

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
29 April 2004 (29.04.2004)

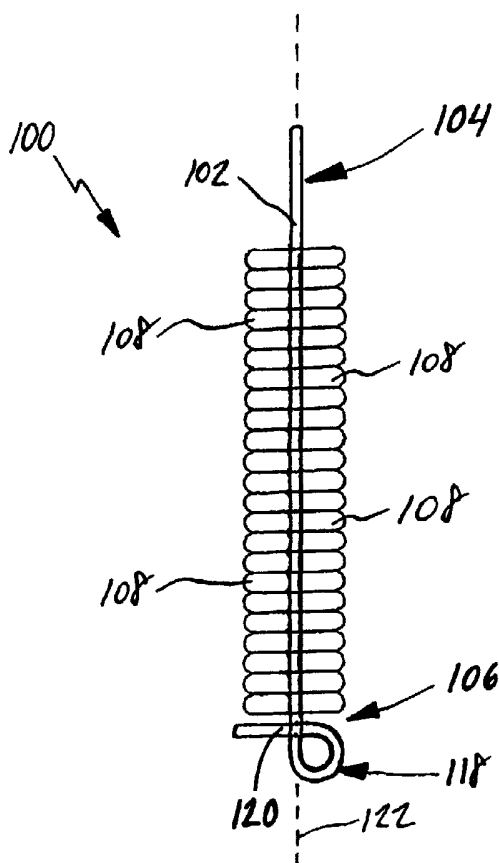
PCT

(10) International Publication Number
WO 2004/034877 A2

- (51) International Patent Classification⁷: **A61B**
- (21) International Application Number:
PCT/US2003/032882
- (22) International Filing Date: 17 October 2003 (17.10.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/419,115 18 October 2002 (18.10.2002) US
- (71) Applicant (for all designated States except US):
GEORGETOWN UNIVERSITY [US/US]; 3800
Reservoir Road, N.W., Washington, DC 20007 (US).
- (72) Inventor; and
- (75) Inventor/Applicant (for US only): **AREVALO, Marcos**
[SV/US]; 7440 Bee Bee Drive, Rockville, MD 20855 (US).
- (74) Agents: **BALANCIA, Victor, N.** et al.; Pennie & Ed-
monds LLP, 1155 Avenue of the Americas, New York, NY
10036 (US).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,
MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC,
SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA,
UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO,
SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM,
GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: FERTILE WINDOW MONITOR



(57) Abstract: A menstrual cycle monitor for a human female user includes a wireform with a stop disposed proximate a distal portion thereof, along with sets of indicators for use therewith. A first set of indicators are each provided with first indicia representing days during which menstrual bleeding is noted by the user. A second set of indicators are each provided with second indicia representing days during which secretions are noted by the user. In addition, a third set of indicators are each provided with third indicia representing days during which no secretions are noted by the user. Each indicator is configured and dimensioned to be disposed on the wireform, and the stop is configured and dimensioned to prevent removal of indicators from the wireform from the distal portion thereof.



Published:

— without international search report and to be republished
upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

FERTILE WINDOW MONITOR

FIELD OF THE INVENTION

5 The invention is related to an apparatus and method for monitoring the fertile window of a woman's menstrual cycle. More particularly, the invention is related to a mnemonic-based approach for monitoring the fertile window of a woman's menstrual cycle.

BACKGROUND OF THE INVENTION

10 Worldwide, substantial numbers of women use periodic abstinence as their method of family planning. This method of family planning, generally referred to as the "rhythm method," typically involves recognition of a woman's fertile period using any one of various methods, including a "guess" based on the length of her menstrual cycle. Ovulation may be assumed to occur mid-cycle, and thus the period of abstinence is set
15 accordingly. Unfortunately, although some women have an accurate understanding of their reproductive cycle and thus know when they are most likely to be fertile, many users of periodic abstinence lack such an understanding, thereby preventing them from reliably using period abstinence as a means for preventing pregnancy. In fact, it has been estimated that of
20 the 50 to 60 million women who use periodic abstinence to avoid pregnancy, more than one third have little or no information about their own fertility. Despite the lack of reliability of many rhythm-based techniques, various religious, philosophic, or health considerations nevertheless have led many women to adopt these techniques.

 Because knowledge of a woman's reproductive cycle could be used by a woman to assist in determining whether to refrain from or engage in intercourse, depending
25 if conception is desired, various techniques have been developed for tracking the reproductive cycle. For example, some researchers have proposed methods of predicting ovulation that are based on biochemical changes in various body fluids, such as saliva, vaginal secretions, or urine. U.S. Patent No. 4,770,186 to Regas et al. is directed to a method and apparatus for predicting and detecting the onset of ovulation. The method
30 involves essentially measuring the electrical resistivity of the user's saliva, and by observing peaks and nadirs of changes in the saliva resistivity, ovulation and fertility periods are predicted. The onset of ovulation can be further established by measuring the electrical resistivity of vaginal mucus, which, during the fertile period, shows a nadir on the day immediately preceding ovulation.

35

In addition, U.S. Patent No. 6,149,591 to Henderson et al. discloses a device for the in vivo detection of refractive indices of cervical mucus at a female's cervical os. The device detects in vivo physiological changes in a female's cervical mucus, with the changes correlating with the timing of ovulation and thus providing a marker for the fertile period of the menstrual cycle.

U.S. Patent No. 5,118,630 to Glaze is directed to a method for determining periodic infertility in females. The natural birth control method comprises observance of the first day of menses followed by measurement of urinary progesterone metabolite levels beginning a predetermined number of days after the first day of menses. Urinary progesterone metabolite measurement is performed on days of planned sexual activity until the concentration level exceeds a threshold value indicative of ovulation occurring more than 24 hours previously. Once such a threshold value is observed, the woman may discontinue testing and can consider herself unable to conceive until after the beginning of the subsequent menstrual cycle.

Despite these developments, there exists a need for alternative means for a woman to accurately predict her fertile window. Further, because many women discontinue use of a given apparatus and method, and millions of women do not use any apparatus or method, there exists a need for a simple, inexpensive alternative apparatus and method.

In particular, despite the aforementioned developments, there exists a need for a less intrusive apparatus and method for monitoring the "fertile window" of a woman's menstrual cycle, to thereby assist in identifying when she can become pregnant. In addition, there exists a need for an apparatus and method for helping a woman identify her fertile window to permit informed decisions about whether to avoid intercourse if she does not want to become pregnant. Further, there exists a need for a mnemonic-based apparatus and method for monitoring the fertile window of a woman's menstrual cycle.

SUMMARY OF THE INVENTION

The invention is related to a menstrual cycle monitor for a human female user including: a wireform with a stop disposed proximate a distal portion thereof; a first set of indicators that are each provided with first indicia representing days during which menstrual bleeding is noted by the user; a second set of indicators that are each provided with second indicia representing days during which secretions are noted by the user; and a third set of indicators that are each provided with third indicia representing days during which no secretions are noted by the user. Each indicator may be configured and dimensioned to be disposed on the wireform, and the stop may be configured and

dimensioned to prevent removal of indicators from the wireform from the distal portion thereof.

5 In some embodiments, the first indicia, second indicia, and third indicia may be different colors from each other and/or different shapes from each other. Also, the stop may be a loop integrally formed with the wireform. The wireform may include a crooked portion. A proximal portion of the wireform may be releasably coupled to the distal portion. The wireform may be configured and dimensioned as a loop that may have a pair of parallel portions with an arcuate section disposed therebetween. The indicators of at least one of the sets each may have a hole through which the wireform is received.

10 The wireform may be formed of metal, and may be any elastically bendable, rigid material. The indicators of at least one of the sets may be formed of a polymer.

The wireform may include a hook portion and optionally a crooked portion demountably attachable thereto. The hook portion and crooked portion may be configured and dimensioned for mutual engagement.

15

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred features of the present invention are disclosed in the accompanying drawings, wherein similar reference characters denote similar elements throughout the several views, and wherein:

20 FIG. 1 shows a partial cross-sectional side view of a first exemplary embodiment of a monitor according to the present invention;

FIG. 2 shows a top view of an exemplary indicator according to the present invention;

FIG. 3 shows a side view of the indicator of FIG. 2;

25 FIG. 4 shows a partial cross-sectional side view of a second exemplary embodiment of a monitor according to the present invention;

FIG. 5 shows a perspective view of a third exemplary embodiment of a monitor according to the present invention;

30 FIG. 6 shows a partial cross-sectional side view of the monitor of FIG. 5 with indicators demountably coupled thereto and a hook in engaged association with a proximal portion of the wireform;

FIG. 7 shows a partial cross-sectional side view of the monitor of FIG. 5, without the indicators, and with a hook in disengaged association with a proximal portion of the wireform;

35

FIG. 8 shows a top view of the stop, hook portion, and crooked portion of the monitor of FIG. 5; and

FIG. 9 shows a fourth exemplary embodiment of a monitor according to the present invention in the form of a compact.

5

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

It is known from biological evidence that each woman has a "fertile window" during her menstrual cycle when she can become pregnant. With this in mind, a method has been developed for identifying the fertile window, so that informed decisions can be made as to whether a woman is probably fertile and should abstain from unprotected intercourse if she wishes to avoid pregnancy.

10

Theoretical Study

A method for monitoring the fertile window of a woman's menstrual cycle was studied by analyzing a large data set of women's menstrual cycles obtained from the World Health Organization study of the Billings Ovulation Method, and data from individual charts from three Natural Family Planning programs. Both data sets included information about women's menstrual cycles, and the number of days with noticeable cervical secretions before and after ovulation.

15

The analysis was designed to determine whether the following method would be effective in helping couples avoid pregnancy: A woman monitors the presence or absence of cervical secretions, by sensation or by observation, to determine on each day whether she is fertile. Secretions, for the purposes of the monitoring, would be any substance the woman perceives as coming from her vagina, except for menstrual bleeding. Each day, the woman asks herself (1) whether she noted secretions on that day, and (2) whether she noted secretions on the previous day. An affirmative answer to either question indicates that the woman noted secretions of any type, while an answer in the negative indicates that the woman did not notice any secretions. If the woman answers either of the questions in the affirmative, i.e. that she noted secretions on that day or the previous day, she is probably fertile and needs to abstain from unprotected intercourse if she wishes to avoid pregnancy. If she notices no secretions on both days, it is very probable that she is not fertile.

20

25

30

Results of this analysis show that the above-identified method would be effective in helping couples avoid pregnancy in both the pre-ovulatory and post-ovulatory phases of the cycle. The estimated probability of pregnancy from intercourse of any given day is no more than 0.025; the mean length of the fertile phase (the days couples would

35

need to avoid unprotected intercourse) with this method is about 10 days. Additional analysis of a large data set from a multi-center study in Europe reached similar conclusions.

In a multi-site pilot study to assess the potential acceptability of the method and to test the teaching protocols, it was confirmed that the method is easy to teach, learn
5 and use. It was also confirmed that women were aware of their vaginal secretions but it was not common to discuss this with their partners, and they did not know that secretions are related to fertility. By the end of the pilot study, clients and service providers reported high satisfaction with the method.

Advantageously, the method does not require literacy or numeracy, and
10 potentially may be used by breast-feeding women. The simplicity of the method in terms of teaching and use may allow the method to be deployed in contexts where unmet need for family planning is high, or where couples rely on some kind of periodic abstinence but have little knowledge about the woman's fertile phase.

Further details can be found in the following publication, which is hereby
15 incorporated by reference in its entirety: Irit Sinai, Victoria Jennings, and Marcos Arévalo, "The TwoDay Algorithm: A New Algorithm to Identify the Fertile Time of the Menstrual Cycle," *Contraception* 60 (1999): 65-70.

Exemplary Devices

Now, referring to FIG. 1, there is shown a first exemplary embodiment of the
20 present invention as a wireform for retaining at least one indicator. Monitor 100 includes a wireform 102 with a proximal portion 104 and a distal portion 106. Indicators 108 are demountably attached to wireform 102. Wireform 102 is preferably generally rigid or semi-rigid, yet ductile so that it may be elastically bent. In particular, wireform 102 is preferably formed of a metal. Alternatively, wireform 102 may be formed of wood. Indicators 108 are
25 preferably formed of a polymer.

As shown in FIGS. 2 and 3, in an exemplary preferred embodiment, indicators 108 preferably have a generally arcuate outer perimetral rim 110, first and second faces 112, 114, respectively, and a through hole 116 extending between faces 112, 114. Through hole 116 is sized such that wireform 102 may extend therethrough. In alternate
30 embodiments, indicators 108 may be demountably attachable to wireform 102 with other means.

Turning again to FIG. 1, a stop 118 is disposed proximate distal portion 106 of wireform 102, to prevent removal of indicators 108 from wireform 102 proximate distal portion 106 thereof. In one embodiment, as shown, stop 118 is configured as a loop with
35 end portion 120 of distal portion 106 disposed transverse to central longitudinal axis 122.

On the other hand, an "entry portion" or proximal portion 104 permits insertion of indicators 108 onto wireform 102.

Although indicators 108 are shown with circular cross-sections, other cross-sections are contemplated such as oblong, rectangular, triangular, trapezoidal, and irregular.

5 Preferably, three sets of indicators 108 are provided for use with wireform 102. In particular, a first set of indicators are each provided with first indicia for representing days during which menstrual bleeding is noted by a user of the monitor. A second set of indicators are each provided with second indicia for representing days during which secretions are noted by the user. And, a third set of indicators are each provided with
10 third indicia representing days during which no secretions are noted by the user. Preferably, first, second, and third indicia are different colors. For example, the first indicia may be the color red, the second indicia may be the color blue, and the third indicia may be the color yellow. In alternate embodiments, each of the first, second, and third sets of indicators 108 may be provided with a different shape, so that, for example, the indicators in the first set
15 have a generally toroidal shape, the indicators in the second set have a generally block-like shape, and the indicators in the third set have a generally cylindrical shape. In yet another alternate embodiment, each of the first, second, and third sets of indicators 108 may be provided with a different symbol, picture, or wording which may represent whether menstrual bleeding, secretions, or no secretions are noted by the user on a given day. In yet
20 another embodiment, each of the first, second, and third sets of indicators 108 may be provided with two or more different indicia. For example, the indicators 108 in the first set may be red and generally toroidal, the indicators 108 in the second set may be blue and generally block-like, and the indicators 108 in the third set may be yellow and generally cylindrical.

25 In use, monitor 100 serves as an aid to assist a woman in tracking whether she had secretions on two consecutive days, and thus know whether she is probably fertile and needs to abstain from unprotected intercourse if she wishes to avoid pregnancy. Preferably, each night a woman places an indicator 108 on wireform 102 from proximal portion 104. Choice of an indicator 108 from one of the first, second, and third sets of
30 indicators 108, as described above, is based on whether the woman noted either menstrual bleeding, secretions, or no secretions on the given day. After placing the appropriate indicator 108 for that given day on wireform 102, the woman preferably holds between her fingers two indicators – the indicator 108 for that given day along with the indicator 108 from the previous day. The woman then notes the indicia provided on each of the two
35 indicators 108. If the indicia indicates no secretions on both days, the woman may have

intercourse without a high probability of becoming pregnant. If the indicia for either of the days indicates that the woman had secretions, the woman could become pregnant and should not have intercourse that day. Each time a woman places on wireform 102 an indicator 108 with indicia representing menstrual bleeding, she should thereafter remove
5 indicators 108 from wireform 102.

Referring to FIG. 4, a monitor 130 is shown generally in the form of a loop. Monitor 130 includes wireform 132 with parallel portions 134, 136 along with central arcuate portion 138 disposed therebetween. A stop 140 is disposed proximate a distal portion 142 of wireform 132, to prevent removal of indicators 108 from wireform 102
10 proximate distal portion 142 thereof. In the embodiment shown in FIG. 4, stop 140 is configured as a loop, however alternate configurations are contemplated as previously discussed with respect to the embodiment of FIG. 1. Proximal portion 144 includes a crooked portion 146 which resists removal of indicators 108 disposed on wireform 132, yet permits indicators 108, as shown for example in FIGS. 2 and 3, to be demountably coupled
15 to wireform 132. As discussed above, indicators 108 are provided in three sets: a first set of indicators each provided with first indicia for representing days during which menstrual bleeding is noted by a user, a second set of indicators each provided with second indicia for representing days during which secretions are noted by the user, and a third set of indicators each provided with third indicia representing days during which no secretions are noted by
20 the user. The discussion above with respect to the types of indicia that may be provided on indicators 108 for use with monitor 100 is also applicable to indicators 108 for use with monitor 130.

With reference to FIGS. 5-8, a monitor 150 is shown generally in the form of a loop. Monitor 150 includes wireform 152 with parallel portions 154, 156 along with
25 central arcuate portion 158 disposed therebetween. A stop 160 is disposed proximate a distal portion 162 of wireform 152, to prevent removal of indicators 108 from wireform 152 proximate distal portion 162 thereof. In the embodiment shown in FIGS. 5-8, stop 160 is configured as a loop, however alternate configurations are contemplated as previously discussed with respect to the embodiment of FIG. 1. Proximal portion 164 includes a
30 crooked portion 166 which resists removal of indicators 108 disposed on wireform 152, yet permits indicators 108, as shown for example in FIGS. 2 and 3, to be demountably coupled to wireform 152. A hook portion 168 is provided on distal portion 162 of wireform 152 to releasably couple distal and proximal portions 162, 164, respectively, to each other to permit the creation of a generally closed path between end portions of wireform 152.

35

Preferably, hook portion 168 is located so that it is generally aligned with crooked portion 166 and demountably attachable thereto.

As discussed above with, indicators 108 for use with monitor 150 are provided in three sets: a first set of indicators each provided with first indicia for
5 representing days during which menstrual bleeding is noted by a user, a second set of indicators each provided with second indicia for representing days during which secretions are noted by the user, and a third set of indicators each provided with third indicia representing days during which no secretions are noted by the user. The discussion above with respect to the types of indicia that may be provided on indicators 108 for use with
10 monitor 100 is also applicable to indicators 108 for use with monitor 150.

In another embodiment, a monitor according to the present invention is formed as a compact 170, as shown in FIG. 9. Areas inside the compact may be separated so that indicators with appropriate indicia, as discussed above, may be placed thereon. In one example, two adjacent compartments may be provided. Alternatively, more than two
15 compartments may be provided such as seven compartments each representing a day of the week, and optionally marked with letters for the days of the week (*i.e.*, M, T, W, Th, F, Sat, Sun).

In an alternate embodiment of a monitor according to the present invention, sets of indicators may be threaded onto a cord or string made of natural or synthetic
20 material. A knot or fixed object serving as a stop may be disposed at one end of the cord to prevent removal of indicators from the end proximate the stop. As described above with respect to other embodiments, various indicia may be used so that three sets of indicators with different indicia are available for disposing on the cord. For example, different cross-sections in the form of perforated beads, chips or buttons may be provided, and/or different
25 colors may be provided to represent menstruation, dry days, and days with secretions. Indicia may also be in the form of different materials for constructing the indicators of the three sets. The ends of the cord may be joined with various types of clasps to form a bracelet-like monitor.

In yet another alternate embodiment, a monitor according to the present
30 invention may be formed of a tablet of cork or other similar material on which groups of cells are denoted. Each cell may represent a day, and optionally may be marked with letters for the days of the week (*i.e.*, M, T, W, Th, F, Sat, Sun). Sets of indicators may be provided in the form of pushpins with different indicia, the pushpins being configured and dimensioned for removable coupling to the tablet in each cell. As described above with
35 respect to other embodiments, various indicia may be used so that three sets of indicators

with different indicia are available. The appropriate pushpins thus could be inserted and left in place in the cells, with a pushpin selected based on whether menstruation, a dry day, or a day with secretions had occurred. In some embodiments, the cells are arranged in various configurations such a calendar-like grid, possibly with rows each having seven cells, or in a snake-like linear pattern, or in a racetrack linear pattern. The tablet may be glued or otherwise fixed to a more rigid base of similar size, for support and to prevent sharp tips of the pushpins from protruding from the monitor.

The inventive monitors described herein may also serve as teaching tools to assist in conveying an understanding of the female reproductive cycle, and in particular may assist in conveying an understanding of the "fertile window" during each woman's menstrual cycle when she can become pregnant. The teaching tools, for example, may be used in health education classes.

While various descriptions of the present invention are described above, it should be understood that the various features can be used singly or in any combination thereof. Therefore, this invention is not to be limited to only the specifically preferred embodiments depicted herein.

Further, it should be understood that variations and modifications within the spirit and scope of the invention may occur to those skilled in the art to which the invention pertains. For example, instead of placing indicators on a metal wireform, the indicators may be placed on the shaft of a small stick or ballpoint pen, preferably so that they may be demountably coupled thereto. Accordingly, all expedient modifications readily attainable by one versed in the art from the disclosure set forth herein that are within the scope and spirit of the present invention are to be included as further embodiments of the present invention. The scope of the present invention is accordingly defined as set forth in the appended claims.

30

35

The Claims

What is claimed is:

- 5 1. A menstrual cycle monitor for a human female user comprising:
a wireform with a stop disposed proximate a distal portion thereof;
a first set of indicators each provided with first indicia representing days
during which menstrual bleeding is noted by the user;
a second set of indicators each provided with second indicia representing
10 days during which secretions are noted by the user; and
a third set of indicators each provided with third indicia representing days
during which no secretions are noted by the user;
wherein each indicator is configured and dimensioned to be disposed on the
wireform, and the stop is configured and dimensioned to prevent removal of indicators from
15 the wireform from the distal portion thereof.
2. The monitor of claim 1, wherein the first indicia, second indicia, and
third indicia comprise different colors from each other.
- 20 3. The monitor of claim 1, wherein the first indicia, second indicia, and
third indicia comprise different shapes from each other.
4. The monitor of claim 1, wherein the stop comprises a loop integrally
formed with the wireform.
- 25 5. The monitor of claim 1, wherein the wireform comprises a crooked
portion.
6. The monitor of claim 1, wherein a proximal portion of the wireform
30 is releasably coupled to the distal portion.
7. The monitor of claim 1, wherein the wireform is configured and
dimensioned as a loop.

35

8. The monitor of claim 1, wherein the loop comprises a pair of parallel portions with an arcuate section disposed therebetween.

5 9. The monitor of claim 1, wherein the indicators of at least one of the sets each comprise a hole through which the wireform is received.

10. The monitor of claim 1, wherein the wireform is formed of metal.

10 11. The monitor of claim 1, wherein the wireform is formed of an elastically bendable, rigid material.

12. The monitor of claim 1, wherein the indicators of at least one of the sets are formed of a polymer.

15 13. The monitor of claim 1, wherein the wireform comprises a hook portion and a crooked portion demountably attachable thereto.

20 14. The monitor of claim 1, wherein the wireform comprises a hook portion.

15. The monitor of claim 1, wherein the wireform comprises a hook portion and a crooked portion configured and dimensioned for mutual engagement.

25

30

35

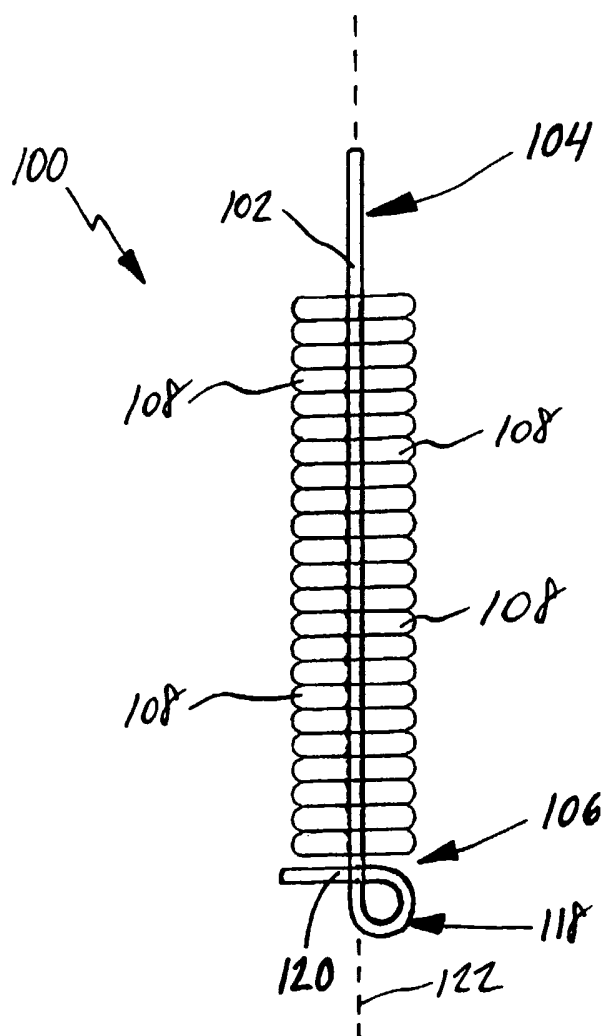


FIG. 1

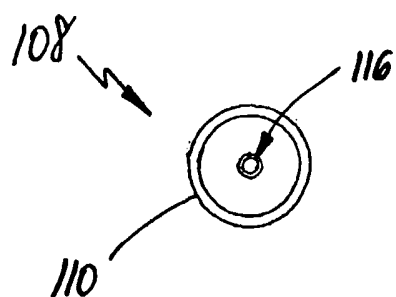


FIG. 2

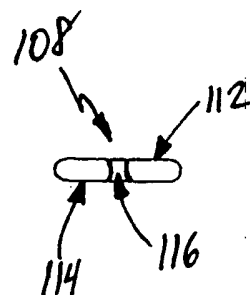


FIG. 3

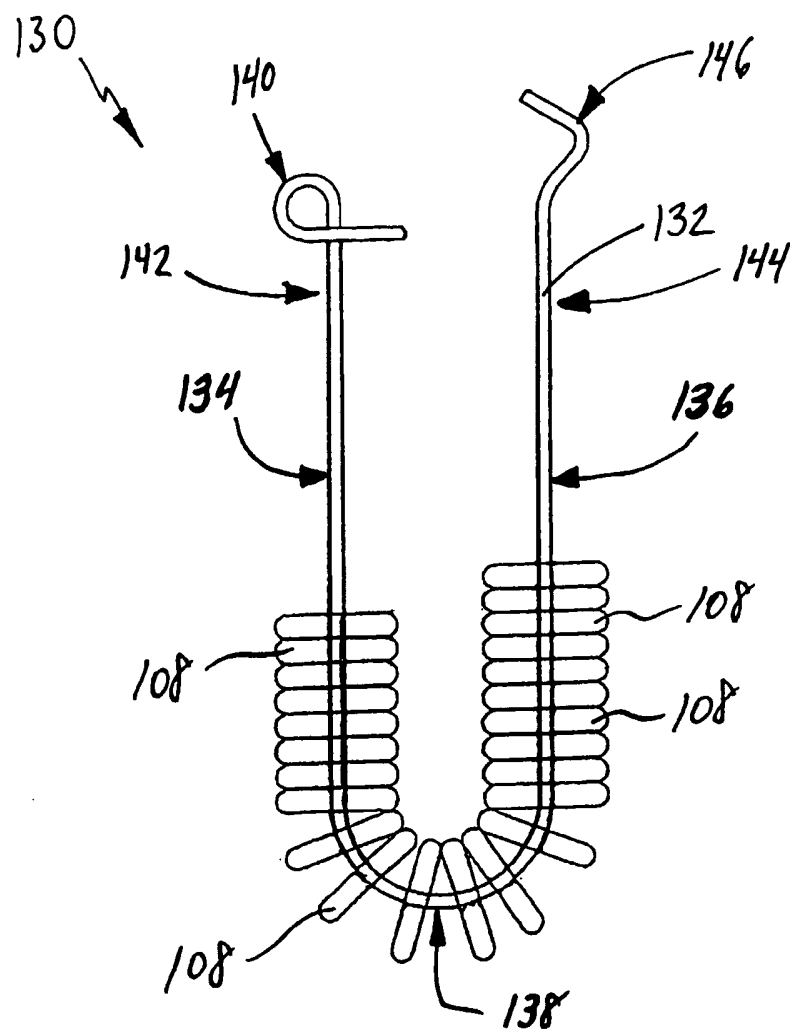


FIG. 4

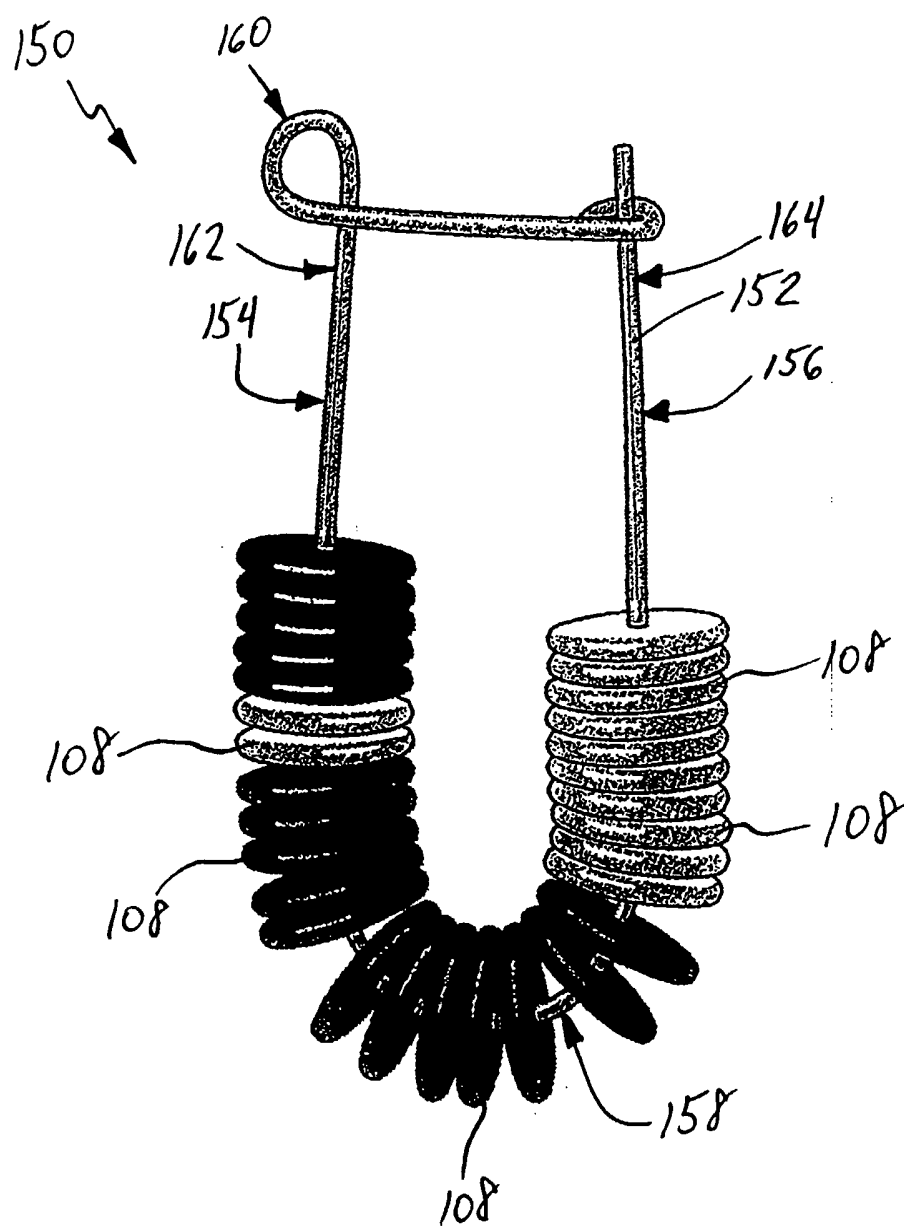


FIG. 5

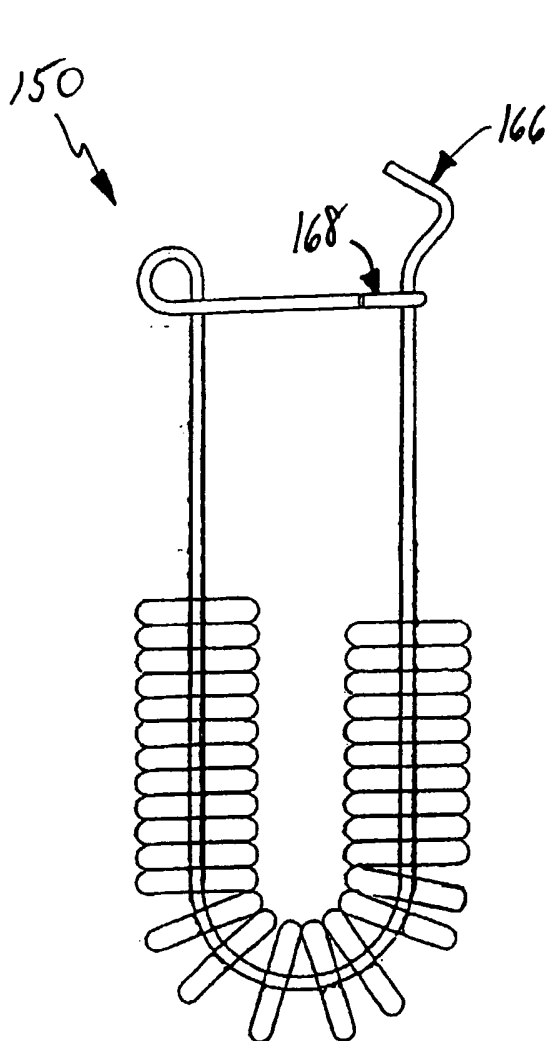


FIG. 6

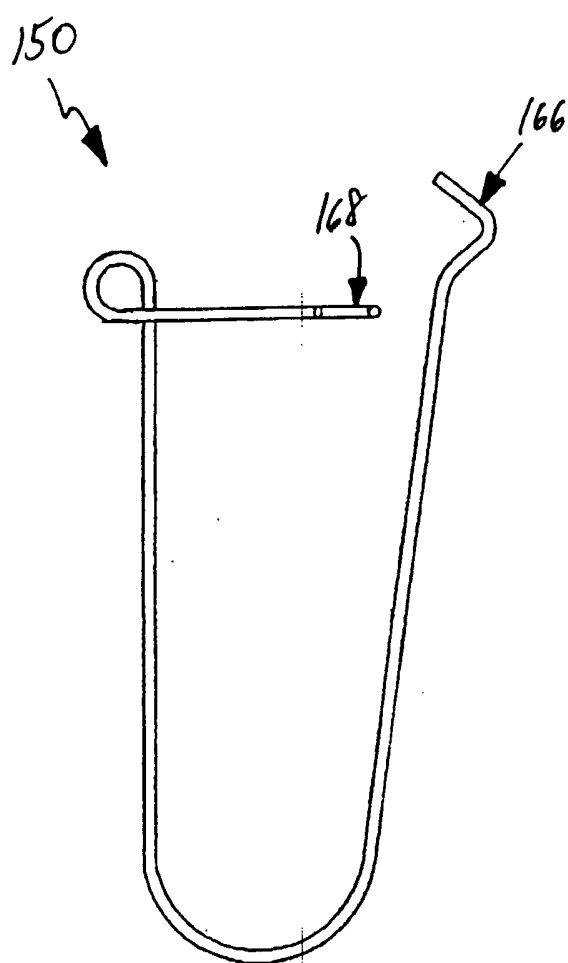


FIG. 7

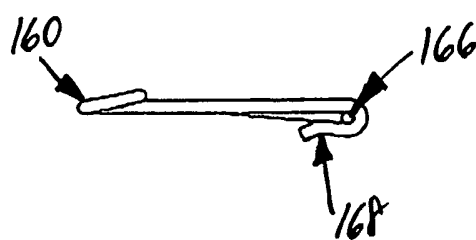


FIG. 8

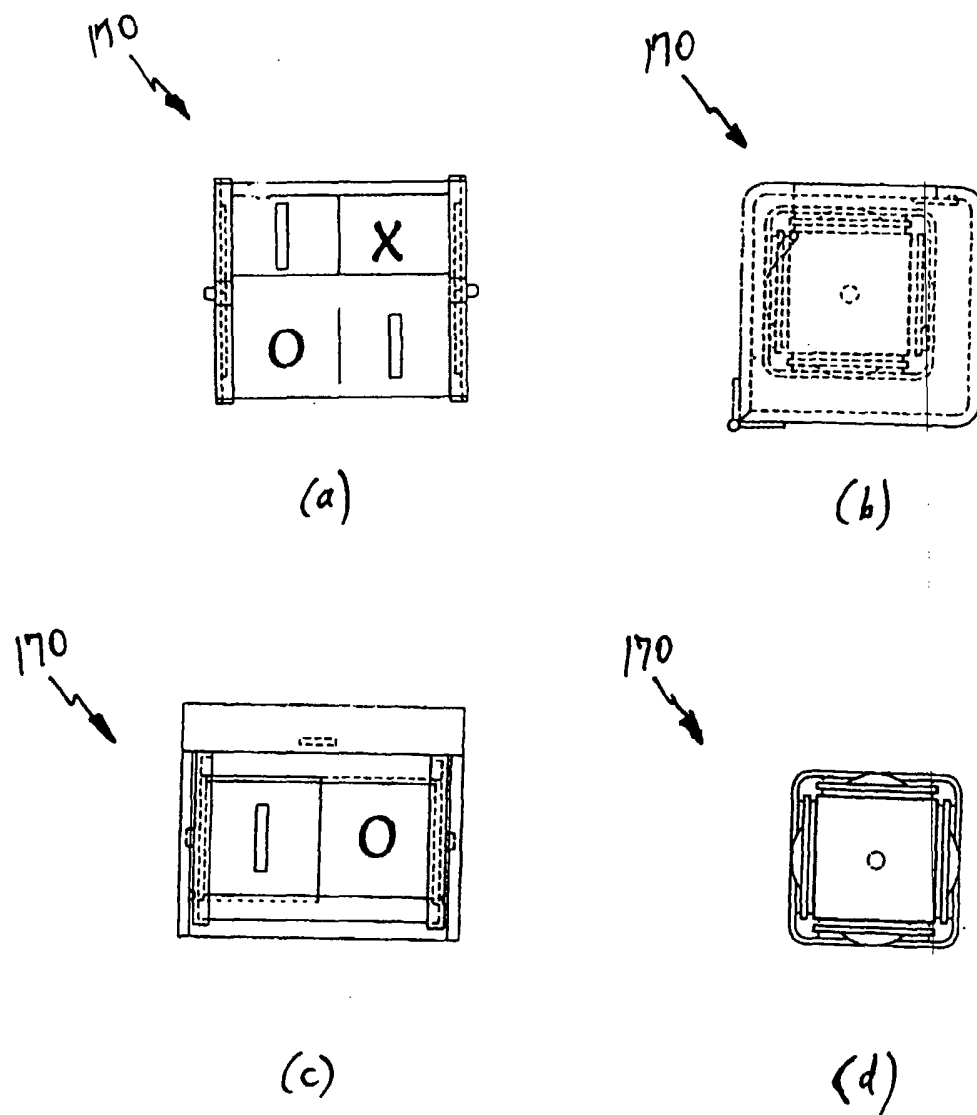


FIG. 9