

Disposable ECG Leadwires Instructions for Use



Instructions for Use



Part Numbers

3PS-050	PS-3SS-036	NK-3SS-036
5PS-050	PS-5SS-036	NK-6SS-036
5VPS-050	PS-5VSS-036	NK-3SS-050
PS-3PS-036	PS-3SS-050	NK-6SS-050
PS-5PS-036	PS-5SS-050	NK-3PS-036
PS-5VPS-036	PS-5VSS-050	NK-6PS-036
PS-3PS-050	GE-3PS-036	NK-3PS-050
PS-5PS-050	GE-5PS-036	NK-6PS-050
PS-5VPS-050	GE-5VPS-036	GE-3PS-050
DR-5PS-036		GE-5PS-050
DR-5PS-050		GE-5VPS-050

Intended Use

These Single Patient Use leadwires are intended to be used to connect electrodes placed at appropriate sites on the patient to an ECG or EKG monitoring device for general monitoring and/or diagnostic evaluation by a healthcare 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.

Cleaning and Disinfection

General Points

- Use only recommended cleaning agents listed in this document. Others may cause damage, reduce product lifetime or cause safety hazards.
- Keep the cable and accessories free of dust and dirt.
- Never immerse or soak the ECG cable.
- Inspect the ECG cable after cleaning.
- Always follow and retain the instructions accompanying the cleaning and substances you are using.
- Dilute according to the manufacturer's instructions.

Cleaning

1. Disconnect the 9Line patient leadwire from the monitoring device.
 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.
- WARNING:** Do not allow the cleaning agent to remain on the cable
- WARNING:** 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.

WARNING: Ensure that that the colors on the leadwire plug end match up to the colors on the monitor/trunk cable

Approved Cleaning Agents

Base	Example of Agent
2% glutaraldehyde solution	Cidex
Alcohol	Ethanol up to 70%
	1-and 2-Propanol up to 70%
	Isopropanol 70%, window cleaner
Ammonias	Dilution of Ammonia <3%, window cleaner
Green Soap, Green Soap Tincture	US Pharmacopeia
Sodium hypochlorite solution	(bleach) 10% solution in water PDI Sani-Cloth Bleach (.63%)

CAUTION

Solutions: Do not mix disinfecting solutions as hazardous gases may result.

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

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

9Line patient leadwires meet the requirements of ANSI/AAMI EC53:2013/(R) 2020 standard for patient leadwires.

In accordance with 21 CFR 898 and ES60601-1:2005/(R) 2012 subclause 8.5.2.3, 9Line patient leadwires are constructed and tested in such a manner as to preclude patient contact with hazardous voltages.

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



www.9lineusa.com

Printed in the USA.
IFU-0001 R4
ISO 13485: 2016
Cert. # US 286/1022084
ISO 9001:2015
Cert. # US 286/1020582



www.rem-supplies.com

Rising Eagle Medical, LLC
75 Waneka Parkway
Lafayette, CO 80026
888.399.0119



Rising Eagle Medical

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 48 years 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.



Our Mission

Establish Rising Eagle Medical as the preeminent SDVOSB servicing United States Government healthcare facilities with high quality products manufactured in the United States.

The Logos



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

MADE IN THE USA

the unique challenges facing this department to ensure the correct supplies are delivered to the right place at the right time.



Rising Eagle Medical has launched 9 Line as the name for our own branded product line. 9 Line is a military term used with MedEvacs to call in injuries sustained during combat or on the battlefield. It is a standardized report with 9 Lines to allow for simplicity in communication during a stressful time.

Holding true to Our Mission, 9 Line disposable ECG Leadwires are the first of its kind to be fully sourced and manufactured in the United States.



www.9lineusa.com



Printed in the USA.

DLA Contract: SPE2D1-22-D-0003

ECAT Contract: SPE2D1-22-D-A008



www.rem-supplies.com

Rising Eagle Medical, LLC
75 Waneka Parkway
Lafayette, CO 80026
888.399.0119

