

DESCRIPTION OF PRODUCT: Self-Releasing Cotton Belt with quick-release buckle. For hospital bed use only.

Rx ONLY



SELF-RELEASING ROLL BELT
AL-67606 Self-Releasing Roll Belt

INDICATIONS FOR USE:

- Patients needing a reminder to call for assistance before exiting a bed, and are able to follow instructions.
- Patients needing a positioning device for added safety while in a bed.

CAUTION This product is designed for self-release. If the patient is not able to easily self-release, it is considered a restraint and must be prescribed by a physician.



CONTRAINDICATIONS:

- **DO NOT** use on a patient who is or becomes highly aggressive, combative, agitated, or suicidal.
- **DO NOT** use on patients with: ostomy, colostomy, or G-tubes; hernias, severe Cardio Obstructive Pulmonary Disease (COPD); or with post-surgery tubes, incisions or monitoring lines. These could be disrupted by a restraint.
- **DO NOT** use on a patient who is unwilling or unable to follow instructions, and is at risk of a fall or re-injury from self-release.

ADVERSE REACTIONS

- Severe emotional, psychological, or physical problems may occur: if the applied device is uncomfortable; or if it severely limits movement. If symptoms of these problems ever appear for any reason, get help from a qualified medical authority and find a less restrictive, product or intervention.

APPLICATION INSTRUCTIONS:

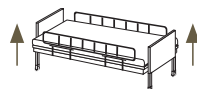
CAUTION Before use, check device for damage and that hook and loop adheres securely. Discard if you have any questions about patient safety.

1. Open the belt and center it across the mattress with the waistband facing up. The hook fastening section will be located on the right side, and the long straps will hang off both sides of the bed.
2. Position the patient in bed with the belt at waist level.
3. Bring the belt around the patient's waist and secure with the hook and loop fastener. Connect the quick-release buckle. The belt must be snug, but not interfere with breathing. To check for proper fit, slide an open hand (flat) between the belt and the patient.
4. Attach the two long straps on each side to a movable part of the bed frame, at waist level, using quick-release ties or buckles.
5. Check that the straps are secure and will not change position, loosen, or tighten if the patient pulls on them, or if the bed is adjusted.

WARNING

Heed these warnings to reduce the risk of serious injury or death:
BED SAFETY

- **ALWAYS** use Hospital Bed Safety Workgroup (HBSW) (<http://www.fda.gov/cdrh/beds/modguide.html>) compliant side rails in the UP position and fill ALL gaps to reduce the risk of entrapment.
- Use side rail covers and gap protectors to help prevent the patient's body from going under, around, through or between the side rails. A failure to do so may result in serious injury or death if a patient becomes suspended or entrapped.



WARNING

- There is a risk of chest compression or suffocation, if the patient's body weight is suspended off the mattress (figs. 1 and 2).
- Monitor per facility policy to ensure that the patient cannot slide down, or fall off the mattress and become suspended or entrapped (figs. 1 and 2).



FIG. 1



FIG. 2

- **STOP USE AT ONCE:** if the patient is at risk to slide forward or down in the device.
- Before leaving the patient unattended, explain the purpose for the belt. Make sure the patient understands:
 - the need to call for assistance before exiting the bed; and
 - how to self-release in an emergency.

ADDITIONAL SAFETY AND LAUNDERING INSTRUCTIONS ON OTHER SIDE

Safety Information for the Use of Torso and Limb Restraining Products

WARNING: ALWAYS Monitor patients per facility policy.
Improper application or use of any restraint may result in serious injury or death.

RX ONLY. NOT FOR HOME USE. Federal law (USA) restricts this device to sale by or on order of a physician. For use in a licensed healthcare facility only.

STAFF TRAINING: Staff must have on going training and be able to demonstrate competency to use this device in accord with: instructions; your facility policies and state and federal regulations (Federal Register, Part IV, 42 CFR Part 482.13(e)(5) and (f)(6))

BEFORE APPLYING ANY RESTRAINT:

- Make a complete assessment of the patient to ensure restraint use is appropriate.
- Identify the patient's symptoms and, if possible, remove the cause. You may need to: cater to individual needs and routines; increase rehabilitation and restorative nursing; modify the environment; or increase supervision.
- Use a restraint only when all other options have failed. Use the least restrictive device, for the shortest time, until you find a less restrictive alternative. Patients have the right to be free from restraint.
- Obtain informed consent from the patient or guardian prior to use. Explain the reason for restraint use to the patient and/or guardian to help ensure cooperation.
- A restraint must only be used in accord with the patient's Individualized Care Plan (ICP). The ICP is an assessment by an interdisciplinary team, which may include, but is not limited to: PT, OT, Nursing, the Physician, and Social Services. The ICP should include: restorative nursing; patient release; and pressure sore prevention.

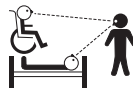


NOTE: Just as patient behavior is not 100% predictable, no product is 100% foolproof. Patient safety requires regular reassessment and monitoring per facility policy. A product that worked in the past may be inappropriate if the patient's mental or physical health status changes. NEVER apply any product that you feel is unsafe. Consult with the proper medical authority if you have questions about patient safety.

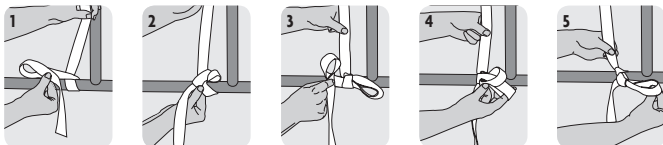
ADDITIONAL WARNINGS:

1. ALWAYS monitor patient per facility policy. Be aware that constant monitoring may be required for:

- Aggressive or agitated patients; and
- Patients deemed at risk of aspirating their vomit. This includes patients in the supine position, or who are not able to sit up. If the patient vomits, he or she could aspirate the vomit and suffocate.
- Be prepared to intervene at the first sign of danger. Such patients require frequent review and evaluation of their physical and psychological status.



How to Tie the Quick-Release Tie



1. Wrap the strap once around a movable part of the bed frame leaving at least an 8" (20 cm) tail. Fold the loose end in half to create a loop and cross it over the other end.
2. Insert the folded strap where the straps cross over each other, as if tying a shoelace. Pull on the loop to tighten.
3. Fold the loose end in half to create a second loop.
4. Insert the second loop into the first loop.
5. Pull on the loop to tighten. Test to make sure strap is secure and will not slide in any direction.
6. Repeat on other side. Practice quick-release ties to ensure the knot releases with one pull on the loose end of the strap.

2. NEVER alter or repair this product. ALWAYS Inspect before each use: Check for broken stitches or parts; torn, cut or frayed material; or locks, buckles, or hook and loop fasteners that do not hold securely. DO NOT use soiled or damaged products. Doing so may result in serious injury or death. Dispose of damaged products per facility policy for BIOHAZARDOUS material.



3. ALWAYS secure straps, to a movable part of the bed or chair frame, out of the patient's reach, using quick-release ties (see drawing below) or buckles. These allow easy release in the event of an accident or fire. Test to make sure straps cannot tighten, loosen, or slip and create excess slack. If this occurs, the patient may slide off the chair or bed, increasing the risk of serious injury or suffocation. Restraint release is an important part of facility fire and disaster drills. Straps can be cut with scissors in an emergency.

4. NEVER use on toilets, or on any chair or furniture that does not allow proper application as directed in the Application Instructions. DO NOT use at home.



5. NEVER expose this product to open flame, fire, smoking materials, or high heat sources. Some products may melt or ignite and burn. The facility smoking/no smoking policy should be strictly enforced.

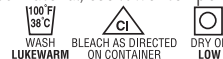


6. NEVER use as a seat belt in a moving vehicle. Not designed to withstand the force of a crash or sudden stop.



LAUNDERING INSTRUCTIONS (if applicable):

- Fasten all buckles and locks to reduce risk of damage during wash and dry cycles. DO NOT put buckles or locks through extractors. For maximum life, launder in a laundry bag.
- Before laundering, zip up and turn the product inside out to protect zipper.
- Hook and loop fasteners may collect lint after repeated use or laundering, reducing grip strength. Fasten the "hook" to the "loop" before laundering to help prevent lint buildup. As needed, use a stiff-bristle brush to remove lint from the "hook" side.
- These products, other than foam products, can be machine washed under CDC* guidelines for material soiled with blood or bodily fluid.
- For non-contaminated material, use lower temperature wash and dry cycles to extend product life.
- For foam products:



WARNING

Test Zippers or hook and loop fasteners before each use. DISCARD device if it does not fasten securely.

STORAGE AND HANDLING:

- This device is designed for use in normal indoor environments.
- This device may be stored in ambient warehouse temperatures at normal humidity levels. Avoid excess moisture or high humidity that may damage product materials.

*www.cdc.gov

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