[0006] As set forth in more detail below, the present disclosure provides an improved injector embodying advantageous alternatives to the conventional devices and methods discussed above.

Summary

[0007] According to an aspect of the present disclosure, an injector includes a container, a seal assembly, a fluid delivery system, and an actuator. The container includes a container wall with an interior surface. The wall of the container defines a bore, and the container further includes a stopper that is moveable along the bore. The seal assembly disposed outside of the container includes a flexible seal assembly wall with an interior surface and an exterior surface, the interior surfaces of the container wall and the seal assembly wall defining a closed sterile reservoir filled with a medical fluid or drug product, and a barrier disposed exterior of the seal assembly wall, the barrier including a surface disposed on the exterior surface of the flexible seal assembly wall, and an enclosed space defined between the flexible wall and the barrier. The fluid delivery system includes a sterile container needle having a point disposed only through the barrier in a storage state such that the sterile container needle is not in fluid communication with the reservoir, and disposed through the flexible wall into the sterile reservoir in a delivery state such that the sterile container needle is in fluid communication with the reservoir. The sterile container needle is attached to a connector, the connector mechanically coupled to the container to secure the sterile container needle to the container with the needle in the storage state.

[0007A] According to another aspect of the present disclosure, an injector includes a container, a seal assembly, a fluid delivery system, and an actuator. The container includes a container wall with an interior surface. The wall of the container defines a bore, and the container further includes a stopper that is moveable along the bore. The seal assembly disposed outside of the container includes a flexible seal assembly wall with an interior surface and an exterior surface, the flexible seal assembly wall fixedly attached to the container wall, the interior surfaces of the container wall, the stopper, and the seal assembly wall defining a closed sterile reservoir adapted to be filled with a medical fluid or drug product, and a barrier disposed exterior of the seal assembly wall, the barrier including a surface disposed on the exterior surface of the seal assembly wall. The fluid delivery system includes a sterile container needle having a point disposed only partially through the seal assembly wall in a storage state such that the sterile container needle is not in fluid communication with the reservoir, and

disposed through the seal assembly wall into the sterile reservoir in a delivery state such that
the sterile container needle is in fluid communication with the reservoir. The sterile container needle is attached to a connector, the connector mechanically coupled to the container to secure the sterile container needle to the container with the needle in the storage state.

[0008] According to another aspect of the present disclosure, a method of assembling an injector includes filling a sterile reservoir of a container with a medical fluid or drug product under sterile conditions, the reservoir defined by an interior surface of a wall of the container, mechanically coupling a sterile fluid delivery system to the container under sterile conditions, the fluid delivery system not in fluid communication with the reservoir in a storage state and in fluid communication with the reservoir in a delivery state, and assembling the remainder of the injector under clean room conditions.

Brief Description of the Drawings

[0009] The disclosure will be more fully understood from the following description taken in conjunction with the accompanying drawings. Some of the figures may have been simplified by the omission of selected elements for the purpose of more clearly showing other elements. Such omissions of elements in some figures are not necessarily indicative of the presence or absence of particular elements in any

We claim:

1. An injector comprising:

a container including a container wall with an interior surface, wherein the wall of the container defines a bore, and the container further comprises a stopper that is moveable along the bore;

a seal assembly disposed outside of the container including a flexible seal assembly wall with an interior surface and an exterior surface, the flexible seal assembly wall fixedly attached to the container wall, the interior surfaces of the container wall and the seal assembly wall defining a closed sterile reservoir filled with a medical fluid or drug product, and a barrier disposed exterior of the seal assembly wall, the barrier including a surface disposed on the exterior surface of the flexible seal assembly wall, and an enclosed space defined between the flexible wall and the barrier; and

a fluid delivery system comprising a sterile container needle having a point disposed only through the barrier in a storage state such that the sterile container needle is not in fluid communication with the reservoir, and disposed through the flexible wall into the sterile reservoir in a delivery state such that the sterile container needle is in fluid communication with the reservoir,

the sterile container needle attached to a connector, the connector mechanically coupled to the container to secure the sterile container needle to the container with the needle in the storage state.

2. An injector comprising:

a container including a container wall with an interior surface, wherein the wall of the container defines a bore, and the container further comprises a stopper that is moveable along the bore;

a seal assembly disposed outside of the container and including a flexible seal assembly wall with an interior surface and an exterior surface, the flexible seal assembly wall fixedly attached to the container wall, the interior surfaces of the container wall, the stopper, and the seal assembly wall defining a closed sterile reservoir adapted to be filled with a medical fluid or drug product, and a barrier disposed exterior of the seal assembly wall, the barrier including a surface disposed on the exterior surface of the seal assembly wall; and

a fluid delivery system comprising a sterile container needle having a point disposed only partially through the seal assembly wall in a storage state such that the sterile container needle is not in fluid communication with the reservoir, and disposed through the seal assembly wall into the sterile reservoir in a delivery state such that the sterile container needle is in fluid communication with the reservoir,

the sterile container needle attached to a connector, the connector mechanically coupled to the container to secure the sterile container needle to the container with the needle in the storage state.

3. The injector of claim 2, wherein the connector is press fit onto the container.

4. The injector of any one of claims 2 to 3, wherein the connector is a first connector of a pair of connectors, a second connector of the pair of connectors being attached to the container, the first and second of the pair of connectors mechanically coupled to secure the sterile container needle to the container in the storage state.

5. The injector of claim 4, wherein the first and second connectors each comprise one of a pair of facing surfaces, the facing surfaces abutting to limit movement of the first and second connectors axially along a longitudinal axis of the sterile container needle.

6. The injector of claim 5, wherein the first and second connectors engage to rotatably couple the pair of connectors to secure the sterile container needle to the container in the storage state.

7. The injector of any one of claims 5 to 6, wherein the first and second connectors threadingly engage to couple the pair of connectors to secure the sterile container needle to the container in the storage state.

8. The injector of any one of claims 4 to 7, wherein the container comprises a rim disposed about an opening, the seal assembly being disposed over the opening in the container, and the second connector comprising a rim and disposed over the seal assembly, the container further comprising a crimp ring formed about the rim of the container and the rim of the second connector with the seal assembly disposed between the rims to secure the seal assembly between the rim of the container and the rim of the second connector.

9. The injector of claim 8, wherein the second connector has a passage therethrough, the sterile container needle disposed through the passage in the second connector in the storage state.

16. The method of claim 15, wherein the step of filling the sterile reservoir follows the step of mechanically coupling the sterile fluid delivery system to the container.

17. The method of any one of claims 15 to 16, wherein the step of mechanically coupling the sterile fluid delivery system to the container follows the step of filling the sterile reservoir.

18. The method of any one of claims 15 to 17, wherein the step of mechanically coupling the sterile fluid delivery system occurs within a fill/finish suite.

19. The method of any one of claims 15 to 18, wherein assembling the remainder of the injector comprises:

attaching the fluid delivery system to the actuator under clean room conditions, the actuator adapted to change the state of the fluid delivery system from the storage state to a delivery state.

20. The injector of any one of claims 1 to 14, wherein the barrier comprises a plate and a rim depending axially from an interior surface of the plate, the rim disposed on the exterior surface of the seal assembly wall.

21. The injector of any one of claims 1 to 14 and 20, wherein the seal assembly wall and the barrier are formed as a single structure.

22. The injector of any one of claims 1 to 14 and 20-21, further comprising an actuator that is adapted to move the container needle from the storage state to the delivery state.