Steelex® Electrode Set

Description
The Steelex® Electrode Set is a sterile, single use special surgical set for temporary electrostimulation after open-heart surgery, classified as CF defibrillation proof Type applied par according to IEC 60601-1. The Steelex® Electrode Set is intended to be implanted temporarily and must not remain in the patient's body long term. The Steelex® Electrode Set comprises of a stainless steel braided wire (AISI 316L), with a plastic isolating cover (Polyethylene). One end of the wire is armed with a 1/2 circle or 3/8 circle round-bodied needle and the other end is armed with a straight needle (break-off). The straight break-off needle also serves as the connection to the adapter cable (no. E4531, Pace Medical Inc.). The Steelex® Electrode Set is sterilized with ethylene oxide.

Indications
The Steelex® Electrode Set is intended for use in temporary cardiac pacing or monitoring.

Mode of action
Steelex® Electrode Set, a temporary non-absorbable electrostimulation set produces minimum tissue reaction.

Contraindications
The temporary cardiac pacing electrode is contraindicated when permanent stimulation is required. The temporary cardiac pacing wire should not be used in conjunction with permanently implantable pacemakers.

The use of a temporary pacing electrode is contraindicated for patients with an allergy to the electrode components.

The anatomy and state of the patient will determine the number of electrodes to be implanted and the implantation site.

Mode of application
It is necessary to inspect the Steelex Electrode Set before use and after implantation for any
visible damage of the insulation. The curved needle is passed through the myocardium once and the free end of the wire is cut off at the exit point of the myocardium. Once the needle is out of epicardium, cut the end assembled to the needle, making sure it is cut as short as possible avoiding a protruding end from the epicardium. The distance between the two electrodes has to be 2-3 mm for good pacing threshold.
The electrodes are then secured to the epicardium with a suture (USP 4/0 or 5/0), applying one stitch to the epicardium at the point where the cable is inserted into themyocardium.
The Steelex Electrode Set must be placed in such a way that the risk of injury when extracting the leads is
minimized.The straight break-off needle is passed through the thoracic wall. It is advisable to secure the electrode cable by suturing it to the skin.
Once the break-off needle is outside the patient's body, it is snapped off showing the pin connector of the electrode which is connected to the adapter cable. Ensure that the pins are well secured into the patient cable connector. Pick the cover connection box (figure 1; a), open it by pressing the lateral walls to release the lock and place the connector of the adapter cable, which is already connected to the electrodes, over the cavity shown in the interior of the box (the cavity is impressed in both lids) (figure 1; b). The box presents two apertures where the cables shall pass through: one aperture in the front for the electrodes cables (figure 1; c) and one aperture in the back for the adapter cable (figure 1; b). Ensuring the cables are correctly placed over the box apertures close the lid and press it to lock the box. Next connect the adapter cable to the external pacemaker which is limited to an output voltage of maximum 24 V AC/DC. Not to be connected to other power supply. The cardiac stimulation can then be initiated.

Before using the Steelex® Electrode Set it is necessary to check that the snap-off needle, the pacemaker cable and pacemaker device are fully compatible.

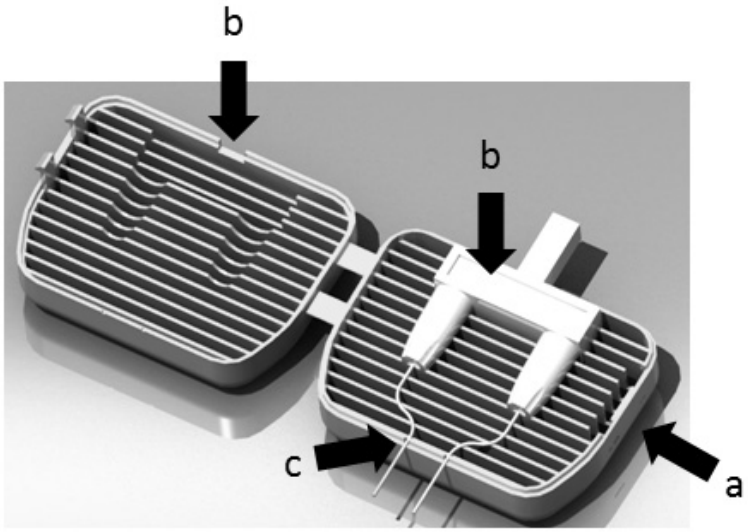

Figure 1. a) Press the wall to unlock. b) Cavity for the connector and back aperture to pass through the adapter cable. c) Front aperture to pass through the electrodes cables.

Prior to removal of the electrodes, ensure that the external pacemaker is switched off. Open the cover connection box by pressing the lateral and pick the adapter cable connector. Disconnect Steelex Electrode Set from the adapter cable. Remove Steelex electrode set one by one. Using aseptic technique first remove the suture stitch that was placed in the skin. Gently pull out the electrode until it is completely out of the patient. After removal check the integrity of the electrode to ensure that has been completely removed. The exit point in the skin can be covered by a small dressing. Remove Steelex® Electrode Set temporary cardiac pacing wire no later than 7 days following the implantation.

Performance

The temporary cardiac pacing wire provides a conductive connection between an external pacemaker and the myocardium.

Warning note

Only specially trained personnel should apply the temporary pacing electrodes and the adapter cables. Instructions for use for connecting Steelex Electrode Set to the adapter connector shall be followed precisely. Do not connect the Steelex electrode set directly to the pacemaker. The Steelex Electrode Set has to be first connected to an adapter cable (use exclusively Pace Line ™ Extension Cable E4231) and then the adapter cable to the pacemaker, avoiding any accidental contact with operator or other apparatuses. The white lead has to be connected to the ventricular channel, meanwhile the blue lead has to be connected to atrial channel.

Never insert the electrodes or the adapter cables into main sockets or electric accumulators.

Medical Electrical Equipment/accessories connected to Steelex Electrode Set shall comply with IEC 60601-1, type CF applied part. Before using the Steelex® Electrode Set it should be first established that this device is compatible with all products from other manufacturers which may be required for use. The connectors shall be checked to ensure there are no unattached ends of lead. If any are found, it indicates that the electrical connection is faulty: the adapter connector shall be opened and Steelex Electrode Set secured again.

An implanted temporary pacemaker electrode means a low-resistance electrical connection to the myocardium. Particular care is therefore required when other device liable to generate electrical energy are used concurrently (e.g. defibrillators, electrosurgical devices). Follow the relevant instructions for use. This applies in particular when checking the safety of the connection between electrode and pacemaker cable or pacemaker.

In order to achieve trouble free stimulation it is necessary to check using an appropriate method that the electrical uniformity of all the junctions between pulse generator and electrode is intact before handling the pacemaker, the adaptor cable and the Steelex electrode Set, steps shall be taken to equalize the electrostatic potential between the user and the patient, for example by touching the patient at a site remote from the Steelex Electrode Set.

The use of MRI is not allowed when Steelex Electrode set is implanted. Use of the mobile phone is not allowed.

When disconnection is necessary, the adaptor cable shall be first disconnected from the pacemaker and not from the Steelex Electrode Set.

For trouble free function of the electrode care should be taken to ensure that its insulation is not damaged or impaired, for example, by twisting the electrode.

The electrodes must be placed in the myocardium in such a way that the risk of injury when extracting the electrodes is minimized.

To avoid damaging needles points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should be careful when handling surgical needles to avoid inadvertent needle sticks. Discard needles in "sharps" containers.

Technical description
The Steelex Electrode Set is a temporary electro stimulation, classified as CF defibrillation proof Type applied part according to IEC 60601-1.

Diameter/Length
Available in diameters: USP 3/0, USP 2/0 and USP 0.
Available length: 60 cm

Isolation Material
The Steelex Electrode Set has an isolating cover made of blue or white co-extrusioned low density polyethylene (LDPE).
Use pacemakers of an output voltage of maximum 24 V AC/DC and a sensitivity of minimum 0.2mV.

EMC advices
MRI and mobile phones not allowed. Distances to and other devices have to be considered according to the following Table.

Rated output power of transmitter P [W]	Safety Distance *d* [m] corresponding to Frequency of Transmitter			
	150 kHz to 80 MHz outside of ISM bands	150 kHz to 80 MHz inside of ISM bands	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = [0.35]\sqrt{P}$	$d = [1.2]\sqrt{P}$	$d = [1.2]\sqrt{P}$	$d = [2.3]\sqrt{P}$
0.01	0.04	0.12	0.12	0.23
0.10	0.11	0.38	0.38	0.73
1.00	0.35	1.20	1.20	2.30
10.00	1.11	3.79	3.79	7.27
100.00	3.50	12.00	12.00	23.00

For transmitters whose rated power output is not specified in the table above, the safety can be calculated using the specified formula for the corresponding frequency. Here *P* is the rated output power of the transmitter in watts [W] and *d* the safety distance in meters [m].

Note 1: At 80 MHz and 800 MHz, the safety distance for the higher frequency range applies.

Note 2: The ISM bands (for industrial, scientific and medical applications) between 150 kHz and 80MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283MHz; and 40.66 MHz to 40.70 MHz.

Note 3: The compliance level in hte ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz is intended to reduce the likelihood that mobile/portable communications devices cause interference if they are unintentionally brought into patient areas. For this reason greater safety distance is recommended separation distance in these frequency ranges (factor 1.2 instead of 0.35).

Note 4: These guidelines do not necessarily apply in all situations. The propagation of electromagnetic waves is influenced by absorption and reflection from structures, objects and humans.

Transport, Storage and Operation Conditions

Transport (to be included the symbols behind this information) Temperature range: -20 °C to 60 °C / Relative humidity: < 90 %
Storage (to be included the symbols behind this information) Temperature range: -20 °C to 60 °C / Relative humidity: < 80%
Operation (to be included the symbols behind this information) Maximum altitude 3.000 m
Working temperature: 10 °C to 60 °C possible but regarding patient safety do not surpass 41 °C Relative Humidity range: 30 to 100 % (humidity: 100 % inside the patient) Check which conditions are fixed by the pacemaker before using it.
Storage life
The Steelex® Electrode Set may not be used after the expiry date. Discard any open, unused or damaged packs. Do not resterilize. Store the Steelex® Electrode Set at room temperature. Avoid prolonged exposure at extreme temperatures.

Caution
Federal (USA) law restricts this device to sale or use by or on the order of a physician.

Symbols used on labeling

Do not re-use / Use-by date / Batch Code / Catalogue Number / Sterilized using ethylene oxide / CF Defibrillation-proof type of applied part / Temperature limit / Humidity limitation / Follow instructions for use / General warning sign / Mobile phone prohibited / MRI prohibited. You can find the concrete temperature and the humidity limits in the instructions for use, on the box and in the primary pack.

CUSTOMER SERVICE

For further information regarding Steelex® Electrode Set Suture please contact Tissue Seal, LLC's Customer Service at 1-877-754-6458 or customerservice@tissueseal.com

Distributed by:

Tissue Seal, LLC
4401 Varsity Drive, Suite D
Ann Arbor, MI 48108 – U.S.A.

506852 01-01/20