

Disposable ECG Leadwires Instructions for Use



Instructions for Use



Intended Use

The ECG Disposable Lead Wires are intended to be used with ECG. The lead wire is used to connect electrodes placed at appropriate sites on the patient to ECG for general monitoring and/or diagnostic evaluation by a health care professional.

Leadwires and electrode placement is color-coded in accordance with Association for the Advancement of Medical Instrumentation (AAMI) recommendations. Apply the appropriate AAMI color-coded lead set to the corresponding recess on your ECG/EKG trunk cable.

Monitor Documentation

For accuracy specifications and further instructions, warnings and cautions, please be sure to read and follow the OEM patient monitor instructions for use.

Maintenance and Testing

Ensure the connectors are in good condition and check for cracks, cuts, tears or breaks in the insulation. Do not use if you see any signs of damage or deterioration.

General Points

This product is designed for single patient use. If it gets soiled, use a mild cleaning agent such as soap and one of the approved cleaning agents.

- Use recommended cleaning agents listed in this document. Others may cause damage, reduce product lifetime or cause safety hazards.
- Keep the leadwire and accessories free of dust and dirt

- Never immerse or soak the product in any liquids
- Inspect the leadwires after cleaning
- Always follow and retain the instructions accompanying the cleaning and substances you are using and dilute according to the manufacturer's instructions.

Directions for Use and Precautions

1. Connect the trunk cable to the patient monitor
2. Connect the leadwire to the trunk cable
3. Skin prep: Shave or cut hair at electrode site, then clean and dry the skin
4. Attach the electrodes to the correct positions on the patient avoiding damaged tissue
5. Please refer to the OEM patient monitor's operation manual for detailed information.
6. To remove the leadwire, disconnect by holding onto the patient leadwire connector tightly, then detach from the trunk cable

CAUTION: To avoid injury, carefully place the leadwires to reduce the possibility of patient entanglement or strangulation.

Cleaning

1. Prior to cleaning, unplug the leadwires from the monitor.
2. Clean with a lint-free cloth or gauze pad, moistened with warm water and soap, a diluted non-caustic detergent, or one of the approved cleaning agents. Wipe all exposed surfaces.
3. Dry all exposed surfaces with a lint-free cloth or gauze pad.

Approved Cleaning Agents

Base	Example of Agent
Alcohol	Ethanol up to 70%
	1-and 2-Propanol up to 70%
	Isopropanol 70%, window cleaner
Green Soap, Green Soap Tincture	US Pharmacopeia

CAUTION

Cleaning Solutions: Do not mix disinfecting solutions as hazardous gases may result. Do not allow the cleaning agent to remain on the cable

Skin contact: Do not allow a cleaning agent to leave residues on any equipment surface. After allowing the appropriate time for the agent to work (as indicated by the agent manufacturer), wipe off residue with a cloth dampened with water.

Local requirements: Observe local laws governing the use of Cleaning agents.

WARNINGS:

- Do not use the device for purposes other than ECG monitoring. Select the suitable ECG patient monitor for connecting and measurement.
- Place the ECG electrodes attached to patients as far away as possible from the defibrillator pad when connecting with a defibrillator to minimize the risk of burns.
- Do not allow liquid to collect around the electrical contacts or seep inside the connector. Trapped liquids and surface residues provide an unintentional electrical path, which may cause noisy signals and false alarms.

MR Unsafe



See instructions before use



Single Patient Use



Nonsterile Packaging



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



Not made with Natural Latex



Do Not Immerse



Do Not Autoclave



Printed in the USA.
IFU-0003R1



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MEDALink patient leadwires meet the requirements of ANSI/AAMI EC53:2013/(R) 2020 standard for patient leadwires and is in accordance with 21 CFR 898 and ES60601-1:2005/(R) 2012 subclause 8.5.2.3.

Product Name

Disposable ECG Leadwires

Part Numbers

M-PS-3PS-050	M-GE-3PS-050
M-PS-5PS-050	M-GE-5PS-050
M-PS-5VPS-050	M-GE-5VPS-050
M-NK-3PS-050	M-NK-6PS-050

Our Story

Rising Eagle Medical is a Service Disabled Veteran-Owned Small Business (SDVOSB) established in 2016 by a retired Warrant Officer (United States Army) with over 21 years of Army medical equipment management experience. The owners of Rising Eagle have combined over half a century of experience in military logistics, equipment and materials management along with extensive medical equipment and consumables sales experience. We proudly serve active duty service members, their families, and veterans across the country by providing medical consumables and healthcare solutions to Government healthcare facilities.

The Rising Eagle logo represents the founder’s prior service as a Warrant Officer in the US Army. The eagle resembles the Warrant Officer Branch insignia known as the “Eagle Rising”. The capital letters in our tagline “Managing EveryDay LOGistics” spell out “MEDLOG”, the key branch we work with as a SDVOSB – Medical Logistics. We fully understand the unique challenges facing this department to ensure the correct supplies are delivered to the right place at the right time.



The Logos



Rising Eagle Medical has launched MEDALink as the name for our own branded product line. MEDA – Medical Equipment and Durable Accessories – was developed to provide reliable, cost effective supply solutions for United States Healthcare facilities.



Printed in the USA.
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