

DESCRIPTION OF PRODUCT: A vest restraint with tie ends. For bed application.

Rx ONLY



Orthotech Six Point Restraint

REF S35151 Breezeline mesh, S-XL

Indications for Use:

- Patients assessed to be at risk of injury from a fall.
- Patients requiring a positioning device to assist medical treatment.

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.

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:

⚠ WARNING Make sure patient wears proper undergarments to protect skin.

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

1. Place the device on the patient with the opening in the back. Make sure side seams are located under the arms. If they are not, the sizing may be incorrect.
2. Secure straps to the bed frame, out of the patient's reach (See below).
3. Slide an open hand (flat) between the device and the patient to ensure proper fit. The device must be snug, but not interfere with breathing.

⚠ WARNING

- A restraint applied incorrectly or worn backwards may result in serious injury or death from suffocation, chest compression or patient escape.
- NEVER criss-cross straps directly behind the patient. Straps may loosen if the patient rotates.
- Make sure straps cannot slide, loosen, or tighten if the patient pulls on them, or if the bed position is adjusted. The patient may suffocate if the straps tighten. If the straps loosen, serious injury or death may occur from: patient escape; or from chest compression or suffocation if the patient becomes suspended in the restraint.

Application Instructions: Bed

1. Secure straps with quick-release ties to a movable part of the bed frame at waist level, out of the patient's reach.

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.

⚠ Additional Warnings:

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> search keyword "HBSW") 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. (Figs. 1 and 2).
- 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. 1 and 2).

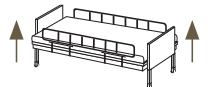


Fig. 1



Fig. 2

- **STOP USE AT ONCE:** if the patient has a tendency to slide forward or down in the device; or is able to self-release.

NOTE: A restraint with a pelvic piece will reduce the risk of sliding, or of the patient pulling the device over his or her head. See Posey Catalog.

ADDITIONAL SAFETY AND LAUNDERING INSTRUCTIONS ON OTHER SIDE

Safety Information for the use of Posey® 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: 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.

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.

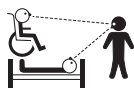


NOTE: Just as patient behavior is not 100% predictable, no product is 100% foolproof. Patient safety requires regular reassessment and monitoring per facility policy. A product that worked in the past may be inappropriate if the patient's mental or physical health status changes. NEVER apply any product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



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 secure restraint strap to side rail.

5. 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.



6. 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.



7. NEVER use a Posey product as a seat belt in a moving vehicle. Posey products are 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:



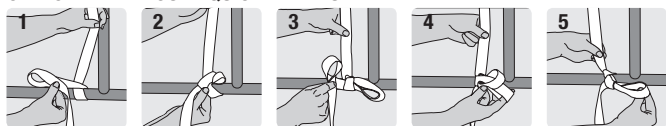
⚠ WARNING Test Zippers or hook-and-loop fasteners before each use. DISCARD device if it does not fasten securely.

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

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 the strap.

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.