

- [54] **RADIO OPAQUE GLOVES**
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- [52] U.S. Cl. **250/516; 250/519**
- [51] Int. Cl. **G21f 3/02**
- [58] Field of Search **250/108 FS, 516, 519**

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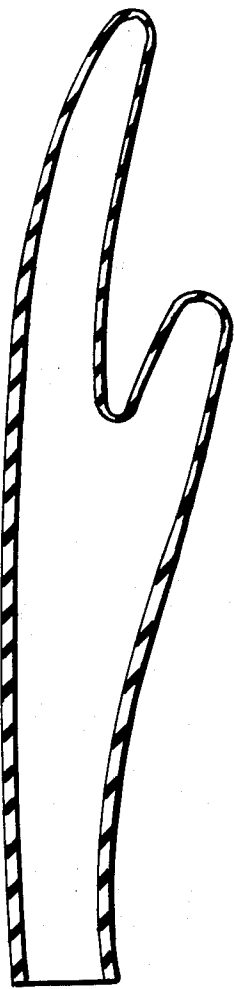
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Primary Examiner—**Archie R. Borchelt**
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[57] **ABSTRACT**

Radiation shielding garments and accessories, such as radio-opaque gloves for surgeons, shielding against the harmful x-ray radiation in a fluoroscopic zone are advantageously different from garments for shielding from other medical uses of x-rays. Such garments are provided with zones of differing opacity, whereby desired sensitivity and “feel” through the glove material is retained. One feature is the provision of an “opacity gradient” across the glove cross section with opacity being relatively low at the fingertip area (lesser shield-thickness), but relatively high at the less nonprehensile hand zones, such as the palm. Glove fabrication techniques for achieving such an opacity gradient are described.

2 Claims, 9 Drawing Figures



PHOTOELECTRIC CROSS-SECTION
AS A FUNCTION OF ENERGY

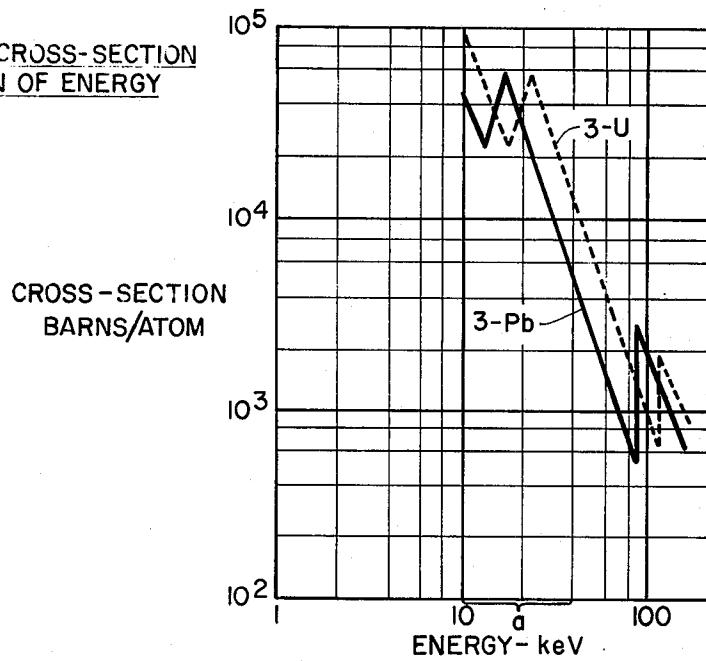


FIGURE 3

DOSE RATE SPECTRA

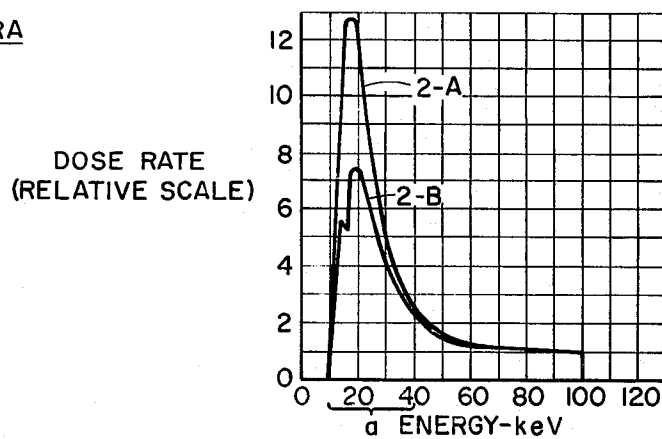


FIGURE 2

X-RAY INTENSITY SPECTRA

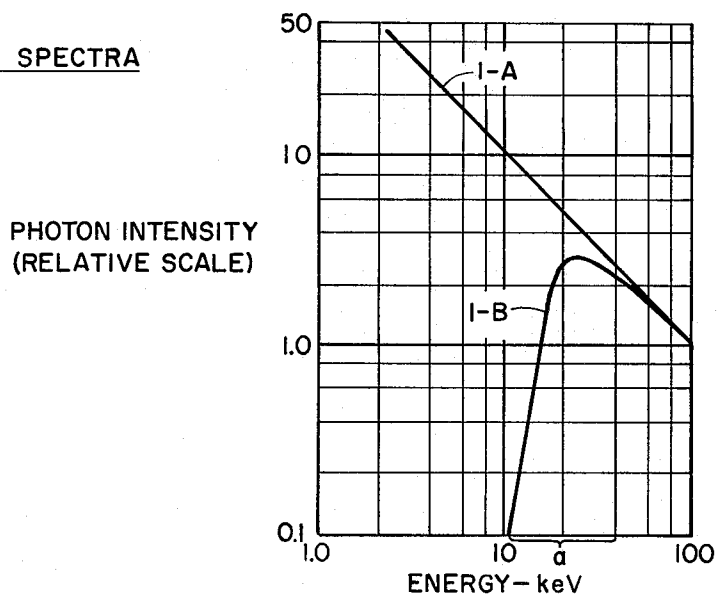


FIGURE 1

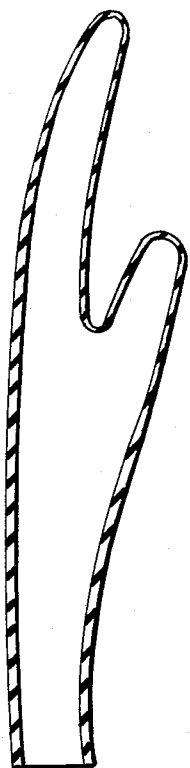


FIGURE 8

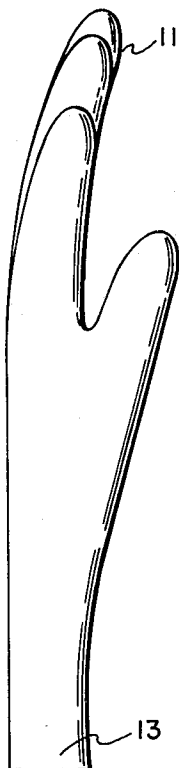


FIGURE 4

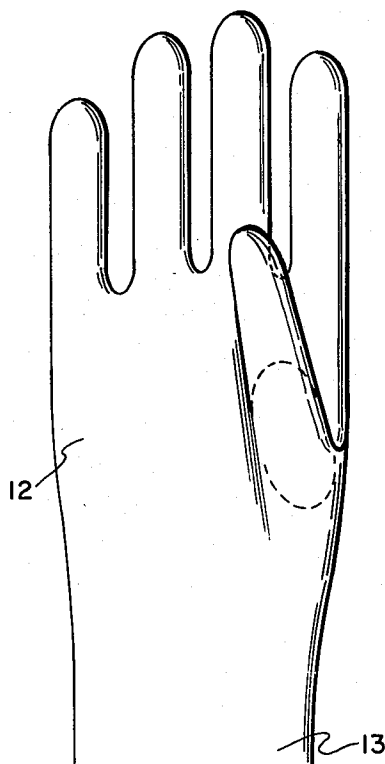


FIGURE 5

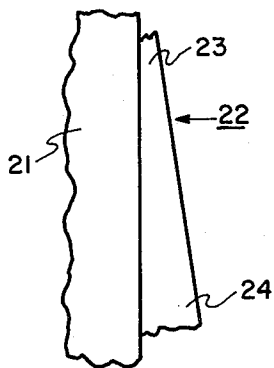


FIGURE 7

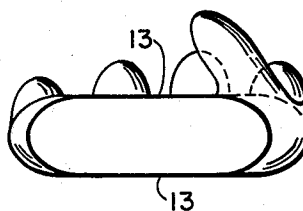


FIGURE 6

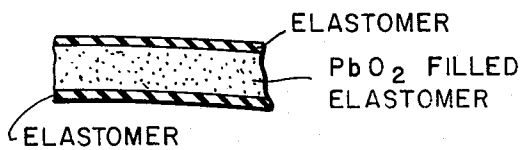


FIGURE 9

RADIO OPAQUE GLOVES

BACKGROUND OF THE INVENTION

1. Field of Invention

This invention relates to garments protecting the wearer from x-rays.

2. Prior Art

Physicians, x-ray technicians, and others who work in radiation environments are customarily confronted with problems of shielding body members from damaging radiation flux, while still providing sufficient freedom of body movement to perform necessary tasks while wearing shield-garments. This is a principal problem dealt with by the present invention.

For instance, surgeons who implant and manipulate heart pacers, and similar devices, in the human body commonly project an x-ray flux through involved bodily regions to derive a radiation-image (e.g., as detected on a fluoroscope) helping them to position and adjust the implanted device. Previous shielding garments have generally been designed to deal with the hazards of a significant variety of medical uses of x-rays instead of being concerned only with the problems unique to fluoroscopy.

Physicians have been offered gloves and mittens made of elastomer containing lead type fillers and having thicknesses such as 30 or 65 mils, and such great thickness and weight has restricted their utility. Such garments have been widely used; but because of their awkwardness, bare hands have often been inserted into a fluoroscopic zone.

High atomic number materials such as lead are preferred for radiation shielding (e.g., see: "Reactor Shielding Design Manual," McMillan and Company, London; and "Alpha-, Beta- and Gamma-Ray Spectroscopy" by K. Sieghahn, North Holland Publishing Company, Amsterdam 1968, Vol. I; and "Fundamentals of Modern Physics," R. M. Eisberg, Wiley & Sons, New York, 1964).

SUMMARY OF INVENTION

In accordance with the present invention, garments providing useful protection from the x-rays in a fluoroscopic situation feature smaller amounts of screening agent than in conventional protective garments. The screening agent concentration is maintained within the range from 10 per cent to 45 per cent and the film thickness is maintained within the range from 5 to 25 mils, whereby the garments are satisfactorily comfortable while still providing worthwhile protection from x-rays in fluoroscopic situations. Zones of varying x-ray opacity are incorporated in a fluoroscopic protective garment such as a glove to provide garments providing reasonable shielding from fluoroscopic hazards without excessively troublesome restraints upon bodily functions. A method features steps for fabricating an elastic surgical glove to attain different thicknesses of x-ray shielding elastomer at selected zones by reliance upon gravitational forces to impart greater thickness (and thus a greater amount of x-ray screening agents) in the zones in which relatively greater protection is desired.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic presentation of a pair of curves depicting a typical energy spectrum for x-radiation of significance in the fluoroscopic zone after passage through a human body.

FIG. 2 is a plot of dose rate for the fluoroscopic situation vs x-radiation energy in the context of FIG. 1.

FIG. 3 is a plot of photoelectric absorption cross-section for two shielding materials as a function of the energy involved in fluoroscopic x-radiation.

FIGS. 4, 5, and 6 are side, front, and end views of an elastic glove. FIG. 7 is a schematic showing of the propensity of the thickness of a coating of a viscous composition to be influenced by gravitational forces.

FIG. 8 is a sectional view schematically showing wrist portions which are at least 25 per cent thicker than fingertip portions of the glove, the thinner portions being not more than 10 mils thick whereby sensitivity through the fingertip portions is preserved.

FIG. 9 is a schematic sectional view showing a thin elastomeric film having inner and outer unloaded layers and an internal layer containing a lead oxide screening agent.

GENERAL DESCRIPTION OF INVENTION

The medically utilized x-rays embrace a wide range of energies, sometimes expressed as a range from about 1 to 4,000 Kev. The penetrating effects are significantly greater at the higher energies. Much of the effort concerned with screening has been to achieve measureable effectiveness in the upper ranges of energy of the x-rays. Technologists have generally appreciated that the shielding garment was going to be less than 100 per cent effective, but stress has been placed upon relative high efficiencies at relatively high energy levels. There has been a propensity to ignore the possibility of providing moderate degrees of protection.

Significant portions of the work with fluoroscopes employs x-ray systems having a range below about 100 Kev. In FIG. 1, the energy distribution for the 10-100 Kev range is schematically represented by the area below line 1-A, the coordinates being on a log-log basis. FIG. 1, line 1-A, is a schematic showing that there is a greater photon intensity, relatively speaking, for the x-rays of lower energies than for the x-rays of high energy. A human body absorbs x-rays in a manner somewhat similar to a body of water about 8 to 10 inches thick. All x-rays having an energy of less than about 10 Kev and smaller proportions of the rays having an energy less than 20 Kev are thus absorbed in passage through the body. In a fluoroscopic zone between the body and the fluoroscope screen, the energy distribution is schematically represented by the area below the curve identified as 1-B of FIG. 1. Particular attention is directed to the fact that in this fluoroscopic zone, the significant energy spectrum is from about 10 to about 40 Kev, such range being identified by *a*.

Data relating to dose rate spectra are schematically represented in FIG. 2, in which the area below curve 2-A corresponds to the dosage received by a hand in a fluoroscopic zone after the x-rays have passed through a thick zone of a living body. In the range from about 10 to about 40 Kev, there is a significantly larger area under curve 2-A than in the area below said curve at about 40 to about 100 Kev. The x-ray dosage rate in the fluoroscopic zone is thus significantly concentrated in the 10 to 40 Kev range. Although x-rays of the 80 to 100 Kev range are more penetrating than those of the 10 to 40 Kev range, they are of less significance to those dealing with fluoroscopy than the higher energy waves because of the relative dosage phenomena. In some applications of medical x-rays, the importance of

protecting the body from such high energy x-rays is quite significant.

For versatility of use, previous shielding garments have generally been designed to approach as nearly as feasible in a flexible garment, the type of shielding accomplished by the large lead shields employed in stationary structures. In accordance with the present invention, shielding garments designed particularly for persons employing x-rays for fluoroscopy feature the combination of thin film and a relatively small amount of x-ray screening agent. Although elements such as lead and uranium provide some absorption of x-rays throughout the entire energy spectrum, there are resonant absorptions of x-rays within certain ranges of energy, whereby either lead or uranium is remarkably effective as a screening agent in the range of particular significance in fluoroscopy. This phenomena is shown by the area beneath curve 2-B of FIG. 2, representing the dosage rate for a person protected by an elastomer containing about 10 per cent by weight of lead (corresponding approximately to about 11 per cent by weight of lead oxide) in an elastomer having a thickness of about 10 mils. In the critical range from about 10 to about 40 Kev, this small amount of shielding is effective in reducing the area under the curve 2-B to an extent which is of significance. The protective value of a shielding garment is controlled by its effectiveness in reducing the dosage rate. Because previous designers of protective garments have stressed the versatility in protecting from high energy x-rays often encountered in medical x-rays, the usefulness of small amounts of shielding from fluoroscopic hazards has been generally ignored. By the use of a concentration of lead or uranium which is more than 10 per cent, but still less than the 45 per cent, an acceptable effectiveness within the fluoroscopically significant range from 10 to 40 Kev is accomplished. Previous screening garments have conventionally used more than 50 per cent screening agent. However, by keeping the concentration of the screening agent below about 45 per cent by weight of the loaded film, significantly better garment characteristics are achieved by the present invention. Of particular importance, the emphasis upon the fluoroscopic use of the shielding garment justifies the provision of significantly thinner films of the pigmented film. The shielded garments of the present invention have advantages attributable significantly to a thinness within the range from about 5 mils to about 25 mils.

As shown in curve 3-Pb of FIG. 3, the photoelectric cross section of lead as a function of the energy of the x-rays within a range from about 10 to about 110 Kev shows that throughout a wide range from about 20 to about 90 Kev, the lead functions in a manner which would be expected from a high atomic number. However, in the critically important range from about 10 to about 20 Kev, lead exhibits a resonant type of absorption of photoelectric energy. Thus, the photoelectric cross section of each lead atoms is larger in this range than might be expected if such resonant absorption were not involved.

Similarly and as represented schematically in curve 3-U of FIG. 3, the photoelectric cross section of uranium benefits from resonance absorption, so that uranium has commendable effectiveness in a range peaking at about 24 Kev and embracing a range such as up to about 35 Kev. It should be particularly noted that a mixture of lead compounds and depleted uranium diox-

ide permits some resonance absorption throughout much of the 10 to 40 Kev range of particular significance to fluoroscopy.

Although either depleted uranium dioxide or lead oxide has some advantages as an x-ray screening agent for fluoroscopy, it is sometimes appropriate to use an approximately equal weight mixture of the two screening agents, as featured in some embodiments of the invention. The resonant absorption of the two atoms is at different portions of the fluoroscopy significant spectrum of the x-ray spectrum. Although such garments might be of a relatively little value in connection with the taking of x-ray pictures and/or the use of x-rays in therapy and/or certain other medical applications of x-rays, such shielding garments can have a significant reduction of hazards in connection with fluoroscopy, by reason of the significant efficiency of their absorption within the 10 to 40 Kev range.

The shielding garments of the present invention are constructed of films having an average thickness of from about 5 to about 25 mils, and containing more than 10 per cent but less than about 45 per cent of the screening agent. In certain embodiments, the invention is employed to fashion an improved version of a surgical glove, made of a flexible elastomer containing a high density filler adapted to be relatively opaque to moderate-energy X-radiation and thereby shield a surgeon's hand from harmful radiation effects. Such a glove is suitable for use with x-ray fluoroscopic monitoring equipment used for "implant surgery." Surgical gloves can be fabricated of thin rubber, polyurethane, neoprene, or other organic polymer having strength as a thin sheet. Such gloves are usually available in small, medium, and large sizes. The accommodation to hands of various sizes is sometimes enhanced by the stretchiness of the gloves attributable to choosing an elastomer for film formation.

The surgeon is typically dealing with a patient lying upon an operating table with his thoracic cavity opened and exposed for delicate, probing manipulations of the surgeon's fingers. In such a situation, the surgeon relies upon the fluoroscopic view of his fingers and instruments in monitoring the location and condition of instruments and body members. A prescribed source directs x-rays from beneath the patient on the operating table, passing beyond and above to activate a responsive phosphor screen for viewing by the surgeon. The surgeon will be understood as interjection his hands into the photon flux passing between the patient and the fluoroscopic screen as he works.

It will be assumed that the cumulative attenuation effected by the table, air space and patient's body approximates about 8 inches of water and that the flux energy in the zone in which the surgeon's hands are placed differs from the initial output of the x-ray unit. This will cut off radiation flux below about the 10 Kev level. The area below curve 1-B of FIG. 1 and below curve 2-A of FIG. 2 are schematic representations pertinent to such zone.

The general appearance of a surgical glove of the present invention has some resemblance to surgical gloves of the prior art. As shown in FIGS. 4, 5, and 6, a fingertip portion 11 is thinner than a palm portion 12, which is thinner than a heel portion 13 at the opening of the glove. As shown in FIG. 7, a mandrel 21 having an approximately vertical side may be coated with a film of viscous gel 22, and the film 22 can drain. The

gravitational forces upon the creeping viscous film cause the thickness of the film to be thinner at an upper zone 23 than at a lower zone 24.

Useful data were obtained from experimental tests with lead loaded polyurethane films. An elastomeric polyurethane matrix (glove material) was homogeneously dispersed throughout a DMA (dimethylacetamide) solvent to permit production of thin films of polyurethane elastomer. Films having controlled opacity to x-rays were prepared by modifying the procedure by including controlled amounts of lead dioxide (conveniently designated by the generic term, lead oxide) filler in the liquid composition employed in the first of the series of steps of dipping, draining, and drying to provide an uncured film on a plate glass form. Cured films containing various concentrations of lead oxide (PbO_2) were tested to measure the absorption of the 1-100 Kev energy range x-rays. The test results are shown in Table 1.

TABLE 1

Wt. % PbO_2	Absorption vs. PbO_2 Matrix Thickness (mils)	% Absorption
10	14	38
20	20	57
30	8	62

A surgical glove is fabricated of polyurethane containing enough lead oxide opaquing filler to screen out a moderate portion of the fluoroscopically significant x-radiation. A series of steps are involved in the total process of glove production.

1. Dispersion of Elastomer: A mixture of about 15 per cent by weight of Texin 480A brand of polyurethane (linear polymer of polyester and aromatic diisocyanate with controlled cross-linking) and about 85 per cent of a suitable solvent such as DMA (dimethylacetamide) is a smooth workable mass of moderate viscosity suitable for production of polyurethane films by dipping techniques. Part of this polyurethane-solvent mixture is set aside for use in preparing the unfilled coatings, and a major portion is employed in formulating the composition in which the filler is dispersed.

2. Filler Mixed-In: Lead oxide powder (available as L-67 from Fisher Scientific Company and having a purity of about 95.8 per cent and having a relatively uniform particle diameter in the sub-micron range, and a density of 9.37 g/cc) is uniformly mixed into said dispersion of polyurethane in DMA by agitation with a mechanical mixer.

3. Seal-dip: An appropriate ceramic mold or form for a hand is arranged to be dip-coated by immersion in the pristine (unfilled) urethane and completely, uniformly coated therewith to a suitable initial depth as an inner seal layer. The former is then withdrawn, drained, and this coating dried (solvent evaporated) until it is suitable for subsequent dippings. The dipping time is about 15 seconds and the withdrawal time is about 30 seconds. The dipped form is inverted so that fingers are pointed upwardly and permitted to drain over the dipping bath for a period from about 5 minutes to about 10 minutes. The dipped and drained form is transferred to a drying zone in which the form rotates about a horizontal axis desirably in a stream of warm air for a period such as about 30 minutes. A period of about 40 minutes is involved in the successive steps of dipping,

withdrawing, draining, drying, and related operations for producing each layer of uncured film, and appropriate variations in the duration of each sub-procedure may be convenient. The average thickness of each layer (from each dipping) is described in terms of the thickness increase (or incremental thickness) of the cured glove. The film of gel applied in a dipping step comprises about 6 times as much DMA solvent as elastomer and hence has a thickness greater than the incremental thickness of the cured glove attributable to such dipping step. The average thickness of the pristine urethane inner seal is about 1 to 2 mils.

Particular attention is directed to a feature of achieving zones of differing thickness of film at different zones of the glove. The initially dipped form has a coating thickness influenced by factors such as viscosity of the solution, drainage time, and complexity of the form. The viscous solution can flow slowly under gravitational forces during the draining period. While gravitational creeping of portions of the dipped coating are possible, its alignment with respect to the gravitational field is important. Glove forms are conventionally dipped with fingers down. Uniformly thick gloves may be prepared by draining forms with suitable inversion steps, such as by inverting the form to have the fingertips in an upward direction during the even minutes of draining, and with the fingertips downwardly directed during the odd minutes of the draining.

In accordance with preferred methods of the present invention, the form is drained with the fingers upwardly directed, whereby the glove has a wrist portion significantly thicker than the fingertip portion. The speed with which the viscous composition gravitationally creeps downward to provide thicker films at the wrist balances with the removal of excess solution during drainage in such a manner that the advantageously different thickness zones are conveniently achieved.

Although the effects of differences in glove thickness by alignment of the form during drainage are conveniently described in connection with the step of preparing an unloaded layer, it should be appreciated that the intentional use of drainage in the inverted (fingers upwardly) position is important primarily in preparing layers comprising lead screening agent.

4. Dip-forming Protective Layers: After the initial coating has adequately dried, the form is dipped in the dispersion of lead oxide containing urethane in DMA composition. Because of the higher viscosity attributable to the PbO_2 filler, each coating increases the glove thickness by an average of from about 3 mils to about 5 mils. Increasing DMA concentration above 85 per cent to decrease viscosity to permit thinner coatings is sometimes advantageous. Several steps of forming PbO_2 containing layers are sometimes desirable.

5. Outer-seal: An outer-seal layer is dip-coated by, essentially, repeating Step No. 3 to provide an outer, non-filled coating of urethane of desired thickness. The inner and outer seal coatings are usually desirable to decrease the likelihood of attrition loss of lead oxide.

In steps 3, 4, and 5 the variations in the thickness of the final glove are controlled to achieve a combination of comfortable thinness at the fingertips and increased protection at the opening portion (conveniently called a heel portion without regard to whether the length of the glove extends to beyond or within or before the wrist) of the glove.

The thickness of the fingertips is desirably from 20 to about 80 per cent of that of the heel portion of the glove, but because the thinness of the fingertips is primarily to permit the user to have adequate sensitivity of feeling through the glove, it should be stressed that desired sensitivity is ordinarily not attainable above a thickness of about 10 mils. Certain embodiments of the invention feature lead loaded surgical gloves having fingertips thinner than 10 mils and heel portions more than 25 per cent thicker than such fingertip portions. Various modifications of fabrication methods are possible while still attaining an embodiment featuring said combination.

6. Curing: After the outer seal layer has been dried, the mandrel is transferred to a forced air oven, and the glove is cured at 50°C. for from about 16 to about 24 hours.

7. Removal: The cured glove is removed from its form, which is then used in making other gloves by the previous steps.

8. Trimming: The opening of the glove may require finishing operations such as trimming.

The glove is an elastic surgical glove having advantageous sensitivity at the fingertips and advantageous resistance to tearing at the opening at the heel. The fingertip thickness is 7.2 mils, and the mid-portion (e.g., palm) is 10.0 mils thick, and the wrist portion is 14.5 mils thick. The amount of flesh to be protected in various zones of the hand corresponds approximately to the varying thickness of glove, thus providing a further advantage for the glove and/or its method of production.

Depleted uranium dioxide previously processed for the removal of costly isotopes has effectiveness in screening x-rays of the fluoroscopically significant range, and resembles lead oxide in several respects. Only in recent years has such depleted uranium oxide been available at a cost suitable for competition with lead oxide as a screening agent in elastomeric garments. As noted in FIG. 3, the portion of the spectrum in which uranium oxide has the advantage of resonant absorption is different from that of lead oxide. A mixture, such as an equal weight mixture, of uranium oxide and lead oxide can be employed as the filler for a surgical glove to achieve various unique advantages of greater significance than the difference in cost of the uranium oxide.

VARIATIONS IN PRODUCTION METHODS

Thin garments of polymers containing x-ray screening pigments are conventionally prepared by various modifications of the general multi-dip method previously described. However, any of the production methods appropriate for achieving the end product (a thin garment having a thickness in the 5 to 25 mil range, and containing from 10 per cent to 45 per cent by weight of screening agent of the class consisting of lead oxide, depleted uranium dioxide, and mixtures thereof) as a protective garment for use in fluoroscopic systems are suitable. calendaring, molding, fluidized coating, and

extruding, are mentioned but are not an exhaustive cataloguing of alternative techniques for projection.

VARIATIONS IN SELECTION OF MATERIALS

Natural rubber, various types of synthetic rubber, neoprene, polydimethylsiloxane elastomer and other synthetic elastomers may be employed instead of the polyurethane rubber of a described embodiment. Although elasticity is highly advantageous in a surgical glove, cheaper organic polymers such as polyvinyl chloride or polyethylene are suitable in the fabrication of other shielding garments useful in fluoroscopic systems. Aprons, gauntlets, and helmets are an incomplete list of other garments benefiting from the advantageous forward advance of the present invention.

Other modifications of the invention are possible without departing from the scope of the appended claims.

The invention claimed is:

1. A glove protecting the wearer from a significant portion of the radiation hazards of fluoroscopic systems consisting of thin polymeric films having inner and outer unloaded layers and an internal layer containing a screening agent of the class consisting of depleted uranium dioxide, lead oxide, and mixtures thereof, said film containing from 10 per cent to 45 per cent by weight of said screening agent, and said film having an average thickness within the range from 5 mils to 25 mils, various portions of the film being at least 25 per cent thicker than other portions to provide greater protection from radiation at such thicker portions, the thinner portions being not more than 10 mils thick, whereby sensitivity through such thin portion is preserved, such thinner portions being at the fingertip portion of the glove whereby tactile sensitivity through the fingertip is enhanced to permit a surgeon to employ such gloves within a fluoroscopic radiation zone.

2. A method of preparing a fluoroscopic protective glove which includes the step of dipping a form into a dispersion comprising polymer in a solvent, withdrawing the coated form, draining the form with upwardly directed finger portions to gravitationally impart greater thickness at the heel portion of the glove than at the fingertip portions, drying such coating, repeating dipping, draining and drying steps, the inner and outer layers being unloaded and the middle layers containing from 10 per cent to 45 per cent by weight lead oxide as a screening agent, heat curing the glove, and removing the glove from said form, the average thickness of the glove being within the range from 5 mils to 25 mils, various portions of the film being at least 25 per cent thicker than other portions to provide greater protection from radiation at such thicker portions, the thinner portions being not more than 10 mils thick, whereby sensitivity through such thin portion is preserved, such thinner portions being at the fingertip portion of the glove whereby tactile sensitivity through the fingertip is enhanced to permit a surgeon to employ such gloves within fluoroscopic radiation zone.

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