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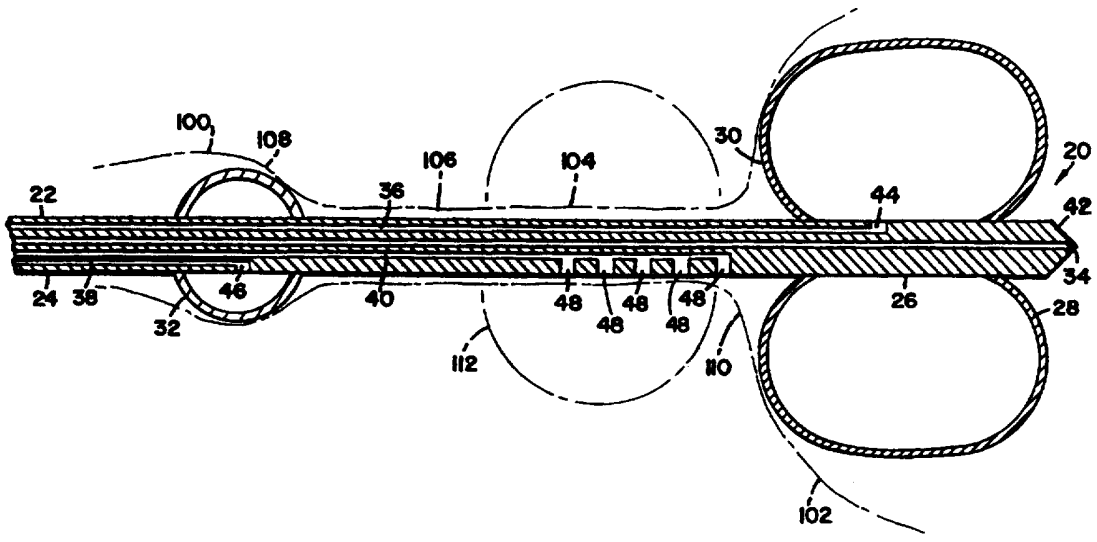

(57) Abstract

The present invention is directed to an apparatus and method for delivering fluid to a patient having a bladder and a urethra. The urethra has a bulbous urethra, a membranous urethra, and a prostatic urethra. The apparatus comprises a catheter having a proximal portion and a distal portion. A first balloon is operably connected to the proximal portion of the catheter. A second balloon is operably connected to the distal portion of the catheter. The second balloon has a proximal end that is generally arcuate and convex when in an inflated state. The distance between the first and second balloons being between about 3 cm and about 7 cm.

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URINARY CATHETER

Technical Field

The present invention relates to catheters, and more specifically to catheters for isolating a segment of a urethra and bladder neck.

Background

Many techniques exist for delivering drugs or other medicaments to body tissue. These techniques include oral administration; injection directly into body tissue, such as through an intramuscular injection; topical or transcutaneous administration where the drug is passively absorbed into, or caused to pass across, the skin or other surface tissue; and intravenous administration, which involves introducing a selected drug directly into the blood stream.

Except for topical or transcutaneous administration, the above drug-delivery systems tend to be systemic. In other words, administration of the drug is delivered throughout the body by the blood stream. Transcutaneous drug-delivery systems deliver a drug locally to a selected area, and are limited to external application of a drug through the patient's skin or other surface tissue. Thus, the above described drug-delivery systems generally are not appropriate for the localized treatment of internal body tissue.

Although many medical situations are satisfactorily treated by the general systemic administration of a drug, there are many treatments that are facilitated and/or improved by the ability to deliver or administer a drug locally to a selected portion of internal body tissue, without appreciably affecting the surrounding tissue. One example is the prostate gland, which is subject to various diseases such as prostatitis, benign prostatic hyperplasia, and prostate cancer. The urethra allows relatively easy access to the prostate from outside the patient by means of a catheter.

The urethra includes the prostatic urethra, the membranous urethra, bulbous urethra, and the pendulous urethra. All of the major ducts of the prostate gland open on the surface of the prostatic urethra. These ducts extend into the prostate and branch into ductules (smaller ducts) and eventually end in acini (rounded sacs). The outside of the prostate gland is surrounded by a tough fibrous capsule that serves as a substantial physical barrier between the spongy prostatic tissue and the rest of the peritoneal environment. By using an appropriately designed catheter that is introduced through the urethra, it is possible to access the prostate via the prostatic ducts that extend deep into the gland.

There are prior devices for delivering drugs to the prostate gland via the prostatic urethra and the prostatic ducts. Such devices include catheters that have

drug-delivery balloons made from a porous membrane. The drug-delivery balloon is placed into the prostatic urethra and inflated with fluid that contains a drug. The fluid is pressurized so that it is caused to pass through the porous or perforated membrane and transported into the prostatic ducts.

There is a significant problem that results from delivering the drug with this type of membranous balloon. Specifically, the transport of the fluid into the prostate gland is impeded and thus much less efficient.

One impediment is that the pressurized balloon expands and exerts a force against the walls of the prostatic urethra. This force compresses the prostatic tissue and causes the ducts to restrict and block the flow of the fluid into the prostate gland. As a result, the fluid typically does not distribute evenly throughout the ducts, nor throughout the prostate gland. Compression of the prostatic ducts also prevents or slows the flow of the fluid solution into the interior of the prostate gland.

Another impediment is the porous membrane through which the drug fluid must pass before it enters the prostatic ducts. Such an impediment slows the flow of the fluid and results in additional inefficiency. Slowing the flow of the fluid results in longer delivery times and most likely lower levels of drug in the prostate gland. Additionally, a longer administration period requires additional time from the caregiver. This expense is passed on to the patient, thereby increasing the cost of treatment.

These impediments are especially significant when preparing a patient for prostatic surgery. It is important to anesthetize the entire prostate gland in order to minimize the discomfort and pain felt by the patient. However, the anesthetic will not reach and thus minimize sensation in all areas of the prostate gland if a balloon or other obstruction compromises openings of the prostatic ducts. Furthermore, nerves in the bladder neck and the membranous urethra can become irritated during prostatic urethra.

Therefore, there is a need for a catheter that is capable of delivering drugs and diagnostic fluids to the prostate gland via the prostatic urethra and prostatic ducts, wherein the catheter does not compromise flow through the prostatic ducts by exerting pressure against the walls of the prostatic urethra. There is also a need for a catheter that can simultaneously deliver a fluid such as an anesthetic to the membranous urethra, bladder neck, and prostate gland.

Summary

The present invention is directed to an apparatus for delivering fluid into a patient's urethra. The patient has a bladder. The apparatus comprises a catheter having a proximal portion and a distal portion. A first balloon is operably connected to the

catheter. A second balloon is operably connected to the distal portion of the catheter. The second balloon has a proximal end that is generally arcuate and convex when in an inflated state.

The present invention is also a method of delivering fluid to a patient having a urethra, bladder, and prostate gland. The urethra includes a prostatic urethra. The method comprises the steps of: substantially isolating a segment of the urethra, the isolated segment including the prostatic urethra; substantially isolating the bladder from the bladder neck so that the isolated segment of the urethra remains in fluid communication with the bladder neck; and delivering a fluid to the isolated segment of the urethra and the bladder neck.

Description of the Drawings

Figure 1 is a view in partial cross-section of the catheter of the present invention located in the drug delivery position within the male urethra and bladder.

Figure 2 is a partial cross-sectional view showing an alternative embodiment of the catheter shown in Figure 1, the alternative embodiment includes a sheath covering an electrode.

Figure 3 is a partial view of an alternative embodiment of the catheter shown in Figure 1, the alternative embodiment includes an intermediate section that has increased elasticity.

Figure 4A is a cross-sectional view of the catheter shown in Figure 3 taken along line 3A-3A.

Figure 4B is a cross-sectional view of the catheter shown in Figure 3 taken along line 4B-4B.

Detailed Description

The invention will initially be described in general terms. Preferred embodiments of the invention will then be described in detail with reference to the drawings, wherein like referenced numerals represent like parts and assemblies throughout the several views. Reference to the preferred embodiment does not limit the scope of the invention, which is limited only by the scope of the claims attached hereto.

The present invention comprises a catheter with multiple balloons for isolating a target area for treatment. The catheter is capable of delivering fluid to the target area of the passageway that is isolated between the balloons. The present invention can also simultaneous deliver the fluid to the membranous urethra, the prostate gland, and the bladder neck. In another embodiment, the present invention can simultaneously deliver fluid to both the prostate gland and the bladder neck.

Thus, the present invention can be used to deliver fluid to the prostate gland and is advantageous in that the prostatic ducts remain substantially open, even when the balloons are inflated. Another advantage is that the present invention can be used to simultaneously anesthetize the prostate gland, bladder neck, and prostatic urethra, thereby minimizing patient discomfort and pain during surgery.

Figure 1 illustrates one possible embodiment of a catheter according to the present invention, generally shown as 20, for isolating and treating a prostate gland. The catheter 20 is shown in a delivery position in a urethra 100 and bladder 102. The urethra includes a prostatic urethra 104, membranous urethra 106, bulbous urethra 108, and pendulous urethra (not shown). A bladder neck 110 forms a junction between the bladder 102 and the urethra 100. The prostatic urethra 104 passes through a prostate gland 112.

The catheter 20 has a catheter body 22 that includes a proximal portion 24 and a distal portion 26. Distal occlusion balloon 28 is affixed and sealed to distal portion 24 of catheter body 22 such that catheter body 22 passes through distal occlusion balloon 28.

The distal occlusion balloon 28, shown in an inflated state, is generally configured in a toroidal shape. When in an inflated state, the distal occlusion balloon 28 has a proximal end 30 that generally has an arcuate shape and is convex. In other words, the proximal end 30 bulges outward.

A proximal occlusion balloon 32 is affixed to the catheter body 22 in a manner similar to the distal occlusion balloon 28. The distance between the proximal occlusion balloon 32 and the distal occlusion balloon 28 is approximately the same as or slightly longer than the combined length of the average prostatic urethra 104 and the average membranous urethra 106. A possible range of distances between the proximal and distal occlusion balloons 32 and 28 is between about 3 cm and about 7 cm.

When the catheter 20 is in the delivery position and the distal occlusion balloon 32 is in an inflated state, the distal balloon 28 is located at the bladder neck 110 such that the proximal end 30 is seated against the bladder wall and creates a seal that substantially isolates the bladder 102 from the bladder neck 110. In this position, the proximal occlusion balloon 32 is located in the bulbous urethra 108 and also creates a seal when in the inflated state. As a result, the prostatic urethra 104 is in fluid communication with the membranous urethra 106 and the bladder neck 110. However, both the bladder 102 and the pendulous urethra are still substantially isolated from the prostatic urethra 103.

This configuration has many advantages. For example, the prostatic urethra 104 remains in fluid communication with the membranous urethra 106 and the bladder neck 110. When delivering and anesthetic prior to prostatic surgery, the anesthetic will

numb the nerves that line the membranous urethra 106 and the bladder neck 110, which can become irritated during surgery. Because there is not a balloon positioned in the prostatic urethra 104, openings to the prostatic ducts do not become compromised and exposure of the anesthetic to the prostate gland 112 is maximized. Additionally, the caregiver can deliver a toxic or otherwise dangerous agent to the prostate gland 112 and surrounding tissue, which can be helpful if an infection or diseased tissue spreads outside of the prostate gland 112.

In an alternative embodiment, the distance between the proximal and distal occlusion balloons 32 and 28 is about the same length as, or slightly longer than, the average prostatic urethra 104. A possible range of distances between the proximal and distal occlusion balloons 32 and 28 in this configuration is between about 3 cm and about 6 cm. In this embodiment, the proximal occlusion balloon 32 substantially isolates the prostatic urethra 104 from the membranous urethra 106 when in the inflated state and when the catheter 20 is in the delivery position.

Proximal and distal occlusion balloons 32 and 28 can be made from either elastic material or inelastic material. Examples of suitable elastic materials include latex, polyurethane, or silicon. Examples of suitable inelastic materials include polyethylene, polycarbonate, or PET.

The catheter body 22 includes 4 lumens: drainage lumen 34, first inflation lumen 36, second inflation lumen 38 and delivery lumen 40. Drainage lumen 34 extends from a distal tip 42 of the catheter body 22 to the proximal portion 24. Drainage lumen 34 is configured to drain urine from the bladder 102.

First inflation lumen 36 extends from the proximal portion 24 to a position proximate the distal occlusion balloon 28. First inflation port 44 passes from first inflation lumen 36 to the interior of distal occlusion balloon 28 so that distal occlusion balloon 28 can be inflated by injecting a fluid through first inflation lumen 36.

Second inflation lumen 38 extends from the proximal portion 24 of the catheter body 22, to a position proximate proximal occlusion balloon 32. A second inflation port 46 passes from the second inflation lumen 38 into the interior of proximal occlusion balloon 32. One skilled in the art will realize that a common inflation lumen could be used to simultaneously inflate both the proximal and distal occlusion balloons 32 and 28.

The delivery lumen 40 extends from the proximal portion 24 of the catheter body 22 to a position proximate the gap between proximal and distal occlusion balloons 32 and 28. Delivery ports 48 pass from delivery lumen 40 to the outer surface of the catheter body 22. The catheter body 22 may define as many as 20 delivery ports 48, which are macroscopic in size. Preferably, there are three or four delivery ports 48. The size of the delivery ports 48 is preferably in the range from

about 1 mm to about 2 mm. The most preferred size for the delivery ports 66 is 1 millimeter.

The procedure for using catheter 20 is as follows. The catheter 20 is inserted into the urethra 100 using lubrication, sterile techniques, and any other technique that is commonly used to insert a Foley-type urological catheter. The catheter 20 is inserted into the urethra 100 until the distal occlusion balloon 28 enters the bladder 102 and is preferably inserted while there is urine within the bladder 102. Having urine within the bladder 102 is useful because the caregiver who inserts the catheter 20 will know that the distal occlusion balloon 28 has entered the bladder 102 when urine is observed in the drainage lumen 34 or when urine can be aspirated through the drainage lumen 34.

Once the distal occlusion balloon 28 is inserted within the bladder 102, fluid is injected through first inflation lumen 36 until the distal occlusion balloon 28 is properly inflated. A predetermined, fixed volume of fluid is preferably used in order to prevent over inflation and bursting of the distal occlusion balloon 28. Any fluid can be used to inflate the distal occlusion balloon 28 including air, water, or saline. However, the preferable fluid is sterile water.

After the distal occlusion balloon 28 is inflated, retrograde tension is applied to catheter 20 by pulling on the proximal portion 24 of the catheter body 22. This action will pull the proximal occlusion balloon 32 into the bulbous urethra 108 and generate axial tension along the catheter body 22. The caregiver can inflate the proximal occlusion balloon 32 once it is located in the bulbous urethra 108 and then release the proximal portion 24 of the catheter body 22. The axial tension will urge the proximal occlusion balloon 32 against the narrowing wall of the bulbous urethra 108. There will then be axial tension along an intermediate segment of the catheter body 22 that is between the proximal and distal occlusion balloons 32 and 28. The axial tension will secure the proximal and distal occlusion balloons 32 and 28 in their seated positions and enhance their sealing effect. The catheter 20 is in the delivery position when the proximal occlusion balloon 32 is seated against the wall of the bulbous urethra 108 and the distal occlusion balloon 28 is seated against the wall of the bladder 102.

Alternatively, if the proximal occlusion balloon 32 is to be positioned in the membranous urethra 106, the caregiver can pull on the catheter body 22 in order to generate axial tension, which will seat the distal occlusion balloon 28 against the bladder wall. Axial tension is maintained by taping or otherwise clamping the proximal portion 24 of the catheter body 22 to the patient's body. Using this alternative procedure and embodiment, the catheter 20 is in the delivery position when the proximal occlusion balloon 32 is in the membranous urethra 106 and the distal occlusion balloon 28 is seated against the bladder wall.

One skilled in the art will realize that a caregiver could practice the present invention without generating axial tension along the catheter body 22. In this situation, the caregiver would rely on the inflation pressure of the proximal and distal balloons 30 and 28 to create seals that isolate a segment of the urethra 100.

After catheter 20 is located in the delivery position, proximal occlusion balloon 30 is inflated by injecting a fluid into second inflation lumen 38. A predetermined, fixed volume of fluid is preferably used in order to prevent over inflation and bursting of the proximal occlusion balloon 32. Any fluid can be used to inflate the proximal occlusion balloon 30, including air, water, or saline. However, the preferred fluid is sterile water.

Fluids such as anesthetics, drugs, diagnostic agents, or the like may be delivered to the prostate gland 112 after catheter 20 is in the delivery position and the proximal and distal occlusion balloons 32 and 28 are inflated. One skilled in the art will realize that a pressure gauge and syringe can be placed in fluid communication with delivery lumen 40 to deliver the drug or diagnostic fluid to the prostatic urethra 104. Any number of types of syringes may be used such as a standard syringe, an adjustable syringe, or a syringe pump. However, an adjustable syringe is preferably used. An adjustable syringe is one that has threads or some other type of self-locking mechanism.

Once delivered, the fluid is pressurized, thereby transporting it into the ducts, ductules, and acini. The pressure on the fluid may range between from about 0.1 psi to about 10 psi. However, the preferable pressure is between about 0.1 psi and about 6 psi. The most preferred range of pressure is between about 0.1 psi and about 5 psi. This pressure causes the fluid to fill the prostatic ducts, ductules, and acini.

Maintaining constant pressure over a period of time, rather than a simple administration of a fixed volume of fluid will more likely result in homogeneous prostatic tissue concentrations. If accurate drug dosing is not required, a fixed volume of fluid can be simply administrated. An example of when a fixed volume of fluid is appropriate is when anesthetic is introduced into the prostate gland 112.

The preferable procedure for withdrawing catheter 20 from the urethra 100 depends on whether toxic or caustic agents were delivered. For nontoxic drugs and diagnostic fluids such as antibiotics, anti-inflammatories, positive contrast agents, etc., the pressure of the fluid is simply reduced to zero, proximal and distal occlusion balloons 32 and 28 are deflated, and catheter 20 is removed from the urethra 100.

If toxic or caustic agents were delivered, an alternative procedure for withdrawing catheter 20 is preferred. A slight negative pressure is applied to the fluid in order to remove the excess drug or diagnostic agent from the prostatic urethra 104 after the administration period is complete. The prostatic urethra 104 may then be

flushed with a saline solution. The saline solution is added and removed via delivery lumen 40 in the same fashion the drug or diagnostic fluid was initially delivered to the prostatic urethra 104. After the saline solution is removed, proximal and distal occlusion balloons 32 and 28 are deflated and the catheter 20 is removed.

In yet another alternative embodiment, the catheter 20 may have a telescoping body (not shown) in which the proximal occlusion balloon 32 is attached to a tubular, outer portion and the distal occlusion balloon 28 is attached to an extendable, inner portion. A hemostatic-type adjustable seal can be used to secure the extendable portion relative to the tubular portion. Such a telescoping catheter body is described in commonly-assigned United States Patent 5,419,763, the disclosure of which is hereby incorporated by reference.

An advantage of a telescoping catheter body is that the distance between the proximal occlusion balloon 30 and the distal occlusion balloon 28 can be adjusted to the length of the patient's urethra 100. Additionally, the relative position of the proximal occlusion balloon 32 can be adjusted so that it is positioned in either the membranous urethra 106 or the bulbous urethra 108 when the catheter 20 is in the delivery position.

Additionally, a telescoping body catheter can be used in an alternative method of creating axial tension. The caregiver can insert the catheter 20 through the patient's urethra 100 so that the distal occlusion balloon 28 is located in the bladder 102 and the proximal occlusion balloon 32 is located in the bulbous urethra 108. The caregiver also inflates the proximal occlusion balloon 32 and the distal occlusion balloon 28.

After the proximal and distal occlusion balloons 32 and 28 are inflated, the caregiver can slide the tubular portion along the extendible portion, thereby causing proximal and distal occlusion balloons 32 and 30 to move toward one until the proximal occlusion balloon 32 becomes seated against the wall of the bulbous urethra 108 and the distal occlusion balloon 28 becomes seated against the wall of the bladder 102.

Alternatively, the caregiver can initially position and then inflate the proximal occlusion balloon 32. Once the proximal occlusion balloon 32 is positioned, the caregiver can secure the tubular portion to the patient's body using tape or a clamping device. The distal occlusion balloon 28 is inflated. The caregiver then retracts the extendable portion until the distal occlusion balloon 28 is seated at the bladder neck 110 and there is a sufficient amount of axial tension between the proximal and distal occlusions 32 and 28. This alternative method of using a telescoping catheter is useful when the proximal occlusion balloon 32 is to be positioned in the membranous urethra 106 during delivery.

Additionally, the catheter 20 can utilize iontophoresis, electroporation, and/or phonophoresis to assist the transportation of the agent into the prostatic ducts. These non-pressure means of transportation also enhance drug penetration across the prostatic epithelium and into prostatic tissue. These methods may also increase cellular penetration of certain agents. Examples of these agents include DNA, RNA, etc. These non-pressure means of transportation may also make penetration into prostatic calculi possible. Iontophoresis, electroporation, and phonophoresis are discussed in more detail in United States Patent 5,419,763, the disclosure of which was incorporated by reference above. Additional information on iontophoresis can be found in United States Patent 5,286,254, the disclosure of which is hereby incorporated by reference.

Figure 2 illustrates an alternative embodiment in addition to those described in United States Patent 5,419,763. For example, the catheter 20 can include a sheath 50 that covers an electrode 52 and the delivery ports 48. The sheath 50 can be tubular and fixed to the catheter body 22 with adhesive 54. The sheath 50 can be formed from a polymer matrix that absorbs fluid that passes through the delivery ports 48. Alternatively, the sheath 50 can be formed from a porous membrane. The pores can be either microporous (0.2-100 micron) or macroporous (100 micron-1 millimeter) depending on the density of the pores and manufacturing process. Specific materials that can be used to form the sheath 50 include PTFE Teflon; woven polymer filaments such as nylon, LDPE, polyurethane, or Kevlar; braided polymers; and extruded or perforated polymeric or elastic tubing.

The catheter body 22 can include a portion 56 that has a narrowed diameter, thereby defining a recess 58. The electrode 52 is positioned within the recess 58. The sheath 50 extends over the recess 58 and forms a delivery chamber 60 that is in fluid communication with the delivery ports 48. In use, the fluid fills delivery chamber 60 and is either absorbed in the sheath 50 or passes through the pores defined in the sheath 50, thereby forming a path between the electrode 52 and the patient's body that is capable of conducting an electric current.

Alternatively, the catheter body 22 has a substantially uniform diameter. In this alternative embodiment, the electrode 52 is still positioned between the proximal and distal occlusion balloons 32 and 28. Additionally, if the sheath 50 is absorbent, the catheter body 22 may define only a single delivery port 48 positioned proximate to one of the sheath's 50 oppositely disposed ends 62 or 64.

The sheath 50 has several advantages. For example, the sheath 50 will prevent the electrode 52 from being placed in direct contact with tissue along the urethral wall. Additionally, the sheath 50 helps to distribute the current so that there is not a single point at which the current will pass from the electrode 52 to the tissue. As a result, hot

spots are prevented, which might otherwise cause the tissue directly adjacent to the electrode 52 to burn.

Figure 3 illustrates yet another embodiment of the present invention that has an elastic portion for generating axial tension. This alternative embodiment is shown positioned within the patient's urethra 100.

A catheter body 66 has a distal portion 68, an intermediate portion 70, and a proximal portion 72. The distal and proximal portions 68 and 72 have a first outer diameter that is substantially uniform. The distal occlusion balloon 28 and proximal occlusion balloon 32 are operably connected to catheter body 66 proximate oppositely disposed ends of intermediate portion 70. The distance between distal occlusion balloon 28 and proximal occlusion balloon 32 is about the same as the combined length of the average prostatic urethra 104 and the average membranous urethra 106.

Figure 4A illustrates a cross-section of the proximal portion 72 of catheter body 66. Figure 4B illustrates a cross-section of the intermediate portion 70 of catheter body 66. As shown in these figures, catheter body 66 defines a delivery lumen 74 having a substantially uniform diameter and a first inflation lumen 76 having a substantially uniform diameter. The first inflation lumen 76 is in fluid communication with distal occlusion balloon 28. A second inflation lumen 78 is in fluid communication with proximal occlusion balloon 32. One skilled in the art will realize that the catheter body 66 can also define a drainage lumen (not shown). As illustrated by Figures 4A and 16B, a cross-section of proximal portion 72 of catheter body 66 has a greater area than the cross-section of intermediate portion 70 of catheter body 66. As a result, the intermediate portion 70 has more elasticity than proximal portion 72.

In use, the catheter body 66 is inserted through the patient's urethra 100 until distal occlusion balloon 28 is positioned within the patient's bladder 102. The distal occlusion balloon 28 is inflated. The caregiver then pulls on the proximal portion 72 of catheter body 66 causing the intermediate portion 70 to expand. This action seals the distal occlusion balloon 28 at the bladder neck 110 and pulls the proximal occlusion balloon 32 into the bulbous urethra 108. The proximal occlusion balloon 32 is then inflated, and the proximal portion 72 of the catheter body 66 is released so that the proximal occlusion balloon 32 will become seated against the narrowing portion of the bulbous urethra 108.

The elasticity of intermediate portion 70 causes axial tension that urges the proximal and distal occlusion balloons 32 and 28 to move toward one another. The axial tension helps to seat the proximal and distal occlusion balloons 32 and 28 and also enhances the sealing effect of the proximal and distal occlusion balloons 30 and

28. As a result, the prostatic urethra 104 and membranous urethra 106 becomes substantially isolated from the bladder 102, bladder neck 110, and bulbous urethra 108.

One skilled in the art will realize that a part of the intermediate portion 70 can have a greater cross-sectional area as shown in Figure 4A, so long as there is a segment of the intermediate portion 70 that has a smaller cross-sectional area so that elasticity is increased enough to permit the caregiver to generate axial tension between the proximal and distal occlusion balloons 32 and 28. One skilled in the art will further realize that the proximal and distal occlusion balloons 32 and 28 are preferably mounted on the catheter body 66 at a point that has the larger cross-sectional area as shown in Figure 4A. This configuration will ensure that the axial tension is concentrated between the proximal and distal occlusion balloons 32 and 28.

In an alternative embodiment, the catheter body 66 can be made from two different materials having different elasticity. For example, the proximal and distal portions 72 and 68 of the catheter body 66 might be formed from one material having a predetermined elasticity. The intermediate portion 70 then can be formed from a second material that has predetermined elasticity greater than the elasticity of the proximal and distal portions 72 and 68 of the catheter body 66. The intermediate portion 70 can be spliced between the proximal and distal portions 72 and 68 using a variety of manufacturing techniques that are well known in the art. In this alternative embodiment, the distal, intermediate, and proximal portions 68, 70, and 72 can have the same cross-sectional area.

In another alternative embodiment of the catheter with an elastic segment, the distance between the proximal and distal occlusion balloons 32 and 28 is about the same length as an average prostatic urethra 104. In this embodiment, one skilled in the art will realize that the caregiver will need to secure the proximal portion of the catheter body 66 to the patient's body in order to maintain axial tension.

While the invention has been described in conjunction with a specific embodiment thereof, it is evident that different alternatives, modifications, and variations will be apparent to those skilled in the art in view of the foregoing description. Accordingly, the invention is not limited to these embodiments or the use of elements having specific configurations and shapes as presented herein.

THE CLAIMED INVENTION IS:

1. An apparatus for delivering fluid into a patient's urethra, the patient having a bladder, the apparatus comprising:

a catheter having a proximal portion and a distal portion;

a first balloon operably connected to the catheter; and

a second balloon operably connected to the distal portion of the catheter, the second balloon having a proximal end that is generally arcuate and convex when in an inflated state.

2. The apparatus of claim 1 wherein the distance between the first and second balloons is about the same as the combined length of the prostatic and membranous urethras.

3. The apparatus of claim 1 wherein the distance between the first and second balloons is about the same as the length of the prostatic urethra.

4. The apparatus of claim 1 wherein the second balloon has a toroidal shape when in the inflated state.

5. The apparatus of claim 4 wherein the second balloon is formed from an elastomer material.

6. The apparatus of claim 5 wherein the second balloon is formed from an elastic material from the group consisting essentially of: latex, polyurethane, and silicone.

7. The apparatus of claim 4 wherein the second balloon is formed from a nonelastic material.

8. The apparatus of claim 1 wherein the catheter defines a surface, a delivery lumen, and a delivery port, the delivery port being in fluid communication with the delivery lumen and positioned between the first and second balloons, the apparatus further comprising:

a first electrode operably connected to the surface of the catheter and positioned between the first and second balloons, the first electrode being connectable to a power supply;

a second electrode configured to be placed against the patient's skin, the second electrode being connectable to the power supply; and

a sheath covering the electrode and the delivery port, the sheath being configured to provide a conductive path so that electrical current can flow between the first and second electrodes.

9. The apparatus of claim 8 wherein the sheath is formed from a polymer matrix configured to absorb fluid through the delivery port.

10. The apparatus of claim 9 wherein the sheath and the catheter define a fluid chamber, further wherein the sheath is formed from a porous membrane.

11. An apparatus for delivering fluid to a patient having a bladder and a urethra, the urethra having a bulbous urethra, membranous urethra, and prostatic urethra, the apparatus comprising:

a catheter having a proximal portion and a distal portion;

a first balloon operably connected to the proximal portion of the catheter; and

a second balloon operably connected to the distal portion of the catheter, the second balloon having a proximal end that is generally arcuate and convex when in an inflated state, the distance between the first and second balloons being between about 3 cm and about 7 cm.

12. A method of delivering fluid to a patient, the patient having a urethra, bladder, and prostate gland, the urethra including a prostatic urethra, the method comprising the steps of:

substantially isolating a segment of the urethra, the isolated segment including the prostatic urethra;

substantially isolating the bladder from the bladder neck so that the isolated segment of the urethra remains in fluid communication with the bladder neck; and

delivering a fluid to the isolated segment of the urethra and the bladder neck.

13. The method of claim 12 wherein the fluid contains an agent, the method comprising the additional step of transporting agent from the isolated segment of the urethra into the prostate gland.

14. The method of claim 13 wherein the step of delivering a fluid includes the step of delivering anesthetic, thereby anesthetizing the bladder neck, the prostate gland, and the isolated segment of the urethra.

15. The method of claim 13 wherein the step of transporting agent from the isolated segment of the urethra into the prostate gland includes the step of pressurizing the fluid in the isolated segment of the urethra.

16. The method of claim 12 wherein the urethra includes a membranous urethra and the method utilizes a catheter having first and second balloons, the second balloon having a proximal end that is generally arcuate and convex when in an inflated state, further wherein the step of substantially isolating the bladder from the bladder neck includes the steps of:

positioning the catheter so that the second balloon is located in the bladder and inflating the second balloon;

seating the proximal end against the bladder wall;

positioning the first balloon in the membranous urethra; and

inflating the first balloon, thereby blocking the urethral passage.

17. The method of claim 16 including the additional step of providing axial tension along the catheter body.

18. The method of claim 12 wherein the urethra has a bulbous urethra and the method utilizes a catheter having first and second balloons, the second balloon having a proximal end that is generally arcuate and convex when in an inflated state, further wherein the step of substantially isolating the bladder from the bladder neck includes the steps of:

positioning the catheter so that the second balloon is located in the bladder and inflating the second balloon;

seating the proximal end against the bladder wall;

positioning the first balloon in the bulbous urethra; and

inflating the first balloon, thereby blocking the urethral passage.

19. The method of claim 18 including the additional step of providing axial tension along the catheter body.

20. A method of delivering fluid to a patient, the patient having a urethra, bladder, and prostate gland, the urethra including a prostatic urethra, the method utilizing a

catheter having first and second balloons, the second balloon having a proximal end that is generally arcuate and convex when in an inflated state, the method comprising the steps of:

positioning and inflating the first balloon in the bulbous urethra;

positioning and inflating the second balloon in the bladder;

providing axial tension along the catheter body thereby seating the first balloon against the wall of the bulbous urethra and seating the proximal end of the second balloon against the bladder wall, wherein the membranous urethra, prostatic urethra, and bladder neck become substantially isolated; and

delivering fluid to the membranous urethra, prostatic urethra, and bladder neck.

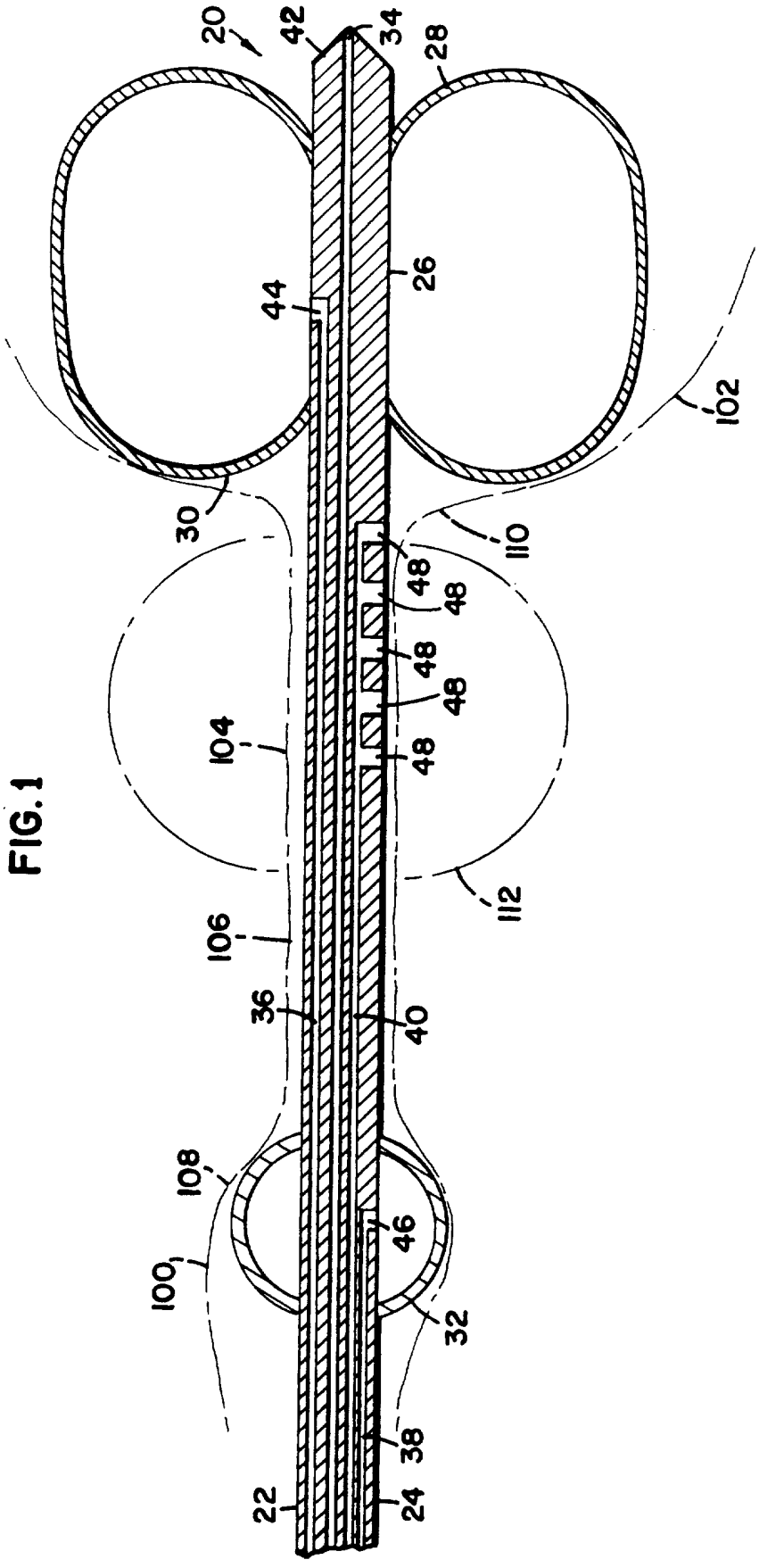
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FIG. 1

FIG. 2

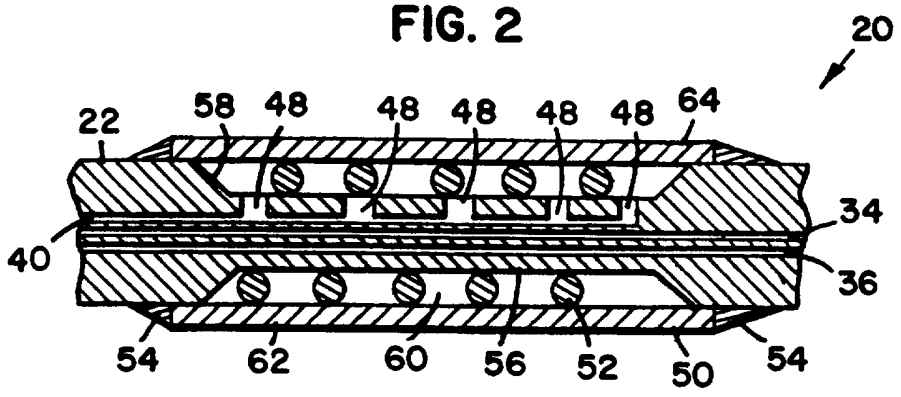
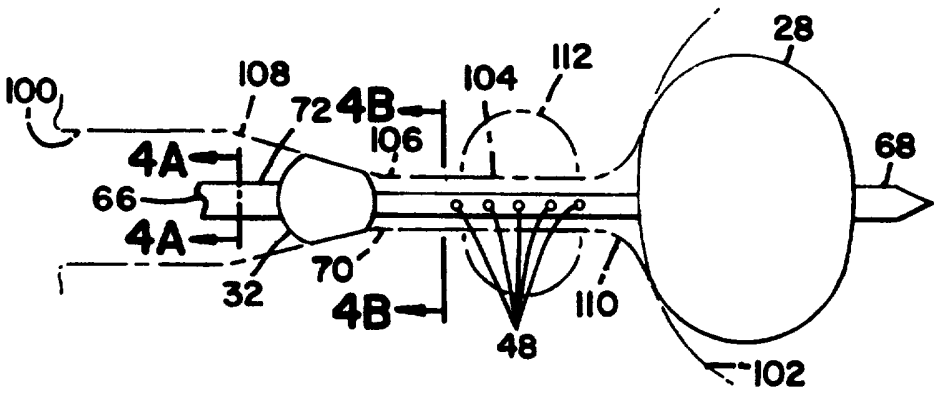


FIG.3



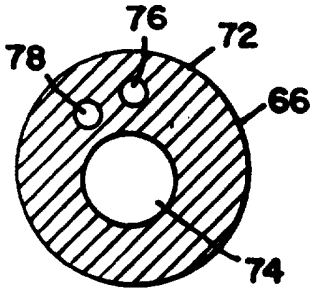


FIG.4A

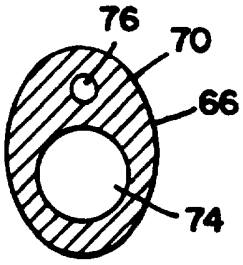


FIG.4B

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/04449

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/10 A61N1/30

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 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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 94 13 272 U (ROEWER) 21 December 1995 see page 5, paragraph 3 - page 7, paragraph 3; figures	1-6,11
X	US 3 543 759 A (MCWHORTER) 1 December 1970 see figure 1	1,4,5
X,P	WO 96 27406 A (AMERICAN MEDICAL SYSTEMS INC) 12 September 1996 see page 7, line 23 - line 33; figure 4	1-6,11
A	US 5 419 763 A (HILDEBRAND) 30 May 1995 cited in the application see the whole document	1-11

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[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

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Date of the actual completion of the international search	Date of mailing of the international search report
25 July 1997	01.08.97

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	Clarkson, P

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/04449

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 286 254 A (SHAPLAND ET AL) 15 February 1994 cited in the application see column 14, line 58 - column 15, line 4; figure 11	1-11
X	"Bardex Ballonkatheter" June 1983 , BARD UROLOGIEBEDARF , LEINFELDEN-ECHTERDINGEN XP002036170 Photograph of urological balloon on page 1 and item 600190 on page A10	1-6,11

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 97/04449

Box I Observations where certain claims were found unsearchable (Continuation of item 1 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.: 12-20
because they relate to subject matter not required to be searched by this Authority, namely:
Please see Rule 39.1(iv) PCT.

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 II Observations where unity of invention is lacking (Continuation of item 2 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/US 97/04449

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		WO 9119529 A	26-12-91
		US 5628730 A	13-05-97