PROTECH LEADED EYEWEAR INC,
DBA PROTECH MEDICAL

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LEAD GARMENTS & ACCESSORIES INSTRUCTIONS FOR USE (IFU)

1. INTENDED USE

Lead Garments are worn by healthcare professionals to protect them from the harmful effects of x-ray radiation during medical & other procedures requiring the use of x-ray/fluoroscopy. Lead garments are usually worn in combination with other products to provide complete protection from x-ray. You must ensure that your lead garment fits correctly and is properly worn for effective protection.

2. CAUTION

Before use, check to ensure your lead garment is in good, working condition, has not been scratched or punctured, and conforms to order details. Protech does not x-ray aprons during its QC process. Pin holes or other damage to the protective core material may go unnoticed and can compromise protection. If any issues are detected, use of Lead Garment should cease immediately until it has been properly repaired or replaced.

IFU Other Languages

(EN) To view this cautionary statement and document in other languages, please scan the QR code.

(ES) Para ver este documento en otros idiomas, escanee el código QR.

(DE) Um dieses Dokument in anderen Sprachen anzuzeigen, scannen Sie bitte den QR-Code.

(FR) Pour visualiser ce document dans d'autres langues, veuillez scanner le code QR.

(PT) Para visualizar este documento em outros idiomas, escaneie o código QR.

3. GENERAL INFORMATION

Upon receipt, please inspect Lead Garment for damages (holes, cuts, tears, rips, undone seams). Protech uses crush proof boxes when shipping its Lead Garments, but accidents do happen! Sizing and other Lead Garment information may vary based upon customization or special requests. For additional product details, please refer to the lead garment's sewn-on label or other included documentation.

Packaging and Storage

Keep Lead Garment out of direct sunlight and prolonged exposure to extreme heat. You may roll Lead Garment and transport in a Protech duffle bag or box, but never sharply fold or crease your Lead Garment. Always store Lead Garment on appropriate metal hanger or lay flat on the ground or a countertop if hanger is not available. Do not subject to extreme temperatures. Store at 70-80°F (21-27°C). Temperature limits approximately 60-100°F (16-38°C).

Maintenance and Repairs

It is important to establish a consistent, deep-cleaning schedule to mitigate the risk of pathogen transmission. Lead garments should be wiped clean after each use. Most dirt and stains (blood, bodily fluids, barium contrast media) on Lead Garment fabrics can be cleaned by using room temperature water along with the following cleaning solutions: mild diluted soap, alcohol or ammonium-based wipes, and highly diluted Clorox hydrogen peroxide (not recommended for long-term use). To apply cleaning fluid, please use a cloth or wipe and always use room temperature water. For repairs, alterations, trade-ins, recovery and other services, please contact Protech or your local representative.

Examples of approved cleaners include: PDI Sani-Cloth® AF3 Germicidal Disposable Wipes, PDI Super Sani-Cloth® Germicidal Disposable Wipes, CaviCide® wipes.

DO NOT: Do not use petroleum-based cleaning solvents. Do not machine wash or dry. Do not use hot or warm water. Do not iron or autoclave. **NOTE:** Protech's lead garment inspection software can help record results of annual PPE (garment) inspections.

Disposal

Users must dispose of Lead Garments and accessories by complying with local, state, and federal or international regulations where applicable.

4. PROTECTION & COMPLIANCE STANDARDS

IEC 61331-1:2014: (EU) Protective devices against Diagnostic Medical X-ray radiation. (Determination of attenuation properties of material)
IEC 61331-3:2014: (EU) Protective devices against diagnostic medical X-radiation Part 3: Protective clothing, Eyewear and Protective Patient shields.
ASTM 2547-18: (USA) Standard test method for determining the attenuation properties in a primary x-ray beam of materials used against radiation.

5. REGULATORY INFORMATION

For detailed Declaration of Conformity info, scan the QR code.

UKCA TYPE EXAMINATION

X-Ray Protection Garments and related accessories ("PPE") described above is in conformity with the provisions of Regulation (EU) 2016/425 as brought into UK Law and amended; the models satisfy the requirements of the manufacturer's technical and quality management specifications with testing based upon IEC 61331-1:2014, IEC 61331-3:2014 and applicable FDA regulations and ASTM testing standards. This is identical to the PPE which BTTG, Approved Body #0338 (6 Wheel Forge Way, Trafford Park, Stretford, Manchester M17 1EH, United Kingdom), performed the EU Module B type-examination on and issued the EU type-examination Certificate #523415/1. The PPE is subject to the conformity assessment procedure set out in Regulation (EU) 2016/425 as brought into UK Law and amended, Module D (Certificate #54180) under surveillance of the Approved Body BTTG, Aproved Body # 0338, performed at Protech Leaded Eyewear, Inc. DBA Protech Medical, 1360 N Killian Dr. Unit 2, Lake Park, Florida 33403.

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EU TYPE EXAMINATION

X-Ray Protection Garments and related accessories ("PPE") described above is in conformity with the provisions of Regulation (EU) 2016/425 and the models satisfy the requirements of the manufacturer's technical and quality management specifications with testing based upon IEC 61331-1:2014 and IEC 61331-3:2014. This is identical to the PPE which Shirley Technologies (Europe) Limited, Notified Body 2895 (Port Tunnel Business Park, Office 13 Unit 21, Dublin 17, ROI), performed the EU Module B type-examination on and issued the EU type-examination Certificate #SH00791. The PPE is subject to the conformity assessment procedure set out in Regulation (EU) 2016/425, Module D (Certificate #SH00654) under surveillance of the notified body Shirley Technologies (Europe), Limited, notified body number 2895, performed at Protech Leaded Eyewear, Inc. DBA Protech Medical, 1360 N Killian Dr. Unit 2, Lake Park, Florida 33403.

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6. WARRANTY POLICY

Protech's **Lead Garments** are warranted to be free of defects in materials and workmanship to the original purchaser for **two years.** If a defect appears, a return request must be made with Protech or authorized reseller. Protech will issue an RMA form to be completed and submitted along with the return of merchandise. All returns must be accompanied by an RMA with valid RMA #. All returns will be evaluated and examined.

Protech will either repair or replace the defective item or part without charge to the purchaser. This warranty is void when the product has been tampered with, when repairs or attempted repairs have been made by unauthorized persons, or when the item has been subject to misuse, abuse or damage in transit.