DESCRIPTION OF PRODUCT: Self-Releasing Belt to remind patient to call for assistance before ambulating. For hospital bed, wheelchair or geri-chair use.

RX ONLY



Photo for application illustration only. See side rail information below.

POSEY OMNI BELT

REF 4116PQ Omni Belt,

polypropylene w/quickrelease buckle

INDICATIONS FOR USE:

- Patients needing a reminder to call for assistance before exiting a chair or bed, and are able to follow instructions.
- Patients needing a positioning device for added safety while in a chair or bed.
- NOTE: This device DOES NOT allow the patient to roll from side-to-side or sit up in bed. If greater range of motion is desired, see Posey Catalog for other options.

ACAUTION 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 reinjury 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: WHEELCHAIR OR GERI-CHAIR

ACAUTION Before use, check device for damage. Discard if you have any questions about patient safety.

- 1. Open the lap belt and position it so that the patient will sit on it.
- 2. Bring the ends of the connecting straps down at a 45-degree angle between the seat and wheelchair sides or around the outside of the chair frame (Geri-chair) (fig. 1).
- **3.** Criss-cross the straps behind the chair and draw them around the opposite side kick spurs (wheelchair), or the lower cross braces (Gerichair) (fig. 2). Insert the strap ends through the white "D" ring on each side, and attach the hook and loop fasteners.
- **4.** Use slide buckles to remove any slack. Check that the straps are secure and will not change position, loosen, or tighten if the patient pulls on them, or if the chair is tilted or adjusted.
- **5.** Position the patient as far back in the seat as possible, with the buttocks against the back of the chair.
- **6.** Lay the lap belt across the patient's thighs and connect the quick-release buckle so the belt is across the patient's lower lap.
- **7.** Use quick-release buckle to adjust the lap belt. 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.

APPLICATION INSTRUCTIONS: HOSPITAL BED

- **1.** Open the belt and center it across the mattress.
- 2. Position the patient in bed with the belt at waist level.
- **3.** Bring the belt around the patient's waist and connect the quick-release buckle.
- **4.** Use quick-release buckle to adjust the belt. 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.
- **5.** Feed the end of each connecting strap around a movable part of the bed frame, at waist level. Insert the strap ends through the white "D" ring on each side, and attach the hook and loop fasteners.
- **6.** Use slide buckles to remove any slack. 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.

AWARNING

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

BED SAFETY

45

FIG. 1

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. Posey offers a full range of side rail pads and/or gap protectors to cover gaps.
- There is a risk of chest compression or suffocation if the patient's body weight is suspended off the mattress or chair seat. Use extreme caution with chair cushions. If a cushion dislodges, straps may loosen and allow the patient to slide off the seat (figs. 3, 4, and 5).
- Monitor per facility policy to ensure that the patient cannot slide down, or fall off the chair seat or mattress and become suspended or entrapped (figs. 3, 4, and 5).







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• STOP USE AT ONCE: if the patient is at risk to slide forward or

- down in the device.
- NOTE: A restraint with a pelvic piece will help to reduce the risk of sliding. See Posey Catalog.
- 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 or chair; and
 - how to self-release in an emergency.

ADDITIONAL SAFETY AND LAUNDERING INSTRUCTIONS ON OTHER SIDE





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Safety Information for the Use of Posey Torso and Limb Restraining Products



MARNING: 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: Posey instructions; your facility policies and state and federal regulations (Federal Register, Part IV, 42 CFR Part 482.13(e)(5) and (f)(6); Posey offers inservice training aids at no charge. Contact Posey online at www.posey.com or call toll-free at 1.800.447.6739 (press 5).

SELECTING THE RIGHT POSEY PRODUCT: Refer to the Posey catalog to help select the right device to meet individual patients' needs.

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 Posey Quick-Release Tie









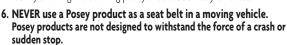


- 1. Wrap the strap once around a movable part of the bed frame leaving at least an 8" (20 cm) tail. Fold the loose end in half to create a loop and cross it over the other end.
- 2. Insert the folded strap where the straps cross over each other, as if tying a shoelace. Pull on the loop to tighten
- 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

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
- 4. NEVER use Posey products 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.



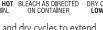




LAUNDERING INSTRUCTIONS (if applicable):

- 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: WASH BLEACH AS DIRECTED ON CONTAINER

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

Sizing Table for Posey Products

ALWAYS use the proper size product. Products that are too small or large may compromise patient comfort and could result in severe injury or death.

BINDING COLOR	SIZE	WEIGHT lb. (kg.)	CHEST in. (cm)
White	X-Small	60-115 (27-52)	25-32 (64-81)
Red	Small	112-160 (51-73)	31-37 (79-94)
Green	Medium	135-203 (61-92)	35-40 (89-102)
Yellow	Large	160-225 (73-102)	38-44 (97-112)
Blue	X-Large	180-247 (82-112)	42-48 (107-122)
Black	XX-Large	220-275 (100-125)	46-55 (117-140)
Yellow/Black	XXX-Large	265-305 (120-138)	54-60 (137-152)
Blue/Black	XXXX-Large	295-340 (133-154)	58-64 (147-163)

Posey Belts are not color-coded, but are sized according to this table.

Flame-retardant fabric is available on request.

Patient weight and size are a general indicator only. Consider individual physical characteristics to choose the right product for each patient. Refer to product label for specific sizing information.



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