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(71) Applicant *(for all designated States except US)*: VEOS FRANCE EURL [FR/FR]; 23, allée Mère Angélique, F–78460 Chevreuse (FR).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: LAVEAN, Michael, G. [US/US]; 108 Mill Street, Box 31, Saranac, MI 48881 (US). TLAPEK, Janet [US/US]; 108 Mill Street, Box 31, Saranac, MI 48881 (US).

(74) Agents: WARN, Philip, R. et al.; Harness, Dickey & Pierce, P.L.C., P.O. Box 828, Bloomfield Hills, MI 48303 (US).

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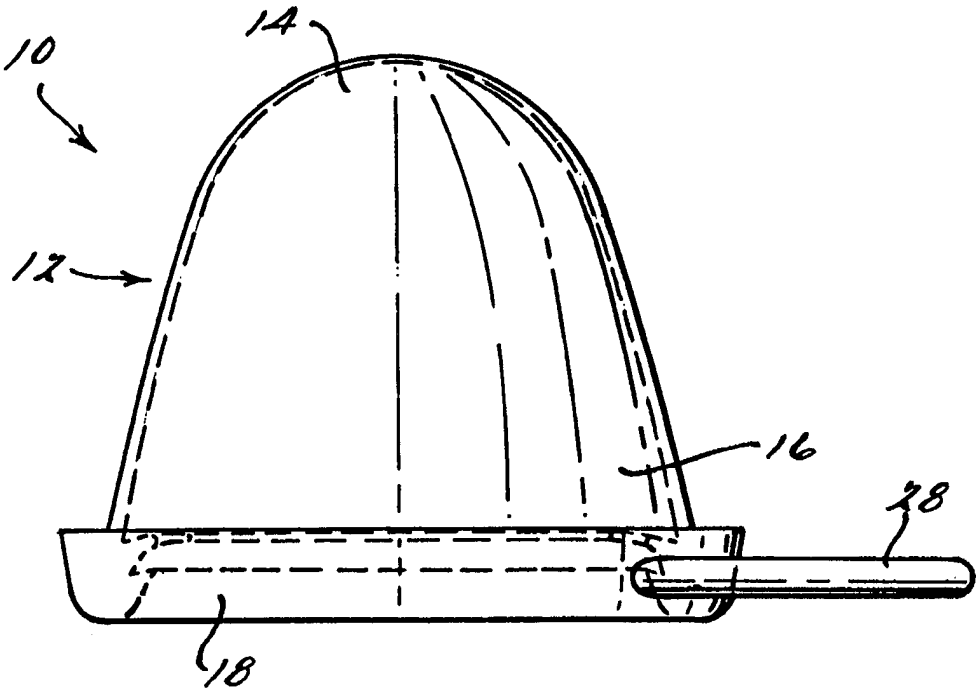

(57) Abstract

This invention is a conception cap (10) comprising a thin, form assuming, flexible dome (12), an annular rim (18), and thin, gripping fingers (24) along the inner surface of the rim (18) that make up a notched indentation to effectively position and secure the cap (10) over the cervix for the concentration of sperm on the cervical Os to effect fertilization independently, or with the aid of biologically active agents. The conception cap (10) is also included as a component in a conception kit, allowing a woman to conduct the steps of the method of conception using the kit in the privacy of her home.

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CONCEPTION KIT

BACKGROUND OF THE INVENTION

1. Field Of The Invention

The present invention relates generally to a conception kit used to concentrate sperm and effect fertilization, and to a method of conception utilizing the kit. More particularly, the present invention encompasses a conception cap used to deliver increased concentrations of sperm to the cervical Os.

2. Discussion of the Related Art

Devices which are intended to be inserted into the vagina are known for use as contraceptive barriers. One particular contraceptive device, the cervical cap, is placed over the cervix to prevent semen from entering the cervical canal and is held in place by a suction grip or surface viscosity on the moist cervical surface. Some of these previous cervical caps are made of latex. However, since latex causes sperm damage, possibly resulting in deformed or abnormal children, the latex cap cannot be used for delivery of sperm. In addition, all of these devices are geared only towards the prevention of pregnancy.

Currently, however, there are parts of the population that are experiencing a decline in fertility and would benefit from an invention that increases the likelihood of conception. Some of the primary factors contributing to a decline in fertility are low sperm counts, problems with sperm motility, and a hostile vaginal environment due to infection or other chronic conditions. A method used to overcome these problems is sperm concentration at the cervical Os, which is the area connecting the uterus and the vaginal cavity. Sperm concentration significantly increases the probability of conception, as fewer sperm are needed to effect fertilization since a higher number reach the uterus intact. Since these sperm travel a shorter distance, a higher proportion remain viable upon reaching the uterus. In cases of low sperm counts or poor motility, this is particularly effective. In addition, a potentially hostile vaginal environment is bypassed.

Methods in use today to address fertility issues are administered only by medical professionals and are very costly. As an example, administration of sperm using a pipet that is inserted through the Os damages fragile cervical tissue and can cause extensive bleeding. In addition, the medical procedure is painful and involves considerable investments of time and money.

Modern technology allows for a woman to reliably predict ovulation, and assess her ability to become pregnant. In addition, sperm can be easily collected in a condom and thereby be mechanically confined to a small volume. Pregnancy tests are available and allow the woman to monitor her success. There is a need, therefore, for an inexpensive vaginal device that can be inserted by a woman and remain in place for an extended period of time. There is also a need for a kit that would provide a woman with all of the materials needed to successfully carry out a sperm concentration procedure at the appropriate biological time and monitor her success.

The present invention provides an improved method and conception cap for concentrating sperm and successfully effecting fertilization, overcoming the aforementioned problems. The conception cap of the present invention is made of a silicone-based material and can be positioned and secured over the cervix while containing sperm to facilitate conception. Moreover, all of the materials to allow a woman to effect this multi-day procedure and monitor its efficacy at a biologically appropriate time in an inexpensive and expedient manner are provided in a conception kit.

SUMMARY OF THE INVENTION

The present invention relates to a conception cap which is positioned over a female's cervix to increase the chances of successful fertilization. The dome of the conception cap has a hollow body and an interior and exterior surface. Further, the dome is designed to contain sperm, and upon insertion, provide a higher concentration of said sperm to the cervical Os. The dome is also thin, flexible, and form-assuming, allowing the conception cap to remain in place over the cervix until removed.

The conception cap of the present invention is additionally held in place over the cervix by an annular rim that is integrally-molded with the base section of the dome. The inner surface of the rim comprises at least two thin, gripping fingers that are utilized to keep the cap positioned over the cervix. The fingers are directly opposite or symmetrically opposed from each other along the inner surface of the rim and define a notched indentation which helps grip the cervix walls. Thus, the thinness of the dome and the rim construction eliminate the need for individual fittings for a

large percentage of the female population, increase sperm concentration at the opening of the cervix, and minimize the possibility of dislodging the cap from its position over the cervix.

A handle or loop integrally-molded to the outer surface of the rim aids insertion and removal of the device. While the conception cap is in use, the handle is compressed between the cervix and the vaginal walls.

The present invention is also directed to a conception cap that comprises biologically active material which would assist in fertilization, or to which the biologically active material can be mixed with sperm within the hollow body of the dome of the cap in order to achieve the desired result.

The use of biologically active materials in either embodiment may stimulate sperm motility, prolong the active life of the sperm or aid in gender selection. Selectively eliminating or altering the behavior of some sperm by significantly changing the pH may bias the activity of the X or Y sperm, resulting in odds which favor one particular sex over the other.

The present invention is also directed to a conception kit used to concentrate sperm and effect fertilization. The kit comprises an ovulation predictor, a conception cap, a condom, and a pregnancy test. The conception kit provides the woman with the means to effect sperm concentration at a biologically appropriate time, aid fertilization and determine the success of her efforts.

The present invention further comprises a method of achieving conception utilizing the components of the conception kit, including the conception cap, to increase the chances of successful fertilization.

Additional advantages and features of the present invention will become apparent from the subsequent description and the appended claims, taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of a preferred embodiment of a conception cap of the present invention;

FIG. 2 is a top elevational view of the conception cap;

FIG. 3 is a sectional view, taken along line 3-3 in **FIG. 2**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIGS. 1-3, a preferred embodiment of a conception cap of the present invention is illustrated and indicated generally by the numeral **10**. Generally speaking, conception cap **10** comprises a flexible, thin, form-assuming dome **12**, a crown section **14**, a base section **16**, and an annular rim **18**. Dome **12** is generally thimble-shaped, with base section **16** inwardly tapering toward crown section **14**. The outer diameter of rim **18** is greater than that of base section **16** of dome **12**.

Referring particularly to FIG. 3, annular rim **18** has an inner surface **20** and an outer surface **22**. Thin, gripping finger **24** projects upwardly and outwardly, as finger **24** is integrally-formed with inner surface **20**. Finger **24** also defines an upper portion of a notched indentation **26** as viewed in FIG. 3. Annular rim **18** contains at least two gripping fingers **24** that are directly opposite or symmetrically opposed from each other along inner surface **20**. However, it will be appreciated to one skilled in the art that more than two fingers could be employed. Fingers **24** effectively grip and hold conception cap **10** over the cervix in order to concentrate the sperm at the Os of the cervix and to successfully effect fertilization. Gripping fingers **24** and notched indentation **26** essentially provide the effect of a chinese finger puzzle by gripping the side walls of the cervix and holding the cap when the circumference of the rim **18** is fitted around the cervix and slightly expands. Conception cap **10** is fixed in place by the use of gripping fingers **24** rather than merely by suction or surface viscosity. Thus, because of the rim construction, conception cap **10** is a size which is a suitable fit for a majority of women.

A handle **28** facilitates insertion and removal of conception cap **10**, and is integrally-molded with annular rim **18**. It is contemplated that dome **12**, annular rim **18**, gripping fingers **24**, and handle **28** will preferably be made of a non-resilient flexible material, such as a silicone-based material. This material may or may not be impregnated with biologically active components. These components may be released therefrom in an amount effective to achieve its purpose during use.

Types of silicone-based materials suitable for use herein are known in the art and include high-consistency and low-consistency silicone-based elastomers prepared using a variety of well-known methods, e.g., platinum-cured systems, selected for compatibility with biological tissue and particular active ingredients being released by the conception cap. An example of a biologically active agent that could be released

by the cap is one that would alter pH, or effect sperm activity. The elastomer can be loaded with the active agent in a manner appreciated by those skilled in the art that incorporates the agent in an excipient matrix with the elastomer, providing sustained release of the agent from the matrix.

Another preferred embodiment of the invention is the incorporation of conception cap **10**, in all of its embodiments, in a conception kit to concentrate sperm and effect fertilization. The kit comprises the conception cap **10**, an ovulation predictor, a condom and a pregnancy test. Ovulation predictors are well-known in the art and may be hormonal or temperature sensitive, such as a basel thermometer. Condoms are also well-known in the art, and for the purposes of the invention are preferably lambskin or polyurethane, but may be latex if the transfer of the sperm from the condom to the conception cap is fast enough to avoid damaging the sperm. Latex damages and kills sperm if it is in contact with the sperm for any significant amount of time. In addition, pregnancy tests are also well-known in the art and widely used.

The present invention also provides a method of achieving conception in a mammalian subject utilizing the conception kit. The method comprises the steps of:

a) determining the period of ovulation with an ovulation predictor,

b) providing viable sperm in a conception cap, and

c) inserting said conception cap into a vaginal cavity and positioning said cap over a cervix of a subject for a selected time period. The method further comprises the steps of obtaining sperm by effecting ejaculation of the sperm into a condom, and carrying out a pregnancy test at the end of the procedure to determine whether fertilization occurred. Moreover, the silicone-based conception cap is a size which is a suitable fit for most women, as the thinness of the dome and rim construction allow for a flexible fit.

Although the description as set forth is in conjunction with human subjects, it will be further appreciated that the claimed compositions and methods may be readily adaptable for use with animal subjects having a cervix.

While it will be apparent that the preferred embodiments of the invention disclosed are well calculated to provide the advantages and features above stated, it will be appreciated that the invention is suspectable to modification, variation, and change without departing from the proper scope or fair meaning of the subjoined claims.

WHAT IS CLAIMED IS:

1. A conception cap positioned over a cervix to concentrate sperm and effect fertilization comprising:

a thin, form-assuming, flexible dome having a hollow body and an interior and exterior surface, said dome comprising a crown section and base section,

an annular rim integrally-molded with said base section having an inner and outer surface, and

at least two thin, gripping fingers projecting upwardly and outwardly, said fingers being integrally-formed with said inner surface of said rim, wherein said fingers are symmetrically opposed from each other along said inner surface of said rim, and wherein each said finger defines a notched indentation in said inner surface of said rim in order to effectively grip and hold said cap over said cervix.

2. The conception cap of claim 1, wherein said cap further comprises sperm within said body of said dome.

3. The conception cap of claim 1, wherein said cap further comprises a handle integrally-molded to said rim.

4. The conception cap of claim 1, wherein said cap is comprised of a silicone-based material.

5. The conception cap of claim 1, wherein said cap is comprised of a biologically active material.

6. The conception cap of claim 1, wherein a biologically active material is mixed with sperm within said hollow body of said dome.

7. A conception kit to concentrate sperm and effect fertilization comprising an ovulation predictor, a conception cap, a condom, and a pregnancy test.

8. The conception kit of claim 7, wherein said ovulation predictor is hormonal.

9. The conception kit of claim 7, wherein said ovulation predictor is temperature sensitive.

10. The conception kit of claim 9, wherein said ovulation predictor is a basel thermometer.

11. The conception kit of claim 7, wherein said conception cap comprises a silicone-based material.

12. The conception kit of claim 7, wherein said condom is selected from the group consisting of lambskin, polyurethane, and latex.

13. A method of achieving conception in a mammalian subject having an ovulation period, comprising the steps of:

a) determining the period of ovulation with an ovulation predictor,

b) providing viable sperm in a conception cap, and

c) inserting said conception cap into a vaginal cavity and positioning said cap over a cervix of a subject for a selected time period.

14. The method of claim 13, wherein said subject is a human.

15. The method of claim 13, wherein said subject is an animal.

16. The method of claim 13, wherein said sperm is obtained by effecting ejaculation of said sperm into a condom.

17. The method of claim 13, including a further step of carrying out a pregnancy test to determine whether fertilization occurred.

18. A method of conception according to claim 13, wherein said ovulation predictor is hormonal.

19. A method of conception according to claim 13, wherein said ovulation predictor is temperature sensitive.

20. A method of conception according to claim 19, wherein said ovulation predictor is a basel thermometer.

21. A method of conception according to claim 13, wherein said conception cap comprises a silicone-based material.

22. A method of conception according to claim 13, wherein said condom is selected from the group consisting of lambskin, polyurethane, and latex.

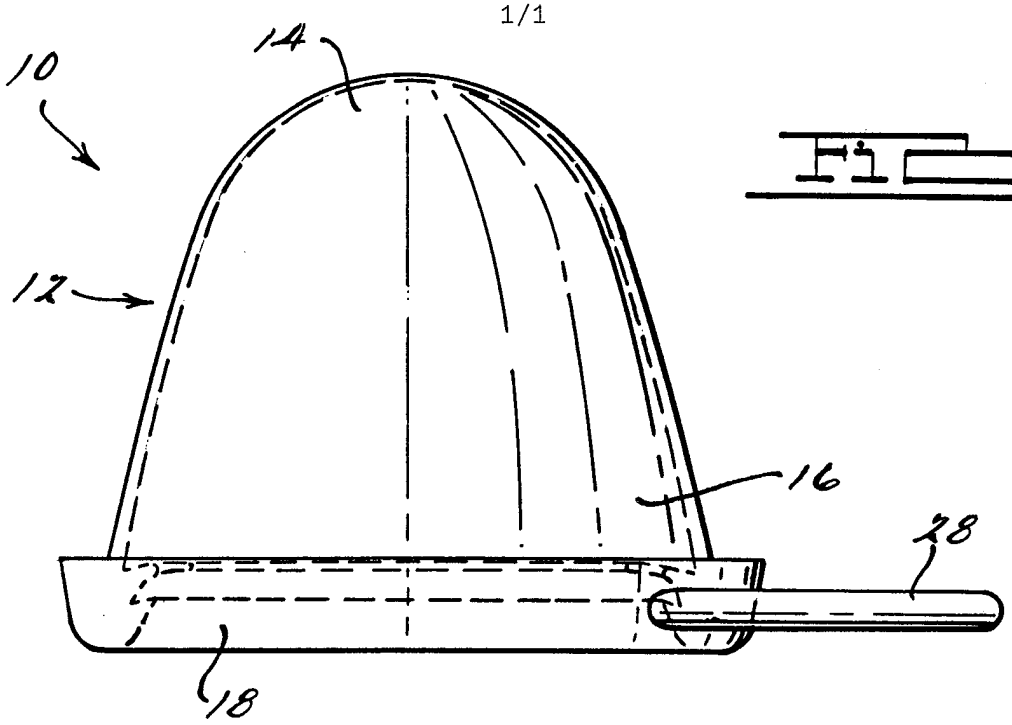

Fig. 1.

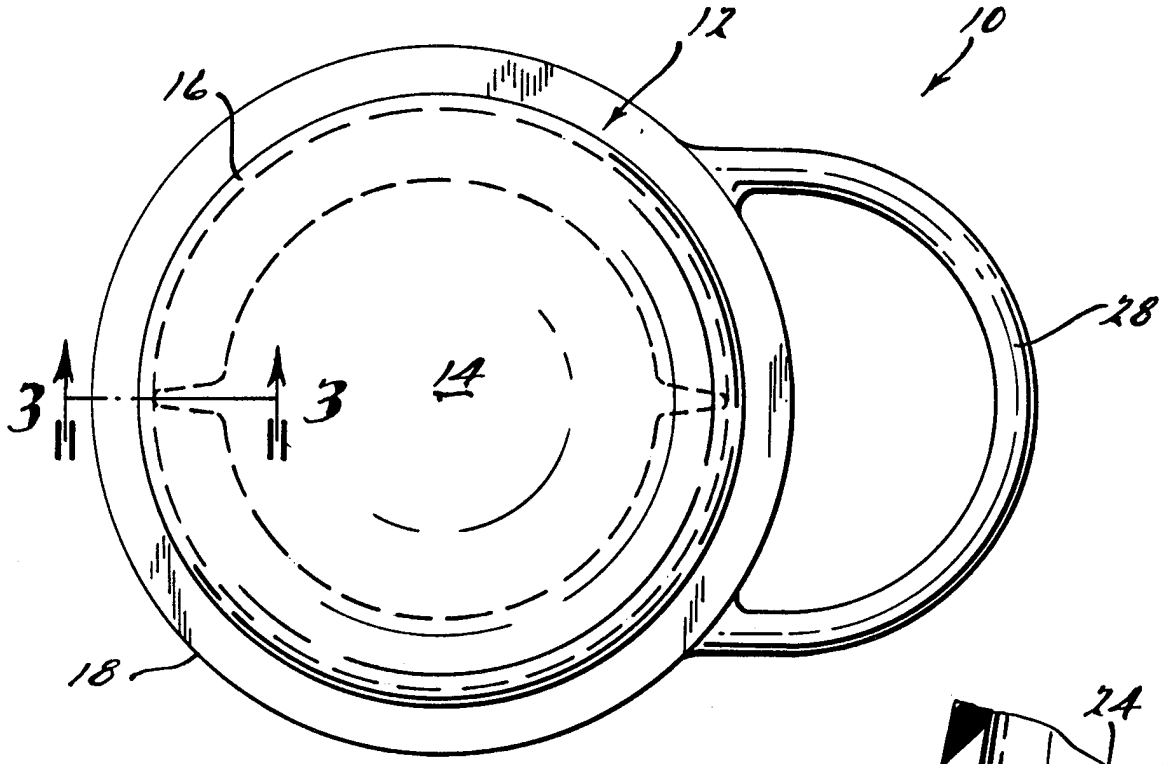

Fig. 2.

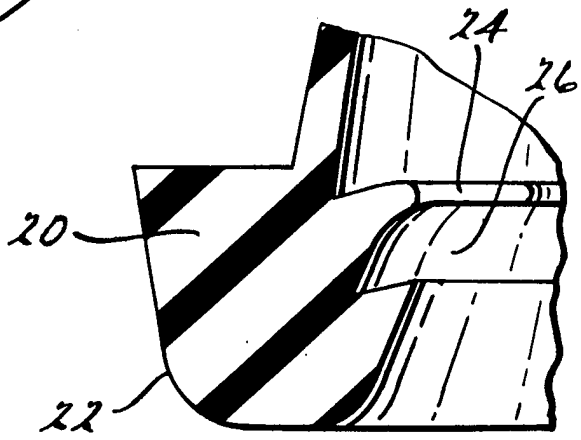

Fig. 3.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/01876

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/43; A61D 7/00
US CL :600/033

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/830-841; 600/033-035;

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 4,785,804 A (TLAPEK et al) 22 November 1988, entire document.	1, 3, 4 --- 7-12
A	US 5,044,376 A (SHIELDS) 03 September 1991, entire document.	1-22
A	US 5,027,830 A (KOCH) 02 July 1991, entire document.	1-22

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Authorized officer
JOHN LACYK

Telephone No. (703) 308-2995

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