

MYO/WIRE® ULTRA-FLEX TEMPORARY PACING WIRES

PRODUCT DESCRIPTION:

A temporary cardiac pacing wire is an electrical connection between the heart and equipment used to monitor the heart's activity or provide external pacing signal to the heart. The electrical connection consists of two wires, a positive and a negative lead. The leads are attached to the heart surface during surgical procedures and the opposite ends are passed through the chest wall exterior to the body. The exterior end is then connected to the monitoring or pacing equipment using various adapters or connectors. Based on patient need and user preference, one of the leads may be placed externally on the skin to complete the electrical connection. Once the electrical connection is complete, monitoring and pacing is possible.

Temporary cardiac pacing wires are offered in various configurations to facilitate different attachment methods. Atrial attachments (epicardial) are configured for surface suturing. Ventricular attachments (intramyocardial) are configured for intramuscular insertion with various curved need options. (See illustration below.) Skin attachments (Indifferent leads) are configured with either a straight or curved needle for inserting through the skin. Temporary cardiac pacing wires are single use, sterile, and disposable.

INDICATIONS FOR USE:

MYO/WIRE®s are indicated as a connection between temporary cardiac pacing or monitoring equipment and the heart. Only trained surgeons or surgical personnel should implant the wire. The basic operating principle is that of an insulated electrical cable.

CONTRAINDICATIONS:

Not to be used when an internal pacemaker is implanted in the patient.

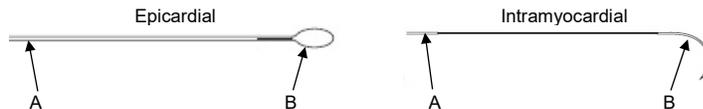
WARNINGS:

- DO NOT ALLOW THE CONNECTOR TO CONTACT ANY EQUIPMENT OTHER THAN THE CARDIAC PACING OR MONITORING UNIT. Only trained medical personnel should handle the pacing wire connector (stub of straight needle). The connector is a direct low resistance electrical path to the heart. Care must be taken to protect the patient from potential fibrillation caused by random leakage currents or electrostatic discharge contacting the connector.
- Do not reuse. Known risks of re-use include device contamination, material degradation, malfunction, and patient/user injury.

PRECAUTIONS:

- Do not use if the product pouch is damaged or open. Product may not be sterile.
- Defibrillation equipment should be readily available during installation and removal.
- Removal of the pacing wires should only be performed by trained, experienced healthcare professionals who are aware of the potential risks associated with removal.

INSTRUCTIONS FOR USE:



- See **PRECAUTIONS**, open the pouch, remove the card. Open the card and extract the wire by pulling the attachment end (B).
- Use standard surgical technique to attach the wire into or on the heart muscle or skin site (Indifferent). Ensure that bare wire of the heart lead is in contact with the heart muscle in order to form the electrical connection. Care should be taken in the site selection to ensure that the wire will not entangle or interfere with grafts, ligatures, or any other item during its postoperative removal.
- 1 The epicardial tapered loop surface electrodes (M-22) can be secured by placing a suture around the electrode neck. Suture should be snug, not tight. Do not place suture through loop, this will prevent removal of the wire. Loop will compress and pass through the suture with gentle traction during removal.
- 2 The epicardial loop surface electrodes (M-21) can be secured with a non-tied continuous suture through the myocardium and wire loop. The suture will release during removal. The temporary pacing wire loop can be cut to permit removal if a suture is used to secure the loop to the myocardium.
- 4 For Ventricular and Skin (Indifferent) attachments, detach and discard the curved needle. Ventricular attachments are secured by the wings or are sutured to the myocardium so they may be removed after use. Indifferent attachments are sutured to the patient's skin
- 5 For heart attachments, pass the remaining wire through the chest or abdominal wall using the straight needle (A). It is important to select the exit point such that the wire is in alignment with the heart attachment so as to minimize forces on the myocardium during removal.
- 6 Snap off the straight needle where it is scored leaving the short stub end as a connector for the external pacing or monitoring equipment. Electrically insulate this connector with tape or other means when not in use. **SEE WARNING INFORMATION.**
- 7 MYO/WIRE®s can be used with external pacing or monitoring equipment which are able to accept the 1mm diameter stub connector.
- 8 Check the electrical connection to the heart prior to chest closure.
- 9 Prior to patient release from the hospital, remove the wire by use of gentle traction.

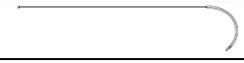
POTENTIAL SIDE EFFECTS:

- It is possible that the wires attached to the heart may move or become dislodged causing pacing threshold elevation, sensing inconsistency, or total failure to pace.
- Potential problems include, but are not limited to, irritation of or damage to the heart muscle, infection, bleeding, or tamponade especially during removal of the pacing wire.
- Skin attachments may become irritated or infected.

STORAGE:

The sterile package should be stored at room temperature not to exceed 50°C (120°F).

PRODUCT LABEL SYMBOLS

	Do not use if package is damaged		Intramycardial MYOWIRE® (M-24)
	Epicardial MYOWIRE® (M-20)		Intramycardial MYOWIRE® (M-25)
	Epicardial Loop MYOWIRE® (M-21)		Intramycardial MYOWIRE® (M-26)
	Epicardial Tapered Loop MYOWIRE® (M-22)		Indifferent Lead (M-27)
	Snap-off Keith Needle		Indifferent Lead (M-27) no curved needle
	Straight Needle		Reverse Cutting Needle Tip
W	White wire insulation color		Taper Point Needle Tip
O	Orange wire insulation color		1/2 Circle Needle
LO	Light orange insulation color		3/8 Circle Needle

The Instructions for Use and a comprehensive symbol glossary can be found at <http://www.aemedical.com/quality/>

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