

Oct. 7, 1969

S. GOLDSMITH

3,470,867

BIOPSY NEEDLE

Filed Nov. 23, 1964

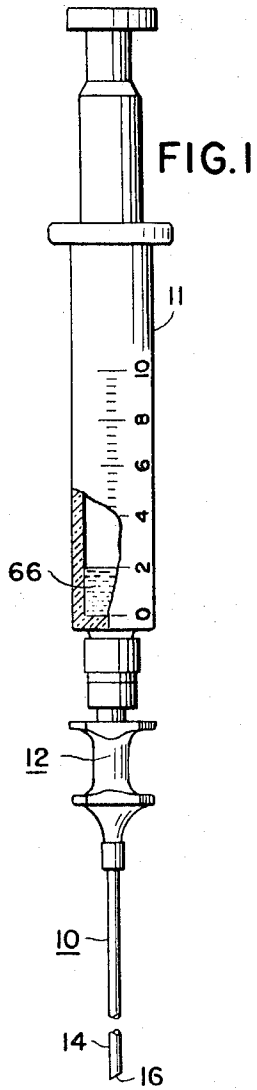


FIG. 2

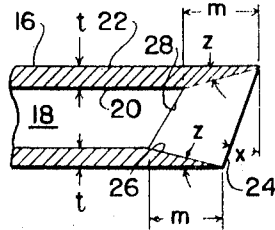


FIG. 3

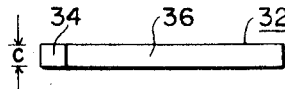


FIG. 4

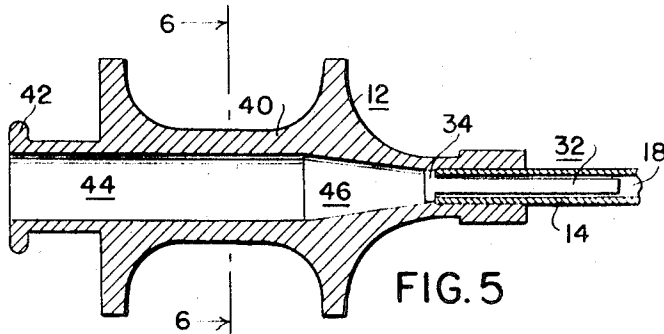
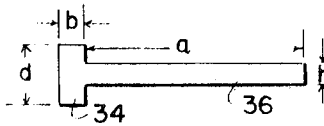


FIG. 5

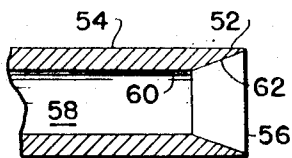


FIG. 7

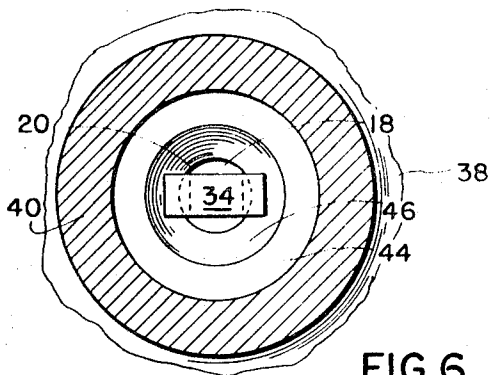


FIG. 6

INVENTOR.
Sidney Goldsmith

by *Milton J. Wayne*

ATTORNEY.

1

3,470,867
BIOPSY NEEDLE
 Sidney Goldsmith, 929 Tyson Ave.,
 Philadelphia, Pa. 19111
 Filed Nov. 23, 1964, Ser. No. 413,046
 Int. Cl. A61m 5/32

U.S. Cl. 128—2

1 Claim

ABSTRACT OF THE DISCLOSURE

A biopsy needle for taking tissue specimens having a needle end wherein the bore has an end taper formed equiangularly around the circumference thereof. A further feature is a stop member frictionally fitted within the other end of the needle bore to help increase the compression on the specimen passing through the equiangular taper. The stop member has a particular cross-section dimension which stops the passage of the specimen passing through the bore but yet allows fluid to flow past the stop member.

This invention relates to a biopsy needle and more particularly to an improvement therein for taking tissue specimens.

Biopsy needles are used to take tissue specimens, such as from the liver, kidney, breast and thyroid. In the prior art difficulty has been encountered in the taking of such specimens in that the specimen was lost in withdrawing the needle or the specimen would fragment and part would be lost so that the part of the specimen left would be unsatisfactory for testing. The loss of the specimen is very serious since the taking thereof involves insertion of the needle a substantial amount into the body and an organ of a patient. If the specimen is lost, then the needle must be inserted again, and repeated insertions may be harmful to the patient. This is very discouraging both to the doctor and the patient, and may result in the use of an alternative procedure in obtaining the specimen wherein an operation is performed to obtain the specimen. Such an "exploratory" operation is obviously to be avoided if possible, but this can only be accomplished by designing a biopsy needle that would be certain to obtain a specimen whenever inserted.

It is an object of the present invention to provide an improved biopsy needle that is certain to obtain a specimen whenever it is inserted in a patient.

It is another object of the invention to provide an improved biopsy needle that is easily and simply manipulated to obtain a specimen.

It is a further object of the invention to provide an improved biopsy needle that has an opening at the end of the needle larger than the bore within.

It is still another object of the invention to provide an improved biopsy needle that has an inside taper to flare out the end of the needle.

It is a still further object of the present invention to provide an improved biopsy needle that has an inside bevel at the end of the needle forming an edge that is inclined with respect to the longitudinal axis of the needle.

It is yet another object of the present invention to provide an improved biopsy needle that receives an improved stop member that substantially fills the needle bore.

It is yet a further object of the present invention to

2

provide an improved stop member for a biopsy needle that has an enlarged end and a shank member substantially filling the bore of the needle but allowing fluid to pass therethrough.

These and other objects will be apparent from the following description when read in connection with the drawings, in which:

FIG. 1 is an elevational view of the improved biopsy needle attached to a syringe shown partly in cross-section;

FIG. 2 is an enlarged showing in cross-section of the end of the needle;

FIG. 3 is a plan view of an improved stop member for use in the improved biopsy needle;

FIG. 4 is an elevational view of the improved stop member;

FIG. 5 is a view of the base portion of the needle in cross-section showing the stop member inserted therein;

FIG. 6 is a cross-sectional view along line 6—6 in FIG. 5; and

FIG. 7 is a cross-sectional view of another embodiment of the end of the needle.

Reference is now made to FIG. 1 wherein the improved biopsy needle 10 is shown connected to a syringe 11. The fitting of the syringe 11 to the needle 10 is conventional so it need not be described herein. Suffice to say that the end of the syringe is inserted into one end of the needle and lock in place by rotation for use. After use, the syringe is rotated in reverse direction for separation from the needle.

The needle comprises a base portion 12 and a needle portion or cannula 14. The needle portion 14 includes an end 16 which is more clearly shown in FIG. 2. The needle portion 14 includes an outside surface 22 and a bore 18 forming inside surface 20. End 16 terminates in edge 24, and it is clearly seen in FIGS. 1 and 2 that edge 24 is inclined at angle x with respect to a plane at right angles to the longitudinal axis of needle portion 14. Edge 24 is seen to be entirely included within a plane that is formed at angle x to the needle longitudinal axis, and a preferred angle in actual practice has been found to be approximately 15° .

Outside surface 22 forms a cylinder of unchanging diameter terminating in the edge 24. From edge 24 a tapered surface 26 extends radially inwardly to intersect inner surface 20 at meeting edge 28. Inner surface 20 extends from edge 28 to form a cylinder of unchanging diameter. It is seen that end 16 presents an inner taper or bevel in the form of surface 26 so that any tissue specimen taken into end 16 and forced up into bore 18 will be compressed as it moves past surface 26.

The taper formed by surface 26 forms an angle z with respect to the longitudinal axis of needle portion 14. The thickness of the needle portion 14 between the inner surface 20 and the outer surface 22 is designated t , and the distance from the edge 24 to the meeting edge 28 is designated m . A desirable ratio is approximately $3t=m$. A preferred embodiment in actual practice for 14 gauge biopsy needle has the following dimensions:

$$\begin{aligned} \text{angle } z &= 17^\circ 23' \\ m &= 0.031 \text{ inch} \\ t &= 0.010 \text{ inch} \end{aligned}$$

A novel stop member 32 is provided in this invention as illustrated in FIGS. 3 and 4. Stop member 32 com-

prises an enlarged end 34 and a shank portion 36. The size of shank portion 36 is critical in that the shank portion 36 which is rectangularly shaped in cross-section (as seen in FIG. 6) must substantially fill bore 18 in cross-section and yet allow fluid to pass therearound. The size of the enlarged end 34 is also critical as will be seen when the stop member 32 is inserted in bore 18 as shown in FIGS. 5 and 6.

In FIG. 5 it is seen that needle base 12 includes curved part 40 shaped to provide for finger gripping. Base 12 also includes rim 42 connected to part 40 and providing locking arrangement with syringe 11. Within base 12 is an enlarged bore 44 that is joined to the smaller bore 18 by a connecting opening 46 of decreasing diameter.

When stop member 32 is inserted through base 12 into needle bore 18, the shank 36 slides therein until enlarged end 34 abuts the end of needle portion 14. The enlarged end 34 has at least one dimension greater than bore 18 which prevents further insertion of the stop member 32 into bore 18. At this point the enlarged end 34 will be in abutment with the tapered wall 46 and the frictional contact thereof along with the complete insertion and close fit of at least one side of shank 36 in bore 18 maintains stop member 32 in place in the needle. To give an example of a preferred embodiment, such as in a 14 gauge needle having a bore 18 measuring 0.063 inch, a stop member had dimensions *a*, *b*, *c*, *d* and *h* as shown in FIG. 4 as follows:

$$\begin{aligned} a &= 1.156 \text{ inches} \\ b &= 0.187 \text{ inch} \\ c &= 0.050 \text{ inch} \\ d &= 0.117 \text{ inch} \\ h &= 0.060 \text{ inch} \end{aligned}$$

From the above dimensions it is to be noted that although the cross-sectional areas of shank 36 fills a substantial portion of bore 18, there is sufficient unfilled area in the bore to allow passage of fluid around the stop member between bores 18 and 44. These measurements of the stop member are critical to insure a proper fit and to insure taking of the specimen in a satisfactory manner, as will be explained hereinafter. The dimension *a*, of course, determines the length of the specimen drawn into the needle and will vary as indicated hereinafter.

A further embodiment of the invention is illustrated in FIG. 7 wherein the end 52 of needle portion 54 is shown with an edge 56 that is formed entirely in a plane positioned at right angles to the longitudinal axis of the needle portion. The bore 58 in needle portion 54 provides an inner surface 60, and from the edge 56 extending radially inwardly is a surface 62 that forms an inner bevel between outer surface 52 and inner surface 60 so that a tissue specimen entering end 52 is compressed as it moves up bore 58.

To take a tissue specimen an initial penetration is first made with a conventional pointed instrument or trocar where the specimen is to be taken. The stop member 32 is inserted in bore 18, and the syringe 11 is then attached to needle 10 and locked in place. The syringe 11 contains a predetermined amount of saline solution 66, such as 2 ml. as shown in FIG. 1. The end 16 of the needle is then inserted in the opening made by the trocar and approximately one ml. of saline is injected to clear bore 18. To take the specimen the syringe 11 is now aspirated to apply suction to the needle, and the needle is simultaneously and rapidly thrust inwardly to a predetermined depth. The thrust is straight forward with no rotation as the inside bevel of edge 24 or 56 provides an improved cutting action for cutting out the desired specimen.

In the prior art the thrust of the needle would cut the specimen for passage into the bore of the needle, but often in the withdrawal of the needle the tissue specimen would be lost or it would fragment into an unsatisfactory form. In the improved needle illustrated the beveled end provides an improved cleaner cut of the specimen which helps prevent fragmentation. Further, the bevel or taper

of the end causes the tissue specimen to be compressed as it passes up the needle bore. At this time the stop member comes into use in two ways. First the length of the stop member determines the length of the specimen to be taken for a certain size needle. Second the stop member allows a pressure relation to be maintained to help take the specimen as will be explained hereinafter.

In 65 biopsies performed with the improved needle, tissue specimens taken ranged from 2 inches to 3 inches, and in every case a tissue specimen was obtained. The tissue specimens obtained with the improved needle having the compression feature were smooth and shiny in appearance as compared to prior art specimens that were ragged and fragile. Preferred dimensions for the improved biopsy needles are as follows:

Liver biopsy needle, adult, 14 gauge—3" long
Liver biopsy needle, adult, 16 gauge—2" long
Liver biopsy needle, child or baby, 18 gauge—2" long
Soft tissue (breast, skin, lymph nodes, etc.) biopsy needle 14 gauge—2" long
Soft tissue (breast, skin, lymph nodes, etc.) biopsy needle 16 gauge—2" long
Biopsy stops for 14 gauge needle should be about 3 cm. long.
Biopsy stops for 16 gauge needles should be about 2 cm. long.
Biopsy stops for 18 gauge needles should be about 2 cm. long.

A further advantage of the improved stop member is the fitting provided by the enlarged end. When the syringe is aspirated, the substantial closure of the needle bore by the enlarged end holds the suction or "back pressure" and prevents suction leakage so that the specimen is moved in a positive manner up into the bore.

After removal of the needle from the body of the patient, the tissue specimen is expelled from the needle bore by ejecting the remaining saline from the syringe. The tissue specimen thus expelled is found to be compact and satisfactory for examination due to the compression feature. The needle may then be separated from the syringe and the stop member removed by insertion of a conventional stylet through the beveled end. The needle and syringe are then cleaned and sterilized in a conventional manner for reuse.

The particular embodiment of the invention illustrated and described is to be considered illustrative only. The present invention includes such other modifications and equivalents as may readily occur to those skilled in the art, within the scope of the appended claim.

It is claimed and desired to secure by Letters Patent:

1. A biopsy needle adaptable for connection to a syringe, comprising a hollow needle portion having longitudinal axis and inner and outer surfaces, said inner surface forming a bore, one end of said needle terminating in a needle base, the other end of the needle portion terminating in an edge all points of which are located in a plane inclined at an angle of approximately 15° with respect to a plane located at right angles to the longitudinal axis of the needle portion, said outer surface formed as a cylinder of unchanging diameter extending from said one end to said edge, a tapered surface formed on said other end and extending radially inwardly from said edge that is located on said outer surface to one end of said inner surface, said tapered surface forming with said outer surface a constant angle of less than 20° around the entire circumference of said edge, the length of the tapered surface being approximately three times the cross-sectional thickness between the inner and outer surfaces, a stop member, said stop member positioned in said bore to provide a close sliding fit therewith, said stop member having a shank portion of rectangular shape with both of the side dimensions being less than the diameter of said bore, said stop member having an enlarged end of rectangular shape, one side of said enlarged end having a

5

dimension less than the diameter of said bore, and the other side of said enlarged end having a dimension greater than the diameter of said bore so that said enlarged end cannot pass therethrough.

References Cited

UNITED STATES PATENTS

3,007,471	11/1961	McClure -----	128—2
3,175,554	3/1965	Stewart -----	121—2
2,426,535	8/1947	Turkel -----	128—2
3,330,268	7/1967	Goldsmith -----	128—2

6

FOREIGN PATENTS

587,586 1/1959 Italy.

OTHER REFERENCES

5 The Lancet, Oct. 10, 1964, p. 794.

RICHARD A. GAUDET, Primary Examiner

KYLE L. HOWELL, Assistant Examiner

U.S. Cl. X.R.

10
128—221