Leadless Pacemaker



- An innovative pacemaker that is implanted under the sternum and does not have any lead wires.
- A FlexArm extends out from the pacemaker body to contact the pericardium for sensing and pacing capabilities.
- When compared to other pacemakers, the device does not come into contact with your blood circulatory system or the inside of your heart.



Potential Benefits Of The Calyan Pacemaker

BENEFITS OF THE CALYAN PACEMAKER	 CALYAN LEADLESS PACEMAKER
Less Invasive	<ul style="list-style-type: none"> • No vascular access required • No active blood stream components • Only contacts surface of heart • No lead fracture risk
Less Procedure Time	<ul style="list-style-type: none"> • ~ 30 Minutes
Faster Recovery	<ul style="list-style-type: none"> • Less time under anesthesia • Faster recovery & healing
Better Physical Appearance	<ul style="list-style-type: none"> • Minimal to no physical appearance- implanted underneath the sternum
Less Post Implant Restrictions	<ul style="list-style-type: none"> • Recommend that the patient have reduced physical activity for 2 weeks post-implant
Easier Device Retrieval	<ul style="list-style-type: none"> • 100% successful device retrieval in all pre-clinical & human studies • Leaves no foreign metal or leads in the body after explanation



Calyan Single Chamber VVIR Pacemaker

The Calyan Single Chamber VVIR Pacemaker has been approved for investigational clinical studies by the US Food & Drug Administration and the Drugs Controller General of India. The Calyan Pacemaker is not available for commercial sale.

This innovative pacemaker is available exclusively through enrolling in this clinical study



LATEST TECHNOLOGY:

Patient will receive the latest cardiac rhythm management technology as a solution with benefits that may exceed currently available traditional pacemakers.



NO OUT-OF-POCKET COST:

All costs pertaining to the procedure & the pacemaker device will be covered, including all diagnostic tests and follow ups*



COMPREHENSIVE CARE:

Through follow-up visits, patients will undergo various tests that evaluate the overall systemic and cardiovascular health of the patient to ensure the highest standard of care*



PATIENT REIMBURSEMENT:

Each patient will be reimbursed for their time involved in the study - for each hospital visit, the patient will be paid ₹2,000 for up to 11 hospital visits*



GUARANTEE FOR REPLACEMENT:

Within the first year of the study, Calyan Technologies will cover all the costs associated with explanting the Calyan Pacemaker and implanting a traditional pacemaker, including the cost of the device and procedure. Beyond the first year, Calyan will warranty the Calyan pacemaker.*

Let us join hands in improving Cardiac Care Together



References

1. Y.V Fleur, Reddy V. Permanent Leadless Cardiac Pacemaker Therapy – A Comprehensive Review. *Circulation*. 2019;135;1458-1470.
2. R.E. Kirkfeldt, J.B. Johansen, E.A. Nohr, O.D. Jorgensen, J.C. Nielsen. Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark. *Eur Heart J*, 35 (2014), pp. 1186-1194.
3. E.O. Udo, N.P. Zuithoff, N.M. van Hemel, C.C. de Cock, T. Hendriks, P.A. Doevendans, K.G. Moons. Incidence and predictors of short- and long-term complications in pacemaker therapy: the FOLLOWPACE study. *Heart Rhythm*, 9 (2012), pp. 728-735.



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