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Groves

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[54] **VAGINAL MEDICATOR**

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[52] **U.S. Cl.** **128/271**, 128/270, 128/285

[51] **Int. Cl.** **A61f 13/20**, A61m 31/00

[58] **Field of Search** .... 128/232, 270 X, 271, 285 X

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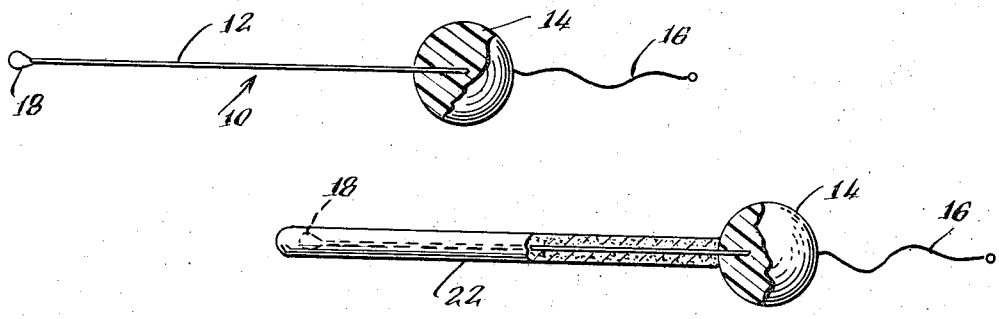
Primary Examiner—Aldrich F. Medbery

Attorney, Agent, or Firm—Wooster, Davis & Cifelli

[57] **ABSTRACT**

A vaginal medicator adapted to be retained within the human vaginal canal to apply medication molded thereon to the vaginal canal and cervix including body-undissolvable stem and anchor means. The stem is formed into various shapes and lengths, each designed to reach along the length of the vaginal canal from its lower end to the region of the cervix thus enabling medication molded thereto to be delivered where desired within the vaginal canal. The stem may include loops, webs and meshes for carrying additional medicaments and for increasing the application of medicaments to the cervix. The anchoring means may be a spherical, ellipsoidal or cylindrical mass connected at one end of the stem adapted to hold the medicator in proper position by virtue of the constricting muscles at the entrance to the vaginal canal. Alternatively, the structure of the stem itself, such as a substantially triangular looped stem or a stem having a cervix surrounding loop at its inner end may adequately serve as the anchoring means.

14 Claims, 15 Drawing Figures



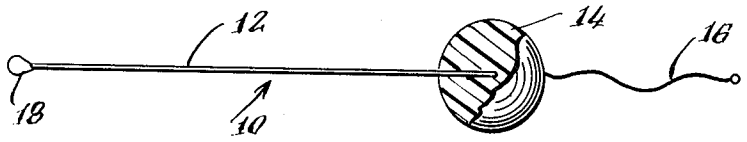
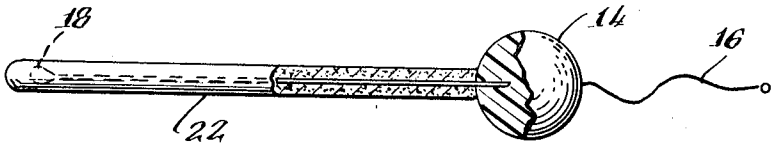


Fig. 1a

Fig. 1b.



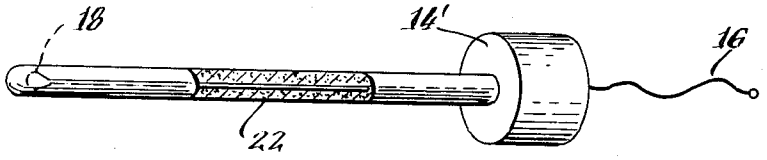
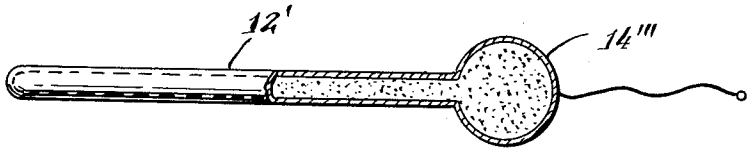


Fig. 2.

Fig. 3.



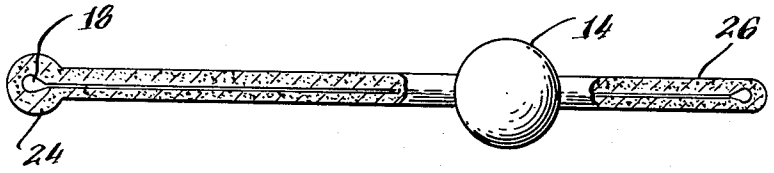
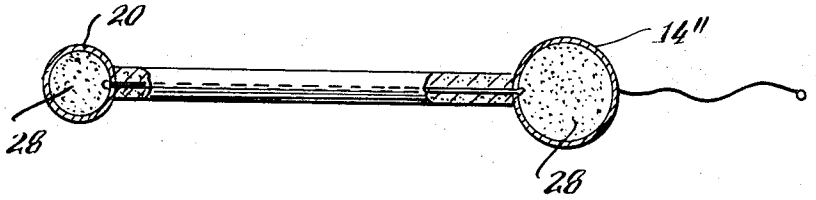


Fig. 4

Fig. 5.



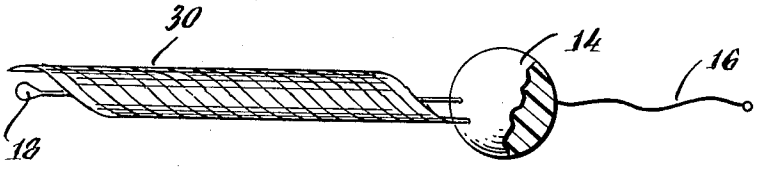
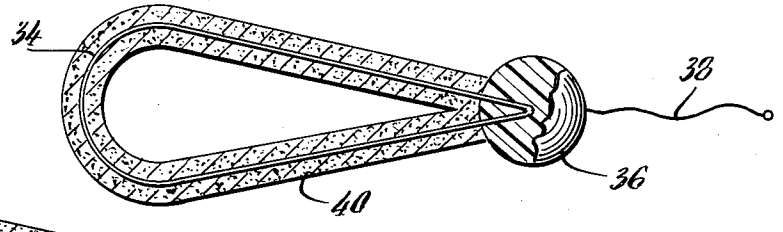


Fig. 6.

Fig. 7a.



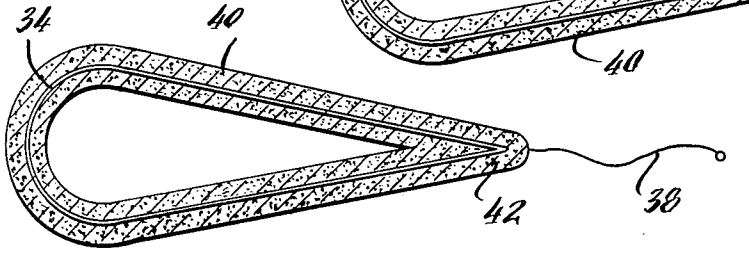
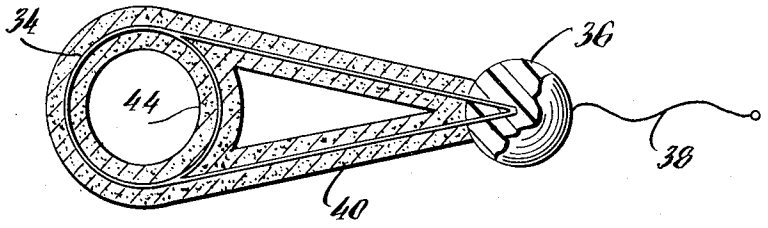


Fig. 7b.

Fig. 7c.



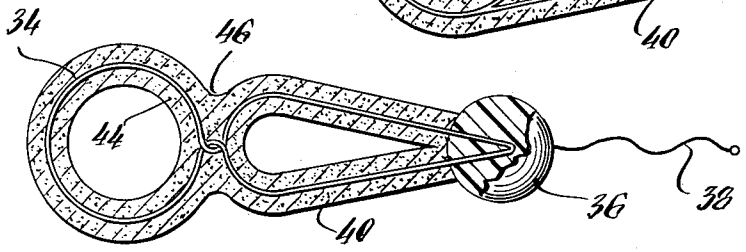
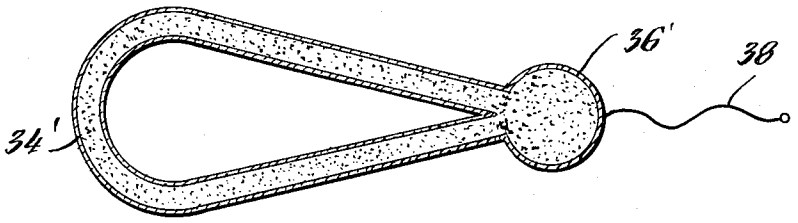


Fig. 7d.

Fig. 7e.



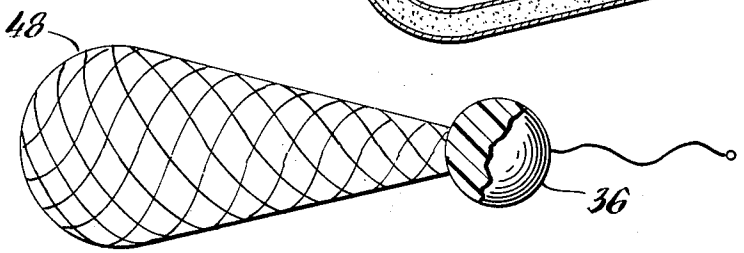
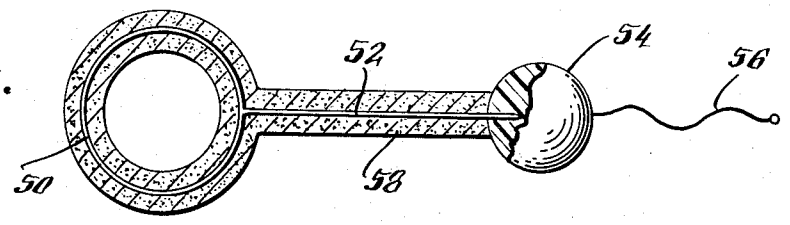


Fig. 8.

Fig. 9a.



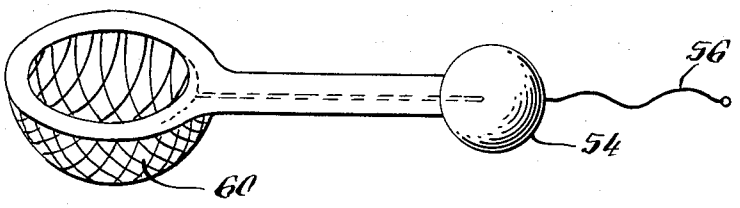


Fig. 9b.

VAGINAL MEDICATOR

BACKGROUND OF THE INVENTION

The present invention relates to medicators and, more particularly, to vaginal medicators or suppositories. One of the principal requirements for applying topical medication to the body is that the medication remain in the desired body area for an extended period of time. For example, in the treatment of vaginal disease, it is desirable that the medication be applied for many hours to remote regions of the vaginal canal and cervix. These regions are not readily reached by conventional vaginal suppositories due to their size and shape. Due to the structure and nature of the human vigina, for example, inserted suppositories or ovules often do not stay in place, or upon melting, the medication may drain out of the vagina, substantially reducing its effectiveness. In either of these cases, the medication is not maintained in the desired location for a sufficient duration of time, nor does it necessarily find its way to affected parts in the vaginal canal which are remote from the normal positioning of suppositories.

Prior attempts at overcoming these problems have not been satisfactory. For example, presently available medicated cotton tampons do not extend along the length of the vaginal canal and, therefore, cannot deliver medication where desired. Furthermore, they do not allow for efficient transfer of medication to affected areas, nor can they be used to apply medication to selected areas because of the highly absorbent nature of the cotton fibers. Other medicators are uncomfortable to insert and use because of their rigid structure.

SUMMARY OF THE INVENTION

These problems and disadvantages are overcome by the present invention by providing a medicator which extends along the entire length of the vaginal canal to the cervix so that medication may be delivered wherever desired and which provides efficient transfer of medication and is comfortable to use. More specifically, the present invention includes a flexible or semi-rigid body-undissolvable stem of plastic or other suitable material formed into various shapes which extends along the entire length of the vaginal canal reaching to the cervix. Medication molded to the stem or any portion thereof can be maintained for extended periods of time in any position desired, depending upon where it is molded to the stem. The medicator is held in place by virtue of the action of the constricting muscles at the lower region of the vaginal canal and the anchoring means of the medicator. The anchoring means may be provided by a mass of body-undissolvable plastic or other suitable material secured to one end of the stem. This mass, which is preferably spherical, ellipsoidal or cylindrical, is dimensioned so as to be retained comfortably in the vagina by the constricting muscles near the entrance of the vagina. Alternatively, the anchoring means may be provided by the configuration of the stem in relation to the anatomy of the vaginal tract. Such configurations include loops to encircle or partially surround the cervix, cup-shaped webs attached to the stem and designed to fit over the cervix and the generally triangular shape of the looped stem which resolves the lateral forces from the constricting muscles and the naturally collapsing walls of the vagina into longitudinal forces serving to urge the medicator upwardly into the vaginal canal.

It is, therefore, a general object of the present invention to provide a vaginal medicator which overcomes the disadvantages of the prior art.

It is a more specific object of the present invention to provide a vaginal medicator which can deliver medication to the entire vaginal canal and the cervix or any portion thereof for extended periods of time.

It is another object of the present invention to provide a vaginal medicator which may be comfortably retained within the vaginal canal for extended periods of time.

It is still another object of the present invention to provide a vaginal medicator which may be maintained in a desired position within the vaginal canal.

It is a further object of the present invention to provide a vaginal medicator which provides for efficient transfer of medication to the affected areas.

BRIEF DESCRIPTION OF THE DRAWINGS

These as well as other objects and advantages will be readily apparent to those skilled in the art from a perusal of the appended claims and the following description when read in conjunction with the attached drawings in which:

FIGS. 1*a–b* are illustrations of a first embodiment of the present invention without and with medication applied, respectively.

FIG. 2 is an illustration of a modified version thereof with a cylindrical anchor.

FIG. 3 is an illustration of another modified version thereof with a hollow drug-permeable stem and anchor.

FIG. 4 is an illustration thereof with additional medication provided at the inner end thereof and along the pullout string.

FIG. 5 is an illustration of a modified version thereof in which a second body-undissolvable bulb is included at the inner end.

FIG. 6 is an illustration of a modified version thereof in which the stem includes a laterally extended web or mesh to increase the surface area and amount of medication.

FIGS. 7*a–e* are illustrations of various modified versions of a second embodiment of the present invention in which the stem is formed in a substantially triangular configuration with a cervix engaging loop.

FIG. 8 is an illustration of a modified version of the FIG. 7*a* medicator in which a mesh extends within the area enclosed by the stem to increase the surface area and amount of medication.

FIGS. 9*a–b* are illustrations of two versions of a third embodiment of the present invention in which the inner end of the stem terminates in a cervix engaging loop and cup, respectively.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Three embodiments of the present invention will now be described, as well as various modifications which may be incorporated in each. Although some of the modifications are described in conjunction with only one embodiment, it will readily be apparent that many of them may be incorporated in other embodiments as well.

Now, with particular reference to FIGS. 1 – 6, a first embodiment of the vaginal medicator, generally designated 10, will be described. The medicator 10 includes a flexible or semirigid stem 12 formed from a body-undissolvable plastic material, a fiber thread, or other suitable material. The stem 12 is secured to an anchor 14 which may be formed from cotton, fibrous material, plastic or other suitable material. A pullout string 16 is attached to the anchor 14 for purposes of manually removing the device after use. This pullout string 16 may be separately attached to the anchor 14 or may be an integral extension of the stem 12.

The anchor 14 is preferably either spherical (14) as shown in FIGS. 1*a* and 1*b*, cylindrical (14') as shown in FIG. 2 or ellipsoidal (not shown). If the anchor 14 is to be made of cotton it may be formed by spinning cotton onto the end of the stem 12; and may be bound to itself through impregnation of the cotton with waxes, resins, sizing compounds, latexes, etc., and subsequently coated with a resin or other materials similar to those indicated above to provide a nonabsorbent surface, or partially absorbent surface as may be desired. The anchor 14 may also be fastened to the stem by using bonding cement or by heat-plasticising the end of the stem 12. The anchor 14 also may be formed by means other than by spinning, for example by sewing together cotton wads and subsequently attaching them to the stem. Alternatively, the anchor can take the form of a conventional tampon of shortened length and sewn or otherwise secured to the end of the stem 12. If the anchor 14 is cotton, it may be designed to expand after insertion while also increasing its absorbency, if so desired, by not applying sizing, bonding, or coating compounds and/or by containing the naturally expansive fibers within a hollow applicator similar to that used to insert conventional vaginal tampons, so that expansion takes place after insertion of the device and subsequent removal of the applicator. If the anchor 14 is plastic, it may be attached to the stem 12 by cement or by means of heat, sonic, or high frequency welding or other methods. In addition to the modes of attachment previously described the stem 12 and anchor 14 may also be formed from a unitary, continuous piece of plastic such as by injection molding.

The inner end of the stem, that is the end remote from the anchor 14 may be provided with a blunt end 18 by spinning a small amount of cotton or other fiber to guard against possible abrasion of body tissues after the medication has been dissolved away. The blunt end 18 may also be provided by dip-coating the inner end of the stem 12 into plastic melts or by bonding a premolded bulb of body-undissolvable material such as plastic to the end of the stem 12. This bulb may be a small blunt tip 18 or a somewhat larger bulb 20 as shown in FIG. 5.

The anchor 14 and the stem 12 may vary in size depending upon the size of the human in which they are to be used. The stem must be long enough to reach to the upper most extremities of the vaginal canal to the region of the anterior or posterior fornices when the anchor is in position in the lower part of the vaginal canal in the same general region occupied by conventional vaginal tampons. For the typical adult human, the stem may be approximately 1/32 to 1/16 inch in diameter and 3 to 4 inches in length, and the anchor may be approximately 3/4 inch in diameter.

A medication 22 shown in partial cross section surrounding the stem 12 in FIGS. 1*b*, 2 and 4 may contain medicaments, drugs, etc. designed for local and/or systemic effects, which may or may not be absorbed by the vaginal mucosa, suspended in a pharmaceutical base designed to melt slowly over a period of hours as a result of the temperature of the body or to dissolve slowly as a result of contact with body fluids. Examples of suitable pharmaceutical bases include polyethylene glycols, glycerogelatins, gelatins, waxes, modified fats and fatty oils. The cross-sectional diameter of the stem 12 and surrounding medication 22 may be approximately 1/4 inch to 3/8 inch and is considerably less than the diameter of the anchor 14. If desired, an increased amount of the medication 22 may be formed at or adjacent the blunt end 18 of the stem 12, such as at 24 (FIG. 4). This provides an increased amount of medication to the cervix and upper portion of the vaginal canal. Additionally, the medication 26 may also be provided around the pullout string 16 to deliver medication to the extreme lower portion of the vaginal canal.

The embodiment of the vaginal medicator 10 as thus far described may also be modified by making either or both the anchor 14 and the enlarged bulb 20 hollow and drug-permeable so that additional medication may be stored therein to slowly migrate through its walls into the surrounding vaginal tissues when subjected to body temperature or when in contact with body fluids. As meant herein, drug-permeable includes any material through which a medication can pass, such as a drug-permeable plastic or a perforated plastic. These modifications are shown in FIG. 5 with the anchor 14'' and the enlarged bulb 20 being made of drug-permeable material and containing additional medication 28. The enlarged bulb 20 whether hollow and containing medication or not gives additional anchoring to the suppository by being located in the vault of the vagina near the cervix. It also may be used to provide additional medication to the area near the cervix by being drug-permeable and containing medication or by surrounding a solid bulb with medication.

In the same manner, the entire medicator 10 may be hollow and formed from a drug-permeable material as shown in FIG. 3. The stem 12 is integral with the anchor 14''' to form a continuous hollow core which may be filled with medication. In this arrangement the stem 12' will be approximately the same dimensions as the stem 12 with medication 22 thereon.

This embodiment of the vaginal medicator 10 may be modified as shown in FIG. 6 to include a mesh or web 30 to which medication may be adhered. Although, as shown, the web 30 extends along the entire length of the stem 12 it should be understood that the web 30 could be designed to extend along only a portion of the stem 12 or, alternatively, could comprise a plurality of individual portions. The addition of the web 30 allows the medicator 10 to carry additional medication and provides a greater surface area of medication if desired. The mesh or web 30 may be formed from flexible plastic netting, fabric mesh, polymeric film or other suitable material, and may be attached to the stem 12 by any suitable method, such as welding, cementing or stitching.

Now with particular reference to FIGS. 7*a–e* and 8 a second embodiment of the present invention will be described. In this embodiment, the vaginal medicator

generally designated **32**, includes a looped stem **34** connected to an anchor **36** which may be identical to any of the various anchors described previously with respect to the first embodiment depicted in FIGS. **1 – 6.** As in the first embodiment, a pullout string **38** is also provided. The looped stem **34** is dimensioned so as to reach the posterior fornix of the vagina and surround the cervix. As in the first embodiment, slow dissolving medication **40** surrounds the stem **34.** In this embodiment the looped stem **34** seats behind the cervix, and the substantially triangular shape of the loop resolves lateral forces from the surrounding musculature of the vagina into longitudinal forces along the longitudinal axis of the medicator **32** urging it upwards into the vagina. Because these features serve to anchor the medicator **32,** the distinct anchor **36** may be omitted as shown in FIG. **7***b* without impairing the utilization of the medicator **32.** In such a modification the pullout string **38** is connected directly to the stem **34** as shown at **42.** Other modifications may also be made in the medicator **32.** For example, as shown in FIGS. **7***c* and **7***d* the inner end of the stem **32** may be formed into a circular loop by including an extra portion **44** or by being necked in as at **46,** respectively, to allow medication to completely surround the cervix. The stem **34** may also be formed as a hollow drug-permeable member **34'**, as shown in FIG. **7***e*, similar to the modification of the first embodiment illustrated in FIG. **3.** The anchor **36'** may also be hollow and drug-permeable, and may form a continuous core with the stem **34'**. Finally, a web or mesh **48** (FIG. **8**) may be extended within the area enclosed by the stem to allow the medicator to carry additional medication and to provide a greater surface area of medication. The mesh or web **48** may be preferably formed in a cup or concave shape so as to permit the inner end of the looped stem **34** to surround the cervix.

A third embodiment of the present invention is illustrated in FIGS. **9***a–b*. This embodiment differs from the first described embodiment only in that a looped end **50** designed to surround the cervix is provided at the inner end of a stem **52.** The remainder of the medicator, including an anchor **54,** a pullout string **56** and medication **58** may be identical to any of the various modifications thereof described previously. For example, a cup shaped mesh or web **60** (FIG. **9***b*) may be included within the looped end **50** in a similar manner to the modifications of the other embodiments described with respect to FIGS. **6** and **8.** In this embodiment, the loop **50** surrounding the cervix may adequately serve to anchor the medicator in place. Therefore, the distinct anchor **54** may be deleted.

Other modifications and variations will also become apparent to those skilled in the art. For example, any of the above embodiments or modifications thereof may be further modified by angling, bending or curving the stem to allow the medicator to more naturally conform to the anterior and posterior fornices of the vagina adjacent the cervix.

Each of the embodiments of the present invention and the various modifications thereof may easily be used. The vaginal medicator is inserted up into the vaginal canal with the inner end of the stem reaching up into the region of the cervix, and the anchor being seated in and held in place by the constricting muscles at the entrance to the vaginal canal. With this configuration, medication whether to be for local or systemic purposes may be administered along the entire length of the vaginal canal or any portion thereof.

Once inserted the medication slowly dissolves either by virtue of body temperature or body fluids. As described in detail previously, various modifications may be made to increase the amount or surface of medication to a desired area. For example, additional medication **24** or a drug-permeable bulb **20** may be included at the inner end of the stem **12** of the first embodiment. Furthermore, where increased delivery of medication is desired in the cervix area the embodiment of FIGS. **7***a–e*, **8** or that of FIGS. **9***a–b* may be utilized so that the cervix is surrounded by medication. Further increases in the amount and surface area of medication may be had by utilizing the mesh or web modifications discussed previously with respect to FIGS. **6, 8** and **9***b*.

In the latter two described embodiments, the loops of the stem may be compressed for ease of insertion, and the medicator is positioned so that the inner loop of the stem surrounds the cervix. The elastic memory of the stems and the amorphous characteristic of the medication will restore the shape of medication and prevent cracking or shifting of the medication. All of these embodiments are easily accommodated within the vaginal canal and are as comfortable to use or wear as an ordinary tampon.

Thus, an improved vaginal medicator has been provided withich significantly improves the application and supply of both local and systemic medication to the vaginal canal, is easily used, and is comfortable to wear.

It is believed that the many advantages of the present invention will now be apparent to those skilled in the art. It will also be apparent that a number or variations and modifications may be made without departing from its spirit and scope. Accordingly, the foregoing description is to be construed as illustrative only, rather than limiting.

What I claim is:

1. A vaginal medicator comprising:

elongated body-undissolvable stem means for extending along substantially the entire length of the vaginal canal to the region of the cervix;

a body-undissolvable anchoring mass connected to one end of said stem means, said anchoring mass being of a size to be retained above the constricting muscles at the entrance to the vaginal canal with at least a portion of the stem means extending upwardly from said anchoring mass to be positioned in the upper portion of the vaginal canal and near the cervix;

medication carried by said stem means for slowly dissolving in the vaginal canal to supply medication thereto; and

pullout means connected to said anchoring mass and extending out from the vaginal canal when the medicator is in place therein for providing easy removal of the medicator.

2. The medicator of claim **1** wherein said anchoring mass is spherical.

3. The medicator of claim **1** wherein said anchoring mass is cylindrical.

4. The medicator of claim **1** wherein said anchoring mass is formed from cotton.

5. The medicator of claim **1** wherein said anchoring mass is formed from plastic.

6. The medicator of claim 1 wherein said anchoring mass is hollow, is formed from a drug-permeable material and contains medication therein which is slowly released to the vaginal canal.

7. The medicator of claim 6 wherein said stem means is a hollow tube-like member formed from a drug-permeable material, said hollow member opening to said hollow anchoring mass to form a continuous core through the medicator.

8. The medicator of claim 1 wherein said stem means is a thin flexible stem and said medication is in the form of a body-dissolvable moldable solid surrounding said stem.

9. The medicator of claim 8 wherein said pullout means is a thin flexible member surrounded by said medication.

10. The medicator of claim 1 wherein said stem means is a hollow tube-like member formed from a drug-permeable material and said medication is carried therein.

11. The medicator of claim 1 wherein said elongated stem is a thin flexible stem with a blunt inner end, and said medication is in the form of a body-dissolvable moldable solid surrounding said stem and said blunt end.

12. The medicator of claim 11 wherein said medication is formed into an enlarged bulb around said blunt end.

13. The medicator of claim 1 wherein said stem means includes web means extending laterally therefrom, on which medication may be adhered.

14. The medicator of claim 1 wherein said stem means is approximately 3 to 4 inches in length.

* * * * *