United States Patent [19]

Semp

[11] **3,892,314**

[45] **July 1, 1975**

[54] **STERILE RUBBER GLOVE OR CATHETER PACKAGE**

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[73] Assignee: **American Cyanamid Company,** Stamford, Conn.

[22] Filed: **Apr. 10, 1973**

[21] Appl. No.: **349,890**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 117,998, Feb. 23, 1971, Pat. No. 3,728,739, which is a continuation-in-part of Ser. No. 770,792, Oct. 25, 1968, abandoned.

[52] **U.S. Cl.** ..... **206/363;** 206/364; 206/439; 206/63.3; 128/349 R

[51] **Int. Cl.** **A61l 17/02;** A41d 19/00

[58] **Field of Search** 206/210, 363–366, 206/438–439

[56] **References Cited**

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2,947,415	8/1960	Garth	206/364
2,998,880	9/1961	Ladd	206/363
3,403,776	10/1968	Denny	206/363
3,494,726	2/1970	Barasch	206/365
3,750,875	8/1973	Juster	206/365

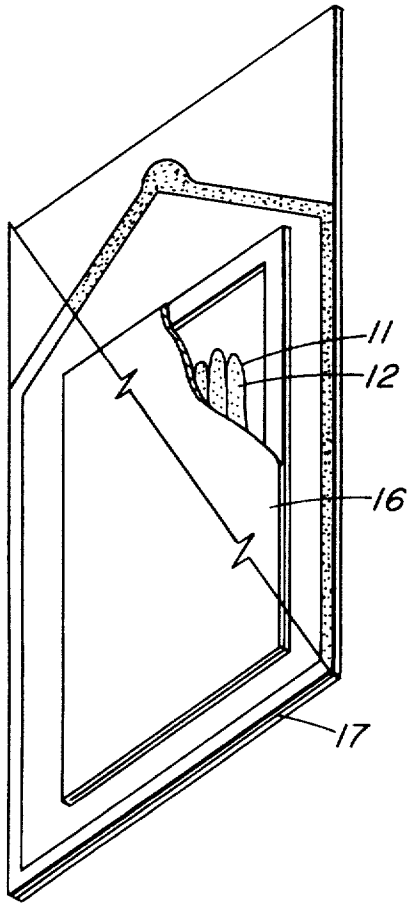
Primary Examiner—William I. Price

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[57] **ABSTRACT**

Natural or synthetic rubber surgical elements such as tubing, catheters, drains and gloves are "lubricated" so as to prevent sticking during storage, and permit easier emplacement, such as putting on the gloves by a surgeon or nurse, by applying to the surface of the rubber element finely divided polyglycolic acid powder. The polyglycolic acid powder is readily absorbed by living tissue without deleterious tissue reaction, thus minimizing tissue reaction from the transfer of the powder from the element such as a glove to internal sites in a subject. The rubber surgical elements are conveniently stored in a strippable package. Polyglycolic acid aids in reducing infection and promotes healing, when in contact with tissue.

7 Claims, 4 Drawing Figures



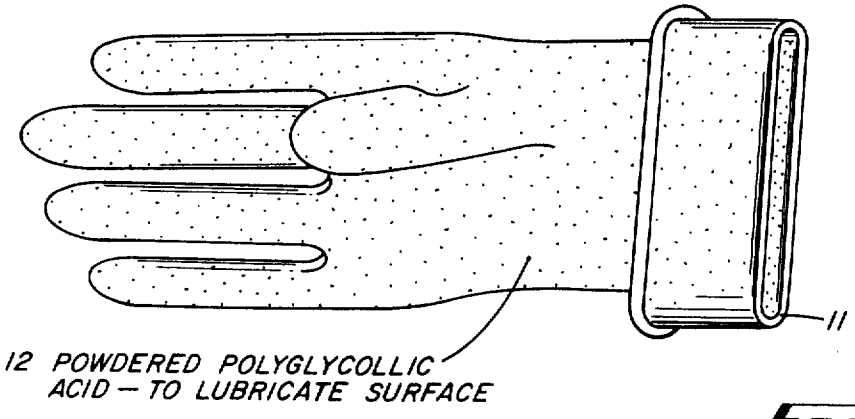


FIG. 1

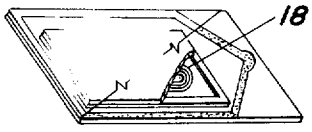


FIG. 4

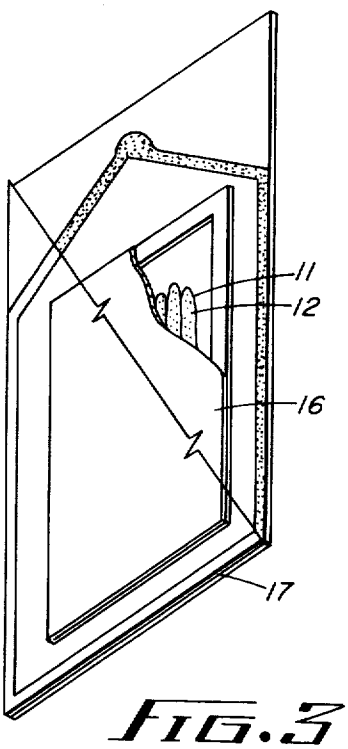


FIG. 3

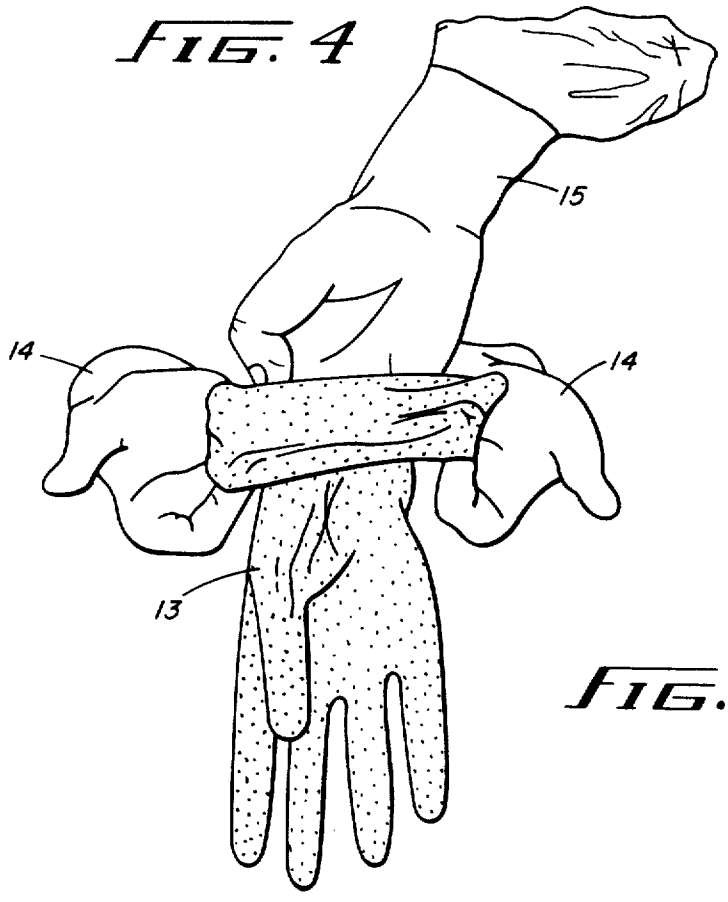


FIG. 2

STERILE RUBBER GLOVE OR CATHETER PACKAGE

RELATED APPLICATIONS

This is a continuation-in-part of Ser. No. 117,998, filed Feb. 23, 1971, now U.S. Pat. No. 3,728,739, Apr. 24, 1973, which application is a continuation-in-part of Ser. No. 770,792, filed Oct. 25, 1968, now abandoned. Another continuation-in-part application of said Ser. No. 117,998 is application Ser. No. 349,875, now U.S. Pat. No. 3,810,458, May 14, 1974.

BACKGROUND OF THE INVENTION

This invention relates to a natural or synthetic rubber surgical glove which is lubricated with a biodegradable dusting powder, and to other rubber elements which contact raw tissue. Various dusting powders have been used on surgical gloves for years with a prime use being to facilitate insertion of the hands of operating room personnel into natural or synthetic rubber or latex gloves worn during surgery.

It is desirable that the powder on the gloves meet the following requirements:

1. It should be non-toxic to living tissue.

2. It should be biodegradable, i.e., absorbed by living tissue. This is most important since, during surgical procedures, powder almost inevitably falls or is rubbed from the surgeon's gloved hand into an exposed body cavity, and may be carried from other areas of the operating room into the exposed body cavity by air currents.

3. The powder should have no adverse effect within the body such as the creation of lesions (i.e., adhesions, granulomas, or such).

4. The glove powder must be capable of sterilization by convenient hospital techniques, preferably both autoclaving and gaseous ethylene oxide sterilization, as well as by radiation, ultrasonic energy, or combinations of these.

5. The powder must possess sufficient lubricity to permit ready insertion of the hand into the glove and must be of sufficiently fine particle size and have characteristics permitting such lubricity.

6. It must be reasonably priced and readily available.

7. It must be non-irritating to skin of both the surgeon or nurse and the patient.

Talc was among the earliest surgical glove powders used by the medical profession. However, after the report by Antopol (Lycopodium Granuloma, Arch. Path. 16, pg. 326 (1933)) that talc caused granulomas in the body, the use of talc as a glove powder was rapidly abandoned. Talc was replaced by starch glove powders since starch was known to be biodegradable and was not believed to cause granulomas or other aggravating conditions within the body. Currently, a widely used commercial surgical glove powder is specially treated homogeneous amylose which contains about 2% magnesium oxide to prevent clumping of the powder.

However, starch glove powders have a number of disadvantages. They offer high resistance to flow and they tend to gelatinize or agglutinate in the presence of hot water thereby creating problems when they are sterilized in a steam autoclave. Ordinarily, the starch must be treated in some way to minimize these properties. For example, as shown in U.S. Pat. No. 2,626,257, the starch may be treated with an agent, such as epichlorohydrin, which partially etherifies the starch in order to make the powder free flowing after steam sterilization.

Starch is also an excellent nutrient medium for virtually all vegetative bacteria such as various pathogenic microorganisms and is objectionable for that reason.

According to Lee and Lehman (Surgery, Gynecology, and Obstetrics 84, pgs. 689–695 (1947)), starch, unlike talc, was completely absorbed within the peritoneal cavity without causing adhesions. This conclusion was challenged by Sneierson and Woo (Annals of Surgery 132, pgs. 1,045 –1,050 (1955)) who reported two cases of large granulomas occurring in surgical wounds as a result of starch powder contamination. McAdams (Surgery 39, pgs. 329–336 (1936)) reported three cases of intraperitoneal granulomas caused by starch glove powder. The Saxens (Acta Pathology Microbiology Scand. 64, pgs. 55–70 (1965)) postulated that the magnesium oxide which acts as an anti-clumping material was causing the lesions. Myllariemi and Frilander (Journal of the International College of Surgeons 44, No. 6681, pgs. 677–681 (1965)) concluded that the harmful effects of starch glove powders containing magnesium oxide might be due to a combined effect of two irritating constituents. Other publications which indicate the serious concern of the medical profession over granulomas traced to starch glove powders are those of Lehman and Wilder (Journal of Abdominal Surgery 4, No. 3, pgs. 77–80 (1962)), Webb and Regan (Archives of Surgery 84, No. 3, pgs. 282–285 (1962)), and Walczak and Collura (American Journal of Surgery 103, No. 5, pgs. 611–612 (1962)).

Despite the aforementioned disadvantages associated with starch glove powders, they are still used by the medical profession due to the unavailability of an improved substitute.

It is clear that a dusting powder which is readily absorbed by tissue without deleterious interactions is desirable, and no powder meeting these requirements is obvious to the medical profession. The present powder meets all these requirements.

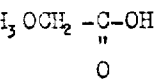
SUMMARY OF THE INVENTION

This invention discloses a natural or synthetic rubber surgical glove having a lubricating coating of powdered polyglycolic acid, hereinafter abbreviated as PGA. The PGA of this invention is completely absorbed by living tissue within 90 days with no observable adverse effects. In the course of biological degradation, the polyglycolic acid powder causes no significant formation of lesions such as adhesions or granulomas (see Example 3 hereinbelow). The powdered glove may be sterilized by autoclaving with no adverse effect upon its desirable properties such as, for example, its ability to flow freely without clumping (see Example 2). The powder can also be sterilized by other known methods such as, for example, gaseous ethylene oxide sterilization. The powder is non-toxic to living tissue, non-irritating to the skin and can be readily prepared synthetically.

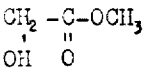
There are also significant indications that when the powder of this invention is applied to living tissue, an environment is created which is bactericidal or bacteriostatic. This is indicated by the ability of wounds deliberately infected with Staphylococcus aureus to heal with no evidence of continuing infection when the wound has also been treated with the powder of this invention (see Example 4). It is further indicated by the failure of aqueous suspensions of the powder to support the growth of organisms such as Staphylococcus aureus

(see Example 5). It is apparent that a medical dusting powder which is also bacteriostatic and bactericidal is a most desirable item.

Polyglycolic acid can be prepared by methods disclosed in U.S. Pat. **3,297,033,** Schmitt and Polistina "Surgical Sutures", January 1967, which patent is incorporated herein by reference. U.S. Pat. **3,297,033** describes an absorbable surgical suture of polyglycolic acid and discusses in greater detail the unusual biodegradable properties of polyglycolic acid. As set forth therein, aa small quantity of methoxyacetic acid,



or methyl hydroxyacetic ester,



or their homologs, such as higher alkoxyacetic acids, or alkyl hydroxyacetic esters may be present during the polymerization as an end group stabilizer controlling the molecular weight and viscosity. Small quantities of other materials may be present in the chain, as for example, d,l-lactic acid, its optically active forms, homologs, and analogs,

Said U.S. Pat. No. 3,297,033 incorporates a reference to U.S. Pat. No. 2,668,162 - Lowe which quantifies a small amount of lactides as up to 15%, disclosing, for example, the preparation of a copolymer of 90/**10** glycolide/lactide offers two advantages over the homopolymer of glycolide. One advantage is that the melting point of the copolymer is lower than the homopolymer, being in the neighborhood of 200°C.; and the entire reaction can be conducted at approximately the melting point of the copolymer. Operation at the lower temperatures decreases the rate of degradation of the polymer which gives a polymer of lighter color.

Example 4 of said U.S. Pat. No. 2,668,162 shows reaction conditions.

Surgical powders of polyglycolic acid can be better seen in most surgical fields if colored so as to contrast with blood and tissue or bandages or other background materials.

BRIEF DESCRIPTION OF PRIOR ART

Surgical sutures and other surgical elements containing polymers of glycolic acid are described in:

U.S. Pat. No. 3,297,033, Jan. 10, 1967, Schmitt and Polistina, SURGICAL SUTURES.

U.S. Pat. No. 3,463,158, Aug. 26, 1969, Schmitt and Polistina, POLYGLYCOLIC ACID PROSTHETIC DEVICES.

U.S. Pat. No. 3,565,077 - Feb. 23, 1971, Glick, DENSIFIED ABSORBABLE POLYGLYCOLIC ACID SUTURE BRAID, AND METHOD FOR PREPARING SAME. U.S. Pat. No. 3,620,218, Nov. 16, 1971, Schmitt and Polistina, CYLINDRICAL PROSTHETIC DEVICES OF POLYGLYCOLIC ACID.

U.S. Pat. No. 3,626,948, Dec. 14, 1971, Glick and McPherson, ABSORBABLE POLYGLYCOLIC ACID SUTURE OF ENHANCED IN-VIVO STRENGTH RETENTION.

U.S. Pat. No. 3,728,839, Apr. 24, 1973, Glick, STORAGE STABLE SURGICALLY ABSORBABLE POLYGLYCOLIC ACID PRODUCTS.

Reference is made to these patents which show additional prior art and for the definitions therein set forth.

Related data incorporated herein by this reference on manufacturing of polyglycolic acid, producing surgical elements thereof and its use for surgical purposes are disclosed in:

U.S. Pat. No. 3,414,939 - Dec. 10, 1968, Chirgwin, APPARATUS FOR QUENCHING MELT-SPIN FIBERS.

U.S. Pat. No. 3,422,181 -Jan. 14, 1969, Chirgwin, METHOD FOR HEAT SETTING OF STRETCH ORIENTED POLYGLYCOLIC ACID FILAMENT.

U.S. Pat. No. 3,435,008 - Mar. 25, 1969, Schmitt, Epstein and Polistina, METHOD FOR PREPARATION OF ISOMERICALLY PURE β-GLYCOLIDE AND POLYMERIZATION METHOD FOR GLYCOLIDE COMPOSITIONS EMPLOYING PARTIAL HYDROLYZATE OF SAID β-GLYCOLIDE.

U.S. Pat. No. 3,442,871 - May 6, 1969, Schmitt, Epstein and Polistina, PROCESS FOR POLYMERIZING A GLYCOLIDE.

U.S. Pat. No. 3,457,280 - July 22, 1969, Schmitt, Epstein and Polistina, α-GLYCOLIDE AND METHODS FOR THE ISOLATION THEREOF.

U.S. Pat. No. 3,468,853 - Sept. 23, 1969, Schmitt and Polistina, PROCESS OF POLYMERIZING A GLYCOLIDE.

U.S. Pat. No. 3,565,869 - Feb. 23, 1971, DeProspero, EXTRUDABLE AND STRETCHABLE POLYGLYCOLIC ACID AND PROCESS FOR PREPARING SAME.

U.S. Pat. No. 3,597,449, Aig. 3, 1971, DeProspero and Schmitt, STABLE GLYCOLIDE AND LACTIDE COMPOSITIONS.

U.S. Pat. No. 3,597,450, Aug. 3, 1971, Schmitt, Polistina, Epstein and DeProspero, PREPARATION OF GLYCOLIDE POLYMERIZABLE INTO POLYGLYCOLIC ACID OF CONSISTENTLY HIGH MOLECULAR WEIGHT.

U.S. Pat. No. 3,600,223, Aug. 17, 1971, Glick and McCusker, PROCESS FOR CLEANING POLYGLYCOLIC ACID FILAMENTS USEFUL AS ABSORBABLE SURGICAL SUTURES.

U.S. Ser. No. 34,593, May 4, 1970, Schmitt and Bailey, SOLUTIONS OF POLYGLYCOLIC ACID, now abandoned.

U.S. Ser. No. 118,974, Feb. 25, 1971, Ramsey and Delapp, PREPARATION OF POLYGLYCOLIC ACID IN FINELY DIVIDED FORM, now U.S. Pat. No. 3,781,349, Dec. 25, 1973.

U.S. Ser. No. 157,521, June 28, 1971, Schmitt and Polistina, POLYGLYCOLIC ACID PROSTHETIC DEVICES, now U.S. Pat. No. 3,739,773, June 19, **1973.**

U.S. Ser. No. 171,320, Aug. 12, 1971, Schmitt and Bailey, POLYGLYCOLIC ACID IN SOLUTIONS, now U.S. Pat. No. 3,737,440, June 5, 1973.

U.S. Ser. No. 176,291, Aug. 30, 1971, Glick and Chirgwin, DOPE-DYED POLYGLYCOLIC ACID SUTURES.

U.S. Ser. No. 190,290, Oct. 18, 1971, Schmitt and Epstein, COPOLYMERS ABSORBABLE BY LIVING MAMMALIAN TISSUES, now U.S. Pat. No. 3,736,646, June 5, 1973, METHOD OF ATTACHING

SURGICAL NEEDLES TO MULTIFILAMENT POLYGLYCOLIC ACID ABSORBABLE SUTURES.

U.S. Ser. No. 277,537, Aug. 3, 1972, Glick and Chirgwin, GREEN POLYGLYCOLIC ACID SUTURES AND SURGICAL ELEMENTS.

Other United States and foreign patents disclose surgical elements in which biodegradability and absorption results from the hydrolytic attack of tissue components on glycolic acid ester linkages in the polymer composing such surgical elements.

The present polyglycolic acid powder provides a synthetic powder which is absorbable by living tissue and is non-toxic. The powder is readily sterilized by autoclaving, preferably in sealed enclosures, or with ethylene oxide vapor.

Natural rubber or synthetic rubber surgical elements have many uses. Probably the most common is that of a rubber glove used by a surgeon or nurse during a surgical procedure or examination of a patient. Other sterile surgical elements may be used such as catheters, or rubber drainage tubes which are placed in the site of a wound to permit drainage during the healing process. Such drains are often removed as soon as the healing process proceeds to the point that a discharge is no longer occurring. Whether the surgical elements such as a drainage tube is to remain in the patient for a matter of several days or whether it is a surgical glove which is to be in contact with the raw tissues of a wound for only a period of a few minutes, any powder on the surface of the rubber may be transferred into the subject. Foreign elements in tissue usually cause adverse reactions. The degree of the adverse reaction can vary over a wide limit but even though the reaction may be minimal, it is desired that it be reduced as far as possible.

To prevent rubber elements from sticking to each other, for example, the turns of a rubber tube or the folds of a surgical glove, during storage in a package, it is desirable that the surface be coated with a finely divided powder to impart lubricity. Lubricity is particularly necessary with a surgeon's glove in order that the glove may be easily donned.

Obviously, it is highly desirable that any such lubricating powder be completely non-irritating to the living tissues of the subject. Although the desirability of an inert powder which is completely absorbable has been recognized, a powder which would meet the requirements of lubricity and still be completely absorbable with a minimal tissue. reaction under any and all conditions has not been obvious to the medical profession.

It has now been found that finely divided polyglycolic acid imparts the desired lubricity to rubber and if present in a wound appears to be completely absorbed by living tissue within a surgical acceptable period of time. When used as a suture, polyglycolic acid is completely absorbed in less than 90 days in normal muscular tissue. Polyglycolic acid dusting powder whether on a drainage tube which is left in a wound or on a glove which is transferred into the wound, is normally present in the wound in but small quantities and appears to be completely undetectable in far less than 90 days. Whereas the quantities which would rub off in the wound are comparatively small, when for test purposes larger quantities are deliberately introduced into a wound site and the wound closed, polyglycolic acid is absorbed with minimal tissue reaction.

Additionally, the polyglycolic acid is an acid and as such has a low pH, which low pH is not favorable to the growth of deleterious microorganisms, so that up until the acidity of the polyglycolic acid is neutralized by contact with other materials, the growth of many microorganisms is at least partially inhibited.

Although surgical elements other than surgeons' gloves do have considerable use, the biggest use is that of the dusting powder for the surface of the surgeons' glove. Therefore, the present invention will be described in greatest detail in connection with such gloves, having a coating of lubricity imparting polyglycolic acid.

Because the polyglycolic acid to be used on the surface of the rubber gloves and other rubber goods as a dusting powder need not be mechancially strong, and may, in fact, be somewhat elastic, a copolymer of polyglycolic acid containing lactic acid moieties, as for example, by the copolymerization of polyglycolic acid and lactic acid is acceptable. Usually, this is produced from glycolide and lactide, mixed. Usually a copolymer tends to be more elastic or rubbery than a homopolymer. Where maximum strength is desired, frequently a homopolymer has unique characteristics, but in a powder such as here where tensile strength is not a criteria, a copolymer gives good lubricity.

Up to about 15% lactic acid linkages change the characteristics of the powder but slightly. Over 15% lactic increases the solubility in solvents such as chloroform or xylene or toluene. Such copolymer may be powdered by spray drying a solution. The production techniques required for maximum tensile strength which are advantageous where polyglycolic acid is used as a suture, are not necessary in a glove powder as in the glove powder the lubricity is the key feature, and if the rubber glove having the dusting powder on its surface permits ready gloving, that is, permits the surgeon to insert his hand into the glove readily, with the glove sliding onto his hand even if somewhat moist, in such fashion as to give the feel to which the surgeon is accustomed, the powder has filled its requirements. It is, of course, necessary that the glove slide on the surface of the skin of the surgeon sufficiently that the thin rubber membrane does not interfere with the sensitivity of the surgeon's fingers so that the surgeon may readily feel through the glove. The low pH of the polyglycolic acid powder tends to retard growth of many microorganisms on the surgeon's hands inside the rubber gloves.

Polyglycolic acid in the form of a suture has a tensile strength that compares favorably with that of steel on a size basis and on a weight basis compares favorably with alloy steel but as a lubricant in connection with surgical glove, the strength requirements are such that batches of polyglycolic acid which do not meet the tensile strength requirements of a suture may be pulverized and used as a perfectly satisfactory glove powder.

A high molecular weight polymer has greater strength, and absorbs more slowly. For a powder, a lower molecular weight and rapid absorption is acceptable, and often an advantage.

DRAWINGS

In the drawings:

FIG. 1 is a surgical glove having on the surface thereof polyglycolic acid.

FIG. 2 shows a user donning a surgical glove.

FIG. 3 shows a surgical glove lubricated with polyglycolic acid in a sterile package.

FIG. 4 shows a catheter lubricated with polyglycolic acid in a sterile package.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The inventive dusting powder may be prepared by grinding or otherwise pulverizing polyglycolic acid to the desired particle size by the use of conventional grinding equipment and techniques well known to those skilled in the art. For example, polyglycolic fiber or filament as prepared in U.S. Pat. No. 3,297,033 is placed in an ordinary ball mill and ground for periods of anywhere from 15 to 48 hours. The grinding equipment is preferably grounded during the grinding operation to prevent undesirable aggregation of the particles caused by the static electrical charges which can accumulate on the particles during grinding. The ground material can then be removed from the mill and vibrated through a series of screens of varying mesh mounted on a Ro-Tap testing sieve shaker as supplied by W. S. Tyler Co.

Particle size of the ground polymer is an important criteria in selecting a powder which is suitable for a glove powder.

It is desirable that all the powder particles be small enough to pass through a 100 mesh screen (149 micron designation in the U.S. Sieve Series). However, small amounts (up to about 1% by weight) of somewhat larger sized particles can also be present in the powder without unduly adverse effect on the lubricating properties of the polyglycolic acid powder. It is preferred that all of the powder particles pass through a 200 mesh screen (74 micron designation in the U.S. Sieve Series).

In preparing the glove powder, it is equally important that it not be made too fine in order to minimize the escape of excessive powder into the environment in the course of powdering the hands, surgical gloves, or other items. As discussed heretofore, the powder, on the other hand, should not be of an excessively large particle size nor should it contain substantial amounts of exceptionally large particles since this will create an undesirable abrasive effect upon the skin of the hand when the powder is used. A suitable particle size range is from about 0.5 to about 149 microns with a range of from about 10 to 20 microns preferred.

When polyglycolic acid powder is to be sterilized in an environment which contains substantial amounts of water such as, for example, in an autoclave, it is essential that the powder be contained within a package which is substantially impervious to the water or steam. If this precaution is not taken, the water can hydrolyze the polymer causing it to become gummy and sticky. A particularly suitable water impervious container is the laminate of Mylar and polyethylene such as that described in U.S. Pat. No. 2,949,181, said patent being herein incorporated by reference. U.S. pat. No. 3,728,839, supra, discloses a very useful metal foil laminate for polyglycolic acid products. When polyglycolic acid is packaged in water impervious containers such as those described above, it can be autoclaved and still retain the free flowing properties required of a medical dusting powder (see Example 2).

Glove powder is used in a variety of ways by the medical profession. Rubber surgical gloves are typically sold unsterile in pairs with a package of glove powder inserted in the cuff of one of the gloves. When it is desired to use the gloves, the gloves and the package of glove powder are sterilized, usually by autoclaving. The surgeon will then open the package of glove powder (the package usually contains about 1.5 grams of powder) and pour the powder onto his hands. After working the powder over the surface of his hands, the surgeon inserts his powdered hands into the surgical gloves, the glove powder providing the lubricity required to facilitate this insertion. In cases where the gloves are reusable, the gloves, at the end of the operation, will be washed, dried, inspected for holes and then repowdered, usually on both the internal and external surfaces of the glove for subsequent reuse of the glove. This powdering is ordinarily accomplished by placing the gloves and a prescribed amount of glove powder in a tumbler and tumbling for a sufficient period of time to powder the inside and outside surfaces of the glove. The powdered gloves are then repackaged, autoclaved, and presented to the surgeon for use. Since the outside of the glove is often powdered, it is readily apparent how some of the powder may spill off the glove and into the exposed surgical cavity of a patient.

Disposable surgical gloves usually made of latex are also available to the medical profession. These gloves can be offered as a unit of one pair of gloves and one package of glove powder contained in a suitable package. However, they are ordinarily offered as a powdered glove, i.e., the inner and outer surfaces of the glove are prepowdered with a suitable dusting powder. When the contents of the envelope, i.e., the gloves and the powder are sterile, the entire envelope must first be autoclaved or otherwise sterilized. At the end of the operation the gloves are discarded.

Typical glove packages are described in U.S. Pat. No. 3,107,786 and 3,181,695.

The gloves of the present invention may be sealed in a strippable enclosure of the type shown in U.S. Pat. No. 2,949,181, there described for sutures, but adaptable to surgical gloves. A larger size strippable laminate enclosure is used for gloves.

From the foregoing it becomes apparent that the glove powder of this invention can be offered either separately in a single package of a suitable material or in combination with a pair of surgical gloves in either a sterile or unsterile condition. The powder itself may be either sterile or non-sterile.

It is desirable when a sterile powdered surgical glove, sterile powder, or a sterile combination of a surgical glove and separately packaged glove powder is to be offered, to package the aforementioned sterile items in a sterile inner enclosure which is then packaged in a sterile outer enclosure. The outer enclosure is provided with a strippable seal, which then allows for convenient serving of said sterile item to the potential user by merely stripping away the outer enclosure to present a totally sterile enclosure, i.e., the outer surface as well as the contents of the inner enclosure are sterile, containing the sterile item to the user. The user can then open the package and remove the sterile item therein without risk of contaminating the contents from contact with the outer surface of the inner enclosure.

The following examples are provided to further illustrate the invention.

EXAMPLE 1

PREPARATION OF POLYGLYCOLIC ACID LUBRICATING POWDER

Polyglycolic acid filaments such as typically prepared by the teachings of U.S. Pat. No. 3,297,033 were placed in a Wiley Mill and ground for several hours. The ground product consisted of chopped pieces of filament ranging from 2 to 4 mils in width and 12 to 20 mils in length. The particles were flat rather than cylindrical in shape and fibrillated.

The product ground on the Wiley Mill was then ball milled for 3 hours and examined microscopically to determine if a further breakdown in size had occurred. Acicular particles were found ranging in size from 0.5 micron to large fragments of the chopped filaments.

Ball milling of the product was continued for another 15 hours. At this point, more than 90% of the ground material passed through a 7 mil sieve opening and the bulk of this material was found to have a particle size ranging from less than 0.5 micron to 15 microns. The larger sized material which passed through the 7 mil sieve was either acicular with a diameter in the aforementioned range or static aggregates. The powder retained by the 7 mil sieve was discarded, or reground.

EXAMPLE 2

STERILIZATION OF POLYGLYCOLIC ACID DUSTING POWDER

The powder prepared in Example 1 was placed in a transparent envelope fabricated from a laminate of the polymeric ester of ethylene glycol and terephalic acid (Mylar) and polyethylene. Such a laminate is available commercially from the Minnesota Mining and Manufacturing Co. under the name Scotch-Pak. This laminate is known to resist penetration by water in either liquid or vapor form. The particular laminate employed had a Mylar thickness of about 1.1 to 1.5 mils and a polyethylene thickness of about 3 to 3.5 mils. The polyethylene layer of the laminate forms the inner surface of the package to facilitate heat sealing of the package.

The package was then heat sealed and placed in a standard autoclave (15 psig steam pressure, 250°F.) for 1 hour. The package was then removed and opened. The package contents were free flowing and gave no indication of being tacky or sticky. The powder was applied to the hands of a subject who then proceeded to glove his hands with a pair of rubber surgical gloves. The performance of the powder in facilitating insertion of the hands into the gloves was quite satisfactory. Continued wearing of the gloves indicated that the powder was non-irritating to the skin.

EXAMPLE 3

IN-VIVO COMPARISON OF THE LESION PRODUCING PROPERTIES OF STARCH AND POLYGLYCOLIC ACID DUSTING POWDER

Lateral incisions were made through the peritoneal wall on both sides of two albino New Zealand female rabbits. On one side, a 5% solution of sterile saline and the polyglycolic acid powder prepared in Example 1 was placed on the peritoneal wall. On the other side was placed an identical solution of a widely used commercial starch powder.

The rabbits were sacrificed after 3 months and gross and histological examinations of the peritoneal wall were made for, and of, any lesions which were present. The portion of the wall treated with polyglycolic acid powder was substantially free from lesions except for the presence of a few small nodule granulomas. The portion of the wall treated with the starch powder, however, contained numerous readily apparent lesions and contained several granulomas and a large adhesion.

The above results indicate that reduced formation of lesions can be expected when the polyglycolic acid powder of this invention is used compared to the currently used starch powder.

EXAMPLE 4

IN-VIVO BACTERIOSTATIC AND BACTERICIDAL PROPERTIES OF POLYGLYCOLIC ACID POWDER

Two ventral incisions were made in two albino New Zealand female rabbits. Both incisions were deliberately infected with *Staphylococcus aureus*. Sterile polyglycolic acid powder as prepared in Example 2 was applied to one of the wounds. No powder was applied to the other wound. Both wounds were then repaired by suturing. After a 7 day healing time, there was no evidence of any infection whatsoever in the wound which had been treated with polyglycolic acid powder and the wound appeared to have healed satisfactorily. It was readily apparent from examination of the untreated wound, however, that this wound was still badly infected.

The above results indicate that polyglycolic acid powder appears to have in-vivo bacteriostatic and bactericidal properties.

A current discussion on the effect of acidity appears in Medical World news, Dec. 15, 1972, at page 25 ACIDITY: KEY TO WOUND HEALING, which discloses that at a more acid pH, the oxygen supply is improved.

EXAMPLE 5

IN-VITRO BACTERIOSTATIC AND BACTERICIDAL PROPERTIES OF POLYGLYCOLIC ACID POWDER

Four grams of polyglycolic acid powder as prepared in Example 1 were added to 80 cc. of water. The pH of the resulting suspension was slightly less than 2. 10 cc. of this suspension were placed in a test tube labeled No. 1. The pH of the remaining 70 cc. was raised to **6** by adding approximately 0.5 gm. of sodium bicarbonate. 10 cc. of the pH 6 suspension was placed in test tube No. 2. The pH of the remaining 60 cc. was raised to 7 by adding approximately 0.4 gm. of sodium bicarbonate. 10 cc. of the pH 7 suspension was placed in test tube No. 3. Test tube No. 4 contained deionized water.

0.5 cc. of a 48 hour nutrient broth suspension of *Staphylococcus aureus* were added to each of the 4 test tubes. The tubes were incubated at 37°C. for 24 hours. At this point, 0.4 cc. of each tube were removed and transferred to agar pour plates. These plates were incubated at 37°C. for 48 hours. Results are shown below:

Tube No.	pH	Result
1	2	No Growth
2	6	Moderate Growth
3	7	Heavy Growth
4	–	Heavy Growth

The above results show that aqueous suspensions of polyglycolic acid powder have in-vitro bacteriostatic and bactericidal properties. The acid pH is an important factor on gloves or in a wound. Until the pH is increased, the environment is not favorable for many microorganisms.

EXAMPLE 6

Powdered Gloves

A group of freshly dipped latex gloves as manufactured and before dusting were placed in a drum with about 1 gram per glove of the dusting powder of Example 1. The gloves were tumbled and shakened till the gloves were uniformly coated with the powder after which the gloves were shaken to remove excess powder, paired and folded and then placed between two sheets of a laminate of polyester film and polyethylene. The material is described in detail in U.S. Pat. No. 2,949,181. The laminate was sealed polyethylene to polyethylene, leaving a lip and a strippable seal as described in said U.S. Pat. No. 2,949,181 and then a group of the packaged gloves were placed in an autoclave and heated to sterilizing temperature.

As so produced, the gloves could be released by stripping the package, to release the gloves in sterile condition and were then ready to be donned by a user.

EXAMPLE 7

A group of the gloves dusted with powdered polyglycolic acid as described in the preceding example were sealed between a polyester, polyethylene laminate as above described using a strippable seal and a group of the gloves were then placed in an ethylene oxide chamber to allow the ethylene oxide to penetrate through the laminate seal as described in more detail in U.S. Pat. No. 2,917,878 Canarius and Kaufman.

The individual gloves before sterilization are indicated in FIG. **1**, the surface of the glove **11** has powdered polyglycolic acid **12** spread thereover.

FIG. **2** shows the surgeon donning the glove. The glove **13** is held by a nurse whose hands **14** hold the glove with the cuff slightly stretched while the hand of the surgeon **15** is inserted therein to.

FIG. **3** shows the surgical glove **11**, having powdered polyglycolic acid **12** on its surfaces, folded in a paper wrapper **16**, inserted in an outer strippable envelope **17**.

It is convenient to powder the glove with the finely divided polyglycolic acid before the glove is sterilized, and sterilize the powdered glove and keep it in sterile condition until ready for use. It is also convenient to use the powdered polyglycolic acid in sterile form to be applied to the surface of sterile gloves at the time they are being put on. The time of powdering the glove and the time for storing can vary with the technique and schedules of the particular user, such as a hospital or individual surgeon. If sterile gloves are used, a single use disposable glove is convenient. If the gloves are to be reused, the time of applying the powder and the sterilizing can be varied depending upon the number of gloves used in the inventory available or preferences.

When used in patients during surgical procedures, no deleterious effects which could be ascribed to the glove powder were observed.

FIG. **4** shows a catheter **18** similarly packaged in a similar strippable package.

I claim:

1. A sterile surgical element package comprising a strippable laminate container having therein
- a surgical element of natural or synthetic rubber;
- having on the surface of said element in a small but lubricity imparting quantity;
- a finely divided biodegradable powder consisting essentially of a polymer containing hydrolytically degradable glycolic acid linkages,
- whereby in surgical use, any of the lubricity imparting powder which is transferred into a wound is readily absorbed by living tissue without adverse side effects.

2. The package of claim **1** in which the biodegradable powder is homopolymeric polyglycolic acid of a particle size of 0.5 to 149 microns.

3. The package of claim **1** in which the surgical element is a pair of surgical gloves.

4. The package of claim **2** in which the surgical element is a pair of surgical gloves.

5. The package of claim **1** in which the surgical element is a catheter.

6. The package of claim **2** in which the surgical element is a catheter.

7. A sterile surgical element package comprising in combination
- a strippable interiorally sterile laminate container having therein
  - a. a sterile surgical element of natural or synthetic rubber, and
  - b. a finely divided biodegradable powder consisting essentially of a polymer containing hydrolytically degradable glycolic and linkages, and
  - c. whereby in surgical use, any of the lubricity imparting powder which is transferred into a wound is readily absorbed by living tissue without adverse side effects.

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