



## Instructions for use

### X-MKK-BLH “Fixy Mini”

#### Baby limb holder



#### Intended user:

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

#### Intended purpose:

A limb restraint limits the range of movement to prevent self injury and to prevent the interruption of medical treatment.

#### Indications for use:

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

#### Contraindications:

- NEVER use baby limb holders:
  - If an IV or wound site could be compromised by the device
  - With a dislocation or fracture on the affected limb.



X-MKK-BLH001 (size: 3cmx12cm)



X-MKK-BLH002 (size: 18cmx4cm)

Composition:  
polyester, polyurethane, cotton

#### Explanation of symbols



Manufacturer



Date of manufacture



Medical Device



Catalogue number



Batch code



Consult instructions for use



Disposable



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 in a box of 12 pieces, per pair packed in a transparent pouch.

#### 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 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.
- If possible, 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.

### Application instructions:

Before use, check device for damage. Discard device if you have any questions about patient safety.

1. Wrap the limb holder cuff around the patient's wrist or ankle with the white side toward the skin.
2. Secure the hook-and-loop fastener. Slide one finger (flat) between the cuff and the inside of the baby's wrist or ankle to ensure proper fit. The cuff must be snug, but not compromise circulation.
3. Take the strap directly away from the neonate and secure out of the baby's reach.

**NOTE!** DO NOT wrap the straps around the baby's limb.

4. Leave straps loose enough for extended range of motion, but not enough to allow self-injury or disruption of lines or extubation.
5. Cut off excess strap length, if necessary, to minimize the risk of accidental disconnection or other hazard.

### Monitor per facility policy. Check to ensure that:

- Bed attachment straps cannot slide in any direction or loosen if the baby pulls on them, or if the bed is adjusted;
- Cuffs are properly secured. If applied too tightly, circulation will be restricted; if applied too loosely, the baby may be able to slip his or her limb from the device;
- Cuffs are attached in a way that the baby 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.

### Disposable:

This is a disposable product. Properly dispose of the product per facility's policy for BIOHAZARDOUS materials. Reuse of this product could cause cross-contamination or product malfunctions. Human Protection B.V. cannot be held liable for the risks that come from re-using disposable items.

**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. ALWAYS secure straps, to a movable part of the bed or chair frame, out of the patient's reach, using quick-release ties 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.

6. 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.
7. 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.
8. NEVER use a restraining product as a seat belt in a moving vehicle. Restraining products are not designed to withstand the force of a crash or sudden stop.
9. ALWAYS report severe incidents to Human Protection B.V., the distributor and to the responsible local authorities.