

REF 100036

QTY 50g net/Tube
(15 Tubes/Box)

ULTRABLOX® X-Ray Attenuating Cream Instructions for Use



STERILE R

Single Use
Sterile Unless Package is
Damaged or Opened

Description

- ULTRABLOX® X-Ray Attenuating Cream is a sterile, single use attenuating cream that provides increased clinician safety through effective radiation dose reduction to hands without affecting dexterity or tactile feel.
- Contains no lead, lead by-products or other toxic materials. Biocompatible.
- Manufactured in conformance with ASTM F 2547-06, 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.

Indications for Use

- ULTRABLOX® X-Ray Attenuating Cream is intended for use as a radiation shield from radiation, x-rays and ionizing radiation during medical procedures.
- It is intended to be applied to the user's hands before donning gloves, or applied on a gloved hand, followed by the donning of a second glove.
- For use with natural rubber latex gloves or latex-free poly-isoprene Surgeon's Gloves only.**
- It is intended to offer some degree of protection from radiation exposure during medical procedures where it is necessary for hands to be exposed to radiation. This may include surgical procedures that require the use of fluoroscopy or radiography.

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 forearm to be in the direct path of the primary x-ray beam.

Caution

- Federal law restricts this device to sale by or on the order of a health care professional.
- Once applied on the hand or glove, the cream can be used for a maximum period of three hours.

To Apply

We recommend kneading or shaking the tube for 30 seconds prior to opening.

- SINGLE GLOVE:** Open tube and squeeze out cream into one hand. Spread on desired parts of the hands, making sure to apply an even and thorough coat, including between each finger. Use enough cream so desired areas are completely covered with a paper-thin layer of cream. Apply surgical glove over cream on each hand making sure to encapsulate the cream between the glove and the hand.
- DOUBLE GLOVE:** Put on first pair of gloves. Open tube and squeeze out cream into gloved hands. Spread cream on desired parts of gloved hands, making sure to apply an even and thorough coat, including between each finger. Use enough cream so desired areas are completely covered with a paper-thin layer of cream. Apply the second surgical glove over the cream making sure to encapsulate the cream between the two gloves.

Technical Data

The effect of cream thickness on the attenuation characteristics of the cream was determined in accordance with ASTM F 2547-06 protocol by exposing sterile films of controlled thickness of 0.005", 0.010" and 0.015" using a C-arm fluoroscope at 60, 95 and 110 kVp. A 0.010" thick sterile latex radiation attenuating glove (Radion-X, Medline) was used as a control. Transmitted dose was measured using nanoDot™ 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 % (Table 1).

In practice, cream thickness varies 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 F 2547-06 protocol. An X-ray cabinet (Faxitron, IL) and a 0.6 cc ion chamber detector (Radcal, CA) were used. Due 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, Radion-X (Medline Industries, IL) and International Biomedical (Austin, TX) were used for comparison. Cream was applied onto a glove donned on an anthropomorphic anatomic phantom (Radiology Support Devices, CA) modified to accommodate the ion chamber. Three different operators applied a calibrated amount of cream on the gloved hand phantom to achieve a 0.010" thick cream layer to duplicate realistic clinical conditions. Five replicate measurements were made and the results tabulated (Table 2).

An evaluation of the 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 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 cream demonstrating the ability to attenuate ≥50% of this radiation exposure (Surgeon A – 58%, Surgeon B – 52%, Surgeon C – 50%). Average attenuation among all cumulative cases was 53.5% (Table 3) demonstrating that the cream reduces radiation exposure to the hand by at least 50%.

Handling and Storage

- Product is delivered sterile in an outer peel pouch. Remove product from peel pouch and peel off seal from tube in accordance with your facility's protocol.
- Over time separation may occur. We recommend kneading or shaking the tube for 30 seconds prior to use.
- Store in a cool, dry, well-ventilated place. Handle in accordance with good safety practice. Avoid exposure to temperatures in excess of 40 degrees C (104 degrees F).

Cleaning and Disposal

- To remove cream, wash hands using a mild abrasive soap or a scrubby bar utilizing your normal post-surgical scrub technique.
- Dispose of as with other surgical products.

TABLE 1 Mean % Attenuation of Controlled Thickness Creams and Radion-X Glove
Summary: At equivalent 0.010" thickness the cream blocked between 48% to 93% more radiation than the gloves.

	60 kVp	95 kVp	110 kVp
0.005" thick cream	37.4 ±3.9	36.6 ±3.3	36.1 ±2.0
0.010" thick cream	62.6 ±3.1	58.1 ±2.9	49.9 ±2.1
0.015" thick cream	76.6 ±2.0	63.0 ±1.2	63.2 ±2.7
Radion-X Glove	42.4 ±1.4	30.1 ±2.0	26.5 ±1.8

TABLE 2 Mean % Attenuation of X-Ray Attenuating Cream

		Attenuation of X-Ray Cream			Attenuation of Gloves (from manufacturer's claims)	
		User 1	User 2	User 3	Int. Biomed.	Radion-X
60 kVp	Mean	81.1	83.5	85.3	56.5	55
	Std Dev	8.4	9.1	7.7	-	-
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	-	-

TABLE 3 Dominant Hand Exposure and % Attenuation During Cumulative Case Series at a Level 1 Trauma Center
Summary: The cream reduced dose exposure by at least 50% without impairing tactile feel.

Surgeon	Dosimeter	Cumulative Unshielded Dose (mRem)	Cumulative Shielded Dose (mRem)	Attenuation %
A	A5	128	53	58.6
B	A1	92	46	50.0
C	A2	81	39	51.9
	MEAN	100	46	53.3
	Std Dev	25	7	4.5

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