

Reprocessed by



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Instructions for Use Hygia Reprocessed ECG Leads IFU

Reprocessed Device for Single Use.

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

NON-STERILE NOT MADE WITH NATURAL RUBBER LATEX

Indications for Use

The Hygia Health Services Reprocessed ECG Leads is a non-invasive device to provide continuous electrocardiograph (ECG) monitoring by transmitting signals from patient electrode pads to the ECG monitor. The Reprocessed ECG Leads meets the requirements of CFR Title 21 Part 898 and the ANSI/AAMI Standard, ECG Cables and Leads (ANSI/AAMI EC53-1995).

Warnings

- Do not immerse in water or cleaning solutions.
- Do not use the leads during MRI scanning.

Directions for Use

1. Ensure that the proper reusable adapter is plugged into the monitor.
2. Remove leads set from bag and plug the connector into the adapter.
3. Peel the leads as needed and connect the leads connectors to the appropriate electrodes by pushing the pink button and securing the connection.
4. If the product becomes soiled, clean with mild soap and water.

The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

This product and its packaging have been exposed to ethylene oxide gas (EtO). Even though the product is processed in compliance with all applicable laws and regulations relating to EtO exposure, proposition 65, a State of California voter initiative, requires the following notice:

Warning: this product and its packaging have been exposed to ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.