

We claim:

1. A drug delivery device for deployment in a renal pelvis of a patient, the drug delivery device comprising:

an elastic body, wherein the elastic body comprises

- (i) an outer tube comprising an elongated outer wall, and
- (ii) an elongated, arcuate inner wall located within the outer tube and integrally connected to an inner surface of the outer wall along two opposed edges of the arcuate inner wall, the outer and inner walls together defining (a) a guidewire lumen on a concave side of the inner wall, and (b) a drug reservoir lumen on an opposed convex side of the inner wall, the drug reservoir lumen being closed off at its opposed ends; and

a drug payload disposed in the drug reservoir lumen, wherein the drug payload comprises at least one drug,

wherein the drug delivery device is elastically deformable between a deployment shape for passage of the drug delivery device through a ureter and into the renal pelvis of the patient, and a retention shape which is configured to mitigate migration of the device from the renal pelvis, such that the drug delivery device can be wholly contained within the renal pelvis, with the optional exception of a retrieval string extending at least into the patient's ureter.

2. The drug delivery device of claim 1, wherein the device is biased to be in the retention shape in the absence of a guidewire inserted into the guidewire lumen.
3. The drug delivery device of claim 1, wherein the retention shape has a helical portion.
4. The drug delivery device of claim 3, wherein the retention shape further comprises straight end portions which extend in the longitudinal direction of the device.
5. The drug delivery device of claim 3, wherein the helical portion comprises from two to ten turns.
6. The drug delivery device of claim 5, wherein at least two of the turns are separated by an intermediate straight portion.

7. The drug delivery device of any one of the claims 1 to 6, wherein one or both ends of the device body is tapered.
8. The drug delivery device of any one of claims 1 to 6, wherein the outer tube comprises two different materials of construction, of which a first material is impermeable to the drug when the drug is in solution and a second material which is permeable to the drug when the drug is in solution; and wherein the second material is adjacent to the drug payload.
9. The drug delivery device of claim 8, wherein the second material is in the form of a drug permeable stripe extending the length of the elongated outer wall.
10. The drug delivery device of claim 9, wherein the outer wall is cylindrical and the drug permeable stripe has an arc angle of ~~about~~ 30 ° to ~~about~~ 120 ° of the circumference of the outer wall in the cross section.
11. The drug delivery device of claim 10, wherein the drug permeable stripe has an arc angle of ~~about~~ 55 ° to ~~about~~ 120 ° of the circumference of the outer wall in the cross section.
12. The drug delivery device of claim 9, wherein the first material comprises a ~~tecoflex~~ first polyurethane.
13. The drug delivery device of claim 9, wherein the first material further comprises a radio-opaque filler.
14. The drug delivery device of claim 9, wherein the second material comprises a ~~teophilie~~ second polyurethane.
15. The drug delivery device of any one of claims 1 to 6, wherein the drug reservoir lumen has a crescent cross-sectional shape.
16. The drug delivery device of any one of claims 1 to 6, wherein the guidewire lumen has a circular cross-sectional shape.
17. The drug delivery device of any one of claims 1 to 6, further comprising a retention frame lumen and a retention frame disposed in the retention frame lumen, the

retention frame being an elastic wire configured to bias the drug delivery device into the retention shape.

18. The drug delivery device of any one of claims 1 to 6, wherein the retention shape comprises a helical portion and the drug delivery device has a length of ~~about~~ 5 cm to ~~about~~ 15 cm when in the deployment shape.
19. The drug delivery device of claim 18, wherein the drug delivery device has a length of ~~about~~ 0.8 cm to ~~about~~ 2 cm when in the retention shape.
20. The drug delivery device of any one of claims 1 to 6, wherein each of the opposed ends of the drug reservoir lumen is sealed by a spacer.
21. The drug delivery device of claim 20, further comprising at least one middle spacer disposed in the drug reservoir lumen at a position between the opposed ends.
22. The drug delivery device of claim 20 or 21, wherein the elastic body, the end spacers, and/or the at least one middle spacer comprises a radio-opaque filler material.
23. The drug delivery device of any one of claims 1 to 20, further comprising a retrieval string attached to the drug delivery device.
24. The drug delivery device of claim 23, wherein the retrieval string has a length sufficient for an end of the retrieval string to reside in the patient's bladder when the drug delivery device is deployed in the renal pelvis.
25. The drug delivery device of any one of claims 1 to 6, wherein the drug payload is in a solid or a semi-solid form.
26. The drug delivery device of claim 25, wherein the drug payload is the form of a powder or a plurality of tablets.
27. The drug delivery device of claim 25, wherein the drug payload is the form of a plurality of tablets which have a crescent cross-sectional shape.
28. The drug delivery device of any one of claims 1 to 6, wherein the outer tube and the inner wall are formed together by a co-extrusion process.

29. The drug delivery device of any one of claims 1 to 6, wherein the elastic body is thermally shape set to have the retention shape.
30. A system for administration of a drug to a patient in need thereof, the system comprising:
the drug delivery device of any one of claims 1 to 29; and
a guidewire deployment system for deploying the drug delivery device in a renal pelvis of the patient, wherein the guidewire deployment system including (i) a guidewire configured for operable association with the drug delivery device and having a distal end portion capable of extending into the renal pelvis while an opposed proximal end portion extends out of the patient's urethra, and (ii) a plunger device for pushing the drug delivery device over the guidewire and off of the distal end and into the renal pelvis,
wherein the guidewire has a cross-sectional area dimensioned to pass through the guidewire lumen of the drug delivery device.
31. The system of claim 30, wherein the plunger device comprises:
a plunger;
a handle;
a sheath extending between the plunger and the handle, the sheath transferring to the plunger a driving force applied to the handle; and
an internal bore for receiving the guidewire, such that the plunger device can travel over the guidewire.
32. The system of claim 31, wherein the plunger further comprises a stop configured to indicate that the drug delivery device has separated from the guidewire.
- ~~33. A method of administering a drug to a patient in need thereof, the method comprising:
deploying a drug delivery device in a renal pelvis of the patient, wherein the drug delivery device is wholly contained in the renal pelvis, with the optional exception of a retrieval string configured to extend into the patient's bladder, or through the bladder and into or through the patient's urethra, of the patient; and
releasing a drug from the drug delivery device into the renal pelvis.~~
- ~~34. The method of claim 33, wherein the drug is released via transwall diffusion through at least a portion of an outer wall of the drug delivery device.~~

35. The method of claim 34, wherein:

- the outer wall comprises two different materials of construction, of which a first material is impermeable to the drug when the drug is in solution and a second material which is permeable to the drug when the drug is in solution;
- the second material is adjacent to a payload comprising the drug; and
- the drug is released via transwall diffusion through the second material.

36. The method of any one of claims 33 to 35, wherein the deploying of the drug delivery device comprises:

- elastically deforming the drug delivery device into a deployment shape;
- inserting the drug delivery device through the patient's urethra, bladder, and ureter; and
- releasing the drug delivery device into the patient's renal pelvis such that the drug delivery devices elastically deforms into a retention shape.

37. The method of claim 33, wherein the deploying the drug delivery device comprises:

- inserting a distal end of a guidewire through the patient's urethra, bladder, ureter, and into a renal pelvis of the patient;
- advancing the drug delivery device along the guidewire toward the distal end and away from a proximal end of the guidewire, wherein the guidewire is positioned within the guidewire lumen, until the drug delivery device is positioned within the renal pelvis; and then
- withdrawing the guidewire from the guidewire lumen and from the patient.

38. The method of claim 37, wherein the drug delivery device is elastically deformable between a coiled or helical retention shape and a relatively straightened insertion shape, and wherein:

- during the step of advancing the drug delivery device along the guidewire, the guidewire located in the guidewire lumen exerts a load on the drug delivery device to bias the drug delivery device into the relatively straightened insertion shape, and
- following the step of withdrawing the guidewire from the guidewire lumen, the drug delivery device elastically deforms to the coiled or helical retention shape suited to retain the drug delivery device within the renal pelvis of a patient.

39. ~~The method of claim 33, wherein the drug delivery device comprises a radiopaque marker or agent, and wherein the method further comprises determining placement of the drug delivery device in the patient by radiography.~~
40. ~~The method of claim 33, wherein, following the deploying of the drug delivery device in the renal pelvis, urine diffuses into the drug reservoir lumen and contacts the drug in the payload, and produces a solution of the drug, which subsequently is released into the renal pelvis.~~
41. ~~The method of claim 40, wherein:~~
~~————— the outer wall comprises two different materials of construction, of which a first material is impermeable to the drug when the drug is in solution and a second material which is permeable to the drug when the drug is in solution; and~~
~~————— following the deploying of the drug delivery device in the renal pelvis, urine diffuses into the drug reservoir lumen by transwall diffusion through the first and/or second materials, contacts the drug contained the drug reservoir lumen, and produces a solution of the drug, which subsequently is released into the renal pelvis by transwall diffusion through the second material.~~
42. ~~The method of claim 33, wherein a rate of the release of the drug from the drug delivery device is essentially zero order for a period ranging between 36 hours and 7 days.~~
43. ~~A method of administering a drug to a patient in need thereof, comprising:~~
~~————— deploying a drug delivery device into a renal pelvis of the patient; and~~
~~————— continuously releasing a drug from the deployed drug delivery device into urine in the renal pelvis over an extended treatment period of at least 24 hours,~~
~~————— wherein the drug delivery device is wholly contained within the renal pelvis, with the optional exception of a retrieval string extending at least into the patient's ureter.~~
44. ~~The method of claim 43, wherein the treatment period from one day to 90 days.~~
45. ~~The method of claim 43, wherein the drug is released from the drug delivery device by transwall diffusion or by osmotic pressure through an aperture in a wall of the drug delivery device.~~

46. — ~~The method of any one of claims 43 to 45, wherein the patient is in need of treatment or prophylaxis of a urinary tract infection or pyelonephritis.~~
47. — ~~The method of any one of claims 43 to 45, wherein the patient is in need of treatment of renal cell carcinoma.~~
48. — ~~The method of any one of claims 43 to 45, wherein the patient is in need of treatment of upper tract urothelial carcinoma.~~
49. — ~~The method of any one of claims 43 to 45, wherein the patient is in need of treatment of hyperfibrinolysis.~~
50. — ~~The method of any one of claims 43 to 45, wherein the patient is in need of treatment of urinary stones.~~
51. — ~~The method of claim 50, wherein the deployment of the drug delivery device into the renal pelvis follows treating the patient with extracorporeal shock wave lithotripsy for treatment of kidney stones in the patient.~~
52. — ~~A drug delivery device for deployment in a renal pelvis of a patient, the drug delivery device comprising:~~
~~————— an elongated elastic body, wherein the elastic body comprises a guidewire lumen and a separate drug reservoir lumen; and~~
~~a drug payload disposed in the drug reservoir lumen, wherein the drug payload comprises at least one drug,~~
~~wherein the drug delivery device is elastically deformable between a deployment shape configured for passage of the drug delivery device through a ureter and into the renal pelvis of the patient, and a helical retention shape configured to mitigate migration of the device from the renal pelvis.~~
53. — ~~The drug delivery device of claim 52, wherein the device is biased to be in the retention shape in the absence of a guidewire inserted into the guidewire lumen, and wherein the elastic body (i) is thermally shape set to have the retention shape, and/or (ii) further comprises a retention frame lumen and a retention frame disposed in the retention frame lumen, the retention frame being an elastic wire configured to bias the drug delivery device into the retention shape.~~

- ~~54. The drug delivery device of claim 53, further comprising a retrieval string attached to the elongated elastic body and having a length sufficient for an end of the retrieval string to reside in the patient's bladder when the drug delivery device is deployed in the renal pelvis.~~
- ~~55. The drug delivery device of claim 53, wherein the drug payload is the form of a powder or a plurality of tablets.~~
- ~~56. The drug delivery device of claim 55, wherein the elongated elastic body comprises a water permeable wall configured to permit urine to diffuse into the drug reservoir lumen to contact the drug payload.~~
- ~~57. The drug delivery device of claim 56, wherein the elongated elastic body comprises a drug permeable wall adjacent to the drug reservoir lumen, the drug permeable wall being configured to permit the drug, in solution, to diffuse out of the device.~~
- ~~58. The drug delivery device of claim 57, wherein drug permeable wall is in the form of a drug permeable stripe extending the length of the elastic body.~~
- ~~59. The drug delivery device of claim 57, wherein the elongated elastic body further comprises a drug impermeable wall adjacent to the drug reservoir lumen.~~
- ~~60. The drug delivery device of claim 58, wherein the drug permeable wall comprises tecophilic polyurethane and the drug impermeable wall comprises a tecoflex polyurethane.~~
- ~~61. The drug delivery device of claim 60, wherein the tecoflex polyurethane is either EG-100A-B20 or EG-80A-B20.~~
- ~~62. The drug delivery device of any one of claims 52 to 61, wherein the helical retention shape further comprises straight end portions which extend in the longitudinal direction of the device.~~
- ~~63. The drug delivery device of claim 62, wherein opposed ends of the drug reservoir lumen are each sealed by an end spacer.~~

- ~~64. The drug delivery device claim 63, further comprising at least one middle spacer disposed in the drug reservoir lumen at a position approximately midway between opposed ends of the elongated elastic body.~~
- ~~65. The drug delivery device of claim 64, wherein the end spacers and the at least one middle spacer comprise a radio-opaque filler material.~~
- ~~66. The drug delivery device of any one of claims 52 to 61, wherein the drug reservoir lumen has a crescent cross sectional shape and the drug payload comprises a powder or a plurality of crescent shaped tablets.~~
- ~~67. A drug tablet, comprising:~~
~~_____ a drug; and~~
~~_____ one or more excipients combined with the drug;~~
~~_____ wherein the combination of the drug and the one or more excipients are in a tablet form which has a crescent-shaped cross-sectional profile.~~
- ~~68. The drug tablet of claim 67, wherein the tablet has flat end walls.~~
- ~~69. The drug tablet of claim 67 or 68, wherein the drug comprise from 90% to 99% by weight of the tablet.~~