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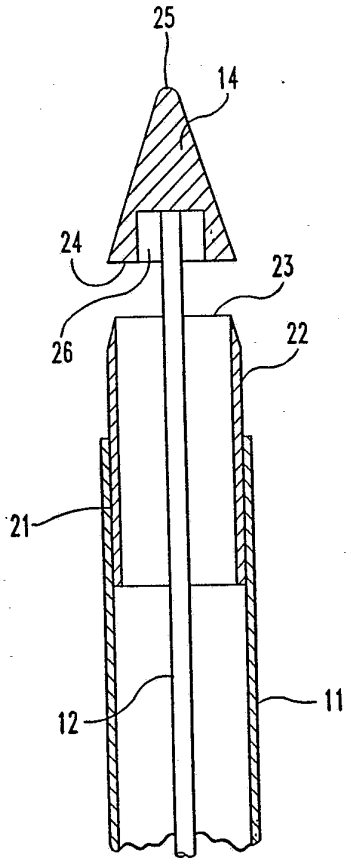
(54) Title: LATERAL BIOPSY DEVICE

(57) Abstract

A lateral biopsy device (10) for retrieving tissue samples atraumatically from within a patient's body. Biopsy device (10) comprises an elongated flexible catheter (11) which terminates at its distal tip in an annular cutting edge (23). Disposed within the central lumen of catheter (11) is an elongated flexible shaft (12) which is somewhat longer than the catheter. An anvil (14) having a rounded outer tip (25) is securely attached to the distal end of shaft (12). The anvil includes an annular surface (24) that contacts annular cutting edge (23) of catheter (11) when shaft (12) is retracted with respect to the catheter. Gripping means (13) attached to the proximal end of the shaft (12) enables the operator to advance and retract anvil (14) with respect to annular cutting edge (23) to retrieve a tissue sample positioned there between.



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LATERAL BIOPSY DEVICE

BACKGROUND OF THE INVENTION

This invention relates generally to a method and device for performing biopsies or for removing fragments of tissue to relieve an obstruction in areas of stenosis. In particular, the invention relates to biopsy sampling or removing tissue in any remote luminal structure or cavity within a patient.

It is often necessary to obtain tissue samples for microscopic, chemical or bacteriologic analysis from deep within luminal structures that can only be approached by catheterization methods using endoscopic or fluoroscopic control, or on occasion blindly by palpitation. General methods and devices currently in use for biopsy include needles with hooks that allow the tearing of the tissue samples, sharpened needles that allow the cutting of fragments, and punch or grasping forceps that either cut or tear the samples. These devices all require pushing or pulling the device against the tissue to be sampled. Also, it is often difficult to position these biopsy devices adjacent to the area that must be sampled. The stiffness and shape of these devices make them difficult and often impossible to position or guide through a long and tortuous lumen in a patient, and particularly to bend the device around curves in the lumen.

What is needed is a biopsy device that is structurally simple but which obtains a tissue sample without pulling on the tissue to be sampled, and which includes a thin flexible body which enables the device to travel through nonlinear passageways within a patient to reach otherwise inaccessible locations.

SUMMARY OF THE INVENTION

A biopsy device for obtaining tissue samples from remote locations within a patient according to one embodiment of the present invention comprises a flexible catheter having a lumen, a distal end and a proximal end. A flexible shaft is slidably disposed within the lumen of the catheter. Finally, a cutting means is located near the distal end of the catheter. The cutting means is actuated to cut tissue when the flexible shaft is moved with respect to the catheter toward the proximal end of the catheter.

A method of performing a biopsy according to another aspect of the invention utilizing the above described device includes guiding the distal end of the catheter through a non-linear passageway within a patient until the cutting means of the device is adjacent the area where a tissue sample is to be removed. After the device is properly positioned within the patient, the cutting means is exposed to the tissue, thus allowing tissue to come into contact with the cutting means. Next, the shaft is retracted back toward the distal end of the catheter thereby actuating the cutting means to cut a tissue sample. Finally, the biopsy device is withdrawn from the patient's body and the tissue sample is removed from the distal end of the biopsy device for further analysis.

One object of the present invention is to provide an improved biopsy device for sampling and/or removal of tissue in any luminal structure or cavity within a patient.

Another object of the present invention is to provide an improved device and method for relieving obstructions in areas of stenosis within a patient.

Another object of the present invention is to provide a device which allows repetitive biopsies or scraping of tissue samples without the need to remove the device between samples.

Still another object of the present invention is to provide a less invasive method for obtaining tissue samples from remote locations within a patient.

Related objects and advantages of the present invention will be apparent from the following description.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a partially sectioned side elevational view of a biopsy device according to the present invention.

FIG. 2 is a sectional view of the distal end of the biopsy device shown in FIG. 1.

FIG. 3 is a sectional view of the distal end of the biopsy device according to another aspect of the present invention.

FIGS. 4-6 show a sequence using the biopsy device according to the present invention approaching and removing a tissue sample from within a patient.

FIG. 7 is a cross-section view of the device of Fig. 1 looking in the direction of the arrows labeled A.

FIG. 8 is a cross-section of a two-lumen catheter according to another aspect of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

FIG. 1 shows a lateral biopsy device 10 according to one aspect of the present invention. The device includes an elongated flexible catheter 11 and an elongated flexible shaft 12 disposed within a central lumen 19 of catheter 11. Catheter 11 could range from a few to several hundred centimeters in length, depending upon the particular application. Attached to the proximal end of shaft 12 is gripping means 13. Gripping means 13 is shown as a releasable clamp but could equally well be any structure which permits the physician to advance and retract shaft 12 with respect to catheter 11. Attached to the distal end of shaft 12 is anvil 14. Anvil 14 may be attached by any suitable means such as by threaded engagement with shaft 12, adhesive, or by a welded connection. The diameter of shaft 12 is significantly smaller than central lumen 19 of catheter 11 in order that fluid may pass freely along the length of the central lumen of catheter 11. The proximal end of catheter 11 is connected to a standard Tuohy-Borst adapter 15 which is well known in the art and includes an injection-aspiration port 18. Nut 16 is attached to the proximal end of adapter 15 and compresses washer 17 in place to keep exit port 9 fluid-tight. In this way, any fluid

injected, or suction applied, at port 18 acts through central lumen 19 and out the distal end of catheter 11.

When gripping means 13 is advanced toward nut 16, against the action of spring 20, the flexible shaft 12 advances within central lumen 19 and results in separating anvil 14 from the distal end of catheter 11. When gripping means 13 is released, spring 20 acts to automatically retract flexible shaft 12 back to its original position with anvil 14 once again in contact with the distal end of catheter 11. Biasing spring 20 is a desirable but not essential element to the proper functioning of the invention; without bias spring 20, the operator would simply have to manually retract anvil 14 by pulling backward on gripping means 13. Depending on the specific application, catheter 11 could be as small as one millimeter in diameter, but a typical size for the catheter is a 7 French catheter. Catheter 11 could be formed from any suitable flexible medical grade tubing material. Also, depending upon the application, catheter 11 could also be made to have variable stiffness along its length.

FIG. 2 depicts the distal end of the biopsy device shown in FIG. 1 after gripping means 13 has advanced shaft 12 with respect to catheter 11, thus separating anvil 14 from the distal end of catheter 11. Anvil 14 includes a smoothly rounded tip 25 which aids in the atraumatic insertion of the biopsy device, and an annular lower surface 24 which is remote from the rounded tip. Also shown is metal tube portion 22 which is attached to the distal end of catheter 11 at circumfrential location 21 by a suitable attachment means such as mating threads or adhesives. Tubular portion 22 includes an annular cutting edge 23 which extends beyond the distal end of catheter 11 and contacts annular surface 24 of anvil 14 when the anvil is retracted against the tubular portion 22. The word "annular" is meant to refer to any closed shape which includes but is not limited to circles, ellipses, and polygons. In this case, anvil 14 includes a

cavity 26 which can serve to hold a portion of the tissue sample which is removed from the patient. Again, depending upon the particular application and the desired sample size, cavity 26 could be sized to a variety of volumes, or be eliminated altogether. Anvil 14 is preferably formed of medical grade stainless steel but could alternatively be formed of a radiopaque material, such as a platinum alloy, which would enable the physician to track the position of the device via x-rays during the catheter insertion procedure. It may also be desirable to inject radiopaque fluids out the distal end of the biopsy device to further aid the physician during the insertion procedure. This could be accomplished by injecting radiopaque fluids through port 18 of Fig. 1 while slightly separating the anvil from the distal tip of the catheter to permit the radiopaque fluid to escape into the patient.

FIG. 3 shows another embodiment of a biopsy device 30 according to another aspect of the present invention. While only the distal end of device 30 is shown, the remainder of the device is identical in configuration to the biopsy device 10 shown in FIG. 1. Biopsy device 30 includes a flexible elongated catheter 31, and a flexible elongated shaft 32 running through the central lumen of catheter 31. Attached to the distal end of shaft 32 is anvil 35. This device is different from the device shown in FIG. 2 in that the annular cutting edge 34 is included on the lower portion of anvil 35, and is received against the annular surface 33 on the distal tip of catheter 31. In FIG. 2, on the other hand, the annular cutting edge 23 is part of the distal tip of the catheter as opposed to part of the anvil 14.

FIGS. 4-6 depict another embodiment of the present invention during the biopsy procedure within a patient. In this case, biopsy device 50 includes a filiform wire guide tip 55 extending distally from the anvil 54 in order to aid the physician during the catheter insertion procedure, but

which is otherwise identical to the device of Fig. 1. Guide tip 55 typically ranges in length from one to fifteen centimeters in length, but could be outside this range depending upon the particular application. Guide tip 55 could also include a radiopaque element to aid the physician during the insertion procedure. FIG. 4 shows the biopsy device 50 being advanced through a portion of a non-linear passageway 58 within a patient toward a tissue growth 59 which is desired to be sampled. FIG. 5 shows the biopsy device 50 after it has arrived at the desired location and after the anvil 54 has been separated from the distal tip 53 of catheter 51 in order to draw in a portion of the tissue 59 to be sampled. The cutting means of the device are thereby exposed to the tissue when anvil 54 is separated from the distal end of the catheter. In order to increase the size of a tissue sample taken, suction can be applied though the central lumen of the catheter 51 via an aspiration port located at the proximal end of the catheter, such as port 18 shown in FIG. 1. The size of the biopsy sample is determined by a number of independently controllable factors including the separation distance of the anvil from the catheter before cutting, the diameter of the central lumen of the catheter, the diameter of the shaft, the size of any cavity that may exist on the underside of the anvil, and the vacuum or suction level utilized during the cutting procedure. It may also be desirable to include calibration marks, such as the marks 8 shown in Fig. 1, on the proximal end of the biopsy device so that the physician can precisely determine and control the separation distance between the anvil and the catheter during the cutting procedure.

FIG. 6 shows biopsy device 50 after a tissue sample 60 has been removed. Tissue sample 60 is removed by retracting shaft 52 thereby positioning anvil 54 against the distal tip 53 of catheter 51. The tissue sample 60 is cut when the annular surface of anvil 54 is forced into contact with the

annular cutting edge 53 of the distal tip of catheter 51. After removing the tissue sample 60 from the tissue area 59, the biopsy device 50 is withdrawn from the patient. However, if a larger tissue sample is required, or if the device is being used to remove a stenosis from a lumen within a patient, then the steps shown in FIGS. 5 and 6 are repeated as necessary before withdrawing the biopsy device from the patient.

FIG. 7 shows a cross-section of the biopsy device 10 shown in FIG. 1 looking in the direction of the arrows labeled A. As can be seen, central lumen 19 of catheter 11 is significantly larger than the diameter of shaft 12 thereby allowing fluids to pass freely through central lumen 19 adjacent to shaft 12. FIG. 8 shows a cross-section of still another embodiment of the present invention in which a dual lumen catheter 41 is used in place of the single lumen catheter shown in the earlier figures. In this case, first lumen 43 includes a flexible shaft 42 which is functionally analogous to the shaft 12 shown earlier. Also shown is a second lumen 44 which receives a wire guide 45. In this embodiment, the biopsy device is used by first positioning the wire guide 45 within the patient adjacent to the area to be sampled. After wire guide 45 is properly positioned, the biopsy device is threaded over the wire guide by threading lumen 44 over wire guide 45, and then advancing the biopsy device over the wire guide 45 until the distal end of the biopsy device is adjacent the tissue to be sampled. Wire guide 45 may be withdrawn after the biopsy device is in place, or wire guide 45 may be left in place after the biopsy device has been used and subsequently withdrawn from the patient. In this way, the physician could obtain a biopsy prior to placing a stent or performing a balloon dilation. Also, the biopsy device could be used after a balloon dilation in order to remove any remaining stenosis from the dilated lumen.

Biopsy devices according to the above invention could be made for repeated use or could be made disposable for single use only. Also, because the anvil normally is closed against the distal end of the catheter while the device is being withdrawn from the patient, the bacteriologic sample could be retrieved and submitted for culture analysis without risking contamination of the sample by unnecessary contact with other tissues within the patient, or other contaminated matter. Another feature which could be added to the invention would be to supply electric current to the cutting means so that the surrounding tissue is cauterized after a tissue sample has been removed.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character. For instance, the invention can be used in a myriad of locations within a patient including blood vessels, the urinary tract, the gastrointestinal tract, the esophagus or small intestine, the lungs, or any other non-linear passageway such as a fistula or a cavity. The invention is also equally applicable to veterinary medicine. It being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

I CLAIM:

1. A biopsy device comprising:

a flexible catheter having a lumen, a proximal end and a distal end;

a flexible shaft slidably disposed within said lumen of said catheter and having a distal end;

a smoothly rounded tip attached to said distal end of said shaft that projects distally beyond said distal end of said catheter; and

cutting means, including a cutting edge attached to one of either said catheter or said shaft and a cutting surface in opposition to said cutting edge attached to the other of said catheter or said shaft, for cutting tissue near said distal end of said catheter, said cutting means being actuated to cut tissue when said flexible shaft is moved with respect to said catheter toward said proximal end of said catheter.

2. The biopsy device of claim 1 wherein said shaft has a diameter significantly smaller than said lumen of said catheter, thereby allowing the free passage of fluids along the length of and within said lumen adjacent said shaft and out said distal end of said catheter when said cutting edge is separated from said cutting surface.

3. The biopsy device of claim 2 wherein said cutting edge is operably connected to said shaft near said distal end of said shaft and said cutting surface is disposed on said catheter in opposition to said cutting edge.

4. The biopsy device of claim 3 wherein said cutting edge is annular.

5. The biopsy device of claim 4 wherein said catheter includes a side port near said proximal end of said catheter, said side port being in fluid communication with said lumen.

6. The biopsy device of claim 5 wherein said shaft is spring biased to maintain said cutting edge in contact with said cutting surface.

7. The biopsy device of claim 6 wherein said cutting surface is said distal end of said catheter; and

said cutting edge is formed on an anvil, said anvil being attached to said distal end of said shaft and having a smoothly rounded distal tip.

8. The biopsy device of claim 7 wherein said anvil includes a wire guide leader attached thereto and extending distally therefrom.

9. The biopsy device of claim 8 wherein said anvil is formed from a radiopaque material.

10. The biopsy device of claim 7 wherein said catheter further includes a second lumen adjacent said first lumen and adapted to receive a wire guide therethrough.

11. The biopsy device of claim 2 wherein said cutting edge is attached to said distal end of said catheter; and

said smoothly rounded tip is a portion of an anvil attached to said distal end of said shaft, said anvil includes said cutting surface disposed in opposition to said cutting edge.

12. The biopsy device of claim 11 wherein said catheter includes a side port near said proximal end of said catheter,

said side port being in fluid communication with said lumen.

13. The biopsy device of claim 12 wherein said shaft is spring biased to maintain said cutting surface of said anvil in contact with said cutting edge of said catheter.

14. The biopsy device of claim 13 wherein said anvil includes a wire guide leader attached thereto and extending distally therefrom.

15. The biopsy device of claim 14 wherein said anvil is formed from a radiopaque material.

16. The biopsy device of claim 13 wherein said catheter further includes a second lumen adjacent said lumen and adapted to receive a wire guide therethrough.

17. A method of performing a biopsy comprising the steps of:

providing a flexible catheter having a lumen and having a flexible shaft slidably disposed within said lumen, said shaft having a distal end terminating in a smoothly rounded tip that projects distally beyond said distal end of said catheter, and cutting means that is disposed near the distal end of the catheter for cutting tissue, wherein the cutting means is operable to cut tissue when the flexible shaft is retracted with respect to the catheter;

guiding the distal end of the catheter through a non-linear passageway within a patient until the cutting means is adjacent the area where a tissue sample is to be removed;

exposing the cutting means to the tissue;

retracting the shaft with respect to the catheter thereby actuating the cutting means to cut a tissue sample; and

withdrawing the catheter from the patient's body.

18. The method of claim 17 wherein said step of guiding the distal end of the catheter includes injecting radiopaque fluid through the lumen and out the distal end of the catheter.

19. The method of claim 17 wherein said catheter includes a second lumen adjacent the first lumen and adapted to receive a wire guide therethrough; and

said step of guiding the distal end of the catheter comprises the steps of:

guiding a wire guide along a non-linear passageway within a patient until a portion of the wire guide is adjacent the tissue to be sampled

threading the proximal end of the wire guide into the second lumen of the catheter; and

advancing the catheter over the wire guide until the cutting means is adjacent the tissue to be sampled.

20. The method of claim 17 further comprising the step of applying suction through the lumen of the catheter after said step of exposing the cutting means.

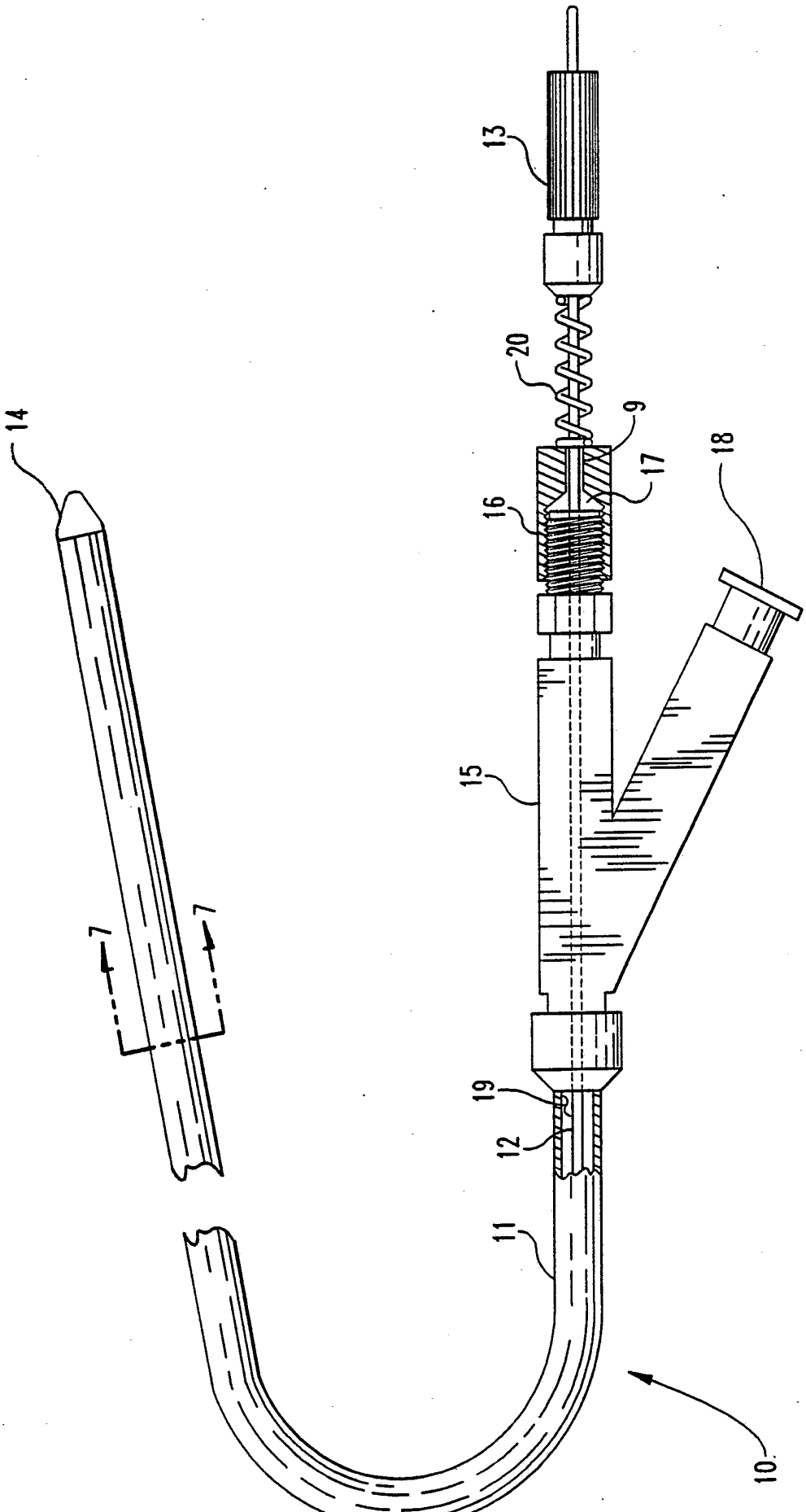


Fig.1

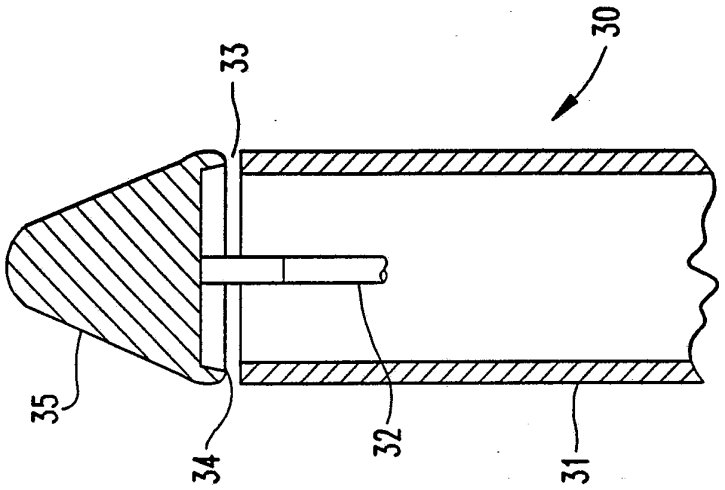
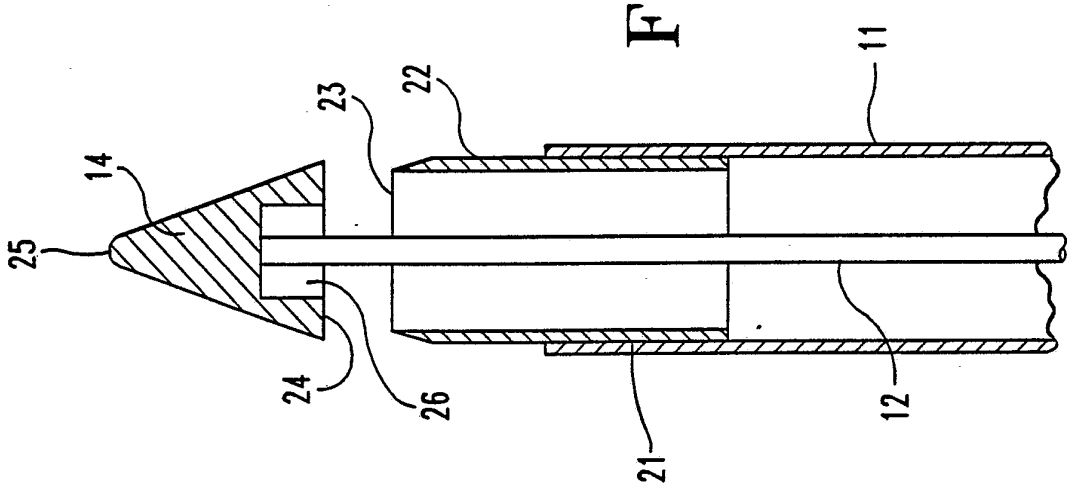


Fig. 3

Fig. 2



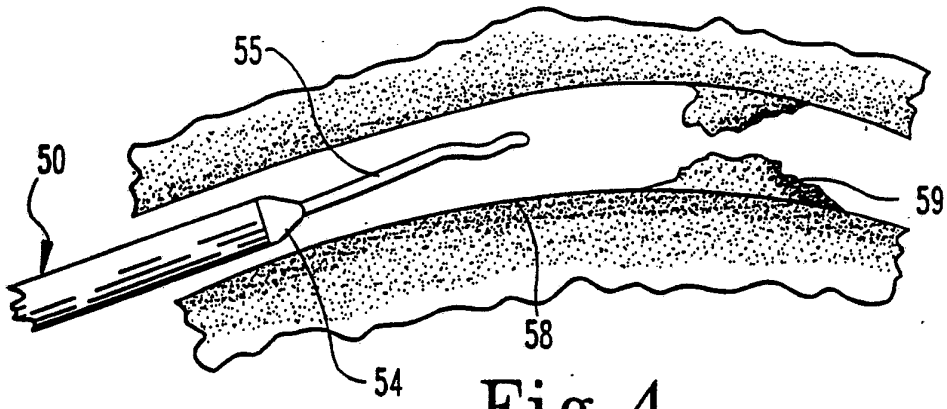


Fig.4

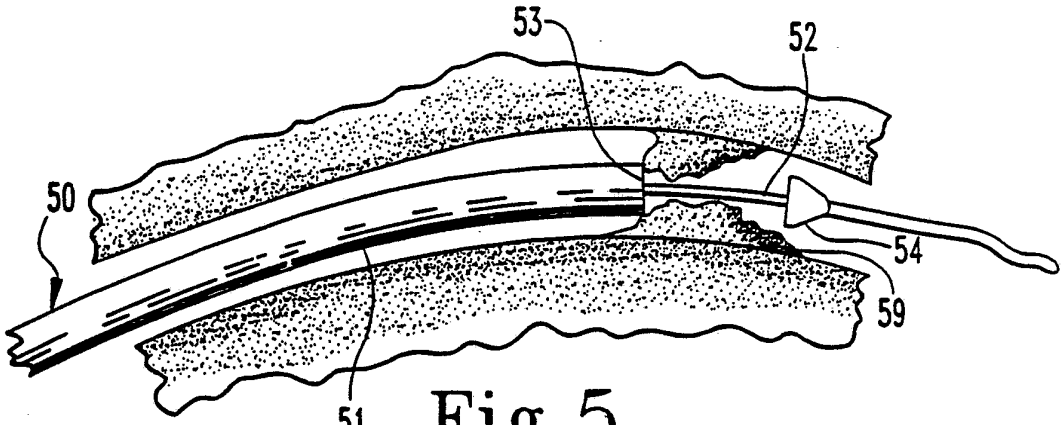


Fig.5

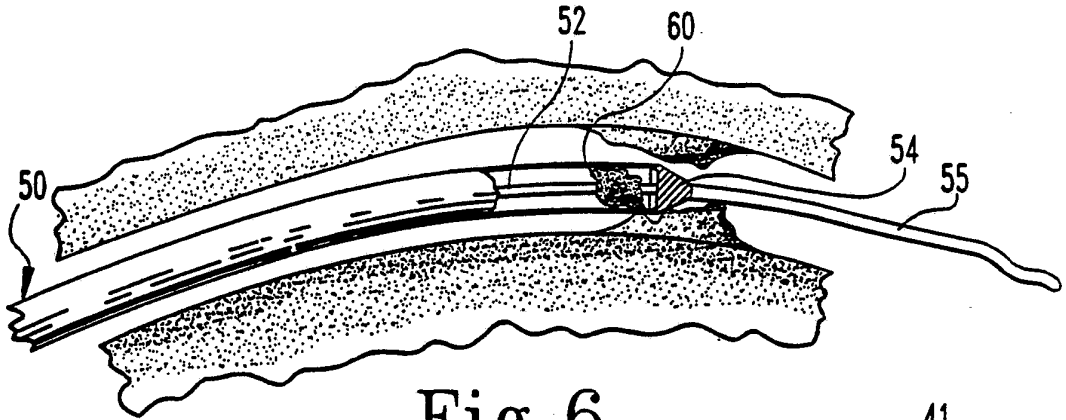


Fig.6

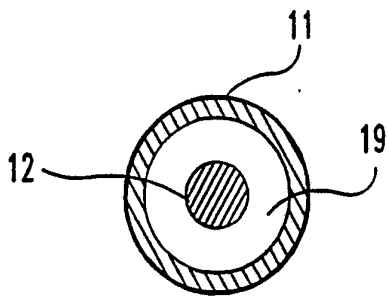


Fig.7

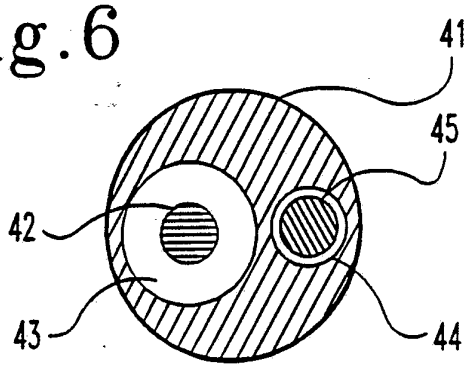


Fig.8

INTERNATIONAL SEARCH REPORT

International application No
PCT/US92/07419

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 10/00
US CL :128/754
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/753,752,751,749; 606/167,170,171,159; 604/164,170,280,284

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P Y	US,A, 5,085,659 (RYDELL) 04 FEBRUARY 1992 (See entire document)	15,11,12,17, 20 6-10,13-16,18,19
Y	US,A, RE33,258 (ONIK ET AL) 10 JULY 1990 (See element 54)	6,7,13
Y	US,A, 4,867,156 (STACK ET AL) 19 SEPTEMBER 1989 (See element 52)	8,9,14,15,18
Y	US,A, 4,946,440 (HALL) 07 AUGUST 1990 (See element 76)	10,16,19

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

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Date of the actual completion of the international search
30 OCTOBER 1992

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US92/07419

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A, 4,907,598 (BAVER) 13 MARCH 1990 (See entire reference)	1-20