

- [54] **TAMPONS IMPREGNATED WITH
CONTRACEPTIVE COMPOSITIONS**
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Md.
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3,108,043	10/1963	Somerville	128/270
3,108,043	10/1963	Millman	128/270 X
3,424,159	1/1969	Whitehead et al.	128/263
3,490,454	1/1970	Goldfarb et al.	128/285
3,521,637	7/1970	Waterbury	128/270
3,639,562	2/1972	Gordon et al.	128/270 X
3,679,102	7/1972	Charle	128/260 X
3,749,094	7/1973	Duncan	128/270
3,756,238	9/1973	Hanke	128/270
3,850,173	11/1974	Dash	128/261

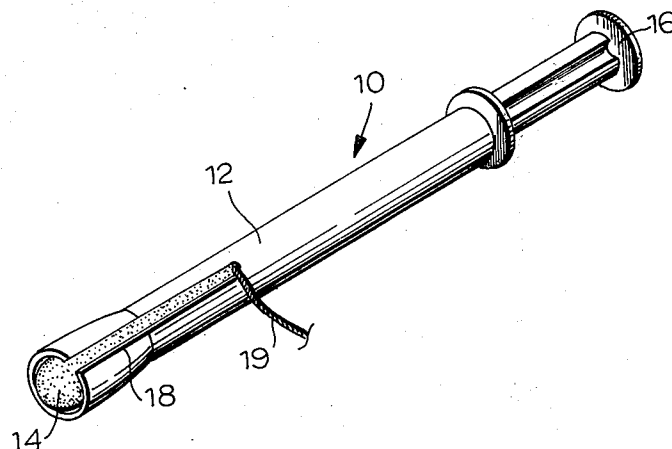
- [52] **U.S. Cl.** **128/270; 128/260; 128/263;**
424/16
[51] **Int. Cl.²** **A61F 13/20; A61K 7/00**
[58] **Field of Search** **128/260, 270, 285, 290 R,**
128/268, 263, 261; 424/16, 45

Primary Examiner—Aldrich F. Medbery
Attorney, Agent, or Firm—Sherman & Shalloway

- [56] **References Cited**
UNITED STATES PATENTS
702,570 6/1902 Lohlein 128/263
2,943,979 7/1960 Elias 424/16
3,091,241 5/1963 Kellett 128/270

[57] **ABSTRACT**
Vaginal sponges and/or tampons impregnated with contraceptive compositions and methods of preventing conception or implantation by insertion in an animal organism of said sponge or tampon prior to exposure to conception.

3 Claims, 5 Drawing Figures



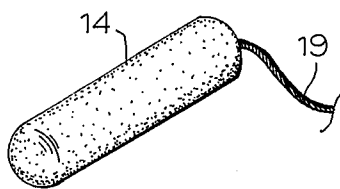
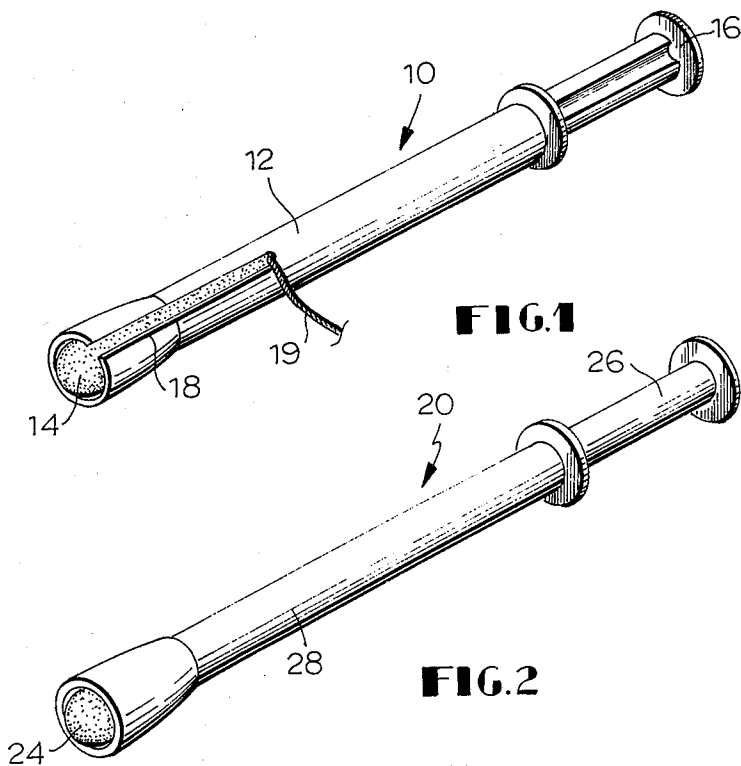


FIG. 3

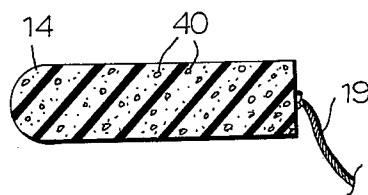


FIG. 4

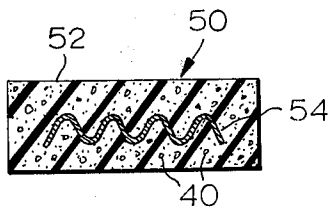


FIG. 5

TAMPONS IMPREGNATED WITH CONTRACEPTIVE COMPOSITIONS

BACKGROUND OF THE INVENTION

This invention relates to novel contraceptive means and to methods for preventing conception by implantation by employing such means. More specifically, this invention relates to novel sponges and/or tampons which are impregnated with contraceptive compositions. Preferably, the contraceptive compositions are encapsulated in a microcapsule which is either rupturable, soluble, or a mixture thereof.

DESCRIPTION OF THE PRIOR ART

It has long been an object of the pharmaceutical industry to discover a safe and effective method of preventing conception which can be utilized pre-coitus that is non-interfering and easy to use.

Heretofore, it has been known to impregnate tampons with an abortive facient, such as prostaglandin, in order to terminate a conception in the very early states of the "pregnancy."

Additionally, prior art methods are known for preventing conception by utilization of vaginal foams or creams containing contraceptive compositions. The prior art means of preventing conception are either inconvenient to use or have physiological or psychological drawbacks once pregnancy has begun.

U.S. Pat. No. 3,105,128 shows a method of microencapsulation.

U.S. Pat. No. 3,691,271 shows a sanitary napkin with microcapsules filled with a bactericidal and fungicidal deodorant.

U.S. Pat. No. 3,814,809 shows the combination of a suppository and tampon with a contraceptive drug for use after exposure.

SUMMARY OF THE PRESENT INVENTION

It is a general feature of the present invention to avoid and overcome the foregoing and other difficulties and objections to prior art contraceptive means by the provision of a more effective and generally acceptable means. More specifically, a feature of the present invention is to provide a vaginal sponge or tampon which is impregnated with a known safe and effective contraceptive composition.

Further, another feature of the present invention is to provide a vaginal sponge or tampon which is impregnated with a contraceptive drug that is microencapsulated so that there is a sustained release of the contraceptive composition before, during and/or after coitus.

It is still another feature of the present invention to provide a means for insertion of the sponge or tampon into the vagina which can be packaged as a single unit.

A yet further feature of the present invention is to provide a means for housing the impregnated sponge or tampon, inserting the sponge or tampon and, if desired, removing the sponge or tampon from the vagina.

The aforesaid features of the present invention, and other features which will become apparent as the description proceeds, are accomplished by providing a vaginal sponge or tampon that is impregnated, preferably with a microencapsulated contraceptive composition. The vaginal sponge or tampon is preferably compressed and prepackaged in an elongated housing having a plunger for insertion into the vagina. Microcap-

sules which may be used are those which provide a sustained release and/or those which are pressure rupturable. The contraceptive composition may include any of the known steroidal or non-steroidal compounds.

A method having certain features of this invention includes the step of inserting and maintaining in the vagina a sponge or tampon impregnated with a contraceptive composition, preferably a composition which is microencapsulated.

DETAILED DESCRIPTION OF THE PRESENT INVENTION

For a better understanding of the present invention, reference should be made to the accompanying drawings, wherein like numerals indicate similar parts throughout the several views and wherein:

FIG. 1 is a perspective view of a tampon and applicator in accordance with this invention.

FIG. 2 is a perspective view of a further applicator and tampon of the present invention.

FIG. 3 is a perspective view of a tampon of this invention.

FIG. 4 is a cross-sectional view of the impregnated tampon of FIG. 3.

FIG. 5 is a cross-sectional view of an impregnated sponge having a spring means.

PREFERRED EMBODIMENTS OF THE PRESENT INVENTION

In accordance with one embodiment of the present invention, there is provided an applicator 10 having a housing 12 in which an impregnated tampon 14 is compressed and contained in the front end portion. The applicator 10 is provided with a plunger 16 which is movable in the housing 12 so as to eject the tampon 14 from the housing 12. If the tampon 14 is provided with a means for removal, such as a string 19, the housing 12 may be provided with a slot 18 so as to accommodate the string.

FIG. 2 illustrates a further embodiment of the invention wherein there is provided an applicator 20 having a housing 28 containing an impregnated tampon 24 in the front end portion. The applicator 20 is provided with a plunger 26 which ejects the tampon 24 and is capable of providing a vacuum suction so as to withdraw the tampon when desired.

FIG. 3 shows the tampon prior to compression and insertion into the applicator shown in FIG. 1. The tampon comprises any of the known cellulosic tampons that are well known in the art. The tampon includes those which contain the conventional polyurethane foams, the reaction product of liquid polyols (polyester or polyether) and a disfunctional isocyanate, usually toluene diisocyanate. A catalyst such as tin, an amine, a flowing agent, generally water, and foaming stabilizers are also employed. The required cylinders for tampon use are cut from the prepared foam. The string 19 is provided for removal of the tampon either pre- or post-coitus.

FIG. 4 is a cross-sectional view of the tampon of FIG. 3 showing the microencapsulations 40. The microcapsules used in the present invention can be made of any conventionally employed material in the microencapsulation field. Representative of polymeric materials to produce the microcapsules are such polymers as polyvinyl alcohol, polyethylene, polypropylene, polystyrene, polyacrylamides, polyethers, polyesters, polyam-

ides, polybutadiene, polyisoprene, epoxy resins, polyurethanes, ethyl cellulose, carboxymethyl cellulose and the like. The nature and the size of the walls will be generally chosen for their compatibility with the contraceptive composition used. Generally, the ratio of the weight of the wall to the total weight of the filled microcapsule ranges from between 3-10:100.

Any conventional technique of microcapsule fabrication can be used, particularly microencapsulation by mechanical means such as centrifugal microencapsulation. In this method, droplets of the material to be microencapsulated are formed by the centrifugal force of a turntable which then traverse by means of the velocity with which they thus acquire a thin film of fluid product designed to form the wall of the microcapsule. Conventional wall-hardening treatment can be employed which, in a case where the wall is prepared from a thermoplastic material, can simply be a sudden cooling of the microcapsules formed. Representative suitable microencapsulation operation can be found in the literature, for instance U.S. Pat. No. 3,015,128.

The material encapsulated in the microcapsules can be, for instance, such contraceptive compounds as nonylphenoxypolyethoxyethanol and an estrogenic compound such as 3-methoxy-19-nor-17 α -pregna-1,3,5(10)-trien-20-yn-17-ol; 19-nor-17 α -pregn-4-en-13 β , 17 diol and the like.

FIG. 5 is a cross-sectional view of a vaginal sponge 50 which comprises preferably a cellular resilient material 52 having therein a spring 54 for maintaining the sponge in an expanded state. The sponge 52 may comprise any of the known water-resistant cellular matter such as cellulosic sponge, polyurethane, polyesters, and the like which are compatible with the body. The sponge 50 contains throughout the microcapsules 40 containing the contraceptive material. The size and composition of the capsule wall is preferably varied in solubility and rupturability so as to provide a sustained release during usage. Additionally, the microcapsules may contain in addition to the contraceptive compositions any spermicide which is known in the art. The microencapsulation permits the utilization of known compatible compositions simultaneously.

The method in accordance with this invention comprises inserting in the animal organism one vaginal tampon which is impregnated with a contraceptive composition and/or spermicidal composition between one hour and twenty-four hours prior to exposure. As stated above, the contraceptive has a sustained release in the vagina during and after coitus so that any externally inserted fluids, such as semen resulting from coitus, will be exposed to the contraceptive compositions and any accompanying spermicide released by the rupturability and solubility of the micro capsules 40 in the normal mucosa fluid present in the vagina.

Obviously, the dosage form will depend upon the contraceptive composition employed, besides that the microcapsules generally have a size ranging from about 50 - 1,000 microns in diameter. The thickness of the wall of the microcapsule will vary according to the materials used and to the effect desired.

The microcapsules are introduced either directly into the sponge or tampon at a moment in which its fluidity is still sufficient, the density of the microcapsules more-over being close to that of the liquid phase, and/or they are introduced by spraying when it is desired to incor-

porate them before termination of the polymerization of the sponge.

In general, microcapsules are introduced into the sponge or tampon in the course of manufacture in the form of a liquid or suspension; the best possible homogenization is obtained by suitable mixing by agitation, shaking or blowing in of a gas. The density of the liquid or of the suspension is then adjusted to that of the microcapsules by addition of a suitable inert substance. It is also possible to select microcapsules whose density corresponds to that of the liquid or suspension at the time of their introduction into the sponge or tampon. The following non-limiting examples, in which parts and percentages refer to weight, are given by way of illustration and allow a fuller understanding of the present invention.

EXAMPLE I

Tampon containing a microencapsulated contraceptive composition:

The following contraceptive composition is prepared:

Contraceptive Compound	4.0
Vaseline	6.0
Glycerol	10.0
Anti-ferment	0.1
Water to make-up	100.0

The contraceptive composition is then microencapsulated by the known technique, using polypropylene, the microcapsules having an average diameter of 50-100 microns and preferably 60-80 microns. Microcapsules are dispersed either by a suitable mechanical device or by projection using compressed air or gas.

The contraceptive compound may be any of the known estrogenic agents such as Enovid (Trademark).

EXAMPLE II

The sponge containing microencapsulated contraceptive composition:

The following solution is prepared:

Glycerin	5.00
Contraceptive Compound	10.00
Oxytoxin	0.50

This composition containing the contraceptive composition is then microencapsulated by any known technique, utilizing ethyl cellulose or polyvinyl acetyl, the microcapsules having a size between 50-100 microns, preferably 60-100 microns.

The sponge is then impregnated by forming the microcapsules into a suspension and then blowing into the sponge using compressed air or gas.

Additionally, the microcapsules prepared according to Example I may be introduced so as to have a variable and sustained contraceptive action.

EXAMPLE III

The following composition is prepared:

Spermicide	10.00
Glycerine	10.00
Sodium Lauryl Sulfate. Solution (30%)	30.00

This composition containing the spermicide is then microencapsulated utilizing polyvinyl alcohol by any

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known technique and mixed with the microcapsules of Example I and blown into a sponge or tampon.

If desired, in addition to the microencapsulated compositions, the vaginal sponge or tampon may be surface coated or impregnated with a contraceptive composition dissolved or suspended in a melt of a low-melting, biodegradable wax. The wax with the contraceptive compound incorporated is then either powdered or the melt is poured over a cold surface and a waxy material scraped off in the forms of powder or flakes. Among the vehicles for slow release of the contraceptive composition in biological fluids are acetyl palmitate, carbona wax, lauric acid, a mixture of sodium laurate and lauric acid, a mixture of stearic acid and sodium stearate, a mixture of archidonic acid and sodium archidonate and acetyl palmitate.

Obviously, the embodiments shown are exemplary only and a wide variety of embodiments may be devised without departing from the spirit and scope of the invention.

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What is claimed is:

1. The method of preventing conception or implantation which comprises inserting into the vagina of a mammal a sponge tampon impregnated with microcapsules having a contraceptive composition prior to exposure to exteriorally inserted fluids and permitting said sponge tampon to remain in the vagina until at least an effective amount of said composition is released and leaving the sponge tampon in the vagina at least during the insertion of said exterior fluids so as to prevent conception or implantation from said fluids.

2. The method of claim 1 wherein said composition is microencapsulated in a sustained release form and said composition is caused to be released by the biological muscosa fluid.

3. The method of claim 1 wherein said microcapsules include a spermicide and said spermicide is released with said contraceptive composition.

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