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Instructions for Use

Temporary Cardiac Pacing Wire

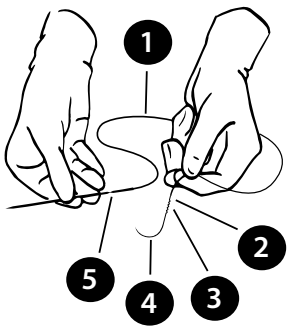
Description

This Temporary Cardiac Pacing Wire is a sterile single-use product. Temporary Cardiac Pacing Wires consist of the following configurations and optional accessories:

1. The monopolar leads consist of one insulated multifilament stainless steel conductor coated with colored polyethylene.
2. The intracorporeal end of the wire has a section of exposed, uninsulated wire electrode terminating with an attached stainless steel needle.
3. The exposed, uninsulated section of the intracorporeal end of the wire is either straight or has one or more multiple pre-formed curves (pre-formed wave).
4. The extracorporeal end of wire has a straight needle with breakaway tip attached.
5. The wire length is 60 cm.
6. Wires range in multiple diameters from 0 to 2-0, depending on the product code.

The lead consists of:

Item 1 - Insulated multifilament conductor coated with colored polyethylene.



Item 2 - Uninsulated, multifilament wire (intracorporeal) electrode.

Item 3 - Optional wave pre-formed into the uninsulated, intracorporeal wire end.

Item 4 - Intracorporeal curved needle.

Item 5 - Extracorporeal straight breakaway needle.

Temporary Cardiac Pacing Wire is intended for use only by healthcare professionals who are trained in the use of this device.

The clinical benefit to be expected is that the temporary epicardial cardiac pacing wire along with an appropriate generator and monitoring system aids in the diagnosis and treatment of some cardiac arrhythmias.

A summary of safety and clinical performance can be found at the following link (upon activation): https://ec.europa.eu/tools/eudamed

Indications / Intended Use

Temporary Cardiac Pacing Wire is intended for use in temporary epicardial cardiac pacing or monitoring and should be removed after temporary pacing has been discontinued.

Contraindications

Use of Temporary Cardiac Pacing Wires is contraindicated for permanent cardiac pacing or for monitoring.

Patient Target Group(s)

Temporary Cardiac Pacing Wire is to be used for those in which temporary cardiac pacing or monitoring is required for monitoring or treatment of cardiac arrhythmias or in cardiac surgeries in which postoperative arrhythmias may be anticipated.

Warnings

- If a connection cable (not supplied) is being used between the pacing wire and the pacemaker and temporary disconnection is necessary, be careful to disconnect the connecting cable in such a way as to prevent damage to the pacing wire itself or accidental dislodgment of the pacing wire from the myocardium.

- An implanted Temporary Cardiac Pacing Wire provides a low-resistance electrical connection to the myocardium. Particular care is therefore required when other devices liable to generate electrical energy are used concurrently (e.g., defibrillators, electrosurgical devices, and other devices that generate electromagnetic frequency). Follow the relevant instructions for use.
- The use of a transmit/receive RF body coil to perform an MRI examination in a patient with the Temporary Cardiac Pacing Wire may cause injury due to excessive MRI-induced heating.
- The pacing wires must be placed in the myocardium and trimmed in such a way that the risk of injury when placing and extracting the pacing wires is minimized.
- Do not resterilize/reuse. Reuse of this device (or portions of this device) may create a risk of product damage that may result in device failure and/or cross-contamination that may lead to infection or transmission of blood-borne pathogens to patients and anyone coming in contact with the device.
- Discard unintentionally opened / partially used / used devices and packages.

Other potential complications of temporary cardiac electrical pacing include:

- Impairment or loss of sensing due to lead dislodgment, or fracture, changes in the myocardium, or failure of the pulse generator.
- Increased pacing threshold or loss of pacing due to lead dislodgment or fracture, changes in the myocardium, or failure of the pulse generator.
- Arrhythmias due to myocardial irritability.
- Infections, which can be systemic, local, or myocardial.
- Bleeding or myocardial damage.

Precautions

Before using the Temporary Cardiac Pacing Wire, it should first be established that this device is compatible with all products from other manufacturers that may be required for use. This particularly applies when checking the safety of the connection between pacing wire and pacemaker or pacemaker cable. Failure to do so may result in treatment failure.

Care should be taken regarding the following:

- Avoid disruption of the polyethylene coating or damage to the conductive wire, i.e., by twisting, manipulation with instruments, or by tying knots.
- Avoid any possible unintentional contact between the Temporary Cardiac Pacing Wire and any equipment.
- Particular care should be taken to ensure that no components which might touch each other, and conduct electricity are present at the junction (e.g., projecting needle tips).
- Ensure that all the electrical junctions between the pulse generator and Temporary Cardiac Pacing Wire(s) are intact to provide optimum performance, following relevant instructions for use where applicable.
- Care should be taken to avoid damage when handling surgical needles. When positioning the curved needle in the needle driver, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the attachment end to the point. Grasping in the point area could impair the penetration performance and cause fracture of the needle. Grasping at the attachment end could cause bending or breakage. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking.
- Healthcare professionals should exercise caution when handling surgical needles to avoid inadvertent needle stick injury that may result in transmission of blood-borne pathogens from contaminated needles. Broken needles may result in extended or additional surgeries or residual foreign bodies. Use caution when handling the straight needle and snapping off the snap off portion of the straight needle to avoid needlesticks. In the event of a product malfunction before use, such as a bent, broken or detached needle, or suture damage, the product should be discarded and a new one obtained to begin the procedure. In the event of product malfunction during use, it is up to the discretion of the healthcare professional whether to continue or discontinue usage of the product and how to complete the procedure.

Adverse Reactions / Undesirable Side Effects

Adverse reactions associated with the use of this device include allergic response in some patients with known sensitivities to stainless steel or constituent metals (such as chromium and nickel), minimal initial inflammatory tissue reaction, and transient local irritation at the wound site. Like all foreign bodies, stainless steel may potentiate an existing infection.

Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of blood-borne pathogens.

Healthcare professionals should convey adverse reactions, undesirable side effects and risks associated with the product and the procedure to the patient and advise the patient to contact a healthcare professional in case of any deviation from the normal postoperative course.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the country-competent authority.

Magnetic Resonance Imaging (MRI) / Carcinogenic, Mutagenic, Toxic to Reproduction (CMR) / Endocrine Disrupting (ED) Safety Information

MR Conditional

This Temporary Cardiac Pacing Wire is MR Conditional. Conditions outlined below apply for imaging with a transmit/receive head coil. Any imaging using the Body Transmit Coil (e.g., utilizing receive-only coils such as head array, spine array, etc. coils) may result in serious injury to the patient. A patient with this device can be scanned safely, immediately after placement under the following conditions:

- Static magnetic field of 1.5 Tesla or 3 Tesla, only.
- Maximum spatial gradient magnetic field of 1000 gauss/cm (extrapolated).
- Transmit/receive RF head coil, only.
- Maximum MR system reported, transmit/receive RF head coil specific absorption rate (SAR) of 3.2 W/kg for 15 minutes of scanning (i.e., per pulse sequence).
- Normal Operating Mode of operation for the MR system.

In non-clinical testing and numerical modeling, the Temporary Cardiac Pacing Wire produced a temperature rise of less than 0.5°C at a maximum MR system calculated transmit/receive RF head coil SAR of 3.2 W/kg in 1.5 Tesla/64 MHz and 3 Tesla/128 MHz MR systems.

Additional MRI Safety Information

- Do not perform an MRI procedure if the Temporary Cardiac Pacing Wire is damaged or otherwise not functioning properly.
- The Temporary Cardiac Pacing Wire must be disconnected from the pulse generator prior to entry into the MR system room and the ends of the leads should be properly secured to prevent movement.
- The proximal electrode must be electrically isolated from the patient during MRI. This insulation could be achieved with a gauze pad or similar method.
- The use of a transmit/receive RF body coil to perform an MRI examination in a patient with the Temporary Cardiac Pacing Wire may cause patient injury due to excessive MRI-induced heating.

Image Artifact Information

In non-clinical testing, the image artifact caused by the Temporary Cardiac Pacing Wire extends approximately 20 mm from this device when imaged using a gradient echo pulse sequence and a 3 Tesla MR system.

CMR and ED Safety Information

No known CMR Category 1a/1b and ED substances are present at >0.1%. Category 1a/1b are defined as known or presumed human carcinogen (H340), mutagen (H350) or reproductive toxicant (H360) based on human evidence and animal studies.

Application / Instructions for Use

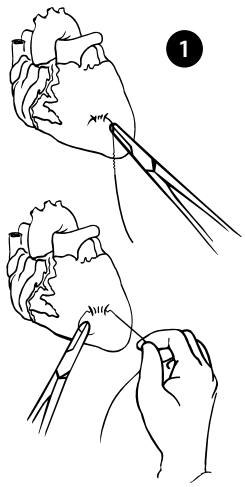
Removing Pacing Wires from Package

Temporary Cardiac Pacing Wire is offered in various horizontal and vertical configurations with 12 or more pouches per box. After removing the plastic outer wrap, open the box and select one Temporary Cardiac Pacing Wire(s) pouch. Over the sterile field, carefully peel back the clear polymeric portion of the pouch and withdraw the paper folder. Open the paper folder by lifting the tab(s). Then remove the device(s) to the sterile field. Avoid disruption of the polyethylene coating or damage to the conductive wire, i.e., by twisting, or by manipulation with instruments.

Intracorporeal Placement (Applicable to All Pacing Wires)

The intracorporeal end of the Temporary Cardiac Pacing Wire is attached to the myocardium as indicated by surgical circumstances, clinical judgment, and the preference of the operator. The Temporary Cardiac Pacing Wires should be placed in a position that allows uncomplicated removal and minimizes the risk of trauma when treatment is complete. The following is a suggested method for placement of the intracorporeal end(s) of the Temporary Cardiac Pacing Wire:

For all product types (non-color coded and color coded), healthcare professional clinical judgment determines the location and technique employed for wire placement. When applicable, the light and dark blue wire coatings may be helpful, after implantation, in differentiating the positive and negative wires or in differentiating atrial and ventricular wire placement.



Ventricular / Atrial Use

Utilize the curved needle on the intracorporeal end of the Temporary Cardiac Pacing Wire to place the wire into the myocardium. Care should be taken in the placement of the wire to minimize the risk of unintended trauma to tissue upon removal (Figure 1 for ventricular example). If a needle is not utilized on the intracorporeal end of the pacing wire or to minimize trauma to the tissue and facilitate easy removal,

the pacing wire can be brought into contact with the myocardium using a small loop of suture passed through the surface of the myocardium. Use scissors to cut excess exposed wire and the attached needle when present.

Optional Atrial Use

If the healthcare professional chooses, the following technique can be used to minimize trauma to the atrial tissue, provide close contact with the atrial tissue and facilitate easy removal: place the uninsulated wire in a fold created on the epicardial surface of the atrial tissue using a suture loop. Use scissors to cut excess exposed wire and the attached needle when present.

Pre-Formed Wave Use

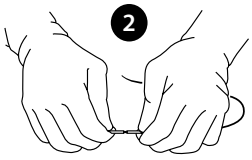
For wires that include the optional pre-formed wave in the exposed wire of the intracorporeal end, the wave should be gently pulled into and left embedded in the myocardium. Use scissors to cut excess exposed wire and the attached needle when present.

Extracorporeal Placement (Applicable to All Pacing Wires)

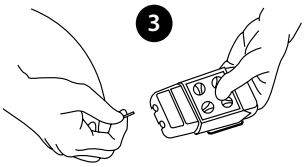
The extracorporeal end(s) of the Temporary Cardiac Pacing Wire is managed as indicated by surgical circumstances, clinical judgment, and the preference of the operator. The following is a suggested method for placement of the extracorporeal end(s) of the Temporary Cardiac Pacing Wire:

The extracorporeal end of the Temporary Cardiac Pacing Wire is brought through the chest wall using the attached needle.

For products with Straight Breakaway extracorporeal needles, there is no exposed wire at the point of swage and the straight needle is scored, eliminating the need to cut the needle off.



The needle is broken off at the score mark (Fig. 2) to create a connector pin (stainless steel electrode).



The connector pin is attached to the connecting cable of the pacemaker or as determined by clinical need, directly to the temporary pacing unit or monitoring unit per the manufacturer's instructions (Fig. 3).

Note: If a pacemaker will be attached later, clinical judgment should be exercised to determine the optimal means of isolating the electrodes in such a way that no exposed metal remains.

Important: Before using the cardiac pacing wire, it is necessary to check that the Temporary Cardiac Pacing Wire electrode and the pacemaker cable or pacemaker device are fully compatible. The electrode, once the needle is broken off, is 20 to 38 mm length by 0.7 to 1.0 mm diameter, depending on the product code. Particular care should be given to ensuring that no components which could conduct electricity might touch each other at the connection point (e.g., projecting needle tips).

Removal of Temporary Cardiac Pacing Wire

The Temporary Cardiac Pacing Wire is removed as indicated by surgical circumstances, clinical judgment, and the preference of the operator. The following is a suggested method for removal of the intracorporeal end(s) of the Temporary Cardiac Pacing Wire:

When temporary pacing has been discontinued, the lead can be removed with gentle traction. Care should be taken to prevent traction on the lead that may cause inadvertent premature removal.

Discard needles in "sharps" containers. Discard unintentionally opened / partially used / used devices and packaging according to your facility's policies and procedures concerning biohazardous materials and waste.

Performance / Actions

The Temporary Cardiac Pacing Wire provides a conductive connection between an external pacemaker and the myocardium.

Electrical parameters for Temporary Cardiac Pacing Wires:

- Lead conductor resistance (9.1 ± 2.1 Ω)

Temporary Cardiac Pacing Wire is a short-term surgically invasive device with a useful clinical life that covers the acute postoperative period to less than 30 days. It is then removed from the patient.

Sterility

The product is sterilized by irradiation. Do not use if the package is damaged or opened. Discard opened, unused product. Do not resterilize.

Storage

No special storage conditions required. Do not use after the expiry date.

How Supplied

Please note that not all sizes are available in all markets. Please contact your local sales representative for size availability.

Temporary Cardiac Pacing Wire is available in one dozen units per box.

Traceability

The following specific information can be found on the device packaging label: Catalogue number, Batch Code, expiry and manufacturing date, manufacturer name, address and the website and a Unique Device Identification bar code with the Global Trade Item Number information.

Symbols Used on Labeling

REF	Catalogue number
MD	Medical Device
	Do not use if package is damaged
	Caution
	Do not re-use
	Do not resterilize
	Single sterile barrier system with protective packaging inside
STERILE R	Sterilized using irradiation
LOT	Batch code
	Date of manufacture
	Use-by date
UDI	Unique Device Identifier
	Manufacturer
EC REP	Authorized Representative in the European Community
	Packaging unit
	Electronic Instructions for use (e-IFU) website link. EU: Call paper on demand help desk to get paper copies free of charge within 7 days.
MR	MR Conditional