A self-micro-powered implanted device contains a store of medicine in powdered, liquid or other dispensable form and which is gradually discharged incrementally over a substantially long period of time.

11 Claims, 8 Drawing Figures
IMPLANTED MEDICATION DISPENSING DEVICE AND METHOD

BACKGROUND OF THE INVENTION

1. Field of the Invention:
This invention pertains to dispensing medicine internally and more specifically to dispensing a premeasured dosage at specific intervals over a long period of time.

2. Description of the Prior Art:
Dosages of medicine have conventionally been dispensed in capsules which release the medication either immediately or on a delayed basis normally measured at the most in terms of a number of minutes or relatively few hours. It has been proposed to have orally administered capsules which can be caused to disintegrate by externally applied heat or other forms of radiation designed to penetrate the body and break down the capsule housing. There has further been proposed a device (U.S. Patent No. 3,527,220) suited to be implanted and designed to discharge successively, by pumping units of liquid medication with the operating power for the device being supplied by an external rotating magnetic field and whose timing depends on an external source. It has also been proposed to provide a multi-unit capsule designed to release one strength medication at one time and another strength medication at another time.


A review of all the known prior art reveals that there has not been available a device operative on and timed by its own micropower source, suitable to being entirely implanted and adapted to dispensing premeasured dosages of a given medication, liquid, powdered or otherwise, to a patient at specific intervals, which might be 12 hours, 6 hours or even 6 days, over a long period of time measured in terms of 1 to 2 years. In particular, there is no device presently known which can be implanted in narcotic addicts and/or psychiatric patients which can be used to administer medication internally on a predetermined long term schedule. Long term treatment of the addict with narcotic antagonist medication is a means of blocking the effects of subsequent self-injected narcotic drugs. In a similar vein, long term administration of an anti-psychotic medication to certain psychiatric patients would be of marked benefit in rendering them more adaptable to themselves and society.

SUMMARY OF THE INVENTION

The present invention resides around the concept of implanting a container within which there is mounted a battery powered, mic source of power, a store of premeasured dosages of a given medication and a mechanism operated and timed by the power source and designed to eject the dosages at specific intervals over a long period of time.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side elevation view of the device with one cover side section removed.

FIG. 2 is an enlarged fragmentary partial section view taken substantially along line 2—2 of FIG. 1.

FIG. 3 is a fragmentary section view taken substantially along line 3—3 of FIG. 2.

FIG. 4 is an enlarged fragmentary partial section view, similar to FIG. 2, of a second embodiment.

FIG. 5 is a fragmentary section view taken substantially along line 5—5 of FIG. 4.

FIG. 6 is an enlarged fragmentary partial section view of a third embodiment.

FIG. 7 is a fragmentary partial section view of the pump component shown in FIG. 6.

FIG. 8 is a fragmentary partial section view of the bladder component of FIG. 6.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The device of the invention includes a case 10 having two side sections 11 and 12 secured by a suitable threaded connection 13. The outer surface of case 10 provides an essentially solid surface with the exception of an aperture 14 through which the individual dosages are ejected at specific intervals. Case 10 can be thought of as essentially resembling the case of an ordinary pocket watch and in one embodiment is 6 centimeters in diameter by 1.4 centimeters thick. The surface should be smooth.

Since case 10 is designed to be implanted, the choice of material of which case 10 is made is somewhat critical. Such material should be of minimum weight, non-allergenic, non-reactive to body fluids and adapted to mass fabrication. Stainless steel is one such material though plastics and other materials may be employed.

Within case 10 there is mounted a suitable battery powered "micro" power and timing source 24 which is preferably a so-called "Accutron" movement made by the Bulova Watch Company of Flushing, N.Y. A movement of this kind is relatively light in weight and can be obtained designed to turn one revolution per day so as to drive a drive shaft 20 and a drive wheel 21 at one revolution per day and for a period of time up to and approximately two years according to battery life. At this speed output shaft 20 can be made to produce approximately 0.42 ounce/inch of torque and with a very nominal increase in speed at this loading. Such a power and timing source is considered a "micro" power and timing source. The invention recognizes the unique capability of the "Accutron" movement to serve as a micropower and timing source outside its conventional use for watches and clocks. The invention also recognizes that pistons, cocking mechanisms and the like within the realm of watchmaking technology can be practically applied in a medicine dispensing device.

A circular wheel member 25 has an outer peripheral face 26 in which there are formed a plurality of cavities 27 in which the individual dosages C are contained. In one example, 72 such cavities are formed in wheel 25 and each such cavity containing one capsule C of the desired medication. Each cavity has an associated piston member 31 which when moved radially outward in a timed sequence ejects its respective capsule C through aperture 14. Thus, for a 72 cavity wheel member 25 there are 72 piston members 31.

Drive wheel 21 mounts on its periphery an indexing pin 28 which is positioned perpendicular to the plane of wheel 21. As drive wheel 21 rotates at one revolution per day it causes indexing pin 28 to rotate at the same
speed and to drive a link 29 which in turn is connected to oscillate a piston pusher member 30. Piston pusher member 30 thus moves back and forth once a day in the embodiment being described. As piston pusher 30 moves forward it is adapted to engage a selected piston member 31 each of which has a compression spring 32, a pusher head 33 and a piston 34 which bears against the capsule C. Each compression spring 32 tends to always retain its particular associated piston member 31 moved radially inwardly. Indexing of wheel member 25 is effected by means of indexing pin 28 successively engaging each one of a plurality of peripherally spaced indexing tabs 35 formed internally of wheel 25 as shown in the drawings. Wheel 25 is supported on a precision pin 36 mounted in suitable bearings 37 and 38. A washer 39 provides support for piston pusher 30 which is guided by a guide pin 40 internally secured to case side section 12. To prevent the entry of moisture internally of case 10 an O-ring seal 41 is suitably adhered to case 10 around the aperture 14.

Here it should be noted that since body fluids may contact O-ring 41 and may also contact the interior of each individual capsule-cavity and piston member 31 that the same criteria applying to case 10 applies to the choice of materials selected. That is, none of the materials employed in wheel member 25, piston member 31 or O-ring 41 should be allergenic or reactive with any body fluid which might make contact with the same. Those skilled in the art will however recognize a wide choice of materials.

In one embodiment the device is implanted in the patient's abdominal intraperitoneal cavity, a cavity that has a glistering moistened surface but does not maintain fluid levels except in pathological conditions. The device is sutured by suture threads secured to anchoring stays 15. The device of the invention then dispenses medication into this cavity for absorption through the intraperitoneal surface. The device is intended as a general application for any feasible medication; however, there are specific applications for which it is being developed. One such application is to implant the device into the abdomen of narcotic addicts with a sufficient number of dosages of a narcotic antagonist, to be dispensed over a long period of time. The narcotic antagonist dispensed actively, blocks the euphoriant effect of any subsequent use of narcotics. A psychiatric medication can also be administered to psychiatric patients. This means that from the viewpoint of the patient, the doctor, and society, that the patient obtains the required daily dosage of a given drug without having to rely on his own willpower and initiative.

In the embodiment of the medication dispensing device used as an example, an Accutron movement or battery powered micro power plant is used to provide the timing mechanism as well as a source of power and the movement is geared to drive the output At FIGS. shaft clockwise, one revolution per day. In the more general application, any "micro" power and timing mechanism could be used. However, by using extreme care in reducing weight and friction in all of the moving parts of the device the Accutron movement in the present state of the art is preferred and can provide sufficient torque as well as long term continuous operation.

In use, the device is assembled with each dosage cell or cavity of wheel member 25 being loaded with a capsule C of the active medication and is suitably implanted. Each capsule C with the medication inside is successively ejected by means of its associated respective piston member 31 into the body cavity and subsequently dissolves as wheel member 25 gradually indexes around. In the embodiment of the example, the piston member 31 is designed to have a stroke of approximately 0.50 centimeters and each indexing tab 28 a movement of approximately five degrees and for each rotation of drive wheel 21 indexing pin 28 will contact a particular indexing tab 35 over approximately 30° of movement of wheel 21. This motion is thus repeated once a day and one capsule C is thus ejected each day. At the end of the battery life of the Accutron movement, the device may be removed, a new battery installed, wheel 25 reloaded and the device reassembled and reimplanted. It may also be noted that while capsules C are shown on FIGS. 2 and 3, each cavity 27 could be loaded with a liquid, powdered or granular medication and sealed with a fracturable seal as depicted in FIGS. 4 and 5 and later explained.

FIGS. 4 and 5 illustrate a second embodiment in which the "case" is formed by a stationary circular medication storage wheel member 50 and a base plate 51 having a suitable threaded connection 52. The same "micro" power and timing source 24 is employed to drive a similar output shaft 20, drive wheel 21 and indexing pin 28. Spaced indexing tabs 55, similar to tabs 35 of FIGS. 1 and 3, are provided on an internal peripheral surface of wheel member 50. In this embodiment, wheel member 50 remains stationary and is provided on an outer peripheral surface with plural cavities 56, e.g. 72 in number, each of which is shown loaded with a dosage of granular or powered medication M. Each cavity 56 is sealed by a rupturable film seal 57 of suitable thinness and strength that is ruptured when the particular dosage is ejected. A piston 50 is located in each cavity 56 and is formed integral with a piston rod 61 and a pusher head 63. A compression spring 62 forces piston 60 in a radially inward direction.

Each respective pusher head 63 is successively engaged by a piston pusher 65 which is guided by a guide pin 66 and a bearing pin 67. Piston pusher 65 mounts a vertical locking pin 68 which successively slides in and out of each corresponding indexing slot 69 as each respective pusher head 63 is engaged. Piston pusher 65 is in turn linked to indexing pin 28 by means of a link 70 and a pin 71.

The micro power and timing source 24 indexes itself in a slow rotative movement around the bearing pin 67 by means of indexing pin 28 going in and out of successive indexing slots 69. That is, as wheel 21 rotates, indexing pin 28 rotates and causes power source 24 as well as all of the linkage shown mounted above power source 24 to index by the angular difference between slot locations. Ball bearings 49 support the power source 24 and bearing pin 67 provides low friction surfaces. Furthermore, as indexing pin 28 leaves a particular indexing slot 69, piston pusher 65 is moved to engage a respective pusher head 63 and to cause locking pin 68 to enter and lock itself in an opposite indexing slot 69 (now effectively a "locking slot"). As piston
pusher 65 continues to move under the influence of indexing pin 28, which is always in slow constant rotation, the respective piston 60 pushes on the respective dosage M and ruptures the seal 57 which allows the dosage M to dump internally of the body in which the device is implanted.

In a third embodiment shown in FIGS. 6, 7 and 8, the medication is in liquid form and is stored in a bladder 80 having a flexible discharge line or tube 81 converted to a micro powered and timed pump-valve unit 82 which discharges through a flexible line or tube 83. Lines 81 and 83 should preferably be flexible and may be in the nature of rubber tubing. The bladder and pump-valve unit 82 may be sutured by means of suture stays 84, 85 and line 83 is placed where desired in the body.

Bladder 80 includes a self-sealing port preferably having two self-sealing membranes 90, 91 and an internal filling cavity 92 with a one-way valve generally represented at 93. The outer case of bladder 80 is preferably of hard rubber except at the port and a hard rubber striker plate 95 is provided internally to prevent inadvertent puncturing and also to prevent entry of the syringe needle beyond the filling cavity 92. In use, bladder 80 is filled with the desired liquid medication by syringe injection into the cavity 92 such that the one-way valve 93 opens and allows the liquid medication to fill the interior of bladder 80. Once the syringe has been withdrawn it can be seen that bladder 80 is effectively filled with a pressurized liquid medication yet the patient, e.g. an addict, cannot withdraw the medicine himself as he normally would be tempted to do.

A suitable pressure reducing valve 100 controls the flow to line 81 and to the pump unit 82 having a pair of spring-loaded one-way ball valves 101, 102; valve 101 controlling entry and valve 102 controlling discharge of liquids from cylinder 103. A piston 105 has a piston rod 106, loaded by spring 109, that is connected to and cocked by a cocking pin 107 mounted on a constantly driven wheel 108 driven by the same type micro power and timing source 24 previously mentioned, e.g. an Accutron movement, fixed to a base 111 threadably secured to a cover 112.

In the third embodiment of FIGS. 6, 7 and 8, it will be understood that bladder 80 is refilled when depleted. However, the pump-valve unit 82 operates continuously and is limited only by the battery life of the power source 24. Thus, increments of liquid can be dispensed on some predetermined time schedule according to the particular design of cocking mechanism and subject to maintaining bladder 80 filled can be dispensed over a relatively long period of time. Tube pinching devices or other devices for controlling flow through lines 81 and 83 could be operated by a micro power source and used instead of the pump-valve unit 82. Furthermore, the patient, e.g., the addict or psychiatric patient, such as a schizophrenic patient, is not required to have control over the medication and that this device can insure a steady supply of the drug internally with such a device. With such device these patients could realize their full potential and become useful members of society. In all prior art devices there has been virtually no way to insure treatment of such patients on an out-patient basis because such patients are often negligent in meeting medical appointments and taking their regular medication. Considering the scope of the problem, it can be seen that the present invention opens up an entirely new method of treating and dispensing medication. Examples of medication deemed suited to the invention include cyclazocine in powder and liquid form for addicts, stelazine in powder form for psychiatric patients and methadone and naloxone in liquid form for addicts.

In the first and second embodiments illustrated by FIGS. 1–8, it will of course be appreciated that in order to save time during reimplantation procedures the wheel medication storage members 25 and 50 can be prefilled and held in inventory as spares. During reimplantation, the full spare storage member can then be substituted for the empty storage member and used with the other parts of the device being reimplanted. Thus, both battery replacement and medication replacement become relatively inexpensive and easy to accomplish during the reimplantation procedure.

While primarily intended for medical purposes and applications it is contemplated that other applications will reveal themselves where it is necessary to have an unattended micro size and micro powered timing and dispensing apparatus. Thus, such broader applications are contemplated by the invention.

It is contemplated that the sealing means shown in the drawings may require modification for some applications where the device is in a high moisture or high fluid environment. Thus, the piston mechanism may require a form of sealing in such applications.

It should also be noted that the term “body” and “animal body” as used in the claims are intended to include animal, human and other living bodies. Further, the term “body” is intended to encompass any environmental body, whether living or otherwise adapted to receiving a self, micro powered and timed device for incremental dispensing of substances into such body.

What is claimed is:

1. A device adapted to be positioned internally of a selected body for dispensing materials therein, comprising:
   a. a storage member adapted to be positioned within the selected body and to store a quantity of the material to be dispensed;
   b. a micro size power source secured within said body proximate said storage member and having an output member capable of being driven by said source over a predetermined period in terms of at least several days and at a substantially precise rate; and
   c. dispensing means powered and timed by said micro power source and adapted to discharge from said storage member and into said body on a predetermined time schedule successive increments of said material.

2. A device as claimed in claim 1 wherein said body is that of an animal including human, said material is a liquid, said storage member constitutes a bladder and said dispensing means constitutes pump and valve means powered and timed by said source and having an inlet connected to said bladder and an outlet whereby said liquid may be withdrawn from said bladder and discharged from said outlet in increments.
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3. A device as claimed in claim 1, wherein said body is that of an animal including human, said material is a medication, said storage member provides a plurality of cavities each having a predetermined unit of said medication, and said dispensing means includes a piston operator for each such cavity and linkage means operated by said power source whereby each respective such piston operator is activated in turn and effects successive discharge of each respective said unit from said storage member.

4. A device as claimed in claim 3 wherein said storage member is circular and is rotatively indexed by said power source to effect discharge of said units.

5. A device as claimed in claim 3 wherein said storage member is circular and fixed relative to said power source and said power source rotatively indexes itself to effect discharge of said units.

6. A device as claimed in claim 1 including a case providing an internal void and having an aperture in the wall thereof and wherein said micro power source and dispensing means are mounted within said case and dispensing of said material is through said aperture.

7. An implantable device for dispensing a medication material within an animal body, said device comprising in combination:
   a. a case adapted to be implanted in the body and providing an internal void;
   b. a micro power source secured within said void and having an output member capable of being driven by said source over a predetermined period in terms of at least several days and at a substantially precise rate;
   c. holder means mounted within said void and loosely mounting premeasured units of said material in a circular configuration; and
   d. ejection means powered by said output member in timed relation with said holder means and operative upon each successive said unit of material whereby each said unit is successively discharged from said holder means internally of said body.

8. A device as claimed in claim 7 wherein said case includes an aperture in the wall thereof, said holder means rotates and is driven by said output member to bring each successive unit to a position opposite said aperture and said ejection means operates upon each said unit successively upon reaching such position.

9. An implantable device for dispensing liquid drugs into an animal body, including human, comprising:
   a. a bladder adapted to be implanted in the body and to be filled by external injection;
   b. a metering means having an inlet connected to said bladder and an outlet adapted to discharge into said body said metering means being adapted in one mode to withdraw and discharge predetermined uniform units of said material and in another mode to block flow of said material;
   c. a micro power source connected to said metering means and adapted to power and time said metering means in said modes whereby said units may be discharged at spaced time intervals and over a substantially long period of time; and
   d. a case adapted to be implanted and mounting both said metering means and micro power source.

10. A device as claimed in claim 9 wherein said metering means constitutes a pumping device.

11. The method of dispensing a drug in a body, comprising the steps:
   a. implanting within the body a container having a substantially large supply of the drug to be dispensed;
   b. with said container implanting a micro power source and dispensing means operated and timed by said micro power source for drawing off and discharging successive uniform units of said drug in said body; and
   c. allowing said source and dispensing means to operate on said supply over a substantially long period of time until said supply is exhausted.

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