United States Patent

[11] 3,590,808

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[54] **BIOPSY TOOL**
9 Claims, 12 Drawing Figs.

[52] **U.S. Cl.** ..... **128/2 B,** 128/305
[51] **Int. Cl.** **A61b 10/00**
[50] **Field of Search** ..... 128/2, 2 B, 349, 356, 305, 309, 303—314

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ABSTRACT: A biopsy tool that includes a rigid tip affixed to the distal end of a flexible intestinal intubation tube and is provided with a body portion having a longitudinal duct for the passage of an exchange guide and a radial cavity connected through the lumen of the tube to a vacuum source to draw a tissue sample thereinto. A pneumatically operable knife is longitudinally reciprocable across the open end of the cavity to sever the tissue sample contained therein.

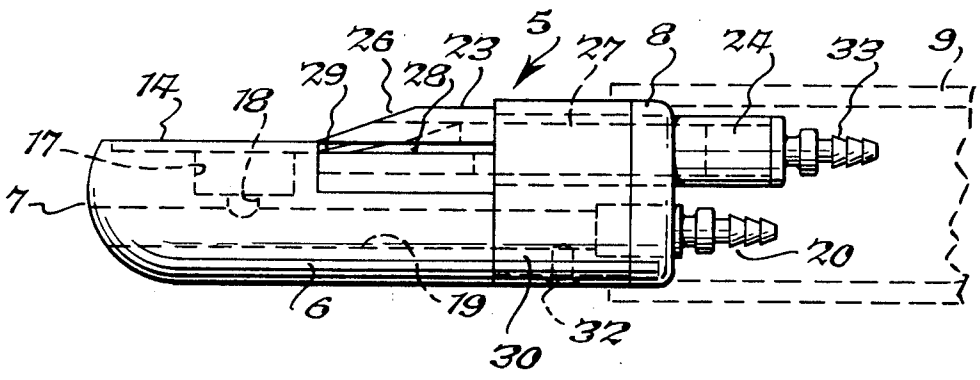

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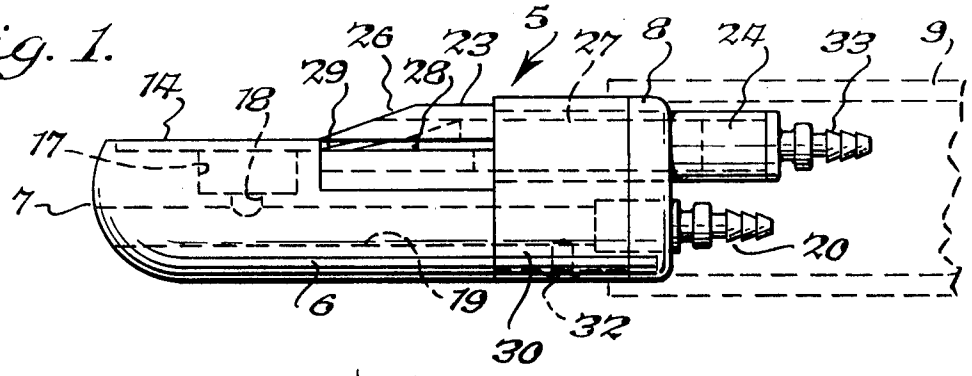
Fig. 1.



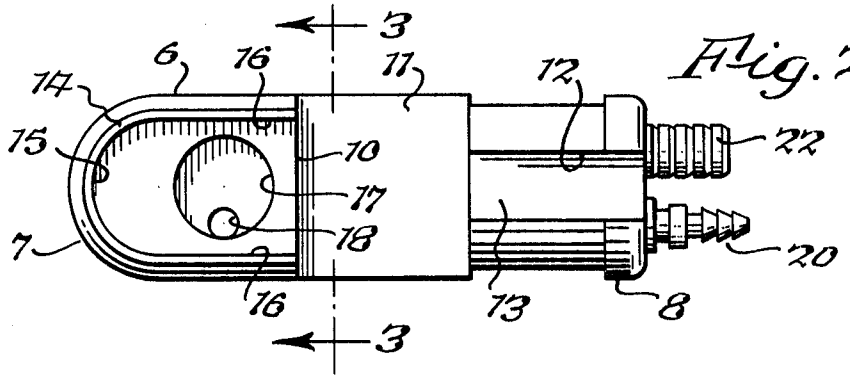


Fig. 2.

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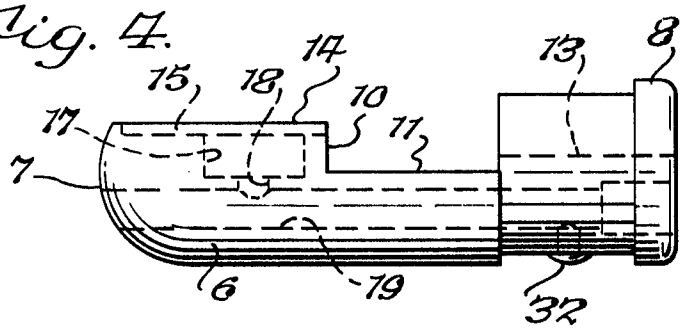

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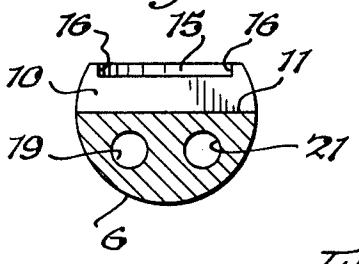

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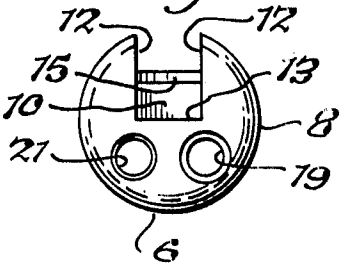

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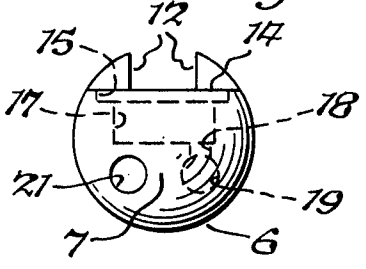

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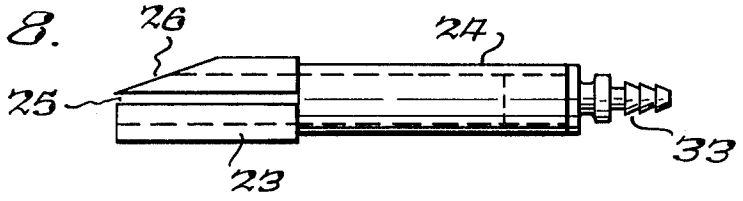
Fig. 8.



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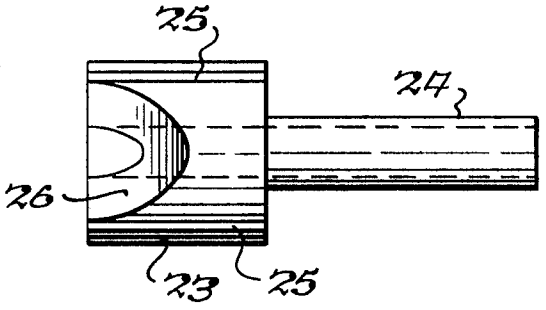

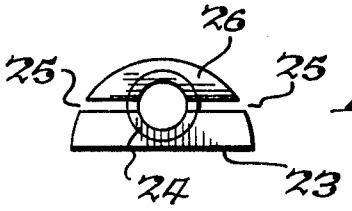

Fig. 9.

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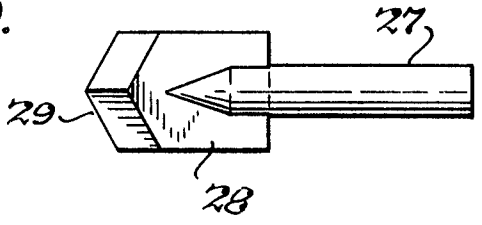

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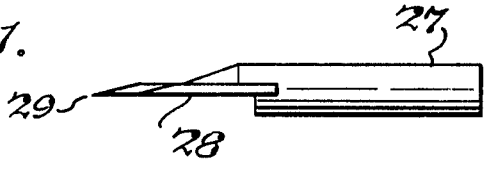

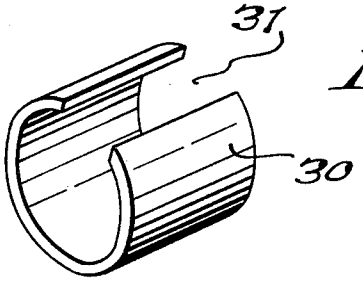

Fig. 12.

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BIOPSY TOOL

THE INVENTION

This invention relates generally to new and useful improvements in biopsy tools and particularly seeks to provide a novel biopsy tool that is affixed to and forms the distal tip of a flexible intestinal intubation tube, particularly of the type of intubation tube that is adapted to be advanced along a previously inserted exchange guide.

Heretofore it has been a long and difficult procedure to insert intubation tubes into the upper gastrointestinal tract through a patient's nostril because it was necessary to slowly advance (over a period of several hours) the tube under fluoroscopic control while manipulating the patient through many difficult postures or positions so that the distal end of the tube would follow the desired path of travel into the stomach and the several sections of the duodenum.

More recently techniques have been developed through which a soft woven catheter containing a proximally controllable distal tip spring guide may be fully inserted into a patient in from 10—15 minutes under fluoroscopic control with a minimum of manipulation of the patient. After this initial insertion has been completed the spring guide is withdrawn from its associated catheter and is replaced by an exchange guide normally having a length somewhat greater than twice the inserted length of the catheter so that its exposed proximal end portion is sufficiently long to accept the full length of the intubation tube to be inserted. Then the catheter is withdrawn over the exchange guide, leaving the exchange guide in place ready to receive and lead the intubation tube into its fully inserted position.

A particularly suitable type of controllable tip spring guide for these techniques is disclosed and claimed in my copending application Ser. No. 563,927, filed June 29, 1966, now U.S. Pat. No. 3,452,742 and a particularly suitable exchange guide therefor is disclosed and claimed in my copending application Ser. No. 757,326, filed Sept. 4, 1968.

Although the above-described techniques and equipment are effective for the simple and rapid insertion of intubation tubes, the problem still remains of how to quickly and safely obtain biopsy samples, especially from locations in the upper gastrointestinal tract.

A past approach to solving this problem has been through the use of an intubation tube having its distal end closed by a rigid hollow tip with a radial aperture extending through the wall of the tip and of the tube. A wire-operated cylindrical knife is reciprocable within the tip to sever a tissue sample that has been drawn through the wall aperture by vacuum applied from within the tube.

Even though such knife-containing tubes are believed to be the best currently available for obtaining biopsy samples, several objections have been made thereto; principally that they can be inserted only through the above-mentioned hours long technique and cannot be used with the short time exchange guide technique, and that there is no way to control the total force of the vacuum so that there is a substantial risk of rupturing the tissue wall by drawing too much tissue through the wall aperture of the tube. Furthermore, there is no positive control over operation of the cylinder knife and it is difficult to determine whether or not a tissue sample has been fully and cleanly severed.

However, a biopsy tool constructed in accordance with this invention overcomes the above-discussed problems and is fully compatible with the exchange guide technique of insertion.

Therefore, an object of this invention is to provide a novel tool for taking biopsy samples, especially those from the upper gastrointestinal tract.

Another object of this invention is to provide a tool of the character stated that may be quickly and simply inserted to its final position over a prepositioned exchange guide.

Another object of this invention is to provide a tool of the character stated that includes a rigid tip affixed to the distal end of a flexible intubation tube and is provided with a body portion having a longitudinal duct for the passage of an exchange guide.

Another object of this invention is to provide a tool of the character stated in which the body portion thereof is provided with a radial cavity having a flat outer end and having its inner end connected through the lumen of the tube to a source of vacuum whereby a predetermined and controllable quantity of tissue sample is drawn into the cavity.

A further object of this invention is to provide a tool of the character stated that includes a pneumatically operated knife assembly removably attached to the tip body to clearly and positively sever the tissue sample contained within the radial cavity.

A further object of this invention is to provide a tool of the character stated in which a friction-reducing tube is positioned within the lumen of the tube and extends from the proximal end of the exchange guide-receiving duct in the tip body to the proximal end of the tube to facilitate advance of the tube over the guide.

A further object of this invention is to provide a tool of the character stated in which vacuum is applied to the radial cavity through the lumen of the tube and air under positive or negative pressure is supplied to the knife assembly for reciprocation of the knife through a separate tube positioned within the lumen of the tube and extending from the proximal end of the knife assembly to the proximal end of the tube.

A further object of this invention is to provide a tool of the character stated in which the reciprocable knife is a flat spear-pointed blade arranged to have its point pass across a diameter of the body cavity whereby to first pierce the tissue sample and then clearly sever same as the knife is advanced.

With these and other objects in view, the nature of which will become apparent, the invention will be more fully understood by reference to the drawings, the accompanying detailed description and the appended claims.

IN THE DRAWINGS:

FIG. 1 is a side elevation of an assembled unit constructed in accordance with this invention;

FIG. 2 is a top plan view of the body of the biopsy tool;

FIG. 3 is a transverse section taken along line 3–3 of FIG. 2;

FIG. 4 is a side elevation of the body thereof;

FIG. 5 is a left end elevation of the body thereof;

FIG. 6 is a right end elevation of the body thereof;

FIG. 7 is a top plan view of the operating cylinder;

FIG. 8 is a side elevation of the operating cylinder;

FIG. 9 is a left end elevation of the cylinder;

FIG. 10 is a top plan view of the piston and knife blade assembly;

FIG. 11 is a side elevation of the piston and knife blade assembly; and

FIG. 12 is an isometric view of the cylinder retaining split sleeve.

Referring to the drawings in detail, the invention as illustrated is embodied in a biopsy tool assembly generally designated 5 and includes a body 6 (see FIGS. 2—6) machined from solid rod stock and having a rounded distal end 7 and a flanged proximal end 8 adapted to be secured within the distal end of a long flexible plastic catheter or intestinal intubation tube indicated at 9 by dotted lines on FIG. 1.

A transverse channel 10 of rectangular cross section is machined across the top of the body 6 intermediate the ends thereof and has its flat bottom 11 forming a plane surface passing through the centerline of the body. The channel 10 is adapted to receive the knife guiding portion of an operating cylinder as will be hereinafter more fully explained. A longitudinal channel 12 of rectangular cross section is machined along the top of the body 6 at the proximal end thereof and

has its flat bottom 13 lying in a plane slightly above that of the channel bottom 11.

The top of the distal end of the body 6 is machined to a flat surface 14 which in turn is machined to define an open-ended U-shaped pocket 15 having undercut lateral walls 16 to receive and guide the lateral edges of a knife blade as will be hereinafter more fully described.

A cylindrical cavity 17 for receiving and retaining a biopsy sample extends downwardly from the surface 14 and terminates at a plane slightly below that containing the centerline of the body 6. A short radial duct 18, located adjacent the wall of the cavity 17, has its upper end in open communication with the cavity and its lower end in open communication with a longitudinal duct 19 extending therefrom to the proximal end of the body 6. A fitting 20 is affixed within the proximal end of the duct 19 for connection through tubing (not shown) to a source of vacuum so that a biopsy sample may be drawn into the cavity 17 when the tool has become properly positioned within a patient.

A duct 21 is disposed in spaced parallel relation to the duct 19 and extends the full length of the body 6 to permit passage of an exchange guide therethrough. The proximal end of the duct 21 is provided with a fitting 22 for connection with the distal end of a friction-reducing tubular sheath (not shown) so that the tool 5 and its associated intubation tube 9 may be more readily advanced over the exchange guide.

The body 6 also carries a pneumatically operable knife to sever the biopsy sample that has been drawn into the cavity 17. To this end (see FIGS. 7, 8 and 9) a cylinder having a generally hemicylindrical distal portion 23 and a tubular proximal extension 24, is fitted in the transverse and longitudinal channels 10 and 12 and is provided with a horizontal knife receiving and guiding slot 25, the bottom of which is coplanar with the bottom of the U-shaped pocket 15. The upper portion of the distal end portion 23 is bevelled as at 26 to reduce resistence when the tool is being inserted into a patient.

A cylindrical piston 27 is reciprocable within the bore of the cylinder 24 and is provided at its distal end with a flat knife blade 28 having a double bevel spear point cutting edge 29.

The cylinder and knife assembly is removably retained within the body 6 by a sleeve 30 (see FIG. 1 and 12) having a longitudinal split 31 of a width somewhat greater than the outside diameter of the tubular extension 24 so that when the sleeve is rotated until the split 31 is aligned therewith, the entire cylinder and knife assembly may be readily removed for cleaning and for replacement of the knife whenever it becomes too dull for further use. The proximal end 8 of the body 6 is provided with a round-headed stud 32 that is received within the split 31 when the sleeve 30 has been rotated to its cylinder-securing position. Springiness of the sleeve 30 permits the edge of the split 31 to ride up over the stud 32 when the sleeve is rotated.

A fitting 33 is affixed to the proximal end of the tubular extension 24 for connection through suitable tubing to an air syringe (not shown) for actuation of the piston 27 and its knife blade 28. Advancement of the plunger of the syringe will compress air to effect advancement of the knife to sever the tissue sample that has been drawn into the cavity 17, and withdrawal of the syringe plunger will create a vacuum to retract the knife. After the knife has thus been reciprocated one or two times, it is again advanced to cover the cavity 17 and the biopsy sample contained therein and is kept in this advanced position until the tool has been withdrawn from the patient, thus assuring retention of the sample and preventing it from being contaminated during withdrawal of the tool.

It will be appreciated from the foregoing description that the biopsy tool of this invention must be quite small, otherwise it would not be readily insertable through the designated internal passages. Typically, the body 6 would have an outside diameter in a range of 0.10 inch to 0.65 inch, preferably about 0.25 inch and a length in a range of 0.30 inch to 2.0 inch, preferably about 0.75 inch.

Thus it will be seen that this invention provides a novel biopsy tool in which a tissue sample is vacuum displaced within a cavity of fixed volume and severed by a reciprocable knife that can be actuated to close the sample-containing cavity as the tool is withdrawn.

It is, of course, to be understood that variations in arrangement and proportions of parts may be made within the scope of the appended claims.

I claim:

1. A biopsy tool comprising a generally cylindrical body having a smoothly rounded distal end, a proximal end and a longitudinal axis, a plane surface extending proximally from the distal end of said body, a sample-receiving cavity extending into said body from said plane surface, a flat-bladed knife reciprocable across said cavity along said surface, knife actuating means adjacent to said surface, a first bore extending axially from end-to-end of the body and open at both ends, and a second bore extending axially from the proximal end of the body to a point adjacent said cavity and being in communication with said cavity.

2. A biopsy tool according to claim 1 in which said surface lies parallel to said axis and said knife is reciprocable axially.

3. A biopsy tool according to claim 1 in which the knife actuating means includes a piston fixed to the knife, a cylinder adapted to receive said piston and a fitting for connection of the cylinder to a source of actuating fluid.

4. A biopsy tool according to claim 3 in which the cylindrical body is longitudinally recessed adjacent its proximal end, the cylinder is formed in the distal end of a separate cylinder block, said block is fitted in said longitudinal recess, and which includes releasable means for holding said block in said recess.

5. A biopsy tool according to claim 4 in which said releasable means is a rotatable collar.

6. A biopsy tool according to claim 2 in which the knife has parallel sides and a double bevel spear point cutting edge, the distance between said sides being greater than the corresponding dimension of the sample-receiving cavity.

7. A biopsy tool according to claim 6 in which the plane surface is bounded by a U-shaped rim around the distal and lateral edges of said surface, the lateral portions of said rim being parallel and spaced to guide freely the parallel sides of the knife.

8. A biopsy tool according to claim 4 in which the cylinder block is provided with a distally extending portion slotted in a plane parallel to the axis of the cylinder, the knife being slidable in said slot.

9. A biopsy tool according to claim 1 which includes a fitting at the proximal end of said second bore for connection thereof to a source of vacuum.