

Reprocessed by



Sustainability Solutions

Instructions for Use








Reprocessed DeRoyal® Bed Sensor Pad Exposed to Vaporized Hydrogen Peroxide (VHP)

Reprocessed Device for Single Patient Use

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

- NOT MADE WITH NATURAL RUBBER LATEX
- NON-STERILE

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.

Reprocessed DeRoyal® Bed Sensor Pad Description

The Reprocessed DeRoyal® Bed Sensor Pads are sensor pads designed for use with the DeRoyal® Fall Monitors to alert staff and patients in the event the patient attempts to exit the bed, wheelchair and/or recliner.

Indications for Use

The Stryker Sustainability Solutions Reprocessed DeRoyal® Bed Sensor Pads alert staff and patients in the event the patient attempts to exit the bed, wheelchair and/or recliner. It is not claimed that the device will stop elopement and/or stop falls. The device is designed to augment caregiver's comprehensive resident mobility management program.

Warnings

- **FAILURE TO COMPLY WITH WARNING MAY RESULT IN INJURY.** The device is not suitable for all individuals. Other devices may be required. The device is not a substitute for visual monitoring for caregiver. It is not claimed that this device will stop elopement and/or stop falls. Sensor pad and fall monitor systems are prone to difficulties. Be sure that the cord cannot entangle or choke the user. The device is designed to augment caregivers' comprehensive resident mobility management program. Test the device before each use. Read the instructions including warnings before each use.
- The Stryker Sustainability Solutions Reprocessed DeRoyal® Bed Sensor Pad for use with the DeRoyal® Fall Monitor System is designed to be installed by the end-user. As such, it is the entire responsibility of the buyer to ensure that the system is properly installed and tested. Further, the system is not designed to replace good caregiving practices including but not limited to:
 - a. Direct patient supervision
 - b. Adequate training for staff personnel for resident fall prevention and elopement
 - c. Testing of the system before each use

Storage and Handling

- Protect the device from light sources; keep away from sunlight.
- Protect the device from moisture; keep dry.

Set-Up Instructions

1. Install new batteries into the DeRoyal fall monitor. The battery compartment door is secured with the small Phillips-head screw.
2. Plug the cord end of the sensor pad into the bottom of the DeRoyal fall monitor. Pinch the cord together and loop it through the strain relief recess on the fall monitor (near plug input).
3. Test the system. Put pressure on the sensor pad to activate the pad and fall monitor. The fall monitor will beep two times to indicate that the sensor pad and fall monitor are in use. The "In Use" or "Status" light will blink when pressure is on the pad. When pressure is removed, the fall monitor will sound the alert tone. Press the reset button to silence the alert.
4. Position the sensor pad under the patient.
To be alerted when the patient sits up in bed, place the sensor pad under the patient's shoulders. To be alerted when the patient vacates bed, place the sensor pad under the patient's hips.

Maintenance

- When using a sensor pad in conjunction with foam or gel cushions, test the systems to make sure it functions properly
- To minimize spreading infection, it is recommended to use a new sensor pad for each patient.
- To clean sensor pads, use disinfectant wipes or anti-bacterial cleaners.
- DO NOT fold the sensor pad.
- DO NOT immerse the sensor pad in any liquid cleaning solution.
- DO NOT expose the sensor pad to high temperature sanitizers.

Troubleshooting

1. Make sure that the sensor pad is plugged into the fall monitor.
2. Check the power supply. If you are using battery power, install new batteries. Or, if you are using an AC Adapter, make sure that the adapter is plugged into a power outlet.
3. Check monitor switches:
 - a. When using a monitor with a Safety Auto Reset™ button. For normal operation (in Reset mode) the switch on the left-hand side of the fall monitor must be in "Reset Button On" position. To silence the fall monitor, press the "Reset" button or place pressure on the sensor pad (to automatically reset the monitor).
 - b. If you are using a fall monitor with an On/Off switch (on left side of the monitor), make sure the switch is in the "On" position.
4. If the steps above do not resolve your problem, call manufacturer for technical support. Make sure both the sensor pad and the fall monitor are with you at the time of the call.

Warranty

MP2200-BP - This product is warranted for up to 30 days from recorded "in-use date," in accordance with Stryker's standard limited warranty.

Reprocessed Products

Unless agreed otherwise in writing, 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; (5) products that have been repaired with any unauthorized or non-Stryker components; or (6) failure to follow the instructions for use.

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 reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

Warning: This product can expose you to chemicals including bisphenol A, which is known to the State of California to cause birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

DeRoyal® is a registered trademark of DeRoyal Industries.

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