



ROTHBAND

PATIENT POSITIONING

INSTRUCTIONS FOR USE
FOAM POSITIONING PADS – PLAIN FOAM
VERSION 2.0

**UK
CA CE**

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INTRODUCTION

The use, suitability and positioning of the product is beyond our control, so we do not offer guidance on these matters. The user should satisfy themselves as to suitability for intended use.

We recommend that Plain foam is always used in a protective, fluid resistant cover or, if not possible, then should be disposed of after use.

These Instructions cover the following models:

PRODUCT CODES
FPXX

INTENDED USE

The Rothband, foam positioning pads have been designed for use with medical imaging equipment.

The positioning pads do not make any claims on maximum weight limit as it will conform to the maximum limit of the table on which it is placed.

The design of the closed cell foam positioning pads provides a radiolucent, homogenous area that focuses on minimising the x-ray attenuation properties in order to minimise dose to the patient.

REGULATORY COMPLIANCE

The Plain foam positioning pad 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 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
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



- 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.
- The medical professional is responsible for applying his/her best medical judgment when positioning a patient using the positioning aids.
- The positioning aids is suitable for continuous use.
- 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 place heavy objects on the surface of foam pads when not in use.
- 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.
- Patient with a high risk of pressure sore formation should not lie positioning pad for more than 10 minutes. Pressure points such as Elbows, Heels, Neck and Sacrum should be supported appropriately.

CLEANING INSTRUCTIONS

Plain foam products are difficult to clean and should be placed within a disposable, radiolucent cover.

The product should be disposed of when contaminated.

DISPOSAL

We recommend final disposal to be as clinical waste.

CONTACT DETAILS



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