PEDIATRIC LIMB HOLDERS

Applicable Products: REF 4733, 4734

DESCRIPTION OF PRODUCT: Limb holder for limiting limb movement of infant and pediatric patients.

Rx ONLY



POSEY PEDIATRIC LIMB HOLDERS

REF 4733 Infant to 2 years **REF 4734** 2-5 years

INDICATIONS FOR USE:

- Patients assessed to be at risk of disrupting life-saving treatments (e.g., chronic tube pulling).
- Patients assessed to be at risk of line pulling, which may prevent monitoring of vital signs.
- Patients whose picking, pulling, scratching, or peeling exacerbates a skin condition, causes self-injury, or compromises wound site integrity.

CONTRAINDICATIONS:

- **NEVER** use on a patient:
 - With a dislocation or fracture on the restrained limb; or
 - If an IV or wound site could be compromised by the device. See the Posey Catalog for other options for such a patient.

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:

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

- **1.** Wrap the limb holder cuff around the patient's wrist or ankle with the blue side toward the skin.
- 2. Secure the hook and loop fastener. Slide one finger (flat) between the cuff and the inside of the patient's wrist or ankle to ensure proper fit. The cuff must be snug, but not compromise circulation.
- **3.** Take the strap directly away from the patient and secure out of the patient's reach.

NOTE: DO NOT wrap the straps around the patient's limb.

Leave straps loose enough for extended range of motion, but not enough to allow self-injury or disruption of lines or extubation.

AWARNING

ADDITIONAL OR DIFFERENT BODY OR LIMB RESTRAINTS MAY BE NEEDED:

- If the patient pulls violently against the bed straps;
- To reduce the risk of the patient getting access to the line/ wound/tube site;
- To prevent the patient from flailing or bucking up and down causing self-injury.

See Posey Catalog.

MONITOR PER FACILITY POLICY. Check to ensure that:

- Straps cannot slide in any direction or loosen if the patient pulls on them, or if the bed is adjusted;
- Cuffs are properly secured. If applied too tightly, circulation will be restricted; if applied too loosely, the patient may be able to slip his or her limb from the device;
- Cuffs are attached in a way that the patient is not able to use his or her teeth or otherwise remove the device;
- Cuffs are intact, and not torn or damaged. DO NOT allow patients to ingest product material.

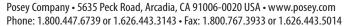
BED SAFETY

- 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. Posey offers a full range of side rail pads and/ or gap protectors to cover gaps.

ADDITIONAL SAFETY AND LAUNDERING INSTRUCTIONS ON OTHER SIDE











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









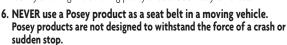


- 1. Wrap the strap once around a movable part of the bed frame leaving at least an 8" (20 cm) tail. Fold the loose end in half to create a loop and cross it over the other end.
- 2. Insert the folded strap where the straps cross over each other, as if tying a shoelace. Pull on the loop to tighten
-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



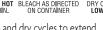




LAUNDERING INSTRUCTIONS (if applicable):

- 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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