



ROTHBAND

PATIENT POSITIONING

INSTRUCTIONS FOR USE

FOAM POSITIONING PADS – CLOSED CELL FOAM

VERSION 2.0

**UK
CA CE**

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INTRODUCTION

Our closed cell foam product range, utilises the Azote® foam product.

Foams from the Azote® product ranges find use in many applications that may require regular cleaning, disinfection or sterilisation of finished articles. Some cleaning and sterilisation method can affect the properties of the foam.

These Instructions cover the following models:

PRODUCT CODES
FPXX - Z

INTENDED USE

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

The closed cell foam 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 Rothband mattress 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 mattress/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

CLEANING

Azote® products can be washed using household soaps and detergents in warm water. If automatic washing cycles are used a cool wash cycle, not exceeding 40 °C, is recommend. Drying of the materials after the cleaning process can either be achieved by application of towels or similar absorbent materials or air drying at room temperature.



It should be noted that heating the material either through use of hot cleaning fluids or hot air in the drying process can affect the properties of the foam. Such effects can include densification, shrinkage and deformation in extreme cases.

No tests have been performed by Zotefoams, with regard to resistance of Azote® foams to industrial cleaning fluids. As these are often mixtures of active agents it is difficult to predict the effect of such cleaning fluids on the foam as interactions can enhance or reduce the effect of any of the single ingredients..

DISINFECTION

The following method is suggested:

Fill 5-10 litres (1-2 gallons) of water, hand-hot, into a suitable container.

Add 30 ml (1/2 fluid oz) of a commercially available detergent/ hypochlorite Preparation.

Using a dry clean cloth, thoroughly wash the appliance.

If the appliance has a cellular surface i.e., it does not possess a continuous skin, rinsing should be repeated. However, it is not necessary to dry the appliance between the rinses.

This method of disinfection is based on that described by Boycott. (Boycott J.A. Lancet; September 29, 1956. p.678-9)

If other disinfectants are used suitability should be tested prior to wide ranged use.

Drying can either be achieved by use of a clean cloth or air drying at ambient or slightly elevated temperatures.



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

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