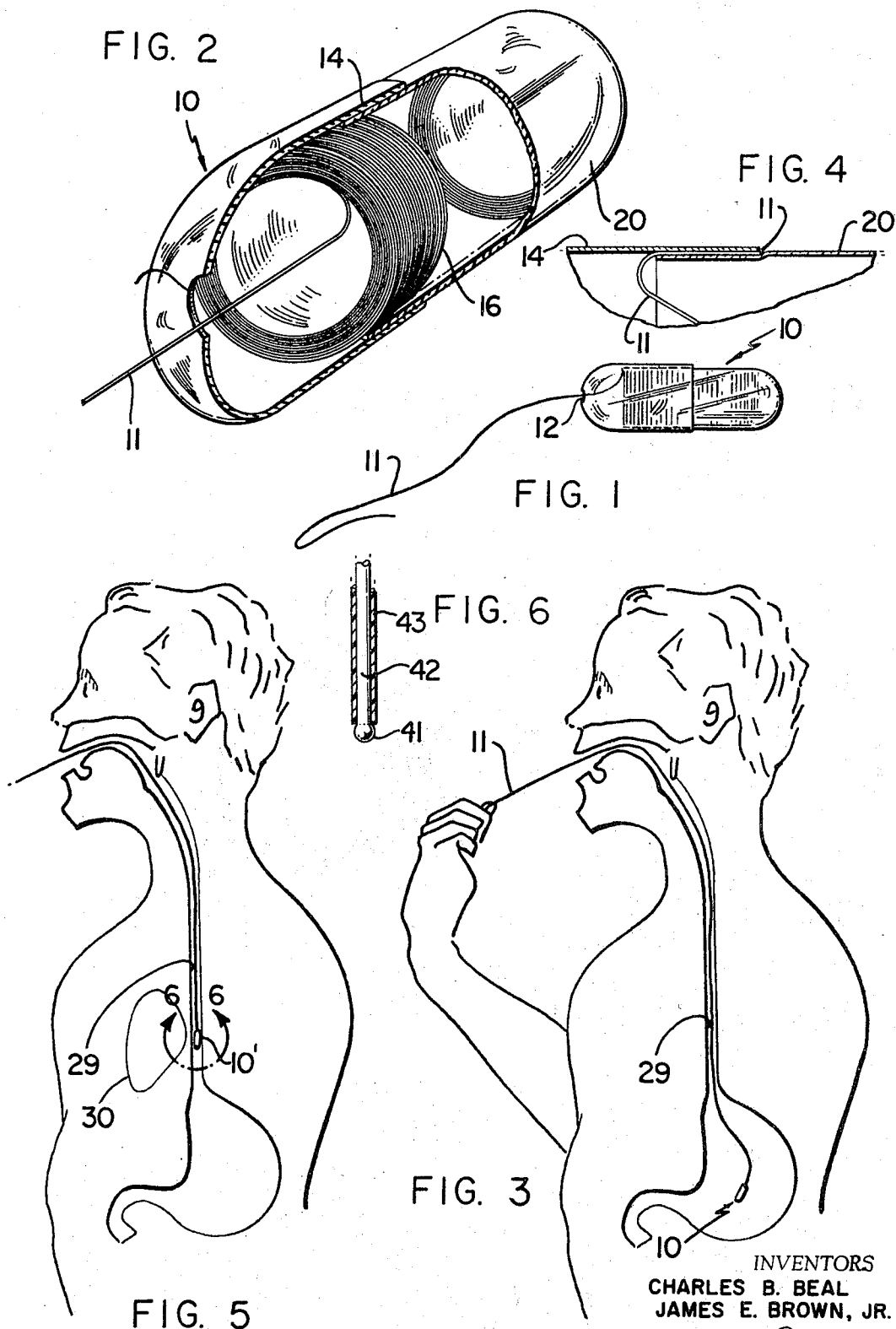


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METHOD AND DEVICE FOR ORALLY ADMITTING AN ELONGATED
FLEXIBLE ELEMENT IN THE ALIMENTARY CANAL
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METHOD AND DEVICE FOR ORALLY ADMITTING AN ELONGATED FLEXIBLE ELEMENT IN THE ALIMENTARY CANAL

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10 Claims

ABSTRACT OF THE DISCLOSURE

A device consisting of a hollow capsule with a flexible elongated element such as a line or tube coiled within in a single non-overlapping layer in radial compression against the inner capsule wall. The elongated element: (a) having an electrical conductor when used to record electrocardiograms, (b) being a ribbon or having a roughened surface to obtain cells from mucous lining of esophagus for diagnosis of cancer of esophagus, (c) being impregnated with an indicator solution which will change color in the presence of varying degrees of hydrogen ion concentration for pH tests, (d) being a single or double hollow tube for aspiration of stomach contents or, (e) made from an absorbent material to obtain a sample of stomach contents.

BACKGROUND OF THE INVENTION

The present application is a continuation in part of my prior copending United States patent application Ser. No. 441,154 filed Mar. 19, 1965 and now abandoned.

This invention has resulted from the need for an inexpensive device for obtaining information within the body by means of orally admitting the device to the alimentary canal and orally retrieving at least a portion of the device. A primary consideration was the comfort of the patient which concomitantly added to the ability to obtain such information and to obtain it more reliably.

Determination of the acidity of the stomach, for instance, is very important in diagnosing many physiological conditions. As an example, individuals with cancer of the stomach have a high instance of gastric achlorhydria, that is absence of acid. All individuals with pernicious anemia exhibit gastric achlorhydria. Most patients with duodenal ulcers have an increased gastric acidity.

A standard method of measuring gastric acidity is by insertion of a hollow, flexible tube through the nose into the stomach and withdrawing some of the gastric contents by aspiration. This particular method is very uncomfortable for the patient and could result in damage to the esophagus or stomach.

Other tests have been devised in an attempt to measure gastric acidity without intubation. When methods other than gastric intubation are used, considerable time and/or expense is involved in the test procedure. Some of these tests depend upon the ingestion of substances which react with the hydrochloric acid of the stomach and the resultant excretion of substances in the urine which can be measured colorimetrically. In one test a radio transmitter is swallowed which is activated by the acid content of the stomach. The signal is picked up by a receiver placed on the abdomen of the patient.

It has also been found that extremely useful electrocardiograms can be taken by recording the electrical impulses from the posterior aspect of the heart. Here the problem was to admit and retrieve an electrical conductor in the alimentary canal.

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Still another problem was to admit an absorbent material to retrieve samples of stomach contents for pH measurement, bacteriological, cytological, or chemical examination.

SUMMARY

The gist of the invention is the use of an elongated flexible element such as a line or tube coiled within a gelatin capsule in which the capsule carries the end of the line to the point in the alimentary canal where the information is to be obtained.

The device of the present invention is characterized by its extreme simplicity, lightweight, low cost, accuracy and speed with which it can be used and the results made known to the diagnostician. The use of the device in diagnosis causes little or no discomfort to the patient and the test can be repeated within a few minutes to confirm the results first obtained if desired.

Preferably, the present invention comprises a small capsule such as the conventional two-piece hard shell gelatin capsule with a string which has been impregnated with an acid-base indicator coiled therein, one end of which protrudes from a hole in one end of the capsule. The other end of the string is held between the overlapping parts of the capsule. Hard-shell gelatin pharmaceutical capsules are described on pages 389-392 of Remington's Practice of Pharmacy, 1956, and the disclosure thereof is incorporated herein by reference.

To admit the device, the patient holds one end of the protruding string, places the capsule in his mouth, and swallows it, with the aid of water if desired. The string uncoils as the capsule passes down the esophagus into the stomach. The capsule immediately softens and the string can be pulled loose from it and out of the stomach. The string is then examined for any action of the contents of the stomach on the indicators impregnated in the string or the contents themselves are studied.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a plan view of the device of the present invention.

FIG. 2 is an enlarged perspective, partly in cross section, of the device of the present invention.

FIG. 3 is a view diagrammatically illustrating one use of the device of the present invention.

FIG. 4 is an enlarged partial cross section of the capsule showing the string held between the overlapping halves of the capsule.

FIG. 5 is a view diagrammatically illustrating another use of the device of the present invention.

FIG. 6 is a cross sectional view of a portion of the device taken substantially along line 6—6 of FIG. 5 with the capsule removed.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIGS. 1, 2 and 4, it will be seen that the device comprises a two-piece capsule 10 having a thread, tube or string 11 wound in a single layer non-overlapping coil 16 as shown in FIG. 2. Preferably the coil is tightly wound and then released against the side walls of the capsule so as to be normally held in radial compression. As the capsule moves through the canal, the end of the line is held by the patient and pays out through the opening. The helical coil is held in radial compression against the wall of the capsule and does not bunch up against the wall around the opening so as to know and stop the progress of the capsule. The end of the string 11 protrudes through an aperture 12 at one end of the capsule. Preferably, the capsule is a conventional two piece hard-shell gelatin capsule of the type widely used in the pharmaceu-

tical industry and comprising overlapping halves 14 and 20. Gelatin is preferred because it moves quickly and easily through the alimentary canal and quickly disintegrates when it reaches the stomach and thus frees the string which is coiled within as shown in FIG. 2 so that it can make contact with the contents of the stomach. Capsules of other materials can, of course, be used but it is preferred that the inexpensive, readily available, gelatin capsules be employed. When string is used it may be of any suitable absorbent, inert material such as No. 40 white cotton thread of about 70 centimeters in length. Obviously, strings of other materials of different sizes and different lengths may be employed. The only requirement is that the string be long enough to extend from the stomach to a few inches outside the mouth. As can be seen in FIG. 4, one end of the string is held between overlapping halves 20 and 14 of the capsules 10, thus insuring that the line will be fully extended. As the capsule becomes soft in the stomach it will release the line.

In one use of the device, all or part of the thread may be impregnated with a solution of an indicator such as, for example, a 1 percent solution of Congo Red. If the contents of the stomach are at a pH of 3.0 or lower, the thread will turn to a very dark blue or almost black color. At a hydrogen ion concentration of 3.5, the string will turn to a purple color and at a pH of 4.0 or above, it will be red. Of course, other indicators such as Thymol Blue, Methyl Yellow, Methyl Orange, Bromophenyl Blue, Bromocresol Green, Bromothymol Blue, Phenol Red, and others may be used for various pH ranges that may be encountered. Wide spectrum acid-base indicators may also be used for preliminary examination in which case a different diagnostic capsule would be subsequently swallowed to determine the pH more accurately in the range indicated by the wide spectrum indicator. Another variation involves impregnating the string with fixed indicators which, when once affected by the stomach acid, retain their color change despite subsequent contact with body fluids having a different pH than that of the stomach. Another modification of the present invention involves treating short sections, i.e., about two inches, of one end of the string with several different indicators effective at different pH levels.

As will be apparent from FIG. 3, the device of the present invention may be used by the patient by simply grasping the free end of the thread 11 and placing the capsule in his mouth and swallowing it. The string should be allowed to remain in the stomach for at least a minute and preferably a little longer to allow the gelatin to disintegrate. The thread is then removed by the patient or by his nurse or physician by simply pulling it out of his mouth and the lower end of the string is examined to determine the color to which it has changed. This should be done promptly to avoid change of color by the impregnated string as it comes in contact with saliva of the mouth.

The line may have no pH indicator but be made of absorbent material obtain a sample of stomach contents for pH measurement, bacteriological, cytological, or chemical examination.

The device of the present invention can be administered without the sensation of gagging. The test can be performed without prior preparation and the results determined quickly. If an unsatisfactory result is obtained, the test can be repeated immediately thereafter. The diagnostic device may be used with individual patients or with groups. There is no danger of injury to the patient as would be the case when inserting a tube or other mechanical device.

The reason the present device is safer and easier for the patient to take is evident in comparing the prior art devices such as Kaslow 2,773,502 in which the end of the line is weighted and the string trails the weight all the way down to the stomach. This long moving string rubbing against the alimentary canal 29 causes gagging and can cause injury to overly sensitive areas.

In the present device, the string or tube is coiled within the tube and only the moistened slippery gellatin capsule moves in relation to the alimentary canal.

In its broadest sense, the device can be used for extending a coated or uncoated string or tube to the stomach and beyond for several different purposes. The capsule has a size and shape suitable for swallowing and for moving to the stomach by normal peristalsis. It is essential that the line pay out evenly and smoothly without bunching at the mouth of the opening in the capsule without binding or lodging in the alimentary canal before the distal end of the string reaches the stomach. Such bunching of the string could cause gagging and destroy the ability to conduct the test.

One way of loading the capsule is to tightly wind the line or tube or ribbon on a pair of spaced rods, insert the rods into the capsule, and upon bringing the rods together, the coils spring against the walls of the capsule and are held there in radial compression.

The object of the use of a coiled radially compressed line is to insure the thread will pay out of the capsule evenly and without jamming against the mouth of the capsule opening.

Another use of the device 10' is to position a line 11' containing an electrical conductor in the alimentary canal, behind the heart 30 to record electrocardiogram or heart sounds. The proper amount of line is cut as shown in FIG. 5.

Still another use is to form the line of ribbon or the line may be roughened to obtain cells from mucous lining of the esophagus for diagnosis of cancer of the esophagus.

The device may be constructed with the line being a hollow tube for aspiration of the stomach contents or liquid food or diagnostic chemicals may be introduced into the stomach. A miniature pump may even be attached to the end of a single or double thin-walled flattened tube to deliver stomach contents.

A further use of the device is to determine point of origin of bleeding within the upper gastrointestinal tract. This may be done by preparing the line with radio-opaque markers for X-ray visualization.

Another use of the device is to carry a small device at its distal end to take small biopsy specimens of mucosal lining of the gastrointestinal tract for the determination of abnormalities.

Referring to FIG. 6, the device used to record electrocardiograms consists of an enlarged end 41 of a small wire conductor 42. A suitable insulation 43 is provided on the wire.

We claim:

1. A device for orally admitting a flexible elongated element in the alimentary canal which comprises:

(a) a hollow light weight capsule soluble in the alimentary canal and having an opening therein, said capsule having a size and shape suitable for swallowing and moving by normal peristalsis;

(b) a single layer non-overlapping line coiled within said capsule and contained therein by the capsule walls;

(c) one end of said line extending outwardly of said capsule through the capsule opening;

(d) the one end of said line being releasable from said capsule when in its fully extended position by the softening of said capsule and the normal peristaltic force, and

(e) means associated with said line for indicating a body condition.

2. A device of claim 1 wherein the capsule is a pharmaceutical capsule and said line is held in radial compression by said capsule wall.

3. A device of claim 1 wherein the means for indicating is at least a portion of said line within said capsule impregnated with a pH color indicator.

4. A device of claim 3 wherein the pH indicator is Congo Red.

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5. A method for determining gastric achlorhydria which comprises:

- (a) swallowing a pharmaceutical capsule described in claim 3;
- (b) the line in said capsule being of a length at least equal to the distance between the mouth and stomach;
- (c) restraining the end of the line end protruding from the capsule being swallowed therewith, whereby the line uncoils and is pulled out of the capsule during the capsule's passage into the stomach; and
- (d) after the pH indicator has been in contact with the fluids in the stomach, removing the line from the stomach by pulling the restrained end and finally examining the color indicator.

6. A device for orally admitting a line into the alimentary canal as described in claim 1 which comprises; one end of said line held between the overlapping halves of said capsule.

7. A device as described in claim 1 wherein the means for indicating is an electrical conductor to record electrocardiogram from the posterior aspect of the heart.

8. A device as described in claim 1 wherein the means for indicating is a portion of said line roughened to obtain cells from mucous lining of the esophagus for diagnosis of cancer of the esophagus.

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9. A device as described in claim 1 wherein the means ofr indicating is the absorptive material of the line to obtain samples of stomach contents for pH measurement, bacteriological, cytological or chemical examination.

10. A device as described in claim 1 wherein the means for indicating is the hollow tube construction of the line for aspiration of stomach contents.

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