PROTECH LEADED EYEWEAR INC,
DBA PROTECH MEDICAL

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RADIATION PROTECTION TABLE DRAPES INSTRUCTIONS FOR USE (IFU)

1. INTENDED USE

Table Drapes are intended to provide supplemental protection against scatter radiation exposure to healthcare personnel during medical procedures involving fluoroscopic imaging. Table Drapes are designed for use in operating rooms, catheterization laboratories, interventional radiology suites, and other procedural environments where a C-arm or mobile fluoroscopy system is utilized. Table Drapes are available in two configurations. Single-sided table drapes contain a protective layer on one side, while double-sided table drapes have radiation protective panels on both sides.

2. CAUTION

Before use, check to ensure your table drape is in good, working condition, has not been scratched or punctured, and conforms to order details. Protech does not x-ray table drapes or garments during its QC process. Pin holes or other damage to the protective core material may go unnoticed and can compromise protection. If any issues are detected, use of Table Drape should cease immediately until it has been properly repaired or replaced.

Table drapes are intended as supplemental shielding only and do not replace standard personal protective equipment (PPE), such as lead aprons and thyroid collars. Always ensure proper positioning and securement before each use. Incorrect setup may result in reduced radiation protection. Table drapes are heavy; handle carefully to avoid strain or injury. Do not use in MRI environments.

3. GENERAL INFORMATION

Upon receipt, please inspect your Table Drape for damages (holes, cuts, tears, rips, undone seams). Protech uses crush proof boxes when shipping its table drapes, but accidents do happen! Sizing and other Table Drape information may vary based upon customization or special requests. For additional product details, please refer to the lead garment's sewn-on label or other included documentation.

Single-Sided Drape Installation

Clean and dry the table edge where the drape will be positioned to ensure proper adhesion. Apply the provided adhesive-backed hook (Velcro) strip along the side edge of the table. Press firmly to remove any creases, bubbles, or gaps. **Important: Allow the adhesive strip to cure undisturbed for 24 hours before affixing the drape. Failure to wait the full curing time may compromise adhesion.** After curing, align the loop (Velcro) portion of the drape with the installed hook strip and press to secure. Confirm that the drape is properly aligned and free from folds or obstructions.

Double-Sided Drape Installation

Carefully unfold the drape and position it over the patient table. Ensure the saddle portion of the drape is centered evenly on the table surface. Adjust the side panels so that they hang freely and evenly on both sides of the table. When positioned correctly, the counterweight of the drape panels will hold the drape in place without shifiting. Confirm that no part of the drape obstructs equipment or compromises the sterile field, if applicable.

Packaging and Storage

Keep table drape out of direct sunlight and prolonged exposure to extreme heat. You may roll table drapes and transport in a Protech duffle bag or box, but never sharply fold or crease your drapes. Always lay table drapes flat on the ground or on a suitable table. Single-sided table drapes may be customized with grommets and hung on the wall. Do not subject to extreme temperatures. Store at 70-80°F (21-27°C). Temperature limits approximately 60-100°F (16-38°C).

Disposal

Users must dispose of table drapes, garments and accessories by complying with local, state, and federal or international regulations where applicable.

Maintenance and Repairs

It is important to establish a consistent, deep-cleaning schedule to mitigate the risk of pathogen transmission. Table drapes should be wiped clean after each use. Most dirt and stains (blood, bodily fluids, barium contrast media) on drape fabrics can be cleaned by using room temperature water along with the following cleaning solutions: mild diluted soap, alcohol or ammonium-based wipes, and highly diluted Clorox hydrogen peroxide (not recommended for long-term use). To apply cleaning fluid, please use a cloth or wipe and always use room temperature water. For repairs, alterations, trade-ins, recovery and other services, please contact Protech or your local representative.

Examples of approved cleaners include: PDI Sani-Cloth® AF3 Germicidal Disposable Wipes, PDI Super Sani-Cloth® Germicidal Disposable Wipes, CaviCide® wipes.

DO NOT: Do not use petroleum-based cleaning solvents. Do not machine wash or dry. Do not use hot or warm water. Do not iron or autoclave. **NOTE:** Protech's lead garment inspection software can help record results of annual PPE (garment) inspections.

4. PROTECTION & COMPLIANCE STANDARDS

IEC 61331-1:2014: (EU) Protective devices against Diagnostic Medical X-ray radiation. (Determination of attenuation properties of material)
IEC 61331-3:2014: (EU) Protective devices against diagnostic medical X-radiation Part 3: Protective clothing, Eyewear and Protective Patient shields.
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

For detailed Declaration of Conformity info, scan the QR code.

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.

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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.

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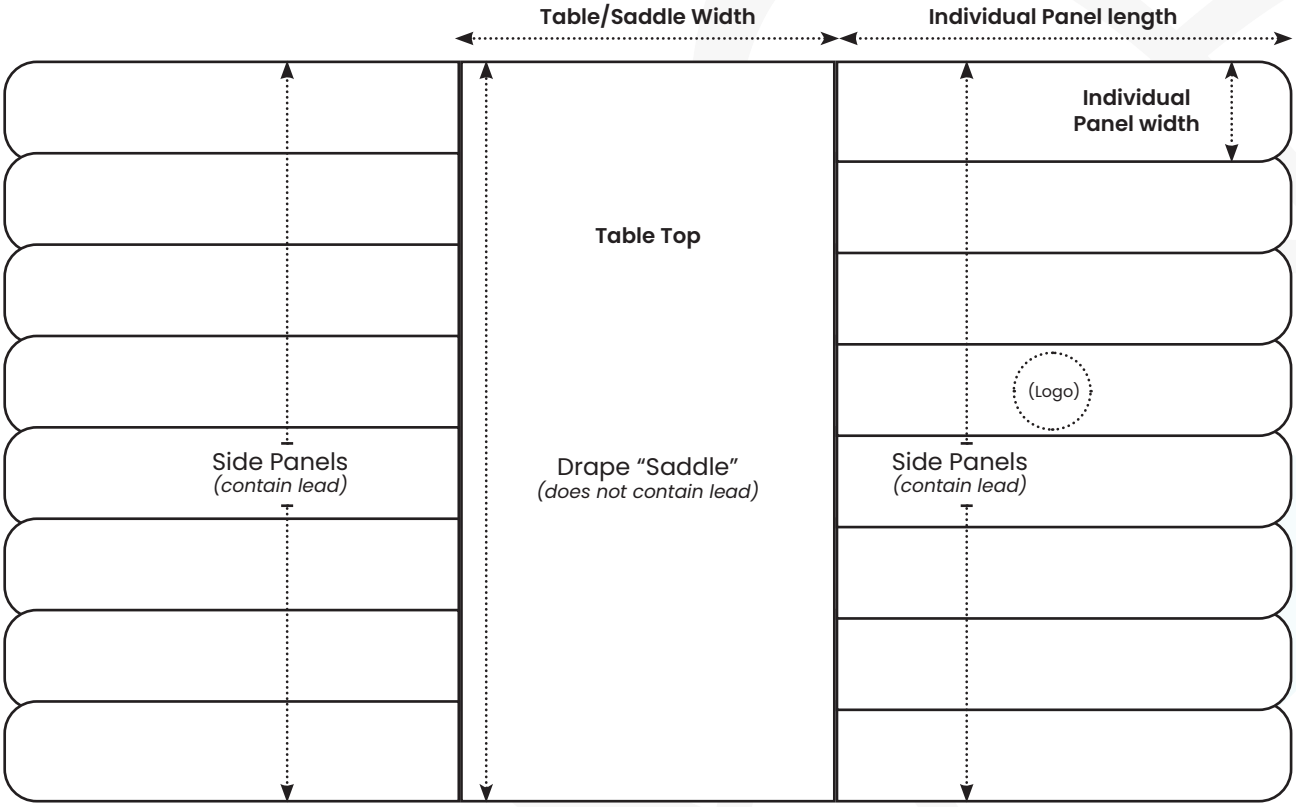
6. WARRANTY POLICY

Protech's **Table Drapes** are warranted to be free of defects in materials and workmanship to the original purchaser for **one year.** If a defect appears, 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 either repair or replace the defective item or part without charge to the purchaser. This warranty is void when the product has been tampered with, 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.

Double-sided Table Drape Design (aka "Saddle bag Design")



Single-sided Table Drape Design