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Product Name
Sterile Radiation Attenuating Surgical Gloves

Brand Name
ARGUARD XR, PROGUARD RR, PROGUARD ELITE, & PROGAURD ECO

Trade Name
RFB GLOVES

Trade Mark

FOR SINGLE USE ONLY

Material of Construction
Dry Natural Rubber and Lead oxide (RFB RX)
Natural Rubber latex and Bismuth Oxide (RFB BX)
Polyisoprene and Bismuth oxide (RFB PX)
Polyisoprene and Tungsten (RFB WX)

General Device Description
The radiation attenuating surgical gloves are the sterile powder free surgical gloves worn by the healthcare professional during surgical intervention involving X-ray (fluoroscopy).
These surgical gloves provides the aseptic conditions during surgical procedure and in addition with this it protects the users hand from scattered secondary ionising radiation. It does not protect from direct or primary X-ray. These gloves consist the radiation attenuating particles embedded in the biocompatible polymer. The surgical gloves are sterilized by EtO sterilization method.

Intended Purpose
The radiation attenuating surgical glove is a sterile, single-use, powder-free medical device intended to be worn by healthcare professionals during fluoroscopically guided diagnostic and interventional procedures. It serves as a barrier to prevent cross-contamination between the patient and the healthcare professional and contains radiation-attenuating particles to reduce the user's hand exposure to scattered or secondary ionizing radiation. These gloves are not intended for use in direct or primary X-ray beam.

Indication
The gloves are indicated for use in clinical settings where there is a risk of cross-contamination between the patient and the healthcare professional and where the user may be exposed to secondary X-ray, such as in radiologically guided surgical or diagnostic procedures.

Contraindication
- The device are contraindicated for use in the direct/primary X-ray beam as it may lead to a significant increase in radiation exposure for the user.
- The device is contraindicated in user and/or patients with known hypersensitivity/allergic reaction to the materials used in the variants.

Intended Patient Population
The sterile radiation attenuating surgical gloves (RFB RX, RFB PX, RFB BX, & RFB WX) can be used in all patient population irrespective of their age, sex, & ethnicity.
Patient selection criteria:
The sterile radiation attenuating surgical gloves can be used in all patient population except in patients with known allergy to the raw materials used in the device.

Intended User
Healthcare professionals

Performance Characteristics
- The sterile radiation attenuating surgical gloves provide the radiation attenuation (min. 50% at 60 kVp and min. 35 % at 120 kVp).
- The gloves prevent from cross contamination by providing non-porous barrier with the thickness ranging from minimum of 0.22 to 0.36 mm.

Potential Side Effects/Complications
The sterile radiation attenuating surgical gloves are associated with the following side effects:
- Itching;
- Temporary discomfort;
- Skin irritation;
- Skin inflammation;
- Allergic reaction;
- Hypersensitivity;
- Infection/ cross contamination
- Mutagenicity due to residual EO exposure, cancer due to excessive radiation exposure
Use of the device under primary X-ray beam may lead to overexposure of user to the radiation which will likely cause secondary complications.

Use Instructions
Inspection:
- Before use, visually inspect the glove pouch for defects or openings to ensure the sterile seal has not been tampered with.
- The pouch must be discarded and replaced if visibly damaged with holes, cuts, tears, undone welding.
- The same attention must be paid when inspecting the gloves before use: they must be in perfect condition, clean and intact.
- If a glove is not perfectly intact (i.e. visibly damaged - cut or torn) nor clean (i.e. soiled) it must be discarded and replaced.
Donning Procedure:
- Wash and dry or sanitize hands before donning the gloves.
- For maximum comfort choose the gloves size most appropriate to users hands. Donning the correct size will reduce the risk of strain/fatigue on hands during use;
- Remove the walleted gloves (inner wrapper) from the pouch (outer wrapper) by peel open from the corner for pouch (peel down to open pouch);
- Using the thumb and the first two fingers of the nondominant hand, pinch the cuff of the folded edge of the glove cuff for the dominant hand, touching only the inside surface of the glove;
- Slide dominant hand in to the gloves keeping hand point downwards and pull up to wrist;
- Using the glove hand insert the 4 fingers under the cuff of

the other glove and pull the glove up to the arm;
- Adjust the gloves as necessary;
- In order to reduce risk of barrier failure and to ensure protection during Procedure which extends beyond 24 hour, users are advised to change the gloves after 24 hour.
Removal Procedure:
- Take hold of the first glove at the wrist;
- Fold it over and peel it back, turning it inside out as it goes. Once the glove is off, hold it with your gloved hand;
- To remove the other glove, place your bare fingers inside the cuff without touching the glove exterior;
- Peel the glove off from the inside, turning it inside out as it goes. Use it to envelope the other glove;
- Discard the soiled gloves and change to new ones immediately: as soon as any puncture, tear or damage is noticed and after contact with contaminated or unsterile surface.

Duration of Use
Short term (Maximum cumulative use more than 60 minutes and less than 24 hours)

Method of Sterilization
Sterilized with ethylene oxide gas.

Storage Conditions
Store in a dry place between 5°C to 35°C. Keep away from sunlight.

Precautions
- Before usage, inspect the gloves for any defects or imperfections. If in doubt do not use the glove, get a new pair;
- The gloves should be worn on dry hands only;
- Remove any jewellery or sharp objects from hands & finger before wearing gloves;
- Healthcare professional should not have sharp fingemail;
- Sterility and performance are not guaranteed on devices that have passed their use by date or if the packaging or seals have been damaged. If label including use by date is illegible, do not use;
- Care must be taken when selecting the correct glove size to reduce the risk of strain/fatigue on hands during use;
- Promptly and safely dispose of any gloves that have touched a potentially contaminated surface in accordance with relevant local regulations pertaining to safe disposal of clinical waste.
- Aggressively pulling on the cuff and over stretching the glove while donning may lead to tearing or damage.

Warnings
- Do not use if the pouch is torn or compromised, as it may alter the sterility of device.
- Do not use if the glove is visibly torn or damage;
- Do not reuse, if reused-loss of sterility, high risk of cross-contamination, deterioration of gloves property;
- Do not re-sterilize the device by any method, RFB Gloves assumes no liability for devices that have been re-sterilized;
- Do not use the device after use by date;

- Do not use for more than 24 hour to reduce the risk of strain/fatigue on hands and loss of barrier protection.

Limitations
- The gloves are not intended to protect from primary x-ray beams, any abrasions, cuts, tears, punctures, heat & fire.
- The gloves shall not be used for more than 24 hours.

Device Supply
Packaging configuration
- Protective packaging (Wrapper): Right and Left Glove
- Primary packaging (Pouch): 1 pair
- Secondary packaging (Inner box): 5 pairs (5 pouches)
- Tertiary packaging (Inner carton): 20 pairs (4 inner boxes)
- Shipper: 40 pairs (2 inner carton)

Disposal Instructions
For RX:
These devices contain lead a substance classified as hazardous to human health and the environment. Therefore , used or expired gloves must be disposed of in accordance with applicable local, national, or regional regulations governing hazardous waste.

For PX,BX and WX:
These devices contains tungsten and bismuth, a substance classified as non-hazardous and less toxic but due to its environmental persistence we recommend to dispose the used or expired gloves in accordance with applicable local, national, or regional regulations governing clinical waste management.

Notice For User
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

Information on Known Characteristics and Technical Factors

The gloves are intended for single use only, re-use of the device may lead to cross contamination and/or secondary complications. The gloves comes in sterile condition and re-sterilization of the gloves may lose its sterility or may change in the physical properties of the gloves from which they have made. Use of such re-sterilized gloves may cause contamination to patient and or secondary complications to the user.

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**RFB GLOVES**

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CMC Medical Devices & Drugs S.L.

Address: Plot No. 129G/53,

Address: C/ Horacio Lengo No 18,

Noida Special Economic Zone,

CP 290 06, Málaga, Spain

Noida – 201 305, UP, India

Contact Number: +349 512140 54

Contact Number: +91 9999004037

EmailAddress:

Email

ID:

heera@rfbgloves.com

info@cmcmmedicaldevices.com

Website: www.rfbgloves.com

<http://www.cmcmmedicaldevices.com/es/>

Symbol	Title	Symbol	Title	Symbol	Title
	Manufacturer		Authorized representative in the European Community/European Union		Date of manufacture
	Use by date		Batch code		Catalogue number
	Importer		Country of manufacture		Sterilized using ethylene oxide
	Do not use		Do not re-use		Do not use of package is damaged and consult instruction for use
	Consult instruction for use		Single sterile barrier system with protective packaging inside		Keep away from sunlight
	Keep dry		Temperature limit		Caution
	Medical device		Unique device identifier		Notified body identification number
	Contains or presence of natural rubber latex		Do not contains latex rubber		

