en English

ECG Leadwire Sets

Instructions for Use

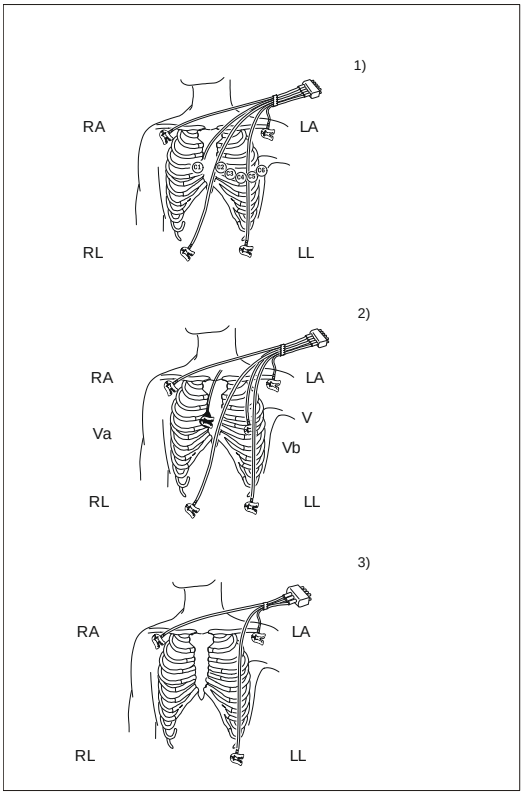
REF

394111-501	ECG Leadwire Set, 3-Lead for ApexPro™ FH, Grabber, AHA, 75 cm/ 29 in
394111-502	ECG Leadwire Set, 5-Lead for ApexPro™ FH, Grabber, AHA, 75 cm/ 29 in
394111-503	ECG Leadwire Set, 6-Lead for ApexPro™ FH, Grabber, AHA, 75 cm/ 29 in
394111-511	ECG Leadwire Set, 3-Lead for ApexPro™ FH, Snap, AHA, 75 cm/ 29 in
394111-512	ECG Leadwire Set, 5-Lead for ApexPro™ FH, Snap, AHA, 75 cm/ 29 in
394111-513	ECG Leadwire Set, 6-Lead for ApexPro™ FH, Snap, AHA, 75 cm/ 29 in

REF	Catalogue Number		Consult Instructions for Use
LOT	Lot Number		Follow Instructions for Use
X	Quantity		Temperature Limit
	Manufacturer	LATEX	Not made with natural rubber latex.
	Date of Manufacture	Rx ONLY	U.S. Federal law restricts this device to sale by or on the order of a physician.
	Caution Non-Sterile	MR	MR Unsafe

Intended use

The reusable ApexPro™ FH leadwires are used to transmit signals from patient electrodes to the ApexPro™ FH Telemetry device for monitoring purposes.



1) 5-lead ECG, 2) 6-lead ECG, 3) 3-lead ECG

Instructions for use

1. Connect the leadwire set to the FH-device.
2. Prepare the skin: Shave any hair from the selected electrode sites, and clean and dry the skin.
3. Attach the electrodes to the correct positions. With snap leadwire: attach the electrode first to the snap leadwire and then to the patient. See the monitor user documentation for instructions on positioning the electrodes.
4. Connect the leadwire set to the electrodes.

These products are indicated for use by qualified medical personnel only. Please refer to the monitor user documentation for detailed information.

Maintenance

Before use, check that the product is intact and clean.
Manufacturer has successfully tested the enclosed reprocessing instructions for 80 cycles.

Warnings

- MR unsafe. Do not use this product in MRI environment.
- Do not let the conductive product parts contact any other conductive parts including earth.
- Do not allow humidity or liquid to enter the product.
- Inspect the product for physical damage before use. Do not use product if you see any visual signs of damage. A damaged product should be discarded immediately. Never try to repair a damaged product, do modifications to product or use a product repaired by others.
- Products are supplied non-sterile and must be unpacked, cleaned and disinfected prior to first use. Products must be reprocessed prior to each use.
- Adequate cleaning is a necessary requirement for subsequent effective disinfection.
- Only use equipment and product-specific validated procedures for cleaning and disinfection.
- The used equipment and accessories must be maintained and checked regularly according to the manufacturer's instructions.
- Additionally all applicable laws, standards and guidelines for reprocessing must be followed.
- The use of personal protective equipment is the responsibility of the user.
- Deviation from the defined procedures within this instruction is the responsibility of the user.
- Manufacturer is not responsible for damages resulting from improper reprocessing. It rests with the user to validate their procedures and to comply with the validated parameters during every reprocessing.
- Use only accessory combinations and monitor as mentioned in this IFU for proper and accurate functioning of measurement. Using accessories or monitor other than the ones referenced might result in a measurement error or hazardous connection. Observe connector part color coding and/or markings on products to ensure appropriate compatibility with monitor and other accessories.
- To ensure appropriate and safe functioning of the product and system, check stability of connections with monitor and other accessories initially and occasionally over time.
- Check appropriate placement or position of the cable initially and occasionally over time to prevent entanglement, pressure, tripping, etc. to occur as they might cause airway obstruction, irritation, decubitus, falling of other items or people, etc.

Pre-Processing Instructions

1. Ensure all pre-processing instructions are followed prior to cleaning and disinfecting.
2. Initiate cleaning and disinfection of device as soon as possible after use (recommended within 1 hour).
3. Transport devices via the institution's established transport procedure.
4. Remove excess soil as soon as possible after use by wiping the device.
5. Device shall be cleaned and disinfected utilizing a minimum of one (1) cleaning method and one (1) disinfection method outlined below.

Cleaning Instructions

1. Ensure all pre-processing instructions are followed prior to cleaning.
2. Prepare the enzymatic / neutral pH detergent, utilizing tap water entailing a temperature range of 27°C to 44°C (81°F to 111°F), per manufacturer's instructions.
3. Use a soft, clean cloth saturated with the cleaning solution to manually clean all surfaces of the devices including cracks and crevices for a minimum of 5 minutes. In conjunction with this step, use an appropriately

sized brush (soft-bristled), to remove all visible soil from the device paying particular attention to cracks, crevices and other hard to clean areas. Note: It is recommended that enzymatic or neutral pH detergent solution should be changed when it becomes grossly contaminated (bloody and/or turbid).
4. Rinse the device thoroughly by using a soft, clean cloth saturated with lukewarm tap water with a temperate range of 27°C to 44°C (81°F to 111°F) for a minimum of 30 seconds. Repeat two (2) additional times for a total of three (3) total rinse cycles.
5. Drying: Dry the device with a soft, sterile cloth.
6. Visually examine each device for cleanliness.
7. If visible soil remains, repeat cleaning procedure until the device is thoroughly clean.

Disinfection

Intermediate level disinfection instructions (option 1)

1. Prepare a 2% Glutaraldehyde disinfectant solution (CIDEX® or equivalent) according to the manufacturer's directions.
2. Using a sterile, soft cloth saturated with the disinfection solution, manually disinfect all contaminated surfaces of the device for a minimum of 15 minutes.
3. In conjunction with this step, use an appropriately sized brush (e.g. standard soft bristle toothbrush or lumen brush) to disinfect hard-to-reach areas paying particular attention to cracks and crevices ensuring a slightly wet surface is maintained at room temperature for the duration of this disinfection step.
4. Using a sterile, soft cloth saturated with purified water (PURW) at 27°C – 44°C, manually rinse by wiping the device for 30 seconds. Repeat two (2) additional times for a total of three (3) rinse cycles, utilizing fresh purified water each time.
5. Drying: Dry the device using a sterile, lint-free cloth.

Intermediate level disinfection instructions (option 2)

1. Prepare a 70% IPA disinfectant solution according to the manufacturer's directions.
2. Using a sterile, gauze saturated with the disinfection solution, manually disinfect all contaminated surfaces of the device for a minimum of 15 minutes.
3. In conjunction with this step, use an appropriately sized brush (e.g. standard soft bristle toothbrush or lumen brush) to disinfect hard-to-reach areas paying particular attention to cracks and crevices ensuring a slightly wet surface is maintained at room temperature for the duration of this disinfection step.
4. Using a sterile, gauze saturated with purified water (PURW) at 27°C – 44°C, manually rinse by wiping the device for 30 seconds. Repeat two (2) additional times for a total of three (3) rinse cycles, utilizing fresh purified water each time.
5. Drying: Dry the device using a sterile, lint-free cloth.

Storage

Storage temperature -30°C/-22°F to +70°C/+158°F

Disposal

This product and package should be disposed of according to local environmental and waste disposal regulations.

Technical description

- This product is classified as defibrillation-proof type CF applied part.
- The product meets the requirements of the standard, *ECG trunk cables and patient leadwires (ANSI/AAMI EC53)*. This product is intended for multi-patient use.
- Not made with natural rubber latex.

Designed by Vyaire.

Ordering information

For further information, please contact your local sales representative or visit vyaire.com.

Vyaire Medical Oy
Kuortaneenkatu 2
FI-00510 Helsinki, Finland
+1-833-327-3284

Customer Service:
customersupport@vyaire.com

1000004390/A 2019-09