PROTECH LEADED EYEWEAR INC,
DBA PROTECH MEDICAL

1360 North Killian Drive, Unit 2
Lake Park, FL 33403, USA

Phone: 561.627.9769
Email (USA): sales@protechmed.com
Email (Intl.): global@protechmed.com

SCATTERGUARD SMART CAP INSTRUCTIONS FOR USE (IFU)

1. INTENDED USE

Tested in accordance with ASTM F2547-06 and IEC 61331-1:2014. 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. CAUTION

Scatterguard Smart Caps offer protection against x-ray but are not intended to replace radiation protection apparel worn by medical professionals.

3. PROTECTION & COMPLIANCE STANDARDS: IEC 61331-1:2014 | ASTM F2547-18

- **Global Protection Options: 0.125, 0.25, 0.35, 0.375, 0.50, 0.75, and 1.00mm LE Pb**
- **CE Protection Options: 0.25, 0.35, and 0.50mm LE Pb**

4. GENERAL INSTRUCTIONS

INSTRUCTIONS

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 & STORAGE

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

EXPIREY DATE/SHELF LIFE

The shelf life of a sterile and non-sterile cap 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 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.

5. EU TYPE

This PPE is in conformity with the provisions of Regulation (EU) 2016/425 and the models satisfy the requirements of the manufacturer's technical specifications, testing based upon IEC 61331- 1:2014 and internal quality management procedures. This is identical to the PPE which is the subject of EU Module B Type-Examination Certificate 523415/1 issued by the Notified Body, BTTG with notified body number 2895, and is subject to the procedure set out in Regulation (EU) 2016/425, Module D under the supervision of the notified body BTTG, performed at Protech Leaded Eyewear, Inc., 1360 N Killian Dr. Unit 2, Lake Park, Florida 33403.

6. 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.