

May 8, 1962

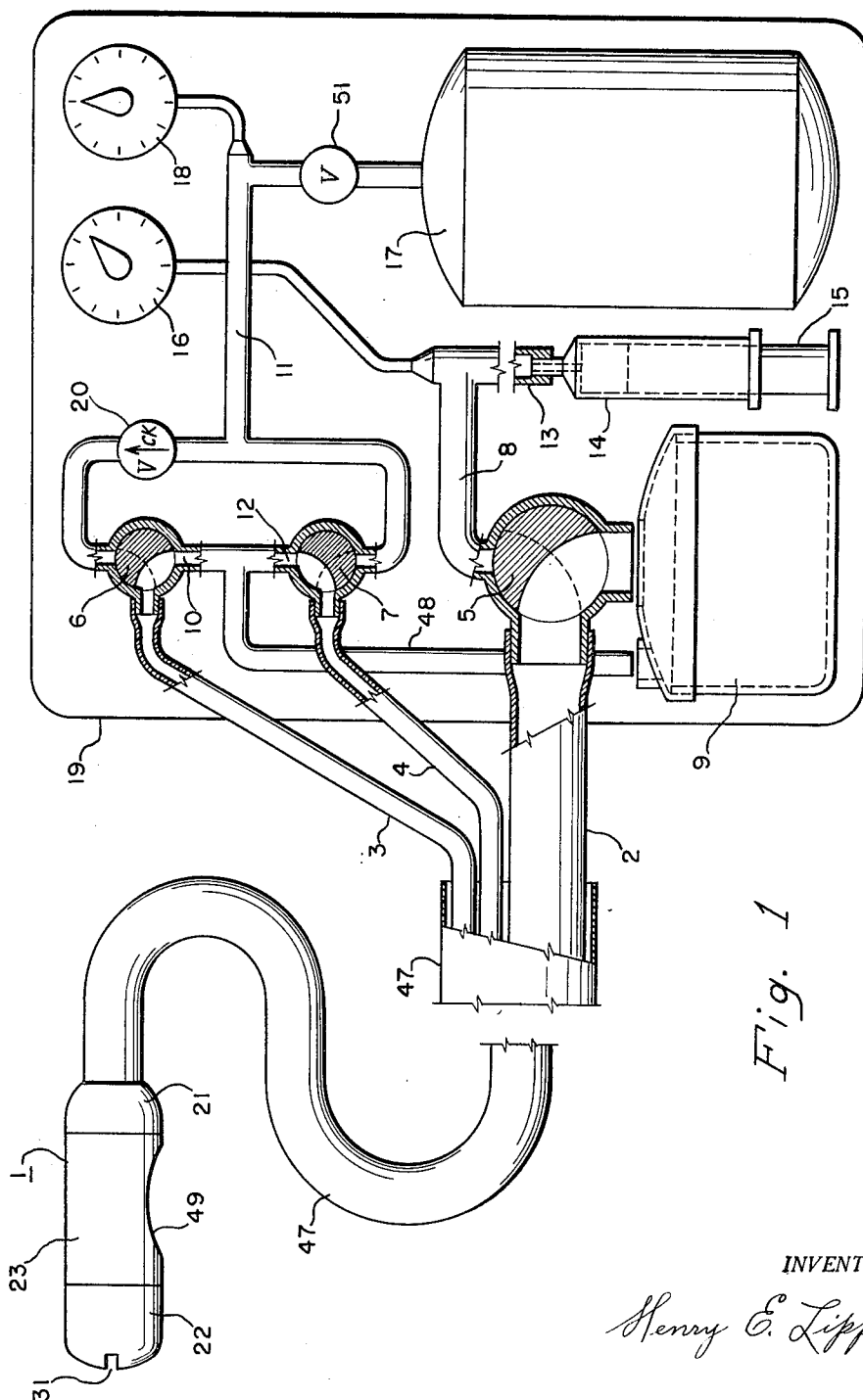
H. E. LIPPERT

3,033,194

BIOPSY CAPSULE AND APPARATUS

Filed Nov. 8, 1960

2 Sheets-Sheet 1



INVENTOR.

Henry E. Lippert

May 8, 1962

H. E. LIPPERT

3,033,194

BIOPSY CAPSULE AND APPARATUS

Filed Nov. 8, 1960

2 Sheets-Sheet 2

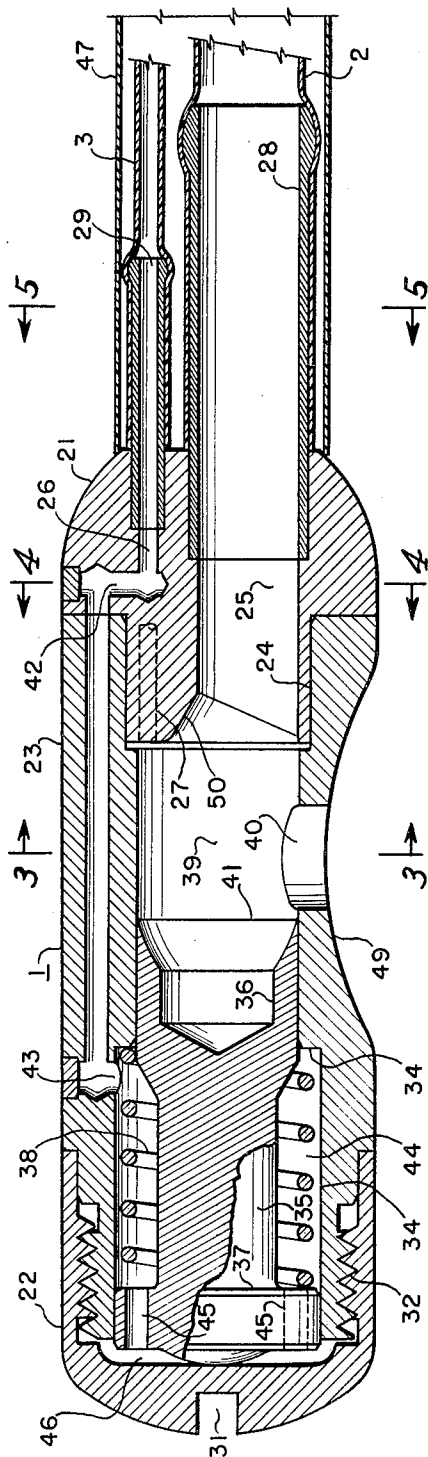


Fig. 2

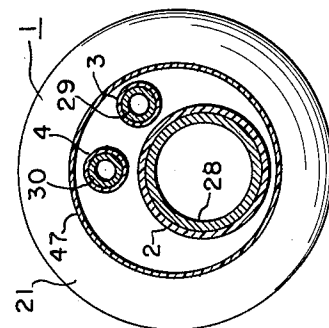


Fig. 5

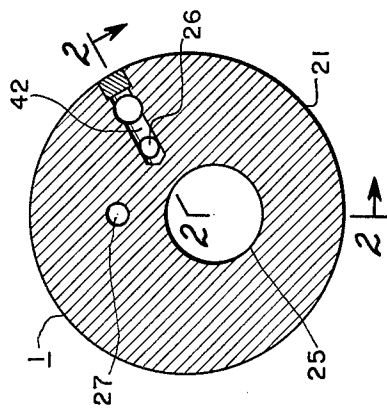


Fig. 4

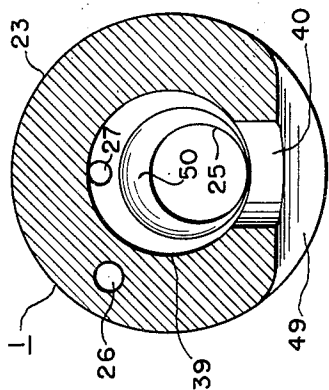


Fig. 3

INVENTOR.

Henry E. Lippert

1

3,033,194
BIOPSY CAPSULE AND APPARATUS
Henry E. Lippert, 130 SW. 12th St., Miami 36, Fla.
Filed Nov. 8, 1960, Ser. No. 67,993
16 Claims. (Cl. 128-2)

This invention relates to a new technique for taking specimens from the human body for biopsy purposes, and relates specifically to an apparatus for removing a desired number of mucosa specimens from various locations throughout any part of the digestive system.

Generally stated, this is now accomplished by having the subject or patient swallow a metal capsule secured to the end of a flexible plastic tube, and when the capsule has moved through the body of the subject to a position where a specimen of mucosa is wanted, by the attending physician or operator of the apparatus, action performed by the operator at the proximal end of the tube, causes movement of a knife in the capsule, and this knife amputates a specimen, which specimen is a small piece of flesh. This specimen, that remains in the capsule, is brought to the outside of the subject's body through the mouth by slightly pulling on the plastic tube.

This present method of obtaining biopsy specimens is lacking, primarily, in that only a single specimen can be taken with one intubation, that is, with one swallowing of the tube. One intubation may require the subject or patient the inconvenience or hardship of keeping the tube in his mouth anywhere from several hours to over a half a day. It can readily be understood what the patient must endure if a half dozen or more specimens are needed for biopsies.

It is an object of this invention to provide an apparatus that will obtain any desired number of mucosa specimens from the alimentary tract of the human body with only one intubation, and deliver each specimen individually, and immediately after its amputation, to an appropriate receiving container exterior of the patient's body.

Attempts have been made in the past to accomplish the above stated object of this invention. However, these attempts were not considered sufficiently successful to warrant continued use of the devices employed, chiefly because the specimens, when they finally were delivered, were crushed together and thereby damaged to an extent that any biopsy thereof, in numerous cases, was worthless.

Another object of this invention is to provide apparatus for obtaining several specimens with a single intubation, the apparatus being designed to function in such manner that each delivered specimen is undamaged and in proper condition for all of the necessary biopsy tests.

Those experienced in the field of gastroenterology can realize the importance of having mucosa specimens in good condition, delivered in a comparatively short period of time, from various selected locations in any part of the digestive tract of the human body. A device that can accomplish this, permits accurate diagnosis of physical conditions and hence an early beginning of remedial treatment.

Referring now to the drawings, forming a part hereof: FIG. 1 is a schematic layout of the apparatus comprising this invention, and the different parts and units are not drawn to the same scale. It is believed that this particular disclosure, when taken in conjunction with the accompanying description, best illustrates and permits ready understanding of the invention.

2

FIG. 2 is a longitudinal section on an enlarged scale, taken through the axis of the new biopsy capsule on line 2-2 of FIG. 4,

FIG. 3 is a transverse section taken on line 3-3 of FIG. 2,

FIG. 4 is a transverse section taken on line 4-4 of FIG. 2, and

FIG. 5 is a transverse section taken on line 5-5 of FIG. 2.

In FIG. 1 a metal biopsy capsule is designated as a whole by the numeral 1. Three separate pieces of flexible plastic tubing 2, 3 and 4 are each attached at their distal ends to the capsule 1. These tubes are of approximately the same length, say about six or eight feet long. The proximal ends of tubes 2, 3 and 4 are, when the entire apparatus is in operative condition, connected to valves 5, 6 and 7, respectively. These tubes provide three separated passageways or channels between the capsule and the valves.

The valve 5 can put tube 2 in communication with either a vacuum line 8 or a specimen receiving container 9. The valve 6 can join tube 3 with either an exhaust port 10 or a pressure line 11, and the valve 7 can connect tube 4 with either the exhaust port 12 or pressure line 11.

The end of vacuum line 8 remote from valve 5 is provided with a fitting 13 adapted to receive a syringe 14 having a plunger 15. A manometer or gauge 16 is inserted in the vacuum line 8 to indicate the negative pressure in the line when the plunger 15 is withdrawn from the syringe.

The end of pressure line 11 remote from valves 6 and 7 is connected to and communicates with a source of pressure fluid, here shown as a sealed tank 17. A gauge 18 is inserted in the pressure line 11 to indicate the positive pressure of the fluid in this line. A control valve 51 is provided to completely disconnect the pressure fluid system. A check valve 20 is interposed between valve 6 and pressure line 11, to prevent a reduction of pressure in tube 3 when valve 7 is operated to connect tube 4 with pressure line 11, which is described later with reference to operation of the apparatus. Exhaust ports 10 and 12 of valves 6 and 7, respectively, are arranged to discharge into line 48 which herein extends to the specimen receiving container 9, but this line could discharge to any suitable point of drainage.

In the preferred embodiment of this invention, that portion of the apparatus including the valves, gauges, specimen receiving container 9, source of pressure fluid 17 and the interconnecting lines, is mounted in a compact arrangement on a transportable panel 19.

Referring now to FIG. 2 to FIG. 5 inclusive, the casing of capsule 1 is made in three parts; namely, a front end piece 21, a rear end cap 22 and a somewhat cylindrically shaped center piece 23 to which the end parts are secured. The external dimensions of the capsule are approximately 1½ inches for the length and ¾ of an inch for the diameter, and a capsule of this size can be swallowed with little inconvenience to the patient.

The forward end of center part 23 is provided with a counterbore 24 into which the front end piece 21 extends. End piece 21 is tightly secured to the center part 23 by having a light press fit in this counterbore. Front end part 21 has three eccentrically located ports 25, 26 and 27 extending therethrough. Port 25 is considerably larger than ports 26 and 27 for reasons hereinafter described.

Nipples 28, 29 and 30 are tightly secured in the front ends of ports 25, 26 and 27, respectively, and these nipples protrude from the capsule so that tubes 2, 3 and 4, respectively, can be securely attached thereto.

The rear end cap 22 is tightly fastened to the center part 23 by means of the screw driver slot 31 and threads 32, and the cap 22 closes off the rear end of the capsule. Center piece 23 has at its rearward end a counterbore 33 terminating at shoulder 34. A combination piston-knife 35 is slidably mounted in the main body portion 23 of the capsule. The piston-knife 35 has at its forward end a cylindrical knife portion 36, and a piston 37 on its rear end mounted in the counterbore 33. A spring 38 is interposed between shoulder 34 and the piston 37 to normally maintain the piston-knife 35 in its rearward position, as shown in FIG. 2.

It is apparent from the drawings that when all the parts of the capsule are assembled, a chamber 39 is provided near the center of the capsule. An aperture 40 through the side of the capsule body, immediately forward of the knife edge 41 is provided to permit a specimen of mucosa to be drawn into the chamber 39, when this chamber is under negative pressure, as will later be set forth.

Referring again to the front end piece 21, the ports 25 and 27 extend from their respective nipples substantially straight through the part 21 and communicate at their rearward ends with the chamber 39. Port 26 is offset, as shown at 42, and it extends rearwardly through the center piece 23, and communicates at 43 with the spring chamber 44. A pair of holes 45 through piston 37 provides communication between the spring chamber 44 and the space 46 behind the piston 37.

In explaining the operation and functioning of this apparatus, it is believed unnecessary to detail the medical aspects of the process any more specifically than has heretofore been mentioned. Preparation of the patient, healing of the wound, preservation of the mucosa specimen, sterilization and care of the apparatus are all well known to hospital technicians as well as to physicians familiar with related techniques.

Prior to having the patient swallow the capsule, the three lengths of tubing are secured at one end to their respective nipples on the capsule. Tube 2, which conveys the mucosa specimen and is therefore the efferent channel, is made of clear transparent plastic. Tubes 3 and 4, the efferent channels are made of different colored plastic so that they are easily distinguishable from each other, and hence can readily be attached to the proper valves. A thin vinyl sheathing tube 47 encloses or contains the other tubes to keep them closely together and thus give the patient the feeling or belief that only one tube is being swallowed. Sheathing tube 47 extends from the capsule to a point a little short of the ends of the tubes it encloses, thus permitting the inside tubes to be connected at their ends to the proper nipples on the capsule and on the valves.

The patient swallows the capsule 1 under the directions of the attending physician and/or the operator of the apparatus. After a period of time, when the capsule has reached the place or location in the body of the subject where the first specimen is to be taken, the control panel 19 is brought to a location near the bed of the patient. The operator of the apparatus makes certain that valves 6 and 7 are not connected to pressure line 11. He then secures tubes 2, 3 and 4 to valves 5, 6 and 7, respectively. Valve 5 is set so that communication is provided between tube 2 and vacuum line 8.

The operator attaches a syringe of 100 cc. capacity to the fitting 13, and then begins to slowly withdraw plunger 15 from the syringe, thus creating a partial vacuum in the capsule chamber 39, by way of tube 2, and causing a specimen of mucosa to be sucked into the chamber 39 through the aperture 40 in the side of the capsule. From prior use of the apparatus and from directions supplied with the device, the operator knows, by watching the indi-

cator of gauge 16, when the specimen is in the capsule and ready for amputation. It might be mentioned at this point that, comparatively speaking, the measured negative pressure to accomplish induction of the specimen into the capsule is very slight.

The operator now adjusts valve 5 so that the external end of tube 2 can discharge to the specimen receiving container 9. The other end of tube 2 communicates with port 25 and chamber 39 in the capsule. The spring 38 in the capsule prevents the piston-knife 35 from moving when the chamber 39 is under negative pressure.

Valve 6 is now operated to connect tube 3 with pressure line 11, thereby providing pressure fluid to the rear end of piston-knife 35, by way of port 26, and causing the knife edge 41 to sweep across and beyond aperture 40, to amputate the mucosa specimen contained in the chamber 39. The movement of piston-knife 35 stops when spring 38 is completely compressed, and the parts are designed so that knife edge 41 will not strike front piece 21 of the capsule. At this time, the aperture 40 is sealed off by the cylindrical portion 36 of the piston-knife. The piston-knife 35 must be replaced by a new one when its edge 41 has been reground to such an extent that the edge will not completely pass across the aperture 40.

The check valve 20, between valve 6 and pressure line 11, prevents a reduction of pressure in tube 3, port 26 and the space 46 behind the piston 37, when valve 7 is opened, and thereby holds the piston-knife 35 at the forward end of its stroke.

The apparatus is now prepared to flush or deliver the specimen from the capsule to the receiving container 9. Valve 7 is operated to connect tube 4 with pressure line 11. Tube 4 communicates with port 27 of the capsule and specimen chamber 39. The introduction of pressure fluid into chamber 39 of the capsule, by means of tube 4 and port 27, discharges the loose piece of mucosa from chamber 39 through port 25, tube 2 and valve 5 into the specimen receiving container 9, from which, the specimen can be readily removed and properly identified. The diameter of port 25 and the inside diameter of tube 2 are approximately the same as the diameter of admission aperture 40, which is slightly less than $\frac{1}{8}$ of an inch. Hence, the mucosa specimen has room for passage, without being damaged, during its travel to the receiving container 9. The front end piece 21 is filed away at 50 to eliminate any obstruction to the delivery of the specimen. After the specimen has been delivered, valves 6 and 7 are turned to their original positions, thereby releasing pressure in tubes 3 and 4, and in the capsule. The spring 38 will then return the piston-knife 35 to its rearward position, thus opening aperture 40 so that a new specimen can be received by the capsule. Since it is very likely that the next specimen be taken from a different location in the patient's body, by slightly pulling on the tubing, and with the use of a fluoroscope, the capsule can be re-positioned. If valve 5 is now operated to connect tube 2 to vacuum line 8, the apparatus is again set or prepared to start another cycle.

It is preferable that the exterior surface of the capsule be smooth, and that the ends of the capsule be rounded to permit its easy swallowing and withdrawal. The exterior surface 49 immediately adjacent the aperture 40 is made concave so that the chamber 39 of the capsule will come as close as possible to mucosa lining of the patient's body prior to sucking the specimen into the capsule, thus reducing the travel of the mucosa portion that is later amputated.

In devices for taking biopsies by capsule, it is not uncommon to provide an element that will assist in causing travel or movement of the capsule through the body of the subject. This is done by tying a small deflated rubber balloon to the tubing in close proximity to the capsule, and then inflating the balloon after the capsule has been swallowed, thereby increasing frictional contact between the apparatus and the inside surface of the patient's body.

Such an accessory is useful when taking specimens from the lower duodenum, but it is unnecessary as an element to an operative combination of this invention, and for this reason has been omitted from the drawings.

The apparatus and the technique for using it, as above described, have all been with relation to a biopsy capsule adapted for swallowing by a patient. It should be understood that the same device and method can also be used through the rectum, for taking specimens from the colon and lower bowel, simply by substituting a relatively short piece of stiff tubing, immediately adjacent the capsule, for the flexible thin sheathing tube 47.

Separate tubes are herein shown connecting the capsule to the control apparatus, but since polyethylene can be extruded in just about any desired form, it may be desirable, as when a valve of special design is employed, to make the tubing in one piece and provide therethrough, a plurality of separated passages of proper size. Numerous other changes in details of design may be made without departing from the spirit and scope of this invention. By way of illustration, two separate sources of pressure fluid may be provided in the apparatus, instead of a common source as shown. Distilled water under pressure could be used only to flush the specimen from the capsule to the receiving container, and air pressure could be utilized to actuate the knife in the capsule.

The piston-knife 35 can be provided with one or more ribs or vanes in a manner so that pressure from port 43 will rotate the knife during its forward or cutting stroke. Also, the knife edge 41 may be helical, instead of circular, and thus cause a scissor or guillotine action between the knife and the edge of aperture 40 when the mucosa specimen is snipped off.

I claim:

1. The combination in an apparatus for taking biopsy specimens from the human body, of a capsule adapted for swallowing by a patient, said capsule having an aperture therein through which a specimen of mucosa can be received, flexible tubing secured to said capsule and extending to a point exterior of the patient's body, means for causing the specimen to enter the capsule, a knife slidably mounted in said capsule and arranged to move across said aperture for amputating the specimen, pressure fluid means for moving said knife, and means for discharging the specimen from the capsule through said tubing to a point exterior of the body of the patient, said tubing having three channels continuous therethrough and providing communication between the capsule and the means for causing the specimen to enter the capsule, the means for moving the knife and the means for discharging the specimen from the capsule.

2. The subject matter set forth in claim 1, wherein the specimen discharging means consists of pressure fluid arranged to deliver the specimen to a container exterior of the patient's body.

3. The subject matter set forth in claim 1, with the addition of mechanical means for returning the knife to its original position when the pressure fluid is released.

4. The subject matter set forth in claim 1, with the addition of a gauge exterior of the patient's body for indicating when amputation of the specimen should be made.

5. The combination in an apparatus for taking biopsy specimens from the human body, of a capsule adapted for swallowing by a patient, said capsule having an aperture therein through which a specimen of mucosa can be received, a source of negative pressure, a source of pressure fluid, a pressure fluid actuated piston-knife slidably mounted in said capsule and arranged to move across said opening for amputating the specimen, flexible tubing connected to said capsule and extending to a point exterior of the patient's body, said tubing comprising a pair of afferent channels arranged to provide communication between said source of pressure fluid and chambers in said capsule forward and rearward of said piston-knife and an efferent channel, larger than said afferent channels, ar-

ranged to provide communication between said source of negative pressure and and only the chamber in said capsule forward of said piston-knife, means for controlling communication between said source of pressure fluid and said capsule, and means for controlling communication between said source of negative pressure and the capsule.

6. The subject matter set forth in claim 5, with the addition of mechanical means for returning said piston-knife to its original position when the pressure fluid is released.

7. The subject matter set forth in claim 5, with the addition of a gauge exterior of the patient's body for indicating when amputation of the specimen should be made.

8. The combination in an apparatus for taking biopsy specimens from the human body, of a capsule adapted for passage within the alimentary tract of a patient and having an aperture therein through which a mucosa specimen can enter the capsule, a knife movably mounted within said capsule, a source of negative pressure, a source of pressure fluid, a specimen receiving container exterior of the patient's body, flexible tubing providing communicating passageways between said source of negative pressure and said capsule, between said receiving container and said capsule and between said source of pressure fluid and said capsule, means for controlling communication between the capsule and said source of negative pressure, and means for controlling communication between the capsule and said source of pressure fluid.

9. The subject matter set forth in claim 8, with the addition of mechanical means for moving said knife in one direction only.

10. The subject matter set forth in claim 8, wherein the negative pressure in one of the passageways is used to suck the specimen into the capsule, and the pressure fluid is used to discharge the specimen through the same passageway to a point exterior of the patient's body.

11. As a new article of manufacture, a biopsy capsule for taking specimens of mucosa from the human body, said capsule comprising a front end portion, a cylindrical center portion having a bored hole therethrough and a rear end counterbore concentric therewith, an aperture in said cylindrical center portion through which a mucosa specimen can be received, and a rear end removable cap portion, a specimen receiving chamber in the cylindrical portion adjacent said aperture, a piston-knife slidably mounted in said cylindrical portion having a knife edge at its forward end and a piston head at its rearward end, the knife edge end of said piston-knife bearing in the first said bored hole and the piston head end of said piston-knife bearing in said counterbore, a spring tending to maintain said piston-knife toward the rearward end of the capsule, a pair of ports extending from said chamber to the front end of the capsule, and a third port extending from the front end of the capsule through said cylindrical portion to a point rearward of said chamber.

12. The subject matter set forth in claim 11, wherein the said ports are located excentrically of the axis of the capsule.

13. The subject matter set forth in claim 11, wherein the forward ends of said ports terminate in individually fitted nipples.

14. The subject matter set forth in claim 11, wherein said front end portion is secured to said cylindrical portion for permanent attachment, and said rear end cap portion is threaded on said cylindrical portion to allow for disassembly of the capsule.

15. The combination in an apparatus for taking biopsy specimens from the human body, of a capsule adapted for swallowing by a patient, said capsule having an aperture therein through which a specimen of mucosa can be received, a knife slidably mounted in said capsule and arranged to move across said aperture for amputating the specimen, a source of negative pressure, a source of pressure fluid, a pair of channels arranged to provide

communication between said source of pressure fluid and opposite ends of said capsule, means in each of said channels for controlling such communication, and a third channel arranged to provide communication between said source of negative pressure and one end of said capsule, said third channel being adapted to receive the specimen and direct it to a point exterior of the body of the patient.

16. The subject matter set forth in claim 15, with the addition of specimen receiving means at the proximal end of said third channel, and means in said third channel for controlling communication between the capsule

and the source of negative pressure, and between the capsule and said specimen receiving means.

References Cited in the file of this patent

UNITED STATES PATENTS

2,701,559 Cooper Feb. 8, 1955

FOREIGN PATENTS

1,161,400 France Mar. 24, 1958

1,220,773 France Jan. 4, 1960

OTHER REFERENCES

The Lancet, page 686, Sept. 24, 1960.