

[54] **CARRIER SYSTEM FOR DELIVERY OF AN END OF AN ELONGATED MEMBER TO THE UPPER GASTROINTESTINAL TRACT**

[72] Inventor: **Charles B. Beal**, 1875 Oakdell Dr., Menlo, Calif. 94025

[22] Filed: **Oct. 2, 1970**

[21] Appl. No.: **77,574**

**Related U.S. Application Data**

[63] Continuation-in-part of Ser. No. 771,573, Oct. 29, 1968, abandoned.

[52] U.S. Cl. .... **128/2 W, 128/260, 128/271**

[51] Int. Cl. .... **A61b 10/00**

[58] Field of Search ..... **128/2 R, 2 W, 2 A, 2 B, 2 F, 128/2 G, 2 M, 2 P, 260, 264, 213, 172, 271, 272**

[56] **References Cited**

**UNITED STATES PATENTS**

813,829	2/1906	Robarts .....	128/271
1,880,964	10/1932	Kunzstler .....	128/2
2,701,559	2/1955	Cooper .....	128/2
2,773,502	12/1956	Kaslow et al. ....	128/260
3,074,396	1/1963	Maclean .....	128/2
3,097,636	7/1963	Haynes, Jr. et al. ....	128/2
3,155,091	11/1964	Nissenbaum et al. ....	128/2
3,421,499	1/1969	Bray et al. ....	128/2

3,483,859 12/1969 Pittman .....128/2

**FOREIGN PATENTS OR APPLICATIONS**

281,869 2/1915 Germany .....128/1.3

194,270 3/1967 U.S.S.R. ....128/2

**OTHER PUBLICATIONS**

Gladstone, S. A., Amer. Journ. of Clinical Pathology, Vol. 19, No. 9, Sept. 1949, pp. 891-894.

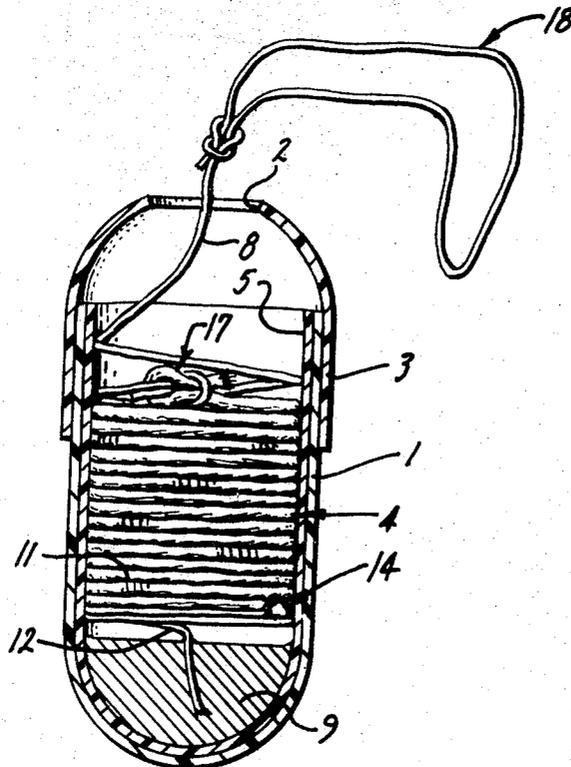
*Primary Examiner*—**Kyle L. Howell**

*Attorney*—**Milmore & Cypher**

[57] **ABSTRACT**

A two stage device for delivering an elongated member to the upper gastrointestinal tract consisting of an outer gelatin pharmaceutical capsule which dissolves in the stomach, an inner open ended capsule contained in said outer capsule and being nonsoluble in the gastro-intestinal tract and having walls inwardly deflectable under peristaltic action of the upper gastro-intestinal tract in the absence of the outer capsule and carrying a weight and a portion of the elongated member. The device being used to deliver cord or tubing at least as far as the duodenum where the carrier separates from the elongated member and passes harmlessly out with the stool. The elongated member as a tube carries medicines, other liquids or gas to the duodenum, and as a yarn is retrieved and examined for diagnosing infection, parasites and other disorders.

**8 Claims, 9 Drawing Figures**



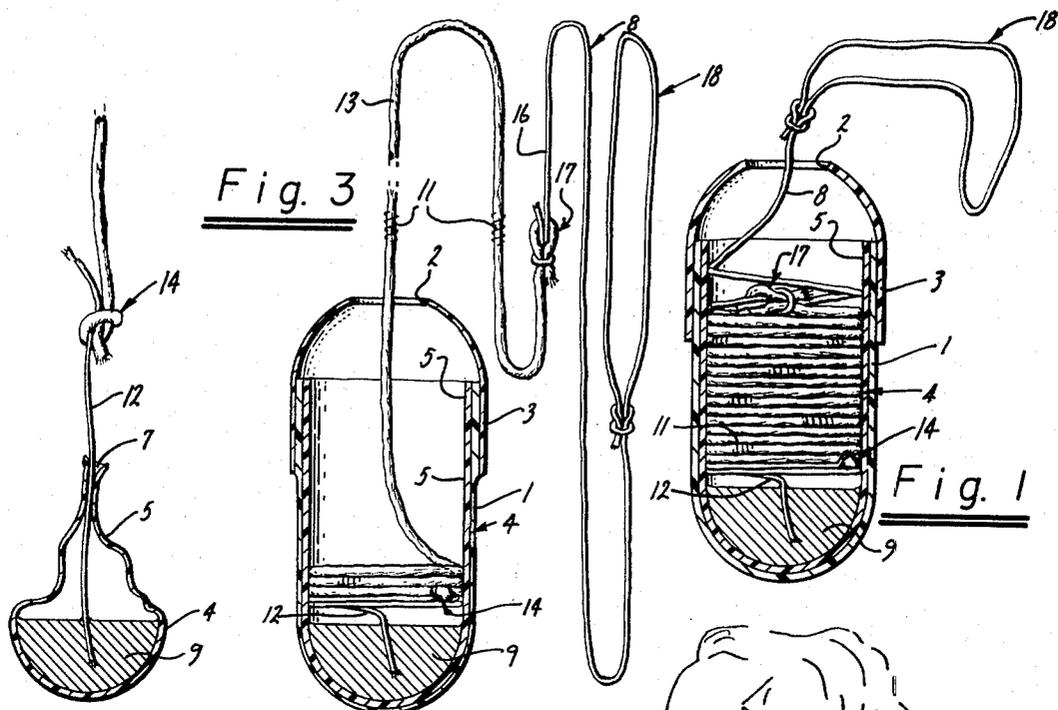


Fig. 3

Fig. 1

Fig. 5

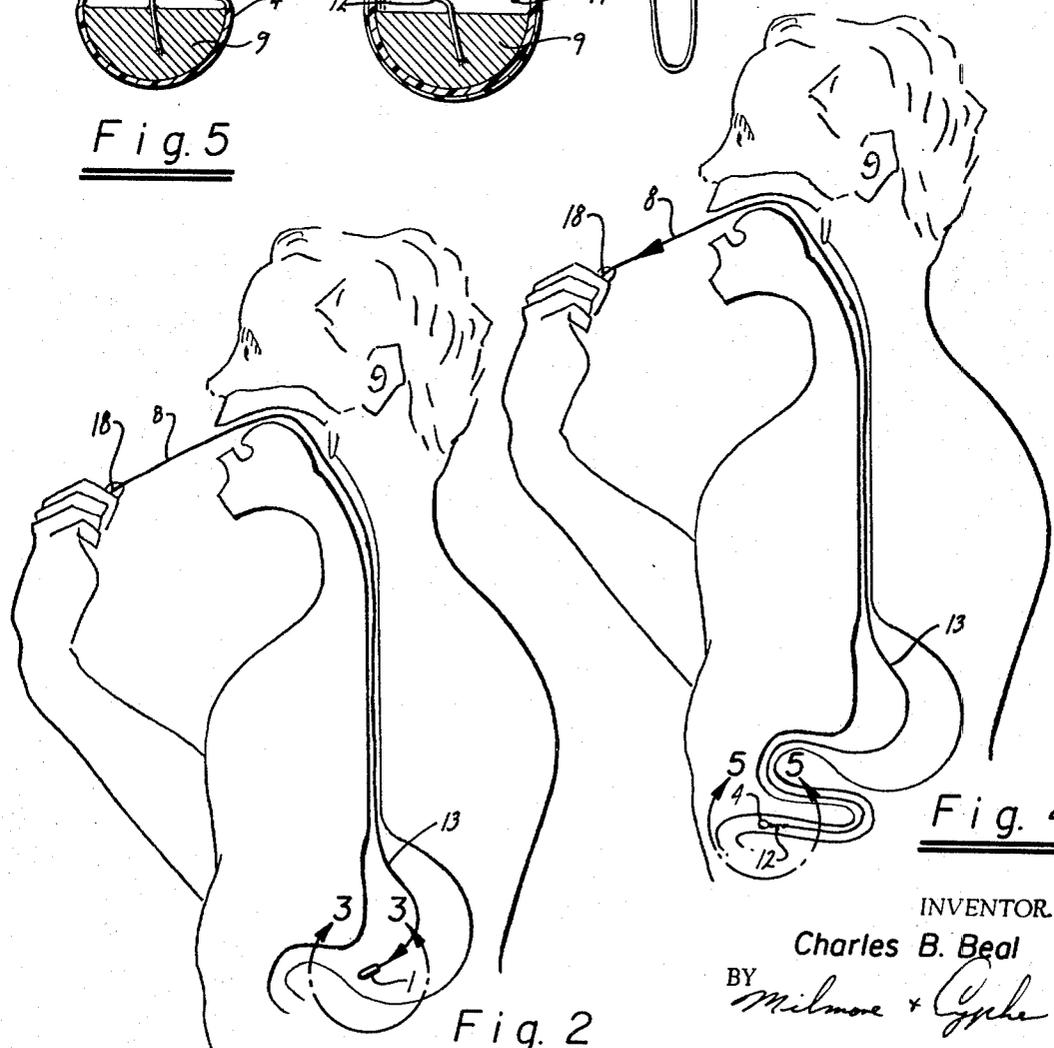


Fig. 4

Fig. 2

INVENTOR.  
Charles B. Beal  
BY *Milmore & Cypha*  
Attorneys

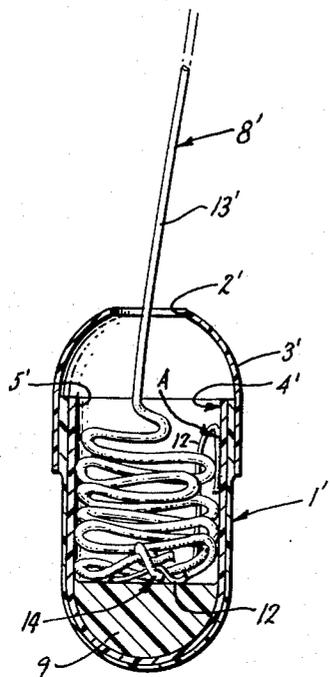


Fig. 6

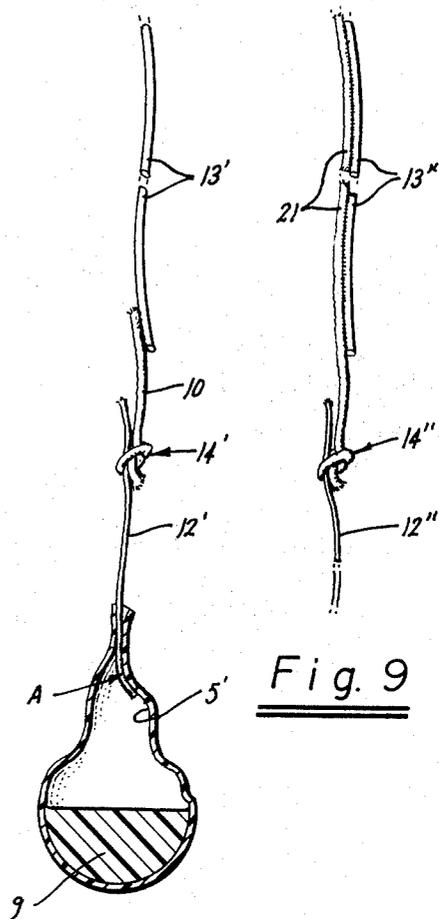


Fig. 9

Fig. 8

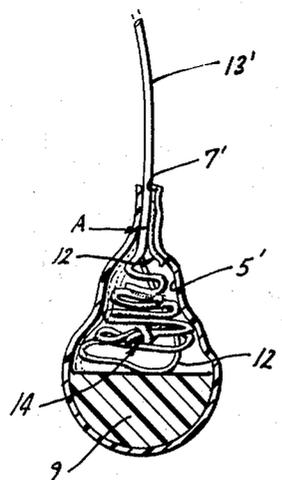


Fig. 7

INVENTOR  
Charles B. Beal  
BY *Malcolm C. Gypka*  
Attorneys

## CARRIER SYSTEM FOR DELIVERY OF AN END OF AN ELONGATED MEMBER TO THE UPPER GASTROINTESTINAL TRACT

The present application is a continuation in part of my prior co-pending U.S. Pat. application Ser. No. 771,573 filed Oct. 29, 1968 now abandoned.

### BACKGROUND OF THE INVENTION

Existing methods of sampling the contents of the upper gastrointestinal tract consist in swallowing a weight and line, inch by inch. Many patients have great difficulty in carrying out this test because the movement of the line against the oropharynx causes them to gag on the string and nausea often results.

Other methods consist of passing a small tube to the small intestine through the nose or mouth into the stomach and then into the duodenum by inserting a wire or mandrel through the entire length of the tube. This method is difficult, extremely uncomfortable for the patient, time consuming for doctors, immobilizes the patient for several hours, and frequently requires x-ray verification to determine whether the tube has passed into the duodenum.

Other methods of determining the contents of the upper gastrointestinal tract such as the presence of parasites is by examination of the fecal contents. This method often fails to reveal their presence, particularly those parasites living in the duodenum or bile ducts. Again, this method is time consuming for the laboratory technician.

### SUMMARY

The gist of this invention is the use of a two stage capsule which encapsulates a line or tube. The capsule is swallowed and the line or tube pays out an opening. As the two stage capsule travels to the duodenum, only the capsule is moving in relation to the tract and the sensation of gagging is reduced or completely eliminated.

The outer capsule is a gelatin pharmaceutical capsule which is easily swallowed and moves freely through the alimentary canal to the stomach where it dissolves and drops away from the inner capsule. The weighted inner capsule does not dissolve but instead the upper thin walls collapse forming a miniature bag which is of sufficient size with a low specific gravity so that it moves from the stomach, through the pylorus and into the duodenum. The walls of the inner capsule are collapsed by the peristaltic action present in the tract and lightly grasp the line or tube as it passes out of the capsule, thus preventing too rapid pay out and consequent knotting.

Accordingly, an object of the present invention is to provide a system for delivering the end of a string or tube to the upper intestinal tract which is simple, inexpensive, presents minimal discomfort for the patient, can be administered with little expenditure of time for technical personnel and which will nearly always pass into the duodenum spontaneously, avoiding the need of x-ray verification.

### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross sectional view of the device constructed in accordance with the present invention.

FIG. 2 is a schematic view of the device shown in use as it passes through the stomach.

FIG. 3 is a cross sectional view of the device taken substantially along line 3—3 of FIG. 2 showing the condition of the device as it would occur immediately after entry in the stomach.

FIG. 4 is a schematic view of the device shown in use immediately after reaching the target area in the duodenum.

FIG. 5 is a cross sectional view of the device taken substantially along the line 5—5 showing the condition of the device as it would occur upon reaching the sampling area.

FIG. 6 is a cross sectional view of an alternate form of the device for delivering a tube to the duodenum.

FIG. 7 is a cross sectional view of a portion of the alternate device shown in FIG. 6 as it would appear passing through the stomach and pylorus.

FIG. 8 is a cross sectional view of a portion of the alternate device shown in FIG. 6 as it would appear in the duodenum and just prior to release of the inner capsule from the tube.

FIG. 9 is a partial view of still another form of the invention.

### DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention consists briefly of an outer number 00 gelatin pharmaceutical capsule 1 dissolvable in the stomach from the normal presence of moisture and warmth and having an opening 2 in one end. The capsule may be formed with or without a separate cap 3. If provided with a cap, it may or may not have an inner lining insoluble in the upper gastrointestinal tract. Such lining would have no opening therein and should be attached to the capsule 4 described below. An inner open ended capsule 4 non soluble in the upper gastrointestinal tract is nested within the first capsule which has side walls 5 which deflect inwardly and form a miniature bag with a constructed opening 7 as shown in FIG. 5 upon being subject to the normal peristaltic action in the upper gastrointestinal tract for lightly grasping an elongated flexible element 8 contained by the inner capsule for playing out of the capsule openings. The inner capsule is weighted such as with a small amount of lead 9. The weight serves the dual purpose of structurally maintaining a portion of the walls so that a certain volume and specific gravity will be maintained so that the inner capsule will have sufficient bulk to be readily advanced by normal peristaltic action through the pylorus and into the small intestine.

The two stage capsule may act as a carrier of a small tube 13' to the upper gastrointestinal tract which can be used directly for transmission of pressure for operation of microinstruments carried with or in the capsule to the area of sampling. The tubing may be used to inject medicines or liquid radiopaque material to the duodenum for x-rays. Air may be injected to cause foam to take out folds so as to x-ray the duodenum. Medicines such as Atabrine for the treatment of tapeworm are best delivered by tube to the duodenum so they are not destroyed in the stomach or cause nausea.

The tubing may be of any conventional type such as the thin walled silicone rubber tubing sold by Dow Corning under the name Silastic. This tubing has an outside diameter of 0.070 inch and an inside diameter of 0.060 inch. The length is 90 - 100 cm.

In its simplest form, the elongated element merely consists of a cord or yarn 13 which will detach from the other parts of the capsule upon reaching the prescribed terminus so that the weighted portion will not be drawn up the length of the alimentary canal when the cord is removed from the mouth.

In still another form of the invention, the elongated element may include radiopaque markers 11 attached to the element so that the position and course of the line in the gastrointestinal tract may be determined by x-ray. The markers may be made of fine metal wire such as stainless steel or aluminum, coiled around the line or they may be barium loaded rubber or latex members affixed to the cord. The markers may also be formed by merely coating the string with barium loaded rubber.

In still another form of the invention the elongated element consists of a distal end 12 consisting of a short length of leader thread such as a 1.5 cm No. 70 weight thread, which in turn is attached to the lead weight as shown in FIG. 5, or thread 12' attached to the inside top wall of the inner capsule as shown in FIG. 8. Packed in the capsule is a length of yarn 13 such as a three-ply white nylon yarn of about 80 cm. length. The length should be shorter for children. The distal end of the yarn is attached to the leader by a simple overhand knot 14. The leader thread is placed in the knot in a manner to avoid sharp angulation of the thread. The knot grasps the thread tightly enough so that the capsule will pull the yarn behind it as it passes from the stomach into the duodenum, but loosely enough so that a vertical pull on the yarn will cause it to separate from the leader thread. The knot is adjusted so that a force of 30, plus or minus, 5 grams of vertical steady traction will cause it to separate from the thread, when tested in the dry state. The knot will hold the weight or the inner capsule when suspended in the dry state. The free ends of the thread and yarn at the knot are cut short, leaving only a 2-3 mm length on either side of the knot preventing the free ends from becoming entangled in use.

It has been found that thread is less irritating to the throat than the yarn. Further, the thread may be coated with a substance such as silicone rubber to make it still more acceptable. Accordingly, the proximal end of the yarn is securely attached to a 20 cm. length or so of thread 16 such as a size No. 24 thread, in a knot 17. A 2-3 cm. loop 18 is made on the free end of the thread. The loop protrudes through the opening in the capsule. After administration of the capsule, the thread is taped to the face and left in place.

The outer capsule is a hard shell gelatin pharmaceutical capsule such as a size No. 00 with a hole of approximately 4 mm in diameter in the top. The inner capsule may be constructed in several ways. It may be formed as a separate capsule of rubber, silicone rubber or a plastic such as that sold under the trademark Mylar, or it may be merely a thin coating of a flexible, non-toxic plastic such as polyvinylchloride or Neoprene coated on the interior surface of the outer capsule. This coating may have a dry weight of about 100-150 mgm. Other types of coatings could be used such as the film produced from the polyester of ethylene glycol and terephthalic acid known by the trademark Mylar, or silicone rubber. One form of silicone rubber which may be used is Silastic, Medical

Adhesive Silicone Type A, as sold by Dow Corning. The Silastic is mixed with toluene and coated on the inside of the outer gelatin capsule. The toluene evaporates and the Silastic cures leaving a wall thickness of between 0.010 to 0.020 inch.

The weighted inner capsule may be provided with a hemispheric shaped lead weight 9, as shown in FIG. 5, weighing approximately 1 gram.

The method of using the present invention is as follows. The loop of the thread is held in one hand and the patient swallows the test capsule with approximately one-half cup of water. The loop of thread is then attached to the face or, if desired, to a tooth. The capsule descends into the stomach, the thread and yarn playing out as required. The purpose of the gelatin capsule is to provide the appropriate rigidity, shape, texture and solubility for public acceptability and ease in swallowing. Note, for instance, that the outer capsule wall in FIG. 3 is decreased in section to indicate the solubility of the outer capsule.

The packing of the line inside the capsule allows it to be delivered into the gastrointestinal tract without any motion of the yarn in respect to the oropharynx thereby avoiding the nausea producing sensation of a line or tube moving across the back of the throat. Only persons with a very sensitive gag reflex are bothered by the presence of the thread in the throat.

In the stomach, the gelatin of the outer capsule melts completely leaving the inner flexible, non-absorbable, weighted capsule. The walls of the inner capsule are sufficiently thin that they collapse inwardly under normal peristaltic pressure and the inner cylindrical capsule now assumes the shape of a miniature bag substantially closed at its open end. The purpose of the inner plastic capsule is fivefold:

1. To house the line, allowing it to play out as needed.
2. To deflect inwardly at its open end, thereby offering some resistance to the playing out of the yarn to prevent too rapid play out and possible knotting.
3. To encase and contain the lead weight.
4. To add bulk to the weight, providing a bolus of sufficient size to be readily advanced by peristaltic action.
5. To diminish the specific gravity of that of the lead weight itself, thereby increasing the tendency of the capsule to be swept into the duodenum with the liquid contents of the stomach.

The sensation of swallowing the device is similar to that of swallowing an ordinary pharmaceutical capsule of similar size. Though passage of the capsule from stomach to duodenum may require 1-3 hours or more, very little discomfort is experienced by the patient. Nor is he restricted in any way except from eating solid food during the course of the test. After a period of 3-4 hours the yarn is removed simply by pulling it out of the mouth. The process requires about 4 seconds and is accompanied by only momentary gagging in most subjects. The inner capsule with its weight continues down the intestines and passes out unnoticed with the stool.

The part of the yarn that had been in the intestine generally is colored yellow or green from bile staining. The mucous material clinging to the yarn may be scraped off and examined as desired. Usually five to six drops are obtained.

The device has been successfully used to make a positive diagnosis of various parasites in the upper intestines such as the finding of hookworm eggs. Other conditions which may be diagnosed by obtaining a sample of duodenal contents are: (1) parasitic infections of the duodenum or bile ducts; (2) bacterial infections of the small intestine; (3) typhoid carrier state; (4) gall bladder stones in certain instances; (5) deficiency of the digestive enzymes of the pancreas; (6) bleeding in the esophagus, stomach or duodenum. (7) cancer in the upper gastrointestinal tract, gall bladder or pancreas. The latter abnormality may be detected by examining microscopically the desquamated cells collected with the mucous.

An alternate form of the device, shown in FIGS. 6, 7 and 8 is identical in nearly all respects to the form of the invention shown in the previous figures. The main difference is the substitution of a tube for the yarn. Accordingly, only the differences in construction will be set forth to avoid repetition.

Referring to FIG. 6, the two stage delivery device consists briefly of an outer gelatin capsule 1' having an opening 2' in one end. The capsule may be formed with or without a separate cap 3'. An inner open ended capsule 4', non-soluble in the upper gastrointestinal tract, is nested within the first capsule and has side walls 5' which deflect inwardly and form a miniature bag with a constricted opening 7' as shown in FIG. 7 upon being subject to the normal peristaltic action in the upper gastrointestinal tract for lightly grasping an elongated flexible element 8' contained by the inner capsule for playing out of the capsule openings. The inner capsule is weighted, as with a small amount of lead 9'.

As stated previously, the capsules carry a small tube 13' made of silicone rubber such as the Silastic tubing sold by Dow Corning. This tubing folds flat so that a length of approximately 1 meter can be easily stored within the capsule. The tubing need not be coiled within the capsule but may be merely stuffed therein in somewhat accordion style to avoid knotting as the tube plays out.

As in the previous form of the invention, the weighted inner capsule is attached to the elongated member, or tube in this instance, in such a manner so that it separates from the tube when the tube is manually pulled back. As shown in FIG. 8, the tube is attached to a short length of soft yarn 10, made of nylon or cotton the yarn is attached to the tubing by silicone glue or other means. The yarn contains an overhand knot 14' through which a short length of thread 12' is placed. The knot holds the thread as previously described, and releases under an approximately 30 gram steady pull.

Preferably, the thread is attached to the upper end of the inner capsule by a silicone glue in the approximate location shown in FIG. 8 denoted by the arrow A. Thus, in the event the knot does not release by pulling back the proximal end, the distal attached end of the thread will tear away from the inner capsule, preventing the likelihood of discomfort to the patient in withdrawing the tube with the weight connected thereto.

The elongated tube may be used alone to inject medicines directly into the duodenum as set forth above, or it may be used with a length of yarn to perform all of the tests set forth in relation to the form of the invention set forth in FIGS. 1-5. This alternate

form is shown in FIG. 9. This form of the invention is in all respects identical to the two previous forms except that a length of yarn 21 runs the entire length of the tube 13' and slightly beyond. The yarn is attached to the tube by silicone rubber and carries an overhand knot 14' which receives a length of yarn 12' which in turn is attached to the inner capsule as in FIG. 8. The form of the invention operates precisely as in the previous forms with the thread 12' separating from the knot 14' when the capsule (not shown) reaches the duodenum.

The operation of the alternate forms of the invention shown in FIGS. 6-9 are as follows: The patient swallows the capsule while he or a technical medical person holds the proximal end of the tube. The gelatin capsule moves downwardly; playing out the tube through its opening. By the time the outer capsule reaches the stomach, it is partially dissolved, and the dissolution is completed therein. Having completed its function to carry the tube to the stomach, the outer gelatin capsule drops away from the inner capsule, permitting the light inner capsule walls to collapse as shown in FIG. 7. A quantity of tubing remains in the inner capsule while the device is still in the stomach as shown in FIG. 7. The upper walls, collapsed by the peristaltic action normally present, grasp the tube lightly and prevent all of the remaining tubing from coming out of the capsule at once. The inner collapsed capsule, now in the form of a miniature bag finds its way through the pylorus to the duodenum. When the bag reaches the full length of the tube and the tube is manually pulled back, the small thread 12' or 12'' pulls through the knot 14' or 14'' respectively and the inner bag and weight finds its way out in the stool. The normal peristaltic action and the anatomical construction of the upper gastrointestinal tract resist the pull back of the bulky bag. The lead weight insures the requisite bulk so that peristaltic action will act upon the bag. As stated above, if the knot does not release the thread 12' or 12'', the end of the thread is lightly attached to the inner capsule so that it will tear away under the manually pulling back. At this point, the end of the tube is in the duodenum. Placing a quantity of air or medicine through the tube will expand it from its collapsed state and permit the air or medicine to be conveyed directly to the duodenum. After the procedures are completed, the tube may be recovered by withdrawing it. If the tube is accidentally swallowed, it will make its way out with the stool, and without discomfort to the patient.

In the form of the invention shown in FIG. 9, the tube and the yarn are recovered and mucous absorbed by the yarn may be examined.

I claim:

1. A carrier system for delivery of an end of an elongated member to the upper gastrointestinal tract comprising:

- a. an outer gelatin pharmaceutical capsule dissolvable in the upper gastrointestinal tract from the normal presence of moisture and warmth and having an opening in one end thereof;
- b. an inner capsule enclosed by said outer capsule having an open end substantially coaxially aligned with the opening of said outer capsule, and being non-soluble in said gastrointestinal tract and completely contained within said outer capsule,

and having inwardly deflectable walls collapsible in the absence of said outer capsule by peristaltic action present in the upper gastrointestinal tract for lightly grasping the element of paragraph (d) below between the edges of the walls:

- c. a weight, non-dissolvable in the upper gastrointestinal tract, carried in the bottom portion of said inner capsule and providing structural support to the walls of the inner capsule at said bottom portion so that said inner capsule is of sufficient bulk to be readily advanced by peristaltic action through the stomach;
- d. an elongated flexible element releasably connected to said inner capsule and having a first position substantially contained within said inner and outer capsules for playing out of said capsule openings to a second distended position within said gastrointestinal tract, said inner capsule containing said elongated element which is adapted for remaining after said outer capsule has dissolved and until said inner capsule has moved to the duodenum; and
- e. said elongated element and said inner capsule adapted for remaining connected during delivery of the distal end of said element to the duodenum, and said inner capsule adapted for being releasable from said element in the duodenum upon manually withdrawing said elongated element.

2. A device as described in claim 1 wherein said elongated element is a flexible line of yarn.

3. A device as described in claim 1 including radiopaque markers attached to the elongated element at selected intervals so that the position and course of the line in the gastrointestinal tract may be determined by x-ray.

4. A device as described in claim 1 comprising:

5  
10  
15  
20  
25  
30  
35  
40  
45  
50  
55  
60  
65

- a. a first thread connected to said inner capsule;
  - b. the distal end of said elongated element being formed with a knot; and
  - c. the free end of said first thread being connected to said elongated element by said knot and releasable therefrom in the duodenum by manual withdrawal of said elongated element.
5. A device as described in claim 1 comprising:
- a. said inner capsule is made from silicone rubber; and
  - b. a second thread connected to the proximal end of said elongated member, having a length adapted to extend from the mouth through the throat.
6. A device as described in claim 1 wherein said elongated element is a flexible collapsible tube.
7. A device as described in claim 6 comprising:
- a. a length of yarn connected to the distal end of said tube and having a knot formed in its free end.
  - b. a connector thread attached to the upper inner wall of said inner capsule and attached to said length of yarn by said knot; and
  - c. said knot adapted for holding said connector thread until said inner capsule reaches the duodenum.
8. A device as described in claim 1 comprising:
- a. said elongated element consisting of a yarn;
  - b. an elongated collapsible tube having substantially the length of said yarn element and being connected thereto along substantially the entire length;
  - c. a connector thread attached to the upper inner wall of said inner capsule and attached to said element consisting of a yarn until said capsule reaches the duodenum where it is adapted for release upon manual withdrawal of said elongated element.

\* \* \* \* \*