

DESCRIPTION OF PRODUCT: A double padded mitt to hinder picking and tube pulling.

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

- **DO NOT** use on a patient who is or becomes highly aggressive, combative, agitated, or suicidal.
- **NEVER** use mitts on a patient:
 - If an IV or wound site could be compromised by the device; or
 - With a dislocation or fracture on the affected limb.

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

(Repeat Steps 1-4 for each mitt):

1. Insert the patient's hand into the mitt, palm down.
2. Wrap the wrist strap around the smallest part of the patient's wrist, over the top of the wrist, through the plastic ring, and secure it onto itself.
3. Slide ONE finger (flat) between the device and the inside of the patient's wrist to ensure proper fit. The strap must be snug, but not compromise circulation.

To view hand/fingers:

1. Reach under the inspection flap, detach the hook and loop fastener, and pull back the flap to expose the hand.
2. To close the inspection flap, tuck into the end of the mitt and press the hook and loop closure together firmly.

! WARNING !

ADDITIONAL OR DIFFERENT BODY OR LIMB RESTRAINTS MAY BE NEEDED
(See www.reptonmedical.co.uk)

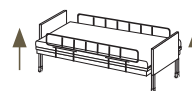
- If the patient pulls violently.
- To reduce the risk of the patient getting access to the line/wound/tube site;
- To prevent the patient from flailing or bucking up and down and causing self-injury.



MONITOR THE PATIENT PER FACILITY POLICY.

Check to ensure that:

- Mitts 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;
- Mitts are intact, not torn or damaged, and hook and loop closes securely. **DO NOT** allow patients to ingest mitt material;
- The patient cannot use his or her teeth or otherwise remove the device and inflict self-injury;
- Monitor closely when the patient is out of bed. Patients who ambulate while wearing this device may be at risk of injury from a fall.



BED SAFETY

- **ALWAYS** use 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.

ADDITIONAL SAFETY AND LAUNDERING
INSTRUCTIONS ON OTHER SIDE

Safety Information for the use of 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.

⚠ WARNING: Test Hook & Loop fasteners before each use. Discard device if the product does not function correctly.

NOT FOR HOME USE. Only to be used under the direction of a doctor / medical professional. For use in a licensed healthcare facility only.

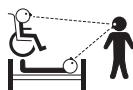
STAFF TRAINING: Staff must have on going training and be able to demonstrate competency to use this device in accordance with your facility policies. **Repton Medical Ltd** offers inservice training aids at no charge.

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 accordance 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. **NEVER use Repton 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.**



4. **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.

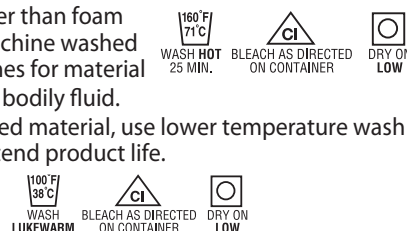


5. **NEVER use a Repton Medical product as a seat belt in a moving vehicle.** Repton Medical products are not designed to withstand the force of a crash or sudden stop.



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:



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