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Staab

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[54] **DISSOLVABLE DEVICE FOR CONTRACEPTION OR DELIVERY OF MEDICATION**

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Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 880,093, May 7, 1992, abandoned.

[51] **Int. Cl.**[6] **A61F 9/02;** A61F 13/15; A61F 13/20; A01N 25/08

[52] **U.S. Cl.** **424/436;** 424/409; 424/430; 424/431; 424/432; 424/433; 424/445; 424/DIG. 14; 514/772.3; 514/777; 514/781; 514/784; 514/785; 514/841; 514/843; 514/953; 514/967; 604/358; 604/378; 604/904

[58] **Field of Search** ..... 424/400, 405, 407, 409, 424/430, 431, 432, 433, 436, 443, 444, 445, 486, 488, DIG. 14; 514/772.3, 777, 781, 784, 785, 841, 843, 953, 967; 604/904, 358, 378

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[57] **ABSTRACT**

A dissolvable element containing an agent material is used for local administration of the agent material in an internal body area. The dissolvable element is made of dissolvable polymer material and/or complex carbohydrate material which are food grade materials and have selected dissolving properties, such that it remains in substantially solid form before use, and dissolves due to human body temperatures and moisture during use to release the agent material in a desired timed release and dosage. As a contraceptive, the dissolvable element is preferably a film made of polyvinyl alcohol, polyethylene oxide, hydroxypropyl methyl cellulose and/or carboxymethyl cellulose. The dissolvable element may be formed as a laminate of different film layers for compound release properties, or it may be ground into particles and incorporated in a tampon or suppository. The dissolvable element may be foamed as a means for increasing its dissolution rate. The agent material can be a spermicide, such as Nonoxynol-9, and/or a drug or medication. The device of the invention can also be applied topically as for example in the treatment of wounds, burns and ulcers, as well as to treat, irritations, Herpes, and ulcerations and blisters of the oral cavity. It is also possible to prepare dressings in which the dissolvable element of the invention comprises the bottom most layer. This permits painless application of medication to wounds.

24 Claims, 2 Drawing Sheets

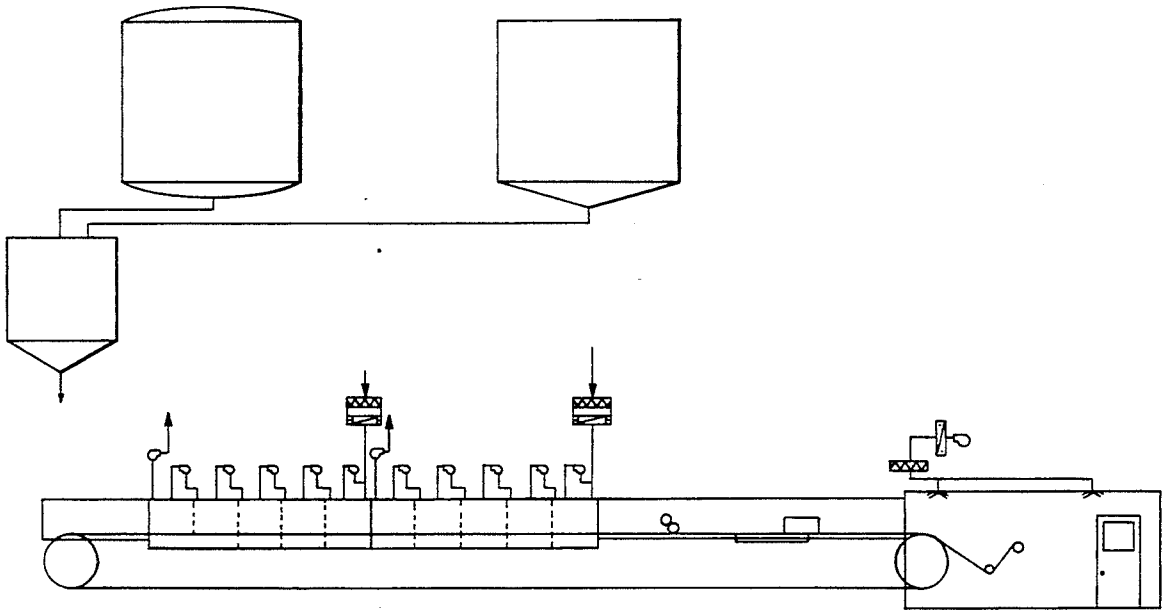


FIG. 1

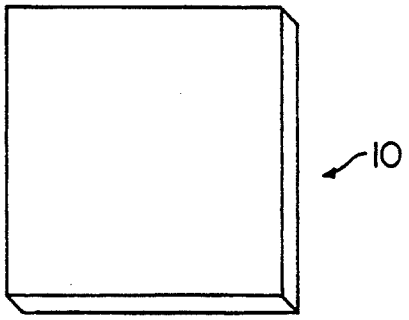


FIG. 2

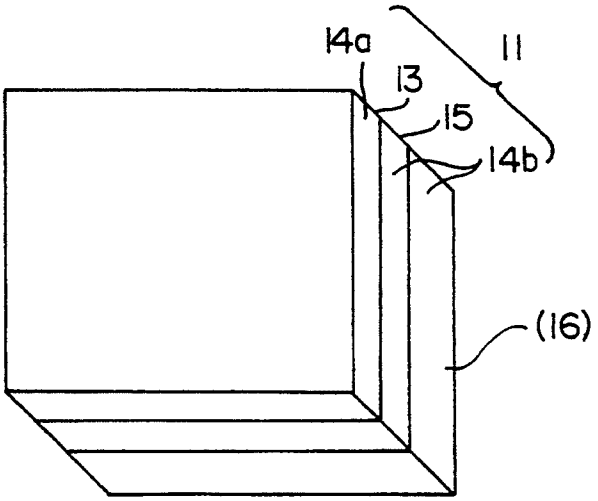


FIG. 3

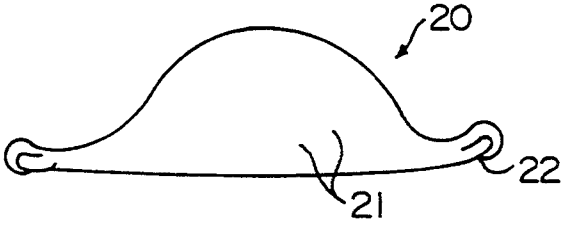
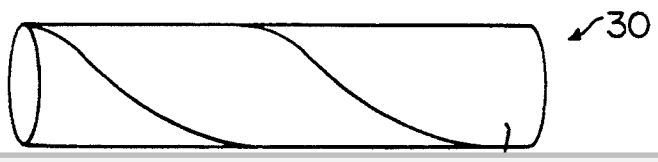


FIG. 4



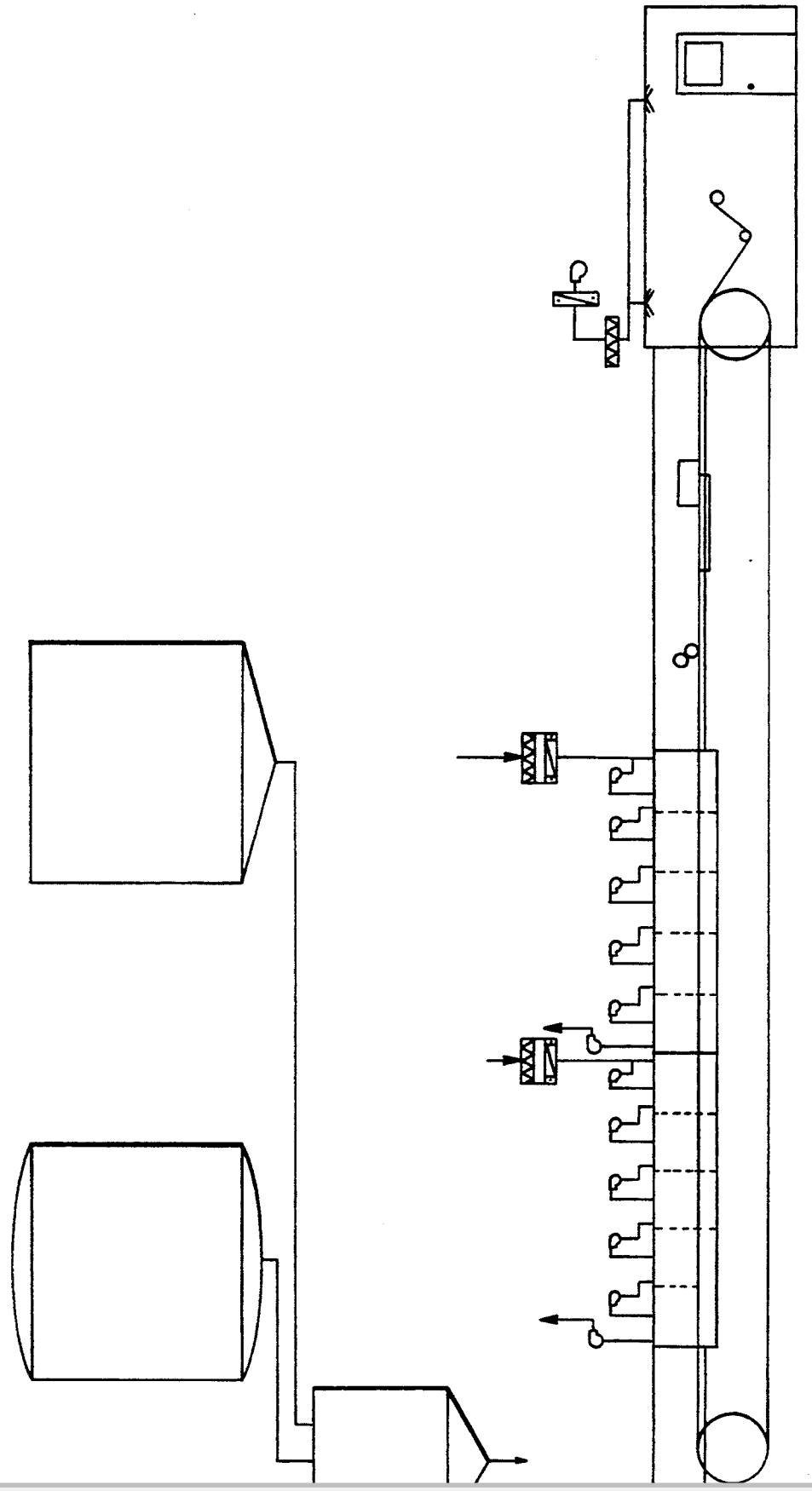


FIG. 5

DISSOLVABLE DEVICE FOR CONTRACEPTION OR DELIVERY OF MEDICATION

This application is a continuation-in-part of application Ser. No. 880,093, filed May 7, 1992, now abandoned.

FIELD OF THE INVENTION

This invention generally relates to a dissolvable device for use as a contraceptive or for internal delivery of medication, and more particularly, to films made of a safe, polymer material incorporating a spermicide and/or medication that is released by dissolution of the film over time. The films may be adapted for rapid dissolution (for example in 5–60 seconds) or for dissolution over prolonged periods (for example up to 12–24 hours).

BACKGROUND ART

Due to the growing awareness of medical complications associated with the use of oral contraceptives and intra-uterine devices, interest in other contraceptive methods has increased. Other contraceptive methods presently in use include diaphragms, sponges, cervical caps, spermicidal creams, foams, and suppositories for women, and condoms for men. Diaphragms and cervical caps usually require fitting by trained medical personnel, and must be refitted or replaced on a regular basis. Sponges take up a relatively large volume, which may result in a feeling of discomfort. Chemical barrier contraceptives such as creams, foams, jellies, tablets, and suppositories are often inconvenient and messy to apply and use, and in some cases cause irritation. Condoms are considered inconvenient to use during sexual activity and interfere with the sensation of the users, Thus, all such contraceptive methods in current use cause some inconvenience to users and detract from the users spontaneity or feeling of pleasure during sexual activity.

Moreover, it is often desirable to administer medication in the vagina or other internal areas of the body such as the mouth, rectum, nose, ear and eye. In the case of the vagina, medication can be administered, either in conjunction with use of a contraceptive device or separately. In the treatment of vaginal disorders, it is often desirable that the medication be applied throughout the areas of the vaginal tract and cervix over an extended period of time, for example, several hours or days. The remoter areas of the vaginal tract might not be readily reached by conventional vaginal suppositories due to the compact size and shape required for convenience of insertion. Also, because of the structure and shape of the vagina, inserted suppositories or tablets often do not stay in place, or, upon melting, the medication may drain out of the vaginal passage, thereby reducing the effectiveness of the applied medication. Medicated tampons also do not extend far enough or widely enough into the vaginal tract to deliver medication throughout the vaginal tract. Other types of rigid applicators have similar delivery problems and are uncomfortable to insert and use. Thus, under current methods, the desired medication may not be applied or maintained effectively in the vaginal tract for a sufficient period of time.

A recent commercial product is a contraceptive film sold under the name "VCF" by Apothecus, Inc., of Great Neck, New York. The VCF film is made of polyvinyl alcohol (PVA) and contains the spermicide called "Nonoxynol-9" and glycerine as a plasticizer material. However, the VCF film does not dissolve readily, and has poor stability in hot, humid environments. The texture of the film is relatively hard, and the film has a sharp edge. The film also delivers only 65 mg. of spermicide, which may be insufficient. It is also expensive to make and unlike a preferred embodiment of the present invention as illustrated in FIG. 3 infra, it has no capacity to be used as a barrier contraceptive.

More importantly, the VCF product suffers from deficiencies of all like prior art products in that it does not dissolve readily and in addition is not stable to prolonged storage at high temperature and high humidity, such as is generally encountered in numerous tropical third world countries as well as seasonally in more temperate climates. Such products become, under exposure to adverse humidity conditions, sticky and excessively hygroscopic. To resolve this problem, prior art devices, as typified by the VCF device, employ expensive protective packaging, such as foil-packs and the like. Such packaging greatly increases the cost of the product to the end user. The high cost discourages use in areas of the world where the product is most needed. Moreover, foil packaging increases package components and since the foils used are not readily decomposable in landfills, such packages have a disadvantaged environmental impact.

It should be noted that as used herein, high temperature means up to 140° F., high humidity means up to 99% relative humidity and prolonged storage means in excess of three years.

SUMMARY OF THE INVENTION

In accordance with the present invention, a device adapted for local administration of an agent material in an internal body area such as the vagina, rectum, oral cavity, nasal passages and the like, comprises a dissolvable element and an agent material carried in said dissolvable element, wherein said dissolvable element is made of dissolvable polymer material, particularly, a mixture of polyvinyl alcohol, polyethylene oxide, and/or complex carbohydrate material, which are selected such that the dissolvable element remains in solid form before use, and dissolves due to human body temperatures and moisture during use to release said agent material for local administration in the internal body area.

The preferred dissolvable element is a film made of polyvinyl alcohol, polyethylene oxide, and/or a complex carbohydrate material such as hydroxypropyl methyl cellulose which are safe, food-grade materials selected to obtain a desired release characteristic for the agent material. Two or more film layers may be combined as a laminate for compound release properties. Alternatively, a larger film layer or multiple laminates may be used as a barrier contraceptive. The dissolvable material may also be employed as an applicator tube for delivery of a contraceptive or delivery of medication or medical device. The dissolvable element dissolves within the body area so that it does not have to be physically removed after use. It can also dissolve completely when flushed away, so that no plumbing blockage or ecologically disturbing solid waste occurs.

The dissolution properties and texture of the dissolvable element may be modified by adding nitrogen or other suitable gases in forming the film, as well as the use of polyethylene oxide alone or in mixtures with polyvinyl alcohol and/or complex carbohydrate material. Forming the film in the invention with different

film layers or polymer materials allows varied dissolution properties. The polyethylene oxide and complex carbohydrate materials add lubricity to the product as an added benefit. The composition of the dissolvable element is selected to have an improved heat and humidity stability, feel, texture, and dissolution time (2 to 3 times quicker) as compared to the conventional VCF film. The VCF film does not use gases to modify dissolution properties, nor does it use polyethylene oxide or complex carbohydrate materials either alone or in combination with polyvinyl alcohol to modify dissolution or texture. As compared to the invention, the VCF film also does not employ a laminate of dissolvable films for compound release properties, and cannot be used as a barrier contraceptive.

It should be noted that heretofore, the significance of the addition of gases in the formation of the film to alter the texture and solubility of the film has not been recognized.

The active agent(s) may be incorporated into either the entire portion of the device i.e., as a homogeneous blend or in the case of a laminate, the device may include a layer of active material, the other layer or layers containing different active materials or have been selected with a view to the overall dissolution properties.

As a contraceptive device, the dissolvable film incorporates a spermicide and is inserted by hand or by means of an applicator or inserter into the vaginal tract adjacent to the cervix. The contraceptive film is safe and fully dissolvable. It can be made at substantially lower cost and does not have the problems of removal, cleaning, reuse, and/or refitting as compared to conventional diaphragms and sponges. Alternatively, the film may be molded with a dissolvable flexible rim like a conventional diaphragm for greater expansion and retention in the area of the cervix.

The dissolvable element may also be in tubular form as a vaginal tampon, the dissolvable device being inserted within the vaginal cavity using an applicator, or as a suppository, or ground as timed-release powders filled into other delivery devices. It can also be used to deliver medications such as anti-infectives, anti-inflammatories, coronary vasodilators, anesthetics, antitussives, expectorants, estrogenic, progestational, or prostaglandin agents, and the like. It may include fragrance, flavorants, coloring agents, preservatives, etc., to provide a more acceptable, environmentally sound product for consumers, as well as a plasticizer or gas additive for better handling, lubricity, and/or release characteristics.

Other objects, features , and advantages of the present invention will become apparent from the following detailed description of the best mode of practicing the invention when considered in conjunction with the drawings as follows:

DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic diagram of a dissolvable device in accordance/with the present invention in the form of a contraceptive film.

FIG. **2** shows a contraceptive device made of a laminate of film layers.

FIG. **3** shows a variation using the dissolvable film in a barrier contraceptive incorporating a dissolvable flexible rim for shape retention.

FIG. **4** shows a contraceptive or medication applicator formed by a roll of dissolvable film.

FIG. **5** is a flow sheet showing an embodiment of the process of the invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

In the invention, a dissolvable device for contraception or delivery of medication contains a dissolvable element made of a dissolvable polymer material, particularly, a mixture of polyvinyl alcohol, polyethylene oxide, and/or complex carbohydrate material, used for local administration of a spermicide and/or medication agent in an internal body area. The dissolvable polymer material is preferably a food-grade material safe for internal use. The dissolvable element is designed to be heat stable (e.g., up to 140° F.), and humidity stable (e.g., up to 99% relative humidity) so as to remain in substantially solid form and not begin dissolving before its intended use. Lubricity is another desirable property for use in the vagina and other internal (e.g., rectal) areas where sensitive tissues are likely to be encountered.

The preferred dissolvable element is in the form of a film made of the combination of grades of polyvinyl alcohol, polyethylene oxide, and/or complex carbohydrate material. Polyvinyl alcohol (PVA) is a preferred material for the film because it is non-toxic and medically safe to use internally. PVA comes in different grades that can be classified as cold water soluble (dissolves from 400 to 212° F.), intermediate dissolving (1100 to 212° F.), fully hydrolyzed (1400 to 212° F.), and superhydrolyzed (1800 to 212° F.). PVA is commercially available from companies such as Air Products Company, of Allentown, Pennsylvania. The cold water soluble and intermediate dissolving grades are the most useful for the desired moisture and heat- dissolving properties for contraceptive purposes. A particularly preferred cold water soluble grade of PVA is an 80% hydrolyzed polyvinyl alcohol having a molecular weight of 9,000–10,000; for intermediate solubility, an 87–89% hydrolyzed polyvinyl alcohol having a molecular weight of 13,000–23,000 for a slow dissolving, a 98–99% hydrolyzed polyvinyl alcohol having a molecular weight of 31,000–50,000 and for the least dissolving, a fully hydrolyzed 99% of polyvinyl alcohol having a molecular weight of 85,000–186,000 being preferred. All of the aforementioned polyvinyl alcohol preparations are available from Aldrich Chemical, Milkwaukee, Wis. However, in the invention, a film of the higher temperature or water soluble grade may be combined with a film of the lower temperature or water soluble grade in order to alter the temperature dissolution and moisture, solubility and stability properties so that the film can be used most suitably in the vaginal environment. The PVA material or materials are selected for contraceptive use to dissolve relatively quickly, e.g., over several minutes, or in some cases as low as several seconds. For use in delivering medications, the film composition may be selected for a longer release time, such as several days. In the case of medications to be administered via the oral cavity, it is advantageous that dissolution take place fairly rapidly.

Polyethylene oxide is another good material for the film because it has very good moisture, particularly humidity, stability and further is a food contact grade material. It is very compatible with the spermicide nonoxynol-9 and many other medications. It also has the added benefit of good lubricity, which makes the film structure even more comfortable to insert and use

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