DEVICES AND METHODS FOR ENGAGING INDEXED VALVE AND PRESSURIZED CANISTER ASSEMBLY WITH COLLAR AND FOR LINEAR ACTUATION BY PLUNGER ASSEMBLY INTO FLUID COMMUNICATION WITH DEVICE FOR REGULATING DRUG DELIVERY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] Not Applicable.

STATEMENT CONCERNING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] **Not** Applicable.

BACKGROUND OF THE INVENTION

[0003] Various keying and canister or cylinder actuation devices are known. In the technology concerning the inhalation of drugs from pressurized cylinders, the cylinders have been large and not easily portable. The cylinders are also unprotected to the surrounding hospital environment, which can be physically rigorous. The connection between the cylinder and the regulation device can be cumbersome.

[0004] Perhaps the most significant drawback, however, is the risk of connecting a cylinder containing an inappropriate, wrong or otherwise unsuitable drug and/or dosing concentration to the regulation device.

[0005] Hence, devices that provide improved connection of the cylinder to the regulation device, improved protection of the cylinder, enhanced portability of the cylinder, and, means for ensuring that a cylinder containing the correct drug and dosing concentration is connected to the drug delivery and regulation device would be advantageous.

SUMMARY ~~OF THE INVENTION~~

[0005a] In accordance with one aspect, there is provided an indexed drug containment device for a drug delivery and regulation device, comprising: a gas canister containing an active pharmaceutical ingredient and an inactive gas carrier for delivery to a drug delivery and regulation device, a valve assembly comprising a housing and a valve in fluid communication with the gas canister and aligned with the gas canister along a longitudinal axis, and, a first indexed member integral to one of the gas canister and the valve assembly and comprising a first opening and a second opening disposed on an

opposite side of the canister from the first opening, the first indexed member adapted to be complementary to a second indexed member of the drug delivery and regulation device when aligned with the second indexed member via a relative movement that is perpendicular to the longitudinal axis.

[0005b] In accordance with another aspect, there is provided an indexed drug delivery device comprising: a valve assembly comprising a housing and a valve, a canister containing an active pharmaceutical ingredient and an inactive gas carrier to be delivered to a regulation device in communication with the valve assembly and aligned with the valve assembly along a longitudinal axis, a first indexed member integral to one of the canister or the valve assembly, the first indexed member adapted to be complementary to a second indexed member when aligned with the second indexed member via a movement that is perpendicular to the longitudinal axis, the first indexed member comprising a first opening and a second opening disposed on an opposite side of the canister from the first opening, and a collar comprising the second indexed member, the second indexed member integral to the collar and comprising a key to engage one of the first opening and the second opening to form a flush interface for actuation of the valve to permit fluid communication between the canister and a regulation device, a receiving assembly comprising a receptacle adapted to engage at least a portion of the housing, and, a seat adapted to engage the valve, and, a plunger assembly adapted to linearly actuate the valve assembly and canister along an axis and to engage the valve and seat, the plunger assembly comprising: a carriage fixed to the collar, and, a lever having a cam adapted to engage a spring, the spring adapted to linearly actuate the carriage, valve assembly, canister and collar along the axis.

[0005c] In accordance with another aspect, there is provided a drug delivery device for regulating delivery of an active pharmaceutical ingredient to a patient comprising: a valve assembly comprising a housing and a valve aligned along a longitudinal axis, a first indexed member integral to the housing, the first indexed member adapted to be complementary to a second indexed member when aligned with the second indexed member via a movement that is perpendicular to the longitudinal axis, a canister in fluid communication with the valve assembly, the canister containing the active pharmaceutical ingredient and an inactive carrier gas, a collar comprising the second indexed member, the second indexed member integral to the collar, a receiving assembly comprising a receptacle adapted to engage at least a portion of the housing, and, a seat adapted to engage the valve, a plunger assembly adapted to linearly actuate the valve assembly and canister along the longitudinal axis and to engage the valve and seat, the plunger assembly comprising: a

carriage fixed to the collar, and, a lever having a cam adapted to engage a spring, the spring adapted to linearly actuate the carriage, valve assembly, canister and collar along the longitudinal axis, and, a controllable drug delivery and regulation device adapted to regulate the delivery of the active pharmaceutical ingredient to the patient.

[0006] One ~~aspect~~ exemplary embodiment of the ~~invention~~ disclosure is an indexed valve assembly comprising a housing and a valve, the valve disposed within the housing, and, a first indexed member integral to the housing, the first indexed member adapted to be complementary to a second indexed member.

[0007] In an exemplary embodiment of the indexed valve assembly, the assembly further comprises a third indexed member integral to the housing, the third indexed member

[0019] In another exemplary embodiment of the indexed valve assembly, the first indexed member is an opening, the second indexed member is a key, the third indexed member is an opening, and, the fourth indexed member is a key.

[0020] In another exemplary embodiment of the indexed valve assembly, the first indexed member is a slot, the second indexed member is rail, the third indexed member is a slot, and, the fourth indexed member is a rail.

[0021] Another ~~aspect~~ exemplary embodiment of the ~~invention~~ disclosure is an indexed drug containment device for inhalation comprising a valve assembly comprising a housing and a valve, the valve disposed within the housing, a first indexed member integral to the housing, the first indexed member adapted to be complementary to a second indexed member, and, a canister in fluid communication with the valve assembly, the canister containing an API and a inactive carrier gas.

[0022] In an exemplary embodiment of the indexed drug containment device, the device further comprises a third indexed member integral to the housing, the third indexed member adapted to be complementary to a fourth indexed member, the first indexed member is non-complementary to the fourth indexed member, and, the third indexed member is non-complementary to the second indexed member.

[0023] In another exemplary embodiment of the indexed drug containment device, the device further comprises a plurality of indexed members, each indexed member adapted to be complementary to a corresponding indexed member and non-complementary to a non-corresponding indexed member.

[0024] In another exemplary embodiment of the indexed drug containment device, one or more indexed members are predeterminately adapted to indicate the identity and canister concentration of the API.

[0025] In another exemplary embodiment of the indexed drug containment device, the API comprises nitric oxide, the inactive carrier gas comprises nitrogen gas (N_2), and, the canister concentration is in the range of approximately 50 ppm or 100 ppm to 800 ppm, 2400 ppm, 2500 ppm or 10,000 ppm.

[0026] In another exemplary embodiment of the indexed drug containment device, the indexed members are further predeterminately adapted to indicate an initial volume of approximately 32 L of compressible gas or 0.16 L of liquid.

[0027] In another exemplary embodiment of the indexed drug containment device, the API comprises carbon monoxide, the inactive carrier gas comprises oxygen gas (O_2) and,

optionally, the balance comprising N_2, and, the canister concentration is in the range of approximately 500 ppm or 3000 ppm to 5000 ppm, 10,000 ppm, 15,000 ppm or 20,000 ppm.

[0028] In another exemplary embodiment, the carrier gas comprises around 30% O_2 and 70% N_2.

[0029] In another exemplary embodiment of the indexed drug containment device, the API comprises a chalcogenide compound at a suitable concentration.

[0030] In another exemplary embodiment of the indexed drug containment device, the valve is a spring-biased needle valve.

[0031] In another exemplary embodiment of the indexed drug containment device, the first indexed member or second indexed member is a key.

[0032] In another exemplary embodiment of the indexed drug containment device, the key is a tongue, prong, post, ridge, protrusion or rail.

[0033] In another exemplary embodiment of the indexed drug containment device, the first indexed member or second indexed member is an opening.

[0034] In another exemplary embodiment of the indexed drug containment device, the opening is a groove, slot, channel, aperture or hole.

[0035] In another exemplary embodiment of the indexed drug containment device, the first indexed member is an opening, the second indexed member is a key, the third indexed member is an opening, and, the fourth indexed member is a key.

[0036] In another exemplary embodiment of the indexed drug containment device, the first indexed member is a slot, the second indexed member is rail, the third indexed member is a slot, and, the fourth indexed member is a rail.

[0037] Another ~~aspect~~ exemplary embodiment of the ~~invention~~ disclosure is an indexed drug actuation device comprising a valve assembly comprising a housing and a valve, the valve disposed within the housing, a first indexed member integral to the housing, the first indexed member adapted to be complementary to a second indexed member, a canister in fluid communication with the valve assembly, the canister containing an API and a inactive carrier gas, and, a collar comprising the second indexed member, the second indexed member integral to the collar.

[0038] In an exemplary embodiment of the indexed drug actuation device, the device further comprises a third indexed member integral to the housing and a fourth indexed member integral to the collar, the third indexed member adapted to be complementary to the fourth indexed member, the first indexed member is non-complementary to the fourth indexed member, and, the third indexed member is non-complementary to the second indexed member.

[0051] In another exemplary embodiment of the indexed drug actuation device, the first indexed member is a slot, the second indexed member is rail, the third indexed member is a slot, and, the fourth indexed member is a rail.

[0052] Another exemplary embodiment~~aspect~~ of the ~~invention~~ disclosure is an indexed drug delivery device comprising a valve assembly comprising a housing and a valve, the valve disposed within the housing, a first indexed member integral to the housing, the first indexed member adapted to be complementary to a second indexed member, a canister in fluid communication with the valve assembly, the canister containing an active pharmaceutical ingredient and an inactive carrier gas, a collar comprising the second indexed member, the second indexed member integral to the collar, a receiving assembly comprising a receptacle adapted to engage at least a portion of the housing, and, a seat adapted to engage the valve, and, a plunger assembly adapted to linearly actuate the valve assembly and canister along an axis and to engage the valve and seat, the plunger assembly comprising a carriage fixed to the collar, and, a lever having a cam adapted to engage a spring, the spring adapted to linearly actuate the carriage, valve assembly, canister and collar along the axis.

[0053] In an exemplary embodiment of the indexed drug delivery device, the device further comprises a third indexed member integral to the housing and a fourth indexed member integral to the collar, the third indexed member adapted to be complementary to the fourth indexed member, the first indexed member is non-complementary to the fourth indexed member, and, the third indexed member is non-complementary to the second indexed member.

[0054] In another exemplary embodiment of the indexed drug delivery device, the device further comprises a plurality of indexed members, each indexed member adapted to be complementary to a corresponding indexed member and non-complementary to a non-corresponding indexed member.

[0055] In another exemplary embodiment of the indexed drug delivery device, one or more indexed members are predeterminately adapted to indicate the identity and canister concentration of the API.

[0056] In another exemplary embodiment of the indexed drug delivery device, the API comprises nitric oxide, the carrier gas comprises N2 and, the canister concentration is in the range of approximately 50 ppm or 100 ppm to 800 ppm, 2400 ppm, 2500 ppm or 10,000 ppm.

[0057] In another exemplary embodiment of the indexed drug delivery device, the indexed members are further predeterminately adapted to indicate an initial volume of approximately 32 L of compressible gas or 0.16 L of liquid.

[0058] In another exemplary embodiment of the indexed drug delivery device, the API comprises carbon monoxide, the inactive carrier gas comprises O_2 and, optionally the balance comprises N_2, and, the canister concentration is in the range of approximately 500 ppm or 3000 ppm to 5000 ppm, 10,000 ppm, 15,000 ppm or 20,000 ppm.

[0059] In another exemplary embodiment of the indexed drug delivery device, the API comprises a chalcogenide compound.

[0060] In another exemplary embodiment of the indexed drug delivery device, the valve is a spring-biased needle valve.

[0061] In another exemplary embodiment of the indexed drug delivery device, the first indexed member or second indexed member is a key.

[0062] In another exemplary embodiment of the indexed drug delivery device, the key is a tongue, prong, post, ridge, protrusion or rail.

[0063] In another exemplary embodiment of the indexed drug delivery device, the first indexed member or second indexed member is an opening.

[0064] In another exemplary embodiment of the indexed drug delivery device, the opening is a groove, slot, channel, aperture or hole.

[0065] In another exemplary embodiment of the indexed drug delivery device, the first indexed member is an opening, the second indexed member is a key, the third indexed member is an opening, and, the fourth indexed member is a key.

[0066] In another exemplary embodiment of the indexed drug delivery device, the first indexed member is a slot, the second indexed member is rail, the third indexed member is a slot, and, the fourth indexed member is a rail.

[0067] In another exemplary embodiment of the indexed drug delivery device, the cam is adapted to engage a compression spring, and, the compression spring is adapted to engage the carriage.

[0068] Another exemplary embodiment~~aspect~~ of the ~~invention~~ disclosure is a valve assembly comprising a housing and a valve, the valve disposed within the housing, and, a radio frequency identification device adapted to communicate with a radio frequency receiver.

[0069] Another exemplary embodiment~~aspect~~ of the ~~invention~~ disclosure is a pressurized drug containment device for inhalation comprising a valve assembly comprising a housing and a valve, the valve disposed within the housing, a radio frequency identification device adapted to communicate with a

radio frequency receiver, and, a canister in fluid communication with the valve assembly, the canister containing an API and a inactive carrier gas.

[0070] Another exemplary ~~aspect is a~~ method of engaging the above pressurized drug-containing canister comprising linearly actuating along an axis the above drug containment device to engage a receptacle and to engage the valve with a seat, is disclosed.

[0071] Another exemplary embodiment~~aspect~~ of the ~~invention~~ disclosure is a method of engaging a pressurized canister comprising linearly actuating along an axis an indexed drug-containing pressurized canister to engage a receptacle and to engage the valve with a seat.

[0072] Another exemplary embodiment~~aspect~~ of the ~~invention~~ disclosure is a method of engaging a pressurized canister comprising linearly actuating along an axis an indexed pressurized canister to engage a receptacle and to engage the valve with a seat.

[0073] Another exemplary embodiment~~aspect~~ of the ~~invention~~ disclosure is a drug delivery device for regulating delivery of an API to a patient comprising a valve assembly comprising a housing and a valve, the valve disposed within the housing, a first indexed member integral to the housing, the first indexed member adapted to be complementary to a second indexed member, a canister in fluid communication with the valve assembly, the canister containing the API and an inactive carrier gas, a collar comprising the second indexed member, the second indexed member integral to the collar, a receiving assembly comprising a receptacle adapted to engage at least a portion of the housing, and, a seat adapted to engage the valve, a plunger assembly adapted to linearly actuate the valve assembly and canister along an axis and to engage the valve and seat, the plunger assembly comprising a carriage fixed to the collar, and, a lever having a cam adapted to engage a spring, the spring adapted to linearly actuate the carriage, valve assembly, canister and collar along the axis, and, a controllable drug delivery and regulation device adapted to regulate the delivery of the API to the patient.

[0074] In an exemplary embodiment of the drug delivery device, the device further comprises a third indexed member integral to the housing and a fourth indexed member integral to the collar, the third indexed member adapted to be complementary to the fourth indexed member, the first indexed member is non-complementary to the fourth indexed member, and, the third indexed member is non-complementary to the second indexed member.

[0075] In another exemplary embodiment of the drug delivery device, the device further comprises a plurality of indexed members, each indexed member adapted to be complementary to a corresponding indexed member and non-complementary to a non-corresponding indexed member.

[0088] In another exemplary embodiment of the drug delivery device, the cam is adapted to engage a compression spring, and, the compression spring is adapted to engage the carriage.

[0089] Another exemplary embodiment~~aspect~~ of the ~~invention~~ disclosure is a method of producing pulmonary vasodilation in a patient in need thereof comprising providing any of the above drug delivery devices for delivering nitric oxide, and, delivering a controlled and regulated pharmaceutical dose or dose rate of nitric oxide to the patient.

[0090] Another exemplary embodiment~~aspect~~ of the ~~invention~~ disclosure is a method of treating a disease or disorder selected from the group consisting of outcomes in organ transplant, delayed graph function associated with organ transplant, cystic fibrosis, liens, necrotizing enterocolitis, vascular restenosis, hepatitis, acute liver failure associated with hepatitis and hemorrhagic shock, in a patient in need thereof comprising providing any of the above drug delivery devices for delivering a controlled and regulated pharmaceutical dose or dose rate of carbon monoxide to the patient.

[0091] Another exemplary embodiment~~aspect~~ of the ~~invention~~ disclosure is a drug delivery device for regulating delivery of an API to a patient comprising a receiving assembly comprising a receptacle adapted to engage at least a portion of an indexed drug containment device, a seat adapted to engage the valve of the indexed drug containment device, a plunger assembly adapted to linearly actuate the valve assembly and canister along an axis and to engage the valve and seat, the plunger assembly comprising a carriage fixed to the collar, and, a lever having a cam adapted to engage a spring, the spring adapted to linearly actuate the carriage, valve assembly, canister and collar along the axis, and, a controllable drug delivery and regulation device adapted to regulate the delivery of the API to the patient.

BRIEF DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

[0092] FIG. 1 shows a partial perspective view of the collar canister assembly.

[0093] FIG. 2 shows several partial front views illustrating interfaces between the collar and the canister.

[0094] FIG. 3 shows a side sectional view of the collar canister assembly of FIG. 1 illustrating the receptacle before engaging the assembly.

[0095] FIG. 4 shows a side sectional view of the collar canister assembly of FIG. 1 illustrating the receptacle engaging the assembly.