CLAIMS

1. A peritoneal dialysate bag comprising:

a first inlet/outlet port;

a second inlet/outlet port;

a first region comprising a first peritoneal dialysate concentrate, the first region being fluidly connected to the first inlet/outlet port;

a second region fluidly separate from the first region and comprising a second peritoneal dialysate concentrate, the second region being fluidly connected to the second inlet/outlet port;

an external tubing fluidly connecting the first and second inlet/outlet ports; and

a breakable barrier separating the first region from the second region, the breakable barrier being configured to break along substantially its entire length,

wherein the dialysate bag is configured such that breakage of the breakable barrier results in the first region being fluidly connected to the second region; and

wherein the first and second inlet/outlet ports have an open state and a closed state,

when in the open state each of the first and second inlet/outlet ports fluidly connect the inner chamber to an exterior of the dialysate bag, and

when in the closed state each of the first and second inlet/outlet ports fluidly isolates the inner chamber from the exterior of the dialysate bag.

2. The peritoneal dialysate bag according to Claim 1, where a maximum volume of the first region is lower than a maximum volume of the second region.

3. The dialysate bag according to Claim 1 or Claim 2, wherein the first region comprises less than 40 vol. % (e.g. less than 35 vol. % or less than 30 vol. %) of a total maximum volume of the dialysate bag.

4. The dialysate bag according to any one of Claims 1 to 3, wherein:

(a) the breakable barrier is configured to break upon inflation of the first region; and

(b) the breakable barrier is configured to break along at least 60% of its length(e.g. at least 70% of its length, at least 80% of its length, such as at least 90% of its length),

optionally wherein the breakable barrier comprises a peelable seal and/or a frangible seal.

5. The dialysate bag according to any one of Claims 1 to 4, wherein the dialysate bag comprises edges, and the breakable barrier extends from a first edge to an opposite edge.

6. The dialysate bag according to any one of Claims 1 to 5, wherein the first dialysate concentrate and second dialysate concentrate are together suitable for forming a dialysis fluid suitable for direct administration to a patient by mixing with an appropriate volume of physiologically acceptable aqueous liquid (e.g. water for injection).

7. The dialysate bag according to any one of Claims 1 to 6, wherein:

(a) the first peritoneal dialysate concentrate occupies from 10 to 90 vol% (e.g. from 10 to 50 vol%) of the maximum volume of the first region; and/or

(b) the second peritoneal dialysate concentrate occupies from 10 to 90 vol% (e.g. from 10 to 50 vol%) of the maximum volume of the second region.

8. The dialysate bag according to any one of Claims 1 to 7, wherein:

the first and second regions together comprise an amount of first and second dialysate concentrate suitable for preparing n litres of dialysis fluid,

n is from 2 to 15 (e.g. 5 to 13, 7 to 12, such as 8 to 11), and

a maximum volume of the dialysate bag is suitable for administrating the n litres of dialysis fluid to a patient.

9. The dialysate bag according to any one of Claims 1 to 8, wherein the dialysate bag comprises a tapered region and where the first inlet/outlet port is located on (e.g. at the apex of) the tapered region,

optionally wherein the tapered region forms part of the first region.

10. The dialysate bag according to any one of Claims 1 to 9, wherein the dialysate bag comprises one or more (e.g. one) sparging tubes configured to increase distribution of fluid flowing through the dialysate bag,

11. The dialysate bag according to Claim 10, wherein:

(a) one of the one or more sparging tubes is attached to the first inlet/outlet port; or

(b) one of the one or more sparging tubes is attached to the breakable barrier;

12. The dialysate bag according to Claim 10 or Claim 11, wherein the breakable barrier, in an unbroken state, is configured to prevent passage of liquid through the sparging tube.

13. The dialysate bag according to any one of Claims 1 to 12, wherein the dialysate bag comprises:

a third region fluidly separate from the first and second regions and comprising a third dialysate concentrate; and

a second breakable barrier separating the second region from the third region, optionally wherein a maximum volume of the third region is greater than a maximum volume of each of the first and second regions.

14. The dialysate bag according to any one of Claims 1 to 13, wherein the first inlet/outlet port comprises two or more (e.g. three or more, four or more or five or more) diverging channels configured to distribute fluid flowing through the first inlet/outlet port in two or more (e.g. three or more, four or more or five or more) directions,

optionally wherein the second and/or third inlet/outlet ports, when present, each comprise two or more (e.g. three or more, four or more or five or more) diverging channels configured to distribute fluid flowing through the second and/or third inlet/outlet ports, respectively, in two or more (e.g. three or more, four or more or five or more) directions.

15. A peritoneal dialysis fluid reconstitution system comprising:

a peritoneal dialysate bag according to any one of Claims 1 to 14; and

a source of physiologically acceptable aqueous liquid in fluid communication with the dialysate bag.

16. A method of preparing peritoneal dialysis fluid within a dialysate bag as defined in any one of Claims 1 to 14, comprising:

(i) providing a peritoneal dialysate bag as defined in any one of Claims 1 to 15; and

(ii) providing a physiologically acceptable aqueous liquid through the inlet/outlet port of the dialysate bag so as to form a dialysis fluid.

17. The method according to Claim 16, wherein when the dialysate bag is as described in any one of Claims 1 to 14, then step (ii) comprises:

(iia) providing the physiologically acceptable aqueous liquid through the first inlet/outlet port to the first region of the dialysate bag to form a first intermediate dialysis fluid from the first dialysate concentrate and physiologically acceptable aqueous liquid,

where providing the physiologically acceptable aqueous liquid to the first region inflates the first region and breaks the breakable barrier, thereby allowing fluid communication with the second region;

(iib) providing additional physiologically acceptable aqueous liquid through the first inlet/outlet port to form a second intermediate dialysis fluid from the first intermediate

dialysis fluid, additional physiologically acceptable aqueous liquid and the second dialysate concentrate; and

(iic) mixing the second intermediate dialysis fluid to form the dialysis fluid suitable for direct administration to a patient or;

18. The method according to Claim 16, wherein when the dialysate bag is as described in Claim 13 or Claim 14, as dependent upon Claim 13, then step (ii) comprises:

(iia2) providing the physiologically acceptable aqueous liquid through the first inlet/outlet port to the first region of the dialysate bag to form a first intermediate dialysis fluid from the first dialysate concentrate and physiologically acceptable aqueous liquid,

where providing the physiologically acceptable aqueous liquid to the first region inflates the first region and breaks the breakable barrier, thereby allowing fluid communication with the second region;

(iib2) providing additional physiologically acceptable aqueous liquid to the second region through the first inlet/outlet port to form a second intermediate dialysis fluid from the first intermediate dialysis fluid, additional physiologically acceptable aqueous liquid and the second dialysate concentrate,

where providing the physiologically acceptable aqueous liquid to the second region inflates the second region and breaks the second breakable barrier, thereby allowing fluid communication with the third region;

(iic2) providing further physiologically acceptable aqueous liquid through the first inlet/outlet port to form a third intermediate dialysis fluid from the second intermediate dialysis fluid, further physiologically acceptable aqueous liquid and the third dialysate concentrate; and

(iid2) mixing the third intermediate dialysis fluid to form the dialysis fluid suitable for direct administration to a patient.

19. A system for preparing a peritoneal dialysis fluid comprising:

(i) a source of physiologically acceptable aqueous liquid (e.g. water for injection);

(ii) a dialysate bag comprising one or more dialysate concentrates as described in any one of Claims 1 to 14; and

(iii) a fluid connection between the source of physiologically acceptable aqueous liquid and dialysate bag,

where the source of physiologically acceptable aqueous liquid, dialysate bag and fluid connection together form a fluid flow path consisting of the source of physiologically acceptable aqueous liquid, dialysate bag and fluid connection, and wherein:

the fluid connection is connected to a first inlet/outlet port of the dialysate bag; and

the dialysate bag comprises a second inlet/outlet port fluidly connected to the fluid connection *via* an external connection so as to form a circulating fluid flow path through the first inlet/outlet port, dialysate bag, second inlet/outlet port, external connection and fluid connection.

20. A method of preparing a peritoneal dialysis fluid comprising the steps:

(a) providing a system comprising:

(i) a source of physiologically acceptable aqueous liquid (e.g. water for injection);

(ii) a dialysate bag comprising one or more dialysate concentrates as described in any one of Claims 1 to 14; and

(iii) a fluid connection between the source of physiologically acceptable aqueous liquid and dialysate bag,

where the source of physiologically acceptable aqueous liquid, dialysate bag and fluid connection together form a fluid flow path consisting of the source of physiologically acceptable aqueous liquid, dialysate bag and fluid connection;

(b) providing physiologically acceptable aqueous liquid from the source of physiologically acceptable aqueous liquid to the dialysate bag and mixing the physiologically acceptable aqueous liquid with the dialysate concentrate to form a dialysis fluid, wherein:

(1) the fluid connection is connected to a first inlet/outlet port of the dialysate bag; and the dialysate bag comprises a second inlet/outlet port fluidly connected to the fluid connection *via* an external connection so as to form a circulating fluid flow path through the first inlet/outlet port, dialysate bag, second inlet/outlet port, external connection and fluid connection, and where step (b) comprises recirculating the physiologically acceptable aqueous liquid and dialysate concentrate around the circulating fluid flow path to form a dialysis fluid; or

(2) step (b) comprises mixing the physiologically acceptable aqueous liquid with the dialysate concentrate manually; by using an orbital shaker or vibrating table; or by using a robotic arm.