

Rx ONLY

DESCRIPTION OF PRODUCT: Padded limb restraints with double-security closure. 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 ٠ 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 alternative form of intervention or method of restraint.

Application Instructions

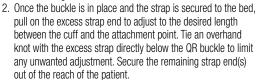
- AWARNING Before each use, check cuffs and straps for cracks, tears, and/or excessive wear or stretch, cracked or broken buckles or locks, and/or that hook-and-loop adheres securely, as these may allow patient to remove cuff. Discard if device is damaged.
- If you have any questions about patient safety,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

The order of either application of the straps to the bed OR applying the cuff to the patient is to be determined by the clinician/physician depending on the situation.

NOTE: ALWAYS secure both wrists to help prevent patient release. APPLICATION OF CONNECTING STRAP ENDS TO THE BED OR

STRETCHER/GURNEY (Repeat steps 1 to 2 for each side):

1. Wrap the connecting strap at least once around a movable part of the bed or stretcher/gurney, and out of the reach of the patient (Fig. 1). Make sure that the connecting strap moves with the patient when the bed height and/or the incline/decline features are in use. If buckle does not fit an opening, use the alternate method in Fig 2. Close the gray quick-release buckle by sliding the male end into the female end (Fig. 3). The gray QR buckle will only release when applying pressure on all three buttons in Fig 3.



APPLYING THE CUFFS (Repeat steps 1 to 4 for each side):

- 1. Wrap the neoprene piece around the ankle or wrist of the patient. Attach the black hook-and-loop pieces together, followed by the colored hook-and-loop pieces. The loop piece should be sandwiched between the two pieces of hook (Fig. 4). Be sure to overlap at least one inch (3cm).
- 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 or wrist to ensure proper fit.
- 3. Open the buckle and then twist the male end once before inserting back in place with the female end (Fig. 5). Secure the male and female ends of the cuff's quick-release buckle, listen for "clicking" sound.
- 4. Adjust the connecting strap(s) length from the bed to allow desired freedom of movement without compromising patient or caregiver safety. Ensure the remaining strap end(s) are secured and out of the reach of the patient.

27000/ 27000L

Posey Twice-As-Tough Cuffs

REF 27000 Universal QR. single strap cuff. regular size **REF** 27000L Universal QR. single strap cuff. large size Patent Pending 29626361

TO LIMIT LOWER LIMB RANGE OF MOTION (Fig. 6):

- 1. Attach the cuff that is secured to the bottom right side of the bed to the left ankle.
- 2. Criss-cross the straps and attach the cuff secured to the bottom left side of the bed to the right ankle.

3. Adjust connecting straps as necessary.

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

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- 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:

- Bed attachment 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 to 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) (https://www.fda.gov/MedicalDevices/ ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/HospitalBeds/default. htm) 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. 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.





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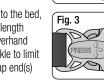
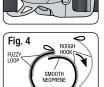


Fig. 1







WARNING: ALWAYS Monitor patients per facility

policy. Improper application or use of any restraint may result in serious injury or death.

RX ONLY. 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: Posey offers training aids at no charge. Contact Posey online at www.posey.com or call toll-free at 1.800.447.6739.

BEFORE APPLYING ANY RESTRAINT:

Follow your hospital's restraint policies and procedures which are in compliance with CMS guidelines and state laws.

ADDITIONAL WARNINGS:

- 1. ALWAYS monitor patient per facility policy. Be aware that constant monitoring may be required for:
- Aggressive or agitated patients; and

BIOHAZARDOUS material.

• Patients in a supine positon; ensure that being in this position would not cause any complications for those who are at risk of vomiting while being restrained.



- 2. NEVER alter or repair this product. ALWAYS Inspect before each use: Check for broken stitches or parts; torn, cut or fraved 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
- 3. ALWAYS secure straps to a part of the frame that moves with the patient (not foot/head board or siderails, out of the patients 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 or head/foot board.
- 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.



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

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:



BIOTHANE:

- Sanitize by submerging the entire product in 70% isopropyl alcohol for 10 minutes; or
- Apply an OSHA approved intermediate level disinfectant per manufacturer instructions. After cleaning, products MUST be rinsed with water to remove any residual chemicals.
- Make sure products are completely dry before use.
- Stainless Steel Locks: Posey recommends that locks be treated with a dryfilm lubricant (silicone) after each cleaning. For best results, spray a small amount into the lock. Work the action of the lock with a key several times to ensure that all the surfaces are well lubricated.

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



- 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.



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