

INSTRUCTIONS FOR USE

SterilMed, Inc.
Reprocessed Bed and Chair Sensor Pads
Manufactured by SterilMed, Inc.
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www.SterilMed.com

Caution: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

These devices are reprocessed bed and chair sensor pads from various original equipment manufacturers (OEM). Bed and chair sensor pads are designed to provide effective monitoring of patients that are susceptible to falling.

Each OEM provided an Instructions for Use (IFU) document with the original device. The health institution that wishes the device to be reprocessed should retain this original document.

DEVICE DESCRIPTIONS

Reprocessed bed and chair sensor pads are used to help the monitoring of patients that are at risk of falling. Bed and chair sensor pads consist of a pressure sensitive sensor mat. When the pressure applied to the sensor mat changes for more than a pre-selected number of seconds an alarm tone alerts the staff that the patient is no longer on the sensor mat and may be unsafe.

These bed and chair sensor pads have been cleaned, evaluated for continued integrity, and packaged prior to use. These devices were shipped from an owner, reprocessed, and returned for a single, subsequent use. Devices are tracked throughout the reprocessing steps to monitor the number of times reprocessed.

This device has been reprocessed for a single use. If the device is to be used again, it must undergo reprocessing prior to use.

CONTRAINDICATIONS

No contraindications known.

STERILMED®
*Reprocessing, Repair and Refurbishment
of Medical Devices, Equipment & Instruments*

WARNINGS AND PRECAUTIONS

SterilMed bed and chair sensor pads are reprocessed for a single use only and must be returned for reprocessing prior to another use.

1. It is necessary to have adequate training and a thorough understanding associated with the use and applications of bed and chair sensor pads.
2. The device and packaging should be inspected prior to use. If the package/product appears to be damaged, do not use.
3. Verify all appropriate accessories/equipment and settings to be used with bed and chair sensor pads are present and correct.
4. Folding or bending of the device may cause a lack of functionality.

DIRECTIONS FOR USE

1. Place the bed or chair sensor pad on the sitting area. The bed or chair sensor pad should be placed directly under the patient's buttocks on a flat surface.
2. Connect the device to the control unit.
3. The device will now monitor the patient.
4. Daily testing of the unit is recommended when continually used.

POTENTIAL ADVERSE EVENTS

There are no adverse effects that have been reported associated with the use of these devices.

GENERAL INSTRUCTIONS AND INFORMATION

Verify product receipt and ensure that owner's name is appropriate on the label. Inspect package and product for signs of damage. The manufacturer packaged an Instruction for Use document with the original device, and the health institution that wishes the device to be reprocessed should retain this original document.

Open product using appropriate technique when needed for use.

Use of this reprocessed device should be limited to those physicians and/or staff trained in use of this device and associated equipment.

If additional reprocessing of the product is desired, wipe the device with a moist sponge to remove any visible blood or tissue, package product, label as "biohazard", and ship product back to SterilMed.



METHODS TO TEST REPROCESSED DEVICES

Validated methods are used for cleaning and packaging. Inspection and pre-release testing are used to ensure appropriate device integrity and function of each device prior to returning the device.

Instructions for Use can be found at www.SterilMed.com. Further questions or concerns by the health practitioner can be addressed directly by contacting your SterilMed Customer Service Associate and/or the SterilMed Quality Department at 1-888-541-0078.

