



US005393528A

United States Patent [19]

[11] Patent Number: **5,393,528**

Staab

[45] Date of Patent: **Feb. 28, 1995**

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

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[21] Appl. No.: **68,778**

[22] Filed: **Jun. 1, 1993**

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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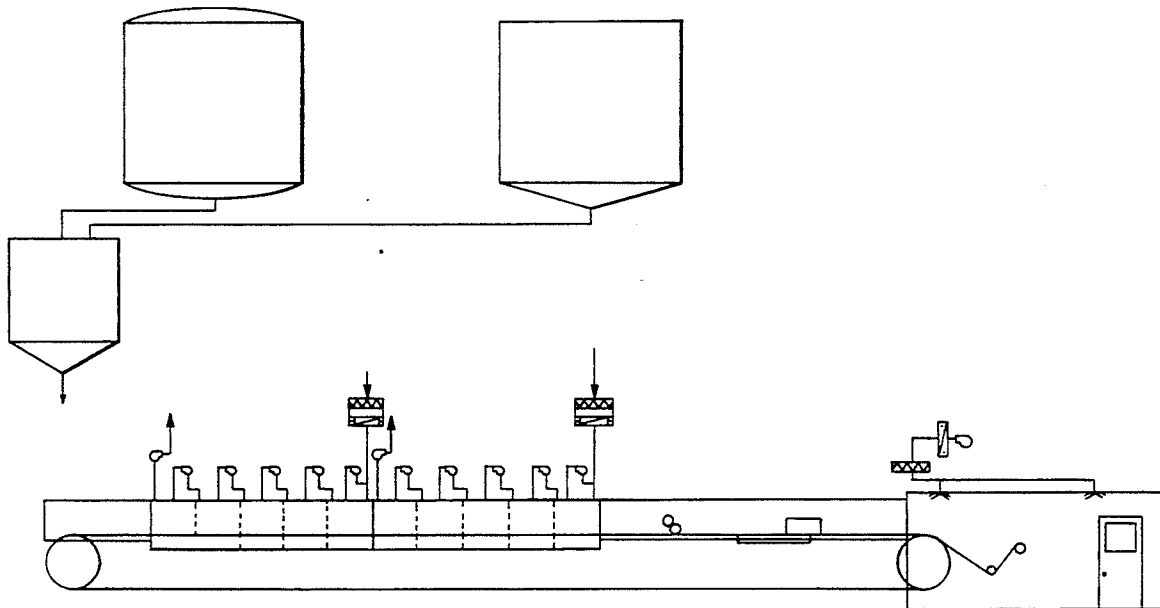
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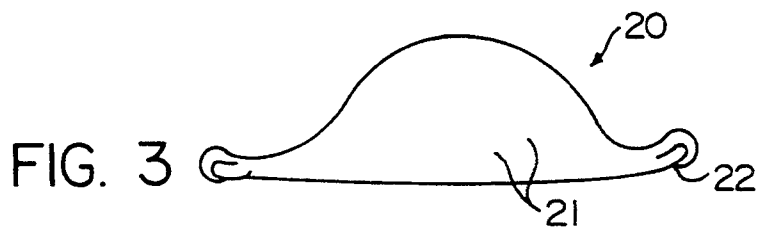
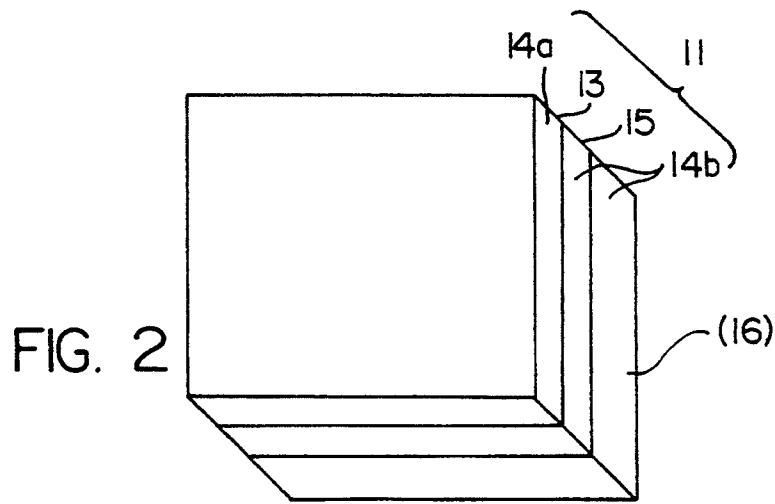
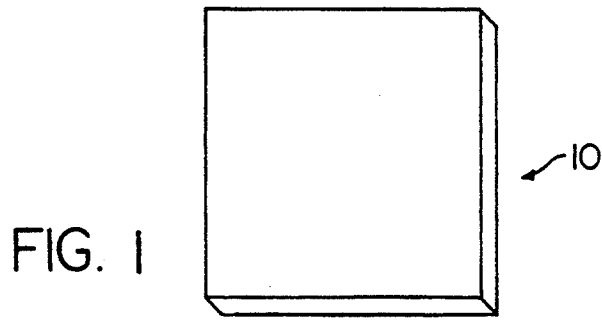
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[57] ABSTRACT

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





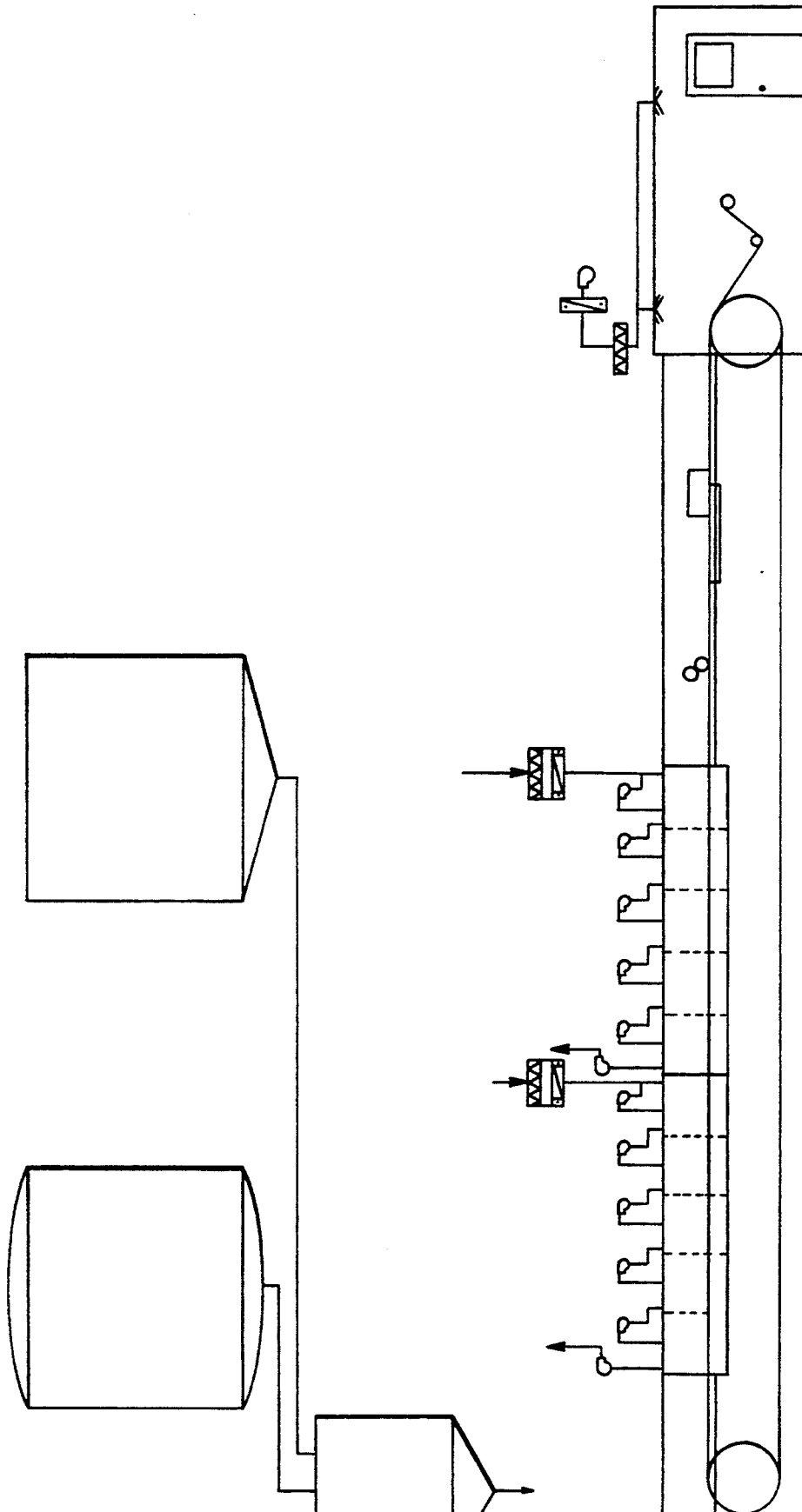


FIG. 5

DISSOLVABLE DEVICE FOR CONTRACEPTION OR DELIVERY OF MEDICATION

This application is a continuation-in-part of applica- 5
tion Ser. No. 880,093, filed May 7, 1992, now aban-
doned.

FIELD OF THE INVENTION

This invention generally relates to a dissolvable de- 10
vice 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 dissolu- 15
tion (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 complica-
tions 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 25
caps, spermicidal creams, foams, and suppositories for
women, and condoms for men. Diaphragms and cervi-
cal caps usually require fitting by trained medical per-
sonnel, and must be refitted or replaced on a regular
basis. Sponges take up a relatively large volume, which 30
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. Con-
doms are considered inconvenient to use during sexual 35
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 medica- 40
tion 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 separ- 45
ately. 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 50
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 55
stay in place, or, upon melting, the medication may
drain out of the vaginal passage, thereby reducing the
effectiveness of the applied medication. Medicated tam-
pons also do not extend far enough or widely enough
into the vaginal tract to deliver medication throughout 60
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 effec-
tively in the vaginal tract for a sufficient period of time.

A recent commercial product is a contraceptive film 65
sold under the name "VCF" by Apothecus, Inc., of
Great Neck, New York. The VCF film is made of poly-
vinyl 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 sper-
micide, 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 pro-
longed 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 expo-
sure to adverse humidity conditions, sticky and exces-
sively hygroscopic. To resolve this problem, prior art
devices, as typified by the VCF device, employ expen- 20
sive 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 compo-
nents and since the foils used are not readily decompos-
able in landfills, such packages have a disadvantaged
environmental impact.

It should be noted that as used herein, high tempera-
ture 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 dissolv-
able element and an agent material carried in said dissolv-
able element, wherein said dissolvable element is
made of dissolvable polymer material, particularly, a
mixture of polyvinyl alcohol, polyethylene oxide, and- 40
/or complex carbohydrate material, which are selected
such that the dissolvable element remains in solid form
before use, and dissolves due to human body tempera-
tures and moisture during use to release said agent mate-
rial for local administration in the internal body area.

The preferred dissolvable element is a film made of
polyvinyl alcohol, polyethylene oxide, and/or a com-
plex 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 com-
bined 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 com-
pletely when flushed away, so that no plumbing block-
age or ecologically disturbing solid waste occurs.

The dissolution properties and texture of the dissolv-
able 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 mater-
ial. 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, Milwaukee, 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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