United States Patent

Rudel

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[54] INTRAUTERINE MEDICATOR

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[52] **U.S. Cl.** **128/264**, 128/130

[51] **Int. Cl.** **A61m 31/00**

[58] **Field of Search** 128/264, 130, 127, 265, 251, 128/270, 271, 263, 260, 261; 901/81

[56] **References Cited**

UNITED STATES PATENTS

2,122,579	7/1938	Meckstroth	128/130
3,442,266	5/1969	Kreici et al.	128/130
3,545,439	12/1970	Duncan	128/130
1,603,767	10/1926	Harris	128/271
1,605,894	11/1926	Homan	128/271
2,623,841	12/1952	Taub	128/127 X
2,962,023	11/1960	Chappaz et al.	128/260
3,409,721	11/1968	Applezwein	128/130

FOREIGN PATENTS OR APPLICATIONS

13,324	7/1894	Great Britain	128/127

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[57] **ABSTRACT**

An intrauterine medicator and method for local application of medication to the uterus. The medicator includes a perforated tube containing a supply of medication; apparatus for maintaining medication adjacent the perforations for distribution to the uterine wall, and apparatus resiliently retaining the device in the uterus.

12 Claims, 6 Drawing Figures

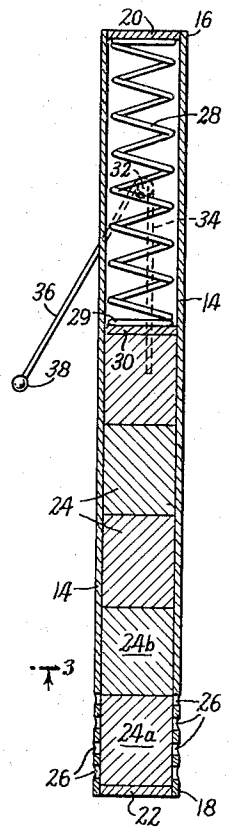

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Fig 1

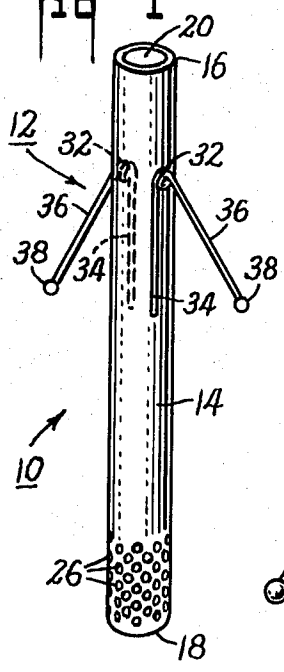


Fig 3

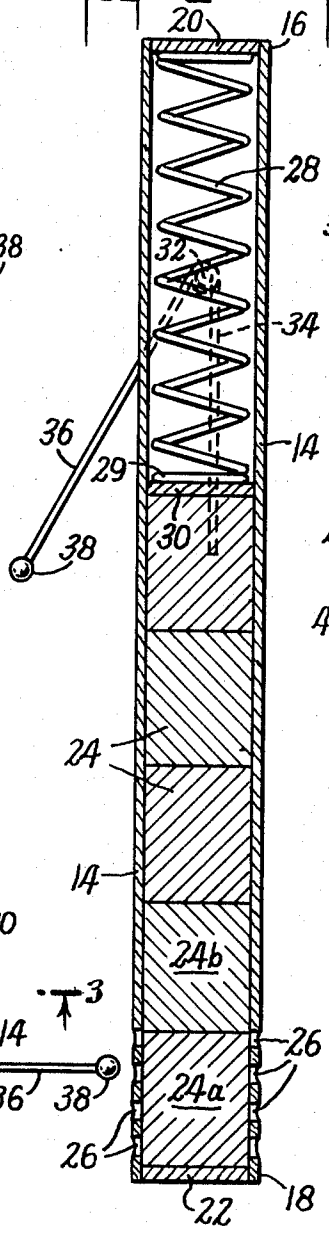


Fig 4

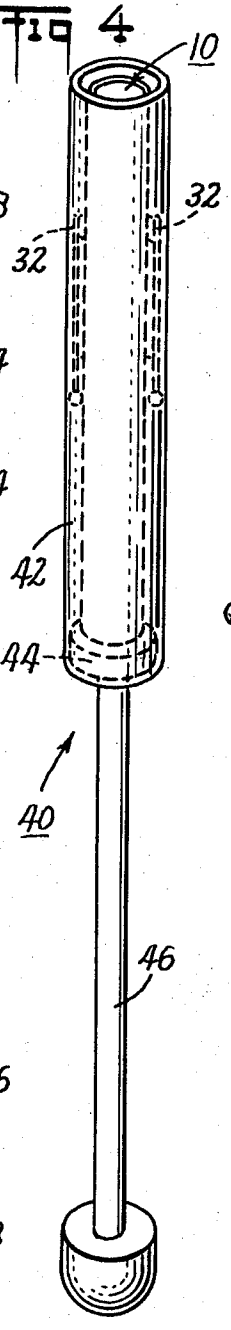


Fig 5

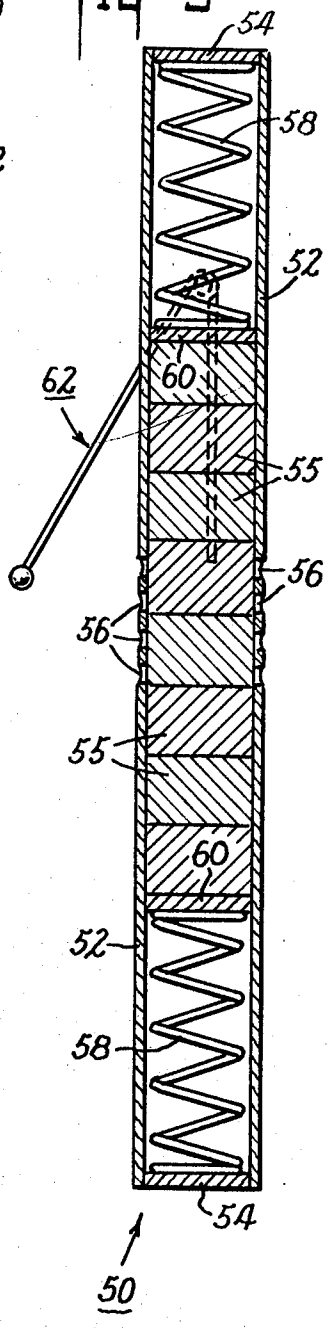


Fig 2

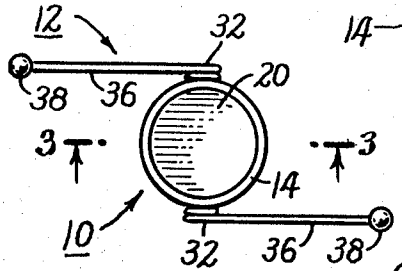
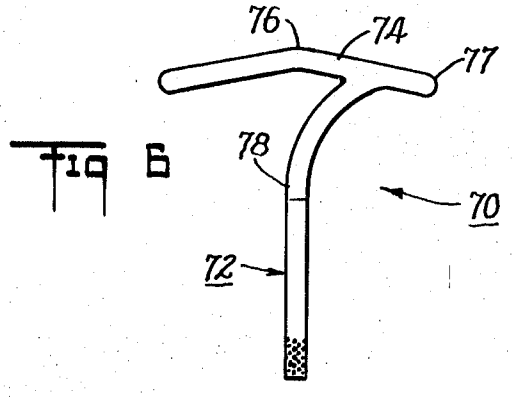


Fig 6



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INTRAUTERINE MEDICATOR

The present invention relates to intrauterine medicator devices and in particular to intrauterine carries of medication for locally supplying medication to the uterine walls. One of the embodiments of the invention is directed to an intrauterine carrier of antifertility agents.

In the practice of medicine it has been found desirable to furnish certain therapeutic and biologically active materials to the uterus by local rather than systemic administration of the drug. For example, certain biologically active materials such as progesterone and progestational compounds, which are known in the prior art as effective antifertility agents, have been administered systemically in the past with resulting undesirable side effects in certain patients. However, it has been found that these side effects can be avoided by locally supplying these agents to the uterine wall.

Specifically, progesterone and progestational compounds when supplied locally to the uterus produce changes in the endometrium which are characteristic of the biological action of the same progestational compounds given systemically. Such changes, characterized as premature maturation of the endometrium, are capable of significant antifertility effects and can be achieved with doses of progestational agents small enough not to inhibit ovulation.

While local administration of natural progesterone hormones has been attempted in the past, success has been achieved only by repeated and frequent applications.

It is an object of this invention to supply antifertility agents and other medication, locally, to the uterine wall. It is another object of the invention continuously to provide such medication over extended periods of time. Another object of the invention is to provide apparatus for retaining a container of medication in the uterus. A still further object of the invention is to provide a method for locally administering biologically active medication to the uterus. It is a further object of the invention to provide a simple and inexpensive intrauterine medicator device.

In accordance with the preferred embodiment of the present invention there is provided an intrauterine medicator having a perforated tube, such as of corrosion-resistant or coated metal, or of plastic, in which a supply of a medication, is enclosed. The drug is suitably in the form of individual pellets and is urged under the force of means, such as a compressed spring, in the tube to a position adjacent the perforations. The tube is adapted to be inserted in the uterus so that body fluids can leach the medication from the tube through the perforations for local administration to the uterine wall. As the drug dissolves in the area of the perforations, the compressed spring pushes a new supply of the drug adjacent the perforations so that a continuous controlled release of the drug is obtained. The drug utilized in the medicator tube may be any therapeutic or biologically active material which is adapted to local administration; however, in the preferred embodiments an antifertility agent such as progesterone is utilized.

The medicator tube is retained in the uterus by a pair of generally inverted V-shaped springs, each having one leg fixed to the tube. The free leg of each spring extends beyond the tube and resiliently engages the uterine wall to maintain the position of the device in the uterus. In another embodiment the tube may be formed as part of a so-called intrauterine contraceptive device or IUD, such as the well-known Lippes Loop or other such devices. In this manner the tube of the present invention supplements the function of the IUD and is held thereby in position in the uterus.

The construction of the preferred embodiment as well as further objects and advantages thereof will become further apparent from the following specification when considered in conjunction with the accompanying drawings wherein:

FIG. 1 is a perspective view of the intrauterine medicator of the present invention;

FIG. 2 is a plan view of the device illustrated in FIG. 1;

FIG. 3 is a view taken on line 3—3 of FIG. 2;

FIG. 4 is a perspective view of the intrauterine medicator contained within an instrument for insertion of the device into the uterus;

FIG. 5 is a view similar to FIG. 3, of another embodiment of the present invention; and

FIG. 6 is a front view of the medicator of the present invention formed as part of an intrauterine contraceptive device.

Referring now to the drawings, and in particular to FIG. 1, there is shown an intrauterine medicator **10** having spring retaining apparatus **12** which is adapted to maintain the medicator in position in the uterus.

Medicator **10** includes a cylindrical tube **14** having top and bottom ends **16** and **18** respectively. In the preferred embodiment tube **14** has a diameter of about 1.5–2.0 millimeters and a length of about 2 centimeters. Ends **16** and **18** are closed by plates **20** and **22** respectively, which serve to retain a column of pellets **24** of a biologically active material, such as an antifertility agent, within tube **14**.

The lower portion of tube **14** adjacent end **18** includes a plurality of perforations **26** through which the medicament is leached by body fluids within the uterine cavity. As individual pellets **24** dissolve, a new pellet will be moved into position adjacent perforations **26** by spring **28** to provide continuous release of medication. Spring **28** is a compression spring retained between the top plate **20** of tube **14** and bearing plate **30**. Plate **30** is slidable within tube **14** and cooperates with spring **28** to push pellets **24** toward perforations **26**. In addition, plate **30** prevents mutilation of the uppermost pellet **24** by the end **29** of spring **28**.

The number of perforations **26** and the size of pellets **24** may be correlated such that a single pellet will provide sufficient medication for a given period of time. The lowermost pellet **24***a* dissolves during the course of the desired time period and at the end of this period is weakened sufficiently so that it crumbles under the force of spring **28**. Spring **28** then urges the entire column of pellets **24** downwardly towards lower end plate **22** whereby the next pellet, **24***b* in FIG. **2**, is presented adjacent perforations **26** to again furnish the medication to the uterus for the desired time period. It is foreseen, for example, that the perforations **26** and the size and composition of pellets **24** may be correlated to an individual women's menstrual cycle so that a new pellet **24** is presented adjacent perforations **26** at the beginning of each cycle.

Pellets **24**, as previously noted, are formed of a biologically active material. Such materials, in the preferred embodiment, include steroid hormones such as progesterone or related synthetic progestational compounds, estrogen, and testosterone, or other antifertility agents such as quinacrine, azauridine, or metallic copper grains. It is also foreseen that tube **14** can also carry therapeutic agents such as antibiotics for intrauterine treatments.

Intrauterine medicator **10** is maintained in position in the uterus by retaining apparatus **12** which includes a pair of inverted generally V-shaped spring members **32**, which may be of metal, plastic, or some other resilient material. Each spring **32** has a pair of diverging legs **34** and **36** lying in parallel planes tangent to tube **14**. Each leg **34** is fixed to the exterior surface of tube **14**, for example, by adhesive, brazing, etc., and extends longitudinally therealong. Legs **36** are formed at an acute angle to legs **34** and diverge from one another to form a large inverted V as seen in FIG. **1**.

When inserted in the uterus, the diverging free ends of legs **36** engage the uterine walls to retain the medicator in its proper position. Balls **38** or other similar blunt structure are formed on the free ends of legs **36** to prevent injury to the uterine wall. In addition, by the construction described, the coiled portions of spring members **32** lie in parallel planes, tangent to tube **14** whereby they are relatively flat against tube **14** and provide a compact, safe assembly. It is also noted that any corrodable or otherwise objectionable metal parts of the medicator i.e., the spring, are suitably coated with a benign material such as "Silastic."

In FIG. 4 there is illustrated an applicator 40 containing medicator 10 prior to insertion in the uterus through the vaginal canal. Applicator 40 includes cylindrical tube 42 which receives medicator 10 and maintains spring members 32 in a compressed state during insertion. A plunger member 44 is also provided which is slidable within tube 42 upon actuation of handle 46. Medicator 10 remains in applicator 40 in the condition shown in FIG. 4, during the insertion operation. When the proper uterine position is achieved, plunger 44 is actuated by movement of handle 46 to push medicator 10 through the open top of tube 42 until arms 36 are freed to spring open to their uncompressed state and engage the uterine wall. In this manner medicator 10 is lodged in place and applicator 40 is then withdrawn.

The intrauterine medicator of the present invention may be constructed in a somewhat modified form as shown in FIG. 5. In this embodiment a cylindrical medicator 50, including a tube 52 closed at its opposed ends by plates 54, has a plurality of perforations 56 located intermediate the ends thereof. A column of medication, conveniently in pellet form 55, is retained as in the prior embodiment within tube 52 between a pair of elastic members such as springs 58, which serve to maintain the central portion of the column adjacent perforations 56. Springs 58 act in compression and are contained between end plates 54 and the ends of column 55. Bearing plates 60, similar to plate 30 of the prior embodiment, are provided so that springs 58 do not damage the endmost pellets of medication.

Spring retaining means 62, similar to spring retaining means 12 of the prior embodiment, are provided on the exterior surface of medicator 50 to retain the device in the uterus during use.

The dual spring construction of the embodiment illustrated in FIG. 5 provides a shorter working distance for spring members 58 so that a generally uniform force is applied to the column of medication as it dissolves during use. Thus, variations in the forces applied by springs 58, due to their spring constants and the distance over which they act, are minimized.

While certain preferred embodiments of the intrauterine medicator of the present invention are intended, as disclosed above, to be self-contained units adapted to provide complete antifertility protection, it is foreseen that this medicator may be utilized to supplement presently available intrauterine contraceptive devices, i.e., the well-known IUD.

It is known in the prior art that the presence of foreign objects in the uterus discourages conception, and it has been found that the larger an IUD is, the more effective it is in preventing conception. The employment of such devices, however, is subject to a number of disadvantages, particularly as their size is increased. The more common problems involve discomfort, bleeding, muscular spasms tending to eject the IUD from the uterus, and danger of puncturing the uterine wall during insertion. Each of these problems may be substantially avoided by decreasing the size of the IUD, with a resultant loss, however, in its effectiveness. It is foreseen that this loss can be compensated by supplementing an IUD with the medicator of the present invention to increase its effectiveness.

In FIG. 6, there is illustrated an intrauterine contraceptive device 70 having an intrauterine medicator 72, similar in construction to the medicator 10 disclosed in FIG. 1. IUD 70 is formed in the general shape of a 7, including a transverse arm 74 having a downwardly concave flexure 76 substantially at its midpoint and a longitudinally extending arm 78 depending from one end 77 of arm 74. Medicator 72 is formed integrally in arm 78 to supplement the contraceptive effects of the device. Both IUD 70 and medicator 72 may be formed of a rigid but flexible physiologically inert material, commonly a plastic such as polyethylene, polypropylene, nylon, "Silastic," "Dacron,"or the like.

The device is retained in the uterus in part by the lateral pressure exerted by the resilient material of the device around the flexure 76 which tends to engage the ends of transverse arm 74 into the uterine wall. Accordingly, the spring retaining means 12 of the prior embodiments are not required to retain medicator 72 in the uterus, and additionally, the entire device may be decreased in size as medicator 72 will supplement the contraceptive effects of arms 74 and 78.

While only one form of IUD has been illustrated in FIG. 6, and described above, it is foreseen that the medicator of the present invention may be used in combination with other well-known configurations of IUD's.

The above description of the invention is intended to be illustrative only, and various changes and modifications in the embodiment described may occur to those skilled in the art. These changes may be made without departing from the scope of the invention, and thus it should be apparent that the invention is not limited to the specific embodiments described or illustrated in the drawings.

What is claimed is:

1. A device for the controlled release of a biologically active solid substance in the uterus, said device comprising a supply of said substance and a container therefor, said container being adaptable to containment within the uterine cavity and having perforations in a wall thereof, means within said container for urging said supply of solid substance into the vicinity of said perforations, and resilient retaining means affixed to an external wall of said container for retaining said device within the uterine cavity.

2. A device as defined in claim 1 wherein said solid substance is an antifertility agent.

3. A device as defined in claim 1 wherein said antifertility agent is progesterone.

4. A device as in claim 1 wherein said biologically active substance is in the form of pellets.

5. A device as defined in claim 1 wherein said retaining means comprises, a pair of spring members mounted on said container, each of said spring members having a first end portion fixed to said container and an angularly related second end portion adapted to engage the uterine walls.

6. A device as defined in claim 1 wherein said retaining means comprises a first transverse arm and a second arm coplanar with said first arm and dependent therefrom, said second arm including said container.

7. An intrauterine medicator device for the controlled release of biologically active materials, said device comprising a container for said materials adaptable to containment within the uterine cavity and having an elongated generally cylindrical side wall and opposed end wall members, said side wall having a plurality of perforations therein, a column of biologically active material retained within said container and adapted to be released through said perforations into the uterus, means within said container for urging said material towards said perforations and maintaining a supply thereof adjacent said perforations, and resilient retaining means affixed to an external wall of said container for retaining said device within the uterine cavity.

8. A device as defined in claim 7 wherein said perforations are formed in said side wall at locations substantially intermediate said end walls, and said means for urging said material towards said perforations comprises a compression spring positioned within said container at each end thereof for bearing engagement with its associated end wall and the opposed end of said column whereby the central portion of said column is maintained adjacent said perforations during release of said material.

9. A device as defined in claim 7 wherein said perforations are formed in said side wall at one end thereof, and said means for urging said material towards said perforations comprises a compression spring positioned within said container in bearing relation between the other of said end walls and one end of said column to maintain the other end of said column adjacent said perforations and against said one wall during release of said biologically active material.

10. An intrauterine medicator device comprising, in combination, a generally cylindrical tube having closed end por-

tions and formed of an inert material, said tube having a plurality of perforations adjacent one end portion thereof, a column of individual pellets of biologically active material contained within said tube, a compression spring positioned in said tube in bearing relation between the other end portion of said tube and one end of said column to urge said column towards said one end and to continuously maintain a portion of said column adjacent said perforations, a pair of spring members mounted on said container, each of said spring members having a first end portion fixed on said container and extending parallel to the longitudinal axis thereof and a second end portion diverging at an acute angle from said first portion adapted to engage the uterine walls to retain said device in the uterus, whereby body fluids leach said biologically active material through said perforations for local application to said uterine walls.

11. A device as defined in claim **10** wherein said second end portions of said spring members lie in parallel planes, tangent to said tube and extend in generally opposite directions whereby said spring members form an inverted V-shaped retaining means.

12. A device as defined in claim **11** including, a bearing pad positioned between said compression spring and one end of said column.

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