Directions for Use

Indicates this device is in

compliance with MDR 2017/745 Caution: Federal (U.S.A.) law

restricts this device to sale by or on order of a physician.

Device name: ECG/EKG Cable and Leadwires

Shenzhen Med-link Cable / Leadwire is intended to be used with ECG and EKG monitoring devices. The cable / leadwire is used to connect electrodes, catheters and/or sensors placed at appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by heath care professional.

Instructions for use

- Connect the cable / leadwire to monitor.
- 2. Connect the leadwire set to the trunk cable.
- 3. Prepare the skin by cleansing and drying the areas where the electrodes will be attached. Typically 70% alcohol is used for this purpose. Be sure to dry
- 4. Attach the electrodes to the correct positions. See the monitor user documentation for instructions on positioning the electrodes.
- 5. Connect the leadwire set to the electrodes. Please refer to the monitor user documentation for detailed information.

Maintenance

Before use, check that the product is intact and clean.

NOTE: Do not treat the cables with oils (e.g. household or lubricating) or aggressive fluids or solvents (e.g. acetone)

Cleaning

1) Disconnect the Med-link cable / leadwire from the monitoring device.

WARNING: When disconnecting pull on the plug itself not on the cable.

- 2) Dampen a clean cloth or gauze pad with an appropriate cleaning solution and wipe all exposed surfaces.
- 3) Dampen a clean cloth or gauze pad with sterile or distilled water and again wipe all exposed surfaces.
- 4) Dry all exposed surfaces with a clean, dry cloth or gauze pad.

WARNING: Never immerse Med-link cable / leadwire in any liquid.

CAUTION: Do not sterilize Med-link cable / leadwire by autoclave, radiation or steam.

NOTE: Med-link cable / leadwire device is not made with natural rubber latex.

NOTE: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

Disinfect with a chemical disinfectant, such as ethanol, propanol, phenolic disinfectant.

NOTE: Do not immerse the products in liquids. Protect from strong UV radiation.



- 1) Med-link can't be held liable for any trouble resulting from failure to observe the installation and operating rules stated in these directions for use.
- 2) As with all medical equipment, carefully route cables to reduce the possibility of patient entanglement or strangulation.
- 3) Do not use the cables during MRI scanning. Conducted current may cause burns.
- See the monitor user documentation for instructions on positioning the electrodes.
- 5) Ensure that lead wire connector is properly inserted into trunk cable/instrument.
- 6) Do not use lotion or oil prior to the test. Skin must be clean and dry.
- 7) This product is not suitable for PVC, TPU and ABS plastic allergy patients and users.
- 8) Cable / leadwire are designed for use with specific monitors, the operator is responsible for checking the compatibility of the monitor, cable and leadwire before use, and incompatible components can result in degraded performance.
- 9) Do not use the cable / leadwire if the cable, wires and connector was broken.

Duration of use: recommendations for every 6 months to replace once. If it is necessary to use, please to evaluate, and the use of period should be tightened inspection.

Disposal



Waste electrical and electronic equipments must be disposed of in accordance with the local applicable regulations, not with domestic waste.

Note: *All registered trademark and brand style mentioned in this information is always belonging to original made possessor.

The following symbols may appear on the product or product labeling:

Refer to instruction manual/ booklet	Non-sterile	Temperature limitation	Humidity limitatio	•	nospheric pressure limitation	Keep dry
	NON	-10 °C	, <u>"</u>	80 % 86 kP	106 kPa	7
Country of manufacture	Do not immerse	Do not autoclave	Medical device	Serial number	Unique Device Identifier	Model number
₩	9		MD	SN	UDI	#



E-mail: sales@med-linket.com

Shenzhen Med-link Electronics Tech Co., Ltd. 4th and 5th Floor, Building Two, Hualian Industrial Zone, Xinshi Community, Dalang Street, Longhua District, 518109 Shenzhen, PEOPLE'S REPUBLIC OF CHINA



Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany Tel: +49-40-2513175 Fax: +49-40-255726