be made impermeable to water such that an air pocket is formed in the retention frame lumen about the elastic wire. A coating or sheath may be applied to the walls, on either the inside or outside, to reduce the water permeability.

One example device may have a mass of about 0.40 grams or less and a density of about 0.7 g/mL or less when unloaded. The device may be loaded with a drug having a mass of about 275 mg or less. In such embodiments, the device when loaded may have a mass of about 0.675 grams or less and a density of about 1.1g/mL or less. Such a device may be well tolerated in the bladder. Devices of smaller masses and densities would likewise be well tolerated. The device may also be somewhat larger, for example, the L650 device described in Example ~~3~~ 2 below.

The exact configuration and shape of the intravesical drug delivery device may be selected depending upon a variety of factors including the specific site of deployment/implantation, route of insertion, drug, dosage regimen, and therapeutic application of the device. The design of the device may minimize the patient's pain and discomfort, while locally delivering a therapeutically effective dose of the drug to a tissue site (e.g., urothelial tissue) in a patient.

The implantable drug delivery device can be made to be completely or partially bioerodible so that no explantation, or retrieval, of the device is required following release of the drug formulation. As used herein, the term "bioerodible" means that the device, or part thereof, degrades *in vivo* by dissolution, enzymatic hydrolysis, erosion, resorption, or a combination thereof. In one embodiment, this degradation occurs at a time that does not interfere with the intended kinetics of release of the drug from the device. For example, substantial erosion of the device may not occur until after the drug formulation is substantially or completely released. In another embodiment, the device is erodible and the release of the drug formulation is controlled at least in part by the degradation or erosion characteristics of the erodible device body.

Alternatively, the implantable drug delivery device may be at least partially non-bioerodible. In some embodiments, the device is formed from materials suited for urological applications, such as medical grade silicone, natural latex, PTFE, ePTFE, PLGA, PGS, stainless steel, nitinol, elgiloy (non ferro magnetic metal alloy), polypropylene, polyethylene, polycarbonate, polyester, nylon, or combinations thereof. Following release of the drug formulation, the device and/or the retention frame may be removed substantially intact or in multiple pieces. In some embodiments, the device is

6,160,084 to Langer et al. The elastic wire also may include a relatively low modulus elastomer, which may be relatively less likely to irritate or cause ulcer within the bladder or other implantation site and may be biodegradable so that the device need not be removed. Examples of low modulus elastomers include polyurethane, silicone, styrenic thermoplastic elastomer, and poly(glycerol-sebacate) (PGS). The elastic wire may be coated with a biocompatible polymer, such as a coating formed from one or more of silicone, polyurethane, styrenic thermoplastic elastomer, Silitek, Tecoflex, C-flex, and Percuflex.

For example, in the embodiment shown in **FIGS. 1-32**, the retention frame **114** is an elastic wire formed from a superelastic alloy, such as nitinol, and surrounded by the wall **124** of the retention frame lumen ~~3~~**110**, which forms a protective sheath about the retention frame **114.** Thus, the wall **124** may be formed from a polymer material, such as silicone. In other embodiments, the retention frame may be an elastic wire formed from a superelastic alloy, such as nitinol, that is covered in a polymer coating, such as a silicone sheath and is attached to the drug reservoir portion.

In some embodiments, the retention frame lumen **110** may include the retention frame **114** and a filling material, such as a polymer filling. An example filling material is a silicone adhesive, such as MED3-4213 by Nusil Technology LLC, although other filling materials may be used. The filling material may fill the void in the retention frame lumen **110** about the retention frame **114**. For example, the filling material may be poured into the retention frame lumen **110** about the retention frame **114** and may cure therein. The filling material may reduce the tendency of the drug reservoir lumen **108** to stretch along, or twist or rotate about, the retention frame **114**, while maintaining the drug reservoir lumen **108** in a selected orientation with reference to the retention frame **114**. The filling material is not necessary, however, and may be omitted.

When the retention frame is in the relatively expanded shape, such as the coiled shapes shown in **FIG. 1**, the device may occupy a space having dimensions suited to impede expulsion from the bladder. When the retention frame is in the relatively lower-profile shape, such as the elongated shapes shown in **FIG. 2,** the device may occupy an area suited for insertion into the body, such as through the working channel of a deployment instrument. The properties of the elastic wire cause the device to function as a spring, deforming in response to a compressive load but spontaneously returning to its initial shape once the load is removed. The polymer coating may make the outer surface

Use and Applications of the Device

The device may be implanted in a body cavity or lumen, and subsequently may release one or more drugs for the treatment of one or more conditions, locally to one or more tissues at the deployment site and/or regionally to other tissues distal from the deployment site. The release may be controlled over an extended period. Thereafter, the device may be removed, resorbed, excreted, or some combination thereof.

In one example, the device is implanted by passing the drug delivery device through a deployment instrument and releasing the device from the deployment instrument into the body. In cases in which the device is deployed into a body cavity such as the bladder, the device assumes a retention shape, such as an expanded or higher profile shape, once the device emerges from the deployment instrument into the cavity. An example is illustrated in **FIG. 7**, which shows the device **700** assuming a retention shape as the device exits a deployment instrument **702**. The deployment instrument **702** may be any suitable lumen device, such as a catheter, urethral catheter, or cystoscope. These terms are used interchangeably herein, unless otherwise expressly indicated. The deployment instrument 7021~~102~~ may be a commercially available device or a device specially adapted for the present drug delivery devices.

Once implanted, the device may release the drug. The device may provide extended, continuous, intermittent, or periodic release of a desired quantity of drug over a desired, predetermined time period. In embodiments, the device can deliver the desired dose of drug over an extended period, such as 12 hours, 24 hours, 5 days, 7 days, 10 days, 14 days, or 20, 25, 30, 45, 60, or 90 days, or more. The rate of delivery and dosage of the drug can be selected depending upon the drug being delivered and the disease or condition being treated.

In embodiments in which the device comprises a drug in a solid form, elution of drug from the device occurs following dissolution of the drug within the device. Bodily fluid enters the device, contacts the drug and solubilizes the drug, and thereafter the dissolved drug diffuses from the device or flows from the device under osmotic pressure or via diffusion. For example, the drug may be solubilized upon contact with urine in cases in which the device is implanted in the bladder.

Subsequently, the device may be retrieved from the body, such as in cases in which the device is non-resorbable or otherwise needs to be removed. Retrieval devices for this purpose are known in the art or can be specially produced. The device also may be

We claim:

1. Use of ~~A medicament~~ lidocaine in the manufacture of a medicament for use in the treatment of bladder pain and/or irritative voiding symptoms, wherein the medicament is to be continuously ~~adminstered~~ administered over a treatment period of ~~24 hours or more~~from 2 to 28 days in an amount effective to achieve a therapeutic effect which is sustained beyond the end of the treatment period,

   and wherein the continuous administration is into a patient's bladder at a mean average amount from 10 mg to 30 mg lidocaine (FBE) per day of the treatment period.

2. The use of claim 1, wherein the duration of continuous release is from 10 to 14 days.

3. The use of claim 1, wherein the cumulative amount of lidocaine (FBE) administration continuously over the treatment period is from 20 mg to 400 mg.

4. The use of claim 1, wherein the rate of lidocaine (FBE) released into bladder is from 15 mg to 30 mg day per day over the first 1 to 4 days of the treatment period and then tapers to a rate of from 15 mg to 3 mg per day over the remainder of the treatment period.

5. The use of claim 4, wherein the measurable plasma concentration of lidocaine does not exceed 65 ng/ml at a time of peak lidocaine exposure in the bladder.

6. The use of claim 1, wherein the rate of lidocaine (FBE) released into bladder is from 25 mg to 60 mg day per day over the first 1 to 6 days of the treatment period and then tapers to a rate of from 25 mg to 10 mg per day over the remainder of the treatment period.

7. The medicament of claim 6, wherein the measurable plasma concentration of lidocaine does not exceed 65 ng/ml at a time of peak lidocaine exposure in the bladder.

8. The use of claim 1, wherein the therapeutic effect is sustained more than 48 hours beyond the end of the treatment period.

9. A drug delivery device comprising a medicament according to any one of the preceding claims, configured to release lidocaine when inserted into the bladder.

~~10. The drug delivery device of claim 9,~~ wherein the drug delivery device is~~.~~ configured to release lidocaine continuously from 2 to 28 days, preferably from 3 to 21 days.

~~11~~10. The drug delivery device of claim 9, configured to release lidocaine continuously from 10 to 14 days.

~~12~~11. The drug delivery device of claim 9, configured to be wholly deployed into the bladder of a patient during the treatment period, for releasing lidocaine or other anesthetic agent to the bladder.

~~13~~12. The use of claim 1, wherein continuous administration of the lidocaine to the bladder is by pumping into the bladder through a urethral catheter which is deployed into the bladder during the treatment period.

~~14. The use of claim 1, wherein continuous administration of the lidocaine administered to the bladder is by release from a coating substance that is transurethrally applied to the bladder wall, the coating substance comprising lidocaine and one or more excipient materials that promote adherance of the coating substance to the wall of the bladder and provides continuous controlled release of the lidocaine over the treatment period.~~

~~15~~13. Use of lidocaine in the manufacture of a medicament for the treatment of bladder pain and/or irritative voiding symptoms, wherein the medicament is to be continuously administered to the bladder of the patient in an amount effective to achieve a therapeutic effect which is sustained beyond an end of the treatment period,

and wherein the lidocaine is to be administered continuously over a treatment period of from ~~2~~ 10 to 28 days,

wherein a cumulative amount of the lidocaine (FBE) administered over the treatment period is between 150 mg and 1000 mg.

~~16. The use of claim 15, wherein the lidocaine is to be administered continuously into the bladder for between 2 and 14 days.~~