Steradian Shield™ Instructions for Use from Radux Devices, LLC
Radiation Attenuation Pad

USA Caution
Federal (USA) law restricts this device to sale by or on the order of a health care professional.

Caution
Steradian Shield™ should be used by physicians, radiology technologists, or physician extenders with adequate training in the use of the device.

Device Description
Steradian Shield™ is comprised of a radiation-reducing, adjustable, flexible pad that is designed to adhesively attach to a surgical drape or an object associated with the patient. An interior seam of flexible adjustable material provides strength and support for positioning the device in multiple configurations. The pad retains stability when adjusted to a variety of angles. Steradian Shield™ (Figure 1) is a sterile, single use disposable device.

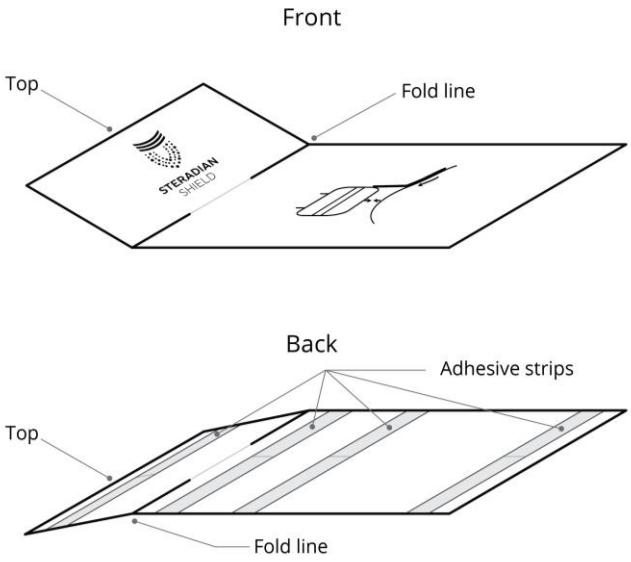

Figure 1. Steradian Shield™

Intended Use
Steradian Shield™ is intended for use during fluoroscopic procedures to reduce radiation exposure to the operator and staff.

Contraindications
None known.

Warnings and Precautions
- Product is sterile in unopened, undamaged package. If package is damaged, DO NOT USE. Discard and open another package.
- Do not use if the device is damaged in any way.
- Single use only. DO NOT RESTERILIZE. DO NOT REUSE. Attempts to resterilize and / or reuse this device may result in product failure and increased risk to the user.

Potential Complications

- Infection
- Allergic reaction to adhesive

Directions for Use

1. Open pouch and remove enclosed, sterile-covered Steradian Shield™ from pouch.
2. Transfer covered Steradian Shield™ into sterile field. Pouch should NOT enter sterile field.
3. Once in sterile field, unfold and remove sterile cover to reveal Steradian Shield™.
4. Locate four (4) sterile adhesive strips on back side of Steradian Shield™ (Figure 1). Prior to removing adhesive backing, confirm desired position of Steradian Shield™.
    - Vascular access:
        - Bend and form the vertical component of Steradian Shield™ based on the amount of perpendicular distance required to cover the vertical scatter gap (usually 5 inches, 12.7 cm should cover the vertical gap, which is the space between the image intensifier and patient).
        - Position Steradian Shield™ with adhesive and pad indentations / vertical component, as close to image intensifier / patient interface as possible without entering the primary beam.
        - The vertical component of Steradian Shield™ should cover the exposed and visible vertical gap between the operator and the site-line of the primary beam.
        - If positioning does not allow for access to skin entry site, delay placing pad until access is made and site stabilized.
            - Note: any attenuation pad placed within the primary beam will increase radiation to both patient and the operator.
    - General interventional fluoroscopy:
        - Form the vertical component of Steradian Shield™ to cover the vertical gap.
        - Place adhesive pad just outside of fluoroscopic direct beam.
        - Place the formed Steradian Shield™ between axis of patient and image intensifier and as close as possible to the primary beam /scatter interface to maximize scatter radiation absorption and protection.

5. Remove adhesive backing (Figure 2).

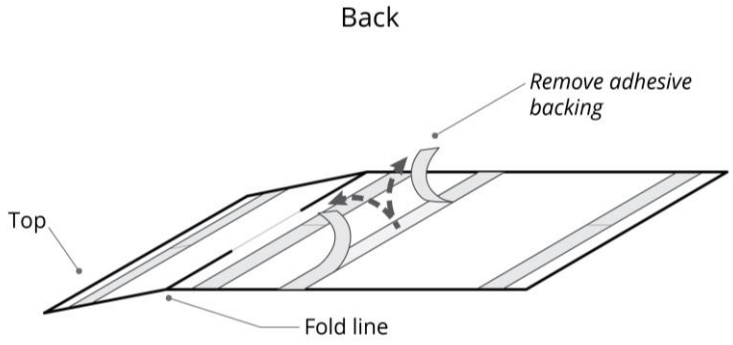

Figure 2. Remove Adhesive Backing

6. Reposition Steradian Shield™ at desired angle (Figures 3a and 3b).

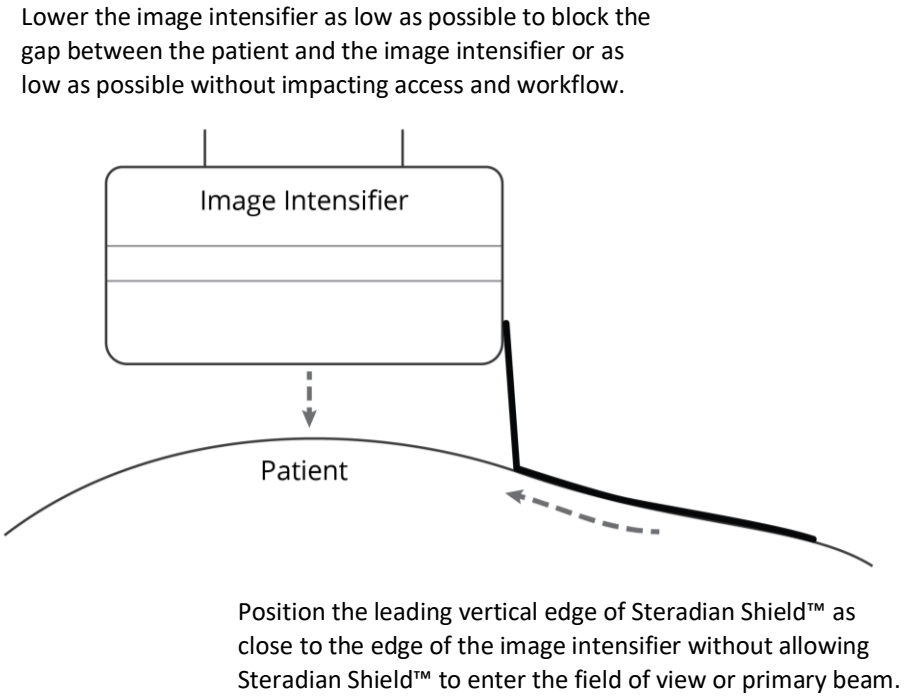

Figure 3a: Position Steradian Shield™ - Lower image intensifier to minimize the vertical gap.

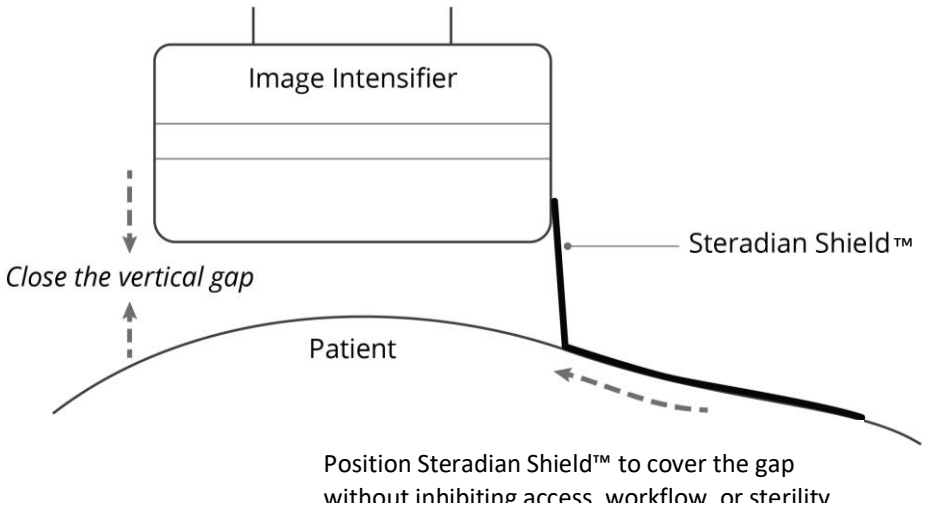

Figure 3b: Position Steradian Shield™ – Elevate table position to close the vertical gap.

Packaging and Storage
Steradian Shield™ has been sterilized with ethylene oxide. Keep dry and store in a cool, dry place.

Limited Warranty
Radux Devices warrants that Steradian Shield™ is free from defects in workmanship and materials prior to the stated expiration date. Liability under this warranty is limited to refund or replacement of the product which has been found by Radux Devices to be defective in workmanship or materials. Radux Devices shall not be liable for any incidental, special, or consequential damages arising from use of the product. Damage to the product through misuse, alteration, improper storage, or improper handling shall void this limited warranty. No employee, agent, or distributor has any authority to alter or amend this limited warranty in any respect. Any purported alteration or amendment shall not be enforceable against Radux Devices.

Symbols Legend

Symbol	Definition	Title and Designation Number of Standard	Reference Number
	Catalog Number	ISO 15223-1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.1.6
	Number of devices included in the package	NA	NA
	Batch Code	ISO 15223-1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.1.5
	Sterilized using ethylene oxide	ISO 15223-1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.2.4
	Prescription Use Only	21CFR 801.109	NA
	Consult instructions for use	ISO 15223-1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.4.3
	Use by date	ISO 15223-1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be	5.1.4

Symbol	Definition	Title and Designation Number of Standard	Reference Number
		supplied – Part 1: General requirements	
	Do not use if packaging is damaged	ISO 15223-1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.2.8
	Do not reuse	1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.4.2
	Do not resterilize	ISO 15223-1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.2.6
	Manufacturer	ISO 15223-1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.1.1

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