ROTHBAND
RADIATION PROTECTION

INSTRUCTIONS FOR USE

STOKE LATERAL SCATTER SHIELD

VERSION 2.0

UK CA CE

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Introduction

These Instructions for Use contain information necessary for the correct use of this device.

Please contact us regarding any questions or issues on the use of the device arising from information found in these Instructions for Use

The company or its authorized distributor is not responsible for any injury incurred by the user or patient due to any apparent negligence or improper use by the user.

Hereinafter,

"device" refers to [RPAB Scatter Shield]
"We" or “Us" refers to WSR Medical Solutions Limited

These Instructions for Use emphasizes the safety procedures and precautions for the device use by using the terms below.
Please acquaint yourself with the warnings, cautions and references stated in these Instructions for Use in order to safely use the device.

WARNING	Conditions, hazards, or unsafe practices that can result in serious personal injury or loss of life.
CAUTION	Conditions, hazards, or unsafe practices that can result in minor or moderate personal injury, damage to the device, or loss of treatment data stored in the device, particularly if precautionary steps are not taken.
NOTICE	Used to denote items that are important during installation, operation, or maintenance of the device.

Overview

Thank you for purchasing RPAB Scatter Shield. This device can be effectively and safely used for a long period if you familiarize yourself with the instructions, warnings, precautions, and notices contained in these Instructions for Use prior to its use.

WARNING	The RPAB Scatter Shield does not replace normal radiation protection precautions such as wearing PPE that should be exercised in a controlled area according to IRR and IRMER Regulations

You must follow the instructions, warnings, cautions, and notices in these Instructions for Use when using this device.

The manufacturer will not be responsible for any problems involving the device that are caused by the user's negligence.

Device Description

The product has been designed with the clinicians and staff at Royal Stoke University Hospital and has been developed to provide additional protection for physicians undertaking trans radial catheterisation procedures. The device provides support for the patient's arm whilst the radial procedures take place. It can, however, be applied in most endovascular procedures.

The Scatter Shield system, integrates 0.5mm LE protection into the sides of a radiolucent carbon fibre board and this provides additional protection against scatter radiation emitted from the patient, during a radiographic procedure.

The device has a carbon fibre construction that
Integrates lead shielding into
two of its three surfaces.

1	CARBON FIBRE UPPER - LEAD LINED WITH 0.5 MM LE (15CM)
2	CARBON FIBRE CURVED - LEAD LINED WITH 0.5 MM LE (10CM)
3	CARBON FIBRE BLADE - NO LEAD LINING WITH 0.4% ATTENUATION

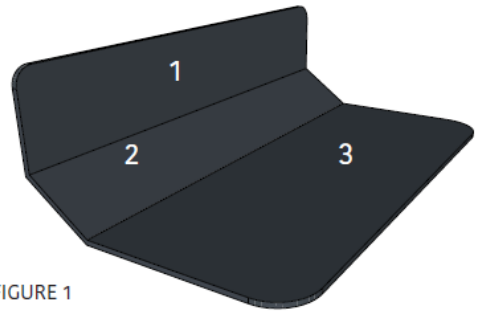

FIGURE 1

Indicated Use

The RPAB has been design for use with interventional procedures. Any situation that involves the surgeon standing close to the patient during radiographically guided intervention would benefit from the addition protection provided against scatter radiation emitted laterally from the patient.

CAUTION	When in use the RPAB should always be covered with a sterile barrier.

Intended Users

The RPAB should only be placed by qualified healthcare professional who are familiar with interventional procedures and radiation safety. The use of this device should comply with IR(M)ER 2018 and Ionising Radiation Regulations 2017.

Contraindications

The device should be avoided if the patient or operators have allergies to epoxy resins.

Prior to use

- Ensure the device has been thoroughly disinfected using a suitable cleaning agent.
- Check the device for damage and ensure the surfaces are free of cracks or chips.
- If there is visual damage please check the integrity of the radiation protection under fluoroscopy.

WARNING	**DO NOT USE:** • If any of the lead material is exposed • If there are visible defects in the lead protection under fluoroscopy • If there is any laminating in the layers of carbon fibre • If the carbon fiber blade (3) has any visible defects that could cause image artefact

Positioning Instructions

NOTICE	If the patients skin is at risk of becoming breached and/or compromised a sterile barrier must be placed between the device and the patients skin.

1.

With the patient lying on the table, align the blade of the scatter shield just below the shoulder joint.

(Figure 2)

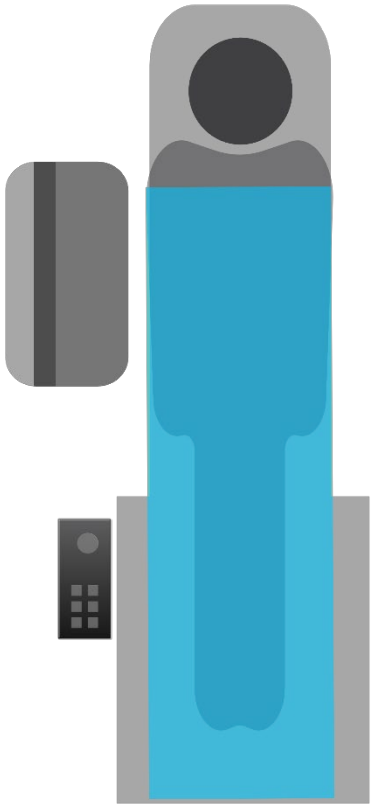

Figure 2

2.
Slide the blade between the mattress and the x-ray table until angled section butts up to the mattress. (figure 3)

The weight of the patient on the mattress will support the Lateral Scatter Shield.

Place sterile drapes as necessary

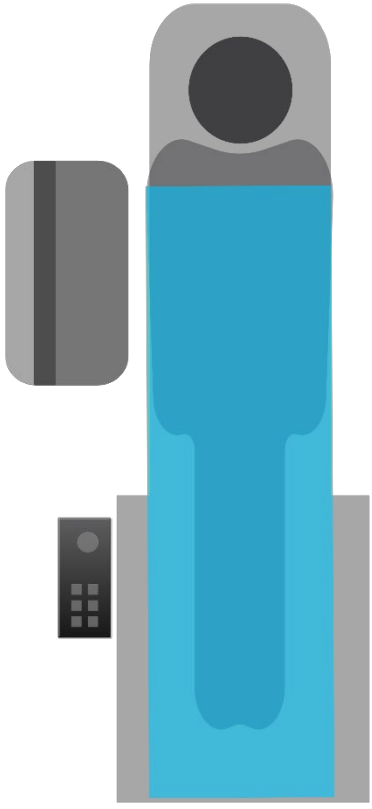

Figure 3

WARNING	The Device has not been designed to bear weight. Avoid unnecessary strain on the device.

Cleaning Instructions

WARNING	DO NOT AUTOCLAVE! Irreversible damage may occur exposing the lead core.

The device should always be placed in a sterile bag to avoid contamination.

The device may be cleaned using suitable disinfectant wipes/spray.

High concentration chlorine based cleaners may cause damage over a longer term and should be avoided.

Safety Instructions

Avoid using the device is the patient or operator have allergies to epoxy resins

Always ensure the radiolucent blade (3) is placed under the patient. Placing the leaded section under may unnecessarily increase radiation dose to the patient (if it is placed in the primary beam.)

Avoided placing weight on the device.

The device should be screened every 12 months as part of an ongoing radiation safety program.

Regulatory compliance

The Wipeable 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 61331-1 2014 BBG*	Protective devices against diagnostic medical X-radiation. Determination of attenuation properties of materials.
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.

Disposal

The lifespan of the device is estimated at 20 years.

This product contains lead.
For disposal it should be returned to the manufacturer or a local representative so it may be disposed of following the relevant legislative guidance.

MANUFACTURER

WSR Medical Solutions Ltd (Rothband)
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WARNINGS

Hypersensitivity. Ensure patient has no allergic reactions to Epoxy Resin.

CE

MDR (EU) 2017/745 (EU) and MDD 93/42/EEC (UKCA)

It is classified under the harmonized standards BS EN 60601-3-2008 Section 10.1