SCATTER GUARD

PROTECH LEADED EYEWEAR INC,
DBA PROTECH MEDICAL

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SCATTERGUARD SMART CAP INSTRUCTIONS FOR USE (IFU)

1. INTENDED USE

Scatterguard Disposable Smart Caps are specially designed for fluoroscopic procedures to reduce scatter radiation dose to the wearer. This cap is to be used in addition to and not in place of standard radiation protective devices.

2. GENERAL INSTRUCTIONS

Instructions for Use:
Scatterguard Smart Caps should be carefully removed from their pouch. If sterile, emphasis should be placed on maintaining your sterile field. You must inspect the pouch for any punctures or damage before use. Place the cap on your head and position for comfort. Tighten the cap using the headstraps on the back. After use, remove cap and dispose of through normal waste procedures.

Packaging and Storage:
Caps should remain in their original packaging and should be stored in normal room temperature and low humidity conditions away from direct sunlight.

Expiration/Shelf Life:
The shelf life of a sterilized cap is 3 years from manufactured date. While a non-sterile cap does not have an expiration date, be sure to check the condition of the cap before use. 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 radiation or ethylene oxide, may be used as long as it has been stored properly in suitable conditions and has intact packaging.

Disposal:
Scatterguard Smart Caps are lead-free and may be disposed of through normal waste procedures and in accordance with local laws and regulations.

3. PROTECTION & COMPLIANCE STANDARDS

Global Protection Options: 0.125, 0.25, 0.375, 0.50mm LE Pb
CE Protection Options: 0.25, 0.375, and 0.50mm LE Pb

EN 61331-1:2014: (EU) Protective devices against Diagnostic Medical X-ray radiation. (Determination of attenuation properties of material)

ASTM 2547-18: (USA) Standard test method for determining the attenuation properties in a primary x-ray beam of materials used against radiation.

4. REGULATORY INFORMATION

UKCA Type Examination:

X-Ray Protection Garments and related accessories ("PPE") described above is in conformity with the provisions of Regulation (EU) 2016/425 and 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.

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.

5. WARRANTY POLICY

Protech's Scatterguard Smart Caps are warranted to be free of defects in materials and workmanship to the original purchaser for three year while still in their original, unopened packaging. If a defect is detected, 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 replace the defective item or part without charge to the purchaser. This warranty is void when the product has been tampered with, sterile seal broken or package opened, 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.