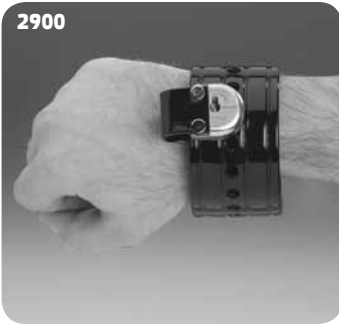


**DESCRIPTION OF PRODUCT:** Biothane® locking restraint cuffs for wrist and ankle.

**Rx ONLY**



2900

**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.



2900

**POSEY BIOTHANE® CUFFS**

**REF 2900** Biothane Cuff, 14"L x 2"W (36 cm x 5 cm), 5"-12" (13 cm-31 cm) Circumference

**REF 1074** Posey Universal Key (Connecting straps sold separately)

**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:**

**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.

Following these steps to apply device (repeat steps 1-5 on the other limb):

1. Wrap the cuff around the patient's limb.
2. Insert the metal post through the most suitable adjustment hole.
3. Secure the lock to the post.
4. Check for proper fit by inserting one finger between the cuffs and the patient's wrist or ankles. The cuffs must be snug enough to prevent escape, but not interfere with circulation.
5. Check that the lock "clicks" shut. If a lock is not completely closed, it can pop open. Before leaving the patient's side, test the lock by trying to open it without the key.

**To Unlock Cuffs:**

1. Insert the Posey Key into the lock and turn counterclockwise. This will prevent jamming (fig. 1).

**NOTE:** Universal Posey Keys fit all Posey locks. To order extra keys, contact Posey at 1.800.447.6739, press 5, and ask for Cat. #1074.

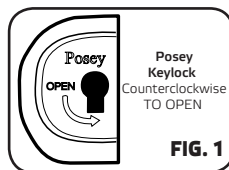


FIG. 1

**APPLICATION INSTRUCTIONS: CONNECTING STRAPS (sold separately)**

1. Loop the connecting strap (sold separately) through the U-bar on the cuff.
2. Wrap the strap around a movable part of the bed frame, out of the patient's reach. Ensure that the strap is wrapped around the frame at least once before passing the end of the strap through the buckle or lock.

**WARNING**

Posey Keys **MUST** be readily available to staff at all times. In an emergency, it is difficult to cut the cuffs with scissors to free the patient.

**NOTE:** Keep excess strap out of reach to prevent patient from pulling strap and damaging or opening lock.

Use extreme caution when using any type of padding with the limb holder. If the patient pulls violently, the padding may compress and allow the patient to remove the cuff and cause injury to himself/herself or others.

**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**

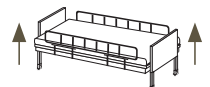
- Posey recommends constant direct supervision for patients deemed to be at risk of injury to themselves or others. For times when direct supervision is not possible, monitor by line of sight or by a video/audio device.
- **NEVER** allow a patient to have access to any tool, utensil, or object that might 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](http://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.

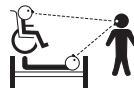


**NOTE:** Just as patient behavior is not 100% predictable, no product is 100% foolproof. Patient safety requires regular reassessment and monitoring per facility policy. A product that worked in the past may be inappropriate if the patient's mental or physical health status changes. NEVER apply any 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 supervision (by line of sight or a video/audio device) may be required for:**

- Highly 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 use connecting straps that are designed for use with high security restraint cuffs.** Straps that are not designed for use with Posey high security cuffs may break and increase the risk of death or serious injury to the patients or others.

**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):**

**COTTON AND POLYPROPYLENE PRODUCTS:**

- These 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.
- 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.
- Inspect all buckles, locks, and metal parts after drying. Discard if damaged.



**LEATHER PRODUCTS:**

**CAUTION** DISCARD any leather product contaminated with blood or bodily fluid. There is no CDC accepted method to sterilize or disinfect leather. Normal methods (i.e., bleach, autoclaving, steam or ETO gas sterilization) cannot be used because leather is very porous, and will deteriorate if exposed to germicidal chemicals, high heat, or moisture. Also, residual chemicals may accumulate and pose a risk of injury to the caregiver or patient.

**SYNTHETIC LEATHER OR 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 dry-film 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.