

DESCRIPTION OF PRODUCT: Padded limb restraints with double security closure.

Rx ONLY



POSEY TWICE-AS-TOUGH CUFFS

REF 2791 Ankle pair; single strap (color coded - red)

REF 2791Q Ankle, or large wrist, pair, single strap with quick-release buckles (color-coded red)

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.
- Patients assessed as being in extreme danger of injury to themselves or to others.

CONTRAINDICATIONS:

- **DO NOT** use this device on a patient who is or becomes: suicidal; highly aggressive or combative; self-destructive; or deemed to be an immediate risk to others, **UNLESS** the patient is under constant supervision.
- **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 the patient is likely to cause injury to him/herself or others, get help from a qualified medical authority to find an alternate intervention or method of restraint.

APPLICATION INSTRUCTIONS:

(Connecting Straps) (repeat steps 1-2 for each side)

WARNING

- Before each use, check cuffs and straps for cracks, tears, and/or excessive wear or stretch; cracked or broken buckles or locks; and/or that hook and loop adheres securely, as these may allow patient to remove cuff. Discard if device is damaged.
- If you have any questions about patient safety, ask the appropriate medical authority for alternatives.

NOTE: ALWAYS secure both ankles to help prevent patient release.

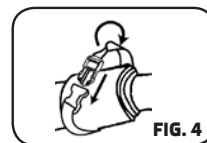
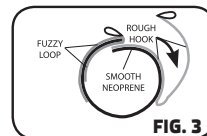
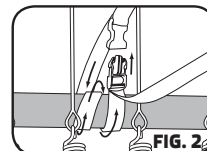
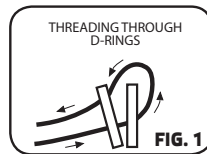
1. Follow these steps to apply device:
2. **2791**-Wrap the connecting strap to a movable part of the bed frame, out of the patient's reach, by pulling the strap back between the first and second D-ring (fig. 1), or attach with a quick-release tie.
2. **2791Q**-Wrap the connecting strap once around a movable part of the bed frame, out of the patient's reach. Close the quick-release buckle. Listen for a "snapping" sound. Pull firmly on straps to ensure a good connection (fig. 2).

APPLYING THE CUFFS (repeat steps 1-4 for each limb):

1. Wrap the neoprene piece (the red side should be positioned against the skin) around the ankle. Attach the black hook and loop pieces together, followed by the red hook and loop pieces. The fuzzy piece should be sandwiched between the two pieces of hook (fig. 3). Be sure to overlap at least one inch (3 cm).
2. Press the hook and loop closure together firmly and make sure it adheres securely. Slide ONE finger (flat) between the cuff and the inside of the patient's ankle to ensure proper fit. The cuffs must be snug enough to prevent escape, but not interfere with circulation.
3. **2791**-Pass the end of the limb strap over the top of the cuff and through the two D-rings on the cuff. Bring the strap back over the first ring and through the two D-rings on the cuff (fig. 1).
2791Q: Release the quick-release buckle, twist, and reconnect. Listen for a "snapping" sound. Pull firmly on straps to ensure a good connection (fig. 4).
4. Adjust the bed strap(s) to allow desired freedom of movement, without compromising patient or caregiver safety

TO LIMIT PATIENT RANGE OF MOTION (fig. 5):

1. Attach the cuff that is secured to the bottom right corner of the bed to the left ankle.
2. Criss-cross the straps and attach the cuff secured to the bottom left corner of the bed to the right ankle.
3. Adjust connecting straps as necessary.



WARNING

ADDITIONAL OR DIFFERENT BODY OR LIMB RESTRAINTS MAY BE NEEDED (See Posey Catalog):

- 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 and causing self-injury.

MONITOR PER FACILITY POLICY. Check to ensure that:

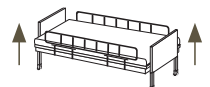
- Straps cannot slide in any direction, tighten or loosen if the patient pulls on them, or if the bed is adjusted;
- Cuffs are attached in a way that the patient is not able to use his or her teeth or otherwise remove the device;
- Cuffs are intact, and not torn or damaged. **DO NOT** allow patients to ingest product material.

MONITORING

- Posey recommends constant direct supervision for patients deemed to be at risk of injury to themselves or others. For times when direct supervision is not possible, monitor by line of sight or by a video/audio device.
- **NEVER** allow a patient to have access to any tool, utensil, or object that might be used to unlock or damage cuffs.
- Be aware that a sudden mood swing may cause agitated or aggressive behavior. Contact the medical team **AT ONCE** if this occurs. No level of monitoring may avoid the risk of serious injury to highly agitated or aggressive patients.
- Check the patient regularly to ensure that:
 - Circulation is not impaired. Serious injury may occur if the cuffs restrict circulation.
 - Cuffs are secure. Death or serious injury to the patient or others may occur if the patient can remove the cuffs.

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

⚠️ 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 (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.

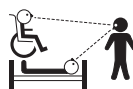


NOTE: Just as patient behavior is not 100% predictable, no product is 100% foolproof. Patient safety requires regular reassessment and monitoring per facility policy. A product that worked in the past may be inappropriate if the patient's mental or physical health status changes. NEVER apply any product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

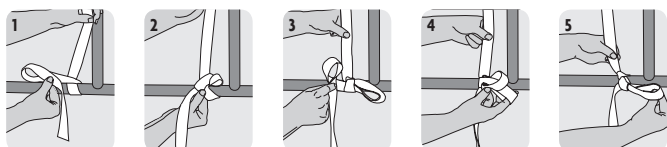
⚠️ ADDITIONAL WARNINGS:

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 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 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.



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.

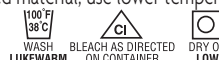


6. NEVER use a Posey product as a seat belt in a moving vehicle. Posey products are not designed to withstand the force of a crash or sudden stop.



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

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.