volume of sterilising medium than that which might be required to ensure that sterilisation occurs irrespective of the volume of the chamber. There is a need for repeatability and accuracy of formation of the chamber. In addition, there is little positive feedback to ensure that the chamber has been formed, nor in other configurations so as to provide feedback to an operator that the desired configuration has been achieved. Furthermore, when subjected to external forces, there remains a need to prevent inadvertent movement of the valve halves leading to misalignment or failure of the valve to open or close as desired.

In accordance with an aspect of the present ~~invention~~disclosure, there is provided a split valve assembly, comprising a first valve portion and second valve portion, having displacement means for displacing the valve portions when they are engaged between discrete configurations comprising a first configuration wherein the valve portions are secured to one another such that they do not separate and the valve is open such that material may pass therethrough, and a second configuration wherein the valve portions are secured to one another but displaced from the first configuration to form a space therebetween and the valve is closed, wherein the displacement means comprises a mating pair, each valve portion comprising one member of the pair, and wherein the mating pair permits movement of the valve portions between the first and second configuration whilst the first and second valve portions are secured to one another.

The first and second valve portion may each comprise at least one cam or at least one cam follower. The at least one cam follower may be disposed on a first valve portion and the at least one cam may be disposed on a second valve portion.

The cam may comprise a cylindrical cam such that rotational displacement of the cam gives rise to linear displacement of the cam follower.

The linear motion of the cam follower may be parallel to the rotational axis of the cam. The cam may have a cam profile comprising a profiled groove or slot.

The valve may comprise a plurality of grooves or slots.

The cam may be rotatably mounted to a valve portion.

The system may comprise an actuator to rotate a valve portion relative to the other to move between configurations.

The cam may be rotatably connected to the main body by means of at least one fastener such that it can rotate but remain connected to the main body of the valve portion.

The main body may possess guides that are complementarily shaped to the cam follower and receive the cam follower when the valve portions are mated.

The guide prevents the cam follower from moving along the groove or slot unless the first portion is rotated.

In accordance with a further aspect of the present ~~invention~~disclosure there is provided a split butterfly valve comprising a first and a second valve portion, said first and second valve portions capable of being mated to permit the passage of material therethrough wherein one valve portion has an axially disposed cam, the other having a cam follower for engagement with and co-operation with the axial cam such that rotational movement of the axial cam or the cam follower causes displacement of the other valve portion.

The axial cam is formed via two discrete components secured together. The first provides the upper limit of the axial cam whilst the second provides the lower limit. When secured together they provide a slot dimensioned to receive the cam follower and guide the cam follower on a path that will give rise to displacement of the cam follower and the valve portion to which it is attached.

The first valve portion may comprise one or more cams. Advantageously, the valve comprises three cams. The second valve portion may comprise a correspondingly number of cam followers.

The cams are disposed about the circumference first valve portion and the cam followers on the second valve portion are correspondingly disposed.

More advantageously, there are four cams and four cam followers.

Two of the cams are positioned proximally to one another with respect to the other two which are disposed equidistantly around the circumference of the valve.

The present ~~invention~~disclosure may provide a mechanism that gives rise to accurate and reproducible configurations of the valve portions when mated to accurate control the various configurations and ensuring that the chamber formed between valve portions is consistent in volume. This assists in improving the sterilising step as a known volume of sterilising medium can be introduced for a given process step, which removes the necessity to use more sterilising medium or contact time than presently used as the chamber volume is difficult to accurately predict with known split butterfly valves and therefore to avoid potential issues, excessive volume of sterilising medium is used and the contact time is increased to be certain that sufficient sterilising has occurred. In the present ~~invention~~disclosure, it will no longer be necessary to do this at the volume is more accurately predicted and reproducible enabling the specific volume of sterilising medium to be used for a given contact time. Therefore, processing can times can be better controlled and the cost of sterilising medium/impact used in the process is reduced as is the impact on manufacturing environment and resources minimised.

In accordance with the present ~~invention~~disclosure, there is provided a split valve assembly comprising two valve portions complementarily shaped such that the first can sealingly engage with and co-operate with the second to allow the movement of material therethrough, each valve portion comprising a housing, a valve seat and a valve closure member moveable between a first position in which the valve closure member is displaced from the valve seat and the valve is open, and a second position in which the valve closure member co-operates with the valve seat and the valve is closed, wherein the assembly has a first configuration in which the first and second valve portions engage with one another, the

The inlet and/or outlet may be disposed in the first and/or second valve portion.

In a third configuration, the two valve portions are undocked, in the first configuration the two valve portions are engaged and the valve closure members separated and in the second configuration the two valve portions are completely docked such that the valve closure members may open or close to selectively open or close the valve.

The valve of the present ~~invention~~disclosure is able to operate in a complete sterile manner, by use of an 'in situ' sterilisation step applied before completion of each docking (i.e. when in said first configuration), regardless of how many times the valve is split open and re-docked, i.e. engaged and disengaged, ensuring sterile conditions on product or material contact surfaces.

The present ~~invention~~disclosure allows the valve to have a capability to have an intermediate stage during docking that allows a chamber which can be isolated from the surrounding environment to be formed between the surfaces which have been exposed to the atmosphere and which are not sterilised. These surfaces need to be sterilised before they can become exposed to the internal sterile parts of the assembly and material which may pass therethrough when the valve is fully docked and open so as to prevent contamination.

The present ~~invention~~disclosure allows sterilisation to be maintained throughout the process of several product or material transfers, and is capable of allowing several dockings and un-dockings (engagement and disengagement), without compromising the sterility of the material to be transferred or internal process equipment upon which the valve portions of the present ~~invention~~disclosure may be mounted. The chamber may also be cleaned using fluid gases or fluids before and after the sterilisation step, or in any sequence during the engagement/disengagement cycle, enabling the valve to be aseptic and under class A conditions without the need for sterile isolators or aseptic external environments.

Each valve portion of the assembly may be mountable on a vessel for containing material, conveyance means, such as a hose, for conveying material and/or other process equipment

known to the art. The means for mounting the valve portions may comprise any means known to the art, such as for example a screw thread, interference fit, bayonet attachment etc. In an alternative ~~embodiment~~example, the valve portions may be integrally formed with a vessel or conveyance means.

The inlet and outlet of the chamber may be closed once the movement from the first to the second configuration is complete. In so doing, the assembly ensures that the material being transferred therethrough is not contaminated with sterilising medium.

The valve seat and valve closure member are preferably complementarily shaped to ensure that a seal is formed when the valve closure member is closed.

The valve assembly may be a split butterfly valve, split ball valve, any other split valve or quick release coupling known to the art. Preferably, the assembly is a split butterfly valve.

The inlet and/or outlet of the chamber may be formed in the housing of one of the valve portions. Preferably, both the inlet and the outlet are formed in the housing of one of the valve portions.

Preferably, the valve portions form a mating pair, one being a male valve portion, the other female. The inlet and/or outlet may be formed in the housing of one or both of the valve portions. More preferably, the inlet and outlet for the chamber is formed in the female valve portion.

In one ~~embodiment~~example, the chamber has circular cross section.

In an ~~embodiment~~example, the inlet and outlet is radially disposed with respect to the chamber.

The valve assembly may comprise a plurality of inlets and outlets through which sterilising medium may pass. Preferably, the number of inlets corresponds directly to the number of outlets. More preferably, the assembly comprises one inlet and one outlets . Where the

chamber has a circular cross section, the inlet and outlet are preferably disposed diametrically opposite one another about the circumference of the chamber

The valve closure member may be pivotally mounted within the valve housing by means of opposed spindles projecting from the closure member and located in corresponding recesses within the valve housing. The valve housing may be provided with a valve seat and the valve closure member can be pivotable into and out of engagement with the valve seat to close and open the valve respectively. Preferably, the spindles are integrally formed with the valve closure member. Advantageously, the spindles and the valve closure member, may be machined from a single piece of material.

Preferably, the valve seat comprises a seal member. The seal member may preferably comprise an abutment portion and a resiliently deformable portion, such as a O-ring, located between the abutment portion and the valve housing.

In an alternative ~~embodiment~~example, the valve closure member may be provided with a recess for receipt of a seal which, in use, is adapted to engage against a solid portion of the valve housing.

In the case where the seal is located in a recess in the valve closure member the valve closure member may further comprise an elastomeric material covering the valve closure member and the seal located thereon.

The valve seal may be located either on the valve housing or on the valve closure member.

In order to ensure that the chamber, defined by the housing of one or both of the first and second valve portions and the valve closure members, is capable of being sealed from the surrounding environment, an O ring and/or inflatable seal may be disposed on the housing of one or both of the valve portions. This ensures that during cleaning, whereby sterilising medium is passed through the chamber when the assembly is in its first configuration and when material is transferred through the valve there is a significantly reduced possibility of cross-contamination between the chamber and the surrounding environment, thus ensuring that the material transferred is not contaminated and maintaining operator safety.

The sterilising medium suitable for use with the assembly of the present ~~invention~~disclosure may comprise a fluid, vapour and/or gas. Preferably, the medium is vaporised hydrogen peroxide, filtered nitrogen, filtered air and/or water. For materials sensitive to heat, vaporised hydrogen peroxide is preferably used, whilst for materials not generally heat sensitive, steam under pressure can be used. Pressurised and filtered air and/or nitrogen or other such gases may be used as a cleaning medium to blow any debris, particles, residues, impurities etc. out of the chamber in lieu of or in combination with other sterilising media. If it is to be used as a sterilising medium, then the aim is preferably filtered to remove potential contaminants.

The outlet may be connected to filter means and/or a catalyst to treat any waste stream from the chamber.

During use, the assembly may be switched from the first to the second configuration to allow material to be transferred therethrough. Once the material has been transferred, the assembly is switched back to the first configuration and the surfaces which are to be exposed to the surrounding environment cleaned before disengaging the two valve portions so as to prevent the operator from being exposed to any residual material left on the exposable surfaces, and thus ensuring operator safety.

In accordance with an example~~aspect~~ of the present ~~invention~~disclosure, there is provided a locking ring for a split valve having a first and second valve portion having discrete configurations in which the position of each valve portion relative to one another may change, wherein the locking ring comprises a slot for receiving the locating pin of one valve portion communicating with a profiled guide slot in which the locating pin is received for displacing the locating pin and thus the associated valve portion between discrete configurations with respect to the other valve portion.

In accordance with a further example~~aspect~~ of the present ~~invention~~disclosure, there is provided a method of moving a material from one vessel to another without exposing the material to the surrounding environment comprising the use of a valve assembly as described hereinabove, the method comprising the steps of:

a) Engaging or securing the valve portions such that the assembly conforms to its first configuration;

b) optionally cleaning the chamber;

c) sterilising the chamber;

d) displacing the valve portions such that the assembly conforms to its second configuration; and

e) opening the valve to allow the movement of material therethrough.

Once the requisite quantity of material has been transferred, the method may also comprise the subsequent steps of:

f) displacing the valve portions such that the assembly conforms to its first configuration;

g) optionally cleaning the chamber;

h) optionally sterilising the chamber; and

i) disengaging the valve portions.

In accordance with a further aspect of the present disclosure, there is provided a method of moving a material from one vessel to another without exposing the material to the surrounding environment comprising the use of a valve assembly as described hereinabove, the method comprising the steps of:

a) Engaging or securing the valve portions such that the assembly conforms to its first configuration;

b) optionally cleaning the chamber;

c) sterilising the chamber;

d) displacing the valve portions such that the assembly conforms to its second configuration; and

e) opening the valve to allow the movement of material therethrough.

f) displacing the valve portions such that the assembly conforms to its first configuration;

g) optionally cleaning the chamber;

h) optionally sterilizing the chamber; and

i) disengaging the valve portions.

In accordance with a further example~~aspect~~ of the present ~~invention~~disclosure, there is provided a split valve comprising a first and second valve portion, each having a housing having a valve closure member and a valve seat, wherein the valve seat is retained between the housing and a releasably securable valve seat retaining member.

The valve seat retaining member may comprise a cover plate securable to the housing and between which is located the valve seat in use.

The cover plate may be releasably secured to the housing via fastening means. The fastening means may comprise one or more fastening members. The fastening member may comprise a bolt with a threaded shaft. The housing may comprise complementarily shaped threaded bores to receive the threaded shaft of the fastening member.

The cover plate may be a planar circular body having a centrally disposed aperture sized to correspond to the diameter of the valve closure member such that the valve closure member may rotate to open the valve portion and be accommodated within the aperture of the cover plate

Extending around the aperture and set a distance from the edge of the aperture may be a circumferential upstanding wall which serves to help retain the valve seat in place when assembled.

The valve seat has a cylindrical body having a circumferential flange around one end and two cut outs in the side wall at the other end, diametrically spaced apart and semi-circular in profile. The cut outs accommodate the spindles which open and close the valve closure members.

It is the flange that is accommodated by the upstanding wall and the circumferential edge of the flange abuts against the upstanding wall retaining the valve seat in position.

To replace a valve seat, rather than the valve seat having to be manufactured from a deformable material, more prone to wear and tear, the valve seat may be manufactured from a more resilient material and does not need to have the great flexibility found in known valve seats to facilitate easier replacement. Instead, the cover is removed by loosening and removing the fastener means and the valve seat simply displaced without having to deform its shape.

The need to deform the shape of the valve seat also makes replacement more difficult for an operator as they are required to deform the shape whilst ensuring that the cut outs overlie the spindle shafts so that the seat is correctly aligned and will not fail. No need for use of tool to prise the seat out of place or locate the seat in place.

The present disclosure~~invention~~ dispenses with the need for this feature in the valve seat and the associated difficulty with the method of replacement currently employed. Rather the present disclosure~~invention~~ permits a valve seat to be simply removed and then replaced in correct alignment in a straightforward manner by providing a valve portion having a housing having a removable cover to expose the channel in which the flange is received of the valve seat.

## CLAIMS

1. A split valve assembly, comprising a first valve portion and second valve portion, having displacement means for displacing the valve portions when they are engaged between discrete configurations comprising a first configuration wherein the valve portions are secured to one another such that they do not separate and the valve is open such that material may pass therethrough, and a second configuration wherein the valve portions are secured to one another but displaced from the first configuration to form a space therebetween and the valve is closed, wherein the displacement means comprises a mating pair, each valve portion comprising one member of the pair, and wherein the mating pair permits movement of the valve portions between the first and second configuration whilst the first and second valve portions are secured to one another.

2. An assembly as claimed in claim 1 wherein the first and second valve portion each comprise at least one cam or at least one cam follower.

3. An assembly as claimed in claim 2 wherein:

the at least one cam follower is disposed on a first valve portion, ~~and~~

the at least one cam is disposed on a second valve portion, and

the at least one cam comprises a cylindrical cam with a cam profile comprising a plurality of profiled grooves or slots.

~~4. An assembly as claimed in claim 1, 2 or 3 wherein the cam comprises a cylindrical cam.~~

~~5. An assembly as claimed in any one of claims 1 to 4 wherein the cam has a cam profile comprising a profiled groove or slot.~~

~~6. An assembly as claimed in claim 5 having a plurality of grooves or slots.~~

4~~7~~. An assembly as claimed in ~~any one of claims 2 to 6~~claim 3 wherein the cam profile further comprises:

at least two sections, wherein a first section of the cam profile comprises an inclined ramp extending towards an apex; and, a second section comprises a declined ramp, extending away from

the apex.

~~8. An assembly as claimed in claim 7 wherein one section of the cam profile comprises an inclined ramp extending towards an apex; and, a second section comprising a declined ramp, extending away from an apex.~~

5~~9~~. An assembly as claimed ~~in any one of claims 2 to 8~~in claim 4 wherein:

the cam follower ~~will be caused to be~~is displaced in a plane perpendicular to the plane of rotation of the cam as it moves along the profile,

the cam follower is received by an alignment member to ensure that the cam follower is in correct alignment prior to rotation of the cam and the displacement of the valve portions between configurations, and

the groove or slot is open at one end, proximal the first section to permit the cam follower to be received.

~~10. An assembly as claimed in any one of claims 2 to 9 claim 9, wherein the cam follower is received by an alignment member to ensure that the cam follower is in correct alignment prior to rotation of the cam and displacement of the valve portions between configurations.~~

~~11. An assembly as claimed in any one of claims 5 to 10 wherein the groove or slot is open at one end, proximal to the first section to permit the cam follower to be received.~~

~~12. An assembly as claimed in any one of claims 2 to 11 wherein the cam is rotatably mounted on a valve portion.~~

6~~13~~. An assembly as claimed in claim ~~12~~5 further comprising a valve portion and an~~n~~ actuator to rotate the~~a~~ valve portion ~~relative to the other to move between configurations~~, wherein the cam is rotatably mounted on the valve portion such that it can rotate but remain connected to the main body of the valve portion.

~~14. An assembly as claimed in claim 12 or 13 wherein the cam is rotatably mounted on a valve portion such that it can rotate but remain connected to the main body of the valve portion.~~

715. An assembly as claimed in ~~any one of the previous claims~~claim 6 wherein the~~a~~ valve portion ~~possess~~ further comprises one or more guides that are complementarily shaped to the cam follower and receive the cam follower when the valve portions are mated, and the one or more guides prevents the cam follower from moving along the groove or slot unless the valve portion is rotated.

~~16. An assembly as claimed in claim 15 wherein the guide prevents the cam follower from moving along the groove or slot unless the first valve portion is rotated.~~

817. A split butterfly valve comprising a first and a second valve portion, said first and second valve portions capable of being mated to permit the passage of material therethrough wherein one valve portion has an axially disposed cam, the other having a cam follower for engagement with and co-operation with the axial cam such that rotational movement of the axial cam or the cam follower causes displacement of the other valve portion.

918. A valve as claimed in claim 8~~17~~, wherein the axial cam is formed via two discrete components secured together, the two discrete components comprising a first and second component when secured together provide a slot dimensioned to receive the cam follower and guide the cam follower on a path that will give rise to displacement of the cam follower and the valve portion to which it is attached.

~~19. A valve as claimed in claim 18 wherein the two discrete components comprise a first and second component when secured together provide a slot dimensioned to receive the cam follower and guide the cam follower on a path that will give rise to displacement of the cam follower and the valve portion to which it is attached.~~

1020. A valve as claimed in ~~any one of claims 17 to 19~~claim 9 wherein the first valve portion comprises one or more cams.

~~21. A valve as claimed in any one of claims 17 to 20 comprising four cams.~~

11~~22~~. A valve as claimed in claim ~~21~~ 10 wherein the second valve portion comprises a corresponding~~ly~~ number of cam followers.

12~~23~~. A valve as claimed in ~~any one of claims 17 to 22~~claim 11 wherein the cams are disposed about the circumference first valve portion and the cam followers on the second valve portion are correspondingly disposed.

13~~24~~. ~~A split valve assembly~~A valve as claimed in claim 8 wherein the ~~comprising~~ two valve portions are complementarily shaped such that the first can sealingly engage with and co-operate with the second to allow the movement of material therethrough, each valve portion comprising a housing, a valve seat and a valve closure member moveable between a first position in which the valve closure member is displaced from the valve seat and the valve is open, and a second position in which the valve closure member co-operates with the valve seat and the valve is closed, wherein the assembly has a first configuration in which the first and second valve portions engage with one another, the valve closure members being closed, and the valve closure members being disposed a distance apart defining, with the housing, a chamber therebetween, which is capable of being sealed from the surrounding environment, and a second configuration in which the valve closure members engage with one another and are movable from their first to their second position, and a third configuration in which the two valve portions are disengaged from one another wherein one or more of the valve portions comprises means for selectively displacing one of the valve portions towards or away from the other whilst in an engaged configuration.

14~~25~~. ~~An~~ A valve~~assembly~~ as claimed in claim 13~~24~~ wherein:

the means for displacing the valve portions comprises the cooperation between one or more cams disposed on one valve portion and one or more cam followers disposed on the other valve portion, and

the means for selectively displacing the one or more valve portions comprises an upper and lower profiled surface between which one or more locating pins are located, the one or more locating pins extending perpendicularly to the central axis of the valve portion and movement of material through.

~~26. An assembly as claimed in claim 25 wherein the means for selectively displacing the one~~

~~or more valve portions comprises a upper and lower profiled surface between which the one or more locating pins are located.~~

~~27. An assembly as claimed in claim 26 wherein the one or more locating pins may extend perpendicularly to the central axis of the valve portion and movement of material through.~~

15~~28~~. ~~An~~ A ~~assembly~~valve as claimed in ~~any one of claims 24 to 27~~claim 13 wherein

the ~~profiled~~ lower profiled surface ~~may~~ comprises a first and second section that meet at an apex above which is a complimentarily shaped upper surface to accommodate a cam follower, and the valve portion with which it is associated, is displaced away from the other valve portion whilst in an engaged configuration, and

the split valve assembly further comprises an inlet and an outlet through which a sterilizing medium may pass.

~~29. An assembly or valve as claimed in any one of the previous claims having an inlet and an outlet through which sterilizing medium may pass.~~

~~30. An assembly or valve as claimed in claim 29 wherein the inlet and/or outlet is disposed in the first and/or second valve portion.~~

16~~31~~. ~~An~~ A ~~assembly or~~ valve as claimed ~~in any one of the previous claims~~in claim 15 having a third configuration, the two valve portions are undocked, in the first configuration the two valve portions are engaged and the valve closure members separated and in the second configuration the two valve portions are completely docked such that the valve closure members may open or close to selectively open or close the valve.

~~32. An assembly or valve as claimed in any one of the previous claims being a split butterfly valve, split ball valve, any other split valve or quick release coupling.~~

17~~33~~. A valve as claimed in claim 13, the valve further comprising a locking ring, the~~A~~ locking ring ~~for a split valve having~~ comprising a first and second valve portion having discrete configurations in which the position of each valve portion relative to one another may change,

wherein the locking ring comprises a slot for receiving the locating pin of one valve portion communicating with a profiled guide slot in which the locating pin is received for displacing the locating pin and thus the associated valve portion between discrete configurations with respect to the other valve portion.

18~~34~~. A method of moving a material from one vessel to another without exposing the material to the surrounding environment comprising the use of a valve assembly as described hereinabove, the method comprising the steps of:

a) Engaging or securing the valve portions such that the assembly conforms to its first configuration;

b) optionally cleaning the chamber;

c) sterilizing the chamber;

d) displacing the valve portions such that the assembly conforms to its second configuration; and

e) opening the valve to allow the movement of material therethrough.

f) displacing the valve portions such that the assembly conforms to its first configuration;

g) optionally cleaning the chamber;

h) optionally sterilizing the chamber; and

i) disengaging the valve portions.

~~35. A method as claimed in claim 34 comprising the subsequent steps of:~~

~~f) displacing the valve portions such that the assembly conforms to its first configuration;~~

~~g) optionally cleaning the chamber;~~

~~h) optionally sterilizing the chamber; and~~

~~i) disengaging the valve portions.~~

19~~36~~. A valve as claimed in claim 13~~split valve~~ ~~comprising a first and second valve portion,~~ each of the first and second valve portions having a housing having a valve closure member and a valve seat, wherein the valve seat is retained between the housing and a releasably securable valve seat retaining member.

2037. A valve as claimed in claim 1936 wherein the valve seat retaining member comprises a cover plate releasably secured~~able~~ to the housing and between which is located the valve seat in use, wherein the cover plate comprises a planar circular body having a centrally disposed aperture sized to correspond to the diameter of the valve closure member such that the valve closure member may rotate to open the valve portion and be accommodated within the aperture of the cover plate.

~~38. A valve as claimed in claim 36 or 37, wherein the cover plate is releasably secured to the housing.~~

~~39. A valve as claimed in claim 38 wherein the cover plate may be a planar circular body having a centrally disposed aperture sized to correspond to the diameter of the valve closure member such that the valve closure member may rotate to open the valve portion and be accommodated within the aperture of the cover plate.~~