



Instructions for use

X-MKK-PM “Mitty Mini”

Pediatric mitt



Intended user:

This medical device is intended to be used by healthcare professionals.

Intended purpose:

A mitt provides a polstered cover around the hand and fingers to prevent self injury and to prevent the interruption of medical treatment.

Indications for use:

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

Contraindications:

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



X-MKK-PM-S (Neonatal) 0-1 year old



X-MKK-PM-M (Toddler) 1-3 years old



X-MKK-PM-L (Child) 3-7 years old

Composition:

36% cotton, 64% polyester

Explanation of symbols



Manufacturer



Date of manufacture



Medical Device



Catalogue number



Batch code



Consult instructions for use



Single patient - multiple use



Keep dry



Keep away from sunlight



Non-sterile



Do not use if package is damaged

Potential complications:

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.

Product description:

Packaging:

The product is packed per pair in a transparent bag.

Storage and handling:

- This device is designed for use in 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.





Operating instructions:

Before applying:

- Make a complete assessment of the baby to ensure restraint use is appropriate.
- Identify the baby'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.
- If possible, obtain informed consent from the baby or guardian prior to use. Explain the reason for restraint use to the baby and/or guardian to help ensure cooperation.
- A restraint must only be used in accord with the baby'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.

Application instructions (repeat steps 1-3 for each mitt):

1. Insert the baby or child's hand into the mitt, palm down. Separate the fingers so each finger fits its own slot.
2. Wrap the wrist strap around the smallest part of the baby or child's wrist, over the top of the wrist, through the plastic ring and secure it by attaching the Velcro strap.
3. Slide one finger between the device and the inside of the baby or child'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.

Monitor per facility policy. Check to ensure that:

- Mitts are properly secured. If applied too tightly, circulation will be restricted; if applied too loosely, the baby or child 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 baby or child to ingest mitt material;
- The baby or child cannot use his or her teeth or otherwise remove the device and inflict self-injury;
- Monitor closely when the baby or child is out of bed. Babies or children who ambulate while wearing this device may be at risk of injury from a fall.

Single patient - multiple use:

Reuse of this product on different patients could cause cross-contamination or product malfunctions. Human Protection B.V. and the distributor cannot be held liable for the risks that come from re-using single patient - multiple use items on different patients.

LAUNDERING INSTRUCTIONS (if applicable):

- Fasten all buckles and locks to reduce risk of damage during wash and dry cycles. For maximum life, launder in a laundry bag.
- 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.
- Use lower temperature wash and dry cycles to extend product life. Maximum washing temperature is 60 degrees Celsius, do not bleach.



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. Improper application or use of any restraint may result in serious injury or death.
2. ALWAYS monitor patient per facility policy.
3. Be aware that constant monitoring may be required for:
 - o 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.
 - o Be prepared to intervene at the first sign of danger. Such patients require frequent review and evaluation of their physical and psychological status.
4. 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.
5. NEVER use restraining 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. ALWAYS report severe incidents to Human Protection B.V., the distributor and to the responsible local authorities.