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POWDER LUBRICATED SURGEON'S
RUBBER GLOVE

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This invention relates to lubricating surgeon's gloves and other articles of rubber designed for use under aseptic conditions.

The accidental introduction of foreign substances into the human body during surgical operations has been known to cause complications such as the development of adhesions within the body after an abdominal operation. Foreign substances in the form of dusting powder are often introduced into the human body by the surgeon despite the most elaborate and careful precautions to prevent this occurrence. The dusting powder is used on rubber gloves worn by the surgeon in order to enable the gloves to slip on easily over his hands. Some of this powder enters the human body either directly from the gloves or from the fine powder which falls upon the surgical instruments during the procedure. In the last 20 years, the dusting powder used by surgeons on rubber gloves has been talc. This talc material, known as talcum powder, is known to be responsible for most of the above-mentioned undesired complications. It has been ascertained that talc cannot be absorbed by the human body and, moreover, that talc may find its way into any part of the human body upon which the operation is performed. Talc, even in the form of the finest dusting powder, shows up under the microscope as sharp, needle-like particles interspersed with thin platelets having sharp, pointed corners. It is known that talc has been the cause of suppurating wounds and granulomas on even the tough palms of adults and is much more dangerous on the tender skin of babies.

Medical literature is replete with reports emphasizing the irritating qualities of talc when injected into-peritoneally, intra-pleurally, intra-pericardially or subcutaneously. In fact, in a certain type of heart disease talc has been recommended to produce pericardial adhesions in an attempt to promote better collateral circulation. Numerous operations and experiments have definitely proven that talc is responsible for all types of adhesions ranging from a massive type of occlusion of almost the entire peritoneal cavity to less massive localized adhesions of the stomach, spleen, liver and omentum or intestinal loops (folds) or merely thin adhesive bands of fixed omental strands that not infre-

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quently cause death from intestinal obstruction sometimes referred to as strangulation. The need for a substitute for talc as a substitute for dusting powder has been urgent and a search for such a substitute has been long and continuous.

A method of lubricating surgeon's gloves whereby the lubricant will withstand steam sterilization without injury to the gloves or loss of dusting powder and whereby the lubricant, if accidentally implanted in the tissues of the human body, will be readily and harmlessly absorbed by the body, is most urgently desired by the medical profession.

One of the objects of the present invention is to provide novel lubricated surgeon's gloves whereby the lubricant will withstand steam sterilization without the loss of its dusting properties and whereby the lubricant will be readily and harmlessly absorbed by the body when occluded in body tissues.

Another object is to provide a novel combination consisting of surgeon's gloves having a surface coating of insoluble sodium metaphosphate, or insoluble potassium metaphosphate.

A further object is to provide a novel lubricant for surgeon's gloves.

Other objects will become apparent from the following description and example.

According to the present invention, generally stated, surgeon's rubber gloves may be satisfactorily and successfully lubricated by dusting the gloves with a portion of finely divided insoluble sodium metaphosphate. This material is prepared by heating monosodiumphosphate at a temperature of 300–350° C. for a period of time, for example, two hours, until the resulting product is substantially completely water insoluble and thereafter cooling the product and milling and screening it to the proper particle size, for example, approximately 300–400 mesh. Insoluble sodium metaphosphate prepared in this manner has been found to possess the very desirable characteristic of becoming readily and completely absorbed in the tissue of the human body without injury or harm thereto. In addition, insoluble sodium metaphosphate has been found to possess excellent lubricating properties when applied to surgeon's gloves and these properties are retained even after steam steriliza-

tion, for example, 15 pounds steam pressure. Moreover, there is no apparent injury to the substance of the gloves arising as to the use of insoluble sodium metaphosphate in powdered form as a lubricant on the gloves.

The novel method of the present invention comprising dusting insoluble sodium metaphosphate, in finely divided form, on the gloves by any suitable means, for example, by sprinkling the powdered material on the gloves or patting the powder on the gloves from a sachet or any other suitable dusting bag such as that provided by folding several layers of gauze over a portion of the insoluble sodium metaphosphate. If desired, any excess of the powder may be removed from the gloves by any suitable means, for example, by shaking the gloves. Following this procedure, the gloves may be placed in a steam sterilizer and subjected to steam at 15 pounds pressure or even higher to render the gloves aseptic. After the sterilization, it is customary to exhaust the steam from the sterilizer during which time any moisture present is removed from the gloves. Thereafter, the gloves are removed from the sterilizer, cooled and applied to the surgeon's hands. As a result of this powdering, neither the inner nor the outer surfaces of a rubber glove adhere to opposing surfaces, as invariably happens if the glove is not suitably powdered. It is desirable also, to lubricate the surgeon's hands with a portion of finely divided insoluble sodium metaphosphate before applying the gloves. In this instance, a dusting powder containing the phosphate product may be employed if desired.

In place of insoluble sodium metaphosphate, the corresponding insoluble potassium metaphosphate prepared in a manner analogous to that described hereinabove for the insoluble sodium metaphosphate, may be employed. The results are substantially the same with either the sodium or the potassium compound.

The following example will serve more fully to illustrate the present invention and the novel composition effected thereby.

Example

Insoluble sodium metaphosphate, prepared by heating monosodiumphosphate for at least two hours at 300–350° C. and subsequently cooling and milling the product, was applied to surgeon's rubber gloves. The insoluble sodium metaphosphate employed for this purpose had the following characteristics:

P₂O₅ content not greater than 69%
Na₂SO₄ less than 0.4%
NaCl less than 0.1%
Fe and Al phosphates less than 0.5%
Fluorine less than 25 p. p. m.
pH of an aqueous suspension, 5–6
Water soluble content not more than 4%
Loss on ignition at 1400° F. for 30 minutes not greater than 0.5%
Particle size not greater than 0.1% on a 200 mesh screen and not greater than 3% on a 400 mesh screen

The insoluble sodium metaphosphate was applied to the surgeon's gloves by dusting the powder on the gloves and thereafter shaking off the excess. The gloves were then placed in a steam autoclave and subjected to 15 pounds of live steam for approximately 20 minutes. Thereafter, the steam was exhausted from the autoclave and the gloves were removed and cooled. The gloves were found to be lubricated satisfactorily and

were readily applied to a surgeon's hands. Separate portions of 300–400 mesh insoluble sodium metaphosphate were blended with 0.5, 1, 2 and 3% by weight of substances such as magnesium carbonate and zinc stearate. The resulting compositions were found to possess less tendency to agglomerate during the sterilization operation described hereinbefore.

In order to test the absorption characteristics of insoluble sodium metaphosphate powder of the type hereinabove described, portions of the material were inserted in the peritoneal cavity of mice, rats and guinea pigs using 4 to 6 mg. in a 25 g. mouse, 5 to 20 mg. in a 250 g. rat and 40 to 200 mg. in a 750 g. guinea pig. At periods of time, ranging from several days to several weeks, the peritoneal cavity of respective test animals was opened and an examination of the cavity and the vital organs was made. There was no evidence of any silicotic-like fibrosis. There also was no evidence of intraperitoneal adhesions, such as are encountered following the similar use of talc. In the foregoing tests on experimental animals, there was no evidence of any irritating effects upon the tissue with which the powder came into contact and the powder appeared to be completely absorbed biologically. The same amounts of talc inserted in the peritoneal cavity of test animals for comparison purposes revealed extensive silicotic-like fibrosis in each instance. In using the novel dusting powder of the present invention on surgeon's gloves and on surgeon's hands, it was found that the powder possessed excellent lubricating properties and enabled the surgeon to place the gloves on his hands without a tendency for the rubber to adhere to the hands or to other portions of the glove.

It is also possible to mill insoluble sodium or potassium metaphosphate to larger particle size, for example, 80 mesh or even greater. However, the lubricating qualities of the material are most satisfactory when the particle size is in the range of 300–400 mesh. If desired, small percentages, for example, 1 to 3% or more of certain substances may be added for the purpose of augmenting the free flow of the insoluble sodium metaphosphate dusting powder and avoiding any tendency of the powder to agglomerate during the sterilization operation. Illustrative of such materials which may be added are tricalcium phosphate, magnesium carbonate and zinc stearate.

We claim:

1. An article of manufacture consisting of surgeon's rubber gloves having a coating thereon of finely divided water-insoluble sodium metaphosphate.

2. An article of manufacture consisting of surgeon's rubber gloves having a coating thereon of water-insoluble sodium metaphosphate, said metaphosphate having an average particle size in the range of 300–400 mesh.

3. An article of manufacture consisting of surgeon's rubber gloves coated interiorly and exteriorly with an intimate mixture of finely divided water-insoluble sodium metaphosphate and a lubricant for said insoluble sodium metaphosphate consisting of 0.5–3% of a finely divided water-insoluble biologically absorbable salt.

4. An article of manufacture consisting of surgeon's rubber gloves having a coating thereon of material selected from the group consisting of water-insoluble sodium metaphosphate and water-insoluble potassium metaphosphate, said material having an average particle size in the range of 300–400 mesh.

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5. An article of manufacture consisting of surgeon's rubber gloves coated interiorly and exteriorly with an intimate mixture of a material selected from the group consisting of finely divided water-insoluble sodium metaphosphate and finely divided water-insoluble potassium metaphosphate, and a lubricant for said material consisting of 0.5-3% of a finely divided water-insoluble biologically absorbable salt.

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