FLUID TRANSFER DEVICE

CROSS-REFERENCE RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Patent Application No. 60/003,364, filed on November 16, 2007 the entire contents of which are incorporated by reference herein.

The present invention relates to a fluid transfer device. More particularly, it relates to a disposable, sterile, fluid transfer device in the form of a flow-through connector or valve for use in the pharmaceutical and biopharmaceutical industries.

BACKGROUND OF THE INVENTION

In the pharmaceutical, biotechnology and even food, beverage and cosmetic industries, it is often desired to provide large scale processing systems that are capable of handling fluids in a sterile manner. These large scale processing systems are designed to prevent unwanted and often dangerous organisms, such as bacteria, as well as unwanted and potentially harmful environmental contaminants, such as dust, dirt and the like from entering into the process stream and/or end product. In order to prevent these types of outside contaminants from entering these systems it is desirable to have a completely sealed processing system. However, completely closed processing systems are not always possible since there is a need for the introduction or removal of materials from the process stream in order to add components of the product, such as media or buffers to a bioreactor; withdraw samples from the process stream to check for microbial contamination, quality control, process control, etc; and to collect the product into its final container such as vials, syringes, sealed boxes, bottles and the like.

Traditionally, processing systems have been made of stainless steel, wherein the stainless steel systems are exposed to live steam before use, and then cleaned with chemicals such as caustic solutions after use, to ensure that all contaminants and the like are removed. Steaming is the most effective means of sterilization. The use of steam in a set system is known as steaming in place or SIP. Saturated steam carries 200 times the BTU heat transfer capacity of heated air because of the latent heat released by the steam as it changes from vapor to liquid.

However, several disadvantages exist with the use of steam. Any connection to, or opening of, the processing system made after the system has been steamed in place is an aseptic (but not sterile) connection or opening. This increases the risk of contamination of the entire system. Typically alcohol wipes or an open flame are used to clean the components intended to be connected to the system, (e.g., connecting a sample collection bag to a system after SIP has occurred) and thus minimizes the risk of contamination.

Also, the high temperatures and pressure differentials associated with steam make the selection of filter materials and other components difficult and limited. Additionally, accidental pressure differential at high temperatures can cause a filter, membrane or other non-steel component to fail.

Processing systems that are reused need to undergo rigorous testing and validation to prove to the necessary regulatory authorities that the system is sterile before each use. The validation process and the required cleaning regiment of a previously used system are expensive and time consuming, typically taking up to 1 to 2 years for approval. In addition, certain components are difficult to adequately clean after use in preparation for their next use. Since manufacturers are often looking for ways to reduce both the costs and the time to market for their products, one possible approach at reducing costs and time to market for a product is to adopt an all disposable system that is set up in a sterile fashion, used once and then discarded.

Another possible approach to alleviating the time and expense associated with a systems' cleaning regiment is the use of disposable components for certain reusable components that are more expensive and/or time consuming to clean than other components.

Additionally, disposable components that are used in place of time consuming to clean reusable components should be easy to remove and replace. For example, the ease with which large scale disposable fluid transfer devices, such as valves or connectors, can be removed and replaced, and the manner in which large scale disposable assemblies are integrated into traditional stainless steel processing systems via disposable fluid transfer devices, have the potential to reduce processing costs and improve the efficacy and productivity of these systems.

SUMMARY OF THE INVENTION

The present invention relates to a sterile transfer device for fluids, wherein the fluids are liquids or gases. In one embodiment, the transfer device includes a body, a bore formed through at least a portion of the interior of the body, and a linearly moveable plunger contained within the bore. In one embodiment, the bore is a lateral central bore formed through the entire interior length of the body, wherein the body is formed from a rotating first section and a stationary second section, such that the first section rotates around a portion of the stationary second section and the plunger. The rotation of the first section engages the stationary second section and the plunger, driving the plunger linearly within the bore, thereby actuating (i.e., opening/closing) the fluid transfer device. One end of the body includes a connecting component for attaching the device to an upstream component, and one end of the plunger includes a connecting component for attaching the device to a downstream component. In one embodiment, the plunger includes first and second openings, and a fluid channel in at least a portion of the interior of the plunger, connecting the first and second openings, thereby forming a pathway for fluid to travel from an upstream component to a downstream component when the fluid transfer device is in the opened position. When the device is in the closed position, the first end of the plunger is in alignment with the connecting component at one end of the body, forming a seal against fluid in the upstream component from entering the device, thereby forming a steamable face and a sterile barrier against environmental contaminants for any downstream component.

In another embodiment, the present invention relates to a fluid transfer device in use, wherein the device is in the closed position and attached to a downstream component(s), such as tubing connected to a bag, at one end of the plunger at a connecting component. Next, the entire fluid transfer device and the attached downstream component are sterilized, such as with gamma radiation or the like. Next, an upstream component (s), such as a filter outlet, a tank outlet, or a pipe is attached to a face formed at another end of the device when the device is the closed position. This face is formed when a connecting component at one end of the body is in alignment with the bottom portion. Next, the upstream component attached to the device at the face, are then steam sterilized in place (SIP). Finally, the device is then opened when needed, establishing a sterile pathway for fluids traveling from the upstream component through the fluid transfer device to the downstream component.

In another embodiment, the present invention relates to a disposable fluid transfer device for use in traditional stainless steel processing systems or disposable processing systems. The fluid transfer device of the present invention provides a steam sterilizing mating point between the transfer device and an upstream component, and a sterilizeable mating point between the transfer device and a downstream component. Additionally, the transfer device can be conveniently removed from the processing system and discarded after use, thereby not requiring a cleaning regiment.

In another embodiment, the present invention also relates to disposable large scale fluid transfer devices for the integration of large scale disposable upstream and/or downstream assemblies into traditional stainless steel systems or disposable systems. The fluid transfer device of the present invention provides a steam sterilizing mating point between the transfer device and an upstream component, and a sterilizeable mating point between the transfer device and a downstream component. Additionally, the transfer device can be conveniently removed from the processing system and discarded after use, thereby not requiring any cleaning regiment.

IN THE DRAWINGS

The present invention will become more fully understood from the detailed description given herein below and the accompanying drawings which are given by way of illustration only, and thus are not limitative of the present invention, and wherein:

Figure 1a is a cross sectional view of an embodiment of the present invention in a closed position;

Figure 1b is a cross section taken along line 1b--1b;

Figure 2 is a cross sectional view of the embodiment of the present invention of Figure 1 in an opened position;

Figures 3a and 3b are perspective views of additional embodiments of the present invention of Figure 1, along with alternative embodiments of upstream and downstream attachment components; and

Figures 4a and 4b are perspective views of an embodiment of the present invention of Figure 1.

DETAILED DESCRIPTION OF THE INVENTION

In general, the present invention is a sterile fluid transfer device, such as a flow-through connector or valve, wherein the fluids are liquids and/or gases. In one embodiment, the fluid transfer device has a body, a bore located in the interior of the body, and a linearly movable plunger contained within the bore. The body is formed from a first and a second section. The first section has a first end containing a first opening and a termination attachment component, such as a flange or the like surrounding the first opening for attaching the body to an upstream component(s). The second section has a second end containing a second opening, wherein the bore connects the first and second openings. The first section rotates around a portion of the second section.

The linearly movable plunger includes a first end containing a first opening, a second end containing a second opening, a fluid channel located in the interior of the plunger connecting the first and second openings of the plunger. In one embodiment, the plunger includes a component for inhibiting its rotation, while promoting its linear movement within the bore during rotation of the first section of the body when the device is actuated (i.e., opened/closed).

The fluid transfer device is in the closed position when the first end of the plunger is in alignment with the termination attachment component surrounding the first opening of the body, thereby forming a fluid resistant seal and a steamable face. The device is in the opened position when the first end of the plunger is not in alignment with the termination attachment component surrounding the first opening of the body, thereby permitting fluids to enter the device from an upstream component.

To the extent that the same reference numbers apply to the figures they have been kept the same.

One embodiment of the invention shown in Figures 1a and 2 includes a device 12 having a body 14 having a bore 20 formed through at least a portion of the interior of the body, and a generally hollow moveable plunger 62 contained within the bore. Bore 20, as shown, is a lateral central bore formed through the entire interior length of the body 14. Body 14, as shown, is formed from two sections, a rotating first section 26 and a stationary second section 28. First section 26 rotates partially around a portion of the stationary second section 28 and plunger 62. Bore 20, as shown, is formed of two sections, a rotating bore section 34 which generally corresponds to the

inner wall of rotating first section 26, and a stationary bore section 36 which generally corresponds to the inner wall of stationary second section 28. In the embodiment depicted in Figures 1a and 2, each of the bore sections (34, 36) has different diameters. As will be described in greater detail herein, device 12 is actuated (i.e., opened/closed) when first section 26 of the body is rotated, engaging second section 28 of the body and plunger 62, driving the plunger linearly within the bore 20, thereby actuating (i.e., opening and closing) the device.

As shown in Figures 1a and 2, the first section 26 of the body 14 is generally hollow and has an opening 18 at one end for receiving the plunger. As shown in Figures 1a and 2, the first section 26 includes a protruding lip or edge component 38 that is rotatably engaged by a stationary wall receiving groove 44 on the outer stationary 28 wall section.

In Figure 2, the first section 26 also includes an inner wall having a stationary wall engaging section 40, and forms a rotating bore section 34 having four sections. There is a first rotating bore set diameter 34a, a transition rotating bore section 34b, a second rotating bore diameter 34c and a third rotating bore diameter 34d. The first set diameter 34a engages the plunger as it moves linearly within the bore 20. The transition section 34b is arranged between the first and second diameters (34a, 34c) and has an outwardly tapering diameter along its length. The diameter of the transition section 34b is preferably a linear outward progression from the first diameter section 34a, wherein the diameter of the transition section 34b adjacent the first diameter 34a is equal to the first diameter 34a, and the diameter of the transition section 34b adjacent the second diameter 34c is equal to the diameter 34c. The third diameter 34d is preferably less than diameter 34c and preferably greater than the diameter 34a.

As shown in Figures 1a and 2, the stationary second section 28 of the body 14 is generally hollow and has an opening 16 at one end that permits a fluid provided from an upstream source (not shown) to pass through it when opened. The opening16 also receives the bottom 63 of the plunger when the device is closed. The stationary section 28 includes an outer wall component 42 for rotatably engaging the inner wall section 40 of the rotating section 26. As shown in Figures 1a and 2 the inner wall of the second section 28 forms the stationary bore section 36 having four sections. There is a first stationary bore diameter 36a, a first transition stationary bore section36b, a second stationary bore diameter 36c, and a second transition stationary bore section 36d. The first bore diameter 36a is less than the second bore diameter 36c. The second bore diameter 36c

is a set diameter. The first transition bore section 36b is arranged between the first and second bore diameters (36a, 36c) and has an outwardly tapering diameter along its length. The diameter of the first transition section 36b is preferably a linear outward progression between the first and second bore diameters (36a, 36c). The diameter of the first transition section 36b adjacent the first diameter 36a is equal to the diameter 36a, and the diameter of the first transition section 36b adjacent the second diameter 36b is equal to the diameter 36b.

As shown in Figures 1a and 2 plunger 62 has three general regions comprising a first, second and third region. The first region 24 has a diameter equal to or less than the first rotating bore set diameter 34a. The second region 25 has a diameter equal to or less than the second stationary bore diameter 36c. The third region 29 has a diameter equal to or less than that of the first stationary bore diameter section 36a. The plunger has a bottom component 63 at the end of the third region 29 for blocking the opening 16 of the stationary section 28 when the device is in the closed position, as shown in Figure 1a. One embodiment of the invention as depicted in Figures 1a and 2 includes a static diaphragm seal 60 located on the bottom 63 of the plunger forming a tight fluid resistant seal between the outer wall 61 of the bottom end 63 of the plunger, and the inner wall 82 of stationary section 28 of the body forming the opening 16.

Plunger 62 also has at least two openings, a first opening 64 and a second opening 66. A channel 68 is located in the interior of the plunger and connects the first and second openings (62, 64), thereby forming a fluid pathway to a downstream component. As shown in Figures 1a and 2, the first opening 64 is located in the first portion 24 of the plunger, and the second opening 66 is located in the second portion 25 of the plunger. In other embodiments, plunger 62 can contain additional openings and interior fluid pathways. In one preferred embodiment, the plunger contains at least openings in the second portion 25. (not shown)

One embodiment of the invention as depicted in Figures 1a and 2 includes plunger 62 having a component for inhibiting the rotation of the plunger within the bore, while promoting linear movement of the plunger when the fluid transfer device 12 is actuated (i.e., opened/closed). One embodiment for accomplishing the linear movement of the plunger, as shown in Figure1a and 2, depicts the plunger having a pair of wings (74, 76), fins, or the like, that extend from the outer wall of the plunger towards the inner wall of the second section 28 of body 14. Second section 28 has a component for interacting with wings (74, 76) comprising two corresponding pairs of parallel slots

(70, 72), grooves, or the like located on the inner wall of the section 28 for receiving the wings (74, 76) in order to restrict the rotation of the plunger 62 and promote the linear movement of the plunger within the bore 20 Wings (74, 76) ride between each corresponding pair of slots (70, 72) thereby facilitating the linear movement of the plunger within the bore during actuation (opening/closing) of the device 12.

As shown in Figure 1a, when device 12 is in the closed position the bottom end 63 of the plunger is in alignment with flange 80, forming a face 90, and providing the device with a steamable surface and a sterile barrier against the environment for the interior of the device, plunger and any downstream components. In the closed position, the bottom end 63 of the plunger does not permit fluid to enter opening 16 in the device from an upstream component (not shown), thereby preventing any fluid from traveling downstream.

As shown in Figure 2, device 12 is in the opened position when the plunger 62 is linearly moved within the lateral bore 20 by the rotation of section 26 of the body 14, such that the bottom end 63 of the plunger 62 is moved back from the flange 80, permitting fluid, depicted by an arrow, to travel from an upstream component (not shown), through opening 16 in section 28 of the body. The fluid then travels through the second hole 66 of the plunger, into the interior channel 68 of the plunger, out opening 64, and into a downstream component. (not shown) Plunger 62 is not permitted to rotate within the bore during the rotation of the rotating section 26, but is forced to move linearly by wings (74, 76) of the plunger located within the parallel slots (70, 72) on the inner wall of section 28.

Additionally, by preventing the plunger from rotating when the device is opened or closed, the problem of torsion between device 12 and an attached upstream or downstream component can be averted, since it is not necessary to twist or turn the upstream or downstream components, or the device, when removing or actuating the device since the plunger moves within the bore linearly, and not rotationally.

As shown in Figures 3a, 3b, 4a, and 4b, the plunger 62 can contain one or more cams 56 (only one shown) that ride in one or more cam slots 58 (only one shown) located in the rotating section 26 of the body 14. The arrangement of the cam 56 and slot 58 acts to limit the length the plunger 62 travels linearly within the bore 20 when the device is actuated (opened or closed). When device 12 is in the closed position, as shown in Figure 4a, the cam 56 sits in the closed

position of the cam slot 58. When device 12 is in the opened position, as shown in Figure 4b, the cam 56 sits in the opened position of the calm slot 58. The arrow in Figure 4b depicts the rotational movement of rotating section 26 and cam slot 58.

As shown in Figures 3a and 3b, device 12 has at one end of the stationary section 28 of the body a component for attaching the device to an upstream component. In this embodiment, a flange 80 attaches to a flange 88 of an upstream component. As shown in Figure 3a, the end of the first plunger region 24 includes, in this embodiment, a barb termination 92 for connecting the device to a downstream component, in this instance, tubing 72.

As shown in Figure 3b, the end of first plunger portion 24 includes, in this embodiment, a termination flange 94 for connecting the device to a downstream component, in this embodiment, a termination flange 78.

By way of example, the downstream components attached to the device by the termination connection feature on the plunger can be plastic tubing 72 and the like, as shown in Figure 3a, attached to a plastic bag or other type of known receptacle (not shown), and the like.

By way of example, the upstream component attached to the device can be a pipe, a stainless steel or disposable plastic tank having an outlet, and the like, having an attachment flange 88 (as depicted in Figures 3a and 3b), or any other mode of attachment for connecting components to transfer devices as are commonly known in the art. For example, flange 80 on device 12 can be connected to an upstream component or pipe by a clamp such as a Tri-Clover™ fitting, Ladish™ fitting, ClickClamp™ clamp and the like.

When using device 12 to fill a downstream component such as a bag, or any collection vessel attached the tubing 72, the device is opened by rotating section 28 of the body, which moves the plunger 62 linearly (see Figure 4b) away from the face 90, permitting fluid to enter opening 16 (see Figure 2) and to eventually flow out the opening exit 64 through tube 72, and into a bag, or any collection vessel or other fluid transport device. (not shown) Once a bag is full, the rotating section 28 is rotated in the opposite direction to move the plunger linearly again, this time in the opposite direction, in order to seal the opening 16 closed (see Figure 1) to the fluid from an upstream component. By way of example, an attached bag can then be closed off via a clamp or hemostat (not shown) and removed for further processing or use.

One or more seals are arranged along the length and end of the plunger 62 to form a fluid tight seal between various portions of the plunger 62 and the bore 20 when the device is in the closed or opened positions. As shown in Figures 1a and 2, seals 60 and 54 are partly contained within grooves 48, and 46 and 44 respectively.

As shown in Figures 1a and 2, the seals may be mounted on the plunger 62. However, if desired, a different configuration of seals and their placements can also be used. For example, Figures 1a and 2 show seals 46 and 60 formed in grooves on the plunger 62. A linear or gland seal 51 is retained within a groove 50 on the inner wall of the stationary bore section and within a groove 46 on the plunger 62.

Other embodiments of the present invention are also contemplated, such as molding the device 12 into a disposable plastic container such as a disposable process bag for the manufacture and transfer of biotech products and the like. Such bags are readily available from companies such as HyClone (which is part of Thermo Fisher Scientific) of Logan, Utah and Stedim Biosystems of Concord, CA.

Since the fluid transfer device 12 is preferably provided in a sterile condition, (i.e., the interior of the system and any component connected downstream of the device is pre-sterilized such as with gamma radiation, ethylene gas or the like and shipped in a sterile condition), some type of use indicator (not shown) may be helpful, and capable of informing a user when a system has been used. As an alternative, or in addition to any of the indicator mechanisms discussed above, a shrink wrap indicator (not shown) may be located over the device or at least over the rotating first section of the device to indicate whether the device had been used.

The device is preferably formed a plastic material and may be formed by machining the body and plunger assemblies and then applying the necessary seals and the like, or preferably by molding the body and the plunger separately and assembling them together with the necessary seals and other components. Alternatively, the body may be molded into two separate halves and assembled by attaching the plunger component with the necessary seals and other components to one half of the body, followed by the attaching the remaining half of the body to the plunger, necessary seals, other components, and the first half of the body.

The device may be made of any plastic material capable of withstanding in line steam sterilization. The temperature and pressure of such sterilization is typically about 121°C and 1 bar

above atmospheric pressure. In some instances, it may be desirable to use even harsher conditions such as 142°C and up to 3 bar above atmospheric pressure. The body and at least the face of the plunger should be capable of withstanding these conditions. Preferably, the entire device is made of the same material and is capable of withstanding these conditions. Suitable materials for this device include but are not limited to PEI (polyetherimide), PEEK, PEK, polysulphones, polyarlysulphones, polyalkoxysulphones, polyethersulphones, polyphenyleneoxide, polyphenylenesulphide and blends thereof. Alternatively, one can make the face portion from ceramic or metal inserts alone, or that are overmolded with a plastic cover. One can also form a polymeric face with a metal outer layer using plasma coating processes.

The seals of the present invention can be made of a variety of materials typically used for making resilient seals. These materials include but are not limited to natural rubber, synthetic rubbers, such as silicone rubbers, including room temperature vulcanizable silicone rubbers, catalyzed (such as by platinum catalysts) silicone rubbers and the like, thermoplastic elastomers such as SANTOPRENE ® elastomers, polyolefins such as polyethylene or polypropylene, especially those containing gas bubbles introduced either by a blowing agent or entrained gas such as carbon dioxide, PTFE resin, thermoplastic perfluoropolymer resins such as PFA and MFA resins available from Ausimont, USA Inc., of Thorofare, New Jersey and E.I. DuPont de Nemours of Wilmington, Delaware, urethanes, especially closed cell foam urethanes, KYNAR® PVDF resin, VITON® elastomer, EPDM rubber, KALREZ resin and blends of the above.

Suitable materials for molded in place seals can be curable rubbers, such as room temperature vulcanizable silicone rubbers, thermoplastic elastomers such as SANTOPRENE ® elastomers, polyolefins such as polyethylene or polypropylene, especially those containing gas bubbles introduced either by a blowing agent or entrained gas such as carbon dioxide and elastomeric fluoropolymers

Other materials used in the devices should also be FDA grade components such as FDA grade silicones, PTFE resins and the like.

The present invention provides a sterile and steam sterilizable in place connecting device for fluid transfer. It may be single actuation (one open one close) or it may be multiple actuations with a single sterile connection (multiple openings and closings) so long as the sterile connection upstream and downstream is maintained. Additionally, with the use of multiple seals or seals of

long length, one is able to ensure that the sterility of the device is maintained even with multiple actuations.

Many modifications and variations of this invention can be made without departing from its spirit and scope, as will be apparent to those skilled in the art. The specific embodiments described herein are offered by way of example only and are not meant to be limiting in any way. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

What is claimed is:

1. A fluid transfer device, comprising:

a body comprising:

a first section having a groove on a surface and a first end containing a first opening and a flange surrounding the first opening for attaching the body to a process component;

a second section rotatably engaged with the first section and having a second end containing a second opening; and

a bore located in the interior of the body connecting the first and second openings;

a linearly movable plunger movable between a closed position corresponding to a closed position of the device and an open position corresponding to an open position of the device, the linearly movable plunger being contained within the bore and having,

a groove,

a first portion containing a first opening and a bottom end, wherein the bottom end being in alignment with the flange surrounding the first opening of the body forms a fluid-resistant seal and a steam sterilizable face,

a second portion containing a second opening,

a fluid channel located in the interior of the plunger connecting the first and second openings of the plunger, and

a component for inhibiting rotation of the plunger within the bore during actuation of the device; and

a linear or gland seal arranged along a length of the plunger between the first opening of the plunger and the second opening of the plunger, a first portion of the linear or gland seal being retained within the groove on the surface of the first section of the body and a second portion of the linear or gland seal being retained within the groove on the plunger in sealing contact with the plunger and an inner surface of the first section of the body,

wherein the plunger is linearly movable between a closed position and an open position by rotating the second section of the body; the device is in the closed position when the bottom end of the plunger is in alignment with the flange surrounding the first opening of the body; and the device is in the open position when the bottom end of the plunger is not in alignment with the flange surrounding the first opening of the body.

2. The device of claim 1, wherein the component for inhibiting rotation of the plunger within the bore during actuation of the device comprises a protruding member located on the

outer wall of the plunger, and the first section of the body further comprises a receiving member located on the inner wall of first section of the body for receiving the protruding member, and inhibiting the rotation and promoting the linear movement of the plunger within the bore during rotation of the second section of the body during actuation of the device.

3. The device of claim 1, wherein the second section of the body comprises a protruding lip, and the first section of the body comprises a second groove for receiving the lip and permitting the rotation of the second section around the first section during actuation of the device.

4. The device of claim 1, wherein the bore is a central bore through the entire length of the body.

5. The device of claim 1, further comprising a cam located on the plunger that rides in a cam slot located on the second section of the body for limiting the length the plunger travels linearly within the bore during actuation of the device.

6. The device of claim 1, wherein the first portion of the plunger includes at least one additional opening in fluid communication with the fluid channel.

7. The device of claim 1, further comprising one or more seals arranged along a length or the bottom end of the plunger between the bottom end of the plunger and the first opening of the plunger, the one or more seals forming the fluid-resistant seal when the bottom end of the plunger and the flange are in alignment.

8. The device of claim 1, wherein the body is formed of a plastic selected from the group consisting of polyetherimides (PEI), polyetheretherketone (PEEK), polyetherketone (PEK), polysulphones, polyarylsulphones, polyalkoxysulphones, polyethersulphones, polyphenyleneoxide, polyphenylenesulphide and blends thereof.

9. The device of claim 1, wherein at least the steam sterilizable face is formed of material selected from the group consisting of polyetherimides (PEI), polyetheretherketone (PEEK), polyetherketone (PEK), polysulphones, polyarylsulphones, polyalkoxysulphones, polyethersulphones, polyphenyleneoxide, polyphenylenesulphide, ceramic, metal and combinations thereof.

10. The device of claim 1, wherein the plunger is formed of a material selected from the group consisting of polyetherimides (PEI), polyetheretherketone (PEEK), polyetherketone (PEK), polysulphones, polyarylsulphones, polyalkoxysulphones, polyethersulphones, polyphenyleneoxide, polyphenylenesulphide, ceramic, metal and combinations thereof.

11. The device of claim 1, wherein the device is selected from the group consisting of a connector and a flow through valve.

12. A process for the sterile transfer of a fluid, comprising:

a. providing a fluid transfer device, comprising;

a body comprising:

a first section having a groove on a surface and a first end containing a first opening and a flange surrounding the first opening for attaching the body to a process component,

a second section rotatably engaged with the first section and having a second end containing a second opening; and

a bore located in the interior of the body connecting the first and second openings;

a linearly movable plunger movable between a closed position corresponding to a closed position of the device and an open position corresponding to an open position of the device, the linearly movable plunger being contained within the bore and having,

a groove,

a first portion containing a first opening and a bottom end, wherein the bottom end being in alignment with the flange surrounding the first opening of the body forms a fluid-resistant seal and a steam sterilizable face,

a second portion containing a second opening,

a fluid channel located in the interior of the plunger connecting the first and second openings of the plunger, and

a component for inhibiting rotation of the plunger within the bore during actuation of the device; and

a linear or gland seal arranged along a length of the plunger between the first opening of the plunger and the second opening of the plunger, a first portion of the linear or gland seal being retained within the groove on the surface of the first section of the body and a second portion of the linear or gland seal being retained within the groove on the plunger in sealing contact with the plunger and an inner surface of the first section of the body,

wherein the plunger is linearly movable between a closed position and an open position by rotating the second section of the body; the device is in the closed position when the bottom end of the plunger is in alignment with the flange surrounding the first opening of the body; and the device is in the open position when the bottom end of the plunger is not in alignment with the flange surrounding the first opening of the body;

b. connecting the device to a first process component and sterilizing the first process component and the device when the device is in the closed position;

c. attaching the first end of the body of the transfer device to a second process component when the device is in the closed position to form a liquid tight seal;

d. steam sterilizing the second process component and the steam sterilizable face;

e. opening the device by moving the plunger linearly in a first direction so as to allow for fluid communication between the second process component, the fluid channel within the plunger and the first process component; and

f. closing the device by linearly moving the plunger in a direction opposite to the first direction to seal the fluid channel within the plunger and the first process component from the second process component.

13. The process of claim 12, wherein the bore of the transfer device is a central bore formed through the entire length of the body.

14. The process of claim 12, wherein the fluid is selected from the group consisting of liquids and gases.

15. The process of claim 12, wherein the device is formed of polyetherimides (PEI), polyetheretherketone (PEEK), polyetherketone (PEK), polyarylsulphones, polyalkoxysulphones, polyethersulphones, polyphenyleneoxide, polyphenylenesulphide and blends thereof.

16. The process of claim 12, wherein the device is capable of forming a sterile to sterile connection.

17. The process of claim 12, wherein the device is capable of forming a sterile to non-sterile connection.

18. The process of claim 12, wherein the transfer device and the first process component are sterilized by gamma radiation.

19. The process of claim 12, wherein the first process component is formed of a tube having a first end connected to the second end of the body and a bag attached to a second end of the tube.

20. The process of claim 12, wherein the first process component is formed of a tube having a first end connected to the second end of the body and an encapsulated filter attached to a second end of the tube.

21. The process of claim 12, wherein the second process component is a process pipe, fitting, or T-fitting.

22. A fluid transfer device comprising:

a body having a bore through at least a portion of its interior, the bore formed by a first section of the body rotatably engaged with a second section of the body, the first section of the body further including a groove on a surface and a connecting component for attaching the fluid transfer device to a process component;

a linearly movable plunger contained within the bore, comprising:

a groove,

a bottom end, where the bottom end being in alignment with the connecting component forms a fluid-resistant seal and a steam sterilizable face,

a fluid channel located in the interior of the plunger connecting a first opening in a first portion of the plunger to a second opening in a second portion of the plunger, and

a component for inhibiting rotation of the plunger within the bore during actuation of the device; and

a linear or gland seal arranged along a length of the plunger between the first opening of the plunger and the second opening of the plunger, a first portion of the linear or gland seal being retained within the groove on the surface of the first section of the body and a second portion of the linear or gland seal being retained within the groove on the plunger in sealing contact with the plunger and an inner surface of the first section of the body,

wherein the plunger is linearly movable between a closed position corresponding to a closed position of the device and an open position corresponding to an open position of the device by rotating the second section of the body; the device is in the closed position when the bottom end of the plunger is in alignment with the connecting component, and the device is in the open position when the bottom end of the plunger is not in alignment with the connecting component.

23. A device for fluid transfer, comprising:

a body comprising:

a first section having a groove on a surface and a first end containing a first opening and a flange surrounding the first opening for attaching the body to a process component;

a second section rotatably engaged with the first section and having a second end containing a second opening; and

a bore located in the interior of the body connecting the first and second openings;

a linearly movable plunger movable between a closed position corresponding to a closed position of the device and an open position corresponding to an open position of the device, the linearly movable plunger being contained within the bore and having:

a groove,

a first portion containing a first opening and a bottom end,

a second portion containing a second opening,

a fluid channel located in the interior of the plunger connecting the first and second openings of the plunger, and

a component for inhibiting rotation of the plunger within the bore during actuation of the device;

a non-rupturing seal, arranged along a length or the bottom end of the plunger between the bottom end of the plunger and the first opening of the plunger, that forms a fluid-resistant seal when the plunger is in the closed position, at least a portion of the non-rupturing seal and at least a portion of the flange forming a steam sterilizable face and a sterile barrier between the environment and at least a portion of the bore and the plunger when the plunger is in the closed position; and

a linear or gland seal arranged along a length of the plunger between the first opening of the plunger and the second opening of the plunger, a first portion of the linear or gland seal being retained within the groove on the surface of the first section of the body and a second portion of the linear or gland seal being retained within the groove on the plunger in sealing contact with the plunger and an inner surface of the first section of the body,

wherein the plunger is linearly movable between a closed position and an open position by rotating the second section of the body; the device is in the closed position when the bottom end of the plunger is in alignment with the flange surrounding the first opening of the body; and the device is in the open position when the bottom end of the plunger is not in alignment with the flange surrounding the first opening of the body,

24. The device of claim 23, further comprising an outer wall component to further secure the linear or gland seal to the first section of the body.

25. The device of claim 1, further comprising an outer wall component to further secure the linear or gland seal to the first section of the body.