VVIR Single Chamber Pacemaker

Instructions for Use

Model P200

CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use.

Table of Contents

1. Introduction & System Overview

a) About this manual

This manual describes the operation and intended use of the Calyan VVIR Single Chamber Pacemaker model P200 implantable pacing system.

b) Manual Conventions

Throughout this manual, the word “Device” refers to the Calyan VVIR single chamber implantable pacemaker.

c) Product Literature

Before implanting the Device, it is strongly recommended that you take the following actions:

- Read the product literature provided for information about prescribing, implanting, and using the Device, and for conducting a patient follow-up session
- Discuss the Device and implant procedure with the patient and any other interested parties

d) Technical Support

Calyan employs highly trained representatives and engineers to serve you and, upon request, to provide training to investigational sites personnel in the use of Calyan products. In addition, Calyan maintains a professional staff of consultants to provide technical consultation to product users. For more information, contact your local Calyan representative at the address below:

Calyan Technologies
7300 Hudson Blvd N, Oakdale, MN 55128 Suite 290
Support Email: info@calyantech.com
Website www.calyantech.com

e) Explanation of Symbols

Below is a table explaining the meaning of various symbols on the Device packaging.

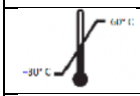
Symbol	Explanation
	Model Number
	Serial Number
	Use by Date
	Date of Manufacture
	Manufacturer
	Do not use if package is damaged
	Do not re-use
	Consult Instructions for Use
	Temperature Limits (-30C – 60C)
	Sterilized using Ethylene Oxide
	Sterilized using Ethylene Oxide
Safety In MRI not Evaluated	Safety in MRI not evaluated
	Lot # / Batch Code
	For use by prescription only

Table 1: Explanation of Packaging/Labeling Symbols

f) Notice

The Patient Information screen of the programmer software application is provided as an informational tool for the end user. The user is responsible for accurate input of patient

information into the software. Calyan makes no representation as to the accuracy or completeness of the patient information that end users enter into the Patient Information screen. Calyan SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES TO ANY THIRD PARTY WHICH RESULT FROM THE USE OF THE PATIENT INFORMATION SUPPLIED BY END USERS TO THE SOFTWARE.

g) Abbreviations and Terminology

Term	Description
Programmer	Calyan VVIR Single Chamber Pacemaker Programmer Software
Device	Calyan VVIR Single Chamber Pacemaker Device
IFU	Instructions for Use
BPM	Beats per minute
HR	Heart Rate
mV	Millivolts
msec	Milliseconds
dBm	Decibels
EGM	Electrogram
PCT	Pacing Capture Threshold
ERI	Elective Replacement Indicator
EOS	End-of-Service
PSP	Programmable Service Period
ACC	American College of Cardiology
AHA	American Heart Association
HRS	Heart Rhythm Society
BLE	Bluetooth Low Energy
EFS	Early Feasibility Study

Table 2: Explanation of Abbreviations and Terms

I. System Description

Calyan Technologies has conceived a novel medical Device for pacing and sensing outside the heart's pericardium, referred to as the "Device" in this document along with a system of support software, hardware, and firmware collectively referred to as the "System" in this document.

The System consists of the following components:

- Pacemaker (Device)
- Pacemaker Delivery System
  - Primary Dilator
  - Secondary Dilator
  - Delivery Tool

- Physician Programmer

The pacemaker Device is the implanted portion of the system that is inserted under the patient's xiphoid and sternum. It contains a battery, electronics with embedded firmware programming, and a FlexArm lead. The FlexArm lead is in contact with the patient's heart's pericardium and paces according to treatment parameters and algorithms defined by the firmware and powered by the battery. The pacemaker delivery system consists of a series of tools for creating a tunnel under the xiphoid/sternum, properly placing the pacemaker with the FlexArm electrode in contact with the heart's pericardium, and securing the pacemaker to the xiphoid/sternum. The physician programmer communicates with the pacemaker via Bluetooth Low Energy (BLE) to set the treatment parameters and read data events and treatment parameters stored in the pacemaker.

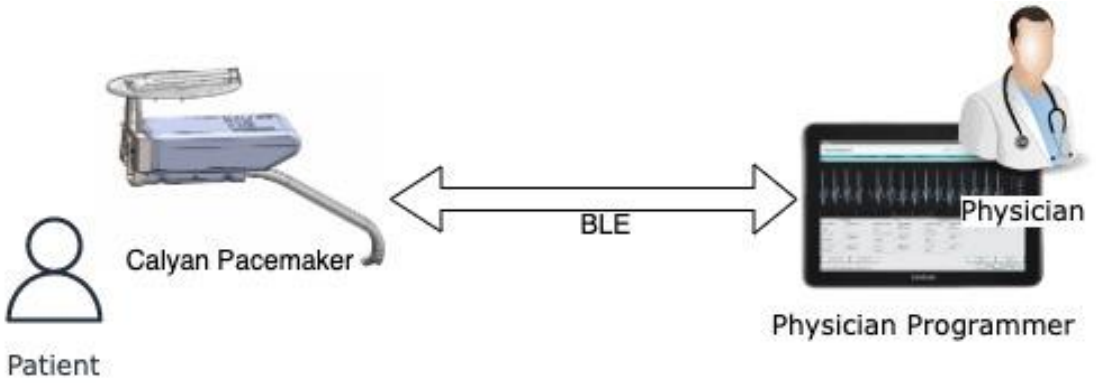
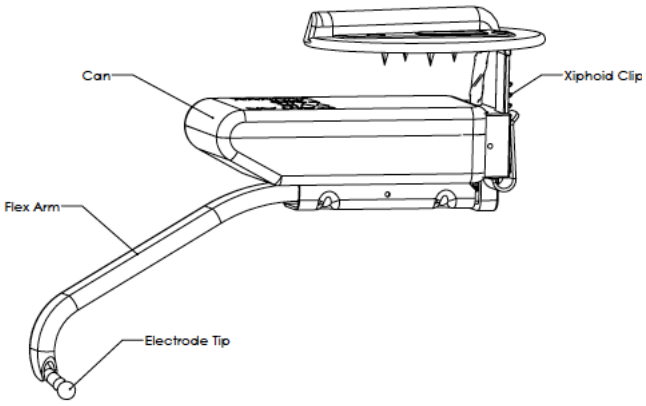
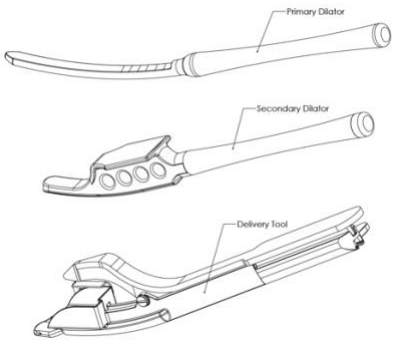


Figure 1: System Description

The Calyan VVIR single chamber pacing system is a programmable implantable cardiac Device that monitors and regulates the patient's heart rate by providing rate-responsive bradycardia pacing to the right ventricle. The Device senses the electrical activity of the patient's heart, monitors the heart rhythm for bradycardia and responds to bradycardia by providing pacing therapy based on the pacing parameters programmed. The Device provides rate response to elevate patient pacing rate to accommodate patient physical activity, controlled through an activity-based sensor.

Image	Description
 Pacemaker Device	The pacemaker Device is the implanted portion of the System that is inserted under the patient's xiphoid and sternum. It contains a battery, electronics with embedded firmware programming, and a FlexArm lead. The FlexArm lead is in contact with the patient's heart's pericardium and paces according to treatment parameters and algorithms defined by the firmware and powered by the battery. The Calyan VVIR pacemaker is delivered via the system accessory tools and provides bipolar sensing and pacing outside of the right ventricle. The Device has an active fixation mechanism consisting of a lockable titanium clip which is affixed to the xiphoid process of the sternum. The Device is capable of collecting data and transmitting it to the Programmer via Bluetooth Low Energy (BLE). Only the programmer can access pacing parameters and other settings on the pacemaker. The wireless BLE link is activated temporarily and proximally by a magnetic reed switch. The Device contains the identification serial number printed on the top of the can.
 Pacemaker Delivery System	The pacemaker delivery system consists of a series of tools for creating a tunnel under the xiphoid/sternum, properly placing the pacemaker with the FlexArm lead in contact with the heart's pericardium, and securing the pacemaker to the xiphoid/sternum. A primary tunneling tool is used to create a pathway within the chest cavity under the xiphoid to the anterior pericardium. A secondary tunneling tool is used to widen the initial pathway and allow delivery of the Device. A final Delivery Tool is used to appose the FlexArm to the surface of the heart and affix the Device's Clip to the xiphoid.
	The Physician Programmer is a handheld Android based tablet running the Calyan

 Calyan Programmer Application	Programmer Software that communicates with the Device via BLE to set the pacing parameters, read data events, and store treatment parameters sourced from the Device. The Calyan Programmer Software is used to program the Pacemaker Device for implant testing and patient follow-up sessions. The use of a Calyan programming magnet is required for communication between the Device and the programmer tablet. Programmers from other manufacturers are not compatible with Calyan Devices and will not damage Calyan Devices. The Physician Programmer is used only by Physicians, Clinicians, and Calyan Representatives, and is supplied and customized by Calyan. For security purposes, the Programmer is modified with mobile Device management software and is intentionally unable to communicate with cellular or Wi-Fi networks, and software installation is disabled.

Table 3: Calyan VVIR Single Chamber Pacing System

The Device is provided in a sterile package that contains one implantable Device. The Device is packaged in a sealed pouch and sterilized with ethylene oxide gas. For the pacing system to be sterile, the pouch must not be damaged or opened. The outer surfaces of the pouch are nonsterile and must not be placed in the sterile field. For instructions to open the sterile package, see section “How to open the sterile package”.

II. Indications and Usage

The Calyan VVIR single chamber pacing system is indicated for use in patients who have Class I or IIa indication for implantation of a single-chamber ventricular pacemaker, according to ACC/AHA/HRS guidelines.

Rate-responsive pacing is intended to provide increased heart rate appropriate to increasing levels of activity.

This is an investigational Device, which should only be used for clinical investigations at participating investigational sites.

III. Contraindications

Below are Contraindications derived from the Early Feasibility Study protocol patient exclusion criteria. Patients who meet any of the following criteria are not eligible for implant:

1. Patients in whom a substernal Device implant should be avoided:
    a. any prior sternotomy
    b. any prior medical condition or procedure that leads to adhesions in the anterior mediastinal space
    c. any marked sternal abnormality, such as pectus excavatum or pectus carinatum
    d. prior abdominal surgery in the epigastric region
    e. prior or planned sternotomy
    f. prior or planned chest radiotherapy
    g. hiatal hernia that distorts mediastinal anatomy
    h. severe obesity so that subxiphoid/substernal tunneling cannot be safely performed
2. Patients with severe RV dilation, gross hepatosplenomegaly, or severe obesity such that sub-xiphoidal/substernal tunneling cannot be safely performed
3. Patients with a class III indication for a permanent pacemaker
4. Patients with decompensated heart failure not due to bradycardia and expected to worsen with chronic RV pacing
5. Patients with a current or planned implantation of a cardiac pacemaker, cardioverter defibrillator, cardiac resynchronization Device, or neurostimulator Device
6. Patients who have previously undergone an open-heart surgical procedure.
7. Patients with an active infection
8. Patients with a condition in which pericardial pacing would be difficult or impossible, such as acute pericarditis, chronic pericardial effusion or pericardial thickening or calcification, cardiac tamponade, or chronic restrictive pericarditis
9. Patients who have tested positive for the COVID-19 in the past 3 months, or are currently showing symptoms consistent with COVID-19
10. Women of childbearing potential who are or might be pregnant at the time of the study or breastfeeding
11. Subjects with a life expectancy of less than 12 months
12. Patients who are currently enrolled or planning to participate in any concurrent clinical study with an investigational therapy
13. Patients with indications (Class I, IIa, or IIb) for AV sequential or biventricular pacing

14. Patients with complete AV block or other pacemaker dependent conditions
15. Patients with COPD with oxygen dependence
16. Use of the Calyan Programmer tablet while plugged in to power
17. an implanted cardiac or non-cardiac Device that would preclude the implant of the Calyan Device or interfere with its operation.
18. a substernal Device implant
19. any pre-existing medical condition which would require the patient to undergo an MRI scan
20. has any medical condition or procedures that leads to adhesions in the anterior mediastinal space
21. decompensated heart failure not due to bradycardia and expected to worsen with chronic RV pacing.
22. Patients that are planned to receive:
    a. therapeutic levels of ultrasound energy
    b. therapeutic levels of ionizing radiation

IV. Pre-Implant Consideration

Patient evaluation for the implant of the Device should include that the Device is intended to be removed following the End of Service (EOS) condition.

Calyan can provide the necessary precautions and warnings related to the implant procedure. For information about how to contact Calyan, see address provided below:

Calyan Technologies
7300 Hudson Blvd N, Oakdale, MN 55128 Suite 290
Support Email: info@calyantech.com

Note: The Device has not been tested with active or inactive coexisting devices.

2. Warning, Precautions, and potential Adverse Events

I. General Warnings and Precautions

MRI compatibility – The Device has not been tested for MRI compatibility. Before an MRI scan is performed on a patient implanted with the Device, the cardiology and radiology professionals involved in this procedure must ensure the Device is explanted prior to MRI.

Note: Safety in MRI for the Device has not been evaluated.

Cell Phones & Wireless Compatibility – Devices that communicate wirelessly via radio frequency, such as mobile phones, tablets, laptops and the physician programmer should be kept at least 15 cm (6 inches) away from the implantable pacemaker at all times.

Anti-coagulation – General recommendations are to discontinue anti-coagulation therapy 48 hour prior to surgery and continue anti-coagulation therapy 48 hours following surgery.

External defibrillation equipment – Throughout the implant procedure, keep external defibrillation equipment nearby for immediate use whenever tachyarrhythmias are possible.

Multiple Devices – The use of deactivated Devices in situ and an active Device, or an active transvenous pacemaker or defibrillator, has not been clinically tested to determine whether EMI or physical interaction is clinically significant. The Device should be explanted upon an EOS notification. No bench testing for multiple devices has been conducted to ensure EMI mitigation or physical interaction. Currently recommended end of device life care for a Device includes the addition of a replacement device with explant of the Device.

Patient's age and medical condition – The patient's age, medical condition, physical anatomy, and overall health should be considered by physicians as they select the pacing system, mode of operation, and implant technique best suited to the individual.

Rate-responsive mode – A rate-responsive mode may not be appropriate for patients who cannot tolerate pacing rates above the programmed Lower Rate.

Environments – Seek medical guidance before entering environments that could adversely affect the operation of the Device. This typically includes areas protected by a warning preventing entry by patients.

Cybersecurity – Because the Calyan Pacemaker is an electronic device with wireless connectivity, there are cybersecurity risks that malicious actions may be taken by third parties to access patient treatment data or change the programming of the implantable device. Calyan has taken steps to minimize these risks to an acceptably low level by allowing wireless access to the implantable device only when enabled by a physician with physical access and verbal consent from the patient and only using a secure, proprietary programming tablet controlled by the physician or a Calyan representative. This tablet has all wireless communications connections disabled (WiFi, LTE, etc) except for the short-range Bluetooth link necessary to communicate with the Calyan Pacemaker device. All information contained on the Calyan Pacemaker and programmer tablet and communicated over this Bluetooth link are de-identified, encrypted and stored securely. Measures are also in place to prevent unauthorized

changes to Calyan Pacemaker parameters and software. The net result of these cybersecurity mitigation efforts is that the risks to the patient and patient data are acceptably low.

Warning: BLE security risks include eavesdropping, man-in-the-middle and brute force attacks that may lead to modification or capture of patient treatment parameters and data.

Warning: If there is a cybersecurity breach, please contact your local Calyan representative

Quality of Service – Wireless communications typical of the intended use environment are unlikely to interfere with the communications between the Device and Programmer so long as they are kept a sufficient distance from the physical communications link.

- Wi-Fi, Bluetooth and Cellphone nodes operating in the 2.4-2.5GHz ISM band with Effective Isotropic Radiated Power (EIRP) below 10mW should be kept at least 0.35 meters away from the physical communications link.
- In-Band and Co-Channel signals of EIRP above 10mW should, if reasonable, be kept at least 1.11 meters from the physical communications link, and signals of EIRP above 100mW should be kept at least 3.51 meters away.

If the connection between Pacemaker and Programmer drops unexpectedly, it is likely caused either by an interfering wireless signal source or the Device and Programmer are too far away from each other. In this case, the Programmer should be moved closer to the Device. Any sources of interference should be identified and, if reasonable, either turned off or moved further away from the physical communications link. A Relative Signal Strength Indicator(RSSI) and a "CONNECTED"/"DISCONNECTED" status indicator are present on the Programmer User Interface to confirm connectivity. If the RSSI drops below -60, it is recommended that the Programmer be moved closer to the Device. In the event that communications become disconnected, the Device will automatically revert to its last saved set of programmed parameters to continue delivering therapy to the patient. Communications can be re-established by swiping a magnet across the Device and connecting to its Bluetooth address via the Programmer.

II. Explant and Disposal Under Care

Consider the following information about the explant and disposal of the Device:

End of Service (EOS) – When the EOS condition is met, the clinician will permanently program the Device to Off and explant the Device as described in the “Device Explanation” section.

Note: Explant of the Device may be difficult because of the development of fibrotic tissue. If removal of the device is required, it is recommended that the removal be performed by a trained clinician who been trained in the removal of the Device.

When the EOS condition is met, the Device should be turned-off and explanted. For the purpose of this EFS, the implant of a new Device will not be permitted. After device explant, the patient should be managed per the standard of care.

Return mailer kits – Contact Calyan for return mailer kits to return explanted Devices for analysis and disposal.

III. Explant and Disposal Postmortem

Postmortem – The Device is intended to be explanted postmortem. In some countries, explanting battery-operated implantable Devices postmortem is mandatory because of environmental concerns. Contact Calyan for return mailer kits to return explanted Devices for analysis and disposal.

Device malfunction – If the Device is removed because of a malfunction, return it to Calyan for analysis and disposal. The Device is intended for single use only. Do not re-sterilize and reimplant explanted Devices.

Return mailer kits – Contact Calyan for return mailer kits to return explanted Devices for analysis and disposal.

IV. Handling and Storage Instructions

Carefully observe these guidelines when handling or storing the Device.

Checking and opening the package – Before opening the sterile pouch, which is the sterile barrier, visually check for any signs of damage that might invalidate the sterility of the package contents. The Device is contained in a plastic tray. The tray and Device are contained inside a heat-sealed pouch. The outer surface of the plastic pouch is non-sterile and can be handled by personnel outside of the sterile field. The pouch is kept in a cardboard box, called the Sales Container, and is placed within another cardboard container, called the Shipping Container.

If the package is damaged – The Device packaging consists of a sterile barrier pouch, sterile tray, Sales container, and Shipping container. If the sterile barrier pouch is wet, punctured, opened, or damaged, do not use the Device. Return the Device to Calyan because the integrity of the sterile packaging or the Device functionality might be compromised. This Device is not intended to be resterilized.

If the package is dropped – Return the Device to Calyan because the Device functionality might be compromised.

Sterilization – Calyan has sterilized the sterile pouch contents with ethylene oxide before shipment. This Device is for single use only and is not intended to be resterilized.

Device temperature – Allow the Device to reach room temperature before it is programmed or implanted. Device temperature above or below room temperature may affect initial Device function.

Handle with care – When handling the pacing system, do not allow the FlexArm to whip the implantable Device against hard surfaces. If this action occurs inside or outside of the sterile field, do not implant the Device.

Handling the Device – Avoid contact with the FlexArm before implanting the Device. Do not allow the FlexArm electrode surface to come into contact with surface contaminants.

Handling the clip – When handling the Device Clip, use precaution as the four fixation spikes are very sharp.

Placing the clip on the sternum – Do not anchor the Device to the xyphoid until after the proper measurements have been taken.

"Use by" date – Do not implant the Device after the "Use by" date.

For single use only – Do not re-sterilize and reimplant an explanted Device.

Avoid magnets – To avoid damaging the Device, store the Device in a clean area away from magnets, kits containing magnets, and any sources of electromagnetic interference.

Temperature limits – Store the pacemaker package at room temperature. Excursions are permitted in the range of -30 to 60°C (-22 to 140°F).

V. Device Operation

Accessories – Use this Device only with Calyan provided accessories such as:

- Pacemaker Delivery System comprising of:
  - Primary Dilator
  - Secondary Dilator

    - Delivery Tool
- Calyan Physician Programmer
- Calyan Provided Magnet

Device status indicators – If any of the Device status indicators (for example, ERI) are displayed on the programmer after interrogating the Device, inform a Calyan representative immediately. If these Device status indicators are displayed, pacing therapies may not be available to the patient. Refer to the Calyan VVIR Single Chamber Pacemaker Programmer IFU for more details on Device status indicators.

Elective Replacement Indicator (ERI) – The programmer displays the ERI indicator on the menu bar when the Device battery reaches the ERI condition which is the recommended replacement time (RRT), after which the Device is running in the prolonged service period (PSP) . The ERI indicator will appear if the ERI condition is met 6 months prior to EOS. At this point, the patient should be scheduled to have the Device explanted. Patient should be managed per standard of care after explant of the Device.

Recommended Replacement Time (RRT) indicator – The programmer displays the ERI/RRT indicator when the Device battery SOC reaches the RRT condition which is equivalent to ERI. If the programmer displays the ERI/RRT indicator, schedule an appointment with the patient to implant a new Device. The Device will continue to operate in PSP mode for a minimum of 6 months.

Electrical reset – An electrical reset can occur, however there is no indicator for this. When the Device is interrogated, the physician should note that the pacing parameters have been changed to default values, indicating a reset. Intended electrical reset can occur through over-the-air firmware updates. Unintended electrical resets can occur through strong electromagnetic fields, as well as extremely low temperature conditions (-30°C). Observe temperature storage limits to avoid exposure of the Device to cold temperatures. To restore the Device to its previous values, it must be reprogrammed. Inform a Calyan representative if your patient's Device has reset.

Warning: If an electrical reset occurs on the Device, this will not be displayed on the main programmer screen. To view the errors that are present active or historic errors on the Device, tap GET DEVICE STATUS and a dialog box will in be invoked indicating various errors.

End of Service (EOS) indicator – The programmer displays an EOS indicator when the Device battery voltage is below 3V. If EOS occurs, this will show up as a low battery indication on the programmer. This indication states that the battery is in the last few percent of Stage-of-

Charge (SOC). When EOS occurs, it is recommended that the patient immediately get a replacement Device.

Prolonged Service Period (PSP) – The PSP criteria is met when the ERI indicator has been set. The PSP has a 6-month minimum.

Pacing safety margins – Provide an adequate safety margin when selecting values for pacing amplitude. Calyan recommends that the Pacing Amplitude be programmed at 150% of the observed pacing capture threshold. During patient's follow-up visit, use physician discretion when evaluating the patient's pacing amplitude setting.

Programmers – Only use the Calyan Programmer Software to communicate with the Device. Programmers and software from other manufacturers are not compatible with the Devices.

Rate-responsive mode – Do not program the rate-responsive mode for patients who cannot tolerate rates above the programmed Lower Rate. The rate-responsive mode may cause discomfort for those patients.

Default values – Do not use default values for pacing amplitude and sensitivity without verifying that the values provide adequate safety margins for the patient.

VI. Warnings, Precautions, and Guidance for Clinicians performing Medical Procedures on Calyan Cardiac Device Patients

This section is intended for physicians and other health care professionals who perform medical procedures on patients with Calyan implanted cardiac Device systems and who consult with the patients' cardiologists. This section provides warnings, precautions, and guidance related to medical therapies and diagnostic procedures that may cause serious injury to a patient, interfere with a Calyan implanted cardiac Device system, or permanently damage the system. This section also lists some common medical procedures that should not add risk to patients implanted with a Device.

For guidance on medical procedures that are not addressed in this section, contact your Calyan representative.

Ablation (RF ablation or microwave ablation) – Ablation is a surgical technique in which radio frequency (RF) or microwave energy is used to destroy cells by creating heat. Ablation used in cardiac Device patients may result in, but is not limited to, induced ventricular tachyarrhythmias, oversensing, unintended tissue damage, Device damage, or Device malfunction. Pulse-modulated ablation systems may pose higher risk for induced ventricular

tachyarrhythmias. The Device is designed to withstand exposure to ablation energy. After the ablation procedure, interrogate the Device with the programmer and verify Device parameter settings.

Warning: When performing endocardial and epicardial ablation procedures program the device to VOO or OOO mode. After the procedure, restore the pre-procedure Device parameters.

To mitigate risks, observe the following precautions:

- Ensure that temporary pacing and defibrillation equipment is available.
- Avoid direct contact between the ablation catheter and the implanted system.
- Position the return electrode patch so that the electrical current pathway does not pass through or near the Device.
- Ensure the programmer is available.

Always monitor the patient during ablation with at least two separate methods, such as arterial pressure display, ECG, manual monitoring of the patient's rhythm (taking pulse) or monitor by some other means such as ear or finger pulse oximetry, or Doppler pulse detection. To avoid or mitigate the effects of oversensing, if appropriate for the patient, initiate asynchronous pacing by programming the Device to an asynchronous pacing mode (for example, VOO). After the ablation procedure, restore Device parameters.

Capsule endoscopy, pH capsule procedures – Capsule endoscopy is a procedure in which a capsule containing a tiny camera is swallowed by the patient to take pictures of the patient's digestive tract. Capsule endoscopy and pH capsule procedures should pose no risk of electromagnetic interference.

Dental procedures – Dental equipment, such as ultrasonic scalers, drills, and pulp testers, poses no risk of electromagnetic interference. Keep the Device at least 15 cm (6 in) away from magnets, such as magnets found in dental office pillow headrests.

Diagnostic radiology (CT scans, fluoroscopy, mammograms, x-rays) – Diagnostic radiology refers to the following medical procedures:

- Computerized axial tomography (CT or CAT scan)
- Fluoroscopy (an x-ray procedure that makes it possible to see internal organs in motion by producing a video image)
- Mammograms
- X-rays (radiography, such as chest x-rays)

Normally, the accumulated dose from diagnostic radiology is not sufficient to damage the Device. If the Device is not directly exposed to the radiation beam, no risk of interference with Device operation occurs. However, if the Device is directly in a CT scan beam, see the following precautions in "CT scan". Similar interference may be observed for some forms of high-intensity fluoroscopy.

CT scan – A CT scan is a computerized process in which two-dimensional x-ray images are used to create a three-dimensional x-ray image. If the Device is not directly in the CT scan beam, the Device is not affected. If the Device is directly in the CT scan beam, oversensing may occur for the duration of time the Device is in the beam. If the Device will be in the beam for longer than 4s, to avoid or mitigate the effects of oversensing, if appropriate for the patient, initiate asynchronous pacing by programming the Device to an asynchronous pacing mode (for example, VOO). After completing the CT scan, restore Device parameters.

Diagnostic ultrasound – Diagnostic ultrasound is an imaging technique that is used to visualize muscles and internal organs, their size, structures, and motion as well as any pathological lesions. Diagnostic ultrasound, such as echocardiogram, poses no risk of electromagnetic interference. For precautions about therapeutic ultrasound, see "Diathermy treatment (including therapeutic ultrasound)".

Diathermy treatment (including therapeutic ultrasound) – Diathermy is a treatment that involves the therapeutic heating of body tissues. Diathermy treatments include high frequency, short wave, microwave, and therapeutic ultrasound. Except for therapeutic ultrasound, do not use diathermy treatments on cardiac Device patients. Diathermy treatments may result in serious injury or damage to an implanted Device. Therapeutic ultrasound (including physiotherapy, high intensity therapeutic ultrasound, and high intensity focused ultrasound), is the use of ultrasound at higher energies than diagnostic ultrasound to bring heat or agitation into the body. Calyan recommends a minimum separation distance of 15 cm (6 in) between the applicator and the Right Ventricle/Device, as long as the ultrasonic beam is pointing away from the Right Ventricle/Device. To avoid or mitigate the effects of oversensing or potential interference with Device function, if appropriate for the patient, initiate asynchronous pacing by programming the Device to an asynchronous pacing mode (for example, VOO). After completing ultrasound therapy, restore the Device parameters. Presence of a physician programmer for Device assessment during and after treatment is required.

Electrolysis – Electrolysis is the permanent removal of hair by using an electrified needle (AC or DC) that is inserted into the hair follicle. Electrolysis introduces electrical current into the body, which may cause oversensing. Evaluate any possible risks associated with oversensing with the patient's medical condition. To avoid or mitigate the effects of oversensing or potential interference with Device function, if appropriate for the patient, initiate asynchronous pacing

by programming the Device to an asynchronous pacing mode (for example, VOO). After completing electrolysis therapy, restore the Device parameters. Presence of a physician programmer for Device assessment during and after treatment is required.

Warning: When performing electrolysis procedures program the device to VOO or OOO mode. After the procedure, restore the pre-procedure Device parameters.

Electrosurgery – Electrosurgery (including electrocautery, electrosurgical cautery, advanced energy surgical incision technology, and hyfrecator) is a process in which an electric probe is used to control bleeding, to cut tissue, or to remove unwanted tissue. Electrosurgery used on cardiac Device patients may result in, but is not limited to, oversensing, unintended tissue damage, tachyarrhythmias, Device damage, or Device malfunction. If electrosurgery cannot be avoided, consider the following precautions:

- Ensure that temporary pacing and defibrillation equipment is available.
- Use a bipolar electrosurgery system or advanced energy surgical incision technology, or hyfrecator, if possible.
- If a unipolar electrosurgery system is used, position the return electrode patch so that the electrical current pathway does not pass through the Right Ventricle/Device and if possible, within 15 cm (6 in) of the Right Ventricle/Device.
- Use short, intermittent, and irregular bursts at the lowest clinically appropriate energy levels.
- Always monitor the patient during electrosurgery. If the ECG tracing is not clear due to interference, manually monitor the patient's rhythm (take pulse); alternatively, monitor the patient by some other means such as ear or finger pulse oximetry, Doppler pulse detection, or arterial pressure display.
- To avoid or mitigate the effects of oversensing or other interference, if appropriate for the patient, initiate asynchronous pacing by programming the Device to an asynchronous pacing mode (for example, VOO). After completing electrosurgery, restore the Device parameters.
- Presence of a physician programmer for Device assessment during and after treatment is required.

To avoid or mitigate the effects of oversensing, if appropriate for the patient, initiate asynchronous pacing by programming the Device to an asynchronous pacing mode (for example, VOO). After completing electrosurgery, restore the Device parameters.

External defibrillation and cardioversion – External defibrillation and cardioversion are therapies that deliver an electrical shock to the heart to convert an abnormal heart rhythm to a normal rhythm. Calyan cardiac Devices are designed to withstand exposure to external

defibrillation and cardioversion. While damage to an implanted Device from an external shock is rare, the probability increases with increased energy levels. These procedures may also temporarily or permanently elevate pacing thresholds or temporarily or permanently damage the myocardium. If external defibrillation or cardioversion is required, consider using the lowest clinically appropriate energy. After the therapy is delivered, use a Calyan programmer to evaluate the Device.

Hyperbaric therapy (including hyperbaric oxygen therapy, or HBOT) – Hyperbaric therapy is the medical use of air or 100% oxygen at a higher pressure than atmospheric pressure. Hyperbaric therapies with pressures exceeding 3.0 ATA, approximately 30 m (100 ft) of seawater, may affect Device function or cause Device damage. To avoid or mitigate risks, do not expose implanted Devices to pressures exceeding 3.0 ATA.

Lithotripsy – Lithotripsy is a medical procedure that uses mechanical shock waves to break up kidney or gallbladder stones. If the Calyan Device is at the focal point of the lithotripter beam, lithotripsy may permanently damage the Device. If lithotripsy is required, keep the focal point of the lithotripter beam a minimum of 15 cm (6 in) away from the Device. To avoid or mitigate the effects of oversensing, if appropriate for the patient, initiate asynchronous pacing by programming the Device to an asynchronous pacing mode (for example, VOO). After completing the lithotripsy treatment, restore Device parameters.

Magnetic resonance imaging (MRI) – An MRI is a type of medical imaging that uses magnetic fields to create an internal view of the body. The Calyan Device has not been tested for MRI compatibility. Before an MRI scan is performed on a patient implanted with the Calyan Device, the cardiology and radiology professionals involved in this procedure must ensure the Calyan Device is explanted prior to MRI.

Note: Safety in MRI for the Device has not been evaluated.

Radiotherapy – Radiotherapy is a cancer treatment that uses radiation to control cell growth. When performing radiotherapy, take precautions to avoid oversensing, Device damage, and Device operational errors.

Stereotaxis – Stereotaxis is a catheter navigation platform that allows clinicians to steer catheter-based diagnostic and therapeutic Devices throughout the body by using magnetic navigation. During a stereotaxis procedure, the magnetic field may cause interference to the Device. To avoid or mitigate the effects of oversensing, if appropriate for the patient, initiate asynchronous pacing by programming the Device to an asynchronous pacing mode (for example, VOO) prior to stereotaxis. After completing the stereotaxis, restore Device parameters or evaluate the Device.

Transcutaneous electrical nerve stimulation (TENS) – TENS (including neuromuscular electrical stimulation or NMES) is a pain control technique that uses electrical impulses passed through the skin to stimulate nerves. A TENS Device is not recommended for in-home use for Calyan cardiac Device patients due to a potential for oversensing, inappropriate therapy, inhibition of pacing, or asynchronous pacing. If a TENS Device is determined to be medically necessary, contact a Calyan representative for more information.

Warning: When performing TENS procedures program the device to VOO or OOO mode. After the procedure, restore the pre-procedure Device parameters.

Transurethral needle ablation (TUNA) and transurethral microwave therapy (TUMT) – TUNA and TUMT are surgical procedures used for benign prostatic hyperplasia (BPH) in which precisely focused energy is used to ablate prostate tissue. Patients with implanted cardiac Devices may conditionally undergo procedures that use a TUNA or TUMT system. To avoid affecting the cardiac Device function when performing a TUNA or TUMT procedure, position the return electrode on the lower back or lower extremity at least 15 cm (6 in) away from the implanted Device.

Warning: When performing TUNA procedures program the device to VOO or OOO mode. After the procedure, restore the pre-procedure Device parameters.

VII. Warnings, Precautions, and Guidance related to Electromagnetic Interference (EMI) for Calyan Cardiac Device Patients

Many cardiac Device patients resume their normal daily activities after full recovery from surgery. However, there might be certain situations that patients need to avoid. Because a Calyan cardiac Device is designed to sense the electrical activity of the heart, the Device may sense a strong electromagnetic energy field outside of the body and deliver a therapy that is not needed or withhold a therapy that is needed. The following sections provide important information to share with patients about electrical equipment or environments that may cause interference with their implanted cardiac Device. For additional guidance about EMI, contact your Calyan representative.

General EMI guidelines for patients – Patients should observe the following general guidelines regarding EMI:

- Careful consideration should be given to patient exposure to external electromagnetic interference if programming a pacing inhibition sensitivity setting more sensitive than

2.0 mV. More sensitive settings than 2.0 mV are considered to represent an increased risk from sensing either inappropriate physiologic signals or non-physiologic electromagnetic interference from external sources. These more sensitive settings should therefore be programmed only for those patients requiring such sensitivity parameters rather than routine programming without further evaluation.

- More sensitive settings than 2.0 mV are considered to represent an increased risk from sensing either inappropriate physiologic signals or non-physiologic electromagnetic interference from external sources. These more sensitive settings should therefore be programmed only for those patients requiring such sensitivity parameters rather than routine programming without further evaluation.
- Area restrictions – Before entering an area where signs are posted prohibiting persons with an implanted cardiac Device, such as a pacemaker or ICD, consult with your doctor.
- Symptoms of EMI – If you become dizzy or feel rapid or irregular heartbeats while using an electrical item, release whatever you are touching or move away from the item. The Device should immediately return to normal operation. If symptoms do not improve when you move away from the item, consult with your doctor.
- Proper grounding of electrical items – To avoid interference from electrical current that may leak from improperly grounded electrical items and pass through the body, observe the following precautions:
    - Make sure that all electrical items are properly wired and grounded.
    - Make sure that electrical supply lines for swimming pools and hot tubs are properly installed and grounded according to local and national electrical code requirements.

Household and hobby items with motors or other items that cause EMI – Household and hobby items that have motors or items that generate electromagnetic energy fields could interfere with a cardiac Device. Keep the Device at least 15 cm (6 in) away from the following items:

- Handheld kitchen appliances, such as electric mixers
- Sewing machines and sergers
- Personal care items, such as handheld hair dryers, electric shavers, electric or ultrasonic toothbrushes (base charger), or electric massagers
- Wireless Power Transfer (WPT) devices. These include wireless cellphone chargers, NFC and Qi chargers.

The following household and hobby items require special precautions:

- Boat motors – Keep the Device at least 30 cm (12 in) away from electric trolling motors or gasoline-powered boat motors.

- Electronic body fat scale – Using this type of scale is not recommended for cardiac Device patients because it passes electricity through the body and can interfere with the Device.
- Electronic pet fences or invisible fences – Keep the cardiac Device at least 30 cm (12 in) away from the buried wire and the indoor antenna of electronic pet fences or invisible fences.
- Home-use electric kilns – Keep the cardiac Device at least 60 cm (24 in) away from home-use electric kilns.
- Induction cook tops – An induction cook top uses an alternating magnetic field to generate heat. Keep the cardiac Device at least 60 cm (24 in) away from the heating zone when the induction cook top is turned on
- Portable electric generators up to 20 kW – Keep the cardiac Device at least 30 cm (12 in) away from portable electric generators.
- UPS (uninterruptible power source) up to 200 A – Keep the cardiac Device at least 30 cm (12 in) away from a UPS. If the UPS is operating by battery source, keep the cardiac Device at least 45 cm (18 in) away.

Home power tools – Most home power tools should not affect cardiac Devices. Consider the following common-sense guidelines:

- Keep all equipment in good working order to avoid electrical shock.
- Be certain that plug-in tools are properly grounded (or double insulated). Using a ground fault interrupter outlet is a good safety measure (this inexpensive Device prevents a sustained electrical shock). Some home power tools could affect Device operation. Consider the following guidelines to reduce the possibility of interference:
    - Electric yard and handheld power tools (plug-in and cordless) – Keep the Device at least 15 cm (6 in) away from such tools.
    - Soldering guns and demagnetizers – Keep the Device at least 30 cm (12 in) away from these tools.
    - Gasoline-powered tools and gasoline-powered yard equipment – Keep the Device at least 30 cm (12 in) away from components of the ignition system. Turn off the motor before making adjustments.
    - Car engine repair – Turn off car engines before making any adjustments. When the engine is running, keep the Device at least 30 cm (12 in) away from components of the ignition system.

Industrial equipment – After recovering from implant surgery, you likely will be able to return to work, to school, or to your daily routine. However, if you will be using or working near high-voltage equipment, sources of high electrical current, magnetic fields, or other EMI

sources that may affect Device operation, consult with your doctor. You may need to avoid using, or working near, the following types of industrial equipment:

- Electric furnaces used in the manufacturing of steel
- Induction heating equipment and induction furnaces, such as kilns
- Dielectric heaters used in industry to heat plastic and dry glue in furniture manufacturing
- Industrial magnets or large magnets, such as those used in surface grinding and electromagnetic cranes
- Electric arc and resistance welding equipment
- Broadcasting antennas of AM, FM, shortwave radio, and TV stations
- Microwave transmitters
- Power plants, large generators, and transmission lines. Note that lower voltage distribution lines for homes and businesses are unlikely to affect cardiac Devices.

Radio transmitters – Determining a safe distance between the antenna of a radio transmitter and the Device depends on many factors such as transmitter power, frequency, and the antenna type. If the transmitter power is high or if the antenna cannot be directed away from the Device, you may need to stay farther away from the antenna. Refer to the following guidelines for different types of radio transmitters:

- Two-way radio transmitter (less than 3 W) – These low-power Devices present low risk to the Device.
- Portable transmitter (3 to 15 W) – Keep the Device at least 30 cm (12 in) away from the antenna.
- Commercial and government vehicle-mounted transmitters (15 to 30 W) – Keep the Device at least 60 cm (24 in) away from the antenna.
- Other transmitters (125 to 250 W) – Keep the Device at least 2.75 m (9 ft) away from the antenna.

For transmission power levels higher than 250 W, contact a Calyan representative for more information.

Security systems – When passing through security systems, follow these precautions:

- Electromagnetic anti-theft systems (EAS), such as in a store or library, and point-of-entry control systems, such as gates or readers that include radio frequency identification (RFID) equipment – These systems should not affect the Device, but as a precaution, do not linger near or lean against such systems. Simply walk through these systems at a

normal pace. If you are near an electromagnetic anti-theft or entry control system and experience symptoms, promptly move away from the equipment. After you move away from the equipment, the cardiac Device will resume its previous state of operation.

- Airport, courthouse, and jail security systems – Given the short duration of security screening, it is unlikely that metal detectors (walk-through archways and handheld wands) and full body imaging scanners (also called millimeter wave scanners and three-dimensional imaging scanners) in airports, courthouses, and jails will affect a cardiac Device. When encountering these security systems, follow these guidelines:
    - Minimize the risk of temporary interference with your Device while going through the security screening process by not touching metal surfaces around any screening equipment.
    - Do not stop or linger in a walk-through archway; simply walk through the archway at a normal pace.
    - If a handheld wand is used, ask the security operator not to hold it over or wave it back and forth over your cardiac Device.

VIII. Physician Training

Device Implantation and ongoing System management must be performed by Electrophysiologist physicians trained in the operation, handling, and implanting of the Calyan System and must follow procedures described in the appropriate instructions. Inadequate training or failure to follow instructions may result in harm to the patients.

This Device is only to be used exclusively for clinical investigations. Due to the novelty of the Calyan System, it is recommended that the implanting facility has open-heart surgery capabilities and that a cardiothoracic surgeon is a part of the procedure in conjunction with the electrophysiologist.

IX. Potential Adverse Events

Potential adverse events associated with the use of the Calyan pacing system include, but are not limited to, the following events:

- bleeding
- cardiac, pulmonary, or vascular trauma, such as cardiac perforation, dissection, rupture, or tear, possibly resulting in tamponade, cardiac perforation, lung perforation, pericardial perforation, pleural perforation
- Device dislodgment or migration
- endocarditis
- pericarditis
- general surgery risks and complications from comorbidities, such as hypotension,

- dyspnea, syncope, pneumonia, hypertension, cardiac failure, renal failure, anemia, and death
- heart, or vessel damage, including coronary arterial constriction
- impaired cardiac function due to Device
- incision site complication such as excessive fibrotic tissue growth
- incision site infection or other infection
- induction or acceleration of arrhythmias, including heart block
- ineffective rate response
- myocardial damage
- nerve damage
- nerve or extracardiac stimulation
- oversensing, undersensing, or loss of pacing therapy
- pacemaker syndrome
- pain at incision site or chest
- pericarditis, pericardia effusion, or pericardial rub
- threshold elevation
- thrombus which may result in embolism (for example, deep vein thrombosis, pulmonary embolism or cerebrovascular accident)
- tissue necrosis
- toxic/allergic reactions, including body rejection phenomena and local tissue reaction
- acute bowel ischemia
- acute renal dysfunction
- cardiopulmonary resuscitation
- cardiogenic shock
- Device malfunction
- hematoma
- hemothorax
- heart failure
- hepatic failure
- infection
- myocardial infarction
- neurological dysfunction
- organ laceration
- pacing induced cardiomyopathy
- persistent abdominal pain/discomfort
- pneumothorax
- respiratory failure
- skin erosion / wound dehiscence

- vascular complications
- venous thromboembolism event

3. Preparing for an Implant

The following implant procedures are provided for reference only. Proper surgical procedures and sterile techniques are the responsibility of the implanting physician. Each physician must apply the information in these procedures according to professional medical training and experience. In general, Calyan recommends that implanting physicians choose the level of anesthesia that minimizes patient risk and is commonly used in their implanting centers. It is recommended that implantation of the Calyan System is done with a trained Electrophysiologist in a catheter lab with assistance from a Cardiothoracic Surgeon at a facility with open heart surgery capabilities. In the previous studies, sedation has ranged from general anesthesia, local topical anesthesia near the sternum, and fully intubated, deep central anesthesia. Ensure that you have all of the necessary instruments, system components, and sterile accessories to perform the implant procedure successfully.

This is an investigational Device, which should only be used for clinical investigations at participating investigational sites.

Note:

- It is recommended that patients on anticoagulation therapy discontinue anticoagulation therapy 48 hours prior to the procedure and re-start therapy 48 hours post-operatively
- During the procedure general anesthesia is recommended
- Application of a local topical anesthetic (Bupivacaine & Lidocaine (2-5%)) consisting of are recommend at the incision site prior to the patient being taken off anesthesia
- Prior to the procedure, it is recommended that continuous IV antibiotic therapy is provided for 1 hour
- Post-operative medication recommendations are 5-days daily dosage of painkiller and antibiotic therapy
- Refer to the Calyan VVIR Single Chamber Pacemaker Programmer Software IFU for details on Device sensing and configuration

I. Instruments, components, and accessories required for implant

The following non-implanted, non-sterile instruments and equipment are used to support the implant procedure:

- Calyan Physician Programmer
- Calyan Magnet
- External defibrillator

- Tissue Impedance Simulator

Note: For patients deemed at more significant risk of VT or VF, place adhesive defibrillation electrode patches on the patient prior to Device implant.

The following sterile system components and accessories are used to perform the Device implant:

- Calyan VVIR Pacing System Model P200
- Primary Dilator
- Secondary Dilator
- Delivery Tool
- Surgical Instruments:
  - Scalpels
  - Hemostats
  - Skin Sutures
  - Weitlaner Retractors
  - Other surgical tools as preferred by implanting physician and clinical team

II. Setting up the Calyan Programmer and starting the application

For instructions about how to set up and use the physician programmer, see the Calyan Technologies VVIR Single Chamber Pacemaker Programmer Instructions for Use. After setting up the programmer, follow these steps to start the application:

- Open the Calyan Software Programmer application and choose Implant Mode
- Establish telemetry with the Device and conduct the Lead Impedance test

III. Warnings and precautions when preparing for Device implant

Before implanting the Device, see the Contraindications section.

Warning: Keep external defibrillation equipment nearby for immediate use. Potentially harmful spontaneous or induced tachyarrhythmias may occur during Device testing, implant procedures, and post-implant testing.

Warning: Do not allow physical contact between the patient and Physician Programmer tablet during the implant procedure.

Warning: Maintain a distance of 15cm (6in) between the implanted Device and the physician programmer tablet during the implant and post-implant.

Caution: Do not implant the Device after the "Use by" date on the package label.

IV. Preparing the Device for implant and conducting the Lead Impedance Test

Please refer to the Calyan Technologies VVIR Single Chamber Pacemaker Programmer Instructions for Use for detailed steps on interrogating the Device. The Lead Impedance Test is conducted to ensure proper Device functionality prior to implant. Before opening the Sales Container (White Box), perform the following steps to prepare the Device for implant:

1) Interrogate the Device and view the Device data on the Calyan Programmer.

2) Change the Pacing Mode from OOO to VOO and change the Pacing Amplitude to 0.

3) Conduct a Lead Impedance Test. To do this press the Start Lead Data button. Ensure that the Lead Impedance value is between 800 – 1100 Ohms (Ω).

4) Conduct a battery voltage check. Check to confirm that the battery voltage is at least 3.4 V at room temperature. To do this, go to Settings > Get Battery Voltage.

If the Device has been exposed to low temperatures, the battery voltage will be temporarily lower. Allow the Device to warm to room temperature and check the battery voltage again. If an acceptable battery voltage cannot be obtained ($\geq$ 3.4 V), contact a Calyan representative.

Note: The Device automatically measures the battery voltage once a day at 02:00 local programmed time (24-hour time). The automatic daily battery voltage measurement is displayed on the Device Settings screen.

5) Upon setting the Device to VOO mode, the following parameter will be automatically set:

    a) Current Time on Physician Programmer Tablet

6) Select Patient Information to input the following information:
    a) Date (YYMMDD)
    b) Patient DOB (YYMMDD)
    c) Patient Initials

Notes:

- Do not enable a pacing feature that affects the pacing rate before implanting the Device, VVIR for example. Doing so may result in an elevated pacing rate that is faster than expected.
- Patient information is typically entered at the time of initial implant, and it can be revised at any time.

7) Change the Pacing Mode from VOO to OOO to prepare it for the implant. Confirm the settings by hitting the "Set Parameter" button.

V. How to open the sterile package

Open the sterile package containing the Device by following these instructions:

1) Open the Sales Container, inside is the sterile pouch containing the sterile tray, Device, and impedance simulator circuit

2) Open the package by placing an index finger and thumb on the top of the package, and another index finger and thumb on the bottom of the package. Pull the package apart slowly to open the sterile package.

3) Remove the tray containing the pacing system from the pouch and place the tray in the sterile field.

4) Remove the single piece of tape at the bottom of the tray then fold back the top tray cover. Using the two pieces of tape at the top as a hinge.

5) Hold the can of the pacing system with one hand and remove it from the tray, while holding the clamshell with the other hand. When Device comes out of sterile pack only the 1st rung on the can clip should be engaged as depicted in the image below.

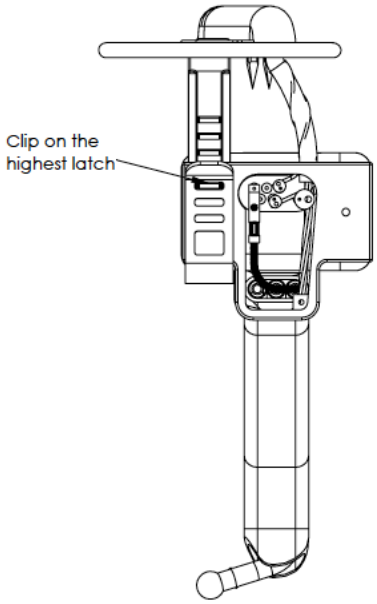


Figure 2: Device with clip on the highest run/latch

Caution: Please use caution when handling the Device Clip as the fixation spikes are extremely sharp.

Caution: If the Device is dropped, do not use the Device as its function may have been compromised.

Caution: After removing the Device from the packaging, check the Device for any damage. If there is any visible damage, do not use the Device.

Caution: Do not place the Device back in the sterile tray after removing the Device because doing so may expose the Device to static buildup in the tray.

Caution: If the Device or any pacemaker delivery instrument component is damaged, do not use it. Return the Device or instrument to Calyan.

6) Load the Device onto the Delivery Tool as indicated in Section: Preparing the Delivery Tool and Device for implant. Extend the Delivery Tool tongue out by sliding the tab forward and place the Delivery Tool with Device in a sterile field.

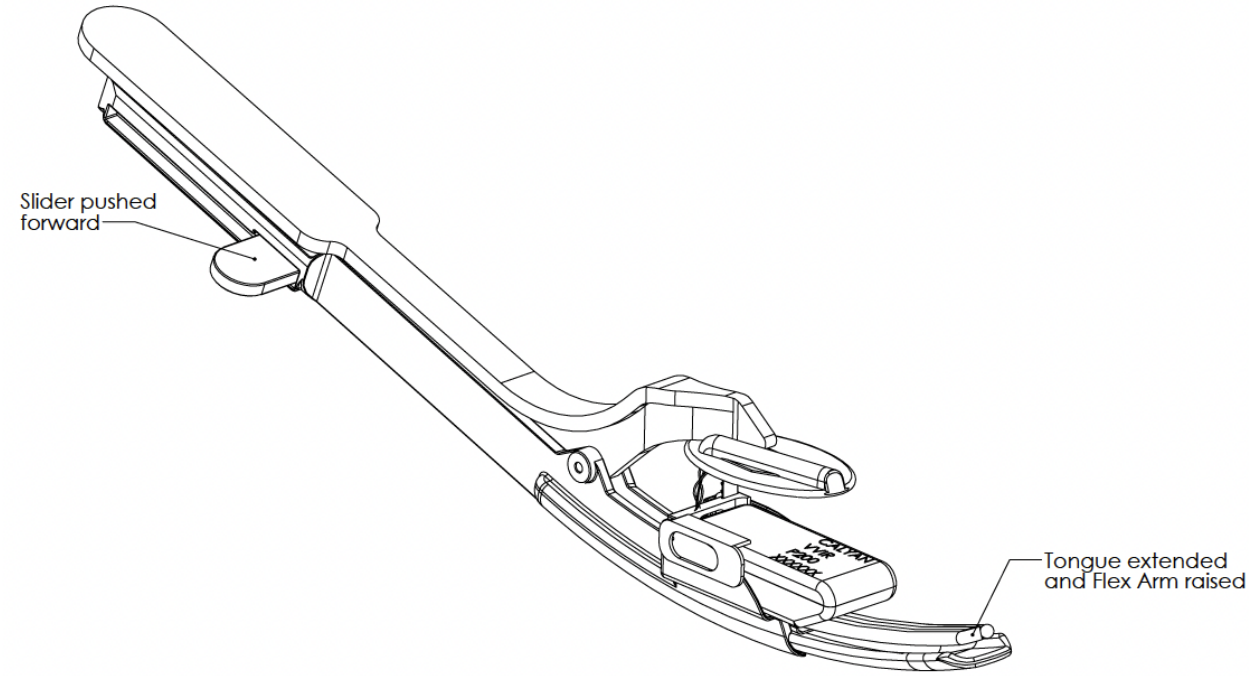


Figure 3: Device loaded onto Delivery Tool

4. Implanting the Device

The Device implant consists of the following tasks:

1) Patient anatomy qualification
   a) Confirming patient anatomy with X-Ray imaging
   b) Confirming patient anatomy with CT imaging
2) Performing the implant procedure
   a) Preparing the Delivery Tool and Device for implant
   b) Creating initial incision
   c) Tunneling via Primary and Secondary Dilators
   d) Device implantation via Delivery Tool
   e) FlexArm placement verification via Fluoroscopy
   f) Device positioning and electrical verification
   g) Anchoring the Device
   h) Withdrawing Delivery Tool
   i) Confirming Device Fixation
   j) Re-verify FlexArm placement via Fluoroscopy
   k) Re-verify electrical measurements
   l) Incision closure
   m) Final FlexArm placement verification via Fluoroscopy

n) Final electrical measurements & final implant verification

I. Patient anatomy qualification

To confirm if the patient's anatomy is adequate to receive the Calyan implant, X-Ray or CT imaging must be conducted prior to the implant surgery. The purpose of this is to allow the anatomic fit assessment of the Device with adequate positioning of the FlexArm electrode tip in contact with the heart in the projection space comprised between the 4th and 6th rib (inclusive of the 4th and 5th intercostal space, and the space directly under the 4th and 6th rib) and if the patient has the proper anatomy to receive the implant.

a) Confirming patient anatomy with X-Ray imaging

1) Lay the patient down and place a ≥ 100mm radiopaque ruler on the patients right pectoral region right under the right clavicle

2) Palpate the patient's chest to identify the location of the xiphoid, confirm the absence or presence of any xiphoid abnormalities

3) Take an X-Ray image of the patient's chest in the following positions (optionally, at physician discretion, CT imaging with measurement software can be used in place of X-Ray imaging and Step 1 above):
   (1) AP (Anterior-Posterior)
   (2) LAT (Lateral)

4) Visually confirm the following:
   a) On both images, confirm that the xiphoid is present and there are no gross abnormalities with the xiphoid process. The following criteria should be taken into consideration when evaluating the xiphoid:
      - Xiphoid process inflammation
      - Rounded xiphoid
      - Bifurcated xiphoid
      - See Contraindications section for other examples such as Pectus excavatum, or Pectus carinatum

   b) On the AP image:
      Aiming towards the patient's left shoulder, use a caliper to measure the distance from the bottom of the xyphoid to the space between the 4th and 6th rib (inclusive of the 4th and 5th intercostal space, and the space directly under the 4th and 6th rib). This distance from the bottom of the xiphoid to this space should be approximately 75mm.

5) Once confirmed, a determination can be made if the patient meets the criteria for the implant. Ensure that the following is documented in the Case Report Form:
   a) Does the patient meet the criteria for the implant?
      i) YES
         (1) If YES, document where the 75mm mark resides relative to the 4th, 5th, and 6th rib
      ii) NO
         (1) If NO, document the reasons why (distance too short, too long, xiphoid abnormalities, etc)
      iii) What type of imaging was used to make the determination (CT or X-Ray)

b) Confirming patient anatomy with CT imaging

1) Palpate the patient's chest to identify the location of the xiphoid, confirm the absence or presence of any xiphoid abnormalities

   Take a CT scan of the patient's chest with a field of view (FOV) that covers at the minimum the projection space between the 4th rib and the xiphoid appendix.

2) Visually confirm the following:
   a) On CT images, confirm that the xiphoid is present and there are no gross abnormalities with the xiphoid process. The following criteria should be taken into consideration when evaluating the xiphoid:
      - Xiphoid process inflammation
      - Rounded xiphoid
      - Bifurcated xiphoid
      - Pectus excavatum
      - Pectus carinatum
      - See Contraindications section

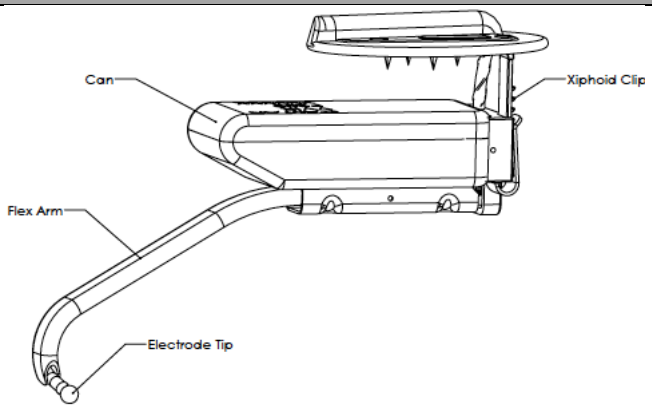
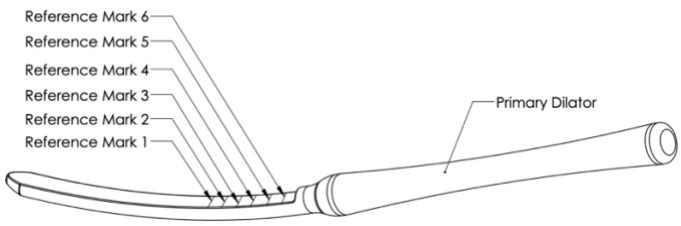
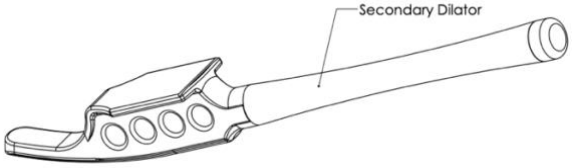
   b) On the CT reconstructed images:
      i) Aiming towards the patient's left shoulder, use the CT images with measurement software to measure the distance from the bottom of the xyphoid to the space between the 4th and 6th rib (inclusive of the 4th and 5th intercostal space, and the space directly under the 4th and 6th rib). This distance from the bottom of the xiphoid to this space should be approximately 75mm.

3) Once confirmed, a determination can be made if the patient meets the criteria for the implant. Ensure that the following is documented in the Case Report Form:
   a) Does the patient meet the criteria for the implant?

i) YES
   (1) If YES, document where the 75mm mark resides relative to the 4th, 5th, and 6th rib
ii) NO
   (1) If NO, document the reasons why (distance too short, too long, xiphoid abnormalities, etc)
iii) What type of imaging was used to make the determination (CT or X-Ray)

II. Performing the implant procedure

This section describes how to prepare the Device for implant, create the incision, navigate the dilator tools via blunt dissection, and deploy the Device via the Delivery Tool.

System Component	Image
VVIR Single Chamber Pacemaker Device	
Primary Dilator	
Secondary Dilator	

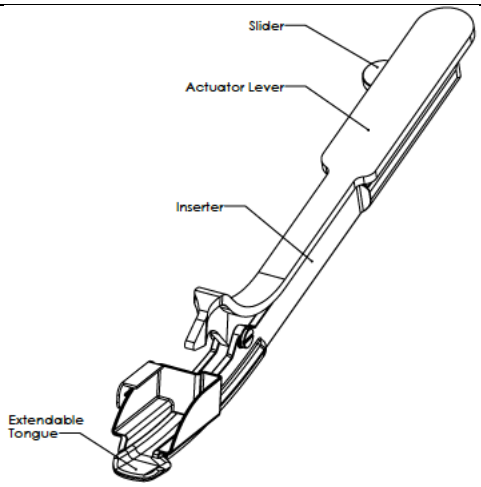
Delivery Tool	

Table 4: Detailed Calyan VVIR Single Chamber Pacing System

a) Preparing the Delivery Tool and Device for implant

Observe the following warnings and instructions to prepare the delivery system and Device for navigation through the incision

Caution: Please use caution when handling the Clip as the fixation spikes are extremely sharp.

Caution: If the Device is dropped, do not use the Device as its function may have been compromised.

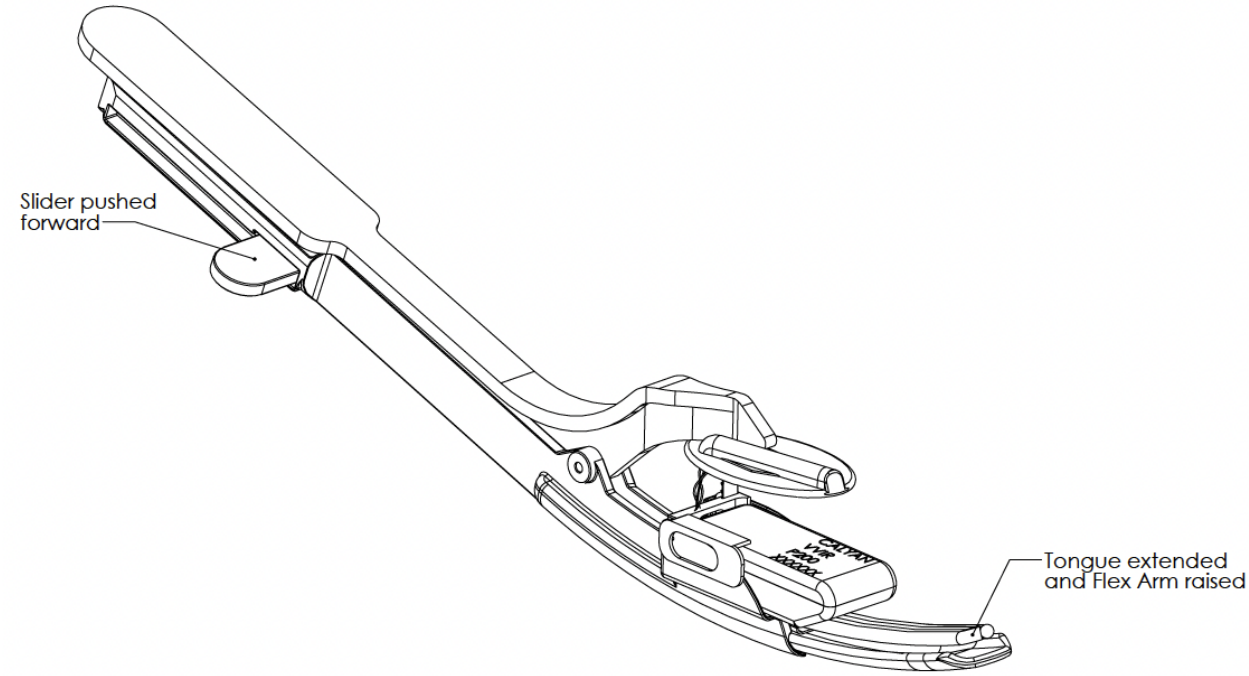


Figure 4: Device loaded onto Delivery Tool

1) Have the sterile nurse place the Device into Delivery Tool ensuring deep fit
2) Clip should be just under tool finger with about 2-3 mm free space
3) Slide right tab on Delivery Tool forward to extend tool tongue to lift FlexArm
4) Device and Delivery Tool preparation is complete

b) Creating initial incision

1) To aid in the initial incision – create a mark along the midline incision site near the xiphoid
2) Create a 3cm sub-xiphoidal vertical incision
3) Extend the incision 1.5cm superiorly
4) Allow about 1.5cm of xiphoid to be exposed by incision to allow placement and visualization of clip

c) Tunneling via Primary and Secondary Dilators

The purpose of this step is to create a tunnel via blunt dissection to gain access to the space between the 4th and 6th rib (inclusive of the 4th and 5th intercostal spaces, and the space directly under the 4th and 6th rib), and the anterior pericardium over the right ventricle.

Observe the following warnings and instructions to create the tunnel for Device placement over the right ventricle:

Warning: Please use caution when using the Primary & Secondary Dilator and creating the tunnel to avoid puncturing the pericardium or surrounding organs.

Warning: Do not use your finger for blunt dissection through the sub-xiphoidal plane, doing so could result in migration of the FlexArm.

1) Primary Dilation
   a) Using the Primary Dilator, enter incision maintaining pressure against underside of xiphoid and sternum
   b) At the tip of the xiphoid, separate the subcutaneous tissue from the abdominal fascia (rectus abdominus muscle)
   c) Use blunt dissection with the Primary Dilator to create a tunnel in the sub-xiphoidal plane (anterior to the pericardium) towards the left shoulder
      i) only moderate force is required and should be consistent along the dilation tool path
   d) Dilate to reference mark 5
   e) Withdraw Primary Dilator

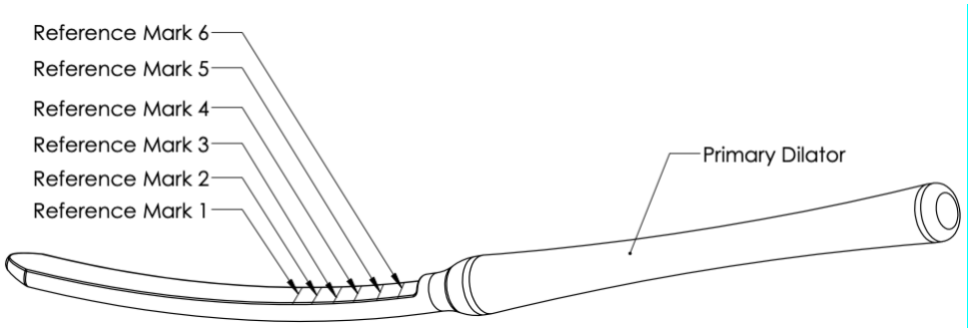


Figure 5: Primary Dilator with reference marks

2) Secondary Dilation
   a) Using Secondary Dilator, enter incision maintaining pressure against underside of xiphoid and sternum and follow the sub xiphoidal plane opened by the Primary Dilator
      i) Enlarge the opening between the abdominal fascia (rectus abdominus muscle) and anterior pericardium
   b) Aiming to the left shoulder, dilate to about 10mm (1cm) deeper than the rear marked edge of large dilation tool
   c) Withdraw Secondary Dilator

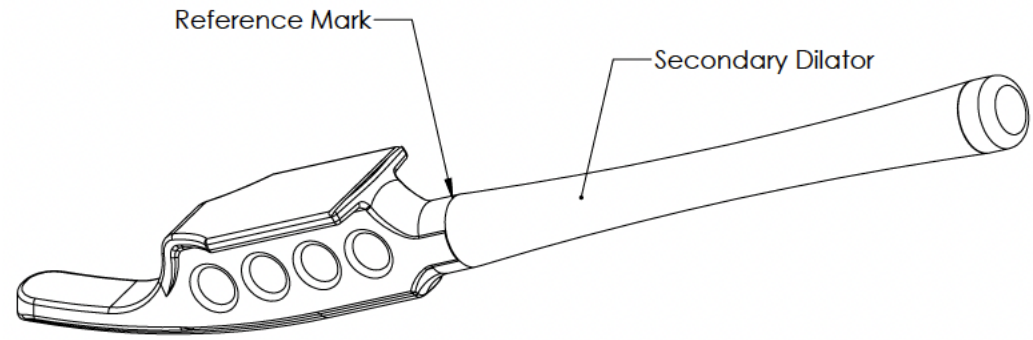


Figure 6: Secondary Dilator

d) Device implantation via Delivery Tool

To navigate the Delivery Tool and deploy the Device at the implant location, follow these instructions:

Warning: Please use caution to avoid puncturing the pericardium when deploying the Device with the Delivery Tool.

Warning: Ensure the tongue on the Delivery Tool is extended out prior to entering the incision.

Warning: The implanter should push the entire Delivery Tool down against the abdominal region with moderate force when entering the incision with the Delivery Tool. Doing so will create adequate space under the patients xyphiod/sternum to insert the Delivery Tool.

Warning: Ensure that the Delivery Tool is not pointing down (i.e. posteriorly) when entering the incision and guiding through the blunt dissection.

Warning: Do not bend the clip on the Device prior to loading onto the Delivery Tool or when deploying the Device via the Delivery Tool

Note:

- Per physician discretion, fluoroscopy imaging may be used to guide the Device Implantation via Delivery Tool step.
- Remove any excess anterior sternal tissue/muscle if present, doing so will allow for an adequate anchoring surface for the Device clip.

1) Using the Delivery Tool loaded with the Device, enter the incision maintaining pressure against underside of xiphoid and sternum
2) From the xiphoid, aim the Delivery Tool towards the left shoulder

3) Guide the tip of the Delivery Tool through the sub-xiphoidal plane, following the bluntly dissected tunnel created by the dilation tools
   a) Ensure that adequate force is applied with the Delivery Tool so that the Clip resides above the xiphoid while the can resides below the xiphoid
   b) Ensure that the insertion of the Delivery Tool does not extend or enlarge the bluntly dissected tunnel
4) Insert until Clip touches the xiphoid, with a minimum of 2 fixation spikes over the xyphoid
5) Retract Delivery Tool tongue by pulling back right tab on Delivery Tool

e) FlexArm placement verification via fluoroscopy

The purpose of this step to verify placement of the FlexArm electrode between the 4th and 6th ribs and that FlexArm electrode is residing on the anterior pericardium over the right ventricle

1) Utilizing fluoroscopy verify the following
   a) FlexArm electrode tip is located between the 4th and 6th ribs, this is inclusive of the 4th and 5th intercostal spaces, and the space directly under the 4th and 6th rib.
   b) FlexArm electrode tip is located over the right ventricle
2) Visually confirm that the FlexArm electrode ball tip is moving in unison with the expansion/contraction of the heart
   a) If the FlexArm electrode ball tip is not moving in unison with the expansion/contraction of the hear, Device repositioning is required

f) Device positioning and electrical verification

The purpose of this step to orient the Device to increase the chance of capture and determine the Pacing Amplitude voltage setting. The Physician Programmer will be used to determine an initial Pacing Amplitude setting and then fine tune that setting through a series of steps described below.

Warning: Ensure that the Calyan magnet is placed in a sterile pouch or sleeve prior to activating the magnetic reed switch.

Warning: On the Physician Programmer, do not exceed 6.4V for the Pacing Amplitude setting.

Warning: Before taking the electrical measurements, be sure to pull back the Delivery Tool tongue. If the tongue is not pulled back, the electrical measurements may be incorrect.

Warning: Before moving the Device, ensure that the Delivery Tool tongue is extended out.

Notes:

- Use Physician discretion consistent with Device and study training and in consultation with Calyan Representative when incrementally changing the Pacing Amplitude voltage to establish capture.

1) Establish telemetry communication with the Device via the Calyan programmer. To do this, swipe the Device with the Calyan magnet placed in a sterile pouch or sleeve
2) Using the Calyan Programmer, configure the following settings with the Device:
   a) Set Mode: **VVI**, Pulse Width: **500µs**, Pacing Amplitude: **4V**
   b) Set Pacing Rate: 20-30BPM higher than the intrinsic rate as indicated on the ECG monitor
3) **Device Positioning**
   a) Confirm capture at **4V** at the **initial Device location**, if capture is not observed try the following:
      i) Reposition the Device by extending the Delivery Tool tongue, and pivoting the Device so that the FlexArm moves to the **left** of the initial Device location
         (1) Retract the tongue on the Delivery Tool up and evaluate capture
            (a) If capture is NOT observed, try the following:
         (2) Reposition the Device by extending the Delivery Tool tongue, and pivoting the Device so that the FlexArm moves to the **right** of the initial Device location
            (a) If capture is NOT observed, try the following:
         (3) Reposition the Device by extending the Delivery Tool tongue, and adjusting the Device so that the FlexArm moves **inferior** to the initial Device location, ensure that a minimum of 2 spikes from the can clip reside over the xyphiod.
            (a) If capture is NOT observed, try the following:
         (4) Reposition the Device by extending the Delivery Tool tongue, and adjusting the Device so that the FlexArm moves **left of the inferior position**, ensure that a minimum of 2 spikes from the can clip reside over the xyphiod.
            (a) If capture is NOT observed, try the following:
         (5) Reposition the Device by extending the Delivery Tool tongue, and adjusting the Device so that the FlexArm moves **right of the inferior position**, ensure that a minimum of 2 spikes from the can clip reside over the xyphiod.
      ii) If capture was observed at any of the positions, return to the position where optimal operation was found and begin the Electrical Verification process described in Step 4 below
      iii) If capture was not observed at any of the positions, return to the **initial Device location** and set the Pacing Amplitude level to **6.4V**
         (1) Confirm capture at the **initial Device location**
         (2) If capture is not observed, try to re-position the Device as defined in the above steps and confirm capture in one of the six positions

(a) If capture was observed at any of the positions, return to the position where optimal operation was found and begin the Electrical Verification process described in Step 4 below

(b) **If capture is not observed in any of the six positions, the patient is not a viable Calyan Pacemaker implant candidate. The Device should be explanted, and the patient managed per physician discretion, and the standard of care.** The patient will be followed in the study up to discharge or 30 days, whichever is longer.

4) Electrical Verification

a) Beginning at the Pacing Amplitude setting where capture was observed, reduce the Pacing Amplitude by 2V and observe if capture is maintained. If capture is lost, increase voltage by 1V. If capture is maintained, reduce voltage by 1V.

b) After the 1V change, if capture is lost, increase voltage by 0.5V. If capture is maintained, decrease voltage by 0.5V

c) After the 0.5V change, if capture is lost, increase voltage by 0.25V. If capture is maintained, decrease voltage in 0.25V successive increments until capture is lost.

d) After capture is lost, increase voltage in 0.25V steps until capture is reacquired.

e) This voltage setting is the observed pacing capture threshold. Make note of the pacing capture threshold.

f) Observe the implant site for extracardiac stimulation

The presence of extra-cardiac stimulation will be determined by visual inspection and by palpating the muscles in the chest. If extra-cardiac stimulation is observed, the stimulation parameters will be adjusted (e.g. reduction in amplitude and/or pulse width) to avoid extra-cardiac stimulation. **If extra-cardiac stimulation cannot be avoided, the patient is not a suitable candidate. The Device should be explanted, and the patient managed per physician discretion, and the standard of care.** The patient will be followed in the study up to discharge or 30 days, whichever is longer.

5) Turn off Pacing by setting the Calyan Programmer Pacing Amplitude to 0.0v.

g) Anchoring the Device

Notes:

- Only conduct this step after the Device Positioning and Electrical Verification step is complete.
- Only conduct this step after FlexArm Placement verification via Fluoroscopy is complete.

Warning: When anchoring the Device ensure minimal motion of the Delivery Tool and Device to ensure adequate FlexArm placement over the right ventricle.

Warning: Do not bend the clip on the Device prior to loading onto the Delivery Tool or when deploying the Device via the Delivery Tool

1) Using moderate pressure, lift the actuator arm on the Delivery Tool upward
2) Lift the actuator arm until significant resistance is felt. During the locking process, you will be able to hear and/or feel the clip rungs engage with the Device can
3) Once significant resistance is felt, the Device is locked into place

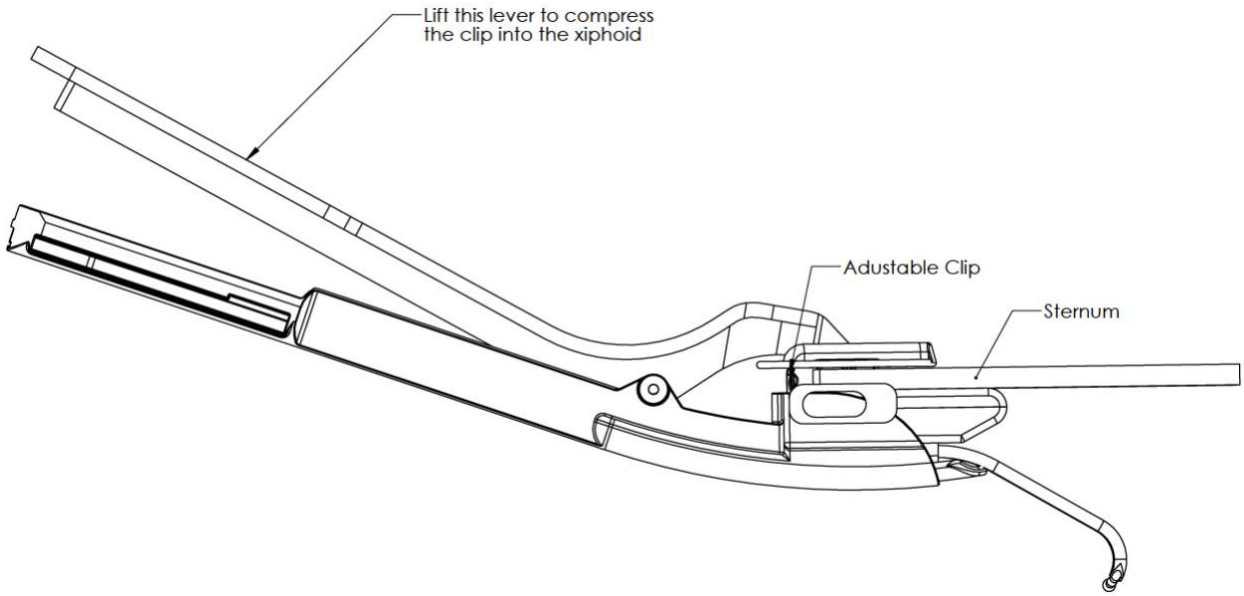


Figure 7: Delivery Tool with lever lifted to anchor Device to patient sternum

h) Withdrawing Delivery Tool

1) Pull tool inferiorly along Device axis to remove
   a) Retract Delivery Tool before lifting on the handle. Doing so ensures the Device body is not torqued away from xiphoid.

Warning: When withdrawing the Delivery Tool ensure minimal motion of the Delivery Tool and Device.

Warning: Do not angle the Delivery Tool when exiting the sub-xiphoidal plane.

Warning: When removing the Delivery Tool through the xiphoidal plane, ensure that the Delivery Tool is being removed parallel to the xiphoid/sternum.

i) Confirming Device fixation

After positioning the Device FlexArm over the right ventricle, it is important that you assess the adequacy of the Device anchoring to the patient's xiphoid. Confirming Device fixation is designed to be an aid to determine whether the Device is anchored to the xiphoid properly. This assessment can be performed based on visual confirmation, EGM waveform, and initial electrical measurements. This visual confirmation can only be conducted after the Delivery Tool has been withdrawn.

1) Have the implanting physician/circulating nurse visually confirm that 2, 3, or 4 fixation spikes are fixated in the xiphoid

j) Re-verify FlexArm placement via Fluoroscopy

The purpose of this step to re-verify placement of the FlexArm electrode between the 4th and 6th ribs and that FlexArm electrode is residing on the anterior pericardium over the right ventricle

1) Utilizing fluoroscopy verify the following
   a) FlexArm electrode tip is located in the projection space between the 4th and 6th ribs, this is inclusive of the 4th and 5th intercostal spaces, and the space directly under the 4th and 6th rib.
   b) FlexArm electrode tip is located over the right ventricle
2) Visually confirm that the FlexArm electrode ball tip is moving in unison with the expansion/contraction of the heart
   a) If the FlexArm electrode ball tip is not moving in unison with the expansion/contraction of the hear, Device repositioning is required

k) Re-verify electrical measurements

1) Note the Pacing Capture Threshold setting step from step F Electrical Verification, set the Pacing Amplitude accordingly
2) Re-verify that capture is occurring at the previously established Pacing Capture Threshold
3) The established threshold should be within 0.5v of the prior reading.
   a) Consider repositioning the Device if the threshold has risen above 4V.
4) Observe the implant site for extracardiac stimulation
   a) The presence of extra-cardiac stimulation will be determined by visual inspection and by palpating the muscles in the chest. If extra-cardiac stimulation is observed, the stimulation parameters will be adjusted (e.g. reduction in amplitude and/or pulse width) to avoid extra-cardiac stimulation. **If extra-cardiac stimulation cannot be avoided, the patient is not a suitable candidate. The Device should be explanted and the patient will be managed per physician discretion, and the standard of care.**

l) Incision closure

1) Use sterile suturing techniques to close the incision by suturing along the three layers of sternal muscle, subcutaneous tissue, and skin.

m) Final FlexArm placement verification via fluoroscopy

The purpose of this step is to verify the final placement of the FlexArm electrode between the 4th and 6th ribs and that the FlexArm electrode is residing on the anterior pericardium over the right ventricle. The final Device electrode position will be determined by capturing Anterior-Posterior (AP) and Lateral (LAO 40° and RAO 40°) fluoroscopy images:

1) Utilizing fluoroscopy verify the following
   a) FlexArm electrode tip is located between the 4th and 6th ribs, this is inclusive of the 4th and 5th intercostal spaces, and the space directly under the 4th and 6th rib.
   b) FlexArm electrode tip is located over the right ventricle
2) Visually confirm that the FlexArm electrode ball tip is moving in unison with the expansion/contraction of the heart. This is to ensure that the Device is implanted properly, within the right location, and making adequate contact w/ the pericardium.

n) Final electrical measurements & final implant verification

1) Re-verify that capture is occurring at the previously established Pacing Capture Threshold.
2) The established threshold should be within 0.5v of the prior reading.
   a) Consider repositioning the Device if the threshold has risen above 4V.
3) Ensure that the Device parameters are within the ranges defined in the table below. This is to ensure that the implanted pacemaker has acceptable pacing parameters post-implant and has been deemed successful.

Parameter	Acceptable Range
Pulse Amplitude	0.5 – 6.4V
Pulse Duration	0.1 – 1.5 ms
R-Wave Amplitude	≥ 1 mV
Battery Voltage	3.3 – 3.6V

Table 5: Final implant acceptable pacing and Device parameters

4) Set the Pacing Amplitude setting to 150% of the observed pacing capture threshold voltage setting in the previous step.
5) Observe the implant site for extracardiac stimulation
   a) The presence of extra-cardiac stimulation will be determined by visual inspection and by palpating the muscles in the chest. If extra-cardiac stimulation is observed, the stimulation parameters will be adjusted (e.g. reduction in amplitude and/or pulse width) to avoid extra-cardiac stimulation. **If extra-cardiac stimulation cannot be avoided, the**

patient is not a suitable candidate. The Device should be explanted and, the patient managed per physician discretion, and the standard of care.

6) Set the Device to pace immediately

Note: Calyan recommends that the Pacing Amplitude be programmed at 150% of the observed pacing capture threshold. During patient's follow-up visit, use physician discretion when evaluating the patient's pacing amplitude setting.

Warning: Calyan recommends that the patient has reduced physical activity post-implant for two weeks to aid in encapsulation of the FlexArm electrode to the anterior pericardium.

5. Post Implant

See below for Post Implant considerations such as Rate Response, Device Programming, Device Explantation, and Device Repositioning.

I. Rate Response

Rate response is designed to advance the pacing rate based on the detected level of patient physical activity. The pacing rate setting on the Rate Response screen on the Programmer will define the maximum increase in pacing rate during the highest level of activity, with a maximum combined pacing rate of 180bpm. The exertion threshold defines the minimum sustain activity level to being increasing pacing rate. Please refer to the Calyan VVIR Single Chamber Pacemaker Programmer IFU for details on rate response and rate response configuration.

II. Patient Follow-ups

When conducting post-implant patient follow ups, ensure the Device parameters are within the ranges below:

Parameter	Acceptable Range
Pulse Amplitude	0.5 – 6.4V
Pulse Duration	0.1 – 1.5 ms
R-Wave Amplitude	≥ 1 mV
Battery Voltage	≥ 3V

Table 7: Patient follow-up acceptable pacing and Device parameters

Note:

- Calyan recommends that the Pacing Amplitude be programmed at 150% of the observed pacing capture threshold. During patient's follow-up visit, use physician discretion when evaluating the patient's pacing amplitude setting.
- Observe the implant site for extracardiac stimulation

- The presence of extra-cardiac stimulation will be determined by visual inspection and by palpating the muscles in the chest. If extra-cardiac stimulation is observed, the stimulation parameters will be adjusted (e.g. reduction in amplitude and/or pulse width) to avoid extra-cardiac stimulation.

III. Device Explant

The purpose of the Device Explanation procedure is to remove the Device from the patient.

Warning: Retrieval of the Device after it is fully encapsulated may result in injury to the patient's abdominal fascia tissue.

Warning: Keep external pacing equipment nearby for immediate use. The patient does not receive pacing therapy from the implanted Device when it is being retrieved, repositioned, or removed.

Warning: Please use caution when handling the Clip as the fixation spikes are extremely sharp.

Warning: When removing the Device from the anchoring site, ensure that the clip is removed from the can prior to Device removal. Doing so will automatically de-anchor the can from the sternum/xyphoid.

1) Re-open the incision and retain the open incision with a retractor. Ensure that the retractor handle resides superior to the incision site.
2) Excise the fibrotic tissue growth around the clip that resides on top of the sternum as well as the inferior portion of the Device that is encapsulated with fibrotic tissue.
3) Using a mosquito hemostat, gently and carefully pull back the tab of the clip spring. The tab protrudes out allowing for a hemostat to grab onto. To avoid bending, do not pull the clip spring more than a couple of millimeters back from its original position.
4) While the clip spring is being held back, utilize another hemostat to elevate the clip from the sternum.
5) Utilizing the first hemostat that is holding onto the clip spring, pull the Device inferiorly. The Device can now be removed.
6) Remove the Device.
7) Use sterile suturing techniques to close the incision by suturing along the three layers of sternal muscle, subcutaneous tissue, and skin.

IV. Device Repositioning Post Index Procedure

The purpose of the Device Repositioning procedure is to reposition the Device to obtain pacing capture thresholds to facilitate RV pacing.

Warning: Retrieval of the Device after it is fully encapsulated may result in injury to the patient's abdominal fascia tissue.

Warning: Keep external pacing equipment nearby for immediate use. The patient does not receive pacing therapy from the implanted Device when it is being retrieved, repositioned, or removed.

Warning: Please use caution when handling the Clip as the fixation spikes are extremely sharp.

Warning: When removing the Device from the anchoring site, ensure that the clip is removed from the can prior to Device removal. Doing so will automatically de-anchor the can from the sternum/xyphoid.

Warning: If the Device or any Pacemaker Delivery System instrument is damaged, do not use it. Return the Device or instrument to Calyan

1) Re-open the incision and retain the open incision with a retractor. Ensure that the retractor handle resides superior to the incision site.
2) Excise the fibrotic tissue growth around the clip that resides on top of the sternum as well as the inferior portion of the Device that is encapsulated with fibrotic tissue.
3) Using a mosquito hemostat, gently and carefully pull back the tab of the clip spring. The tab protrudes out allowing for a hemostat to grab onto. To avoid bending, do not pull the clip spring more than a couple of millimeters back from its original position.
4) While the clip spring is being held back, utilize another hemostat to elevate the clip from the sternum.
5) Utilizing the first hemostat that is holding onto the clip spring, pull the Device inferiorly. The Device can now be removed.
6) Remove the Device.
7) Clean any excess fibrotic tissue off the can and clip.
8) Insert the clip back into the Device can, ensuring only one rung is engaged in the clip spring.

Warning: If the Device or any Pacemaker Delivery System instrument is damaged, do not use it. Return the Device or instrument to Calyan

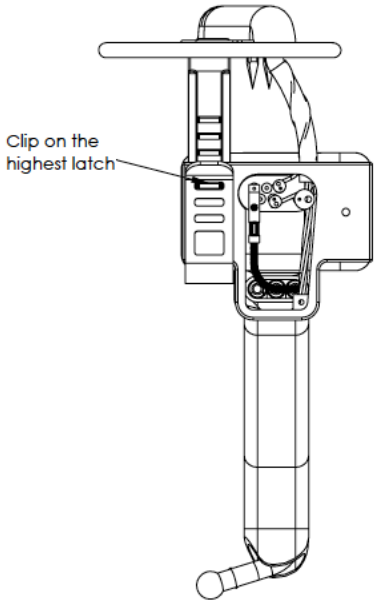


Figure 8: Device with clip on the highest run/latch

9) Load the Device onto the Delivery Tool ensuring deep fit

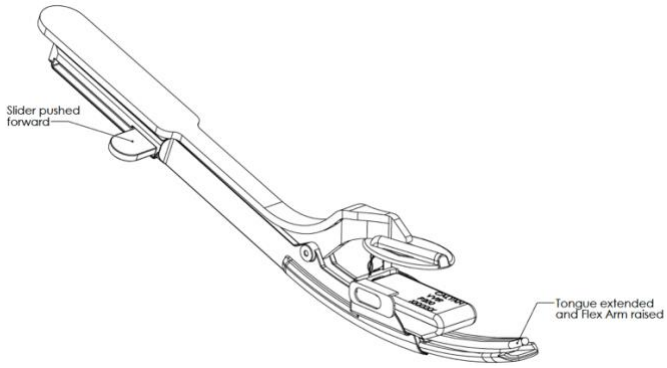


Figure 9: Device loaded onto Delivery Tool with tongue extended

10) While holding Device in Delivery Tool, extend the Delivery Tool tongue out by sliding the tab forward
11) Place the Delivery Tool with Device in the sterile field
12) Start the implant procedure starting at step 2.II.c Tunneling via Primary and Secondary Dilators

6. Technical Specifications

I. Device & Pacemaker Delivery System Components, Dimensions, and Materials

Pacemaker Model P200	
Dimensions	84 x 27 x 59 mm
Mass	24 grams
Volume	13 cm^3
FlexArm length (exposed beyond can)	6 cm
Cathode (Tip Electrode) surface area/material	22 mm^2/ Titanium Nitride coated
Anode (Can) surface area/material	40 cm^2/ Titanium
Cathode to anode spacing	42 mm
Clip fixation anchor penetration length	3 mm
Materials in chronic contact with human tissue	Titanium, titanium nitride, stainless steel, polyurethane, silicone elastomer, silicone medical adhesive NOTE: the Device does not contain any medicinal substances
FlexArm insulation material	polyurethane
FlexArm conductor material	MP35N
Battery	Hermetically sealed lithium thionyl chloride
Delivery Tools	
Primary Dilator Material	Stainless steel
Primary Dilator Dimensions	8 mm diameter; 233 mm length
Primary Dilator Mass	107 grams
Primary Dilator Surface Area	64 cm^2
Secondary Dilator Material	Stainless steel
Secondary Dilator Dimensions	11 mm width; 210 mm length

Secondary Dilator Mass	183 grams
Secondary Dilator Surface Area	98 cm^2
Delivery Tool Materials	Stainless steel, polysulfone
Delivery Tool Dimensions	23 mm width; 263 mm length
Delivery Tool Mass	230 grams
Delivery Tool Surface Area	345 cm^2

Table 8: Device & Pacemaker Delivery System Components, and Dimensions

II. Device Parameters & Modes

Table 9 below describes the Device parameters and mode as shipped. When the Device is shipped it is in Storage mode. When taken out of Storage mode, below are the default Device parameter settings.

Parameter	As Shipped (Default Settings)
Mode	OOO
Rate-Adaptive Mode	VVIR
Rate-Response Sensor	Activity
Rate Modulation	OFF
Sensing/Pacing Configuration	Unipolar
Basic Rate	60 BPM
Sensitivity	2mV
Pulse Amplitude	4V
Pulse Duration	0.5ms
Refractory Period	300 ms

Table 9: Default Device parameters as shipped

The input impedance is > 3000 Ω, this is a non-programmable characteristic.

Tables 10 and 11 below describes the various Devices modes, settings, and ranges of various Device parameters.

Parameter	Range
Modes	Storage, OOO, OVO, VOO, VVI, VVIR
Sensing/Pacing Configuration	Unipolar
Basic Rate	30 – 150 bpm
Rate Modulation	VVIR, Basic rate – 180 bpm

Sensitivity	0.45 – 11.3mV
Pulse Amplitude	0.13 – 12.0V
Pulse Duration	0.1 – 1.5ms
Pulse Interval Range	333-2000 ms

Table 10: Default Device parameters as shipped

Mode	Chamber(s) Paced	Chamber(s) Sensed	Response to Sensing	Rate Modulation
Emergency	Ventricle	None	None	None
Storage	None	None	None	None
OOO	None	None	None	None
OVO	None	Ventricle	None	None
VOO	Ventricle	None	None	None
VVI	Ventricle	Ventricle	Inhibited	None
VVIR	Ventricle	Ventricle	Inhibited	ON

Table 11: Pacing modes available

Figure 12 below describes the pulse shape, with the points defined as it relates to pulse amplitude (leading edge) and pulse duration.

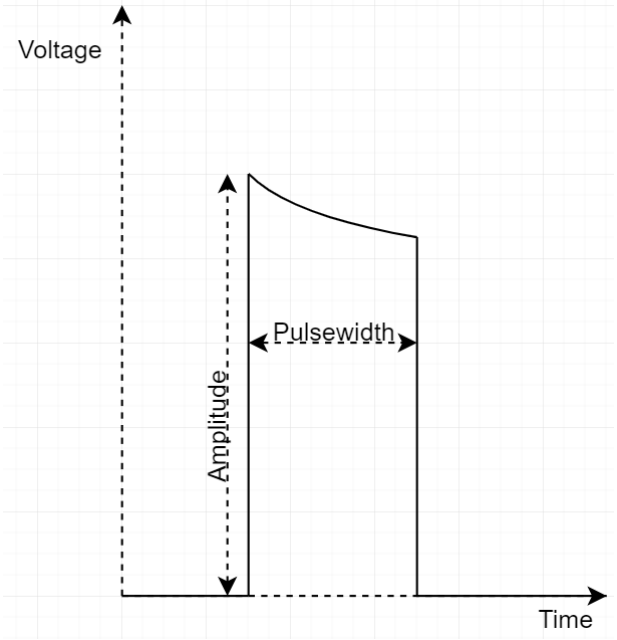


Figure 13: Pulse Shape

Sensitivity ranges from 0.45mV to 11.3mV. The default value is 2mV.

I. Battery Specifications

The battery in the Calyan pacing system is a Lithium / Thionyl Chloride Battery. The usable capacity of the power source is 600mAh based on statistical testing. The current consumption when pacing into 500 Ω ± 1% loads, VVIR, at 4V is 30µA +/- 20%, the current consumption when inhibited is 9µA +/- 20%.

Battery Performance Specifications

Parameter	Unit Value
Nominal Open Circuit Voltage, 25°C	3.67V
Nominal Working Voltage, 25°C	3.5V
Nominal Capacity, 25°C	750 mAh (600 mAh based on statistical testing)
Volume	0.1625 cubic inches
Weight	6.8 g
Operating Temperature	-40°C to +95°C
Case Material	304 Stainless Steel, Hermetically Sealed (case positive polarity) Terminal and Support Pins are .030" dia. (solder tinned)
Cell Type	Lithium Thionyl Chloride

Table 12: Battery technical specifications

Dimensions and Weight

Parameter	Measurement
Width/Diameter (Inches)	0.65
Length/Depth (Inches)	1.00
Weight (grams)	6.8
Height/Thickness (Inches)	0.26

Table 13: Battery dimensions and weight

a) Longevity Table

The nominal projected service life under the following conditions (Pacing %: 100%, Pacing Rate: 60 BPM, Pulse Amplitude: 5V, Impedance 600 Ω, Pulse Width: 400 ms) is 2.1 years.

Pacing Mode	VVIR pacing %	Amplitude [V]	Pacing Rate [bpm]	Impedance [Ω]	Pulse width [µs]	Estimated Longevity [years]
VVI	0	2.5	60	600	400	14.5
VVIR	0	2.5	60	600	400	11.8
VVI	50	2.5	60	600	400	4.9
VVIR	50	2.5	60	600	400	4.7
VVIR	50	5	60	600	400	3.3
VVIR	50	8	60	600	500	2.2
VVI	100	2.5	60	600	400	3.4
VVIR	100	2.5	60	600	400	2.9
VVIR	100	5	60	600	400	2.2
VVIR	100	8	60	600	500	1.2
VVI	100	2.5	60	400	400	3.1
VVI	100	2.5	60	1000	400	3.3
VVIR	100	2.5	60	400	400	2.6
VVIR	100	2.5	60	1000	400	2.7

Table 14: Calyan VVIR Single Chamber Pacemaker Longevity Table

Note:

- Longevity reduction for 18 months of storage is 3%
- Assumption is 600 mAh usable capacity for battery

7. Contact Information

Calyan employs highly trained representatives and engineers to serve you and, upon request, to provide training to investigational sites personnel in the use of Calyan products. In addition, Calyan maintains a professional staff of consultants to provide technical consultation to product users. For more information, contact your local Calyan representative at the address below:

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7300 Hudson Blvd N, Oakdale, MN 55128 Suite 290
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