Brief Summary

Orifice-free drug delivery devices are provided. In one aspect, the present invention refers to a drug delivery device comprising a body having at least one water-permeable wall bounding a reservoir defined within the body, wherein the body comprises an elastic portion; a drug formulation which comprises a drug, the drug formulation being disposed within the reservoir; and at least one restraining plug closing off an opening of the body, the opening being in fluid communication with the reservoir, wherein the at least one water permeable wall permits water to enter the drug delivery device and contact the drug formulation located in the reservoir, and wherein the at least one restraining plug contacts the elastic portion of the body and controls release of the drug from the device by the transient formation of one or more microchannels between the elastic portion of the body and the at least one restraining plug. In one ~~aspect~~example, a drug delivery device is provided that includes: a body having at least one water-permeable wall bounding a reservoir defined within the body, wherein the body comprises an elastic portion; a drug formulation which comprises a drug, the drug formulation being disposed within the reservoir; and at least one restraining plug closing off an opening of the body, the opening being in fluid communication with the reservoir, wherein the at least one restraining plug contacts the elastic portion of the body and controls release of the drug from the device by the transient formation of one or more microchannels between the elastic portion of the body and the at least one restraining plug. In one ~~embodiment~~example, the device includes a restraining plug having an outer diameter, and the elastic portion of the body defines an opening having an inner diameter, wherein the outer diameter of the restraining plug exceeds the inner diameter of the elastic portion of the body by at least 3 %, for example, from 5% to 25%.

In one ~~embodiment~~example, the device is elastically deformable between a relatively straightened shape suitable for insertion through a lumen into a body cavity of a patient and a retention shape suited to retain the device within the body cavity. In a preferred ~~embodiment~~example, the lumen may be the urethra and the body cavity may be the bladder.

Methods of administering a drug to a patient also are provided. In one ~~embodiment~~example, the method includes inserting the drug delivery device of claim 1 into a lumen or body cavity of a patient; and permitting water influx into the reservoir to develop a hydrostatic pressure in the reservoir effective to form one or more microchannels between the elastic portion of the body and the at least one restraining plug, thereby causing the drug to flow from the reservoir, through the microchannels, and out of the device and into the lumen or body cavity of the patient. In one ~~embodiment~~example, the drug is initially is a solid form,

and following insertion into the body, the water that enters the reservoir of the device, contacts and solubilizes the drug, and thereafter the dissolved drug exits the device via the microchannels. For example, the drug may be solubilized upon contact with urine when the device is deployed in the bladder.

Brief Description of the Drawings

FIGS. 1A-1B are plan and cross-sectional views, respectively, showing part of a drug delivery device in which microchannels are formed to permit release of drug.

FIG. 2 is a plan view of an embodiment of a drug delivery device.

We claim:

1. A drug delivery device comprising:

a body having at least one water-permeable wall bounding a reservoir defined within the body, wherein the body comprises an elastic portion;

a drug formulation which comprises a drug, the drug formulation being disposed within the reservoir; and

at least one restraining plug closing off an opening of the body, the opening being in fluid communication with the reservoir,

wherein the at least one water permeable wall permits water to enter the drug delivery device and contact the drug formulation located in the reservoir, and

wherein the at least one restraining plug contacts the elastic portion of the body and controls release of the drug from the device by the transient formation of one or more microchannels between the elastic portion of the body and the at least one restraining plug.

2. The drug delivery device of claim 1, wherein:

the at least one restraining plug has an outer diameter,

the elastic portion of the body defines an opening having an inner diameter, and

wherein the outer diameter of the restraining plug exceeds the inner diameter of the elastic portion of the body by at least 3 %.

3. The drug delivery device of claim 2, wherein the outer diameter of the restraining plug exceeds the inner diameter of the elastic portion of the body by at least 5 %.

4. The drug delivery device of claim 2, wherein the outer diameter of the restraining plug exceeds the inner diameter of the elastic portion of the body by at least 10 %.

5. The drug delivery device of claim 2, wherein the outer diameter of the restraining plug exceeds the inner diameter of the elastic portion of the body by at least 15 %.

6. The drug delivery device of claim 2, wherein the outer diameter of the restraining plug exceeds the inner diameter of the elastic portion of the body by at least 20 %.

7. The drug delivery device of claim 2, wherein the outer diameter of the restraining plug exceeds the inner diameter of the elastic portion of the body by at least 25 %.

8. The drug delivery device of claim 1, wherein the body further comprises an inelastic portion.

9. The drug delivery device of claim 1, wherein the at least one restraining plug is secured within the opening in the elastic portion of the body with an adhesive.

10. The drug delivery device of claim 1, wherein the drug formulation is in a solid form.

11. The drug delivery device of claim 1, wherein the drug comprises lidocaine or another anesthetic agent.

12. The drug delivery device of claim 1, further comprising an osmotic agent.

13. The drug delivery device of claim 12, wherein the osmotic agent is a component of the drug formulation.

14. The drug delivery device of claim 1, wherein the at least one restraining plug is substantially cylindrical.

15. The drug delivery device of claim 1, wherein the at least one restraining plug comprises a wedged, tapered, angled, or rounded surface.

16. The drug delivery device of any one of claims 1 to 15, wherein the Shore durometer of the elastic portion of the body is from ~~about~~ 40A to ~~about~~ 60A, and the Shore durometer of the at least one restraining plug is from ~~about~~ 70A to ~~about~~ 100A.

17. The drug delivery device of any one of claims 1 to 15, wherein the Shore durometer of the elastic portion of the body is from ~~about~~ 45A to ~~about~~ 55A, and the Shore durometer of the at least one restraining plug is from ~~about~~ 75A to ~~about~~ 85A.

18. The drug delivery device of any one of claims 1 to 15, wherein the Shore durometer of the elastic portion of the body is about 50 A, and the Shore durometer of the at least one restraining plug is about 80 A.

19. The drug delivery device of claim 1, wherein the device is elastically deformable between a relatively straightened shape suitable for insertion through a lumen into a body cavity of a patient and a retention shape suited to retain the device within the body cavity.

20. The drug delivery device of any one of claims 1 to 19, wherein the body is formed from an elastomeric tube.

21. The drug delivery device of any one of claims 1 to 19, wherein the body portion defining the reservoir for the drug is formed from a material that is both elastomeric and water permeable.