

1. What are RadiaXon Radiation Protection Gloves?

Radiation protection gloves (or RPGs) are sterile disposable gloves used for the strict and sole purpose of attenuation of scattered and/or stray radiation (also known as "incidental radiation"). This hand specific device is a personal protective shield intended for use during medical procedures i.e. fluoroscopic procedures, to protect the operator or other persons from unnecessary exposure to radiation.

2. Where are RadiaXon Protection Gloves used?

RPG gloves can be used during the following fluoroscopic examination procedures

- Percutaneous transluminal angioplasty (coronary and other vessels)
- Radiofrequency cardiac catheter ablation
- Vascular embolization
- Stent and filter placement
- Thrombolytic and fibrinolytic procedures
- Percutaneous transhepatic cholangiography
- Endoscopic retrograde cholangiopancreatography
- Transjugular intrahepatic portosystemic shunt
- Percutaneous nephrostomy
- Biliary drainage
- Urinary/Biliary stone removal
- Beta Radiation catheterization (Y-90 source)
- Percutaneous transmyocardial revascularization
- Percutaneous coronary interventions
- Radioactive seed implants
- Transmyocardial Revascularization
- Treatments of Gynaecologic (Gynecologic) and Reproductive Disorders
- Neuro-Radiology
- Embolectomy and Thrombectomy
- Vascular Embolization & Occlusion
- Treatments Of Abdominal Aortic Aneurysms
- Rotational Atherectomy
- Orthopaedics (Orthopedics)
- Chemotherapy Labs
- Electrophysiologic (EP) studies

3. What types of radiation exposure are RadiaXon RPG's designed for?

This personal protective shield is only designed for protection from secondary scattered ionizing radiation.

4. What sets the WRP RadiaXon gloves apart from the competition?

The WRP **RadiaXon** RPG glove has many distinctive advantages over the competition.

Lead Free

Unlike many of the other RPG's, **RadiaXon** contains no lead. **RadiaXon** attains its superb attenuation characteristics from a proprietary bismuth oxide based formulation.

Powder Free

RadiaXon RPG's are treated with the same state of the art surface modification technologies used in the production of sterile surgical gloves to provide optimized and consistent grip in a powder-free environment.

Excellent Attenuation

The **RadiaXon** RPG has a revolutionary thin film design to offer enhanced dexterity with better sensitivity and comfort. These benefits are afforded while still delivering excellent attenuation characteristics. This allows the wearer to have the best of fit, feel and comfort without compromising on protection.

Disposable

RadiaXon RPG's are very friendly to the environment and are readily disposable. They do not have the same costly disposal requirements that many of the competitions lead based products do.

5. Why is it important for a product to be lead free?

Lead is a highly toxic metal that presents numerous toxicological and environmental challenges in the healthcare setting

- Lead's toxic effects can have adverse effects on most of the organs and systems in the human body, particularly the nervous, renal and reproductive systems.
- Lead can affect the neurological and physiological development of young children.
- Unlike most medical products, devices containing lead can pose a very serious disposal problem. Due to its highly toxic nature, products containing lead cannot be incinerated. Lead also poses a major problem in landfills where it may enter the environment due to the degradation of products containing it. This could allow lead to be absorbed into ground water.

6. What type of potential skin injuries can be caused by over exposure to secondary radiation.

Depending on a number of factors, typical threshold doses will cause various complications such as:

Absorbed Dosage	Adverse Skin Effects
3 Gy	Temporary Epilation (Loss of Hair)
6 Gy	Main Erythema (Skin Inflammation)
15 to 20 Gy	Necrosis (Skin Decay)

7. How can the effectiveness of radiation protection gloves be determined?

Currently there are a wide variety of test methodologies in use for determining the attenuation properties of RPG Gloves, however, the **RadiaXon** RPG glove is tested to the only recognized and internationally accepted test method: EN61331-1.

8. How much protection do they provide?

RadiaXon RPG's provide up to 59% attenuation (see chart for full details).

9. Are RadiaXon Radiation Protection Gloves classified as a medical device?

The **RadiaXon** RPG is classified as a personal protective shield and is not a medical device. If the gloves are used in a situation where an institution's policies require the use of a medical glove (i.e. contact with blood or other bodily fluids) the **RadiaXon** RPG must be used in combination with appropriate medical gloves.

10. To what standards do the RadiaXon RPG's conform?

- **RadiaXon** RPG's conform to the following standards:
- EN 61331-1 for attenuation testing
- EN 420, EN374-2 and EN 388 for Personal Protective Equipment

11. Are RadiaXon RPG's safe to wear?

Yes, **RadiaXon** RPG's have been tested per the following standards:

- Skin Irritation Test (Draize method)
- Skin Sensitization Test (Buehler method)

Main Applications

- Diagnostic heart catheterizations
- Coronary angioplastics
- Angiocardiography
- Gynecology
- Urology
- Electrophysiologic (EP) Studies
- Orthopedics
- Examination procedures using Fluoroscopy
- Pain management

Attenuation Level¹

Beam Energy Level	Skin Dose Reduction
60 kVp	59%
80 kVp	49%
100 kVp	42%

¹ Test methodology for attenuation measurements according to EN 61331-1 at nominal thickness of 0.3mm. Lead equivalence value: 0.03-0.04mm Pb.

Product Information


Type	Value	Glove Size
Thickness at Fingertips	Min. 0.30mm	6.5
Length	Min. 290mm	7.0
Tensile Strength (MPa)	Min. 14 (unaged)	7.5
		8.0
		8.5
		9.0

Values may vary slightly within permissible product specifications depending on glove size, thickness, glove weight and accuracy of measurement of the equipment.

CAUTION:

This glove is not intended for use in the direct or primary x-ray beam. The purpose of this radiation protective glove is to protect the hands from scattered secondary radiation exposure originating from the x-ray beam during fluoroscopic procedures.

Product Compliance: In compliance with EN 420, EN 374-2, EN 388, EN 61331-1, ICRP60 & ICRU51 (International Commission on Radiological Protection)

Quality Assurance: Manufacturing process is in compliance with US FDA Quality System Regulation (QSR) and BS EN ISO9001 Quality System RadiaXon® is an approved product of OSHA, Germany 



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12. There is no requirement to wear Radiation Protection Gloves in the workplace, is there?

Although there are no requirements or regulations currently in place (other than OSHA-Germany) that specifically require the use of RPG's, it does not mean they are not required. Concepts such as ALARA (As Low As Reasonably Achievable) are being widely implemented in working environments worldwide. The ALARA approach assumes that occupational exposure to ionizing radiation is hazardous and mandates that measures be taken to limit exposure to it. Personal Protective Shields such as RadiaXon RPG's are one of the most effective ways to achieve this requirement.

13. Can RadiaXon RPG's be reused?

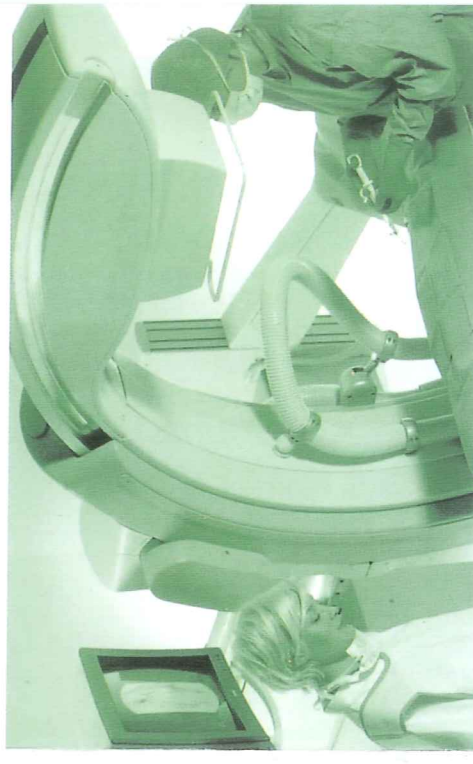
Reprocessing or re-sterilization of RPG's may reduce their strength, barrier properties and/or attenuation properties. For these reasons, reuse is not recommended.

14. I have difficulty finding gloves that fit me well. Are RadiaXon RPG's offered in a wide range of sizes?

Yes, RadiaXon RPG's are offered in a full range of sizes (6½ through 9), moreover they are manufactured on state of the art anatomically designed forms. This ensures comfort and reduced hand fatigue during long procedures.

15. How are RadiaXon RPG's packaged?

RadiaXon RPG's come in cases of 4 dispenser boxes each. Each dispenser box contain 5 separately packed sterile pairs.



Environmentally Friendly and Disposable

Lead Free & Non Toxic

Powder Free

Sterile



Frequently Asked Questions

Your Partner In Protection™

