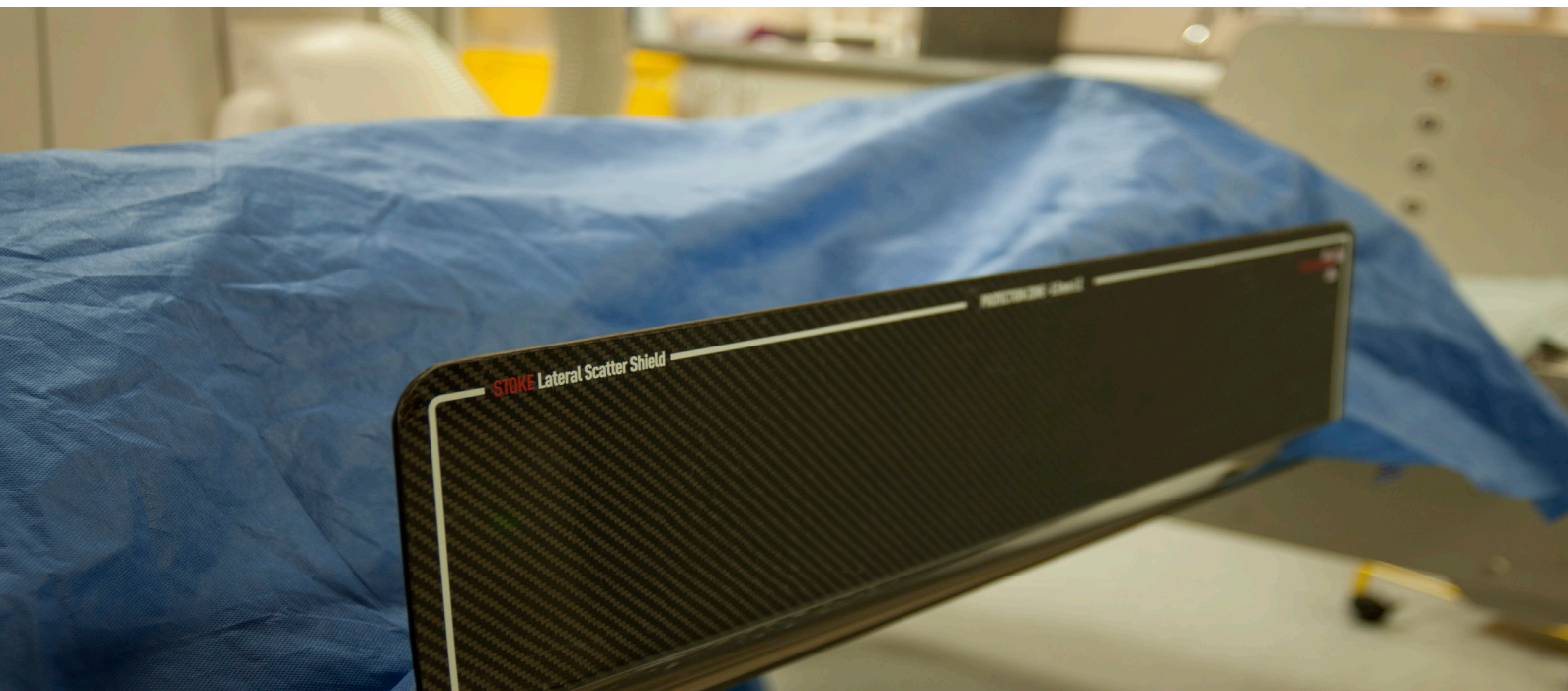


INSTRUCTIONS FOR USE

FOR THE STOKE LATERAL SCATTER SHIELD



This IFU describes the correct use of the Rothband's Lateral Scatter Shield System.

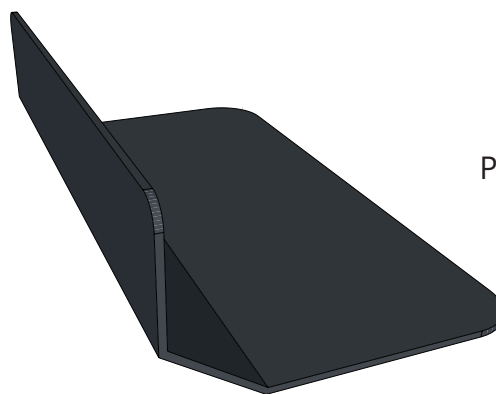
The product has been designed with the clinicians and staff at Stoke Hospital and has been developed to provide additional protection for physicians undertaking trans radial catheterisation procedures.

The Lateral Scatter Shield system provides support for the patients arm whilst the radial procedures take place. Although it can be applied in any endovascular procedure.

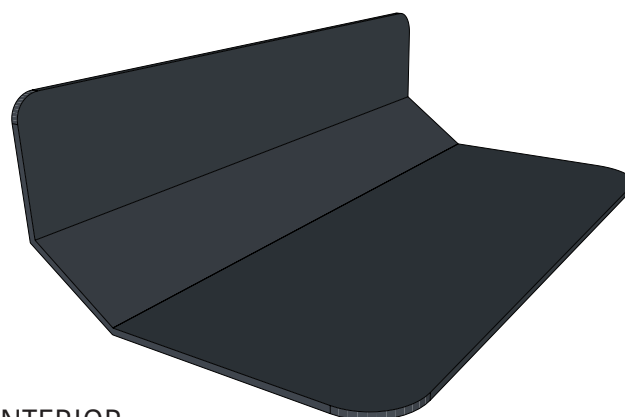
The Scatter shield system, integrates 0.5mm LE protection into the sides of a radiolucent carbon fibre board and this provides additional protection against scatter radiation emitting from the patient during the procedure.

For more information please visit us:

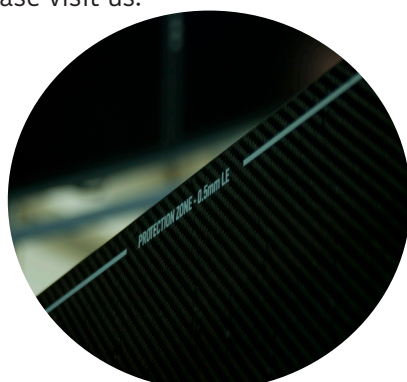
www.rothband.com



POSTERIOR



ANTERIOR



DEVICE STRUCTURE

- 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

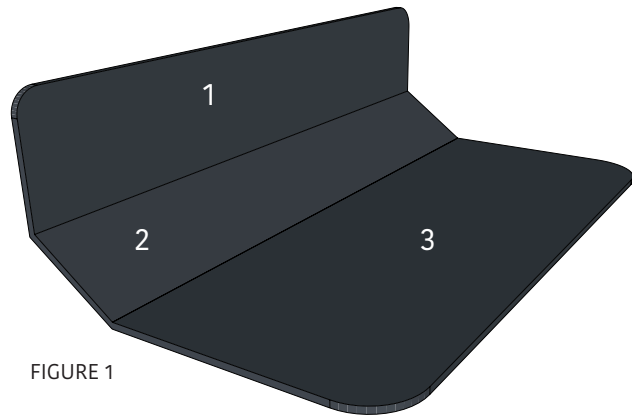
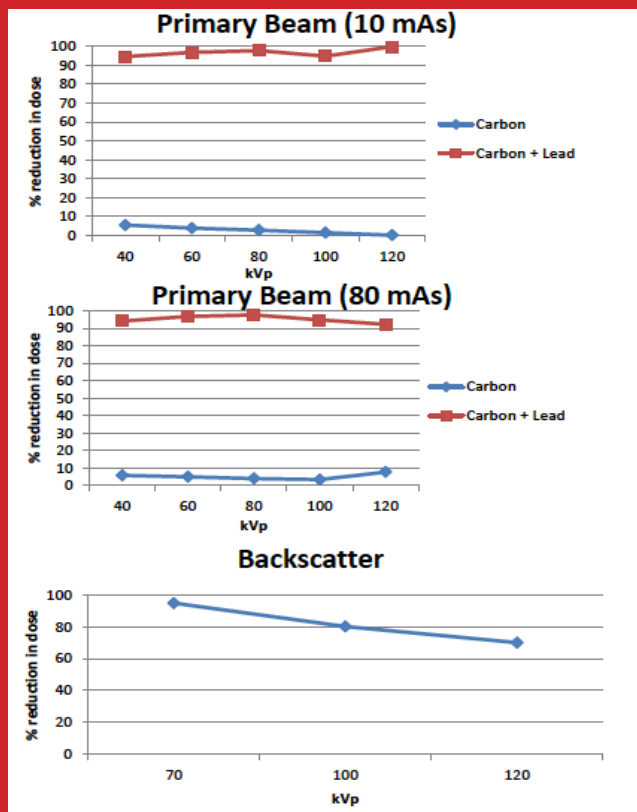


FIGURE 1

Dose Reduction Data

(With thanks to the University of Salford)



PRIOR TO USE

Check the device for damage and ensure the surfaces are free of cracks or chips.

Ensure the device has been thoroughly cleaned using the recommended cleaning agent.

POSITIONING INSTRUCTIONS

1. With the patient lying on the table, align the blade of the scatter shield just below the shoulder joint as illustrated in Figure 2.
2. While slightly lifting the patient, slide the blade between the mattress and the x-ray table until angled section butts up to the mattress. The weight of the patient on the mattress will support the Lateral Scatter Shield. (See Figure 3)
3. Add some absorbent padding under the arm if desired.

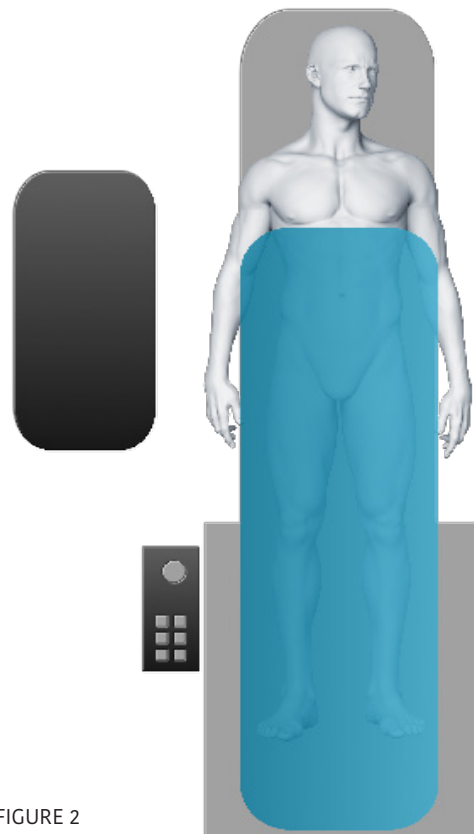


FIGURE 2

POSITIONING INSTRUCTIONS CTD

5. It is possible to cover the Scatter Shield with disposable cover.
6. Adjust the drapes to sit around the Lateral Scatter Shield.



FIGURE 3

CLEANING INSTRUCTIONS

The STOKE LATERAL SCATTER SHIELD can be cleaned as per your standard hospital/clinical protocol for similar apparatus.

It should be sprayed and/or wiped down with a suitable cleaning agent. (Rothband recommend Fantex) If desired, the Lateral Scatter Shield can be placed inside a clean plastic bag during procedures to help protect it further.

High concentration, Chlorine based cleaners should be avoided as it may de nature the carbon fibre.

SAFETY INSTRUCTIONS

THE Stoke Lateral Scatter Shield has been designed to support an upper limb during a radial access procedure.

It has not been designed to weight bear and care should be taken to avoid putting strain on the system.



WARNINGS

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



MANUFACTURER

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Lancashire BB4 4RX



CLASS I Medical Device

This device complies to