



PROTECH LEADED EYEWEAR INC,
DBA PROTECH MEDICAL

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RADIOGRAPHIC PROTECTION GLOVES INSTRUCTIONS FOR USE (IFU)

1. INTENDED USE

To protect the user's hands from scattered secondary radiation originating from the X-ray beam during fluoroscopic procedures by providing an attenuating barrier to radiation. They are not intended for use in direct or primary X-ray beams. These gloves are ideal where the user needs excellent dexterity combined with protection from ionizing radiation during various types of procedures such as General X-Ray & Fluoroscopy, Radiography, Neuroradiology, Urology, MRI, CT, Radiotherapy and Nuclear Medicine.

2. CAUTION

These gloves are intended to protect against:

- Low level of ionizing radiation,
- Micro-organisms (fungi and bacteria, not virus)

They are not intended to protect from:

- Abrasions, cuts, tears, punctures
- Heat and fire or other uses not mentioned

The glove complies with safety standards only if worn as recommended and only if in perfect condition.

Glove is sterile and is single use only. Do not wear if packaging is damaged or has been tampered with.

3. GENERAL INSTRUCTIONS

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.

When donning the glove, care must be taken. A nurse or attendant should assist by properly opening the cuff to allow easy insertion of the hand and fingers. Aggressively pulling on the cuff and over stretching the glove while donning may lead to tearing or damage.

PACKAGING & STORAGE

The glove must be stored in its original packaging, in a dry place away from light and heat sources (below 35°C). Care should be taken to avoid sharp objects as punctures will allow radiation to pass to the wearer.

EXPIRY DATE

The shelf life of a sterilized glove is 3 years. This Indication may be found on the label on the original external packaging and indicates the period of time during which the device, sterilized with Ethylene Oxide, may be used as long as it has been stored properly in suitable conditions and has intact packaging.

DISPOSAL

Users MUST dispose of PPE and accessories by complying with local, state, and federal or international regulations where applicable.

4. PROTECTION AND COMPLIANCE STANDARDS

EN 61331-1:2014: (EU) ; EN 61331-3:2014: (EU) ; ASTM 2547-18: (USA) ; EN ISO 374-1:2016 ; EN ISO 374-5:2016 ; EN 420:2003+A1:2009 ; EN 421:2010 (excluding clause 4.3)

5. EU TYPE EXAMINATION

This is to certify that the product group reference, Proguard RR1 "Protex PX1" / Proguard RR2 "Protex PX2" / and Proguard RR3 "Protex PX3" comprising various sizes and protection thicknesses has been subject to **EU Type Examination Module D, performed by SATRA Technology Europe Ltd, with Notified Body Number 2777** and residing at Bracetown Business Park, Clonee, Co. Meath, D15 YN2P, Ireland and is in conformity with the provisions of Regulation (EU) 2016/425, satisfying the manufacturer's technical specifications and testing based upon IEC 61331-1:2014 and IEC 61331-3:2014 and defined in EU Module B Type Examination Certificate.