

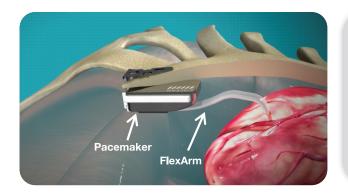
Indication: Class I or IIa indication for implantation of a single chamber ventricular pacemaker - according to ACC/AHA/HRS guidelines.

Caution: Investigational device, limited to investigational use only.



CALYAN SINGLE CHAMBER VVIR PACEMAKER

Innovative leadless pacemaker that is implanted under the sternum and gently sustains contact on the pericardial surface of the heart to provide pacing therapy.



IMPLANT PROCEDURE: (~30 Minutes)

- Small vertical incision below the sternum
- Two dilator tools are used to create a small pocket for the device to reside
- A final delivery tool is used to implant the device and clip onto the xiphoid process
- FlexArm electrode is oriented to contact the pericardial surface of the heart

POTENTIAL BENEFITS OF THE CALYAN PACEMAKER	CALYAN LEADLESS PACEMAKER	TRADITIONAL PACEMAKER
Less Invasive	 No vascular access required No active blood stream components Only contacts surface of heart No lead fracture risk 	 Requires vascular access Bloodstream components prone to infection Screw-like structure anchors inside the heart
Less Procedure Time	∼ 30 Minutes	• ~ 1 Hours
Faster Recovery	Less time under anesthesiaFaster recovery & healing	More time under anesthesiaSlower recovery, more healing required
Better Physical Appereance	 Minimal to no physical appearance- implanted underneath the sternum 	Obvious physical appearance Below the patient's collarbone
Less Post Implant Restrictions	 Recommend that the patient have reduced physical activity for 2 weeks post-implant 	 May have restrictions such as no lifting arm for up to 3 weeks, no heavy lifting for up to 6 weeks, no driving, sleeping disturbances
Easier Device Retrival	 100% successful device retrieval in all pre-clinical & human studies Leaves no foreign metal or leads In the body after explanation 	 Lead wires, adhered to heart often abandoned & left in the body forever



CALYAN SINGLE CHAMBER VVIR PACEMAKER

The Calyan Single Chamber VVIR Pacemaker has been approved for investigational clinical studies by the US Food & Drug Admnistration 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 waranty the Calyan pacemaker.*



TECHNOLOGIES