

Reprocessed by



## Sustainability Solutions











### Instructions for Use Reprocessed ECG Lead and Wire System

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

- **NON-STERILE (Exposed to Vaporized Hydrogen Peroxide)**
- **Not made with natural rubber latex**

This system meets the requirements of the ANSI/AAMI Standard, ECG Cables and Lead Wires (ANSI/AAMI EC53-1995).

#### Explanation of Symbols

Symbol	Rules/ Standard Reference	ISO 7000 Registration Number	Symbol Title	Description
Rx Only	21CFR801	N/A	Prescription only	Indicates Federal (USA) law restricting device to sale by or on order of a physician
	ISO 15223-1 Clause 5.1.1	3082	Manufacturer	Indicates the medical device manufacturer
	ISO 15223-1 Clause 5.2.7	2609	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 15223-1 Clause 5.1.3	2497	Manufacturing Date (Reprocessing Date)	Indicates the date which the medical device is manufactured
	ISO 15223-1 Clause 5.1.6	2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1 Clause 5.1.5	2492	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1 Clause 5.4.3	1641	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1 Clause 5.4.2	1051	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	N/A	N/A	Does not contain natural rubber latex	Notification that natural rubber latex was not used as a material in the finished product or packaging.
	ASTM 2503-20	N/A	MR Unsafe	Indicates a medical device poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.
	N/A	N/A	DEHP Free	Indicates product that does not contain the phthalate plasticizer DEHP.

**ECG Lead and Wire System Description**

The Reprocessed ECG Lead and Wire system consists of lead systems, lead telemetry systems and a dual connect cable. The various ECG Leads provide connection between patient applied electrodes, which are placed on the chest of the patient as well as on the limbs, and various telemetry and bedside monitoring units allowing for the noninvasive, transcutaneous monitoring of electrical impulses generated by the heart over a period of time, resulting in an electrocardiogram (ECG). Each ECG Lead is labeled (LA, LL, V, RL, RA, V2, V3, V4, V5, and V6) for the correct placement on the patient. **Read and follow all instructions that come with telemetry and bedside monitoring units utilized.**

**Indications for Use**

ECG Leads and Wires provide connection to patient applied electrodes and various telemetry and bedside monitoring units allowing for the electrical activity to be monitored. Non-invasive, transcutaneous monitoring of electrical impulses generated by the heart over a period of time results in an electrocardiogram (ECG).

**Contraindications for Use**

- MR Unsafe – These devices are known to pose hazards in all MR environments

**Warnings**

- None

**Precautions**

- This product is intended for single patient use only. If it becomes soiled; clean with mild soap and water. Do not use bleach, alcohol, solvents or immerse in any liquids.
- Do not connect lead wires to monitoring unit if connectors are wet as it may cause an electrically conductive path resulting in an error on the monitoring device. Allow lead wires to air dry if other methods are not effective.

**Adverse Reactions**

- None

**Directions for Use****Kendall™ DL Disposable 3 Lead Cable and Lead Wire System (31103)**

1. Remove Lead Wire System from packaging.
2. Plug male end of appropriate reusable adapter (not included) into monitor. Verify adapter connection to monitor.
3. Plug Lead Wire System male connector into female end of reusable adapter ensuring heart symbols line up.
4. Slide Wire Clip(s) away from leads to separate leads as needed. Remove Wire Clip(s) and peel cable if further lead separation is required.
5. Push pink button on lead housing and connect to electrode.
6. Trace
7. Disconnect Lead System from reusable adaptor and retain reusable adaptor.
8. Push pink button and slide lead housing axially to remove electrodes. Place used Lead Wire System in Stryker Sustainability Solutions collection bin.

**Kendall™ DL Disposable 5 Lead Cable and Lead Wire System (33105)**

1. Remove Lead Wire System from packaging.
2. Plug male end of appropriate reusable adapter (not included) into monitor. Verify adapter connection to monitor.
3. Plug Lead Wire System male connector into female end of reusable adapter ensuring heart symbols line up.
4. Slide Wire Clip(s) away from leads to separate leads as needed. Remove Wire Clip(s) and peel cable if further lead separation is required.
5. Push pink button on lead housing and connect to electrode.
6. Trace
7. Disconnect Lead System from reusable adaptor and retain reusable adaptor.
8. Push pink button and slide lead housing axially to remove electrodes. Place used Lead Wire System in Stryker Sustainability Solutions collection bin.

**Kendall™ DL Disposable 10 Lead Cable and Lead Wire System (33110)**

1. Remove Lead Wire Systems from packaging.
2. Plug male end of appropriate reusable adapter (not included) into monitor. Verify adapter connection to monitor.
3. Plug Lead Wire Systems male connectors into female end of reusable adapter (not included) ensuring heart symbols and V symbols line up.
4. Slide Wire Clip(s) away from leads to separate leads as needed. Remove Wire Clip(s) and peel cable if further lead separation is required.
5. Push pink button on lead housing and connect to electrode.
6. Trace
7. Disconnect Lead Wire Systems from reusable adaptor and retain reusable adaptor.
8. Push pink button and slide lead housing axially to remove electrodes. Place used Lead Wire Systems in Stryker Sustainability Solutions collection bin.

**Kendall™ DL Disposable Chest Leads (33111)**

1. Remove Chest Lead System from packaging.
2. Plug male end of appropriate reusable adapter (not included) into monitor. Verify adapter connection to monitor.
3. Plug Chest Lead System male connector into female end of reusable adapter ensuring V symbols line up.
4. Slide Wire Clip(s) away from leads to separate leads as needed. Remove Wire Clip(s) and peel cable if further lead separation is required.
5. Push pink button on lead housing and connect to electrode.
6. Trace
7. Disconnect Chest Lead System from reusable adaptor and retain reusable adaptor.
8. Push pink button and slide lead housing axially to remove electrodes. Place used Chest Lead System in Stryker Sustainability Solutions collection bin.

**Kendall™ DL Disposable 5 Lead System for Use with GE Telemetry System – Direct Connect (33112)**

1. Remove Lead Systems from packaging.
2. Plug the connector into the telemetry unit.
3. Move clip up or down to size to patient.
4. Push pink button on lead housing and connect to electrode.
5. Trace.
6. Place used Lead Wire Systems in Stryker Sustainability Solutions collection bin.

**Kendall™ DL Disposable 5 Lead System for Use with Philips Veridia Telemetry System – Direct Connect (33113)**

1. Remove Lead Systems from packaging.
2. Plug the connector into the telemetry unit.
3. Move clip up or down to size to patient.
4. Push pink button on lead housing and connect to electrode.
5. Trace.
6. Place used Lead Wire Systems in Stryker Sustainability Solutions collection bin.

**Kendall™ DL Disposable 5 Lead System for Use with Philips Intellivue Telemetry System – Direct Connect (33114)**

1. Remove Lead Systems from packaging.
2. Plug the connector into the telemetry unit.
3. Move clip up or down to size to patient.
4. Push pink button on lead housing and connect to electrode.
5. Trace.
6. Place used Lead Wire Systems in Stryker Sustainability Solutions collection bin.

**Kendall™ DL Disposable 6 Lead System for Use with GE Apex Pro CH Telemetry System – Direct Connect (33125)**

1. Remove Lead Systems from packaging.
2. Plug the connector into the telemetry unit.
3. Move clip up or down to size to patient.
4. Push pink button on lead housing and connect to electrode.
5. Trace.
6. Place used Lead Wire Systems in Stryker Sustainability Solutions collection bin.

**Kendall™ DL Disposable 6 Lead System for Use with GE Apex Pro FH Telemetry System – Direct Connect (33126)**

1. Remove Lead Systems from packaging.
2. Plug the connector into the telemetry unit.
3. Move clip up or down to size to patient.
4. Push pink button on lead housing and connect to electrode.
5. Trace.
6. Place used Lead Wire Systems in Stryker Sustainability Solutions collection bin.

**Kendall™ DL Disposable 5 Lead System for Use with Draeger Dual Pin – Direct Connect (33132)**

1. Remove Lead Systems from packaging.
2. Plug the lead set into the cable.
3. Peel as needed. Push pink button on lead housing and connect to electrode.
4. Trace.
5. Place used Lead Wire Systems in Stryker Sustainability Solutions collection bin.

**Kendall™ DL Disposable 5 Lead System for Use with Spacelabs Telemetry System – Direct Connect (33133)**

1. Remove Lead Systems from packaging.
2. Plug the connector into the telemetry unit.
3. Move clip up or down to size to patient.
4. Push pink button on lead housing and connect to electrode.
5. Trace.
6. Place used Lead Wire Systems in Stryker Sustainability Solutions collection bin.

**Kendall™ DL Disposable 6 Lead System for Use with Nihon Kohden – Direct Connect (33134)**

1. Remove Lead Systems from packaging.
2. Plug the connector into the telemetry unit.
3. Move clip up or down to size to patient.
4. Push pink button on lead housing and connect to electrode.
5. Trace.
6. Place used Lead Wire Systems in Stryker Sustainability Solutions collection bin.

**Kendall™ DL Disposable Dual Connect 5 Lead Cable and Lead Wire System (33135)**

1. Remove Dual Connect Cable and Lead Wire System from packaging.
2. Plug male end of appropriate reusable adapter (not included) into monitor. Verify adapter connection to monitor.
3. Plug Lead Wire System male connector into female end of Dual Connect Cable connector ensuring heart symbols line up.
4. Plug Dual Connect Cable male connector into female end of reusable adapter ensuring heart symbols line up.
5. Slide Wire Clip(s) away from leads to separate leads as needed. Remove Wire Clip(s) and peel cable if further lead separation is required.
6. Push pink button on lead housing and connect to electrode.

7. Trace
8. Disconnect Dual Connect Cable from reusable adaptor and retain reusable adaptor.
9. Push pink button and slide lead housing axially to remove electrodes. Place used Dual Connect Cable and Lead Wire System in Stryker Sustainability Solutions collection bin.

For telemetry monitoring:

1. Disconnect Dual Connect Cable from monitor.
2. Disconnect Dual Connect Cable from the Lead Wire System.
3. Plug male end of appropriate reusable adapter (not included) into telemetry unit. Verify adapter connection to telemetry unit.
4. Plug Lead Wire System male connector into female end of reusable adapter ensuring heart symbols line up.
5. Slide Wire Clip(s) away from leads to separate leads as needed. Remove Wire Clip(s) and peel cable if further lead separation is required.
6. Push pink button on lead housing and connect to electrode.
7. Trace
8. Disconnect Lead Wire System from reusable adaptor and retain reusable adaptor.
9. Push pink button and slide lead housing axially to remove electrodes. Place used Dual Connect Cable and Lead Wire System in Stryker Sustainability Solutions collection bin.

#### **Kendall™ DL Disposable Dual Connect 5 Lead Cable and Lead Wire System (33135T)**

1. Remove Dual Connect Cable and Lead Wire System from packaging.
2. Plug male end of appropriate reusable adapter (not included) into monitor. Verify adapter connection to monitor.
3. Plug Lead Wire System male connector into female end of Dual Connect Cable connector ensuring heart symbols line up.
4. Plug Dual Connect Cable male connector into female end of reusable adapter ensuring heart symbols line up.
5. Slide Wire Clip(s) away from leads to separate leads as needed. Remove Wire Clip(s) and peel cable if further lead separation is required.
6. Push pink button on lead housing and connect to electrode.
7. Trace
8. Disconnect Dual Connect Cable from reusable adaptor and retain reusable adaptor.
9. Push pink button and slide lead housing axially to remove electrodes. Place used Dual Connect Cable and Lead Wire System in Stryker Sustainability Solutions collection bin.

For telemetry monitoring:

1. Disconnect Dual Connect Cable from monitor.
2. Disconnect Dual Connect Cable from the Lead Wire System.
3. Plug male end of appropriate reusable adapter (not included) into telemetry unit. Verify adapter connection to telemetry unit.
4. Plug Lead Wire System male connector into female end of reusable adapter ensuring heart symbols line up.
5. Slide Wire Clip(s) away from leads to separate leads as needed. Remove Wire Clip(s) and peel cable if further lead separation is required.
6. Push pink button on lead housing and connect to electrode.
7. Trace
8. Disconnect Lead Wire System from reusable adaptor and retain reusable adaptor.
9. Push pink button and slide lead housing axially to remove electrodes. Place used Dual Connect Cable and Lead Wire System in Stryker Sustainability Solutions collection bin.

#### **Kendall™ DL Disposable Dual Connect Lead Set (33136)**

1. Remove Dual Connect Lead Set from packaging.
2. Plug male end of appropriate reusable adapter (not included) into telemetry unit. Verify adapter connection to telemetry unit.
3. Plug Dual Connect Lead Set male connector into female end of reusable adapter ensuring heart symbols line up.
4. Slide Wire Clip(s) away from leads to separate leads as needed. Remove Wire Clip(s) and peel cable if further lead separation is required.

separation is required.

5. Push pink button on lead housing and connect to electrode.
6. Trace
7. Disconnect Dual Connect Lead Set from reusable and retain reusable adaptor.
8. Push pink button and slide lead housing axially to remove electrodes. Place used Dual Connect Lead Set in Stryker Sustainability Solutions collection bin.

Lead System can also plug into Dual Connect Cable for bedside monitoring.

1. Plug Dual Connect Lead Set male connector into female end of Dual Connect Cable (33145, sold separately) connector ensuring heart symbols line up.
2. Plug male end of appropriate reusable adapter (not included) into monitor. Verify adapter connection to monitor.
3. Plug Dual Connect Cable male connector into female end of reusable adapter ensuring heart symbols line up.
4. Slide Wire Clip(s) away from leads to separate leads as needed. Remove Wire Clip(s) and peel cable if further lead separation is required.
5. Push pink button on lead housing and connect to electrode.
6. Trace
7. Disconnect Dual Connect Cable from reusable adaptor and retain reusable adaptor.
8. Push pink button and slide lead housing axially to remove electrodes. Place used Dual Connect Cable and Dual Connect Lead Set in Stryker Sustainability Solutions collection bin.

#### **Kendall™ DL Disposable Dual Connect Lead Set (33136T)**

1. Remove Dual Connect Lead Set from packaging.
2. Plug male end of appropriate reusable adapter (not included) into telemetry unit. Verify adapter connection to telemetry unit.
3. Plug Dual Connect Lead Set male connector into female end of reusable adapter ensuring heart symbols line up.
4. Slide Wire Clip(s) away from leads to separate leads as needed. Remove Wire Clip(s) and peel cable if further lead separation is required.
5. Push pink button on lead housing and connect to electrode.
6. Trace
7. Disconnect Dual Connect Lead Set from reusable and retain reusable adaptor.
8. Push pink button and slide lead housing axially to remove electrodes. Place used Dual Connect Lead Set in Stryker Sustainability Solutions collection bin.

Lead System can also plug into Dual Connect Cable for bedside monitoring.

1. Plug Dual Connect Lead Set male connector into female end of Dual Connect Cable (33145T, sold separately) connector ensuring heart symbols line up.
2. Plug male end of appropriate reusable adapter (not included) into monitor. Verify adapter connection to monitor.
3. Plug Dual Connect Cable male connector into female end of reusable adapter ensuring heart symbols line up.
4. Slide Wire Clip(s) away from leads to separate leads as needed. Remove Wire Clip(s) and peel cable if further lead separation is required.
5. Push pink button on lead housing and connect to electrode.
6. Trace
7. Disconnect Dual Connect Cable from reusable adaptor and retain reusable adaptor.
8. Push pink button and slide lead housing axially to remove electrodes. Place used Dual Connect Cable and Dual Connect Lead Set in Stryker Sustainability Solutions collection bin.

#### **Kendall™ DL Disposable Dual Connect Cable (33145)**

1. Plug Lead Wire System (sold separately) male connector into female end of Dual Connect Cable connector ensuring heart symbols line up.
2. Plug male end of appropriate reusable adapter (not included) into monitor. Verify adapter connection to monitor.
3. Plug Dual Connect Cable male connector into female end of reusable adapter ensuring heart symbols line up.
4. Slide Wire Clip(s) away from leads to separate leads as needed. Remove Wire Clip(s) and peel cable if further lead separation is required.

5. Push pink button on lead housing and connect to electrode.
6. Trace
7. Disconnect Dual Connect Cable from reusable adaptor and retain reusable adaptor.
8. Push pink button and slide lead housing axially to remove electrodes. Place used Dual Connect Cable and Lead Wire System in Stryker Sustainability Solutions collection bin.

**Kendall™ DL Disposable Dual Connect Cable (33145T)**

1. Plug Lead Wire System (sold separately) male connector into female end of Dual Connect Cable connector ensuring heart symbols line up.
2. Plug male end of appropriate reusable adapter (not included) into monitor. Verify adapter connection to monitor.
3. Plug Dual Connect Cable male connector into female end of reusable adapter ensuring heart symbols line up.
4. Slide Wire Clip(s) away from leads to separate leads as needed. Remove Wire Clip(s) and peel cable if further lead separation is required.
5. Push pink button on lead housing and connect to electrode.
6. Trace
7. Disconnect Dual Connect Cable from reusable adaptor and retain reusable adaptor.
8. Push pink button and slide lead housing axially to remove electrodes. Place used Dual Connect Cable and Lead Wire System in Stryker Sustainability Solutions collection bin.

**AMC&E 3 Lead DIN to Pinch Leadset, Shielded Disposable (LW-309DS50/3A)**

1. As applicable, ensure that the proper reusable adapter is plugged into the monitor.
2. Remove Leadset from packaging.
3. Plug the connector into the adapter or directly into the monitoring system.
4. Connect the leads connectors to the appropriate electrodes.
5. If the product becomes soiled, clean with mild soap and water.

**AMC&E 5 Lead DIN to Pinch Leadset, Shielded Disposable (LW-309DS50/5A)**

1. As applicable, ensure that the proper reusable adapter is plugged into the monitor.
2. Remove Leadset from packaging.
3. Plug the connector into the adapter or directly into the monitoring system.
4. Connect the leads connectors to the appropriate electrodes.
5. If the product becomes soiled, clean with mild soap and water.

**AMC&E 5 Lead DIN to Pinch Telemetry Leadset, Shielded Disposable (LW-309DS50/5AT)**

1. As applicable, ensure that the proper reusable adapter is plugged into the monitor.
2. Remove Leadset from packaging.
3. Plug the connector into the adapter or directly into the monitoring system.
4. Connect the leads connectors to the appropriate electrodes.
5. If the product becomes soiled, clean with mild soap and water.

**AMC&E 5 Lead Grouped Set, Pinch (Grabber) to Multi-Link® Shielded Disposable (LW-341DS50/5A)**

1. As applicable, ensure that the proper reusable adapter is plugged into the monitor.
2. Remove Leadset from packaging.
3. Plug the connector into the adapter or directly into the monitoring system.
4. Connect the leads connectors to the appropriate electrodes.
5. If the product becomes soiled, clean with mild soap and water.

## Warranty

### Reprocessed Products

Stryker warrants all reprocessed products, subject to the exceptions provided herein, to be free from defects in reprocessing and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for one use in accordance with the instructions for use of such product.

**STRYKER SHALL NOT BE LIABLE FOR ANY DAMAGES TO THE EXTENT CAUSED BY ANY DEFECT IN MATERIAL, WORKMANSHIP OR DESIGN BY THE ORIGINAL MANUFACTURER OF THE PRODUCT OR ANY ACT OR OMISSION OF THE ORIGINAL MANUFACTURER OF THE PRODUCT.**

### Products for which Stryker is the Original Manufacturer

Stryker warrants all products for which it is the original manufacturer, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for a period of one year from the date of purchase.

### General Warranty Terms Applicable to All Products

**TO THE FULLEST EXTENT PERMITTED BY LAW, THE EXPRESS WARRANTY SET FORTH HEREIN IS THE ONLY WARRANTY APPLICABLE TO THE PRODUCTS AND IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTY BY STRYKER, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL STRYKER'S LIABILITY ARISING IN CONNECTION WITH THE SALE OF THE PRODUCT (WHETHER UNDER THE THEORIES OF BREACH OF CONTRACT, TORT, MISREPRESENTATION, FRAUD, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER THEORY OF LAW) EXCEED THE PURCHASE PRICE, CURRENT MARKET VALUE OR RESIDUAL VALUE OF THE PRODUCTS, WHICHEVER IS LESS. STRYKER SHALL NOT BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR UNDER ANY OTHER LEGAL THEORY.**

This warranty shall apply only to the original end-user purchaser of products directly from Stryker or a Stryker authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker personnel without the prior written consent of Stryker; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker representative; (4) products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components.

If a valid warranty claim is received within thirty (30) days of the expiration of the applicable warranty period, Stryker will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product or (2) refund the purchase price of the product. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial applicable warranty period or, if the initial warranty period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.



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

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