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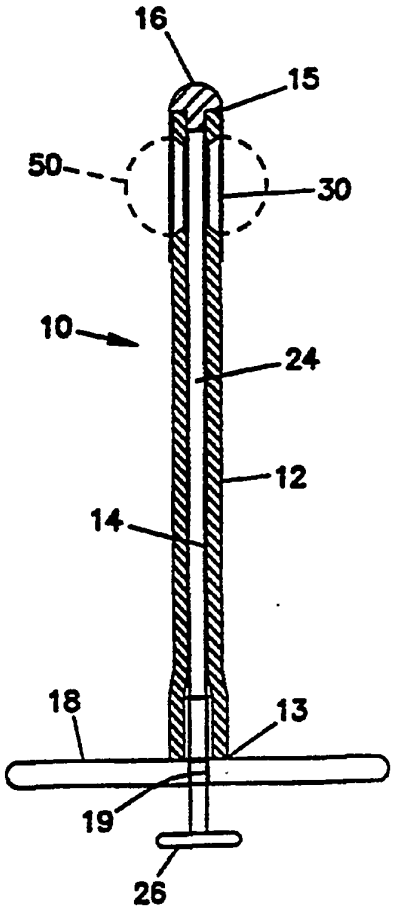
(54) Title: INCONTINENCE TREATMENT

(57) Abstract

An incontinence control apparatus includes a smart polymer expansion member which expands within either the urethra or the bladder to seal fluid flow through the urethra.



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INCONTINENCE TREATMENT

I. BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention pertains to an apparatus and method of treatment for incontinence. More particularly, this invention pertains to a plug for insertion into the urethra to seal fluid flow through the urethra.

2. Description of the Prior Art

Incontinence is defined as the involuntary loss of urine. Incontinence affects a large percentage of the population. For example, among women, incontinence is estimated to affect 25 to 41% of all women. From 6 to 8.3% are so troubled by incontinence that they must wear incontinence absorption pads or the like. See, e.g., "The Urethral Plug: A New Treatment Modality for Genuine Urinary Stress Incontinence in Women", The Journal of Urology, Vol. 144, November 1990, pages 1199-1201.

Numerous apparatus and treatment methods have been developed to address incontinence. For example, U.S. Patent No. 3,372,695 to Belliveau dated March 12, 1968 teaches a plug for insertion in the urethra. The plug includes a retainer member which engages the wall of the bladder. U.S. Patent No. 3,503,400 teaches a urethral valve as does U.S. Patent No. 3,642,004.

U.S. Patent No. 3,841,304 to Jones dated October 15, 1974 teaches an inflatable balloon-like bulb. The bulb end is inserted into the bladder and inflated. The bulb is inflated by a pumping bulb shown as element 18 in Figure 1 of the '304 patent. More recently, U.S. Patent No. 5,030,199 dated July 9, 1991 teaches an incontinence control device with a magnetically operable valve. U.S. Patent No. 5,082,006 to Jonasson dated January 21, 1992 teaches a device to be inserted into the urethra. U.S. Patent No. 5,131,906 to Chen dated July 21, 1992 teaches an incontinence

device for use in males. U.S. Patent No. 5,090,424 to Simon teaches a urethral plug having a expandable chamber.

Urethral plugs seal within the bladder at the entrance to the urethra with the sealing occurring above the sphincter. Alternatively, a urethral plug may seal within the urethra against the urethral wall.

To be effective, urethral plugs should be comfortable and easy to use. Prior art devices such as U.S. Patent No. 3,841,304 require the use of external apparatus to inflate the plug. This requires user manipulation as well as a user determining the degree of inflation. Such requirements for user interaction can result in user error. Further, such devices require manipulation which may be difficult for certain patients due to other physiological factors (for example, arthritis and the like). It is desirable to provide incontinence devices which are easy to use and are automatically actuated to seal.

II. SUMMARY OF THE INVENTION

According to a preferred embodiment of the present invention, an incontinence control apparatus is provided having an expansion member formed at least in part of a material having a rest state and an enlarged swell state. The material is characterized by changing from a rest state to the swell state in response to predetermined characteristics of an environment of the material. The member is inserted at least partially into the urethra and the member expands to its swelled state to block fluid flow through the urethra.

III. BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of an urethral plug according to the present invention;

Fig. 2 is a side cross-section view of the plug of Fig. 1;

Fig. 3 is an enlarged view of a distal end of the plug of Fig. 1;

Fig. 4 is a side sectional view of an alternative plug according to the present invention;

Fig. 5 is an enlarged view of a distal end of the plug of Fig. 4;

Fig. 6 is an end view of the plug of Fig. 4;

Fig. 7 is a side sectional view of a further alternative plug according to the present invention;

Fig. 8 is an enlarged view of a proximal end of the plug of Fig. 7; and

Fig. 9 is an enlarged view of a distal end of the plug of Fig. 7.

IV. DESCRIPTION OF THE PREFERRED EMBODIMENT

With reference now to the various drawing figures in which identical elements are numbered identically throughout, a description of the preferred embodiment to the present invention will now be provided. With initial reference to Figs. 1 through 3, a urethral plug 10 is shown. For the purposes of discussing a preferred embodiment, the urethral plug 10 will be shown with representative sizes and configuration for use in treating female incontinence. It will be appreciated that a urethral plug for male incontinence according to the present invention is also contemplated and can be fabricated according to the teachings of the present invention while changing the relative dimensions necessary to properly size the plug with reference to male anatomy.

The plug 10 includes catheter 12 which is generally tubular in shape and has a hollow bore 14 extending along its axial length. Preferably, catheter 12 is formed of a flexible material which is smooth on its external surfaces to permit insertion of the catheter 12 into the urethra such that the catheter 12 may conform with the shapes of the urethra upon

insertion and with minimized trauma to the urethral wall.

An axial distal end 15 of the catheter 12 is provided with a cap 16 which is secured to the catheter 12. In the preferred embodiment, the catheter has a length of about 2.69 inches. The diameter of the catheter 12 is about .158 inches (12 Fr.).

The proximal end 13 of the catheter is provided with a flange 18. The flange 18 has a hole 19 which is axially aligned with the bore 14.

Approximate the distal end 15 of the catheter, the catheter has a reduced diameter portion 20 (shown best in Fig. 3), such that the wall thickness of the catheter in reduced diameter portion 20 is substantially narrowed.

A flexible push rod 24 extends through the bore 14 and terminates at an end abutting cap 16. The push rod 24 has a handle 26 external of the bore 14 and opposing the flange 18.

The catheter is preferably formed of silicon rubber or polyurethane with a hardness of 20 to 60 durometer such that the catheter is both flexible and stretchable along its axial length. The diameter is 12 french (about 4.0 millimeters).

Best shown in Fig. 3, the reduced diameter portion 20 separates the catheter 12 into an upper portion 21 and a lower portion 23. By pushing handle 26 toward flange 18, the push rod 24 acts against the cap 16. The thin reduced diameter portion 20 stretches in response to this action such that portions 21,23 move apart in response to pushing the rod 24.

An expansion member 30 connects the portions 21,23. Expansion member 30 is substantially tubular surrounding the catheter 12 at the upper portion 21 and surrounding portion 23 as well as surrounding reduced diameter portion 20.

Preferably, the bonding of the member 30 (through adhesive or the like) to the upper portion 21 occurs along a length or bonding area 40 which is preferably 2 to 3 millimeters long and immediately adjacent the reduced diameter portion 20. A terminal end 31 of the expansion member 30 is bonded in a region 42 to lower portion 23. Again, the bonded portion 42 is approximately 2 to 3 millimeters long and immediately adjacent the reduced diameter portion 20.

Figs. 2 and 3 show the expansion member 30 in a rest state in which the expansion member 30 is substantially tubular and of generally equal diameter to the catheter 12. Accordingly, with expansion member 30 in the rest state, the device 10 may be inserted into the urethra without interference.

The expansion member 30 is expandable to an expanded shape shown by phantom lines 50 in Figs. 2 and 3 and shown in Fig. 1. In the expanded shape or swelled shape, the expansion member has a diameter substantially greater than the outside diameter of catheter 12. In the swelled state, the expansion member 30 preferably has an outside diameter of about .59 inches (about 30 french) with a volume of about 2 to 5 cubic centimeters.

The preferred expansion member 30 is formed, at least in part, from a so-called "smart polymer". Smart polymers are recognized in the polymer technologies as polymers which substantially change in volume or dimension in response to changes in the environment of the polymer. Examples of smart polymers are discussed in POLYMER GELS FUNDAMENTALS AND BIOMEDICAL APPLICATIONS, Derossi et al. editors, Plenum Press, New York, New York, 1991. A preferred polymer is polyacrylonitril (PAN) discussed on p. 269 of the aforementioned publication. Further examples are also found in an article entitled "Reports Collapse of Gels in an Electric Field", SCIENCE, Vol. 218, pages 467-469 (1982).

Smart polymers may expand from a rest state to a swelled state showing an increase in volume of one hundred times over the rest state. In the aforementioned article "SCIENCE", the change in volume is activated by a voltage applied to the polymer. However, smart polymers can also show a change in size in response to other environmental factors including temperature, moisture, pH and other factors including the presence of preselected ions (e.g., Na+, K+, C1-). In the preferred embodiment, the smart polymer of expansion member 30 responds to moisture to change from the rest state to the swelled state. The moisture is provided by contact with the urethral wall and the moisture within the urethra or bladder.

Expansion member 30 may be either completely formed of the smart polymer or may be an elastomeric tube having inner woven or encapsulated threads of the smart polymer along its length or helically around the tubular expansion member 30. By encapsulating a smart polymer within an elastomeric tubular expansion member 30, the amount and geometry of the smart polymer may be varied to provide an expansion member 30 having any one of a number of desired characteristics. For example, the amount of expansion and balloon pressure of the swelled expansion member 30 may be varied for a wide variety of sizes and applications of the plug 10. In the preferred embodiment shown in Figs. 1-3, the expansion member 50 expands to an outside diameter of about 30 french. It is believed such an expansion member 30 may seal against 100 mm Hg of water pressure in the urethra.

In the preferred embodiment, the plug 10 is sized such that the catheter 12 may be inserted in the urethra with the flange 18 abutting the urethra meatus (i.e., the entrance to the urethra). The length of the catheter 12 is selected such that the expansion member 30 resides within the bladder at the bladder neck.

Accordingly, when the expansion member 50 expands in response to the environmental conditions within the bladder, the expanded expansion member seals the bladder neck to prevent urine from passing through the urethra. Also, the swelled expansion member 30 within the bladder together with the flange 18 abutting the urethra meatus results in the plug 10 being securely anchored within the urethra.

In addition to the smart polymer of the expansion member 30 being selected to swell in response to any one of a plurality of different environmental conditions, the smart polymer can be selected so that its expansion occurs over a controlled amount of time. For example, the full expansion of the expansion member 30 can be controlled to occur after a predetermined time following insertion (e.g., 10 seconds to 5 minutes).

When a user desires to evacuate, the plug 10 may be removed by simply depressing handle 26 against flange 18. This causes the rod 24 to urge the plug 16 away from the flange 18. In response to this force, the reduced diameter portion 20 stretches resulting in the expansion member 30 being forced against its expanded state back to a tubular state in which the entire plug 10 may be easily removed through the urethra and disposed.

With the invention thus described, the urethra is sealed from urine flow automatically following insertion of the expansion plug 10. There is no need for alternative mechanisms (such as syringes or the like) to expand the member.

Figs. 4-6 show an alternative embodiment of the present invention where a plug 10a includes a catheter 12a secured to a flange 18a. A push rod in the form of a flexible spring 24a is disposed within the catheter bore 14a and terminates at an exposed handle 26a.

The catheter 12a includes an elastomeric expansion end 80 which is a well-known melicot expansion end in the form of four ribs 81. By manipulation of the plug 26a, the elastomeric expansion member 80 stretches to the outside diameter of the catheter 14a or an expanded state as shown in Figs. 4-6.

The expanded member 80 is connected to the catheter 12a by means of a tubular expansion member 30a which is a smart polymer such as expansion member 30 of the embodiment of Fig. 1. With the embodiment of Figs. 4-6, the plug 10a is inserted into the urethra by depressing the handle 26a such that the expanded anchor 80 is of the outside diameter of the catheter 12a.

The plug 10a is inserted into the urethra with the anchor portion 80 positioned within the bladder. Pulling back on the handle 26a, the spring 24a forces the anchor 80 to its expanded state such that the device is anchored within the bladder by reason of anchor 80.

The expansion member 30a responds to moisture or other preselected environmental factors within the urethra to expand to an expanded state shown in the phantom lines 50a. The expansion member 30 then seals against the urethral wall.

Comparing Figs. 1-3 with Figs. 3, 4-6, the embodiment of Figs. 1-3 provides the smart polymer expansion member 30 to both seal and anchor the plug 10. In the embodiment of Figs. 4-6, the plug 10a is anchored within the urethra by means of the mechanical melicot expansion anchor 80 positioned within the bladder. The sealing of the urethra is provided by the expansion member 30a sealing against the urethra wall directly. To remove the embodiment of Fig. 3, the handle 26a is further depressed which both forces both the expansion anchor 80 and the expansion member 30a to the tubular configuration such that the plug 10a may be removed through the urethra.

Figs. 7-9 show a further embodiment 10b. The plug 10b includes an outer catheter 12b having a bore 14b. The proximal end of the catheter is provided with a flange 18b which includes a battery housing 100. The distal end of the catheter includes the smart polymer expansion member 30b. The smart polymer of the expansion member 30b (instead of responding to moisture) responds to an electro-magnetic field provided by a coil 106 connected to the battery 102 housed in housing 100. Electrical leads 103,104 extend from the battery to the coil 106 such that the voltage of the battery 102 may be applied against the coil 106 to generate a magnetic field to expand the polymer to the expanded shape 50b. The polymer of expansion member 30b is positioned within the bladder neck to both anchor and seal. The plug 10b is removed by simply rotating the battery housing 100 about its axis to change the polarity of the battery 102 causing the magnetic field to reverse resulting in the smart polymer 30b to revert to its rest state. A smart polymer which responds to a magnetic field is acid-acrylamide copolymer gel (PAAM) discussed on p. 238 of the aforementioned Polymer Gels Fundamentals publication.

Due to the foregoing detailed description of the preferred embodiments, it has been shown how the objects of the invention have been obtained in the preferred manner. However, modifications and equivalents of the disclosed concepts such as those which readily occur to those skilled in the art are intended to be included within the scope of the present invention.

WHAT IS CLAIMED IS:

1. An incontinence control apparatus comprising:

an expansion member formed at least in part of a material having a rest state and an enlarged swell state, said material changing from said rest state to said swell state in response to predetermined characteristics of an environment of said material;

said member in said rest state sized to be inserted at least into a patient's urethra;

said member in said swell state sized to block fluid flow through said urethra; and

insertion means for inserting said expansion member into said urethra.

2. An apparatus according to claim 1 wherein said insertion means includes stop means to limit insertion of said expansion member into said urethra with a proximal end of said insertion means opposing a patient's urethra meatus.

3. An apparatus according to claim 1 wherein said expansion member includes first and second ends separated by a wall, said first and second ends secured to said insertion means for said first and second ends to be in generally fixed and spaced apart relation.

4. An apparatus according to claim 1 comprising means to deform said expansion member out of said swell state for removal of said member from said urethra.

5. An apparatus according to claim 3 comprising means to force said first and second ends apart to urge said expansion member from said swell state to said rest state.

6. An apparatus according to claim 1 wherein said insertion means is sized for said expansion member to reside in a bladder.

7. An apparatus according to claim 1 wherein said insertion means is sized for said expansion member to reside in said urethra.

8. An apparatus according to claim 1 wherein said predetermined characteristic is a voltage applied to said expansion member material, said apparatus further including a battery electrically connected to said material and switch means for selectively applying said voltage to said material.

9. An apparatus according to claim 1 wherein said material is selected for said predetermined characteristic to be moisture.

10. An apparatus according to claim 1 wherein said predetermined characteristic of said material is selected to be a predetermined level of pH.

11. An apparatus according to claim 1 wherein said material is selected for said predetermined characteristic to be temperature.

12. An apparatus according to claim 1 wherein said material is selected for said predetermined characteristic to be a predetermined ion.

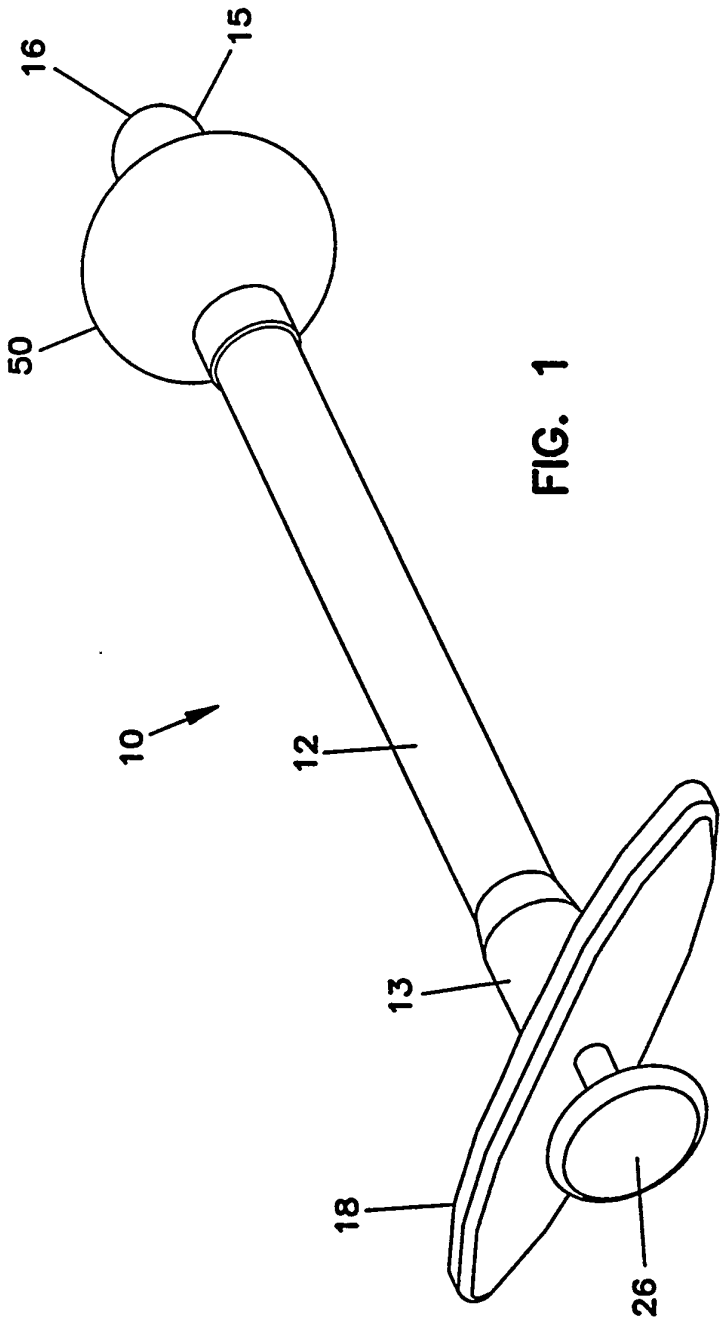

FIG. 1

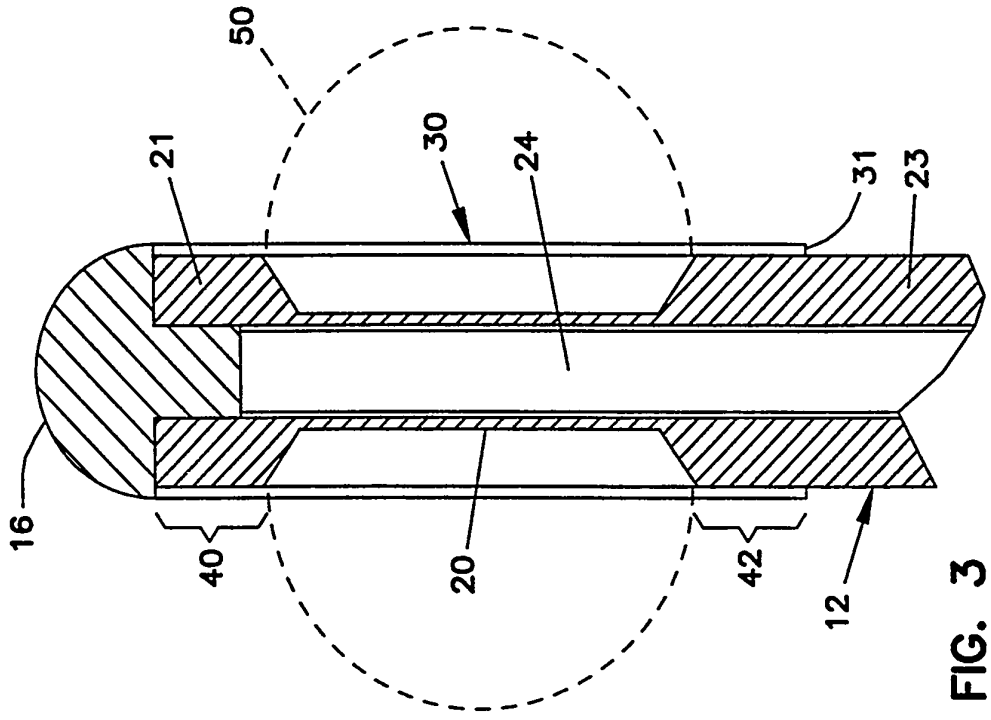

FIG. 3

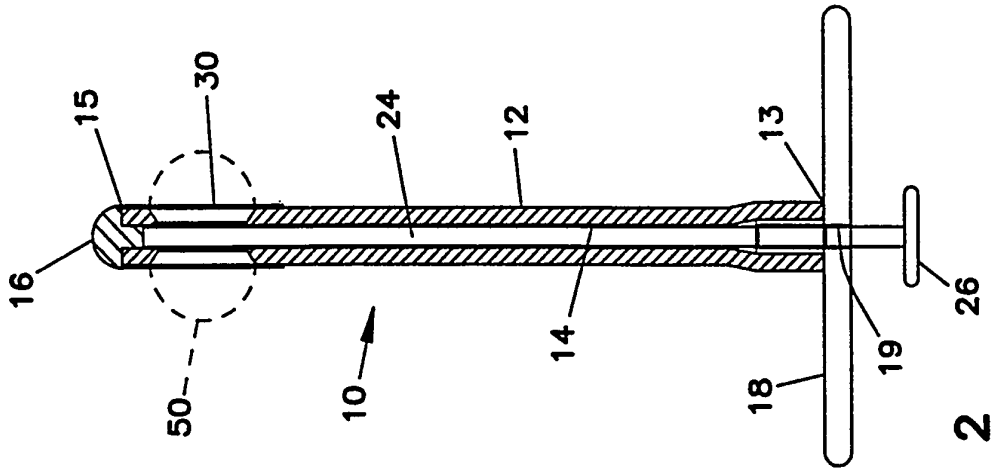

FIG. 2

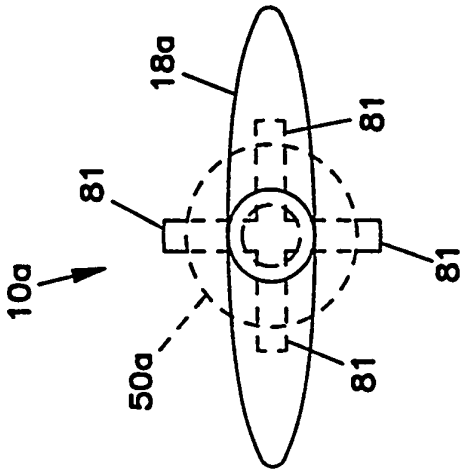

FIG. 6

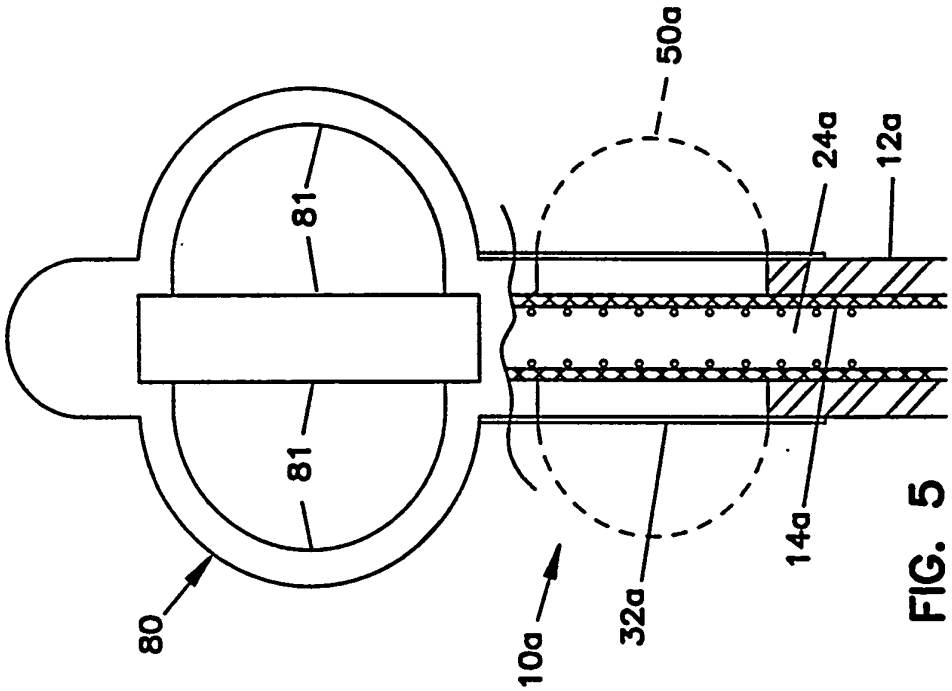

FIG. 5

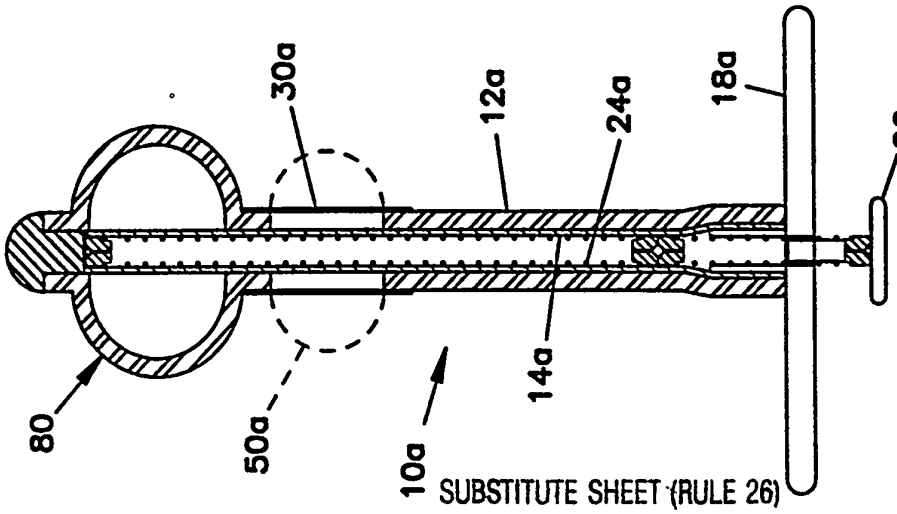

FIG. 4

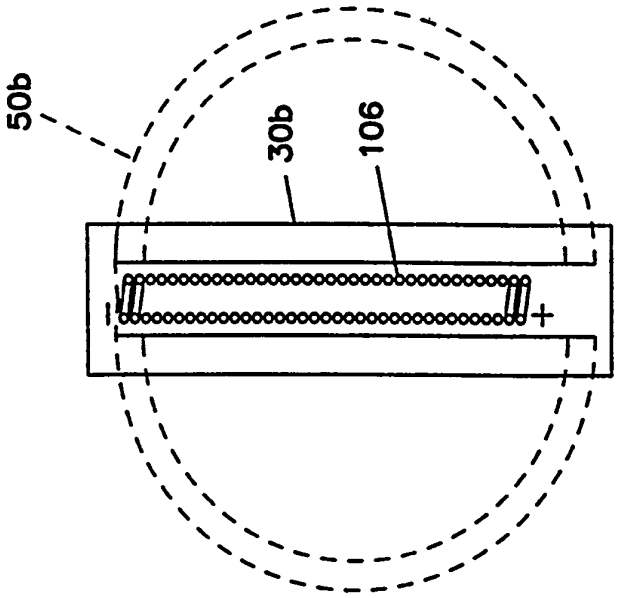

FIG. 9

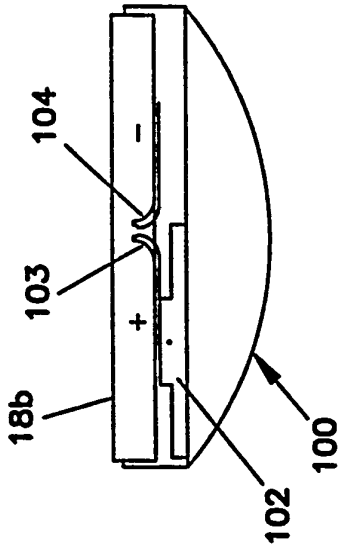

FIG. 8

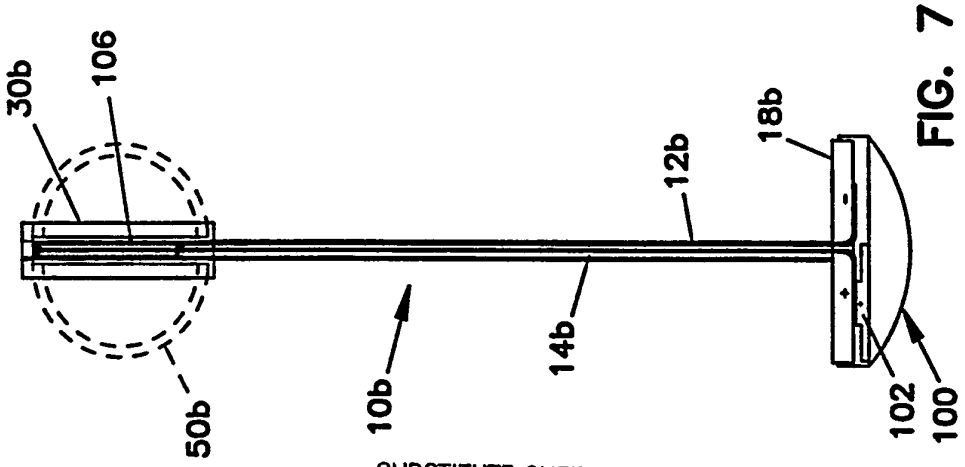

FIG. 7

INTERNATIONAL SEARCH REPORT

Int onal Application No
PCT/US 95/07548

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/00

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)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US,A,5 030 199 (BARWICK ET AL.) 9 July 1991 cited in the application see column 4, line 49 - column 5, line 14; figures 1,2	1-6 8
X	WO,A,92 19192 (COLOPLAST A/S) 12 November 1992 see abstract; figures	1-5,7
X	WO,A,92 11826 (UROMED CO.) 23 July 1992 cited in the application & US,A,5090424 see abstract	1-4,7
X	EP,A,0 193 406 (MEDTRONIC, INC.) 3 September 1986 see the whole document	1-3,7,9

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
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INTERNATIONAL SEARCH REPORT

Int onal Application No
PCT/US 95/07548

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP,A,0 265 207 (VANCE PRODUCTS INC.) 27 April 1988 see abstract; figures 1,2	1,3-7
P,X	WO,A,94 26215 (UROMED CO.) 24 November 1994 see claims 33-46; figures see page 16, paragraph 2	1-7,9-12
Y	US,A,3 642 004 (OSTHAGEN ET AL.) 15 February 1972 cited in the application see abstract; figures 3,4	8
A	US,A,3 447 533 (SPICER) 3 June 1969	

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INTERNATIONAL SEARCH REPORT

Int onal Application No
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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-5030199	09-07-91	AU-B-	634321	18-02-93
		AU-B-	6791590	13-06-91
		BE-A-	1003673	19-05-92
		DE-A-	4038527	13-06-91
		GB-A,B	2238961	19-06-91
		JP-A-	4108445	09-04-92
		NL-A-	9002710	01-07-91
WO-A-9219192	12-11-92	NONE		
WO-A-9211826	23-07-92	US-A-	5090424	25-02-92
		AU-B-	657940	30-03-95
		AU-B-	9166091	17-08-92
		BR-A-	9107193	21-06-94
		CA-A-	2096632	01-07-92
		EP-A-	0565616	20-10-93
		JP-T-	6503982	12-05-94
EP-A-0193406	03-09-86	JP-A-	61247451	04-11-86
EP-A-0265207	27-04-88	AU-B-	7990887	21-04-88
		JP-A-	63177853	22-07-88
WO-A-9426215	24-11-94	AU-B-	6916094	12-12-94
US-A-3642004	15-02-72	NONE		
US-A-3447533	03-06-69	NONE		