

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



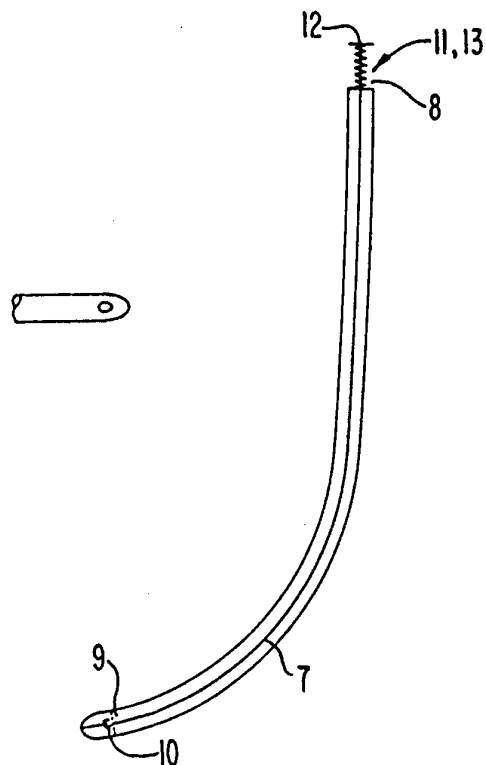
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : A61M 25/00	A1	(11) International Publication Number: WO 94/25094 (43) International Publication Date: 10 November 1994 (10.11.94)
(21) International Application Number: PCT/US94/04906 (22) International Filing Date: 5 May 1994 (05.05.94) (30) Priority Data: 08/056,532 5 May 1993 (05.05.93) US (71)(72) Applicant and Inventor: LYELL, Mark, S. [US/US]; Suite 102-A, 4105 Hospital Road, Pascagoula, MS 39581 (US). (74) Agent: CHEEK, Warren, M., Jr.; Wenderoth, Lind & Ponack, Southern Building, Suite 700, 805 Fifteenth Street, N.W., Washington, DC 20005 (US).		(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: SUPRAPUBIC CATHETER PLACEMENT APPARATUS (LYELL SOUND)

(57) Abstract

A surgical apparatus is provided for placing a suprapubic catheter within the bladder of a patient. The apparatus includes an elongate element (2) defining a hollow tube and having an end for insertion through the urethra, a flexible wire (7) disposed within the elongate element extending along the length of the element, and a means (11) for reciprocating the wire (7) such as a spring (13) within the element.



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	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

SUPRAPUBIC CATHETER PLACEMENT APPARATUS (LYELL SOUND)

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to a surgical apparatus for placement of a catheter within a body cavity. More particularly, the invention relates to an apparatus and method for placement of a suprapubic catheter within the bladder.

Description of Related Art

Suprapubic catheters and instruments are used in many clinical settings where continuous bladder drainage is desired. Suprapubic catheterization offers a number of advantages over transurethral catheterization, especially for long term catheterization, such as increased patient comfort, minimized infection, improved irrigation and drainage, etc.

Current methods for placing suprapubic catheters essentially fall into two categories, those employing an "outside-to-inside" technique and those employing an "inside-to-outside" technique.

The outside-to-inside technique for suprapubic catheter placement employs the use of a sharp trocar or catheter-obturator combination device. The surgeon pierces the lower abdomen with the trocar or obturator to create a passageway into the bladder. The end of a catheter containing the inlet drain is then inserted through the passageway and positioned in the bladder. Thus as the name implies, the catheter is placed directly into the bladder from outside to inside.

The inside-to-outside technique is less common and employs a grasping device placed in the bladder which is used to pull the catheter end containing the inlet drain into the bladder through a passageway created in the lower abdomen. Initially the surgeon passes the grasping device into the bladder via the urethra and presses the distal end against the bladder dome. A desired penetration site is selected by suprapubic palpitation. The distal end of the grasping device is commonly equipped with a sharp tip capable of piercing through the bladder, fascia and abdominal wall. After positioning, the surgeon presses the instrument tip through the bladder, fascia and abdominal wall near the symphysis to create the passageway. The end of a catheter containing the inlet drain is then coupled to the instrument via a coupling mechanism and the catheter is pulled into the bladder. The catheter is released and left in a

suprapubic placement.

The grasping device may alternatively possess a blunt tip rather than a piercing tip. A suitable site for passage of the catheter may be determined by palpitation using the blunt tip. An incision may then be extended by the surgeon from the exterior abdominal wall to the bladder to provide a passageway for the instrument advancement. The rest of the procedure may be performed substantially the same as described above using the instrument with a piercing tip.

Several conventional instruments which have been used to place a suprapubic catheter into the bladder using the inside-to-outside technique include the Lowsley retractor, uterine packing forceps, and modified urethral sound.

Other more specialized instruments are also known for placing a suprapubic catheter using the inside-to-outside technique or variations on this technique.

U.S. Patent No. 5,152,749 to Giesy et al. disclose a surgical apparatus which comprises a needle having a tissue piercing tip, the needle being slidably accommodated within a sheath, and the sheath including a handle means for exposing the tissue piercing tip of the needle. The needle tip also includes or can accommodate a coupling means and a locking means for coupling the catheter to the apparatus.

U.S. Patent No. 4,684,369 to Wildemeersch disclose a surgical apparatus which comprises a needle having a tissue piercing tip at one end and having an interlocking device for

connecting the needle to a catheter at the other end. The tissue piercing tip of the needle is passed through the urethra via a guide means or sheath into the bladder. The needle tip is used to create a passageway through the bladder and abdominal walls, and the needle coupled with the catheter is pulled through the passageway out of the abdomen until the posterior end of the catheter which contains the inlet drain is properly positioned.

There are also known various catheter placement apparatuses for related purposes, such as the apparatuses disclosed in U.S. Patent No. 4,826,481 to Sacks et al. and U.S. Patent No. 4,762,519 to Frimberger for placing a feeding tube in the stomach.

SUMMARY OF THE INVENTION

The present invention is designed to provide an improved and simplified device for placement of an instrument such as a catheter within a body cavity. While the present device is especially intended for the placement of suprapubic catheters, it will be apparent to any skilled person in the art that the device may be applied to other medical applications.

The apparatus of the present invention comprises an elongate element defining a hollow tube having a gripping portion for gripping and manipulating the apparatus and a curved portion for insertion through the urethra into the bladder of the patient. The terminal end of the elongate element at the gripping and

manipulating portion is defined as the first end, and the terminal end of the elongate element at the curved portion for insertion into the body is defined as the second end.

Disposed within the elongate element is a flexible wire having a length substantially extending from the first end to the second end of the elongate element. The ends of the flexible wire are defined as corresponding to the first and second ends of the elongate element, so that the first end of the flexible wire is that end which terminates at or near to the first end of the elongate element to be gripped, and the second end of the flexible wire is that end which terminates at or near to the second end of the elongate element to be inserted into the body.

The second end of the flexible wire includes a coupling for coupling the flexible wire to a catheter end, particularly to the catheter end containing the inlet drain or opening. The coupling is preferably a hook, more preferably a hook configuration formed in the end of the flexible wire.

The apparatus includes a means for reciprocating the flexible wire within the elongate element. The reciprocating means includes a handle operatively connected to the first end of the flexible wire. When the handle is moved to a first position, the wire is reciprocated within the elongate element so that the second end of the flexible wire projects from the second end of the elongate element for coupling with the catheter tip. When the handle is moved to a second position, the wire is reciprocated back within the elongate element so that the second end of the

flexible wire coupled to the catheter tip are retracted within the elongate element.

The reciprocating means is preferably a spring disposed either within the elongate element at a suitable location or outside the elongate element at the first end of the elongate element. In most cases when the reciprocating means is a spring and when the handle is in the first position, the spring will be in a fully compressed condition. When the handle is in the second position, the spring will be in a relaxed condition. The apparatus may be designed so that some compression is maintained on the spring in the second position. This compression may help to retain the coupled catheter within the second end of the elongate member so that the apparatus and catheter may be easily drawn by the surgeon through the incision into the bladder.

The preferred embodiment of the apparatus includes a removable cap which is removably engageable with the second end of the elongate element. The removable cap is adapted to cover the second end of the elongate element which is inserted through the urethra in order to assist in the passage of the apparatus through the urethra. The cap preferably has a blunt tip portion and a rear portion designed for attachment to the second end of the elongate element. Most preferably the rear portion has an opening or passageway therethrough for coupling with a hook of the flexible wire.

In an alternative embodiment, the elongate element is provided with a recessed inner end wall disposed within the

elongate element at the second end. The recessed inner end wall preferably has a slot therein for passing therethrough the flexible wire and coupling.

BRIEF DESCRIPTION OF THE FIGURES

Fig. 1 is a front elevational view of a first embodiment of a catheter placement apparatus according to the present invention.

Fig. 2 is a partial exploded front elevational view thereof showing the second end of the elongate element, in particular showing the flexible wire in the first position projecting from the second end of the elongate element, and showing an assembly of a hook coupled to a removable cap.

Fig. 3 is a partial exploded front elevational view thereof showing the second end of an elongate element and a catheter tip, in particular showing the flexible wire in a first position projecting from the second end of the elongate element and showing an assembly of a hook coupled to a catheter tip.

Fig. 4 is a partial exploded front elevational view thereof showing the second end of an elongate element and a catheter tip, in particular showing the flexible wire in a second position, and showing an assembly of the flexible wire and catheter tip retracted within the second end of the elongate element.

Fig. 5 is a front elevational view thereof showing an assembly of the suprapubic catheter placement apparatus of the

present invention coupled to a catheter.

Fig. 6 is an illustration showing the internal structure of a second embodiment of the catheter placement apparatus of the present invention taken from a front elevational view, showing an external spring reciprocating means and a different handle.

Fig. 7 is an illustration showing the internal structure of a third embodiment of the catheter placement apparatus of the present invention taken from a front elevational view, showing an internal spring reciprocating means and showing an alternative structure of the second end having a recessed inner end wall and a slot.

Figs. 8 to 11 are illustrations showing the method of placing a suprapubic catheter in a bladder using a catheter placement apparatus according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

The preferred embodiment of the surgical apparatus of the present invention for placement of a suprapubic catheter within the bladder of a patient is shown in Fig. 1.

The apparatus 1 comprises an elongate element 2 defining a hollow tube having a gripping portion 3 for gripping and manipulating the apparatus and a curved portion 4 for insertion through the urethra into the bladder of the patient. The terminal end of the elongate element at the gripping and manipulating portion is defined as the first end 5, and the terminal end of

the elongate element at the curved portion for insertion into the body is defined as the second end 6.

As shown in Figs. 6 and 7, disposed within the elongate element is a flexible wire 7 having a length substantially extending from the first end to the second end of the elongate element. The ends of the flexible wire are defined as corresponding to the first and second ends of the elongate element, so that the first end 8 of the flexible wire is that end which terminates at or near to the end of the elongate element to be gripped, and the second end 9 of the flexible wire is that end which terminates at or near to the end of the elongate element to be inserted into the body. The second end of the flexible wire includes a coupling 10 for coupling the flexible wire to the catheter tip. The coupling is preferably a hook and more preferably is a hook formed in the end of the flexible wire as shown in Fig. 2.

The apparatus includes a means for reciprocating 11 the flexible wire within the elongate element. The reciprocating means includes a handle 12 operatively connected to the first end of the flexible wire. When the handle is moved to a first position, the wire is reciprocated within the elongate element so that the second end of the flexible wire projects from the second end of the elongate element for coupling with the catheter tip. When the handle is moved to a second position, the wire is reciprocated back within the elongate element so that the second end of the flexible wire and the catheter tip are retracted

within the elongate element.

The reciprocating means is preferably a spring 13 disposed either within the elongate element or outside the elongate element at the first end of the elongate element. See Figs. 6 and 7. Thus when the handle is in the first position, the spring is in a fully compressed condition, and when the handle is in the second position, the spring is relaxed or under some compression. The apparatus may be designed so that the surgeon need only apply hand pressure to the handle to move the handle to the second position and project the coupling from the second end. When hand pressure is released the apparatus can be designed to automatically return the handle to the first position thereby automatically retracting the coupling within the second end.

The preferred embodiment of the apparatus includes a removable cap 14 which is removably engageable with the second end of the elongate element. The removable cap is adapted to cover the second end of the elongate element to assist in the easy passage of the curved portion of the apparatus through the urethra. The cap preferably has a blunt tip portion 15 and a rear portion 16 designed for attachment to the elongate element. Most preferably the rear portion has an opening or passageway 17 therethrough for coupling with a hook in the flexible wire.

In an alternative embodiment, the elongate element is provided with a recessed inner end wall 18 disposed within the elongate element at the second end. The recessed inner end wall preferably has a slot 19 therein for passing therethrough the

flexible wire and coupling when the coupling is disengaged. See Fig. 7.

The elongate element may be composed of any suitable rigid material. Preferably the elongate element is composed of a rigid plastic or metal. The handle, flexible wire and reciprocating means may be constructed from any suitable known material. The apparatus may be economically manufactured and sold in sterile packaging, as a disposable instrument, and in a disposable set or kit with a suitable catheter. The apparatus of the invention may be designed to use with most conventional catheters.

In summary, the apparatus of the present invention provides a simplified construction of an apparatus for placing a suprapubic catheter within a bladder.

In practice, a suprapubic catheter is placed within the bladder according to the following method, with reference to the figures.

As illustrated in Fig. 8, the curved portion of the elongate element is initially inserted through the urethra into the bladder while the handle is in the second position, i.e. the flexible wire is fully retracted within the elongate element. The second end of the elongate element is pressed against the bladder and abdominal walls. The surgeon selects an incision point by suprapubic palpitation. An incision is extended by the surgeon through the abdominal wall, fascia and bladder near the symphysis. Then the second end of the elongate element is pushed through the incision as shown in Fig. 9.

The handle is then moved to the first position, so that the flexible wire and coupling project from the second end of the elongate element. The catheter tip is coupled with the coupling to the apparatus. If the apparatus includes a removable cap, the cap must first be disengaged from the coupling before the catheter tip is engaged, as shown in 10. Upon coupling the catheter to the wire, the handle is moved to the second position. This retracts the coupling together with the catheter tip within the second end of the elongate element.

Once the apparatus and catheter are coupled, the assembly is pulled into the bladder and through the urethra to the extent that the catheter tip may be disengaged from the second end of the elongate element. Once the catheter is disengaged, the catheter is drawn back through the urethra and positioned within the bladder as shown in Fig. 11.

It should be understood that the foregoing description of my invention has been illustrated merely by example and such description should not be interpreted as being restrictive in any way. Obvious changes in its construction will be apparent to one skilled in the art and such changes are intended to be encompassed by this inventive description.

CLAIMS

I claim:

1. A surgical apparatus for placement of a suprapubic catheter within the bladder of a patient, comprising:

an elongate element defining a hollow tube having a gripping portion for gripping and manipulating the apparatus and a curved portion for insertion through the urethra into the bladder of the patient, said gripping portion terminating in a first end and said insertion portion terminating in a second end,

a flexible wire disposed within said elongate element, said flexible wire having first and second ends corresponding to said first and said second ends of said elongate element and having a length substantially extending from said first end to said second end of said elongate element, said second end of said flexible wire including a coupling for coupling said flexible wire to a catheter tip, and

a means for reciprocating said flexible wire within said elongate element, said reciprocating means including a handle operatively connected to said first end of said flexible wire, so that when said handle is in a first position, said second end of said flexible wire projects from said second end of said elongate element for coupling with the catheter tip, and when said handle is in a second position, said second end of said flexible wire and the catheter tip are retracted within said second end of said elongate element.

2. The surgical apparatus according to claim 1, wherein

said coupling is a hook.

3. The surgical apparatus according to claim 1, further comprising a removable cap for covering said second end of said elongate element, said removable cap having a blunt tip portion and a rear portion engageable with said second end of said elongate element.

4. The surgical apparatus according to claim 3, wherein said coupling of said flexible wire is a hook, and wherein said rear portion of said removable cap has an opening for passing therethrough said hook for coupling said removable cap to said elongate element.

5. The surgical apparatus according to claim 1, wherein said elongate element is provided with a recessed inner end wall disposed within said elongate element at said second end, said recessed inner end wall having a slot for passing therethrough said flexible wire.

6. The surgical apparatus according to claim 1, wherein said reciprocating means is a spring disposed within said elongate element, so that when said handle is in the first position, said spring is compressed and said second end of said flexible wire projects from said second end of said elongate element for coupling with the catheter tip, and when said handle is in the second position, said spring is uncompressed and said second end of said flexible wire and the catheter tip are retracted within said second end of said elongate element.

7. The surgical apparatus according to claim 1, wherein

said reciprocating means is a spring disposed outside of said elongate element at said first end of said elongate element, so that when said handle is in the first position, said spring is compressed and said second end of said flexible wire projects from said second end of said elongate element for coupling with the catheter tip, and when said handle is in the second position, said spring is uncompressed and said second end of said flexible wire and the catheter tip are retracted within said second end of said elongate element.

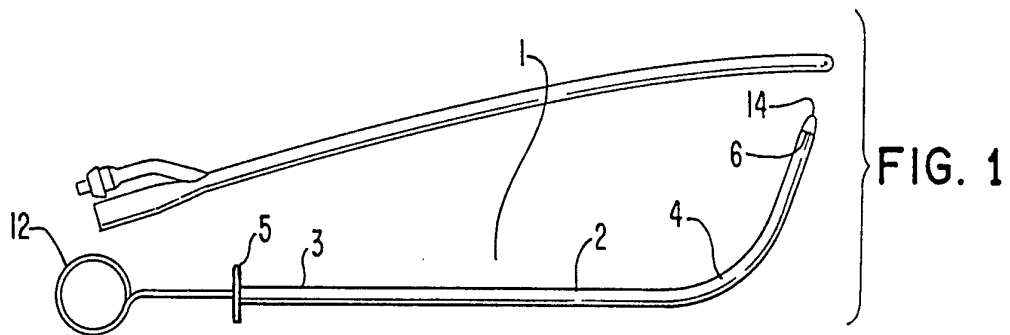


FIG. 2

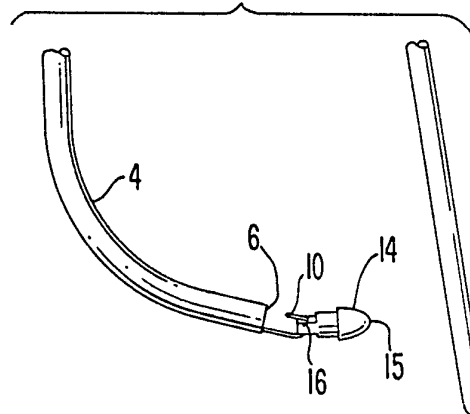


FIG. 3

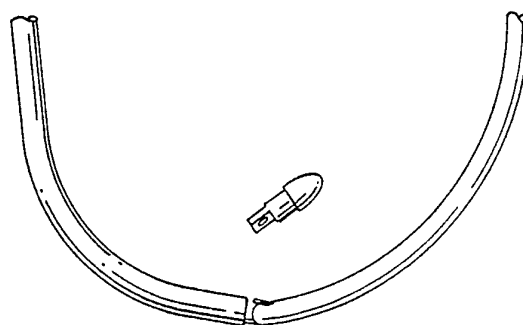


FIG. 4

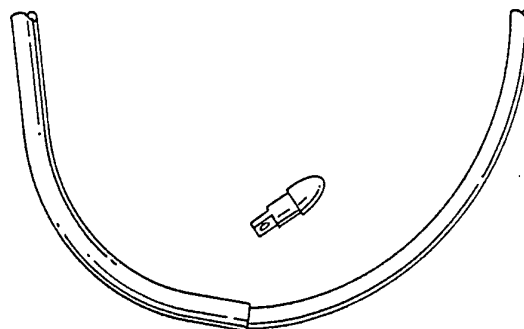


FIG. 5

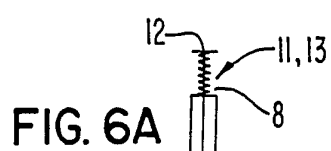
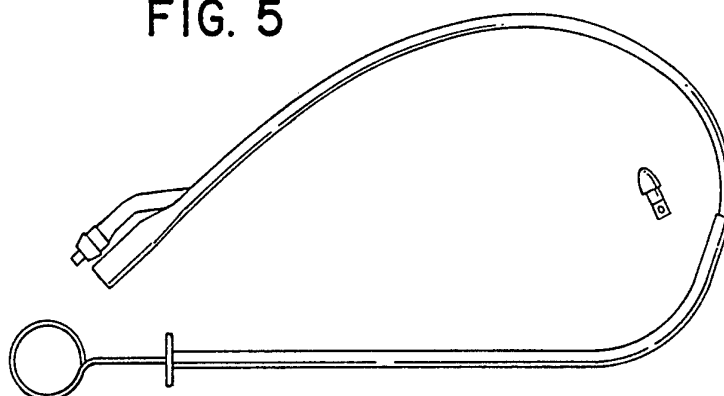


FIG. 6B

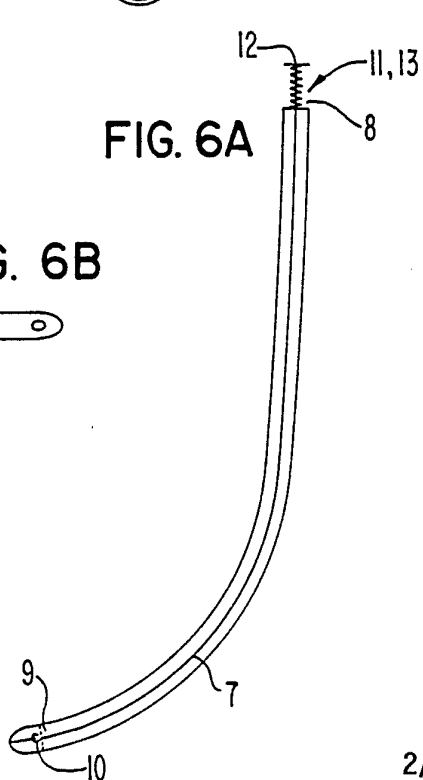


FIG. 7A

FIG. 7B

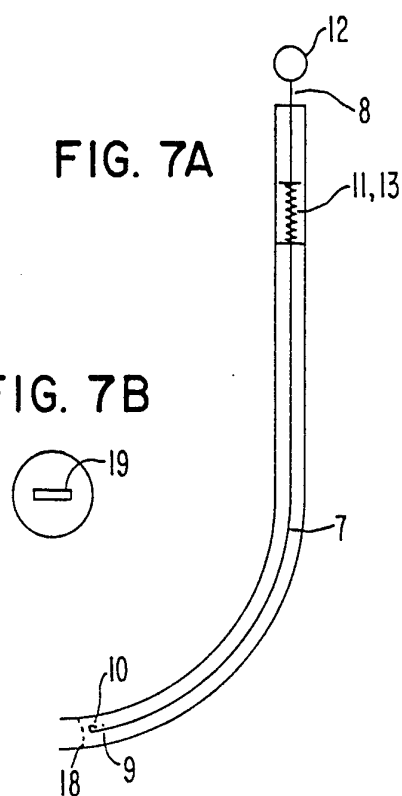


FIG. 8

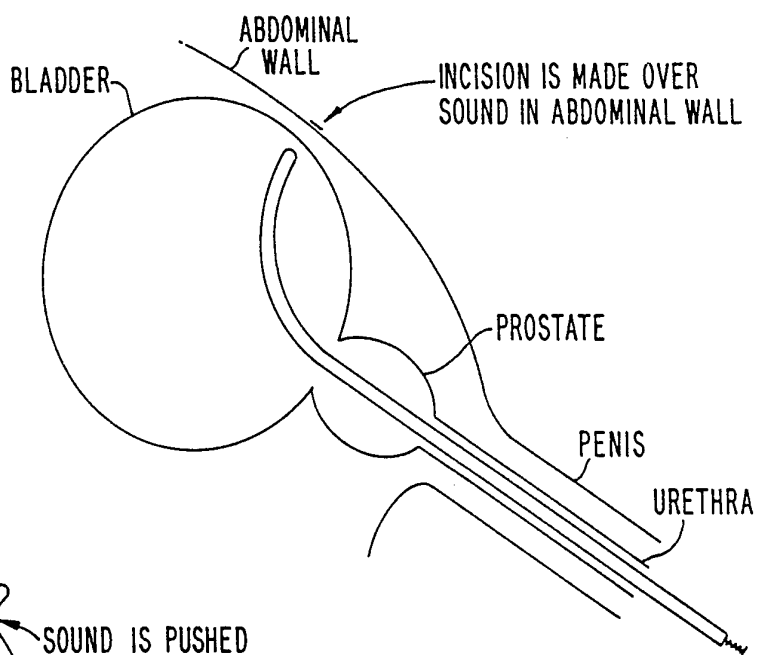


FIG. 9

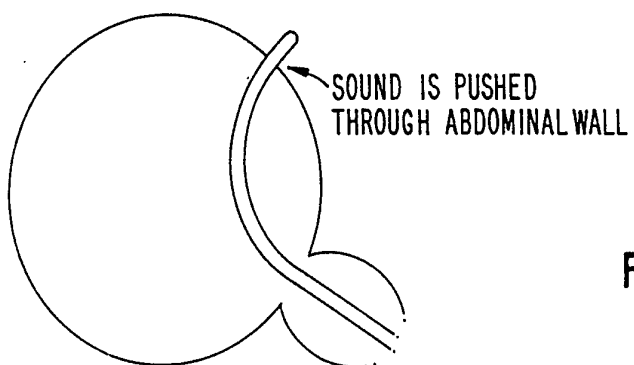
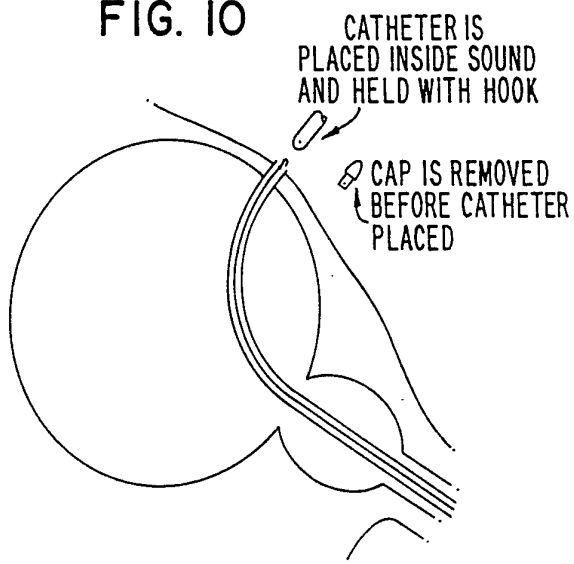
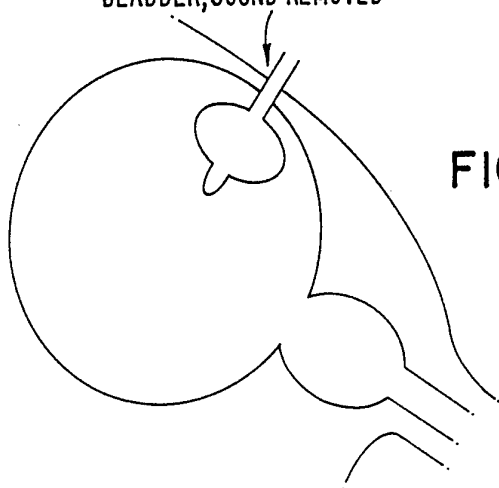


FIG. 10



CATHETER PULLED INTO BLADDER,
RELEASED FROM SOUND BALLOON,
INFLATED TO HOLD IN
BLADDER, SOUND REMOVED

FIG. 11



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US94/04906

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) : A61M 25/00

US CL : 606/108

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/108,106,113,138,205,206

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
noneElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
none**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,865,030 (Polyak) 12 September 1989, see figs. 1 & 2.	1,6,7
Y	US, A, 5,108,406 (Lee) 28 April 1992, see fig. 1-4.	2
A	US, A, 5,098,440 (Hillstead) 24 March 1992.	1-7

☐ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:	*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
A document defining the general state of the art which is not considered to be part of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*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
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)	*Z* document member of the same patent family
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	

Date of the actual completion of the international search

06 SEPTEMBER 1994

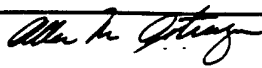
Date of mailing of the international search report

OCT 07 1994

 Name and mailing address of the ISA/US
 Commissioner of Patents and Trademarks
 Box PCT
 Washington, D.C. 20231

Facsimile No. (703) 305-3590

Authorized officer

 For 
 Max Hindenburg

Telephone No. (703) 308-3130