



ROTHBAND

PATIENT POSITIONING

INSTRUCTIONS FOR USE

STANDING FOOT PLATES

VERSION 1.0

**UK
CA CE**

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INTRODUCTION

The Standing foot plate is a simple, lightweight, radiolucent device to help support patient limbs when they are positioned for weight bearing x-rays of the lower limb.

These Instructions cover the following models:

PRODUCT
Standing Foot Plates 3543
Standing Foot Plate 2430
Deluxe Standing Foot Plate

INTENDED USE

The Rothband Standing Footplate range has been designed for use with medical imaging equipment.

The purpose of the standing footplates is to protect medical imaging plates for standing foot examinations during which a patient is required to weight bear whilst a DP image of the foot is acquired.

CE COMPLIANCE

The Standing foot plate range complies with MDR (EU) 2017/745 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 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

- There are no special skills required to use this positioning aid.
- The medical professional is responsible for applying his/her best medical judgment when positioning the surgical patient supports.
- The Standing foot plate is suitable for continuous use.
- Not suitable for sterilisation.
- Do not place device on or near a heat source.
- 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 relevant section 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.
- The device has a weight limit of 250Kg

POSITIONING RECOMMENDATION



1. Place the imaging plate on the floor.
2. Position the standing foot plate over the cassette.
3. The patient should stand on the standing foot plate aided by a trained healthcare professional.
4. Following the examination, the patient should step off the standing foot plate and the plate should be removed.

CLEANING INSTRUCTIONS

Use a solution of mild soap or detergent or disinfectant* in hand-hot water.

Apply using a soft cloth & light pressure to prevent swirls.

Rinse off with clean water and dry by blotting with a soft cloth/towel.

WSR Medical Solutions Limited recommend Envirolex hard surface cleaner.

*DO NOT Use Solvents or Alcohol based cleaning products.

DO NOT Use any scouring materials/pads to clean the product as this will damage the surface finish.



Cross contamination is a major hazard to patients. The Surgical Patient Supports should therefore be cleaned in between patients.

CONTACT DETAILS



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