United States Patent [19]

Banford et al.

[11] **3,892,238**

[45] **July 1, 1975**

[54] **DRUG SUPPORTING ANCHOR**

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[73] Assignee: **Abbott Laboratories,** North Chicago, Ill.

[22] Filed: **Jan. 14, 1974**

[21] Appl. No.: **433,062**

Related U.S. Application Data

[63] Continuation of Ser. No. 181,007, Sept. 16, 1971, abandoned.

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

[51] **Int. Cl.** **A61m 31/00;** A61f 5/46

[58] **Field of Search** ..... 128/127, 130, 131, 260, 128/285, 266, 269, 270, 271, 263, 128, 272; 30/351; 24/73 B, 123 B, 123 F, 129 B

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[57] **ABSTRACT**

A drug supporting anchor for insertion and retention in body cavities including an elongated member having a drug support surface with a spiral configuration for supporting a drug to be administered, and the combination of a drug supporting anchor as described above with a drug supported thereon in either strip form or as a uniform layer. A method for inserting a flexible spiral anchor having a drug supported thereon in a body cavity including stretching the anchor to reduce the diameter thereof, inserting the anchor in the body cavity and releasing the stretched anchor to permit the anchor to return to the original diameter after insertion.

17 Claims, 17 Drawing Figures

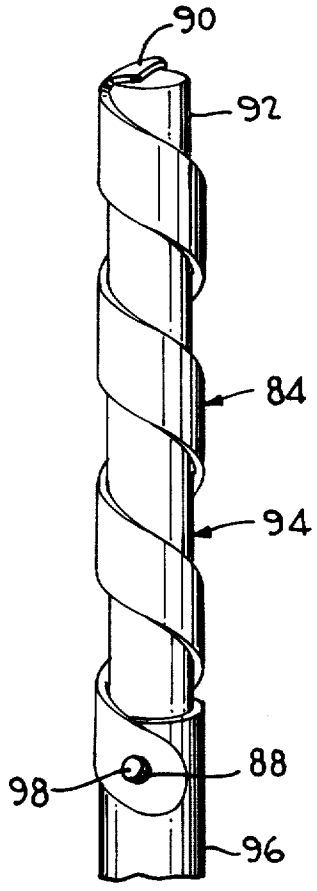

FIG. 1

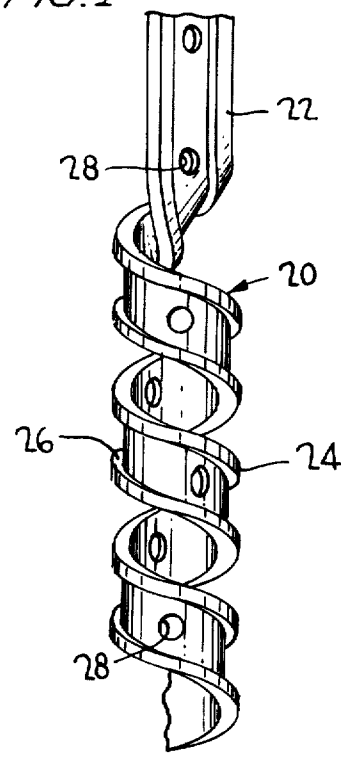

FIG. 2

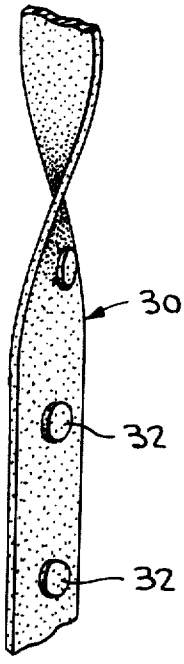

FIG. 3

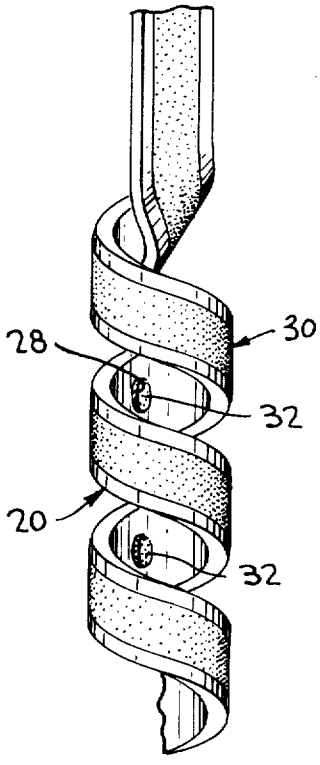

FIG. 4

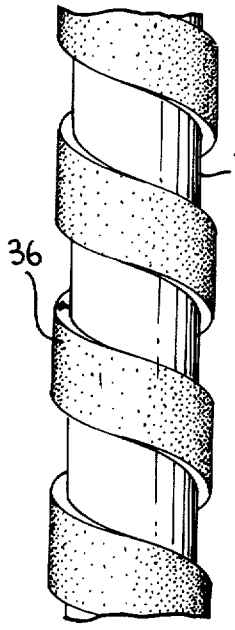

FIG. 5

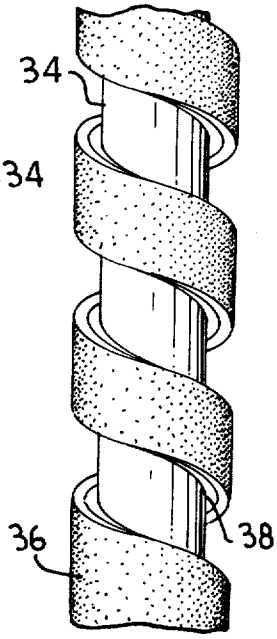

FIG. 6

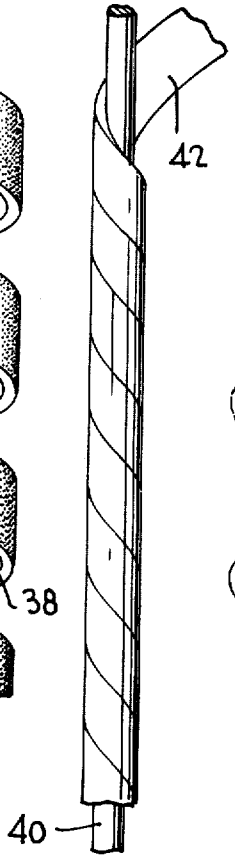

FIG. 7

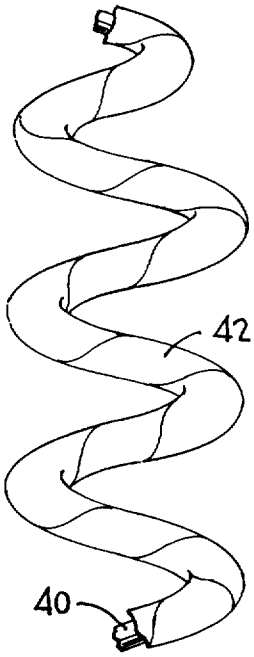

FIG. 8

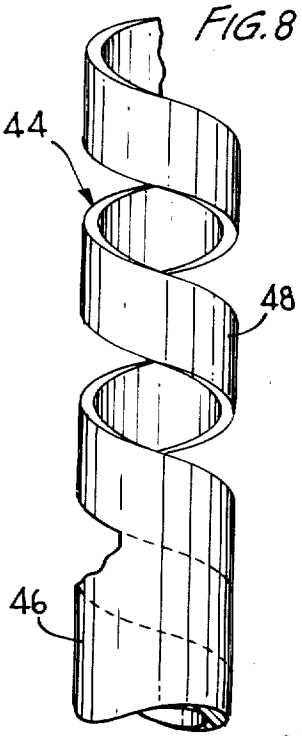

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FIG. 9

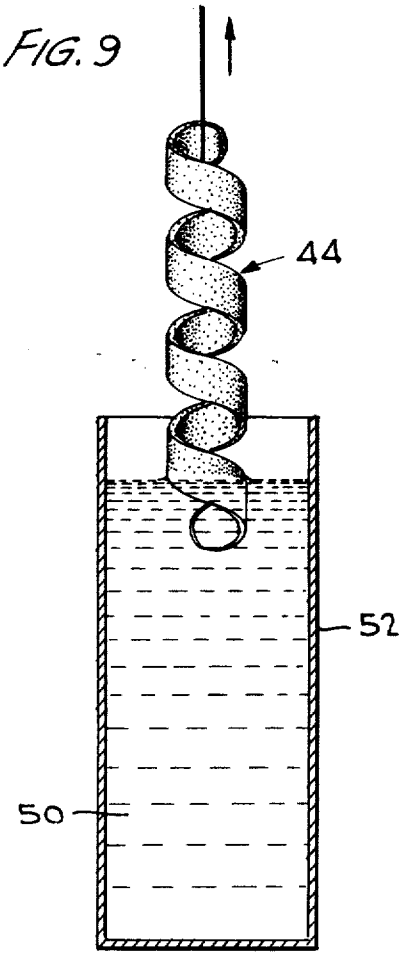

FIG. 10

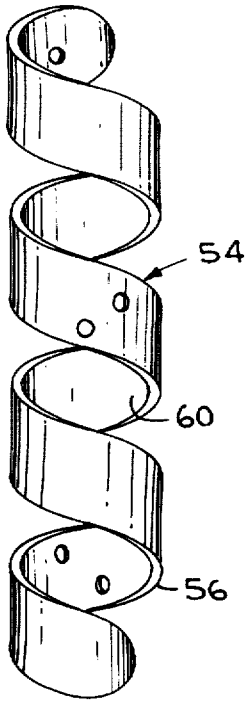

FIG. 11

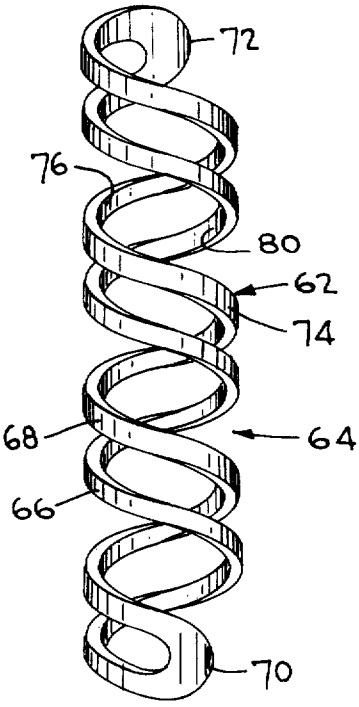

FIG. 12

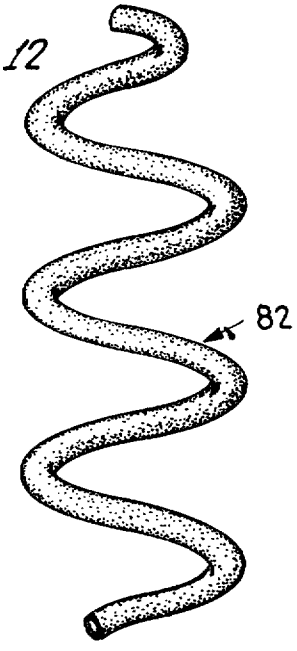

FIG. 13

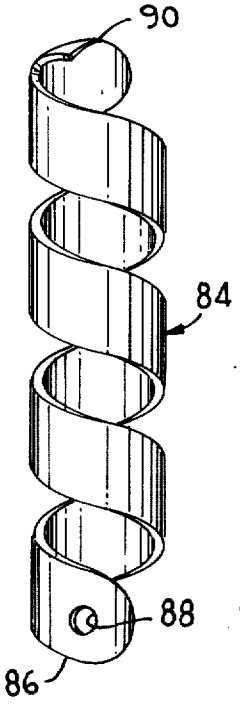

FIG. 14

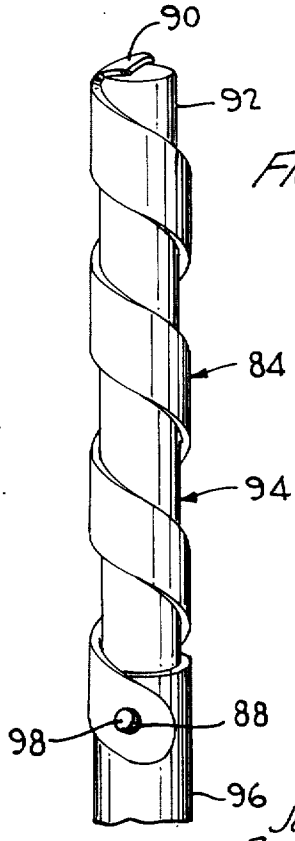

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FIG. 15

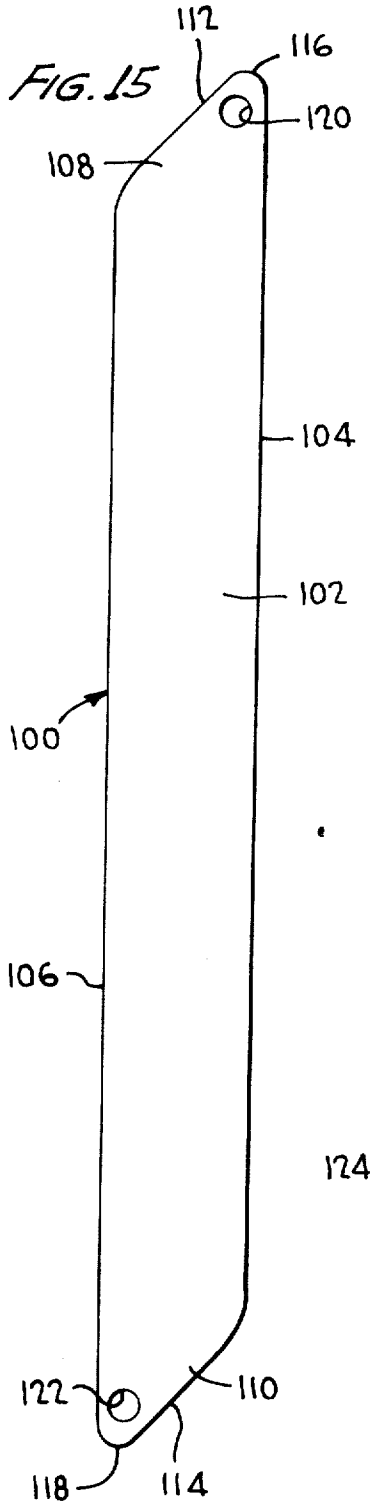


FIG. 16

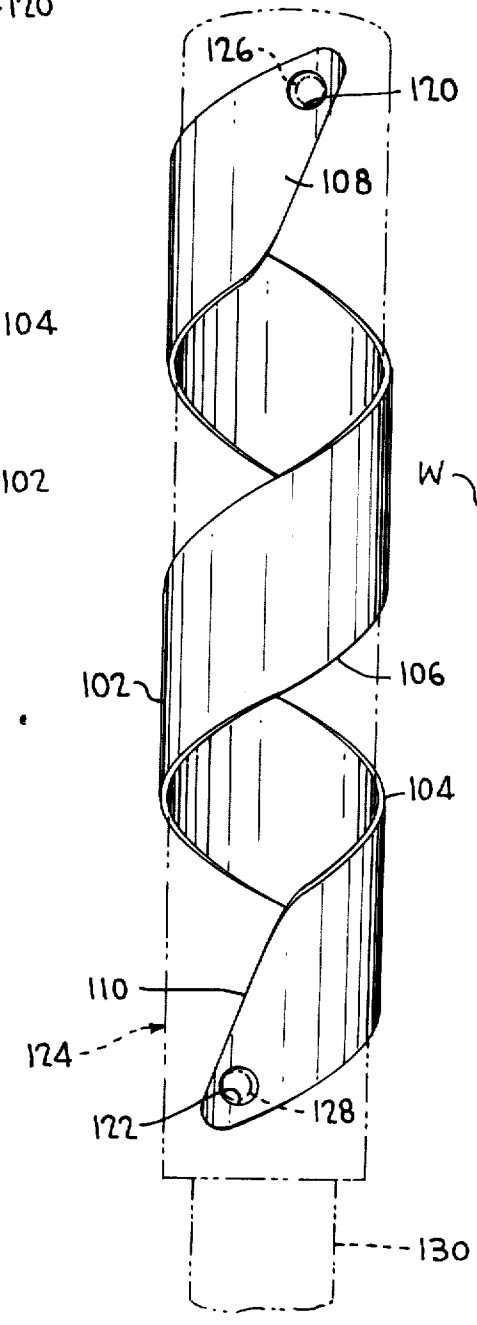
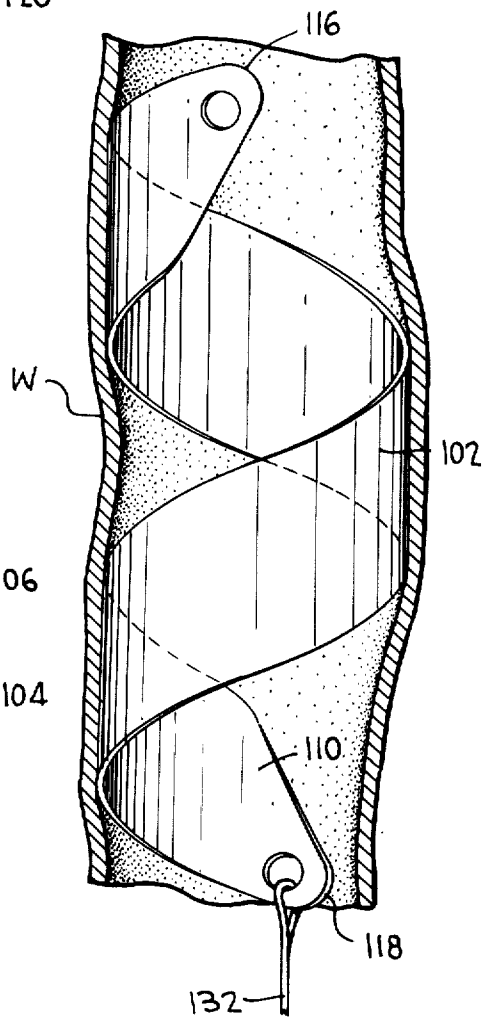


FIG. 17



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DRUG SUPPORTING ANCHOR

This is a continuation of application Ser. No. 181,007, filed Sept. 16, 1971, now abandoned.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention pertains to pharmaceutical anchors for insertion in body cavities and, more particularly, to such anchors for intravaginal insertion.

2. Dicussion of the Prior Art

It is desirable to treat mammals with the use of slow release drugs inserted in a body cavity; however, such treatment has presented a problem in the past due to the difficulty of proper insertion of the drug, the retention of the drug in proper position within the body cavity and removal of any device utilized to support the drugs within the body cavity.

Slow release drugs are particularly useful for insertion in the vagina of mammals, particularly for purposes of artificial insemination. That is, the drug may be, for example, a hormone utilized to control the heat cycle of a mammal whereby insertion of the slow release hormone stops the normal physiological heat cycle; and, when the hormone is removed from the mammal, physiological heat cycling will be initiated. Accordingly, the use of such hormone facilitates artificial insemination in that a group of mammals may be artificially inseminated at the same time.

In order to permit the application of such drugs in an effective manner, the drug must be inserted in the mammal in such a manner as to reduce pain and injury therefrom at a minimum. Furthermore, the drug must be maintained within the body cavity in such a manner that it cannot be expelled either at the mammal's volition or during normal physical activities and physiological body functions, as is the case when sponges are utilized to support such drugs, and the device utilized to support the drug must be easily removed.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a drug supporting anchor for insertion and retention in body cavities to facilitate release of a drug carried thereby.

The present invention is generally characterized in a drug supporting anchor for insertion and retention in body cavities including an elongated member for supporting a drug to be administered, the elongated member having a drug support surface with a spiral configuration.

Another object of the present invention is to utilize a drug strip spirally wound around an elongated member for insertion in body cavities in order to administer slow release drugs.

A further object of the present invention is to provide an elongated drug supporting member for insertion and retention in body cavities with a spiral configuration.

The present invention has another object in that a drug supporting anchor is made of a flexible material with a helical configuration to permit the diameter of the anchor to be reduced by longitudinal stretching to facilitate insertion of the anchor in a body cavity.

Another object of the present invention is to provide a method of inserting a spiral drug supporting anchor in a body cavity by reducing the diameter of the anchor during insertion.

Yet another object of the present invention is to utilize an anchor having a hollow spiral configuration with spaced coils to support a slow release drug for insertion in a body cavity.

A further object of the present invention is to utilize the combination of a spiral drug supporting anchor having apertures therein and a strip of drug material having protrusions extending therefrom adapted to be inserted in the apertures in the anchor in order to facilitate the administering of a slow release drug in a body cavity.

The present invention has another object in that the quantity or dosage of a drug to be administered in a body cavity is provided with an enlarged surface area by use of an anchor having a spiral configuration.

Some of the advantages of the present invention over the prior art are that the drug support anchor of the present invention locks into the tissue within a body cavity to prevent expelling thereof, the drug support anchor is flexible to facilitate insertion into and removal from a body cavity, and an enlarged surface area for drug material is provided to increase the dosage or quantity of drug which is capable of being released.

Other objects and advantages of the present invention will become apparent from the following description of the preferred embodiments taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a broken elevation of a drug supporting anchor constructed in accordance with the present invention.

FIG. 2 is a broken elevation of a strip of drug material to be carried by the anchor of FIG. 1.

FIG. 3 is a broken elevation of the anchor of FIG. 1 combined with the strip of drug material of FIG. 2.

FIG. 4 is a broken elevation of another embodiment of a combination of a drug supporting anchor and a strip of drug material of the present invention.

FIG. 5 is a broken elevation of the combination of FIG. 4 after spiral cutting.

FIG. 6 is a broken elevation of a further embodiment of a combination of a drug supporting anchor and a strip of drug material of the present invention.

FIG. 7 is a broken elevation of the combination of FIG. 6 after spiral twisting.

FIG. 8 is a broken elevation of a partially cut drug supporting anchor according to another embodiment of the present invention.

FIG. 9 is a side elevation illustrating the coating of the anchor of FIG. 8 with a drug material.

FIGS. 10, 11 and 12 are elevations of modifications of the drug supporting anchor of the present invention.

FIG. 13 is an elevation of a flexible drug supporting anchor according to the present invention.

FIG. 14 is a perspective view of the anchor of FIG. 13 mounted on an insertion rod.

FIG. 15 is a side elevation of another embodiment of a drug supporting anchor according to the present invention.

FIG. 16 is a perspective view of the anchor of FIG. 15 mounted on an insertion rod.

FIG. 17 is a perspective view of the anchor of FIG. 15 after insertion in a body cavity.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

A drug supporting anchor **20** according to the present invention is illustrated in FIG. **1** and is composed of a strip of material **22** provided with a spiral or helical configuration to define an elongated, hollow spiral member **24** having spaced adjacent coils. Strip **22** has a longitudinal channel **26** formed therein, and a plurality of spaced apertures **28** are centered in channel **26.** Anchor **20** may, for example, be formed of a strip of plastic approximately **4**mm. thick which is longitudinally cut to form channel **26** and punched or bored to provide apertures **28** at **5**cm. centers starting approximately **1**cm. from each end of the strip. The length and width of the strip will be determined by the surface area required for the drug to be administered and the shape and size of the body cavity into which the anchor is to be inserted. The grooved and punched strip is then wrapped around a cylindrical mandrel to provide the hollow spiral configuration. The diameter of the spiral member **24** is determined in accordance with the shape and size of the body cavity into which the anchor is to be inserted, and the pitch of the spiral configuration is determined by the surface area required for the drug to be administered. Of course, the anchor **20** could be formed in one or more steps by any conventional method such as injection molding or extrusion.

A strip **30** of slow release drug material is illustrated in FIG. **2** and is formed with a width and length corresponding to the width of channel **26** and the length of strip **22** of anchor **20,** respectively. A plurality of button-like protrusions or knobs **32** extend from strip **30** and are spaced according to the spacing between apertures **28** in anchor **20.** Strip **30** may be composed of any pharmaceutical or drug desired to be administered and compatible slow release carrier. For example, when the anchors are designed for intravaginal placement, the drugs may include digitoxin, triiodothyronine, isoproterenol, atropine, histamine, nitrogen mustard, vitamin B_{12}, pyrimethamine, hormonal substances, i.e., estrogenic substances, progestation substances, androgenic substances, e.g., estradiol, progesterone, androstenedione, testosterone, cortisol, medroxyprogesterone acetate, melengestrol acetate, chlormadinone, and the like as long as such drugs have the property of being capable of passage through the carrier. The carrier may be any slow or controlled release, drug-permeable polymeric material, such as organopolysiloxane of the linear type converted to rubber by heat curing and known as dimethylpolysiloxane. Such drugs and slow release carriers of the silicone rubber type are more fully described in U.S. Pat. No. **3,545,439,** the disclosure of which is incorporated herein by reference.

The strip of drug material **30** is assembled with the anchor **20** as illustrated in FIG. **3** such that the strip of drug material is received within channel **26** with protrusions **32** extending through apertures **28.** By providing the protrusions **32** with a knob-like or bulbous configuration, the strip of drug material **30** can be mounted on the anchor **20** with a snap-type action; and the strip of drug material will be firmly held such that the drug material is not susceptible to being inadvertently detached from the anchor during insertion of the combination anchor and drug material in a body cavity. Of course, the strip of drug material **30** may be secured to the strip **22** prior to spiraling thereof to form member **24,** and any mating configuration may be utilized to fasten the drug strip with the anchor. For instance, the drug strip can be provided with spaced apertures while the anchor has mating protrusions extending therefrom to be received in the apertures.

Another embodiment of the present invention is illustrated in FIG. **4** wherein a relatively large diameter rod **34** has a strip of drug material **36** similar to drug material **30** wrapped therearound to provide a spaced spiral configuration. The drug material may be secured to rod **34** in any suitable manner such as by attachment means at the ends of the rod and strip of drug material to provide a hook-and-eye or similar type fastening, or by means of a compatible adhesive or cement. Once the strip of drug material **36** is properly positioned on the rod **34** the rod is spirally cut to provide a spiral groove **38** as illustrated in FIG. **5** to form a helical land corresponding to the spacing between coils of the spiraled drug strip **36** defining a support surface for the drug strip. After cutting the combination anchor and drug strip will have a deep spiral configuration to thereby facilitate insertion and removal of the combination anchor and drug strip and to provide a large surface area for drug material.

A further embodiment of the present invention is illustrated in FIGS. **6** and **7** wherein an anchor for the drug material is formed of a solid, cylindrical, small diameter rod **40,** and a strip of drug material **42** similar to drug strip **30** is wrapped tightly around rod **40** with no gaps therebetween. The strip of drug material **42** may be secured to the rod **40** in any suitable manner as mentioned above with respect to the embodiment of FIG. **4,** and the combination anchor and drug strip is then twisted or spiraled around a suitable cylinder or other forming mandrel to provide the spiral configuration illustrated in FIG. **7.**

An anchor **44** is illustrated in FIG. **8** and is formed from a hollow cylindrical tube **46** of high density polyethylene which is spirally cut to form an elongated helical member **48.** The anchor **44** may be formed by placing a pre-cut spiral metal sleeve around tube **46** such that tube **46** may be cut in the same spiral form as the metal sleeve in a stencil-like fashion.

In order to coat the anchor **44** illustrated in FIG. **8** with a suitable slow release drug material, the drug and an appropriate slow release compound such as silicone adhesive rubber as described above with respect to the drug strip of FIG. **2,** are dissolved in a solvent such as cyclohexane. The cyclohexane solvent sufficiently dilutes the slow release compound to form a solution **50** which is supported in a container **52,** and anchor **44** is dipped into the solution such that the drug and slow release compound adhere to the helical member **48** on both the outer and inner surfaces thereof. After the anchor **44** is removed from the container **52,** the solvent evaporates to leave remaining anchor **44** coated with the silicone rubber impregnated slow release drug material in a helical configuration.

Other embodiments of anchors according to the present invention are illustrated in FIGS. **10, 11** and **12,** and all of these anchors may be coated with a slow release drug material in the same manner as above described with respect to anchor **44** as shown in FIG. **9.**

An anchor **54** is illustrated in FIG. **10** and has a hollow, elongated helical member **56** with flat outer and inner drug supporting surfaces **58** and suitably respectively. Anchor **54** is desirably made of a plastic material

such as a transparent acrylic resin and may be suitaably formed by molding or extrusion processes as well as by winding or twisting around a forming mandred.

An anchor **62**, shown in FIG. **11**, has a hollow, elongated member **64**; however, member **64** differs from the elongated member **56** of anchor **54** in that member **64** has a double helical configuration. That is, body member **64** includes a pair of spaced strips **66** and **68** joined at ends **70** and **72** and having outer and inner drug supporting surfaces **74, 76, 78** and **80**, respectively. In other words, anchor **60** differs from anchor **54** primarily in that the flat strip forming the elongated member of anchor **54** is slotted in anchor **60.**

The anchor **82** illustrated in FIG. **12** differs from anchors **54** and **60** in that anchor **82** is formed of a tube of material which is twisted about a mandrel to provide a helical configuration similar to rod **40** in the embodiment of FIGS. **6** and **7.**

An especially advantageous embodiment of the present invention is illustrated in FIGS. **13** and **14.** An anchor **84** has the same configuration as anchor **54**; however, anchor **84** is made of a flexible material and has a proximal end **86** with an aperture **88** therein and a distal end **90** shaped to receive the flat end of a movable arm **92** of an insertion rod **94.** Insertion rod **94** includes a stationary sleeve **96** which slidably carries movable arm **92** and pin **98** extending therefrom and adapted to be received in aperture **88** in proximal end **86** of anchor **84.** Anchor **84** may be coated with a slow release drug material by dipping as described with respect to FIG. **1** or a strip of slow release drug material may be secured to anchor **84** in the manner described relative to FIGS. **1** through **7.**

A method for inserting anchor **84** in a body cavity such as the vagina includes the step of disposing anchor **84** over insertion rod **94** with pin **98** engaging aperture **88.** Arm **92** is then moved out of sleeve **94** to engage distal end **90**; and, thereafter, as arm **92** is moved further out of sleeve **96,** anchor **84** is stretched as shown in FIG. **14** such that the diameter of anchor **84** is reduced. The anchor and drug material carried thereby are then inserted in the vagina with a twisting or screwing motion to facilitate insertion; and once the anchor is properly inserted, proximal end **86** is disengaged from pin **98** such that the insertion rod may be removed leaving the anchor in the vagina. Any suitable means may be utilized to effectively reduce the diameter of the anchor by stretching; and, similarly, the means illustrated for detachably securing the anchor to the movable and stationary portions of the insertion rod are of an exemplary nature and other suitable means may be utilized therefor. The shape of distal end **90,** however, is particularly advantageous in that it provides firm engagement of the end of movable arm **92** while not requiring specific detachment for removal of the insertion rod.

In order to remove anchor **84** or any of the other anchors of the present invention, the lips of the vulva are opened and the anchor is withdrawn such as by pulling a previously attached string which is left hanging outside of the body cavity after insertion.

Another embodiment of a drug supporting anchor **100** in accordance with the present invention is illustrated in FIGS. **15, 16,** and **17** with a precursor strip **102** illustrated in FIG. **15.** Strip **102** has an elongated flat configuration with parallel side edges **104** and **106** of equal length terminating at end portions **108** and **110.** Ends **108** and **110** have the general configuration of isosceles triangles and are oriented on opposite sides of the strip. End portions **108** and **110** have inclined edges **112** and **114** making apex angles **116** and **118** with side edges **104** and **106** of **45°**, respectively. Near the tip of apexes **116** and **118** are disposed apertures **120** and **122,** respectively, which are utilized in deforming strip **102** as will be described hereinafter. Strip **102** is made of a flexible, resilient material which will spring back to its original configuration after deformation.

Anchor **100** may be coated with a slow release drug material by dipping or may carry a strip of slow release drug material as described above. In any case, anchor **100** initially has the flat, linear configuration illustrated in FIG. **15** and will, accordingly, try to return to the flat, linear configuration after being deformed into a helical configuration.

In order to insert the drug supporting anchor **100,** the strip **102** is wound around an insertion rod **124** having a pin **126** extending from a distal end thereof and a pin **128** extending from a proximal end which has a handle **130** extending therefrom and mechanically linked with pins **126** and **128** such that the pins may be withdrawn into insertion rod **124.** To facilitate winding of strip **102** around insertion rod **124** as illustrated in FIG. **16,** the aperture **120** in end portion **108** may be positioned to receive pin **126,** and the insertion rod is rotated about its longitudinal axis while end portion **110** is held stationary. Once the proper number of coils have been formed in the strip, pin **128** is inserted in aperture **122** to hold the strip **102** in a tightly coiled deformed configuration.

The drug supporting anchor **100** is inserted in the vagina or other body cavity by grasping the handle **130** and inserting the combination anchor and insertion rod. Once the drug supporting anchor **100** is properly positioned within the vagina, the anchor is released by withdrawing pins **126** and **128** such that the strip **102** tries to return to its initial flat, linear configuration; however, the walls **10** of the vagina will prevent return to the initial configuration as illustrated in FIG. **17.** Thus, drug supporting anchor **100** will be retained in the vagina with a helical configuration having a diameter greater than the diameter during insertion, and the spaced coils will lock into the tissue to resist expelling of the anchor. The **45°** incline at the end portions **108** and **110** allow appreciably better retention in the vagina than anchors with substantially rounded ends; that is, apexes **116** and **118** increase the locking action with the tissue.

A string **132** is tied to anchor **100** through aperture **122,** as illustrated in FIG. **17,** such that the anchor may be easily removed from the vagina by pulling string **132** which hangs outside the vagina. Strip **102** returns to its initial flat, linear configuration as the anchor is removed from the vagina to facilitate such removal.

The anchors illustrated in FIGS. **1, 5, 7, 8, 10** through **13** and **15** may be constructed of compatible non-absorbable plastic or metal materials. Examples of such materials include transparent acrylic resins such as those known commercially as Plexiglas and Lucite, high or low density polyolefins such as polyethylene, polypropylene, copolymers of ethylene and propylene, linear polyamides (nylons), polystyrene, polycarbonate and metals such as stainless steel or high carbon steel. Flat strips of high carbon and stainless steel have inher-

ently a spring or flexibility and are, accordingly, extremely advantageous for use with the embodiments of FIGS. **13** and **15**.

As previously mentioned, the drug material is combined with a slow release compound such as dimethylpolysiloxane or a block copolymer of dimethylopolysiloxane and polycarbonate, and the slow release drug material for any of the above described anchors may be applied thereto either as a strip of drug material or by dipping as illustrated in FIG. **9**.

The spaced helical configuration of the anchors of the present invention provides an increased surface area for drug material and excellent retention within the vagina since the spacing between adjacent coils permits the anchor to lock into the tissue thereby requiring twisting for removal. The flexible anchor of the embodiments of FIGS. **3** and **15** are particularly advantageous due to the reduced diameter caused by stretching which facilitates both insertion and removal and the embodiment of FIG. **15** is further advantageous due to ease of manufacture, low cost and increased retention characteristics.

Inasmuch as the present invention is subject to many variations and changes in detail, all matter described above or shown in the accompanying drawings is intended to be interpreted as illustrative and not in a limiting sense.

What is claimed is:

1. A drug supporting anchor for insertion and retention in body cavities comprising an elongated member defined by a plurality of spaced helices having flat peripheral outer surfaces defining a helical drug support and formed of a flat strip of flexible material, said elongated member having at its distal end means for engaging the end of an insertion means and at its proximal end means for attachment with said insertion means whereby said elongated member can be stretched to reduce the diameter thereof.

2. The drug supporting anchor as recited in claim **1** wherein said flexible material is metal.

3. A drug supporting anchor for insertion and retention in body cavities comprising an elongated member defined by a plurality of spaced helices having flat peripheral outer surfaces defining a helical drug support surface and formed of a flat strip of flexible material, said elongated member including a slow release drug supported on said helical drug support surface.

4. The combination as recited in claim **3** wherein said elongated member is solid with raised helical lands defining a helical drug support surface, and said drug strip is supported on said drug support surface.

5. The combination as recited in claim **3** wherein said elongated member carries attachment means and said drug strip carries engaging means having a configuration to mate with said attachment means, said engaging means being engaged with said attachment means to secure said drug strip to said elongated member.

6. The combination as recited in claim **5** wherein said attachment means includes a plurality of apertures spaced along said elongated member and said engaging means includes a plurality of protrusions extending from said drug strip and received in said apertures.

7. The combination as recited in claim **6** wherein said elongated member is formed of a flat strip of material having a helical configuration and an outer surface defining a drug support surface, and said drug strip is aligned with said drug support surface.

8. The combination as recited in claim **7** wherein said flat strip of material has a channel recessed in said outer surface and said apertures are centered in said channel.

9. A combination for insertion and retention in body cavities for administering drugs comprising an elongated member having a spiral configuration, said elongated member being formed of a flat strip of flexible material in the form of a helical strip having a flat outer surface defining a drug support surface, a layer of slow release drug material supported on said drug support surface, a proximal end and a distal end of said strip of flexible material carrying means for engaging the end of an insertion means and said proximal end of said strip of flexible material carrying means for attachment with the insertion means whereby said elongated member may be stretched to reduce the diameter thereof.

10. The combination as recited in claim **9** wherein said elongated member is formed of a strip of material having flat inner and outer surfaces to define said drug support surface.

11. In combination, an insertion rod having a distal end and a proximal end, an anchor for supporting a drug including an elongate strip of flexible, resilient material spirally wound around said insertion rod to form a plurality of spaced coils having flat peripheral drug supporting surfaces, said strip of material engaging said distal and proximal ends to have a spiral configuration, and a slow release drug material carried on said flat peripheral drug supporting surfaces.

12. The invention as recited in claim **11** wherein said strip of material is metal and has a flat linear initial configuration whereby said strip expands when released from said insertion rod.

13. The invention as recited in claim **12** wherein said insertion rod has a first pin extending from said distal end and a second pin extending from said proximal end, and said strip has apertures in opposite ends thereof removably engaging said first and second pins.

14. The invention as recited in claim **13** wherein said opposite ends of said strip have a generally triangular configuration.

15. The invention as recited in claim **14** wherein said strip has parallel side edges and said ends have inclined edges making angles of **45°** with said side edges.

16. The drug supporting anchor recited in claim **3** wherein said slow release drug is diposed in a coating on said helical drug support surface.

17. The drug supporting anchor recited in claim **3** wherein said elongated member has apertures at its distal and proximal ends for attachment of said elongated member to an insertion means.

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