VVIR Single Chamber Pacemaker Delivery System

Instructions For Use

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 Calyan VVIR Single Chamber Pacemaker Delivery System. For a comprehensive overview of the Calyan VVIR Single Chamber Pacemaker System and implant procedure, refer to the Calyan VVIR Single Chamber Pacemaker System IFU.

b) 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

c) 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

d) Explanation of Symbols

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

Symbol	Explanation
	Model Number
	Lot # / Batch Code
	Manufacturer

	Consult Instructions for Use
	Shipp non-sterile

Table 1: Explanation of Packaging/Labeling Symbols

e) Abbreviations and Terminology

Term	Description
Programmer	Calyan Programmer Application
Device	Calyan VVIR Single Chamber Pacemaker device
PDS	Pacemaker Delivery System
BPM	Beats per minute
HR	Heart Rate
IFU	Instructions For Use
EFS	Early Feasibility Study

Table 2: Explanation of Abbreviations and Terms

2. Pacemaker Delivery System Description

The pacemaker delivery system consists of a series of tools for creating a pocket in the patient's tissues under the xiphoid/sternum, properly placing the pacemaker in the pocket with the FlexArm in contact with the heart's anterior pericardium and anchoring the pacemaker to the xiphoid/sternum. The instruments are shipped non-sterile in individual poly bags inside a shipping container. The hospital must clean, and steam sterilize the Pacemaker Delivery System, prior to conducting an implant procedure.

The Primary Dilator tool is used to create a pathway within the chest cavity under the xiphoid to the anterior pericardium. The Secondary Dilator tool is used to widen the initial pathway in the sub-xiphoidal plane to allow device delivery. The final Delivery Tool is used to place the FlexArm to the surface of the heart and affix the device's Clip to the xiphoid.

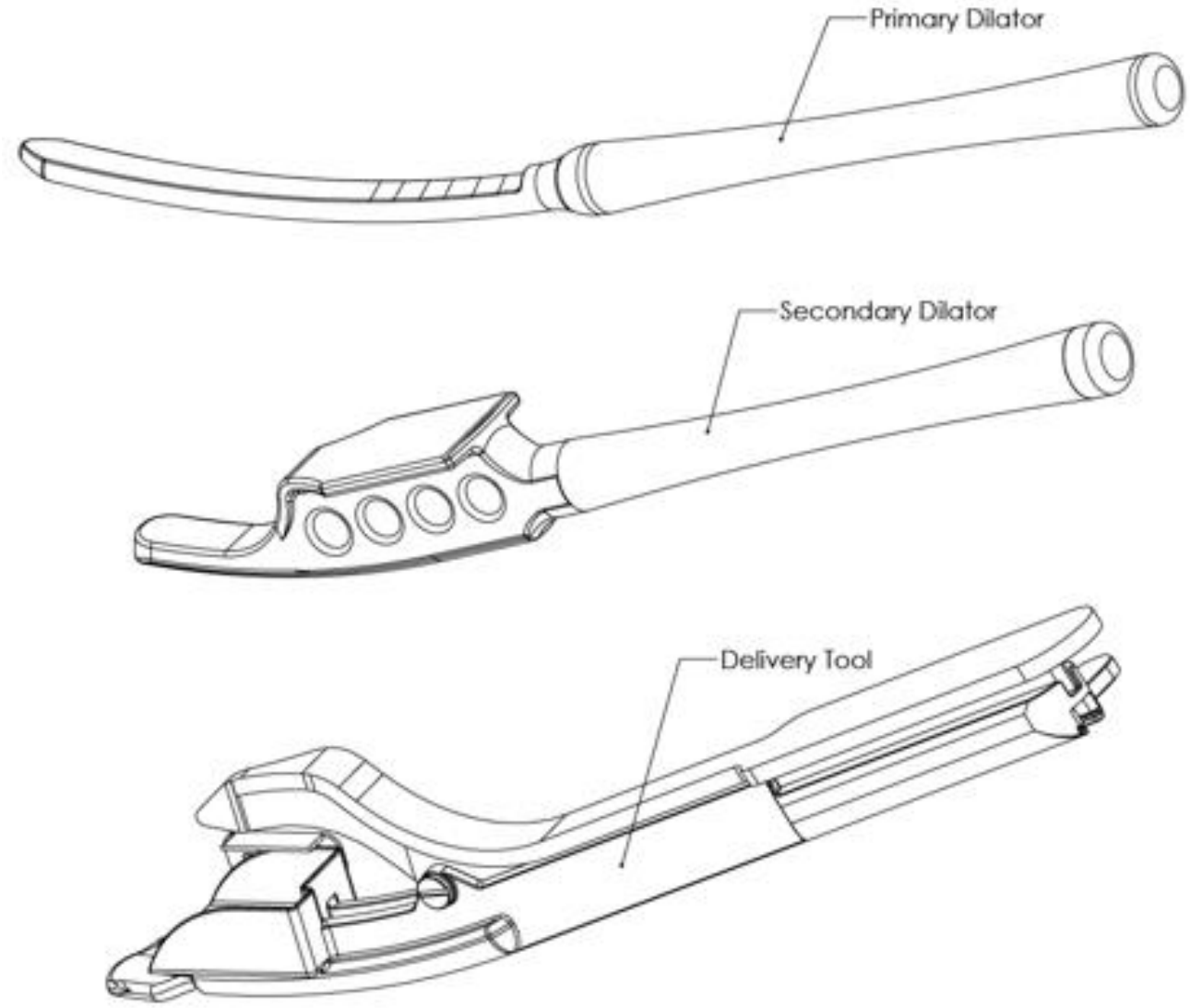

Figure 1: Calyan Pacemaker Delivery System

I. Primary Dilator

The Primary Dilator tool is used for the initial blunt dissection to create a pathway within the sub-xiphoidal space to the anterior pericardium. There are six reference marks on the Primary Dilator which are used to aid the depth of the initial blunt dissection.

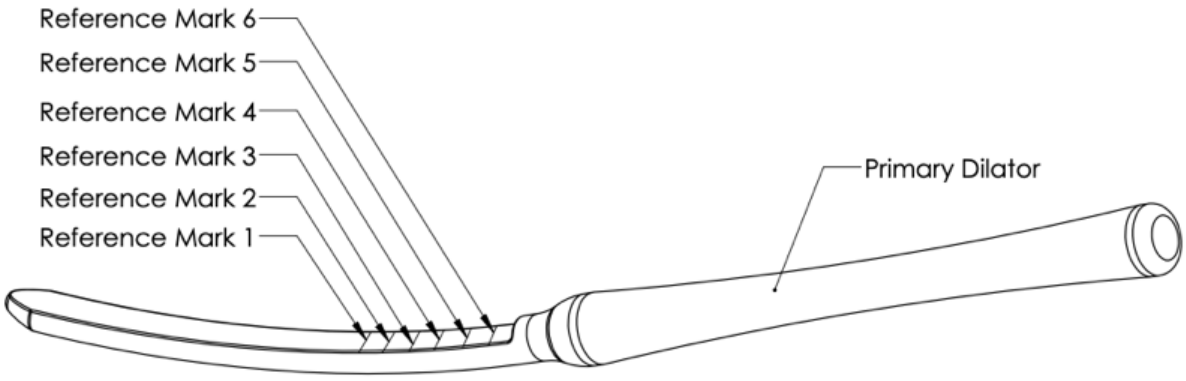

Figure 2: Primary Dilator

II. Secondary Dilator

The Secondary Dilator tool is used for the secondary blunt dissection to create additional pocket space within the sub-xiphoidal plane. This pocket space serves as an area for the device to reside. There is one reference mark on the Secondary Dilator which is used to aid the depth of the secondary tunneling step.

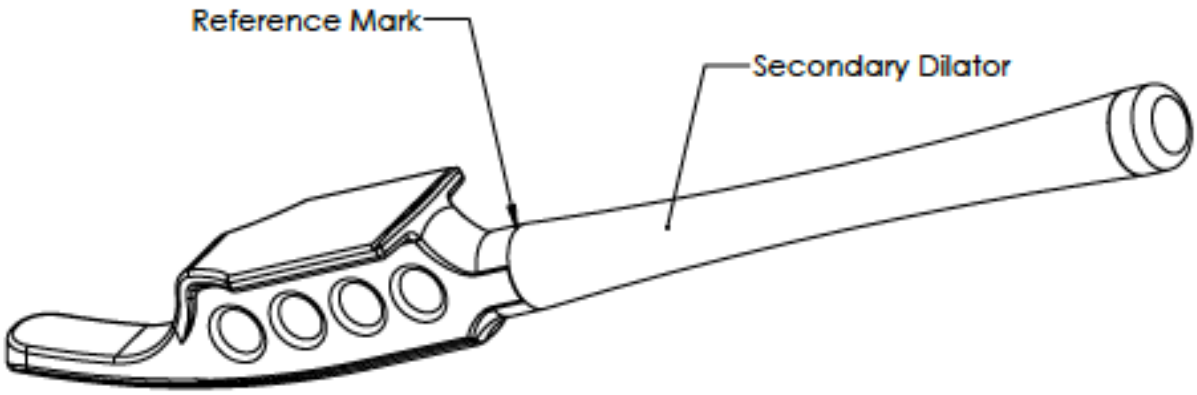

Figure 3: Secondary Dilator

III. Delivery Tool

The Delivery Tool is used to load and deliver the device within the sub-xiphoidal plane and anchor the device to the patient's xyphoid/sternum. The Delivery Tool allows the device to be inserted into the incision and navigated to allow the FlexArm to reside over the anterior pericardium. The Delivery Tool has an Extendable Tongue that facilitates cradling of the FlexArm during the implant procedure. The Extendable Tongue can be retracted and extended via the Slider tab. The Actuator lever enables the anchoring of the device to the patient's xyphoid /sternum by compressing the device clip down.

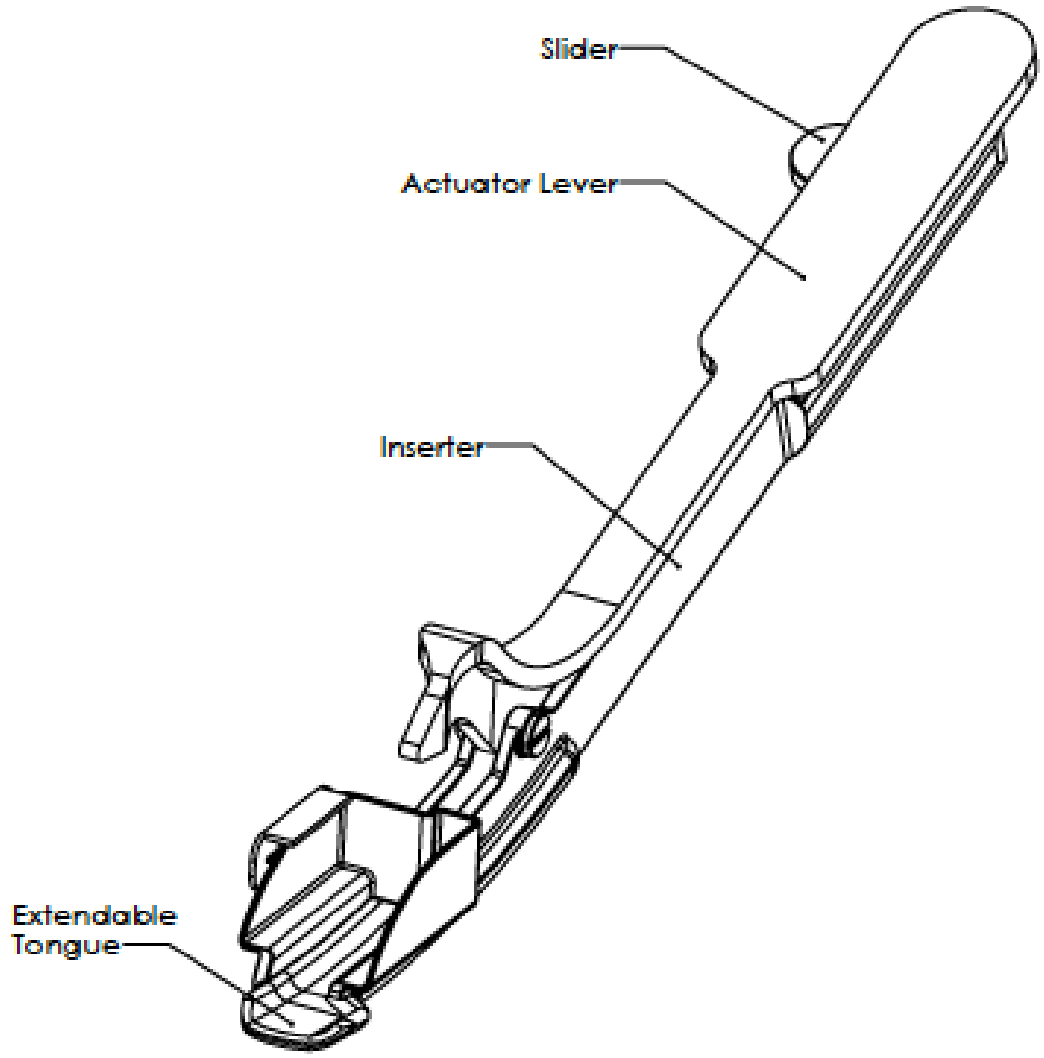

Figure 4: Delivery Tool

I. Handling and Storage Instructions

Carefully observe these guidelines when handling or storing the Pacemaker Delivery System.

Checking and opening the package – Before opening the poly bag, visually check for any signs of damage. If any of the instruments look to be damaged, contact a Calyan representative.

If the package is damaged – The package consists of three instruments each individually bagged in a poly bag. If there is any sign of damage, do not use the instruments and contact a Calyan representative.

Sterilization – Calyan has not sterilized the instruments before shipment. The instruments are re-usable and intended to be re-sterilized between implant procedures.

Re-use – When re-using the Pacemaker Delivery System, ensure the tools are cleaned and re-sterilized according to the cleaning and sterilization protocols provided below.

Handle with care – When handling the Delivery Tool, handle with care

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

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

II. Contraindications

Refer to the Calyan VVIR Single Chamber Pacemaker System IFU for a full list of contraindications.

3. Warning, Precautions, and potential Adverse Events

Refer to the Calyan VVIR Single Chamber Pacemaker System IFU for a full list of Warnings, Precautions, and potential Adverse Events.

Warning: Ensure the Pacemaker Delivery System is cleaned prior to starting the implant procedure.

Warning: Ensure the Pacemaker Delivery System is sterilized prior to starting the implant procedure.

Warning: If any of the instruments appear damaged upon visual inspection, please return to Calyan.

Warning: Ensure all parts of the instruments are cleaned prior to starting an implant procedure.

Warning: Ensure all parts of the instruments are steam sterilized prior to starting an implant procedure.

Warning: Use appropriate routine safety procedures in handling the test articles during cleaning and steam sterilization

4. Implant and Post Implant Considerations

The Calyan Pacemaker 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. It is recommended that implantation of the Calyan pacemaker 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. Ensure that you have all of the necessary instruments, system components, and sterile accessories to perform the implant procedure successfully. Refer to the Calyan VVIR Single Chamber Pacemaker System IFU for an overview of the implant procedure.

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

5. Cleaning & Steam Sterilization

Based on the clinical indications for use, the device set will likely become contaminated by direct contact with surgical field along with touching and handling of the device set during use. The primary contaminant will likely be blood and other soluble protein-based liquids (serum). Surgical debris and tissue are additional other potentially infectious material the device set may encounter during use.

The Pacemaker Delivery System must be manually cleaned according to the Cleaning and Steam Sterilization instructions. The required tools and materials for cleaning and steam sterilization are:

- Enzol Enzymatic Detergent
- Soft bristled brush
- Clean cloth
- Cardinal Health (or equivalent) Self-Sealing Sterilization Pouch. Use a pouch that is close in size to the device set.

- Steam autoclave that is calibrated and complies with medical industry guidance and standards

I. Manual Cleaning Steps

Follow the cleaning instructions outlined in Table 3: Manual Cleaning Instructions:

Step Number	Cleaning Instructions
1	Soak the devices in cold water for 5 minutes to loosen any adhered material.
2	Use a soft cleaning brush and clean the devices under cold running tap water.
3	Prepare a neutral pH enzymatic detergent, Enzol® at 1oz per gallon using lukewarm tap water. Note: Label instructions indicate 2-minute soak time.
4	Rinse and flush the devices with lukewarm RO/DI water for one minute
5	Dry the devices using a clean cloth

Table 3: Manual Cleaning Instructions

Note: Observe the devices for any signs of damage post cleaning and sterilization, if damaged please contact a Calyan Representative.

II. Steam Sterilization Steps

After completing the Manual Cleaning steps, follow the packing instructions outlined in Table 4: Pre-Vacuum Steam Sterilization Instructions:

Step Number	Instructions
1	After cleaning, each device will be individually placed into a Cardinal Health Self-Sealing Sterilization Pouch. Label each packaged device to maintain traceability. **Note: Use a pouch that is close in size to the device set.**
2	The packaged devices will be positioned on the bottom shelf of the autoclave. The autoclave will be set to the parameters outlined below in Table 5.

Table 4: Pre-Vacuum Steam Sterilization Instructions

After completing the Pre-vacuum packing instructions, follow the Steam Sterilization Cycle specifications as outlined in Table 5: Autoclave Cycle Specifications.

Cycle Type	Cycle Time	Temperature	Over Temp.	Pulses	Drying Time
Pre-vacuum	3 minutes	134 ºC	3 ºC	4	30 minutes

Table 5: Autoclave Cycle Specifications

Note: The temperature during the full cycle may vary by + 3 °C.

Note: Observe the devices for any signs of damage post cleaning and sterilization, if damaged please contact a Calyan Representative.

6. Pacemaker Delivery System Technical Specifications

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 6: Pacemaker Delivery System Technical Specifications

7. Contact Information

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