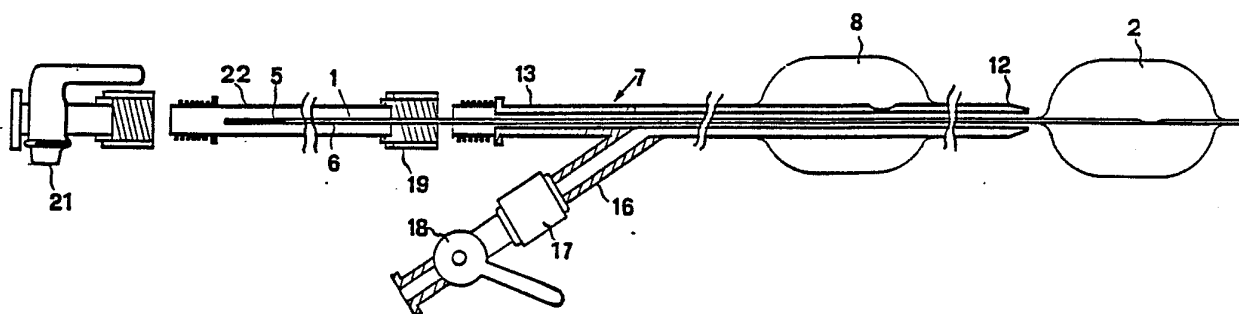




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(54) Title: TWO BALLOONED CATHETER DEVICE FOR DIAGNOSTIC AND OPERATIVE USE



(57) Abstract

A two ballooned catheter device comprising an inner catheter (1) and an outer catheter (7) slidable one with respect to the other, and a coaxial conduit (17) connected to the proximal end of the outer catheter, a lateral conduit (16) being connected to the outer catheter for introduction of a fluid into a peripheral annular space (11) in communication with the balloon of the outer catheter, the inner catheter being connected to the other balloon, and the central annular space between the inner catheter and the outer catheter being in communication with the coaxial conduit, so that a fluid under pressure can be selectively introduced into each balloon and the space between the balloons through the central annular space. The device can be used for confining a sector of a duct or vessel of the body between the two balloons to convey a medicinal or diagnostic fluid into the confined sector or operating through dilation and relaxation of the sector of duct, particularly for the extraction of calculi.

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TWO BALLOONED CATHETER DEVICE FOR DIAGNOSTIC AND OPERATIVE USE.

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BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a catheter device for diagnostic, therapeutic and operative use in a duct or vessel of the body of a patient, particularly in ureter and urethra.

The device can be used for radiologic diagnosis in a duct. It can also be used for therapeutic purposes to bring pharmacological substances into a desired sector of a duct. It can also be used advantageously and in particular for removing stones from the urinary passages.

2. Description of the Prior Art

Catheter devices are well known from the prior art for operating in the ureter in order to carry out a mechanical extraction of calculi.

Among said devices, basket and loop catheters, catheters similar to the latter, but provided moreover with a dilator balloon, and catheters with two inflatable balloons are known, as well as a device formed by two catheters sliding one with respect to the other, each having an inflatable balloon at its end.

This catheter is described in US patent number 4295464. This device comprises two coaxial catheters, of which the inner and thinner one is introduced, with the balloon deflated, until above the ureter sector in which the calculus is sited. The second catheter, which slides over the first one, is positioned in such a way that its end is below the position of the calculus. Then the balloon which is on the tip below the calculus is inflated. The balloon is inflated gradually until a muscle relaxation of the ureter sector involved is obtained. Successively the balloon of the first catheter

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is inflated and it is manipulated, also with the aid of strings connected thereto, thus trying to detach the calculus from the wall of ureter sector and cause it to fall downwards. Having obtained this result, the balloon of the second catheter is deflated and brought to a lower position, where it is inflated again. Then the upper catheter is also lowered to try and push the calculus downwards. The above operations are repeated in succession, until the expulsion of the calculus from the orifice of the ureter is obtained. The aforementioned device operates on the calculus by means of a mechanical force which has the function of detaching the calculus from the wall of the ureter and dragging it down. The enlargement of the ureteral passage obtained by the dialating balloon serves the purpose of preparing an easy passage for the calculus, however it has to be observed that it does not act on the ureteral sector in which the calculus is housed, when said calculus remains fixed in its seat. In that case, in fact, the calculus is held blocked to the ureteral wall by an edema which the calculus itself has produced. Consequently a purely mechanical extraction by means of a downwardly directed force on the calculus can produce abrasions and dilaceration of the ureteral wall and very often simply does not succeed.

An object of the present invention, in the case of extraction of calculi, is to obtain an extirpation of the calculus from the ureteral wall by means of dilation (and eventually contraction) movements of the sector of ureter in which the calculus is fixed, this being obtained by the introduction of a fluid under pressure directly into the ureteral sector in which the calculus is sited, said sector being confined between two inflated balloons which inhibit the same fluid from invading the rest of the urinary passages. This treatment allows

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the calculus to free itself from the ureteral wall and then to be dragged to the outlet. This treatment cannot be effected by the above described device of the prior art which operates through a mechanical push.

5 A further object of the present invention is to bring into the area confined between the two inflated balloons, substances to be used for diagnosis, particularly for radiology, as well as medicinal substances which can be confined within the desired sector of the urinary
10 passage. This function is completely independant of the extraction of calculi and it can be applied, for instance, to the entire canal of the ureter or urethra or in particular areas thereof.

 The device of the present invention considerably
15 widens the actual diagnostic and therapeutic capabilities attainable with the conventional instrumentation. Its use, besides, requires an operation which is not very invasive, bloodless, highly efficient and practically without risks.

20 The efficiency of this method in the extraction of ureteral calculi is grounded on a number of observations of basic importance. A calculus migrating in the ureter stops when it meets a narrow or non-dilatable sector of the passage. Once the calculus has stopped, it lies
25 on the wall producing an edema which further reduces the canal lumen in correspondance with the calculus. For this reason the calculus ends by strongly adhering to the ureteral wall and it becomes difficult, if not impossible, to move it either downwards or upwards.

30 The catheters for extraction of ureteral calculi known from the state of the art can be divided into two large groups: simple extractors (basket or loop) and extractors provided with a balloon for dilation. Those belonging to the first group can be used only
35 in the lower third of the ureter and they are inavoidably

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damaging to the ureteral mucosa with a possible immediate or delayed injury. Those belonging to the second group are formed by two units: an extractor, basket, loop or balloon, and a dilator. Such instruments have the purpose of being less traumatic than the first group, but they are somewhat inefficient in that they do not deal with the fact that the calculus, for the above mentioned reasons, is rather fixed in the point in which it stops.

The device according to the present invention operates through a completely new mechanism by dilating a more or less extended sector of ureter containing the calculus and producing the detachment of the calculus by the mechanical action of dilation, if necessary repeated and alternated to a relaxation of the wall. Only in a few cases is it necessary to resort to using the balloon of the inner catheter to make the movement of the calculus easier. From a diagnostic point of view it allows, moreover, the examination of the ureter and urethra with the nearby organs in a novel and advantageous manner. Additionally, it permits therapeutically active substances and drugs to be brought directly into contact with such structures, restricting such contact only to the desired sectors, protecting the kidney in the upward direction and the bladder in the downward direction for use in the ureter, and the bladder in an upward direction for use in the urethra.

SUMMARY OF THE INVENTION

The present invention provides a catheter device for diagnostic and operative use in ducts and vessels of a patient, including an inner catheter in fluid communication with a first balloon fixed to its distal end, and an outer catheter around the first catheter and in fluid communication with a second balloon fixed to its distal end, the first and second catheters being

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slidable the one with respect to the other, said device being characterized in that:

the inner catheter is substantially coaxial to the outer catheter and provided with a removable plug which closes its proximal end; the first balloon is centered on the distal end of the inner catheter; the outer catheter is formed with coaxial inner and outer walls which define between them an annular peripheral space, such annular peripheral space being closed at both the distal and proximal ends of the outer catheter and being in fluid communication with the second balloon, a central annular space being formed between the outer and the inner catheters, the central annular space being open at both the proximal and distal ends of the outer catheter, and the proximal end of the outer catheter being provided with connection means; a lateral conduit for the introduction and extraction of a fluid, in fluid communication with the peripheral annular space, is integral with the outer wall of the outer catheter at the proximal end thereof; first valve means on the lateral conduit for controlling a fluid flowing therethrough; a coaxial conduit for fluid introduction and extraction connected by said connection means to the proximal end of the outer catheter and in fluid communication with the central annular space, the coaxial conduit being coaxial to the inner catheter and containing its proximal end; and second valve means on the coaxial conduit for controlling a fluid flowing therethrough, whereby when a desired sector of a duct or vessel of a patient has been confined between the first and second balloons placed at a preestablished distance and inflated, a fluid under pressure can be introduced into said sector for diagnostic, therapeutic or operative purposes.

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BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be better illustrated with reference to the accompanying drawings, wherein:

figure 1 shows (a) a thin metal guide, (b) the inner catheter and (c) the outer catheter with the coaxial conduit connected to it;

figure 2 shows the entire catheter device in a cross section;

figure 3 shows the catheter device in an enlarged longitudinal cross section; and

figure 4 is a cross section along line IV-IV of figure 3.

DETAILED DESCRIPTION

Referring to the drawings, the catheter device according to the invention is illustrated in detail. In view of the particular use of the present device for operations effected on the human body, some preferred dimensions of the various parts of the device will also be indicated.

Figure 1(b) shows the inner catheter, which preferably has a diameter of 1 mm (3 French) and a variable length, with a flexible tip having a rounded end about 1,5 cm long and a distal end which are X-ray opaque for a length of about 5 cm. At the distal end 3 of the catheter 1, a first inflatable balloon 2 is set, of an elastic material capable of withstanding a pressure of about 4 atmospheres or more, having a diameter of at least 2 cm when completely inflated. The inner catheter 1 has internally a single central cavity which is used to house a thin metal guide 4 (see figure 1 (a)) and simultaneously as an inflating room of the first balloon 2.

A brown coloured line is drawn circumferentially, preferably at about 70 cm from the tip. Similarly at about 73, 74 and 75 cm from the tip 3 lines are drawn, for example, of yellow, green and blue colour. At about

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80 cm from the tip a similar line of red colour is drawn. Said coloured lines help the operator to have a reference point in the operations to be carried out.

5 In figure 1 (b) a plug 5 is also shown for closing the proximal end 6 of the catheter 1, as will be described hereinafter.

10 Turning now to figure 1 (c) an external catheter 7 is shown, having preferably an outer diameter of 4,2 mm (14 French) or less, a variable length and a second inflatable balloon 8 having the same features as the balloon 2 of the inner catheter 1. As can be seen from figures 3 and 4, the outer catheter 7 is formed with an outer wall 9 and an inner wall 10 between which a periferal annular space 11 is defined.

15 The annular space 11 is closed in correspondance with the distal end 12 as well as the proximal end 13 of the outer catheter 7. An opening 14 in the outer wall 9 puts the annular space 11 in communication with the interior of the second balloon 8.

20 The inner wall 10 of the outer catheter 7 defines a longitudinal cavity which runs along the whole catheter 7 from its proximal end 13 to the distal end 12. As the inner catheter 1, as will be described hereinafter, is inserted into the longitudinal cavity of the catheter 7, between the inner catheter 1 and the outer catheter 7 a central annular space 15 is defined.

25 Near the proximal end 13 of the catheter 7, a lateral conduit 16 is integrally united to the outer wall 9, said lateral conduit 16 being open to the periferal annular space 11 of catheter 7. The outer catheter 7 consequently has two passages, a central one through the central annular space 15, to enable the inner catheter 1 to penetrate in its interior and a liquid or gas to pass through, and a periferal passage through the annular space 11, fed by the lateral conduit 16. The lateral

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conduit 16 is provided with a screw connection 17 of the Luer Lock type for a cock 18 of one-through stop-cock type, to enable a fluid to pass for inflating the second balloon 8. The outer catheter 7 moreover is
5 provided with a screw connection 19 of the Luer Lock type at its proximal end 13.

The screw connection 19 acts to connect a coaxial conduit 22 formed by a straight tubular section of transparent plastic material, having the same diameter as
10 the outer catheter 7. The coaxial conduit 22 has at the proximal and distal ends, screw connections of the Luer Lock type to enable the connection of the proximal end 13 of the catheter 7 and assembly of a one-through stop-cock 18 at its proximal end. From the foregoing
15 it can be observed that the device according to the present invention shows three routes of fluid flow. The first route goes through the interior of the inner catheter 1 and is in communication with the interior of the first balloon 2 through an opening 19. The second
20 route passes through the lateral conduit 16, the peripheral annular space 11, the opening 14 to the second balloon 8. A third route is through the coaxial conduit 22, the central annular space 15, outside the distal end 12 of the outer catheter 7, in the space comprised between
25 the first balloon 2 of the inner catheter 1 and the second balloon 8 of the outer catheter 12.

The device according to the present invention allows carrying out of diagnosis, medical treatments and operative functions in a plurality of clinical situations
30 concerning pathologic damages affecting tubular structures such as blood vessels, ducts, ureter, urethra and the like. In fact it is devised to act on a more or less extended sector of a canal, so determining, through the inflation of the balloons 2 and 8, of catheters
35 1 and 7 respectively, a confinement of this sector from

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the rest of the canal. A liquid or gas fluid can reach such a confined sector through the central route passing through the coaxial conduit 22 and the central annular space 15, in order to produce a hydraulic dilation of the sector, or to bring medicinal substances into contact with said sector for therapeutic purposes, or to inject a contrast fluid for diagnostic purposes.

EXAMPLES OF USE

Whichever the canal be in which it is used, the device according to the present invention is employed according to the following methods.

The catheter 1 is introduced first, provided with the metal guide 4 in its interior. The catheter 1, having a reduced gauge thanks to the end 3 thinned and rounded in an atraumatic manner, can easily pass over stenotic sections or obstacles, such as calculi, neoformed tissue and the like, possibly present in the duct lumen. Having reached the desired position, the metal guide is withdrawn and the balloon 2 of catheter 1 is inflated by applying a suitable sealed syringe on a sealed junction at the proximal end 6 of the catheter 1. When a desired pressure of inflation has been obtained, the catheter 1 is clamped and the proximal portion exceeding the distance at which the inflated balloons have to be placed in the duct, is cut. To this end, in a particular use of the device of the present invention in the ureter, on the proximal portion of the catheter 1 some lines of different colours are drawn as a reference for carrying out the cutting. After having effected the cutting of catheter 1, a plug 5 is applied at the proximal end 6 and the clamp is removed.

Successively the distal end 12 of the outer catheter 7 is threaded over the proximal end 6 of the catheter 1. The distal end 12 of the catheter 7 has a tapered frustoconical shape. On passing through the central

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cavity of the catheter 7, catheter 1 forms the central annular space 15.

5 In the case of the access to the canal being narrow, such as at the junction of ureter and bladder, at cutaneous planum or aponeurotic muscle, for percutaneous access and the like, before applying the catheter 7 it is necessary to proceed with progressive dilations with known dilators which are forwarded along catheter 1 as a guide.

10 The catheter 7 is stopped in the desired position and the balloon 8 is inflated through the lateral conduit 16 and the periferal annular space 11. In such a way a sector of the canal of a desired length is confined between the two balloons.

15 Successively the coaxial conduit 22 is connected to the proximal end 13 of the outer catheter 7. By means of the screw connection 19 a syringe is applied to the proximal end of the coaxial conduit 22. It is now possible to inject a therapeutic or diagnostic fluid into the confined sector or canal. The cock 18 at the
20 proximal end of the coaxial conduit 22 enables the liquid to be maintained in situ for a desired time.

At the end of the treatment, the coaxial conduit 22 can be disengaged from the outer catheter 7. Consequently after having withdrawn the fluid from the confined
25 tubular sector, the proximal end 6 of the catheter 1 can be handled. In the case of extraction of calculi, tissue fragments, extraneous bodies, the balloon 2 of the catheter 1 can be used as an extractor. To this
30 end, the plug 5 at the proximal end 6 is withdrawn to produce a partial deflation of the balloon 2 in order to enable a movement of the balloon 2 downwards without encountering resistance.

For withdrawal of the catheter device, after having
35 completely deflated the balloon 2 of the catheter 1

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and the balloon 8 of the outer catheter 7, the device can be completely removed.

In order to better clarify the method of use of the catheter device of the present invention, some applications of particular interest will be described in detail.

Extraction of ureteral calculi

The catheter device of the present invention can be employed for the bloodless extraction of ureteral calculi of medium/small size.

For this purpose the inner catheter 1 is first introduced with the metal guide until the calculus is overrun by at least 4 cm, as shown by radiologic control of the X-ray opaque end. The metal guide is removed and a syringe is applied to the proximal end 6 of catheter 1, by means of a sealed junction, for inflating the balloon 2 slowly and gradually until a certain resistance to inflation is felt. The proximal end 6 of catheter 1 is clamped and it is cut in the desired point in correspondence with one of the coloured lines drawn on the catheter. Then the plug 5 is applied and the clamp is removed.

On leaving the catheter 1 in situ with the balloon inflated for an autostatic effect, a series of ureteral dilators of increasing gauge are introduced using the catheter 1 as a guide. Successively the outer catheter 7 is introduced in the same way as the dilators. The introduction is stopped when the proximal end 13 of the catheter 7 coincides with one of the lines drawn on the catheter 1, which will indicate, according to its colour, the distance between the two balloons. The balloon 8 of the catheter 7 is then inflated through the lateral conduit 16.

The coaxial conduit 22 is connected to the proximal end 13 of the catheter 7 and an oily liquid is injected into the ureter area comprised between the two balloons,

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where the calculus is situated, by means of a sealed syringe applied to the proximal end of the coaxial conduit 22. The patient is made to take a position as inclined as possible on the urologic bed, to cause the calculus to fall downwards by gravity.

In the case of the calculus not immediately dislodging itself from the ureteral wall, it is possible to go on with a cyclic withdrawal of the oily liquid and successive dilation of the ureteral sector. This action of distention and relaxation of the ureteral wall, produced by introducing and withdrawing the liquid in the ureteral sector comprised between the two balloons, will lead in most cases to a dislodgement of the calculus from the ureteral wall, even when the calculus has been settled for a long time in that seat and has produced flogistic and edematous alterations of the wall. If necessary the balloon 2 of the catheter 1 can also be used as an extractor.

After having obtained the dilation of the ureteral sector in which the calculus is seated, the coaxial conduit 22 is disengaged from the catheter 7 and after removing the plug 5 from the proximal end 6 of the catheter 1, traction is made on the catheter 1 with careful handling, starting the movement downwards when the balloon has been deflated to reduce its volume so that it can slide in the ureteral lumen with a minimum friction. The plug 5 is then applied again and the catheter 1 is drawn downwards, until the balloon 2 of the catheter 1 stops at the end of the catheter 7. In this position the proximal end 13 of the catheter 7 will be in correspondance with a line drawn on the catheter 1. To make the calculus proceed downwards until it comes out of the ureteral meatus, the balloon 2 of the catheter 1 is inflated again and the outer catheter 7 is pulled downwards after having its balloon 8 deflated. The

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balloon 8 is inflated again when it is at a desired distance from the balloon 2 of the catheter 1 and the operation is progressively repeated. In correspondance with the ureteral meatus, the balloon 8 of the outer catheter 7 can be employed as a dilator of the papilla.

Use for diagnosis and endo-ureteral therapy

The catheter device of the present invention can be used for a radiologic diagnosis of the whole ureter or a portion thereof. For a diagnosis of the whole ureter the procedure is like that of an extraction of calculi as above described, blocking the balloon 2 of the catheter 1 in a subjunctional seat and the balloon 8 of the catheter 7 in correspondance with the ureter and bladder junction. A sealed syringe is applied to the proximal end of the coaxial conduit 22 and a contrast medium is injected at a desired pressure for displaying the whole canal so as to put into evidence some very important features, such as the distension ability and the elasticity of the wall, the presence of angulations or fixed points, the presence of not distensible stenotic portions, the presence of any fistula or solution of continuity.

The method of double contrast (liquid and gas) can also be used with success, by withdrawing the liquid medium after injection thereof and by insufflating air. This makes it possible to detect highly mucose irregularities and eventual urothelium papilloma, and to make a precise differential diagnosis of the defects of ureteral filling between X-ray transparent calculi and urothelium papilloma (double contrast ureterography).

The same method can be applied in the same way to a more restricted sector of the canal, where an injury has been already detected (fistulous confluence of traumatic delaceration).

The two balloon catheter device can be therapeutically

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used for determining the hydraulic dilation of stenotic portions and to bring drugs, such as cortisone, anti-plastics and the like, into contact with portions thereof. For such use the catheter can be held in situ for the time of treatment without hampering the urinary drain by maintaining only the balloon of the outer catheter 7 partially inflated.

Diagnostics and endo-urethral therapy

The catheter device can be advantageously used for diagnosis of urethra in man and woman. By following the above described method a contrast medium can be injected into the canal or part thereof. Stenosis, fistulae, diverticula which cannot be displayed by the conventional methods can thus be evidenced. The uretro-prostatic and uretro-deferental reflux can also be observed, featured by the contrast display of the deferens and prostate gland ducts.

In the therapeutic field, solutions can be injected containing drugs for the treatment of flogistic processes affecting the rear urethra and the prostate.

The device can also be used for the hydraulic dilation of stenotic segments.

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CLAIMS

1. Catheter device for diagnostic, medicinal and operative use in a duct or vessel of the body of a patient, including an inner catheter (1) in fluid communication with a first balloon (2) fixed at its distal end (3) and an outer catheter (7) which embraces said inner catheter and in fluid communication with a second balloon (8) fixed at its distal end (12), said first and second catheters being slidable one with respect to the other, said catheter device being characterized in that:

said inner catheter (1) is substantially coaxial to said outer catheter (7) and provided with a removable plug (5) which closes its proximal end (6);

said first balloon (2) is centered on the distal end (3) of the inner catheter;

said outer catheter (7) is formed with coaxial inner and outer walls (10, 9) which define therebetween a periferal annular space (11), said periferal annular space (11) being closed at both the distal (12) and proximal (13) ends of said outer catheter and being in fluid communication with said second balloon (8), a central annular space (15) being formed between said outer catheter (7) and said inner catheter (1), said central annular space (15) being open at both the distal and proximal ends of said outer catheter and said proximal end (13) of said outer catheter being provided with connection means (19);

a lateral conduit (16) in fluid communication with said periferal annular space (11) is integral with said outer wall (10) of the outer catheter in correspondance with said proximal end;

first valve means (18) on said lateral conduit for controlling a fluid flowing therethrough;

a coaxial conduit (17) connected to said proximal

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end (13) of the outer catheter (7) through said connection means (19), in fluid communication with said central annular space (15), said coaxial conduit (17) being coaxial to the inner catheter and containing the proximal end thereof;

and second valve means (20) on said coaxial conduit for controlling a fluid flowing therethrough,

whereby when a desired sector of a duct or vessel of a patient has been confined between said first (2) and second (8) balloons, placed at a desired distance one from the other and inflated, a fluid under a desired pressure can be introduced into said sector for diagnostic, medicinal or operative purposes.

2. A device according to claim 1, wherein said connection means (19) comprise a screw connection of the Luer Lock type.

3. A device according to claim 1, wherein said first and second valve means (18, 20) are stop cocks.

4. A device according to claim 1, wherein said inner catheter (1) has a diameter of about 3 French (1 mm) and said outer catheter (7) has an outer diameter of about 14 French (4,2 mm).

5. A method for extracting from the urinary canal of a patient, a stone which is held fixed by the wall of the urinary canal, comprising:

(a) confining a sector of the urinary canal wherein the calculus is fixed, between two inflated balloons which adhere to the wall of said sector;

(b) introducing a fluid under pressure into said sector for dilating the wall of the urinary canal in said sector;

(c) withdrawing said fluid from said sector to relax the wall in said sector;

(d) repeating the operation of introducing and withdrawing the fluid, until the calculus is removed from

-17-

said wall;

(e) and repeating the operations (a) to (d) in progressively lower sectors of the urinary canal, to bring the calculus to the outlet of the urinary canal of the patient.

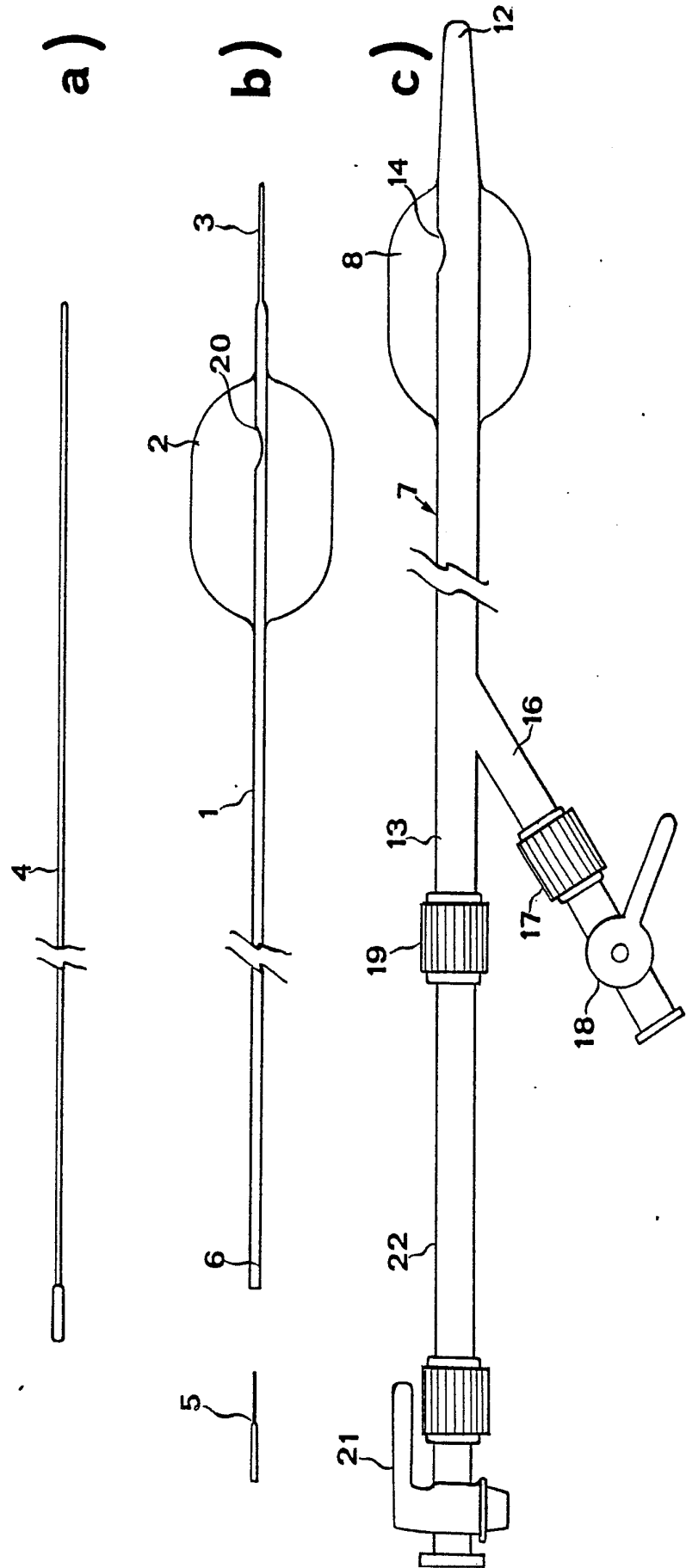
6. A method for confining a diagnostic or medicinal fluid in a sector of a duct or vessel of a patient, comprising:

(a) confining said sector between two inflated balloons which adhere to the wall of said sector;

(b) introducing said fluid into said sector; and

(c) maintaining said fluid in said sector for a time required to obtain a diagnostic or medicinal effect.

FIG. 1



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FIG. 3

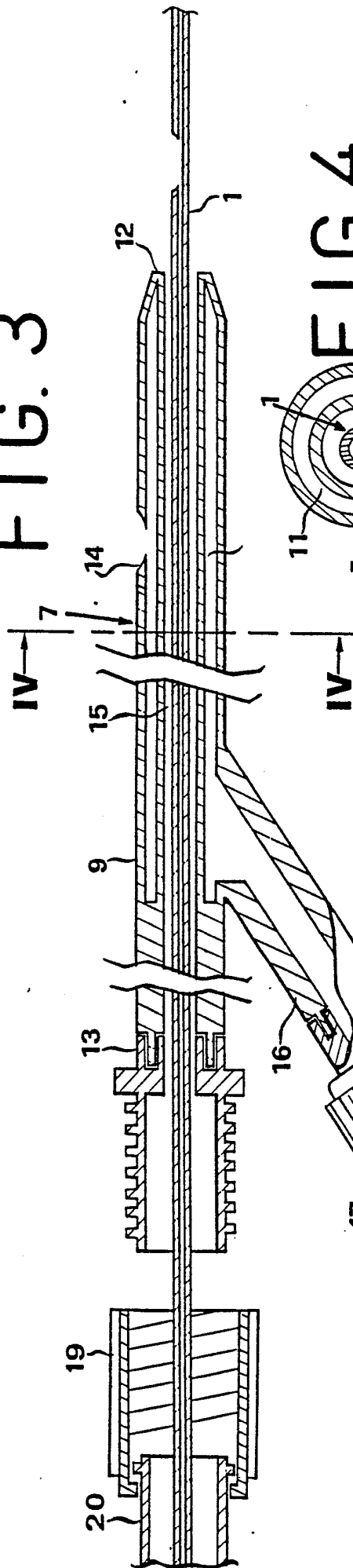


FIG. 4

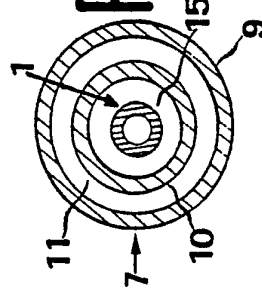
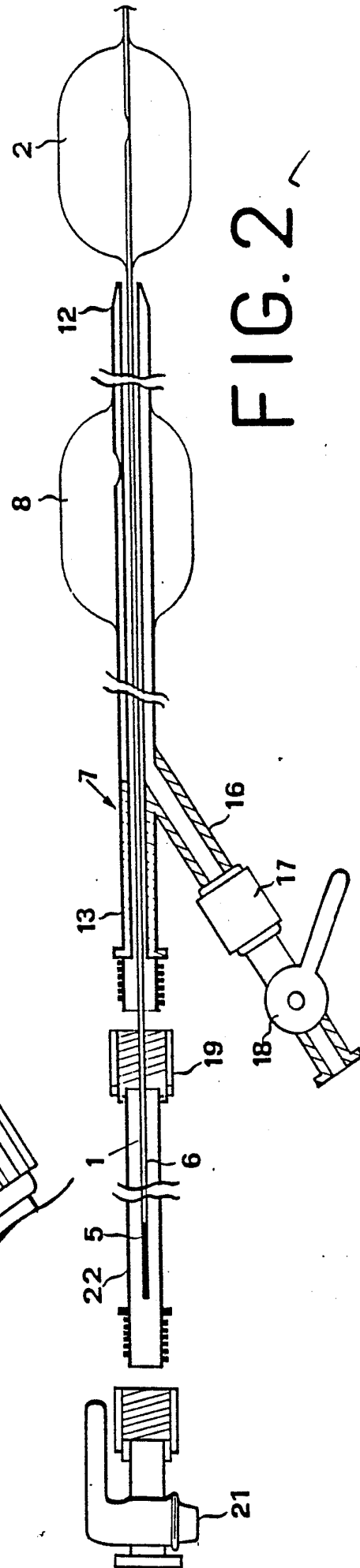


FIG. 2



INTERNATIONAL SEARCH REPORT

International Application No

PCT/IT 87/00059

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) *		
According to International Patent Classification (IPC) or to both National Classification and IPC IPC ⁴ : A 61 M 29/02		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
IPC ⁴	A 61 M	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched *		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁸		
Category *	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	US, A, 4295464 (SHIHATA) 20 October 1981 see figures 1-6 cited in the application --	1
X,P	US, A, 4655746 (DANIELS et al.) 7 April 1987 see figure 1 --	1-4
X,P	WO, A, 86/06285 (BARD) 6 November 1986 see figures 1,9-13 --	1-4
A	FR, A, 2546757 (CARLIER) 7 December 1984 see page 4, lines 22-28; figure 4 --	1,2
A	US, A, 4573470 (SAMSON) 4 March 1986 see figure 1 --	1
A	US, A, 4453545 (INOUE) 12 June 1984 see figure 6 --	1
A	WO, A, 82/03333 (LeVEEN et al.) 14 October 1982 see figure 1 --	3
* Special categories of cited documents: ¹⁰ "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "A" document member of the same patent family		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
15th September 1987	19 OCT 1987	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	M. VAN MOL	

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

A

Medizinische Technik, volume 31, no. 10,
October 1986, (Berlin, DE),
M. Orłowski: "Medizinisch-technische
Kriterien zu Dilatationskathetern für
die perkutane transluminale Angio-
plastik", pages 239-245
see page 243, figure 10

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V. ☒ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE ¹

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☒ Claim numbers XX because they relate to subject matter not required to be searched by this Authority, namely:

Claims 5,6

See PCT Rule 39.1(iv)

Methods for treatment of the human or animal body by means of surgery or therapy, as well as diagnostic methods.

2. ☐ Claim numbers because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claim numbers because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING ²

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:
3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:
4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- ☐ The additional search fees were accompanied by applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON

INTERNATIONAL APPLICATION NO.

PCT/IT 87/00059 (SA 17587)

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 02/10/87

The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4295464	20/10/81	None	
US-A- 4655746	07/04/87	None	
WO-A- 8606285	06/11/86	AU-A- 5865286	18/11/86
		EP-A- 0220285	06/05/87
		NL-A- 8620177	02/03/87
		GB-A- 2185190	15/07/87
		DE-T- 3690224	27/08/87
FR-A- 2546757	07/12/84	None	
US-A- 4573470	04/03/86	None	
US-A- 4453545	12/06/84	EP-A, B 0064701	17/11/82
		JP-A- 57183861	12/11/82
		CA-A- 1181311	22/01/85
WO-A- 8203333	14/10/82	EP-A- 0075596	06/04/83
		US-A- 4404971	20/09/83
		US-A- 4520823	04/06/85

For more details about this annex :
see Official Journal of the European Patent Office, No. 12/82