DRUG DELIVERY DEVICES WITH DRUG-PERMEABLE COMPONENT AND METHODS

Cross-Reference to Related Application

This application claims priority to U.S. Provisional Patent Application No. 61/799,733, filed March 15, 2013, which is incorporated herein by reference.

Background

The present disclosure is generally in the field of implantable medical devices, and more particularly relates to drug-delivery devices with a drug-permeable component.

Implantable medical devices and methods are known for targeted, e.g., local or regional, drug delivery in order to avoid the problems associated with systemic drug delivery. Local delivery of drug to some tissue sites, however, has room for improvement, particularly with respect to extended drug delivery with minimally invasive devices and methods with minimum patient discomfort from the presence of the device itself. The problem is particularly acute for certain drugs, e.g., those having relatively low water solubility, and/or for certain therapies in which the drug needs to be controllably released at therapeutic levels over an extended periods of several days or weeks, while keeping the devices sufficiently small to avoid unnecessary discomfort and pain during and following deployment of the device into patient.

U.S. Patent Application Publications No. 2012/0203203 (TB 121), No. 2012/0089122 (TB 117), No. 2011/0060309 (TB 108), No. 2011/0152839 (TB 112), and No. 2010/0331770 (TB 101) by TARIS Biomedical Inc. describe various drug delivery devices that provide controlled release of drug from a housing. The device may be free floating in a patient's bladder, yet tolerably and wholly retained in the patient's bladder while locally releasing the drug over an extended period. It would be desirable, however, to provide new designs of intravesical drug delivery devices, and other implantable devices capable of delivering drugs at effective release rates for a range of different drugs.

Summary

In one aspect, the present disclosure refers to a drug delivery device comprising: a housing having a closed drug reservoir lumen bounded by a first wall structure constructed of a first material and a hydrophilic second wall structure constructed of a second material;

and a drug contained in the drug reservoir lumen, wherein the first material of the first wall structure is impermeable to the drug, and the second material of the second wall structure is permeable to the drug, wherein the first wall structure forms a cylindrical wall of a tube and the second wall structure is an end wall disposed at at least one end of the tube, and wherein the durometer of each of the first and second materials is selected to make the device compliant in the bladder of a patient.

In one example, implantable drug delivery devices are provided, including a housing having a closed drug reservoir lumen bounded by a first wall structure and a hydrophilic second wall structure, and a drug contained in the drug reservoir lumen, wherein the first

wall structure is impermeable to the drug, and the second wall structure is permeable to the drug. In one example, the first wall structure is a cylindrical tube and the second wall structure is an end wall disposed at at least one end of the cylindrical tube. In another example, the first wall structure and the second wall structure are adjacent one another and together form a cylindrical tube.

In another example, methods of providing controlled release of drug to a patient are provided, including (i) deploying a drug delivery device in the patient, the device comprising a closed drug reservoir lumen bounded by a first wall structure and a hydrophilic second wall structure, and (ii) releasing a drug from the drug reservoir lumen via diffusion through the second wall structure, wherein the first wall structure is impermeable to the drug, and the second wall structure is permeable to the drug. In one example, the first wall structure is a cylindrical tube and the second wall structure is an end wall disposed at at least one end of the cylindrical tube. In example embodiment, the first wall structure and the second wall structure are adjacent one another and together form a cylindrical tube.

Brief Description of the Drawings

FIG. 1 is a cross-sectional plan view of one embodiment of an implantable drug delivery device wherein the second wall structure is an end wall.

FIG. 2 is a cross-sectional plan view of one embodiment of an implantable drug delivery device wherein the second wall structure is an end wall.

FIG. 3 is a cross-sectional plan view of one embodiment of an implantable drug delivery device wherein the second wall structure is an end wall.

FIG. 4A is an exploded perspective view of a portion of one embodiment of an implantable drug delivery device wherein the second wall structure is an end wall.

FIG. 4B is a perspective view of the portion of the device of **FIG. 4A**.

FIG. 4C is a cross-sectional perspective view of the portion of the device of **FIG. 4B**.

FIG. 4D is a cross-sectional view of the portion of the device of **FIG. 4B**.

FIG. 5 is a partial cross-sectional plan view of one embodiment of an implantable drug delivery device wherein the second wall structure is an end wall.

FIG. 6 is a partial cross-sectional plan view of one embodiment of an implantable drug delivery device wherein the second wall structure is an end wall.

Claims

We claim:

1. A drug delivery device comprising:

a housing having a closed drug reservoir lumen bounded by a first wall structure constructed of a first material and a hydrophilic second wall structure constructed of a second material; and

a drug contained in the drug reservoir lumen,

wherein the first material of the first wall structure is impermeable to the drug, and the second material of the second wall structure is permeable to the drug,

wherein the first wall structure forms a cylindrical wall of a tube and the second wall structure is an end wall disposed at at least one end of the tube, and

wherein the durometer of each of the first and second materials is selected to make the device compliant in the bladder of a patient.

2. The device of claim 1, wherein the device is configured for intravesical insertion and retention.

3. The device of claim 2, wherein the device is elastically deformable between a relatively straightened shape suited for insertion through the urethra of a patient and into the patient's bladder and a retention shape suited to retain the device within the bladder.

4. The device of claim 3, further comprising a retention frame lumen and a retention frame disposed therein.

5. The device of claim 1, wherein the first wall structure comprises silicone.

6. The device of claim 1, wherein the second wall structure comprises a thermoplastic polyurethane.

7. The device of claim 1, wherein the second wall structure is in the form of a disk stabilized in a lumen of the cylindrical tube.

8. The device of claim 7, wherein the disk is sandwiched between an inner washer and an outer washer.

9. The device of claim 1, wherein the drug is in the form of one or more solid drug units.

10. The device of claim 1, wherein the drug is a low solubility drug.

11. The device of claim 1, wherein the drug is a high solubility drug.

12. The device of claim 1, wherein the drug comprises lidocaine, gemcitabine, docetaxel, carboplatin, cisplatin, oxaliplatin, trospium, tolterodine, oxybutynin, or mitomycin C.