PROTECH LEADED EYEWEAR INC,
DBA PROTECH MEDICAL

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SCATTERGUARD PATIENT 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 highly absorbent, 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. GENERAL INFORMATION

Instructions for Use:

1. 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.

2. Unfold the drape. Place and position drape on patient so it lies between direct beam and doctor or technician to maximize safety shadow.

3. Secure drape in proper position on patient. Remove the external adhesive cover and place the external adhesive side onto the patient (do not place adhesive directly on patient's skin). For more details on proper positioning, please reference Protech's "Proper Drape Positioning Instructions" located in the Scatterguard Drape Technical File.

4. After use, dispose of through normal waste procedures.

Packaging and Storage:

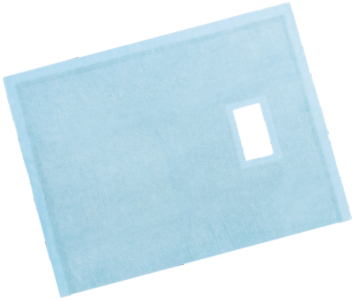
Drapes should remain in their original packaging and should be stored in normal room temperature and low humidity conditions away from direct sunlight.

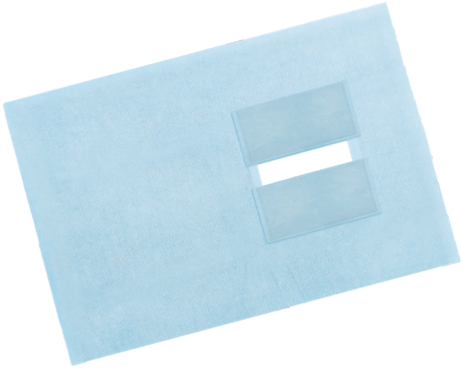
Expiration/Shelf Life:

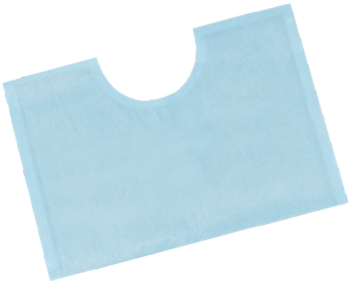
The shelf life of a sterilized drape is 3 years. This Indication may be found on the label on the original external packaging and indicates the period of time during which the sterilized device may be used as long as it has been stored properly in suitable conditions and has intact packaging.

Disposal:

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







4. PROTECTION & COMPLIANCE STANDARDS

Global Protection Options: 0.06, 0.125, 0.25, 0.375, 0.50mm LE Pb
CE Protection Options: 0.25 and 0.375mm 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.

5. 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 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. 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, 7960 Central Industrial Drive, Suite 125, West Palm Beach, FL 33404 USA.

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, 7960 Central Industrial Drive, Suite 125, West Palm Beach, FL 33404 USA.

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.