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- (72) Inventors JURGEN DINTER and HEINZ FUCHS



(54) BIOPSY INSTRUMENT

(71) We, B. BRAUN MELSUNGEN AKTIENGESELLSCHAFT, a body corporate organised under the laws of Germany of Melsunge, Germany, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The present invention relates to an instrument for removing samples of tissue from a human or an animal body by puncturing and subsequent biopsy. The term biopsy in this context means the separation of a strip of cells for histological examination.

Various instruments are known for removing histological samples of tissue which function in such a way that a cannula which cuts in the direction of insertion is pushed in that direction over an obturator which takes up the tissue to be removed, and a piece of tissue is detached in the process. After this operation, the obturator can either be removed from the cannula with the piece of tissue, or the entire instrument may be removed from the body with the piece of tissue.

With the instrument of this type, it is necessary for biopsy to exchange the obturator, after puncturing but prior to biopsy, for a second obturator which is to be used for taking up the sample. This is generally split lengthwise at its insertion end into two branches, therefore it spreads when introduced into the tissue after being pushed in the insertion direction by the cutting cannula and is closed by pushing the cutting cannula in the insertion direction over the spread branches, so that a sample may be obtained by plucking rather than by cutting. The obturator and cutting cannula may be moved toward each other over arbitrary distances.

In another known instrument of the type described at the outset (French Patent No. 1 267 960), the obturator has to be rotated axially about 180° after puncturing before the cutting process can be carried out. The cannula may be displaced on the obturator over arbitrary distances.

An instrument of the type described above is known from German Patent No. 1 817 555. Its

obturator and cutting cannula have guide members at the rear end which together provide a hold which limits the path of the cutting cannula during the biopsy process at the front and the rear by stops integrated in the hold.

The known instruments have considerable disadvantages in practical use, reference to which will be made below.

Operation demands both hands, but it would be desirable if the position of the instrument in the body could be constantly controlled with the second hand during the biopsy. The interruption in puncturing for feeling, required with the known biopsy instruments, prolongs quite considerably the duration of the biopsy with the fairly complicated handling of the instruments themselves, which may endanger the patient and leads to the biopsy in undesirable positions.

If the displacement of the cutting cannula to the obturator is not structurally limited in the known instruments, there is a danger of inadvertent puncturing of adjacent organs with the obturator. Inadvertent puncturing of the bladder and its consequences frequently leads to complications during biopsy of the prostate.

In the instrument according to German Patent No. 1 817 555 with a structurally limited displacement section, the user is particularly easily induced to advance the obturator into undesirable areas if he actually wishes to withdraw the cutting cannula by a certain distance, in order to subsequently carry out the biopsy.

The subject of the application is a biopsy instrument which may be used with only one hand in all phases of the operation and during use of which the disadvantages described above may be substantially avoided.

According to the invention there is provided a biopsy instrument for removing samples of tissue from a human or an animal body, comprising an obturator having a handle at one end which comprises a pair of rings connected by a connecting plate, the connecting plate having an elongate groove therein defined by a surface thereof and a pair of flanges facing towards one another and spaced from the said surface, and a hollow cannula which receives the obturator for sliding movement therein, the

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cannula having a cutting surface at one end and a handle which is connected to the other end by a holder, is slidably received in the said groove and is surmounted by a ring for insertion of a thumb, withdrawal of the cannula being limited by the said holder and insertion of the cannula being limited by a flexible plate fixed along one edge to the handle surface and being bendable so as to protrude from the plane of the surface of the handle and depressible into the plane of the handle surface.

Both the handles preferably have contacting sliding surfaces which maintain the desired orientation of the rings in relation to each other as well as of the cutting sections of obturator and cutting cannula in relation to each other, acting as a safety device against twisting.

Another feature of the apparatus according to the invention is the restriction of the displacement distance by stops on the sliding surfaces.

It is particularly advantageous that the biopsy instrument according to the invention may be used with only one hand, without surrounding it, in a simple manner during the puncturing of the organ and the removal of a sample of tissue. The other hand of the user is therefore always available during puncturing for controlling by feel the position of the instrument in the body, for example during biopsy of the prostate, or for fixing an area of tissue provided for biopsy, for example during biopsy of the mamma. With the known instruments, the accuracy of aim during bioptic puncturing can usually be achieved only with the aid of an assistant.

The new instrument makes biopsy simpler and safer in that the instrument is ready for biopsy after locating the suspected area of tissue without further manipulation and only a backward and forward movement of the thumb is required for cutting a sample for the tissue. Errors are eliminated since insertion and withdrawal movements are limited to the correct degree by suitable stops on the instrument.

It should also be pointed out that according to experience available up till now, the mode of operation of the instrument according to the invention is usually discerned on first observation, whereas the operation of the conventional instruments is not normally understood without detailed instructions and is mastered only after practice.

An advantage of the new instrument is that it is possible to remove several samples from the suspected area of tissue with only one puncture since, after cutting out a sample, the obturator with the sample located in its sample notch is withdrawn from the cutting cannula left behind in each case, and is introduced into it again for removing the next sample.

With reference to the accompanying drawings:

Fig. 1 shows a plan of the obturator with associated handle;

Fig. 2 shows a plan of the handle to the cannula;

Fig. 3 shows a cross-section through the operating handle for the obturator, the type of guide for the handles, the positional relationship of the sliding surfaces and cannula tube, being illustrated;

Fig. 4 shows a plan of the complete instrument in the puncturing position, capable of operating;

Fig. 5 shows in plan the complete instrument in the cutting (biopsy) position;

Fig. 6 shows the obturator end and the cutting cannula end in the cutting position in a side view, illustrating schematically the position in the organ;

Fig. 7 shows a complete instrument after biopsy, the obturator being withdrawn from the cutting cannula together with the sample (not shown).

The biopsy instrument according to the invention comprises an obturator 4 with associated firmly attached handle. The obturator 4 is a round solid metal rod with a ground surface 6 suitable for penetrating the tissue at its insertion end as well as a so-called sample notch 5 which comprises a recess over a distance of about 2 cm and to a depth of about half the thickness of the obturator. At its end remote from the insertion end, the obturator is rigidly fixed to the associated handle 18, to which it is fixed in a suitable manner in a semi-circular projection 3. Two rings 1 are arranged to the sides of the obturator, of such dimensions and at such a distance from each other that the index and middle finger may be inserted through them with comfortable handling. A connecting plate 2 between the two rings 1 has on one side the projection 3 for receiving the obturator 4 and is provided on its other side with a sliding surface 7. Obturator 4 and handle 18 form an inseparable assembly.

A second inseparable assembly, shown in Fig. 2, is formed by cutting cannula 14 and associated handle 19 having a handle body 10. The cutting cannula 14 is an internally hollow cylindrical tube, the internal diameter of which corresponds to the external diameter of the obturator 4 with a small clearance. It has at its insertion end a knife-sharp ground surface for detaching a piece of tissue. Its other end is fixed in a holder 13 which at the same time acts as a cannula withdrawal stop for the projection 3 of the obturator handle 18. A cannula insertion stop comprises a rectangular plate 11 which is bent up from the plane of the handle body 10 and, if necessary, can be pressed down into the plane of a sliding surface 12 thereof, which plate is rigidly fixed only at its base 16 to the cannula handle body 10, whereas the three remaining edges are

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clear of the body 10 due to an opening 17 in the handle body 10. Between the stops 11, 13, this face of the handle body 10 is designed as the sliding surface 12 corresponding to the sliding surface 7 of the obturator handle 18. The length of the sliding surface 12 is the sum of the length of the sliding surface 7 (Fig. 3) and the desired displacement distance for the cutting cannula 14 at the front end of the instrument. Retaining flanges 8 shown in Fig. 3 in cross-section prevent the sliding surfaces 7 and 12 from lifting apart and are arranged on both sides of the sliding surfaces 7. At the end opposite the holder 13, the handle body 10 bears a gripping ring 9 for the insertion of the thumb, which ring is designed transversely substantially oval and corresponds, in dimension and distance from the gripping rings 1, to a desirable hand position, taking into consideration the possible displacement distance.

Fig. 3 shows a cross-section through the obturator handle 18 as well as the handle 19 of the cutting cannula and shows the guidance direction of the handles 18, 19 when sliding toward each other. The sliding surface 7 of the obturator handle and the sliding surface 12 of the handle 19 are also shown in cross-section. The sliding faces are prevented from moving apart by the flanges 8, which retain the handle 19 on both sides. Fig. 3 also shows the obturator 4, the projection 3 in which the obturator is fixed and the gripping rings 1 of the obturator handle 18.

Fig. 4 shows the instrument in readiness for operation, the sample notch 5 being covered by the cutting cannula and the gripping ring 9 being located at a short distance from the gripping rings 1.

In this position, the instrument is introduced into the body by puncturing so that the thumb positioned in gripping ring 9 exerts the necessary pressure on the instrument and the index and middle fingers positioned in the gripping rings 1 safely control the direction of the prick. Once the point of the instrument has entered the tissue which is to form the subject of the biopsy, the gripping ring 9 is withdrawn by pronation of the thumb without changing the position of the hand, until the cannula withdrawal stop 13 connected to the gripping ring 9 by the handle body 10 strikes the counter-bearing projection 3. The cutting cannula 14 is thus simultaneously withdrawn far enough for the sample notch 5 of the obturator 4 to lie free in the surrounding tissue. Fig. 5 shows the instrument in this position. The position of the obturator 4 remains unchanged during this manipulation, fixed by the index and middle fingers in the gripping rings 1.

The free sample notch 5 now fills with the surrounding tissue previously pushed away, as

shown schematically in Fig. 6. The cutting cannula 14 is moved forwards, in the direction of insertion, by supination of the thumb and therefore separates the portion of tissue embedded in the sample notch 5. Excessive forward movement is prevented in this case by the cannula insertion stop 11. The puncturing and biopsy process is thus completed.

Now the instrument can be removed from the body together with the sample contained or, if further biopsies are necessary at the same position, the stop 11 can be pressed down and the obturator withdrawn from the cutting cannula, in which case it carries the sample with it (Fig. 7). After reintroducing the obturator, the next biopsy can be performed.

WHAT WE CLAIM IS:—

1. A biopsy instrument for removing samples of tissue from a human or an animal body, comprising an obturator having a handle at one end which comprises a pair of rings connected by a connecting plate, the connecting plate having an elongate groove therein defined by a surface thereof and a pair of flanges facing towards one another and spaced from the said surface, and a hollow cannula which receives the obturator for sliding movement therein, the cannula having a cutting surface at one end and a handle which is connected to the other end by a holder, is slidably received in the said groove and is surmounted by a ring for insertion of a thumb, withdrawal of the cannula being limited by the said holder and insertion of the cannula being limited by a flexible plate fixed along one edge to the handle surface and being bendable so as to protrude from the plane of the surface of the handle and depressable into the plane of the handle surface.

2. An instrument as claimed in claim 1 wherein the obturator is fixed in a projection located on the surface of the connecting plate remote from the groove and is arranged to be interactable with said holder so as to limit the withdrawal of the cannula.

3. An instrument as claimed in claim 2 wherein the projection is semi-circular in cross-section.

4. An instrument as claimed in any preceding claim wherein the surface of the cannula is ground to provide the cutting surface.

5. An instrument as claimed in any preceding claim wherein the flexible plate is rectangular and fixed along one edge to the handle surface so as to extend over an opening in the handle surface, the opening having such dimensions that the three remaining edges of the plate are clear of the handle surface.

6. A biopsy instrument substantially as herein described with reference to any of figures 1 to 7 of the accompanying drawings.

ELKINGTON AND FIFE,
Chartered Patent Agents,
High Holborn House,
52—54 High Holborn,
London, WC1V 6SH,
Agents for the Applicants.

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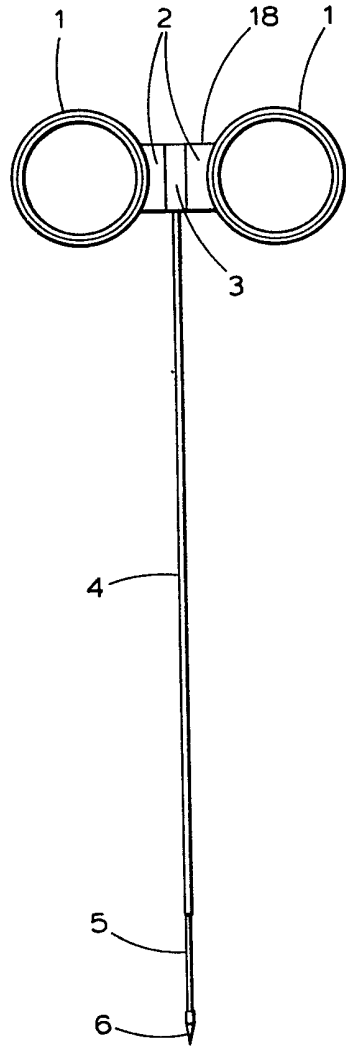


Fig. 1

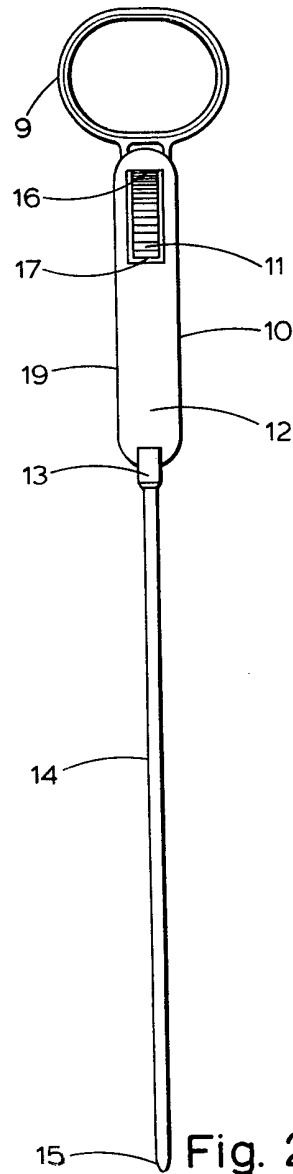
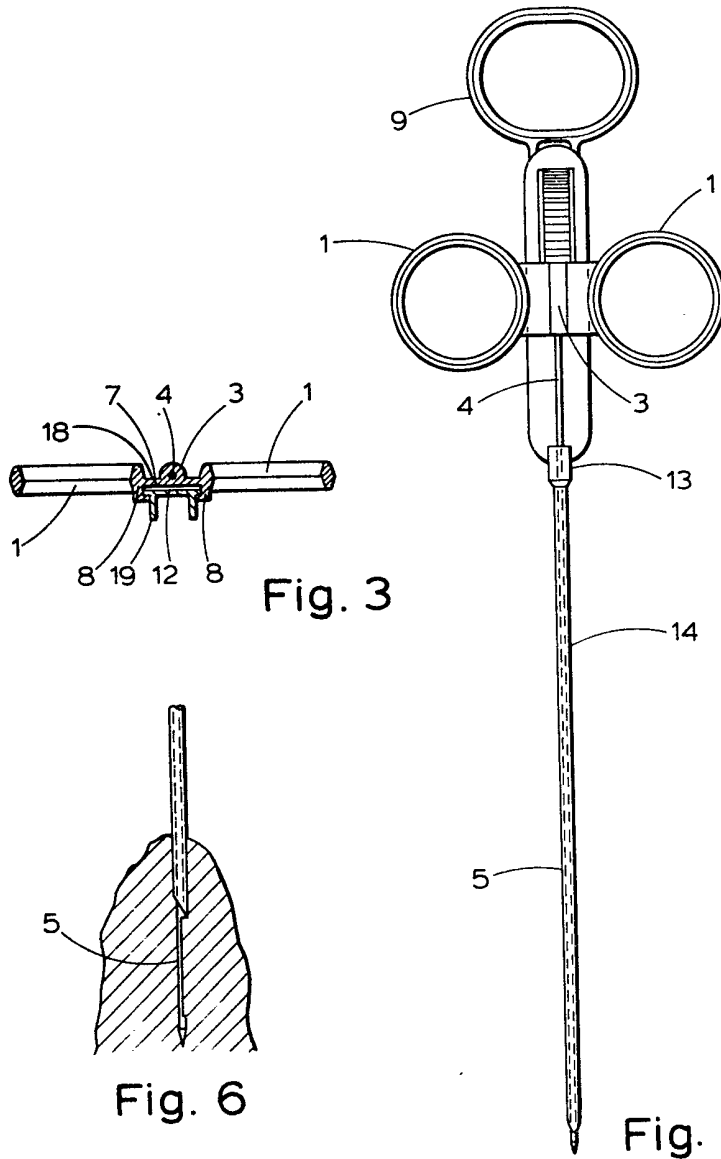


Fig. 2



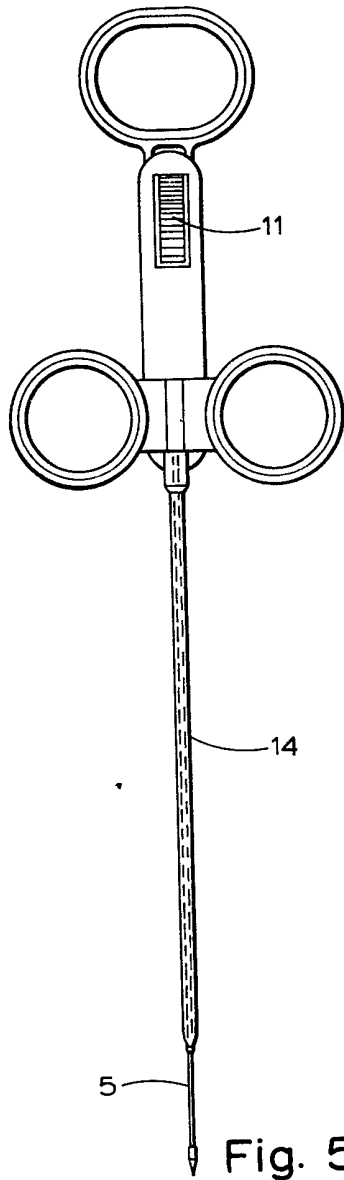


Fig. 5

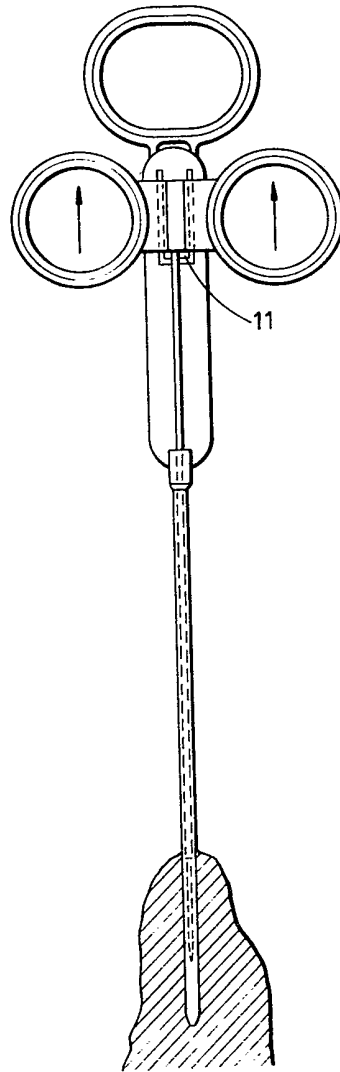


Fig. 7