

# INSTRUCTIONS FOR USE

## MAMMOSHIELD

WSR Medical Ltd. ensures, as far as it is reasonably practicable, that the products it manufactures are designed & constructed to be safe & without risk to health when properly used. The following Safety, Hazard, Cleaning, Labelling & Disposal information relates to all of our flexible radiation protective products. Fastening instructions are only for our range of Aprons.

### INTENDED USE

Protecting persons from x-ray scatter radiation during radiological examination/treatment.

### SAFETY

IT IS THE USER'S RESPONSIBILITY TO ENSURE THAT THE LEVEL & THE EXTENT OF ADDITIONAL PROTECTION OFFERED BY THE PRODUCT (BASED ON ITS EQUIVALENT LEAD THICKNESS), IS ADEQUATE FOR ITS INTENDED USE OF PROTECTING PERSONS FROM X-RAY SCATTER RADIATION DURING RADIOLOGICAL EXAMINATION/TREATMENT.

Radiographic screening & visual inspection of covers & fastenings should be carried out both before initial use & on a regular basis (at least annually), as the rate of wear of the product is determined predominantly by the actual conditions of use & storage.

Should any damage to the protective qualities be found, the product must be taken out of use & advice should be taken as to whether the product is repairable.

### HAZARD INFORMATION

Our products use either metallic Lead or a mixture of heavy metal composites (Antimony and Bismuth) for shielding. These metallic particles are encapsulated within a PVC matrix, which is itself then contained within protective outer coverings, so under normal conditions of use, wearer contamination is not possible. Shielding materials are only hazardous if ingested (or if on fire, their fumes inhaled), so if a product's outer covering is torn we recommend that the hole is taped over & the product is returned to us for repair.

If the exposed shielding material is handled, then to avoid hand/mouth contamination & any possibility of skin irritation, thoroughly wash your hands & nails. Fire-fighters should wear breathing masks to avoid fume inhalation.

### FASTENINGS AND WEARING GUIDE

**Buckles:** Fasten buckle & then tighten by pulling on free end of webbing. To loosen, angle buckle slightly & pull away from body. To release, grip the buckle between forefinger & thumb & press on prongs.

**Velcro Strap:** Thread both free ends through the loops on the apron front & bring back to fasten on the hook velcro at the rear, ensuring the apron edges overlap.

**For specific wearing instructions, please visit [www.rothband.com/how-to-wear](http://www.rothband.com/how-to-wear)**




**WARNING: Using the fastening to hold/carry the apron will put stress on the outer fabrics and potentially tear the apron - DAMAGE OF THIS NATURE IS MISUSE AND FALLS OUTSIDE OF WARRANTY.**

### CLEANING INSTRUCTIONS

The outer covers may be cleaned by the use of mild disinfectant or detergent. Strongly acidic, alkaline, alcohol/phenol based or abrasive products should not be used. DO NOT LAUNDRY. The product cannot be sterilised. Clean the hook (rough) part of Velcro fastenings regularly with a stiff bristled brush to ensure maximum fastening efficiency.

We recommend our bespoke apron cleaning solution which has been tested with all of our fabrics. For further information please visit [www.rothband.com](http://www.rothband.com)

### CORE MATERIALS

Core Material		Lightweight Lead			Edge Bilayer Low Lead*			Edge Bilayer Lead Free		
Symbol										
Area Density	LE Pb mm	0.25	0.35	0.5	0.25	0.35	0.5	0.25	0.35	0.5
	Kg M²	3.3	4.62	6.6	2.85	3.97	5.7	2.76	3.86	5.6
Tested Tube Voltage		60-150 kV			60-150kV			60-110kV		

\* SUBJECT TO AVAILABILITY

### ATTENUATION FIGURES

All attenuation figures, for all materials can be found on our website:

<https://www.rothband.com/certificates-downloads/>

### LABELLING

In accordance with the IEC 61331-3:2014 standard the following labels are applied to our Aprons and Thyroid collars

Information	Example	Location
A Name or trade mark of the manufacturer or supplier	Rothband	Outside or garment and the warranty label.
B Letter designating the Apron Category	L,H,HC,LC	Warranty Label
C Value of the Lead Equivalence in thickness of lead expressed as the symbol Pb followed by the thickness in mm.	0.25 mm Pb 0.35 mm Pb	Front of Garment and Warranty Label.
D The x-ray Tube Voltage used to determine the values of the Pb Equivalence.	50 kV - 110kV 50kV - 150kV	Warranty Label
E The Area Density required to provide the value of lead equivalence stated in (c) at the x-ray tube voltage as stated in (d)	4.6 Kg M²	IFU
F The size and length of the protective aprons referenced against EN 13402-3 by way of a sizing chart in the accompanying documentation.	S,M,L 85CM, 90CM ETC	Sizing label in neck-line, length stated on warranty label.
G Reference to the IEC 61331-3 Standard		Warranty Label
H Reference to the Notified Body	CE 0338	Warranty Label
I Warranty Label enabling tracking back to date & details of manufacture through our ISO9001 Quality Assurance system. Warranty will be invalidated if removed.	WSR 123456	Warranty Label

### WARRANTY

See current catalogue terms & conditions for full details.

3 month warranty period for this item. For further information please contact the manufacturers or your local Agent.

### SIZING

The MammoShield is available in one size only.

Specific sizing requirements are available on request.

### TESTING - IMPORTANT

Please screen the lead apron before use, to ensure it has not been damaged in transit.

All protective garments should be screened regularly to ensure no damage has occurred.

**DUE TO THE NATURE OF THIS PRODUCT AND THE MULTI-DIRECTIONAL STRESSES PLACED ON THE CORE MATERIAL, WSR RECOMMEND THIS ITEM IS X-RAY SCREENED ON A WEEKLY BASIS TO ENSURE NO STRESS FRACTURES OCCUR.**

### STORAGE

The protective sheeting can be damaged by prolonged creasing or by exposure to extremes in temperature. Store at room temperature away from direct heat using one of our approved hangers, or lay flat to ensure long life. Cold can render the sheet brittle so ensure it reaches room temperature before unpacking or use.

### DISPOSAL

Under the Hazardous Waste Directive (HWD Council Directive 91/689/EC) both Lead & No-Lead products are classified as non-Hazardous waste (EWC code 12 01 99). Dispose of in registered landfill in accordance with local regulations. Incineration is not recommended due to risk of toxic fumes.

### REGULATORY REQUIREMENTS

#### EU - Regulations

Shirley Technologies Sky Business Centre, Port Tunnel Business Park, Office 13, Unit 21, Clonsilla Business and Technology Park, Dublin 17, ROI. approved body 2895 performed the EU / EC type-examination (Module B, Cert: SH00743) The item is subject to the conformity assessment procedure Module D (Cert: SH000799)

All PPE products conform to the requirements of PPE Regulation (EU) 2016/425 and Harmonised Standard EN ISO 13688:2013. and meet the technical specifications as outlined in EN 61331-1:2014; EN 61331-3:2014

#### UK - Regulations

This item is classed as Personal Protective Equipment (PPE) by the UK Personal Equipment Regulations (Regulation 2016/425 as brought into UK law and amended.)

All PPE products conform to the requirements of Harmonised Standard EN ISO 13688:2013. and meet the technical specifications as outlined in EN 61331-1:2014; EN 61331-3:2014

The Declaration of conformity for this product can be downloaded at:

[www.rothband.com/certificates-downloads](http://www.rothband.com/certificates-downloads)

