HUMAN PROTECTION

Human Protection B.V.
The Netherlands

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Instructions for use
X-MKK-CA "Fixy CA"
Limbholder Classic Ankle

CE

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

Intended purpose:
An ankle restraint limits the range of movement to prevent self injury and to prevent the interruption of medical treatment.

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

Contraindications:
- DO NOT use on a patient who is or becomes highly aggressive, combative, agitated, or suicidal.
- NEVER use on a patient:
  - 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-CA

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 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 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.

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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 (follow these steps to apply device: Step 1-5):

1. Wrap the limb holder cuff around the patient's ankle so the strap attachment point is on the outside of the ankle.
2. Secure the Velcro fastener. Slide ONE finger (flat) between the cuff and the inside of the patient's ankle to ensure proper fit. The strap must be snug, but not compromise circulation.
3. Attach the strap to a movable part of the bed frame, out of the patient's reach, with a quick-release tie.
4. Check to make sure the strap cannot slide in any direction or loosen if the patient pulls on it, or if the bed is adjusted.
5. Adjust the bed strap(s) to allow desired freedom of movement, without compromising patient or caregiver safety.

Monitor per facility policy. Check to ensure that:

- Straps cannot slide in any direction or loosen if the patient 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 patient may be able to slip his or her limb from the device;
- Cuffs are attached in a way that the patient 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 pro ducts 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.