ROTHBAND
PATIENT PROTECTION

INSTRUCTIONS FOR USE

Shield All

VERSION 2.0

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INTRODUCTION

Shield-All consists of 4 parts, as shown in Figure 1:

The base unit and three extender pieces (small, medium and large).

NB In general use only the base unit and one of the extender pieces will be used.

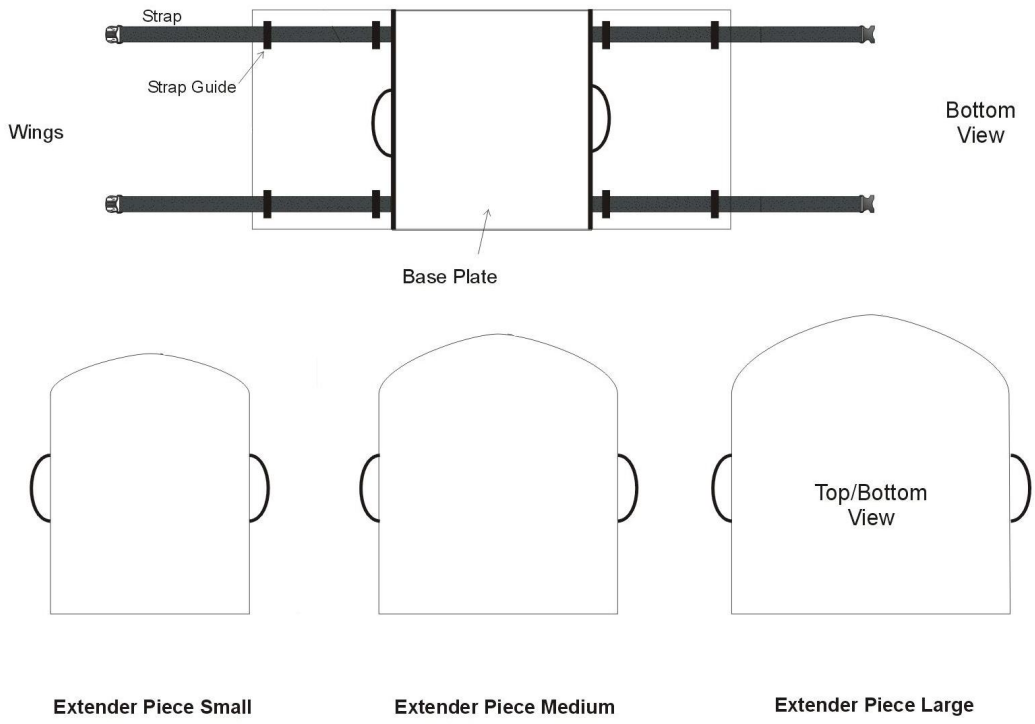

Figure 1: The constituent parts of Shield All

BACKGROUND

CT scanning is a high dose imaging procedure where special considerations are needed in order to keep the radiation dose As Low As Reasonably Practicable (ALARP).

Recent studies in the USA have highlighted the high doses associated with CT scanning and the related lifetime risk of cancer.

Whilst the majority of the radiation dose arising from a CT scan is delivered to the region being imaged, the scattered dose to organs outside the region of interest can be as high as the doses associated with a standard radiographic image of that area.

PRODUCT DESCRIPTION

Shield All is a lead rubber based shielding device which has been designed to provide the same level of radiation protection as 0.7mm Pb (i.e. the front and back of a 0.35mm Pb lead apron).

However, the device has been constructed in a way so that the weight distribution leads to improved patient comfort when compared with using standard lead apron. Furthermore, Shield All is also easier for Radiographers to move and position on the patient and can thus lead to a reduction in moving and handling problems.

One novel aspect of Shield All is the extender pieces that ensure that the device can be used on patients of all sizes, up to and including the largest patient that can fit in the bore of any CT scanner on the market today. The design of the extender pieces also ensures that the protection conforms to patient shape.

INTENDED USE

Shield All can be used during scans of all parts of the body and on adult and paediatric patients alike.

The main benefit of Shield All is in reducing the radiation dose to organs outside the region of interest. This can significantly reduce the dose to some of the most radiosensitive organs in the body: for example when performing a chest scan Shield All would reduce the dose to the colon by 33% and the dose to the testes by 72%.

These reductions in organ dose lead to a reduction in effective dose (whole body dose) of approximately 5%. This 5% effective dose saving comes with no effect on image quality and as such is a 'cost-free' dose saving.

Some recommendations of which body part to protect during a range of scans are given below:

Scan region	Area to protect
Head	**Chest**
Neck	**Chest**
Chest	**Abdomen/Pelvis**
Abdomen/Pelvis	**Chest**
Legs	**Abdomen/Pelvis**
Extremities	**Area closest to the extremity**

Table 1: Suggested use of Shield All for different scan regions

USE DURING PREGNENCY

A specific benefit of Shield All is its suitability for foetal protection when scanning pregnant patients. As mentioned previously the design of Shield All ensures that the minimum amount of weight is placed on the patient; this is of particular importance during pregnancy.

The extender pieces have been designed such that they conform to the shape of the pregnant abdomen throughout each trimester. A number of publications have shown that use of 0.7mm Pb shielding yields foetal dose savings of approximately 35% in all stages of pregnancy, although the dose saving can be as high as 55%. Dose savings of this order halve the likelihood of radiation induced cancer in the progeny.

STEP BY STEP GUIDE TO CORRECT PLACEMENT

These step by step instructions show how to use Shield All for a chest CT scan covering the whole of the lung field. In this example the patient is in the head first supine position. These basic steps should be followed when using Shield All to protect other areas of the body.

1. Position the base unit of Shield All on the scanner couch and open out the wings such that they hang over the edge of the couch. Ensure that the straps are facing downwards.

   See Figure 2

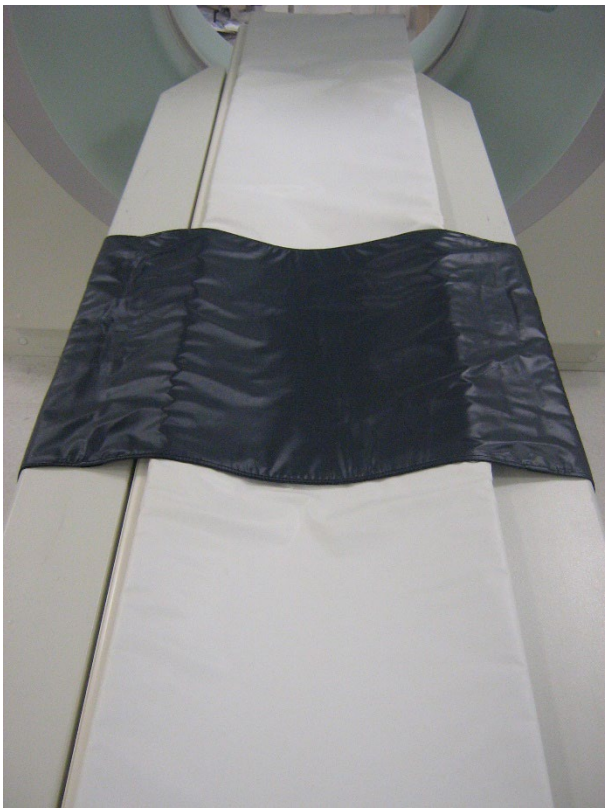

Figure 2

2. Position the patient on the couch such that the base plate of Shield All is at the posterior of the abdomen and pelvis. Ensure that the superior edge of the device is close to, but does not extend into, the region to be scanned.

   See Figure 3

3. Based on patient size and/or shape decide which extender piece is needed.

   a. If the patient is slim or in the early stages of pregnancy with no discernible bump, position the extender piece on top of the patient such that the straight edge is superior and lines up with the superior edge of the base plate, again ensuring that the extender does not encroach into the region to be scanned.

Figure 3

   b. If the patient is in the later stages of pregnancy or has a more rounded abdomen, position the extender piece on top of the patient such that the curved edge is superior and lines up with the superior edge of the base plate, again ensuring that the extender does not encroach into the region to be scanned.

      See Figure 4

Figure 4

4. With the extender piece in place, fold the wings over the top of the extender and use the straps and clips to secure the wings in place.

   If necessary the straps can be taken out of one or more of the strap guides in order to achieve the best fit to the patient size/shape. **NB** take care not to over tighten the straps and thereby cause discomfort to the patient.

   See Figure 5

Figure 5

5. Once the patient has been scanned the extender piece can be removed from the patient and stored. The wings can be folded onto the base plate which can then remain on the scanner couch for use on the next patient. The ends of the straps can be tucked under the edge of Shield All to prevent them interfering with the table motion.

CE COMPLIANCE

The Shield All complies with MDR (EU) 2017/745 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 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.
EN ISO 61331-12014 BBG*	Protective devices against diagnostic medical X-radiation - Part 1: Determination of attenuation properties of materials.

CAUTIONS AND WARNINGS

- Do not position Shield All in such a way that it covers, or partly covers the region being scanned.
- Do not use if the whole body is being scanned in one acquisition, e.g. for Trauma scans – for the reasons given above.
- Do not place directly onto broken skin or open wounds.
- Do not use if the patient cannot tolerate the weight of the device.
- Never place Shield All over the head or face of a patient.

PATIENT INFORMATION

FAQs:

Q: Why should lead shielding be used outside of the region being imaged?
A: Scattered radiation results in organs outside the scan volume receiving a radiation dose. Up to approximately 70% of this radiation dose can be saved by using lead shielding.

Q: Isn't the scatter just internal scatter from the scan volume?
A: Internal scatter does contribute to the patient dose but external scatter (i.e. leakage from the x-ray tube, scatter from the CT gantry, scatter from the walls/ceiling etc) also makes a significant contribution. It is the external scatter that is minimised through the use of lead shielding.

Q: Doesn't the radiation bounce back from the inside of the shield and increase the patient dose?
A: Extensive research has shown that the amount of radiation scattered back from the inside of the shielding is very low at approximately 1-2%, which is considerably less than the percentage savings achieved by using shielding.

Q: How much dose can be saved?
A: The dose to a particular organ can be reduced by up to 70% whilst the total body dose is reduced by approximately 5%. The dose to the foetus when the mother to be has a CT scan can be reduced by up to 55%.

Q: We've never used lead shielding in CT before, why should we start now?
A: There has been a lack of conclusive evidence to show that lead shielding should be used in CT scanning. Recently a number of published papers have agreed that significant dose savings can be achieved using such shielding on pregnant and non-pregnant patients alike.

Q: Is ShieldAll just for pregnant patients?
A: Whilst ShieldAll has a specific use for scans of pregnant patients the device is designed to be used on all patients undergoing CT scans.

Q: What is the lead equivalence of ShieldAll?
A: ShieldAll is constructed of varying thicknesses of lead but the overall level of protection is equivalent to 0.7mm Pb.

REFERENCES

Kennedy E, Iball G, Brettle D, Investigation into the effects of lead shielding for fetal dose reduction in CT pulmonary angiography. Br J Radiol, 80, 631-638, 2007.

Iball G, Kennedy E, Brettle D, Modelling the effect of lead and other materials for shielding of the fetus in CT pulmonary angiography. Br J Radiol, 81, 499-503, 2008.

Doshi S, Negus I, Oduko J, Fetal radiation dose from CT pulmonary angiography in late pregnancy: a phantom study. Br J Radiol, 81, 653-658, 2008.

CLEANING INSTRUCTIONS

Use a solution of mild soap or detergent or disinfectant* in hand-hot water.

Rinse off with clean water and dry by blotting with a soft cloth/towel.

WSR Medical Solutions Limited recommend Envirolex hard surface cleaner.

*DO NOT Use Solvents or Alcohol based cleaning products.

Cross contamination is a major hazard to patients. The Surgical Patient Supports should therefore be cleaned in between patients.

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