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C. A. ABELLA ET AL
CAPSULE FOR THE STUDY OF THE DIGESTIVE
TRACT AND METHOD OF USING THE SAME
Filed May 21, 1957

3,057,344

FIG. 5

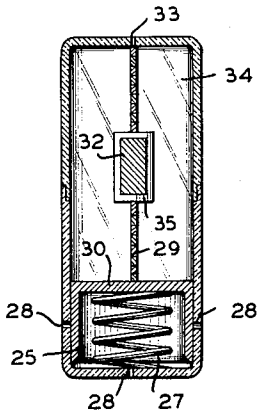


FIG. 6

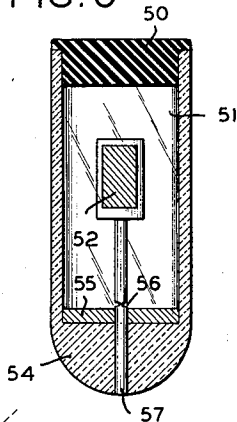


FIG. 10

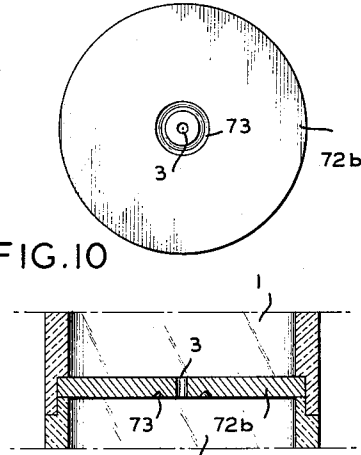


FIG. 2

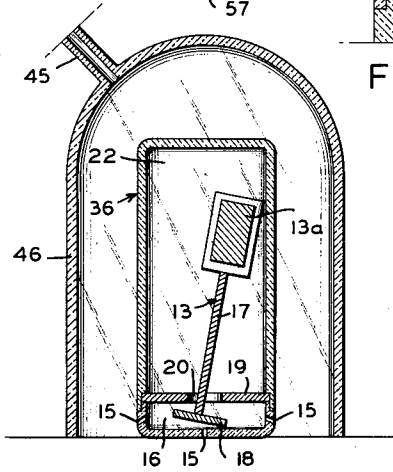
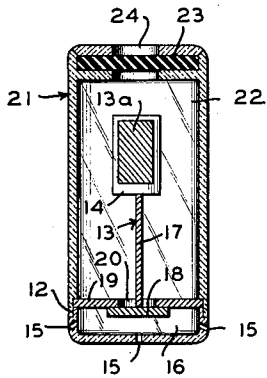


FIG. 9

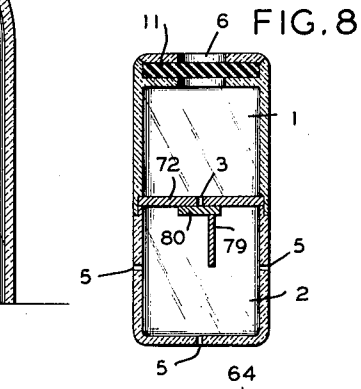


FIG. 4

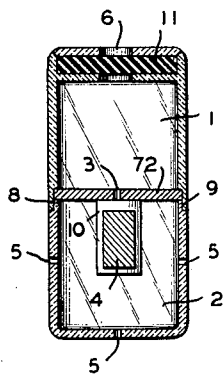


FIG. 1

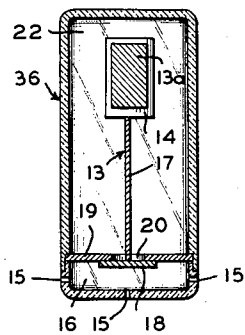
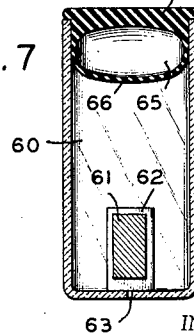


FIG. 3

FIG. 7



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CAPSULE FOR THE STUDY OF THE DIGESTIVE TRACT AND METHOD OF USING THE SAME

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13 Claims. (Cl. 128-2)

This invention is directed to a process of clinical, physiological, and physiopathological examination or treatment of the digestive tract and to a capsule which is used in such examination or treatment.

Briefly, the process comprises the ingestion by the patient of a small capsule, as hereinafter described, of such size and shape that, as shown by experiment, it can be swallowed with perfect ease. The movement of said capsule along the digestive tract can be observed by an operator by means of X-rays, for example, and when the capsule reaches the predetermined sector of interest in a particular study to be made, it is opened by radiant energy means external of the body so as to extract samples of the medium in which it is present or to discharge the contents of the capsule into the medium or both. Thus, the capsule serves to abstract samples of the contents of the digestive tract at different levels—of the esophagus, stomach, duodenum, jejunum-ileum, for example—in a simple manner, without disturbances or molestation to the patient. With the samples thus obtained, any desired tests will be made, whether they be chemical, enzymatic, cytological, bacteriological or parasitological, in accordance with the section of the digestive tract under consideration and in accordance with the study or treatment being carried out.

Furthermore, there can be exposed to the digestive secretion of a given zone in the conventional manner, a wide variety of substances, whether they be foods, organic or inorganic chemicals, medicaments, etc. Then by means of the capsule there can be extracted a sample of the fluids in this zone. The capsule with its contents will be recovered in the feces. The contents of the capsule can be carefully analyzed to determine the effect of these substances on the digestive fluids and vice versa.

The capsule can also be constructed, still governed by the same principles, in such a way that it can adhere to the digestive mucous membrane and act as a parasite sucking its secretions directly until the capsular cavity is filled. This makes it possible to obtain samples of cellular and intercellular liquid. By a study of these liquids it is possible to greatly expand the present day limited knowledge of these liquids.

As a result of this invention, therefore, it will be possible to perform all of the analyses mentioned above and to extend them to zones of the alimentary canal practically unexplored until the present time.

Alternatively, the capsule can be used in such a manner that, before its ingestion by the patient, it may be charged with a chemical, a medicament, a radio-active isotope, or any other reagent which may be desirable under the circumstances. After ingestion of the capsule, its travel may be observed by the operator and at any particular zone it may be opened by radiant energy external of the body and thereby discharge its contents into the zone. In this manner, there can be introduced into the body at a specific location any materials which circumstances warrant in high concentrations and without having the materials acted on in the other portions of the alimentary canal.

The use of radio-active substances employing tracer techniques is particularly feasible and desirable. In this manner, the absorption and the path of passage in the various sectors can be studied and thereby afford infor-

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mation not available by techniques known prior to this invention.

Furthermore, a particular interest resides in the probable knowledge to be obtained about the interactions between digestive mucous membrane and the various chemical agents which a combined use of an injecting capsule and an absorption capsule could provide.

As can be realized, there is opened up a vast field of research in biology, physiology, physiopathology, bacteriology, digestive pathology, and general pathology, and their relations with the digestive processes. The results of said research are more realistic since this system, because of the absence of danger and molestation, does not change the patient's psychological condition and consequently has no repercussion on the digestive sphere, producing immediately results more faithful to reality.

This invention will be understood by reference to the accompanying drawings which are purely diagrammatic. In these drawings:

FIGS. 1, 2, 3, 5, 6, 7, 8 and 9 each show a longitudinal cross-section of various modifications of the device of the invention.

FIG. 4 is a longitudinal cross-section of the apparatus used to create reduced pressure in the capsule.

FIG. 10 is a plan view of wall 72b of FIG. 9.

In general, the capsule is of substantially cylindrical shape having rounded edges or of any form, such as oval, which causes no disorder in its passage through the digestive tract. The capsule is made of material which is inert to the media of the digestive tract.

FIG. 1 shows one of the preferred forms of the capsule. It consists of two chambers 1 and 2 separated from each other by wall 72. Communication between these chambers is provided by a conduit 3 which is preferably of capillary dimensions. Chamber 2 contains a magnet 4 which may be covered with inert material 10 if necessary. Chamber 2 communicates with the atmosphere outside the capsule by means of conduit means such as capillaries 5. In one of the walls of chamber 1 there is a self-sealing member 11 made of elastic material. This member may be punched by means of a punching element such as an injecting needle, in order to introduce or remove fluids from the chamber 1. Upon removal of the needle, by virtue of the elasticity of the elastic material, the opening made by the needle seals itself. The needle is inserted through this wall at opening 6. The two chambers 1 and 2 and the intermediate wall 72 are assembled by means of a friction joint such as shown at 8 and 9. Of course, if so desired, these members may be threaded and the entire assembly screwed together.

When preparing the capsule for ingestion, the magnet is placed against the capillary 3, utilizing if necessary the aid of an electro magnet to maintain its position. Alternatively, it may be applied to its seat by means of a substance such as liquid petrolatum which serves to keep the magnet temporarily in position and which is inert to body fluids. If desired, some or all the walls of the capsule may be made of a transparent material in order to permit inspection of the interior during the assembly of the capsule. After the magnet has been placed in position, it serves as a sealing valve. There is introduced into chamber 1 through the elastic wall 11 the point of the injection needle, and by means of a suitable syringe a vacuum is produced in chamber 1. The needle is withdrawn and the opening created thereby will be sealed because of the self-sealing nature of the wall 6. The capsule, having thus been prepared, is ingested by the patient and its passage through the digestive tract is observed by means of X-rays. When it reaches the desired location, the magnet is displaced, with the aid of an external magnetic field. This opens capillary 3. As a

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result of reduced pressure in chamber 1, the fluids in the digestive tract surrounding the capsule are drawn into chamber 2 through capillaries 5. Later, the capsule with its contents is recovered in the feces.

In the modification shown in FIG. 2, the chamber in which the reduced pressure is created has been enlarged in order to provide for a better vacuum. The capsule is shown generally at 21. 22 represents the chamber wherein the vacuum is created, having a self-sealing insert 23. Chamber 16 has capillaries 15 connecting with the external surface of the capsule. The valve means 13 consists of a magnet 13a, and a sealing plate 18 connected to the magnet by means of lever arm 17. The magnet may have an inert coating 14 thereon.

The chambers and the wall 19 are assembled as shown by joint 12. The lever arm extends from chamber 16 into chamber 22 by means of aperture 20. Then an injection needle is inserted at 24 to produce the vacuum necessary to hold the valve in place. In this modification, the lever arm transmits the force applied on the magnet to the sealing plate in a considerably increased degree, resulting in requiring less magnetic force to actuate the valve.

In the modification shown in FIG. 3, the self-sealing member is eliminated since it is not possible to get as high a degree of vacuum as desired when using the sealing member. Otherwise, the structure of the capsule 36 shown in FIG. 3 is identical with that of FIG. 2.

In order to evacuate chamber 22 of capsule 36, it is placed in a bell jar as shown in FIG. 4 with the sealing plate 18 away from the opening 20. The bell jar 46 is then evacuated through conduit 45. When the desired degree of vacuum is obtained, the valve means 13 is positioned by means of an external electro-magnet. The bell jar is then opened to the atmosphere. The external pressure will maintain the valve in position.

The modification of FIG. 5 uses a movable wall 30 in the form of a piston between the chambers 25 and 34. The wall is displaceable from its position by a resilient member such as spring 27. In using this modification, the piston 30 is pressed downward into chamber 27 and kept in position by a column of loose pieces 29 in which there is positioned magnet 32, with inert coating 35 if necessary. The column of loose pieces covers capillary 33. This modification may be used to both take up fluids from the digestive tract and to place fluids in the digestive tract. Chamber 34 may be initially charged with a fluid which is to be supplied into the digestive tract. After ingestion of the capsule, magnet 35 may be displaced by an external magnet thereby releasing the piston to force fluid out of capillary 33 and simultaneously draw into chamber 25 digestive fluid through capillaries 28.

The modification in FIG. 6 contains a single chamber. Capillary 57, preferably made of glass, passes through wall 54 into the chamber 51. The capillary has a weakened constriction as at 56 and a magnet 52 is mounted on the capillary. The capsule is sealed by stopper 50. In use, the chamber 51 may be evacuated or alternatively it may be filled with fluid under pressure. After ingestion, action on the magnet 52 serves to break the capillary thereby either releasing the fluid within the chamber or drawing fluid into the chamber.

In this figure is shown plate 55 which may be used in any of the other capsules if necessary. This plate is opaque to X-rays and serves, together with the magnet, as a means to determine the location and position of the capsule in the body.

FIG. 7 shows another preferred modification to be used in discharging substances into the interior of the digestive tract. This capsule has chambers 60 and 65 separated by a movable elastic wall 66. Wall 66 may be created as part of the stopper 64 which is made of an elastic material such as rubber. In this modification, the chamber 65 is similar to a blister. A magnet 61 having

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an inert coating 62 is positioned over capillary 63. In operation, after the valve 61 has been positioned over the capillary and the capsule filled with the desired product, stopper 64 is inserted into the capsule and air under pressure is injected into the blister to partially expand wall 66. After the capsule is ingested and the magnet displaced, the internal pressure of the blister will dilate wall 66 thereby forcing the fluid from chamber 60 into the digestive tract.

FIG. 8 represents another modification of FIG. 1. Except for the structure of the valve on wall 72, the capsule is identical with that of FIG. 1. On wall 72 there is positioned a sealing member 80 to which is fastened a small blade 79 capable of entering into resonance when it is excited by an ultra-sonic wave produced by a source outside the digestive tract. Fastened to blade 79 is sealing plate 80 which is positioned over capillary 3. In operation, the sealing plate 80 is normally held against wall 72 thereby closing capillary 3. Air is evacuated from chamber 1 by inserting a needle through 11 at 6. After ingestion, the sealing plate is displaced from the capillary by the ultrasonic vibrations.

FIGS. 9 and 10 represent another modification of FIG. 1. Except for wall 72b, the structure is identical to that of FIG. 1. On the surface of wall 72b there is a groove 73 around the capillary 3. When this is filled with a substance such as petrolatum, it serves to provide a better seal.

In using this capsule in carrying out the method of the invention, the capsule is either evacuated or filled with fluid in the manner described in the discussion of the figures. The capsule is ingested by the patient and its path through the alimentary canal is followed. At a predetermined location, the valve means is actuated by a magnet or electro-magnet external of the patient. Alternatively, where the valve is responsive to ultra-sonic vibrations, it may be actuated by an ultra-sonic generator outside the body such as a tuning-fork of such frequency that it causes the blade of said valve to enter into resonance. A blade which is responsive to ultra-sonic vibrations may be used in any of the modifications. The valve, being open, permits the passage of the fluids through the capillaries.

The capsule may be made of an appropriate material transparent or opaque, such as glass, metal or plastic. If the material is not inert to the digestive fluids or the treating fluids, it may be coated with an inert material. The auxiliary opaque plate 55, as shown in FIG. 6, may be used in any of the other modifications. The magnet being opaque and the plate being opaque, both serve to indicate, by means of X-rays, the precise position of the capsule in the body and specifically whether the capsule is directed upward or downward.

Instead of the opaque plate, one wall of the capsule, such as the wall 54 in FIG. 6 may be thickened and made of materials opaque to X-rays. This will serve the same function as the opaque plate.

We claim:

1. A capsule for insertion into the digestive tract for treatment or examination thereof, comprising at least one chamber, conduit means providing communication between the interior of the chamber and the exterior of said capsule, and movable valve means, said valve means being movable to obstruct said conduit means and being actuatable by radiant energy from a source exterior of said capsule to move said valve means to unobstruct said conduit means.

2. A capsule as recited in claim 1, wherein said valve means comprises a movable member maintainable in its obstructing position by means of a differential between the pressure in the interior of said chamber and atmospheric pressure.

3. A capsule as recited in claim 1, wherein said capsule has a wall provided with a self-sealing elastic member penetrable by a needle.

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4. A capsule as recited in claim 1, wherein said valve means includes a blade with a natural frequency of vibration in the range of ultrasonic vibrations, said blade being actuatable by ultrasonic radiant energy.

5. A capsule as recited in claim 1, wherein said valve means includes a movable paramagnetic member actuatable by magnetic energy.

6. A capsule as recited in claim 1, including a second chamber and a movable wall between said chambers, said wall being elastic.

7. A capsule as recited in claim 1, including a second chamber, a wall slidably mounted in a pistonlike manner between said chambers, and resilient means urging said wall from one chamber into the other chamber.

8. A capsule for insertion into the digestive tract for treatment or examination thereof, comprising a first chamber, a second chamber, a first conduit providing communication between said chambers, a second conduit providing open communication between said second chamber and the exterior of said capsule, and movable valve means in one of said chambers, said valve means being movable to obstruct said first conduit and being actuatable by radiant energy from a source exterior of said capsule to move said valve means to unobstruct said first conduit to provide communication between said chambers.

9. A capsule as recited in claim 8, wherein said radiant energy is magnetic energy and said valve means comprises a paramagnetic member positioned in one of said chambers, a sealing plate positioned in the other of said chambers, and a lever arm connecting said paramagnetic member with said plate, said lever arm passing through said first conduit and being rockably supported so that said magnetic energy can move said paramagnetic member and, therefore, said arm in a direction transverse to the axis of said arm.

10. A capsule for insertion into the digestive tract for treatment or examination thereof, comprising at least one chamber, conduit means providing communication between the interior of the chamber and the exterior of said capsule, said conduit means including a sealed capillary tube in said chamber obstructing communication between the interior of the chamber and the exterior of the capsule, and a paramagnetic member in said chamber and mounted on said capillary tube so that said paramagnetic member is movable by magnetic energy from a

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source exterior of said capsule to break said capillary tube to provide communication between the chamber and the exterior of the capsule.

11. A method of treating or examining the digestive tract, comprising providing a capsule having at least one chamber and valve means controlling communication between the interior of the chamber and the exterior of the capsule, said valve means being actuatable by radiant energy from a source exterior of the digestive tract to provide communication between the interior of chamber and the exterior of the capsule, positioning said capsule within the digestive tract, and while said capsule is in the digestive tract, actuating said valve means by radiant energy from a source exterior of the digestive tract to provide said communication between the interior of the chamber and the exterior of the capsule.

12. A method as recited in claim 11, wherein said capsule is charged with fluid prior to positioning it within the digestive tract so that when said valve means is actuated said fluid will be discharged out of the capsule into the digestive tract.

13. A method as recited in claim 11, wherein the pressure in said chamber is subatmospheric prior to positioning the capsule in the digestive tract so that when said valve means is actuated fluid will flow from the digestive tract into said capsule.

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