sampling device and reservoir, and where many samples can be taken using the same equipment. Furthermore, the invention does not require external means of sterilization, for example, to inject high pressure steam or ethylene oxide. Rather the invention can be made from entirely disposable parts.

Examples of the present invention will now be described with reference to the accompanying drawings, in which:

Figures 1a and 1b are schematic diagrams showing the principle of the invention;

Figure 2 shows the outward form of the first preferred embodiment of the invention;

Figures 3a to 3e show the mechanism and operation of the first preferred embodiment of the invention;

Figures 4a to 4e show the mechanism and operation of the second preferred embodiment of the invention;

Figure 5 shows a cut-away detail of the first preferred embodiment of the invention; and

Figure 6 shows further descriptions of the first preferred embodiment of the invention.

The invention is an aseptic sampling system which comprises two mating assemblies shown schematically in Figure 1a. A sampler assembly 2 whose function is to withdraw or infuse a single sample, and an interface assembly 1 whose function is to provide the interface between the sampler assembly and the reservoir 38 to be sampled. The interface assembly 1 is usually retained with the reservoir 38 for the duration of an aseptic culture, and allows the repeated taking of samples through the use of one or more units of the sampler assembly 2.

The sampler and interface assemblies 2,1 together comprise the following parts. Firstly, an outer protective surface is provided, made up of a housing 8,5 of each of the sampler and interface assemblies 11,6. This outer protective surface makes a sterile enclosure by forming a barrier between the outer non-sterile atmosphere and the inner sterile atmosphere. Secondly, an air lock is provided that allows the joining of the sterile enclosure in the sampler and interface assemblies. Thirdly, a re-sealable liquid connection mechanism is provided that contains a connector in each of the sampler and interface assemblies 2,1. At least one of the connectors is moved through the sterile enclosure and air lock to mate with the opposite connector in the liquid connection mechanism, without sliding on any surfaces that could be non-sterile.

The liquid connection mechanism, sterile enclosure 18 , outer protective surface 5,8 and air lock 11,6 each are shown schematically and operated as shown in Figure 1 and described as follows. First the sampler assembly 2 is mated with the interface assembly 1 via the air lock 11,6 (Figure 1bi). The air lock is opened, keeping the sterile enclosure 18 free of contamination of outside air. Second, the parts of the liquid connection mechanism 7,9,10 are joined within the sterile enclosure, and without sliding past surfaces 11,6 of the air lock

that may be non-sterile (Figure 1bii). The liquid connection mechanism 7,9,10 thus creates a sealed aseptic liquid flow path. A sample is then infused or withdrawn from the reservoir 38. The sampler and interface assemblies 2,1 are then separated by reversing the above procedure: first the liquid connection mechanism 7,9,10 is resealed and separated, and then the air lock is disengaged.

The invention does not depend on particular forms of the component mechanisms. The novelty of this aseptic sampling system is the combination of a re-sealable liquid connection mechanism within a sterile enclosure 18, protected by an air lock 11,6 and an outer protective surface 5,8, so that the liquid connection can be made without the parts of the connection mechanism being exposed to outside air or being made to contact any surfaces that could be non-sterile, and that the liquid connection can be disconnected without contamination of the sampler or interface assemblies. These properties of the invention are necessary for the utility of the system: to take repeated samples without contamination of sample or reservoir 38, or the use of external sterilizing equipment.

The description below starts with to a first embodiment, but the invention is not limited to the geometry, mechanisms and motions described below.

The first embodiment, as shown in Figure 2, comprises two mechanical assemblies, an interface assembly 1 and a sampler assembly 2. The interface assembly provides a connector 3 to a reservoir and the sampler assembly provides a connector 4 to a sample vessel. Figure 2 shows female luer connectors for features 3 and 4. However, alternative embodiments would include barbed tube fittings, flanged sanitary fittings and flanged welded seals to connect to disposable bag bioreactors or disposable sampling bags.

Each mechanical assembly comprises separate parts, detailed in the cross section diagram of Figure 3. The interface 1 comprises a housing 5, shutter 6, and liquid valve 7. The connector to the reservoir is here a moulded pipe fitting 3 on the outside of the housing 5. The sampler 2 comprises a housing sheath 8, slider 9, inner cap 10 and outer cap 11. The shutter 6 is locked in position in the housing 5 by an interlock hook 15, which fits in an interlock aperture 16.

The operating mechanism and sequence for the first embodiment is described with reference to Figures 3a-3e. Figure 3a shows the first embodiment before sampling.

The first step of sampling is shown in Figure 3b, where the sampler assembly 2 is pushed into a mating aperture 12 of the interface assembly 1. The outer cap 11 is then fully contained in a slot 13 of the shutter 6. Simultaneously an interlock protrusion 14 pushes the interlock hook 15 out of the interlock aperture 16. This allows the shutter 6 to slide vertically. The mating faces of the housing sheath 8 and housing 5 form an air-tight surface 17.

The second step of sampling is shown in Figure 3c, where the shutter 6 is slid down. This moves the outer cap 11 away from the housing sheath 8 which has the effect of joining the sterile atmospheres in the sampler and interface assemblies 2,1 into a single sterile

sampling device and reservoir, and where many samples can be taken using the same equipment. Furthermore, the invention does not require external means of sterilization, for example, to inject high pressure steam or ethylene oxide. Rather the invention can be made from entirely disposable parts.

Examples of the present invention will now be described with reference to the accompanying drawings, in which:

Figures 1a and 1b are schematic diagrams showing the principle of the invention;

Figure 2 shows the outward form of the first preferred embodiment of the invention;

Figures 3a to 3e show the mechanism and operation of the first preferred embodiment of the invention;

Figures 4a to 4e show the mechanism and operation of the second preferred embodiment of the invention;

Figure 5 shows a cut-away detail of the first preferred embodiment of the invention; and

Figure 6 shows further descriptions of the first preferred embodiment of the invention.

The invention is an aseptic sampling system which comprises two mating assemblies shown schematically in Figure 1a. A sampler assembly 2 whose function is to withdraw or infuse a single sample, and an interface assembly 1 whose function is to provide the interface between the sampler assembly and the reservoir 38 to be sampled. The interface assembly 1 is usually retained with the reservoir 38 for the duration of an aseptic culture, and allows the repeated taking of samples through the use of one or more units of the sampler assembly 2.

The sampler and interface assemblies 2,1 together comprise the following parts. Firstly, an outer protective surface is provided, made up of a housing 8,5 of each of the sampler and interface assemblies 11,6. This outer protective surface makes a sterile enclosure by forming a barrier between the outer non-sterile atmosphere and the inner sterile atmosphere. Secondly, an air lock is provided that allows the joining of the sterile enclosure in the sampler and interface assemblies. Thirdly, a re-sealable liquid connection mechanism is provided that contains a connector in each of the sampler and interface assemblies 2,1. At least one of the connectors is moved through the sterile enclosure and air lock to mate with the opposite connector in the liquid connection mechanism, without sliding on any surfaces that could be non-sterile.

The liquid connection mechanism, sterile enclosure 18 , outer protective surfaces of the housing 5,8 and interface assemblies 11,6 each are shown schematically and operated as shown in Figure 1 to form air lock 11',6', and described as follows. First the sampler assembly 2 is mated with the interface assembly 1 via the air lock 11',6' (Figure 1bi). The air lock is opened, keeping the sterile enclosure 18 free of contamination of outside air. Second, the parts of the liquid connection mechanism 7,9,10 are joined within the sterile

enclosure, and without sliding past surfaces of the interface assemblies 11,6 of the air lock that may be non-sterile (Figure 1bii). The liquid connection mechanism 7,9,10 thus creates a sealed aseptic liquid flow path. A sample is then infused or withdrawn from the reservoir 38. The sampler and interface assemblies 2,1 are then separated by reversing the above procedure: first the liquid connection mechanism 7,9,10 is resealed and separated, and then the air lock is disengaged.

The invention does not depend on particular forms of the component mechanisms. The novelty of this aseptic sampling system is the combination of a re-sealable liquid connection mechanism within a sterile enclosure 18, protected by an air lock 11',6' and outer protective surfaces of the housing 5,8, so that the liquid connection can be made without the parts of the connection mechanism being exposed to outside air or being made to contact any surfaces that could be non-sterile, and that the liquid connection can be disconnected without contamination of the sampler or interface assemblies. These properties of the invention are necessary for the utility of the system: to take repeated samples without contamination of sample or reservoir 38, or the use of external sterilizing equipment.

The description below starts with to a first embodiment, but the invention is not limited to the geometry, mechanisms and motions described below.

The first embodiment, as shown in Figure 2, comprises two mechanical assemblies, an interface assembly 1 and a sampler assembly 2. The interface assembly provides a connector 3 to a reservoir and the sampler assembly provides a connector 4 to a sample vessel. Figure 2 shows female luer connectors for features 3 and 4. However, alternative embodiments would include barbed tube fittings, flanged sanitary fittings and flanged welded seals to connect to disposable bag bioreactors or disposable sampling bags.

Each mechanical assembly comprises separate parts, detailed in the cross section diagram of Figure 3. The interface 1 comprises a housing 5, shutter 6, and liquid valve 7. The connector to the reservoir is here a moulded pipe fitting 3 on the outside of the housing 5. The sampler 2 comprises a housing sheath 8, slider 9, inner cap 10 and outer cap 11. The shutter 6 is locked in position in the housing 5 by an interlock hook 15, which fits in an interlock aperture 16.

The operating mechanism and sequence for the first embodiment is described with reference to Figures 3a-3e. Figure 3a shows the first embodiment before sampling.

The first step of sampling is shown in Figure 3b, where the sampler assembly 2 is pushed into a mating aperture 12 of the interface assembly 1. The outer cap 11 is then fully contained in a slot 13 of the shutter 6. Simultaneously an interlock protrusion 14 pushes the interlock hook 15 out of the interlock aperture 16. This allows the shutter 6 to slide vertically. The mating faces of the housing sheath 8 and housing 5 form an air-tight surface 17.

The second step of sampling is shown in Figure 3c, where the shutter 6 is slid down. This moves the outer cap 11 away from the housing sheath 8 which has the effect of joining the sterile atmospheres in the sampler an interface assemblies 2,1 into a single sterile

CLAIMS

1. An aseptic sampling system comprising: a sampler assembly and an interface assembly, each assembly comprising a housing, each housing defining a separate sterile enclosure for each of the assemblies; an air lock arranged to provide, in use, the aseptic joining of the sterile enclosures within the sampler and interface assemblies; and a re-sealable liquid connection mechanism positioned to operate within the air lock, wherein: the sampler assembly and interface assembly are arranged such that, when connected together, they form an outer protective surface comprising the housings of each of the sampler and interface assemblies, the outer protective surface providing a sterile internal enclosure and air lock and an air-tight barrier between the outer non-sterile atmosphere and the inner sterile atmosphere, and wherein the re-sealable liquid connection mechanism is contained within the sterile enclosure and contains at least one liquid connector from each of the sampler and interface assemblies and is configured such that, in use, at least one of the liquid connectors can move across the sterile enclosure and air lock to connect with the other connector in the liquid connection mechanism, without contacting any internal surfaces within the air lock.

2. An aseptic sampling system according to claim 1, where the air lock is provided by an outer cap in the sampling assembly which mates with a shutter that slides within a housing in the interface assembly.

3. An aseptic sampling system according to claim 2, where the shutter slides in a linear path.

4. An aseptic sampling system according to claim 2, where the shutter slides in the path of a circle or arc.

5. An aseptic sampling system according to any preceding claim, where the liquid connection mechanism is provided by a rotating valve comprising two parts that, when joined, provide a sealing cylindrical surface with at least one internal channel.

6. An aseptic sampling system according to any of claim 1 to 4, where the liquid connection mechanism is provided by a re-sealing linear or rotary valve.

7. An aseptic sampling system according to any of claims 1 to 4, where the liquid connection mechanism is provided by a deformable septum, a piercing needle and an interface septum.

8. An aseptic sampling system according to any of claims 1 to 4, where the liquid connection mechanism is provided by a piercing needle, a septum and a linear valve.

9. An aseptic sampling system according to any preceding claim, arranged such that the separate sterile enclosure within the sampler assembly is no longer provided after the sampler assembly has been removed from the interface assembly.

10. An aseptic sampling system according to any preceding claim, configured such that the liquid connectors, in use, can subsequently be re-sealed, disconnected and separated.

CLAIM(S):

1. An aseptic sampling system comprising: a sampler assembly and an interface assembly, each assembly comprising a housing, each housing defining a separate sterile enclosure for each of the assemblies; an air lock arranged to provide, in use, the aseptic joining of the sterile enclosures within the sampler and interface assemblies; and a re-sealable liquid connection mechanism positioned to operate within the air lock, wherein: the sampler assembly and interface assembly are arranged such that, when connected together, they form an outer protective surface comprising the housings of each of the sampler and interface assemblies, the outer protective surface providing a sterile internal enclosure and air lock and an air-tight barrier between the outer non-sterile atmosphere and the inner sterile atmosphere, and wherein the re-sealable liquid connection mechanism is contained within the sterile enclosure and contains at least one liquid connector from each of the sampler and interface assemblies and is configured such that, in use, at least one of the liquid connectors can move across the sterile enclosure and air lock to connect with the other connector in the liquid connection mechanism, without contacting any internal surfaces within the air lock, said air lock being provided by an outer cap in the sampling assembly which mates with a shutter that slides within a housing in the interface assembly.

2. An aseptic sampling system according to claim 1, where the shutter slides in a linear path.

3. An aseptic sampling system according to claim 1, where the shutter slides in a path of a circle or arc.

4. An aseptic sampling system according to any preceding claim, where the liquid connection mechanism is provided by a rotating valve comprising two parts that, when joined, provide a sealing cylindrical surface with at least one internal channel.

5. An aseptic sampling system according to any of claims 1 to 3, where the liquid connection mechanism is provided by a re-sealing linear or rotary valve.

6. An aseptic sampling system according to any of claims 1 to 3, where the liquid connection mechanism is provided by a deformable septum, a piercing needle and an interface septum.

7. An aseptic sampling system according to any of claims 1 to 3, where the liquid connection mechanism is provided by a piercing needle, a septum and a linear valve.

8. An aseptic sampling system according to any preceding claim, arranged such that the separate sterile enclosure within the sampler assembly is no longer provided after the sampler assembly has been removed from the interface assembly.

9. An aseptic sampling system according to any preceding claim, configured such that the liquid connectors, in use, can subsequently be re-sealed, disconnected and separated.