



Instructions for use

X-MKK-PEY Phototherapy eye protector Y shaped



Intended use:

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

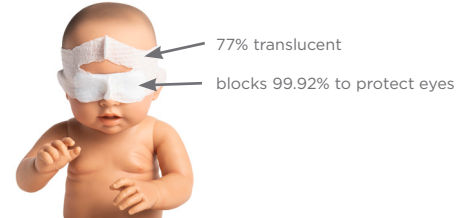
Indications for use:

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

Contraindications:

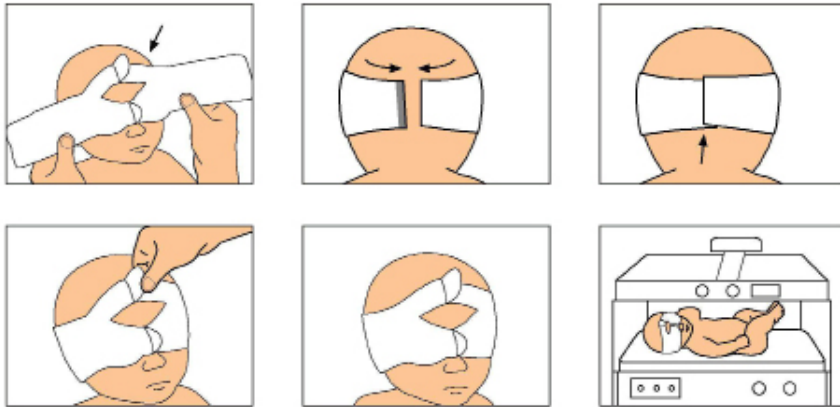
NEVER use on a patient:

If a wound site could be compromised by the device.



- X-MKK-PEY-S (Size S: 24cm)
- X-MKK-PEY-M (Size M: 28cm)
- X-MKK-PEY-L (Size L: 33cm)

Application Instructions:



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.

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.

Before applying any medical device:

- 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 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.



**Disposal:**

This is a disposable product. Properly dispose of the product per facility's policy for BIOHAZARDOUS materials.

Please be aware that quality of the product cannot be guaranteed if disposable products are being re-used. 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.

Just as baby's behavior is not 100% predictable, no product is 100% foolproof. Baby's safety requires regular reassessment and monitoring per facility policy. A product that worked in the past may be inappropriate if the baby'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 baby's 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. and to the responsible local authorities.

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.