



## Radux Steradian Shield Instructions for Use

### Radiation Protection Shield

#### USA Caution

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

#### Caution

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

#### Device Description

The Radux Steradian Shield is a device for use in procedures at or near the vascular access site or where hands are near the direct radiation field. The Steradian Shield device is comprised of a radiation-reducing shield attached to an adjustable base that is designed to adhesively attach to patient skin or an object associated with the patient. It decreases operator radiation exposure and acts as a fluid barrier. The adjustable base allows the shield to move in a cranial-caudal direction while simultaneously rotating on the horizontal axis to maximize scatter radiation protection and fluid protection

The Steradian Shield (Figure 1) includes the following disposable components:

- Shield
- Adjustable base with adhesive pad

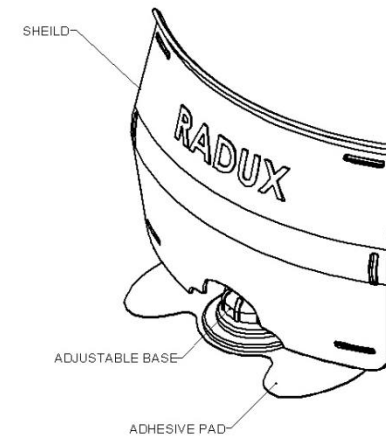


Figure 1. Steradian Shield

#### Intended Use

The Radux Steradian Shield is intended for use during fluoroscopic procedures to reduce radiation exposure to the operator.

#### 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. Detach shield from base.
2. Prior to removing adhesive backing, confirm desired position of base:
  - Vascular access: Position with adhesive pad indentations as close to vascular sheath skin entry site as possible with base center on operator side.
  - General interventional fluoroscopy: Place adhesive pad just outside of fluoroscopic direct beam. Place Steradian Shield as perpendicular between axis of patient and image intensifier as possible to maximize scatter radiation absorption and protection.
3. Remove the adhesive backing and secure the base into the desired position. Note: Placing the base perpendicular to the planned shield placement can enhance stability

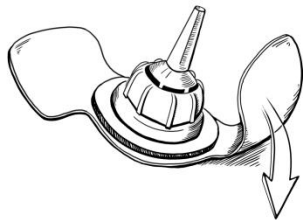


Figure 2. Remove Adhesive Backing

4. Attach shield to base.
5. To adjust shield angle, rotate the locking mechanism on the base counterclockwise  $\frac{1}{4}$  turn.
6. Position shield at desired angle.



Figure 3. Position Shield

7. Lock by rotating the locking mechanism clockwise until secure. Note: Shield and/or shield post can be removed from the base at any time.

### Packaging and Storage





The Steradian Shield has been sterilized with gamma radiation. Keep dry and store in a cool, dry place.





### Limited Warranty

Radux warrants that the 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 to be defective in workmanship or materials. Radux 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.

Symbols Legend

Symbol	Definition	Title and Designation Number of Standard	Reference Number
<b>REF</b>	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
<b>CONTENTS</b>	Number of devices included in the package	NA	NA
<b>LOT</b>	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
<b>STERILE R</b>	Sterilized using gamma	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
<b>R</b> Only	Prescription Use Only	21CFR 801.109	NA

Symbol	Definition	Title and Designation Number of Standard	Reference Number
	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
	Keep dry	ISO 15223-1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.3.4
	Keep away from sunlight	ISO 15223-1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.3.2
	Use by date	ISO 15223-1:2016 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.1.4

Symbol	Definition	Title and Designation Number of Standard	Reference Number
	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



Radux Devices, LLC  
11292 86th Ave N  
Maple Grove, MN 55369  
Phone: (800) 935-3137  
customerservice@raduxdevices.com