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(71) Applicant *(for all designated States except US)*: **MEDILATOR** [IL/IL]; P.O.Box 73, 23100 Migdal Emek (IL).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **CONDREA, Alexander** [IL/IL]; 7 Saleit Street, 34792 Haifa (IL). **VADASZ, Arie** [IL/IL]; 20/12 Hashal Street, 32446 Haifa (IL). **CHIEL, Eliran** [IL/IL]; 18 Granit St., 17906 Shimshit (IL).

(74) Agent: **REINHOLD COHN AND PARTNERS**; P.O.Box 4060, 61040 Tel Aviv (IL).

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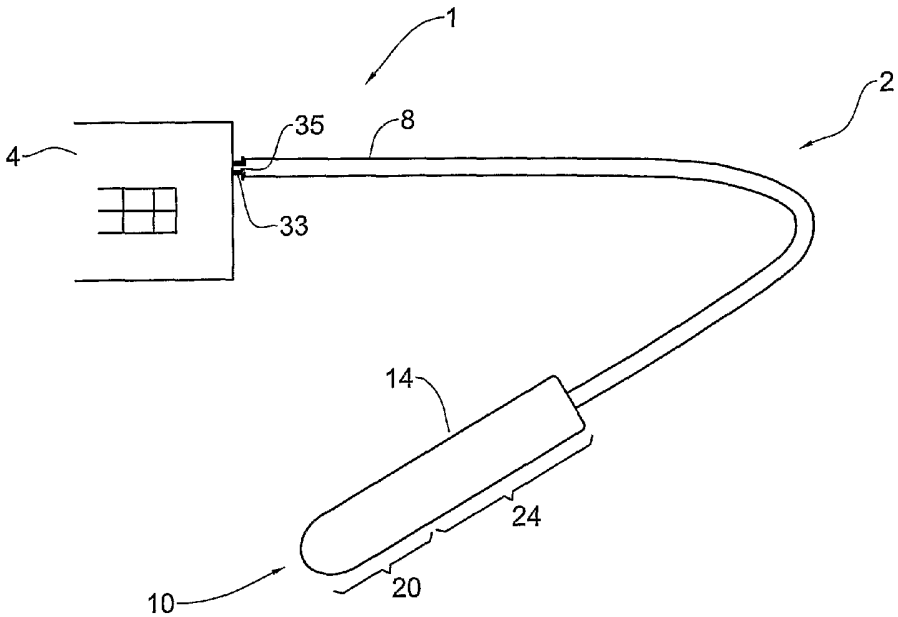
(54) Title: CATHETER AND METHOD FOR DILATING A BODY PASSAGEWAY



(57) Abstract: The invention provides catheter for expanding a body passageway leading to a body cavity, such as a cervix leading to a uterus. The catheter comprises an inflatable balloon located at the distal end of the catheter. The balloon has an anterior portion and a posterior portion. The anterior portion is inflatable prior to inflation of the posterior portion. The invention also provides a system for inflating a body passageway leading to a body cavity comprising the catheter of the invention.

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CATHETER AND METHOD FOR DILATING A BODY PASSAGEWAY

FIELD OF THE INVENTION

This invention relates to devices for dilating a body passageway such as a cervix.

BACKGROUND OF THE INVENTION

There are several situations necessitating the dilation of a body passage way, such as a cervix. For example, it is known to insert into the cervix a series of insertion devices of increasing caliber to achieve a gradual dilation of the cervix. It is also known to insert an absorbent material into the cervix. The material is allowed to absorb a body liquid or other liquid so as to expand, thus dilating the cervix.

It is also known to achieve dilation of the cervix by inserting an uninflated balloon into the cervix and inflating the balloon. Such devices are disclosed, for example, in US Patent No. 4,664,114 to Ghodsian, U.S. Patent No. 3,900,033 to Leininger et al, U.S. Patent No. 4,089,337, to Kronser, and U.S. Pat. No. 4,490,421 to Levy.

SUMMARY OF THE INVENTION

In its first aspect, the present invention provides a system for dilating a body passageway leading to a body cavity. The body passageway may be, for example, a cervix and the body cavity a uterus. The system of the invention comprises a catheter and a control unit **4**. The catheter comprises an elongated shaft having a proximal end connected to the control unit. At the distal end of the shaft is an inflatable balloon. The shaft may be flexible or rigid, as required in

any application. The shaft comprises at least one lumen for delivering a pressurized fluid from the control unit to the balloon for inflating the balloon in order to inflate the passageway. The balloon has an anterior portion and a posterior portion. In accordance with the invention, the pressurized fluid is delivered from the control unit to the balloon via the lumen or lumens of the shaft so as to inflate the anterior portion of the balloon prior to inflation of the posterior portion. The balloon may be of various dimensions (length, diameter, etc.) and shapes (short conical, elongated conical, elliptical, spherical combinations) as required in any application. The balloon may be made from an elastic material which stretches as the balloon is inflated. Alternatively, the balloon may be made from an inelastic flexible material in which case the balloon has a defined maximal volume to which it can be inflated.

In its second aspect, the invention provides a catheter for use in the system of the invention.

In its third aspect, the invention provides a method for dilating a body passageway leading to a body cavity. The body passageway may be, for example, a cervix and the body cavity a uterus. In one embodiment of the method of the invention, the distal end of the catheter is introduced into the body passageway with the balloon uninflated and folded around the shaft. The distal end of the catheter is positioned with the anterior portion in the body cavity. Pressurized fluid is then delivered to the anterior portion only so as to inflate the anterior portion in the body cavity to a diameter that exceeds the diameter of the passageway. After inflation of the anterior portion is completed, the catheter is displaced proximally so as to lodge the inflated anterior portion at the opening of the passageway into the cavity. The anterior portion may be deflated at this point and pressurized fluid delivered to the posterior portion so as to inflate the posterior portion with the anterior portion deflated, or the pressurized fluid may be delivered to the posterior portion to inflate the posterior portion with the anterior portion inflated. As the posterior portion is inflated, the body passageway is dilated.

In another embodiment of the method of the invention, only the anterior portion of the catheter is introduced into a first portion of the passageway with the balloon uninflated and wrapped around the shaft. The anterior portion is then inflated to dilate that specific part of the passageway. Subsequently, the anterior portion is deflated and the catheter is introduced further into the. Then the anterior portion is inflated once again to dilate that specific part of the passageway. The anterior portion is then deflated and the process is repeated until the anterior portion has reached end of the passageway. Then either the entire balloon just the posterior portion of the balloon is inflated to dilate the passageway to a final diameter. The balloon is then deflated and catheter is removed from the passageway.

Thus, in its first aspect, the invention provides a catheter for expanding a body passageway leading to a body cavity, comprising:

(a) an elongated shaft having a proximal end and a distal end, a wall and at least one lumen; and

(b) an inflatable first balloon located at the distal end of the shaft having an anterior portion and a posterior portion;

wherein the anterior portion is inflatable prior to inflation of the posterior portion.

In its second aspect, the invention provides a system for inflating a body passageway leading to a body cavity, comprising:

(a) A catheter of the invention having a first socket on the proximal end of the shaft; and

(b) A control unit having a second socket mating with the first socket; the control unit providing pressurized fluid to a lumen of the shaft when the first socket is attached t the second socket.

In its third aspect, the invention provides a method for dilating a body passageway leading to a body cavity, comprising:

(a) inserting the distal end of a catheter of the invention into the passageway with the first balloon in an uninflated state;

(b) positioning the anterior portion of the first balloon inside the body cavity;

(c) inflating the anterior portion of the first balloon in the body cavity;

(d) displacing the distal end proximally so as to lodge the inflated anterior portion in an opening of the passageway into the body cavity; and

(e) inflating the posterior portion in the passageway so as to expand the passageway.

In its fourth aspect, the invention provides a method for dilating a body passageway leading to a body cavity, comprising:

(a) delivering the anterior portion of a catheter according to any one of Claims 1 to 28 to a segment of the passageway with the first balloon in an uninflated state;

(b) inflating the anterior portion of the first balloon in the segment;

(c) displacing the distal end proximally;

(d) inflating the posterior portion in the passageway; and

(e) repeating steps (b) to (d) as required to achieve a desired dilation of the body passageway.

In its fifth aspect, the invention provides method for determining whether the resistance of a wall of a body passageway at a first location in the passageway is normal comprising:

(a) inserting a distal end of a catheter of the invention into the passageway;

(b) positioning the first balloon at the first location in the passageway;

(c) inflating the balloon; and

(d) determining whether an external pressure exerted by the passageway wall on the inflated balloon is above a predetermined threshold;

an external force exerted on the balloon above the predetermined threshold being indicative of a normal resistance.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in practice, a preferred embodiment will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

Fig. 1 shows a system for dilating a body passageway in accordance with one embodiment of the system of the invention;

Fig. 2 shows a catheter in accordance with one embodiment of the invention;

Fig. 3 shows the control unit of the system of Fig. 1;

Fig. 4 shows a catheter in accordance with another embodiment of the invention;

Fig. 5 shows a catheter in accordance with another embodiment of the invention;

Fig. 6 shows a catheter in accordance with another embodiment of the invention;

Fig. 7 shows a catheter in accordance with another embodiment of the invention;

Fig. 8 shows a catheter in accordance with another embodiment of the invention;

Fig. 9 shows a catheter in accordance with another embodiment of the invention;

Fig. 10 shows a catheter in accordance with another embodiment of the invention;

Fig. 11 shows a catheter in accordance with another embodiment of the invention;

Fig. 12 shows a catheter in accordance with another embodiment of the invention;

Fig. 13 shows a catheter in accordance with another embodiment of the invention;

Fig. 14 shows a method for dilating a body passageway in accordance with one embodiment of the invention;

Fig. 15 shows a method for dilating a body passageway in accordance with another embodiment of the invention;

Fig. 16 shows a catheter in accordance with another embodiment of the invention; and

Fig. 17 shows a catheter in accordance with another embodiment of the invention;

DETAILED DESCRIPTION OF PREFERRED EMBODIMENT OF THE INVENTION

Fig. 1 shows a system **1** for dilating a body passageway leading to a body cavity in accordance with one embodiment of the invention. The system **1** comprises a catheter **2** and a control unit **4**. The catheter **2**, comprises an elongated shaft **6** having a proximal end **8** connected to the control unit **4** and a distal end **10**. At the distal end **10** of the shaft **6** is an inflatable balloon **14**. The shaft **6** may be flexible or rigid, as required in any application. The shaft **6** comprises at least one lumen for delivering a pressurized fluid from the control unit to the balloon **14** for inflating the balloon. The balloon **14** has an anterior portion **20** and a posterior portion **24**. As explained below in relation to the various embodiments of the catheter **2**, the pressurized fluid is delivered from the control unit **4** to the balloon **14** via the lumen or lumens of the shaft **6** so as to inflate the anterior portion **20** prior to inflation of the posterior portion. The anterior portion **20** and the posterior portion **24** may be adjacent to each other along the balloon **14**, or may be separated by an intervening central region. The balloon **14** may be of various dimensions (length, diameter, etc.) and shapes (short conical, elongated conical, elliptical, spherical combinations) as required in any application. The balloon **14** may be made from an elastic material which stretches as the balloon **14** is inflated. Alternatively, the balloon **14** may be made

from an inelastic flexible material in which case the balloon **14** has a defined maximal volume to which it can be inflated.

Fig. 3 schematically shows the control unit **4** in greater detail. The control unit **4** has a socket **33** that mates with a socket **35** at the proximal end **8** of the shaft **6**, for attachment of the shaft **6** to the control unit **4**. The control unit **4** includes a pressure generator **30** for pressurizing a fluid to be delivered to the distal end **10** of the catheter **2**. The fluid may be a gas such as air, or may be a liquid such as water. The pressure generator **30** may be an electric pump located inside the control unit **4**, as shown in Fig. 3. Alternatively, the pressure generator may be an electric pump located outside of the control unit **4**, in order to avoid vibrations in the control unit **4**. In this case, the pressure generator may be located remotely from the control unit **4**. For example, the control unit may be connected via a tube to a tap of a pressurized fluid such as compressed air or water. The pressure generator may also be a manually or foot-operated pump.

The control unit **4** also includes a pressure gauge **32** for monitoring the pressure of the pressurized fluid. The pressure of the fluid may be displayed on a digital display **34**. The control unit **4** may also comprise a regulated heating unit **36** for heating the fluid to a selectable temperature before flowing into the catheter **2**. The selected temperature and/or the actual temperature of the fluid may be displayed on the digital display **34**.

The controller may also be provided with an alarm that generates a sensible signal when the fluid pressure or fluid temperature exceeds a pre-set level. The alarm may be, for example, an audio alarm or a visual alarm, such as a flashing light.

Fig. 14 shows use of the system of the invention for dilation of a body passageway **17** leading to a body cavity **29** in accordance with one embodiment of the method of the invention. The body passageway **17** may be, for example, a cervix and the body cavity **29** a uterus. As shown in Fig. 14a, the distal end **10** of the catheter **2** is introduced into the body passageway **17** with the balloon **14** uninflated and folded around the shaft **6**. The distal end of the catheter **2** is

positioned with the anterior portion **20** in the body cavity **29** to which the passageway **17** leads. Pressurized fluid is then delivered from the control unit **4** to the anterior portion **20** through one or more lumens in the shaft **6** so as to inflate the anterior portion **20** as shown in Fig. 14b. The anterior portion **20** is inflated in the body cavity **29** to a diameter that exceeds the diameter of the body passageway **17**. After inflation of the anterior portion **20** is completed, the catheter **2** is displaced proximally so as to lodge the inflated anterior portion **20** at the opening **37** of the passageway **17** into the cavity **29** as shown in fig. 14c. The anterior portion **20** may be deflated at this point and pressurized fluid delivered to the posterior portion **24** from the control unit **4**, so as to inflate the posterior portion **24** with the anterior portion **20** deflated, as shown in Fig. 14d. Alternatively, pressurized fluid is delivered to the posterior portion **24** so as to inflate the posterior portion **24** with the anterior portion **20** inflated. As the posterior portion **24** is inflated, the body passageway **17** is dilated. Inflation of the posterior portion **24** is terminated when the passageway **17** has attained a predetermined dilation, or when a predetermined external pressure is exerted on the posterior portion **24** by the wall of the passageway **17**. The external pressure may be determined from the pressure of the pressurized fluid (as registered by the pressure gauge **32**) and by the amount of the fluid that has been introduced into the balloon **14**. Inflation of the posterior portion **24** may be done in a gradual fashion with small increments of inflation. The catheter **2** may be pushed distally so that the distal end of the posterior portion **24** is located in the opening **37** before the posterior portion **24** is inflated. By doing so, the entire passageway **17**, including the opening **37** is dilated as the posterior portion **24** is inflated.

In another embodiment of the method of the invention, the anterior portion **20** of the catheter **2** is introduced into a first portion of the passageway **17** with the balloon **14** uninflated and wrapped around the shaft **6**, as shown in Fig. 15a. Then the anterior portion **20** is inflated as shown in Fig. 15b. As a result, that specific part of the passageway **17** is dilated. Subsequently, the anterior portion **20** is deflated and the catheter **2** is introduced further into the passageway

17, for a distance about equal to the length of the anterior portion **20** (Fig. 15c). Then the anterior portion **20** is inflated once again (Fig. 15d). As a result, that specific part of the passageway is dilated. The anterior portion **20** is then deflated and the process is repeated until the anterior portion **20** has reached end of the passageway **17** (Fig. 15e). Then either the entire balloon **14** is inflated or just the posterior portion **24** of the balloon **14** is inflated. The result is a dilation of the passageway **17** to a final diameter.

Then the balloon **14** is deflated and catheter **2** is removed from the passageway **17**.

In one embodiment of the method of the invention, a catheter **2** is first used having a small caliber, in order to obtain a first dilation of the passageway **17** in order to prepare the passageway **17** to receive larger caliber catheter **2** for dilating the passageway **17** to a final dilation. In this case, the final inflated caliber of the small caliber catheter should be around the initial uninflated caliber of the large caliber catheter.

First Embodiment

Fig. 2 shows the distal end **10** of a catheter **2a** that may be used for the catheter **2.** At the tip of the distal end is a blunt protector cap **12** to prevent wounding of a subject during insertion of the distal end **10** into the passageway. Fig. 2a shows the distal end **10** of the catheter **2a** in a perspective view with the balloon **14** collapsed onto the shaft **6**. A constraining ring **16** surrounds the balloon **14** at a central section **22** along the longitudinal axis **20** of the balloon **14**. The constraining ring **16** thus divides the balloon into three sections. The anterior portion **20,** distal to the constraining ring **16,** the central section **22** underlying the constraining ring **16**, and the posterior portion **24** proximal to the constraining ring **16**. Fig. 2b shows a cross section of the tip of the catheter **2a** in greater detail. The shaft **6** is hollow and has a single lumen **28** extending from the control unit **4** to the distal end **10** for conducting pressurized fluid from the control unit **4** to the distal end **10** of the catheter **2** as explained below. The pressurized fluid leaves the lumen **28** of the shaft **6** by means of one or more

holes **26** located in the wall of the shaft **6**. The one or more holes **26** are located only within the anterior portion **20** of the balloon **14**. When pressurized fluid enters the anterior portion **20** through the hole or holes **26**, the anterior portion **20** expands as shown in Fig. 2c. The central portion **22** at this point is prevented from expanding due to the presence of the constraining ring **16**. The constraining ring **16** also prevents flow of the fluid from the anterior portion **20** to the posterior portion **24**.

Once a first predetermined pressure has been attained in the anterior portion **20**, the constraining ring **16** expands slightly, allowing the fluid to flow from the anterior portion **20** to the posterior portion **24**, so that the balloon **14** attains the "*dumbbell*" shape shown in Fig. 2d. The constraining ring **16** may be made, for example, from silicone rubber. Once a second predetermined pressure has been attained in the entire balloon **14**, the constraining ring **16** expands further until the balloon **14** has attained the cylindrical shape shown in Fig. 2e. Inflation of the anterior portion **20** thus occurs prior to inflation of the posterior portion **24**.

The constraining ring **16** may be tethered to the shaft **6** in order to prevent the expanded constraining ring **16** from separating from the catheter after subsequent deflation of the balloon. This may be accomplished, for example, by means of a thin extension over the posterior portion **24**, attaching the constraining ring **16** to the shaft **6** (not shown). The extension may be from the same material as the constraining ring **16**, so as to allow the constraining ring **16** and the extension to be produced in a single molding operation.

Second embodiment

Fig. 4 shows the distal end **10** of a catheter **2b** that may be used in the system **1** for the catheter **2**. The catheter **2b** has several elements in common with the catheter **2a**, and similar elements are indicated by the same reference numeral without further comment.

Fig. 4a shows the distal end **10** of the catheter **2b** in a perspective view with the balloon **14** collapsed onto the shaft **6**. A constraining ring **42** surrounds the balloon **14** at a central section **44** along the longitudinal axis **20** of the balloon **14**. The constraining ring **42** may be made, for example, from silicone rubber. The constraining ring **42** thus divides the balloon into three sections. The anterior portion **20,** distal to the constraining ring **42,** the central section **44** underlying the constraining ring **42**, and the posterior portion **48** proximal to the constraining ring **42**. Fig. 4b shows a cross section of the tip of the catheter **2b** in greater detail. The pressurized fluid leaves the lumen **28** of the shaft **6** by means of the one or more holes **26** located in the wall of the shaft **6** that are located only within the anterior portion **20** of the balloon **14**. When the pressurized fluid enters the anterior portion **20** through the hole or holes **26**, the anterior portion **20** expands as shown in Fig. 4c. The central section **44** at this point is prevented from expanding due to the presence of the constraining ring **42**. The constraining ring **42** also prevents flow of the fluid from the anterior portion **20** to the posterior portion **24**.

As the anterior portion **20** expands, the constraining ring **42** slides proximally allowing a longer portion of the distal end of the balloon **14** to be inflated, as shown in Fig. 4d. This process continues until the constraining ring **42** has completely slid off the balloon **14** onto the exposed portion of the shaft **6,** as shown in Fig. 4e, so that the posterior portion 24 of the balloon 14 is completely inflated. Inflation of the anterior portion **20** thus occurs prior to inflation of the posterior portion **24**.

Third embodiment

Fig. 5 shows the distal end **10** of a catheter **2c** that may be used in the system **1** for the catheter **2.** The catheter **2c** has several elements in common with previously described embodiments of the catheter **2,** and similar elements are identified by the same reference numeral without further comment.

Fig. 5a shows the distal end **10** of the catheter **2c** in a perspective view with the balloon **14** collapsed onto the shaft **6**. A constraining ring **52** surrounds the balloon **14** at a central section **54** along the longitudinal axis **20** of the balloon **14**. The constraining ring **52** thus divides the balloon **14** into three sections. The anterior portion **20** distal to the constraining ring **52**, the central section **54**, and the posterior portion **24** proximal to the constraining ring **52**.

The constraining ring **52** is formed from a filament **58** that is wrapped around the central region **54** of the balloon **14**. The filament **58** may be formed from any biocompatible material used in the manufacture of filaments such as cotton or a metal. The filament **58** is tied in a slip-knot **60**, and the ends **62a** and **62b** extend proximally along the length of the balloon **14** and the shaft **6** to the proximal end of the shaft **6** (not shown).

Fig. 5b shows a cross section of the tip of the catheter **2c** in greater detail. Pressurized fluid leaves the lumen **24** of the shaft **6** by means of the one or more holes **26** located in the wall of the shaft **6** that are located only within the anterior portion **20** of the balloon **14**. When pressurized fluid enters the anterior portion 20 through the hole or holes **26**, the anterior portion **20** expands, as shown in Fig. 5c. The central section **58** at this point is prevented from expanding due to the presence of the constraining ring **52**. The constraining ring **52** also prevents flow of the fluid from the anterior portion **20** to the posterior portion **24**.

After the anterior portion **20** has been inflated to a predetermined size, the constraining ring is removed by pulling on one or both of the ends **62a** and **62b** of the filament **58**. Pulling one or both of the ends **62a** and **62b** releases the slip-knot **60** so that the filament **58** may be removed. Removal of the constraining ring **58** allows the pressurized fluid previously restricted to the anterior portion **20** of the balloon **14** to enter the central section **54** and the posterior portion **24** of the balloon as indicated in Fig. 5d. Additional fluid may then be delivered to the balloon **14** until the balloon **14** is completely inflated as shown in Fig. 5e. Inflation of the anterior portion **20** thus occurs prior to inflation of the posterior portion **24**.

Fourth embodiment

Fig. 6 shows the distal end **10** of a catheter **2d** that may be used in the system **1** for the catheter **2.** The catheter **2d** has several elements in common with the previously described embodiments of the catheter **2** and similar elements are identified by the same reference numeral without further comment.

The distal end **10** of the catheter **2d** comprises an inner balloon **50** located in the interior of the balloon **14** and confined to the anterior portion **20** of the balloon **14.** Inflation of the inner balloon **50** expands the anterior portion of the balloon **14.** The inner balloon **50** may be, for example, spherical in shape when inflated but it may have any shape (e.g. cylindrical) and dimensions (various diameters and/or lengths) as well as compliant properties as required in any application.

The shaft **6** of the catheter **2d** has two lumens **63** and **64.** The lumen **63** conducts the pressurized fluid from the control unit **4** to the inner balloon **50** via a hole **64** in the wall of the shaft **6'.** The second lumen **64** conducts the pressurized fluid from the control unit **4** to the posterior portion **24** of the balloon **14** balloon **14** via a hole **66** after inflation of the anterior portion **20.** Inflation of the anterior portion **20** thus occurs prior to inflation of the posterior portion **24.**

Fifth embodiment

Fig. 7 shows the distal end of a catheter **2f** that may be used in the system **1** for the catheter **2.** The catheter **2f** has several elements in common with the previously described embodiments of the catheter **2** and similar elements are identified by the same reference numeral without further comment.

In the catheter **2f,** the shaft **6** delivers the pressurized fluid from the control unit **4** to the lumen of an inner balloon **61** through the hole **26.** The inner balloon **61** is located in the interior of the balloon **14** and confined to the anterior portion **20** of the balloon **14.** As shown in Fig. 7a, the pressurized fluid may be delivered to the lumen of the inner balloon **61** so as to inflate the inner balloon

61, thereby inflating the anterior portion **20** of the balloon **14**. Pressurized fluid continues to be delivered to the inner balloon **60** until the pressure inside the first balloon exceeds a predetermined level at which the inner balloon **60** bursts.

When the inner balloon **61** bursts (Fig. 7b), the fluid previously contained in the lumen of the inner balloon **61** is released into the entire lumen of the balloon **14**. Pressurized fluid continues to be delivered into the lumen of the balloon **14** from the control unit **4** through the lumen of the shaft **6** via the hole **26**, so as to continue the inflation of the outer balloon **14**. Inflation of the anterior portion **20** thus occurs prior to inflation of the posterior portion **24**.

Sixth embodiment

Fig. 8 shows the distal end **10** a catheter **2g** that may be used in the system **1** for the catheter **2**. The catheter **2g** has several elements in common with the previously described embodiments of the catheter **2** and similar elements are identified by the same reference numeral without further comment.

Two inner balloons **80** and **82** are contained in the interior of the balloon **14** and confined to the anterior portion **20** of the balloon **14**. The inner balloon **80** is smaller in diameter when inflated than the inner balloon **82**. The catheter **2g** has a shaft **6″** containing three lumens **84**, **86** and **88**. The lumen **84** delivers the pressurized fluid to the inner balloon **80** via a hole **90**. The lumen **86** delivers the pressurized fluid to the inner balloon **82** via the hole **92**. Sequential inflation of the inner balloon **80** followed by inflation of the inner balloon **82** provides controlled inflation of the anterior portion **20** of the balloon **14**. Following inflation of the anterior portion **20** of the balloon **14**, the posterior portion **24** may be inflated via the lumen **88**. Inflation of the anterior portion **20** thus occurs prior to inflation of the posterior portion **24**.

Seventh embodiment

Fig. 10 shows the distal end **10** of a catheter **2h** that may be used in the system **1** for the catheter **2**. The catheter **2h** has several elements in common

with the previously described embodiments of the catheter **2** and similar elements are identified by the same reference numeral without further comment.

In the catheter **2h**, the shaft **6** has two lumens **66** and **68**. The lumen **68** delivers pressurized fluid to each of a plurality of inner balloons **85** located in the interior of the balloon **14**. 8 inner balloons **85**a to **85**h are shown in Fig. 10. This is by way of example only, and the catheter **2h** may have any number of inner balloons **85** as required in any application. Each of the inner balloons **85**a to **85**h receives pressurized fluid from the lumen **68** via the holes **70** to **70**h, respectively. At least the most anterior balloon (**85a**) is located in the anterior portion **20** of the balloon **14** so that the anterior portion **20** may be inflated prior to inflation of the posterior portion **24**. The dimensions (diameter and/or length) of the inner balloons **85** may be selected as required in any application. In Fig. 10a, the inner balloons **85** are identical in size and shape. In Fig. 10b, the balloons **85** have equal longitudinal lengths but form a conical shape when inflated that tapers towards the distal end **10** of the catheter **2h**. The inflation of the balloons **85** may occur simultaneously via the lumen **68** or sequentially via a single lumen in the shaft but with a fluid conducting system that selectively permits sequential filling of the internal balloons **85**. As shown in Fig. 10b, the fluid conducting mechanism may comprise, for example, a rod **72** inserted into the lumen **68**. Initially, the rod extends to the distal end of the catheter **2h**, so as to block all of the holes **70** (Fig. 10b). As the rod **72** is withdrawn proximally in the lumen **68**, the holes **70**a to **70**h are sequentially opened so as to allow sequential filling of the balloon s **85a** to **85h.** Alternatively, a single balloon **85** may be attached to the shaft **6** intermittently with bands **74** that divide the balloon **85** into compartments **78**. Fluid is delivered via a single hole **76** in the wall of the shaft **6.** When the pressure in the compartment **78a** exceeds a predetermined pressure, the band **74a** ruptures allowing inflation of the two most anterior compartments **78a** and **78b**. This process continues with the sequential rupturing of the bands **74b** to **74g**, until the inner balloon is completely inflated. After inflation of the inner balloon or balloons **85**, the posterior portion **24** of the

balloon **14** is inflated by delivering pressurized fluid to the balloon **16** via the lumen **66** and a hole **67**. Inflation of the anterior portion **20** thus occurs prior to inflation of the posterior portion.

The catheter **2h** may be used to expand a body passageway when a differential dilatation is needed at different parts of the passageway.

Eighth embodiment

Fig. 11 shows the distal end of a catheter **2j** that may be used in the system **1** for the catheter **2**. The catheter **2j** has several elements in common with the previously described embodiments of the catheter **2** and similar elements are identified by the same reference numeral without further comment.

In the catheter **2j**, the shaft **6** has two lumens **94** and **96** which deliver pressurized fluid from the control unit **4** to the balloon **14**. A shallow circular groove **91** is formed in the shaft **6**. The groove **91** accommodates a ring **84** surrounding the balloon **14**. The ring **84** separates the anterior portion **20** of the balloon **14** and the posterior portion **24** of the balloon **14**. The ring **84** fits tightly over the balloon **14** so that fluid cannot flow between the anterior and posterior portions of the balloon **14**. The anterior portion **20** of the balloon **24** is inflatable by means of the lumen **9** and hole **97a**, while the posterior portion **24** is inflatable by means of the lumen **96** and the hole **97b**. The anterior and posterior portions **20** and **24** are thus individually inflatable. Inflation of the anterior portion **20** thus occurs prior to inflation of the posterior portion.

Ninth embodiment

Fig. 12 shows the distal end of a catheter **2k** that may be used in the system **1** for the catheter **2**. The catheter **2k** has elements in common with the previously described embodiments for the catheter **2**, and similar components are identified by the same reference numeral without further comment.

In the catheter **2k**, the shaft **6** has a single lumen **86** that conducts the pressure of fluid from the control unit **4** to the balloon **14**. A first hole **88** is

located at the tip of the shaft **6** that is larger than a second hole **89** located in the wall of the shaft **6.** A shallow groove is formed in the wall of the shaft **6** between the holes **88** and **89.** A ring **96** separates the anterior portion **20** and the posterior portion **24** the balloon **14.** The posterior portion **24** may be inflated via the lumen **86** only through the hole **89.** Due to the presence of the ring **96,** no fluid can pass between the anterior and posterior portions of the balloon **14.** As shown in Fig. 12a, initially, a plurality of spherical beads **96** are located inside the lumen **86.** The beads **96** are made from a compressible material such as rubber. The diameter of the uncompressed beads **96** is slightly larger than the inner diameter of the lumen **86.** Therefore, when the beads **96** are inserted into the lumen **86** the beads **96** are somewhat compressed so that the lumen **86** is blocked so as to prevent the flow of the pressurized fluid in the distal end of the lumen **86** and thus preventing inflation of either the anterior portion of the posterior portion. The anterior portion **20** is inflated by introducing the spheres **96** into the anterior portion **20** of the balloon **14** by delivering the pressurized fluid into the lumen **86** so as to ram the spheres **96** distally into the anterior portion **20,** as shown in Fig. 12b. The number of the beads **96** is selected to be slightly more than the number of beads required to completely fill and inflate the anterior portion **20.**

Fluid delivery is stopped when the last bead **97** is located just proximally to the hole **89** so that the posterior portion **24** cannot be inflated as the hole **89** is blocked. When it is desired to inflate the posterior portion **24,** an additional volume of the pressurized fluid is delivered into the lumen **86** to push the bead **97** distally beyond the hole **89,** as shown in Fig. 12c, so as to allow inflation of the posterior portion **24.** Inflation of the anterior portion **20** thus occurs prior to inflation of the posterior portion **24.** The margins of hole **88** diverge as shown in Fig. 12 to allow recovery of the beads **96** from the anterior portion **20** back into the lumen **86** when needed.

In the catheter **2k,** the beads **96** may be replaced by a cord formed from a compressible material having a diameter slightly larger than the diameter of the lumen **86.** The length of the cord is determined so that the cord has a volume

slightly larger than the volume needed to inflate the anterior portion **20.** A plunger may be used instead of the pressurized fluid to push the cord from the lumen **86** into the anterior portion **20** (not shown).

In the catheter **2k,** the beads **96** may be replaced with a colloidal suspension of particulate material. In this case the hole **89** is replaced with a plurality of pores small enough to prevent passage to the colloidal particles through the wall of the shaft. A plunger may be used to deliver the suspension from the lumen **86** to the anterior portion **20** (not shown).

Tenth embodiment

Fig. 9a shows the distal end of a catheter **2m** that may be used in the system **1** for the catheter **2.** The catheter **2m** has several elements in common with previously described embodiments of the catheter **2,** and similar elements are identified by the same reference numeral without further comment.

In the catheter **2m,** the shaft **6** has a single lumen **46.** Pressurized fluid is delivered to the anterior portion **20** via a hole **48** at the end of the shaft **6** and is delivered to the posterior portion **24** via a hole **49.** The anterior and posterior portions are completely separated by a ring **56.** When the filling process starts, pressurized fluid is delivered to the distal end of the lumen **46.** The hole **48** is larger than the hole **49.** The anterior chamber **20** is thus inflated faster than the posterior chamber **24.** Moreover, because the volume of the anterior portion **20** is much smaller than that of the posterior chamber, the difference of the filling times of the anterior and posterior portions is sufficiently large that the anterior portion **20** is essentially inflated prior to inflation of the posterior portion **24.** The differential of the inflation rates of the two compartments is described in the graph shown in Fig. 9b. The initial filling pressure in Fig. 9b is relatively low (i.e. the pressure P_1) until the anterior portion **20** is fully inflated. The filling pressure is then increased (e.g. any one of the pressures P_2, P_3, P_4, P_5 in Fig. 9b) in order to accelerate the inflation of the posterior portion **24.**

Eleventh embodiment

Fig. 13 shows a catheter **2n** that may be used in the system **1** for the catheter **2**. The catheter **2n** has several elements in common with previously described embodiments of the catheter **2** and similar components are identified with the same reference numeral without further comment.

In the catheter **2n**, the shaft **6** has a single lumen **9.** The anterior portion **20** and the posterior portion **24** of the balloon **24** are separated by a ring **15**, so that the pressurized fluid cannot flow between the anterior and posterior portions. The pressurized fluid is delivered to the anterior portion **20** and the posterior portion **24** from the lumen **9** via holes **11** and **13**, respectively.

At the proximal end of the shaft **6** are two openings. A side opening **19** is provided with the socket **35** for attachment to the socket **33** of the control unit **4.** An end opening **21** receives a plunger **23**, as shown in Fig. 13b. The plunger **23** has a bulge **25** at its distal end. The bulge **25** has a canal **27** passing through it (Fig. 13c).

The rod **23** is initially positioned so that the bulge **25** covers and blocks the hole **13.** Pressurized fluid is delivered to the anterior portion **20** via the hole **11** and the canal **27**. After the anterior portion **20** has been inflated, the piston **23** is pulled back so as to uncover the hole **13** so that the pressurized fluid can pass via the canal **27** and the hole **13** into the posterior portion **24** so as to inflate the posterior portion **24**. Inflation of the anterior portion **20** thus occurs prior to inflation of the posterior portion **24**.

Twelfth embodiment

Fig. 16 shows a catheter **2o** that may be used in the system **1** for the catheter **2.** The catheter**2o** has several components in common with previously described embodiments of the catheter **2,** and similar elements are identified with the same reference numeral without further comment.

As shown in Fig. 16a, the balloon **14** is initially enfolded and wrapped around the shaft **6** which has a single lumen **101.** The balloon **14** is located in a lumen **100** of an outer sleeve **102.** The shaft **6** has a bulb **106** that fills the lumen of the sleeve **102** but enables relative movement of the shaft **6** and the outer

sleeve **102.** The pressurized fluid is delivered from the control unit **4** through the lumen **101** via a hole **108** in the shaft **6** to the balloon **14.**

In order to inflate the anterior portion **20** of the balloon **14,** the outer sleeve **102** is pulled proximally relative to the shaft **6** so as to cause only the anterior portion **20** of the balloon **14** to be exposed at the distal end of the catheter **20,** as shown in Fig. 16b. In this configuration, delivery of the pressurized fluid will inflate only the exposed anterior portion **20,** while the posterior portion **24** is prevented from inflating due to the presence of the sleeve **102** (Fig. **16**c).

In order to inflate the posterior portion **24** of the balloon **14,** the sleeve **102** is pulled proximally relative to the shaft **6** so as to expose the posterior portion **24.** As the pressurized fluid continues to be delivered to the balloon **14** in this configuration, the posterior portion **24** inflates, as shown in Fig. 16d. Inflation of the anterior portion **20** thus occurs prior to inflation of the posterior portion.

Thirteenth embodiment

Fig. 17 shows a catheter **2p** that may be used in the system **1** for the catheter **2.** The catheter **2p** has several components in common with previously described embodiments of the catheter **2,** and similar elements are identified with the same reference numeral without further comment.

In the catheter **2p,** the shaft **6** has a single lumen **116.** As shown in Fig. 17a, the pressurized fluid enters the balloon **14** from a hole **110** located at the distal end of the shaft **6** and the proximal end of the balloon **14.** The balloon **14** is folded onto the shaft **6** by pushing the shaft proximally into the balloon **14** so that the distal end of the shaft **6** enters the anterior portion **20,** as shown in Fig. 17b. In this configuration, the anterior portion **24** is folded on itself, while the proximal portion **20** extends beyond the distal end of the shaft **6.** An external sleeve **114** may be used to maintain the balloon **14** in this configuration during insertion of the balloon **14** into the body passageway.

After insertion of the balloon **14** into the passageway, the sleeve **114,** if present, is withdrawn proximally. The anterior portion **20** is then inflated by delivering the pressurized fluid to the anterior portion **20** through the lumen **116** of the of the shaft **6** via the hole **110**, as shown in Fig. 17c. The shaft **6** is then withdrawn proximally so as to bring the distal end of the shaft **6** into the posterior portion **24**, as shown in Fig. 17d. Pressurized fluid is then delivered to the posterior portion **24** via the hole **110** as shown in Fig. 17e. Inflation of the anterior portion **20** thus occurs prior to inflation of the posterior portion.

Fourteenth embodiment

Fig. 18 shows a catheter **2q** that may be used in the system **1** for the catheter **2.** The catheter **2q** has several components in common with previously described embodiments of the catheter **2,** and similar elements are identified with the same reference numeral without further comment.

In the catheter **2q**, the shaft **6** has a single lumen 120 that delivers the pressurized fluid to the balloon **14** via one or more holes **26.** the balloon 14 is initially folded around the shaft **6.** The posterior portion **24** is contained inside a cylindrical sleeve **122.** The sleeve **120** is made from an inelastic flexible material, and may be made from the same material as the balloon. The sleeve **120** has a final diameter that is sufficiently large to contain the enfolded posterior portion **24** of the balloon **14.** The sleeve **120** cannot be stretched beyond the final predetermined diameter. Therefore, when the posterior portion **24** of the balloon **14** is located inside the sleeve, its inflation is strictly limited by the final diameter of the sleeve **120.** The anterior portion **20** can be inflated without any limitation imposed by the sleeve, as shown in Fig. 18c. After the anterior portion **20** is inflated the sleeve **120** is withdrawn proximally, as shown in Fig. 18d. The posterior portion **24** of the balloon **14** is now freed from the sleeve **120** and maybe inflated without any limitation other than resistance of the passage, and the final predetermined diameter of the balloon **14,** as shown in Fig. 18d.

CLAIMS:

1. A catheter for expanding a body passageway leading to a body cavity, comprising:

(a) an elongated shaft having a proximal end and a distal end, a wall and at least one lumen; and

(b) an inflatable first balloon located at the distal end of the shaft having an anterior portion and a posterior portion;

wherein the anterior portion is inflatable prior to inflation of the posterior portion.

2. The catheter according to Claim 1 wherein the shaft has one lumen.

3. The catheter according to Claim 1 wherein the shaft has two lumens.

4. The catheter according to any one of the previous claims wherein the anterior and posterior portions of the first balloon are separated by a ring surrounding the balloon.

5. The catheter according to Claim 4 wherein the ring prevents passage of fluid between the anterior portion and the posterior portion when a fluid pressure in the anterior portions is below a predetermined pressure.

6. The catheter according to Claim 5 wherein the shaft has a single lumen and a hole in the wall of the shaft for inflating the anterior portion.

7. The catheter according to Claim 5 or 6 wherein the ring expands when the fluid pressure in the anterior pressure is above the predetermined pressure.

8. The catheter according to Claim 5 or 6 wherein the ring slides distally over the first balloon when the fluid pressure in the anterior pressure is above the predetermined pressure.

9. The catheter according to Claim 5 or 6 wherein the ring is formed from a cord wrapped around the first balloon, the cord being detachable from the first balloon by pulling on an end of the cord.

10. The catheter according to any one of Claims 1 to 3 comprising a second balloon located in the anterior portion of an interior of the first balloon.

11. The catheter according to Claim 10 wherein the shaft has a first lumen in fluid communication with the interior of the second balloon and a second lumen in fluid communication with the interior of the posterior portion of the balloon.

12. The catheter according to Claim 10 wherein the shaft has a lumen in fluid communication with the second balloon, the second balloon bursting when a fluid pressure in the second balloon exceeds a predetermined pressure.

13. The catheter according to Claim 1 comprising a second balloon and a third balloon, the second and third balloons being located in the interior of the first balloon, wherein the shaft has a first lumen in fluid communication with the interior of the second balloon, a second lumen in fluid communication with the third balloon, and a third lumen in fluid communication with the posterior portion of the first balloon.

14. The catheter according to Claim 1 comprising a plurality of inner balloons located in the interior of the first balloon, at least an anterior most of the inner balloons being located in the anterior portion of the first balloon, the shaft having a first lumen in fluid communication with each of the inner balloons and having a second lumen in fluid communication with the posterior portion of the first balloon.

15. The catheter according to Claim 14 further comprising a rod dimensioned to be slidable in the first lumen and to prevent passage of fluid from the first lumen into one or more of the inner balloons.

16. The catheter according to Claim 1 comprising a second balloon in the interior of the first balloon, at least a portion of the second balloon being located in the anterior portion of the first balloon, the second balloon being divided into compartments by bands surrounding the second balloon, the shaft having a lumen in fluid communication with an anterior most compartment.

17. The catheter according to Claim 16 wherein a band bursts when a fluid pressure in a compartment adjacent to the band is greater than a predetermined fluid pressure.

18. The catheter according to Claim 1 wherein the shaft has a lumen having a first hole in the anterior portion and a second hole in the posterior portion, and further comprising beads dimensioned to fit in the lumen and to pass through the first hole and not to pass through the second hole, the beads inflating the anterior portion when introduced into the anterior portion.

19. The catheter according to Claim 18 further comprising a rod for ramming the beads into the anterior portion.

20. The catheter according to Claim 18 or 19 wherein a bead in the lumen in contact with the second hole blocks the second hole preventing flow of fluid from the lumen into the posterior portion.

21. The catheter according to Claim 1 wherein the shaft has a lumen having a first hole in the anterior portion and a second hole in the posterior portion, and further comprising a cord dimensioned to fit in the lumen and to pass through the first hole and not to pass through the second hole, the cord inflating the anterior portion when introduced into the anterior portion.

22. The catheter according to Claim 21 further comprising a rod for ramming the cord into the anterior portion.

23. The catheter according to Claim 21 or 22 wherein the cord blocks the second hole preventing flow of fluid from the lumen into the posterior portion.

24. The catheter according to claim 1 wherein the shaft has a lumen having a first opening in the anterior portion and a second opening in the posterior portion, the first opening being larger than the second opening.

25. The catheter according to Claim 1 wherein the anterior portion and the second portion are separated by a ring preventing flow of fluid between the anterior portion and the posterior portion, and wherein the shaft has a lumen having a first hole in the anterior portion and a hole in the posterior portion, the catheter further comprising a rod having a piston slidable in the lumen, the piston having a canal for transfer of fluid through the piston, the piston preventing flow of fluid from the lumen into the posterior portion when the piston covers the second hole.

26. The catheter according to Claim 1 having an outer sleeve slidable from a first position in which the posterior portion of the balloon is contained in the sleeve and a second position in which the posterior portion of the balloon is not contained in the sleeve.

27. The catheter according to Claim 26 wherein the sleeve is made from an inelastic flexible material.

28. The catheter according to Claim 1 wherein the shaft has a single lumen and the shaft terminates at the distal end of the balloon.

29. The catheter according to any one of the previous claims wherein the body passage is a cervix.

30. A system for inflating a body passageway leading to a body cavity, comprising:

(a) A catheter according to any one of the previous claims having a first socket on the proximal end of the shaft; and

(b) A control unit having a second socket mating with the first socket; the control unit providing pressurized fluid to a lumen of the shaft when the first socket is attached t the second socket.

31. A method for dilating a body passageway leading to a body cavity, comprising:

(a) inserting the distal end of a catheter according to any one of claims 1 to 29 into the passageway with the first balloon in an uninflated state;

(b) positioning the anterior portion of the first balloon inside the body cavity;

(c) inflating the anterior portion of the first balloon in the body cavity;

(d) displacing the distal end proximally so as to lodge the inflated anterior portion in an opening of the passageway into the body cavity; and

(e) inflating the posterior portion in the passageway so as to expand the passageway.

32. A method for dilating a body passageway leading to a body cavity, comprising:

(a) delivering the anterior portion of a catheter according to any one of Claims 1 to 29 to a segment of the passageway with the first balloon in an uninflated state;

(b) inflating the anterior portion of the first balloon in the segment;

(c) displacing the distal end proximally;

(d) inflating the posterior portion in the passageway; and

(e) repeating steps (b) to (d) as required to achieve a desired dilation of the body passageway.

33. A method for determining whether the resistance of a wall of a body passageway at a first location in the passageway is normal comprising:

(a) inserting a distal end of a catheter according to any one of Claims 1 to 29 into the passageway;

(b) positioning the first balloon at the first location in the passageway;

(c) inflating the balloon; and

(d) determining whether an external pressure exerted by the passageway wall on the inflated balloon is above a predetermined threshold;

an external force exerted on the balloon above the predetermined threshold being indicative of a normal resistance.

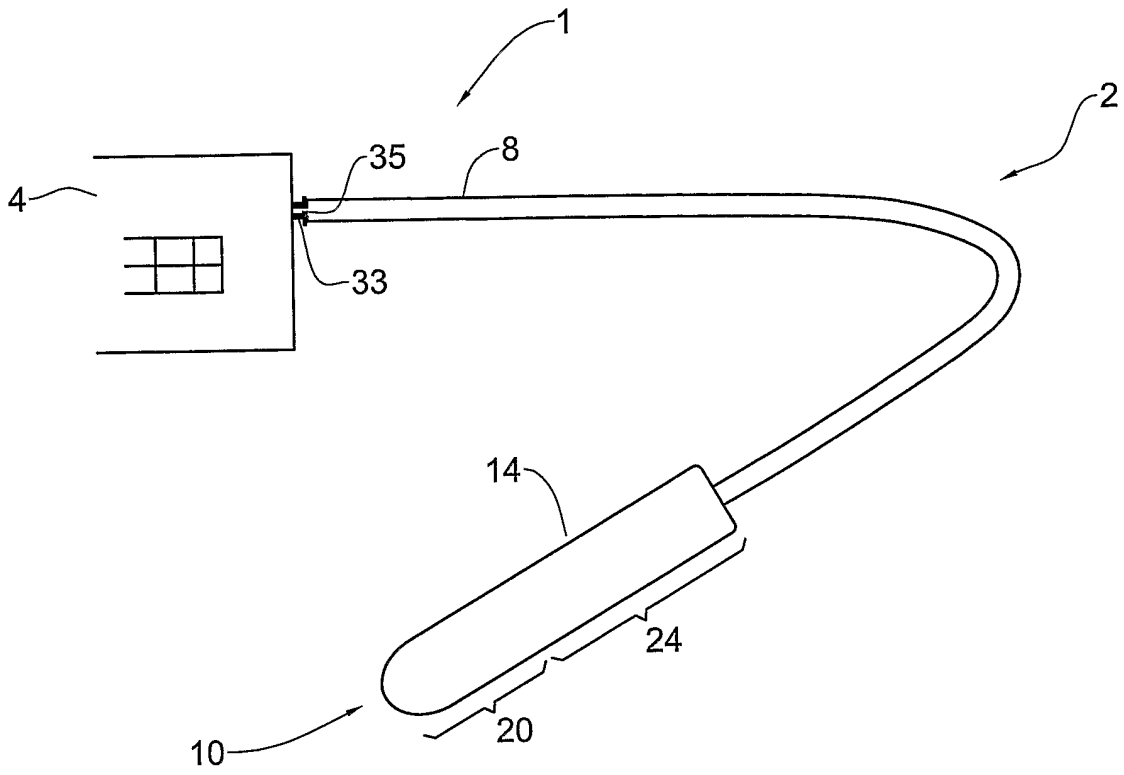


FIG. 1

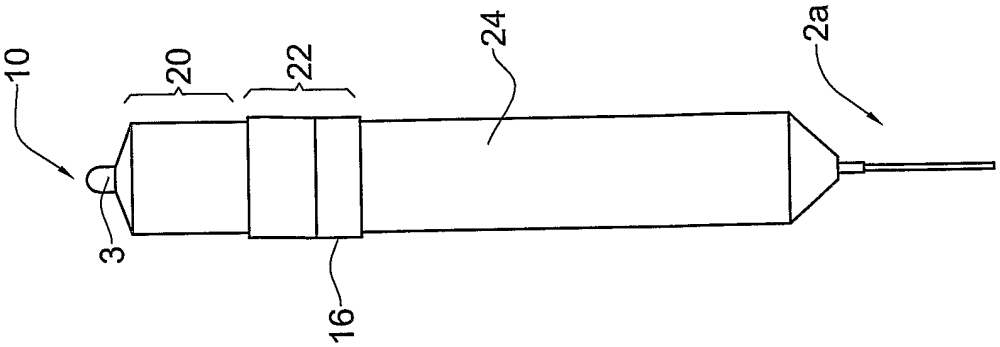


FIG. 2E

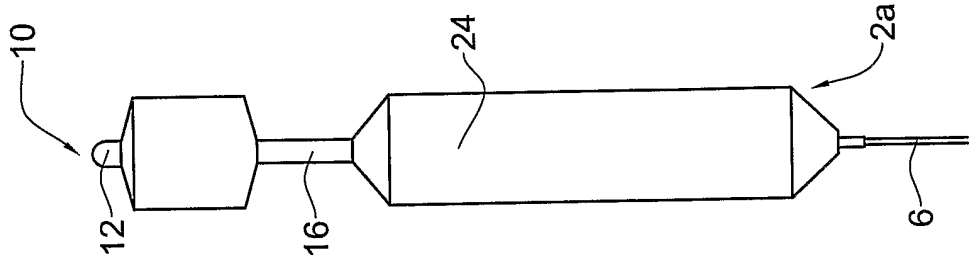


FIG. 2D

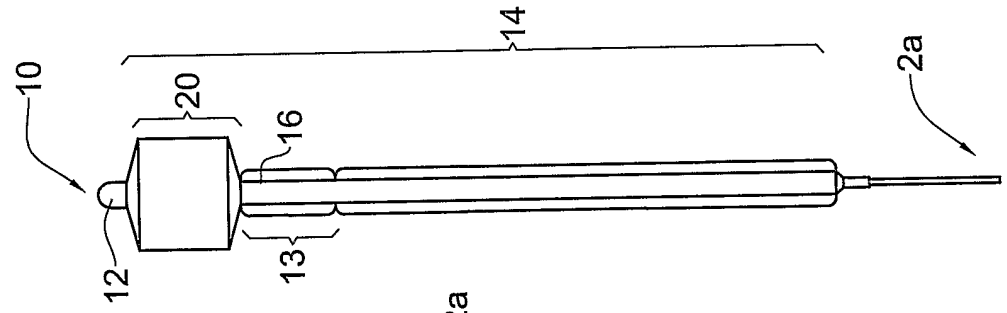


FIG. 2C

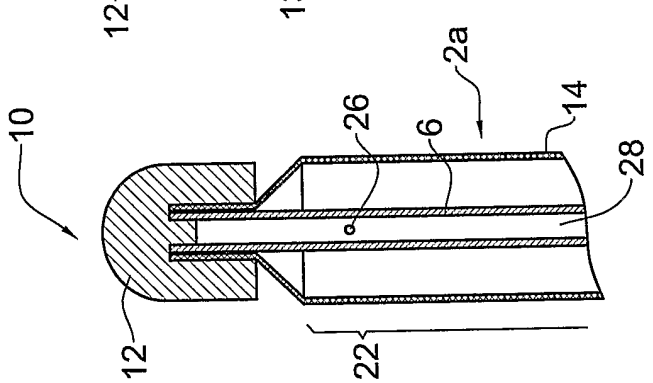


FIG. 2B

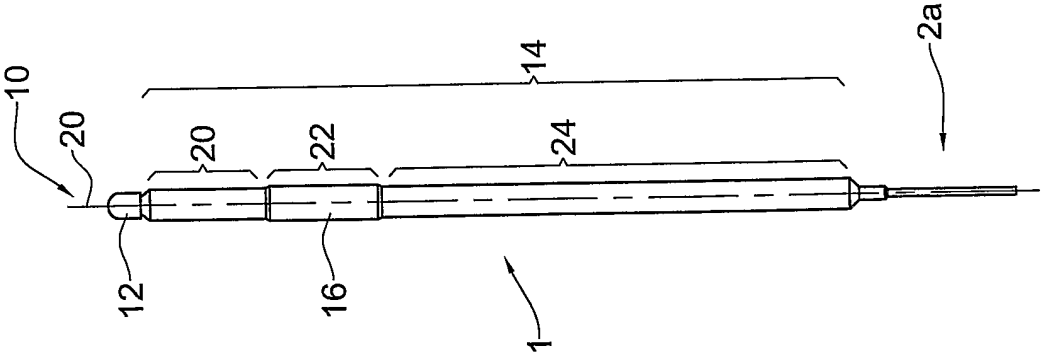


FIG. 2A

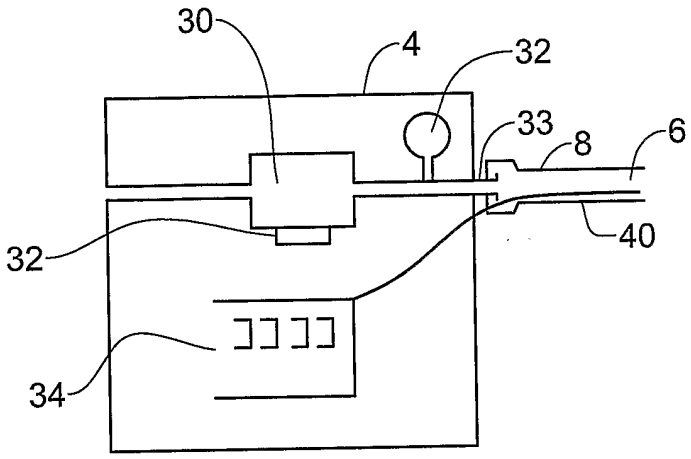


FIG. 3

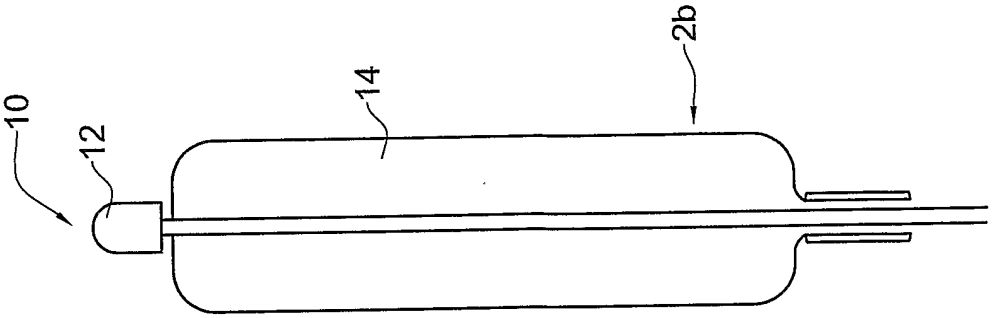


FIG. 4E

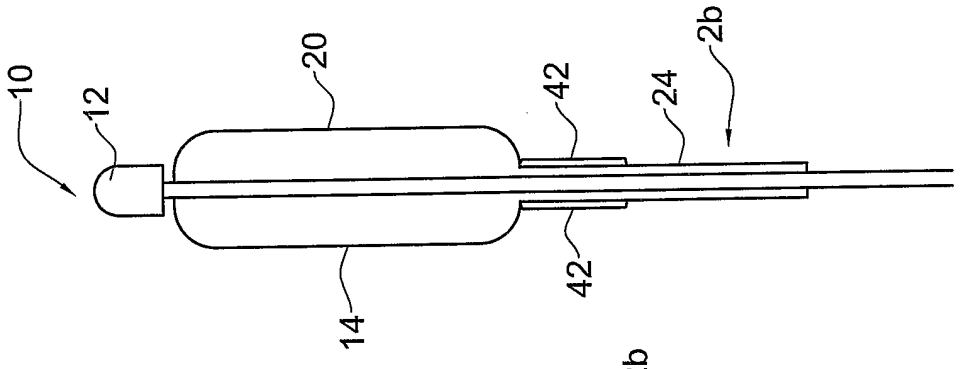


FIG. 4D

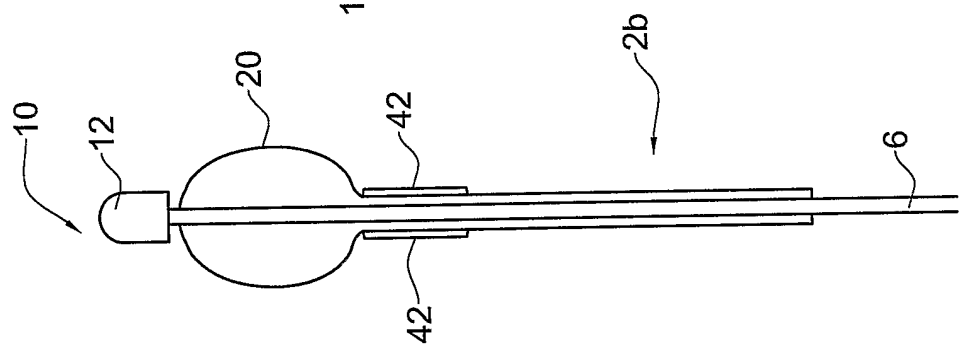


FIG. 4C

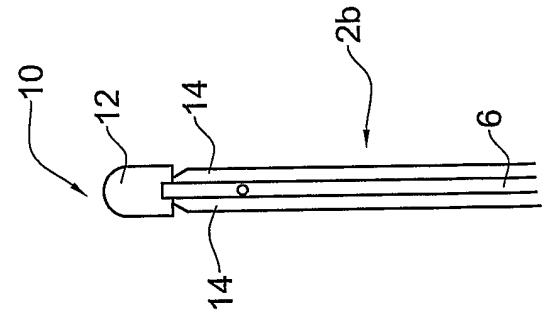


FIG. 4B

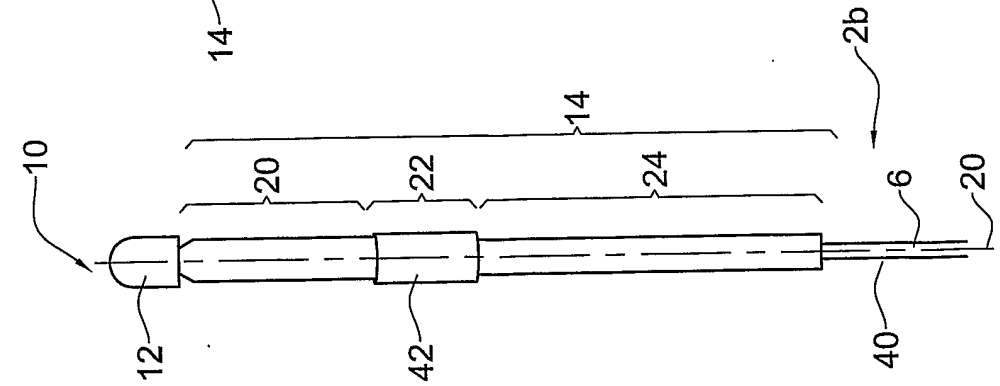


FIG. 4A

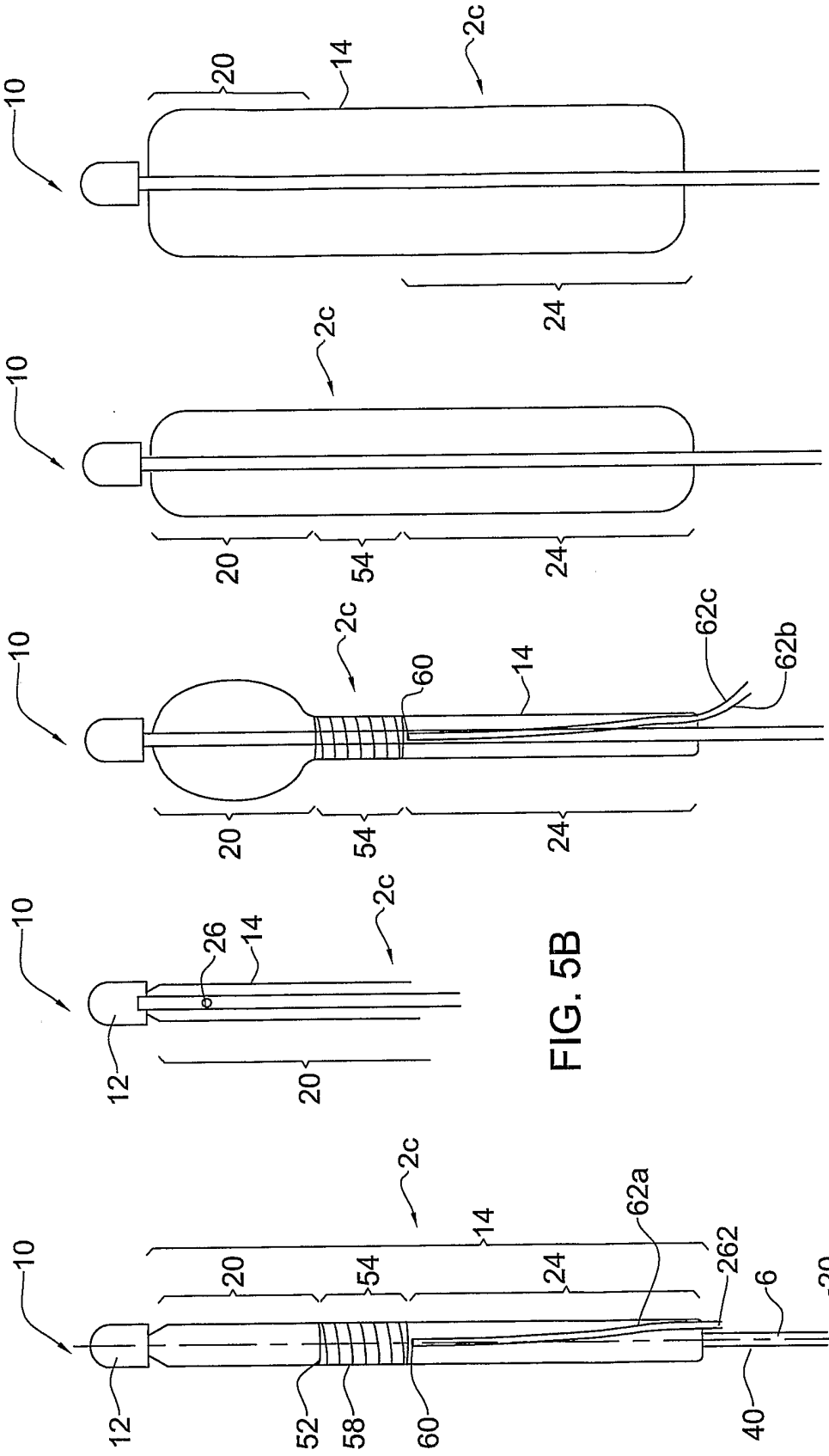


FIG. 5A

FIG. 5B

FIG. 5C

FIG. 5D

FIG. 5E

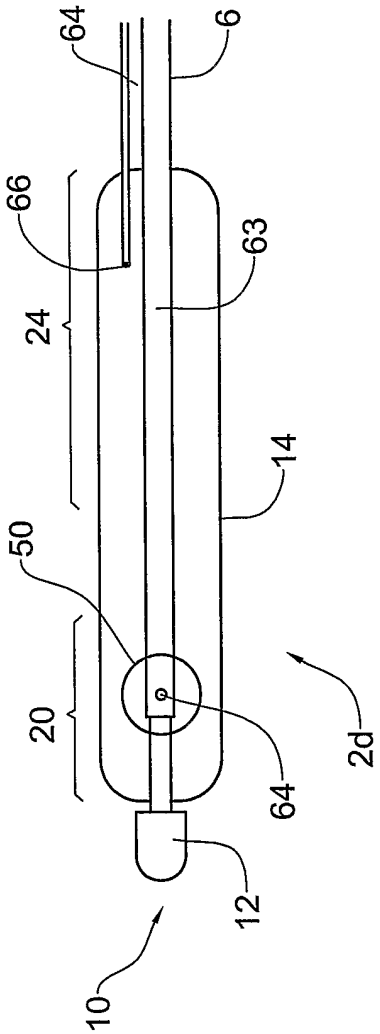


FIG. 6

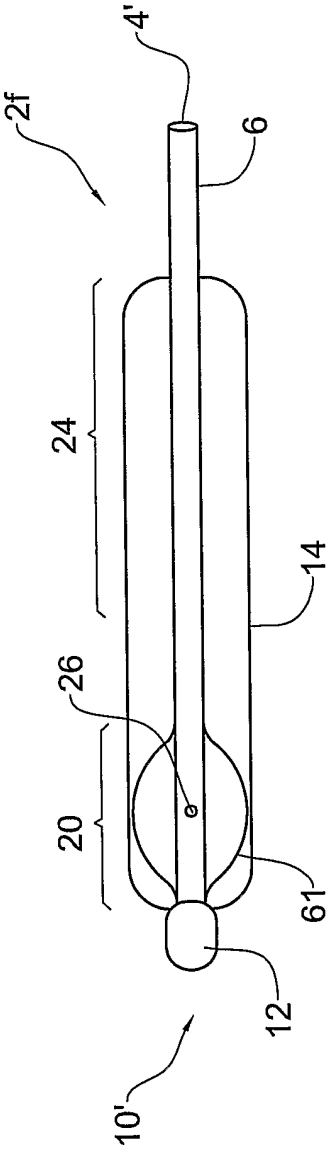


FIG. 7A

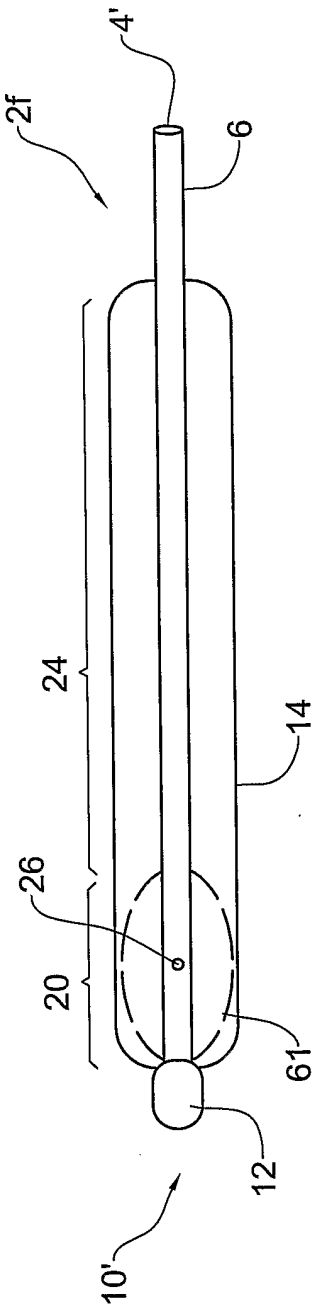


FIG. 7B

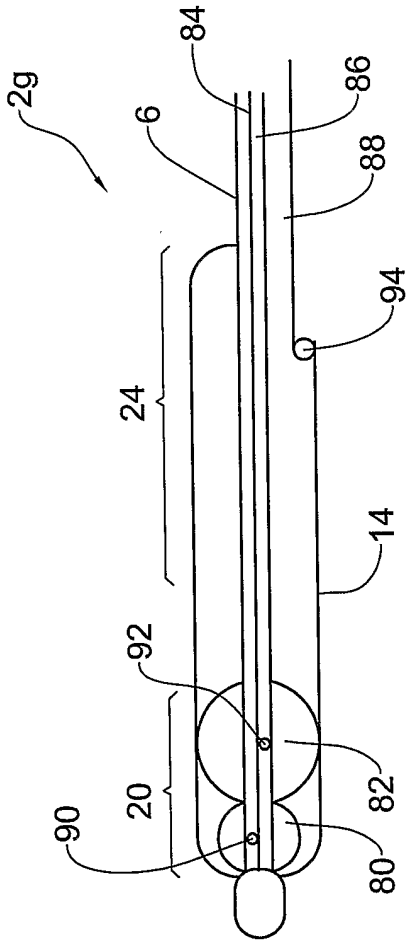


FIG. 8

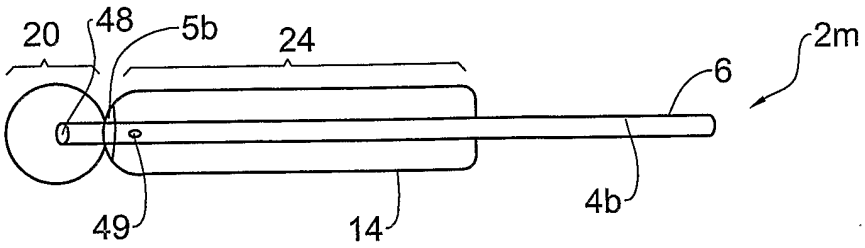

20
48
5b
24
2m
6
49
14
4b

FIG. 9A

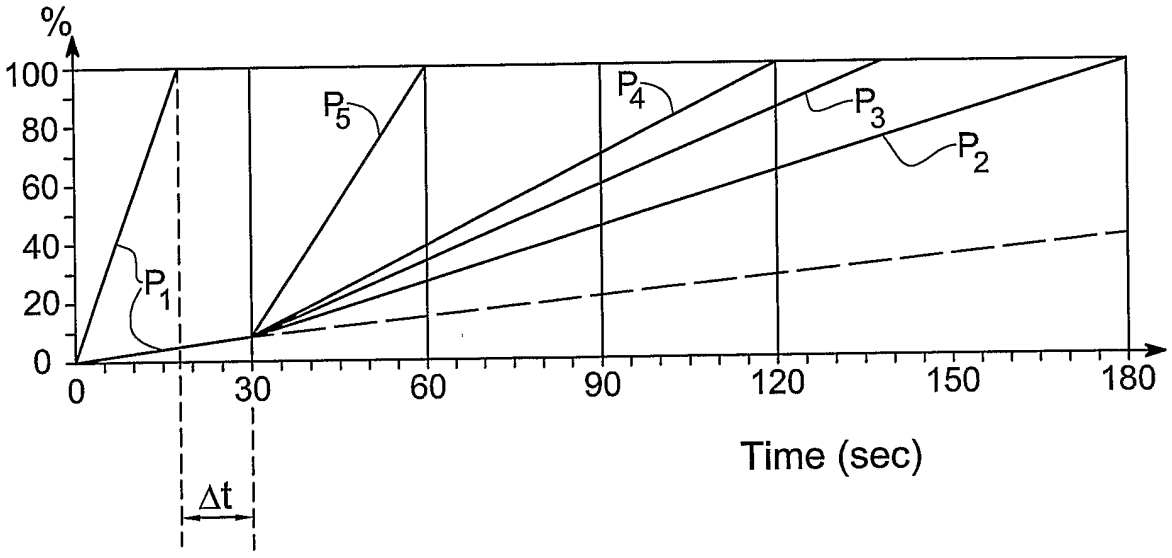

%
100
80
60
40
20
0
P1
P5
P4
P3
P2
0
30
60
90
120
150
180
Time (sec)
Δt

FIG. 9B

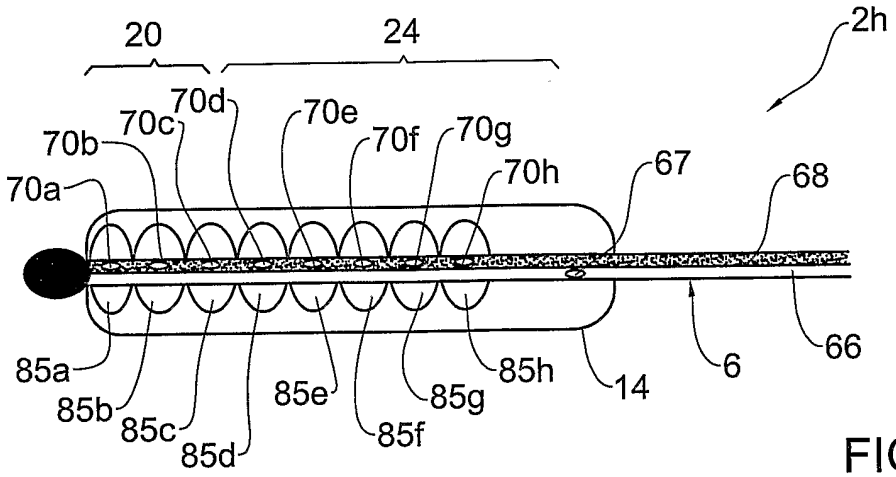


FIG. 10A

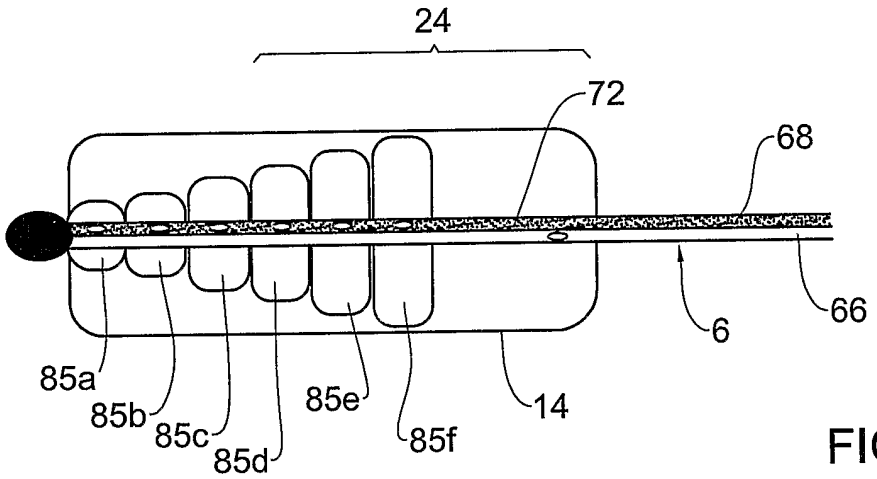


FIG. 10B

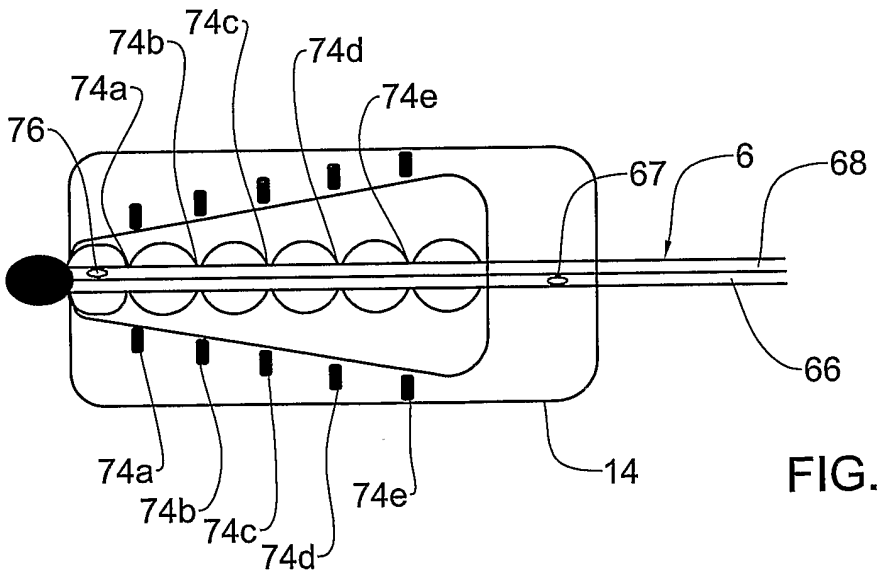


FIG. 10C

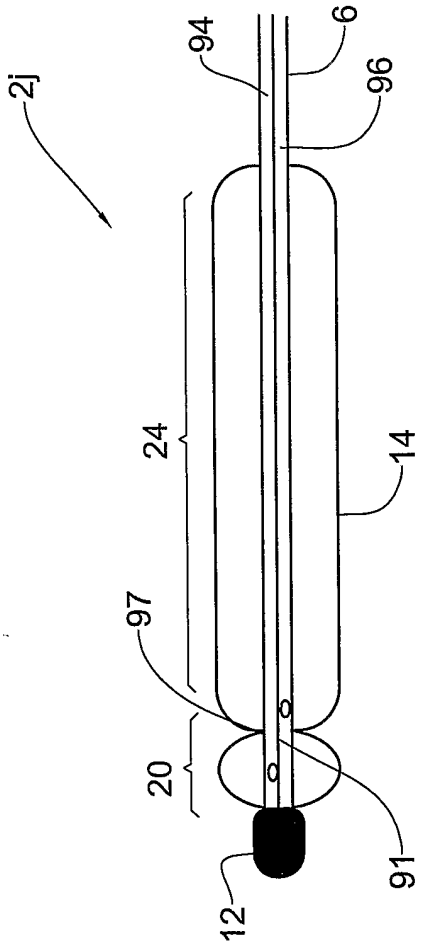


FIG. 11

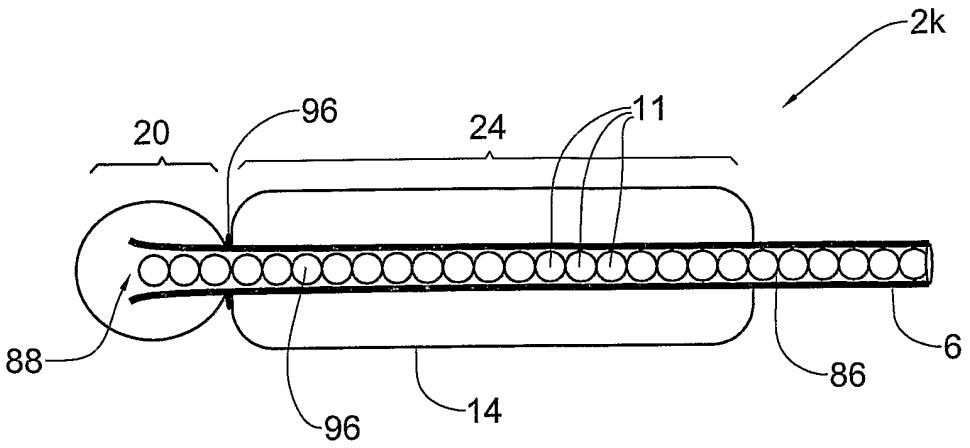


FIG. 12A

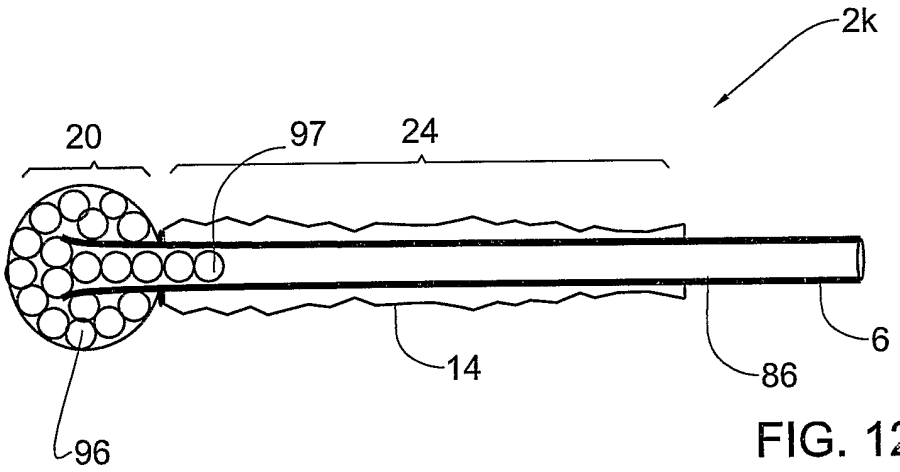


FIG. 12B

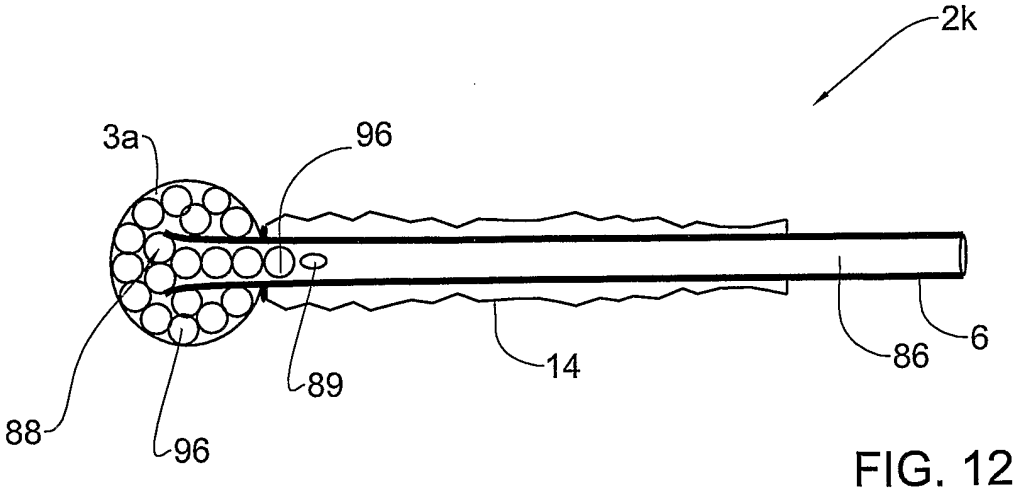


FIG. 12C

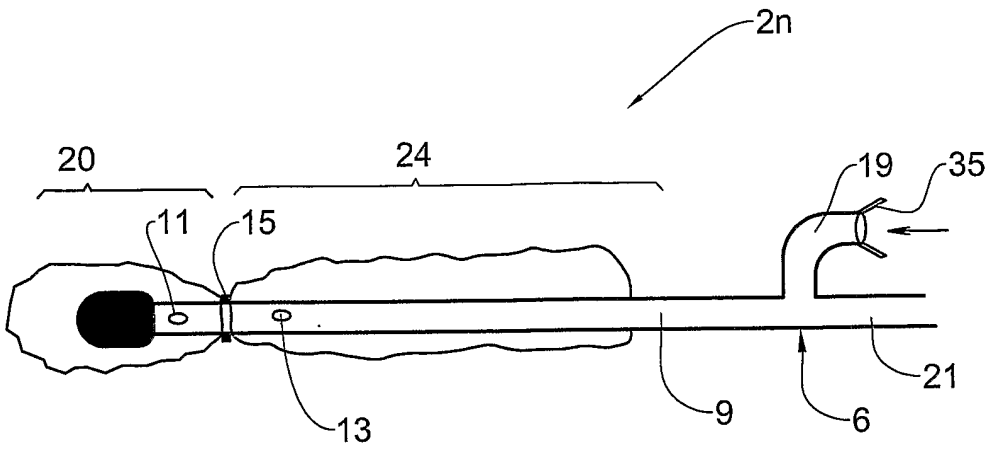


FIG. 13A

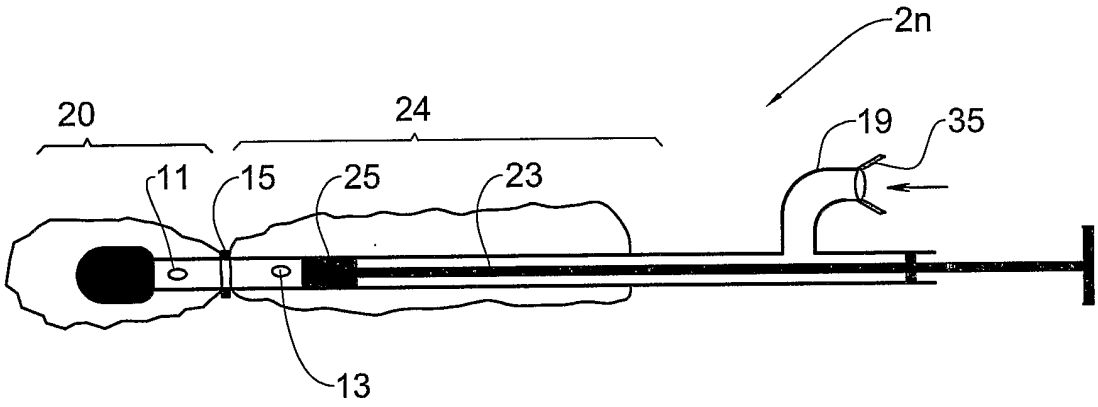


FIG. 13B

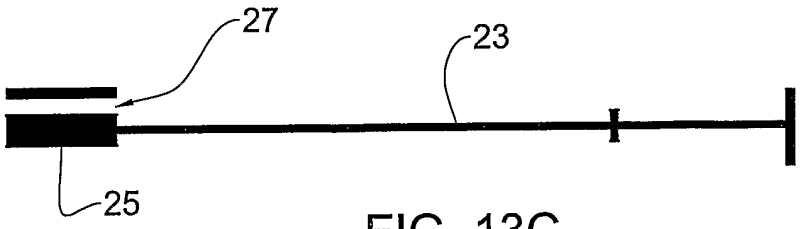


FIG. 13C

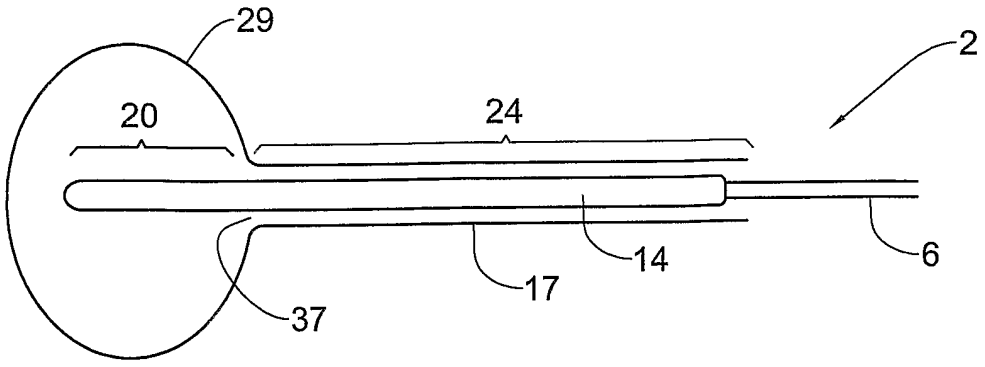


FIG. 14A

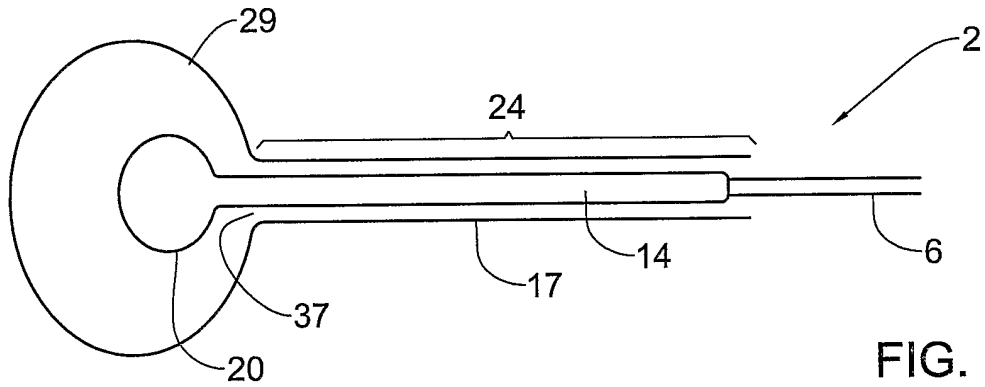


FIG. 14B

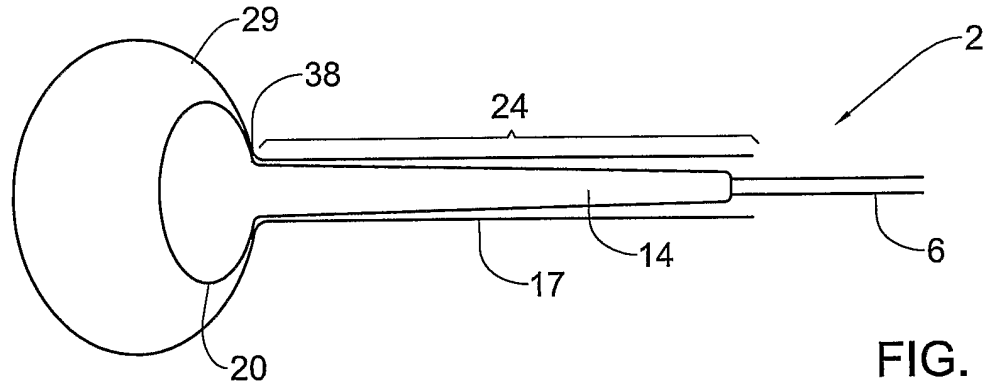


FIG. 14C

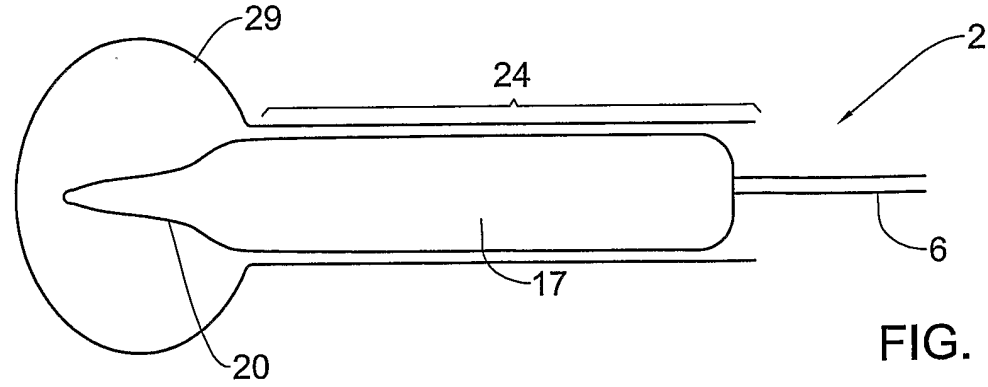


FIG. 14D

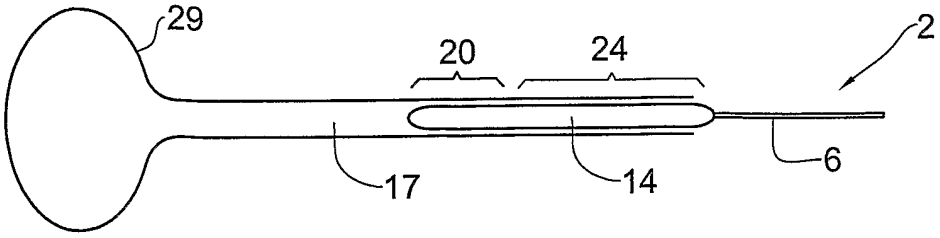


FIG. 15A

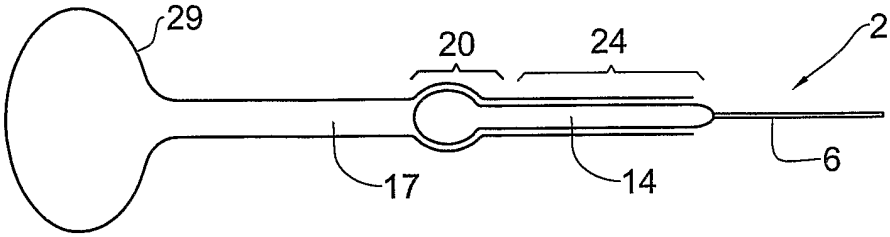


FIG. 15B

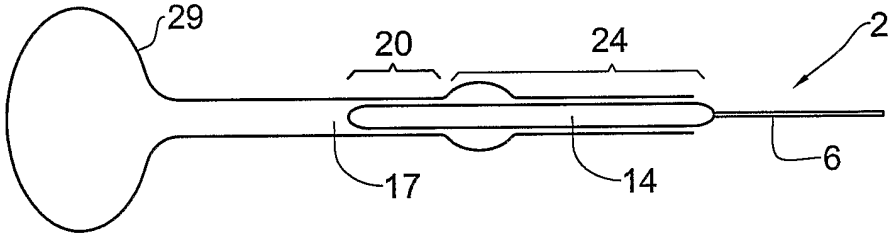


FIG. 15C

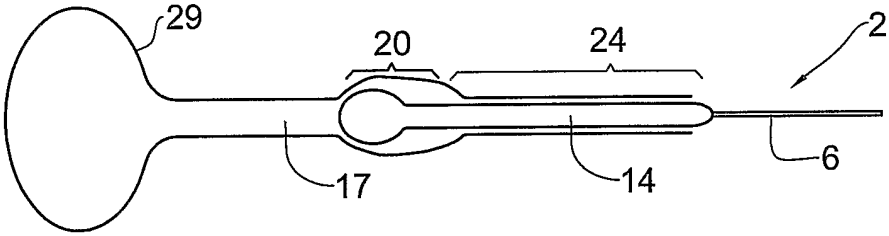


FIG. 15D

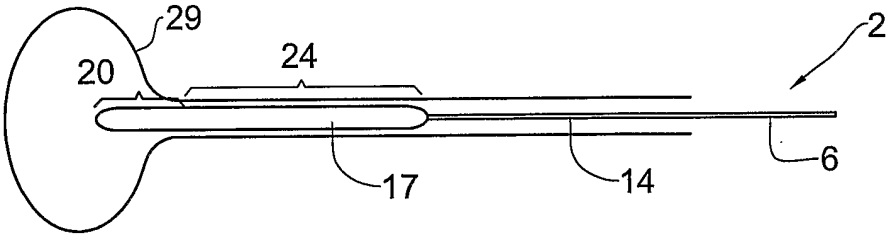


FIG. 15E

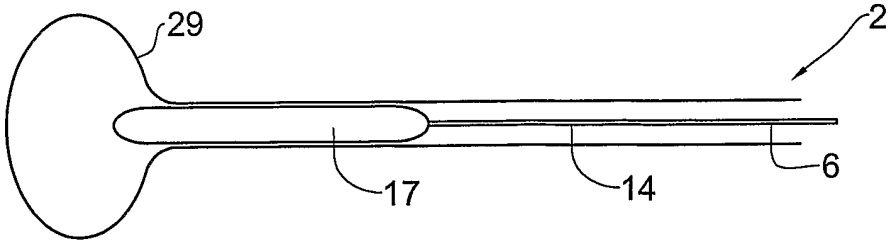


FIG. 15F

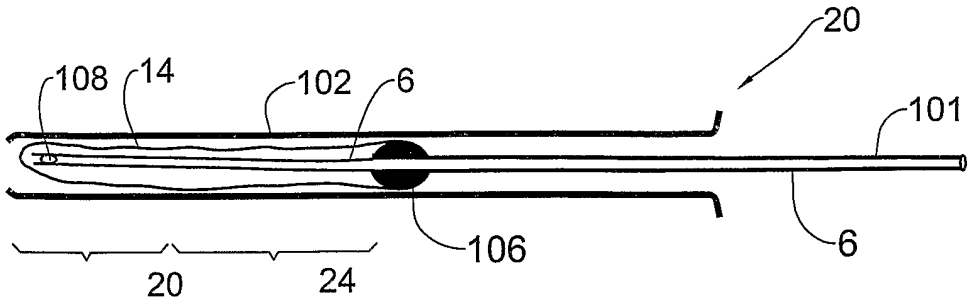


FIG. 16A

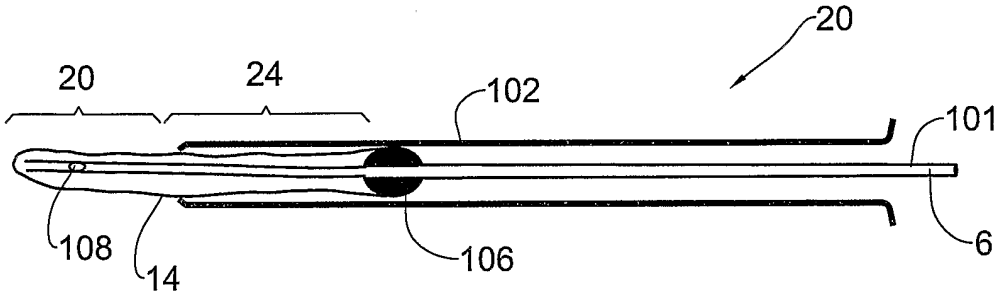


FIG. 16B

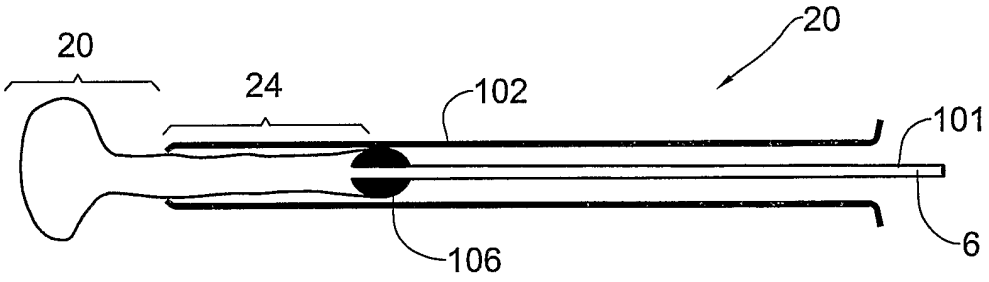


FIG. 16C

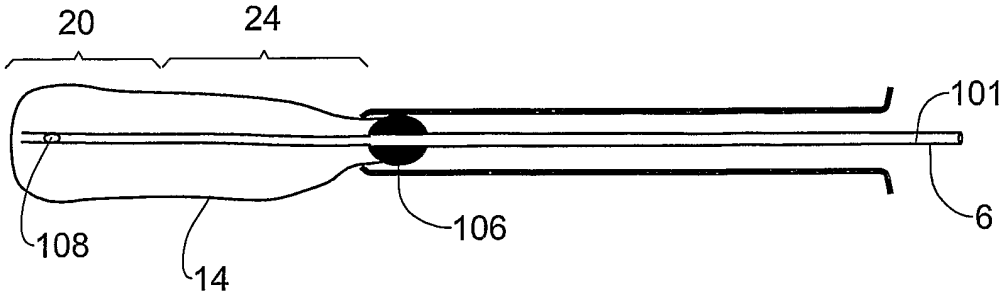


FIG. 16D

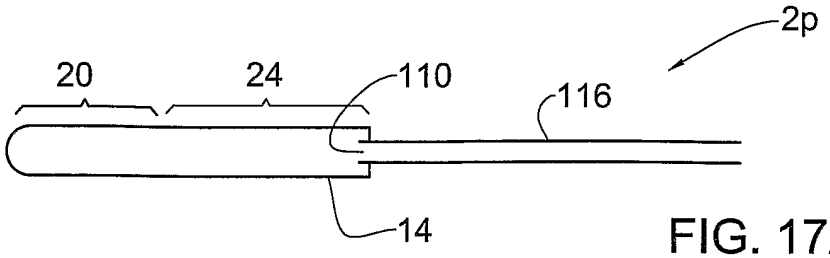


FIG. 17A

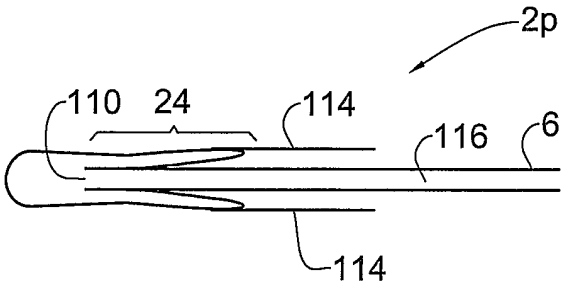


FIG. 17B

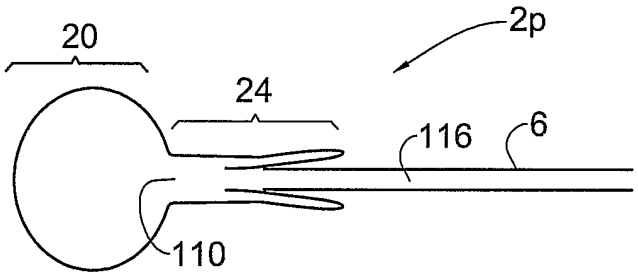


FIG. 17C

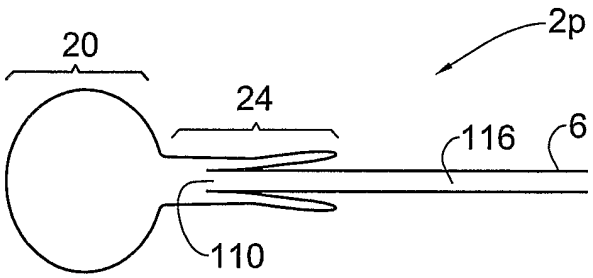


FIG. 17D

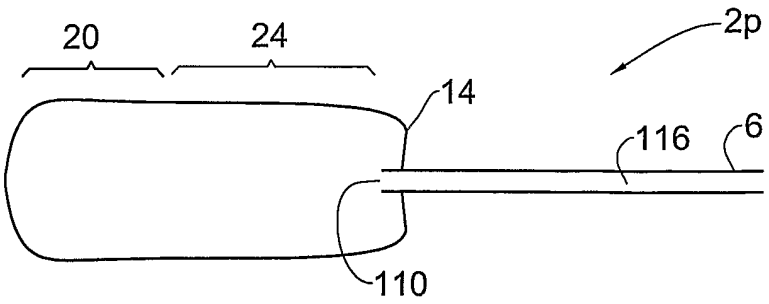


FIG. 17E

FIG.18A

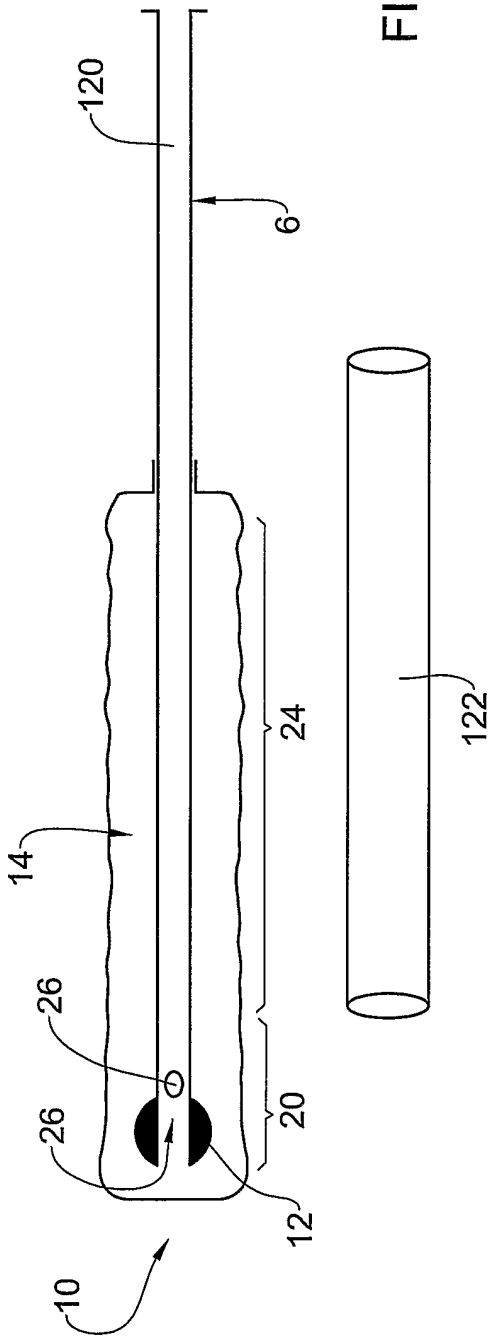
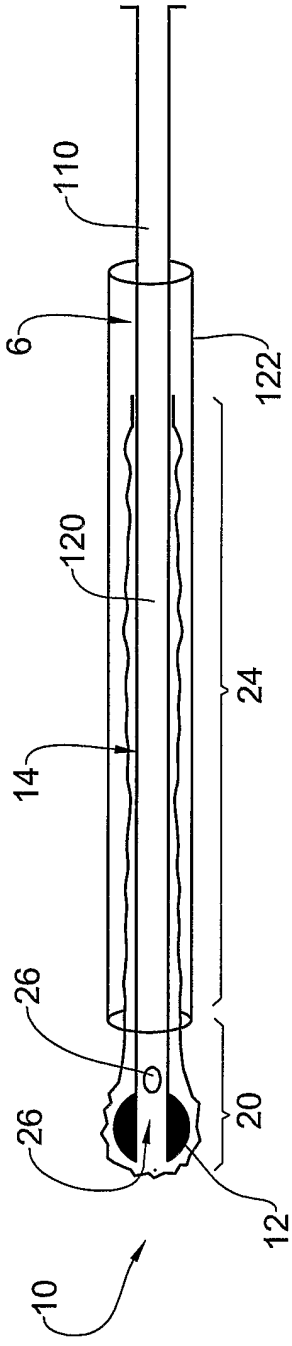


FIG.18B



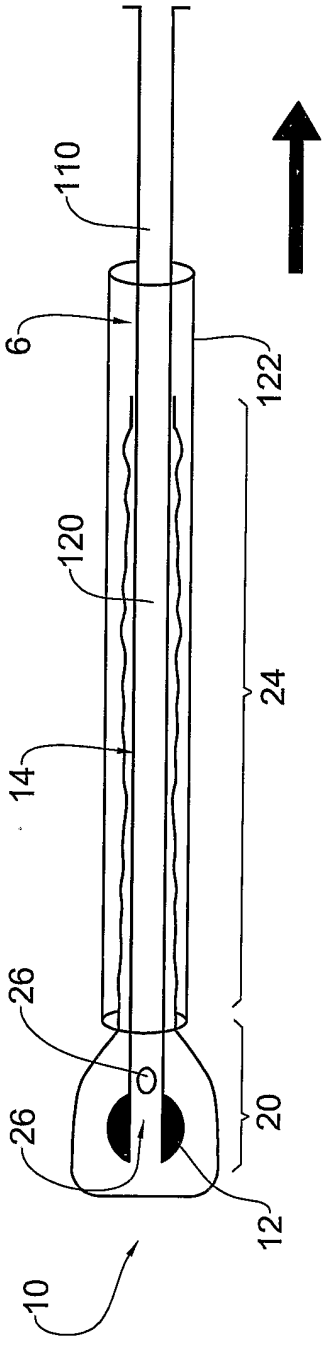


FIG. 18C

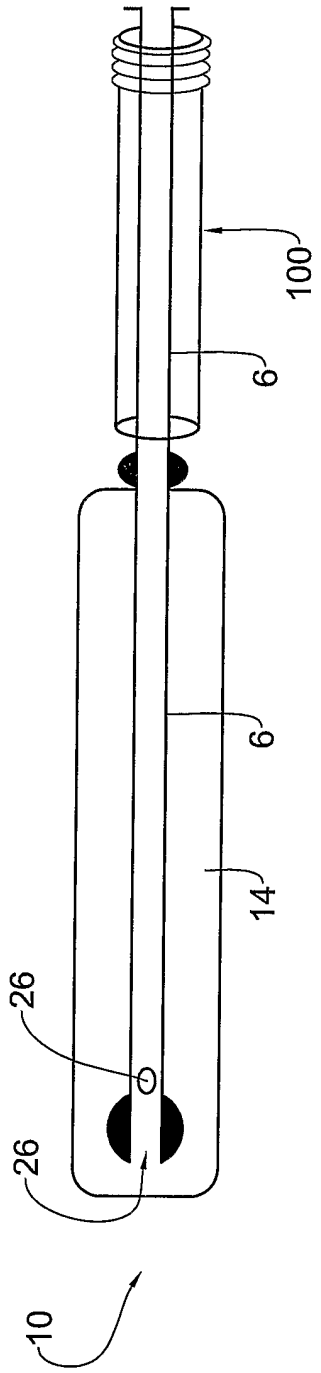


FIG. 18D

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IL2005/000271

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M29/00 A61M25/10

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 7 A61M

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)
EPO-Internal, WPI Data, PAJ

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 2003/014007 A1 (EIDENSCHINK TRACEE E.J ET AL) 16 January 2003 (2003-01-16) paragraphs '0023! - '0025!, '0049! - '0052!, '0080!; figures 2,3,5-7	1-3,10, 11,13, 14,16,30 4-8,26
X Y	EP 0 260 107 A (JANG, G. DAVID) 16 March 1988 (1988-03-16) figures 12-25	1-3,16, 30 26
X	DE 100 10 467 A1 (GIP MEDIZINTECHNIK GMBH) 13 September 2001 (2001-09-13) column 6, lines 34-41; figures 1-4	1-3
Y	EP 0 904 799 A (SCHNEIDER GMBH) 31 March 1999 (1999-03-31) figure 1	4-8

-/--

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

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"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 when the document is taken alone

"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

Date of the actual completion of the international search	Date of mailing of the international search report
8 July 2005	25/07/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Cuiper, R

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/IL2005/000271

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/100916 A1 (LEE JEONG S ET AL) 29 May 2003 (2003-05-29) paragraphs '0019! - '0021!	1,2
X	WO 94/02193 A (ADVANCED CARDIOVASCULAR SYSTEMS, INC) 3 February 1994 (1994-02-03) figure 3	1,2
X	US 5 549 551 A (PEACOCK, III ET AL) 27 August 1996 (1996-08-27)	1
Y	figure 12 figures 1,4	26
X	US 5 961 536 A (MICKLEY ET AL) 5 October 1999 (1999-10-05)	1
Y	column 4, line 60	26
X	US 6 695 863 B1 (RAMZIPOOR KAMAL ET AL) 24 February 2004 (2004-02-24) figures 1,2,5,6	26
X	US 5 246 421 A (SAAB ET AL) 21 September 1993 (1993-09-21) figures 1-5	1,26
A	US 3 900 033 A (LEININGER ET AL) 19 August 1975 (1975-08-19) cited in the application the whole document	1-30
A	US 4 664 114 A (GHODSIAN ET AL) 12 May 1987 (1987-05-12) cited in the application the whole document	1-30

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2005/000271

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 31-33
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IL2005/000271

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IL2005/000271

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