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| [21] | Appl. No. | 773,787 |
| [22] | Filed | Nov. 6, 1968 |
| [45] | Patented | Sept. 28, 1971 |

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|-----------|---------|-------------------|------------|
| 1,485,298 | 2/1924 | Schroyer | 128/347 UX |
| 2,865,374 | 12/1958 | Brown et al..... | 128/347 X |
| 3,496,932 | 2/1970 | Prisk et al. | 129/347 X |

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Attorney—Howard C. Miskin

- [54] METHOD FOR THE BIOPSY OF SUBCUTANEOUS
MASSES**

6 Claims, 9 Drawing Figs.

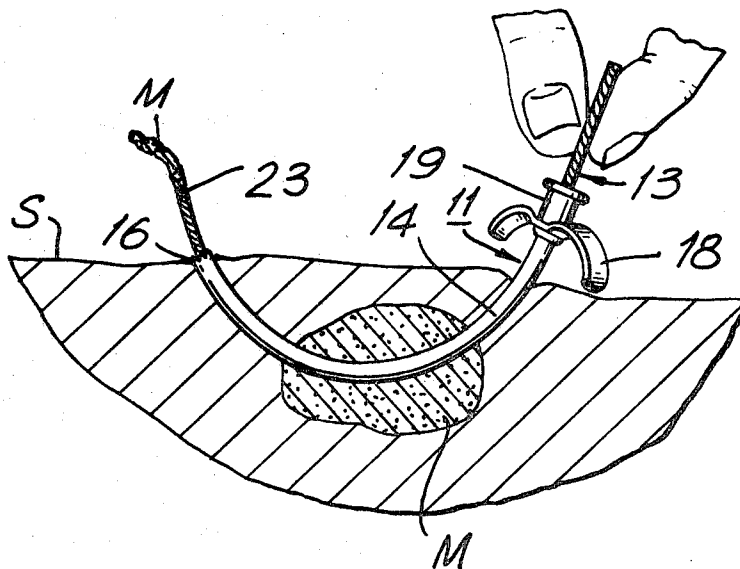
- [52] **U.S. Cl.**..... **128/2,**
128/314, 128/329, 128/347
[51] **Int. Cl.**..... **A61b10/00,**
A61b 17/34, A61b 17/32
[50] **Field of Search**..... 128/2, 305,
314, 329, 347

- [56]
- References Cited**

UNITED STATES PATENTS

- | | | | |
|-----------|--------|----------------|-----------|
| 2,919,692 | 1/1960 | Ackermann..... | 128/314 X |
| 3,342,175 | 9/1967 | Bulloch | 128/2 |

ABSTRACT: An instrument for the biopsy of subcutaneous masses includes an arcuate cannula having a serrated distal cutting end and is provided for alternative insertion, a correspondingly curved pointed stylet and a flexible ejector element. In performing a biopsy, the skin is punctured and the cannula engaged stylet inserted through the puncture into the surface of the mass from its lateral or inferior aspect. The stylet is removed and the cannula advanced through the mass to cut and draw a specimen thereof into the cannula and the cannula is pushed through the overlying tissue to the skin, which is then punctured and the distal end of the cannula pushed through the puncture. The ejector is then pushed through the proximal end of the cannula to eject the specimen.



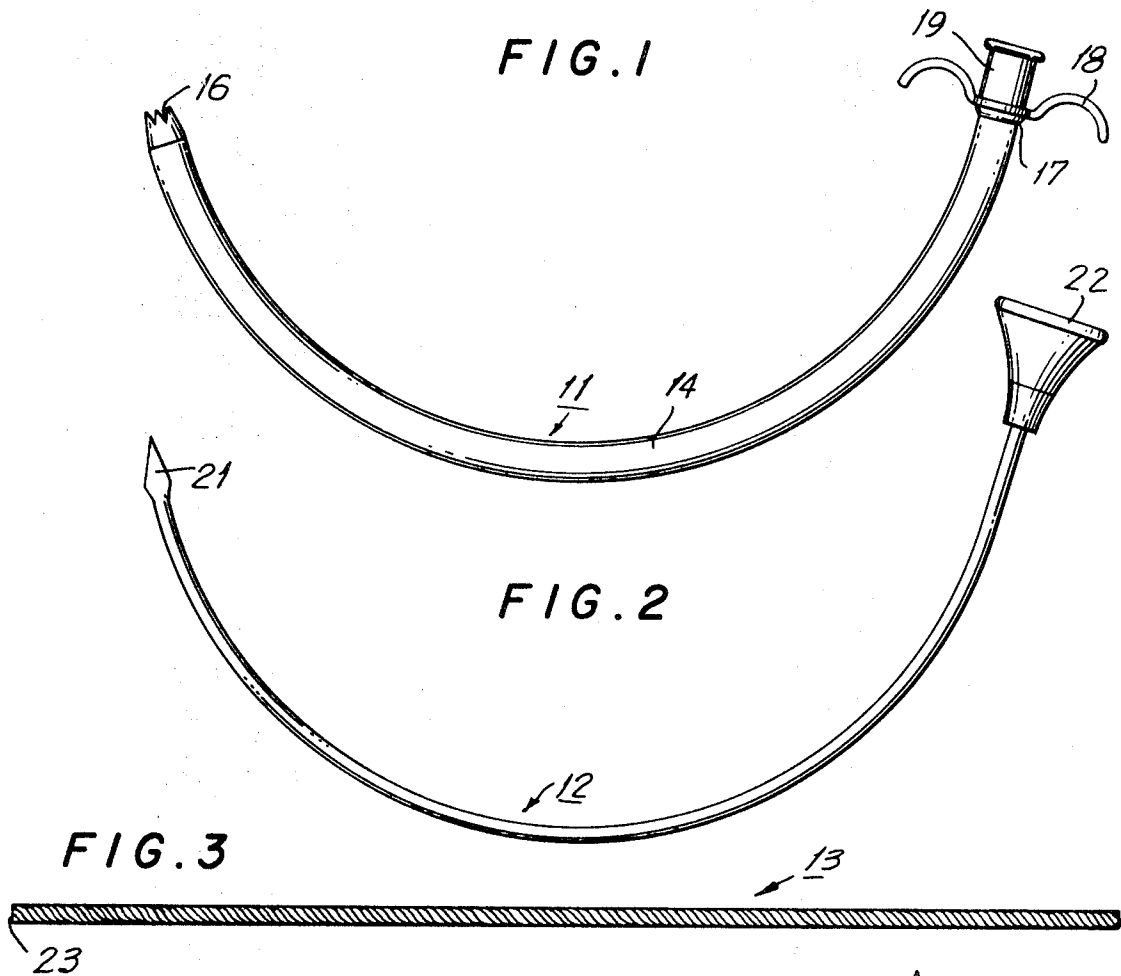


FIG. 5

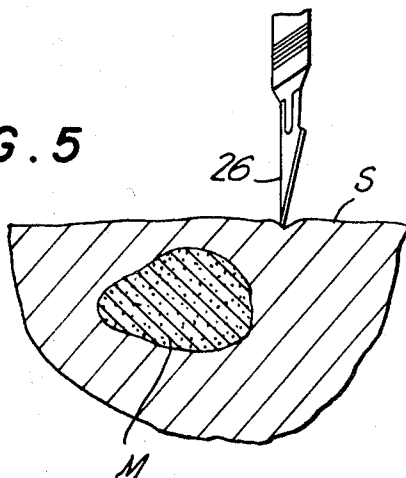
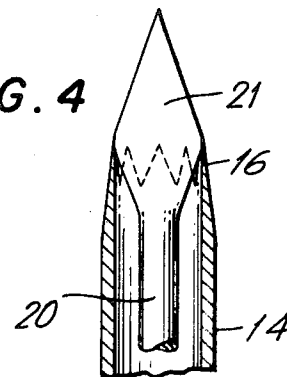


FIG. 4



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FIG. 6

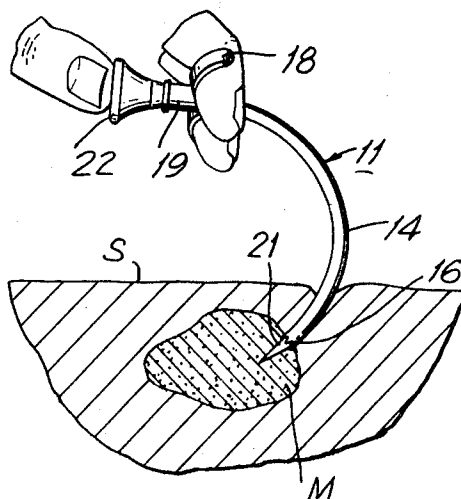


FIG. 7

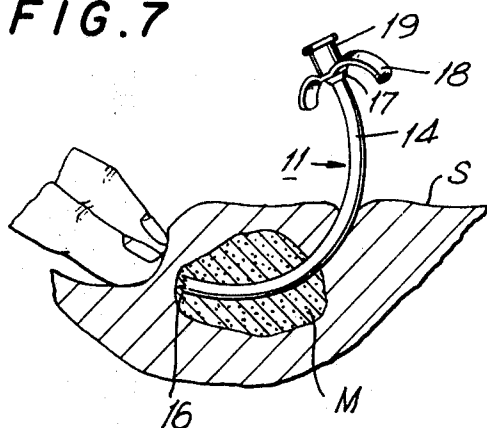


FIG. 8

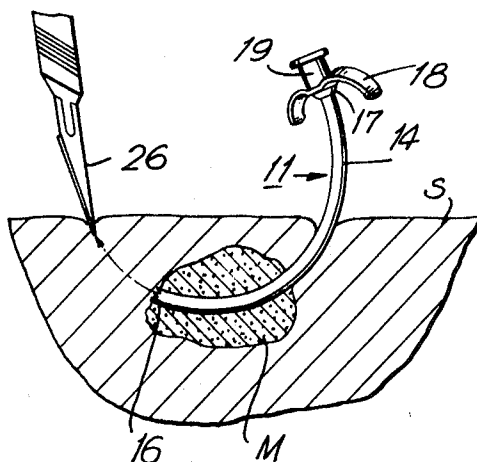
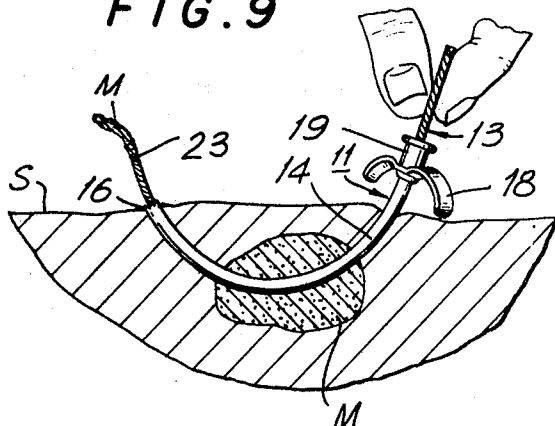


FIG. 9



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METHOD FOR THE BIOPSY OF SUBCUTANEOUS MASSES

BACKGROUND OF THE INVENTION

The present invention relates generally to improvements in sampling methods and instruments and it relates particularly to an improved method and instrument for obtaining biopsy specimens from subcutaneous masses, such as lymph nodes or tumors.

The procedures conventionally employed for obtaining biopsy specimens pose numerous drawbacks and disadvantages, particularly when applied to subcutaneous masses. They are usually accompanied by damage to the surrounding tissue as the result of surgical incision and dissection, and frequently effect the transfer of some of the sampled mass to the surrounding tissue, a consequence which is highly undesirable and should be assiduously avoided. Moreover, when straight needles are employed to obtain biopsies of lymph nodes or subcutaneous masses, the plug which is impaled in the barrel, in most instances will remain in situ when the needle is withdrawn, because its distal end has not been severed from the bulk of the mass. These tissues possess an inherent elasticity and connective tissue framework, which is resilient and has sufficient strength to retain a specimen which is cut on only three sides. It is because of this common experience that needles previously used for this purpose employed various undercutting mechanisms for retaining the cut plug, e.g. a screw, a hook, compressible jaws or a side cutting device.

SUMMARY OF THE INVENTION

It is a principal object of the present invention to provide an improved sampling method and instrument.

Another object of the present invention is to provide an improved method and instrument for obtaining biopsy specimens.

Still another object of the present invention is to provide an improved method and instrument for obtaining biopsy specimens of subcutaneous masses.

A further object of the present invention is to provide an improved method and instrument for obtaining biopsy specimens of subcutaneous masses with a minimum of damage to the surrounding tissue and the obviation of any transfer of the sampled mass to the surrounding tissue.

Still a further object of the present invention is to provide a method of the above nature, characterized by its convenience, simplicity, high reliability, versatility and minimum discomfort to the subject.

The above and other objects of the present invention will become apparent from a reading of the following description taken in conjunction with the accompanying drawing, which illustrates a preferred embodiment thereof.

In a sense the present invention contemplates the provision of the method for obtaining a biopsy of a subcutaneous mass comprising the steps of advancing a curved cannula through a first area of the skin, through said mass to cut and receive a specimen thereof, and thence through a second area of the skin, and thereafter ejecting said specimen from said cannula while projecting through the skin of the second area. The cannula is advantageously curved and preferably arcuate with a radius of curvature advantageously between 3 and 5 centimeters and advantageously extends between 45° and 180° preferably between 120° and 130°, and is of a length between 5 and 12 centimeters. The distal end of the cannula is provided with a serrated cutting edge and the proximal end is provided with finger engageable wings. A similarly curved stylet is slidably received within the cannula and is provided with a proximal button and a distal pointed tip projecting through the cannula distal end. A blunt ended flexible ejector is slidably received within the cannula alternatively with the stylet. According to the preferred procedure, the skin on one side of the mass is punctured and the stylet engaged cannula inserted therethrough and advanced into engagement with the mass. The stylet is then removed and the cannula advanced through

the mass to obtain a specimen thereof and thence through the surrounding tissue and another skin opening. The ejector is pushed through the proximal end of the cannula to eject the biopsy specimen through the distal end thereof external to the skin.

The improved procedure is simple, rapid, convenient, versatile and reliable. It results in a minimum of damage to the surrounding tissue and prevents any transfer of the biopsied mass to the surrounding tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a front elevational view of the cannula section of an instrument embodying the present invention;

FIG. 2 is a front elevational view of the stylet section thereof;

FIG. 3 is a front elevational view of the ejector section thereof;

FIG. 4 is an enlarged longitudinal sectional view of the distal end of the assembled instrument;

FIG. 5 is an elevational view illustrating a step of preparing the site in the practice of the improved process;

FIG. 6 illustrates the insertion of the cannula into the exposed mass;

FIG. 7 illustrates the obtaining of the biopsy specimen;

FIG. 8 illustrates the preparation of the skin exit site; and

FIG. 9 illustrates the ejection of the biopsy specimen.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawing, and particularly FIGS. 1 to 4 thereof, which illustrate an instrument embodying the present invention, the improved instrument includes a cannula 11, a stylet or piercing member 12, and an ejector member 13. The cannula 11 comprises an arcuate tubular body member or barrel 14, provided at its distal end with a sharp serrated cutting edge 16, as best seen in FIG. 1. The bore of the cannula barrel 14 is uniform throughout its length, the outer face at the distal end being tapered to the cutting edge 16.

An annulus 17 is fitted over the proximal end of the barrel 14 and a wing-shaped finger piece provided with a medial opening is also fitted over the proximal border of the barrel 14 and rests on the annulus 17. A standard Luer-lok receptacle or coupling collar 19 engages the distal end of the barrel 14 and is affixed to the barrel 14 with the annulus 17 and finger piece 18, by soldering, welding or the like.

The stylet 12 includes an accurately shaped rod 20 of the same curvature as the cannula barrel 14, and is of lesser cross-sectional diameter than the bore of the barrel 14. The rod 20 terminates at its distal end in an enlarged pointed tip 21 and is provided at its proximal end with a thumb rest or button 22. The cannula 11 and stylet 12 are so dimensioned that when the stylet 12 is fully inserted in the cannula 11, the button 22 rests on the coupling collar 19 and the tip 21 projects through the distal end of the cannula barrel 14 with its face forming a smooth continuous surface with the outside face of the cannula barrel distal border, as seen best in FIG. 4.

The ejector member 13, is a flexible rod or wire of an outside diameter, about equal to the inside diameter of the barrel 14, and is provided with a blunt distal end face 23. The ejector member 13 is advantageously formed of Teflon rod or other suitable material.

As a specific example, the cannula barrel 14 is formed of stainless steel with an inside diameter of 3 millimeters and an outside diameter of 4 millimeters. The overall length of the cannula barrel 14 is 10 centimeters and the chord distance from end to end is about 9 centimeters. It has a radius of curvature of about 4.5 cm. and extends for about 120°. The taper leading to the cutting edge 16 is about 4 millimeters long. The rod 20 is stainless steel of 2 millimeters diameter and the conical tip 21 is 6 millimeter long.

Considering now the practice of the improved method employing the instrument described above, and referring to FIGS. 5-9 of the drawing, the skin S, about 2 centimeters from

the mass M which is to be biopsied, is infiltrated with procaine and from this side additional procaine is injected subcutaneously about mass M. Skin S is punctured, as seen in FIG. 5, with a surgical blade 26 in an area slightly offset from the side of mass M. The opening in the skin is further enlarged by stretching with a small curved hemostat or pointed scissors, not shown. With the same instrument a tract is made to the mass M by penetration and separation of the subcutaneous tissue. The cannula 11, with the pointed stylet 12 in place is then inserted along the prepared tract and inserted into the side of or the undersurface of the mass M, as seen in FIG. 6. The free hand can often assist by holding the mass. After entry has been confirmed by moving the cannula 11 and mass M as one, the pointed stylet 12 is removed. With the thumb of the free hand, the mass M is pushed down and in this manner the open cannula 11 traverses one entire diameter of the mass M, as seen in FIG. 7. In some situations it is advantageous to rock the proximal end of the cannula to and fro; this turns serrated cutting edge 16 of barrel 14 and facilitates its passage through the mass M. When the mass M has been penetrated, the arc is further extended to raise the skin S at the opposite side of the mass M. With procaine, puncture and tract prepared as above, as seen in FIG. 8, the specimen loaded cannula 11 emerges. The clearing stylet or ejector 13 is inserted in the cannula 11, as shown in FIG. 9, and the specimen is picked up on either a square of blotting paper or with thumb forceps and dropped into a bottle containing the fixing solution. The cannula 11, is easily withdrawn by reversing the direction of the arc. Pressure is applied to the punctures for 2 minutes and two Band-Aids are applied to each of the two puncture sites and left in place for 24 hours.

In employing the improved instrument in the method described above, highly satisfactory biopsy specimens were obtained and the proper diagnosis made in a large number of patients. No false negative diagnosis were encountered. It is important to note that there were no complications associated with the improved procedure. The specimens biopsied

represented a variety of lesions from the point of view of size, consistency and diagnosis and the improved method has proven sufficiently versatile to adapt to most of the situations encountered.

While there has been described and illustrated a preferred embodiment of the present invention, it is apparent that numerous alterations, omissions and additions may be made without departing from the spirit thereof.

What I claim is:

1. The method for obtaining a biopsy of a subcutaneous mass comprising the steps of advancing a cannula inwardly through a first area of the skin laterally of the area above the mass and through said mass to undercut and receive a specimen from said mass and thence advancing outwardly cannula with the specimen therein out through a second area of the skin, on the side of the area above the mass opposite the first area and thereafter ejecting said specimen from said cannula while projecting through said skin.

2. The method of claim 1 wherein said cannula is advanced through said first skin area to said mass, while engaged by a stylet provided with a pointed end positioned at the distal end of said cannula, and removing said stylet from said cannula prior to said cannula being advanced through said mass.

3. The method of claim 1 wherein said specimen is ejected through said cannula by advancing a plunger through said cannula.

4. The method of claim 1 including the step of puncturing said first area of said skin with a sharp instrument prior to the insertion of said cannula.

5. The method of claim 1, including the step of puncturing the skin at said second area following the penetration of the mass by the cannula and before the emergence of the cannula through said second area.

6. The method of claim 1, including the step of applying pressure to said mass through the surrounding tissue in a direction towards said cannula during the advance of said cannula through said mass.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,608,539 Dated December 13, 1971

Inventor(s) DANIEL G. MILLER

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Abstract: 1. 5 "ment. In performing a biopsy, and the skin is punctured and" Change to -- ment. In performing a biopsy, the skin is punctured, and--

Column 2, l. 19 - "Fig. 4 is a enlarged longitudinal" Change to --Fig. 4 is an enlarged longitudinal--

Column 4, l. 14-15 - "said mass and thence advancing outwardly cannula with the specimen therein out through a second area of the skin, on the" Change to --said mass and thence advancing said cannula with the specimen therein outwardly through a second area of the skin, on the--

Signed and sealed this 25th day of April 1972.

(SEAL)
Attest:

EDWARD M. FLETCHER, JR.
Attesting Officer

ROBERT GOTTSCHALK
Commissioner of Patents