Reprocessed by

stryker®

Sustainability Solutions

Instructions for Use
Reprocessed Posey® Bed Alarm 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.

- NON-STERILE
- Not made with natural rubber latex

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.

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Reprocessed Posey® Bed Alarm Sensor Pad Description

The Reprocessed Posey® Bed Alarm Sensor Pads are sensor pads designed for use with Posey® Fall Alarms to detect when a patient has taken weight off the sensor to help notify nurses and caregivers that the patient has gotten up from a sitting or resting position.

Indications for Use

The Stryker Sustainability Solutions Reprocessed Posey® Bed Alarm Sensor Pads alert staff that a patient has taken weight off the sensor and may be at immediate risk of falling. However, fall alarm systems DO NOT prevent falls or injury from falls and are not a substitute for patient care, caregiver rounding and a comprehensive fall management protocol in your facility.

Warnings

- ALWAYS check sensor pad when connecting it to a Posey® alarm. You can check a sensor pad by attaching it to the sensor input on the alarm, activating the alarm and placing pressure on the sensor pad. When the pressure is released, the alarm should sound. Repeat this pressure/release test in several different areas along the entire length of the sensor pad to ensure entire sensor pad functions properly both with the bed in the flat position and the head and/or foot articulated. If the alarm and/or sensor pad do not function properly, remove the alarm and sensor pad from service and replace them with a properly functioning alarm and/or sensor pad. DO NOT use the alarm or sensor pad if it does not activate each time weight is removed from the sensor pad.
- To reduce the risk of serious injury, ALWAYS follow the Directions for Testing Sensor Pad (see below) after putting the sensor pad in place and before leaving patient unattended. DO NOT use any alarm or sensor pad that does not alarm each time it is tested.
- DO NOT use with memory foam or low air-loss mattresses or overlays. A foam pad on top of the mattress may diffuse patient's weight and prevent sensor pad from activating.
- NEVER roll, fold, or crease sensor pad. This will damage sensor pad and may cause false alarm or no alarm.
- The position of the sensor pad is vital when using a restraint. Make sure the restraint is applied correctly per instructions for that device. Straps must NOT cross over sensor pad.
    - If straps cross over sensor pad and patient moves, pressure from straps may prevent alarm from activating. If patient falls out of bed and is suspended in the restraint, serious injury may occur from chest compression or suffocation.
    - ALWAYS use Hospital Bed Safety Workgroup (HBSW) compliant bed side rails. Use gap fillers to reduce the risk that patients' body or limbs may fit over, under, around, through or between rails. Full compliant side rails must be UP when restraints are used on a patient.
    - To reduce the risk of entrapment, use side rail covers, especially with split side rails. A failure to do so may result in serious injury if patient's body goes under, around, through or between the bed side rails.

Precautions

- This device may not be suitable for all high fall-risk patients.
- Ensure all parts of this system are operational before leaving a patient unattended. The sensor pad DOES NOT prevent falls or injury from falls and is not a substitute for patient care, caregiver rounding and a comprehensive fall management protocol in your facility.
- NEVER connect the Reprocessed Posey® Bed Alarm Sensor Pads to other manufacturers' alarms.
- Sensor pads beyond expiration date are out of warranty and may not function properly, causing false alarm or no alarm. When putting sensor pad into use, calculate expiration date 30 days from initial use.
- To avoid inconvenience to staff and patients, and to protect sensor pads from damage, you should follow these steps:
    - Only use Reprocessed Posey® sensor pads with the Posey® alarm.
    - When routing sensor pad cord to alarm, check that there is no stress on cord. Cord must be clear of all moving parts of bed to prevent sensor pad failure.
    - NEVER jerk or pull on the cord to remove plug. Doing so will damage cord wires or plug.
    - ALWAYS use the plastic tab to release plug.
    - Make sure sensor pad intake ("neck" of sensor pad) is clear and not blocked. Air must flow freely in and out of sensor pad for alarm to function. Make sure liquid does not enter at "neck" of sensor pad, as this will damage sensor pad. If needed, use an incontinence pad to protect sensor pad from urine or other liquids.
    - NEVER roll, fold or crease sensor pad. This will damage sensor pad and may cause false alarm or no alarm.
    - Make sure sensor pad lays FLAT on mattress surface, directly under patient's weight, and that sensor pad cord is not folded back under the sensor pad.

Directions for Use

1. Read all sensor pad and alarm instructions prior to use.
2. Check that sensor pad, cord, and plug are clean and undamaged. Discard entire sensor if there is any damage.
3. When putting sensor pad into use, calculate expiration date 30 days from initial use.

4. Choose a position for sensor pad (refer to Figure 1):
    a. Centered at patient's shoulder blades; or
    b. Centered under patient's buttocks.
5. Place sensor pad flat on top of mattress across the width of the bed with the labeled side UP.
6. Be sure to properly secure and align sensor pad to prevent false alarm events. Use metal clips to secure the sensor pad to the mattress.
7. Place the bottom sheet over the sensor pad.
8. If needed, use an incontinence pad to protect sensor pad from urine or other liquids. Sensor pad may fail if liquid enters at the "neck" of the sensor pad.
9. Route the sensor pad cord to the alarm. Check that the sensor pad cord has slack, is not stressed, is clear of moving parts of bed, and does not pose a tripping hazard.
10. Insert plug into sensor pad input on the alarm. Check that that the plug on the sensor pad cord is not damaged (plug broken, or wires disconnected) and is securely connected to the alarm.
11. Test sensor pad and alarm (refer to Directions for Testing Sensor Pad).

Directions for Testing Sensor Pad

1. Make sure alarm is ON and in monitoring mode.
2. Check that the plug on the sensor pad cord is not damaged (plug broken, or wires disconnected) and is securely connected to the alarm.
3. Disconnecting the sensor pad from the alarm when the power is on will cause the alarm to activate. This is called a "failsafe" mode. Disconnect the sensor pad to make sure the failsafe mode works. DO NOT use the alarm if the alarm does not sound when the sensor pad is disconnected. ALWAYS use plastic tab to release plug.
4. When connecting the alarm to the nurse call system, check that the nurse call cable is securely connected to the alarm and the nurse call panel. ALWAYS test alarm and nurse call function if nurse call cable is plugged into the alarm and wall jack. Remove pressure from sensor pad to activate alarm and make sure the nurse call light for the proper bed and room activates in the appropriate nurses' station location. Remove the cable from the wall jack and make sure the visual or audible alert at the nurses' station immediately activates.
5. Inspect sensor pad cord and nurse call cable (if in use) to ensure they are out of the footpath and DO NOT pose a tripping hazard.
6. The sensor pad will not work if plugged into a phone outlet.

Storage and Handling

- Store reprocessed sensor pads flat or hang in a dry, secure environment. DO NOT roll, bend or fold sensor pads, as it may damage internal electronic parts and cause a malfunction.
- This device is designed for use in normal indoor environments.
- This device may be stored in ambient warehouse temperatures at normal humidity levels (10 to 50%). Avoid excess moisture or high humidity that may damage product materials (greater than 90%).

Compatibility

- The Reprocessed Posey® Bed Alarm Sensor Pads are designed for over-mattress bed use only with Posey® Fall Alarms. Never use Reprocessed Posey® Bed Alarm Sensor Pads with other manufacturers' sensors and alarms.

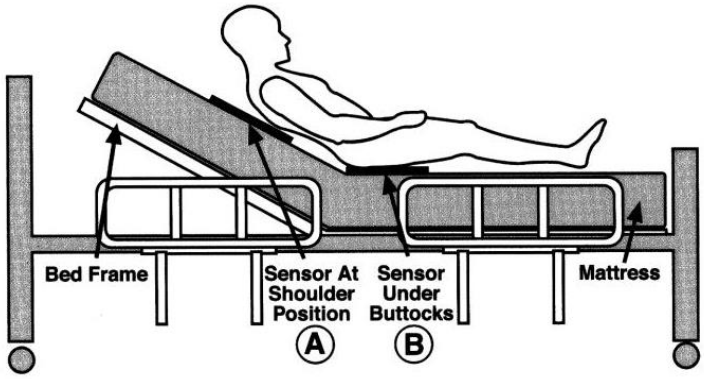

Figure 1 – Reprocessed Posey® Bed Alarm Sensor Pad Positioning

Warranty

8283 – This product is warranted for a period of thirty (30) days from date of first use.

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 LAIBLE 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 Nickel, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

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