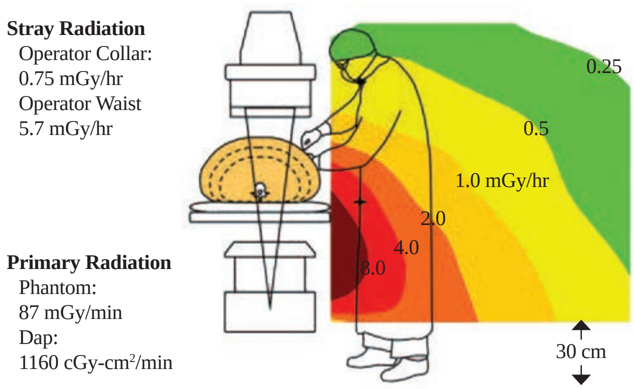
THE SCIENCE BEHIND BLOXR® XPF® TECHNOLOGY

Radiation Exposure and the Need for Better Protection

Introduction and the Need

Diagnostic and interventional imaging has revolutionized modern image-guided medicine. It is estimated that there were approximately 214.2 million x-ray procedures performed in the US in 2018, including both fixed and mobile x-ray systems;[1] this number continues on an upward trend. As a result, there is a heightened concern of occupational exposure to the harmful effects of ionizing radiation. Experts estimate that 29,000 additional cancers could arise from excessive radiation exposure per year.[2] Recent literature points to potential causal links between excessive radiation exposure and malignancies.[3] There is consensus that reducing radiation exposure to "as low as reasonably achievable," or ALARA, is prudent in decreasing long-term consequences of chronic low dose exposure.[4]



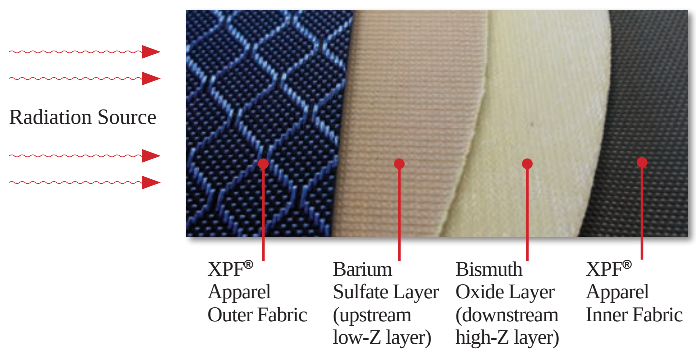
Source: Schueler, Beth, et. al. "An Investigation of Operator Exposure in Interventional Radiology," Mayo Clinic - Dept. of Radiology. *RadioGraphics* 2006. RSNA. Vol. 26, No. 5, p. 1533-1540.

The majority of occupational radiation exposure is derived from radiation scatter which emanates from the patient and x-ray source.[5] Surgeons in the Operating Room and Cath Lab are performing more surgeries and fluoroscopic procedures, leading to extended exposure to the lowest sub-40 kVp energy levels (the most dangerous for the body) and increasing overall cumulative dose. Despite best practices, the operator might insert parts of their anatomies into the primary beam. Historically, clinicians have used lead or "light-lead" aprons, which pose risks to clinicians in the form of spine injuries and back pain from their extended use. With 50% of interventional clinicians suffering from spine injuries and 33% reporting occupational injury claims for back pain, effective lightweight radiation protection is crucial.[6]

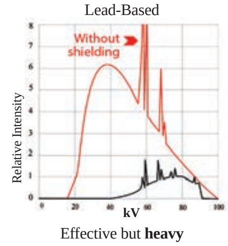
In terms of hand protection, clinicians routinely forgo the use of radiation attenuating gloves because of diminished tactile feel. Studies show that clinicians' hands receive among the highest scatter radiation doses.[7,8] Signs of radiation overexposure include peeling skin, halted hair growth and discoloration of the nail beds. It is recognized that "long-term, low doses of ionizing radiation can lead to significant somatic DNA damage in professionally exposured physicians."[9] A means to effectively cut dose to unprotected hands without reducing tactile feel is important.

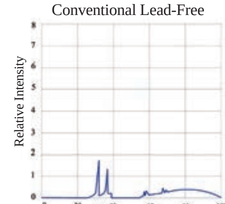
XPF® and ULTRABLOX® Redefine Protection

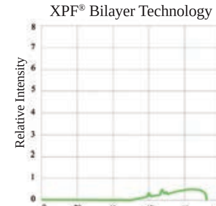
BLOXR® XPF® Technology includes scatter radiation protection apparel with a novel bi-layered construction that uses a non-heavy metal combination of barium sulfate in one layer and bismuth oxide in the other layer. This design is optimized for the reduction of scatter radiation. The energy (keV) of scattered radiation is significantly less than that of the incident energy, due to Compton scattering.[10]



The K absorption edge of lead (69 keV) is higher than the energy of much of the scatter radiation energy present in medical imaging. The first layer of barium sulfate in XPF garments, with K edge of ~ 37 keV, has a higher mass attenuation coefficient than lead and thus can effectively reduce dose at lighter weight. In reducing dose, barium sulfate itself generates fluorescent energy peaks at ~ 37 keV. These sub-40 keV peaks are known to be biologically more harmful. The second layer of bismuth oxide removes these fluorescence peaks. This barium sulfate upstream/ bismuth oxide downstream bilayer configuration is particularly effective in eliminating the more harmful sub-40 keV radiation spectrum, rendering XPF® Technology safer than other lead-free alternatives. Studies show that XPF offers the highest attenuation per unit weight, enabling lighter, more comfortable protective garments.







THE SCIENCE BEHIND BLOXR® XPF® TECHNOLOGY

XPF is more flexible and tear-resistant than conventional materials, withstanding over 1 million cycles of bending without cracking or change in attenuation levels.[11] With no heavy metals and a flexible, patented design, XPF garments can be folded or hung for storage and can be cleaned in a washing machine. When a garment comes to the end of its useful life, it can be disposed of without special consideration or removal costs. XPF is "greener" than shielding containing lead, tungsten and antimony.

ULTRABLOX® Cream utilizes bismuth oxide as a radio-contrast agent to provide attenuation protection from harmful scatter radiation exposure in the diagnostic imaging range of up to 130 kVp. The cream is sterile, biocompatible and, unlike lead gloves, one size fits all.

Independent Clinical Evidence

Independently conducted randomized, prospectively-controlled clinical studies show that XPF thyroid collars transmit 18% lower dose than 0.5mm Pb equivalent collars.[12] Not only does XPF Technology provide greater overall dose reduction, but it also eliminates the more harmful sub-40 keV spectrum and is more comfortable and crack-resistant than other alternatives. XPF was proven slightly more effective than lead for scatter radiation up to 80 kVp paired with the advantage of being less susceptible to damage.[18] Numerous other studies have also validated the performance benefits of XPF Technology in reducing scatter in actual clinical practice.[13,14,15] In addition, XPF Radiation Protective Apparel is cleared by the FDA as 0.5mm Pb lead equivalent product (K110900).

ULTRABLOX Cream is the world's first attenuating cream for protecting hands from scatter radiation. Clinical studies have shown that the cream provides up to 85% dose reduction, twice that of sterile attenuating surgeon's gloves.[16,17] Clinicians can protect their hands without loss of tactile feel or dexterity. Cleared by the FDA (K123422, K133684).

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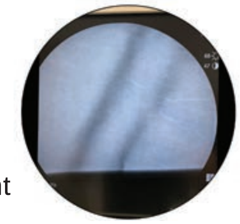
Fluoroscopic Inspection of XPF

When conducting a fluoroscopic inspection on a true lead apron or one with heavy metals, a light or grayed area indicates a crack or breach of protection. BLOXR XPF Garments are different. They are non-lead and non-heavy metal. The attenuating bilayer commonly shows areas of light and dark contrast upon fluoroscopic inspection, often along the fold lines, and sometimes with a mottled or striped appearance (see photo). BLOXR refers to these contrasts as light density artifacts but the attenuating performance is equivalent; it does not mean a garment is cracked or out of specification.



Our proprietary manufacturing process removes concern over metal fatigue and provides outstanding resistance against cracking. Should something compromise the XPF attenuating material, it would appear as white in the image. XPF technology is uni-directional; the BLOXR logo should face the radiation source.

Innovation in Radiation Protection

BLOXR® XPF® Radiation Protection Apparel and ULTRABLOX® X-Ray Attenuating Cream provide increased clinician safety through effective scatter radiation dose reduction. XPF Apparel features a comfortable, lightweight material that can be bent and folded without cracking, while providing 0.5mm lead equivalent protection -- and is machine washable. ULTRABLOX Cream is the first and only X-ray attenuation cream. It is proven to reduce radiation exposure to a clinician's hands by up to 85% without affecting dexterity or tactile feel.[16,17]

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U.S. Patent No. 8,754,389, 8,993,989 and 9,114,121.
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