



Instructions for use

X-MKK-PEM “Blinky Mask”

Phototherapy eye protector mask



Intended user:

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

Intended purpose:

Eye protectors provide eye protection during ultraviolet (UV) phototherapy treatment.

Indications for use:

Neonates requiring eye protection during ultraviolet (UV) phototherapy treatment of jaundice.

Contraindications:

- **NEVER** use on a patient:
– If a wound site could be compromised by the device.



REF

X-MKK-PEM (size: 18cm+25cm)
one size fits all

Composition:
polyester, polyurethane, 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:

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.

A premature infant's skin is very delicate and can easily rupture. Avoid obstructing the nose. Check regularly to ensure the eye protector is not blocking the patient's airway.

DO NOT over tighten - causing excessive pressure on the eyes. Make sure the strap is covering the ear, not hooked over the ear, and that the ear is not folded over. Replace the eye protector with a new one if it becomes over-stretched.

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.

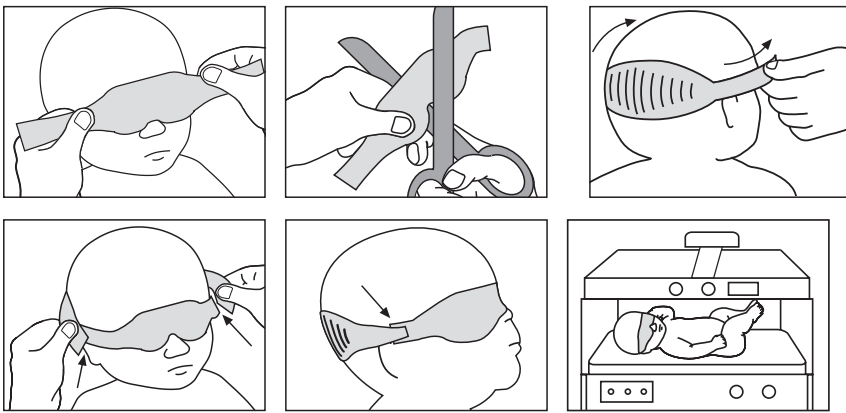


Operating instructions:

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:



Monitor per facility policy. Check to ensure that:

- The eye protector is properly secured. If the eye protector is applied too tightly, circulation will be restricted; if applied too loosely, the patient may be able to slide off the device;
- The eye protector is intact, not torn or damaged, the Velcro fastener closes securely. DO NOT allow patients to swallow parts of the eye protector.
- The patient is unable to detach the eye protector.

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 eye protectors may result in serious injury.
2. ALWAYS monitor baby per facility policy.
3. 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. Dispose of damaged products per facility policy for BIOHAZARDOUS material. 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. ALWAYS report severe incidents to Human Protection B.V., the distributor and to the responsible local authorities.