



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: IEC 61331-1:2014 | ASTM F2547-18 | ASTM F3094-14

- **Protection Options: 0.125, 0.25, 0.375mm LE Pb**
- **CE Protection Options: 0.25mm LE, 0.35mm LE Pb represented as (0.375mm LE)**

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” found on our website at: <https://www.protechmed.com/resources/product-information>

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.

EU TYPE:

Regulation (EU) 2016/425, Module B EU Type Examination Cert #: 523548/1

BTTG Testing & Certification Ltd. (Notified body #0338)

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