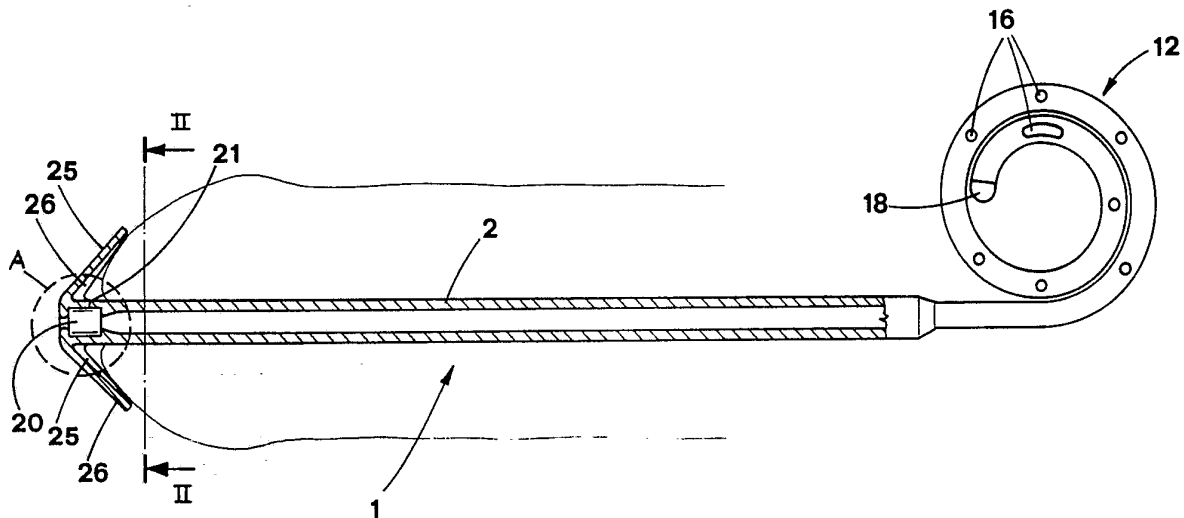




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<p>(21) International Application Number: PCT/IT92/00051 (22) International Filing Date: 15 May 1992 (15.05.92) (30) Priority data: B091A000459 5 December 1991 (05.12.91) IT (71)(72) Applicant and Inventor: GIGANTE, Luigi [IT/IT]; Via Ricciarelli, 157, I-44100 Aguscello (IT). (74) Agent: DALL'OLIO, Giancarlo; Invention S.N.C., Via Arienti, 26, I-40124 Bologna (IT). (81) Designated States: AU, BB, BG, BR, CA, DE, FI, HU, JP, KP, KR, LK, MG, MW, NO, PL, RO, RU, SD, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LU, MC, NL, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, SN, TD, TG).</p>		<p>Published <i>With international search report.</i></p>

(54) Title: VALVE OPERATED CATHETER FOR URINARY INCONTINENCE AND RETENTION



(57) Abstract

A valve operated catheter for urinary incontinence and retention comprises a flexible duct (2) designed to be inserted in the patient's urethra, provided with a spiral shaped end portion (12), having a plurality of holes (16) for the passage of urine, said duct (2) is provided, in correspondence with the other end, with a seat (21) in which there is housed a valve (20) made of elastic material, that is usually closed because of the elastic action; the valve (20) may be operated by the patient through light compressive action on two winglets (25) which are fixed to the end of the duct near to the valve and positioned symmetrically to the longitudinal axis of the same valve, outside the top of glans in such a way as to cause the opening of the passage (22) because of the elastic deformation of the valve (20).

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VALVE OPERATED CATHETER FOR URINARY INCONTINENCE
AND RETENTION

5 TECHNICAL FIELD

The invention relates to the technical field concerned with the production of vesical catheters.

Such kind of catheter are commonly applied to patients to eliminate, or at least relieve, inconveniences resulting from problems caused by the urinary incontinence and retention.

15 BACKGROUND ART

There are known valve operated vesical catheters made of plastic material or, more generally, of synthetic resin.

20 These catheters generally consist of flexible ducts produced in various standardized lengths.

A catheter having a certain length must be chosen in accordance with the actual necessity.

A catheter that is presently used is provided with a valve of elastic material, housed inside the duct at a small distance from the outer opening.

The valve can be operated by the patient through a slight pressing action exerted from outside on a section of the penis situated in correspondence with the point of location of the valve.

30 This point can be located by the patient thanks to a series of protuberances specially formed on the

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outside surface of the duct, near to the valve.

The distal end of the duct is positioned inside the bladder and has a spiral shape.

There are numerous holes provided along the terminal section of the catheter near the distal end, for the entrance of the urine into the catheter.

The principal drawback connected with the use of the above described catheters, results from the fact that it is difficult for the patient to locate the valve by the touch, what is a consequence of poor touch sensibility of the major part of the patients who have the catheters fit on.

A further inconvenience that has been found when such a type of catheter is used, results from the fact that the patient must perform a pressing action on the penis to operate the valve.

In the long run this pressing action, that often is not light, could provoke more or less serious local traumas, with a damage for the penis.

20

DISCLOSURE OF THE INVENTION

The main object of the present invention is to propose a catheter provided with a system that allows the patient to operate the valve directly and not through the penis, with a simple and safe action.

A further object of the present invention is to propose a simply adaptable catheter that can be used by any patient without causing traumas of any of the urinary system organs.

The above indicated objects are achieved by means

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of a valve operated catheter for urinary incontinence and retention comprising a flexible duct designed to be inserted into the patient's urethra and having a spiral shaped distal portion 12, that is designed to
5 be housed inside the bladder.

The terminal section of the catheter, near to the distal end, is provided with a plurality of holes for the outflow of the urine from the bladder to the inside of the duct.

10 A seat is made at the end of the catheter that remains outside and houses a valve elastically deformable and provided with a slit normally elastically closed.

The valve can be operated by the patient through
15 a pressing action on two winglets fixed at the end of the duct that is placed outside, resting against the top of the glans.

In this way the deformation of the part of the duct correspondent to the seat consequently causes the
20 elastic deformation of the valve until the slit opens.

The main advantage of the present invention is the fact that it provides a catheter with a system for operating the valve that is of immediate localization by the patient and being therefore, of simple and safe
25 use.

The system that is the subject of this invention allows the patient to operate the valve of the catheter without acting on the penis that is not subjected to any pressing action.

30 A further advantage of the present invention is the fact that it provides a catheter of a simple conformation and such that it can be used by any patient

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without provoking traumas of any urinary system organs.

It is to be stressed that the patient does not have to act directly on the penis in any way.

5 The winglets remains located outside of the penis so that they can be quickly and easily located, even if the patient has a poor touch sensibility.

Nevertheless the construction of the catheter is rather compact and the duct does not extend from the
10 glans.

Therefore also practical or psychologic problems for the patient are avoided or highly reduced.

15 BRIEF DESCRIPTION OF THE DRAWINGS

The features of the invention will be pointed out in the following with the help of the accompanying drawings, in which:

- 20 - fig. 1 is a sectional view of the catheter, that is the subject of the present invention;
- fig. 2 is a cross section view according to the line II-II of fig. 1
- fig. 3 is a sectional view of the valve indicated as
25 the particular A of fig. 1 when it is open;
- fig. 4 is a sectional view of the valve indicated as the particular A of the fig. 1 when it is closed;
- fig. 5, 6 and 7 show the valve made with a polygonal section, an oval section and with blocking pro-
30 trusions, respectively.

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MODES OF CARRYING OUT THE INVENTION

With reference to these figures, 1 shows the catheter.

5 The catheter includes a duct 2 made of flexible material, for instance a siliconated material.

The duct 2 is particularly adapted to be inserted in the urethra by means of a rigid body, generally called a mandrel, designed to be removed afterwards.

10 The distal portion 12 of the duct, near to the distal end of the duct and designed to be positioned inside the bladder, has a shape of a spiral and is elastically deformable.

The axis of the spiral is perpendicular to the
15 duct.

The distal portion 12 has a plurality of holes 16, the last of which has a form of a slot, through which the urines in the bladder may freely flow into the catheter.

20 As illustrated in fig. 1, at the distal end of the catheter there is a capsule 18 holding a substance having a disinfecting and antibacterial action.

The spiral shaped distal portion 12, may be unrolled in a measure such as to achieve the length
25 necessary for the other end to reach outside.

At the end of the duct 2 situated outside there is made a seat 21, inside which there is located a valve 20 made of elastic material and having a slit 22 for the passage of the urines.

30 The slit 22 is normally closed, as a result of the elasticity of the material of which the valve is made.

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The portion of the duct 2, corresponding to the seat 21, is harder than the remaining part of the catheter, and this hardness is obtained by a special processing of the material in this zone while manufacturing the catheter.

As illustrated in fig. 1, two winglets 25 are fixed to the outside end of the duct 2, symmetrically to the longitudinal axis of the catheter and of the valve 20.

The winglets 25 remain outside and rest against the top of the glans.

The winglets have a double function: first they prevent the catheter from sliding inside the urethra and second they allow the patient to operate from outside the valve 20 to evacuate the urine.

Also the winglets 25 are harder than the rest of the catheter, thanks to a different hardness of the material of which they are made.

This hardness is further increased by the presence of two reinforcement ribs 26 which extend along their side which remain turned toward the glans.

The pressing action on the winglets causes, also thanks to the reinforcement ribs, the deformation of the duct part correspondent to the seat 21, which in turn causes a pressing action on the sides of the valve and the opening, because of the elastic deformation of the latter, of the slit 22.

Therefore, the patient who normally retains the urines with the valve 20 closed (position K, fig.4), makes the valve to open (position H, fig.3) by performing a light pressure on the winglets 25.

The pressure will be kept during the whole period

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of time necessary to evacuate the urines completely.

In order to avoid possible rotations of the valve 20 inside the relative seat 21, both valve and seat may be made with polygonal (fig. 5) or oval (fig. 6) profile.

Otherwise one or more blocking protrusions can be formed on the outside surface of the valve (fig. 7) which are designed to engage with correspondent grooves made inside the seat.

In particular, the polygonal form of the fig. 5 is obtained by two plane opposing extension of the surface of the valve 20.

15 INDUSTRIAL APPLICABILITY

The catheter manufactured in accordance with the present invention allows many people obtain an improvement in quality life avoiding many physical and psychological problems.

The result obtained by this invention was possible thanks to a particular production process that provides a different way of working of different part of the same article.

Also the material (silicone resin) was important to achieve the result, in conjunction with the production process.

CLAIMS

1) Valve operated catheter for urinary incontinence and retention comprising a flexible duct (2) designed to be inserted into the patient's urethra and having a spiral shaped distal portion (12) designed to be inserted inside the bladder, said distal portion being provided with a plurality of holes (16) for the out-flow of the urine from the bladder to the inside of said duct, said catheter being characterized in that it includes:

a seat (21) that is made at the end of the catheter that remains outside of the penis;

a valve (20) elastically deformable and provided with a slit (22) that is normally closed, said valve (20) being housed inside said seat (21);

two winglets (25) fixed at the end of the duct (2) and placed outside of the penis resting against the top of the glans, in such a way as to cause, as a consequence of the patient being pressing on them, the deformation of the part of said duct (2) correspondent to said seat (21), and consequently, the elastic deformation of said valve (20) until the cited slit (22) opens.

25

2) Catheter according to claim 1, characterized in that the part of said duct (2) correspondent to said seat (21) is harder than the remaining part of said duct (2).

30

3) Catheter according to claim 1, characterized in that said winglets (25) are harder than the remaining

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part of said catheter.

4) Catheter according to claim 1, characterized in that a reinforcement rib is formed along the side of each of said winglets that remains turned towards the glans.

5) Catheter according to claim 1, characterized in that the profile of the cited valve (20) and of the correspondent seat (21) is polygonal.

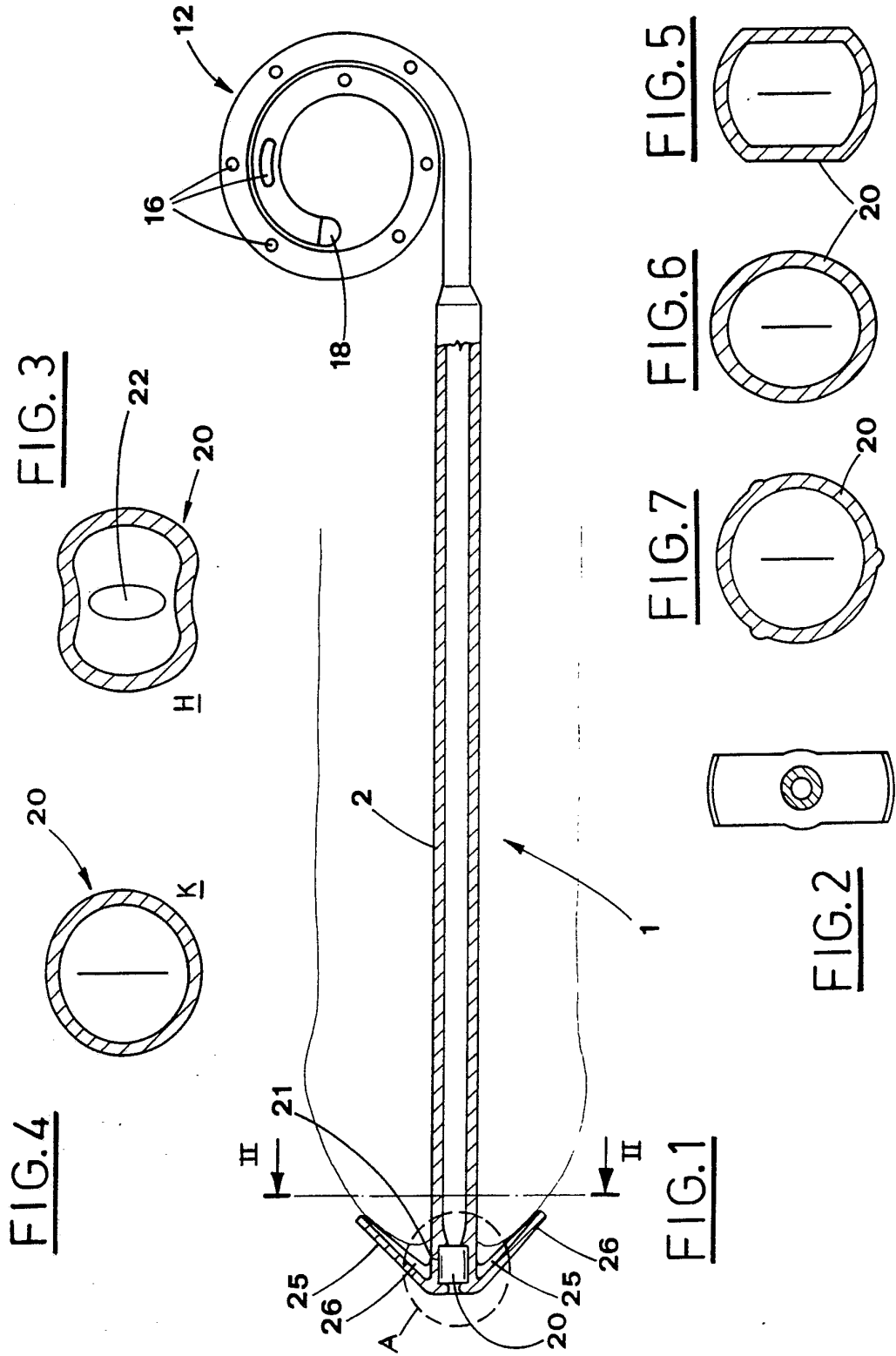
6) Catheter according to claim 1, characterized in that the profile of the cited valve (20) and of the correspondent seat (21) is oval.

15

7) Catheter according to claim, 1 characterized in that at least one protrusion is formed on the outer surface of said valve (20), said protrusion being designed to engage at least one correspondent groove made inside said seat (21).

8) Catheter according to claim, 1 characterized in that the distal portion (12) of said duct (2), positioned inside the bladder, has a shape of a spiral and is elastically deformable, said spiral having its axis perpendicular to the duct.

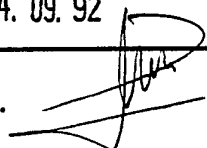
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INTERNATIONAL SEARCH REPORT

PCT/IT 92/00051

International Application No

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int.Cl. 5 A61M25/00; A61F2/00		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
Int.Cl. 5	A61M ; A61F	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
A	WO,A,9 004 431 (CHEN) 3 May 1990 see page 13, line 26 - page 15, line 23; figures 11,16-18 ---	1-8
A	US,A,4 932 938 (GOLDBERG ET AL.) 12 June 1990 see abstract; figures ---	1-8
A	US,A,4 946 449 (DAVIS, JR.) 7 August 1990 see abstract; figures ---	1-8
<p>¹⁰ Special categories of cited documents :</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"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</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"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.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
01 SEPTEMBER 1992	14. 09. 92	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	MIR Y GUILLEN V. 	

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO. IT 9200051
SA 60301**

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
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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US-A-4932938	12-06-90	AU-A- 5470190 CA-A- 2015831 DE-A- 4014369 FR-A- 2646610 GB-A- 2231801 JP-A- 3109065	08-11-90 05-11-90 08-11-90 09-11-90 28-11-90 09-05-91
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