



INSTRUCTIONS FOR USE

FISHTANK LEG SUPPORT



Table of Contents

INTRODUCTION	3
WEIGHT LIMITS	3
REGULATORY COMPLIANCE.....	4
INTENDED USE	5
CAUTIONS AND WARNINGS.....	6
CLEANING INSTRUCTIONS.....	7
WARRANTY	8
CONTACT DETAILS	8

INTRODUCTION

Thank you for purchasing a Rothband Positioning Device. In doing so, you have chosen a quality product which has been designed to provide excellent functionality.

To ensure the device is always used in a safe manner, please read this document thoroughly and strictly follow all the operating, cleaning and maintenance instructions.

These Instructions cover the following models:

Perspex Positioning Aids	
Product Code	UDI-DI
SDS	5057326002848
SPSJ	5057326002855
SPSL	5057326002862
SPSC	5057326002879

Lower Leg Supports	
Product Code	UDI-DI
FTLS	5057326001483
GPFC354	5057326002763
GPFC243	5057326002770
GPFC354D	5057326002787

WEIGHT LIMITS

The Rothband positioning device range has been designed for use with medical imaging equipment to aid in the positioning of patients undergoing a diagnostic medical procedure.

Each product is has been tested individually and displays a maximum weight limit:

The design of the product provides a radiolucent, homogenous area that focuses on minimising the x-ray attenuation properties in order to minimise image artefact.

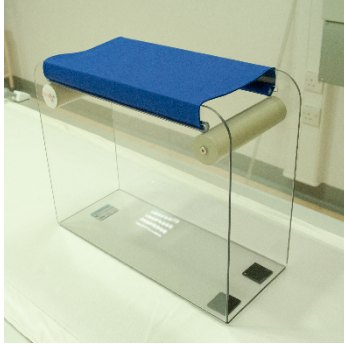
Product Code	Weight Limit
LHLS	20 Kg
FTLS	20 Kg
GPFC354	150 Kg
GPFC243	150 Kg
GPFC354D	150 Kg
SDS	
SPSJ	
SPSL	
SPSC	

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.

INTENDED USE



The Fish tank leg support is designed to elevate a patients contralateral lower limb to allow the imaging of the affected one. Typically for a lateral hip of Lateral femur exposure 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 affected limb to be imaged.

This product should only be used by a suitably qualified imaging professional who is familiar with lateral hip imaging.



CAUTIONS AND WARNINGS

- If the positioning aid is visibly faulty or damaged in anyway it must be IMMEDIATELY taken out of use.
- The positioning aid must be x-rayed prior to use, to ensure there are no artefacts.
- 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.

CLEANING INSTRUCTIONS

- Maintaining the perspex and keeping it clean is a simple process. Another benefit of this plastic material is how hygienic it is. Perspex can be wiped clean and disinfected with the majority of regular cleaners.
- Use warm, soapy water and a sponge or microfiber cloth: You do not need to use any additional chemicals to clean Perspex. Make sure to clean with soft materials and not apply too much pressure to avoid scratching the material.
- Avoid using anything containing ammonia: Ammonia is a no-go chemical around Perspex as it can cause the plastic to turn cloudy, ruining the appearance of your plastic. You should also avoid items such as window and glass cleaners.
- Leave to air dry or use a clean cloth: Do not wipe your Perspex with paper towels or materials with a rough surface. Leaving Perspex to air-dry is absolutely fine.
- In some cases it can be necessary to disinfect surfaces, it should be noted here that only some commercially available disinfectants are suitable, as some contain additives that can damage the surface of the brand Perspex glass.
- However, bacteria and viruses can be wiped off the surface without any problem using isopropanol (2-propanol) and a soft cloth. This does not attack the surface of the Perspex.
- Isopropanol is used as a cleaning agent or disinfectant in industry and the medical sector.



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

CONTACT DETAILS



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