

[54] METHOD FOR BIRTH CONTROL

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Related U.S. Application Data

[62] Division of Ser. No. 190,780, Oct. 20, 1971, Pat. No. 3,779,241.

[52] U.S. Cl. 128/130; 128/129; 128/260

[51] **Int. Cl.²** A61F 5/46

[58] **Field of Search** 128/127, 128, 129, 130,
128/131, 260, 268

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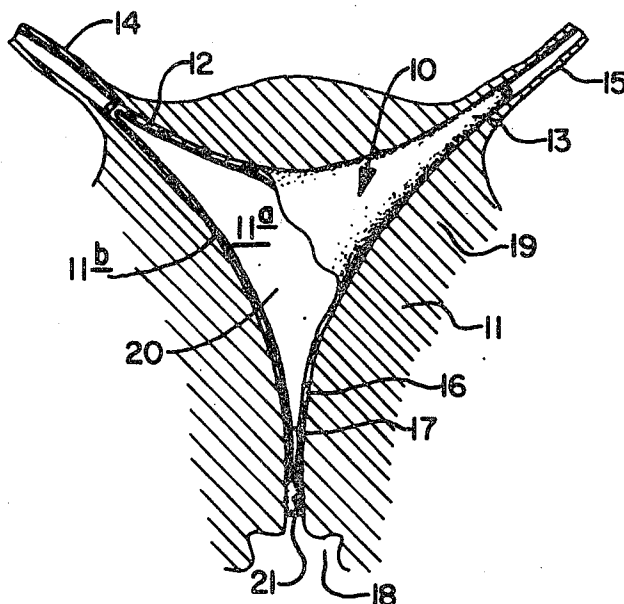
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[57] **ABSTRACT**

A method and apparatus for birth control utilizing an intrauterine contraceptive device which includes a preformed, hollow body with thin, flexible walls, the hollow body having the approximate size and shape of the uterine cavity. A flexible, compressible, filler material substantially completely fills the hollow body so that the walls of the hollow body make contact with a major portion of the walls of the uterine cavity when the device is in position within the uterine cavity. In a preferred form, the hollow body is filled with a polymerizable organosiloxane material after being placed in the uterine cavity and the material is then polymerized to produce a device having substantially the size and shape of a normal uterine cavity.

5 Claims, 12 Drawing Figures



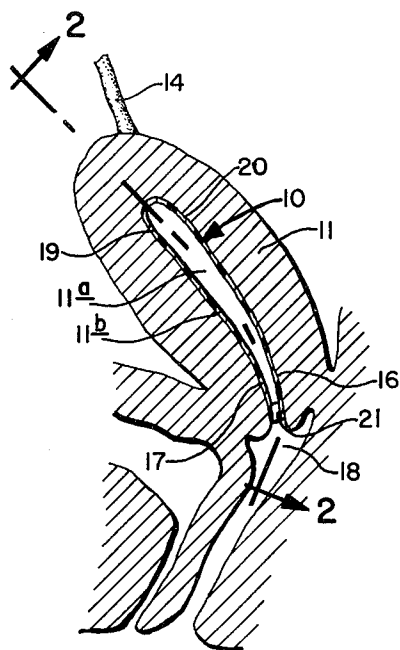


FIG. 1.

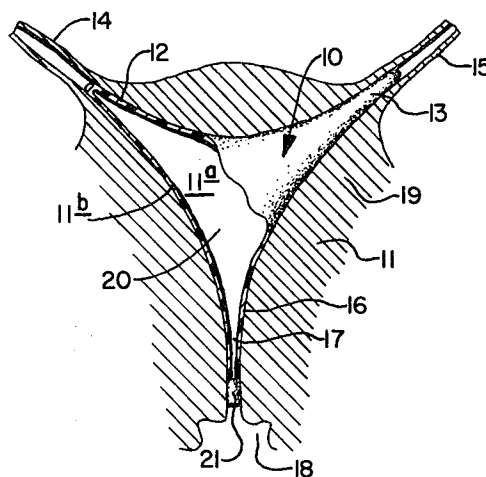


FIG. 2.

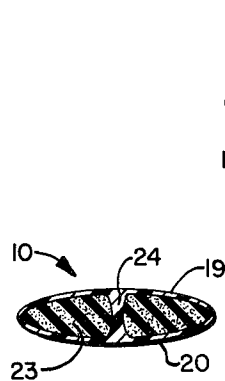


FIG. 4A

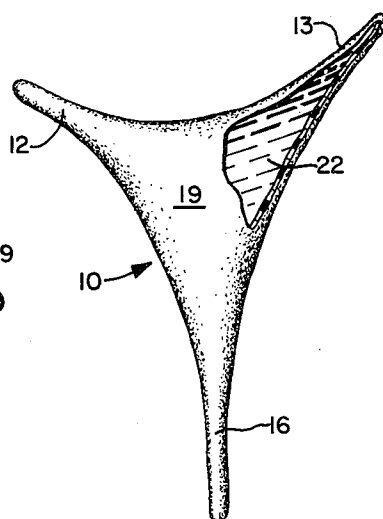


FIG. 3.

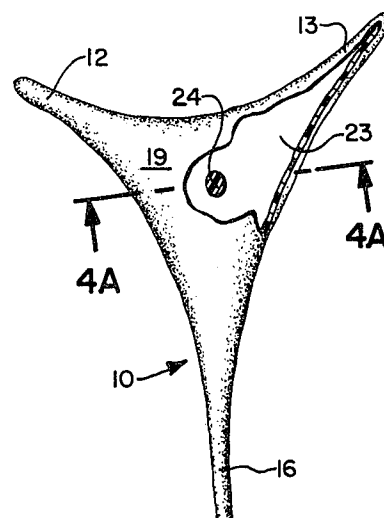


FIG. 4.

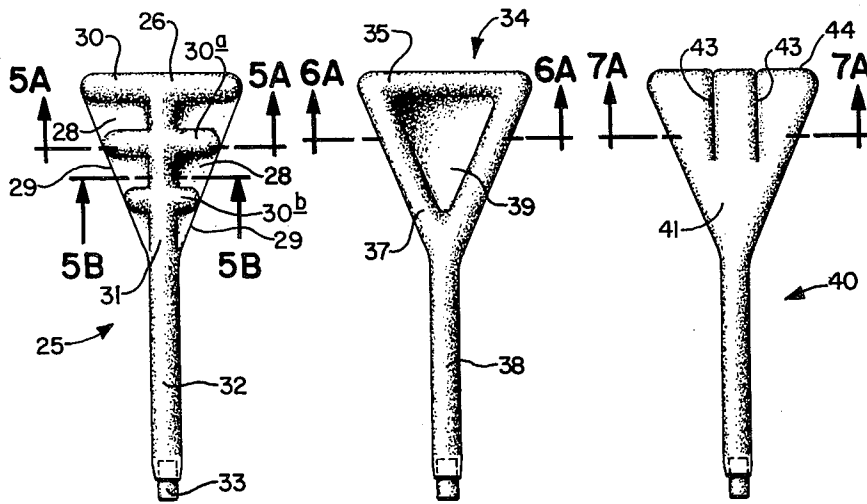


FIG. 5.

FIG. 6.

FIG. 7.

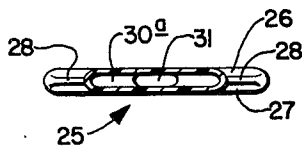


FIG. 5A.

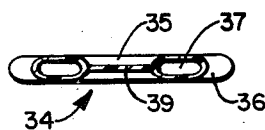


FIG. 6A.

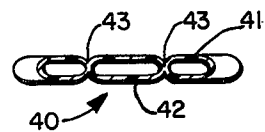


FIG. 7A.

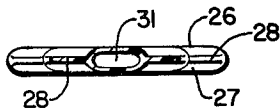


FIG. 5B.

METHOD FOR BIRTH CONTROL

This is a division of application Ser. No. 190,780, filed Oct. 20, 1971, now U.S. Pat. No. 3,779,241.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates, in general, to a method and apparatus for birth control utilizing a novel intrauterine contraceptive device.

2. Description of the Prior Art

Intrauterine contraceptive devices are well known in the art and have been in wide use for many years. The devices are fabricated from many different materials and take the form of spirals, loops, bows, rings, etc., as exemplified by devices known as the Lippe's loop, Margulie's spiral, Birnberg bow and the Grafenberg ring. Very early devices were made from silver metal; however, their use has declined and thermoplastic material has replaced the former metal structures.

Many of the prior art intrauterine contraceptive devices suffer from two principal deficiencies which have prevented their widespread adoption by the medical profession. In very early work with intrauterine contraceptive devices, it was discovered that the natural contractions of the uterine cavity would expel the earlier devices from the uterus and lead to unwanted pregnancies when the female was unaware that the device had been expelled. This led to designing the intrauterine devices into very elaborate configurations in order to permit compression and collapse for insertion through the cervix into the uterus and subsequent expansion in the uterus to assume a form which would not be easily expelled by the natural muscle contractions. The second problem associated with the prior art intrauterine contraceptive devices has been the tendency of these devices to produce physiological complications in the patient. Many women are unable to accommodate intrauterine contraceptive devices because of inflammation and irritation and sometime bleeding which occurs in certain patients.

A recent study of IUD's by E. J. David, M.D., and John Lesinski, M.D., has been published in Volume 36, No. 3, September 1970 issue of *Obstetrics and Gynecology* entitled "Mechanism of Action of Intrauterine Contraceptives in Women." The conclusion is reached in this article that the contraceptive efficacy of devices molded of plastic materials of similar composition correlates with the total surface area of the plastic article coming in contact with the endometrium, irrespective of the variations in geometric design. Further, the authors observed that chemical composition of the device significantly influences pregnancy rates when the rates accompanying devices of identical size, shape and surface area are compared. In the studies conducted, it was found that an IUD constructed in the form of a shield had the lowest percent pregnancy rate of any of the comparative devices tested, e.g., a "B" loop and a double coil. Efficiency for this shield-shaped IUD was 98.9 percent pregnancy prevention. While the device disclosed in the foregoing study is an improvement over prior art IUD's, nevertheless, there exists the problem of placing the device within the uterus. Because of its size and configuration, it is difficult to collapse the device into a sufficiently small size to permit convenient insertion through the dilated cervical canal. Further, after entry, opening the device and positioning it prop-

erly between the walls of the uterus presents significant problems.

Therefore, there is a need in the IUD art to provide a device which can contact as much of the uterine wall area as possible and yet permit easy placement within the uterus and easy withdrawal therefrom, if it is desired to remove the device.

SUMMARY OF THE INVENTION

10 It is an object of the present invention to provide an intrauterine contraceptive device which provides maximum surface area contact between the walls of the device and the walls of the uterus.

15 It is a further object of the present invention to provide an intrauterine contraceptive device which may be readily placed in the uterus and also readily removed therefrom.

20 It is also an object of the present invention to provide an intrauterine contraceptive device which has a shape substantially the same as that of the uterine cavity.

It is still another object of the present invention to provide an intrauterine contraceptive device which is flexible and compressible so as not to produce significant irritation of the walls of the uterus.

25 The foregoing objects are realized in an intrauterine contraceptive device which includes a preformed hollow body having thin, flexible walls which have the approximate size and shape of the uterine cavity. A flexible, compressible, filler material substantially completely fills the hollow body, whereby the walls of the hollow body will make contact with a major portion of the walls of the uterine cavity when the device is positioned in the uterine cavity.

30 The method aspects of the present invention are realized in a method of birth control comprising the steps of positioning a preformed, hollow body having thin, flexible walls within the uterine cavity and expanding said body to substantially fill the cavity.

35 The intrauterine contraceptive device of the present invention overcomes the disadvantage found in prior art devices by providing maximum contact between the IUD and the walls of the uterus. The IUD of the present invention also overcomes the difficulty of fitting IUD's to various women having uteri of significantly different sizes. By preparing the IUD of the present invention in the form of a flexible, thin wall, hollow body shaped like the uterus, the device, when placed in the uterus and filled, is made to substantially fit the contours of the uterus and substantially fill the same. By forming the hollow body portion of the IUD of the present invention out of thin wall, flexible, soft, collapsible, polymeric material, e.g., natural rubber or silicone rubber, the hollow body can be folded or collapsed for easy insertion into the uterus through the cervical passage. By 40 utilizing either a removable filler material, such as air or water, or a solid filler material which is easily compressed, such as a foamed elastomeric material, the IUD of the present invention can be easily withdrawn from the uterus.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a side, elevational, sectional view of the human female reproductive organs showing one embodiment of the IUD of the present invention in place in the uterus;

FIG. 2 is a plan, sectional, partially broken view of FIG. 1 taken along the line 2—2;

FIG. 3 is a perspective, elevational, partially broken view of another embodiment of the IUD of the present invention;

FIG. 4 is a perspective, elevational, partially broken view of still another embodiment of the IUD of the present invention;

FIG. 4A is a cross-sectional view of FIG. 4 taken along line 4A—4A;

FIG. 5 is a plan view of a further embodiment of the IUD of the present invention;

FIG. 5A is a cross-sectional view of FIG. 5 taken along line 5A—5A;

FIG. 5B is a cross-sectional view of FIG. 5 taken along line 5B—5B;

FIG. 6 is a plan view of a still further embodiment of the IUD of the present invention;

FIG. 6A is a cross-sectional view of FIG. 6 taken along line 6A—6A;

FIG. 7 is a plan view of a different embodiment of the IUD of the present invention; and

FIG. 7A is a cross-sectional view of FIG. 7 taken along line 7A—7A.

Description of the Preferred Embodiments

Referring now to FIGS. 1 and 2, one embodiment of the intrauterine contraceptive device of the present invention includes a hollow body, designated generally by the numeral 10, which is shown in its expanded or inflated position in the uterus 11. When inflated by filling with a fluid medium, the hollow body substantially completely occupies the uterine cavity 11a and makes contact with the walls 11b of the uterus. The hollow body 10 includes a thin, flexible top wall 19 and a bottom wall 20. When inflated, the hollow body generally has the shape of an equilateral triangle having generally parabolic sides. The hollow body includes two spaced apart, substantially equal length, left and right leg portions 12 and 13 which project into the "horns" or the respective left and right Fallopian tube entrances 14 and 15. The lower neck portion 16 of the hollow body is elongated and is received in the cervical canal 17. The lower end of the neck portion terminates in the cervical canal just short of its entrance into the vagina 18. A plug 21 made of soft elastomeric material, which may be integrally formed on the end of neck 16, closes the open end of neck portion 16 and permits the collapsed, hollow body to be inflated by means of a hypodermic needle and syringe.

Another embodiment of the IUD of the present invention is shown in FIG. 3. The hollow body 10 in this embodiment is filled with a liquid material 22 in place of a gaseous medium used in the embodiment shown in FIGS. 1 and 2. The liquid filling material may be any suitable sterile liquid such as water, mineral oil, medical grade silicone fluids, saline solutions, or any other non-toxic sterile liquid.

In another embodiment of the invention, the fluids used to fill the hollow body have dissolved or suspended therein suitable concentrations of bacteriostatic agents or medicants, and the hollow bodies are made of a liquid-permeable film so that a very gradual release of the fluid from the hollow body to the uterus occurs. Among suitable bacteriostatic materials are 2,2'-thiobis-(4,6-dichlorophenol) (sold under the trademark "Actomer" by Monsanto Chemical Company) and 2,2'-methylenebis(3,4,6-trichlorophenol) (sold under the trademark "Hexachlorophene" by Sindar

Corporation). Suitable medicants are the penicillins and the sulfa drugs. Other bacteriostatic agents and medicants may also be used.

In a further embodiment of the present invention, the bacteriostatic agents or medicants may be incorporated into the film-forming material of the hollow bodies, e.g., by mixing with the plastic material prior to forming the hollow body (see U.S. Pat. No. 2,919,200) or by impregnating the hollow body after being formed.

A still further embodiment of the present invention is to incorporate natural and synthetic fragrances in the fluids contained within the liquid-permeable hollow body.

Still another embodiment of the IUD of the present invention is shown in FIGS. 4 and 4A. The preformed body 10 is first collapsed or folded and inserted into the uterus. The body is then filled by means of a hypodermic syringe and needle with a liquid-curable or polymerizable material, such as a prepolymer or a monomer containing a curing agent or polymerization catalyst. The material is then allowed to cure or polymerize to provide a solid or cellular, flexible, compressible filler insert having the exact shape of the uterus. As seen in FIG. 4A, the filler insert 23 is formed of a cellular material produced by adding any suitable foaming agent to the liquid material used to form the filler insert. Preferred are foaming agents which have boiling points slightly below the normal temperature of the human body, i.e., below 98.2°F, such as isopentane, n-butane, dimethyl ether, diethyl ether, ethyl chloride, 2,2'-azobis(2,4-dimethylvaleronitrile), and others.

The upper wall 19 and the lower wall 20 of the hollow body may be joined by an integrally formed connector stem or rib 24 as seen more clearly in FIG. 4A. This stem or rib prevents excessive thickening of the IUD so that the entire IUD may be removed from the uterus through the cervical canal 17 when dilated. It has been observed that the muscle tone of the upper and lower wall sections of the uterus is weakened in women who have experienced multiple childbirth. This condition results in the filler material assuming an undesirable, semi-spherical, cross-sectional shape rather than the desired elliptical, cross-sectional shape, as shown in FIG. 4A. The stem or rib 24 prevents undue thickening of the IUD in those uteri having poor muscle tone.

As seen in FIGS. 1—4A, the IUD of the present invention, when expanded with a filling material, will have its maximum thickness at the mid-portion thereof where the uterus has its normal maximum diameter. The depiction of the IUD of the present invention, as seen in FIGS. 1—4A, represents an average of the shape that the device is expected to assume; however, it is understood that the final shape of the IUD of the present invention will be determined solely by the shape of the individual uterus in which the device is placed, or in part by the length of the stem 24 when this form of the IUD is utilized.

In FIGS. 5, 5A and 5B, another embodiment of the IUD of the present invention is depicted. The hollow body, or envelope, 25 is formed from a thin wall, flexible material and has a top wall 26 and a bottom wall 27. The top and bottom walls are welded together, as by being integrally formed, in a plurality of spaced apart, generally rectangular sections 28 which extend inwardly from the side edges 29—29 of the body 25. Top, intermediate and bottom, hollow, transverse channels

30, 30a and 30b are provided in body 25 between the fused top and bottom wall areas. These transverse channels intersect a longitudinal channel 31 which is an extension of the bore defined by the stem 32 of the hollow body. The stem is closed by plug 33.

The hollow body 34, as seen in FIGS. 6 and 6A, has the same general shape as that of hollow body 25, but is provided with a centrally located area 39 which has the shape of an equilateral triangle wherein the top and bottom walls 35 and 36 are fused together. A triangularly shaped, hollow channel 37 surrounds the fused area 39 and joins the bore provided in stem 38.

In FIGS. 7 and 7A, another embodiment of the hollow body 40 is shown wherein top wall 41 and bottom wall 42 are joined together along spaced-apart, parallel lines 43—43 which extend inwardly from the top edge 44 of the body.

In all of the embodiments shown in FIGS. 5-7A, the fused portions of the top and bottom walls limit transverse expansion of the hollow body when the hollow body is expanded in the uterus by filling with the selected filling material, e.g., water, air, silicone rubber. However, the constructions still provide for a substantial contact between the wall areas of the IUD's and the walls of the uterus which has been determined to be directly related to the efficiency of an IUD in preventing pregnancy. The top and bottom walls of the IUD's of the present invention may be joined by any suitable means at any number of points.

The hollow body portion of the IUD may be made from any suitable material which is non-toxic, flexible, and capable of forming a reasonably strong, thin film. Among suitable materials for forming the hollow body are silicone rubbers (organosiloxane polymers), synthetic rubbers, natural rubbers, polyethylene, polypropylene, plasticized polyvinyl chloride, plasticized polyvinylidene chloride, polyvinyl alcohol, polyesters, polyethers, polyvinyl acetate, polyethylene oxide, polyurethanes, polyvinyl pyrrolidone, and water soluble polystarches and polycellulosics.

The hollow body can be formed by fusing thin sheets of the material precut in the desired shape of the hollow body. A preferred method for forming the hollow body when using elastomeric type materials is by dipping a mold having the desired shape into a latex solution and curing the latex which adheres to the mold. Rotational molding using hollow molds of the desired shape can also be used. Resin monomers and prepolymers may also be used to form the hollow body by coating a mold having the shape of the walls of the uterus and then polymerizing the monomer or prepolymer.

When it is desired to use a solid or semi-solid filler material for the IUD, these filler materials may be formed in situ in the hollow body after placing the hollow body within the uterus by curing any curable material which produces a soft, elastomeric polymer. It is preferred that the filler material be formed of a non-irritating, flexible, elastomeric material, particularly one prepared from a polyorganosiloxane material. Among the preferred materials are the medical grade silicone rubber prepolymers marketed by Dow-Corning under the trade name "Silastic." In certain applications, Dow-Corning medical adhesive Type A may be used as the prepolymer and catalyzed to provide the polymerized, finished IUD device. The preferred material for forming the filler material of the IUD of the present invention is Dow-Corning's Silastic RT-382

which is a room-temperature-curing silicone rubber or prepolymer. The viscosity of Silastic RT-382 can be reduced by mixing with Dow-Corning RTV thinner (dimethyl silicone fluid) to achieve the desired viscosity for injecting the prepolymer into the hollow body using a hypodermic syringe.

In the method of the present invention, the deflated hollow body 10 is rolled into a tubular conformation or otherwise folded into a compact tubular shape. It is then placed in a hollow insertion device for insertion into the uterus through the vagina and cervical canal. U.S. Pat. No. 3,509,877 discloses a suitable insertion device and its disclosure is hereby incorporated by reference. After placement in the uterus, the hollow body 10 is inflated by piercing plug 18 with a hypodermic needle and forcing the selected filler material through the needle from a filled hypodermic syringe. To remove the device when it is filled with a gas or a liquid, the operation described above is reversed to empty the hollow body and permit its collapse for easy withdrawal. The neck 16 can then be grasped with a suitable instrument and the device removed through the cervix, which may be dilated if necessary. When a solid or semi-solid filler is used, it is recommended that the cervix be dilated before removing the IUD.

Another embodiment of the IUD of the present invention is prepared using water soluble polymers such as polyvinyl pyrrolidone (PVP), polystarches, polycellulosics, and polyvinyl alcohol (PVA) to fabricate the hollow body. These materials are soluble in the uterine fluids and a hollow body made from these polymers, when placed in the uterus and filled with a filler that polymerizes in situ, e.g., silicone prepolymer, will dissolve and leave the polymerized silicone material in the uterus to serve as the IUD.

From the foregoing examples of exemplary embodiments of the invention, it is seen that numerous modifications and changes will readily occur to those skilled in the art. Thus, the exact construction and operation described hereinbefore is not to be taken to limit the invention, and all embodiments coming within the scope of the claims are intended to be covered herein.

What is claimed is:

1. The method of birth control which includes: positioning an inflatable, non-irritating, flexible, hollow body substantially within the uterine cavity, said body being formed from a material selected from the group consisting of polyvinyl pyrrolidone, polycellulosics, and polyvinyl alcohol, which material is soluble in fluids normally present in the uterine cavity; filling said hollow body with a liquid polymerizable prepolymer or monomer to produce a flexible, compressible intrauterine contraceptive device having the shape of the uterus; and dissolving said hollow body with uterine fluids.

2. The method of claim 1 including foaming said prepolymer or monomer prior to polymerizing to produce a cellular intrauterine contraceptive device.

3. A method of birth control including: positioning an empty, preformed, intrauterine contraceptive device within the uterine cavity, said device comprising a preformed hollow body having a shape approximating an equilateral triangle with a continuous, imperforate top wall joined at its periphery to a continuous, imperforate bottom wall, said walls being formed of a thin, flexible material and being connected to each other by connector stem means at one or more points intermediate their peripheries to limit expansion of said body; means

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defining an opening in one of the apices of said hollow body for filling and emptying said hollow body; means closing said opening; and expanding said device by substantially filling said hollow body with a flexible, compressible, filler material whereby the walls of said body will make contact with a major portion of the walls of said uterine cavity when said device is positioned in said uterine cavity.

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4. The method of claim 3 wherein said filler material is selected from the group consisting of water, mineral oil, silicone fluids and saline solutions.

5. The method of claim 3 wherein said filler material contains a member selected from the group consisting of bacteriostats, medicaments, and fragrances.

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