

Type Procedures: For procedures using X-Rays

Disposable: For Single Use Only

Lead Free: This product contains no lead lead by-products or other toxic metals.

Application: Squeeze out entire contents of tube and apply to hands evenly to create a uniform opaque coating. Allow to dry for up to 60 seconds before putting on Surgeon's Gloves. Or you may apply the cream to uniformly coat the first glove, allow to dry for up to 60 seconds before putting on the second Surgeon's glove. Check to make sure cream is completely encapsulated within glove(s).

Disposal: Dispose as with other surgical products, or wash off with soap and water



QTY 50g net

REF 100036

WARNING: This device is not intended to be used in or adjacent to the primary X-ray beam or the transmitted beam and should not be used in lieu of a Radiographic Procedure Glove, which is used in radiography for those studies requiring the physician's hand or fore arm be in the direct path of the primary X-ray beam

Caution:

(i) Federal law restricts this device to sale by or on the order of a health care professional.

(ii) Once applied on the hand or glove, the cream shall be used for a maximum period of three hours.

Sterile until opened

Indications for Use

The UltraBLOX X-ray Attenuating Cream is intended for use as a radiation shield. It is intended to be applied to the user's hand before donning gloves, or it may be applied on a glove on the hand, followed by donning a second glove. The UltraBLOX X-ray Attenuating Cream is intended to be used during medical procedures where hands are necessarily exposed to radiation to offer some degree of protection from radiation exposure in the diagnostic imaging range of up to 130 kVp. This may include surgical procedures that require the use of fluoroscopy or radiography or other procedures.

NOTE: For use with natural rubber latex and latex-free poly-isoprene Surgeon's Gloves only.

The effect of cream thickness on the attenuation characteristics of the X-ray Attenuating Cream was determined in accordance with the ASTM F2547-06 protocol by exposing sterile films of controlled thickness of 0.0050, 0.010 and 0.015 inch, using a C-arm fluoroscope at 60.95 and 110 kVp. A 0.010 inch thick sterile latex radiation attenuating glove (Radlon-X-Medline) was used as a control. Transmitted dose was measured using nanoDQ™ dosimeters (Landauer, IL) placed under the films or radiation glove specimens. Incident dose was measured separately. Five replicate measurements were made. Attenuation was calculated as a ratio of blocked dose to incident dose expressed as % as shown in the table below.

Mean % Attenuation of Controlled Thickness Creams and Radlon-X Glove		At equivalent 0.010 inch thickness, the cream blocked between 46% to 93% more radiation than the gloves.	
		60 kVp	110 kVp
0.005" thick cream		37.4 ± 3.9	36.5 ± 3.3
0.010" thick cream		62.6 ± 3.1	58.1 ± 2.9
0.015" thick cream		76.6 ± 2.0	63.0 ± 1.2
Radlon-X Glove		42.4 ± 1.4	50.1 ± 2.0
			26.5 ± 1.8

In actual practice, cream thickness will vary depending on the user. To determine the effect of user-to-user variation in cream application on attenuation a study was conducted using a modified ASTM F2547-06 protocol. An X-ray cabinet (Faxtron, IL) and a 0.6 Ci ion chamber detector (Radcal, CA) were used. Owing to the size limitations of the X-ray cabinet the ion chamber was placed proximally below the attenuating specimen. Data from two sterile attenuating surgical gloves, Radlon-X (Medline Industries, IL) and International Biomedical (Austin, TX) were used for comparison. The cream was applied to a glove donned on an anthropomorphic mannequin phantom hand (Radiology Support Devices, CA) modified to accommodate the ion chamber. Three different operators applied a calibrated amount of cream on the glove hand phantom to achieve a 0.010 inch thick cream layer. This technique was designed to duplicate realistic clinical conditions. Five replicate measurements were made and the results tabulated as below.

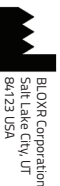
Mean % Attenuation of X-ray Attenuating Cream		Attenuation of Xray Attenuating Cream		Attenuation of Attenuating Gloves (from Manufacturer's Performance Claims)		
		User 1	User 2	User 3	Int. Biomed Glove	Radlon-X
60 kVp	Mean	81.1	83.5	85.3	56.5	55
	Std Dev	8.4	9.1	7.2	-	-
80 kVp	Mean	72	74.5	77.2	47.1	43
	Std Dev	8.6	11	9.6	-	-
100 kVp	Mean	62.6	67.2	69.9	41.6	34
	Std Dev	8.2	11.1	9.9	-	-
120 kVp	Mean	58.3	57.5	64.4	37.7	26
	Std Dev	8.4	17.2	11.5	-	-

Finally, an evaluation of the X-ray attenuating cream was conducted with a low-risk IRB approved protocol by clinicians at a level 1 trauma center. Three fellowship-trained orthopaedic trauma surgeons monitored radiation exposure to their dominant hand during 60 individual trauma cases (20 per surgeon) and 75 cumulative trauma cases (25 per surgeon) requiring the use of large C-arm fluoroscopy. Each surgeon wore two dosimeters side-by-side on the dorsum of their dominant hand for each case, one dosimeter covered with a thin layer (0.2mm) of the X-ray radiation attenuating cream and the other adjacent dosimeter without any protection. Both dosimeters were placed within a sterile package and affixed to the surgeon's hand under his or her surgical gloves prior to each case.

During cumulative exposure over 25 cases, the surgeons' hand was exposed to an average of 100 mrem (range 81 - 128) with the X-ray radiation attenuating cream demonstrating the ability to attenuate 39% of this radiation exposure (Surgeon A - 98%, Surgeon B - 52%, Surgeon C - 50%). Average attenuation amongst all cumulative cases was 53.5% as shown in the table below. This study demonstrates that the X-ray attenuating cream reduces radiation exposure to the hand by at least 50%.

Dominant Hand Exposure and Attenuation during Cumulative Case Series at a Level 1 Trauma Center				
Surgeon	Dosimeter	The X-ray Attenuating Cream reduces dose exposure by at least 50% without impairing tactile feel.		Attenuation %
		Cumulative Unshielded Dose (mRem)	Cumulative Shielded Dose (mRem)	
A	A5	128	53	58.6%
	A1	92	46	50.0%
B	A2	81	39	51.9%
	A1	100	46	53.3%
C	MEAN	100	46	53.3%
	Std. Dev.	25	7	4.5%

ASTM F 2547-06, Standard Test Method for Determining the Attenuation Properties in a Primary X-ray beam, of Materials used to Protect Against Radiation Generated During the Use of X-ray Equipment.
* Fluoroscopic Radiation to the Orthopedic Traumatologist's Hand & Efficacy of a Novel Radiation Attenuation Product. Erika J. Mitchell MD, Hope Summers, MD, Evan Dougherty MD and Michael D. Stover MD. AAOS Annual Meeting, Chicago, 2013.



BLOXR Corporation
Salt Lake City, UT
84123 USA

BLOXR Corporation, Salt Lake City, UT 84123
www.bloxr.com





Important Expanded Indication

UltraBLOX™ X-ray Attenuating Cream has received 510(k) clearance (K133684) for an expanded surgical glove indication, which now includes compatibility with latex-free poly-isoprene Surgeon's Gloves. See reverse side for updated Instructions for Use.

Note: For use with natural rubber latex and latex-free poly-isoprene Surgeon's Gloves only.

BLOXR Corporation, Salt Lake City, UT 84123
www.bloxr.com

MKT 720-01-67 Rev.A

