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A. GOLDFARB ETAL

3,464,413

MEDICAL BANDAGES

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FIG 1.

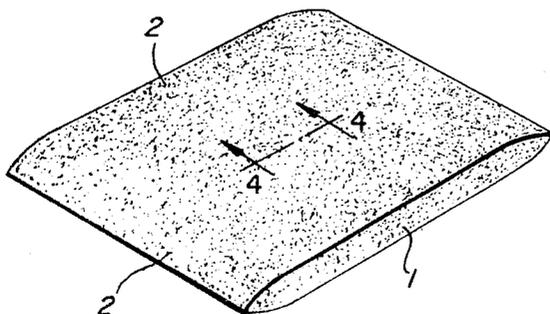


FIG 2.

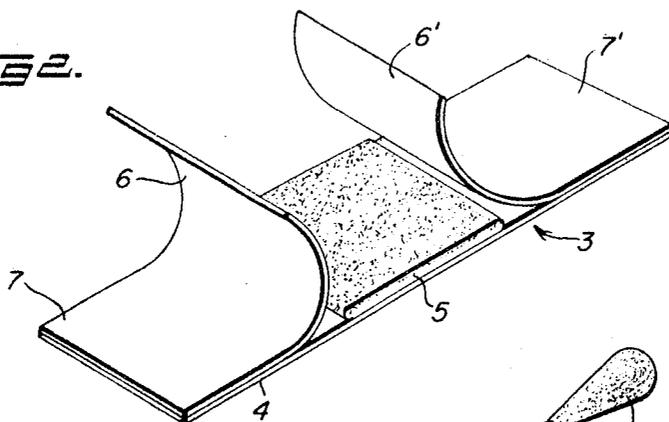


FIG 3.

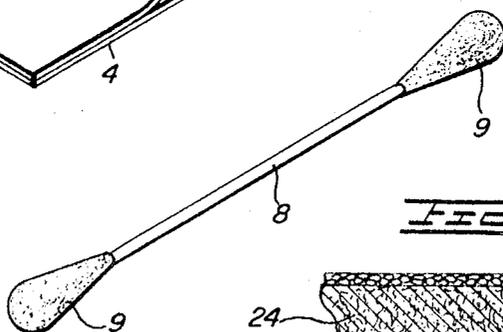


FIG 4.

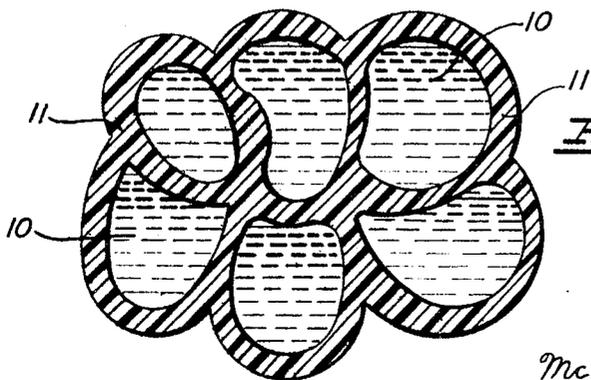
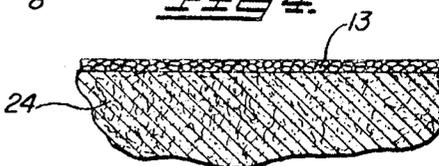


FIG 5.

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MEDICAL BANDAGES

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5 Claims

ABSTRACT OF THE DISCLOSURE

A medical dressing construction comprising a dressing substrate having adhered thereon a multiplicity of microscopic discrete rupturable capsules, each of the capsules comprising liquid droplets encapsulated within an outer shell, and each of the droplets containing a medicament material capable of aiding in the healing of injuries.

BACKGROUND OF THE INVENTION

This invention relates to medical bandages or dressings of the type employed in the direct application thereof to the area of injury. The surface of the bandages or dressings of this invention which are to be applied to the injury are provided with a multiplicity of discrete microscopic rupturable capsules, each of the capsules comprising liquid droplets encapsulated within an outer shell with each droplet containing a medicinal material which, when released will aid in the healing process. The construction is such that, when the bandage is applied, the discrete capsules will be ruptured and the medicament released to commence the healing.

The art of medical dressing or bandage construction is ancient and a tremendous variety of such materials are available on today's commercial market. Among these various dressings or bandages now available, there may be mentioned surgical dressings, first-aid type bandages, such as Band-Aids, military medical bandages, operational bandages, such as "swabs," and the like. In general, these prior art bandages comprise a layer of absorbent material, such as gauze, which is applied to the injured area of the skin by means of an adhesive material associated therewith which is applied to an adjacent uninjured area. In use, a medicament is usually initially applied to the injury to aid the healing process and the bandage or dressing is then applied thereover.

Many proposals have been made heretofore to provide bandages or dressings of the above-mentioned type wherein the absorbent portion to be applied to the injury is further provided with the medicinal material adhered directly thereto. The advantage of a dressing or bandage construction of this type, of course, resides in the elimination of the intermediate step of applying the medicament to the injury. A further advantage is realized by the elimination of the possibility that the medicinal, which is often liquid, will be lost by run-off or leakage.

Certain disadvantages, however, have been found to be associated with dressings or bandages of the type provided with a medicament adhered thereto. The most prevalent of these disadvantages is the realization that medicaments cannot be adhered for application in the liquid form by this method and, therefore, such bandages or dressings have been limited to uses involving materials which can be adhered as solids. A second disturbing factor regarding such medicaments resides in the ever-present possibility of contamination of the medicinal materials with the obvious resulting consequences. It is apparent therefore that a distinct need is present in the art for the provision of a medicine-containing dressing or bandage which is not subject to the disadvantages of similar dressings or bandages now known to the prior art.

SUMMARY OF THE INVENTION

It is accordingly an object of the invention to provide a medical bandage or dressing construction wherein the area of the bandage or dressing to be applied to the injury is provided with a releasable medicament, which construction overcomes or otherwise mitigates the several disadvantages of similar medical bandages or dressings now known to the prior art.

A further object of the present invention resides in the provision of medical bandages or dressings wherein the areas thereof to be applied to the injury are provided with the appropriate medicament contained within a multiplicity of rupturable encapsulated microscopic capsules.

According to the present invention, the above objects and advantages are achieved by the provision of a medical bandage or dressing having adhered to the area to be applied to the injury a multiplicity of microscopic discrete rupturable capsules wherein each of the discrete capsules comprise liquid droplets encapsulated within an outer shell and wherein each droplet contains a microscopic amount of an appropriate medicament. When the bandage or dressing is applied to the injury the pressure of the application, reaction with the blood, or other appropriate means, serves to rupture the microscopic capsules thereby freeing the medicament to aid in the healing process.

BRIEF DESCRIPTION OF THE DRAWINGS

Reference is now made to the drawings accompanying the present application wherein:

FIGURE 1 represents a perspective view of a surgical dressing prepared according to the teachings of this invention;

FIGURE 2 represents a perspective view of a first-aid or "Band-Aid" type bandage prepared according to the teachings of this invention;

FIGURE 3 represents a perspective view of an operational dressing of the "swab" type prepared in accordance with this invention;

FIGURE 4 represents an enlarged side elevational view of a section of a surgical dressing prepared according to this invention particularly illustrating the adherence of the microscopic capsules to the dressing; and

FIGURE 5 represents a greatly magnified cross-section of a cluster of the medicament-containing microcapsules employed with the bandages and dressings of this invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

According to the present invention, it has now been discovered that an improved medical dressing or bandage for use in treating injuries may be provided by the adherence to absorbent dressings of the medical bandage or dressing type of a multiplicity of discrete rupturable microcapsules containing chemical agents which, when the capsules are ruptured, are released to effectively aid in the healing of injuries and burns, relieve pain, coagulate blood, etc., in association with the absorbing qualities of the bandage or dressing substrate.

As mentioned, the bandage or dressing may basically comprise any of the various types of such materials now on the market including surgical dressings, adhesive bandages, operational dressings (i.e., swabs), military bandages, etc., as the invention is considered applicable to all types of such materials. The actual construction of the bandage or dressing is not considered to be particularly critical although certain minimal criteria should obviously be observed to ensure proper fit, adherence and breathability with the further requirement that necessary absorbent and protective qualities be present.

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Of the several types of bandage or dressing substrates to which the invention is considered applicable, there may be mentioned surgical dressings, adhesive bandages, operational dressings such as swabs and the like, military dressings and bandages, Ace type bandages, and the like. Certain of these dressings or bandages are illustrated in the drawings accompanying the application in combination with the novel construction of the present invention. However, it is to be understood that the invention is not to be considered limited thereto.

In this regard, it may be seen that FIGURE 1 represents a surgical dressing of the conventional kind which comprises an interior core of absorbent material such as cotton 1 enveloped by a covering of a woven material such as gauze 2. A side view of this construction is shown in FIGURE 4. In FIGURE 2 of the drawing there is exemplified an adhesive bandage construction 3 comprising a base layer of breathable impervious material 4, such as surgical adhesive tape consisting of cellophane, rubber, polyethylene and the like, with a soft absorbent pad or dressing 5 disposed on the adhesive face thereof. A protective facing material 6, such as crinoline, plastic film, coated paper, and the like, may be adapted to overlay the pad for removal just prior to application of the bandage. As may be noted the facing material is usually in two sections 6 and 6' overlapping the pad with the opposite ends 7 and 7' protecting the exposed adhesive portions of the carrier strip 4.

The invention is also considered applicable to the so-called operational dressings or "swabs" and one aspect of a swab construction is illustrated in FIGURE 3. In this embodiment the dressing generally comprises a wood or plastic stick 8 having cotton or other fibrous material 9 secured at one or both ends thereof. The stick 8 may be constructed of wood or plastic as desired and may further be provided at its ends with barbs or an adhesive substance to ensure that the cotton or other fibrous substances remain adhered to the ends of the stock.

The invention is also deemed to be applicable to any other type of medical dressing or bandage known to the prior art. Such bandages may include, for example, the several forms of bandages and dressings employed by the Armed Forces, Ace-type bandages and the like. All of these several types of bandages, and their methods of application, as well as those specifically described in the accompanying drawings, are well known in the art and no necessity is seen for a detailed explanation of their construction except insofar as their construction is altered by the present invention. This latter modification of their construction is, of course, fully described herein and illustrated in the accompanying drawings.

According to the present invention, the above-described bandage and dressing constructions are provided on their surfaces and at the interstices between layers, such as the area surrounding absorbent cores beneath the gauze, with a multiplicity of intrareactive discrete microcapsules containing appropriate medicinal materials which are releasable and become active when the capsule is ruptured.

The rupturable capsules may be generally described as minute encapsulated clusters of smaller individual microcapsules, each individual capsule consisting of a core of substantially water-insoluble material surrounded by its own polymer encapsulating shell, and each cluster of such capsules itself as a whole, being contained in a shell of polymer encapsulating material. A magnified cross-section of a cluster of discrete rupturable capsules is illustrated in the accompanying drawing in FIGURE 5 wherein reference numeral 10 denotes the minute capsules which are encapsulated within wall 11. The core material in each capsule in a cluster may be solid, liquid, liquids, liquids adsorbed on or in solids, or solid material dispersed in a liquid. The clusters each may include capsules containing the same kind of core material, or may include capsules having different core materials. When the capsules in a cluster contain different kinds of core materials, such mate-

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rials may be in liquid or solid form, or both. That is to say, the capsules individually may contain either liquid or solid material, or both liquid and solid material, or the capsules collected in a cluster may be of these various kinds, so that a cluster may contain capsules having only liquid material, only solid material, solid material dispersed in a liquid, or mixtures of any of such capsules. It is to be understood that capsules which contain liquid at one temperature may have their contents solidified by cooling if the core material is of that nature; or, if of a heat solidifiable type, solidified by heat, and conversely, in capsules that originally contained solid core material, the cores may become liquid when raised to a temperature above their melting point.

If a cluster of capsules have heterogeneous core materials, some, or all, of the core materials may be in a liquid or solid state, depending upon the prevailing temperature. In some instances the core material of a capsule may be a liquid having dissolved therein a solid, which solid stays in solution until the temperature surrounding the capsule drops to a point where the dissolved solid becomes insoluble in the liquid and precipitates as a separate phase to provide a core material which is a liquid having dispersed therein a newly-formed solid material. Similarly, if the core material is a solution of two or more liquids, they may be caused to separate by temperature changes. Such solubility conditions may or may not be reversible depending on the core material characteristics.

The walled-clusters of individual capsules make it possible to protect and isolate the medicinal materials until they are ready for use. The materials in the individual capsule cores and the individual capsules themselves are protected against contact with the materials in the cores of adjoining capsules by the capsule walls, and the materials in the cores of the individual capsules of a cluster are protected against contact with, or escape to, the surrounding environment outside the cluster shell, both by the individual capsule walls and by the wall material surrounding each of the capsule clusters as a whole.

In practice, the core materials of the individual capsules of a cluster are exposed for use by removal of the cluster wall and of the individual capsule walls, which removal may be brought about by physical fracture such as pressure, chemical solution, chemical reaction, heat, or equivalent effective means. On removal of the capsule and cluster walls, the medicant becomes available to aid in the healing process.

The encapsulation of the discrete entities of core materials is carried out by use of an aqueous liquid medium containing dissolved therein capsule wall-forming materials or materials which form a wall or shell around each cluster of capsules. The clusters of capsules so-made are completed in the aqueous medium and may be used as a liquid dispersion in the medium, or the residual aqueous medium, together with any undeposited wall-forming material, may be removed, in part or altogether, by filtering, decanting, centrifuging, evaporation, or other commonly used separation means, to obtain the clusters as a concentrated liquid dispersion thereof, or as dry particles, each of which particles may consist of one or more of the walled clusters. Thus, it is apparent that a multiplicity of means are available for forming the microcapsules for use in the invention.

According to the concepts embodied in the present invention, the core materials which are encapsulated for use on the medical dressings or bandages may be generally described as medicinal formulations for the treatment of heat, e.g. burns, etc., pain relievers, medicinals employed in treating injuries, e.g. antiseptics, antibiotics, blood coagulants, disinfectants, local anesthetics and the like, or any material considered to be of value in administering medicinals to injuries.

The presence of such core materials would, therefore, make instantly available by mere application of the dressing or bandage, the proper medicant required to effect the

healing process on the injury. Thus, by merely applying the encapsulated bandage or dressing, pain-relief, blood coagulation, etc., could be achieved without the necessity of an intermediate application of a medicant. As pointed out above, the capsules are adapted to be releasable by pressure, by heat, chemical reaction, solution in the blood or equivalent releasing mechanisms. Thus, release of the appropriate combatant may be controlled so as to be available at the required time.

One process for making the walled clusters of minute capsules for use on the bandages and dressing of this invention requires the formation of an oil-in-water emulsion in which the dispersed phase units each become the nucleus of a capsule and the continuous phase is an aqueous solution or sol of wall-forming colloid materials. These wall-forming materials are caused to separate out as complex colloid-rich phases, in steps, by the phenomenon of coacervation, induced by changing the conditions of the emulsion, the colloid-rich phase which first separates out depositing on the individual nuclei as seed points to form rudimentary minute capsules with colloid-rich liquid walls. The second phase separation deposits as complex colloid-rich liquid walls about clusters of the capsules. The colloid material finally is gelled to form capsules and clusters with solid walls. The mixture may be made for example by forming an aqueous sol of one colloid, emulsifying the selected oil therein, and mixing the emulsion with an aqueous sol of another colloid, or the two sols may be made and mixed and the oil emulsified therein.

The coacervation is caused by dilution and/or by adjusting the pH of the mixture, the latter method being employed in the specific embodiment of this invention. The gellable colloid materials used in the sols must be ionizable and exist in the mixture with opposite electric charges. This may be brought about by selection of the colloid materials, or by adjusting the pH of the sol mixture in which the oil droplets are dispersed in the event one or both of the colloids are amphoteric. In the process of coacervation, the complex colloid material deposits around the oil droplets to thereby form the capsules.

If desired, after the gelation, any further steps of hardening the gelled material; separating the hardened gelled material from the remaining liquid; drying it; and comminuting it to the desired particle size, may be employed, these further steps obviously varying with the materials and medicinals employed and the end results desired.

Either one or both of the colloid materials should be gellable and used in such concentration that the coacervate complex colloid materials is gellable. The process steps, down to the gelation step, are carried out with the ingredients at a temperature above the gel point of the colloid materials used, and gelation is brought about by cooling.

If desired, after hardening and drying where necessary, the agglomerate mass of capsules may be comminuted to form fine granules of any desired size. The capsules, being minute, and tending in the agglomerate form to cleave between the capsules, are not destroyed to any great extent by comminution of the mass.

The droplets of oil disposed in the capsules of the product are centrally located in the capsule and are protected from contact with the surrounding environment by a thick self-supporting tough shell-like film of the colloid materials. The encapsulating complex colloid material may be hardened if desired and water-insolubilized to a point where the capsules are highly resistant to heat and moisture or one of these conditions may be attained so that the capsules are rupturable under one or more of these conditions. The encapsulating film of a capsule may contain one or more droplets of oil, the droplets in the latter case maintaining their identity by persistence of the emulsion interface film.

The oil or oils used herein include any water-non-miscible fluid suitable for making oil-in-water emulsions. Included among the oils are those that occur naturally,

such as olive oil, corn oil, coconut oil, castor oil, fish oils, animal oils, such as sperm oil, essential vegetable oils, mineral oils, such as petroleum lubricating oil, kerosene, and xylene, and synthetic oils, such as chlorinated diphenyl, methyl salicylate, etc. The oils contain dissolved or dispersed therein materials, such as those generally specified above as being effective in the treatment of injuries, burns and the like. The dispersed material should be sufficiently fine to be colloidal in size for use in the capsules of the invention.

The ionizable hydrophilic colloid materials employed in forming the droplets of the present invention include substances such as gelatin, albumen, alginates, such as sodium alginate, casein, agar-agar, starch, pectins, carboxymethylcellulose, Irish moss, gum arabic, and the like.

It has been found necessary in order that coacervation will occur that the two kinds of colloid ions, as they exist in the mixture before coacervation, have different electric charges. Some kinds of hydrophilic colloid ions in aqueous sols are negatively charged, regardless of the pH of the sol; some kinds are positively charged, regardless of the pH of the sol; and some are amphoteric, having an iso-electric point above which they are negatively charged and below which they are positively charged. The electric charge characteristics of a hydrophilic colloid under consideration may be determined by electrophoresis, for example. In the event that one or both of the colloids used are amphoteric, the pH of the sols may be so adjusted that the colloid ions of the two kinds are of different electric charge. Amphoteric hydrophilic colloids of the same iso-electric point generally cannot be used.

The material which forms the walls of the individual capsules and the encapsulating walls of the clusters of capsules should be of a wall-forming nature, and soluble in water or organic solvent, which solution will constitute the medium in which the encapsulation of the core materials and the formation of encapsulated clusters of the capsules take place. The wall-former may be organic or inorganic in nature and be of natural or synthetic origin.

The encapsulating materials, besides being of film-forming nature, should have the property which permits them to act as a barrier for the core materials to be used, and permits of the capsular material being exposed by removal of the encapsulating wall material, by one or more of the noted treatments of fracture, such as by pressure, chemical dissolution, heat, or equivalent means, or combinations thereof. The walled capsules and walled clusters may purposely be made micro-porous in a degree, by special drying techniques, to allow escape of the core materials by liquid leakage or evaporation. Such special microporosity can be controlled by adjusting the porosity, for example.

Inasmuch as the walled-clusters of capsules, which are the subject matter of this invention are to be used in one embodiment in the treatment of living organisms, the encapsulating material for such use should be non-toxic and safe for use in the treatment of injuries. This is the only criticality which must be placed on the selection of the encapsulating materials aside from the obvious qualification that they satisfactorily form the capsule walls.

Encapsulating wall-forming materials, which meet these general requirements, may be chosen from the natural film-forming materials, such as gelatin, gum-arabic, Chondrus, zein and soy bean protein, which substances are ordinarily solid at room temperature (about 20° C.), but other film-forming equivalents may be used. The wall-forming encapsulating materials chosen may also be used in various combinations as desired or in combination with other non-toxic ingredients.

After formation of the capsule clusters containing the above generally described medicaments and agents, a portion thereof is adhered, as by coating or impregnation, on the desired surface of the bandage or dressing to

form the products of this invention. A preferred manner for carrying out this phase of the method is to remove enough solvent from the mixture in order to make a fluid coating, applying it to the dressing or bandage surface by any conventional manner and allowing the solvent to evaporate whereupon the microcapsule coated product remains.

An exemplary illustration of the resulting product is the surgical dressing shown in sectional view in FIGURE 4 of the accompanying drawing, wherein there may be seen a cluster of microscopic capsules 13 coated on a dressing substrate 24. The clusters of microcapsules may also be deposited on intermediate layers of a dressing or bandage.

It is to be appreciated from the nature of the present invention that the diagrammatic showing of clusters of the microscopic capsules and their association with or disposition on, the various dressings and bandages, must be considered as idealistic representations only, as the clusters of liquid-containing capsules cannot be exactly reproduced in a drawing. As a practical matter, the clusters are not perfect spheres, nor are the contained capsules perfect spheres, as forces pushing them together would tend to distort them. In fact, the capsules in a cluster are probably packed as close as space will permit with the polymeric material of the cluster walls penetrating into the interstitial spaces between each capsule.

The materials which are intended to be encapsulated for deposition on the bandages and dressings comprise, in general, materials which are effective to serve in the treatment of burns, injuries, and the like, and particularly include antibiotics, blood coagulants, antiseptics, pain relievers, local anesthetics, and the like. The medicants which perform these functions are well known in the art and will be mentioned only briefly hereinbelow. The only criticality which may be placed on the various medicaments is that they be considered effective for their intended use and be capable of encapsulation.

As antibiotic materials there may be mentioned the penicillins, tetracyclines, sulfa drugs and the like. Pain relievers may include, for example, codeine. Of the local anesthetics to be employed, there may be mentioned xylocaine hydrochloride, carbocaine hydrochloride, procaine hydrochloride and the like.

The most useful area in which the bandages and dressings of the present invention may be employed resides in the administration of antiseptic materials to open injuries. Such materials may include, for example, the well-known merthiolate, mercurochrome, trichotone, clorpectin, and the like.

After preparation of the encapsulated dressings and bandages of the present invention, they are used in the ordinary manner for the binding or covering of burns and injuries. Thus the bandages and dressings from outward general appearances will not be any different than an ordinary dressing or bandage. However, when the dressing or bandage is applied to the burn or injury, the pressure of the application, or equivalent means, causes the capsules to burst thus providing an adequate supply of the proper medicant at the proper time and without danger of contamination or loss through spillage.

The encapsulated bandages and dressings of the present invention are believed to be especially suited to the needs of the military, particularly under wartime conditions. The use of the encapsulated bandages and dressings, as described herein, would be greatly advantageous to the medical corpsman as their use would eliminate the need to carry the required medicants, bandages and dressings separately in situations where space and time are at a premium and would further result in lessening the danger of contamination of the injury and/or the medicant. It is, therefore, to be appreciated that the encapsulated bandages and dressings of the present invention represent a substantial advance in the accepted use of bandages and dressings.

While it was noted hereinabove that the capsules on the dressings are releasable by the pressure exerted during application, it is also contemplated that other means of release may be employed. Thus, the capsule wall may be released by chemical action or solution, as with the blood or with a previously applied medicant. Therefore, any conventional release means is considered to be within the scope of the invention.

The following example describes the production of a surgical dressing according to the teachings of the present invention and is to be considered as exemplary only.

EXAMPLE

This example contemplates the deposition on a surgical dressing of an antiseptic material by use of an emulsion for deposition. The emulsion was prepared as follows:

First, 8.5 grams of corn oil having dissolved therein 1.5 grams of an antiseptic (merthiolate) was emulsified into an aqueous solution of 25 grams of high quality pigskin gelatin and 225 milliliters of water at a temperature of about 45° C. and adjusted to a pH of 9. Thereafter, the emulsion was continuously agitated. To this agitated mixture was then added 27.5 grams of gum-arabic dissolved in 250 milliliters of water and having a temperature of 45° C. and a pH of 9.

The resulting mixture was then diluted under constant agitation with 1900 ml. of water at 45° C. and a pH of 9, whereupon 16 grams of a 5% by weight aqueous solution of polyvinylmethyl ether/maleic anhydride copolymer was added. With continuous agitation, the pH of this coacervatable mixture was then lowered to 6.0 by the drop-by-drop addition of a 20% by weight aqueous solution of acetic acid.

At this point the capsule droplets containing the antiseptic agent start to form and cluster into small units. Thereafter, the drop-by-drop addition of the 20% aqueous acetic acid solution was continued until the pH was reduced to 4.2 which caused coacervate deposition of the fractions of the polymeric material which did not deposit around the capsules at pH 6. The latter deposition of polymer occurred as a dense liquid wall around the cluster units individually to form encapsulated cluster units.

The walled clustered units were then cooled to gel the deposited wall materials. After cooling, the excess liquid was removed by evaporation until a pasty-like semi-liquid was obtained.

Thin layers of this semi-liquid were then coated onto the surface of a surgical dressing, such as that illustrated in FIGURE 1. The coatings were then dried by evaporation of the solvent. Inspection of the surface of the dressing revealed the presence of a multiplicity of minute clusters of capsules thereon.

The coated dressing was thereupon subjected to the application of carefully applied pressure whereby the breakage of the minute bubbles on the surface could be microscopically detected and the presence of a released oil detected. On further application of pressure, the presence of an oily substance on the surface of the dressing could be detected.

Additional dressings and bandages were prepared employing coatings of the previously prepared antiseptic-containing pasty liquid and dried as before. These dressings were then submitted for clinical testing whereupon it was reported that effective medicinal benefits could be obtained using the encapsulated dressings and bandages.

Having described the invention in specific detail and indicated the manner in which it may be carried into practice, it will be readily apparent to those skilled in the art that innumerable variations, applications, modifications, and extensions of the basic principles involved may be made without departing from its spirit or scope. It is, therefore, intended that this invention is to be limited only in accordance with the appended claims.

What is claimed is:

1. A medical dressing comprising a dressing substrate having adhered thereto a multiplicity of microscopic discrete rupturable capsules, said capsules comprising liquid droplets encapsulated within an outer shell, each of said droplets containing a medicinal material capable of aiding in the treatment of injuries and burns. 5
2. A medical dressing construction according to claim 1 wherein the dressing is the surgical dressing type.
3. A medical dressing construction according to claim 1 wherein the dressing is of the adhesive bandage type. 10
4. A medical dressing construction according to claim 1 wherein the medicinal material is one or more of a member selected from the group consisting of antiseptics, antibiotics, pain relievers, blood coagulants, and local anesthetics. 15

5. A medical dressing construction according to claim 1 wherein the capsules are rupturable by means selected from the group consisting of pressure, chemical solution, and chemical reaction.

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ADELE M. EAGER, Primary Examiner

U.S. Cl. X.R.

128—156, 269; 167—64