

CLAIMS

What is claimed is:

1. A valve comprising:

a body having a first section and a second section;

an elongate bore extending through the body and having a proximal end and a distal end;

a longitudinally displaceable plunger disposed in and extending along the bore, the plunger having a proximal end and a distal end and having a first position displaced toward the distal end of the bore and a second position displaced toward the proximal end of the bore, the plunger further comprising a top surface;

a diaphragm seal attached to the proximal end of the plunger and sealing the bore at the proximal end thereof;

a gland seal sealing the bore at a location intermediate the diaphragm seal and the distal end of the bore;

the plunger extending through and being sealingly secured to the gland seal;

a flange attached to the second section of the body or disposed as an integral part of the second section of the body, wherein a top surface of the flange is substantially coplanar with the top surface of the plunger or wherein the top surface of the plunger is higher than a top surface of the flange;

a fluid transfer opening in the bore between the diaphragm seal and the gland seal;

longitudinal displacement of the plunger moving the diaphragm seal to open the bore, the gland seal stretching to accommodate the displacement of and maintain a seal about the plunger, a fluid flow path being established between the open proximal end of the bore and the fluid transfer opening, wherein longitudinal displacement of the plunger towards its first position moves the diaphragm to open the bore.

2. The valve of claim 1, wherein a surface of the flange is approximately coplanar with a surface of the second position when the plunger is displaced toward the proximal end of the bore, creating a zero dead leg position.

3. The valve of either of claims 1-2, wherein the portion of the bore between the diaphragm seal and the gland seal is substantially aseptic.

4. The valve of claim 3, further comprising a substantially aseptic connecting component for attaching the valve to an upstream component.

5. The valve of any of claims 1-4, wherein the diaphragm seal is disposed at least partially inside the proximal end of the bore prior to displacement of the plunger.

6. The valve of any of claims 1-5, wherein the gland seal and/or diaphragm seal is constructed of a silicone elastomer or a solvent resistant fluoroelastomer.

7. The valve of any of claims 1-6, wherein the body comprises a substantially cylindrical outer portion, at least one alignment slot for the plunger, and a groove for the gland seal.

8. The valve of any of claims 1-7, wherein the flange further comprises a boss that extends within the elongate bore.

9. The valve of any of claims 1-8, wherein the flange is capable of forming a bond with a flexible bioreactor bag.

10. The valve of claim 9, wherein the flange forms a heat-sealed bond or an adhesive bond with the flexible bioreactor bag.

11. A kit for transferring fluid comprising:

a valve comprising:

a body having a first section and a second section;

an elongate bore extending through the body and having a proximal end and a distal end;

a longitudinally displaced plunger disposed in and extending along the bore, the plunger having a proximal end and a distal end and having a first position displaced toward the distal end of the bore and a second position displaced toward the proximal end of the bore;

a diaphragm seal attached to the proximal end of the plunger and sealing the bore at the proximal end thereof;

a gland seal sealing the bore at a location intermediate the diaphragm seal and the distal end of the bore;

a flange attached to the second section of the body or disposed as an integral part of the second section of the body;

a flexible bag attached to the flange, wherein the flange is substantially flat and comprises an extended area capable of attaching to the flexible bag;

longitudinal displacement of the plunger moving the diaphragm seal to open the bore, the gland seal stretching to accommodate the displacement of and maintain a seal about the plunger, a fluid flow path being established between the open proximal end of the bore and the fluid transfer opening, wherein a surface of the flange is approximately coplanar with a surface of the plunger when the plunger is displaced toward the proximal end of the bore, creating a zero dead leg position.

12. The kit of claim 11, wherein the valve, a connecting component for attaching the valve to an upstream component, at least one length of flexible tubing, and at least one sample container are connected and substantially aseptic.

13. A valve comprising:

a body;

an elongate bore extending through the body and having a proximal end and a distal end;

a longitudinally displaceable plunger disposed in and extending along the bore, the plunger having a proximal end and a distal end and having a first position displaced toward the distal end of the bore and a second position displaced toward the proximal end of the bore;

at least one seal mounted on the plunger to form a fluid tight seal between the plunger and the bore;

a fluid transfer opening in the plunger between the proximal end of the plunger and the distal end of the plunger;

longitudinal displacement of the plunger opening the bore to form a fluid pathway from an upstream component to a downstream component through the fluid transfer opening and a channel within the plunger.

14. The valve of claim 13, wherein the at least one seal is a diaphragm seal.

15. The valve of either of claims 13-14, wherein the diaphragm seal is attached to the proximal end of the plunger and seals the bore at the proximal end thereof.

16. The valve of any of claims 13-15, wherein the at least one seal is a gland seal.

17. The valve of claim 15, wherein the valve further comprises at least one gland seal.

18. The valve of claim 17, wherein the gland seal seals the bore at a location intermediate the diaphragm seal and the distal end of the bore.

19. The valve of claim 17, wherein the plunger extends through and is sealingly secured to the at least one gland seal.

20. The valve of claim 17, wherein the at least one gland seal stretches to accommodate the displacement of and maintain a seal about the plunger.

21. The valve of claim 15, wherein longitudinal displacement of the plunger towards its first position moves the diaphragm to open the bore.

22. The valve of claim 19, wherein the portion of the bore between the diaphragm seal and the at least one gland seal is substantially aseptic.

23. The valve of claim 22, further comprising a substantially aseptic tank mount.

24. The valve of claim 15, wherein the diaphragm seal is disposed at least partially inside the proximal end of the bore prior to displacement of the plunger.

25. The valve of any of claims 13-24, wherein the at least one seal is constructed of a silicone elastomer.

26. The valve of any of claims 13-25, wherein the at least one seal is constructed of a solvent resistant fluoroelastomer.

27. The valve of claim 17, wherein the body comprises a substantially cylindrical outer portion, at least one alignment slot for the plunger, and a groove for the gland seal.

28. A method for processing biological fluids, comprising:
providing biological fluids within a bag or bioreactor having an inner volume;
providing a valve in downstream fluid communication with the bag or bioreactor; wherein the valve is attached to the bag or bioreactor along an extended area of a flange;

providing means for mixing the biological fluids;
delivering a solid processing agent to the inner volume; and
mixing the solid processing agent with the biological fluids, wherein the mixing is performed absent a dead-leg region.

29. The method of claim 28, wherein a top surface of a plunger of the valve is coplanar with a surface of the flange.

30. The method of claim 28, wherein the valve is the valve of claim 1.

31. The method of claim 28, wherein the means for mixing comprises an impeller.
32. The method of claim 31, wherein the impeller is a magnetically-driven impeller.
33. The method of claim 28, wherein the solid processing agent is an aluminum salt.
34. The method of claim 28, further comprising a step for obtaining a sample of the biological fluid from within the inner volume of the bag or bioreactor via the valve.
35. The method of claim 28, wherein the biological fluid comprises monoclonal antibodies.
36. The method of claim 28, further comprising a step for rendering the valve aseptic.
37. A zero dead-leg fluid transfer system, comprising:
a valve, comprising:
a conical body section having a lower body section and an upper body section, wherein an extended flange is joined to the upper body section; and
a plunger having a central bore that disposed within the conical upper body section, wherein the plunger comprises at least one seal adjacent a face, wherein the valve is open and closed via a pull/push manipulation that causes the plunger to become longitudinally displaceable within the conical body section; and
a locking tool, wherein the locking tool comprises an upper plane and a lower plane having a vertical wall disposed therebetween, further comprising a vertical wall opposite a lower slot and an upper slot, wherein the conical body section of the valve is situated within at least one of the lower slot or the upper slot, and
wherein the at least one seal on the plunger forms a fluid tight seal between the plunger and the extended flange.
38. The fluid transfer system of claim 37, wherein the at least one seal is a diaphragm seal.
39. The fluid transfer system of either of claims 37-38, wherein the diaphragm seal is attached to the proximal end of the plunger and seals the bore at the proximal end thereof.
40. The fluid transfer system of any of claims 37-39, wherein the at least one seal is constructed of a silicone elastomer or a solvent resistant fluoroelastomer.
41. The fluid transfer system of any of claims 37-40, wherein the extended flange is attached to a bag.
42. The fluid transfer system of any of claims 37-41, wherein the plunger comprises a pin.
43. The fluid transfer system of claim 42, wherein the body section comprises an operation slot for housing the pin, wherein the pin restricts the movement of the plunger.