PROTECH LEADED EYEWEAR INC,
DBA PROTECH MEDICAL

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SCATTERGUARD DRAPES INSTRUCTIONS FOR USE (IFU)

1. INTENDED USE

Scatterguard Drapes are intended to be placed on a patient during fluoroscopic procedures and designed to provide excellent radiation protection for fluoro-lab and operating suite personnel during interventional procedures. Scatterguard Drapes, when properly positioned, create a “shadow” or protective area where radiation is blocked or reduced. Scatterguard Drapes are lightweight, lead-free, latex-free, and disposable.

2. CAUTION

Scatterguard drapes 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 drapes should be carefully removed from their sterilized pouch with emphasis being placed on maintaining your sterile field. You must inspect the pouch for any punctures or damage to the sterile seal before use. Gently unwrap the protective fabric layer surrounding the drape once it has been removed from the pouch. Unfold the drape and remove the external adhesive cover; place the external adhesive side onto the patient. Be sure to position the drape in the area of the procedure that offers the most protection from radiation emission. For more details on proper positioning, please reference Protech’s “Proper Drape Positioning Instructions” located in the Scatterguard Drape Technical File.

PACKAGING & STORAGE

Drapes 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 sterilized drape 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, may be used as long as it has been stored properly in suitable conditions and has intact packaging.

DISPOSAL

Scatterguard Drapes 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 Drapes** 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.