# Pin CAM Walker - Instructions for Use

REF PCAM

**The following should be read thoroughly read before use:**

**Important Notes:**
This document is designed to provide instructions on how this product is used. It is not a reference to clinical techniques, and does not replace local or national guidance or protocols.

**Intended User:**
For use by suitably trained healthcare professionals in a healthcare establishment, and 'Lay Users' in a home use environment.

**Intended Purpose:**
Rehabilitation and promotion of ambulation following injury or surgery.

**Indications For Use:**
Grade 2 & 3 ankle sprains, Achilles Tendon repair, stable distal tibia & fibula fractures, soft tissue injuries, post-trauma, post-surgery.

**Product Characteristics / Features:**
The Pin CAM Walker can be used as a fixed position, controlled ROM or free motion walker boot, to promote early ambulation following injury or surgery. Latex free.

Key functional elements include:

- Aluminum ROM hinges with adjustments in 15° increments from 0° to 45°
- Wide foot-bed for stability
- Non-skid soles, cushioned for comfort & shock absorption
- Secure hook and loop strapping, adjustable to fit
- Soft, washable liner
- Universal - fits both left & right

**How it's supplied:**
It is supplied non-sterile and ready for single patient use.

**Devices Required For Use, And Interoperability Requirements:**
The device is not intended to be used in direct contact with the skin, therefore the use of a liner, sock or base layer is recommended.

**Storage Conditions:**
Store in box, away from direct sunlight and heat sources in a cool and dry environment.

**Contraindications:**
Application of this device is recommended only when the fracture is demonstrably stable & there are acceptable limits of angular & rotational deformity. This product should always be fitted on the advice of a healthcare professional.

**Care and Maintenance:**
Hand wash liner in cold water using a mild soap
Use a towel to absorb most of the dampness and then allow to dry at room temperature
Do not dry clean or tumble dry or expose to any heat source
Do not use bleach
The device should be safety checked by the providing service and/or user every 6 months.

**Precautions / Warnings / Residual Risks:**
Do not dry clean or tumble dry - allow to dry naturally away from direct heat sources
Do not expose to alcohol, ointments or solvents
Do not use if package is damaged or broken.
Keep dry and away from direct sunlight and heat sources in a cool and dry environment.
If allergic skin rashes occur, please consult your healthcare professional

**Possible Adverse Reactions:**
None.

**Single Patient Use Precaution:**
This device is designed and sold for single patient use only. The effects of any unauthorised reuse can result in the following complications:
Risk of Cross contamination;
Risk of mechanical fatigue, and/or associated failure.

**Directions For Use / Fitting Instructions:**

Remove the walker from the protective plastic bag and detach the foam bootie. DO NOT remove the plastic sleeves that are over the uprights. These plastic sleeves must remain over the uprights during the initial phases of the fitting procedure.

**Please follow these simple application instructions:**

1. Loosen all the straps and remove the liner from the boot.
2. Place the foot and leg inside the liner with the heel firmly back. Wearing a sock is recommended.
3. Position the liner flaps over the top of the foot before closing the liner snugly, securing the hook and pile closures. Then wrap & fasten the leg section. The liner can be trimmed if required.
4. Spread the uprights and position the heel of the foot against the back of the boot. Brace uprights should be positioned midline over the ankle.
5. When you are sure the uprights are in the proper alignment, remove the plastic sleeves. The Velcro hook on the inside of the uprights will lock onto the foam liner.
6. Secure the boot straps at the toes and then work up the leg.
7. Move the latch to the desired degree of flexion or extension, then fasten the screw using the hex wrench.

**NOTE:** Adjustments should be managed by the clinician directly involved with the patient

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UK CA CE

MD NON STERILE LATEX BHTA APPROVED CODE TRADINGSTANDARDS.GOV.UK nqa. ISO 13485 MEDICAL DEVICES nqa. ISO 14001 ENVIRONMENTAL MANAGEMENT

**Disposal**
Discard after single patient use and dispose of as common waste according to national guidelines.

**Serious Incident Reporting**
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

**Sizes & Codes**

| Size | Shoe Size | | Code |
|---|---|---|---|
| | UK | Euro | |
| Small | < 5 | < 38 | PCAM-S |
| Medium | 5 - 8 | 38 - 42 | PCAM-M |
| Large | 9 - 11 | 43 - 46 | PCAM-L |
| X Large | 12 + | 47 + | PCAM-XL |

| **Labelling Symbology** - EN ISO 15223-1:2020, unless otherwise stated | | | |
|---|---|---|---|
| | | REF | LOT |
| Manufacturer | Non-sterile | Catalogue number | Batch code |
| | GB | | |
| Contains Latex. | Manufactured in the United Kingdom of Great Britain and Northern Ireland on date | Caution | Consult Instructions For Use |
| MD | UDI | | UK CA |
| Medical device | Unique Device Identifier | Single patient - multiple use | UKCA Mark - UK Regulation SI 2002 No 618 |
| | | | |
| Keep away from sunlight | Keep dry | Do not use if package is damaged | Warning, flammable material - Regulation ISO 7010—W021 |
| **QTY** | | | |
| Quantity - abbreviation | | | |

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