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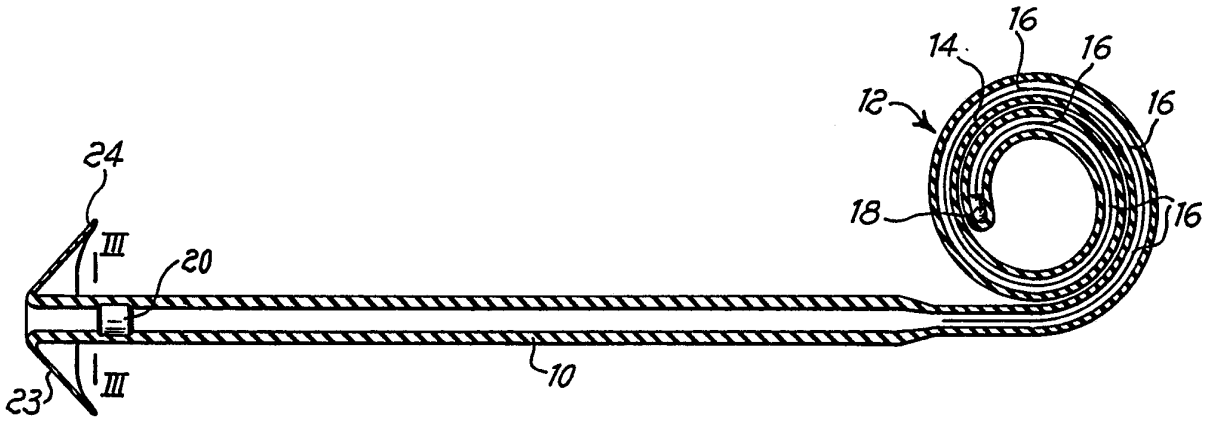

(57) Abstract

There is described herein a valve operated catheter for urinary incontinence and retention. The catheter is essentially comprised of a substantially tubular member (10) of elastic material, adapted to be endourethrally set in place on the patient. A first end portion (12) thereof is adapted to be received within the bladder and it is substantially spiral shaped while inside the opposite end thereof there is provided a normally closed valve (20) which may be opened when manually operated upon by the patient through compression, allowing the urines to be evacuated. The inventive catheter has the purpose of preventing unintentional leaking of urines being sufficient, for said purpose, that the valve mentioned above be not operated. In addition it may apparently be used also in cases of urine retention.

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" A VALVE ACTUATED CATHETER FOR URINARY INCONTINENCE AND RETENTION "

This invention concerns a valve actuated catheter for urinary incontinence and retention.

Catheters for the therapy of the above pathologies are already known, but they have a number of drawbacks which make them difficult if not sometimes impossible to be used.

A catheter which is presently used in the majority of circumstances is essentially comprised of a substantially tubular body, adapted to be inserted in the patient's urethra, and provided at one end thereof with a balloon suitable to be housed within the bladder, while the opposite end, located outside the patient's urethra, is connected to a urine collection bag.

The above catheter has a first important drawback, which is particularly dangerous during long-term catheterizations, where the balloon inserted within the bladder may cause irritations or traumas thereof.

A further drawback is the fact that, due to any occasional pull exerted on the catheter by the patient himself, the above balloon may be the cause of possibly important damages to the bladder as well as to the bladder neck and to the urethra.

A further typical drawback of the above catheter already

known results from the need to use the urine collection bag which has to be constantly carried along by the patient and which provides an obvious inconvenience.

Another drawback of the conventional catheter results from the fact that it cannot be used in all those cases where bladder rehabilitation is required through the so-called "vesical exercise". The conventional catheters already on the market leave the bladder always empty thereby preventing the contracting and releasing functional activity pertaining to the bladder.

There has now been contrived, and it is the subject of this invention, a catheter for urinary incontinence and retention which enables all the drawbacks of the conventional catheters to be overcome .

The features as well as the advantages of the catheter of this invention will become apparent from the following detailed description of a non limiting embodiment thereof, made in reference to the attached Figures wherein:

Figure 1 is a plan view of the catheter according to this invention;

Figure 2 is a view of the catheter according to section II-II of Figure 1;

Figure 3 is a view of the catheter according to section III-III of Figure 2, with the incorporated valve in the

closed position;

Figure 4 is a view of the catheter still according to section III-III of Figure 2, with the incorporated valve in the open condition for urine ejection.

Referring now in particular to Figures 1 and 2, the catheter of this invention is essentially comprised of a substantially tubular duct 10 made of any elastic material, for instance a siliconated material which is adapted to be inserted and fitted within the patient's urethra by means of a mandrel.

Substantially tubular body 10 has a generally circular cross section and has a standardized length, while the diameter thereof follows the usual Cherier scale numbering system.

A first end portion of the inventive catheter, shown in general at 12, set to be fitted within the patient's bladder, includes a length 14 of said tubular member comprising body 10 which is bent substantially according to a spiral curve. Also length 14 is made of the same material as the body 10 and therefore of an elastic material so that portion 12, which in the rest position keeps its spiral shape, is elastically deformable without the necessity of a high strength.

As many be seen in particular from Fig. 2 spirally

curved portion 14 of the inventive catheter is provided, in the longitudinal direction thereof, with a continuous slit 16 through which the urines present within the bladder may freely flow towards the inside of portion 14 and then into the catheter. As a variation the continuous slit 16 may be substituted by a number of openings having the same function. Still referring to Figure 2 it may be noticed that, at the end of portion 14 of the inventive catheter there is provided, on the inside, a capsule 18 holding a substance having a disinfecting or antibacterial action of the type adapted to release said substance continuously in time within the bladder.

Still referring in particular to Figure 2, but with reference to Figures 3 and 4 as well, it may be noticed that at the distal end, or end portion of the catheter, there is located in a special seat a valve 20 having a double function of preventing unintentional leaking of urines and of restoring the outflow thereof in case of retention, through manual compression on said valve.

Valve 20, which is made of an elastic material such as for instance the same material of tubular duct 10, has a passage 22 which is closed in the rest position shown in Figure 3, while it is open in the operative condition shown in Figure 4.

Opening of passage 22 is performed by the patient him-

self through a compressive action as shown schematically by arrows F in Figure 4. Said action will be continued during the whole period of time necessary to evacuate the urines, i.e. until the patient gets relieved of the corresponding stimulation.

As it may be noticed in particular in Figures 1 and 2, the catheter end, in particular the end of tubular duct 10, is provided with a rearward folded portion, or "cap" 23, said portion being shaped in such a way as to comprise a stop member adapted to prevent the catheter from sliding inside the urethra.

According to a further feature of the catheter of this invention cap portion 23 is provided, in a suitable position, with a contoured projection 24 the patient can use as a reference member for directing the pressure action he will have to perform on the valve to obtain ejection of the urines. As it is apparent from the attached drawing,contoured portion 24 is located above passage 22 which extends vertically thereunder.

From the above, the advantages obtained using the catheter of this invention should be apparent, and they will be shortly summarized in the following.

Provision of end portion 12 comprised of elastically deformable spiral stretch 14 makes it possible to obtain

three important advantages.

The first one is that the catheter is made self-stabilizing. The second of said advantages is the fact that the length of tubular duct 10 received within the urethra may be modified according to need, by simply inserting into the urethra the needed length of spiral stretch 14 which will then get shortened while still remaining suitable to perform the function required to it.

The third advantage is the fact that, in case the catheter is subjected to any accidental pull, no more damages nor traumas are caused to the bladder or to the urethra since the elastic deformation of spiral stretch 14 enables tubular duct 10 to come out freely without the patient suffering any traumatizing effect.

A further important advantage achievable by means of the inventive catheter is the fact that it can be used in general, also in those cases when the so called "vesical exercise" is needed. In fact, the subject catheter allows the bladder to fill up freely and then to get empty when the patient feels the miction stimulus. There is then completely preserved the contractile and releasing functionality of the bladder.

A further advantage of the subject catheter is the fact that it may be used in all cases of urine retention,

thanks in particular to the spiral portion 12 received within the bladder. The catheter of this invention has a further advantage that it can be set in place with out-patient procedures, without anaesthesia, and may remain in place for an extended period of time. According to tests, it can be left in place even for more than forty consecutive days.

A further advantage of the catheter of this invention is the fact that it is completely endourethral, without any extensions visible from outside, which makes it possible to achieve an optimum aestethical effect for the patient.

The presence of the capsule for slow release of disinfectant and antibacterial agents within the bladder is a further advantageous feature of the inventive catheter, in that said organ of the patient is kept in the best hygienic conditions, which was impossible with the conventional catheters, therefore no requirements being set for daily vesical washouts, nor for the use of a urine collector, which drawbacks strongly affect the patient.

Eventually, it should be apparent that variations and/or modifications may be made to the endourethral valve operated catheter according to this invention without exceeding the scope of protection thereof.

CLAIMS

1. A catheter for urinary incontinence or retention, characterized in that it is essentially comprised of a substantially tubular duct adapted to be inserted into the patient's urethra by means of a mandrel and made of an elastically deformable material, in that an end portion thereof adapted to be received within the patient's bladder essentially comprises a substantially spiral shaped as well as elastically deformable portion of said tubular duct, said substantially spiral shaped portion being provided, along the length thereof, with a continuous slit to allow the urines to enter into the catheter, at the distal end of said substantially tubular duct there being internally provided a valve having a longitudinal passage which is closed in a rest condition and can be opened by the patient himself through a compressive action on the portion of tubular duct within which said valve is provided.

2. The catheter of Claim 1, characterized in that the valve adapted to allow evacuation of the urines is made of an elastically deformable material.

3. The catheter of Claim 1, characterized in that the catheter end portion received within the bladder is provided internally with a capsule of disinfectant and/or

antibacterial materials, adapted to release said materials within the bladder at a rate delayed in time.

4. The catheter of Claim 1, characterized in that the end of the substantially tubular duct has a rearward folded portion which is left outside the urethra, adapted to prevent the catheter to slide inside the patient's urethra.

5. The catheter of Claim 4, characterized in that said rearward folded portion at the end of the tubular duct is provided with a contoured projection adapted to be used by the patient as a reference member concerning the direction of the pressure he has to apply to control the opening of the valve for urine evacuation.

6. A valve operated endourethral catheter for urinary incontinence and retention, substantially as described above and as shown in the attached drawing.

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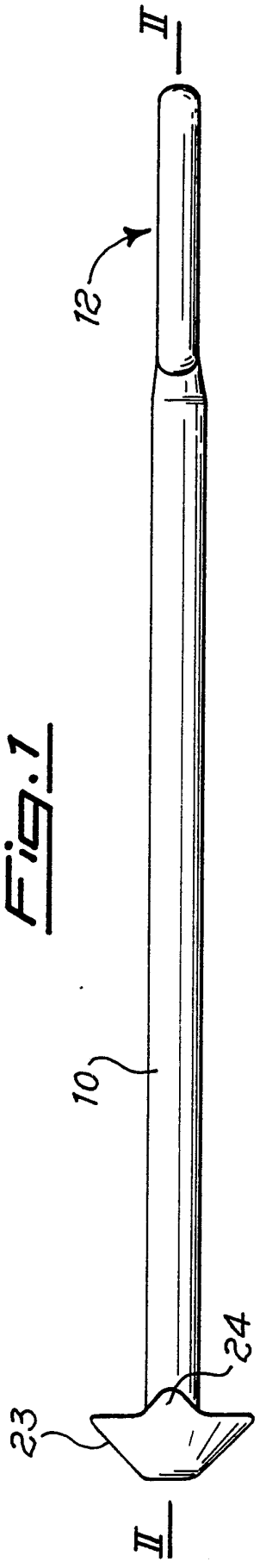

Fig.1

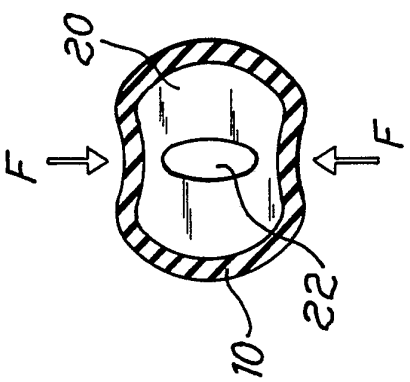

Fig.4

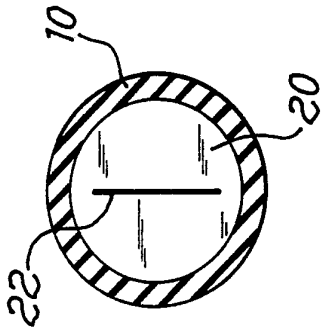

Fig.3

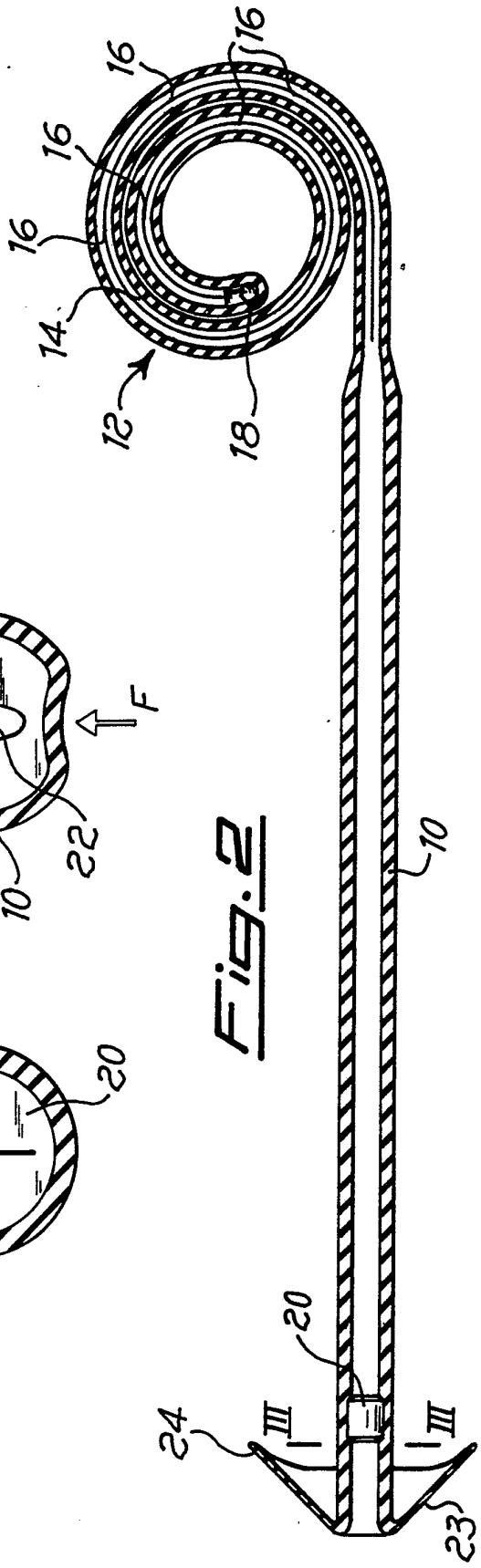

Fig.2

INTERNATIONAL SEARCH REPORT

PCT/IT 91/00051

International Application N

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

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 RELEVANT[9]

Category °	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
X	US,A,4 932 938 (GOLDBERG ET AL.) 12 June 1990 see column 7, line 59 - column 8, line 63; figures 11-13,16,20 ---	1-3,6
A	WO,A,8 905 671 (BARD LIMITED) 29 June 1989 see page 3, last paragraph - page 4, last paragraph; figure 2 ---	3
A	US,A,3 592 197 (COHEN) 13 July 1971 see column 2, line 55 - line 62; figures ---	4-5

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
07 FEBRUARY 1992	03. 03. 92
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	MIR Y GUILLEN V.

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ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. IT 9100051 SA 48356

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 07/02/92
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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-4932938	12-06-90	AU-A-	5470190	08-11-90
		CA-A-	2015831	05-11-90
		DE-A-	4014369	08-11-90
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		EP-A-	0408562	23-01-91
		JP-T-	3501691	18-04-91
US-A-3592197	13-07-71	None		