

SHREE PACETRONIX LTD

TEMPORARY BIPOLAR PACING LEAD

MODEL: JL-1



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Revision History

Revision	Date	Change Description
00	Oct 15 th , 2019	IFU
01	August 21 st , 2020	Reviewed Specification , Added more Information

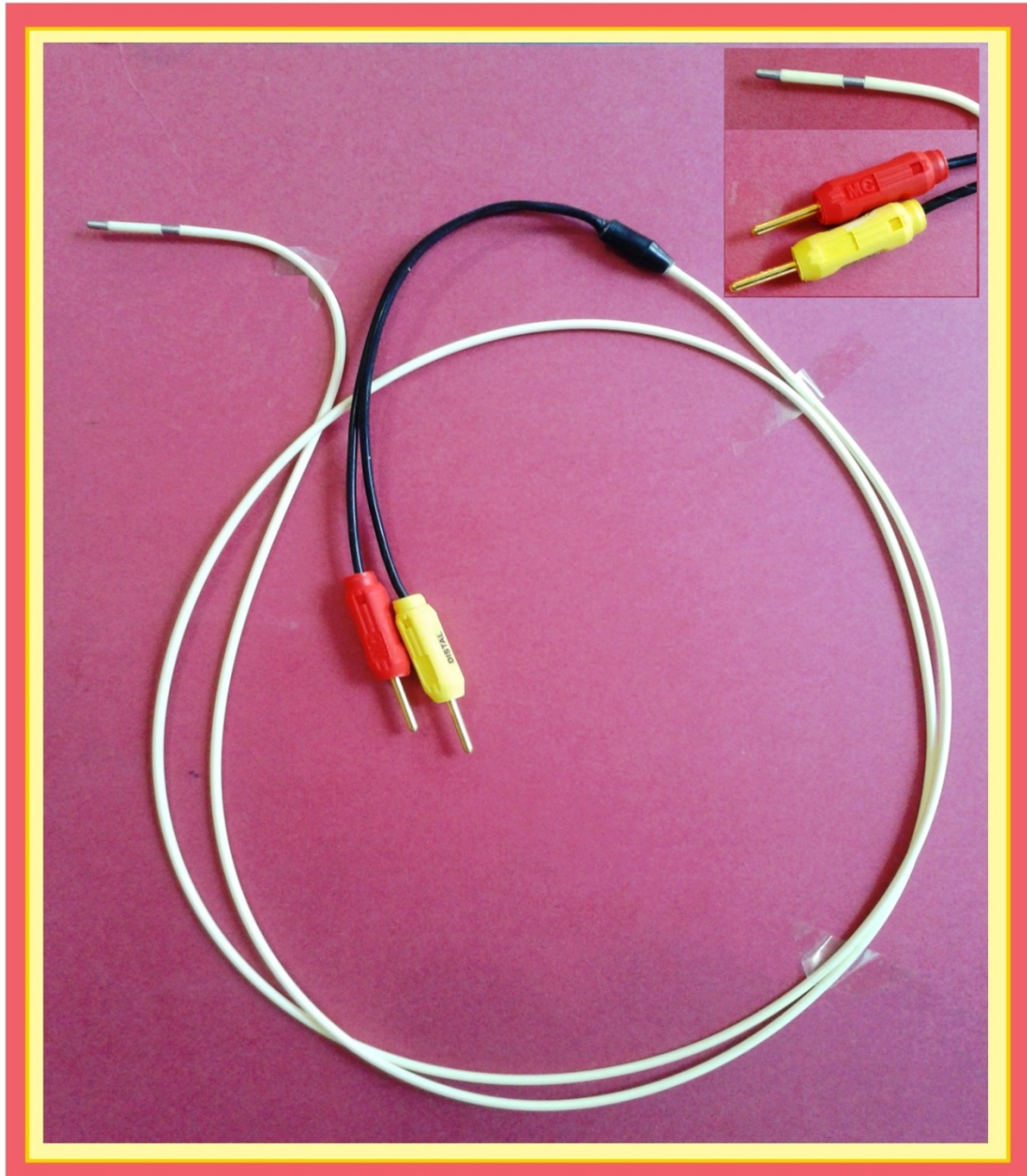
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1. INTRODUCTION:

Temporary Bipolar Pacing Lead, Model JL -1 used for temporary ventricular or atrial pacing in conjunction with a External pacemaker. Temporary Bipolar Pacing Lead, Model JL -1 is a 6 French lead, used for temporary stimulation of the heart in emergency cases of bradycardia.

PICTURE: TEMPORARY BIPOLAR PACING LEAD MODEL JL-1



2. SPECIFICATION:

01 : Technical data

Physical Characteristics		
1.	Polarity	Bipolar
2.	Shape	'J' Shape
3.	Chamber	Ventricle
4.	Length	114 ± 0.5cm
5.	Connector	Shrouded 2 mm Pin
6.	Weight	9.3 ± 0.5 gms
Material		
7.	Insulation Material	Polymide, Radiopaque
8.	Tip Electrode (Heart end side)	SS (Medical grade)
9.	Bush Electrode (Heart end side)	SS (Medical grade)
Diameter		
10.	Lead Body	2.0 ± 0.05 mm
11.	Tip Electrode (Heart end)	1.8 ± 0.05 mm
12.	Bush Electrode (Heart end)	1.8 ± 0.05 mm
Introducer size & Electrode configuration		
13.	Suggested introducer size	6F
14.	Tip electrode configuration (Heart end)	Passive Fixation
15.	Tip electrode Shape (Heart end)	Cylindrical
Surface Area		
16.	Tip surface area	19.0 mm ²
17.	Ring Electrode surface area	25.0 mm ²
Other Characteristics		
18.	Tip to Ring electrodes spacing	7.0 ± 0.05 mm (Heart end)
19.	Unipolar Conductor Resistance	50 ± 5 ohms (Inner)
20.	Bipolar Conductor Resistance	50 ± 5 ohms (Outer)
21.	Fixation	Passive

02: Package Contents

 Temporary Bipolar Pacing Lead, Model JL -1

— This product is packaged sterile (ETO-sterilization) and non-pyrogenic.

3. INSTRUCTIONS FOR USE

TEMPORARY BIPOLAR PACING LEADS, Model JL-1

CAUTION

Prior to implanting the pacing lead, the clinician should become thoroughly familiar with the information given in these instructions and with the warnings against improper use of the leads.

PRODUCT DESCRIPTION

The Temporary Bipolar Pacing Lead Model JL-1 is intended for temporary atrial and ventricular pacing and sensing for contemplated implant duration of 7 days or less. The device is supplied sterile and is intended for SINGLE USE ONLY.

CONTRAINDICATIONS

There are no known general contraindications to temporary post-surgical pacing. The particular medical condition and anatomy of the patient, however, may dictate the lead system and implantation procedure to be used.

WARNINGS

An implanted Temporary Bipolar Pacing Lead Model JL-1 forms a direct current path to the myocardium. During pacing lead insertion and testing, use only battery-powered equipment specially designed for this purpose, to protect against fibrillation that may be caused by alternating currents.

Line-powered equipment used in the vicinity of the patient must be properly grounded.

Temporary Bipolar Pacing Lead Model JL-1 connector pins must be insulated from any leakage currents that may arise from line-powered equipment.

Avoid the possibility of unintentional contact between the pacing lead(s), including extension cable, and any equipment used as well as any conductive surface contact.

Leaving the lead implanted for longer than 7 days may result in difficulty or inability to extract the lead and/or bleeding.

POTENTIAL COMPLICATIONS

The possibility of dislodgement, lead fractures, threshold elevation and sensing inconsistency exists. Other potential complications include, but are not limited to, myocardial irritability, septicaemia and myocardial infections, myocardial bleeding and damage, especially during removal of the pacing lead(s).

PRECAUTIONS

It is recommended that defibrillation equipment is readily available during temporary pacing lead insertion and removal.

The packaging should be inspected prior to use. Should the seal or package be damaged, contact the local representative.

This product should not be exposed to temperatures above 60°C (140°F)

PACKAGING






The sterile packaging for the Temporary Bipolar Pacing Lead Model JL-1 consists of a double pouch configuration. The inner pouch (or package liner) and outer pouch materials are transparent tyvek – polyethylene laminate. The pouches are heat sealed.

RESTERILIZATION

The Temporary Bipolar Pacing Lead Model JL-1 has been ethylene-oxide sterilized prior to shipment. Do not resterilize. Expired products shall be discarded.

INFORMATION ON PACKING








The following information will be provided on the packing of each Temporary Bipolar Pacing Lead Model JL-1 –

-  Model number
-  Serial number
-  Use before date
-  Sterilization Lot number
-  Length

The contents of the package have been sterilized by ethylene oxide gas.

Storage: This product should not be exposed to temperatures above 60°C (140°F)

4. EXPLANATION OF SYMBOLS

Symbol							
English	Lot No.	Serial No.	Sterilization date	Expiration date	Ethylene Oxide Sterilized	Single Use only	Refer to instructions for use

5. TECHNICAL SERVICE

If you have any other questions or would like more information about your Temporary Bipolar Pacing Lead Model JL-1, call Technical Services at the number below.

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Your local sales representative can also provide assistance.