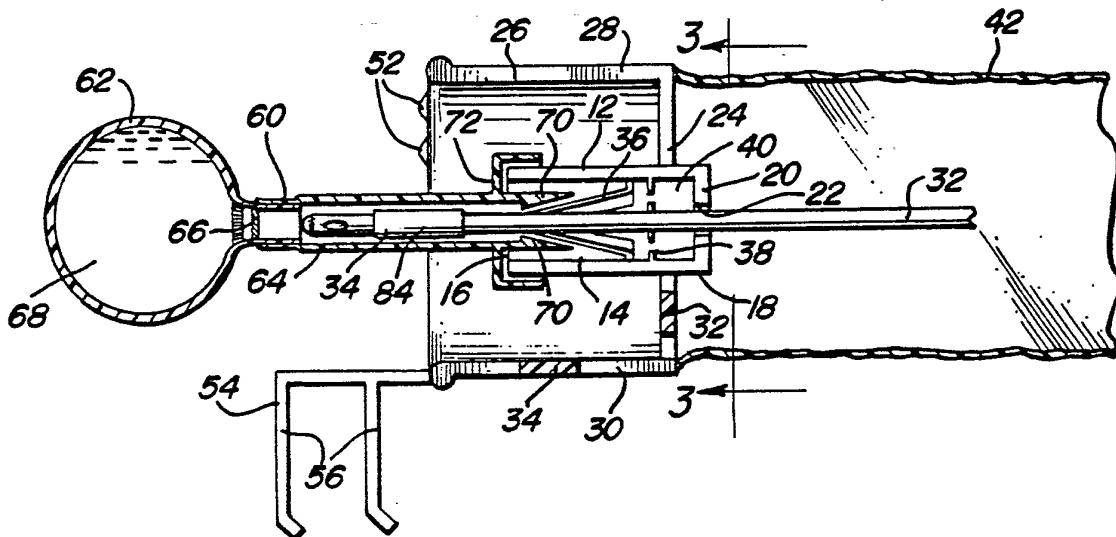




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ³ : A61M 25/00		A1	(11) International Publication Number: WO 86/ 01119 (43) International Publication Date: 27 February 1986 (27.02.86)
(21) International Application Number: PCT/US84/02058 (22) International Filing Date: 13 December 1984 (13.12.84)		JP, KR, LU (European patent), NL (European patent), NO, RO, SE (European patent), SU.	
(31) Priority Application Number: 639,269 (32) Priority Date: 8 August 1984 (08.08.84)		Published <i>With international search report.</i> <i>With amended claims.</i>	
(33) Priority Country: US			
(71)(72) Applicant and Inventor: TANIGUCHI, Tokuso [US/US]; 277 Kaiulani Street, Hilo, HI 96720 (US). (74) Agent: JACOBSON, Harvey, B.; Clarence A. O'Brien & Harvey B. Jacobson, 1217 E Street, N.W., Washington, DC 20004 (US).			
(81) Designated States: AT (European patent), AU, BE (European patent), BR, CH (European patent), DE (European patent), DK, FI, FR (European patent), GB (European patent), HU,			

(54) Title: AUTOMATED CATHETER CONSTRUCTION



(57) Abstract

A catheter assembly (10) for packaging in sterile condition within a protective removable envelope (42). The catheter assembly (10) includes a shield structure (26) incorporating an elongated hollow body (12) defining a bore (14) therethrough. A catheter (32) has its distal end slidingly telescoped into one end of the bore (14) and a tubular lubricant reservoir (60) is provided and includes a first open end (70) and a second collapsible bulbous end (62). The open end (70) is telescoped over the distal end of the catheter (32) and into the corresponding end of the body bore (14). The reservoir (60) has a frangible seal (66) within its open end and telescoping engagement of the open end (70) of the reservoir into the body bore functions to clamp the distal end of the catheter against withdrawal from the body bore (14).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GA	Gabon	MR	Mauritania
AU	Australia	GB	United Kingdom	MW	Malawi
BB	Barbados	HU	Hungary	NL	Netherlands
BE	Belgium	IT	Italy	NO	Norway
BG	Bulgaria	JP	Japan	RO	Romania
BR	Brazil	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	LI	Liechtenstein	SN	Senegal
CH	Switzerland	LK	Sri Lanka	SU	Soviet Union
CM	Cameroon	LU	Luxembourg	TD	Chad
DE	Germany, Federal Republic of	MC	Monaco	TG	Togo
DK	Denmark	MG	Madagascar	US	United States of America
FI	Finland	ML	Mali		
FR	France				

-1-

Description

AUTOMATED CATHETER CONSTRUCTION

BACKGROUND OF THE INVENTION

Various types of lubricatable catheters and catheters specifically designed for sterile packaging heretofore have been designed. Examples of such previously patented catheters may be found in U.S. patent Nos. 3,077,194, 3,154,080, 3,176,691, 3,275,001, 3,345,988, 3,444,860, 3,515,173, 3,556,294, 5 3,595,230, 3,566,874, 3,592,192, 3,605,752, 3,606,889, 10 3,672,376, 3,675,658, 3,677,244, 3,682,173, 3,683,298, 3,750,875, 3,776,915, 3,861,395, 3,898,933, 3,967,728, 15 4,062,363 and 4,140,127. Although these numerous prior types of catheters have been developed, a need still exists for a catheter construction which will lend itself more favorably to sterile packaging, ease in lubrication by lubricant also contained within the sterile packaging and ease of insertion by way of a tubular guide through which the catheter 20 is advanced during insertion and which may be readily separated from about the catheter after insertion.

BRIEF DESCRIPTION OF THE INVENTION

The automated catheter assembly of the instant invention has been designed to simplify the catheterization of either the male urinary bladder or the female urinary bladder. The automated catheter assembly may utilize substantially any accepted rubber catheter or its equivalent and 25 30 includes structure whereby the associated catheter

-2-

may be lubricated in a sterile manner as it is placed in use and inserted into the female urethra or male penis without contamination of the rubber catheter during insertion. Also, the automated 5 catheter assembly is provided with a support body having a bore formed therethrough and the associated catheter is advanced through the bore while one hand supports the body in alignment with the female urethra or the male penis. Still further, the 10 catheter assembly includes structure for inflation of the catheter balloon and the aforementioned support body includes opposite side shield portions whereby adjacent portions of the patient's body are shielded against contact with the distal end of 15 the catheter and body and the shield may be readily broken away from the proximal end of the catheter after the latter has been inserted.

The main object of this invention is to provide a catheter assembly designed to simplify the 20 catheterization of male and female patients. Another object of this invention is to provide a catheter assembly wherein the catheter may be readily lubricated in a sterile state immediately prior to insertion of the distal end of the catheter.

25 Another important object of this invention is to provide for ease of inflation of the catheter balloon.

Still another object of this invention is to provide a catheter assembly including shield 30 structure for shielding the distal end of the

-3-

catheter from contact with parts of the body other than the urethra of the female patient and the penis of a male patient.

Another important object of this invention
5 is to provide an automated catheter assembly in accordance with the preceding objects and which may be used in conjunction with a conventional catheter.

A final object of this invention to be specifically enumerated herein is to provide a
10 catheter assembly in accordance with the preceding objects and which will conform to conventional forms of manufacture, be of simple construction and easy to use so as to provide a device that will be economically feasible, simple to use and relatively
15 trouble free in operation.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side elevational view of a catheter assembly constructed in accordance with the present invention and adapted to be utilized in
20 catheterizing a male patient;

Figure 2 is an enlarged fragmentary vertical sectional view of the anterior portion of the catheter construction;

Figure 3 is a transverse sectional view
25 taken substantially upon the plane indicated by the section line 3--3 of Figure 2;

Figure 4 is a fragmentary elevational view of the posterior end of the catheter with the protective envelope removed;

30 Figure 5 is an elevational view of a

-4-

modified form of catheter which may be used in conjunction with the shield and cover portion of the instant invention;

5 Figure 6 is an elevational view of a catheter assembly constructed in accordance with the present invention and adapted to be utilized in catheterizing a female patient;

10 Figure 7 is an enlarged fragmentary vertical sectional view of the anterior portion of 10 the assembly illustrated in Figure 6;

15 Figure 8 is a transverse vertical sectional view taken substantially upon the plane indicated by the section line 8--8 of Figure 7 and with the lubrication applying attachment removed; and

15 Figure 9 is a transverse sectional view taken substantially upon the plane indicated by the section line 9--9 of Figure 7.

DETAILED DESCRIPTION OF THE INVENTION

20 Referring now more specifically to the drawings the numeral 10 generally designates a catheter assembly for utilization in conjunction with male catheterization. The catheter assembly 10 includes a generally cylindrical body 12 defining a longitudinal bore 14 formed therethrough. The body 25 12 includes a forward or distal end 16 and a rear or proximal end 18 inclusive of a generally circular end wall 20 having a central aperture 22 formed therein.

30 Formed integrally with the end 18 is a generally circular plate 24 and a generally

-5-

5 cylindrical shield 26 which projects forwardly of the outer periphery of the plate 24. The plate 24 is centrally apertured and anchored relative to the body 12. However, the shield 26, plate 24 and body 12 are provided with vertically aligned slots 28 and 30 above and below the aperture 22. Frangible bridging portions 32 and 34 bridge the slot 30 closely beneath the lower portion of the body 12 and along the lower periphery of the shield 26.

10 A conventional catheter 32 has its balloon-equipped anterior end 34 telescoped forwardly through the aperture 22 and the body 12 and the interior of the body 12 includes peripherally spaced inclined fingers 36 which project forwardly and inwardly from 15 the body 12 and closely embrace the catheter 32 at their inner ends. The body 12 also includes an apertured interior partition 38 spaced forward of the end wall 20 and defining a lubrication reservoir 40 between the end wall 22 and the partition 38.

20 A flexible transparent tubular envelope 42 is provided and includes a forward end sealingly secured about and to the periphery of the plate 24 and a rear end 44 which is transversely sealed closed as at 46. The envelope 42 comprises a pair 25 of flat strips superimposed upon each other and secured together along adjacent marginal edges in order to form the envelope. The rear ends of the strips are sealed together and illustrated as at 48 and 50 in Figure 1 and may be pulled apart in order 30 to separate the envelope 42 from about the catheter

-6-

32. In addition, the shield 26 may be separated by engaging the two shield halves disposed on opposite sides of the slots 28 and 30 by the lugs 52 provided thereon and pulling the two shield halves apart. In
5 this manner, the two strips 48 and 50 of the envelope 42 may also be pulled apart inasmuch as each of the strips 48 and 50 is anchored relative to a corresponding shield half. The lower peripheral portion of the forward end of one of the shield halves includes a
10 finger-engageable grip 54 projecting forwardly therefrom and including a pair of depending finger-engageable members 56 by which the shield 26 may be more readily handled, see Figure 1.

With attention now invited more specifically
15 to Figure 2 of the drawings there may be seen a semi-liquid lubricant container 60 including a flexible and squeezable lubricant reservoir 62 and a lubricant outlet neck 64 which opens outwardly of the reservoir 62. The end of the outlet neck 64 adjacent the reservoir 62 has a pressure rupturable seal 66 secured across the interior thereof whereby the semi-liquid lubricant 68 within the reservoir 62 is prevented from drying. The end of the outlet neck 64 remote from the reservoir 62 includes
20 interior wedge surfaces 70 engageable with the fingers 36 to inwardly deflect the adjacent forward ends thereof into lightly clamped engagement with the catheter 32. Thus, when the outlet neck 64 is inserted within the forward end of the body 12 to
25 its limit of insertion defined by engagement of an
30

-7-

abutment wall 72 carried by the outlet neck 64 with the forward end of the body 12 the fingers 36 lightly clampingly engage the catheter 32. Then, when the reservoir 62 is compressed between the 5 fingers in order to break the seal 66 and express the lubricant 68 from the reservoir 62 and out through the outlet neck 64 the catheter 32 will not be projected rearwardly from the body 12. The forward end of the catheter 32 is fully lubricated 10 and excess lubricant passes around the fingers and through the partition 38 and into the chamber 40. The lubricant within the chamber 40 serves to lubricate the catheter 32 disposed posteriorly of the shield 26 as the catheter 32 is inserted into 15 the penis 74. After the anterior end of the catheter 32 has been positioned within the bladder the clamp 76 engaged with the outlet neck 78 of a pressurized liquid reservoir 80 is released and the liquid 82 within the reservoir 80 is allowed to flow from 20 the reservoir 80 along the catheter in order to inflate the balloon portion 84 thereon. The clamp 76 is engaged with the outlet neck 78 through the envelope 42.

As may be seen from Figure 1 of the 25 drawings, the catheter 32 after the lubricant has been expressed from the reservoir 62, may be readily inserted into the penis 17 in a sanitary manner by guiding the catheter 32, through the envelope 42, forwardly through the body 12.

30 If it is desired, a modified form of

-8-

catheter 33 may be used, see Figure 5, and the pressurized reservoir 80 of the catheter 32 may be replaced by a syringe 63 engageable through a plug 65 after the envelope 42 has been removed.

5 With attention now invited more specifically to Figures 6 through 9 of the drawings, there may be seen a modified form of catheter construction referred to in general by the reference numeral 10' and which is similar in many respects to the catheter 10 and therefore has the components thereof utilized on the catheter 10 referred to by prime reference numerals corresponding to the numerals used in conjunction with those similar components of the catheter construction 10.

15 The catheter construction 10' differs from the catheter construction 10 in that a shield referred to in general by the reference numeral 11 and incorporating rearwardly divergent opposite side panels 13 and 15 as well as rearwardly divergent upper and lower panels 17 and 19 is provided. The shield 11 is used in lieu of the shield 10 and includes a plate 24' corresponding to the plate 24 and from which a tubular body 12' corresponding to the body 12 is supported. However, the plates 17 and 19 are vertically slotted as at 25 and 27 and the plate 24' is vertically slotted as at 29 both above and below the body 12'. The plate 24 includes frangible connecting portions 31 and 35 and the body 12' includes vertically registered upper and 30 lower slots 37 and 39 which terminate slightly

-9-

rearward of the forward end of the body 12'. Thus, the body 12' includes connecting portions 41 and 43 which are frangible. In this manner, the shield 11 may have the two halves thereof broken apart by 5 breaking the portions 31, 35, 41 and 43.

The catheter construction 10' includes an envelope 42' corresponding to the envelope 42 and a lubricant reservoir 62' incorporating an outlet neck 64' corresponding to the outlet neck 64 and 10 also including wedges 70' engageable with fingers 36' corresponding to the fingers 36. Further, the body 12' includes a partition 38' corresponding to the partition 38.

The shield 11 is specifically adapted to 15 be used in conjunction with a female patient and will of course prevent portions of the female patient closely adjacent the catheter construction 10 from coming in contact with the catheter 32' thereof.

20 As in the case with the male catheter construction 10, after the catheter 32 has been pushed sufficiently into the bladder and the catheter balloon has been inflated, the shield 11 may be separated by pulling the opposite sides of 25 the shield apart and breaking the shield in the portions 31, 35, 41 and 43 thereof. Here again, the envelope 42' is constructed of a pair of opposite side strips which may be readily separated from the catheter along with 30 the half sections of the shield, or the

-10-

envelope 32' may have its two strips separated from the posterior end of the envelope 42.

-11-

CLAIMS

1. A catheter assembly including an elongated tubular body having opposite open ends, a catheter having its distal end slidingly and guidingly telescoped into said body from one end thereof, a lubricant reservoir from which lubricant may be expressed and including a tubular outlet neck telescopingly receivable within the other end of said body and over said distal end, said outlet neck and body including coacting means operative to lightly clampingly engage said catheter to prevent longitudinal shifting of the latter relative to said body responsive to penetration of said outlet neck into said other end of said body a predetermined extent, whereby lubricant discharged from said outlet neck into said body and toward said one end thereof will not be effective to shift said catheter proximally in said body.
- 20 2. The catheter assembly of claim 1-wherein said one end of said body includes a centrally apertured end wall loosely receiving said catheter therethrough, said body including an apertured partition therein centrally through which said catheter is slidingly received and disposed intermediate said end wall and said coacting means, the interior of said cavity between said partition and said end wall defining a lubricant reservoir for lubricating said catheter proximally of said distal end

-12-

during distal shifting of said catheter relative to said body during insertion of said distal end through the urethra and into the bladder.

3. The catheter assembly of claim 1 wherein said body and outlet neck include coacting abutment means limiting penetration of said outlet neck into said body to said predetermined extent.
4. The catheter assembly of claim 1 wherein said body includes a peripherally extending and outwardly projecting plate, the outer periphery of said plate including a tubular guide shield projecting toward and beyond said other end of said body.
5. The catheter assembly of claim 4 wherein said shield, plate and body are longitudinally slotted into two halves and said two halves are joined by breakable portions bridging between said two halves, whereby said two halves may be manually gripped and pulled apart.
6. The catheter assembly of claim 4 wherein the distal end of said cylindrical guide includes a laterally outwardly projecting finger-engageable portion.

-13-

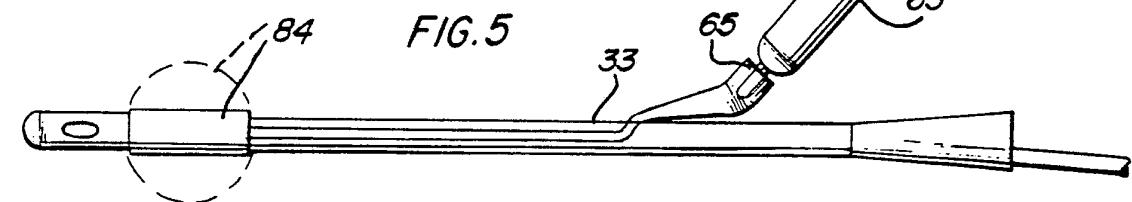
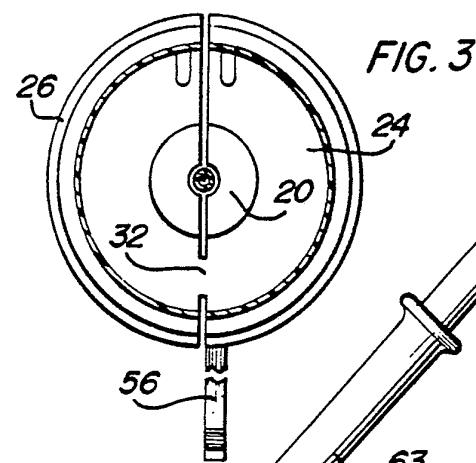
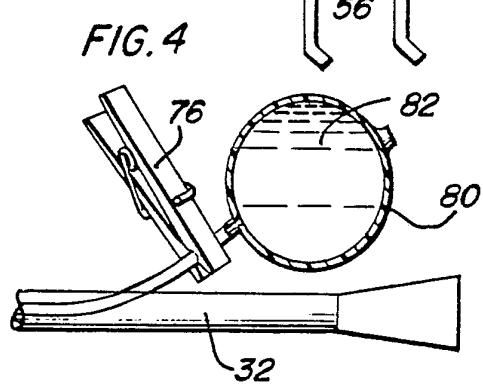
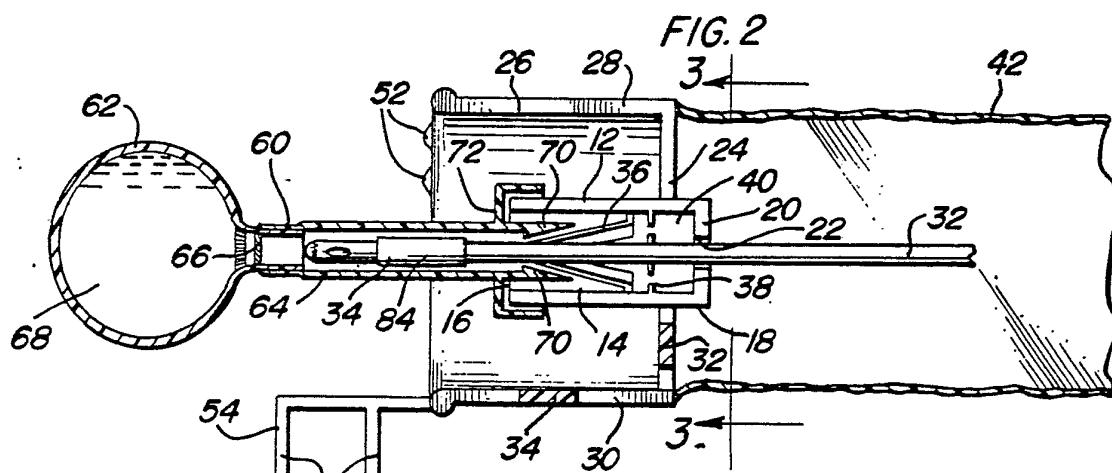
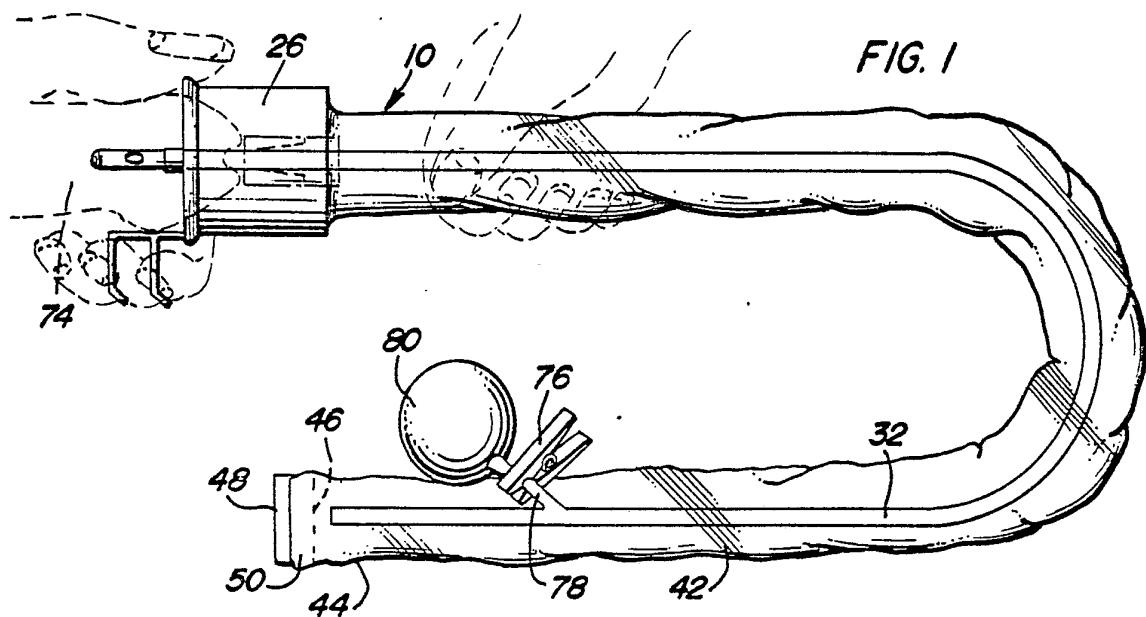
7. The catheter assembly of claim 1 wherein said body includes a peripherally extending and outwardly projecting plate, supported therefrom intermediate the opposite ends of said body, the outer periphery of said plate including opposite side distally and outwardly projecting flanges and upper and lower outwardly and distally inclined flanges.
5
8. The catheter assembly of claim 7 wherein said upper and lower flanges, said plate and body are longitudinally slotted and held together by frangible bridging portions enabling the shield comprising said opposite side flanges and said upper and lower flanges to be manually broken in
10 half.
15
9. The catheter assembly of claim 8 including a tubular flexible envelope comprising opposite side strips secured together along corresponding marginal portions, said envelope being telescoped over the proximal end of said catheter and having its forward end secured to said plate about the proximal end of said body, said strips of said envelope being separable from each other when said shield is broken in half.
20

AMENDED CLAIMS

[received by the International Bureau on 21 March 1985 (21.03.85);
original claim 1 amended; other claims unchanged (1 page)]

1. (Amended) A catheter assembly including an elongated tubular body having opposite open ends, a catheter having its distal end slidingly and 5 guidingly telescoped into said body from one end thereof, a lubricant reservoir from which lubricant may be expressed and including a tubular outlet neck telescopingly receivable within the other end of said body and over said distal end, said body 10 including interior circumferentially spaced and longitudinally extending fingers disposed therein having one set of spaced apart corresponding ends convergent toward said other end of said body and closely embracing said distal end, the other set of 15 corresponding ends of said fingers being supported from said body, said fingers being flexible for deflection of said one set of ends toward each other, said outlet neck being telescopingly engageable over said one set of ends and wedgingly 20 engageable therewith to inwardly deflect the latter into lightly clamped engagement with the distal end of said catheter to prevent longitudinal shifting of the latter relative to said body responsive to penetration of said outlet neck into said other end 25 of said body a predetermined extent, whereby lubricant discharged from said outlet neck into said body and toward said one end thereof will not be effective to shift said catheter proximally in said body.

1 / 2



2 / 2

FIG. 6

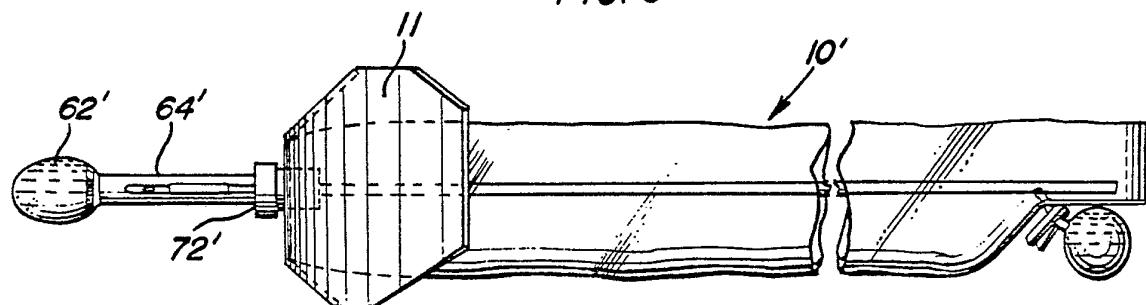


FIG. 7

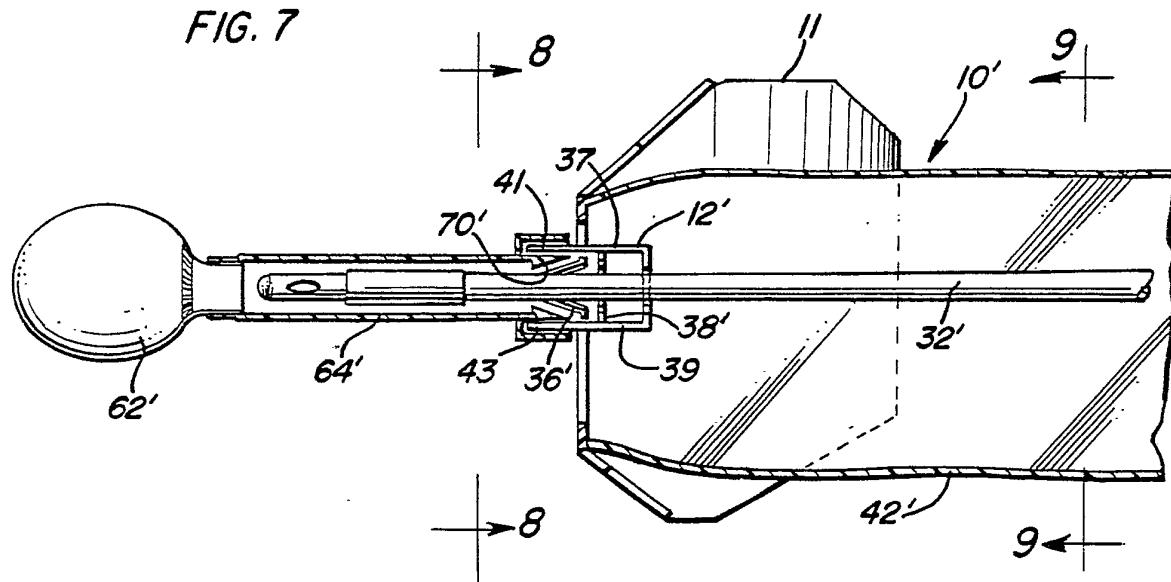


FIG. 8

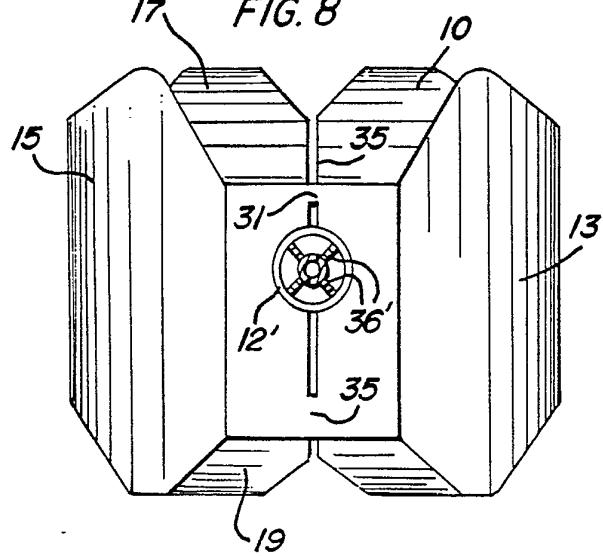
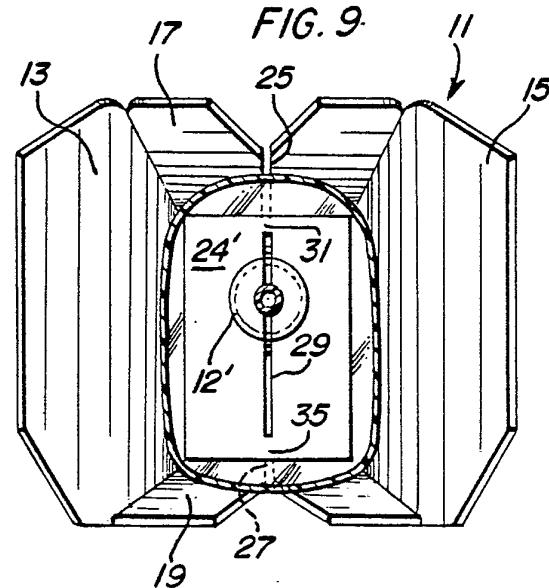


FIG. 9



INTERNATIONAL SEARCH REPORT

International Application No. PCT/US84/02058

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ³

According to International Patent Classification (IPC) or to both National Classification and IPC

US. CL. 604/172
INT. CL. 9 A61M 25/00

II. FIELDS SEARCHED

Minimum Documentation Searched ⁴

Classification System	Classification Symbols
U.S.	604/ 165, 170, 171, 172, 173, 265, 268, 280, 283, 240, 242.

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched ⁵

III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴

Category ⁶	Citation of Document, ¹⁵ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸
Y	US,A, 3,861,395, Published 21 Jan. 1975 Taniguchi	1,2,4-9
Y	US,A, 3,898,993, Published 12 August 1975 Taniguchi	1-9
A	US,A, 3,854,483, Published 17 Dec. 1974 Powers	2,9
A	US,A, 3,648,704, Published 14 Mar. 1972 Jackson	2,3,9
A	US,A, 4,269,310 Published 26 May 1981 Uson	2,9
A	US,A, 3,967,728, Published 6 July 1976 Gordon et al	1,2,9

* Special categories of cited documents: ¹⁵

- "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.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search ²

1 February 1985

Date of Mailing of this International Search Report ²

12 FEB 1985

International Searching Authority ¹

ISA/US

Signature of Authorized Officer ²⁰

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No ¹⁸
A	US,A, 3,556,294, Published 19 Jan. 1971 Walck	1,2,9
A	US,A, 3,825,001, Published 23 July 1974 Bennet et al	1,3
A	US,A, 3,683,928, Published 15 Aug. 1972 Kuntz	1-3
A	US,A, 4,187,848, Published 12 Feb. 1980 Taylor	1,3
Y	US,A, 4,326,520, Published 27 Apr. 1982 Alley	1,3,5,6,9
Y	US,A, 4,235,232, Published 25 Nov. 1980 Spaven et al	1,3,9
A	GB,A, 2,060,400, Published 7 May 1981 Steer et al	1,3
A	US,A, 3,752,510, Published 14 Aug. 1973 Windischman et al	1,3