ROTHBAND
PATIENT POSITIONING

INSTRUCTIONS FOR USE

LATERAL HIP LEG SUPPORT

VERSION 4.0

UK CA CE

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INTRODUCTION

The Lateral hip leg support is designed to elevate a patients contralateral lower limb to allow the imaging of the effected one. Typically for a lateral hip of Lateral femur expo-sure following trauma.

The device can be placed on an imaging table, bed or trolley and positioned close to the patients hip so that it can support a limb in flexion.

Once the limb is lifted out of the way, it allows the effected limb to be imaged.

INTENDED USE

The leg support can be used on beds trolleys and tables.

The overhanging foot rest allows unrestricted angulation of the central ray but is de-signed to give maximum stability against leg extension.

The patient's heel is supported comfortably in the ankle sling with the sole of the foot resting against the back-stop.

Counter traction is achieved by placing a water bottle in the recess and sliding the support towards the patient's hip.

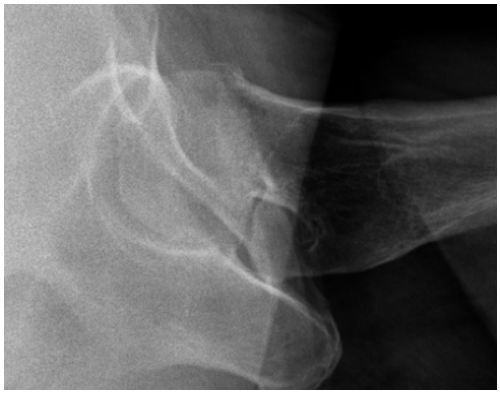
The support is sufficient without a counter-weight when used with co-operative patients provided they can easily maintain 90 degree flexion of the hip.

The traction counter-weight should be used for un-cooperative patients or those who require counter traction to achieve greatest possible flexion of the raised leg.

Flexing the raised hip as near as possible to 90 degrees will greatly improve the image quality and give increased latitude of exposure.

The support is most easily fitted by placing your hand underneath the backstop. It is then possible to use your other hand to assist in lifting and guiding the patient's foot.

Because only one hand is used to lift the support it is not recommended to lift with the bottle (weight) in situ.



REGULATORY COMPLIANCE

The Rothband positioning range complies with MDR (EU) 2017/745 (EU) and MDD 93/42/EEC (UKCA) concerning medical devices (class I) and has been designed and manufactured to comply with the following standards:

Standard	Description
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity. Grade 1 (ISO10993-10) Skin Irritation – classed as non-irritant; Skin Sensitisation – considered to be non-sensitiser
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements.

CAUTIONS AND WARNINGS

- If the positioning aid is visibly faulty or damaged in anyway it must be IMMEDTIATLY taken out of use.
- There are no special skills required to use this positioning aid but it is advised that it is used by a qualified medical professional.
- The medical professional is responsible for applying his/her best medical judgment when positioning a patient using the positioning aids.
- The positioning aids are suitable for continuous use.
- Not suitable for sterilisation.
- Do not place device on or near a heat source.
- The materials used in the manufacture of all components of the system comply with the required fire safety regulations.
- Intended for professional healthcare facility environments where operators with medical training are continually available when patients are present.
- Do not use abrasive cleaners, please see page 5 for the correct cleaning instructions.
- Be aware when using contrast media, as staining may cause radiographic artefact.
- The above warnings, cautions and any safety considerations should be observed on a routine and regular basis, not only upon installation.
- Do not allow any part of the base to overhang the edge of the trolley/table.
- The support must be used with caution when imaging the most uncooperative patients.
- Patients should not be left alone with their leg in the support.
- The Safe working load is 20KG

CLEANING INSTRUCTIONS

The unit is not designed to be sterilised but may be wiped clean using e.g. Clinixell type wipes.
The Sling can be replaced or cleaned down.

Cross contamination is a major hazard to patients. The product should therefore be cleaned in between patients. Always check for fluid ingress.

WARRANTY

All products have a 12 month, return to base warranty

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