



## Instructions for use

### X-MKK-BLB “Flexy Mini”

#### Baby limb boards



#### Intended user:

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

#### Intended purpose:

The limb board prevents the wrist and/or ankle from bending during medical treatment.

#### Indications for use:

Prematures or babies requiring ankle or wrist support to allow safe I.V. application.

#### The product is comprised of three pieces.

- Limb board
- Two (2) fixation straps
- Two (2) touch and close fasteners made of Velcro

#### Contraindications:

- **DO NOT** use on a premature or baby who is or becomes restless.
- **NEVER** use on a premature or baby:  
With a dislocation or fracture on the restrained limb; or If an IV or wound site could be compromised by the device.



- REF** X-MKK-BLB-S (size S: 3cmx8,5cm)
- REF** X-MKK-BLB-M (size M: 4cmx10cm)
- REF** X-MKK-BLB-L (size L: 4,3cmx12,3cm)

Composition:  
polyolefin foam, aluminium, cotton

#### Explanation of symbols

- Manufacturer
- Date of manufacture
- MD** Medical Device
- REF** Catalogue number
- LOT** Batch code
- Consult instructions for use
- Disposable
- Keep dry
- Keep away from sunlight
- Non-sterile
- Do not use if package is damaged

#### Potential complications:

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 25 pieces, individually 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.



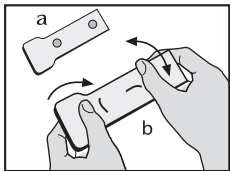
## Operating instructions:

### Before applying:

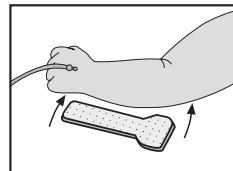
- Make a complete assessment of the patient to ensure restraint use is appropriate.
- Identify the patient's symptoms and, if possible, remove the cause. You may need to: cater to individual needs and routines; increase rehabilitation and restorative nursing; modify the environment; or increase supervision.
- 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:

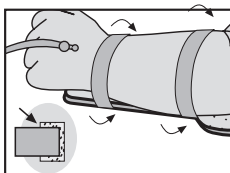
Align the wrist and/or ankle with the limb board and bend the board to the desired position. Make certain that the white cotton cover is in contact with the skin on the wrist and/or ankle. Self-adhesive Velcro fasteners are adhered to the outer side of the board. The fixation straps are wrapped around the baby's arm and/or leg to fixate the baby's wrist or ankle onto the board, and fastened using Velcro touch and close fasteners.



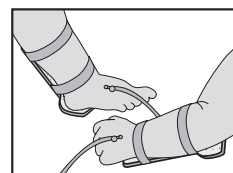
a) Post the Velcro fastener on the backside of the elastic band  
b) Shape the band according to wrist and elbow



Place the band under wrist and arm to support the wrist



Wrap the ribbons around and close to Velcro fastener. Pay attention for not to hinder the blood circulation



Be sure that the band fastens the wrist safely

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

- Fastening straps 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;
- The splint is intact, not torn or damaged, close hooks and loops of the Velcro safely. DO NOT allow patients to ingest product material;
- Fastening straps are attached in a way that the baby is not able to use his or her teeth or otherwise remove the device;
- 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.

### 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/product 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. 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.