


Title: INTEGRATED PIERCEABLE SEAL FLUID PATHWAY CONNECTION AND DRUG CONTAINERS FOR DRUG DELIVERY PUMPS


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Abstract: A sterile fluid pathway connector includes a piercing member, a connector hub, and a pierceable seal; wherein at least a portion of the pierceable seal is configured to move from a first position in which the piercing member is retained within a sterile cavity between the pierceable seal and the connector hub, to a second position in which the pierceable seal has been penetrated by the piercing member. A filter may be utilized to enclose the sterile cavity from the outside environment. Such fluid pathway connections may be integrated into a fluid container having a barrel and a plunger seal. The components of the fluid pathway connector may further be capable of transmitting a signal to the user upon completion of fluid delivery, for example, upon contact between the plunger seal and the pierceable seal. A fluid delivery pump includes such integrated fluid pathway connectors and fluid containers.
We claim:

1. A sterile fluid connector comprising
   a first portion configured to connect a sterile fluid pathway, and
   a second portion comprising a housing configured to mount a sterile fluid container;
   a connector hub;
   a pierceable seal disposed at least partially between the connector hub and the sterile fluid container and forming a sterile cavity between the connector hub and the pierceable seal, wherein the sterile cavity is formed at least partially internal to the sterile fluid container; and
   a piercing member disposed within the connector hub capable of providing a sterile fluid communication between the sterile fluid pathway and a sterile fluid chamber of the sterile fluid container;
   wherein at least a portion of the pierceable seal is configured to transform from a non-activated state wherein the pierceable seal is intact, to an activated state wherein the pierceable seal is disrupted by the piercing member to create a sterile fluid communication between the sterile fluid pathway and the sterile fluid chamber of the sterile fluid container.

2. The connector of Claim 1, wherein the housing is further configured to recess a portion of the connector within the sterile fluid container.

3. The connector of Claim 1, wherein the connector hub further comprises at least one port.

4. The connector of Claim 1, further comprising a piercing member guide disposed about the piercing member.

5. The connector of Claim 1, further comprising at least one sensor configured to indicate the status of fluid transfer from the sterile fluid container to the connector.
6. A sterile fluid pathway assembly comprising
   a sterile fluid container;
   a sterile fluid pathway; and
   a sterile fluid connector comprising
     a first portion configured to connect a sterile fluid pathway; and
     a second portion comprising a housing configured to mount a sterile
     fluid container;
     a connector hub;
   a pierceable seal disposed at least partially between the connector hub and the
   sterile fluid container and forming a sterile cavity between the connector hub and the
   pierceable seal, wherein the sterile cavity is formed at least partially internal to the sterile
   fluid container; and
   a piercing member disposed within the connector hub capable of providing a
   sterile fluid communication between the sterile fluid pathway and a sterile fluid chamber
   of the sterile fluid container;
   wherein at least a portion of the pierceable seal is configured to transform from a
   non-activated state wherein the pierceable seal is intact, to an activated state wherein the
   pierceable seal is disrupted by the piercing member to create a sterile fluid
   communication between the sterile fluid pathway and the sterile fluid chamber of the
   sterile fluid container.

7. The sterile fluid pathway assembly of Claim 6, wherein the housing is further
   configured to recess a portion of the connector within the sterile fluid container.

8. The sterile fluid pathway assembly of Claim 6, wherein the connector hub further
   comprises at least one port.

9. The sterile fluid pathway assembly of Claim 6, further comprising a piercing member
   guide disposed about the piercing member.

10. The sterile fluid pathway assembly of Claim 6, further comprising at least one sensor
    configured to indicate the status of fluid transfer from the sterile fluid container to the connector.

11. The sterile fluid pathway assembly of Claim 6, wherein the sterile fluid container
    comprises at least two mutable internal compartments wherein each compartment-compartment
interface comprises a distinct pierceable seal capable of being disrupted by the piercing member to create a sterile fluid communication between the sterile fluid pathway and that compartment of the sterile fluid container.

12. The sterile fluid pathway assembly of Claim 6, wherein the sterile fluid container comprises a plunger seal configured to engage the connector in the activated state to minimize residual fluid in the sterile fluid container.

13. An infusion pump device comprising
   an insertion mechanism;
   a drive mechanism; and
   a sterile fluid pathway assembly comprising
   a sterile fluid container;
   a sterile fluid pathway; and
   a sterile fluid connector comprising
      a first portion configured to connect a sterile fluid pathway; and
      a second portion comprising a housing configured to mount a sterile fluid container;
      a connector hub;
      a pierceable seal disposed at least partially between the connector hub and the sterile fluid container and forming a sterile cavity between the connector hub and the pierceable seal, wherein the sterile cavity is formed at least partially internal to the sterile fluid container; and
      a piercing member disposed within the connector hub, capable of providing a sterile fluid communication between the sterile fluid pathway and a sterile fluid chamber of the sterile fluid container; and
      wherein at least a portion of the pierceable seal is configured to transform from a non-activated state wherein the pierceable seal is intact, to an activated state wherein the pierceable seal is disrupted by the piercing member to create a sterile fluid communication between the sterile fluid pathway and the sterile fluid chamber of the sterile fluid container;
      wherein actuation of the drive mechanism causes fluid movement from the sterile fluid container through the sterile fluid pathway assembly to the insertion mechanism.
14. The infusion pump device of Claim 13, wherein the sterile fluid connector housing is further configured to recess a portion of the connector within the sterile fluid container.

15. The infusion pump device of Claim 13, wherein the connector hub of the sterile fluid connector further comprises at least one port.

16. The infusion pump device of Claim 13, wherein the sterile fluid connector further comprises a piercing member guide disposed about the piercing member.

17. The infusion pump device of Claim 13, further comprising at least one sensor configured to indicate the status of fluid transfer from the sterile fluid container to the sterile fluid connector.

18. The infusion pump device of Claim 17, wherein the sterile fluid connector comprises the sensor.

19. The infusion pump device of Claim 13, wherein the sterile fluid container comprises at least two mutable internal compartments wherein each compartment-compartment interface comprises a distinct pierceable seal capable of being disrupted by the piercing member to create a sterile fluid communication between the sterile fluid pathway and that compartment of the sterile fluid container.

20. The infusion pump device of Claim 13, wherein the sterile fluid container comprises a plunger seal configured to engage the connector in the activated state to minimize residual fluid in the sterile fluid container.